

**PERCEPTION OF DOCTORS OF THE BARRIERS AND  
FACILITATORS TO THE IMPLEMENTATION OF  
ISONIAZID PREVENTIVE THERAPY GUIDELINES FOR  
HIV PATIENTS IN ANAMBRA STATE, NIGERIA**



UNIVERSITY OF THE  
WITWATERSRAND,  
JOHANNESBURG

**BY**

**JULIET ONYINYECHUKWU NWACHUKWU**

**(2169323)**

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**SUPERVISOR:**

**DR SUMAYA MALL**

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**DECLARATION**

I, Juliet Onyinyechukwu Nwachukwu, declare that this research report is my own, unaided work. It is being submitted in partial fulfilment of the requirements for the Degree of Master of Science in Epidemiology (Field of Implementation Science) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Full Names: Juliet Onyinyechukwu Nwachukwu

Candidate's signature: ..........

Date: 11/10/2021

## **DEDICATION**

This work is dedicated to my husband, Mr Chuka Umeonwuka and my parents, Mr Christopher and Mrs Felicia Oforah, whose unflinching love, encouragement, prayers and support have kept me going. Their belief in me has been essential to my academic growth and success.

I also dedicate this work to the memory of my father-in-law, Late Nze Godson Umeonwuka who was an inspiration, and to all lovers of Knowledge.

## **ABSTRACT**

### **Background**

Tuberculosis (TB), an airborne infectious disease of global public health significance, is a common opportunistic infection in people living with HIV/AIDS (PLWHA). It is the leading cause of death in this group. Nigeria has a high burden of HIV/AIDS and TB as well as a high TB/HIV co-infection rate of 30/100000. To reduce TB/HIV coinfection in PLWHA who are still TB negative, Isoniazid preventive therapy (IPT) is recommended in several countries including Nigeria. Despite epidemiological evidence of its effectiveness, several key questions remain regarding the barriers and facilitators to the implementation of IPT in the Nigerian context.

### **Aim**

This study aimed to explore the perceptions of doctors of barriers and facilitators of doctors to IPT in a Nigerian setting.

### **Methodology**

An in-depth qualitative study guided by the Consolidated Framework for Implementation Research (CFIR) was conducted in two health facilities in Anambra State, south-east Nigeria. Individual interviews were conducted with doctors working in the HIV clinics of both facilities. The data were analyzed using the framework approach to thematic analysis.

### **Results**

Salient themes that arose from the study included participants' awareness of IPT, participants' perception of IPT, participants' description of the process of IPT initiation, participants' perception of patients' related factors that influence IPT guideline implementation,

participants' perception of operational factors that influence IPT guideline implementation, and perception of participants on stakeholder engagement in IPT implementation. The process of initiation entailed screening of the candidates for TB and other contraindications to IPT. This is followed by the enrolment of the eligible candidates for six months course of isoniazid (INH) for the treatment of latent TB and prevention of TB disease. The study showed that unavailability of isoniazid and/or pyridoxine were barriers to IPT implementation. In addition, patients' non-adherence to medication due to fear of drug resistance, pill burden, side effects, financial constraints, lack of sensitization among others also negatively affected doctor's implementation of IPT. A lack of IPT specific training, poor working environment and high workload were also found to hinder the implementation of IPT guidelines. Conversely, care for patient wellbeing, the effectiveness of IPT, availability of the guideline and program sponsor involvement were found to be facilitators of the intervention in this context.

## **Conclusion**

IPT is part of the routine care for patients in these facilities and although the guideline is available, there are numerous barriers to optimal implementation. Patient education and information to increase level of knowledge and more stakeholder involvement in the program will go a long way to improve the implementation of IPT for people living with HIV in Anambra state, Nigeria.

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## DEFINITION OF TERMS

1. **Gene-Xpert assay:** This is a rapid diagnostic test for TB and drug resistance.
2. **Health care provider:** Refers to doctors, nurses, counsellors, pharmacists, laboratory staff and nutritionist involved in the provision of HIV care.
3. **Implementation:** The process of translating evidence-based intervention into routine practice such that it meets the standard necessary to achieve the desired outcome.
4. **Isoniazid:** Also called isoniocotinyhydrazid, Isoniazid is an antibiotic used as a first-line agent in the prevention and treatment of active and latent tuberculosis.
5. **Medical officers:** Junior doctors whose highest qualifications are Bachelor of Medicine, Bachelor of Surgery (MBBS), have concluded internship and practised general medicine in an array of areas. They can be posted to any department.
6. **Principal Medical officers:** These are senior doctors who have practised general medicine for a long while and thus promoted to this level.
7. **Registrars:** These are doctors in speciality training (Community medicine in this case). They have more specialized knowledge.
8. **Senior Medical officers:** They are cadres above the medical officers but below principal medical officers. Their highest qualification is also MBBS and also practice general medicine but have practised longer and had more training than medical officers.
9. **Senior Registrars:** These are doctors in speciality training (community medicine) who have passed the preliminary exams and are a step away from becoming fellows of the college of physicians. They rank higher than Registrars.

## LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency syndrome
ART	Anti-retroviral Therapy
ARVs	Anti-retroviral drugs
CFIR	Consolidated Framework for Implementation Research
COOUTH Hospital	Chukwuemeka Odumegwu Ojukwu University Teaching Hospital
DALY	Disability Adjusted Life Years
HIV	Human Immune-deficiency Virus
HREC	Human Research Ethics Committee
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
LMIC	Low-middle income countries
MBBS	Bachelor of Medicine, Bachelor of Surgery
MDR-TB	Multi-drug Resistant Tuberculosis
NAUTH	Nnamdi Azikiwe University Teaching Hospital
PLWHA	People living with HIV/AIDS
QALY	Quality Adjusted Life Years
TB	Tuberculosis
TB/HIV or HIV/TB	TB and HIV co-infection

TBIPC

Tuberculosis Infection Prevention and Control

WHO

World Health Organization

## **1. CHAPTER ONE: INTRODUCTION**

### **1.1. Introduction to chapter**

This chapter presents data on the global burden of TB and specifically among people living with HIV/AIDS (PLWHA). Global interventions for TB including IPT were also explored as well as how these interventions were being implemented across the globe. TB/HIV and IPT in Nigeria were also looked in. The CFIR framework which guided the questions formulating the interview guide posed to participants for this study is also presented in this chapter.

### **1.2. Background**

#### **Global TB burden**

TB, an infectious airborne disease, is a global public health problem affecting all age groups. However, the majority of TB cases are found in individuals 15 years and above. (1) Globally, one-third of the world has latent TB where a person is infected with the tuberculous bacilli but is asymptomatic. This is known as inactive TB, with 10% then progressing to active TB disease. (2–4) TB is a major contributor to morbidity and mortality, accounting for 1.3 million deaths worldwide, and over 300,000 deaths among PLWHA. (2,4) Thirty of the high burden TB countries, the majority of which, including Nigeria, are in Africa, contribute 82% to this burden. (6)

TB is a common opportunistic infection in PLWHA, who due to suppression of their immune system are at high risk of a range of opportunistic infections including TB. (3) In a meta-analysis conducted by Dianatinasab and colleagues in 2018 examining the risk of TB in PLWHA in prisons, TB was found to be highly prevalent in this group. (7) HIV infection increases the risk of progression of latent TB to HIV infection substantially. (8) HIV was also found to increase the risk of TB in children in studies pooled for a systematic review and meta-

analysis. The risk increases with decreasing immunity. (9) Further, Geremew and colleagues in a systematic review and meta-analysis examining pooled data of the association between TB and CD4 count of PLWHA in Ethiopia also found an increased incidence of TB in this group. (10) Furthermore, TB is a leading cause of mortality in PLWHA who already have compromised immunity thereby hastening disease progression towards premature mortality. (11–13) In 2017, it was estimated that 10 million people developed TB of which 9% of these were PLWHA and 72% of these were in Africa. (1). These epidemiological data suggest TB in PLWHA is an important public health issue.

### **Global TB and HIV Interventions**

The World Health Organization (WHO) encourages the integration of TB and HIV activities in areas where the burden of TB/HIV is high to reach optimal treatment outcomes of reduced morbidity and mortality. (6) Examples of these efforts include recommending 12 joint activities as part of the main TB/HIV prevention and care program. (6)

These interventions include the provision of Antiretroviral therapy (ART), reduction of TB morbidity and/or mortality in HIV positive persons, and the three I's for targeting comorbid HIV/TB. These are Isoniazid Preventive Therapy (IPT) where persons considered to be at high risk of TB who have been screened and found free of active TB infection are given INH for 6 months to treat latent TB and as prophylaxis against active TB, Intensified case finding of TB (screening of all PLWHA for TB at each clinical visit), and infection control for TB (Presence of TB infection control practices like triage and isolation of TB patients, rapid Xpert test for TB, TB surveillance and cough etiquette, in health facilities providing HIV care). (6,14) Studies suggest that the integration of these measures have been effective in LMIC countries to combat TB. (15,16)

The WHO, in the guidelines for intensified tuberculosis case-finding and IPT for people living with HIV in resource-constrained settings (2015) strongly recommends that IPT be given to children and pregnant women who have been exposed to TB and PLWHA who do not have active TB for at least 6 months. (6) These guidelines have the goal of reducing the incidence of active TB and TB morbidity and mortality in areas with high TB and HIV prevalence. IPT has been shown to reduce the incidence of active TB by 33% in HIV positive individuals and by 64% in HIV patients who are also on ARVs. (17,18)

### **Evidence of Effectiveness of IPT.**

IPT has been shown to reduce morbidity and mortality in PLWHA in several studies. (19–23) In a review of 41 studies conducted in low and middle-income countries to assess the effectiveness of IPT in PLWHA by Briggs and colleagues in 2015, substantial evidence suggested that IPT reduced TB incidence and morbidity irrespective of CD4 or ART status but more in people who were TST positive. (22) Evidence of the effectiveness of IPT is expanded in the literature review.

Despite the recommendations by the WHO and evidence of its effectiveness, IPT implementation has been low at the country level. (16,24–26) To reduce TB infection, the global plan target was for IPT to be offered to 1 200 000 PLWHA in 2006, yet only 30 000 persons were reported to have undergone preventive treatment. (26) A study by Date et al (2010) involving 41 respondent countries representing all WHO regions, found that only 21 countries (51%) had developed a national policy on IPT and of these, only 6 of them (28%) had achieved nationwide implementation of the guidelines citing unreliable supply of and resultant unavailability of drugs as well as fear of INH resistance as reasons for delay (24). Cronin et al. (2015), in their retrospective cohort study in Swaziland, found that less than 1%

of patients eligible for IPT between 2012 and 2013 were placed on IPT. (25) In 2017, only 67 countries reported data on IPT use among persons living with HIV who are eligible. (27) Similarly, of the 30 WHO countries with high TB/HIV burden, only 9 reported provisions of preventive therapy for TB in 2015. (26) This has increased to 15 in 2017. According to the WHO report released in 2018, TB preventive therapy coverage among the 15 countries ranges from 1% to 53% in Eswatini and South Africa respectively. (28)

### **Tuberculosis and HIV in Nigeria.**

In Nigeria, where the study is set, the burden of TB is high. Nigeria has the fourth-largest TB epidemic in the world and approximately 4% of global TB infections occur in Nigeria. (29) About 418 000 new cases of TB occurred in Nigeria in 2017 with an estimated incidence of 219/100000 and about 58 000 people having TB/HIV coinfection. (28,30)

Nigeria also has the second-largest population of PLWHA worldwide. In 2016, Nigeria had more than half (59%) of incident HIV infections in Central and West Africa (31,32) and the most recent HIV/AIDS prevalence is at about 1.4%. (33) The life expectancy for the whole population in Nigeria is 54years and more than 50% of those infected with HIV are within the economically productive group (15-44 years), thereby affecting the socio-economic development of the country. (17,30)

Furthermore, the co-infection rate for TB and HIV in Nigeria is as high as 30/100,000. (28) Of all TB cases whose HIV status were known, 14% were positive, (30) thus, contributing immensely to morbidity and mortality of PLWHA. (29) According to the National guidelines for TB control (2008), up to half of those living with HIV in high TB prevalent areas will develop active TB in their lifetime, without IPT or Antiretroviral therapy. (17)

The above data presented suggests that TB prevention is a very important measure in lowering morbidity and mortality in PLWHA especially in a country like Nigeria that has a dual burden of TB and HIV. (34) Nigeria adopted the global stop TB strategy in 2006 which includes IPT use in preventing TB in seropositive persons and provided for it in “the guidelines for clinical management of TB and HIV/AIDS-related conditions in Nigeria (2008)”. (35) Implementation of this guideline has been low as only 30% of newly diagnosed HIV patients were placed on IPT in a cross-sectional study among HIV patients in by Onuka et al. in a tertiary hospital in South East Nigeria, (36) and national coverage of TB prevention in PLWHA was reported to be only about 39% in 2017. (5)

### **Nigeria’s guidelines for the implementation of IPT**

In Nigeria, IPT is part of the integrated TB/HIV services as recommended by the WHO. Provision of IPT is synchronous with the provision of ART, cotrimoxazole for prophylaxis, patient counselling among others. (17) These services are mostly provided free of charge in public sector facilities and are provided for in the National TB and HIV guidelines. According to the national TB and HIV guidelines, all newly enrolled HIV positive individuals are to be screened for TB and started on IPT irrespective of clinical stage and CD4 count. They are to receive IPT for 6 months and a repeat course every 2 years. Patients are screened for TB using a screening card with four specific symptoms as a checklist: cough, fever, weight loss and night sweats. Other contraindications to IPT are also screened for: Active TB, active liver disease, alcohol dependency and allergy to INH, and those who are affected are said to be ineligible for IPT. In addition, those who answer positively to any of the four symptoms on the screening card are sent for further tests to rule out active TB. This screening is done at every appointment and those who pass the screening are placed/continued on IPT. Pyridoxine is also prescribed to prevent peripheral neuropathy, a common side effect of INH. Furthermore, counselling on

TB/HIV interaction, IPT adherence, INH side effects, INH and other drugs interaction, and the immediate recognition and reporting of symptoms of active TB should be provided before commencement and at every clinic appointment. (35)

### **1.3. Problem statement**

Isoniazid Preventive Therapy has been proven to lower the incidence, morbidity and mortality from Tuberculosis in HIV infected people. (20,26,37–39) Although uptake of IPT is on the increase, fewer than 25% of individuals who are HIV positive and are in care are receiving it. (28) In 2017, only 15 of the 30 WHO high burden TB countries reported initiating IPT for People attending HIV care (29) and currently, TB preventive coverage for people living with HIV is only at 36%. (40) In Nigeria, of the 232,822 persons who were enrolled in care in 2017, only about 91,873 (39%) are on any TB prevention. (28) This points to a gap in the implementation of IPT guidelines at the country level.

