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**FACTORS ASSOCIATED WITH TUBERCULOSIS PREVENTIVE THERAPY UPTAKE  
AMONGST PATIENTS RECEIVING ANTIRETROVIRAL THERAPY IN ZAMBIA**

**By**

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**A mini-thesis submitted in partial fulfillment of the requirements for the degree of**

**Masters in Public Health in the Department of Public Health**

**University of the Western Cape, South Africa**

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**i**

## KEYWORDS

HIV

Co-infection

Tuberculosis

Latent Tuberculosis

Uptake

Preventive therapy

Isoniazid

Antiretroviral Therapy

Kapiri Urban Clinic

Mycobacterium Tuberculosis



## **Abstract**

**Background:** Prevention of new Tuberculosis (TB) infections and their progression to disease is important in the reduction of the burden of ill health and loss of life caused by TB. Tuberculosis preventive therapy (TPT) is an important component of care for people living with HIV (PLHIV). The uptake of tuberculosis preventive therapy among PLHIV globally was low through to 2020 though having been introduced by WHO before 2016. This study was undertaken to explore the factors associated with the uptake of TPT among PLHIV through understanding the perspectives of both the health workers and the PLHIV at the Kapiri Urban clinic in the Kapiri district of the Central province of Zambia.

**Method:** An explorative, qualitative study was conducted. The research data was collected through in-depth interviews and focus group discussions (FGDs). A total sample of 22 respondents participated in this study out of which 18 were PLHIV on antiretroviral therapy (ART) and 4 were key informants. The 4 key informants were healthcare workers (HCWs) working from the ART clinic. The key informants included the ART nurse, clinician, Community Health Worker (CHW), and pharmacist. 6 PLHIV who participated in the study, were individually interviewed and 12 participated in the FGDs. Information was audio-recorded, transcribed, and analyzed using a thematic procedure that included coding of data.

Ethical clearance was obtained from the University of Western Cape (UWC) Biomedical Research Ethics Committee (BMREC) as well as from the ERES Converge Institutional Review Board (IRB) and National Health Research Authority (NHRA) in Zambia. Informed consent was

obtained from respondents who voluntarily participated in the study and were given the option to withdraw from the study at any time without providing any reasons. Clinical staff were available to provide medical services to any participant who needed medical attention during the interviews.

**Results:** Overall, the current TB preventive therapy coverage of Kapiri Urban clinic was estimated to be over 90% at the beginning of 2022 when compared to less than 5% in 2018. The estimated high coverage was attributed to the extensive support provided to the health facility by the USAID-supported project, Supporting an AIDS-Free Era (SAFE) in 2021. Financial and human resource donor dependence was another challenge reported hence if the provision of this support comes to an end, this would negatively impact the observed high TPT uptake. In addition to the challenges highlighted above, the following were indicated as factors that would affect the TPT achievements if not addressed and these included supply chain challenges, drug side effects, pill burden, and documentation challenges.

**Conclusion:** Despite the observed high TPT uptake at the study site, there are still challenges highlighted by research participants that could undermine TPT uptake. The reported barriers included human resource challenges, inconsistent stocks of TPT drugs, and the use of manual registers. Addressing these hurdles will maintain the observed TPT uptake as well as enhance treatment restarts following the completion of the 3-year protection period thereby continuing to improve health outcomes among the PLHIV.

## DECLARATION

I declare that the study on *Factors associated with tuberculosis preventive therapy uptake amongst patients receiving antiretroviral therapy in Zambia* is my work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Bibian Ndango

March 2023



Signed:

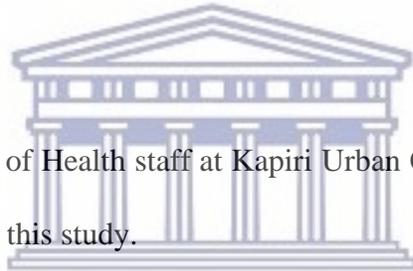
A handwritten signature in black ink, appearing to be "Bibian Ndango", written over a grey rectangular background.

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Last, but not least, I deeply thank my children Adrian, Bupe, and Bibian for their continued encouragement and for having allowed me to use part of the time to be with them for my studies.

## ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARVs	Antiretrovirals
COVID-19	Coronavirus disease 2019
ADR	Adverse drug-resistant
DSD	Differentiated Service Delivery
Global Fund	The Global Fund to Fight AIDS, Tuberculosis, and Malaria
HBC	High burden country
HIV	Human immunodeficiency virus
LMICs	Low and middle-income countries
MMD	Multi-Month Dispensation
NTP	National TB program
PLHIV	People Living with human immunodeficiency virus

TAG	Treatment Action Group
TB	Tuberculosis
TPT	Tuberculosis Preventive Therapy
3HP	Rifampicin/Isoniazid
UHC	Universal health coverage
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
US	United States
USAID	United States Agency for International Development
WHO	World Health Organization



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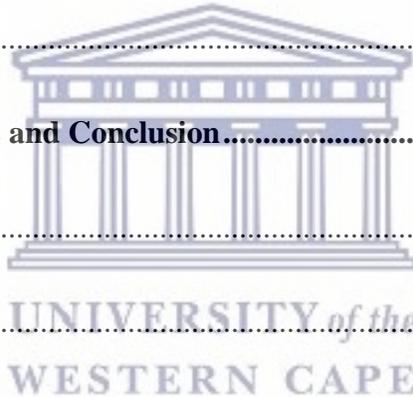


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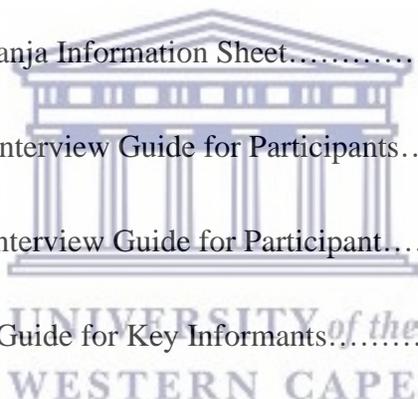


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Table 1: Distribution of participants by Age, Sex, and TPT completion status



## **CHAPTER ONE: INTRODUCTION**

This chapter provides the global and local overview of TB, HIV, and TPT and presents the problem statement as well as the rationale of the study. The chapter ends by providing an outline of the rest of this thesis.

### **1.1 Global Tuberculosis Disease and Prevention Therapy Overview**

TB is among the top ten causes of mortality and morbidity globally and this accounts for around one in three AIDS-related deaths (UNAIDS, 2020 and WHO, 2021). People living with HIV are 20 times more likely to develop TB as compared to those who are HIV-negative (Catholic Relief Services, 2019). In 2020, an annual reduction in TB incidence, notifications, and a rise in the estimated TB deaths was observed and was attributed to COVID-19 (WHO, 2021). For instance, in 2020 5.8 million people were newly diagnosed and reported to have had TB compared to 7.1 million in 2019 worldwide (Global Fund, 2022). About 8% of the newly diagnosed TB cases in 2020 were among PLHIV and of the PLHIV diagnosed with TB, 88% of them were on ART (WHO, 2021). According to WHO (2021), about 214,000 people died of HIV-associated TB in 2020 compared to 209,000 in 2019, an increase attributed to the COVID-19 pandemic which led to health service disruption. The End TB strategy launched by WHO in 2015 states that by 2030, the world should be free of tuberculosis and the target is to achieve a TB reduction in deaths by 90% and a reduction in the incidence by 80% (Moonan et al., 2018; WHO, 2021). According to Raviglione & Ditiu (2013), TB eradication needs to decrease the global TB occurrence from >1250

cases per million people to <100 cases per million people by 2035. Antiretroviral Therapy (ART) on its own decreases the incidence of TB by 65% (Suthar, 2012), and when used together with tuberculosis preventive therapy drugs, occurrence, and mortality from TB is reduced by about 90% (Badge et al., 2017). In 2021, WHO reported an increase in TB preventive treatment from 1.0 million in 2015 to 3.6 million in 2019, however, this positive trajectory was reversed in 2020, with a 21% reduction translating to 2.8 million. The reduction in TB preventive treatment is attributed to health services disruptions caused by the COVID-19 pandemic.

## **1.2 TB and HIV situation in Southern Sahara Africa**

Morbidity and mortality because of HIV-TB coinfection is a major concern in sub-Saharan Africa. Over one-third of PLHIV are found in Sub-Saharan Africa (Gelaw et al., 2019). In 2020, there were about 37.7 million people living with HIV globally (UNAIDS, 2021). Out of the total number of people living with HIV, East and Southern Africa bear the highest global TB/HIV burden with 54% (20.6 million) people living with HIV (UNAIDS, 2021). Over 50% of TB/HIV co-infected cases are found in sub-Saharan Africa and account for 84% of all deaths from HIV-associated TB (WHO, 2018b). In sub-Saharan Africa, about 2.5 million people had TB infection in 2016 and this accounted for a quarter of the new TB cases globally (Nweze et al., 2017).

### **1.3 Burden of TB and HIV in Zambia**

TB and HIV are major public health problems in Zambia. Zambia is among the top 10 Sub-Saharan countries and the top 30 globally with the highest burden of TB (WHO, 2021). Based on the 2018 Zambia Demographic Health Survey (ZDHS), the HIV prevalence for adults was 11.1% (ZDHS, 2018), and the tuberculosis incidence was estimated at 319 per 100,000 people (World Bank, 2020). Tuberculosis co-infected with HIV constitutes a large proportion of patients in Zambia (WHO, 2019). According to WHO (2020), about 59,000 people were diagnosed with TB in Zambia out of whom about 50% were people living with HIV.

### **1.4 Tuberculosis Preventive Therapy (TPT) Overview in Zambia**

TPT is the treatment that is given to both PLHIV and HIV- negative individuals who are at risk of contracting TB infection. According to WHO, TPT is universally recommended for PLHIV once active TB is ruled out (WHO, 2020). In Zambia, TB and HIV clinical services have been integrated thereby ensuring that all PLHIV are screened for TB and if eligible for TPT, are given the 6- or 3-month treatment depending on the drugs (ZCG, 2022). TPT assumes an average of 3 years of protection before a repeat treatment cycle is needed and provided (WHO, 2020).

In Zambia, TB preventive therapy was piloted in 2013 and rolled out countrywide in 2016 (Kangujje et al., 2019). The TB preventive therapy guidelines were launched in March 2019 in Zambia. With the rollout conducted in 2016, uptake of the TB prevention therapy among people

living with HIV was slow with an estimated 20% of PLHIV on antiretroviral therapy being put on TPT in 2019 (MOH, 2021). With the support from PEPFAR, the MOH implemented a TPT surge campaign in 2020 which led to over 300,000 patients initiated on TPT (MOH, 2021; Melgar et al., 2021). As a result of the TPT gains observed, by 2021 the gap in TPT coverage in Zambia was estimated at 30% compared to 70% in 2019 (MOH, 2022).

### **1.5 Problem Statement**

According to WHO (2021), TB is the third prominent cause of death from infectious diseases worldwide and the primary preventable cause of death among people living with HIV. TB is the most common illness presenting among people living with HIV, including among those on antiretroviral therapy. By the end of 2019, there were about 10 million individuals with tuberculosis around the world, out of which 1.2 million were HIV-co-infected (WHO, 2020b). By the end of 2019, only 49% HIV positive clients were enrolled on TB preventive therapy globally giving a gap of 51% (WHO, 2020b). Despite the confirmed effectiveness of TB preventive therapy and global commendations existing for years, its implementation remained slow and inadequate.

Zambia is one of the high TB burden countries with an estimated TB treatment coverage of about 58% and an incidence rate of 319/100,000 in 2020 (Kangujje et al., 2020; World Bank, 2020). In Zambia, based on the estimated 1.2m PLHIV, in 2021, MOH reported having about 70% of people living with HIV enrolled on TB prevention therapy between 2017 and 2021 (MOH, 2022). This entails that a gap of 30% must be covered to reach saturation. Many of the studies conducted in

Zambia on tuberculosis preventive therapy have not brought out the factors which contributed to uptake challenges of TB preventive therapy in the previous years and what could be the current challenges. It is for this reason that this study was conducted to investigate the factors influencing tuberculosis prevention uptake for both the first-time TPT initiations as well as those restarting TPT due to the lapse of the 3-year protective period.

### **1.6 Purpose of the Study**

Tuberculosis preventive therapy is a safe, cheap intervention that has the potential to reduce illness and death caused by TB, especially among individuals living with HIV who are highly at risk of TB infection progressing to the disease. Tuberculosis preventive therapy does not only prevent TB but also benefits individuals living with HIV through the reduction of the burden of TB-associated morbidity and mortality. In turn, this lessens the economic impact of tuberculosis on the health system. Most studies conducted in Zambia on tuberculosis preventive therapy have not focused on determining the factors that contributed to low uptake of the TB prevention treatment because of the limited evidence available concerning the status of and barriers to tuberculosis preventive therapy uptake, this study was therefore conducted to understand the gaps and barriers to TB preventive uptake and make recommendations which could inform future implementation strategies of TPT.

## 1.7 Objectives

The objectives of the study included:

- To explore socio-economic challenges of patients on ART that may influence tuberculosis preventive therapy uptake,
- To ascertain the perceptions that healthcare providers and PLHIV have on tuberculosis preventive therapy.
- To explore tuberculosis preventive therapy drugs-related factors that may influence low tuberculosis preventive therapy uptake.
- To develop a set of recommendations that can contribute to tuberculosis preventive therapy uptake.



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## 1.8 Outline of this Report

This study consists of six chapters. The introduction chapter puts the study into context while the literature review chapter gives a review of the literature related to the scale-up of TPT. The chapter on methodology describes the process that was used to carry out this study whereas the results chapter presents the study findings. The discussion chapter gives in-depth details of the report and interpretation of the study findings. The concluding chapter summarizes the results and shares recommendations based on the study findings.

## **CHAPTER TWO: LITERATURE REVIEW**

### **2.0 Introduction**

This chapter provides a review of the literature that already exists in relation to the scaling up of TBP. Accordingly, this chapter discusses the factors that influence TPT scale-up and some of the challenges leading to the low TPT uptake as outlined by various studies conducted locally and internationally.

### **2.1 TB/HIV Situation globally and in Zambia**

According to WHO (2020), people living with HIV are 18 times more likely to develop active TB disease than people who are HIV-negative. Globally, TB is one of the leading causes of death and the second leading infectious killer after COVID-19 (WHO, 2020).

Zambia is rated as one of the high-burden countries for both TB and HIV. About 50% of individuals diagnosed with TB in Zambia are HIV-co-infected (WHO, 2019). Like in other resource-limited settings, diagnosis of TB in Zambia still poses a challenge hence the need for increased TPT uptake. The Ministry of Health in Zambia recommends TPT with 6 months daily INH or 3 months once weekly 3HP for PLHIV (including aged  $\geq 12$  months and pregnant and breastfeeding women) with no active TB disease. Additionally, Pyridoxine is given to prevent peripheral neuropathy (WHO, 2018; Melgar et al, 2021). In addition to PLHIV, TPT is also given to people who are HIV-negative but are household contacts of individuals who have active TB

disease (WHO, 2018). Household contacts of TB patients who are less than 15 years are supposed to take Isoniazid and those above 15 years are supposed to take Rifampicin/Isoniazid (RH) (MOH, 2022).

## **2.2 Inadequate TB Case Finding**

As a result of increased vulnerability to TB among people living with HIV, early detection and effective treatment of TB are important for the prevention of TB-associated deaths. Based on WHO (2018), around 40% of HIV-associated TB was undiagnosed and untreated in 2017. WHO has also reported that TB case detection is still very low worldwide, with the reported number of new cases in 2017 standing at 64% of the estimated TB new cases (WHO, 2018b). In Zambia, by the end of 2017, the case detection rate was 58% (WHO, 2018a) giving a gap of 12% to reach the WHO target of 70% by 2030 (Mengistu et al, 2020). TB early detection and treatment interject further transmission, hence case finding remains one of the top global health priorities in the management of tuberculosis. Without stopping the progression from latent to active TB through early disease detection and treatment, the TB epidemic will not end.

