HEALTH EDUCATION GUIDE FOR PROMOTION OF UNDERSTANDING AND USE OF ISONIAZID PREVENTIVE THERAPY UPTAKE AMONGST HIV POSITIVE PATIENTS

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DECLARATION

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I declare that the **"Health Education Guide for promotion of understanding and Use of Isoniazid Preventive Therapy uptake amongst HIV Positive patients: a mixed method study"** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

Signature 

Date 20/12/2021

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HEALTH EDUCATION GUIDE FOR PROMOTION OF UNDERSTANDING AND USE OF ISONIAZID PREVENTIVE THERAPY UPTAKE AMONGST HIV POSITIVE PATIENTS: A MIXED METHOD STUDY

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ABSTRACT

PURPOSE: The purpose of this study was to develop a health education guide to promote understanding and use of Isoniazid preventive therapy amongst HIV positive patients to decrease tuberculosis burden in HIV patients.

DESIGN: This study used explanatory sequential mixed methods; quantitative data collection and analysis followed by qualitative data collection and analysis.

METHODS: The quantitative phase was followed by data collection and analysis of the qualitative phase. Structured and semi-structured interview guide questionnaires were used to collect both quantitative and qualitative data. A total of 252 patients and 12 health care providers enrolled in quantitative and qualitative study respectively. Simple random sampling method was used for quantitative study. Descriptive statistics was used, and percentages were calculated. Bivariate and multivariate logistic regressions were applied to identify associations between variables. In subsequent qualitative section of the study, health care providers were interviewed. Qualitative data was organized in themes and analysis was done manually.

RESULTS: Quantitative and qualitative data was analyzed subsequently. Of the 252 study participants, 56.7% of the participants were provided with tuberculosis preventive therapy. However, only 43.3% completed the prescribed treatment within the specified period. In logistic regression analysis, participants' gender (P=0.032), residence (P=0.020), viral load suppression status (P=0.037), awareness and

information on IPT benefit (P=0.000), awareness on IPT reduce the occurrence of tuberculosis (P=0.017), was found significantly associated with IPT acceptance. In addition, in an indepth interview of health care providers: patient's refusal, non-completion, inadequate providers counseling and patient education practices, misconceptions and misunderstandings of patients about IPT, fear of drug resistance, pill burden and drug side effect, lack of training and education guide were identified barriers for IPT implementation.

CONCLUSION: Uptake of isoniazid preventive therapy in PLHIV in a tertiary hospital is sub-optimal and the completion rate among initiated IPT was found low. Intervention focused on initiation as well as completion of IPT needed. Consequently Health education guide developed to improve IPT uptake; client focused individual counseling; BCC and the need for initiation of short term TPT regimens were recommended.

Key terms: Latent TB, TB/HIV, PLWHIV, IPT, Non-completion, Patient education, Misconception, Education guide, Tertiary Hospital, Ethiopia

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LIST OF ABREVATIONS AND ACRONYMS

AAU	**Addis Ababa University**
ABM	**Andersons' behavioral model**
AIDS	**Acquired immune deficiency syndrome**
CD4	**Cluster Differentiation 4**
CHS	**College of Health Sciences**
CI	**Confidence interval**
COR	**Crude odds ratio**
COP	**Country operational plan**
EPHI	**Ethiopian public health institute**
FMOH	**Federal ministry of health**
HIV	**Human immune deficiency virus**
IPT	**Isoniazid preventive therapy**
IEC	**Information education communication**
IGRA	**Interferon-gamma release assay**
ICF	**Intensified case finding**
IC	**Infection control for tuberculosis**
LTBI	**Latent tuberculosis infection**
MOH	**Ministry of health**

PWHIV	**People with HIV**
PNP	**Peripheral neuropathy**
ROP	**Regional operational plan**
SOP	**Standard operating procedure**
SPSS	**Statistical Package for Social Science**
TASH	**Tikur Anbessa Specialized Hospital**
TST	**Tuberculin skin test**
TB/HIV	**Tuberculosis and HIV co-infection**
TB	**Tuberculosis**
TPT	**Tuberculosis preventive therapy**
UN	**United Nations**
UNAIDS	**United Nations Programme on HIV/AIDS**
UNISA	**university of South Africa**
WHO	**World health organization**