### **1.4. Justification for the study**

Few studies have examined or explored factors influencing the implementation of IPT guidelines for PLWHA especially in Nigeria where the prevalence of comorbid TB and HIV is high. Anambra State has the third-highest HIV prevalence in Nigeria (41) and the largest population of PLWHA in the Southeast region of Nigeria. (33) With coverage of IPT among PLWHA in Nigeria reported to be as low as 39%, implementation in this area maybe even lower although no study was found, which had measured the level of implementation of IPT in this area.

Little is known of doctors' perceptions of the barriers and facilitators to the implementation of IPT guidelines in PLWHA in this context. Doctors as team leaders often lead patient treatment

and potentially drive the implementation of interventions which would benefit their clients. The paucity of studies on the perception of doctors to the barriers and facilitators to IPT implementation, informed the need for this study. As such, this study could be informative and could potentially guide strategies to overcome the barriers while enhancing the facilitators of IPT implementation. This study will also serve to inform policies that will improve and enhance the fight against HIV and TB.

### **1.5. Research question**

What are the perceptions of doctors towards the barriers and facilitators to the implementation of Isoniazid Preventive Therapy (IPT) guidelines for people living with HIV in Anambra State, Nigeria?

### **1.6. Aim of the study**

This study aimed to explore doctors' perceptions of barriers and facilitators to the implementation of IPT in a Nigerian setting.

### **1.7. Objectives of the study**

Objective 1: To explore barriers to the implementation of Isoniazid Preventive Therapy (IPT) guidelines for people living with HIV as perceived by medical doctors in Anambra state, Nigeria.

Objective 2: To explore facilitators of Isoniazid Preventive Therapy (IPT) guideline implementation for people living with HIV as perceived by medical doctors in Anambra State, Nigeria.

## **2. CHAPTER TWO: LITERATURE REVIEW**

### **2.1. Introduction to chapter**

The literature review examines TB preventive measures including studies of IPT as a means of informing the study. Studies sourced and synthesized for the literature review fall under the following themes: 1) Global TB prevention interventions, 2) Patients' perceptions and attitude towards TB prevention, and 3) Provider's perceptions of TB prevention.

It is mainly studies that have been conducted on the African and Asian continents examining IPT and the factors that influence its implementation that were considered relevant for this literature review. This literature review presents studies that have been completed in these regions.

### **2.2. Global TB prevention interventions**

Globally, research has examined different prevention methods for TB among various vulnerable groups including children and adolescents, older adults, prisoners and PLWHA. (42–44) Further, interventions have targeted the treatment of latent TB in PLWHA including the progression to active TB. Overall TB core components of TB prevention strategies include case detection and effective treatment, a combination of public health and clinical strategies. Besides, TB is known to have social determinants and thus social, economic and environmental approaches should be central to its control. (45)

Prevention and control of TB as stated above include a number of strategies including vaccination of infants in areas where TB is endemic, active case finding i.e. identification and treatment of cases of TB disease, contact tracing and screening, testing and treatment of vulnerable groups at higher risk of latent as well as active TB. These strategies are aimed at reducing current and future community transmission of TB. (46–49)

Methods used in the treatment of latent TB and prevention of active TB include INH monotherapy for 6-9 months, 4 months of daily Rifampin monotherapy, 3-4 months of daily INH and Rifampin or 3-4 months weekly dose of INH and Rifapentine. Rifamycin based regimens are used especially in areas with low TB prevalence. (50) Studies have suggested that these regimens are as effective as INH monotherapy with better completion rates and lesser toxicity. (50–54) However, 6 to 9 months of INH monotherapy is the preferred preventive measure in areas with high TB burden like Nigeria. This has been attributed to its efficacy, low cost and availability. (50)

### **Perception and attitude of patients to TB prevention**

There has been qualitative research exploring various facets of TB prevention too including among patient and provider samples. Munro and colleagues who conducted a systematic review in 2007 present studies of patient perspectives of TB treatment. They synthesized qualitative studies exploring patient perspectives of TB care. Their pooled studies yielded qualitative evidence suggesting that patient's support system, understanding around health and illness, knowledge and attitude towards treatment, financial obligation, policy, personal attributes and side effects affected their perception of the interventions. (55)

### **Provider perspectives of TB prevention**

Health care providers play an important role in the success of any intervention. Some studies have explored healthcare providers' perspective on TB prevention. Tan et al. (2015) conducted a systematic review of studies on factors influencing TB infection prevention and control (TBIPC) from the healthcare providers' perspective. The most common barrier raised was inadequate funding or resources for the implementation of TBIPC guidelines. Besides, lack of consideration of IPC in TB/HIV integration, unclear guidelines, inadequate health worker

involvement in governance, lack of training on TBIPC, poor work culture, stigma and poor patient sensitization and education were also elucidated as barriers to TBIPC implementation. On the other hand, health workers were motivated to implement IPT in order to protect their families. (56) Furthermore, a qualitative study in Lesotho suggested that providers had a favourable attitude towards TB prevention in children and were in support of it. The authors suggested that drug stockout, unavailability of paediatric formulation of medications, difficulty in identification and screening of children and fear of stigmatization, were barriers to TB prevention. Conversely, training of providers in child TB contact management (CCM), steady and reliable drug supply and community education would facilitate TB prevention efforts specifically IPT. (57)

### **2.3. Isoniazid preventive therapy**

IPT, as earlier stated, is the administration of a daily dose of INH for the treatment of latent TB and prevention of active TB disease in vulnerable groups including PLWHA and children, pregnant women and older adults who have been in contact with an active TB case. (58) INH is given over 6 to 9 months as recommended by the WHO. (18)

#### **Evidence of IPT effectiveness.**

Many studies have been conducted to assess the effectiveness of IPT in PLWHA. IPT was found to reduce the risk of TB in all participants by 35 % with a more substantial reduction (57%) in participants whose tuberculin test was positive in a systematic review and meta-analysis of Randomized Clinical Trials (RCTs) conducted in Africa (8 studies), America (1 study) and Europe (1 study) by Ayele and colleagues in 2015. (20) Another meta-analysis of RCTs conducted in Ethiopia found that IPT reduced the incidence of active TB among HIV positive patients on ART by 74% (RR: 0.26, 95% CI: 0.16 to 0.43). (23) Further, an RCT

conducted in the Ivory Coast called “A Trial of Early Antiretrovirals and Isoniazid Preventive Therapy in Africa” (TEMPRANO), examined the effect of ARVs, IPT or both, found that in addition to ART, a six months course of IPT lowered the risk of severe HIV associated illness by 44% and HIV deaths by 35%. (37) Similarly, a cohort study nested in an RCT in Tanzania suggested that IPT reduced mortality among persons with positive tuberculin test and CD4 count of greater than 200cells/mm<sup>3</sup>. (59) Another prospective observational cohort study in South Africa reported that following IPT, mortality decreased by 49% among HIV positive individuals which remained significant even for those who had had active TB before. (60) A retrospective cohort study in Ethiopia, suggested that those on IPT had a 50% decrease in the incidence of TB (IR 2.22 per 100PY) than those who were not on IPT (IR = 5.06 per 100PY). (39) This body of evidence suggests that IPT is effective in the prevention of TB infection as well as the morbidity and mortality associated with it in PLWHA.

### **Perceptions and Attitude of Patients to IPT**

Patients’ perception of IPT was explored to see if any barriers or facilitators to IPT arise. Studies elucidated that poor adherence to drug use, reluctance to attend follow up, poor understanding of the regimen, previous history of adverse effect, absence of family support, amongst others, negatively affected IPT implementation. (11,61–63)

Patients’ non-adherence to IPT and ART was a common issue. According to Mindachew et al. (2014) in Ethiopia, patient’s adherence to IPT was vital to its implementation. Reasons for nonadherence included inadequate knowledge of IPT due to inadequate information from health workers and fear of stigmatization. (64) A cross-sectional study of the adherence to IPT also in Ethiopia, suggested that the reasons for non-adherence also included forgetfulness, the occurrence of side effects, stigmatization and ill health. (65) Further, Cronin et al. (2015) observed that up to 40% of patients in their study were non-adherent to IPT. This was attributed

to increased pill burden or lack of documentation. (25) Non-adherence was attributed to fear of side effects and increased pill burden in another study. This study further noted that non-disclosure of sero-status to relatives led to the absence of social support and consequently, poor patient adherence to IPT. (62)

Likewise, a qualitative study in rural South Africa suggested that the absence of symptoms, cost of accessing health care, inefficient health care delivery and ineffective communication between patient and service provider, among others, led to patients' rejection of IPT. The study suggested that patients prioritized ART over IPT as most patients continued with ART but rejected IPT. (66)

Furthermore, Takarinda et al. (2017), pointed out that loss to follow-up of patients also affected IPT implementation as it led to non-completion. (67)

Another qualitative study conducted in South Africa suggested that fear of stigma was an important factor for non-adherence. Participants explained that separation of TB and HIV services provided grounds for stigmatization. Poor knowledge about TB was also pointed out as a reason for non-adherence. (68)

### **Health workers' perception of barriers to IPT.**

Several studies have been conducted exploring health workers' perceptions of IPT. It was found that many health workers were unsure of the effectiveness and had limited knowledge of IPT and this negatively impacted their use of the intervention. (64) Another was that the process of IPT implementation was unclear for many healthcare workers. According to Teklay et al. (2016), lack of clarity of the IPT guidelines made for poor implementation. (69) Operational barriers like unavailability of INH and difficulty in screening for TB similarly led

to underutilization of IPT. Likewise, lack of stakeholder commitment and support to IPT implementation discouraged implementation by health workers.

### **Health workers' perceptions of IPT**

Some studies suggest that health care workers' perceptions of IPT may influence them in prescribing or administering the intervention. These perceptions were based on inadequate knowledge and experience around IPT, Fear of inducing drug resistance and inadequate training on IPT.

A qualitative study among health workers and patients in South Africa was conducted by Lester and colleagues (2010). In this study, the doctors expressed a lack of adequate knowledge and experience of IPT. Although all the doctors had heard of IPT, several were unaware of the efficacy of IPT in TB prevention or thought that the evidence for IPT was not clear enough. Also, because IPT was not part of their routine practice, most of the doctors were unfamiliar with it and so were reluctant to implement it. (61) Grace (2019), in their review of literature for barriers to IPT implementation for Children in endemic regions, remarked that lack of knowledge on IPT was a universal barrier to its implementation. (70)

In addition, fear of inducing drug-resistant TB with IPT hindered the implementation of IPT. According to Lester et al. (2010), some doctors believed that the use of IPT could induce resistance and so were disinclined to use it. Some suggested that since the region already had a high TB burden, outright TB treatment was a better option than IPT. (61) A mixed-method study among health workers in Ethiopia also suggested that the fear of inducing resistance affected the implementation of IPT in those facilities. (69) A study which analysed the implementation of IPT in Zimbabwe, noted that healthcare workers feared IPT would increase

TB resistance and their patient's pill burden. They also feared that the high burden of TB in the area meant IPT would be less effective. (71)

Furthermore, lack of adequate training on IPT often impeded the implementation of IPT. A qualitative study conducted among healthcare workers in Ethiopia elucidated that health workers had not received training and were unclear about the benefits of IPT and so, did not adequately inform and prescribe IPT to the patients. (64) This finding was corroborated by Teklay, et al. (2016) who observed that limited specific training on IPT for service providers was a barrier to its implementation. Respondents reported that the lack of specific IPT training affected their confidence in implementing IPT. (72) Another qualitative study in which 18 health care providers were interviewed in Kenya, suggested that healthcare providers needed more information and training to enable them feel comfortable with IPT. (62) Outside Africa, a mixed-method study, again observed that lack of IPT training impeded the implementation of the intervention in India. (73)

### **Health workers' perception of the process of IPT implementation**

Health workers' perceptions often differ in the process of implementation. Studies on the African continent found that lack of clear IPT guidelines influenced the delivery of the intervention. According to Lester et al. (2010), the criteria for IPT varied across different facilities and only one had a standard guideline. This negatively impacted the implementation of IPT in these facilities. (61) Likewise, a lack of guidelines and standard operating procedure for IPT poses a challenge for IPT implementation (62) The absence of a consolidated guideline negatively affected the implementation and scaling up of IPT in Zimbabwe. Kagujje et al. (2019), suggested that the presence of two different guidelines for IPT in the TB and HIV programs led to discrepancies in the process of implementing IPT. (71) According to the WHO, unclear guidelines giving rise to uncertainties about the best time to start IPT as well as how

long each course should last (6 months or 9 months) also serve as a deterrent to its implementation. (6)

Furthermore, it was perceived that the long duration of IPT resulted in increased pill burden and reports of adverse effects by patients. Wambiya et al (2018), observed that health workers believed that the long duration of IPT influenced the delivery of the intervention as this resulted in increased pill burden and reports of adverse effects by patients. (62)

Lack of integration of HIV and TB care often made the implementation of IPT difficult. Kagujje et al. (2019) stated that the absence of a TB/HIV coordinating body made the scale-up of IPT in Zimbabwe difficult. (71)

Some of the studies suggested that some barriers to IPT implementation stemmed from the unavailability of resources including facilities for screening for IPT as well as Medications.

