Implementation Fidelity of the Universal Test and Treat HIV Intervention in eThekwini District, South Africa

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Declaration

I, Simiso Thamsanqa Masondo, declare that this report is the work of my own and was done without any assistance. It is submitted for the partial fulfilment of the Master of Science Degree in Epidemiology: Implementation Science.

Signature: 

Date: 17 September 2019

Dedication

This study is dedicated to all those who have humanity’s best interests at heart.

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Abbreviations

ART – Antiretroviral treatment

CD4 – Cluster of Differentiation 4

CTI – Critical Time Intervention

EFV - Efivarenz

FDC – Fixed Dose Combination

HIV – Human Immunodeficiency Virus

HTS – HIV Testing Services

IQR – Interquartile range

MatCH – Maternal Adolescent and Child Health

PCA – Principal Component Analysis

TB - Tuberculosis

TDF – Tenofovir Disoproxil Furamate

TIER.net – HIV Electronic Register

UK – United Kingdom

UNAIDS – United Nations Programme on HIV/AIDS

USA – United States of America

UTT – Universal Test and Treat

VCT – Voluntary Counselling and Testing

WHO – World Health Organisation

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Abstract

South Africa, in response to the HIV scourge, adopted UNAIDS 90-90-90 targets. In order to achieve the second 90 target, the Universal Test and Treat (UTT) was introduced. A cross-sectional investigation was done to determine whether the healthcare providers in the eThekwini district clinics implemented UTT according to the policy. The study population was the healthcare providers who worked in fixed government clinics. The study was based on Carroll's Conceptual Framework for Implementation fidelity and it focused on the adherence domain as the measure of fidelity. The adherence subdomains were coverage and content. The adherence score for all clinics was 61.6 per cent, which is lower than the target adherence score of 75 per cent. Local government clinics had a higher coverage (65%) than provincial government clinics (62%). The content score for all facilities was 59.8 per cent with local government clinics having a higher content score (63.8%) than provincial clinics (56.3%). Out of the 400 files of HIV-positive patients reviewed, 254 had a record of ART initiation resulting in a 63.5 per cent coverage score for all clinics enrolled in this study. This score was lower compared to the target score of 90 per cent. Neither provincial nor local government clinics ensured that all HIV patients benefitted from the UTT intervention. The findings in this study revealed that UTT was not implemented with fidelity by healthcare providers in the eThekwini district clinics. One of the main limitations of this study was that some elements of the UTT intervention could not be measured due to unavailability of information. There is a need for further research which includes looking at comparing the percentage of HIV-positive patients commenced on ART before and after UTT.

Chapter 1: Introduction

1.1 Key concepts

Implementation science studies involve the use of terminology that may not be comprehensible to the people that are not in the implementation science field. It is therefore necessary to define key concepts for this study. The following are the main concepts that the focus of the study is on:

- *Implementation fidelity*: refers to whether the evidence-based practice is implemented as specified by the developer or not (1). Fidelity is one of the implementation outcomes, and one of its main roles is to act as a preliminary indicator of the effectiveness or success of an intervention (2).
- *Adherence*: delivery of programme elements as prescribed (1, 3).
- *Content*: refers to whether the details of the intervention are being considered in the implementation (4-6).
- *Coverage*: refers to whether all people who should be benefiting from the intervention are doing so (4-6).

1.2 Background

South Africa is among the countries with significant Human Immunodeficiency Virus (HIV) epidemics, globally (7). The eThekwini district is one of the districts with the high HIV prevalence (8).

The targets have been set to ensure that 90 per cent of HIV-positive people know that they are positive (first target), of those that are positive 90 per cent commence ART (second target), and 90 per cent have their viral load suppressed through ART (third target) by 2020 (7). South Africa adopted UNAIDS 90-90-90 targets in December 2014 (9). However, a

recent study has shown that South Africa is lagging behind in achieving UNAIDS 90-90-90 targets (10) and recent evidence has shown that KwaZulu-Natal has achieved 60-70-88 thus far (11). These studies highlight that much is still required to be done in order to achieve these targets, especially the first and second targets.

Several strategies have been introduced and are aimed at achieving the UNAIDS 90-90-90 targets (7). UTT is an intervention aimed at attaining the first and second 90s. A few randomised controlled trial studies assessing the implementation of UTT have shown promising results (12); (13). UTT intervention was introduced in all KwaZulu-Natal districts on the 1st of September 2016, as part of the nationwide strategy. It is important to assess UTT implementation fidelity at the initial stage of implementation in order to ensure that implementation challenges are identified and addressed early.

1.3 Literature Review

Studies on UTT have been conducted and their focus was, among other issues, on perceptions, effects and challenges of UTT (14-16). The search conducted for this study did not reveal any studies on implementation fidelity of UTT.

1.3.1 Universal Test and Treat HIV Strategy

UTT is an HIV prevention strategy that involves the use of treatment for prevention. The distinguishing element of UTT is that ART is offered to those testing HIV-positive without considering the CD4 count or the clinical stage of the patient (13). Using treatment as prevention is not a new phenomenon especially in HIV care. Co-trimoxazole has been used in several countries, including South Africa, to prevent the occurrence of a number of opportunistic infections, and as a result a considerable number of deaths have been averted (17). Antiretroviral treatment has been proven to improve health. The use of UTT is based on the role of antiretroviral treatment in improving health (18). It is imperative that UTT

intervention is implemented in a way that ensures its effectiveness. The assessment of implementation fidelity was undertaken as a way of determining whether the UTT intervention is being implemented effectively or not.

In 2016, the South African Department of Health released a circular on UTT stating the elements that are essential for the successful implementation of UTT. Table 1 summarises the UTT elements as listed in the UTT policy (19).

Table 1: UTT Policy Elements

UTT policy element	Description
Eligibility criteria	All HIV-positive people, regardless of CD4 count, should be offered ART treatment, prioritising those with a CD4 count ≤ 350 cells/mm^3
	Patients in the pre-ART and wellness programme should be considered for UTT
	Willingness and readiness assessment and keeping of patients who are not ready after assessment in the wellness programme, continuous counselling on the importance of early treatment and a scheduled CD4 count
	Baseline monitoring of the CD4 count as a key factor in determining whether to initiate opportunistic infection prophylaxis or not
Timing of ART initiation	Starting of patients on ART as soon as they are ready and within two weeks of a CD4 count being done
Immediate priority	All HIV-positive pregnant and breastfeeding women with no active TB or contraindications to FDC (TDF/FTC/EFV)
Fast track initiation	Patients with a CD4 count ≤ 200 cells/mm^3 (HIV stage 4) should be prioritised
ART initiation in case of TB	If a patient is diagnosed with TB, TB treatment should be started first followed by ART as soon as possible and within eight weeks
	If a patient has a CD4 count < 50 cells/mm^3 ART should be initiated within two weeks after starting TB treatment, when the patient's symptoms are improving and TB treatment is tolerated
	If a patient has a CD4 > 50 cells/mm^3 ART should be initiated within 2 – 8 weeks after starting TB treatment
	If a patient has cryptococcal or TB meningitis ART should be deferred for 4 – 6 weeks
Clinical monitoring for all patients	Clinical monitoring should be done according to the South African clinical guidelines
Differentiated care for stable adult	Successful UTT implementation requires freeing up space and human resources at facilities through implementation of facility decongestion strategies, e.g. spaced and fast lane appointments

Source: 22 8 16 Circular UTT Decongestion CCMT Directorate

1.3.2 Implementation Fidelity

Implementation fidelity refers to whether the evidence-based practice is implemented as specified by the developer or not (1). Fidelity is one of the implementation outcomes, and one of its main roles is to act as a preliminary indicator of effectiveness or success of an intervention (2).

Carroll *et al*'s implementation fidelity framework (Figure 1), proposes that an intervention undergoes at least two kinds of evaluations, i.e. implementation fidelity evaluation and outcome evaluation. It also proposes that implementation fidelity evaluation includes the assessment of potential moderators of implementation fidelity which include: responsiveness of participants, complexity of intervention, quality of delivery and facilitation strategies (5).

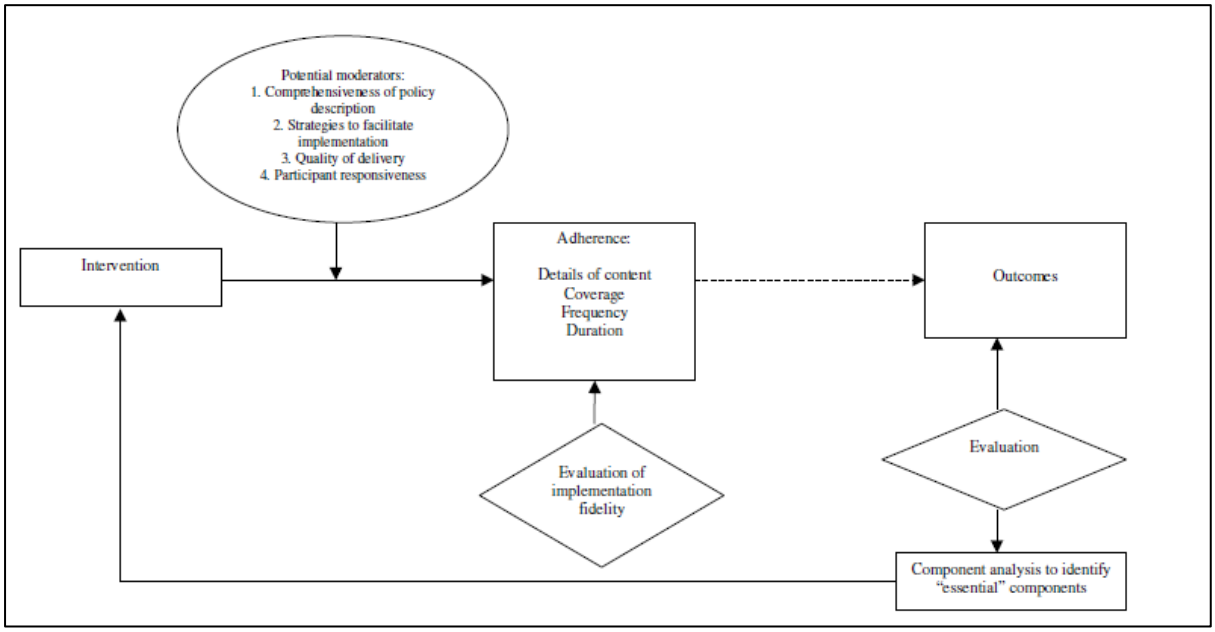


Figure 1: Conceptual framework for implementation fidelity

In a study conducted in one of the health districts in Burkina Faso to measure implementation fidelity of a malaria prevention programme, a modified Carroll's framework for implementation fidelity was used. The focus of the study was on content, coverage and the schedule subcomponents of adherence as well as moderating factors which included intervention complexity, and quality of delivery, among others. This study left out frequency and duration subcomponents of adherence (20). Carroll's framework for implementation fidelity was also applied in assessing the distribution of the Char in Quebec. The assessment of the project focused on content, frequency and duration subcomponents of the adherence domain of fidelity. The assessment included potential moderators such as complexity, facilitation, quality and responsiveness (21). The two studies show that the implemention

fidelity conceptual framework can successfully be implemented with or without adaptation thereof.

