ASSESSING IMPLEMENTATION FIDELITY (ADHERENCE) OF TB PREVENTION IN PEOPLE LIVING WITH HIV IN SELECTED CLINICS IN CENTRAL PROVINCE, ZAMBIA

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A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the Degree of Master of Science in Epidemiology, field of Implementation Science.

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DECLARATION

I, James Tiezye Simukoko, hereby declare that this research work was carried out by me under the supervision of, Prof Jonathan Levin, Dr. Jabulani Ncayiyana and Dr. Thierry Malebe. This thesis was entirely composed by myself and the work contained herein is my own except where explicitly stated otherwise in the text. It is being submitted for the degree of Master of Science in Epidemiology in the field of Implementation Science in the University of the Witwatersrand, Johannesburg. I have taken care in all respect to honour the intellectual property right and have acknowledged the contribution of others for using them in this work and further declare that the work reported in this project has not been submitted and will not be submitted, either in part or in full, for the award of any other degree or diploma in this institute or any other institute or university.

Signature

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ABSTRACT

Background

The World Health Organization 2015 tuberculosis report presented an estimated 10.4 million new tuberculosis (TB) incident cases of which about 1.2 million cases (11% of the total TB cases notified) were human immunodeficiency virus (HIV) positive. Screening for TB and provision of Isoniazid to those who screen negative for TB are recommended in HIV positive people. Fidelity is defined as the extent to which an intervention is being implemented as it was intended by the programme developers. This study assessed the fidelity of implementing TB prevention guidelines for people living with HIV in Zambia.

Objective

The main objective of this study was to assess the extent of fidelity (adherence) of healthcare workers to the implementation of guidelines for Intensified Case Finding (ICF) and Isoniazid Preventive Therapy (IPT) for prevention of active TB infection among People living with HIV/AIDS in Zambia.

Materials and Methods

The research project consisted of secondary analysis of data from patient's medical records from four clinics in which the extent of implementation fidelity to TB prevention by healthcare workers in Zambia was studied. We adopted and constructed a conceptual framework based on Carroll's conceptual framework for measuring implementation fidelity. The explanatory variable were healthcare worker training, profession, gender and geographical location of the clinic. The outcome variables were ICF and IPT fidelity scores. Analysis of variance was conducted to compare the mean ICF score between the different health centres and the patient

visits. Univariable and multivariable logistic regression were used to model the explanatory variables against the outcome of achieving an ICF score of 3 or less versus achieving an ICF score of 4.

Results

The overall health workers ICF adherence fidelity mean score was found to be low 2.40 (50%). There was a significant difference in ICF fidelity by gender of healthcare worker for the first visit but no significant difference for the other visits. There was also a difference in ICF fidelity score for the health centres. The providers' training and profession did not affect their ICF adherence fidelity score for all the visits. The fidelity score obtained for IPT was zero.

Conclusion and Recommendations

Low implementation fidelity scores for TB prevention were obtained in all facilities. Rural facilities had the lower fidelity scores compared to urban facilities. Even after undergoing training as provided by training records and provided with guidelines, ICF fidelity was still low. More studies are needed that will investigate the providers perception of the intervention.

DEDICATION

I humbly dedicate this degree to the Lord almighty who has made it possible for me to come this far in education. A special feeling of gratitude to my loving wife, Edna Mugala, and my children Taiyza and Niza Simukoko, FHI360 Kabwe office for the support during my data collection and many others for their words of encouragement and support during my study and research periods. Special dedication to my grandparents. Through thick and thin, you have provided me all the support to make it to this level of my education come to pass. This project would have not been successful without the encouragements from my friends who always motivated me to work harder despite the challenges.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral Therapy
ARVs	Anti-retroviral drugs
ERC	Ethics and Research Committee
FHI360	Family Health International 360
GRZ	Government of the Republic of Zambia
HIV	Human immune-deficiency Virus
HREC	Human Research Ethics Committee
ICF	Intensified Case Finding
INH	Isoniazid
IOF	Implementation outcome framework
IPT	Isoniazid Preventive Therapy
MOH	Ministry of Health of Zambia
MDR-TB	Multi-drug Resistant Tuberculosis
PEPFAR	US Presidents Emergency program for AIDS Relief
PLWH	People Living With HIV
QIF	Quality Implementation Framework
SOPs	Standard operating procedures
TB	Tuberculosis
TB/HIV or HIV/TB	Co-infection with HIV and TB
UNAIDS	The Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization
XDR-TB	Extensively drug-resistant TB

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CHAPTER ONE

1.0 INTRODUCTION

1.1.1 Burden of TB and TB associated with HIV

Tuberculosis (TB) is a global pandemic which is found in every country (1). The World Health Organization's (WHO) TB report of 2017 reported an estimated 10.4 million people fell ill with TB in 2016. About 1.3 million cases (10% of the total TB cases notified) were human immunodeficiency virus (HIV) positive. The African region accounted for the highest proportion of TB cases associated with HIV; 31% of the notified TB cases in the African region had HIV with some countries in Southern Africa exceeding 50% (1). Despite increased investment in the prevention and treatment of TB, more deaths are being recorded. TB deaths remain highest, claiming an estimate of 1.4 million people in 2015 and an additional 0.4 million deaths are TB associated deaths in people living with HIV (PLWHIV) (1) .

1.1.2 BURDEN OF TB AND TB ASSOCIATED WITH HIV IN ZAMBIA

Among the 25 TB high burden countries in the world, six are from Southern Africa. Zambia is among the six TB high burden countries from Southern Africa (1). In Zambia, TB continues to be a major public health problem. The TB prevalence survey conducted in 2013 to 2014 found the prevalence to be 455 per 100 000 (2). This is slightly higher than the global and African prevalence reported by WHO in the same period. Furthermore, TB/HIV co-infection cases are two-thirds of the TB notifications. In addition, almost one in every four deaths among PLWHIV is due to TB (2, 3).

1.1.3 PREVENTION STRATEGIES FOR TB AND TB ASSOCIATED WITH HIV

The United Nations in 2015 adopted the Sustainable Development Goals (SDGs) to be achieved by the year 2030. One of the goals adopted is to end the global TB epidemic. The World Health Assembly adopted the End TB strategy in 2014 (4). This End TB strategy is a 20-year strategy with a vision of the world with zero deaths, diseases and suffering from TB. The strategy aims for a 90% reduction in TB deaths and an 80% reduction in TB incidence by the year 2030 (1). Under the End TB strategy, countries are advised to optimally use the existing prevention interventions and achievement of universal health coverage that is essential for prevention, treatment and care as well as addressing the social determinants and consequences of TB (4).

There is overwhelming evidence on the effectiveness of Isoniazid in the prevention of latent TB in PLWHIV from progressing to active TB (5-8). The WHO recommends Isoniazid Preventive Therapy (IPT), Intensified Case Finding (ICF), and infection control (IC) as strategies for preventing TB in PLWHIV (9, 10). IPT is the provision of Isoniazid for a specified period to PLWHIV and do not have active TB as a way of preventing them from developing active TB. ICF is the core backbone for prevention, care, and treatment of TB in PLWHIV. ICF involves the screening of all PLWHIV for TB using a standard screening checklist which looks to screen for the presence of cough, night sweats, fever and continuous loss of weight. ICF aims to reduce TB in PLWHIV by detecting the disease early so that treatment can be commenced as soon as possible as well as preventing future TB infections through the provision of IPT for those who do not have the disease. IC are routine infection control mechanisms that facilities must put in place such as provision of respiratory masks to patients with multidrug resistant TB (MDR-TB) and other related activities (11). Only

half of all HIV related TB cases worldwide receive treatment (12).

Zambia started the implementation of ICF and IPT in late 2015. Healthcare workers working in Antiretroviral (ART) clinics were trained in the ICF and IPT by partner organisation supporting the Ministry of Health. Those trained are found at all levels of care; general hospitals, district hospitals and primary care health facilities. In Zambia, ICF should be conducted at every patient visit (frequency) and IPT is given for two months and thereafter every two months (frequency) until taken for six to 9 months (duration) (11). However, the quality of implementing (defined as the extent to which all major elements of an intervention are delivered or how well an intervention is implemented (13, 14)) ICF and IPT has not been measured. Knowing how well an intervention is implemented provides an opportunity for implementers to sustain and provides an opportunity to understand whether the intervention was correctly deployed in relation to the outcomes.