One barrier to IPT implementation was found to be the unavailability of IPT and other supporting drugs. Uncertainties about the availability of INH discouraged IPT initiation. Providers often believed that an irregular supply of INH meant patients may be unable to complete their doses possibly leading to resistance. (72) Okoli and Roets (2016), in their retrospective study on obstacles to IPT implementation, observed that 36.5% did not complete IPT. This was attributed to the unavailability of drugs in 18.4%. Other reasons for this were non-prescription of IPT (68.4%) and loss to follow-up (13.2%). (74) A similar retrospective study by Takarinda and colleagues (2017) in Zimbabwe showed that some patients could not complete IPT as a result of the unavailability of the medication (67). According to Grace (2019), difficulty in procuring INH served as an impediment to IPT initiation. (70) Kagujje et al. (2019) found that some facilities had issues of stockout of INH while others had INH

expiring on them due to excess supply as well. This was attributed to disparities in the quality of reports and requisition, an increase in the number of people eligible for IPT due to better screening and changes in modes of operation. Furthermore, Zimbabwean guidelines recommended simultaneous use of INH and vitamin B12, the unavailability of Vitamin 12 resulted in low administration of INH. (71) Reddy et al. (2020), made a similar finding. Drug stock-out was a major reason for non-initiation and non-completion of IPT in their study. They noted that INH was not available in link ART centres and so patients assessing care there could not receive IPT.(73)

In addition, the difficulty of ruling out TB in patients before initiation was a deterrent to the use of IPT. Lester et al (2010) stated that most of the facilities did not have resources to test patients for TB. Patients had to be referred to other facilities for TB screening resulting in increased waiting time and possible loss to follow-up and the resultant difficulty in initiating IPT. (61) Kerkhoff, et al. (2012), in their systematic review, uncovered that testing for active TB disease was a barrier to the implementation of IPT. This was attributed to the difficulty in the training of health workers and providing the resources required for testing among others. (75) Makoni and colleagues (2015), in their descriptive study, described the lack of screening tools and standard operating procedure which led to poor IPT implementation in Zimbabwe. (76) Similar findings by Lai, et al in a qualitative study in Ethiopia in 2019, suggested that having to check for and rule out active TB before starting patients on IPT proved difficult and was a source of apprehension for the service providers thus, affecting their use of IPT.(77)

Again, Takarinda et al., (2017), learned that a lack of efficient means of data management, as well as clear indicators for measurement of outcome, made IPT implementation difficult. (67) In addition, Kagujja et al., (2019), submitted that incomplete documentation in the IPT register made for improper monitoring and evaluation of the IPT program. (71)

Furthermore, management and other stakeholders are important to the success of any interventions. Some of the studies highlighted the problem of inadequate management and stakeholder involvement in the implementation of IPT. Mindachew et al. (2014), suggested that there was not enough emphasis on IPT by the leaders. Health workers felt that IPT needed more focus from the management. The health workers also pointed out that heavy patient load meant inadequate interaction with patients affecting counselling on IPT (64). Poor support and commitment for the implementation of IPT by stakeholders, and poor integration of IPT-related services was seen to affect the implementation of IPT in a study in Kenya. The authors pointed out that service providers were not involved in the development of the guideline and this affected its implementation. (62)

Reddy et al. (2020), further postulated that there was a lack of demand for IPT due to the unavailability of information, education and communication materials to educate PLWHA and the absence of activities aimed at increasing patient demand for IPT. (73)

### **Health workers' perception of the Facilitators IPT Implementation**

Few studies were found that explored the facilitators to the implementation of IPT. The facilitators include proper training of Health workers, clear guidelines, adequate patient information, social support and acceptance of HIV status amongst others. Berhe et al. (2014) suggested that patients who had a good understanding of IPT were more likely to adhere to it leading to better implementation. (65) Another study further elucidated that information, education, and communication (IEC) materials were necessary for the implementation of IPT as they aided in improving awareness and uptake of the program. Advocacy and sensitization activities were recommended to encourage community and leadership participation in IPT implementation. (76) Further, it was observed that adequate knowledge of IPT, social support,

acceptance of one's HIV status, trust in the health care system, and fear of TB, aided in patients adherence and completion of IPT. (66) In addition, regular monitoring and reporting of IPT outcomes via research, specific IPT training of health workers and active involvement of policy-makers in the implementation of IPT would facilitate IPT implementation.(62)

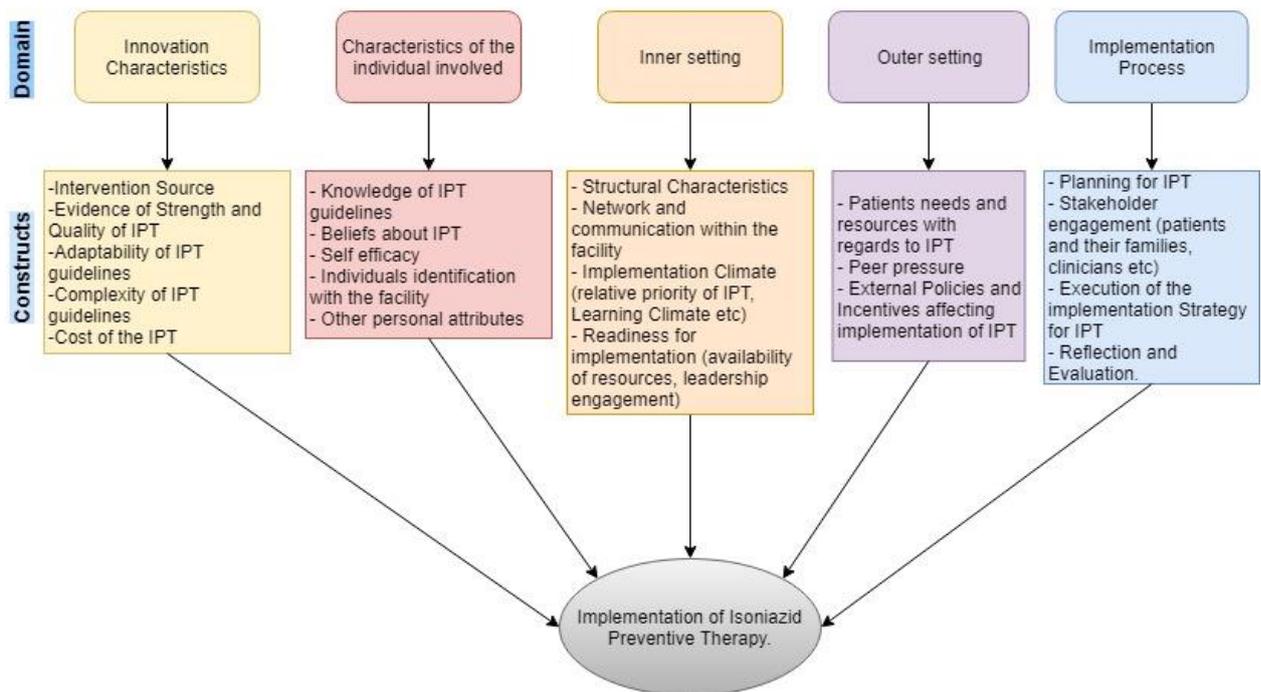
Lastly, Danyuttapolchia et al (2017) and Lai et al (2019) noted that training on TB/HIV, support for health workers and availability of IPT guidelines on site were enablers to the implementation of IPT. (77,78)

From the above, barriers to implementation of IPT from the health providers' perspective have been explored in several countries with a few also exploring facilitators. The barriers highlighted includes patient related factors like patients' non-adherence to IPT as a result of fear of stigmatization, lack of knowledge, pill burden etc. and lack of demand for IPT due to unavailability of IEC materials. Others were health worker related factors (poor knowledge, inadequate training, etc), operational factors (unavailability of medication, unclear guidelines and unfavourable work environment) among others. A few facilitators including provision of IEC materials for patient information, social support, monitoring and evaluation of the implementation process, etc were also found in the literature. Very few studies, however, were found on the implementation of IPT in Nigeria and to the best of my knowledge, no study has been done exploring facilitators and barriers to implementation of IPT guideline in southeast Nigeria. Healthcare providers often drive the implementation of interventions as they serve as the connection between research and the target of those researches (patients in this case). This position gives them a unique view of the intervention from both sides and as such, provides an understanding of the facilitators and barriers from their perception of all sides.

## **2.4. Conceptual framework**

Implementation science is a growing field aimed at bridging the gap between evidence-based interventions such as IPT and clinical practice. (79) Implementation frameworks are developed to help guide the process of implementation, inform on the factors that may influence implementation as well as aid in the evaluation of the implementation process. (80) The Consolidated Framework for Implementation Research (CFIR) developed by Damschroder et al. (2009) serves all three purposes. (81) The framework offers a comprehensive classification of factors that can affect the implementation of an intervention like IPT. The framework has 5 domains (characteristics of the innovation, Outer setting, inner setting, Characteristic of the individual and the Implementation process) made up of different constructs that interact with each other and together influence implementation effectiveness. CFIR has been used guide study findings in previous research. For example, the CFIR framework was used by Meyer et al. (2020) in the classification of barriers encountered in their implementation of an mHealth intervention for TB contact tracing in Uganda. (82) In this study, the framework guided the development of the interview guide to aid in the exploration of the barriers and facilitators to the implementation of IPT guidelines for PLWHA in Anambra state, Nigeria. Figure 1.1 is an illustration of this framework and the components of the different Domains of CFIR.

Illustration of Conceptual Framework: Consolidated framework for Implementation Research



**Figure 2:1: Illustration of the Domains and constructs of CFIR adopted from Consolidated Framework for Implementation Research by Damschroder et al. (81)**

### **3. CHAPTER THREE: METHODS**

#### **3.1. Introduction to chapter**

This chapter describes the methods employed in this research. The study design, setting, the process of data collection and analysis as well as ethical considerations are outlined.

#### **3.2. Study design**

This was a descriptive study which employed an in-depth qualitative study design guided by the CFIR framework described in the review of literature. Qualitative research is useful in exploratory studies in the health sciences to facilitate understanding how providers and patients perceive care. Qualitative methods can encompass a range of methods including individual and focus group interviews. In the field of implementation science research, qualitative research has the potential to explore evidence-based interventions to transition these interventions to policy (83).

The choice of qualitative research in this current study was influenced by the research question to explore barriers and facilitators concerning IPT, a question which to my knowledge has not been explored in the Nigerian context. This study method enabled an in-depth understanding of the barriers and facilitators to IPT guideline implementation from the point of view of the doctors providing the services (84).

The study design was guided by the Critical Appraisal Skills Programme (CASP) checklist as described by Maghaireh et al. (2016) in their Systematic review of qualitative studies. (85)

### **3.3. Study setting**

The study was conducted in the HIV outpatient clinics of two tertiary teaching hospitals in Anambra State, Nigeria.

Anambra is located in the Southern Eastern region of Nigeria and has a population of over 4.2 million as indicated by the 2006 national census and a projected over 5.5 million in 2016, making it one of the most populous states in the country (33,86). It is also one of the most urbanized areas in the country as up to 62% of its population live in urban areas (87). Anambra has a high HIV prevalence (2.4), higher than the national prevalence and the highest in the South East region (31,88). The two tertiary hospitals are the highest referral centres in the state and were selected for this reason as well as size, the high volume of patients accessing HIV and TB services and location.

The two hospitals used as research sites are described in detail below:

Nnamdi Azikiwe University Teaching Hospital (NAUTH) is a government teaching and referral hospital located in Nnewi, an urban city in the state. The clinic has a high patient flow with over 10000 patients in care as at the time of commencement of this study with about 7000 on IPT. The clinic attends to an average of 2044 patients every month with an average of 28 new enrolments into HIV care and 10 patients being enrolled into IPT.

Chukwuemeka Odumegwu Ojukwu University Teaching hospital (COOUTH), previously a general hospital, was upgraded to a state referral and training institution in the year 2000 and is located in Awka, the state capital (89). The HIV clinic had about 3700 patients in care and about half of them on IPT at the time of this study. The clinic provides care to an average of 1575 patients monthly at the time of this study. On average, 31 new patients enrolled on HIV

care monthly with about 13 patients being enrolled into IPT. The National TB program is coordinated by the ministry of health through the National TB and Leprosy Control Program(17).

### **3.4. Study population**

Participants were selected from medical doctors (medical officers, residents and consultants) providing HIV care services at the HIV outpatient Clinics of the selected hospitals for at least 6 months before the commencement of the study. The HIV clinic in NAUTH had 14 Medical Doctors providing HIV care while that in COOUTH had 6 doctors providing HIV care at the time of this study.