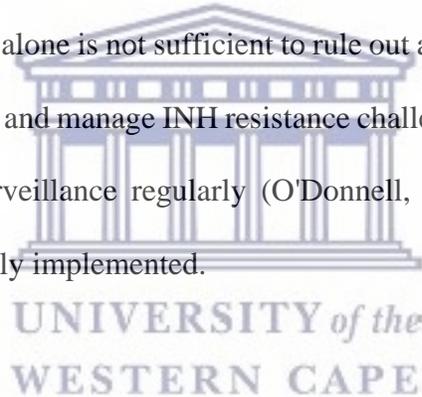
## **2.3 Challenges with Identification of latent TB infection (LTBI)**

To avert active TB, early identification of latent TB infection is needed. Unlike active TB, which can be microbiologically detected, latent tuberculosis is proven indirectly through the detection of

an antigen-specific immune response, through the tuberculin skin test by use of a purified protein derivative (Mack et al., 2009). Additionally, latent TB can also be detected using a blood-based interferon- $\gamma$  release assay (Dheda et al., 2016). Conducting tuberculin skin tests in the context of busy antiretroviral therapy activities is a challenge for both healthcare workers and patients (Khaled, 2009). The long turnaround time for tuberculin skin test result provision contributes to latent TB identification challenges (Khaled, 2009). Additionally, most resource-limited countries experience tuberculin stock availability challenges (Khaled, 2009). As a result of these challenges, tuberculosis preventive therapy is given to individuals living with HIV based on symptom screening hence some health workers have inertia in giving tuberculosis preventive therapy (Akolo et al., 2015). A study conducted in South Africa showed TPT benefits in PLHIV irrespective of them having tested positive for LTBI. The South African study showed similar results as the Cochrane database analysis report which also showed the benefits of TPT for HIV patients who tested both positive and negative for LTBI (Akolo et al., 2010; Rangaka et al., 2014)). The observations of these studies were in sync with the recommendation from WHO which states that LTBI testing should not be a requirement for the initiation of TPT. Zambia is one of the resource-limited countries that has benefited from the cited WHO recommendation as eligibility for TPT does not require a TST test but systematic screening.

## **2.4 Isoniazid Drug Resistance**

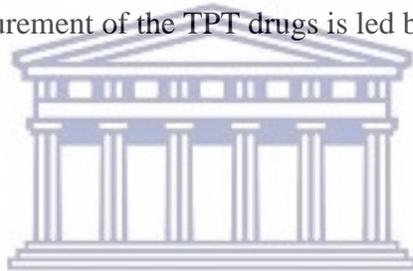
According to WHO (2020a), drugs commonly used for tuberculosis preventive therapy include single Isoniazid, and, a combination of Isoniazid (INH), and Rifapentine which are taken in combination with Vitamin B6. Rifapentine/Isoniazid(3HP) has not been easily accessible due to the high price, the limited number of quality-assured suppliers, and the lack of registration in most countries (Frick, 2019), hence most low-resource countries like Zambia resort to using Isoniazid alone. In Zambia, the use of 3HP was started in quarter 1 of the calendar year 2021 and it is yet to be rolled out countrywide (MOH, 2022). According to the article written by Akolo et al (2015), some healthcare workers were reported not have put people living with HIV on tuberculosis preventive therapy due to the fear that tuberculosis preventive therapy causes isoniazid mono-resistance as symptom screening alone is not sufficient to rule out active TB or may lead to missed TB diagnosis. To timely identify and manage INH resistance challenges, there is a need to conduct national TB drug resistance surveillance regularly (O'Donnell, 2018), especially amongst the population in which TPT is widely implemented.



## **2.5 Integration of TB and HIV programs**

Since the release of the WHO/UNAIDS policy statement on tuberculosis preventive therapy in 1998, there has been uncertainty between the HIV and TB Programs about who takes the responsibility of implementing tuberculosis preventive therapy among people living with HIV (WHO/UNAIDS, 1998). A survey conducted in the PEPFAR-supported countries by Surie et al.

(2017) and a study by Chandra et al (2022) have shown that the low uptake of tuberculosis preventive therapy was due to the uncertainty and confusion about who takes responsibility for the implementation of tuberculosis preventive therapy. Non-integration of the HIV/TB services has been indicated as one of the TPT program management challenges that continue to affect the uptake of TPT (Chandra et al., 2022). Additionally, a study conducted in Namibia also showed unclear roles and responsibilities as some of the major causes of the low uptake of TPT (Roscoe et al., 2020). This was also the case in Zambia as reported in the article written by Kangujje, et al in 2019 which indicated that lack of coordination between the TB and HIV programs affected decision making especially at the service delivery points hence the efforts for scale-up being slowed. In Zambia, the implementation of the TPT at the health facility level is led by the HIV program whereas centrally, procurement of the TPT drugs is led by the TB program.



## **2.6 Policy Environment**

The uptake of TPT is also reported to have been affected by treatment guidelines developed and managed by different Programs – TB and HIV. Focusing on the Zambian tuberculosis preventive therapy and HIV treatment guidelines, the HIV guidelines developed by the HIV program indicated that tuberculosis preventive therapy be given to HIV-positive individuals newly initiated on ART whereas the tuberculosis preventive therapy guidelines developed by the TB program indicated that all eligible people living with HIV should be provided with tuberculosis preventive therapy (Kangujje, et al., 2019; MOH, 2020). This challenge has now been resolved as both

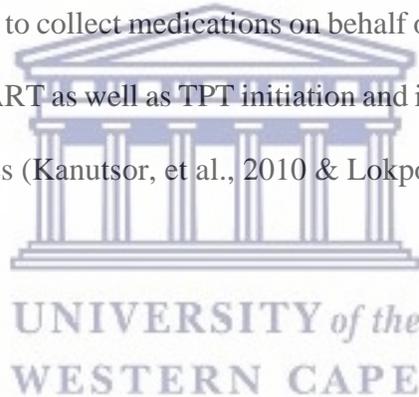
guidelines indicate that all eligible PLHIV should be put on TPT preventive therapy. Additionally, uncertainty on the duration of tuberculosis preventive therapy is another uptake challenge highlighted by a study conducted in Zimbabwe by Nyatic, et al (2019). The study showed that there was uncertainty on whether TPT should be given for 6 months, 12 months or 36 months and this was because the guidelines were not clear. The availability of unstandardized information in the guidelines made it difficult for facility-based staff when wanting to enroll patients on antiretroviral therapy and tuberculosis prevention treatment.

## **2.7 ARVs vs TPT drug pick-up schedules and Multi-Month Dispensation.**

Some studies have indicated that antiretroviral and tuberculosis preventive drug pick-up schedules for individual ART clients have mostly not been put on the same days as the clinical appointment days or synchronized with the days the individuals on ART visit the health facilities for clinical reviews ((Pathmanathan et al., 2017; 2018 & Boyd et al., 2020)

This challenge led to an increase in complexity, and discouragement of TB prevention treatment, hence leading to a decrease in TB preventive therapy coverage (ICAP, 2019). This challenge has also been attributed to individuals on antiretroviral drugs being on multi-month dispensing where ART clients are provided with 3-6 months of antiretroviral drug refills and only receive monthly drug refills of tuberculosis preventive therapy drugs (Boyd et al., 2020). This means ART clients must frequently visit health facilities to pick up TPT drugs only. According to information reviewed by some scholars (Pathmanathan et al., 2018), it has been indicated that to deliver patient-

centered care more efficiently and effectively, there is a need to offer differentiated models of service delivery which includes the implementation of multi-month dispensation (MMD) in the provision of TPT. Additionally, a study by Reddy et al (2020) from India also pointed out that tuberculosis preventive therapy uptake challenges were because of proxy antiretroviral therapy attendance to the clinic which has continued to lead to poor or no tuberculosis preventive therapy initiation due to no availability of the actual ART client. In circumstances where an individual on ART cannot attend scheduled ART clinic visits in person, patient representation is usually an alternative to individual clinic visits (Lokpo, et al., 2020). The patient may thus decide to delegate a representative, mostly a treatment buddy or relative, to collect medications on their behalf (Lwevola, et al, 2021). As outlined by the study conducted in Uganda, although it is permissible for treatment buddies or relatives to collect medications on behalf of the ART patients, the practice may result in poor adherence to ART as well as TPT initiation and incompleteness thereby negatively impacting the treatment outcomes (Kanutsor, et al., 2010 & Lokpo, et al., 2020).



## **2.8 Supply Chain Challenges**

Isoniazid and vitamin B6 stockouts are reported by some studies to have affected many countries and contributed to the uptake of tuberculosis preventive therapy (Melgar, et al., 2020). Additionally, the studies conducted in India and Zimbabwe also pointed out that the continuous shortages of vitamin B6 tablets used in tuberculosis preventive therapy for the prevention of peripheral neuropathy was one of the main supply chain challenges observed (Reddy et al., 2020;

Nyati et al., 2019). With no drugs available in health facilities, individuals living with HIV eligible for tuberculosis preventive therapy cannot complete or be enrolled on TB prevention treatment hence the low tuberculosis preventive therapy uptake.

## **2.9 Effects of Adverse Drug Reactions (ADRs)**

A study conducted in India noted that low uptake of tuberculosis preventive therapy is also because of adverse drug reactions which made patients unable to complete the TB prophylaxis treatment (Reddy et al., 2020). The findings shared the need for effective counseling and eligibility assessments to rule out hepatitis and alcohol use which leads to the occurrence of adverse drug reaction treatment (Reddy et al., 2020). Additionally, a study conducted in Zimbabwe indicated that limited monitoring of drug safety and side effects contributed to the low uptake of TPT (Kawaza et al., 2022). The study showed that continuous mentoring and building the capacity of healthcare workers on the recognition, management, and monitoring of adverse drug reactions resulted in tolerable side effects hence patients continued to take TPT drugs thereby increasing the uptake of TPT. A study conducted in Zambia indicated that HCWs are more likely to overestimate the side effects of TPT drugs, especially in children living with HIV (CLHIV) hence not initiating the eligible PLHIV on TPT and the study also cited concerns by HCWs that TPT is likely to cause mycobacterial resistance to isoniazid among individuals with undiagnosed TB disease (Melgar et al., 2021).

## **2.10 Documentation Gaps and Health care provider related factors**

According to the study conducted by Teklay et al (2016) in Ethiopia, some of the reasons for low implementation of TPT are associated with documentation which included the inadequate application of the symptom screening tool to rule out active tuberculosis. Inadequate application of the symptom screening tool resulted in underestimation of the PLHIV eligibility for TPT. Additionally, the Nigerian study on tuberculosis preventive therapy uptake challenges showed that low uptake of tuberculosis preventive therapy was due to improper filling of the relevant source documents like the tuberculosis preventive therapy registers (Yunusa, 2020). Incomplete filling of TPT registers resulted in under-reporting of the TPT outcomes like completion and reasons for non-completion or the initiation of TPT. To sufficiently monitor and evaluate TPT scale-up, programs may need to adapt manual data collection registers to electronically capture data on TPT duration, completion, outcomes, and monitoring for adverse events which can easily be accessed and analyzed (Pathmanathan, et al., 2018). Lastly, the studies in Ethiopia and South Africa also indicated that challenges of healthcare providers' availability with knowledge regarding TPT contributed to low initiations of tuberculosis preventive therapy resulting in poor uptake (Teklay et al., 2016; Ahmed, et al., 2021).

## **2.11 Pill burden, Patient Drug Adherence, and Treatment Completion**

The pill burden of taking antiretrovirals (ARVs) simultaneously with TPT drugs remains a barrier to TPT scale-up, resulting in most people not completing the therapy (Ngugi et al., 2020). An

article written by Pathmanathan et al (2018) indicates that “adhering to preventive medical regimens can be difficult, especially when patients feel well, and regimens require months to complete”. Additionally, based on the studies conducted in Brazil and South Africa, adherence is indicated to have been inadequate, overestimated through self-reports, and that it reduces with time on treatment (Kendall et al., 2020). Another study conducted in Uganda by Lwevola et al (2021) showed that there is a challenge of adherence to treatment completion, especially in rural areas. Based on this, there is a need for continued adherence counseling by health care providers to avert all potential adherence barriers like clinic opening hours, long waiting times at clinics, cost of clinic visits, insufficient information, health beliefs, and practices. To ensure treatment adherence and completion, treatment and health services need to be patient-friendly.



## **2.12 Impact of COVID-19 on TPT services**

An article by McQuaid et al (2021) has indicated that COVID-19 has led to a reduction in health service accessibility hence impacting TPT scale-up and TB treatment. This has led to an increase in the number of deaths of PLHIV from TB-related illnesses (WHO,2020). A study from South Africa showed increased COVID-19 mortality in PLHIV currently or who previously had TB (Boule et al., 2020). Due to the lockdown, provision and accessibility to health services were reduced. Additionally, WHO (2020) reported disruptions in the public health service provision caused by COVID-19 have had a profound impact on TB case notifications in African countries and in the South-East Asian region. This reduction will in turn affect TPT services, especially to

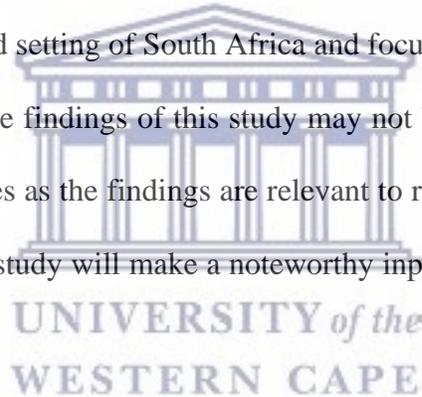
household contacts as the number of individuals eligible for TPT is dependent on the number of those that are bacteriologically positive for pulmonary TB.

### **2.13 Conclusion**

This literature review summarized the literature related to TPT uptake challenges among the PLHIV. It looked at some of the main perceived and reported barriers to TPT uptake. The literature also summarized TPT treatment experiences that would be attributed to the challenges of scaling up TPT. Some of the interventions that could be helpful in supporting the continued uptake of TPT among PLHIV were also explored. Based on the studies reviewed, challenges of TB preventive therapy scale-up have been attributed to inadequate intensified TB case finding, logistic difficulties in performing tuberculin skin tests to diagnose latent TB infection, patient drug adherence potentially leading to isoniazid monoresistance, commodity stockouts, multi-month dispensations of antiretroviral drugs, proxy antiretroviral drug pick up, adverse drug reactions, poor documentation, provider-related factors, policy, and management factors. Like many other healthcare interventions, TPT uptake has also been affected by the COVID-19 pandemic.

## 2.14 Gaps in the literature on TPT uptake

Despite the large body of international and local literature on TPT uptake challenges amongst PLHIV on antiretroviral therapy (ART), it has been observed that much of the data from the literature highlighted above by respectable scholars like Roscore et al (2020), Teklay et al (2016), Pathmanathan, et al (2018), Khaled et al (2009), Melgar, et al (2020) and Nyatic et al (2019), was collected based on document reviews and hence lacked data on patient and health provider perspectives and experiences. Additionally, some of the studies conducted by scholars like Chandra, et al (2022) and Reddy et al (2020) focused on the implementation of TPT in the PLHIV newly initiated on ART hence leaving out those that may have taken TPT drugs or were eligible for TPT but had been on ART for a long time. A study by Ahmed et al (2021) was conducted in the resource-limited setting of South Africa and focused on TPT prescription rates among healthcare providers. The findings of this study may not be generalized to urban areas and other types of health facilities as the findings are relevant to rural resource-limited areas. It is therefore anticipated that this study will make a noteworthy input in bridging the highlighted gaps.



## **CHAPTER THREE:            METHODOLOGY**

### **3.1 Introduction**

This chapter discusses the methodology which was used in the study, and it includes the aim, study design, research population, sample population, sampling procedure, data collection technique, data analysis process, ethical considerations, and the limitations of this study.

### **3.2 Aim**

The aim of the study was to explore the factors that influence the uptake of tuberculosis preventive therapy amongst people living with HIV on antiretroviral therapy in Zambia and come up with recommendations on how best to sustain the TPT scale-up achievements and address challenges related to the uptake of TPT.