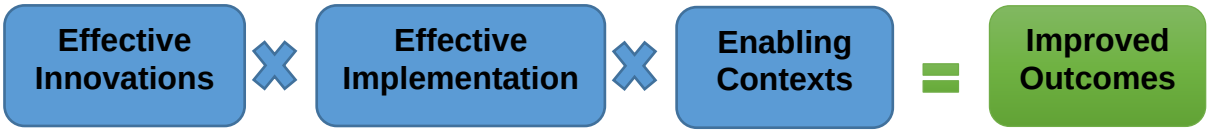
1.1.4 Implementation Background

Implementation in its simplest form is defined as carrying out a plan for doing something. It focuses on operationalising the plan – the How, rather than the What (15). It is important to understand how well we have implemented because if we don't implement well, it is impossible to determine whether an unsuccessful outcome came about because the intervention itself was flawed or because we did not know how to implement it (16).

There is overwhelming evidence of interventions that work. This however does not correspond to outcomes for clients. The deficit is known as the **implementation gap;**

it is the difference between the evidence of what works in theory and what is delivered in practice. Implementation bridges this gap between what is known and what is done (17).

We can determine the quality of implementation by measuring any of the implementation outcomes. Proctor lists acceptability, adoption, appropriateness, costs feasibility, fidelity, penetration and sustainability as implementation outcomes (18). Implementation fidelity is one of the outcomes of implementation of an intervention and can be used to measure how well an intervention is being implemented. By measuring implementation fidelity , we can know the quality with which an intervention has been implemented (19). Fidelity is defined as the extent to which an intervention is being implemented as it was intended by the programme developers (18). Literature has shown that effective interventions that are implemented with high fidelity lead to improved outcomes. Similarly those implemented with low fidelity do not achieve improved outcomes for the population health (20). In order to ensure that implementation results in improved outcomes, the programme should be composed of effective innovations/interventions which should be implemented effectively with maximum fidelity in an enabling context as shown in the figure 1.1 below (21).



Source: National Implementation Research Network (NIRN), UNC Chapel Hill

Figure 1.1: Implementation framework outcomes (21)

Several studies have shown how implementation fidelity should be measured. Five dimensions of measuring implementation fidelity have been described. These are exposure or dose, quality of delivery, adherence to an intervention, programme differentiation, and participant responsiveness. There are several overlaps in the evaluation or measuring process of these five dimensions (22-25).

Which dimension/element to use to measure fidelity depends on the intervention being implemented. In the case of ICF, healthcare workers must adhere to the prevention guidelines. This the reason why adherence was chosen as the main dimension to be used for measuring implementation fidelity (26). Four elements/dimensions of measuring adherence as a measure of fidelity in implementation of interventions exist, they are content, coverage, dosage, and frequency. The content of an intervention is important as the intervention needs to be delivered in full. Measurement of adherence as a measure of fidelity using these elements allows for quantification. One can thus measure how much of an intervention has been delivered in terms of its content, for how long (duration) as well as how frequently. How many have received it among those who are supposed to receive it (coverage) (25, 27)

1.2 PROBLEM STATEMENT

Research has shown that programs or interventions that have not been implemented well would result in poor health outcomes (28-30). Studies that have looked specifically at the implementation of prevention of TB in PLWH in low-income countries found low rates of implementation coverage (31, 32). These studies, however, did not measure the other elements of adherence as a measure of fidelity.

The problem is no research has been conducted to measure implementation fidelity of TB prevention in PLWH in Zambia.

1.3 JUSTIFICATION

To associate the reduction in morbidity and mortality of TB in PLWHIV with implementation of the prevention guidelines, it is important to know whether the TB prevention intervention is being implemented with maximum fidelity. Therefore, this study assessed the extent of adherence to the TB prevention intervention as a measure of adherence fidelity. It provides baseline information for future research that could investigate the link of implementation fidelity and effectiveness of the intervention in real settings and determining strategies that could be used to improve the quality of implementation.

1.4 LITERATURE REVIEW

1.4.1 INTRODUCTION

Implementation quality matters because it links the health outcomes to the intervention. The increasing number of chronic illness such as HIV/AIDS and the associated co-morbidities which include TB, has led to an increase in the number of interventions together with the guidelines on how these can be implemented in order to manage and treat these diseases (33). These interventions have to be implemented with utmost quality if they are to achieve what they are intended to achieve. To understand this influence of implementation on programme outcome, it is important to collect implementation data (19).

This implementation data to be collected should include the outcomes of implementation. Implementation outcomes have been defined as “the effects of deliberate and purposive actions to implement new treatments, practices and services” (34). They provide a way of measuring the success of implementation, they are proximal indicators of implementation processes and are key intermediate outcomes to service or program outcomes in treatment effectiveness and quality of care research (34, 35). A conceptual model developed by Proctor and colleagues in 2009, which was later updated in 2011, describes a taxonomy of eight implementation outcomes namely acceptability, feasibility, adoption (uptake), penetration, cost, fidelity, appropriateness and sustainability (29, 31)

Implementation fidelity as one of the outcomes of implementation can tell us how well we have implemented the intervention (36). Measuring fidelity is specific to the type of programme being implemented. There are many methods in the literature that have been proposed on how implementation fidelity is to be measured (37). Five dimensions of measuring implementation fidelity have been described. These are exposure or dose, quality of delivery, adherence to an intervention, programme differentiation, and participant responsiveness. However, it has been found that there are overlaps in the evaluation/measuring process of these elements/dimensions (22-25).

Adherence to an evidence-based HIV prevention programme offered to fifth and sixth grade students in Bahamas was measured by assessing the fidelity of delivering the HIV programme to the students by teachers. The factors that affected implementation fidelity as well as variations in implementation fidelity with respect to student

outcomes were also measured. Teachers` adherence to the core activities was 16.3 out of 30 and 24 out of 40 of the total activities. Thus, fidelity was around 50%. This study found that comfort with intervention was the main predictor of fidelity. Training and teachers perceptions of the intervention were other factors that resulted in teachers not adhering to the curriculum (38). Another education programme that looked at how well the teachers delivered a pathways intervention on the prevention of obesity and promotion of a healthy diet in fourth and fifth graders found that belief in the intervention by the teachers was the major predictor of adherence to the programme (39).This also shows that if a programme is implemented well, it leads to better outcomes.

A study conducted at a hospital in Sweden measured implementation fidelity of an organizational level occupational health intervention. Fidelity was measured using the conceptual framework for measuring implementation fidelity and implementation factors used to investigate variations in fidelity with the Framework for Evaluating Organizational-level Interventions. The study found that context, the intervention itself and mental models to be major predictors of fidelity (40). Adherence to the American Heart Association (AHA) Resuscitation Guidelines during code simulation was measured after training in the guidelines. This study found that adherence to the guidelines depended on the number of sessions offered during training (41).

The **content** of the programme or innovation consists of the core elements that intervention is seeking to deliver. For ICF TB prevention, content involves screening of PLWHIV for night sweats, fever, loss of weight, and coughing at each clinical visit to the health care facility/clinic/hospital. This is followed by ordering any applicable

diagnoses if any of the patients has any of the above four symptoms. For IPT TB prevention, content will involve Isoniazid being prescribed for a minimum of 6 months and dispensed to the patients for that duration (42).

The other element of adherence is **coverage,** according to the guidelines, all PLWHIV are to be screened for TB each visit and have Isoniazid prescribed if they are found not have any of the TB symptoms described above. Much progress in measuring implementation fidelity has occurred in the behaviour sciences (43). There are a few examples in literature in which these subcategories of adherence were measured such as the Head Start Research Based, Developmentally Informed (REDI) strategy. The REDI was a randomized controlled trial testing the efficacy of a comprehensive preschool curriculum. This study measured fidelity and dosage. It also showed that variation in implementation fidelity could affect the programme outcome.

Moderating factors are reported in literature as those factors which may either facilitate positively or affect negatively the way in which an intervention is delivered. **Facilitation strategies** are activities done to ensure that the implementation of interventions is in a uniform manner (25). The literature does not conclusively suggest that facilitation strategies can indeed ensure effectiveness of a an intervention (44). However there is evidence that implementing the correct and right facilitation strategies leads to increased fidelity that results in improved patient outcomes (45). Participants' responsiveness, complexity of an intervention and quality of delivery all moderate the degree of fidelity with which an intervention is implemented (28). Further the effect of one of these factors may be influenced by

another (25). Though studies have not conclusively suggested that facilitation strategies can indeed ensure effectiveness of an intervention (44), there were instances where participants in an intervention received similar training and support and achieved a higher fidelity to that particular intervention (46). When correct and right facilitation strategies are implemented, higher fidelity will result (45).