Medical officers are junior doctors whose highest qualifications are Bachelor of Medicine, Bachelor of Surgery (MBBS), have concluded internship and practised general medicine in an array of areas. They can be posted to any department. Senior Medical officers are cadres above the medical officers. Their highest qualification is also MBBS and also practice general medicine but have practised for longer and had more training. Principal Medical officers are senior doctors who have practised general medicine for a while and thus promoted to this level. Registrars are doctors in speciality training (Community medicine in this case) and Senior Registrars are also doctors in speciality training who have passed the preliminary exams and are a step away from becoming fellows of the college of physicians. They are involved in the counselling and prescription of IPT medication to the patients.

### **3.5. Inclusion criteria**

Doctors providing health care services to HIV positive patients at the outpatient clinics for at least 6 months before the study commenced as these are believed to have experience and in-depth understanding of how patient care in these centres work.

### **3.6. Study Interview guide**

An interview guide which was informed by the Domains of CFIR (81), was developed by the Principal researcher and discussed with PM, an expert in the field of qualitative research and questionnaire design. (The interview guide is provided in *appendix II*.)

The interview guide was pre-tested in a similar setting and updated. This process is described below.

The interview was recorded using an electronic audio-recording device.

#### **Pre-test of the Interview guide**

Following the development of the interview guide and approval of the study at the study sites, a pre-test of the interview guide was carried out at the HIV clinic of one of the hospitals used. The pre-test sought to test the duration of the interviews, comprehensibility of the questions and ability of participants to smoothly elicit answers to the research questions. Two participants provided informed consent in writing. The interviews were transcribed verbatim by the PR and the transcripts interrogated to assess the quality and validity of the interview guide by the PR and the research supervisor. The guide was found to be well understood and adequate in answering the research question following minor corrections.

### **3.7. Data collection**

The doctors were verbally invited to participate in the study by the PR. In-depth interviews were conducted in English by the PR using the interview guide at the health facilities and at the convenience of the participant. The interviews were conducted in private in the consulting rooms before the start of work or at the end of the work day, whichever was convenient for the participant. Each interview lasted about 40 minutes. Although 11 doctors were interviewed, saturation was reached with this number as similar information was received from all participants.

The interviews were audio-recorded and stored on google drive and will be there for a minimum of three years after which they will be permanently deleted. (90) Consent forms are stored in a separate file on google drive which is accessible to the PR and the supervisor alone. Field notes were taken to capture contextual information.

#### **Research team and reflexivity**

The PR is a medical doctor and was trained at one of the facilities where the research was conducted. However, only one of the interview participants had had contact with the researcher prior to the study. This provides confidence that information provided in the interviews were the perceptions of the participants and not influenced by previous contact. The research assistant is an MSc student at Nnamdi Azikiwe university, Awka and has received training in transcription and analysis of qualitative data. The supervisor is a senior lecturer at the university of the Witwatersrand, Johannesburg and is well-versed in qualitative research.

### 3.8. Data analysis

Analysis was conducted using the **framework approach to thematic analysis**, widely used in the health sciences. The approach was developed by researchers Ritchie and Spencer in 1994.

(91) There are 5 steps to this approach:

- Familiarization;
- identifying a thematic framework;
- indexing;
- charting; and
- mapping and interpretation

Key themes were identified from the data after familiarization with the transcriptions following which the relationships between themes were drawn and explained as described by Sibeko et al. (2016). (91,92)

All the recorded interviews were transcribed verbatim by the Principal Researcher and Research Assistant. Verification of the transcripts was done by the principal researcher by comparing transcripts with audio recordings. Inconsistencies were discussed with the research assistant and addressed. The transcriptions were coded independently by the Principal Researcher, Research Assistant, and the Supervisor of the Masters' thesis to identify themes, keywords and patterns. The framework approach recommends flexibility whereby the themes are refined until the analysis is complete. The codes were matched and harmonized to ensure similarity between researchers. The emergent codes were used to develop a Codebook which was validated by the supervisor. The codes in the codebook were then used to code the rest of the transcripts.

Emerging themes, subthemes and meanings as well as relationships between codes were identified, extracted and analyzed, and barriers and facilitators of IPT guidelines Implementation identified.

MAXQDA software was used to organize and analyse the data.

### **3.9. Ethical considerations**

The study was approved by the University of the Witwatersrand Human Research Ethics Committee (HREC) (certificate number: M1911138) (see *appendix III*). Ethical approval was also received from the ethics board of Nnamdi Azikiwe University Teaching Hospital (Reference: NAUTH/CS/66/VOL.12/232/2019/096) and permission to conduct the study was obtained from the management of the second facility, Chukwuemeka Odumegwu Ojukwu Teaching Hospital (ref: COOUTH/CMAC/Vol.01/2020/0007) (See *appendix IV and V*).

Detailed information was provided to the participants via the information sheet (*appendix VI*). Informed consent for both the interview and audio recording was received in writing from each participant. (See *appendix VII and VIII*). The study was guided by the declaration of Helsinki. (93) Participation in this study was voluntary and participants were free to withdraw from the study at any time without consequence. There was no harm or direct benefit accrued to them from participating in this study.

The audio recordings are stored on google drive. Consent forms and transcriptions are stored in separate files on google drive, which are accessible to the PR and the supervisor alone, and in a password-protected personal computer. They will be used only for this research and will be deleted after three to six years. (90)

## 4. CHAPTER FOUR: RESULTS

### 4.1. Introduction to chapter

This chapter presents the results of the study. The sociodemographic characteristics are represented in a table and quotes used to illustrate themes.

### 4.2. Sample selection

A total of 20 (total number of doctors working permanently in the HIV clinics in both hospitals) doctors were invited to participate in this study while 11 doctors were interviewed. The reasons for exclusion are presented in the flowchart (fig 4.1) which presents the process of recruitment of participants. The reasons for exclusion includes not meeting the inclusion criteria (2), unavailability at the time of the interview (3) and lack of consent (2).

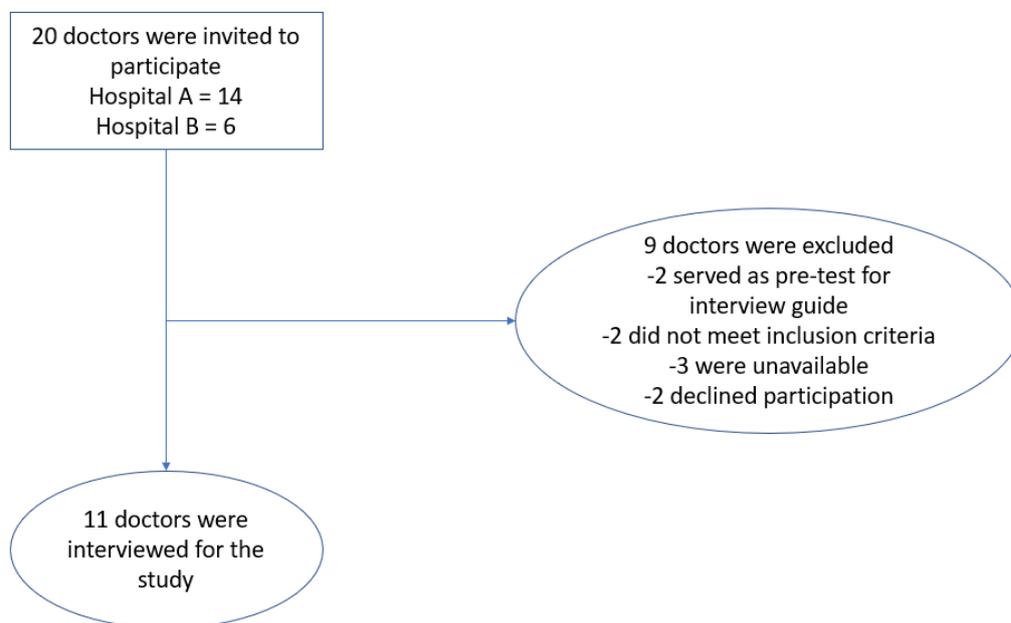


Figure 4. 1: Flowchart illustrating participant recruitment.

### 4.3. Socio-demographic characteristics of the participants

The final sample consisted of 11 doctors as outlined in the methods chapter. They all provided care at the HIV clinics of the two designated facilities. The sociodemographic characteristics of the participants are outlined in table 1 below. Of the 11 participants, 8 were females and the median age was 37 (29-54). Professional categories included: medical officers and Registrars and between them had a median of 3 years of experience in HIV care.

Table 4.1: Sociodemographic characteristics of study participants.

<b>Characteristic</b>	<b>Number</b>	<b>Percentage (%)</b>
<b>Category of profession</b>		
Medical officer	2	18.18
Senior Medical officer	3	27.27
Principal medical Officer	1	9.09
Registrar	3	27.27
Senior Registrar	2	18.18
<b>Gender</b>		
Male	3	27.27
Female	8	72.72
<b>Age (years)</b>		
Median(range)	37 (29 – 54)	
26-35	5	45.45
36-45	5	45.45
46-55	1	9.09
<b>Years of Experience</b>		
Median (range)	3 (0.5 – 10)	
<1 year	1	9.09
1-5 years	6	54.54
>5 years	4	36.36

#### 4.4. Participants' perceptions of the barriers and facilitators to the implementation of IPT guidelines among PLWHA

Following the framework approach to thematic analysis of the interview transcripts, a number of themes emerged. The themes were: participants' awareness of IPT, participants' perception of IPT, participants' description of the process of IPT initiation, participants' perception of patients' related factors that influence IPT guideline implementation, participants' perception of resource constraints that influence IPT guideline implementation, and perception of participants on stakeholder engagement in IPT implementation. Figure 4.2 is a diagrammatic representation of the main findings of the study.

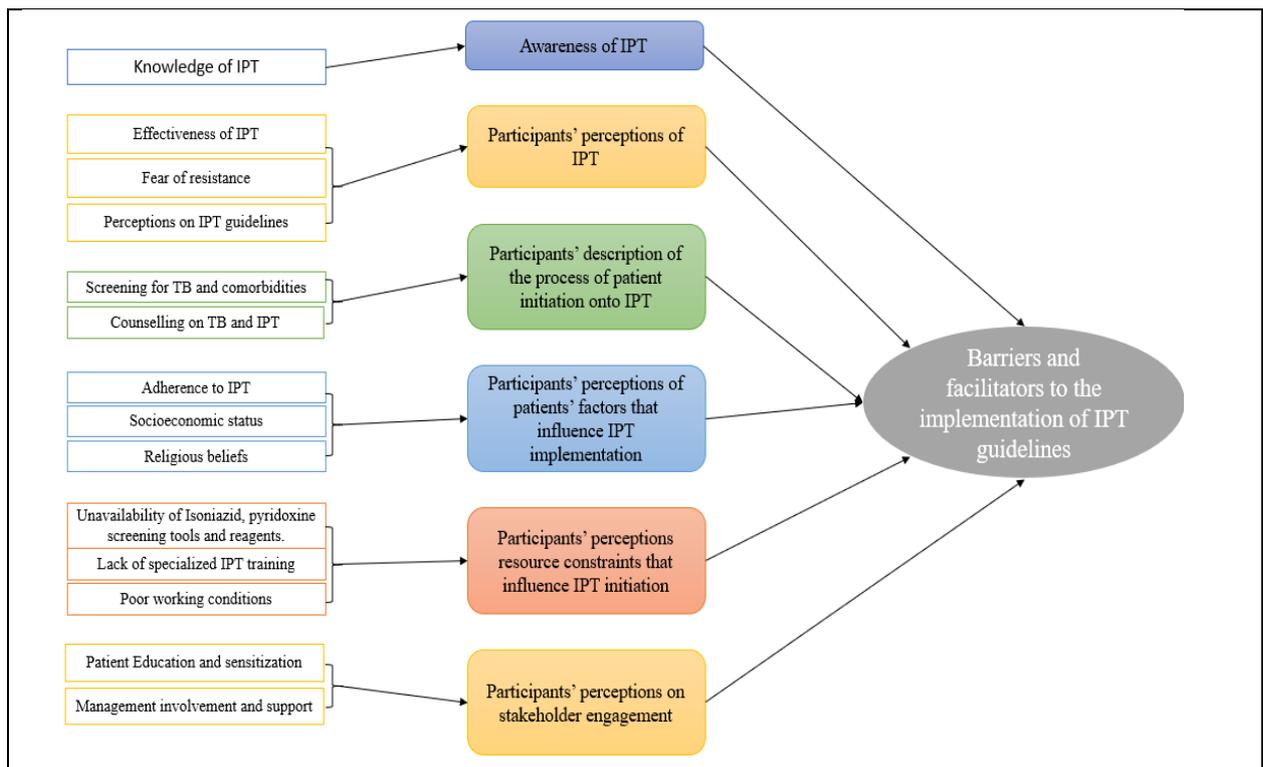


Figure 4. 2: Pictorial representation of the barriers and facilitators to the implementation of IPT guidelines.

## **Participants' description of the process of initiating patients onto IPT**

Participants described the process of deciding and then initiating their patients onto IPT. These processes could be clinical and were based on different criteria which ranged from considerations of symptoms e.g., cough, fever, and weight loss, to poor immunity in HIV positive patients. Participants explained that the processes for initiating patients onto IPT ranged from the public health method of contact tracing to the clinical method of consideration of HIV stage or chronic, comorbid conditions such as diabetes. Processes could have a more behavioural slant and could include counselling patients about the benefits of IPT

One doctor described that HIV positive patients were initiated onto IPT as long as they were not symptomatic of TB. This participant explained that the criterion was based on prior knowledge that it is likely that TB was a common opportunistic infection in HIV and that PLWHA may become at risk. Patients who are experiencing symptoms like cough were sent for GeneXpert assay, a rapid diagnostic test for TB and drug resistance (94), to rule out active TB infection.