CHAPTER ONE

ORIENTATION TO THE STUDY

1.1. INTRODUCTION

According to United Nations Programme on HIV/AIDS, tuberculosis (TB) is the most common opportunistic disease and major cause of mortality among persons living with human immunodeficiency virus (HIV), accounting for one in every three AIDS-related death worldwide in 2018 (UNAIDS, 2019:3). TB was also, until the coronavirus (COVID-19) pandemic, the leading cause of death from a single infectious agent, ranking ahead of HIV/AIDS (WHO, global TB report, 2021:14). In 2020, an estimated 10.0 million people (127 cases per 100,000 population) will contract tuberculosis worldwide, with an anticipated 1.3 million HIV-negative deaths and an additional 214, 000 HIV-positive deaths, up from the 2019 TB report (WHO Global TB report, 2021:1-7). People with HIV (PWHIV) have a higher risk of contracting tuberculosis (TB) than those who do not. As a result, those living with the human immunodeficiency virus are 20 to 37 times more likely to get tuberculosis than those who have not been infected with HIV (Geleto, Abate and Egata 2017:36; WHO consolidated guidelines on tuberculosis: 2020:3).

Around 37.7 individuals (30.2- 45.1) were living with HIV in 2020, with 1.5 million new infections (1.0 million -2.0 million). In the same year, 680,000 individuals living with HIV (between 480000 and 1 million) died of AIDS-related illnesses (United Nations Program for HIV/AIDS, 2021:1).Since the beginning of the HIV/AIDS epidemic, 79.3 million people (55.9 million–110,000 million) have been infected with HIV, and 36.3 million (27.2 million–47.8 million) have died of AIDS-related illnesses like tuberculosis and Kaposi's sarcoma (UNAIDS 2021:1; Ethiopian Ministry of Health 2017: 90–117).

Eastern and Southern Africa have been hit the hardest by the HIV/AIDS epidemic. In Eastern and Southern Africa, 20.6 million (16.8 million-24.4 million) people were living with HIV in 2020 (United Nations Program for HIV/AIDS 2021: 5). In Sub-Saharan Africa, women and girls accounted for 63% of all new infections (United Nations Program for HIV/AIDS, 2021:3). In 2020, 670 000 (470 000- 930,000) new HIV infections were estimated in Eastern and Southern Africa, accounting for 47% of global new HIV infections (United Nations Program for HIV/AIDS; 2021: 1-3). According to the Ethiopian

Public Health Institute's 2018 HIV-related estimate and prognosis, 729,089 Ethiopians were living with HIV in 2017 (Ethiopian public health institute: 2017: 1). Tuberculosis is still the major cause of death among HIV-positive patients, accounting for almost one-third of all AIDS-related deaths. However, nearly 60% (57%) of tuberculosis cases in HIV-positive people were neither recognized nor treated (United Nations Joint Program for HIV/AIDS 2017: 2).

According to the World Health Organization, 1.3 million HIV-negative persons and 214,000 HIV-positive people would die of tuberculosis in 2020, making tuberculosis one of the top ten causes of mortality worldwide. In 2020, the WHO African regions would have more than half of the world's TB and HIV co-infected population. Furthermore, the WHO African and South-East Asia regions accounted for roughly 85% of TB mortality in both HIV-positive and HIV-negative adults (WHO, Global Tuberculosis report, 2021:7, 9, 22). According to the Global Tuberculosis Report, Ethiopia is one of the 30 countries with a high TB and TB/HIV burden (WHO Global Tuberculosis report, 2021:35).