### **3.3 Study design**

A descriptive, exploratory qualitative study design was used to identify and explore factors that contribute to uptake challenges of tuberculosis preventive therapy among individuals living with HIV. According to Hunter et al (2018) the descriptive, exploratory qualitative study design, has been identified as an appropriate methodology that is used to learn about areas within or outside the healthcare practice that have formerly received very little or no attention. This study design

provides a deep insight into the phenomenon as well as descriptions of the perceptions and experiences that the study participants may have had (Doyle et al., 2020 ; Bradshaw et al., 2017). With the descriptive exploratory study design mainly being applicable in healthcare-associated studies, it was used in this study as the researcher felt it would bring out the patient's experience of taking the antiretroviral therapy and TPT drugs.

### **3.4 Study Setting**

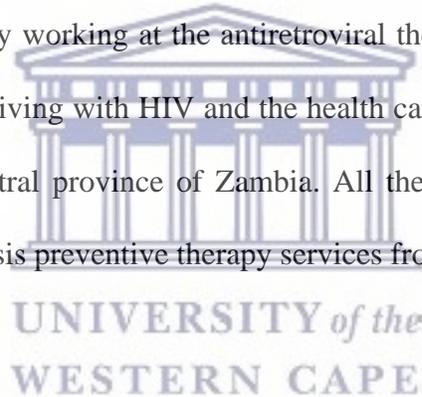
This research was conducted at Kapiri Urban Clinic situated in Kapiri Mposhi town; a town situated about 64 km northeast of Kabwe in central Zambia. Kapiri Mposhi is a peri-urban town in the Kapiri Mposhi district located along a major transport route. Based on the Central Statistics Office (CSO) of Zambia, (2010), and ZDHS (2018), the district is reported to have the highest HIV and TB prevalence rate among the peri-urban districts in Zambia. The central province has the third-highest HIV prevalence of 12.4% among the 10 provinces in Zambia (ZDHS, 2018). Kapiri Urban Clinic provides both antiretroviral and tuberculosis therapy services among the other health care services provided. The health facility was chosen because it has the highest number of PLHIV on ART in the central province, serves people of mixed economic statuses, and has been one of the facilities that were selected as one of the TPT surge facilities in the country. Surge healthcare facilities were provided with increased quantities of TPT drugs between 2020 and 2021 when compared to other health facilities providing TPT in Central Province. As of the end of February 2022, Kapiri Urban clinic had over 6000 PLHIV on antiretroviral therapy (Clinic ART

data, 2022). Based on this, the health facility was selected with the assumption that would provide both the challenges and successes attributed to the TPT scale-up.

### **3.5 Study Population and Sampling process**

#### **3.5.0 Study population**

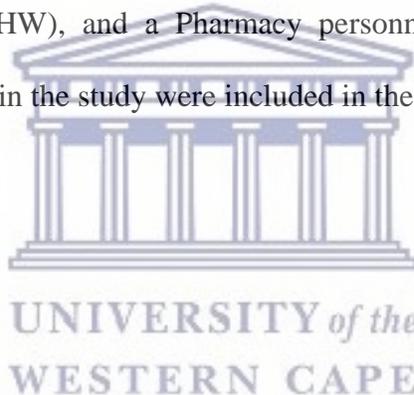
According to Polit and Beck (2008), the population is said to be the aggregation of cases from which the sample is selected. For this study, the sample was selected from the population of people living with HIV who were over 18 years old and on antiretroviral therapy. The study population also included healthcare workers (HCWs) involved in the provision of both ART and TPT services and were at the time of the study working at the antiretroviral therapy (ART) department at the study site. Both the individuals living with HIV and the health care workers (HCW) were drawn from an urban clinic in the central province of Zambia. All the PLHIV included in the study accessed the ART and tuberculosis preventive therapy services from this clinic.



#### **3.5.1 Sampling Procedure**

Polit and Hungler (1993), refer to sampling as the process of selecting a portion of the population that represents the entire population of interest. A purposive sampling method was used to select eligible study participants. To capture the perspectives relating to the interest of this study, the researcher used the maximum variation type of purposive sampling. According to Liamputtong

and Ezzy (2005), maximum variation sampling entails extensive disparities in the experience or process being examined. This study considered the PLHIV who had been on antiretroviral therapy for more than one year and on tuberculosis preventive therapy or should have completed tuberculosis preventive therapy 6 or more months prior to the study, residing within the catchment area of the clinic, scheduled for a clinical visit during the period of the study and were able to communicate in English or local language Nyanja. The inclusion criteria for the HCWs as key informants included them working at the clinic's ART department for more than 1 year and training in both tuberculosis preventive therapy and HIV management. The Targeted informants were HCWs who made clinical management decisions for patients on ART, counseled patients, and prescribed and dispensed TPT drugs. The key informants included the ART nurse, clinician, Community Health Worker (CHW), and a Pharmacy personnel. Only participants and key informants willing to participate in the study were included in the study.



### **3.5.2 Sample population**

A total of 22 study participants were selected and these included 18 adult ART clients on or who had completed tuberculosis preventive therapy and 4 key informants consisting of the ART nurse, clinician, Community Health Worker (CHW), and pharmacist. As outlined by Sandelowski (1996), samples for qualitative studies are mostly small to be able to give depth analysis and collect rich

information from the purposely selected participants hence the total number of 22 participants selected for this study.

### **3.6 Data Collection**

In this section, the process, methods, and instruments used to collect data are discussed. Permission to collect the data from the health facility was sought from the Ministry of Health headquarters and from both the provincial and district health office as well as from the health facility in charge. With support from the HCWs, the probable participants were approached, the nature of the study was explained to them, and asked the identified individuals if they were willing to participate in the study. The information statement was then shared with probable participants who responded positively to participating in the study. The potential participants were then asked if it was feasible to meet with an interviewer at the clinic, on the day they were due for the clinic and drug collection appointment. For all those who expressed willingness, arrangements were made for interviews to be conducted at the health facility. Through the approval of the health facility and ART In-charges, one of the rooms used for adherence counseling was allocated and used for both the in-depth interviews and FGD thereby providing privacy. When the probable participants met with the researcher, the nature of the research was again explained to them, read the consent form, and asked the individuals willing to participate in the study to sign the form. The interview guides, information sheets as well as the informed consent used in this study were translated into the local language for those that did not understand or speak English.

For this study, the methods used to collect data included in-depth interviews and focus group discussions. To ensure that participants freely expressed themselves and shared in-depth information, open-ended questions and probes were used. (Kallio, 2016). Comprehensive notes were taken during and after the individual interviews and focus group discussions. With permission from the participants, all the interview and focus group discussion sessions were audio recorded. The interviews took approximately 30 minutes whereas the FGDs took about 60 minutes to ensure that the discussion topic was fully explored. Comprehensive notes were taken during and after interviews and focus group discussions. With permission from the participants, all the interview and focus group discussion sessions were audio-recorded.

### **3.6.0 In-depth Interviews**

Semi-structured individual face-to-face interviews were conducted with 10 participants (6 PLHIV on ART and 4 key informants). To ensure consistency in the data collected during the in-depth interviews, the researcher used interview guides, one specific for the key informants and the other for the PLHIV. The key informants provided the perspective of healthcare workers on TPT uptake. Both guides had open-ended questions. As stated by Ennis and Chen (2012), the use of open-ended questions ensures flexibility, hence for this study, the researcher opted to administer open-ended questions to ensure flexibility and in-depth responses. This was done to have participants bring out their personalities and perspectives to the interviews. All the research participants were interviewed by the researcher.

### **3.6.1 Focus Group Discussion**

One Focus group discussion (FGD) was held with 12 participants. This involved participants with similar characteristics who were all HIV positive, on ART, taking TPT drugs, or may have completed the TB preventive treatment. Guided by the FGD interview guide, the participants shared their deep thoughts, experiences, and insights about taking tuberculosis preventive therapy drugs. As for in-depth interviews, the questions asked during the FGDs were open-ended. To ensure confidentiality and that all participants were relaxed, a permissive room at the ART clinic that is used during adherence counseling was used. The focus group discussion was conducted with the support of a community health officer in the language understood by the participants. The community health officer works at the ART clinic and is responsible for the provision of health talks to ART patients.



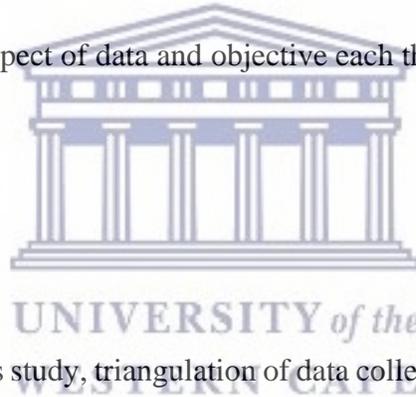
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### **3.7 Data Analysis**

To analyze the collected data, the thematic analysis approach was used. In line with Braun and Clarke (2012), this analysis approach was used to understand the experiences and thoughts on the uptake of TPT among PLHIV. According to Braun & Clarke (2006), thematic analysis is the process of identifying themes within the qualitative data. Open-ended question responses were thematically coded following the interviews and group discussion. The thematic coding was independently conducted by the researcher and the type of thematic analysis used was inductive

which involved reading through the documented data, and identifying, and coding themes from the collected data.

Familiarization with the collected data by the researcher was the start of the data analysis. The researcher listened to audio recordings and transcribed the verbatim, reading/re-reading the transcripts and study notes. After familiarization, using the coding tree - themes>codes>subcodes (Jnanathapaswi, 2021), the codes were then organized into potential and common themes which were then reviewed to check if these themes responded to the research topic. Both the individual interview and FGD responses were coded, separately analyzed, and grouped under similar themes. Analysis of data aimed to explore factors that influence the uptake of TPT among people living with HIV on antiretroviral therapy. The key findings were illustrated by selecting representative quotes and determining which aspect of data and objective each theme fitted under.



### **3.8 Trustworthiness**

To enforce trustworthiness in this study, triangulation of data collection was conducted using more than one method to collect the data. Data were collected from participants through In-depth interviews and FGDs, as verified through interviews of the key informants, and individual interviews were verified through data collected during the focus group discussions. This was done to ensure the credibility the of data. Trustworthiness was also ensured through the researcher keeping a diary detailing the study experience and noting all key discussion points. Additionally,

with the consent of the participants, the discussions were audio recorded. Trustworthiness was also enhanced by comparing the findings of this study with the findings on tuberculosis preventive therapy uptake studies conducted in other countries.

### **3.9 Ethical Considerations**

Ethical approvals of the research proposal were obtained from the Biomedical Research Ethics Committee of the University of the Western Cape, ERES Converge Institutional Review Board (IRB) - Zambia, and the National Health Research Authority (NHRA) in Zambia prior to conducting the research. Permission to collect data from the Urban clinic was sought from the Ministry of Health headquarters as well as the Provincial and District health office. A detailed explanation of the purpose and benefit of the study was described to the study participants and their full willingness to participate in the study was consented to, verbally and written. The study assured the respondents that no names would be attached to responses for confidentiality and that the information will be used strictly for academic purposes. Research participants had the right to abstain from further participation in the research irrespective of any legal or other obligation. Except during focus group discussions, participants were interviewed separately, and the information submitted was treated with strict confidentiality except for the purpose of the study. Confidentiality was achieved by storing the electronic data using the password-protected storage folders on the computer and the hard copy dairies stored in lockable drawers. To ensure confidentiality among the participants who took part in the FGDs, they all signed the

confidentiality binding form thereby agreeing to uphold the confidentiality of the discussions and identity of other participants or any aspects of their contributions to members not part of the focus group discussions. Data storage tools were only accessible to the researcher. The presentation of the results was made with no references to the names (anonymously) of the participants. Both key informants and the PLHIV participants were identified using numbers and sex.



## **CHAPTER FOUR: RESULTS**

### **4.0 Introduction**

This chapter presents the major findings of the study. Additionally, this chapter presents the characteristics of the study participants and their TPT experiences. The themes and subthemes based on the data analysis from the responses of the focus group discussions, participant in-depth and key informants' interviews are also presented in this chapter. The main themes identified during the analysis included participants' experiences and perceptions about TPT and the barriers attributed to TPT scale-up.

### **4.1 Demographic Characteristics of study participants**

#### **4.1.1: Profile of the PLHIV Participants**

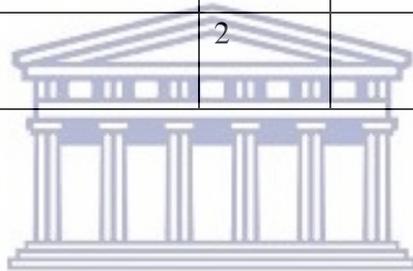
##### **4.1.1.1: Age, sex, and TPT completion status of participants**

Table 1 shows the distribution of participants by age, sex, and the TPT completion status of still on TPT or completed the prevention therapy. A total of eighteen PLHIV on ART participated in the study and of these, some participants had completed the TPT treatment whilst others were still taking the TPT drugs. Most of the participants were middle-aged (36 – 45 years) to older (46 – 55 years) ART patients and 100% of the participants had been on ART for over 6 months prior to the study. Additionally, all males were above 35 years, and all females were below 56 years. Most of the patients who participated in the study had completed TPT.

All the participants indicated to have disclosed their HIV status to their partners and for those with no partners, disclosed to their children and/or other close relatives.

**Table 1: Distribution of participants by Age, Sex, and TPT completion status**

Age (years)	Number of Participants	Sex		Completed TPT	Still on TPT
		Male	Female		
25 – 35	2		2		2
36 – 45	7	2	5	7	
46 – 55	7	4	3	6	1
Greater than 56	2	2		2	



#### **4.1.1.2: Employment and Marital Status of the participants**

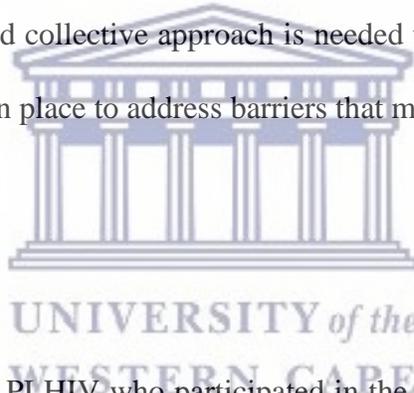
Thirteen of the participants reported that they are married and 5 were not married. Of the married individuals, one was in a discordant relationship from 2008 when he was diagnosed with HIV and put on ARVs. The wife has been taking ARVs for HIV prevention. Of the 18 participants, 10 were in formal employment, 3 were informally employed and 5 who were all women were unemployed.

#### **4.1.2: Profile of the Key Informants**

A total of 4 Key Informants participated in the study. These included an ART nurse, a clinician, a community health worker, and a pharmacist. Three of the 4 informants were male. Half of the key informants had over 5 years working in the HIV program whilst the other half had less than 4 years working in the HIV program.

#### **4.2 Participants' perceptions and experiences with TPT**

Both the participants and the key informants believe that TPT is beneficial to PLHIV as the therapy has contributed to the reduction in the number of individuals being diagnosed with TB disease. They indicated that a positive and collective approach is needed to maintain the success of TPT, and interventions should be put in place to address barriers that may impact the scaleup of TPT.



##### **4.2.0 Perceptions about TPT**

Both the key informants and the PLHIV who participated in the study felt that if TPT drugs are taken as advised by the medical personnel, active TB disease will be averted in most of the PLHIV.

Male participant 10, aged 40 noted: *“I have been on treatment for over 5 years, and I also was on TPT in 2020. I feel taking the drugs based on the advice from clinical staff has helped me to continue leaving healthy”*.

Male Key informant 1 aged 40 reported: *“looking at where we are coming from, I can confidently say that TPT is working as the number of HIV positive people on ART being diagnosed with TB has reduced compared to 5 years ago.”*

#### **4.2.1 TB diagnosis and initiation of treatment experiences**

Some participants who participated in the in-depth interviews reported having been diagnosed and treated for tuberculosis before they were initiated on ART, and for some, they were diagnosed after being on ART for some time. The participants shared the experience they had with TB sickness which resulted in them being very ill. The PLHIV, who were on ART, had to take a lot of pills for both HIV and TB treatment.