*'once a client comes for the first time, for the fact you are not coughing, we will start you on IPT, you take it for six months. But if you are coughing, you have to go for GeneXpert first. If it now says that you don't have TB, we now start you on IPT but if you are coughing, we won't go directly to IPT. Once you have HIV, we start you on IPT, for the fact you are not coughing. Once you have HIV, we start you on IPT because you know HIV coexist with Tuberculosis, so that is why we start on IPT to prevent you from coming down with Tuberculosis. [Participant 4, Facility B]*

Another doctor described a tracing process whereby patient folders are examined to detect patients eligible for INH. The patients are then contacted:

*"...I'm aware that we try to trace all our clients that are supposed to be on IPT and then commence IPT for them. I'm not quite certain of the duration right now, whether it is yearly or two-yearly, but I know that when we see our patients, we go through their folder. There's a marker, like an indicator that says "This person doesn't need IPT or this patient needs IPT. So, for those that need IPT, we always ensure that we...counsel them and encourage them to commence their drugs and it's usually given for about 6 months.... [Participant 1, facility A]"*

This participant further described that all HIV positive patients should be on IPT due to being in a state of poor immunity.

*“Anyone who is positive should be placed on IPT. ...we all know that IPT as the name is, as it implies, is an Intermittent... treatment or Therapy against tuberculosis and we know that our clients are immunocompromised and they're prone to having tuberculosis and it doesn't even matter if they've had it in the past, they can still come down with it. So... being positive and being immunocompromised is criteria that they should be on IPT”*

The same participant explained that the initiation of IPT was routine and compared IPT to malaria prophylaxis.

*‘Just like the way we give our malaria prophylaxis, that's the way it is now, we just give those drugs as a form of prophylaxis against tuberculosis...’*

A third participant who described the screening process for eligibility for IPT also mentioned that patients with comorbidities like diabetes would not be initiated onto IPT:

*“clients that have diabetes, it is also not given to them because of the complications of diabetes...” [Participant 3, Facility A]*

More than one participant described the process of counselling patients to initiate IPT.

*‘I normally counsel them because I feel some of them - it is ignorance. So I counsel them, tell them the need and the importance of that Isoniazid and tell them that it is very disastrous to be managing HIV and then now come down with Tuberculosis. Sometimes, I manage to convince some’ [Participant 4, Facility B]*

*“In the process of commencing this IPT, we kind of give them some form of health education. And with that they... they know what it's all about and they know how to prevent themselves from getting this ailment or getting tuberculosis itself. So If IPT was not there, probably we would not dwell much on educating them on tuberculosis and how to prevent it. But because IPT is here now we kind of give them that much health education and emphasize more on tuberculosis...” [Participant 3, Facility A]*

## **Participants' awareness of IPT**

The majority of participants were aware of IPT suggesting that they had clinical and procedural knowledge of the regimen, potential facilitators. Two participants described their knowledge of side effects of IPT including neuropathy.

*Isoniazid preventive therapy is a form of protection or prophylaxis for HIV positive patients. It is prophylaxis for TB, which means you are trying to prevent your HIV positive population from contracting TB, so it is prophylaxis that has a time frame. Isoniazid is one of the regimens that are used for TB treatment so, it is used for prophylaxis for TB in HIV patients. [Participant 2, Facility A]*

*Isoniazid preventive therapy, let me just tell you a summary of all I know about Isoniazid preventive therapy. Now, mainly it is meant for preventing Tuberculosis and that should be in a non-tuberculous person - eh client-patient, as the case may be. Now for dose, it is about 300mg daily taken with eh Vitamin B6 for the - to prevent the paraesthesia, peripheral neuropathy [Participant 3, Facility A]*

One participant did suggest that her awareness of IPT was not completely comprehensive, a potential barrier to implementation as illustrated by the quote below:

*I don't know much, but I'm aware that we try to trace all our clients that are supposed to be on IPT and then commence IPT for them. I'm not quite certain of the duration right now, whether it is yearly or two-yearly... [Participant 1, Facility A]*

## **Participants' perceptions of IPT**

Participants described their perceptions of IPT. More specifically they described if they believed IPT to be effective or efficacious, potential facilitators:

*It is efficacious. Then, some people may react to it, that's why we give Pyridoxine P6 because of this neuropathy. Otherwise, every other thing is ok. They tolerate it [Participant 1, Facility A]*

*It's effective as in we encourage every client to take it because we don't want them to - they already have HIV- we don't want them to also come with the burden of TB. So we encourage anyone screened out to not have TB already to take it, so at least you know you are dealing with one thing. That's that. [Participant 3, Facility A]*

*Ok, for the fact that you are faithful, that is you are compliant with the way we told you - we tell you - to be taking the drugs, I don't think that – because they take it daily, one-one daily, for 6 months then you stop, next 2 years you repeat it one-one for six months. So for the fact that you took your drugs as we directed you and all that, I don't think that there is any chance for tuberculosis [Participant 4, Facility B]*

Another participant said IPT was not just effective in its preventive properties but also cost-wise and it contributes to the reduction in mortality and morbidity in the general population.

*“It is cost-effective because if you treat, if you intervene now, and prevent your patient from coming up with TB in the near future it is cost-effective... And you are also doing what? Increasing your patient's lifespan, so you are not going to add to morbidity and mortality, unlike if you don't give IPT to your patients, so you are going to be increasing Morbidity and Mortality, but if you intervene with IPT, at the appropriate time, the patient has a longer and healthier life to live and at the end of the day it is cost-effective to the program implementors. So, it is beneficial and advised to give IPT to the HIV population.” [Participant 2, Facility A]*

On the other hand, one of the participants was uncertain about the effectiveness of the intervention due to the absence of documented evidence of effectiveness within their facility and their experience had not been so positive either. Their concerns manifesting as a potential barrier to the implementation of IPT are illustrated in the quote below:

*“I think there should have been studies to measure - ok because, what we have was, we worked on instructions previously. Once upon a time, it wasn't being used, all of a sudden, it appeared. They said it's going to be useful, they started using it. But nobody checked. They didn't have any reduction in the people that came down with TB eventually. There's no proven benefit. I am not sure we have ever checked to find out if this thing is useful or not. We just have 'they told us it was going to be useful, so we use it. ...So, I can't say if the IPT on its own helped to prevent TB for us” [Participant 5, Facility B]*

This participant further explained that one advantage of IPT was improved case finding for TB but she was not convinced of its effectiveness.

*“...but I know it brought out people that had TB, so I don't know. Maybe that's where the advantage is, but did we ever study to find out “o, when you gave them this, the patient did not come down with TB anymore”, no we have not had any. If anything, I think we had one or two*

*who were on IPT and had to stop and go on TB treatment because they had TB. ...It is touted to be effective, so I want to believe it is, but have I proven or found out by myself if this thing is working? No.”*

Further, participants described their motivating, facilitatory factors for the implementation of IPT. The majority pointed out that the patients’ wellbeing was the main motivator as illustrated by these quotes:

*“It is for their wellbeing. You know once, you are HIV positive, you are immunocompromised and if you should have Tuberculosis that means it is going to be very bad for the person. So, because of our patient's wellbeing, we start on IPT to at least help the patient.” [Participant 4, facility B]*

*“Yea, motivation would be the beneficial effects on the patients - that's what motivates me and erm, TB is a killer alright? So I think you would better be motivated to prevent your patient from getting TB in the long run and losing that patient...” [Participant 2, facility A]*

Some of the participants also shared their thoughts on the IPT guideline. Although there was no facility guideline for IPT, participants pointed out that the national guideline was available and was described as handy and easy to use.

*The national guideline covers IPT too. we don't have a separate guideline for IPT. Our national HIV guideline covers Cotrimoxazole preventive Therapy and IPT. It is in my bag here now, we have it in our rooms (pointing at the guideline fixed to the wall) eh, we have it. It's handy, it's here- the guideline it's handy. We can always - even if you have some confusion, you can always peek in to clarify yourself. The algorithm is not complex. It is something that you can just go through and clear any doubts and confusion. [Participant 6, Facility A]*

Participants further described their fears about IPT. They feared that non-adherence may lead to the development of multidrug-resistant TB (MDR-TB) and as such, were hesitant about initiating non-adherent patients onto IPT.

*“Most times, when you see those that are not adherent you will not be that forthcoming because of the fear of getting multidrug-resistant TB, because that one is catastrophic.” [Participant 8, Facility A]*

*...when you assess and see that this person, there are tendencies of poor compliance, it will deter you because there is no point initiating and the person will mess it up, bearing in mind there are chances of developing resistance, so if you assess a client and see, and have a high*

*index of suspicion that this client might not adhere, will be a deterrent too. [Participant 6, Facility A]*

The issue of comorbidities emerged in another interview where a participant described the presence of complications from these comorbidities as a barrier to placing such patients on IPT.

*“...comorbidities like Diabetes, yes. If a patient - if a client is diabetic, we shy away bearing in mind autonomic complications of diabetes. Yes, that's one of our main concern and challenge about who to enrol and who not to enrol. Yes, it is a major factor too”. [Participant 8, Facility A]*

### **Participants’ perception of patients’ factors that influence IPT guideline implementation.**

Participants described patients’ attitudes to IPT. Patients’ attitude amongst other factors was shown to affect IPT implementation in these facilities. The majority of the participants pointed out that patients’ who are adherent and eager for their medication motivated their use of IPT while non-adherence did the opposite. Their views are illustrated in the quotes below:

*...And then like I said, adherence. If you (the patient) are keen and you are interested, keen on adhering to it (IPT) - it motivates me to prescribe IPT.*

*...What discourages me is erm, clearly, if I see that the patient would not adhere, that discourages me from placing the patient on Isoniazid because that's key. Adherence is key. So, if erm, I interact with the patient and the patient is showing clear signs of non-adherence, that just discourages me from prescribing.” [Participant 2, Facility A]*

*...sometimes when a patient comes into the clinic and says 'Hey Doc erm I was given IPT, you didn't ask me to continue.' That's motivation. Sometimes if the patient gets to remind you -maybe you are busy checking other things, and then the patient is expecting you to ask "what about my IPT?" That motivates. [Participant 1, Facility A]*

Patients’ non-adherence to IPT was attributed to several factors including high pill burden especially in those with comorbidities, adverse drug reaction, forgetfulness, lack of proper information and financial constraint.

*...despite explaining and encouraging patients to take some of these drugs, they still refuse to take it based on one, Certain side effects of the drugs, then two, the urge to take the drugs - no inducement- nothing like no reward, or something that should have encouraged them is not there. Then three, some of them lead very busy lives and they tend to forget their drugs and some of them have this belief that once you forget your drugs today, you can still repeat it tomorrow. Some of them basically just don't want to take it. Some of them have the - are financially constrained in the sense that if they can't buy the pyridoxine then they won't be able to use the Isoniazid itself. [Participant 7, Facility A]*

*"Adherence in the sense that these group of patients already have erm their ART to take, some of them have other co-morbidities, so they have issues of erm 'pill-burden.' So, you know, they are telling you "I already have a lot of drugs to take, so the issue of "pill burden". for people that are already taking a lot of drugs they are now confused, "when do I take this, how do I do this and how do I do that" so a lot of instructions might be confusing for them to adhere to if you have to say "Ok, take this at this time, take this at the other time..." [Participant 3, Facility A]*

*They will give you one excuse or the other or that "Eh, I took it once or twice, I experienced this em - tsk - I don't know how I felt and I think - I was thinking it's because of the Isoniazid, so I discontinued." Just on their own. we usually advise them, "If you experience any side effect, come back to us so that we will explore if it is a life-threatening one, you will have to discontinue, but if it is something that with time you will just wean off, we will encourage you and reassure you to continue," but most times for one reason or the other, they will just discontinue it. [Participant 6, Facility A]*

However, according to other participants, some patients resist IPT because of the belief that they would never get infected with TB.

*"... some will tell you that 'Doctor I can't take it, the drugs I am taking are too much, TB won't get me" Like, they won't come down with TB and all that. Some people refuse, they say they don't want." [Participant 4, Facility B]*

*"...but when you tell them, at times they will tell you "Tuberculosis is not our portion o, it's not in our lineage o." We have to reassure them "Please, this one is not witchcraft or any wizard, it's just an infective - infectious disease. Even as I am talking with you the bacteria are flying. We are breathing it out - in and out, so this is not a matter of witchcraft anything. It's just for you to be knowledgeable, prevent yourself because prevention is better than cure because most times they form - "Ah, it's not our portion! Whose portion is it?" It's no body's portion." [Participant 6, Facility A]*

Another participant pointed out that for some patients, religious beliefs are a barrier to their acceptance of ARV and IPT.

*For our society, you know we are too religious, so most of their reasons for not adhering is maybe, they've gone to a faith clinic; they have gone to one of these churches and those pastors that see visions will now tell them 'you are healed' Most times these are the reasons we do get from them or someone who tells you, - erm ok someone could come up and say 'I had a road*

*traffic accident, so I had to go to the hospital and then he to a traditional bone setter to probably set the bones and stuffs like that and they tell you cannot combine herbal drugs with the antiretroviral.' That may be another reason for them dropping their drugs and so these are the things that lead to non-adherence [Participant 1, Facility A]*

According to some of the participants, some of the patients were described as financially handicapped. This impacts their ability to cater for their needs.