At the current moment, Ethiopia has a population incidence rate of 140/100,000 individuals (157,000 people per year) and 21000 TB-related deaths, up from 19/100,000 in 2018. Ethiopian TB, TB/HIV, DR-TB guideline, 2021:186-189) showed an 8-9 percent annual drop in TB incidence, from 421/100,000 in 2000 to 140/100,000 in 2019. In recent years, Ethiopia has seen a decrease in tuberculosis mortality, however at a slower rate than the decrease in incidence (Ethiopian TB, TB/HIV, DR-TB guideline, 2021:186-189).

In addition, a comprehensive study and meta-analysis of dual epidemics (TB/HIV co-infection) in Ethiopia indicated a pooled prevalence of 25.59%, showing that TB/HIV co-infection is becoming more widespread (Tesfaye, Alebel, Gebrie, Zegeye, Tesema and Kassie, 2018:9). In 2020, 108,196 patients with various forms of tuberculosis were notified to the national program, increasing total TB treatment coverage to 71%. Males were more affected, accounting for 56% of notified cases, while children under the age of 14 accounted for 9.9% (Ethiopian TB and TB/HIV guideline, 2021:15). Despite collaborative TB/HIV activities, TB remains the leading cause of death among HIV-positive people in Ethiopia, accounting for approximately 40% of all AIDS-related deaths (Ethiopian TB and TB/HIV guideline, 2021:16).

1.2. BACKGROUND INFORMATION

There are two forms of tuberculosis infection. These are active and latent forms of tuberculosis. During the latent tuberculosis infection state, there will be a form of persistent immune response to stimulation by Mycobacterium tuberculosis bacteria that enters the human body without developing clinically apparent active tuberculosis (CDC, 2021:5).

Those with weakened immune systems, particularly those with HIV infection or other immune suppressive disorders, have a substantially higher chance of contracting tuberculosis disease (Tesfaye et al., 2018:14; Ethiopian TB, TB/HIV guidline, 2021:18).

Almost a quarter of the world's population is infected with latent tuberculosis (WHO, global TB report 2021:31). People who have latent tuberculosis infection do not have active tuberculosis disease and hence cannot transmit the disease. Reactivation of tuberculosis, on the other hand, can result in the formation of clinically apparent tuberculosis at any time during a person's life (WHO global TB report 2021:31).

Tuberculosis disease develops when latent tuberculosis or tuberculosis bacteria, which have been dormant for years due to a healthy immune system, are activated, and cause active tuberculosis (FMOH 2018:97). A person with a documented latent tuberculosis infection has a five to ten percent (5- 10%) lifetime probability of developing active tuberculosis, with the majority of cases occurring within the first five years after infection. The risk of contracting tuberculosis is considerably increased in the presence of predisposing circumstances that lower an individual's immunity, such as infection with the Human Immunodeficiency Virus (WHO global TB report 2021:31).

TB and HIV have a complicated and mutually beneficial interaction. HIV weakens people's immune systems, making them more susceptible to tuberculosis and increasing the likelihood of latent tuberculosis infection reactivation, reinfection, and progression to active TB disease (Anochie, Ajogwu, Kalu, Akpan, Onyeneke, et al., 2018:27; Abdulwasiu, Kazeem, Ifedolapo, et al. 2021:2).

The human immunodeficiency virus (HIV) alters the clinical presentation of tuberculosis, complicates follow-up, and affects therapy response (Fassikaw, Birhanu, Tsehay and

Melaku, 2021-1; Anochie et al., 2018:27; Winter, Smith, Davidson, et al.,2020:1-2). Hence, in order to minimize the burden of tuberculosis, WHO advocated the three I's approach:

- Infection control (IC)
- Isoniazid preventive therapy (IPT) and
- Intensified case-finding (ICF)

1.2.1. Intensified case-finding

At each visit, an adult or adolescent living with HIV (PLWHIV) should be assessed for tuberculosis using a clinical algorithm or screening tool. A current cough, fever, weight loss, or night sweats in adults and adolescents, as well as poor weight gain, fever, current cough, or a tuberculosis case history in HIV-positive children, may indicate tuberculosis and should be checked for tuberculosis and other infections. If a patient's tuberculosis screening is negative, Isoniazid preventative therapy should be administered regardless of age (WHO 2018:5; Ethiopian TB, TB/HIV, DR-TB Guidline 2021:186-189).