Female Participant 1 aged 42 years noted: *“Though I had experienced hotness and painful legs after I had started taking TPT drugs, I did not think of stopping to take the drugs because of what I went through when I had TB. I got very sick due to TB, and I had to take a lot of pills to treat the illness. Taking ARVs and TB drugs at the same time was too much for me hence I religiously took the TPT drugs for fear of going through the TB sickness and treatment experience”.*

The researcher was thus made to understand that TB is one of the main opportunistic infections associated with HIV deaths and illnesses, all PLHIV who have not previously been on TPT are encouraged to take TPT drugs as long as they are eligible to avoid them getting sick of TB and avoid undergoing the complications that come with the illness.

## **4.2.2 Positive experiences and facilitators of TPT uptake and adherence**

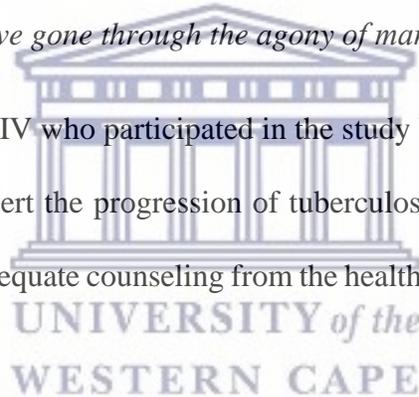
From both FGDs and in-depth interviews, it was clear that TB prevention is appreciated by both the health workers and PLHIV.

### **4.2.2.1 Positive experiences of taking TPT.**

Some of the participants narrated that from the time they completed TPT and continued taking their ARVs as per clinician advice, they had no major health problems. None of the clients that had completed TPT in the last 2 years had TB after taking the prevention medicines.

Male participant 2 aged 52 reported: *“I was diagnosed with HIV in 2005 and was started on ART in the same year. In 2008, I was diagnosed with TB. By then, if I had started taking the TB preventive drugs, I would not have gone through the agony of managing both HIV and TB”*.

Most of the people living with HIV who participated in the study believed that taking both ARVs and TPT drugs can reduce or avert the progression of tuberculosis infection to TB disease. The participants believed that with adequate counseling from the health providers, this can be achieved.



### **4.2.2.2 Facilitators of TPT uptake and adherence**

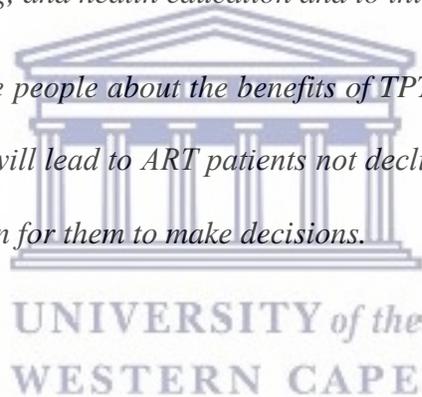
The healthcare workers attributed some improvements in TPT uptake observed after 2020 at the study clinic to improved adherence support and health education provided to PLHIV through health facility health talks, phone calls, SMS, and home visits conducted by clinical staff and

community health workers. Female participant 2 aged 38 reported that: *“I can live like someone without HIV if I take care of myself through taking medications as advised by the health workers and this includes TPT drugs”*.

Male participant 1 aged 41 noted: *“being diagnosed with HIV is not a good thing, it feels like a death sentence, however, when the ARVs and TB prevention drugs are taken as guided by our medical people, one lives a healthy and productive life”*.

Female Key Informant 1 aged 30 noted: *as a facility, we have been provided with phones by a USAID project to call ART patients who are on TPT and due for drug pick, as well as send them messages about the importance of adhering to treatment and clinic appointments. We also conduct home visits to provide counseling, and health education and to initiate eligible clients on TPT.*

*We need to continuously educate people about the benefits of TPT, how the TPT drugs are to be taken and for how long.... This will lead to ART patients not declining to take TPT drugs as they would have adequate information for them to make decisions.*



#### **4.2. 3 Negative experiences and barriers to TPT**

Though the clinic reported that about 90% of the ART clients have either taken or still taking their TPT drugs, there are still several challenges that were shared by both the PLHIV and the health workers, and these included side effects, supply chain challenges, challenges associated with combined ART and TPT treatment, documentation challenges, and human resource shortages.

#### 4.2.3.1 Drug side effects

Most of the participants complained that they had experienced drug reactions attributed to the TPT drugs. Many of the participants narrated having experienced drug side effects after they were started on TPT. The commonly reported drugs' side effects included body rash, painful legs/arms, and dry skin. Some participants had experienced drug side effects; however, they did not stop taking the TPT drugs due to the continued counseling and support received from health workers during the treatment period. Some participants attributed not having experienced any side effects during the treatment period to adhering to the guidance that was given by HCWs.

Female Participant 3 aged 45 who completed her TPT treatment in 2018 noted: *“When I started taking Isoniazid and vitamin B6, I experienced painful legs and had a rash on my arms, I nearly stopped taking the drugs, I, however, continued taking the drugs due the continued education on TPT and counseling from the health workers.*

Male Participant 3 aged 38 shared: *“I developed a rash on my hands and face, however, felt better after applying hydrocortisone cream which was prescribed by the clinician”.*

Though some participants had experienced drug side effects, they did not stop taking the TPT drugs due to the continued counseling and support received from health workers during the treatment period. Some participants attributed not having experienced any side effects during the treatment period to adhering to the guidance that was given by HCWs.

In-depth interview female participant 4 aged 50 noted: *“My husband and I, are both HIV positive and on ARVs. Both of us took TPT drugs and experienced no side effects, what helped us included taking a lot of water until the end of the treatment duration of 6 months. This was based on instructions from our ART nurse”*.

#### **4.2.3.2 TPT Dispensation Schedules**

To deliver patient-centered care more efficiently and effectively, the respondents indicated that differentiated models of service delivery are being offered to people on ART who are stable. Both the PLHIV on ART and the key informants reported that when TPT was rolled out at Kapiri Urban clinic in 2018, clients were being dispensed with drugs for one month at the start, then 2 months and 3 months for the last course though for ARVs they would receive drugs for 3 or more months. All the Key informants indicated that this affected the continuity and completion of TPT as some clients would not go back to the health facility for TPT drug pick up leading to restarting of the preventive treatment. The key informants shared the benefit of modifying the dispensing and prescribing of TPT drugs to align with those for ARVs to ensure PLHIV adheres to TPT.

Female participant 5 aged 28 noted: *“I was issued with ARVs for 6 months and TPT drugs for 3 months, I took the TPT drugs based on the quantity I was given, and to my surprise, I was followed by the community health worker indicating that I needed to go back to the facility and collect more TPT drugs as I had to restart the treatment due me missing two months as I did not continue the treatment after taking the drugs for the first three months. Restarting the treatment made me feel*

*bad and I looked as though I am not serious about managing my own health. To avoid such reoccurring, I then received the same quantities of ARVs and TPT drugs”.*

#### **4.2.3.3 Supply Chain Challenges**

Participants noted that stock availability challenges attributed to TPT scale-up challenges. Some of the challenges highlighted included the delivery of low stocks of vitamin B6 both at central and facility levels. Quantities of Vitamin B6 are not aligned with the quantities of the IHN and 3HP hence consistent stockout challenges of B6 were experienced. It is worth noting the comments from key informants on the current vs the stock status at the beginning of the TPT rollout in 2018 at the clinic as well as the challenges of adequate MOH staff to provide ART services.

Female Key Informant 1 aged 30 noted: *“The program experienced stock challenges with Vitamin B6 and in some cases with Isoniazid as well. Currently, not many stock challenges of the indicated products are being experienced; however, in the last month, we have had stock challenges of Vitamin B6 hence we have been depending on other districts and facilities as well as on our partner USAID SAFE to help us with stocks of this product. Additionally, we haven’t had in stock 3HP the new product which is being preferred by both health workers and ART patients because it is taken once per week for a period of 3 months when compared to a single IHN which is taken daily for 6 months.*

#### **4.2.3.4 Challenges associated with combined ART and TPT treatment.**

Both healthcare providers and PLHIV on ART felt that adherence to medication is likely to be poor due to the high number of oral drugs patients must take during HIV management. In addition to ARVs, patients must take TPT drugs hence the high pill burden. HCWs also reported other practices that may have contributed to the TPT low uptake and one of them included the considerable variation in the timing of preventative therapy initiation relative to ART initiation, which contradicts the recommendations in the Zambia Consolidated Guidelines.

Male participant 4 aged 36 complained of pill burden: *“I am on the second line ARV regimen, which entails taking 3 tablets of ARVs in the morning and 3 in the evening. When I was put on TPT, it meant me taking 5 tablets in the morning and 3 in the evening totaling 8 tablets in a day which was too much for me”*.

Male Key informant 1 aged 40 reported: *Some PLHIV on ART feel that TPT drugs increase the number of pills to be taken hence some don't take both ARTs and TPT drugs together.*

Male Key informant 1 aged 40 reported: *some health care providers have inertia to initiate both TPT and ART at the same time for fear of side effects, uncertainty on patients having latent TB as well wanting to assess the impact of ART treatment before TPT could be initiated.*

#### 4.2.3.5 Human Resource and documentation Challenges

The challenge of human resources was brought out as challenges that have contributed to some poor data documentation. At the clinic where the study took place, documentation of the TPT register is done by the pharmacy staff who also have the responsibility of dispensing ARVs, and other drugs needed to manage other conditions. Additionally, the pharmacy staffs also have the responsibility of updating the electronic and manual pharmacy patients and logistics records. All this is done by the pharmacy staff due to the low numbers of staff at the facility hence creating some gaps in documentation. Improper filling or completion of the relevant source documents like the TPT registers was indicated to have led to documentation gaps. Due to poor filling in of the registers, some patients who may have taken TPT drugs in 2018 may have not been captured and included in the reported statistics. The key informants however stated that the inclusion of TPT in the HIV data quality assurance (DQA) activities has contributed to the improved TPT uptake at the clinic in that some data challenges are resolved during DQAs and where training is needed, recommendations have been shared through the DQA reports. With activities being headed by the HIV team, the key informants reported having observed enhanced monitoring and evaluation of the TPT program when compared to the time when the TPT health facility-level activities were being managed by the TB teams. Additionally, the key informants also indicated that though they have seen some data improvements through DQA, there is a need to have the ART patient electronic tool (SmartCare) to start giving reports for clients that are due for TPT. In doing so, all PLHIV eligible for TPT will timely be put on TPT.

In addition to the above human resource challenges, attrition of the community health workers was reported to be a challenge that has continued to negatively impact community health worker programs both at the facility level and in the communities. Attrition of the community health workers refers to CHWs who leave local health facilities workforce due to various reasons. In this study, the turnover of CHWs was attributed to a lack of incentives as they mostly work as volunteers. Respondents noted that efforts to improve TPT and other HIV programs are mostly hampered by frequent health provider turnover.

Male Key informant 1 aged 40 reported: *The ART department is mostly managed by staff from the USAID implementing partners and at the time that this support is reduced or removed, we will see a change in the uptake of TPT. This is likely to be observed at the end of 2022 once the project starts cutting down on the number of staff in the health facilities.*

Female Key informant 1 aged 30 reported: *The Pharmacy department has 2 MOH staff and one pharmacist seconded by a partner to help with ART activities. One of the pharmacy staff has to work a night shift hence leaving two staff to cover the outpatient department (OPD) pharmacy and the other to manage the ART pharmacy. As a result of the low numbers of staff in the pharmacy department, updating of the ART documents is not done as the service is being given to the ART patients hence the challenge with documentation gaps.*

Male Key Informant 1 aged 40 indicated: *The registers only show 14 clients to have been put on TPT in December 2018. This low number may be attributed to a lack of understanding in filling*

*the registers as well as the challenges we had then with documentation due to no specific cadres to oversee updating of the registers.*

Male Key Informant 3 aged 45 reported: *“in the past, our ART DQA focused on ART, and TPT was not considered hence a lot of data issues were observed before 2020 when compared to the current situation. I know we still have some challenges with documentation but with continued DQA, we will continue to improve our documentation and data management. The DQAs are helping us to monitor the TPT progress and make decisions that will continue to improve the uptake of TPT”.*

Male Key informant 2 aged 36 noted: *lack or low incentives given to the community health workers who are mostly volunteers leads to high attritions thereby creating gaps and constant training of new people.*



### **4.3 Conclusion**

This chapter presented the results and described the findings of the study using narratives. From the above findings, there are several factors that were perceived to contribute to the low uptake of TPT among people living with HIV. The factors included differences in the quantities of ARVs and TPT drugs dispensed due to MMD, TPT drugs' side effects, and decisions on when to initiate TPT to ART-naive PLHIV leading to variations in the timing of initiation of ARVs and TPT drugs.

This chapter also presented the barriers to TPT uptake which included, pill burden, supply chain, continuous changes of community volunteers, and health worker workforce challenges. The next chapter discusses the findings of the study.



## **CHAPTER FIVE: DISCUSSION**

### **5.0 Introduction**

The discussion is centered around the topic of the study which sought to identify factors that contribute to the low uptake of tuberculosis preventive therapy among people living with HIV. Tuberculosis is one of the global health issues and a leading cause of death among people living with HIV (MacNeil et al., 2019) hence the need for the implementation of TPT.

### **5.1 Discussion**

Implementation of TPT at the selected study clinic was started in December 2018 and by end of 2018, coverage was about 1% of all the PLHIV on ART. Based on the responses from the key informants, only 14 clients were reported to have been started on TPT in December 2018 hence the indicated low coverage. The key informants attributed the low TPT coverage in 2018 to several factors which included side effects, supply chain challenges, human resource and documentation challenges, and challenges associated with combined ART and TPT treatment.

Both the key informant and the ART patients who took part in the study reported that some patients developed skin irritations however these reactions were tolerated and the PLHIV on ART continued to take the drugs. The reports on side effects are similar to a study conducted in India however the study findings reported that the side effects made patients unable to complete the TB prophylaxis treatment (Reddy et al., 2020). The findings of the study from India shared the need

for effective eligibility assessments to rule out hepatitis and alcohol use which leads to the occurrence of adverse drug reaction treatment (Reddy et al., 2020).

Supply chain challenges with a focus on drug availability were noted as one of the challenges that contributed to low TPT uptake, hence some patients had to restart the TB prevention treatment due to drug stockouts. Focusing on the lower numbers of TPT before 2020, the challenges in accessing TPT were attributed to national supply chain challenges of Isoniazid and Vitamin B6. The study health facility like many other health facilities in the country experienced an erratic supply of TPT drugs hence the low numbers initiated in 2018 through 2019. This challenge is in line with the findings of the survey conducted in 35 PEPFAR-supported countries which showed that inadequate funding to procure drugs contributed to stock challenges which led to the low uptake of TPT (Masini et al., 2020). Additionally, findings from a multi-site study conducted in Nigeria in 2020 showed stockouts of isoniazid as a reason for low TPT scale-up hence a recommendation for strengthened drug supply logistics to optimize TPT uptake (Yunusa et al., 2020). Drug supply challenges have also been observed in other studies conducted in South Africa, and Ethiopia (Akolo et al. 2015; Teklay et al., 2016). This study brought out the understanding of the supply chain challenges pertaining to the availability of Rifapentine/Isoniazid (3HP) in 2021. In Zambia, 3HP is the preferred TPT drug and has a shorter treatment period of 12 weeks compared to isoniazid which must be taken for about 24 weeks. Rifapentine/Isoniazid (3HP) has not been accessible due to high price, limited number of quality-assured suppliers, failure by the manufacturers to meet the global demand, and lack of registration in most countries (Frick, 2019),

hence most low-resource countries resorted to using Isoniazid alone. With no drugs available in health facilities, individuals living with HIV eligible for TPT cannot complete or be enrolled on TPT hence the low update.

The pill burden resulting from taking TPT drugs and ARVs at the same time was noted as one of the challenges for scaling up TPT. In the case of Kapiri Urban Clinic, the preferred TPT drug - 3HP, was not available at the clinic from September 2021 through to March 2022. This stock-out meant that all patients eligible for TPT had to be put on IHN for a period of 180 days. For patients on second-line ARV drugs, this meant taking about 8 tablets in a day for 180 days, but if 3HP was available, they would take 8 tablets once a week for 12 weeks. The health care providers indicated that 3HP is manageable for patients when it comes to pill burden. In line with the study conducted by Ngugi et al, (2020), pill burden continues to be one of the challenges that influence TPT scale-up among PLHIV on ART.