*"Some of them are financially constrained in the sense that if they can't buy the pyridoxine then they won't be able to use the Isoniazid itself." [Participant 7, Facility A]*

*...cos most times they are indigent, even when it seems to you insignificant amount - 200, 100 naira, some of them don't have it, so poverty is a barrier too. [Participant 6, Facility A]*

*If you need the drug [Pyridoxin], you must pay, and so many patients that are already HIV positive would not be able to afford the bill... [Participant 9, Facility A]*

### ***Participants' perception of resource constraints that influence IPT guideline implementation.***

Resource constraints like drug availability, availability of screening tools, training, communication and records keeping, conduciveness of the work environment, etc., were described by the participants as important to the implementation process. Some of the participants stated that the medications for ART and IPT (except pyridoxine) were provided by the implementation partners. As such, patients got these drugs at no cost. This facilitates IPT implementation as patients did not have to pay out of pocket for most of the medications.

*"...these patients don't pay for these drugs [ARV's and INH], remember they are free, they are freely given to them so they don't have any reason why they should not have them and we don't pay for it, our work is to make sure prescribe and dispense these drugs" [Participant 6, Facility A]*

*IPT is absolutely free because the implementing partners bring all these drugs free, so what we are just required to do, just to prescribe and then the pharmacy dispenses. [Participant 10, Facility A]*

The majority of the participants described the unavailability of INH as a major drawback to the implementation of IPT. Some of these participants described the issue as discouraging.

*...Another thing that may discourage me is the "out of stock" syndrome. If I want to commence a patient on Isoniazid and er I don't see that regimen being completed over a period of six months I'm of course discouraged to prescribe that.*

*...Most times it is out of stock. That's just the more like- set back. Missed prescription because it is eh, how do I put it, is it disheartening or somehow discouraging after everything must have - because before you- most of the clients really do not want to take it, but you end up counselling and telling them the implications and how important it is and after everything, they go to the pharmacy, it's not there. It is more discouraging. [Participant 2, Facility A]*

*Sometimes those that are qualified to take the IPT, IPT may not available by the time they want to start it. We may need to give them another appointment so that they can- So when the pharmacist fails to give them - they may not tell us. They may come again, maybe another two months, instead of writing commenced: "we commenced IPT, continue with the two months" not knowing that the patient has not even started it at all, except you ask the patient. [Participant 8, Facility A]*

Another participant also raised the issue of the unavailability of free pyridoxine. (Although isoniazid is provided free of charge, pyridoxine is often times not provided for free.)

*But here in our facility, most times they need to buy Pyridoxine which is a challenge. Most times they will say - you will prescribe, explain everything to them, then they will come back. As you assess - ah ah- because on each visit, we do drug inspection; bring out your drugs, go through preventive therapy, the main ARVs and IPT, we will find out they have not even taken it, or they will even leave it at home: "Eh! I have not even started." You will say "Ah-ah, but you were supposed to start." "I went home, I looked for Pyridoxine, I did not see it or I lost the prescription." [Participant 6, Facility A]*

This participant suggested that the provision of free pyridoxine to the patients would encourage adherence.

*... If they will also make the Pyridoxine free that will be better so that there will be no need for stories - some will intentionally not buy it, but if it is free and you would give the two of them, I think it would go a long way to encourage them to take it.*

One participant said that the screening tool allowed them to find a lot of patients who had TB.

*...In fact, the only thing that changed for us is that, because of the screening tool that was used, we found a lot of TB positives – a lot. Because when you answer yes to any of those questions, you are screened for TB, so a lot of our patients ended up going for TB treatment. So that is the one thing that came out from those tools. [Participant 5, Facility B]*

However, this participant also explained that the screening tool was at times unavailable.

*“...for these patients who are eligible - you use a screening tool and for those who are eligible, they are given the drugs for a period of 6 months and then subsequently you repeat it every two years.... before now it used to be on paper - it used to be on paper, so we have this guide where the patient arrives at the Triage area, we ask some questions "Do you have a fever?" I think they score - so you have 0,1, like that. So 'do you have a fever? yes/no; cough of any duration? Yes/No; Is there any history of weight loss, night sweat?' and then for the children they added, do you have contact with anybody that has a cough? So, when - depending on the no's and yes of course - if anyone is yes, the person might be eligible for IPT, just screen for TB, ok. But if the person answers no to all the questions the person is eligible for IPT, you mark that the person is eligible in that form. When the Dr. sees, he prescribes IPT for the patient. So that's the tool we use but is not available presently in this program but it used to be available...”*

The need for reagents for testing for TB was highlighted by another participant.

*“The reagents also for the testing to screen out those that are Tuberculous and those that are not Tuberculous for the commencement of IPT to the non-Tb patient should also be made available” [Participant 1, Facility A].*

Further, participants pointed out that they had not received any training on IPT by the facility and all they knew were self-taught or from the National guidelines as illustrated by these quotes:

*“No formal training, no. I know... no. I know we have had a couple of training on - most of the training we have had are just HIV, the drugs when we had to start switching to DTG and some things, but just a specific training on the INH and all that, I have not attended since I came to this facility. The guideline is there. Apart from the guideline, I don't know any other avenue...” [Participant 11, Facility B]*

*The only training is - from - in our national guideline, that's what we are using. That is the one in HIV National Guideline. That is, there has not been any training on IPT per se. It's not facility-based. It's just personal or maybe the IPs on the ground maybe about once twice or - in a year, maybe they will just organize training for facilities under them. That's the only way that we undertake training. And it's not even for every clinician - maybe they will pick one person or so to go. When you train you come and give a stepdown to others. you relate what you learned to others [Participant 6, Facility A]*

Furthermore, participants highlighted poor working conditions in the HIV clinic, inadequate manpower, inadequate management support, poor records keeping and communication gaps as other barriers that affected their service delivery to their patients. One participant stressed the need for the employment of more doctors to even out the workload of others as “physician’s burnout and suicidal instincts” had become a problem for the health sector.

*...our workload, should be evened out. I was on clinic duty yesterday morning. I was on night call all through, I am on clinic duty today. And it runs like that every week. That's not the best. There are many young Doctors out there, unemployed. Why not employ them and have adequate manpower than to stretch a doctor to the point of burnout. Physician’s burnout syndrome and suicidal instincts is a challenge in the health sector.” [Participant 9, Facility A]*

Another pointed out that the work environment was not encouraging.

*We don't even have good chairs. It's just recently they brought these chairs for us, we work in terrible conditions most times, like, you can come in, there is no light, the whole place is heated up, no fan and we could go out, the drainage system behind here is so terrible, the awful smell comes through it. Our patients just leave anyhow because it's not well - things are not well organised. You are coming out, you see a patient urinating out there, I don't know if you get, so things are not well organised and it's not encouraging. [Participant 1, Facility A]*

Also, another participant highlighted gaps in communication as a cause of concern as it interfered with patient care.

*“...I mean, there are times I will get a lot of new clients, maybe we might get 3 in a day, maybe in a week we can get a lot of new people. So, you are busy writing INH, INH, and only to discover at the end of the week that none was dispensed. And you say, "OK well, OK, no problem we don't have INH again, no problem, so what's the point of writing?" You stop writing. And it takes another 2 weeks, maybe by the 2nd week, the drug comes in, you are still not writing the INH, and then by the fourth week, you now get information that the drug was supplied a week ago, and you know... so I think that those things area... it's a bit discouraging anyway, for me...” [Participant 11, Facility B]*

One participant summarized what was needed to facilitate implementation thus:

*My prayer is just, let the tools - by tools I mean, the availability of the drugs, availability of the reagents, even if it is possible, increased manpower so that turnaround time will be short. And free supportive B6 will be in place or at hand so that work will just be free, easy. [Participant 3, Facility A]*

### **Perception of participants on stakeholder engagement in IPT implementation.**

One of the participants felt that not enough emphasis was being laid on IPT. As such, patients were not actively involved in IPT as no awareness campaign or IEC materials was being distributed for their enlightenment. He pointed out that the use of IEC would increase demand and encourage implementation.

*If we emphasize it, as this is here pointing you to Donaval front and floranom, you should see signs telling you, emphasising, beautiful design IEC materials, emphasizing, "Have you been screened today for IPT? IPT- Isoniazid. So have you been screened today? You know, trying to tell clients that they should even ask for it. "Doctor there is an alarm out there, sounding that I should be screened for IPT-Isoniazid. Have you done that for me?" "Oh my client, sorry, I have not. Can I do that?" [Participant 9, Facility A]*

Further, another participant pointed out that involving caregivers in patient care made for better adherence. They noted that patients who had caregivers or “pill partners” living with or close to them were more compliant with their medications as they serve to remind them to take their drugs thereby increasing adherence

*...You know usually, we used to practice this in DOTS like in terms of treatment of tuberculosis. So with that, you need someone who would always remind you "Have you taken your pill for today? Have you had the evening one?" Ok tomorrow comes, the person reminds you 'Have you eaten, have you taken your drugs?' So with that, you are going to now get effective treatment, but if you don't observe closely, and remind this person, 'take your drugs' there's a probability the person will keep skipping the drugs and there's room for resistance in the treatment of tuberculosis, so the caregiver has a lot of roles to play in terms of adherence - will I say the pill partner has a lot of roles to play. [Participant 1, Facility A]*

Participants also described how the facility management and Implementation partners influenced IPT implementation. One participant described how other support staff provide reminders for patients to be placed on IPT as directed by the program sponsors.

*“...sometimes, there are some people that normally come. They will remind you that any new case you are seeing, that any new client that you are seeing without cough, that "ah, Doc you didn't prescribe IPT to those ones" They will go to their care card, they will show you, "This*

*person came two times, you didn't place him or her on IPT so please remember" They have people coming to remind us. [Participant 4, Facility B]*

Another also said that though they didn't need a "pat on the back" to do their work, being listened to and their requests being met by the facility management would boost their output.

*"I don't expect anybody to come and pat you on the back and say well done, but if we demand somethings that we need in the department, we shouldn't be seeing struggling and reminding and reminding them about it. It's something they should just do to encourage us, knowing that we do not work in the best of environment, seeing immunocompromised patients, we are at risk, so they should try and heed to our request anytime that we call on them. I am talking about our management here." [Participant 1, Facility A]*

One of the participants pointed out that previously they were provided incentives that motivated them to implement IPT.

*The previous NGO gave incentives. They gave us - there were incentives from the previous - but it wasn't the management of the hospital per se. Let me say NGO in conjunction with the management. There were incentives in place last year - that was around September or October, in the sense that there were monetary incentives, in the sense that if you hit a target, they reward those who reach their target and their targets are like, you know - IPT coverage and the rest. And the monetary incentive is not really - it is something that will boost your morale, kind of yes. [Participant 7, Facility A]*

In summary, facilitators and barriers to IPT guidelines are spread across different levels of the organization from the intervention itself, through patients' as well as management-related factors.

## **5. CHAPTER FIVE: DISCUSSION**

### **5.1. Introduction to the chapter**

This qualitative study of a sample of 11 doctors aimed to explore the barriers and facilitators of IPT implementation for PLWHA as perceived by the doctors in two public health facilities in Nigeria. The CFIR, a framework used to guide implementation research, informed the formulation of the interview guide and is explained in the literature review. The study yielded interesting findings. In this discussion section, the results are reflected upon and compared within the context of previous research.

### **5.2. Barriers to IPT implementation**

Findings around the barriers to IPT implementation in this study are discussed below and compared with findings of previous studies. Participants' perceptions on the barriers to IPT implementation included fear of multidrug-resistant TB, perceptions of participants on patients' non-adherence, patients' religious beliefs, poor patient knowledge about IPT and low economic status, unavailability of INH, screening and testing tools and supporting drugs, poor working conditions, lack of incentives and absence of managerial involvement among others.

#### **5.2.1. Participants' perception of IPT**

Participants feared that patient non-adherence to the IPT regimen could lead to MDR-TB, a potential barrier to IPT implementation. MDR-TB refers to infection with Tuberculous bacilli resistant to at least two of the most powerful first-line medications, INH and Rifampicin. INH resistance is the second most common type of resistance in TB patients. (98,99) Previous

studies echo these findings suggesting that the fear of IPT induced TB resistance often deterred IPT implementation. (61,69,71). Numerous studies among health care workers who deliver TB or HIV treatment tend to suggest the threat of non-adherence as elucidated by Tola et al (2015) in their review of studies around non-adherence in low-income countries often served as a deterrent to its use for fear of inducing resistance. (100)

### **5.2.2. Participants' perception of patients' attitude that influence IPT guideline implementation**

Patients' adherence to IPT plays a major role in IPT implementation. Earlier studies suggest that non-adherence is a barrier to IPT. In these studies, non-adherence was attributed to increased pill burden, occurrence or fear of side effects, forgetfulness, fear of stigmatization, and inadequate knowledge of IPT. (62,64,65) According to Mindachew et al. (2014), health workers suggested that patients did not have an adequate understanding of the importance of adherence to IPT. (64) Further, Berhe and colleagues in their quantitative research on adherence found that forgetfulness, fear of side-effects and unavailability of drugs were the leading causes of non-adherence among patients. (65) These findings were corroborated by the findings in this study as poor knowledge, fear of side-effects and drug availability also influenced patients' adherence and hence deterred implementation. Non-adherence in this context was also attributed to pill-burden especially in patients with co-morbidities, side effects, forgetfulness and for some, unwillingness to take the medications.

Religious beliefs also played a role in non-adherence in this context. This could be attributed to the fact that patients in this region are quite religious and often believe more in faith-based healing than medicine. Also, previous studies not exploring IPT specifically have suggested that religious beliefs play an important role in attitude towards health in general. (101,102) .