1.4.2 TB ASSOCIATED HIV PREVENTION STUDIES FROM LOW AND MIDDLE-INCOME COUNTRIES

There several studies that have been conducted in Sub-Saharan Africa on the implementation of TB prevention in PLWHIV. Most of these studies have only looked at the aspect of coverage. No studies were found that measured all the subcategories of fidelity (31, 47, 48).

The study by Catherine et al. which looked at survey data from low-income countries in Asia and East Africa, found uptake (coverage) of ICF to be as low as 55%. IPT implementation was at 17%. This study focused on site level implementation uptake. It, however, did not look at the other components namely adherence, content, frequency and duration of implementation at the sites and it also looked at only newly enrolled patients. For IPT, they also looked at uptake by newly enrolled patients (31).

A cohort study that was recently conducted at a hospital in Uganda on the implementation of ICF and IPT in children with HIV found uptake (coverage) of ICF to be 58.8% and IPT coverage at 30.75%. This study also measured only coverage of

both ICF and IPT without considering other adherence dimensions as a measure of fidelity. Nevertheless, initiation of IPT fidelity was considered, which was the time it took to initiate the children on IPT after screening of TB. In addition, they looked at whether IPT was interrupted or not (49).

A survey was conducted in South Africa to assess the implementation of IPT. This was a cross-sectional study that also looked at coverage of IPT. The survey was conducted in selected facilities countrywide. The questionnaire used looked only at whether IPT was being provided or not. Coverage of IPT was 46%. By facility type, they found coverage lowest in community health centres (47). This study also did not consider other adherence dimensions in the measurement of fidelity of screening for TB. They also only looked at whether IPT was initiated or not rather than the follow-up refills and completion of treatment. Nonetheless, the study also looked at other components of TB/HIV integration activities such as availability of guidelines at the facilities, TB-HIV staffing, and availability of a TB-HIV committee. Another survey was carried out to quantify TB-HIV integration services in the three clinics of Johannesburg Metropolitan area, looking at both TB screening, and coverage of IPT. This study found coverage to be very low, below 30%. Some extent of TB screening was also recorded with a cough being the most recorded symptom. The study showed that IPT recording was poor in the clinics (50).

A systematic review looked at implementation of the intervention to prevent TB in low and middle-income countries by geographical and institutional setting as well as generalizability. This review found that there were gaps in coverage and scaling up of the interventions at country level (48).This provides further evidence that implementation of ICF and IPT face many challenges and the need for research that

focuses on implementation may help and provide information to be used for effective implementation of the interventions.

Another study conducted in South Africa looked at the extent of implementation of integrated TB-HIV service delivery at a hospital-based antenatal care service unit. This was a cross sectional record review that looked at records of pregnant women attending antenatal care. TB screening using the four-part symptom and IPT uptake were measured. The study also confirms the lower rate of TB screening and IPT uptake (51). TB prevention activities including ICF and IPT in people PLWHIV if implemented with 100% fidelity can drastically decrease the burden of TB (52)

1.4.3 CONCEPTUAL FRAMEWORK FOR FACTORS AFFECTING FIDELITY

Using a review of empirical literature by Caroll and Dusenbury (19, 24, 26), a synthesis of existing theories and frameworks by Damshroder et al. (53) into the CFIR (Consolidated framework for implementation research) and Chaudoir et al. 2013 (54) who propose a multilevel framework of factors that impact implementation outcomes. A group of factors were adopted to form a framework that groups factors affecting fidelity. Reviewed literature on the TB prevention intervention from low resource settings also guided the framework. The conceptual framework for measuring fidelity of TB prevention is shown in Figure 1.2 below: Strategies that influence implementation of the TB prevention guidelines adopted in the framework below are training of health care workers, availability of guidelines and being situated in an urban area. Availability of Isoniazid (drugs) would influence prescribing and

dispensing (55-58). The adapted framework was used to determine whether training, geographical location, gender and profession would affect fidelity of implementation.

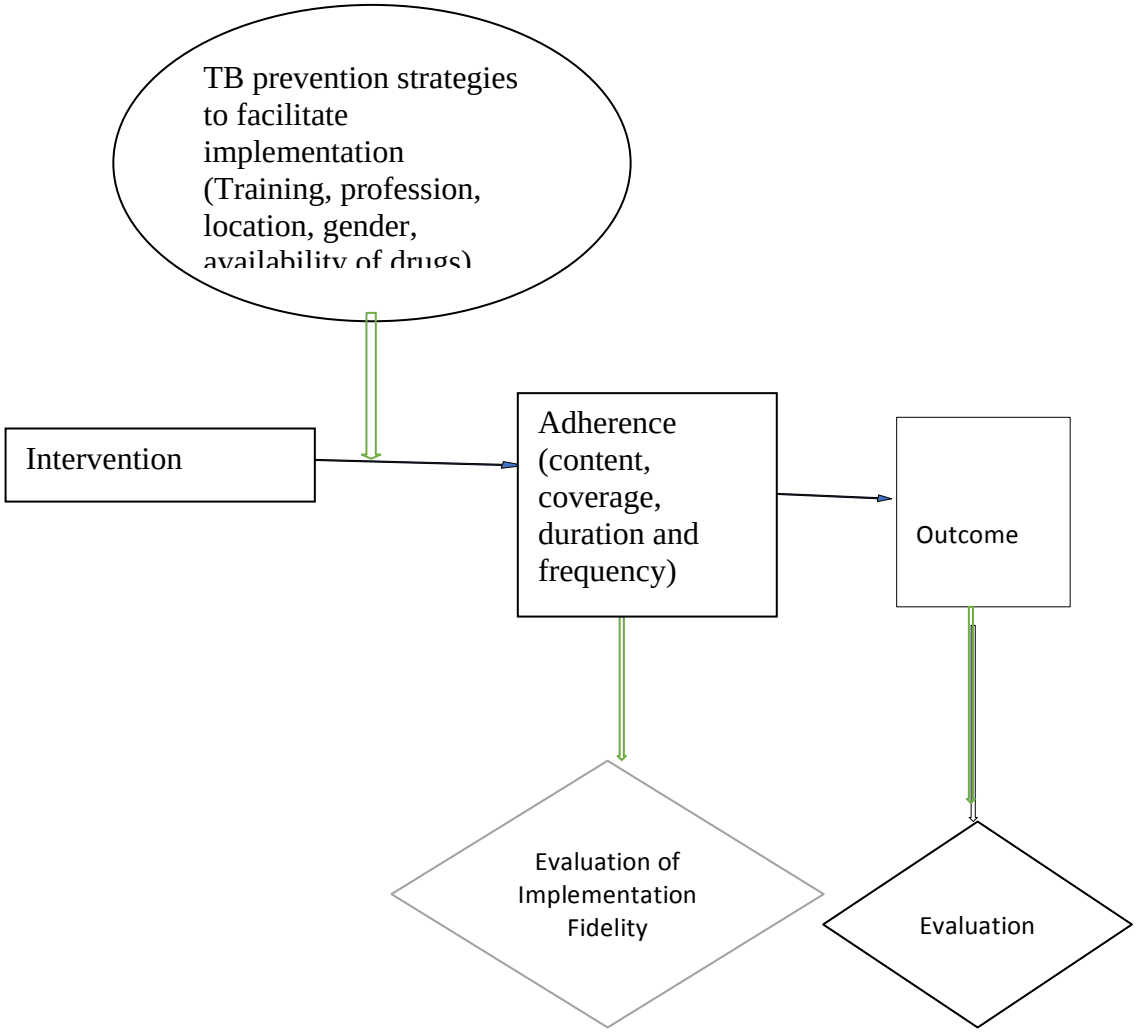


Figure 1.2 Adapted conceptual framework for measuring implementation fidelity (26, 59)

1.5 RESEARCH QUESTION:

What is the extent of implementation fidelity (adherence) to TB prevention guidelines by healthcare workers in people living with HIV/AIDS in Zambia?

1.6 AIM AND OBJECTIVE OF THE STUDY

1.6.1 AIM OF THE STUDY

The aim of this study was to assess the extent of fidelity (adherence) of healthcare workers and factors associated with the implementation of guidelines for ICF and IPT for TB prevention in people living with HIV/AIDS in rural and urban health facilities of central province of Zambia.