Measurement of fidelity of implementation involves looking at five domains, which are: i) *adherence* - delivery of programme elements as prescribed; ii) *exposure* – the amount of the programme delivered in relation to that which is required as per programme requirements. This is common in interventions that involve programmes that are delivered through a number of steps. These require that all steps should be covered in order to ensure full exposure to the intervention; iii) *quality of delivery* – the manner of programme delivery; iv) *participant responsiveness* – reaction of participants to the programme; and v) *programme differentiation* – the level at which key elements of the intervention can be identified. Most of the fidelity of implementation evaluation studies focus on one domain, i.e. adherence, but the recommendation is that the evaluation should cover all of them (1, 3).

There are four subdomains of adherence, namely; i) *content* – which refers to whether the details of the intervention are being considered in the implementation or not , ii) *coverage* – which refers to whether all people who should be benefiting from the intervention are doing so or not , iii) *frequency* – which refers to whether the components of the intervention are being implemented as often as prescribed or not, and iv) *duration* – which refers to how much time it takes for the intervention to be delivered to the target group (4-6). Studies conducted in England, the Netherlands and Finland to assess implementation fidelity showed that adherence and or fidelity scores ranged from ten per cent to 96 per cent.

A study was done in England to assess the implementation fidelity of a non-commitment session of a smoking cessation campaign focussed on the protocol-specified behaviours delivered. This was done by looking at the number of behaviours implemented by advisors against the total number of behaviours identified. Assessment of adherence to the protocol was done through audio recordings of the sessions. The audio recordings were later

transcribed in preparation for analysis. Results showed that individual session adherence ranged from 28.76 per cent to 95.89 per cent (22).

Another implementation fidelity study conducted in the Netherlands focussed on adherence to the intervention model for the homeless and for abused women, known as Critical Time Intervention (CTI). This involved a support model with three 3-month phases where support decreased with time. The CTI forms were reviewed by two fidelity assessors who were knowledgeable in the CTI model. Focus groups were conducted to determine factors associated with adherence to the CTI model components. Compliance results showed that the highest fidelity score (85%) was on the nine-month follow-up item and the lowest (25%) was on the three-phases item. The challenge noted with the 'three phases' item was that there was failure to start and end each of the three phases within the stipulated time (23).

The assessment of implementation fidelity of a geriatric model in the Netherlands involved developing qualitative research questions for collection of data on the coverage, frequency and duration sub-categories of adherence. For the content subcomponent, qualitative data were collected. Results showed that coverage for geriatric assessment, care planning and multidisciplinary care teams ranged from 83 per cent and 91.3 per cent, 94 per cent and 98.7 per cent, zero per cent and 12.5 per cent, correspondingly in the six months period. Only the multidisciplinary care team coverage improved with time, while geriatric assessment and care plan coverage declined as time went on. Frequency increased with time (6).

Another study was conducted in the Finnish University Hospital to assess fidelity evaluation in hand hygiene. Structured observation was conducted in the study based on the Joanna Briggs Institute evaluation criteria. Most of the items on the observation form required a 'yes' or 'no' answer, except for the one that assessed fidelity through duration of handwashing. An expert panel assessed the validity of the form. The inter-rater reliability was evaluated by

infection control experts. The results showed that the handwashing duration that met the criterion was evident in ten per cent of cases (24).

In a study conducted in Baltimore by Dusenbury *et al.* to assess the quality of implementation in dissemination using observation, adherence was one of the constructs of interest. The study involved the observation of teachers' teaching sessions after completing life skills training. The assessment of adherence involved the measurement of six items. Those who met major points and objectives were given full points as opposed to half points when partially met. The teachers implemented 65 per cent of the teaching objectives. The achievement with regard to the main points was 58 per cent. Five of the six items being combined into one scale resulted in an alpha coefficient of 0.89 (25).

1.3.3 Factors Associated with Fidelity of Implementation

According to Carroll *et al.*, there are four moderators which may influence or affect fidelity of implementation. They are: i) quality of delivery; ii) participant responsiveness; iii) facilitation strategies; and iv) comprehensiveness of policy description (5). Some of the other factors that affect implementation fidelity include beliefs of the implementers, resources required, perceived importance of the intervention, and programme ownership (26).

Quality of Delivery

This points to whether the intervention is delivered appropriately or badly (5). In a study conducted to assess the quality of implementation in dissemination using observation, correlation between adherence and other variables such as teachers' understanding of life skills training and teachers' experience in prevention programmes was assessed. Teachers' understanding of life skills training was measured through observation, more especially when they had to answer questions asked by the students. The mean score for the understanding of

concepts on a seven-point scale was 4.7. Most adherence was associated with teachers who had more experience in prevention programme teaching ($r = 0.630$; $p = 0.05$) (25).

Participant Responsiveness

Participant responsiveness concerns how those who participate in the intervention view it (5). A study conducted in the Bahamas, to determine factors affecting implementation fidelity and dose of an HIV prevention programme, focused on how teachers perceived what the programme's curriculum entailed, the experience they had in training and other related factors. Results showed an association between the identified factors and implementation of the programme. The higher implementation group found the programme to be more important (100% against 98% and 89%, respectively), identified more ownership of the programme (72% against 59% and 28%, respectively) and had a higher comfort level in teaching the programme (2.9 against 2.8 and 2.7%, respectively) than the moderate and lower implementation groups (27).

Facilitation Strategies

Facilitation strategies refer to support strategies which include training, manuals, monitoring and feedback for the implementers (5). Experts and literature recommend training, improved access to guidelines and the steering of practice towards guidelines (28).

Comprehensiveness of the Intervention

This refers to the simplicity or how complex the intervention is (5). Comprehensiveness of the intervention or procedure is likely to dissuade healthcare providers from following the guidelines (29). Also guidelines for the procedure or intervention must be easy to read and understand, in order to facilitate the use thereof (30).

Other Factors

These include the beliefs of the implementers, resources required, perceived importance of the intervention and programme ownership (26). In a study conducted in England, association between adherence and factors such as gender, age and whether smoking-cessation advisors worked alone or were assisted was assessed. Data on age and gender were collected through a questionnaire that the advisors completed during their training. Sessions where advisors had assistance had a higher adherence than when advisors worked alone (75.73% vs 64.79%, respectively, p =0.044). There was also a positive correlation between gender and age and the level of adherence. Female advisors had more adherence (72.19% compared to 58.53%) than their male counterparts. Older advisors had more adherence than younger ones (75.41% compared to 61.87%) (22).

1.4 Problem Statement

The ultimate outcome for the use of antiretroviral treatment is viral load suppression in the body of a person living with HIV (31). UTT has been introduced at a time when the country has adopted the 90-90-90 HIV strategy, which among other things is focussing on ensuring that 90 per cent of those diagnosed with HIV are initiated on antiretroviral treatment. One of the main challenges with starting patients on any treatment is ensuring healthcare provider adherence to treatment guidelines (28). The average adult is said to receive about 50 per cent of the health care they are supposed to receive and this problem can be addressed by ensuring

healthcare provider adherence to treatment guidelines (28, 32). An evaluation of the ways to modify the observance of Asthma treatment guidelines by healthcare providers recommends that feedback and an audit among other things have the potential to enhance adherence to treatment guidelines (33, 34).

There is a scarcity of fidelity of implementation studies conducted in HIV evidence-based interventions. Most of the fidelity of implementation studies conducted are in behavioural therapy, family therapy and mental health fields (35-37).

1.5 Justification

Implementation of evidence-based interventions with fidelity can be used as an indicator of whether or not the intervention will be effective in real-life situations (2). Considering the effect of implementation fidelity on the success of the intervention, it is fundamental that the implementation fidelity of the UTT intervention be evaluated. It is also important to evaluate fidelity of implementation in different settings, considering that several factors can have influence on it.

This study has the potential to inform improvements in the UTT implementation, HIV-related programmes and other health programmes. It is also important for this study to focus on the adherence domain of fidelity of implementation because it assesses whether the core elements of the intervention are being implemented or not. Evaluating adherence at the initial stages of the intervention ensures that any deviations from fidelity are identified and acted upon before the development of adverse consequences of poor implementation.

1.6 Research Question

Was the UTT intervention implemented with fidelity by healthcare providers in the eThekwini district clinics during the 01 August 2017 to 31st January 2018 period?

1.7 Aim

To determine whether the UTT policy was implemented with fidelity by healthcare providers for all people testing HIV-positive in the eThekwini district clinics during the period 2017 to 2018.

1.8 Objectives

1. To determine whether the healthcare providers in the eThekwini district adhered to the UTT policy in the 2017 to 2018 period *(content).*

2. To determine whether the type of clinic, i.e. local or provincial, had an effect on the UTT adherence scores *(moderation).*

3. To establish the percentage of HIV-positive patients commenced on ART as soon as they were prepared and within two weeks of doing a CD4 count.*(coverage).*

Chapter 2: Methods

2.1 Design

Cross-sectional.

2.2 Site and Population

The study population was healthcare providers working in the fixed government clinics, both provincial and local government, in the eThekwini district, in the 2017/2018 period. The eThekwini district was chosen because of the high HIV prevalence (8).

2.3 Sampling

The sampling frame for the clinics from which data was collected, was the list of all primary healthcare facilities (clinics) in the eThekwini district enrolled in the HIV Testing Services (HTS) functionality-in-TIER.net project. The selected clinics were those using electronic registers for recording patient data on both HIV counselling and testing as well as antiretroviral treatment.

A stratified random sampling was done in selecting the clinics from which data was collected. Sixteen (16) clinics were selected. Half (8) of those clinics were selected from the provincial clinic list and the other half (8) were selected from the local government list.

All healthcare providers, including lay counsellors on duty on the day of the interviews, were given an opportunity to take part in the study. Four hundred (400) records of patients diagnosed as HIV-positive between the 1st August 2017 and 31st January 2018 were sampled for review. These records were sampled from a total of 2,480 records. The number of records was based on a sample calculation informed by the mean of the adherence scores (84.5%) sourced from the studies on implementation fidelity (6, 22, 23, 38). The number of records reviewed per clinic was proportional to the size of the clinic, and these records were

randomly selected. The process for selecting records included three (3) steps. Firstly, lists of file numbers, or names where files numbers were not available, for all HIV-positive patients were drawn from the HTS register or Voluntary Testing and Counselling (VCT) register. The lists were then imported into the statistical software (Stata) for the drawing of samples. The sampled lists were then used to retrieve patient files.

2.4 Measurement of Fidelity

An adapted implementation fidelity framework was used as a basis for this study. The shapes with dash lines in the diagram indicate what this study did not cover (Figure 1). Potential moderators were not covered because data available were not adequate for the appropriate analysis to be done and the outcome was not evaluated because it fell outside the scope of this study.