For example, a review of studies by Weber and Pargament on the effect of religion on mental health found that religion could promote mental health through community support, positive coping mechanisms and positive beliefs. Conversely, negative religious coping mechanisms, misunderstandings and miscommunication as well as negative beliefs are destructive to mental health. (101) Further, adherence was found to be better in patients who had social support in this and prior studies. (55,62) Caregivers often serve to remind patients of their medications thereby increasing adherence.

Interestingly, fear of stigmatization was a common finding in many of the studies reviewed. Patients were afraid of being stigmatized and as such refused IPT or were non-adherent. (64–66,68) However, the problem of stigmatization did not arise in this study. This could be attributed to the study being carried out in comprehensive facilities which provide diverse services and so have a high influx and efflux of people who are there for different reasons. Further, TB and HIV care are integrated in these facilities allowing patients to access care without having to expose themselves as Ngwenya et al. (2018) in their qualitative study in South Africa found that separation of TB and HIV services fostered stigmatization. (68)

Furthermore, poor economic status was found to be a barrier to IPT implementation as some of the patients could not afford some of the medications. Munroe et al. (2017) corroborate this finding in a review of qualitative studies where he found that patients' economic status affects their perception of the intervention. They pointed out that patients prioritized earning a living over treatment as without jobs they could not afford treatment and they also could not access treatment due to job demands. In addition, some patients described the medications as expensive and often had more pressing needs to attend to. (55) One of the studies included in the review which was conducted in Burkina Faso suggests that financial autonomy was a

problem especially for women in those communities. Also, the opportunity cost (cost of transport and livelihood) for attending appointments were significant issues raised by the participants. (103) Likewise, Jacobson et al. (2017) found that cost of accessing healthcare presented a barrier to IPT implementation. Also, patients often had to forgo income to attend appointments. (66) Away from IPT, a review of studies on factors influencing non-adherence to TB treatment by Tan et al. (2015), found that non-adherence often stemmed from financial constraints including transportation cost, lack of income leading to lack of food and lack of money. (100)

### **5.2.3. Participants' perception of resource constraints that influence IPT guideline implementation**

Although INH was provided free of charge, the unavailability of INH was described as a setback to IPT implementation. This finding is consistent with the findings in previous literature, where the unavailability of isoniazid has been described as a major barrier to the implementation of IPT (61,67,70,73,75). Wambiya and colleagues (2018) in their qualitative study in Kenya, suggested that the inconsistent supply of IPT negatively affected IPT implementation as it signified a lack of support for IPT by the management and policymakers. (62) Frequent drug stockout was also found to be the major reason for the non-initiation of patients onto IPT in a mixed-method study by Reddy et al. (2020) in India. For this reason, participants prioritized and set aside drugs for patients based on various criteria including CD4 count, regularity to clinic and adherence to ART to prevent resistance as a result of non-completion. (73) The unavailability of INH in our setting could be ascribed to the fact that INH is provided by third-party NGOs in charge of the TB/HIV programs in these facilities and as such, are not under the control of the facility leadership. Kugujje et al. (2019) also suggested that the unavailability of Pyridoxine (Vitamin B12) negatively affected IPT implementation.

(71) Our study agrees with this as patients were often non-adherent to IPT if they could not get pyridoxine.

Further, difficulty in screening and testing for active TB in patients also affected IPT implementation. This often resulted from the unavailability of screening tools and reagents necessary for TB testing. This corroborates findings from previous studies where difficulty in testing for TB negatively affected IPT implementation. (61,75–77) A systematic review by Kerkhoff and colleagues (2012) in under-resourced settings suggest that difficulty in training in and procuring testing tools made IPT implementation difficult. (75)

In addition, this study suggests that participants had little or no specific training on IPT from the facilities, although this did not seem to have a significant effect on their delivery of IPT as the majority of the participants were self-taught. However, previous studies have shown that lack of specific IPT training was a barrier to IPT implementation. (61,62,64,69,104) According to Wambiya et al (2018), limited or no specific training on IPT restricted providers ability to deliver the intervention. (62) Danyuttapolchia and colleagues (2017) and Lai et al. (2019), also pointed out that training on TB/HIV were facilitators of IPT implementation. (77,78)

Likewise, sub-optimal working conditions including inadequate manpower, heavy workload, poor record-keeping and communication gaps were barriers to IPT implementation in this study. Previous studies have shown that poor data management negatively affected monitoring and evaluation of the program and as such, its implementation. (67,71). Wambiya et al. (2018) found that the limited number of providers in the HIV clinics did not match the heavy patient load. This made IPT implementation difficult as they considered the procedure very long and thus a burden to them. (62)

#### **5.2.4. Participants' perception of stakeholder involvement in IPT implementation.**

The study pointed out that lack of emphasis on IPT by the leadership was a barrier to proper implementation of IPT.

Previous studies have also shown that support for health workers and health workers participation in guideline development as well as the active involvement of policymakers in the implementation of IPT were enablers of IPT implementation. (62,64,77,78) For example, Wambiya and colleagues (2018) suggested that evidence of management support such as improved INH supply, IPT advocacy and proper monitoring and evaluation of the program, would foster better IPT implementation. (62) These tie in with findings from our study which pointed out that support from the facility management would encourage IPT implementation. Managerial involvement in terms of providing better working environment and seeing to fewer stockout of medications would encourage productivity and implementation. However, poor facility management support in this context may be due to the fact that IPT is provided by an NGO and as such is left in their care.

Lack of patient engagement and enlightenment activities was seen to hinder patient participation in IPT implementation as it resulted in little demand for IPT. The need for IEC materials and patient education and sensitization programs were emphasized in order to pique patient interest and create demand for IPT thereby facilitating implementation. This is in line with previous findings which suggested that advocacy and sensitization programs and also IECs would improve community and leadership participation in IPT (74) and that the unavailability of IEC material and sensitization programs led to a lack of demand for IPT. (73)

### **5.3. Facilitators of IPT implementation**

Facilitators of IPT implementation were discussed under the following themes: Participants description of the process of IPT initiation, participants' awareness of IPT and participants' perception of IPT. Some of the facilitators of IPT implementation include knowledge of most participants of IPT and its effectiveness, care for patient well-being as well as having a guideline for prescribing the intervention.

#### **5.3.1. Participants' description of the process of initiation onto IPT**

Participants appeared to be familiar with the process of Initiation of patients on to IPT which would facilitate its implementation. This begins with the screening of the patients for active TB according to the guidelines as described by the participants. This is in line with WHO recommendation as IPT is aimed at preventing the progression of latent TB to and the development of TB disease in HIV positive patient (6,18,26,28). From the results, patients are initially counselled and screened clinically for symptoms using screening tools and are sent for further investigations if there is suspicion of active disease. They are also assessed generally to rule out comorbid conditions that may be impacted negatively should they be commenced on IPT. IPT is given for a period of 6months to be repeated after 2years. This finding is corroborated by the WHO guidelines for IPT implementation as well as previous studies which pointed out that patients had to be screened for active TB before the commencement of IPT (6,18,62).

#### **5.3.2. Participants' awareness of IPT**

The majority of the participants in this study demonstrated knowledge of IPT as outlined in the Nigerian national guidelines for HIV care outlined in the background of this study (31) which

is in line with WHO recommendation. (6) The description of the IPT guideline by most participants showed an understanding of the guideline and their role in its implementation. Participants' knowledge in this context could be attributed to the fact that IPT is part of routine HIV care practice in these facilities and this facilitates IPT implementation. This finding was contrary to previous studies including one by Lester and colleagues in a comparable setting in the South African public health system which showed that lack of adequate knowledge of IPT was a common barrier to IPT implementation. (61,70). The study by Lester and colleagues found that doctor participants had heard of IPT but were not aware of RCT demonstrating its effectiveness. (61) Further, the review of studies by Grace (2019) suggested that all the articles reviewed cited lack of knowledge on IPT as a barrier to IPT implementation. (68) This was not found to be so in this study.

### **5.3.3. Participants' perception of IPT**

Participants' perception of IPT centred around its effectiveness/efficacy, guideline availability and fear of resistance occasioned by patients' non-adherence to IPT.

This study found that the majority of participants believed that IPT was effective in preventing TB at the individual as well as community levels. Thus, participants are motivated to implement IPT for their patients' benefit as anecdotally only a few patients had been transferred to TB care since the commencement of IPT. This finding was not surprising when compared to previous studies which suggest that IPT is effective in reducing TB incidence and associated morbidity/mortality. (20–23,37,59,60) Studies have also shown that TB reduces the number of years lost to disabilities (DALYs) and improving the quality of life (QALYs) in PLWHA if correctly implemented thereby making it also cost-effective. (95–97) This finding is promising and also in contrast to the South African study by Lester and colleagues who found that there

was limited knowledge of the effectiveness of the treatment. Lester's study was conducted in 2010, a decade before the current study. It is possible that knowledge of the effectiveness of scientifically sound interventions can be attributed to training initiatives around the effectiveness of IPT or other TB interventions for PLWHA as well as relevant engagement with scientific studies. In a more recent study, Danyuttapolchi and colleagues found that IPT could be successfully implemented after they trained health workers and implemented IPT in 7 hospitals in Thailand. (78)

Further, unavailability, non-uniformity and lack of clarity of IPT guidelines were found to be a hindrance to IPT implementation in previous studies. (6,61,62,71) For example, Lester et al. found that different facilities in their study had different guidelines and so staff prescribed according to inconsistent criteria. (61) Also, Wambiya and colleagues found that lack of clarity of the guideline made participants uncomfortable with it. (62) However, this was not the case in this study as guidelines for IPT is outlined in the Nigerian national HIV/AIDS framework and is available in every consulting room and also at strategic locations. (31)

#### **5.4. Strengths and limitations of the study**

Data collection ensued during the early phases of the COVID 19 pandemic and as such prospective participants were unwilling/unavailable to participate in the study, hence the small sample size. Sample size was adequate, however, as saturation was reached.

Secondly, the study was conducted in two purposively selected facilities which are located in urban areas and are the apex of care in this state and as such, HIV care is expected to be better organized and equipped than other facility HIV clinics in the state. Therefore, these findings are context-specific and may not be generalizable to other HIV clinics in the state.

The qualitative nature of this study allows for an in-depth understanding of the barriers and facilitators of IPT in these facilities and provides useful insights for the implementation of IPT and other interventions even in other contexts. Also, the use of a theoretical framework for implementation research provided a foundation that guided the assessment of the implementation of IPT.

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

### **6.1. Conclusion**

In conclusion, IPT and IPT guidelines are considered important and appear to be part of routine care in the facilities studied. Multiple factors influence the implementation of the IPT guidelines in these facilities both positively and negatively.

Although the free provision of INH was a strong facilitator, its unavailability and stockout created a barrier to the optimal implementation of IPT in these facilities. This implies that until measures are put in place to ensure regular supply of the medications, implementation of IPT may not be optimal. Although programme sponsors appeared to be committed to the provision of IPT, the paucity of managerial influence especially in the areas of staff motivation, high workload and provision of enabling work environment made implementation difficult. Lack of enabling environment, high workload and lack of motivation would lead to increased burnout and dampening of the motivation to provide optimal care to patients, leading to even poorer patient care. Further, participants pointed out that patient-specific factors including adherence and poor knowledge, play an important role in the successful implementation of this intervention. Lack of patient education programmes resulted in poor patient participation in their care leading to non-adherence and difficulty in IPT implementation.

### **6.2. Recommendations**

1. Increased facility management involvement in HIV/TB care will ensure that there are fewer issues of drug stock-out syndrome as this will bridge the gap between health care providers and program sponsors.

2. There is a need for more in-depth and widespread studies in non-apex facilities and rural areas to measure the degree to which IPT is being implemented in this region and Nigeria as a whole. Considering that this study is not generalizable, a research into the barriers and facilitators to this intervention in other contexts will throw more light on how to improve IPT implementation in the area.
3. There is a need for more studies to measure the effectiveness of IPT in this context as a marked absence of such was noted at the time of this study.
4. Increased government involvement to provide better work policies especially in the area of job satisfaction, lighter workload and better work environment for health workers is also recommended as this serves as an incentive for better output.
5. There is also a need for increased patient education and involvement through the provisions of IEC materials, sensitization programs and other means of patient education.

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# APPENDIX I: PLAGIARISM DECLARATION FORM



## PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I JULIET ONINYECHUKWU NWACHUKWU (Student number: 2169323) am a student registered for the degree of MSc. EPIDEMIOLOGY (IMPLEMENTATION SC.) in the academic year 2019.

I hereby declare the following:

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

Signature:  Date: 28th April, 2021

## **APPENDIX II: INTERVIEW GUIDE**

### **Title: Perceptions of Doctors of the barriers and facilitators to the implementation of Isoniazid Preventive Therapy guidelines for HIV patients in Anambra State, Nigeria.**

#### **1. The Intervention.**

- Can you tell me what information you are aware of in terms of if Isoniazid preventive Therapy for persons living with HIV works in your environment?  
How does this knowledge affect your perception and use of IPT?
  - What do you think of the intervention in terms of how adaptable is it to your setting (probe: why their answer)?
  - How easy or difficult is it to implement IPT (e.g. number of steps, the complexity of the steps, duration, disruption of existing program etc.)?
  - What cost do you incur when you use the intervention?

#### **2. Individual Factors.**

- What do you think about the risk of TB for people living with HIV?
- What do you think about IPT for PLWHA?
  - How effective do you think IPT is in this setting?
  - What has been your experiences with the administration of IPT? (probe: feelings about the intervention, feelings about the capacity to administer the intervention (how confident are they in their capacity to carry out the intervention), how comfortable are they with carrying out the intervention and why they feel the way they do)
  - What personal factors do you think affects your use of IPT for HIV positive individuals in the facility?
  - What motivates you or discourages you from giving IPT to your patient?