1.6.2 STUDY OBJECTIVES:

i.) To determine the extent of healthcare workers' adherence in implementing ICF guidelines in rural and urban facilities using Smartcare records in patient files from December 2015

ii.) To determine the extent of healthcare workers' adherence in implementing IPT in rural and urban facilities using Smartcare records in patient files from December 2015

iii.) To determine the association of healthcare worker's adherence in implementing ICF and IPT TB prevention guidelines to their profession and training in ICF.

iv.) To determine the difference in ICF fidelity for the visits and geographical location

CHAPTER TWO- METHODOLOGY

2.0. INTRODUCTION

This chapter presents the methodological steps of the whole research study. These include the sampling methodology, the data collection as well as the statistical analysis methods for measuring fidelity.

2.1 STUDY DESIGN.

The study was a cross sectional involving a retrospective medical record review. A quantitative approach was used because of the nature of the variables in the implementation of TB prevention.

2.2 STUDY SETTING

The study focused on defining and measuring implementation fidelity (adherence) as they apply to the TB prevention intervention in the Zambian settings. This study was conducted in two districts of central province of Zambia. One rural district and one urban district. Chibombo district was the rural district and Kabwe district was the urban district. Two clinics providing ART services from each district were part of the study. The rural clinics from Chibombo districts were Kayosha and Mwachisompola rural health centres. Mahatma Ghandi and Kasanda urban clinics were from Kabwe district. All the 4 clinics are public clinics and provide free health care services including ART services to members of the public.

The study made use of the of the Smartcare databases from the chosen healthcare facilities. Smartcare is an electronic medical record system that has been implemented in Zambia in all ART clinics in the public sector as well as some private facilities.

2.3 DESCRIPTION OF THE TB GUIDELINES

The study involved the collection of data from patient medical records retrospectively. It focused on measuring implementation fidelity as it applies to the Managing Tuberculosis in an HIV setting in Zambia guidelines and The Zambia HIV treatment guidelines 2015 (11).

Intensified case finding of TB in adults and adolescents living with HIV includes performing a TB symptom screen at every visit. The symptom screening is part of the routine review whenever an HIV patient visits the clinic for clinical review in any health setting. This symptom screening is applied to all HIV patients. The symptoms that are screened are current cough, fever, weight loss and night sweats. All HIV-infected patients who report or are found with any of these four symptoms may have TB and are evaluated for TB either by performing an X-ray, sputum or GeneXpert diagnostic test depending on the level of the facility and availability of diagnostic services such as laboratory and/or radiology. All those who do not have TB are then provided with Isoniazid Preventive Therapy (11). These steps in implementing the guidelines are summarised in the figure 2.1 below. The first step involves screening the PLWHIV for any symptoms of TB. If a patient is found to have any of the symptoms then a diagnostic evaluation is conducted, while if none of the symptoms are present, Isoniazid should be prescribed and dispensed.

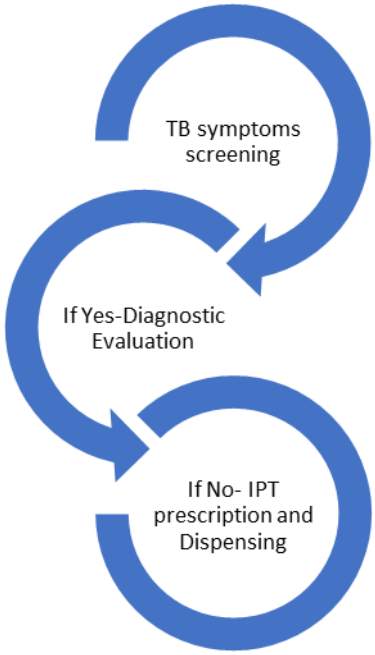


Figure 2.1 Ministry of health intensified case finding components/framework

IPT refers to the provision of isoniazid tablets to all who do not have active TB. The duration for taking Isoniazid in Zambia is usually a minimum six to a maximum of 9 months. All adults and adolescent who are HIV positive and do not have a current fever, cough, weight loss and night sweats and are unlikely to have active TB should be provided with Isoniazid. These include patients who are on ART, those who have been previously treated for TB and HIV infected pregnant women (11)

The healthcare worker ticks on the Smartcare forms placed in the patient file for each clinic visit. The Smartcare form is a ministry of health standard screening form for all patients on ART each time they visit the clinic. The form contains all the four questions as per the guidelines. For each patient visit, a new Smartcare form is placed in the file.

2.4 STUDY POPULATION

The study population consisted of healthcare workers who attended to and reviewed HIV positive patients at Kasanda, Kayosha, Mahatma Ghandi and Mwachisompola health centres. The information was obtained from the patient's medical records and information on whether the healthcare workers were trained in TB/HIV prevention guidelines was obtained from health centre/clinic in-charges. The healthcare workers found to have attended to patients were either Medical officers, Nurses, Clinical officers and others. Any other cadre not a Clinical officer, Nurse or Medical officer was considered as others i.e. Pharmacy Technologist and Environmental Health Technologist.

Only Medical records of PLWHIV who adults or adolescents were (aged 10 years and older) and who commenced ART before December 31^{st,} 2015 were included in the study. Healthcare workers at each of the healthcare facility who attended to any such patients were included. Information from these medical records was used to collect health care workers who attended to them. Medical records of children and of patients who commenced ART after December 31^{st,} 2015 were not part of the study.

2.5 SAMPLING

Kabwe and Chibombo districts were the study districts: one rural and one urban district of central province were purposely selected. Two clinics from Kabwe were chosen because they had the highest number of people on ART in the district. The rural district of Chibombo only had two ART clinics and both were included in the study. We used STATA14™ to estimate the required sample size of patient medical records at a 5% significance level and 80% power to detect a 15% change of the

known fidelity of 55% our sample size was estimated to be a minimum of 290 records. A register of patients on treatment from each facility was obtained from the Smartcare database. Smartcare is an electronic medical records system for ART at each Clinic. A report was generated from Smartcare which contained the number of patients that were registered as ART clients from each facility. STATA 14 was then used to clean the data and generate a sampling frame for each facility to only include those patients that meet the inclusion criteria such as age and ART start date as well as being active on treatment. Excel was then used to calculate the proportion sample of the total sample frame that each facility contributed to the total sample size.

A simple random sample consisting of 5% of the eligible records in each health centre was selected using Stata 14 as shown in the table below. The 5% was chosen from each site to meet the required sample in proportional way based on the number of clients registered at each facility.

TABLE 2.1: SAMPLE SIZE PER HEALTH CENTRE

Facility Name	Total number of records	Proportion of records	% of eligible records in the facility	Number of records Per Facility
Mahatma	2336	0.36	5.00	131
Mwachisompola	1400	0.22	5.00	78
Kasanda	2244	0.35	5.00	126
Kayosha	500	0.08	5.00	28
Total	**6480**			**363**

The total population as shown in table 2,1 above was 6480. 131 patient's medical records where obtained from Mahatma Ghandi, 78 from Mwachisompola, 126 from Kasanda and 28 from Kayosha using simple random sampling in STATA 14. Each

file in the clinic has a patient ART number. A list generated from STATA 14 was used to pull the files from the cabinets.

Exclusion criteria

Information of health care workers from the patients' medical records of Children were not included. Also, those that did not have a maximum of four clinic visits after December 31st, 2015 were excluded. Also, the patients that were not active (lost to follow up patients/had their last clinical visits more than 3 months) were not reviewed to obtain information. These might have been lost to follow up, died or transferred out of the facility. Certain forms did not record who the investigating health care worker was, and these were also excluded. Also, all the other healthcare workers in the facilities who never attended to the ART patients were excluded from the study.

Inclusion Criteria

Patients' medical records for adults and adolescent 10 years and above were included to obtain information about the Health care providers and their adherence to TB prevention guidelines. All healthcare workers who attended to eligible patients were included in the study.

2.7 DATA COLLECTION AND TOOLS

Smartcare forms/medical records of patients who were in care before December 31st, 2015 were reviewed retrospectively to include four clinical visits after December 31st, 2015. An instrument to capture adherence was developed specific to the intervention of preventing TB in PLWH (60). The developed fidelity data list tool was used to collect data from the patient records on ICF and IPT. Information on health care

workers who attended to the patients was also recorded on the same form/tool. The data collection tool was in the form of questions/statements from the TB/HIV collaborative activities, as stated on the form.