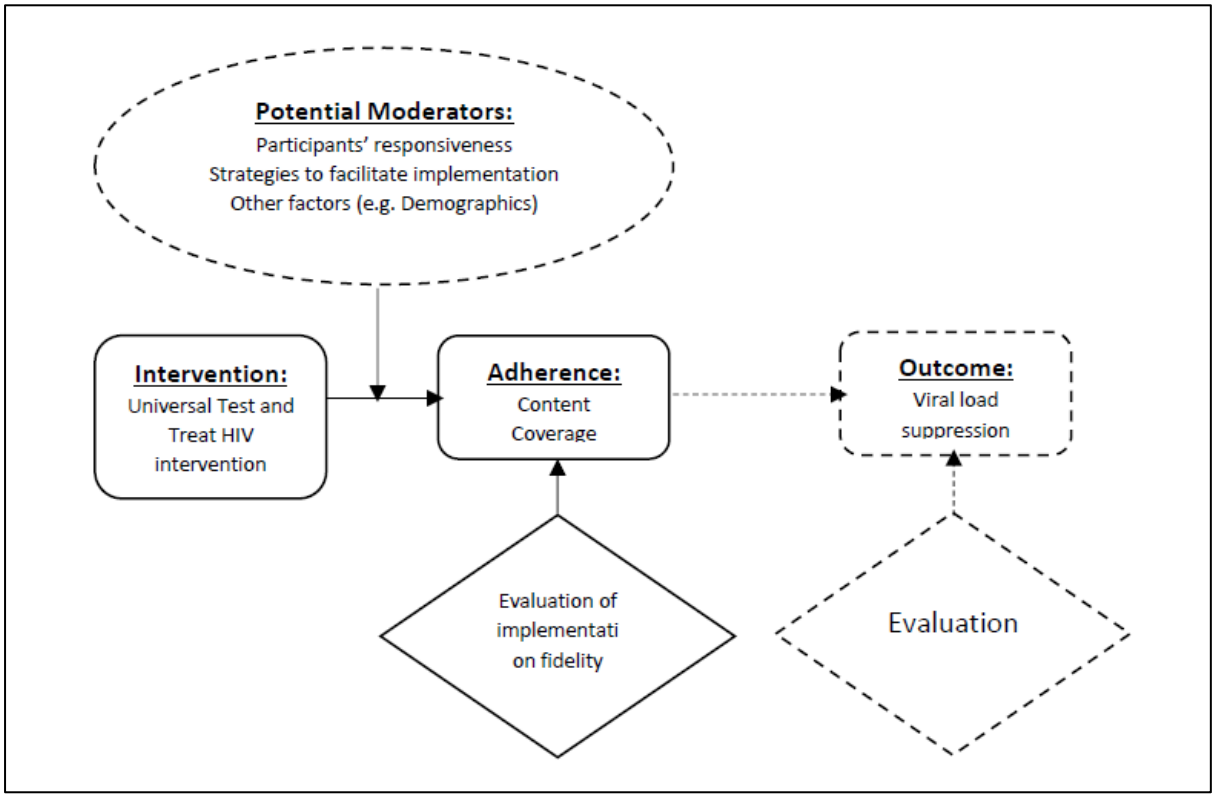


Figure 2: Adapted Conceptual Framework for Implementation Fidelity (5)

The domain chosen for measuring fidelity was adherence. Adherence in this study refers to how far the implementers of the intervention, in this case the healthcare providers, adhere to the UTT policy (4).

This study focused on content and coverage sub-domains of adherence. Coverage, in this study, focussed on the HIV-positive patients started on ART. Content in this study refers to whether the key elements of offering and starting patients on antiretroviral treatment were considered during the management of patients.

Table 2 below shows the elements and sub-elements of UTT referred to in table 1. It shows elements and sub-elements that were measured, those that were not measured in this study and the reasons why they were not measured.

Table 2: UTT policy elements and sub-elements: reasons why some of them were not measured

UTT policy element	UTT policy sub -element	Description	Measured: Yes/No	Reason it was not measured/comments
Eligibility criteria	All HIV-positive patients offered ART	All HIV-positive people, regardless of CD4 count, should be offered ART treatment prioritising those with a CD4 count ≤ 350 cells/mm^3	Yes	Not Applicable
	UTT for pre-ART and wellness programme patients	Patients in the pre-ART and wellness programme should be considered for UTT	No	Information was not available. The only records available were for patients who had been initiated on ART
	Wellness programme for patients who are not ready for ART	Willingness and readiness assessment and keeping of patients who are not ready after assessment in the wellness programme, continuous counselling on the importance of early treatment and a scheduled CD4 count	No	Information was not available. The only records available were for patients who had been initiated on ART
	Baseline CD4 count	Baseline monitoring of the CD4 count as a key factor in determining whether to initiate opportunistic infection prophylaxis or not	Yes	Not Applicable
Timing of ART initiation	ART within two weeks of a CD4 count being done	Starting of patients on ART as soon as they are ready and within two weeks of a CD4 count being done	Yes	Not Applicable
Immediate priority	All HIV-positive patients with a CD4 ≤ 350 cells/mm^3	All HIV-positive pregnant and breastfeeding women with no active TB or	Yes	This study focused on all people with CD4 count ≤ 350 cells/mm^3 because of limited time and resources

Table 2: UTT policy elements and sub-elements: reasons why some of them were not measured

UTT policy element	UTT policy sub -element	Description	Measured: Yes/No	Reason it was not measured/comments
	initiated on ART.	contraindications to FDC (TDF/FTC/EFV)/ All HIV-positive children, adolescents and adults with a CD4 ≤ 350 cells/mm^3 initiated on ART.		
Fast track initiation[1]	Prioritising patients with a CD4 count ≤ 200 cells/mm^3	Patients with a CD4 count ≤ 200 cells/mm^3 (HIV stage 4) should be prioritised for initiation on ART	Yes	For this study the focus was on whether the HIV-positive patients with CD4 count ≤ 200 cells/mm3 were initiated on ART within seven days of being diagnosed as HIV-positive or not.
ART initiation in case of TB[2]	TB treatment before ART	If an HIV-positive patient is diagnosed with TB, TB treatment should be started first followed by ART as soon as possible and within eight weeks	Yes	Not Applicable
	ART within two weeks after TB treatment for a CD4 count < 50 cells/mm^3	If a patient has a CD4 count < 50 cells/mm^3 ART should be initiated within two weeks of starting TB treatment, when the patient's symptoms are improving and TB treatment is tolerated	No	No information
	ART within 2 -8 weeks after TB treatment for a CD4 count> 50 cells/mm^3	If a patient has a CD4 > 50 cells/mm^3 ART should be initiated within 2 – 8 weeks after starting TB treatment	Yes	Not Applicable
	ART deferred for 4 - 6 weeks in cryptococcal or TB	If a patient has cryptococcal or TB meningitis ART should be deferred for	No	There were no cryptococcal or TB meningitis cases as per records sampled

[1] ART initiation within 7 days of being eligible (2013 ART guidelines)
[2] Note: Out of 400 records only 12 had a TB diagnosis

Table 2: UTT policy elements and sub-elements: reasons why some of them were not measured

UTT policy element	UTT policy sub -element	Description	Measured: Yes/No	Reason it was not measured/comments
	meningitis	4 – 6 weeks		
Clinical monitoring for all patients	Clinical monitoring	Clinical monitoring should be done according to the South African clinical guidelines	No	This was not measured due to limited time and resources
Differentiated care for stable adults	Differentiated care	Successful UTT implementation requires freeing up of space and human resources at facilities through implementation of facility decongestion strategies, e.g. spaced and fast lane appointments	No	This was not measured due to limited time and resources

Source: 22 8 16 Circular UTT Decongestion CCMT Directorate

2.5 Data Collection

Adherence data were collected in two ways. Firstly a retrospective review of patient records was conducted. This review focused on patients who tested HIV- positive between the 1st of August 2017 and 31st January 2018. Each patient's record has a section on HIV testing and results of the test as well as a part on antiretroviral treatment which gives the details on ART initiation. A structured data collection form (Appendix 1b) was used to collect data from the HIV-positive patients' records.

Secondly, healthcare providers involved in the counselling, testing and treatment of patients were assessed on how they conducted the process of offering and starting patients on antiretroviral treatment. A structured questionnaire (Appendix 2b) was used to collect data from the healthcare providers. This questionnaire included questions on factors associated with UTT implementation fidelity as well.

There was no specific number of healthcare providers invited to participate in the study as the number would be dependent on whether they were available to participate or not. Healthcare providers who gave consent to be interviewed were asked to answer the questions either verbally or in writing. Interviews were conducted during working hours for those healthcare providers who were willing to give some of their break-time for the interviews. The rest of the healthcare providers took the questionnaires home. The questionnaires that were answered at home were later collected from the clinic managers. The principal investigator administered the questionnaire.

Data collection tools were pre-tested in a clinic that formed part of the study population but not part of the sample, and were adjusted accordingly. Appendices 1a and 2a are pre-test data collection tools and 1b and 2b are post-test data collection tools.

2.6 Data Management

Data were extracted from the data collection tools and a database was developed using Microsoft Excel. Data from Microsoft Excel were imported into Stata 15 in order to develop stata-compatible data files. The missing information was accounted for in the analysis of data. It should be noted that it was either that the patient was initiated on ART or a file was missing, meaning that there was no file with information on ART not being initiated. The correctness of data captured was ensured through double-checking and comparing captured data with data in the electronic register. The database was locked and safely stored, and a backup database created.

2.7 Data Analysis

The Stata 15 statistical software was used for analysis.

Sample characteristics were presented as counts, percentages, medians and interquartile ranges.

The analysis for adherence was done according to the two sub-domains, i.e. coverage and content.

The analysis for the content sub-domain of adherence was done in two ways. Firstly, the proportion or percentage of facilities that were associated with the UTT key sub-elements or variables was determined using the Principal Component Analysis (PCA). A bi-plot was generated. The advantage of the bi-plot following a principal component analysis is that it shows the sizes and levels of the observations in relation to the variables. A simple bi-plot that does not show arrows on the negative section of the plot was used to ensure clarity. The selection of the components for further analysis was done based on the screeplot results. Only components or eigenvectors that had values greater than the mean on the screeplot were selected. The Keyser-Meyer-Olkin assessment was used to measure sampling adequacy. The internal consistency of the content variables was measured.

Secondly, analysis of the content sub-domain of adherence was done through determining the proportion of patients managed according to the UTT sub-elements.

The content sub-domain of adherence would be achieved when 60 per cent of the clinics are associated with the positive UTT sub-elements on the PCA or 60 per cent of the patients in the eThekwini clinics were managed according to the key sub-elements of UTT. The content score is based on a study by Durlak and DuPre which showed that the average result for good implementation is 60 per cent (39).

The adherence score was calculated in two ways. Firstly, the coverage score was added to the PCA content score and the sum was divided by two. Secondly, the coverage score was added to the content score that was based on the proportion of patients managed according to the

elements of UTT, and the sum was divided by two. Achieving an overall adherence score of 75 per cent or more would mean that the UTT was implemented with fidelity. A score of 75 per cent was based on adding the target coverage score (90) to the target content score (60) and then dividing the sum (150) by two.

Comparison between adherence scores for provincial and local government clinics was done through a Mann-Whitney-U test. This test was done to address the challenge of the data that were not normally distributed.

Counts (n) and percentages (%) were used to summarise coverage data. Coverage would be achieved if the healthcare providers initiated at least 90 per cent of the patients diagnosed as HIV-positive on ART. The score of 90 per cent is based on the second 90 of the 90-90-90 strategy (7).

Commencement of ART in relation to the day of HIV test was looked at. Also, the estimation of the effect of the facility type, gender, age, CD4 count at diagnosis and the presence of other diseases on ART initiation within 14 days of HIV diagnosis was done. Odds ratios, confidence intervals and p-values were presented for both the univariate (unadjusted) and multivariate (adjusted) analyses.