1.2.2. Infection prevention and control

People living with HIV are more prone to get tuberculosis in health care facilities and other places where people congregate (TB). To prevent TB transmission in health care and communal settings, TB infection control plans for health care institutions should include managerial, environmental, and personal protection techniques, as well as TB disease surveillance among personnel. IPT should be administered to HIV-positive health-care workers in addition to ART if they are eligible. The recommended and important actions for infection control:

Administrative infection control at facility-level

- Set up a screening system to segregate people suspected of having tuberculosis.
- Separate people with suspected or proven tuberculosis.
- Teach coughing patients to wear masks and follow other safety precautions (use of cough protocol and respiratory hygiene).

Health care providers working on TB Treatment:

- Provide HIV-positive health care workers with an appropriate package of care (Antiretroviral therapy and tuberculosis preventive therapy)
- Provide protective equipment (particulate respirator masks that meet N95 standards or better)
- Assign HIV-positive health care workers to a lower-risk area
- Surveillance and information

Environmental protection

- Make mechanical ventilation available
- Use working area or (working rooms) with adequate natural ventilation

Personal protection

- Spend as much time as possible outdoors
- Cough protocol
- Smear-positive person for TB should sleep alone when the person is positive
- Avoid gathering places and public transportion while smear-positive (Ethiopian TB, TB/HIV guidline, 2021:186-189; WHO guidelines on tuberculosis infection prevention and control, 2019:11-27).

1.2.3. Isoniazid preventive therapy

Isoniazid Preventive Therapy (IPT) is the use of the drug isoniazid to treat latent tuberculosis infection. As a result, isoniazid is given to persons who have latent Mycobacterium tuberculosis infection in order to keep the infection from becoming active. Screening for active TB in HIV-positive patients is the most important step before initiating isoniazid preventive therapy (FMOH 2018: 100-101; Fox, Dobler, Marais & Denholm, 2017:70; Ethiopian national consolidated guidelines for comprehensive HIV prevention, care and treatment, 2018:97). Regardless of CD4 count, antiretroviral therapy uses, previous tuberculosis treatment history, or pregnancy and people with HIV who do not have active tuberculosis should receive isoniazid preventative treatment (IPT, TPT) for at least six months as part of a comprehensive HIV care package (Ethiopian TB, TB/HIV guideline, 2021:62-64).

Persons who have been checked for active tuberculosis using a specific screening algorithm and found to have a low risk of developing tuberculosis disease can begin IPT (Ethiopian TB & TB/HIV guideline, 2021:62-663). Before initiating isoniazid treatment, it's critical to check for active tuberculosis and rule out infection. Depending on the source of infection, a full course of tuberculosis treatment should be commenced for at least six months if a patient tests positive for active tuberculosis during screening (Ethiopian TB, TB/HIV guideline, 2021:62-64).

The screening algorithm includes determining whether there is a presence or absence of cough, fever, weight loss, or night sweats. The lack of all of these signs and symptoms can aid in the identification of HIV-positive adolescents and adults who are not infected with tuberculosis. This screening criteria provides a negative predictive value of 97.7% (95 percent CI 97.4–98.0) at a tuberculosis prevalence of 5% among HIV-positive patients. The screening tool's negative predictive value of 97.7% shows that it can detect 97.7% of true TB negatives. If a child has poor weight gain, fever, or a current cough, the provider can identify those who are likely to have tuberculosis, and IPT should be stopped for a period while they are evaluated for active tuberculosis treatment (Ethiopian TB, TB/HIV guideline, 2021:62-63).

In multiple trials, IPT has been found to prevent tuberculosis, improve the effect of antiretroviral therapy, and reduce the prevalence of new tuberculosis, morbidity, and death, while also being cost effective (Abossie & Yohanes, 2017:366; Pathmanathan, Ahmedov & Pevzner, et al., 2018:9; Busari, Oshikoya, Adejumo, 2021:2). Furthermore, studies in Ethiopia indicated that finishing isoniazid preventative therapy reduced the incidence of active tuberculosis by 96.3% (Semu, Fenta, Medhin, and Assefa, 2017:7) and 50% (Assebe, Reda, Wubneh, Lerebo, Lambert, 2015:8), respectively, when compared to people who did not take it.