In this study, the scale-up TPT between 2018 and 2021 has been attributed to poor documentation. As a result of this, some patients who might have needed their second TPT treatment in 2022, may have been due to documentation challenges hence affecting scale-up. The challenges of documentation highlighted from the study facility are similar to findings from the studies conducted in Ethiopia and Nigeria which also highlighted documentation challenges and improper filling of the relevant source documents which contributed to the scale-up of TPT (Teklay et al., 2016, Yunusa et al., 2020)

The other barriers hindering the scale-up of the TPT program in 2018 at the study site were also attributed to MMD for ARVs versus monthly dispensation of TPT drugs. Both the PLHIV and the health care providers reported that MMD for ARVs only had an impact on the TPT scale in the initial implementation period. Clients would be dispensed with 3 or more treatment months of ARVs and dispensed with one or sometimes 2 months of treatment months for TPT which would lead to some clients not completing the TPT as they would not get back to the health facility to pick up more TPT drugs. This is a barrier that was also reported by various studies that focused on reviewing available evidence to address several commonly reported obstacles to TPT scale-up (Pathmanathan et al., 2018). To avoid increased client visits to the health facility due to different ART and TPT drug refill schedules, studies conducted by Boyd et al (2020) and Rabkin et al (2020) also identified the application of differentiated service delivery (DSD) models to ART only is a barrier to TPT uptake hence the studies recommending on the integration of TPT into the ART differentiated delivery (DSD) models so as to align the duration of TPT refills with ART refills. These TPT scale challenges have also been encountered in other countries as reported by researchers like Roscoe, et al (2020), Teklay et al (2016), Ngugi et al. (2020), and Kagujje, et al (2016) who conducted studies in Namibia, Ethiopia, Kenya, and Zambia respectively. Additionally, a study by Reddy et al., (2020) from India also pointed out that tuberculosis preventive therapy uptake challenges were because of proxy antiretroviral therapy attendance to the clinic which has continued to lead to poor or no tuberculosis preventive therapy initiation due to non-availability of the actual patient. The Indian study findings are similar to the findings of

this study which shows that some of the ART patients eligible for TPT could not be started on TPT early due to them sending their proxy to collect the drugs on their behalf.

In this study, about 6,608 PLHIV were on Antiretroviral therapy at the study clinic in March 2022, and over 90% of patients registered in care were provided with TPT with the recorded completion rate being at over 90% (ART Clinic data, 2022). The achievement in completion at this clinic is higher than the reported national-level achievement which stood at 70% at the end of 2021 (MOH, 2021). The national achievement of 70% was lower when compared to Kenya whose completion rate in 2020 was 86% (Ngugi, et al 2020). The reported high completion rate at the study clinic was attributed to the support provided by the United States Government (USG). The USG supported this clinic through the secondment of HCWs and the provision of funds to follow up patients on TPT. This support was similar to the support that was provided in South Africa, KwaZulu-Natal, where experienced nurse mentors were placed in health facilities through the USG support to help improve TPT uptake through training other HCWs and providing TPT services (Ahmed et al, 2021). In this study, TPT coverage was determined by considering all adults living with HIV registered in the HIV care at the clinic as the denominator, hence excluding children and household contacts. Based on this calculation, the sub-optimal coverage for WHO which is 90% of TPT among PLHIV and household contacts of TB patients by 2025 (WHO, 2013) may have not been achieved based on the exclusion criteria. The study showed that much of the noted TPT scaleup achievement was attributed to donor support.

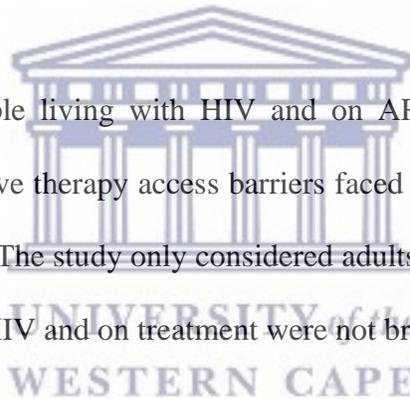
The success of TPT implementation is mainly dependent on continuous resource mobilization, capacity building, and monitoring (Teklay, et al., 2016). Healthcare providers perceived that the current improvement in the coverage when compared to before 2020, was attributed to improved adherence support. The adherence support was provided through phone calls, SMS, and home visits for clients due for drug pick. ART patients visited were those who had missed their treatment appointments, and this was done to avoid, them restarting treatment if they missed TPT treatment for more than a month. This adherence support at the study facility was enhanced with funding and human resource support from the USAID project. The health workers also perceived scale-up challenges in the first two years of implementation as being attributed to delayed sensitization workshops, TPT technical training, and a lack of understanding on how to fill the data in the TPT registers. The health workers also felt that there was no adequate monitoring and evaluation of the implementation which was mostly pushed by the TB program in 2020. This is similar to what was observed in a study conducted in Ethiopia (Teklay et al., 2016) that reported the lack of reinforcement by healthcare workers and stakeholders working in TB resulted in low scale-up of TPT. Additionally, the survey conducted in the PEPFAR-supported countries and a study in South Africa identified non-integration of HIV/TB services as one of the barriers to TPT uptake ((Masini et al., 2020; Chandra et al., 2022). Provision of continuous training or orientation to people providing adherence counseling and general TPT counseling has been found to improve TPT scale-up in other studies (Kagujje., et al., 2019). This is like what the healthcare workers interviewed highlighted. With the high attrition of community healthcare workers, there is a need for continued training for the CHWs being brought on board. Good and constant communication with patients

is vital for proper understanding of the benefits of TPT by patients hence leading to good treatment adherence and treatment completion rates. With most patients being eligible for the second TB prevention treatment, it is cardinal that the health workers start educating clients on the importance of them starting treatment for the second 3-year protection.

Both the survey and study conducted in South Africa indicated that the HIV program staff took TPT as an activity under TB and the TB program staff thought TPT was an HIV issue hence this led to the implementation and uptake not being pushed by either of the program areas (Masini et al., 2020; Chandra et al., 2022).

## **5.2 Study Limitations**

This study was limited to people living with HIV and on ART, hence it is not possible to understand tuberculosis preventive therapy access barriers faced by patients not yet on ART and those who are not HIV positive. The study only considered adults, hence the TPT scale-up issues in children who are living with HIV and on treatment were not brought out.



## **CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS**

This chapter presents the conclusion of the research report and highlights the realistic recommendations on factors associated with the uptake of TPT among PLHIV on ART.

### **6.0 Conclusion**

This study focused on exploring the factors associated with TPT uptake among PLHIV on antiviral therapy. The study findings reviewed that there has been an increase in the coverage of TPT among people living with HIV and on ART. The increase observed was attributed to the financial and human resource support that was provided through the PEPFAR-supported project. Despite these gains, Zambia is still challenged by a lack of continuous TPT training for both healthcare and community workers, inadequate documentation, high community health worker attrition, human resource challenges in public health facilities, and supply chain inefficiencies. To maintain the TPT gains observed, there is a need for the continued support of the Community HIV/TB health workers to continue providing the PLHIV with health education, home visits, and monitoring them through the period of TPT. Addressing these barriers may upsurge TPT initiations and completion thereby averting future tuberculosis cases among the PLHIV.

A crucial challenge with standard TPT is the burden it causes on patients thereby having them to take daily pills for 6 or more months of isoniazid and vitamin B6 in addition to the other medicines they take to treat HIV/AIDS and other conditions. To avert the challenge of taking TPT for 6

months or more WHO added 3HP as a recommended regimen for TPT in 2018. This new shorter regimen significantly reduces the duration and pill burden throughout treatment, therefore increasing the likelihood that patients will take and complete the full treatment cycle. The countrywide rollout of 3HP in Zambian health facilities will reduce the TPT uptake challenges resulting from long treatment periods.

## **6.1 Recommendations**

To ensure a continued increase in TPT uptake, the following are recommended.

1. Systematic and intensified contact tracing, community or home-based delivery of drugs and tests, active engagement of community support groups through increased provision of health information, and creation of awareness on TPT through various media platforms. To achieve this, there will be a need for the government to employ CHW rather than depending on volunteers who may not be available to enhance health education and adherence counseling both at the facility level and in the community.
2. The HIV program to ensure that all stable PLHIV on ART has access to various DSD models for both TPT and ART with a focus on 6MMD and community dispensations should be increased for both adults and children.
3. Increased funding both local and international would result in improved availability of commodities with a focus on 3HP and Vitamin B6 needed for TB prevention therapy.

4. The immediate countrywide rollout of 3HP will improve completion rates, especially in ART naïve clients and those taking the TPT drugs following the end of the 3-year prevention period.
5. It is recommended to both the TB and HIV programs have the manual TPT registers electronically available as well for ease of data analysis and identification of those who have had the 3-year prevention period come to an end. An updated version of SmartCare to be able to show prompts for clients due for TPT and drug refills.
6. It is recommended to the Zambia Medicine and Medical Supplies Agency (ZAMMSA) and MOH, that the issuance of Vitamin B6 and TPT drugs should be in equal treatment quantities when issued to health facilities to avoid stock gaps on any of the drugs and interruption in the provision of the service. To ensure the availability of equal quantities of TPT drugs, it is recommended to the TB/HIV program and donors that drugs for TPT should be procured as core-packs (Vitamin B6 & IHN or 3HP to be core packed).
7. Integration of TPT/TB and HIV services with a focus on the distribution of TPT drugs is vital for increased TPT uptake. It is therefore recommended that TPT drugs should be ordered by health facilities in the same way they order ARVs from the central medical stocks. In so doing, health facilities will order TPT drugs based on their consumption thereby averting overstocks or stockouts caused by a stock distribution that is based on stock allocation lists generated by the TB program.

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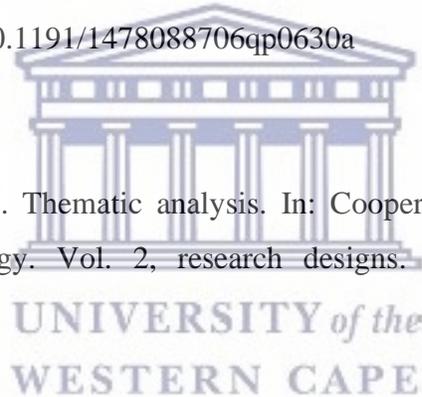
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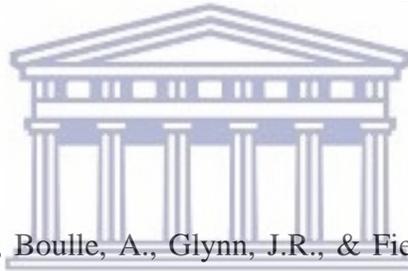
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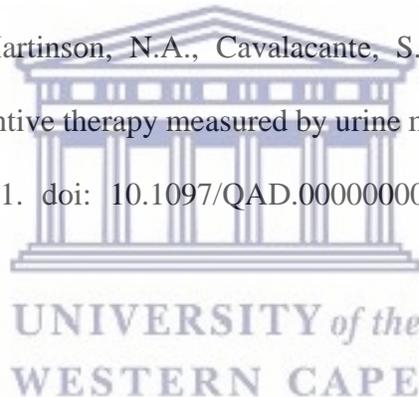
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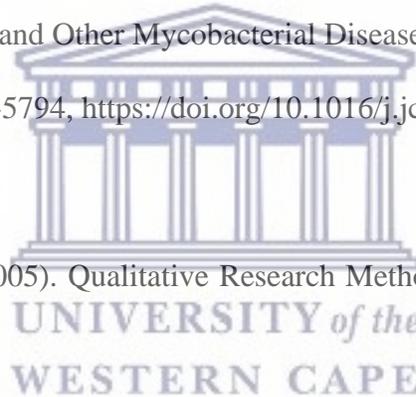
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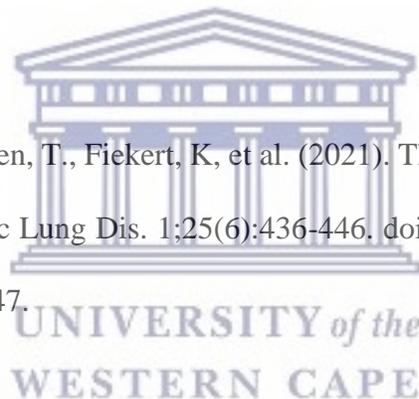
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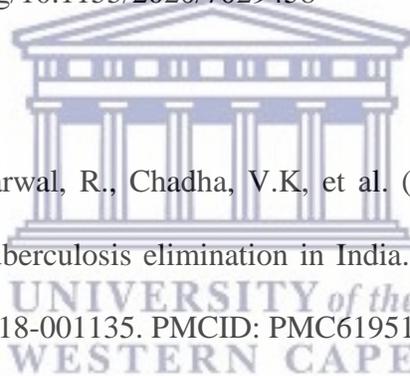


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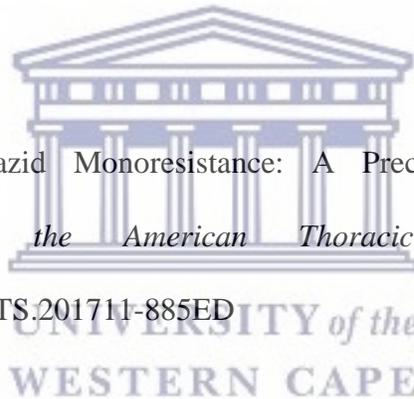
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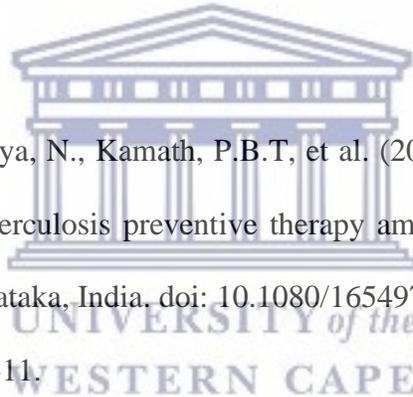
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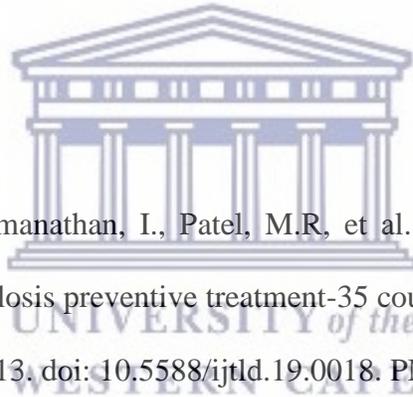


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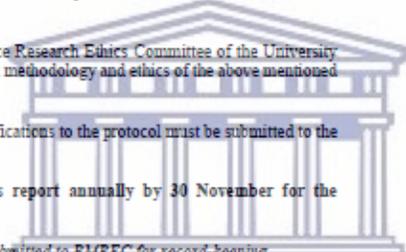
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## APPENDICES

### Appendix 1. Approval letters

	<b>UNIVERSITY of the WESTERN CAPE</b>	
<p>03 May 2021</p>		
<p>Ms B Ndango School of Public Health Faculty of Community and Health Sciences</p>		
<b>Ethics Reference Number:</b>	BM21/02/09	
<b>Project Title:</b>	Factors Associated with Tuberculosis Preventive Therapy Uptake Amongst Patients Receiving Antiretroviral Therapy in Zambia	
<b>Approval Period:</b>	29 April 2021 – 29 April 2024	
<p>I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.</p>		
<p>Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.</p>		
<p><b>Please remember to submit a progress report annually by 30 November for the duration of the project.</b></p>		
<p><i>Permission to conduct the study must be submitted to BMREC for record-keeping.</i></p>		
<p>The Committee must be informed of any serious adverse event and/or termination of the study.</p>		
		
		
<p>Ms Patricia Jozias Research Ethics Committee Officer University of the Western Cape</p>		<p>Director: Research Development University of the Western Cape Private Bag X 17 Bellville 7535 Republic of South Africa Tel: +27 21 959 4111 Email: research-ethics@uwc.ac.za</p>
<p><small>ANZSQC Registration Number: 88493C-139416-059</small></p>		
<p><b>FROM HOPE TO ACTION THROUGH KNOWLEDGE.</b></p>		



Plot No. 272, Co Olive Tree Harvest Road,  
 Westwood Ilex  
 Lusaka - Zambia  
 Tel: +260 955 855 633  
 +260 955 855 634  
 Cell: +260 977 893 220  
 Email: [unesconverge@yafira.co.zk](mailto:unesconverge@yafira.co.zk)  
 I.R.B. No. 00005948  
 F.W.A. No. 00011697

30<sup>th</sup> November, 2021.