Ethics

All the necessary approvals were obtained. Permission to collect data from the patient files was requested from the KZN Department of Health (Appendix 4), the eThekwini Health District (Appendix 5), the eThekwini Health Department (Appendix 6), and the University of the Witwatersrand granted ethical clearance (Appendix 7). The healthcare providers who participated in the study did so after signing an informed consent form. Interviews with

healthcare providers did not interfere with patient care even though they were conducted during working hours. No names or identification details of participants were recorded.

Chapter 3: Results

3.1 Introduction

This part of the report shows the output of the analysis based on the data collected as per the study objectives. The chapter includes the sample characteristics and adherence sections.

3.2 Sample Characteristics

Twenty-four (24) healthcare providers were interviewed. Their median age was 41 (IQR: 36.5 – 45.5). Two (8.3%) of them were males and 22 (91.7) were females. The median length of service for all healthcare providers was 11 (IQR: 7 – 17) years, 11 (IQR: 7 - 17) years for provincial clinics and 11 (IQR: 8 - 16) years for local government clinics. The median length of service in the facility was five (IQR: 5 – 7) years for all clinics. The median for experience in HIV care was five (IQR: 3 – 9) years (Table 3).

Table 3: Characteristics of healthcare providers implementing the Universal Test and Treat intervention, during 2018, in the eThekwini district, South Africa

	Provincial clinics	**Local Government clinics**	**All clinics**	**p-value**
Variable	**(*n* = 14)**	**(*n* = 10)**	**(*n* = 24)**	
Age *M (IQR)*	**44.5 (41 - 48)**	**38.5 (36 - 41)**	**41 (36.5 – 45.5)**	**0.127**
Gender:				**0.229**
Male n (%)	2 (14.3)	0 (0)	2 (8.3)	-
Female n (%)	12 (85.7)	10 (100)	22 (91.7)	-
Length of service as healthcare provider (years) *M (IQR)*	**11 (7 - 17)**	**11 (8 - 16)**	**11 (7 - 17)**	**0.811**
Length of service in this facility *M (IQR)*	**6.5 (5 - 8)**	**5 (3 - 6)**	**5 (5 - 7)**	**0.814**
Experience in HIV care (years) *M (IQR)*	**7 (5 - 8)**	**7 (5 - 8)**	**5 (3 - 9)**	**0.737**
Trained on UTT				**0.118**
Yes n (%)	12 (85.7)	7 (70)	19 (79.2)	-
No n (%)	2 (14.29)	0 (0)	2 (8.3)	-
No information n (%)	-	3 (30)	3 (12.5)	-
Duration of training (days) *M (IQR)*	**2.5 (1 - 4)**	**3 (1 - 5)**	**3 (1 - 4)**	**0.514**
Have a copy of ART guidelines				**0.090**
Yes n (%)	12 (85.7)	6 (60)	18 (75)	-
No n (%)	1 (7.2)	-	1 (4.2)	-
No info n (%)	1 (7.2)	4 (40)	5 (20.8)	-
Supported by a mentor in the last 3 months				**0.261**
Yes n (%)	9 (64.3)	6 (60)	18 (75)	-

Variable	Provincial clinics (*n* = 14)	Local Government clinics (*n* = 10)	All clinics (*n* = 24)	p-value
No n (%)	5 (35.7)	1 (10)	6 (25)	-
No info n (%)	-	3 (30)	3 (12.5)	-

Notes:
M = Median

A total of 19 (79.2%) healthcare providers were trained on UTT. The median duration of UTT training for all clinics was three (IQR: 1 - 4) days. Eighteen (75%) healthcare providers reported to having copies of the ART guidelines, which included those that were shared (Table 3).

Table 4: Health care providers' views about the importance and appropriateness of UTT

Variable	Provincial clinics (*n* = 14)	Local Government clinics (*n* = 10)	All clinics (*n* = 24)
Importance of UTT			
Not important	-	-	-
Somewhat important	1 (7.1)	2 (20	3 (12.5)
Important	6 (42.9)	4 (40)	10 (41.7)
Very important	5 (35.7)	4 (40)	9 (37.5)
No information	2 (14.3)	-	2 (8.3)
Appropriateness of UTT			
Strongly disagree	-	2 (20)	2 (8.3)
Disagree	4 (28.6)	4 (40)	8 (33.3)
Neutral	2 (14.3)	1 (10)	3 (12.5)
Agree	3 (21.4)	2 (20)	5 (20.8)
Strongly agree	4 (28.6)	1 (10)	5 (20.8)
No information	1 (7.1)	-	1 (4.2)

Notes:
M = Median

Twenty-two (91.7%) healthcare providers found UTT to be important. When asked whether UTT was implemented when they had been adequately prepared for it, ten (41.6%) healthcare providers agreed (Table 4).

3.3 Adherence to the UTT policy

This study focused on adherence domain as the measure of fidelity. The adherence subdomains were coverage and content.

Two different methods were used to calculate the two adherence scores. One considered patients and the other one clinics.

Table 5: UTT a dherence Score

Variable	Provincial clinics (%)	Local Government clinics (%)	All clinics (%)
Adherence score (Coverage score + PCA Content score)	56	63.8	59.9
Adherence score (Coverage score + Content score based on the proportion of patients managed according to UTT elements)	59.2	64.4	61.8

The use of two methods resulted in a difference of 1.9 between the two scores. The scores for all clinics were 59.9 per cent and 61.8 per cent. The adherence scores for provincial clinics were found to be lower than those of the local government clinics. (Table 5).

Adherence scores for local government and provincial clinics were compared through the Mann-Whitney U test.

Table 6: Comparison of UTT adherence scores

Variable		
Adherence score	Rank sum	Expected
Provincial clinics	66	68
Local government clinics	70	68
All clinics	136	136

Notes:

- p – value = 0.8336
- This test is on the adherence score calculated by adding the coverage score to content score based on the proportion of patients managed according to UTT elements

The UTT adherence scores for provincial clinics were found to be the same as for local government clinics (Table 6).

3.4 Coverage sub-domain of adherence to UTT policy

This sub-domain of adherence was measured to establish the percentage of HIV-positive patients commenced on ART as soon as they were prepared and within two weeks of doing a CD4 count. Out of the total of 400 patient records reviewed, 254 (63.5%) patients were

started on ART. One hundred and twenty-four (62%) patients were initiated by provincial clinics and 130 (65%) were initiated by the local government clinics. (Table 7).

Table 7: Proportion of patients started on ART

	Provincial clinics (%)	Local Government clinics (%)	All clinics (%)
Patients initiated on ART	124 (62%)	130 (65%)	254 (63.5%)

3.5 Content sub-domain of adherence to the UTT policy

The measuring of this sub-element of adherence to the UTT policy was done to determine whether or not the healthcare providers in the eThekwini district adhered to UTT policy in the 2017 to 2018 period.

The analysis of the content sub-domain of adherence was done through the Principal Component Analysis and determining proportions of patients managed according to UTT policy sub-elements.

3.5.1 Measuring content through the Principal Component Analysis

The selection of the eigenvectors for further analysis was done based on the screeplot (Figure 3). Only eigenvectors that had values greater than the mean were selected, and in this case it was eigenvectors 1 and 2.

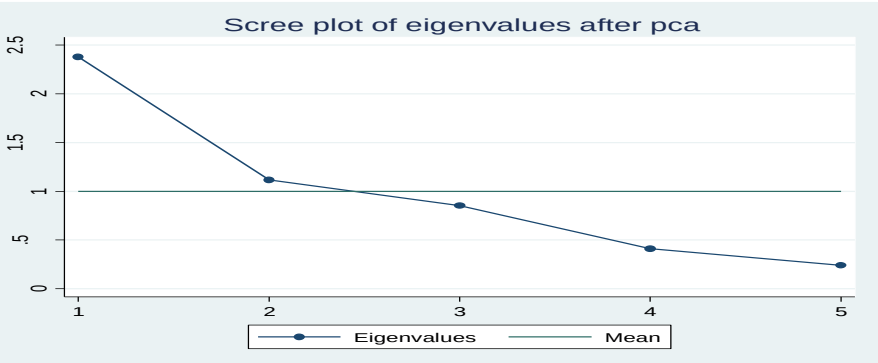


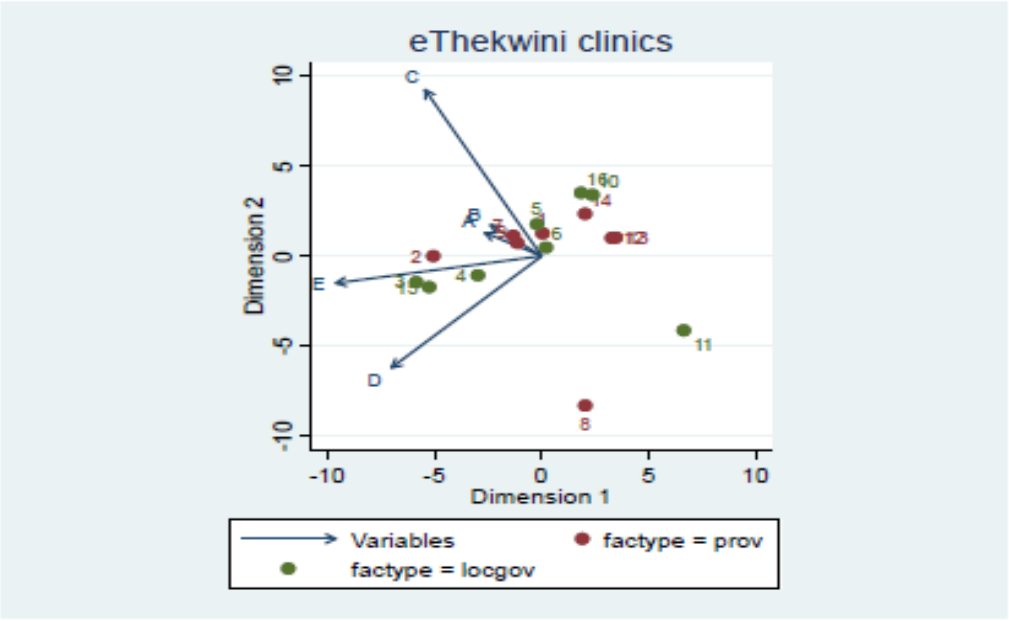
Figure 3: Selection of Eigenvectors

The total variance explained by the selected eigenvectors was 76.8 per cent. The sampling adequacy according to the Keyser-Meyer-Olkin measure was 52 per cent (miserable) but better than unacceptable (<50).

Table 8: Eigenvector Loadings

UTT policy sub-element	Eigenvector 1	Eigenvector 2
All HIV-positive patients offered ART	**0.5148**	-0.2699
Baseline CD4 count	**0.4715**	**-0.3856**
ART within two weeks of CD4 count being done	**0.4075**	**-0.3698**
All HIV-positive with a CD4 $\leq$ 350 cells/mm^3 initiated on ART	**0.4215**	**0.5847**
Prioritising patients with a CD4 count $\leq$ 200 cells/mm^3	**0.4111**	**-0.5475**

Eigenvector 1 had strong positive loadings for all variables whereas eigenvector 2 had one strong positive loading (Table 8). It should be noted that the majority of loadings in eigenvector 2 were negative and strong.