According to a meta-analysis of Ethiopian studies, IPT reduced the risk of active tuberculosis by 74% in the IPT exposed group compared to the non-IPT exposed group (Geremew, Endalamaw, Negash, Eshetie, and Tessema, 2019:5-8). In general, according to these studies isoniazid preventive therapy reduces the occurrence of active tuberculosis. With these factors, the WHO and Ethiopian tuberculosis and HIV implementation guidelines advised that isoniazid preventive therapy be provided as one of the public health interventions for tuberculosis prevention in HIV-positive patients.

Despite this, a number of studies have found that isoniazid preventive therapy coverage, implementation, adherence, and completion rates in Ethiopia are low (suboptimal) (Abdulalim, Garuma, Dibaba and Chaka 2017:4; Assebe et al, 2015:8; Teklay, Teklu, Legesse, 2016: 840 and Demelash, Belaynew and Yeshalem, 2015: 830). This study was designed to promote understanding and use of Isoniazid preventive therapy amongst HIV positive patients and develop health education guide. Therefore, it contributes to the optimum uptake and completion of isoniazid preventive therapy among patients with HIV and further provides input to the reduction and control of incidence of tuberculosis.

1.2.4. MOTIVATION TO THE STUDY

There were three different sources of this research problem. Firstly, the investigator has previous experience in tuberculosis and HIV collaborative services. During these service years, a huge gap was observed in implementing tuberculosis preventive treatment for people living with HIV on follow-up in the study institution and patients unable to take isoniazid preventive therapy.

The second source of the research problem is the review of different literature sources in Ethiopia related to low isoniazid preventive therapy implementation in spite of WHO and Ethiopian ministry of health recommendations. It is strongly advised for adults and adolescents living with HIV who have an unknown or positive tuberculin skin test (TST) and are unlikely to have active TB to get TB prevention treatment as part of a comprehensive HIV care package regardless of the degree of immunosuppression and also to those on antiretroviral treatment (ART), sub optimum uptake and utilization of TB preventive treatment was observed and reported in Ethiopia. The last source of the research problem was unavailability of the data in similar tertiary level specialize teaching Hospital in Ethiopia.

1.2.5. STATEMENT OF THE RESEARCH PROBLEM

Tuberculosis remains the leading cause of morbidity and mortality among people living with HIV/AIDS (United Nations Joint Program for HIV/AID. 2017: 2; Ethiopian Ministry of Health TB, TB/HIV, DR-TB and Leprosy Guideline 2021:15; Khatri & Davis. 2020:21). The risk of acquiring tuberculosis among people living with the human immunodeficiency virus is 20 to 37 times higher than those who have not been infected with human immune

deficiency virus (Belete, Demissie, Gebreegziabher & Kassa et al. 2017:2; Aboma & Nida, 2021:2). Globally, in 2020, there were about 1.3 million (1.2–1.4 million) deaths among HIV-negative people and an additional 214 000 (187 000–242 000) deaths among HIV-positive people which showed a small increase from 209 000 (178 000–243 000) in 2019 (WHO, global TB report, 2021:7).

Furthermore, TB claims the lives of 32,000 Ethiopians each year (Randal and Sahil, 2016:7-10). In 2018, the estimated TB/HIV coinfection rate was 7%, while Isoniazid preventative therapy for newly enrolled HIV patients remained low (49%). Treatment coverage among notified cases was 69%, with 31% missed cases in the same year (Khatri & Davis. 2020:21-22).

The World Health Organization recommends isoniazid preventive therapy as a major tuberculosis control method to reduce tuberculosis incidence, morbidity, and death among HIV-infected adults (WHO, Latent tuberculosis infection Updated and consolidated guidelines for programmatic management 2018:1-3).