### 3. Outer Setting

- How do your patients feel about IPT?
  - Are there any patient characteristics/factors that affect your decision, as the doctor, on whether or not to place the patient on IPT? (Probe for examples depending on the answer)
- What are your colleagues' perceptions/views about IPT?
  - How do their views affect your use of the intervention?
- Are there any performance measures, policies, regulations or guidelines that have influenced your clinic's decision to implement the intervention? Any motivations or incentives from this aspect?

### 4. Inner Setting

- How are communications handled in this facility? Do you get any feedback from your work?
- How does your Facility management support the Implementation of IPT for PLWHA that use the Facility?
- How does the structure help or deter you from implementing IPT?
- Do you think your facility has the resources to enable the effective implementation of IPT? (probe further on the type of resources and how available they are for IPT)
- Have you ever had training on the implementation of IPT? How long ago was that?
- Does your facility provide avenues to get and improve/update Knowledge on IPT?
- To what extent are new ideas embraced and used to make improvements in your facility?

- What kind of incentives are there to ensure that the intervention is successful?  
(motivations and demotivators)
- To what extent do your facility set and review targets for this intervention?  
(what are the current targets?)

#### 5. **The implementation Process**

- Is there a plan for the Implementation of IPT for this facility? Can you describe it? What do you think about the presence (or lack) of such a plan? Does it affect your use of IPT?
- Has IPT been implemented according to the plan of your institution?
- What steps do you take to encourage clients to use IPT? What steps is your facility taking to ensure that the intervention is carried out?
- Can you tell me about the people that influence IPT implementation in your facility?
- Does your facility have goals for implementing IPT? What are they? How are the goals communicated in your facility and to whom?

6. Overall, what do you perceive are the Barriers and/or facilitators to IPT guideline implementation in your Facility?

# APPENDIX III: ETHICS CLEARANCE CERTIFICATE FROM WITS HREC



R14/49 Dr JO Nwachukwu

## HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE CERTIFICATE NO. M1911138

**NAME:**  
**(Principal Investigator)** Dr JO Nwachukwu  
**DEPARTMENT:** School of Public Health  
Division of Epidemiology and Biostatistics  
Medical School  
University

**PROJECT TITLE:** Perception of doctors of the barriers and facilitators  
to the use of Isoniazid preventative therapy guidelines  
for HIV patients in Anambra State, Nigeria

**DATE CONSIDERED:** 2019/11/29

**DECISION:** Approved unconditionally

**CONDITIONS:** Local ethics clearance may be required

**SUPERVISOR:** Dr S Mail

**APPROVED BY:**   
Dr CB Penny, Chairperson, HREC (Medical)

**DATE OF APPROVAL:** 2020/03/11

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

### DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.  
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. I **agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore reports and re-certification will be due early in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

# APPENDIX IV: ETHICS CLEARANCE LETTER FROM NAUTH

## NNAMDI AZIKIWE UNIVERSITY TEACHING HOSPITAL

P.M.B. 5025, NNEWI, ANAMBRA STATE, NIGERIA

Chief Ezekiel Irimiya E. Afukonyo  
BA Hist, MA Int'l Law and Diplomacy.  
Chairman  
Board of Management

Mrs. Chinyelu Ogoamaka Nwofor  
B.Ed, M.Ed, MHP&M, AHA, FCAI  
Director of Administration/  
Secretary to the Board



Professor Anthony O. Igwegbe  
MBBS, FWACS, FICS, FISS  
Chief Medical Director/  
Chief Executive

Dr. Joseph O. Ugboaja  
MBBS (NAU), FRCOG, FWACS, FICS,  
FMAS, DMAS, Dip. ART (Int)

Chairman  
Medical Advisory Committee

E-mail: nauthcmd@yahoo.co.uk  
nauthnnewi@hotmail.com

Our Ref: NAUTH/CS/66/VOL.12/232/2019/096

Your Ref: \_\_\_\_\_

Date: 12<sup>th</sup> February, 2020

Juliet Onyinyechukwu Nwachukwu,  
Department of Epidemiology and Biostatistics,  
School of Public Health,  
Faculty of Health Sciences,  
University of the Witwatersrand,  
Johannesburg.

### ETHICS COMMITTEE APPROVAL

**RE: PERCEPTIONS OF DOCTORS OF THE BARRIERS AND FACILITATORS TO THE IMPLEMENTATION OF ISONIAZID PREVENTIVE THERAPY GUIDELINES FOR HIV PATIENTS IN ANAMBRA STATE, NIGERIA**

We write to inform you that after due consideration of your research proposal, approval is hereby conveyed for you to commence the study.

The principal investigator is required to send a progress report to the Ethics Committee at the expiration of three (3) months after ethical clearance to enable the Committee carry out her oversight function.

Please note that this approval is subject to revocation if you fail to obtain proper authorization from your study site/unit.

Dr. Chisolum Okafor  
Chairman, NAUTH Ethics Committee

Mrs. M.C Onwuka (JP)  
Sec., NAUTH Ethics Committee

## APPENDIX V: PERMISSION LETTER FROM COOUTH

CHUKWUEMEKA ODUMEGWU OJUKWU  
UNIVERSITY TEACHING HOSPITAL, AMAKU  
AWKA

(Formerly Anambra State University Teaching Hospital)  
**PMB 5022 AWKA, ANAMBRA STATE, NIGERIA**

**Dr. Clement Idigo** *B.M.BCh (Eng)*  
Chairman, COOUTH Management Board

**Dr. Emmanuel C. Azuike**  
*MB.BS, MPH, FWACP, FMCPH*  
Deputy Chairman Medical Advisory Committee



**Dr. Basil E. Nwankwo** *JR, RSM, MB.BS, FRICS*  
Chief Medical Director

**Dr. Ifeanyichukwu U. Ezebialu**  
*MB.BS, FWACS, FMCOG, Cert. SRHR*  
Ag. Chairman Medical Advisory Committee

Our Ref:COOUTH/CMAC/Vol. 01/2020/0007

Date:19th March., 2020

Nwachukwu, Juliet Onyinyechukwu

### PERMISSION LETTER

Approval has been given for you to conduct your study here in Chukwuemeka Odumegwu Ojukwu University Teaching Hospital, Amaku- Awka.

This is with respect to your study titled. *"The Perception of Doctors of the Barriers and Facilitators to the Implementation of Isoniazid Preventive Therapy Guideline for HIV Patients in Anambra State, Nigeria"*.

Please ensure that ethical standards are maintained.

  
.....  
**Dr. Emmanuel C. Azuike**  
Deputy CMAC  
*For: Chief Medical Director*

## **APPENDIX VI: PARTICIPANT INFORMATION SHEET FOR IN-DEPTH INTERVIEW**



UNIVERSITY OF THE  
WITWATERSRAND,  
JOHANNESBURG

*University of the Witwatersrand, Johannesburg*  
*School of Public Health*

### **Participant information sheet for in-depth interview**

**Study title:** Perceptions of doctors of the barriers and facilitators to the implementation of Isoniazid Preventive Therapy guidelines for HIV patients in Anambra State, Nigeria.

Dear Sir/Madam,

#### **Introduction:**

Good day. I am Juliet Onyinyechukwu Nwachukwu, a postgraduate student of the University of the Witwatersrand. I am conducting a study to find out Doctors' perspective on the Barriers and facilitators to the implementation of Isoniazid Preventive Therapy guidelines among people living with HIV. Research is a process used in seeking new knowledge. In this study, we want to learn about the factors influencing the doctor's implementation of Isoniazid preventive therapy guidelines for people living with HIV, why and how these factors influence the use of the guidelines to enable us to understand these factors better and generate strategies for better implementation of the guidelines.

#### **Invitation to Participate:**

We are inviting you to take part in a research study.

#### **What the study involves:**

Participation in this study will entail filling out a form that will capture your social demographic data like age, sex, duration of service in the HIV clinic. Audio recorded face to face interview lasting about 45 minutes on your perceptions of the Barriers and facilitators to the implementation of Isoniazid Preventive therapy guidelines for people living with HIV will then follow. An interview guide will be used to guide the interview and probes may be employed to get clarifications on points raised during the interview.

**Risks and Benefits of being involved in the study:** There are no risks or consequences whatsoever to you on participating in this study. Also, there are no direct benefits for taking part in the study.

Participation in this study is Voluntary. You are free to withdraw from the study at any point with no consequences. Refusal to participate in this study will bear no penalty or consequence.

**Confidentiality:**

We will ensure that your personal information remains confidential by assigning pseudonyms and the key to this Pseudonym will be kept by the Researcher alone. You will only be required to provide your name in the consent forms and not anywhere else. The consent form will be stored in a password protected laptop as well as in a protected folder on google drive separate from the Audio recordings and Social demographic forms and will only be accessible to the principal researcher and the supervisor.

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

**Contact details:**

For more information, please contact me on +2348067247113 or send an email to [christyle4essence@gmail.com](mailto:christyle4essence@gmail.com).

You can also contact:

Dr Sumaya Mall (Research Supervisor), University of the Witwatersrand via Email; [sumaya.mall@wits.ac.za](mailto:sumaya.mall@wits.ac.za)

**Output:**

A research report will be submitted to the University of the Witwatersrand at the end of this research. Should you be interested, the results of this research can be sent to you on completion of this study.

**Contact details for HREC administrator and Chair:**

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

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

Thank you for reading this Study Information Sheet.

Please fill in and sign the attached consent form if you are willing to participate in this study.

Your help will be greatly appreciated.

Thank you.

Kind Regards

Juliet Onyinyechukwu Nwachukwu

Phone: +2348067247113

Email: [christyle4essence@gmail.com](mailto:christyle4essence@gmail.com)

## **APPENDIX VII: CONSENT FOR IN-DEPTH INTERVIEWS**

**Study title: Perceptions of doctors of the barriers and facilitators to the implementation of Isoniazid Preventive Therapy guidelines for HIV patients in Anambra State, Nigeria.**

I (full name and Surname) \_\_\_\_\_ accept to be interviewed by Dr Juliet Onyinyechukwu Nwachukwu to discuss my perceptions of the barriers and facilitators to the implementation of Isoniazid Preventive Therapy (IPT) guidelines for people living with HIV/AIDS.

- I have been given a participant information sheet that explains the nature and processes involved in this study, which is attached hereto;
- I was given time to read and understand it;
- I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
- I understand the purpose of the research and what the intended outcome will be;
- I can stop the interview at any time and may withdraw from the study at any time and would not be required to give any reason. If that happened, any data collected about me for this study would be immediately destroyed, unless I give consent for it to be retained.
- The information provided will be treated with confidentiality
- I will not receive any payment for participating in this study and participation will not cost me anything but my time.
- I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

### **Contact Details**

Juliet Nwachukwu (Principal investigator) Cell number: +2348067247114

Or by email at [christyle4essence@gmail.com](mailto:christyle4essence@gmail.com).

Dr Sumaya Mall (Research Supervisor), Email; [sumaya.mall@wits.ac.za](mailto:sumaya.mall@wits.ac.za)

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at [Clement.Penny@wits.ac.za](mailto:Clement.Penny@wits.ac.za).

Ms Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at [Zanele.Ndlovu@wits.ac.za](mailto:Zanele.Ndlovu@wits.ac.za) or [Rhulani.Mkansi@wits.ac.za](mailto:Rhulani.Mkansi@wits.ac.za)

Participants name: \_\_\_\_\_

Date: \_\_\_\_\_

Place: \_\_\_\_\_

Signature: \_\_\_\_\_

Witnessed by

Name of Witness: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

## **APPENDIX VIII: CONSENT FOR AUDIO-RECORDING OF INTERVIEW**

**Study title: Perceptions of doctors of the barriers and facilitators to the implementation of Isoniazid Preventive Therapy guidelines for HIV patients in Anambra State, Nigeria.**

I (Full name and surname) \_\_\_\_\_ give permission to Dr Juliet Onyinyechukwu Nwachukwu to audio-record the interview for her research on the perception of doctors on the barriers and facilitators to the implementation of Isoniazid Preventive Therapy for people living with HIV.

I have been given a participant information sheet that explains the nature and processes involved in this study, which is attached hereto;

I was given time to read and understand it;

I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;

I understand the purpose of the research and what the intended outcome will be;

I can stop the interview at any time and may withdraw from the study at any time and would not be required to give any reason. If that happened, any data collected about me for this study would be immediately destroyed, unless I give consent for it to be retained.

The information provided will be treated with confidentiality

I will not receive any payment for participating in this study and participation will not cost me anything but my time.

I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

### **Contact Details**

Juliet Nwachukwu (Principal investigator) Cell number: +2348067247113

Or by email at [christyle4essence@gmail.com](mailto:christyle4essence@gmail.com).

Dr Sumaya Mall (Research Supervisor), Email; [sumaya.mall@wits.ac.za](mailto:sumaya.mall@wits.ac.za)

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at [Clement.Penny@wits.ac.za](mailto:Clement.Penny@wits.ac.za).

Ms Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at [Zanele.Ndlovu@wits.ac.za](mailto:Zanele.Ndlovu@wits.ac.za) or [Rhulani.Mkansi@wits.ac.za](mailto:Rhulani.Mkansi@wits.ac.za)

Participants name: \_\_\_\_\_

Date: \_\_\_\_\_

Place: \_\_\_\_\_

Signature: \_\_\_\_\_

Witnessed by

Name of Witness: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

## APPENDIX IX: TURNITIN REPORT

2169323:Final\_Turnitin\_JulietThesis.docx

### ORIGINALITY REPORT

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