Legend

1 – 16: Clinics (provincial and local government)

A: All HIV-positive offered ART

B: Baseline CD4 count done

C: All HIV-positive patients with a CD4 ≤350 cells/mm³

D: ART within two weeks of a CD4 count being done

E: Prioritizing patients with a CD4 count ≤ 200 cells/mm³

Figure 4: Measuring content sub-domain of adherence to UTT through Principal Component Analysis

The PCA Biplot (Figure 4) shows the number of clinics per facility type and their association with the variables or the sub-elements of UTT. Out of eight local government clinics (factype = locgov), five (62.5%) were associated with the UTT sub-elements, i.e. have higher values. Of the eight provincial clinics (factype = prov), four (50%) were associated with the UTT sub-elements. Out of 16 eThekwini clinics, nine (56.3%) were associated with the UTT sub-elements.

3.5.2 Measuring content through determining proportions of patients managed according to UTT sub-elements

Table 9 below shows the proportions of patients managed according to the Universal Test and Treat HIV policy elements by healthcare providers working in the eThekwini clinics.

Table 9: Adherence to UTT elements

UTT policy element	Description	Provincial clinics n (%)	Local Government clinics n (%)	All clinics n (%)
Eligibility criteria	All HIV-positive people, regardless of CD4 count, should be offered ART treatment, prioritising those with a CD4 count ≤ 350 cells/mm^3 (N = 400)	**124 (62)**	**130 (65)**	**254 (63.5)***
	Baseline monitoring of CD4 count as a key factor in determining whether to initiate opportunistic infection prophylaxis or not (N = 400)	**66 (33)**	**69 (34.5)**	**135 (33.8)**
Timing of ART initiation	Starting of patients on ART as soon as they are ready and within two weeks of a CD4 count being done (N = 130)	**28 (45.9)**	**27 (39.1)**	**55 (42.3)***
Immediate priority	All HIV-positive pregnant and breastfeeding women with no active TB or contraindications to FDC (TDF/FTC/EFV)/ All HIV-positive children, adolescents and adults with a CD4 ≤ 350 cells/mm3 initiated on ART (N = 60)	**30 (93.8)**	**28 (100)**	**58 (96.7)**
Fast track initiation	Patients with a CD4 count ≤ 200 cells/mm^3 (HIV stage 4) should be prioritised (N = 34)	**8 (36.4)**	**4 (33.3)**	**12 (35.3)**
ART initiation in case of TB	If a patient is diagnosed with TB, TB treatment should be started first followed by ART as soon as possible and within eight weeks (N = 12)	**5 (83.3)**	**6 (100)**	**11 (91.7)**
	If a patient has a CD4 > 50 cells/mm^3 ART should be	**2 (40)**	**3 (75)**	**5 (55.6)**

Table 9: Adherence to UTT elements

UTT policy element	Description	Provincial clinics n (%)	Local Government clinics n (%)	All clinics n (%)
	initiated within 2 – 8 weeks after starting TB treatment (N = 9)			
Coverage score**		**62**	**65**	**63.5**
Content score (M)***		**56.3**	**63.8**	**59.8**
Adherence score		**59.2**	**64.4**	**61.6**

***Note*:**

This table reflects the UTT sub-elements that were measured

The coverage sub-element is in the shaded row

* This refers to patients started on treatment and not necessarily those who had a CD4 count done

** Values are the same as in the shaded row

*** (M) – mean percentages for each of the UTT sub-elements

Source: 22 8 16 Circular UTT Decongestion CCMT Directorate

Local government clinics initiated a higher proportion of patients on ART at 65 per cent (130) than provincial clinics at 62 per cent (124). Local government clinics had a higher proportion at 34.5 per cent (69) of patients for whom CD4 counts were done as compared to provincial clinics with 33 per cent (66). A total of 55 (42.3%) patients were commenced on ART as soon as they were prepared and within two weeks of doing a CD4 count . Out of 12 patients started on TB treatment, 11 (91.7%) were initiated on ART following TB treatment. The local government clinics had a higher mean content score (63.8%) than the one for provincial clinics (56.3%). The mean content score for all clinics was 59.8 per cent (Table 9).

There was a 9.8 per cent difference between the content score from the PCA and the one from calculating the proportions of patients managed according to the Universal Test and Treat HIV policy elements by healthcare providers working in the eThekwini clinics.

3.6 ART initiation and CD4 count

The number of days between HIV testing and ART commencement was measured in order to establish the same day ART initiation. The CD4 count at diagnosis was measured to ascertain whether the healthcare providers were still considering the CD4 count as the criterion for starting patients on ART.

Table 10: CD4 count testing and the commencement of ART in relation to the day of HIV test

	Provincial clinics	**Local Government clinics**	**All clinics**
Variable			
No. of days between HIV diagnosis and ART start *M (IQR) (n= 254)**	**1 (0 - 7)**	**1 (0 - 7)**	**1 (0 - 7)**
Same day initiation (*n=254)* **			
Same day initiation of ART n (%)	33 (26.6)	24 (18.5)	57 (22.4)
Initiation of ART within 14 days of HIV diagnosis n (%) ***	27 (21.7)	16 (12.3)	43 (16.9)
Initiation of ART after 14 days of HIV diagnosis n (%)	11 (8.9)	9 (6.9)	20 (7.9)
CD4 count at diagnosis *M (IQR) (n= 254)** ****	**353 (147 - 501)**	**417 (247 – 588)**	**394 (186 - 582)**

Notes:
*This is based on 120 (47%) observations (observations with the date of HIV diagnosis)
**Date of HIV diagnosis missing from 134 (52.8%) files
*** Initiated between day 1 and day 14 after HIV diagnosis
****This is based on 130 (51%) observations
M = Median

The median CD4 count at diagnosis for all clinics was 394 (IQR: 186 - 582). Local government clinics had a higher CD4 median of 417 (IQR: 247 - 588) compared to the median CD4 count of 353 (IQR: 147 - 501) for provincial clinics. The median days between HIV testing and commencement of ART for all clinics was 1 (IQR: 0 – 7). Out of 254 patients initiated on ART, 57 (22.4%) were initiated on the day of HIV testing, 43 (16.9%) between the first and the fourteenth day after HIV diagnosis and 20 (7.9%) after fourteen days of HIV diagnosis (Table 10).

The effect of some variables on ART initiation within 14 days of HIV diagnosis was determined through univariate and multivariate analysis (Table 11).

Table 11: Estimating the effect of the facility type, gender, age, CD4 count at diagnosis and presence of other diseases on ART initiation within 14 days of HIV diagnosis

	Univariate Analysis			Multivariate Analysis		
	OR (unadjusted)	**p-value**	**95% CI**	**OR (adjusted)**	**p-value**	**95% CI**
Facility type	0.82	0.68	0.31 – 2.14	0.76	0.62	0.26 – 2.24
Gender	0.56	0.24	0.21 – 1.48	0.81	0.71	0.27 – 2.48
Age	0.94	0.92	0.28 – 3.15	1.59	0.51	0.40 – 6.37
CD4 count done	0.41	0.11	0.14 – 1.21	0.49	0.23	0.15 – 1.59
Other diseases	0.29	0.01	0.12 – 0.68	0.29	0.01	0.12 – 0.73

The results show that there was evidence that the odds of having ART commenced within 14 days of HIV testing are lower in patients diagnosed with other diseases than in those with no other diseases diagnosed ($p = 0.01$).

Males were found to be less likely to be initiated on ART within 14 days than females. Older patients were found to be less likely to be commenced on ART within two weeks than patients in the younger age-groups, without adjustment.

Chapter 4: Discussion, Strengths, Limitations, Conclusion and Recommendations

This chapter presents the discussion on the findings, strengths, study limitations, conclusion and recommendations. This study was conducted to determine whether the UTT intervention was implemented with fidelity by the healthcare providers in the eThekwini district clinics. The discussion on the findings are detailed hereunder.

4.1 Discussion

The main finding of this study was that neither provincial nor local government clinics' healthcare providers were adherent to the UTT policy. Not all HIV-positive patients benefitted from the UTT intervention during the 2017 to 2018 period. Local government clinic healthcare providers did better than their provincial counterparts in considering the key elements of offering and starting patients on antiretroviral treatment.

The focus of this study was on the adherence domain of implementation fidelity. The subdomains of adherence were coverage and content. The results showed that the coverage score for all clinics was 63.5 per cent. Local government clinics had a higher coverage score of 65 per cent compared to the provincial clinics at 62 per cent. The content score for provincial clinics was 56.3 per cent and the one for local government clinics was 63.8 per cent. The content score for all clinics was 59.8 per cent. The adherence score for provincial clinics was 59.2 per cent, whilst the one for local government clinics was 64.4 per cent. The percentage of patients put on ART on the day of HIV testing was 22.4 per cent and was the highest compared to that of patients initiated between the 1st and the 14th day, and after 14 days. The results also showed that the presence of other diseases at the diagnosis of HIV was

a significant factor associated with ART initiation taking place after 14 days of HIV diagnosis.

The coverage in this study was lower than 90 per cent demonstrating that the target percentage of HIV-positive patients commenced on ART as soon as they were prepared and within two weeks of doing a CD4 count was not met. The 90 per cent target was based on the second 90 of the UNAIDS 90-90-90 strategy according to a study conducted to monitor the effectiveness of the HIV programme and identify areas where intensive effort is needed if the 90-90-90 targets are to be met (10). The coverage was also low compared to coverages reported in studies by Compaore *et al*. (ranging from 83.2% to 91.3%) and Muntinga *et al.* (100%) (6, 20). The study by Compaore *et al*. was conducted in one of the health districts in Burkina Faso to measure implementation fidelity of a malaria prevention programme and the one by Muntinga *et al*. was conducted to assess implementation fidelity of a geriatric model in the Netherlands.

The attempt to determine whether the healthcare providers in the eThekwini district adhered to the UTT policy in the 2017 to 2018 period showed that the content score achieved by the eThekwini clinics was lower than the target score of 60 per cent as proposed by Durlak and DuPre (39). The target adherence score of 75 per cent for this study was not achieved. Research conducted previously showed that a higher adherence score of 75 per cent could be achieved (40). The findings of the study showed that local government clinics generally performed better than provincial clinics. This demonstrated that the type of clinic had an effect on adherence to UTT.

The poor performance in terms of the adherence score can be attributed to factors which include UTT training not being provided for all healthcare providers, some healthcare

providers not being supported by mentors, and inadequate preparation of healthcare providers for UTT implementation.

The results of the occurence of ART commencement in relation to HIV diagnosis were not comparable to studies previously conducted. The percentage of patients started on ART on the day of HIV testing was very low compared to 97 per cent and 94.9 per cent reported by Sam *et al*. and Pilcher *et al*., respectively (41, 42). With regard to the proportion of patients initiated within 14 days, a study by Larsen *et al.* reported a higher proportion at 53.6 per cent (43). The differences can be attributed to the type of setting, patients included, and the model of care. The Larsen *et al's* study was conducted in three South African districts which did not include the eThekwini district. The study by Sam *et al*., focused on pregnant women, whilst the study by Larsen *et al*. excluded patients younger than 15 years. The study by Pilcher *et al*. showed that more patients could be put on ART on the day of HIV testing if health system modifications are considered.