**Ref. No. 2021-Sep- 009**

The Principal Investigator  
 Ms Bibian Ndango  
 Plot 3 Shantumbu Rd, Chalala  
 LUSAKA, ZAMBIA

Dear Ms, Ndango

**REF: FACTORS ASSOCIATED WITH TUBERCULOSIS PREVENTIVE THERAPY UPTAKE AMONGST PATIENTS RECEIVING ANTIRETROVIRAL THERAPY IN ZAMBIA.**

Reference is made to your protocol resubmission. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	Fasttrack	Approval No. 2021-Sep-009
Approval and Expiry Date	Approval Date: 30 <sup>th</sup> November, 2021	Expiry Date:
Protocol Version and Date	Version - Nil	29 <sup>th</sup> November, 2022
Information Sheet, Consent Forms and Dates	• English	29 <sup>th</sup> November, 2022
Consent form ID and Date	Version- Nil	29 <sup>th</sup> November, 2022
Recruitment Materials	Nil	29 <sup>th</sup> November, 2022
Other Study Documents	Questionnaire	29 <sup>th</sup> November, 2022
Number of participants approved for study		29 <sup>th</sup> November, 2022

Where Research Ethics and Science Converge

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

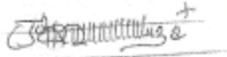
#### Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal-investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- A reprint of this letter shall be done at a fee.

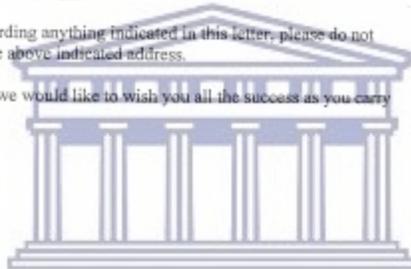
Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,  
**ERES CONVERGE IRB**



Dr. Jason Mwanza  
Dip. Clin. Med. Sc., BA., M.Sc., PhD  
**CHAIRPERSON**



**UNIVERSITY of the  
WESTERN CAPE**



**NATIONAL HEALTH RESEARCH AUTHORITY**  
Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA  
Chalala Office Lot No. 18961/M, Off Kazama Road, P.O. Box 30075, LUSAKA  
Tell: +260211 250309 | Email: [znhrasec@nhra.org.zm](mailto:znhrasec@nhra.org.zm) | [www.nhra.org.zm](http://www.nhra.org.zm)

Ref No: NHRA00005/06/01/2022

Date: 6<sup>th</sup> January, 2022

The Principal Investigator,  
Bibian Ndango,  
University of Western Cape,  
Lusaka, Zambia.

Dear Bibian Ndango,

**Re: Request for Authority to Conduct Research**

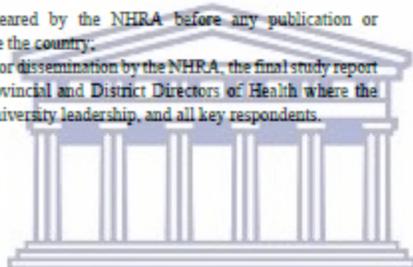
The National Health Research Authority is in receipt of your request for authority to conduct research titled "Factors Associated with Tuberculosis Preventive Therapy Uptake Amongst Patients Receiving Antiretroviral Therapy in Zambia."

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, this study has been **approved** on condition that:

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

Yours sincerely,

Prof. Godfrey Biemba  
Director/CEO  
National Health Research Authority



UNIVERSITY of the  
WESTERN CAPE

All Correspondence should be addressed to the  
Permanent Secretary  
Telephone: +260 211 233040/5  
Fax: +260 211 233544



REPUBLIC OF ZAMBIA  
MINISTRY OF HEALTH

MH/101/23/10

In reply please quote:

No. ....

NDEKE HOUSE  
P. O. BOX 30205  
LUSAKA

20 January, 2022

Ms. Bibian Ndanga  
Plot 3 Shantumbu Road  
Chalala  
LUSAKA

**RE: PERMISSION TO CONDUCT RESEARCH**

The Ministry of Health is in receipt of your request to conduct research entitled  
**"Factors Associated with Tuberculosis Preventive Therapy amongst patients  
receiving Antiretroviral Therapy in Zambia"**.

I wish to inform you that permission to conduct Research has been granted and  
information obtained will be used only for the intended purpose as stipulated in  
the request.

By copy of this letter, Provincial and District Health Directors are hereby informed.

Prof. Lackson Kasonka  
Permanent Secretary- (TS)  
MINISTRY OF HEALTH

cc: PHD- Central Province  
cc: DHD- Kapiri Mposhi District



UNIVERSITY of the  
WESTERN CAPE

All Correspondence should be addressed to the  
Provincial Health Director  
Telephone: +260 215 221765  
Fax: +260 215 221764  
Email: [kabwepho@gmail.com](mailto:kabwepho@gmail.com)



REPUBLIC OF ZAMBIA  
MINISTRY OF HEALTH

In reply please quote file:  
PHO/CP/101/1/20

PROVINCIAL HEALTH OFFICE  
CENTRAL PROVINCE  
P.O. BOX 8066  
KABWE

**CONFIDENTIAL**

9<sup>th</sup> February, 2022

Ms. Bibian Ndango  
Plot 3 Shantumbu Road  
Chalala  
**LUSAKA**

**PERMISSION TO CONDUCT RESEARCH**

Reference is made to minute MH/101/23/10 dated 20<sup>th</sup> January, 2022 from Ministry of Health Headquarters in respect of the above.

I glad to inform you that permission has been granted to conduct research entitled "**Factors Associated with Tuberculosis Preventive Therapy amongst patients receiving Antiretroviral Therapy in Zambia**". Kindly note that the information obtained should be treated **confidential** and will be used only for the intended purpose.

By copy of this minute, Kapiri Mposhi District Health Director is hereby informed.

A handwritten signature in black ink, appearing to read 'Teddy'.

Teddy Wakunuma  
Chief Environmental Health Officer  
For/Provincial Health Director  
**CENTRAL PROVINCE**

All Correspondence should be addressed to:  
Permanent Secretary  
Telephone: +260 211 254000  
Fax: +260 211 253341



REPUBLIC OF ZAMBIA  
MINISTRY OF HEALTH

In reply please quote:  
MH/101/23/10

NDEKE HOUSE  
P. O. BOX 30205  
LUSAKA

20 January 2022



*Received and  
noted.  
Mrs. Wondani K. B. FFB  
Taw. nre.  
02.03.22*

Ms. Bibian Ndango  
Plot 3 Shantumbu Road  
Chalala  
LUSAKA

**RE: PERMISSION TO CONDUCT RESEARCH**

The Ministry of Health is in receipt of your request to conduct research entitled "Factors Associated with Tuberculosis Preventive Therapy amongst patients receiving Antiretroviral Therapy in Zambia".

I wish to inform you that permission to conduct Research has been granted and information obtained will be used only for the intended purpose as stipulated in the request.

By copy of this letter, Provincial and District Health Directors are hereby informed.

Prof. Jackson Kasanka  
Permanent Secretary- (TS)  
MINISTRY OF HEALTH

cc: PHD- Central Province  
cc: DHD- Kapiri Mposhi District



*K. B. FFB  
02/03/22*

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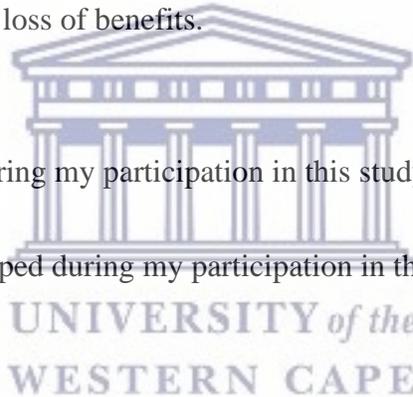
**Appendix 2: Participant English Consent Form**

**Title of Research Project:**                    *Factors Associated with Tuberculosis Preventive Therapy Uptake Amongst Patients Receiving Antiretroviral Therapy in Zambia*

The study has been described to me in language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

\_\_\_ I agree to be audiotaped during my participation in this study.

\_\_\_ I do not agree to be audiotaped during my participation in this study.



1. Participant's name.....
2. Participant's signature.....
3. Date.....

Biomedical Research Ethics Committee

University of the Western Cape

Private Bag X17

Bellville

7535

Tel: 021 959 4111

E-mail: [research-ethics@uwc.ac.za](mailto:research-ethics@uwc.ac.za)



### Appendix 3: Participant Nyanja Consent Form

#### FOMU YOVOMEREZA

**Mutu wa Kafukufuku: *Zinthu Zomwe Zimakhudzana ndi Chifuwa Chodzitchinjiriza Kugwiritsa Ntchito Odwala Omwe Alandira Chithandizo cha Antiretroviral mu Zambia***

Phunziroli lafotokozedwa kwa ine mchilankhulo chomwe ndimamvetsetsa. Mafunso anga okhudza kafukufukuyu ayankhidwa. Ndikumvetsetsa zomwe kutenga nawo mbali ndikuphatikizira ndikuvomera kutenga nawo mbali mwakufuna kwanga komanso mwaufulu. Ndikumvetsetsa kuti dzina langa silidzaululidwa kwa aliyense. Ndikumvetsetsa kuti nditha kusiya kafukufukuyu nthawi iliyonse popanda kupereka chifukwa komanso mosaopa zotsatira zoyipa kapena kutaya phindu.

Ndikuvomereza kuti ndizijambulidwa ndikamachita nawo kafukufukuyu.

Sindikuvomereza kuti ndijambulidwe panthawi yomwe ndimatenga nawo gawo phunziroli

Dzina la wophunzirayo .....

Siginecha yawomwe akutenga nawo mbali .....

Tsiku .....

Biomedical Research Ethics Committee

University of the Western Cape

Private Bag X17

Bellville

7535

Tel: 021 959 4111

E-mail: [research-ethics@uwc.ac.za](mailto:research-ethics@uwc.ac.za)



**Appendix 4: Key Informant English Consent Form**

**Title of Research Project:** *Factors Associated with Tuberculosis Preventive Therapy Uptake Amongst Patients Receiving Antiretroviral Therapy in Zambia*

The study has been described to me in language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

I agree to be audiotaped during my participation in this study.

I do not agree to be audiotaped during my participation in this study.



UNIVERSITY of the  
WESTERN CAPE

4. Key Informant's name.....
5. Key Informant's signature.....
6. Date.....

Biomedical Research Ethics Committee

University of the Western Cape

Private Bag X17

Bellville

7535

Tel: 021 959 4111

E-mail: [research-ethics@uwc.ac.za](mailto:research-ethics@uwc.ac.za)



## Appendix 5: Key Informant Nyanja Consent Form

### MFUNDO YOFUNIKA KWAMBIRI YOPHUNZITSIDWA

#### **Mutu wa Kafukufuku: *Zinthu Zomwe Zimakhudzana ndi Chifuwa Chodzitchinjiriza Kugwiritsa Ntchito Odwala Omwe Alandira Chithandizo cha Antiretroviral mu Zambia***

Phunziroli lafotokozedwa kwa ine mchilankhulo chomwe ndimamvetsetsa. Mafunso anga okhudza kafukufukuyu ayankhidwa. Ndikumvetsetsa zomwe kutenga nawo mbali ndikuphatikizira ndikuvomera kutenga nawo mbali mwakufuna kwanga komanso mwaufulu. Ndikumvetsetsa kuti dzina langa silidzaululidwa kwa aliyense. Ndikumvetsetsa kuti nditha kusiya kafukufukuyu nthawi iliyonse popanda kupereka chifukwa komanso mosaopa zotsatira zoyipa kapena kutaya phindu.

Ndikuvomereza kuti ndizijambulidwa ndikamachita nawo kafukufukuyu.

Sindikuvomereza kuti ndijambulidwe panthawi yomwe ndimatenga nawo gawo phunziroli

Dzina la Informant Lofunika .....

Signature ya Key Informant .....

Tsiku .....

Biomedical Research Ethics Committee

University of the Western Cape

Private Bag X17

Bellville

7535

Tel: 021 959 4111

E-mail: [research-ethics@uwc.ac.za](mailto:research-ethics@uwc.ac.za)



UNIVERSITY *of the*  
WESTERN CAPE

**Appendix 6: Confidentiality Binding for Participants' Focus Group Discussions**

**Title of Research Project:**                    *Factors Associated with Tuberculosis Preventive Therapy Uptake Amongst Patients Receiving Antiretroviral Therapy in Zambia*

The study has been described to me in language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone by the researchers. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits. I understand that confidentiality is dependent on participants' in the Focus Group maintaining confidentiality.

I hereby agree to uphold the confidentiality of the discussions in the focus group by not disclosing the identity of other participants or any aspects of their contributions to members outside of the group.



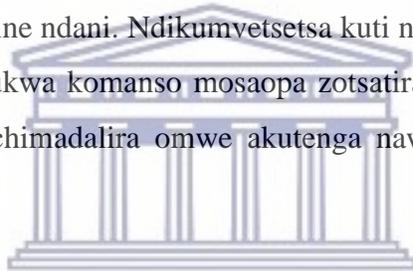
7. Participant's name.....
8. Participant's signature.....
9. Date.....

## Appendix 7: Nyanja Confidentiality Binding for Participants' Focus Group Discussions

### FOMU YA GULU LA CHIKHALIDWE CHOTSIMIKIZA

**Mutu wa Kafukufuku:** *Zinthu Zomwe Zimakhudzana ndi Chifuwa Chodzitchinjiriza Kugwiritsa Ntchito Odwala Omwe Alandira Chithandizo cha Antiretroviral mu Zambia*

Phunziroli lafotokozedwa kwa ine mchilankhulo chomwe ndimamvetsetsa. Mafunso anga okhudza kafukufukuyu ayankhidwa. Ndikumvetsetsa zomwe kutenga nawo mbali ndikuphatikiza ndipo ndikuvomera kutenga nawo mbali mwakufuna kwanga komanso mwaufulu. Ndikumvetsetsa kuti ofufuza sakudziwitsidwa kuti ndine ndani. Ndikumvetsetsa kuti nditha kuchoka phunziroli nthawi iliyonse popanda kupereka chifukwa komanso mosaopa zotsatira zoyipa kapena kutaya phindu. Ndikumvetsetsa kuti chinsinsi chimadalira omwe akutenga nawo mbali mu Gulu Loyang'ana Kusunga chinsinsi.



Ndikugwirizana kuti ndisungire chinsinsi cha zokambirana zomwe zili mgululi posawulula omwe akutenga nawo mbali kapena zomwe apereka kwa omwe sali mgululi.

Dzina la wophunzirayo .....

Siginecha ya omwe akutenga nawo mbali .....

Tsiku .....

## **Appendix 8: Participant English Information Sheet**

Dear Participant,

Thank you for your willingness to participate in this research project which is being conducted for a mini-thesis as part of the requirement for completion of a Master's degree in Public Health (MPH) at the University of the Western Cape.

**Project Title:** *Factors associated with Tuberculosis Preventive Therapy uptake amongst patients receiving antiretroviral therapy in Zambia.*

### **What is this study about?**

The research project is being conducted by Bibian Ndango as a partial fulfillment of a Master's Degree in Public Health, at the University of the Western Cape. We are inviting you to participate in this research project because you are on both the antiretroviral drugs (ARVs) and tuberculosis preventive therapy services. The purpose of this research project is therefore anticipated to bring out the understanding of factors affecting uptake of tuberculosis prevention therapy and make recommendations which will inform future implementation strategies. It is hoped that with your participation, a better understanding of challenges contributing to tuberculosis preventive therapy uptake will be learnt and suggestions on how to improve the programme shared.