The prevention of TB in PLWHIV follows chronological steps, namely ICF (diagnosis and treatment) and IPT (prescription and dispensing). Each step however contains the different components of adherence: ICF content (what is being done to the patient at each stage and or clinical visit), dose (how much / how often is the patient been attended to at the clinical visit), and coverage (how many patients at each clinical visit are receiving each of the steps in the prevention of TB). The questionnaire was structured according to each step in the prevention of TB, each adherence variable was clearly outlined per step and tallying of these points was conducted using a Microsoft Excel spread sheet to limit errors.

The researcher piloted the data collection with 4 patient files per health centre to assess if the information needed would be obtained. The data collection tool was then amended to accommodate the difficulties encountered during the pilot.

Information on whether the healthcare workers who attended to the patients were trained or not was obtained after identifying which health worker had seen the patient at each particular visit. The information on training of these healthcare workers in ART/TB was then collected from the training register or the In-charge at the facility. Information whether isoniazid was available at the clinic was done by checking the stock control cards during the time the patients visited the clinic. These were collected to explore how moderating factors affected adherence to TB prevention in PLWH intervention.

Data was then collected from the Smartcare forms by entering the information on the sheet in the patient files from the first visit after December 31st, 2015 for maximum 4 visits. Files that did not have enough information or visits were replaced by the next eligible file. Information on which providers attended to the patients was also obtained from the same patient's files.

2.8 STUDY VARIABLES AND DATA MANAGEMENT

The implementation outcome variable in the study was fidelity and was measured quantitatively by adherence. Three components used to measure adherence were content, dosage (frequency and duration) and coverage, and these were obtained from the data collection tool. Other variables collected included the geographical location of the clinic and type of care that it offered, as well as demographic data of the patients. The profession as well as training of healthcare workers in TB management in PLWHIV /ART guidelines were the other variables that were collected.

The adherence measurements collected on **dosage** (frequency and duration, whether the patient was screened at each visit compared to the treatment guideline protocols of what has to be done at each visit) and **coverage** (the proportion of patients who had 100% content screened for TB at each visit, for IPT the outcome was whether the patients had been prescribed and dispensed Isoniazid at each clinic visit. Only dosage and coverage were measured because of the nature of the intervention(59).

The above variables were summarised as ranges, percentages/proportions. Each statement was given one point and tallied at the end and converted to a percentage of adherence to the HIV intervention at each stage. Yes/ No and other answers for the content and dosage variables were coded and given a score that complied with the treatment guideline protocol. This information was obtained from patients' medical record files and clinic records.

The explanatory variables were provider profession and provider training in the management of TB. The geographical location of the health facilities was also included.

2.8.1 DATA MANAGEMENT

A Microsoft Excel database was created by the researcher and data was collected and stored into this database. The researcher also coded and cleaned the data using Stata release 14 and Excel to ensure accuracy, completeness and consistency. Data is stored as soft copy on the excel database. Data will be kept in a secure manner for at least three years after the research projected has ended.

Reliability: capturing of data was conducted by the researcher, as well as coding, checking for missing variables and recording. The accuracy of capturing was checked by means of opening the table view of the database against the questionnaire to ensure that there were no missing or duplicate entries. The Microsoft excel database used for capturing data was pre-designed by the researcher.

2.9 DATA ANALYSIS

Stata 14 was used to analyse the data.

Fidelity for ICF was analysed separately from that for IPT. The extent of Implementation fidelity of ICF was analysed in terms of adherence to the guidelines and tallied by enumerating each symptom screened on the patients who were attended to by the healthcare workers as per the guidelines. These were calculated into percentages and further averaged per different visit for ICF and IPT i.e. screening of symptoms of weight loss, night sweats, fever and coughing of more than a week. One yes to any of the above questions would lead to the next stage of applying a standard diagnostic tool to determine presence/absence of TB. A no answer to all the symptoms makes the patient eligible for IPT and leads to the next stage of IPT. Dispensing of Isoniazid is the next and final stage of IPT.

ICF fidelity was tallied and analysed by calculating the percentage of dose recorded (how many times each patient was screened for all the symptoms at each visit). These were further averaged per visit and per stage i.e. ICF, diagnosis and treatment and IPT to gain better understanding of where the gaps in adhering to the intervention were.

Fidelity for IPT was obtained by analysing the proportion of patients who had been screened for all symptoms at each visit and were found not to have any of the symptoms. That is, they answered a NO to all the questions. These are patients who were eligible to have IPT prescribed and dispensed. This was calculated as the

proportion of patients who were prescribed IPT and in addition had Isoniazid dispensed for an adequate number of months as per the guidelines.

Proportion of patients with all the 4 symptoms screened, visit 1, 2, 3 and 4: the numerator was the number of patients who had been screened for all the 4 symptoms at visit and overall, and the denominator was the total number of patients at each visit by the same healthcare worker. The average score of all the four visits was the ICF fidelity score the health care worker on the patient.

Proportion of patients with at least one symptom who had a standard diagnostic test done: the numerator was the number of patients with at least one symptom yes and had a diagnostic test done, and the denominator was the total number of patients with at least one symptom as screened by each healthcare worker.

Proportion of patients who had a positive TB result and received TB treatment: the numerator was the number of patients who had a positive TB result who received treatment, the denominator was the total number of patients who had a positive TB result.

Proportion of patients prescribed and received IPT: the numerator was the number of patients who were dispensed Isoniazid, the denominator was the number of patients eligible for IPT.

2.10 Inferential Statistics

To understand how the factors affected the fidelity score for ICF and IPT, the ICF fidelity score was calculated in terms of adherence to the guidelines and tallied by enumerating each symptom screened on the patients who were attended to by the healthcare workers as per the guidelines. The scores were converted into proportions and further averaged for ICF and IPT i.e. screening of symptoms of weight loss, night sweats, fever and coughing of more than a week. One yes to any of the above answer would lead to the next stage of applying a standard diagnostic tool to determine presence/absence of TB.

The multivariable analysis was used on the moderating factors to explain the mean fidelity score. The moderating factors identified from the conceptual framework were facilitation strategies (training of healthcare workers in TB/HIV, profession, gender and availability of Isoniazid at the clinic during the month of the visit. Carroll et al., 2007 suggested that there is a relationship between moderators which affect the relationship between the intervention and implementation fidelity (59).

The extent of ICF was converted into a binary outcome of low fidelity and high fidelity. If a health care worker adhered to the guidelines or not. The fidelity score for that patient encounter is 4. An average of all the patient encounters is the ICF fidelity score for the provider. Low fidelity score is anything 3 and below. High fidelity score is 4. The maximum score of ICF fidelity was 4. This score was considered high fidelity(11). Univariable logistic regression analysis was carried out for all potential determinants and those significant at p value ≤0.25 were considered for multivariable analysis. The variables that met the inclusion criteria at p-value ≤ 0.25 in univariable

analysis were taken further to multivariable logistic regression analysis. Multivariable variable logistic regression analysis was used to determine provider factors associated with ICF score.

To understand the difference in the extent of ICF fidelity between the different health centres in the different geographical locations, an ANOVA analysis was performed. This analysis enabled the comparing of ICF fidelity among the different health facilities in the study. No comparison was conducted for IPT because the fidelity score for all the health facilities was zero. To obtain the ICF fidelity for the different patient visits, an ANOVA was performed to compare the ICF fidelity score between different patient visits. Patient visit one to four were compared.

2.11 ETHICAL CONSIDERATIONS

Study approval and ethical clearance to conduct the research was obtained from the Wits Human Research Ethics Committee (HREC) and the ERES ethics committee of Zambia. Authority to conduct research was obtained from the Ministry of Health's National Research Authority. Permission to access the selected health facilities was obtained from the Provincial Medical officer, District Medical officers of the respective districts and facility in-charges or management of the respective health facilities.

After identifying healthcare workers who attended to patients, the researcher held a meeting with the supervisor of each clinic to explain what the project was about and after the meeting, the potential health care workers were identified and requested to participate in the study after the study was explained to them. The participants were then given the information sheet and written informed consent was recorded. An

opportunity was given to the participant to ask questions for clarity before they consented to participate. The healthcare workers who had left the clinic either through transfer or other means, the clinic in-charge signed the consent form and provided information on whether they had been trained in ART.

Information about the study was provided to the study participants (healthcare workers) through a detailed information sheet. Voluntary, written informed consent was obtained from the clinic in-charges of the health facilities and some health professionals who attended to the participants after identifying them from the files before collection of their information. Confidentiality of the identity and information provided by the participant was guaranteed and maintained throughout the study period. The information provided from study participants was anonymized during analysis and reporting. After data collection, the survey data collection was entered in an excel database on researcher's password protected computer and will not be used for any other research related activities. The data collected will be completely deleted from the system six years after storage.