The median CD4 count at diagnosis was low, even though the one for local government clinics was slightly higher. The expectation was that the CD4 count should be higher than 500 cells/mm^3 considering that one of the pre-UTT criteria for commencing ART was a CD4 count of 500 (44).

Looking at the factors associated with the early and late initiation of ART, the presence of other diseases was the main factor associated with initiation after 14 days in this study. This is comparable to the findings by Deconinck *et al*. where TB diagnosis resulted in a median of 64 days (IQR, 26 – 109) (45). On the other hand, Palmer *et al*. showed that late ART initiation was associated with a higher viral load at baseline, while Sam *et al*. showed that it was associated with the type of facility the patient was diagnosed at (41, 46).

4.2 Strengths

This study is to the author's best knowledge the first to be conducted on fidelity of UTT implementation in the province of KZN. The study used file review as an implementation assessment method which is not common in implementation studies as most implementation studies use observation and self-report (39). This study has a key role to play in ensuring that the desired outcomes of the UTT intervention are achieved, which has been done by identifying areas for improvement. Attending to these areas has the potential to increase the chances of the desired UTT intervention outcomes being achieved. The sampling of the clinics for this study covered both local government and provincial clinics, ensuring that both clinic types were represented. Representativeness of the clinic sample was also ensured by including both rural and urban clinics. This study is different from the other UTT study conducted in the KZN province because it was conducted in a metropolitan area and not in a purely rural area (18).

4.3 Limitations

Not all key elements of the UTT intervention could be measured due to unavailability of information, e.g. missing files or information. The unavailability of some of the information resulted in a situation where a complete picture of the UTT could not be ascertained. Also, a very small number of healthcare providers participated in the study, resulting in a situation where the potential moderators for implementation fidelity could not be measured.

4.4 Conclusion and Recommendations

The findings in this study revealed that the eThekwini district healthcare providers did not adhere to the UTT policy in the 2017 to 2018 period. This study showed that the type of clinic had an effect on UTT adherence scores as local government clinics had better adherence score than the provincial clinics. Both provincial and local government clinics did

not perform well in terms of ensuring that those that are HIV-positive are commenced on ART as soon as they were prepared and within two weeks of doing a CD4 count. The percentages of the HIV-infected commenced on ART were lower than the target. Comparing the percentage of HIV-infected put on ART before the introduction of UTT and the proportion commenced after the introduction of UTT, would have been worthwhile. This study was mainly quantitative and it would be valuable to conduct a more in-depth study which would include a qualitative element.

References

1. JamesBellAssociates. (2009). Evaluation Brief - Measuring Implementation Fidelity.
2. Proctor, E., Silmere H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., Griffey, R., Hensley M. (2011). Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health*. 38(2), pp. 65-76.
3. Musuuza, JS., Barker, A., Ngam, C., Vellardita, L., Safdar, N. (2016). Assessment of Fidelity in Interventions to Improve Hand Hygiene of Healthcare Workers: A Systematic Review. *Infection Control and Hospital Epidemiology*. 37(5), pp.567-75.
4. Allison, R., Lecky, D.M., Town, K., Rugman, C., Ricketts, E.J., Ockendon-Powell, N., Folkard, K.A., Dunbar, J.K., McNulty, C.A.M. (2017). Exploring why a complex intervention piloted in general practices did not result in an increase in chlamydia screening and diagnosis: a qualitative evaluation using the fidelity of implementation model. BMC *Family Practice*. 18(1), p. 43.
5. Carroll, C., Patterson, M., Wood, S., Booth, A., Rick, J., Balain, S. (2007). A conceptual framework for implementation fidelity. *Implementation Science*. 2, p. 40.
6. Muntinga, M.E., Van Leeuwen, K.M., Schellevis, F.G., Nijpels, G., Jansen, A.P. (2015). From concept to content: assessing the implementation fidelity of a chronic care model for frail, older people who live at home. *BMC Health Services Research*. 15, p. 18.
7. UNAIDS. (2017). Ending AIDS: Progress towards the 90-90-90 targets. Global_AIDS_update.
8. Shisana, O., Rehle, T., Simbayi, L., Zuma, K., Jooste, S., Zungu, N., Labadarios, D., Onoya, D. (2012). South African National HIV prevalence incidence and behaviour survey. HSRC Press.
9. Trust HS. (2016). 90-90-90 Vol FINALweb31oct2016.
10. Takuva, S., Brown, A.E., Pillay, Y., Delpech, V., Puren, A.J. (2017). The continuum of HIV care in South Africa: implications for achieving the second and third UNAIDS 90-90-90 targets. AIDS. 31(4), pp. 545-52.
11. Grobler, A., Cawood, C., Khanyile, D., Puren, A., Kharsany, A.B.M. (2017). Progress of UNAIDS 90-90-90 targets in a district in KwaZulu-Natal, South Africa, with high HIV burden, in the HIPSS study: a household-based complex multilevel community survey. *The Lancet HIV*.
12. Plazy, M., Farouki, K.E., Iwuji, C., Okesola, N., Orne-Gliemann, J., Larmarange, J., Lert, F., Newell. M-L., Dabis, F., Dray-Spira, R. (2016). Access to HIV care in the context of universal test and treat: challenges within the ANRS 12249 TasP cluster-randomized trial in rural South Africa. *Journal of the International AIDS Society*. 19(1), pp. 20913.
13. Hayes, R., Sabapathy, K., Fidler, S. (2011). Universal Testing and Treatment as an HIV Prevention Strategy research questions and methods. *Current HIV Research*. 9, pp. 429 - 445.
14. Mbonye, M., Seeley, J., Nalugya, R., Kiwanuka, T., Bagiire, D., Mugyenyi, M., Namale, G., Mayanja, Y., Kamali, A. (2016). Test and treat the early experiences in a clinic serving women at high risk of HIV infection in Kampala. *AIDS Care*. pp. 33-8.
15. Koening, S., Dorvil, N., Devieux, J., Hedt-Gauthier, B., Riviere, C., Faustin, M., Lavoile, K., Perodin, C., Apollon, A., Duverger, L., McNairy, M L., Hennessey, K.A., Souroutzidis, A., Cremieux, P-Y., Severe, P., Pape, J-W. (2017). Same day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. *Plos Medicine*. 14(7).
16. Bigna, J., Plottel, C., Koulla-Shiro, S. (2016). Challenges initiating antiretroviral therapy for all infected people regardless of CD4 count. *Infectious Diseases of Poverty*.
17. Zachariah, R.M., Massaquoi, M. (2006). Cotrimoxazole prophylaxis for HIV-positive TB patients in developing countries. *Tropical Doctor*. 36(2), pp. 79 - 82.
18. Boyer, S., Iwuji, C., Gosset, A., Protopopescu, C., Okesola, N., Plazy, M., Spire, B., Orne-Gliemann, J., McGrath, N. Pillay, D., Dabis, F., Larmarange, J. (2016). Factors associated with antiretroviral treatment initiation amongst HIV-positive individuals linked to care within a universal test and treat programme: early findings of the ANRS 12249 TasP trial in rural South Africa. *AIDS Care*. 28, pp. 39-51.
19. Health SADo. (2016). 22 8 16 Circular UTT Decongestion CCMT Directorate.

20. Compaore, R., Yameogo. M.W.E., Millogo. T., Tougri, H., Kouanda, S. (2017). Evaluation of the implementation fidelity of the seasonal malaria chemoprevention intervention in Kaya health district, Burkina Faso. *PLoS One*. 12(11), p.e0187460.
21. Gautier, L., Pirkle, C.M., Furgal. C., Lucas, M. (2016). Assessment of the implementation fidelity of the Arctic Char Distribution Project in Nunavik, Quebec. *BMJ Global Health*. 1(3) p. e000093.
22. Sweeney-Magee, M., Kale, D., Galton, S., Hamill, A., Gilbert, H. (2016). Assessing the fidelity of delivery of an intervention to increase attendance at the English Stop Smoking Services. *Implement Science*. 11(1), p. 166.
23. de Vet, R., Lako, DA., Beijersbergen, MD., van den Dries, L., Conover, S., van Hemert, A.M., Herman, D.B., Wolf, J.R.L.M. (2017). Critical Time Intervention for People Leaving Shelters in the Netherlands: Assessing Fidelity and Exploring Facilitators and Barriers. *Administration and Policy in Mental Health*. 44(1) pp. 67-80.
24. Korhonen, A., Ojanpera, H., Puhto, T., Jarvinen, R., Kejonen, P., Holopainen, A. (2015). Adherence to hand hygiene guidelines - significance of measuring fidelity. *Journal of Clinical Nursing*. 24(21-22) pp. 3197-205.
25. Dusenbury, L., Brannigan, R., Hansen, WB., Walsh, J., Falco, M. (2005). Quality of implementation: developing measures crucial to understanding the diffusion of preventive interventions. *Health Education Research*. 20(3), pp. 308-13.
26. Marshall, S.M. (2015). The Identification Of Contextual Factors Influencing Teacher Implementation Of Interventions Related To Students' Individual Education Plans. *Open Access Dissertations*. p. 361.
27. Wang, B., Deveaux, L., Knowles, V., Koci, V., Rolle, G., Lunn, S., Li,. X, Stanton, B. (2015). Fidelity of implementation of an evidence-based HIV prevention program among Bahamian sixth grade students. *Prevention Science*. 16(1), pp. 110-21.
28. NewEnglandHealthcareInstitute. (2008). Improving physician adherence to clinical guidelines.
29. Burgers, J.S., Grol, R.P.T.M., Zaat, J.O.M., Spies, T.H., van der Bij, A.K., Mokkink, H.G.A. (2003). Characteristics of effective clinical guidelines for general practice. *British Journal of General Practice*. 53, pp. 15-19.
30. Cabana, M.D., Rushton, J.L., Rush, A.J. (2002). Implementing practice guidelines for depression: Applying a new framework to an old problem. *General Hospital Psychiatry*. 24, pp. 35-42.
31. Enriquez, M., McKinsey, D.S. (2011). Strategies to improve HIV treatment adherence in developed countries: clinical management at the individual level. HIV AIDS (Auckl). 3, pp. 45-51.
32. Bamiselu, O.F., Ajayi, I., Fawole, O., Dairo, D., Ajumobi, O., Oladimeji, A., Steven, Y. (2016). Adherence to malaria diagnosis and treatment guidelines among healthcare workers in Ogun State, Nigeria. *BMC Public Health*. 16(1), p. 828.
33. Okelo, S.O., Butz, A.M., Sharma, R., Diette, G.B., Pitts, S.I., King, T.M., Linn, S.T., Reuben, M., Chelladurai, Y., Robinson, K.A. (2013). Interventions to modify health care provider adherence to asthma guidelines: a systematic review. *Pediatrics*. 132(3), pp. 517-34.
34. Namuyinga, R.J., Mwandama, D., Moyo, D., Gumbo, A., Troell, P., Kobayashi, M., Shah, M., Bauleni, A., Vanden Eng, J., Rowe, A.K., Mathanga, D.P., Steinhardt, L.C. (2017). Health worker adherence to malaria treatment guidelines at outpatient health facilities in southern Malawi following implementation of universal access to diagnostic testing. *Malaria Journal*. 16(1), p. 40.
35. Farren, L., Snowden, M., Steinman, L., Monroe-DeVita, M. (2014). Development and Evaluation of a Fidelity Instrument for PEARLS. *Front Public Health*. 2, p. 200.
36. Fisher, J., Cornman, D., Osborn, C. (2004) Clinician-Initiated HIV Risk Reduction Intervention for HIV-positive persons. *Journal of Acquired Immune Deficiency Syndrome*. 37, pp. S78 -S87.
37. Hogue, A., Dauber, S. (2013). Assessing fidelity to evidence-based practices in usual care: the example of family therapy for adolescent behavior problems. *Evaluation and Program Planning*. 37, pp.1-30.
38. Oats, R.G., Cross, W.F., Mason, W.A, Casey-Goldstein, M., Thompson, R.W., Hanson, K., Haggerty, K.P. (2014). Implementation assessment of widely used but understudied prevention