### **What will I be asked to do if I agree to participate?**

You will be asked to answer questions about your experience taking antiretroviral (ARVs) drugs and medicines which are used to prevent the disease called tuberculosis. Tuberculosis is a disease which affects the lungs and is spread from one person to another through very small droplets released via coughing and sneezing. The language that will be used is English, however where one

is not able to communicate in English, Nyanja will then be used. The study will include individual interviews and focus group discussions (FGDs). Individual interviews will take about 30 minutes to an hour whereas the focus group discussions will approximately take an hour. This study will take place in a public health facility. For participants who will be involved in individual interviews, will be interviewed from locations of their choice whilst taking into account privacy and quietness. Some of the questions to be asked will include how long have you been on antiretroviral drugs and tuberculosis preventive therapy? what are some of the challenges you face with taking tuberculosis preventive therapy?

### **Would my participation in this study be kept confidential?**

The researcher undertakes to protect your identity and the nature of your contribution. To ensure your anonymity, your names will be coded on all the research documents. Through the use of an identification key, the researcher will be able to link your interview guides to your identity; hence only the researcher will have access to the identification key.

To ensure Confidentiality, the information you provide will not be publicly reported in a way which identifies you. To ensure security, the informed consent you will sign and the data recorded on the external hard drives (Flash disk) will be kept under lock and key and destroyed after the research process is completed. Since this study will use focus groups, therefore the extent to which your identity will remain confidential is dependent on participants' in the Focus Group maintaining confidentiality.

### **What are the risks of this research?**

All human interactions and talking about self or others carry some amount of risks. We will nevertheless minimize such risks and act promptly to assist you if you experience any discomfort, psychological, emotional or otherwise during the process of your participation in this study. Where necessary, an appropriate referral will be made to a suitable health professional for further assistance or intervention.

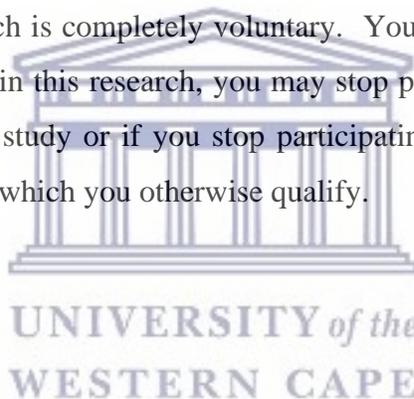
### **What are the benefits of this research?**

This research is not designed to help you personally, but the results may help the investigator learn more about the factors contributing to the low up take of tuberculosis prevention therapy. We hope that, in the future, other people might benefit from this study through improved understanding of the uptake challenges and recommendations made to help improve programme implementation strategies. Additionally, the study will contribute to reduction in tuberculosis disease and deaths.

They will be no cost to you during or after the study period apart from the time you will spend during the interviews or focus group discussions.

### **Do I have to be in this research and may I stop participating at any time?**

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.



### **What if I have questions?**

This research is being conducted by *Bibian Ndango in the school of Public Health at the University of the Western Cape*. If you have any questions about the research study itself, please contact:

Bibian Ndango

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Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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## Appendix 9: Participants Nyanja Information Sheet

### **Wokondedwa Wophunzira,**

Tikukuthokozani chifukwa chofunitsitsa kutenga nawo mbali pulojekitiyi yomwe ikuchitikira mini-thesis ngati chofunikira chokwaniritsa digiri ya Master mu Public Health (MPH) ku University of Western Cape.

**Mutu wa Project:** *Zinthu zomwe zimakhudzana ndi chifuwa chachikulu cha TB zomwe zimatenga pakati pa odwala omwe amalandira mankhwala ochepetsa mphamvu ya kachilombo ku Zambia.*

### **Kodi kafukufukuyu akukamba za chiyani?**

Ntchito yofufuzirayi ikuchitika ndi a Bibian Ndango ngati kukwaniritsidwa pang'ono kwa Master's Degree in Public Health, ku University of Western Cape. Tikukupemphani kuti mutenge nawo mbali pulojekitiyi chifukwa mumalandira chithandizo chamankhwala choteteza kachilombo ka TB komanso chifuwa chachikulu. Cholinga cha kafukufukuyu chikuyembekezeka kutulutsa kumvetsetsa kwa zinthu zomwe zimakhudza kulandira mankhwala a chifuwa chachikulu ndikupanga malingaliro omwe angathandize pakuthandizira mtsogolo. Tikuyembekeza kuti ndi kutenga nawo mbali, kumvetsetsa bwino zovuta zomwe zimapangitsa kuti anthu azikhala ndi chifuwa chachikulu cha TB kudzaphunzira ndi malingaliro amomwe angathandizire pulogalamuyi.

### **Kodi afunsidwa kuti ndichite chiyani ngati ndidzavomera kutenga nawo mbali?**

Mufunsidwa kuti muyankhe mafunso okhudza zomwe mwakumana nazo ndikumwa mankhwala ochepetsa mphamvu ya kachilombo ka HIV (ma ARV) ndi mankhwala omwe amagwiritsidwa

ntchito popewera matenda otchedwa TB. TB ndi matenda omwe amakhudza mapapo ndipo amafalikira kuchokera kwa munthu wina kupita ku ena kudzera m'madontho ang'onoang'ono omwe amatulutsidwa kudzera kukhosomola ndi kuyetsemula Chilankhulo chomwe chidzagwiritsidwe ntchito ndi Chingerezi, komabe pomwe munthu sangathe kuyankhula m'Chingerezi, Nyanja idzagwiritsidwa ntchito . Phunziroli liphatikizanso zoyankhulana payekha komanso zokambirana zamagulu (FGDs). Kuyankhulana kwamunthu m'modzi kumatenga pafupifupi mphindi 30 mpaka ola limodzi pomwe zokambirana zamagulu zimangotenga ola limodzi. Kafukufukuyu azichitikira kuchipatala, pomwe otenga nawo mbali omwe atenga nawo mbali pazofunsidwa payekhapayekha kuchokera kumadera omwe akufuna. Ena mwa mafunso ofunsidwa ndi awa; mwakhala nthawi yayitali bwanji mukumwa mankhwala ochepetsa mphamvu ya kachiroambo ka HIV komanso chifuwa chachikulu cha TB? ndi zovuta zina ziti zomwe mumakumana nazo ndikumwa mankhwala a chifuwa chachikulu?

### **Kodi kutenga nawo gawo phunziroli kungasungidwe chinsinsi?**

Chinsinsi chidasungidwa nthawi yonse yophunzira. Ofufuzawa amateteza kuti mudzidziwitse komanso zomwe mwapereka. Kuonetsetsa kuti simudziwika. Mayina anu adzalembedwa pazolembe zonse zofufuzira. chifukwa chake simudzafunika kuti mugwiritse ntchito dzina lanu lenileni phunziroli. Pogwiritsa ntchito fungulo lodziwitsa, wofufuzirayo athe kulumikiza maupangiri anu amafunsidwe kuzidziwitso zanu; chifukwa chake ndi wofufuza yekhayo amene angakhale ndi mwayi wofufuza.

Kuti muwonetsetse Chinsinsi, zomwe mumapereka sizilengezedwa pagulu m'njira yomwe ikudziwitseni. Kuti muwonetsetse chitetezo, chilolezo chodziwitsidwa chomwe mudzasaine ndi zomwe zalembedwa pama drive akunja (Flash disk) zidasungidwa ndikutsekeka ndikuwonongedwa ndikatha kafukufukuyu. Popeza kuti phunziroli lidzagwiritsa ntchito magulu owunikira, chifukwa chake momwe chizindikiritso chanu chidzakhali chinsinsi chimadalira omwe akutenga nawo mbali mu Focus Group kusunga chinsinsi.

### **Kodi kuopsa kwa kafukufukuyu ndi kotani?**

Kuyanjana konse kwa anthu ndikuyankhula za ife eni kapena ena zimakhala ndi zoopsa zina. Tidzachepetsa zoopsa zotere ndikuchitapo kanthu mwachangu kuti zikuthandizeni ngati mukukumana ndi zovuta zina, zamaganizidwe, zam'malingaliro kapena zina mukamachita nawo kafukufukuyu. Pomwe pakufunika, kutumizidwa koyenera kudzaperekedwa kwa katswiri wazachipatala kuti athandizidwe kapena kuthandizidwa.

### **Ubwino wake ndikufufuza kotani?**

Kafukufukuyu sanapangidwe kuti akuthandizireni nokha, koma zotsatira zake zitha kuthandiza wofufuzayo kudziwa zambiri pazomwe zimapangitsa kuti anthu azitenga chithandizo cha chifuwa chachikulu. Tikukhulupirira kuti, mtsogolomo, anthu ena atha kupindula ndi kafukufukuyu pomvetsetsa bwino zovuta zomwe zatengedwa ndi malingaliro omwe aperekedwa kuti athandize kukonza njira zoyendetsera pulogalamu. Kuphatikiza apo, kafukufukuyu athandizanso kuchepetsa matenda a chifuwa chachikulu komanso kufa.

Sidzakhala a mtengo wapatali kwa inu nthawi yophunzira kapena itatha kupatula nthawi yomwe mudzakhale mukuyankhulana kapena kukambirana pagulu.



### **Kodi ndiyenera kukhala nawo mu kafukufukuyu ndipo ndingaleke kutenga nawo gawo nthawi iliyonse?**

Kutenga nawo gawo kwanu pakafukufukuyu ndi kodzipereka. Mutha kusankha kuti musatenge nawo gawo konse. Ngati mungaganize zokachita nawo kafukufukuyu, mutha kusiya kutenga nawo gawo nthawi iliyonse. Ngati mwasankha kusachita nawo kafukufukuyu kapena ngati mungasiye kuchita nawo nthawi iliyonse, simudzalangidwa kapena kutaya zabwino zilizonse zomwe mungayenerere.

### **Ndingatani ngati ndili ndi mafunso?**

Kafukufukuyu akuchitidwa ndi a Bibian Ndango pasukulu ya Public Health ku University of Western Cape. Ngati muli ndi mafunso okhudzana ndi kafukufukuyu, lembarani:

Bibian Ndango

Student Number: 3908953

Shantumbu road, Plot # 3, Chalala

Box 50718

Lusaka, Zambia

Cell Phone Number: +260 965 147147

[ndangobibiana@gmail.com](mailto:ndangobibiana@gmail.com)

[3908953@myuwc.ac.za](mailto:3908953@myuwc.ac.za)



Ngati mungakhale ndi mafunso okhudzana ndi kafukufukuyu komanso ufulu wanu wochita nawo kafukufukuyu kapena ngati mukufuna kufotokoza mavuto omwe mwakumana nawo okhudzana ndi kafukufukuyu, lembarani:

Prof Uta Lehmann

Head of Department: School of Public Health

University of the Western Cape

Private Bag X17

Bellville 7535

[ulehmann@uwc.ac.za](mailto:ulehmann@uwc.ac.za)

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*Kufufuzaku kuyenera kuvomerezedwa ndi Komiti Yoyeserera ya University of Western Cape.*



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## **Appendix 10: Key Informant English Information Sheet**

Dear Key Informant,

Thank you for your willingness to participate in this research project which is being conducted for a mini-thesis as part of the requirement for completion of a Master's degree in Public Health (MPH) at the University of the Western Cape.

**Project Title:** *Factors associated with Tuberculosis Preventive Therapy uptake amongst patients receiving antiretroviral therapy in Zambia.*

### **What is this study about?**

The research project is being conducted by Bibian Ndango as a partial fulfillment of a Master's Degree in Public Health, at the University of the Western Cape. We are inviting you to participate in this research project because of your experience working with people living with HIV both on antiretroviral drugs and tuberculosis preventive therapy. The purpose of this research project is therefore anticipated to bring out the understanding of factors affecting uptake of tuberculosis prevention therapy and make recommendations which will inform future implementation strategies. It is hoped that with your participation, a better understanding of challenges contributing to tuberculosis preventive therapy uptake will be learnt and suggestions on how to improve the programme shared.

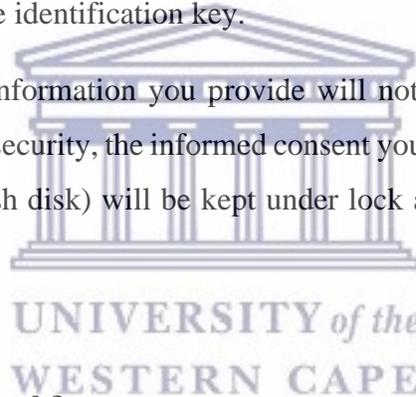
### **What will I be asked to do if I agree to participate?**

You will be asked to answer questions about your experience managing HIV positive individuals on antiretroviral and tuberculosis preventive therapy. You also be asked to share factors contributing the low uptake of tuberculosis preventive therapy. The language that will be used is English, however where clarification is needed, Nyanja will then be used. You will be required to participated in individual interviews which will take about 30 minutes to an hour. This study will take place in a public health facility; hence the interview will be conducted from a room within the facility identified by as being quiet and one which maintains privacy.

### **Would my participation in this study be kept confidential?**

The researcher undertakes to protect your identity and the nature of your contribution. To ensure your anonymity, your names will be coded on all the research documents. Using an identification key, the researcher will be able to link your interview guides to your identity; hence only the researcher will have access to the identification key.

To ensure Confidentiality, the information you provide will not be publicly reported in a way which identifies you. To ensure security, the informed consent you will sign, and the data recorded on the external hard drives (Flash disk) will be kept under lock and key and destroyed after the research process is completed.



### **What are the risks of this research?**

All human interactions and talking about self or others carry some amount of risks. We will nevertheless minimize such risks and act promptly to assist you if you experience any discomfort, psychological, emotional or otherwise during the process of your participation in this study. Where necessary, an appropriate referral will be made to a suitable health professional for further assistance or intervention.

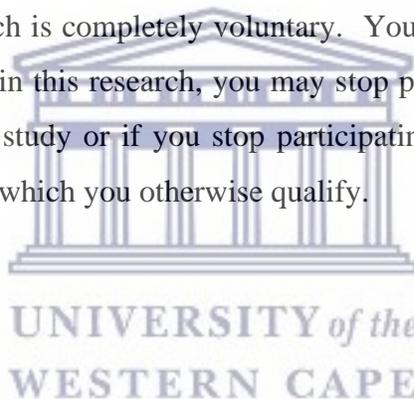
### **What are the benefits of this research?**

This research is not designed to help you personally, but the results may help the investigator learn more about the factors contributing to the low up take of tuberculosis prevention therapy. We hope that, in the future, other people might benefit from this study through improved understanding of the uptake challenges and recommendations made to help improve programme implementation strategies. Additionally, the study will contribute to reduction in tuberculosis disease and deaths.

They will be no cost to you during or after the study period apart from the time you will spend during the interviews or focus group discussions.

### **Do I have to be in this research and may I stop participating at any time?**

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.



### **What if I have questions?**

This research is being conducted by *Bibian Ndango in the School of Public Health* at the University of the Western Cape. If you have any questions about the research study itself, please contact:

Bibian Ndango

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Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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## **Appendix 11: Key Informant Nyanja Information Sheet**

### **Wokondedwa Wofunikira Kwambiri,**

Tikukuthokozani chifukwa chofunitsitsa kutenga nawo mbali pulojekitiyi yomwe ikuchitikira mini-thesis ngati chofunikira chokwaniritsa digiri ya Master mu Public Health (MPH) ku University of Western Cape.

**Mutu wa Project:** *Zinthu zomwe zimakhudzana ndi chifuwa chachikulu cha TB zomwe zimatenga pakati pa odwala omwe amalandira mankhwala ochepetsa mphamvu ya kachilombo ku Zambia.*

### **Kodi kafukufukuyu akukamba za chiyani?**

Ntchito yofufuzirayi ikuchitika ndi a Bibian Ndango ngati kukwaniritsidwa pang'ono kwa Master's Degree in Public Health, ku University of Western Cape. Tikukupemphani kuti mutenge nawo mbali pofufuza chifukwa cha zomwe mumakumana nazo pogwira ntchito ndi anthu omwe ali ndi kachilombo ka HIV pamankhwala ochepetsa mphamvu ya kachilombo ka HIV komanso chifuwa chachikulu cha TB. Cholinga cha kafukufukuyu chikuyembekezeka kutulutsa kumvetsetsa kwa zinthu zomwe zimakhudza kulandira mankhwala a chifuwa chachikulu ndikupanga malingaliro omwe angathandize pakuthandizira mtsogolo. Tikuyembekeza kuti ndi kutenga nawo mbali, kumvetsetsa bwino zovuta zomwe zimapangitsa kuti anthu azikhala ndi chifuwa chachikulu cha TB kudzaphunzira ndi malingaliro amomwe angathandizire pulogalamuyi.