CHAPTER THREE: RESULTS

3.1 INTRODUCTION

In this chapter, results for ICF and IPT fidelity scores measured by adherence of healthcare workers to the TB prevention guidelines/protocol in Zambia are presented from analysis of the data collected from the 4 health facilities. Descriptive analyses are presented in the form of graphs and tables that report row percentages. To determine the difference in fidelity scores for the four health facilities, analysis of the different health centres and the different patient's visits are presented using the results obtained from the analysis of variance for the different health centres and patients visits respectively. Then the analysis of the univariate and multivariate logistic regression models is presented but only multivariate results are discussed. These results are presented for the logistic regression model for ICF content.

3.2 DESCRIPTIVE STATISTICS

The total number of health care workers was 40; there were 26 female healthcare workers and 14 males. 37 of the healthcare workers were trained in TB/HIV management and prevention while 3 were not trained. There were two health care workers classified as other; there were 26 nurses, 21 clinical officers and only 1 medical officer. Table 3.1 below shows the demographic profile of healthcare workers.

TABLE 3.1: SOCIODEMOGRAPHIC DATA OF PROVIDERS

Providers	Variable		% of the total	Total
Gender	Male	14	35	40
	Female	26	65	
Training	Yes	37	92.5	40
	No	3	7.5	
Profession	Nurses	26	65	40
	Clinical Of	21	52.5	
	MO	1	0.025	
	Others	2	0.05	

3.3 ICF FIDELITY SCORE

The health workers adherence ICF fidelity score was obtained for each of the patients. For the first visit the mean ICF fidelity score was 2.76 with SD of 1.84 For the second visit, ICF fidelity score was 2.76, with the SD of 1.82. The third visit ICF fidelity score was 2.49 and the SD 1.89. The fidelity score for the final visit 2.30, SD 1.62. The overall ICF fidelity score was the average of all the fours visits and was 2.55 and its SD was 1.18. Figure 3.1 below shows the distribution of these mean ICF fidelity scores for each visit

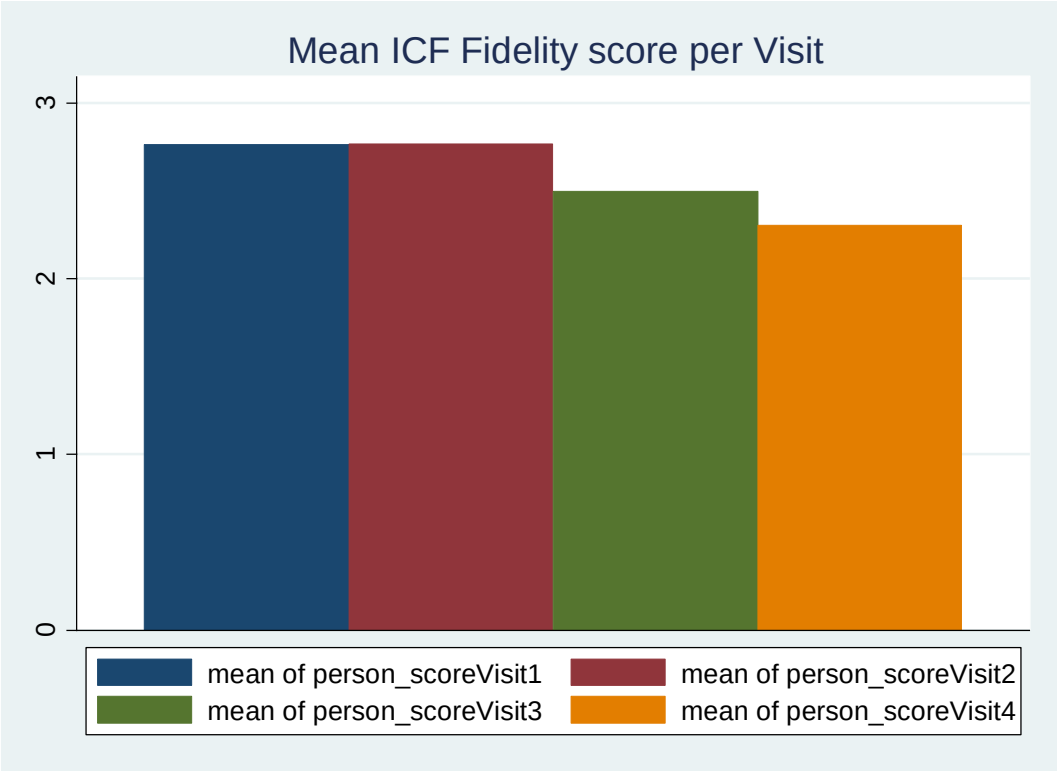


Figure 3.1 the mean ICF score for the 4 patient visits to clinic

By Geographical location, the overall mean fidelity score for the urban health facility number 1 was 2.56, the SD 1.61. The urban facility number 2's fidelity score was 2.24, SD 1.55. The fidelity score for rural health centre number 1 is 1.99, SD 1.70. And for the rural health facility 2.27, SD 1.68. Table 3.2 below shows the distribution of the ICF fidelity score per each health facility.

TABLE 3.2 MEAN ICF FIDELITY SCORE PER HEALTH CENTRE

Health Centre	Urban 1	Urban 2	Rural 1	Rural 2
Fidelity Score	2.56	2.24	1.99	2.27
SD	1.61	1.55	1.70	1.68

Analysis of variance was used to determine whether there was a difference in the mean fidelity scores for the four health facilities and determine the difference in the mean fidelity score for the four visits. The results obtained in table 3.7 showed that the mean fidelity score for the four health centres are different. The F value was

31.62 and the p-value was <0.001, highly significant. The Bonferroni test shows that ICF fidelity score is the same for the urban clinics with p value of 1.00. It is also different for the urban clinics compared to the rural clinics with the p-value <0.001 between urban clinic 1 and the two rural clinics and urban clinic two and the two rural clinics as indicated in Table 3.7. The ANOVA table 3.7 in Appendix 1 shows the results of the difference of the ICF score for the health facilities.

The fidelity score for the four visits are different as shown by the one-way analysis of variance test between the groups. The F value was 19.54. The Bonferroni test shows that visit four is different from group one and two. The other groups are equal. ANOVA table 3.8 in appendix 2 shows the results of the difference in fidelity score of the four visits.

3.4 DIAGNOSIS AND TREATMENT

None of the health care workers prescribed found a patient with any of the four symptoms after screening and hence no diagnostic test was carried out. Therefore, no treatment was required. Thus, fidelity for both diagnosis and treatment was not applicable and hence not considered. To confirm that none of the patients did not have any of the symptoms, we took a random sample of patients and looked at the weight at the first visit and compared it to that taken on the second, third and fourth visit. Some patients were found to have lower weight on their later visits, but the providers did not refer to this and indicated a **“no”** answer to the symptom screen question on weight loss on the screening form. Patients weight is taken by either a nurse or community volunteer and recorded in the patient file for each visit. The provider is not only expected to ask the patient whether they have had a weight loss

but also check and compare the weights for the latest two visits to verify whether the patient is losing weight or not

3.5 IPT

The total number of patients seen by health care providers was 387. Of the 387 patients seen 265 were eligible to receive Isoniazid at visit one. The remaining 122 patients where not eligible to receive isoniazid because no screening was done when they visited the clinic. The percentage of eligible patients for Isoniazid was 68.48. At Visit two 269 patients were eligible to receive isoniazid. These represented 69.51 percent. Those not eligible where 118, which is 30.49 percent. At the third visit 237 patients were eligible to have Isoniazid prescribed and dispensed. They represent 61.24 % of the total patients. And at the fourth and last visit, 203 patients were eligible to have isoniazid prescribed and dispensed, representing 52.45 percent. The table below illustrates the eligibility of to receive isoniazid. The total number of patients seen per each visit is 387

TABLE 3.5: NUMBER OF PATIENTS ELIGIBLE FOR ISONIAZID PER EACH VISIT

Eligible for Isoniazid	Visit 1	Visit 2	Visit 3	Visit 4
	265	269	237	203
%	68.48	69.51	61.24	52.45

3.6 IPT PRESCRIPTION AND DISPENSATION

No health care worker had prescribed Isoniazid at any of the visits at which the patients went to the clinic. This represents the mean IPT fidelity score of zero for all the visits and overall.