programs: an illustration from the Common Sense Parenting trial. *Evaluation and Program Planning*. 44, pp. 89-97.
39. Durlak, J.A., DuPre, E.P. (2008). Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol. 41(3-4), pp. 327-50.
40. Sessoms, J., Reid, K., Williams. I., Hinton, I. (2015). Provider Adherence to National Guidelines for Managing Hypertension in African Americans. *International Journal of Hypertension*. 2015, p. 498074.
41. Sam, D.M., Halle-Ekane, G., Njamen, T.N., Atanga, P.N., Mboh, E.K., Mbu, R.E. (2018). Associated Factors of Early and Late Initiation of ART in HIV Infected Pregnant Women in the South West Region, Cameroon. *International STD Research and Reviews*. 7(3), pp. 1-9.
42. Pilcher, C.D., Ospina-Norvell, C., Dasgupta, A., Jones, D., Hartogensis, W., Torres, S., Calderson, F., Demicco, E., Geng, E., Gandhi, M., Havlir, D.V., Hatano, H. (2017). The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a US Public Health Setting. J Acquir Immune Defic Syndr. 74(1), pp. 44-51.
43. Larsen, A., Cheyip, M., Tesfay, A., Vranken, P., Fomundam, H., Wutoh, G.A. (2018). Timing and Predictors of Initiation on Antiretroviral Therapy Among Newly-Diagnosed HIV-Infected Persons in South Africa. *AIDS and Behaviour*. 2018.
44. Health Do. (2015). Consolidated guidelines for PMTCT and HIV Management.
45. Deconinck, L., Yazdanpanah, Y., Gilson, R.J., Melliez, H., Viget, N., Joly, V., Sabin, C.A. (2014). Time initiation of antiretroviral therapy in HIV-infected patients diagnosed with an opportunistic disease: a cohort study. *HIV Medicine*. 16, pp. 219 - 29.
46. Palmer, A.K., Cescon, A., Chan, K., Cooper, C., Raboud, J.M., Miller, C.L., Burchell, A.N., Klein, M.B., Machouf, N., Montaner, J.S.G., Tsoukas, C., Hogg, R.S., Loutfy, M.R., CANOC collaboration. (2014). Factors associated with late initiation of Highly Active Antiretroviral Therapy Among Young HIV-positive Men an WomenAged 18 to 29 years in Canada. *Journal of the International Association of Providers of AIDS Care.* 13(1), pp. 56-62.

Appendices

Appendix 1a: Patient Data Collection Form

Data collection form:

Health facility information

1.	Facility identity number	:
2.	Type of facility	Provincial [ ] Local Government [ ]

Demographic and other information

1.	Patient Identity (for the purposes of the study – not the actual)	:
2.	Age	:
3.	Gender	Female [ ] Male [ ]
4.	Marital status	Single [ ] Married [ ] Divorced [ ] Widowed [ ]
5.	Level of education	No education [ ] Primary [ ] Secondary [ ] Tertiary [ ]
6.	Date of HIV diagnosis	:
7.	Date started on antiretroviral treatment	:
8.	No. of times patient was tested for HIV	:
9.	CD4 count at diagnosis of HIV	:
10.	Other diseases at diagnosis of HIV	:

Adherence

1.	Patient started on antiretroviral treatment? *If 'Yes', proceed to no. 2* *If 'No', proceed to no. 3*	Yes [ ]	No [ ]	No information [ ]
2.	Date started on antiretroviral treatment	:		
3.	TB diagnosed? *If 'Yes', proceed to no. 4* *If 'No', proceed to no. 7*	Yes [ ]	No [ ]	No information [ ]
4.	TB treatment started? *If 'Yes', proceed to no.5*	Yes [ ]	No [ ]	No information [ ]
5.	TB treatment followed by antiretroviral treatment? *If 'Yes', proceed to no. 6* *If 'No', proceed to no. 7*	Yes [ ]	No [ ]	No information [ ]
6.	Antiretroviral treatment started within 2 – 8 weeks of starting TB treatment?	Yes [ ]	No [ ]	No information [ ]
7.	Patient refusing to start treatment (regardless of the reason)? If 'Yes', proceed to no.8	Yes [ ]	No [ ]	No information [ ]
8.	Patient enrolled in the wellness programme? (Which includes at	Yes [ ]	No [ ]	No information [ ]

least some of the following):

TB symptom screening at every visit	Yes [ ]	No [ ]	No information [ ]
Clinical staging at every visit	Yes [ ]	No [ ]	No information [ ]
Screening of sexually transmitted infections	Yes [ ]	No [ ]	No information [ ]
Management of sexually transmitted infections	Yes [ ]	No [ ]	No information [ ]
Counselling on how to avoid HIV transmission to sexual partners and children	Yes [ ]	No [ ]	No information [ ]
Information and counselling on risk-reduction	Yes [ ]	No [ ]	No information [ ]
Information and counselling on combination HIV prevention approaches	Yes [ ]	No [ ]	No information [ ]
Support for disclosure and partner notification	Yes [ ]	No [ ]	No information [ ]
Information and counselling related to fertility, including planning for conception or contraception, as needed	Yes [ ] N/A [ ]	No [ ]	No information [ ]
Counselling on nutrition and healthy lifestyle	Yes [ ]	No [ ]	No information [ ]
Screening and management of co-	Yes [ ]	No [ ]	No information [ ]

morbidities and non-communicable diseases			
Repeat CD4 testing	Yes [ ]	No [ ]	No information [ ]
Repeat WHO clinical staging 6-monthly in adults and adolescents	Yes [ ]	No [ ]	No information [ ]
Annual cervical cancer screening (pap smear) for all HIV-positive women	Yes [ ] N/A [ ]	No [ ]	No information [ ]
Advised to come back whenever they have health problems	Yes [ ]	No [ ]	No information [ ]

Appendix 1b: Patient Data Collection Form

Data collection form:

Health facility information

1.	Facility identity number	:
2.	Type of facility	Provincial [ ] Local Government [ ]

Demographic and other information

1.	Patient Identity (for the purposes of the study – not the actual)	:
2.	Age	:
3.	Gender	Female [ ] Male [ ]
4.	Marital status	Single [ ] Married [ ] Divorced [ ] Widowed [ ] No info [ ]
5.	Level of education	No education [ ] Primary [ ] Secondary [ ] Tertiary [ ] No info [ ]
6.	Date of HIV diagnosis	:
7.	Date started on antiretroviral treatment	:
8.	No. of times patient was tested for HIV	:
9.	CD4 count at diagnosis of HIV	:
10.	Other diseases at diagnosis of HIV	:

Adherence

1.	Patient started on antiretroviral treatment? *If 'Yes', proceed to no. 2* *If 'No', proceed to no. 3*	Yes [ ]	No [ ]	No information [ ]
2.	Date started on antiretroviral treatment	:		
3.	TB diagnosed? *If 'Yes', proceed to no. 4* *If 'No', proceed to no. 7*	Yes [ ] N/A [ ]	No [ ]	No information [ ]
4.	TB treatment started? *If 'Yes', proceed to no.5*	Yes [ ] N/A [ ]	No [ ]	No information [ ]
5.	TB treatment followed by antiretroviral treatment? *If 'Yes', proceed to no. 6* *If 'No', proceed to no. 7*	Yes [ ] N/A [ ]	No [ ]	No information [ ]
6.	Antiretroviral treatment started within 2 – 8 weeks of starting TB treatment?	Yes [ ] N/A [ ]	No [ ]	No information [ ]
7.	Patient refusing to start treatment (regardless of the reason)? If 'Yes', proceed to no.8	Yes [ ]	No [ ]	No information [ ]
8.	Patient enrolled in the wellness programme? (Which includes at least some of the following):	Yes [ ] N/A [ ]	No [ ]	No information [ ]

TB symptom screening at every visit	Yes [ ]	No [ ]	No information [ ]
Clinical staging at every visit	Yes [ ]	No [ ]	No information [ ]
Screening of sexually transmitted infections	Yes [ ]	No [ ]	No information [ ]
Management of sexually transmitted infections	Yes [ ]	No [ ]	No information [ ]
Counselling on how to avoid HIV transmission to sexual partners and children	Yes [ ]	No [ ]	No information [ ]
Information and counselling on risk-reduction	Yes [ ]	No [ ]	No information [ ]
Information and counselling on combination HIV prevention approaches	Yes [ ]	No [ ]	No information [ ]
Support for disclosure and partner notification	Yes [ ]	No [ ]	No information [ ]
Information and counselling related to fertility, including planning for conception or contraception, as needed	Yes [ ] N/A [ ]	No [ ]	No information [ ]
Counselling on nutrition and healthy lifestyle	Yes [ ]	No [ ]	No information [ ]
Screening and management of co-morbidities and non-communicable	Yes [ ]	No [ ]	No information [ ]

diseases			
Repeat CD4 testing	Yes [ ]	No [ ]	No information [ ]
Repeat WHO clinical staging 6-monthly in adults and adolescents	Yes [ ]	No [ ]	No information [ ]
Annual cervical cancer screening (pap smear) for all HIV-positive women	Yes [ ] N/A [ ]	No [ ]	No information [ ]
Advised to come back whenever they have health problems	Yes [ ]	No [ ]	No information [ ]

Appendix 2a: Healthcare Provider Questionnaire: pre-test

Healthcare provider questionnaire

Health facility information

1.	Facility identity number	:
2.	Type of facility	Provincial [ ] Local Government [ ]

Demographic information

1.	Healthcare provider identity (*for the purposes of the study – not the actual*)	:
2.	Age	:
3.	Gender	Female [ ] Male [ ]
4.	Length of service as a healthcare provider (*time in years/months*)	:
5.	Length of service in this facility Experience in HIV care (*time in years/months if less than a year*)	:
6.	Trained on Universal Test and Treat	Yes [ ] No [ ]
7.	Date of UTT training	:
8.	Duration of UTT training Designation (*Doctor/medical officer, Professional nurse,*	: :

Enrolled nurse, *Other* (specify))

Mentored/visited by the mentor at least once in the past 3 months before the day of interview	Yes [ ] No [ ]
Has a copy of ART guidelines (*including a shared copy*)	Yes [ ] No [ ]

UTT knowledge

Select only one answer for each of the following 3 questions. Make a cross against the answer of your choice.