### **Kodi afunsidwa kuti ndichite chiyani ngati ndidzavomera kutenga nawo mbali?**

Mudzafunsidwa kuti muyankhe mafunso okhudza zomwe mwakumana nazo poyang'anira anthu omwe ali ndi kachilombo ka HIV pa mankhwala ochepetsa kachilombo ka HIV komanso chifuwa chachikulu cha chifuwa chachikulu. Mufunsidwanso kuti mufotokozere ena zomwe zimapangitsa kuti anthu azikhala ndi chifuwa chachikulu cha TB. Chilankhulo chomwe chidzagwiritsidwe ntchito ndi Chingerezi, komabe ngati pakufunika kufotokozera, Nyanja adzagwiritsidwanso ntchito. Mudzafunika kutenga nawo mbali pamafunso omwe angatenge mphindi 30 mpaka ola limodzi. Kafukufukuyu azichitikira kuchipatala cha anthu, chifukwa chake kufunsaku kumachitika mchipinda chomwe chimadziwika kuti ndi chete komanso chosungira chinsinsi.

Kodi kutenga nawo gawo phunziroli kungasungidwe chinsinsi?

Chinsinsi chidzasungidwa nthawi yonse yophunzira. Wofufuzayo amateteza dzina lanu komanso zomwe mwapereka. Kuti muwonetsetse kuti simumadziwika, mayina anu adzalembedwa pazolembe zonse zofufuzira. Pogwiritsa ntchito fungulo lodziwitsa, wofufuzirayo athe kulumikiza maupangiri anu amafunsidwe kuzidziwitso zanu; chifukwa chake ndi wofufuza yekhayo amene angakhale ndi mwayi wofufuza.

Kuonetsetsa Chinsinsi, zomwe mumapereka sizilengezedwa pagulu m'njira yomwe ikudziwikeni. Kuti muwonetsetse chitetezo, chilolezo chodziwitsidwa chomwe mudzasainire ndipo zomwe zalembedwa pama driver akunja (Flash disk) zidzasungidwa ndikutsekedwa ndikufufuzidwa ndikamaliza kafukufukuyu .

Kodi kuopsa kwa kafukufukuyu ndi kotani?

Kuyanjana konse kwa anthu ndikuyankhula za ife eni kapena ena zimakhala ndi zoopsa zina. Tidzachepetsa zoopsa zotere ndikuchitapo kanthu mwachangu kuti zikuthandizeni ngati mukukumana ndi zovuta zina, zamaganizidwe, zam'malingaliro kapena zina mukamachita nawo

kafukufukuyu. Pomwe pakufunika, kutumizidwa koyenera kudzaperekedwa kwa katswiri wazachipatala kuti athandizidwe kapena kuthandizidwa.

### **Ubwino wake ndikufufuza kotani?**

Kafukufukuyu sanapangidwe kuti akuthandizeni panokha, koma zotsatira zake zitha kuthandiza wofufuzayo kudziwa zambiri pazomwe zimapangitsa kuti anthu azitenga kachilombo koyambitsa matenda a chifuwa chachikulu. Tikukhulupirira kuti, mtsogolomo, anthu ena atha kupindula ndi kafukufukuyu pomvetsetsa bwino zovuta zomwe zatengedwa ndi malingaliro omwe aperekedwa kuti athandize kukonza njira zoyendetsera ntchito. Kuphatikiza apo, kafukufukuyu athandizapo pakuchepetsa matenda a chifuwa chachikulu komanso kufa.

Sidzakhala a mtengo wapatali kwa inu nthawi yophunzira kapena itatha kupatula nthawi yomwe mudzagwiritse ntchito pokambirana kapena pokambirana pagulu.

### **Kodi ndiyenera kukhala nawo mu kafukufukuyu ndipo ndingaleke kutenga nawo gawo nthawi iliyonse?**

Kutenga nawo gawo kwanu mu kafukufukuyu ndikodzipereka. Mutha kusankha kuti musatenge nawo gawo konse. Ngati mungaganize zokachita nawo kafukufukuyu, mutha kusiya kutenga nawo gawo nthawi iliyonse. Ngati mwasankha kuti musatenge nawo kafukufukuyu kapena ngati musiya kutenga nawo mbali nthawi iliyonse, simudzalangidwa kapena kutaya mwayi uliwonse womwe mungapindule nawo.

### **Ndingatani ngati ndili ndi mafunso?**

Kafukufukuyu akuchitidwa ndi a Bibian Ndango pasukulu ya Public Health ku University of Western Cape. Ngati muli ndi mafunso okhudzana ndi kafukufukuyu, lembalani:

Bibian Ndango

Student Number: 3908953

Shantumbu road, Plot # 3, Chalala

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[ndangobibiana@gmail.com](mailto:ndangobibiana@gmail.com)

[3908953@myuwc.ac.za](mailto:3908953@myuwc.ac.za)

Ngati mungakhale ndi mafunso okhudzana ndi kafukufukuyu komanso ufulu wanu wochita nawo kafukufukuyu kapena ngati mukufuna kufotokoza mavuto omwe mwakumana nawo okhudzana ndi kafukufukuyu, lembalani:

Prof Uta Lehmann

Head of Department: School of Public Health

University of the Western Cape

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*Kufufuzaku kuyenera kuvomerezedwa ndi Komiti Yoyeserera ya University of Western Cape.*



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## Appendix 12: English In-Depth Interview Guide for Participants

*(To be inserted on the headed page once approved by the Biomedical Research Ethics Committee)*

1. Can you please tell me about your experience living with HIV and also being on TB preventive therapy?

Prompts:

- For how long have you been taking antiretroviral drugs?
- **When were you enrolled on tuberculosis preventive therapy?**
- Any effects with taking lifelong treatments?

2. Based on your experience what are the factors that can affect adherence to art?

Prompt:

- Are you married?
- If you are, does partner know about your HIV status?
- Any other family members know about your being on antiretroviral therapy?
- How helpful have they been?
- Have you faced any problems with your partner as a result of you being on antiretroviral therapy?

3. Kindly also share the factors that affect adherence to tuberculosis preventive therapy?

4. Based on your experience with taking antiretroviral drugs, what do you think are some of the factors that contribute to none adherent to tuberculosis preventive therapy?

Prompt:

how clear was the information on tuberculosis preventive therapy given to you?

- What was your reaction when you were told about being enrolled on tuberculosis preventive therapy?
- How do you feel about taking a number of tablets every day?
- Does knowing that tuberculosis preventive therapy is for prevention make you feel like wanting to stop the prophylaxis?
- Have ever stopped taking tuberculosis preventive therapy drugs? If you have, what caused that?

5. What is your experience with getting to the clinic for pick up of tuberculosis preventive therapy drugs or follow-up visits?

Prompts:

- How do you find the services and health care providers at Kapiri urban?
- Is there anything you want to change and why?
- For how many months do they give you the antiretroviral drugs for?
- During the clinic follow up visits, do you receive the same quantities of antiretroviral drugs and tuberculosis preventive therapy drugs?
  - How do the quantity differences affect you?
- Do you always adhere to your clinic follow up dates?
  - Are there any times that you have asked someone to collect drugs for you? Has this in anyway affected your enrollment on tuberculosis preventive therapy or collection of tuberculosis preventive therapy drugs

6. Are you in any form of employment? Formal or informal?

Prompts:

- Any challenges with taking your drugs due to work?

- Any challenges with drug pick up due to work?
- How far off is your home from the health facility?



## Appendix 13: Nyanja In-Depth Interview Guide for Participants

### **NDONDOMEKO YA KUFUNIKIRA KWA-KUKHALA KWA OTHANDIZA KUTI ALI NDI CHIFUKWA CHOPHWEKA**

1. chonde mungandiuzeke zomwe mwakumana nazo mukukhala ndi kachilombo ka HIV komanso kuti muli pa chithandizo choteteza TB?

Zolimbikitsa:

- Mwatenga nthawi yayitali bwanji mukumwa mankhwala ochepetsa mphamvu ya kachilombo ka HIV?
- Munayamba liti kulandira chithandizo cha mankhwala opatsirana chifuwa chachikulu? ·
- Kodi pali zovuta zilizonse mukalandira mankhwala amoyo wonse?

2. Kutengera ndi zomwe mwakumana nazo ndi ziti zomwe zingakhudze kutsata luso?

Limbikitsani: ·

- Ndinu okwatiwa?
- Ngati muli, kodi bwenzi lanu limadziwa za kachilombo ka HIV?
- Achibale ena onse akudziwa za momwe mulili ndikumwa mankhwala ochepetsa mphamvu ya kachilombo ka HIV?
- Ndiwothandiza bwanji?
- Kodi mwakumana ndi mavuto aliwonse ndi okonedwa anu chifukwa chakumwa mankhwala ochepetsa mphamvu ya kachilombo ka HIV?

3. Mwachifundo tigawaninso zomwe zimakhudza kutsatira mankhwala a chifuwa chachikulu?

4. Potengera zomwe mwakumana nazo pomwa mankhwala ochepetsa mphamvu ya kachilombo ka HIV, mukuganiza kuti ndi zinthu ziti zomwe zimapangitsa kuti aliyense asamamwe mankhwala a chifuwa chachikulu?

Limbikitsani:

- Mwakhalala nthawi yayitali bwanji mukumwa mankhwala opatsirana ndi chifuwa chachikulu?
- Panthaŵi yomwe munali kulembedwa za mankhwala opatsirana chifuwa chachikulu, munamva bwanji za chithandizo chodzitchinjiriza?
- Kodi mumamva bwanji mukauzidwa zakulembetsa chithandizo cha mankhwala opatsirana chifuwa chachikulu?
- Mukumva bwanji pakumwa mapiritsi angapo tsiku lililonse?
- Kodi kudziwa kuti chithandizo chodzitetzeza ku chifuwa chachikulu ndikuteteza kumakupangitsani kumva kuti mukufuna kusiya mankhwalawa?
- Kodi mudasiya kumwa mankhwala opatsirana ndi chifuwa chachikulu? Ngati mwatero, chidachitika ndi chiyani?

5. Kodi mumamva bwanji mukafika kuchipatala kukatenga mankhwala a chifuwa chachikulu cha TB kapena maulendo obwereza?

Zolimbikitsa:

- Kodi mumapeza bwanji othandizira ndi othandizira azaumoyo ku Kapiri m'tawuni?
- Pali chilichonse chomwe mukufuna kusintha ndipo chifukwa chiyani?
- Angakupatseni mankhwala ochepetsa mphamvu ya kachilombo kwa miyezi ingati?
- Mukamakachezera anthu ku chipatala, mumalandira mankhwala ofanana ndi mankhwala opatsirana pogonana komanso chifuwa chachikulu cha TB?

Kodi kusiyanana kwakukula kumakukhudzani bwanji?

- Kodi mumatsatira nthawi zonse kuchipatala?
  - Pali nthawi zina zomwe mudapemphapo wina kuti akutengereni mankhwala? Kodi izi zakhudzanso kulembetsa kwanu pa chifuwa chachikulu cha TB kapena kusonkhanitsa mankhwala opatsirana

6. Kodi muli pantchito iliyonse? Mwakhama kapena mwamwayi?

Zolimbikitsa:

- Zovuta zilizonse zakumwa mankhwala anu chifukwa cha ntchito?
- Zovuta zilizonse ndikutenga mankhwala chifukwa chogwira ntchito?

- Kodi nyumba yanu ili kutali bwanji ndi kuchipatala?



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## Appendix 14: English Interview Guide for Key Informants

1. What is your experience in administering tuberculosis preventive therapy among people living with HIV taking antiretroviral drugs?
  - Any experience with dealing with patients who have refused to be enrolled on tuberculosis preventive therapy
  - Based on experience is there a connection between adherence to antiretroviral drugs and tuberculosis preventive therapy drugs among patients on antiretroviral therapy?
2. What do you think encourages patients on tuberculosis preventive therapy to come for follow-ups visits or drug pick?
3. Based on your experience, what do you think makes ART patients not to come tuberculosis preventive therapy drug picks to the clinic?
4. What are some of the factors that make patients on antiretroviral therapy not to complete tuberculosis preventive therapy drugs?
5. What are some of the challenges with accessibility to tuberculosis preventive therapy drugs when compared to other drugs?
6. How is documentation of tuberculosis preventive therapy in this facility managed?
7. Based on the factors you have shared, what are some of the recommendations you would give to help avert the said challenges?

## **Appendix 15: Nyanja Interview Guide for Key Informants**

### **KALOZERA KUKONZEDWA KWA ANTHU ODZIWA KWAMBIRI**

1. Mukudziwa chiyani popereka chithandizo cha chifuwa chachikulu pakati pa anthu omwe ali ndi kachilombo ka HIV akumwa mankhwala ochepetsa mphamvu ya kachilombo ka HIV?
  - Chidziwitso chilichonse chokhudza kuthana ndi odwala omwe akana kulembetsa nawo chithandizo chodzitchinjiriza cha chifuwa chachikulu
  - Kutengera ndi zomwe mukudziwa pali kulumikizana pakati pa kutsatira mankhwala ochepetsa mphamvu ya kachilombo ka HIV ndi chifuwa chachikulu cha mankhwala opatsirana chifuwa chachikulu pakati pa odwala omwe ali ndi ma ARV?
2. Mukuganiza kuti ndi chiyani chomwe chimalimbikitsa odwala omwe ali ndi kachilombo koyambitsa matenda a chifuwa chachikulu kuti abwere kudzawatsata kapena kudzatenga mankhwala?
3. Kutengera ndi zomwe mwakumana nazo, mukuganiza kuti ndi chiyani chomwe chimapangitsa odwala a ART kuti asamabwere ndi chifuwa chachikulu cha TB popita kuchipatala?
4. Kodi ndi zinthu ziti zomwe zimapangitsa odwala omwe ali ndi ma ARV kuti asamalize mankhwala a chifuwa chachikulu?
5. Kodi zovuta zina ndi ziti popezeka ndi mankhwala opatsirana chifuwa chachikulu poyerekeza ndi mankhwala ena?
6. Kodi zolembapo za chifuwa chachikulu cha TB mu chipatala zimayendetsedwa bwanji?
7. Potengera zomwe mudagawana nawo, ndi malingaliro ati omwe mungapereke kuti muthane ndi zovuta zomwe zanenedwa?

## Appendix 16: English Topic Guide for Focus Group Discussion

1. Share your experiences of being on tuberculosis preventive therapy.
2. What factors do you think prevent or encourage people living with HIV to be on tuberculosis preventive therapy?
3. Have you heard of any individuals from this clinic who have stopped taking tuberculosis preventive therapy drugs?
  - What do you think could have led them to stop?
4. What are some of the challenges with accessibility to tuberculosis preventive therapy drugs when compared to other drugs?
5. Before we finish, I would like to know, what you think should be done to get more people living with HIV on tuberculosis preventive therapy?



## Appendix 16: Nyanja Topic Guide for Focus Group Discussion

### MUTU WOTSOGOLERA ZOKAMBIRANA ZA GULU

1. Nenani zokumana nazo zanu za kumwa mankhwala opatsirana chifuwa chachikulu
2. Mukuganiza kuti ndi zinthu ziti zomwe zimalepheretsa kapena kulimbikitsa anthu omwe ali ndi kachilombo ka HIV kuti azilandira chithandizo cha chifuwa chachikulu cha chifuwa chachikulu?
3. Kodi mudamvapo za anthu ena pachipatalapa omwe asiya kumwa mankhwala a chifuwa chachikulu?
  - Mukuganiza ndi chiyani chomwe chikanawapangitsa kuti asiye?
4. Zovuta zina ndi ziti zomwe zimapezeka ndi chifuwa chachikulu cha TB poyerekeza ndi mankhwala ena?
6. Tisanamalize ndikufuna ndidziwe, zomwe mukuganiza kuti zichitike kuti anthu ambiri omwe ali ndi kachilombo ka HIV amwe mankhwala oteteza ku chifuwa chachikulu?