3.7 UNDERLYING DETERMINANTS OF FIDELITY

After running the bivariate analysis, there was evidence of association between the explanatory variables and ICF fidelity score. The outcome variable of ICF fidelity was either healthcare workers adhered (with ICF fidelity score of four) to the guidelines or not (With ICF fidelity score of three or less) for each patient visit. We then did the logistic regression analysis to identify the facilitators of fidelity per each patient visit. Isoniazid was out of stock for all the dates of patients visits, this was not included in the analysis. Only multivariate logistic regression results after controlling for all other factors (holding other factors constant) were interpreted and discussed. All the factors considered were significant in the univariable model and were included in the multivariable analysis. The multivariable models were run as multilevel models to take into account the correlation between observations within a given health care provider. The multilevel logistic regression models were fitted to consider the effect of all of the provider factors. The models were run separately for each visit.

The provider related factors were all significant in the univariable model**.** These factors were then included in a multivariable model as shown in table 3.7 to 3.7.3.
For the patient's first visit to the clinic, provider profession and location of the health facility were not significant after running the multivariable analysis logistic regression model.

TABLE 3.7: MULTIVARIABLE ANALYSIS LOGISTIC REGRESSION VISIT 1

Factor	Level	OR	95% Confidence Interval	P-value
Health Center Location	Urban1	1	Reference group	
Health Center Location	Urban2	0.68	(0.29 1.59)	0.38
	Rural 1	0.24	(0.08 0.67)	0.01
	Rural 2	0.95	(0.28 3.17)	0.94
Sex	Male	1	Reference group	
	Female	0.43	(0.17 1.01)	0.05
Training in HIV/TB	No	0	Baseline	
	Yes	0.53	(0.17 1.63)	0.27
Provider profession	Clinical Officer and Other	1	Reference group	
	Nurses	0.90	(0.40 2.00)	0.81
	Medical officers	5.31	(0.61 45.75)	0.13

Female health care workers were 57% less likely to adhere to the guidelines of screening for TB compared to their female counterparts, (OR=0.43, CI 0.17-1.01, P=0.05). Health centre geographical location was also significant in affecting fidelity for TB screening. Rural clinic number one was 0.24 times less likely to have fidelity to the guidelines compared to urban clinic number one, [OR=0.24, P value 0.01].

There was no significant difference between the healthcare workers who had been trained in HIV/TB management and those who had not been trained (P> 0.05). Provider profession was also not significant in adhering to the TB screening guidelines when compared to clinical officers and others (P > 0.05. and confidence intervals included 1)**.** Apart from rural clinic number one, when compared to urban clinic number one other clinics where not different in adhering to TB screening guidelines (P> 0.05 and the confidence intervals included 1 as well).

No significant difference in fidelity for all the explanatory variables for the second visit and the fourth visit, all values >0.05 and all the confidence intervals included one.

TABLE 3.8: MULTIVARIABLE ANALYSIS LOGISTIC REGRESSION VISIT 3

Factor	Level	OR	95% Confidence Interval	P-value
Health Center Location	Urban1	1	Reference group	
	Urban2	0.43	(0.21 0.89)	0.03
	Rural 1	0.35	(0.11 1.05)	0.06
	Rural 2	0.66	(0.16 4.80)	0.88
Sex	Male	1	Reference group	
	Female	1.13	(0.53 2.38)	0.74
Training in HIV/TB	No	1	Reference group	
	Yes	0.86	(0.23 3.15)	0.81
Provider profession	Clinical Officer	01	Reference group	
	Nurses	1.24	(0.63 2.44)	0.05
	Medical officers	0.97	(0.32 2.92)	0.96

For the patients' third visit, location of the health facility was significant in affecting the screening of TB. Urban clinic number 2 was 57% less likely to have health care workers to adhere to the guidelines of screening for TB, (OR=0.43, P= 0.05) which was significant. Rural clinic number 2 was 65% less likely to have health care workers screen for TB (OR 0.35, P= 0.06) slightly significant.

Profession did not affect the probability for screening for TB, neither did gender nor whether the healthcare workers were trained.

CHAPTER FOUR: DISCUSSION

4.1 INTRODUCTION

This section discusses the fidelity score for the four health facilities and the four patient visits. We found a difference in the fidelity score between the four patient visits. Evidence on ICF from different countries in sub Saharan Africa is well documented on uptake (61). However, none of the studies have measured fidelity implementation on the follow up visits. This study explored the association between implementation fidelity of the subsequent visits as well as geographical location of urban and rural and facilitation strategies related to the providers as per the TB prevention intervention in PLWHIV in Zambia. The main aim of the study was to explore and compare the extent of implementation fidelity (adherence) in the prevention of TB in PLWHIV in Zambia as per the guidelines on the management, prevention and treatment of TB and HIV in Zambia. The study demonstrated that underlying geographical location and provider (demographical) and facilitation strategies (provider) factors were associated with implementation fidelity (24).

4.2 Extent of ICF fidelity for the Visits.

The difference in the fidelity score between the urban and rural health facilities mighty be attributed mainly to geographical location and the type of cadre that is available. A study conducted in Malawi and South Africa that looked at the integration of TB/HIV services and uptake of ICF between the rural and urban health facilities found uptake to be lower in rural facilities than in urban facilities (62). Another study conducted in Mwanza district of Tanzania found longer delays in

screening for TB for people living rural areas than in the urban areas(63). Among the factors reported that contributed to this difference, were lower level of education, traditional healer visitation and patients not having enough information about TB. A study looking at screening tools for ICF in low resource settings (64) that found that the unavailability of equipment, laboratories and X-ray machines affected the screening for TB in rural clinics compared to the urban clinics that had access to these tools.

The multivariable logistic regression analysis of provider factors found that some provider related factors were not significantly different in affecting the fidelity scores. However, there were some significant differences with regards to the patient visit number, for example for the first visit females were 57% less likely to adhere to the guidelines than their male counterparts and this was significant. Health centre geographical location was also found to be significant. For the visits number two to 4, there was no significant difference with regards to gender of the providers in affecting fidelity of implementing the guidelines.

There was a difference in adhering to the guidelines based on geographical location of the clinics for visit one and three. Visit number two and four had no significant difference in geographical location for affecting fidelity. For visit one, rural clinic one were 76% less likely to adhere to the guidelines compared to urban clinic number one. The differences between urban and rural clinics could be attributed to the non-availability and limited access to diagnostic tools as was found by Reid M.J.A and Shah N.S (64).

Among the provider related factors, there was no significant difference in affecting fidelity for all the visits except for visit number 3 were nurses were1.24 more likely to adhere to the guidelines compared to the clinical officers and others. Training was not significant at any of the visits. This might be due to the attitude of healthcare providers, who even after undergoing training might continue with the same routine work culture(24). A study to find out why the healthcare providers even after undergoing training and provided with guidelines do not improve the screening of patients should be conducted. These findings do not agree with the conceptual framework that training and guidelines are facilitation strategies of implementation fidelity as described by Carroll (25).

4.3 DIAGNOSIS AND TREATMENT FIDELITY

The diagnosis and treatment fidelity were not calculated. This is because no single patient medical record had a yes response to any of the four symptoms. On all the four patient visits, it was found that none had any of the four symptoms of weight loss, night sweat, fever and cough of more than one week. When one of these symptoms is available, the patient is eligible to have a standard diagnostic test (Chest X-ray, GeneXpert or microscopy) done.. This means there was no consistency in the responses written by the providers and many patients that are eligible to undergo a diagnostic test did not do so. Therefore, TB may be missed in this group of patients. This raises questions as to whether the responses written are the correct ones or providers just tick without even asking/screening patients.

4.4 IPT FIDELITY

Over two hundred patients on each visit were eligible to be prescribed and dispensed Isoniazid. This is based on the responses given of not having any of the four symptoms described above. None of these patients was prescribed Isoniazid as per the treatment guidelines. No prescription meant isoniazid cannot be dispensed. Most providers attending to these patients underwent ART training which included ICF and IPT recommendations, but none prescribed it. We went further to check the stock control cards in the pharmacy at the clinics for availability of Isoniazid. There was a stock-out of Isoniazid during the duration of visits in all the clinics. This may be a contributor to providers not prescribing the drug.

4.5 LIMITATIONS

The limitations of this study are discussed in three parts namely data, bias and study design.