1. Which of the following HIV-positive patients would you offer antiretroviral treatment:
   - i. Patients with a CD4 count of ≥ 350 cells/mm3 [ ]
   - ii. Patients with a CD4 count of < 200 cells/mm3 [ ]
   - iii. Patients not on antiretroviral treatment [ ]
   - iv. none of the above [ ]
   - v. iii, ii and i [ ]
2. In which of the following situations would you not initiate an HIV-positive patient on antiretroviral treatment:
   - i. Patient not willing to start antiretroviral treatment [ ]
   - ii. Patient not ready to start antiretroviral treatment (e.g. in a case where patient is [ ]

willing to start treatment but cannot because of other conditions which include TB, etc.)

iii. All of the above [ ]

v. None [ ]

3. Which of the following would you do for a HIV-positive patient who is not willing to start antiretroviral treatment:

i. Counsel the patient on the importance of early treatment [ ]

ii. Keep the patient in the wellness programme [ ]

iii. Make the patient sign a 'refused medical treatment form' [ ]

v. ii and i [ ]

vi. none of the above [ ]

Factors associated with UTT implementation fidelity

4. Importance of UTT

How would you rate the importance of UTT? (*Make a cross against the most appropriate answer*)

Not important [ ]

Somewhat important [ ]

Important [ ]

Very important [ ]

5. Appropriateness

UTT implementation was started when we as healthcare providers were adequately prepared for it. (Make a cross against the most appropriate answer)

Strongly disagree [ ]

Disagree [ ]

Neutral [ ]

Agree [ ]

Strongly agree [ ]

Appendix 2b: Healthcare Provider Questionnaire: post-test

Healthcare provider questionnaire

Health facility information

1.	Facility identity number	:
2.	Type of facility	Provincial [ ] Local Government [ ]

Demographic information

1.	Healthcare provider identity (*for the purposes of the study – not the actual*)	:
2.	Age	:
3.	Gender	Female [ ] Male [ ]
4.	Length of service as a healthcare provider (*time in years/months*)	:
5.	Length of service in this facility Experience in HIV care (*time in years/months if less than a year*)	:
6.	Trained on Universal Test and Treat	Yes [ ] No [ ] No info [ ]
7.	Date of UTT training	:
8.	Duration of UTT training	:
	Designation (*Doctor/medical officer, Professional nurse,*	:

Enrolled nurse, *Other* (specify))

Mentored/visited by the mentor at least once in the past 3 months before the day of interview	Yes [ ]	No [ ]	No info [ ]
Has a copy of ART guidelines (*including a shared copy*)	Yes [ ]	No [ ]	No info [ ]

UTT knowledge

Select only one answer for each of the following 3 questions. Make a cross against the answer of your choice.

1. Which of the following HIV-positive patients would you offer antiretroviral treatment:
   i. Patients with a CD4 count of $\geq$ 350 cells/mm3 [ ]
   ii. Patients with a CD4 count of < 200 cells/mm3 [ ]
   iii. Patients not on antiretroviral treatment [ ]
   iv. none of the above [ ]
   v. iii, ii and i [ ]
2. In which of the following situations would you not initiate an HIV-positive patient on antiretroviral treatment:
   i. Patient not willing to start antiretroviral treatment [ ]
   ii. Patient not ready to start antiretroviral treatment (e.g. in a case where patient is [ ]

willing to start treatment but cannot because of other conditions which include TB, etc.)

iii. All of the above [ ]

v. None [ ]

3. Which of the following would you do for a HIV-positive patient who is not willing to start antiretroviral treatment:

i. Counsel the patient on the importance of early treatment [ ]

ii. Keep the patient in the wellness programme [ ]

iii. Make the patient sign a 'refused medical treatment form' [ ]

v. ii and i [ ]

vi. none of the above [ ]

Factors associated with UTT implementation fidelity

4. Importance of UTT

How would you rate the importance of UTT? (*Make a cross against the most appropriate answer*)

Not important [ ]

Somewhat important [ ]

Important [ ]

Very important [ ]

No information [ ]

5. Appropriateness

UTT implementation was started when we as healthcare providers were adequately prepared for it. (Make a cross against the most appropriate answer)

Strongly disagree [ ]

Disagree [ ]

Neutral [ ]

Agree [ ]

Strongly agree [ ]

No information [ ]

Appendix 3: Study Information Document and Consent Form

STUDY INFORMATION DOCUMENT FOR HEALTHCARE PROVIDERS

Study title:

Implementation Fidelity of Universal Test and Treat HIV intervention in eThekwini district, South Africa

Greeting:

Hello. My name is Simiso Masondo a student at the University of the Witwatersrand.

Introduction:

I am doing research on the implementation fidelity of the Universal Test and Treat HIV Intervention in eThekwini district clinics.

Invitation to Participate:

You are invited to take part in this research study.

If you agree to participate in the research study, you will be asked to respond to a few predetermined questions. The questions will cover general information which includes age, length of service, training on Universal Test and Treat (UTT), etc.; knowledge of UTT and factors associated with UTT implementation. The two options for responding to the questions include participant completing a questionnaire or the researcher interviewing the participant using the same questionnaire. The process of responding to the questions is expected to take up to 30 minutes. The questionnaires will be administered on the day the researcher visits the clinic.

Risks of being involved in the study:

There are no known risks attached to the research study.

Benefits of being in the study:

The main benefit will be discovering things that will help the clinic and the KwaZulu-Natal Department of Health to improve the way Universal Test and Treat is being implemented. There are no direct or personal benefits to you.

Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to the participant; the participant may discontinue participation at any time without penalty, or loss of benefits to which the participant is otherwise entitled. There is no requirement to provide a reason for withdrawing and any data collected on such a person will in default be destroyed, unless the participant specifically consents to its retention.

Payment for participation in the study:

There will be no payments or reimbursements in this study.

Confidentiality:

Information collected will be treated in the strictest confidence and will only be available to the Principal Investigator (PI) and his Supervisor.

All data collected in the course of the study will be securely retained for two (2) years, if a scientific publication arises from the study and six (6) years, if there is no publication. Thereafter it will be destroyed accordingly.

Anonymity:

No names or any other form of personal identification of the participants will be included in the data that will be collected.

Contact details of researcher/s:

The following details are provided to enable participants to get further information, or report any event related to the research study:

Principal investigator:	Mr. Simiso Masondo	**Email address/ Contact number:**	thamsanqa.s.masondo@gmail.com 083 387 8482
Supervisor:	Dr Jabulani Ncayiyana	**Email address/ Contact number:**	jabulani.ncayiyana@uct.ac.za 021 460 4563
Supervisor:	Dr Arthi Ramkissoon	**Email address/ Contact number:**	aramkissoon@match.org.za 031 275 1541

Outputs:

A research study report will be compiled and will include analysis of data, findings of the research study and recommendations. A copy of the report will be made available to the participants on request.

Contact details of HREC administrator and chair:

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concerns over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

Date: May 2018

Consent Form

Please make a cross [X] to indicate you consent to the following		
I have read, or have had read to me in the language I understand, and I understand the Participant Information Sheet.	Yes [ ]	No [ ]
I have been given an opportunity to consider whether or not to participate in this study.	Yes [ ]	No [ ]
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes [ ]	No [ ]
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without loss of benefits.	Yes [ ]	No [ ]
I consent to the research staff collecting and processing my information.	Yes [ ]	No [ ]
I understand my responsibilities as a study participant.	Yes [ ]	No [ ]

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Appendix 4: KwaZulu-Natal Department of Health

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

330 Langalibalele street
Private Bag X9051 PMB 3200
Tel.: 033 395 2605/3189/3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
Health Research & Knowledge Management (HRKM)

Reference: HRKM079 /18
KZ_201803_031

15 March 2018

Dear Mr S T Masondo
(Wits)

Subject: Approval of a Research Proposal

1. The research proposal titled '**IMPLEMENTATION FIDELITY OF THE UNIVERSAL TEST AND TREAT HIV INTERVENTION IN ETHEKWINI DISTRICT, SOUTH AFRICA**' was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

   The proposal is hereby **approved** for research to be undertaken at the selected clinics at eThekwini District.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facilities before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. **Your final report must be** posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee
Date: 16/03/18

Fighting Disease, Fighting Poverty, Giving Hope

Appendix 5: eThekwini Health District

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

DIRECTORATE:
eThekwini District Office

Physical Address: 83 King Cetshwayo Highway; Highway House; Mayville; 4091
Postal Address: Private Bag x54318, Durban,4000
Tel: 031 2405308 Fax: 031 2405555 Email: Karen.moodley@kznhealth.gov.za
www.kznhealth.gov.za

05 January 2018

Simiso T. Masondo
330 Langalibalele Street
Natalia Building
Pietermaritzburg
3200

RE: SUPPORT FOR RESEARCH STUDY ON IMPLEMENTATION FIDELITY OF THE UNIVERSAL TEST AND TREAT HIV INTERVENTION IN ETHEKWINI DISTRICT, SOUTH AFRICA

I have pleasure in informing you that I support your conduct of the research study entitled Implementation fidelity of the Universal Test and Treat HIV Intervention in EThekwini District, South Africa.

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Please ensure this office is informed before you commence your research.
4. The District Office/Facility will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to the District Office/Facility.

Thanking you.

Sincerely

Mrs T P Msimango
Chief Director
EThekwini District

Appendix 6: eThekwini Health Department

20 April 2018

Dear Researcher,

Subject: Approval of a Research Proposal

The research protocol titled: **Implementation Fidelity of the Universal test and Treat HIV intervention in eThekweni District South Africa,** has been reviewed by the eThekweni Municipality Health Department Research Committee. The study is hereby approved at the following sites: Township Centre, Umlazi AA, Seacow Lake, Grove end, Newlands West, Westville, Caneside and Klaarwater facilities.

The following conditions need to be noted:

- Submission of the indemnity form obtainable from the EThekwini Municipality Health Unit before commencement of the study.
- Prior arrangements to be made with the facility and an assurance that all services will not be disrupted.
- No staff member should be used for collecting data for the researchers.
- Progress reports to be provided and the final report of the study to the eThekwini Municipality Health Unit or emailed to: rochelle.peters@durban.gov.za
- Obtain permission from the eThekwini municipality health department for press releases and release of results to communities/stakeholders.
- The department has to receive recognition for the assistance given.
- Any amendment to the study must be communicated with the eThekwini Municipality Health Unit and the relevant amendment form obtainable from the unit to be submitted.
- Withdrawal of permission to conduct research will be left to the discretion of the eThekwini Municipality Health Unit.

Yours faithfully

Head of Health

Appendix 7: University of the Witwatersrand Human Research Ethics Committee (Medical) Clearance Certificate

R14/49 Mr ST Masondo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M180233

NAME: (Principal Investigator)	Mr ST Masondo
DEPARTMENT:	School of Public Health Division of Epidemiology and Biostatistics Medical School University
PROJECT TITLE:	Implementation fidelity of the Universal Test and Treat HIV intervention in EThekwini district, South Africa
DATE CONSIDERED:	23/02/2018
DECISION:	
CONDITIONS:	
SUPERVISOR:	Dr J Ncayiyana
APPROVED BY:	Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	18/04/2018

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 on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit 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 February and will therefore be due in the month of February each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

25 April 2018
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 8: Plagiarism Declaration Report

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY:

I SIMISO THAMSANQA MASONDO_____ (Student number: 1479027_) am a student registered for the degree of MASTER OF SCIENCE IN EPIDEMIOLOGY: IMPLEMENTATION SCIENCE__ in the academic year 2019_.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature:_____ Date: 17 SEPTEMBER 2019_____