Data and Analysis: The limitations that are associated with the data are that the data are composed of hierarchical data at provider level. This meant conducting a multilevel logistic regression. Hence the data was collapsed to get the provider facilitation strategies effects. The study utilised secondary data from patient's medical records which made it difficult for the researcher to have all the information related to provider variables because some files had incomplete information. It was difficult to locate the providers from the patients' medical records. Most providers did not write their names after seeing the patients but only appended the signatures and left the name provision blank. Most importantly others did not sign nor write anything on the provisions for name and signature.

Bias: Providers may be ticking as having screened the patients when in fact they had not. To verify this, a random sample of patient medical records found that there were inconsistence in the information provided. Thus, information bias could be one of the limitations in obtaining ICF fidelity.

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

The low mean implementation fidelity score of TB prevention in people living with HIV/AIDS observed continues to impact on TB infections in people living with HIV/AIDS. These low mean fidelity scores could be due to health worker's perceptions of the intervention. They may consider them as either complex or else they do not believe in the intervention. It could also be lack of behaviour change and attitudes of the providers to the guidelines. Even after undergoing training and the

provision of guidelines at the health centre level. More studies are needed that will investigate the providers perception of the intervention in terms of the complexities. The studies should also look at the quality of delivery of the intervention through observation of the providers as they deliver the intervention.

There is a need to conduct a study that will have enough numbers of observations. This will enable provider and other facilitation strategies to be analysed by a hierarchical model

The was no patient for whom a diagnostic test was ordered. This is because none was found to have any of the symptoms described above. This was not consistent with random observations of the weights of some patients. It is possible that providers are not investigating these symptoms. It will be important to conduct a study that will interview the providers on why they have not been recording correct information in the patient files on the symptoms. Revision sessions of the training material should be held in which it should be emphasized that not investigating the symptoms is putting the patients at risk of contracting and developing TB which is difficult and expensive to treat.

The other measures recommended that may improve fidelity are increased supervision. Health centre in charges must conduct weekly to monthly supervisory check. Mentorship of providers by experienced and qualified staff is also another strategy that may improve fidelity. Availability of commodities (Isoniazid and Vitamin B6) can compel providers to be prescribing the drugs to eligible patients and hence improve IPT fidelity. Monitoring and evaluation activities should also be strengthened. These should be accompanied by feedback mechanisms that inform facility staff on the progress, barriers to and facilitators to implementation. Emphasis

should be given towards availability of provider information/records on each patient visit. This will ensure accurate and complete records that can be used for research or other analyses of data that can be used for information generation at facility, district, provincial as well as national level.

It was not surprising that none of the providers prescribed isoniazid to the eligible patients. This mighty be because there was a stock out of isoniazid in all the health facilities. The districts should ensure that they supply isoniazid to health care facilities. This should be followed by supportive supervision to ensure that it is put to effective use. Also, a monthly reporting mechanism should be put in place to help with decision making and guide technical supervisory support visits.

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APPENDICES

APPENDIX 1 SENATE PLAGIARISM DECLARATION POLICY

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I _JAMES TIEZYE SIMUKOKO_ (Student number: _1079648_) am a student registered for the degree of _MSc Epidemiology Implementation Science_ in the academic year _2018_.

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: ___11th June 2018

TABLE 3.7: ANALYSIS OF VARIANCE FOR THE DIFFERENCE IN FIDELITY SCORE FOR HEALTH CENTRES

Source	Degrees of freedom	Sum of squares	Mean square	*F* ratio	*P*
Between Groups	3	259.65	86.55	31.62	0.0000
Within Groups	383	1048.48	2.74		
Total	386	1308.13	3.39		

APPENDIX 2 BONFERRONI TABLE FOR THE DIFFERENCE FOR THE HEALTH CENTERS

Row Mean-Col Mean	Urban1	Urban2	Rurar1
Urban2	0.0991		
Rurar1	-1.92 0.00	-2.02 0.00	
Rural2	-1.16403 0.002	-1.26292 0.001	0.760606 0.161

APPENDIX 3,

TABLE 3.8: ANALYSIS OF VARIANCE FOR THE DIFFERENCE IN FIDELITY FOR DIFFERENT VISITS

Source	Degrees of freedom	Sum of squares	Mean square	*F* ratio	*P*
Between Groups	3	58.64	19.55	19.55	0.00
Within Groups	1544	4990.1	3.23		
Total	1547	5048.74	3.26		

APPENDIX 4: BONFERRONI TABLE FOR THE DIFFERENCE IN PATIENT VISITS OF ANOVA ANALYSIS

Row Mean-Col Mean	1	2	3
2	2584.0001		
3	-0.27 0.24	-0.27 0.23	
4	-0.459948 0.002	-0.46253 0.002	-0.1938 0.804

APPENDIX 5: DATA COLLECTION FORM

PART ONE: HEALTH FACILITY INFORMATION

1. Type _____ (Rural, Urban)
2. Provider ID _____
3. Level of care _____ (health centre, district hospital, general hospital)

PART TWO: PROVIDER INFORMATION

1. Trained in TB prevention _____(Y/N)
2. Gender _____ (Male, Female)
3. Profession _____ (nurse, doctor, clinical officer, other)

PART THREE: PATIENT INFORMATION

1. **Socio-demographic information**

1.1. Patient ID _____

1.2. Age _____

1.3. Gender _____ (Male, Female)

1.4. Employment _____ (Y, N)

1.5. Level of education _____ (Primary, Secondary, Tertiary, None)

	Visit 1	Visit 2	Visit 3	Visit 4
Content	Cough____(Y/N) Weight loss____(Y/N) Night S_____(Y/N) Fever_____(Y/N)	Cough____(Y/N) Weight loss____(Y/N) Night S_____(Y/N) Fever_____(Y/N)	Cough____(Y/N) Weight loss____(Y/N) Night S_____(Y/N) Fever_____(Y/N)	Cough____(Y/N) Weight loss____(Y/N) Night S_____(Y/N) Fever_____(Y/N)

2.0 ICF

Fidelity (adherence)

2.2. Coverage

2.2.1. Has TB been screened _____ (Y, N)

2.3. ICF Content

2.3.1. If any of the above is YES:

- Has TB standard diagnostic test been performed? _____ (Y, N)
- Has TB been treated? _____ (Y, N, N/A)
- Follow up for IPT _____ (Y, N, N/A)

2.3.2 If all No, go to IPT (2.4)

2.3.3 Frequency of TB screening

- Number of Visits____
- Number screened for TB___

2.4. IPT

2.6.1. Coverage

- Is the patient eligible for IPT? _____ (Y, N)
- Is the patient receiving IPT? _____ (Y, N)

2.3.2. Duration

- Number of months of IPT: _____

APPENDIX 6: ETHICS CLEARANCE

R14/49 Mr James Tiezye Simukoko

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M161195

NAME: (Principal Investigator)	Mr James Tiezye Simukoko
DEPARTMENT:	Epidemiology and Biostatistics School of Public Health Kusanda and Mahatma Ghandi Urban Health Centres Mwachisompola and Kayosha Rural Health Centres, Zambia
PROJECT TITLE:	Implementation Fidelity (Adherence) of Tuberculosis Prevention in People Living with Human Immunodeficiency Virus in Zambia
DATE CONSIDERED:	25/11/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Jabulani Ncayiyana and Dr Thiery Malebe
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	31/03/2017

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore be due in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 7: RESEARCH AUTHORISATION

THE NATIONAL HEALTH RESEARCH AUTHORITY
C/O Ministry of Health
Haile Selaisse Avenue,
Ndeke House
P.O. Box 30205
LUSAKA

In response please quote
No. MH/101/23/10/1

1 March, 2017.

Mr. James Simukoko
15 Chinika Road
Northrise
Ndola.

Dear Mr. Simukoko,

RE: REQUEST FOR AUTHORITY TO CONDUCT RESEARCH

The National Health Research Authority is in receipt of your request for authority to conduct research entitled **"Implementation fidelity of Tuberculosis Prevention in People Living with HIV/AIDS in Zambia".**

I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, the Authority has granted you authority to carry out the above mentioned exercise on condition that:

1. The relevant Provincial and District Health Directors where the study is being conducted are fully appraised;
2. Progress updates are provided to the Authority quarterly from the date of commencement of the study;
3. The final study report is cleared by the Authority before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by the Authority, the final study report is shared with all relevant Provincial and District Health Directors where the study was being conducted, and all key respondents.

Yours sincerely,

Mrs. A. Ngomah-Moraes
For/Director