The WHO latent tuberculosis infection treatment guideline (WHO 2018:9) and Ethiopian government guidelines for tuberculosis and HIV implementation (Ethiopian ministry of health 2017:98) both recommend isoniazid preventive therapy for people with HIV who have been screened negative for active tuberculosis using a screening tool. However, uptake and completion of TB preventive therapy or IPT in Ethiopia is low. According to the Ethiopian federal ministry of health national tuberculosis control program report; provision of tuberculosis preventive therapy for newly enrolled people living with HIV in 2015 surveillance reporting period was 18.2% (Belete, Demissie, Gebreegziabher & Kassa et al., 2017:1,4).

Reviewing patients' medical records in Ethiopian regions revealed limited implementation, uptake, and completion of isoniazid preventive therapy (Teklay et al 2016:1-2). According to a study in Ethiopia, s ome of the issues with low IPT adoption and implementation among persons living with HIV may be due to issues with providers or clinicians. Clinicians' knowledge, attitudes, and beliefs about IPT were among the factors impacting or facilitating IPT.

Clinicians believed that IPT causes medication resistance and has a negative impact on patients had low IPT performance, while providers who had undergone TB/HIV training were found to be favorably associated with high IPT uptake (Lai, Dememew, Jerene, et al. 2019:1-6). In other studies, researchers advised that health workers, customers, and the general public be educated about isoniazid preventive therapy (IPT) by providing training and distributing IEC (information, education, and communication) materials. Studies else where on IPT uptake and completion also showed IPT-related health education and counselling of patients as the main facilitator (Ngugi, Muiruri, Odero, et al., 2020:6-7).

In addition, a study in Uganda on barriers and facilitators to TB preventive therapy revealed some of the barriers like inadequate understanding of IPT, fear of potential side effects, concerns about the effectiveness of IPT, potential pill burden which indicates the need for strong information education and communication recommended as a strategy to improve uptake and implementation of IPT (Semitala, Musinguzi, Ssemata, et al., 2021, 5-10).

During situational analysis in the study institution, the researcher discovered eligible patients who had not been started on isoniazid preventive therapy, and some of the patients who had been started on isoniazid preventive therapy had not completed (discontinued) their recommended six-month dose, indicating that more research is needed. In order to identify impediments to Isoniazid preventive medication uptake and completion, researchers collected primary data from patients and reviewed their medical records. This study also discovered factors that influence isoniazid preventive treatment uptake and completion.

Furthermore, no analogous investigation was conducted in an Ethiopian tertiary health facility. The results of this study are expected to add to the body of knowledge that informs TB/HIV program planners, decision-makers, and project implementers by providing evidence-based information on determinants, rate of uptake, and completion of isoniazid preventive therapy.

1.2.6. BACKGROUND INFORMATION ABOUT ETHIOPIA

Ethiopia is located in the Northeastern part of the African continent in the “Horn of Africa” with a total surface area of 1.1million square kilometers. Ethiopia is surrounded by Sudan on the west, Eritrea and Djibouti on the northeast direction, Somalia to the east end and southeast, and Kenya on the south. Ethiopia lies between the Equator and Tropic of Cancer, between the 3^0 N and 15^0 N Latitude or 33^0 E and 48^0 E Longitude. Administratively, Ethiopia is structured into ten regional states namely Tigray, Afar, Amhara, Oromya, Somali, Benishangul-Gumuz, Southern Nations Nationalities and People, Gambela, Sidama and Harari and two city administrations, namely Addis Ababa and Diredawa. Ethiopia is the tenth largest and the second most populated state in Africa next to Nigeria (CIA World fact book, 2018).

Ethiopia was controlled by emperors and kings with a feudal style of administration until 1974, when the country was administered by a military government. There is currently a federal government in place, with political leaders being elected every five years (CIA World fact book, 2018:1).

1.2.7. ETHIOPIAN POPULATION AND HEALTH CARE SYSTEM

According to the latest United Nations Department of Economic and Social Affairs Population Division estimates or World Population Prospects, the population of Ethiopia in 2018 was 107,315,465. Ethiopia is a predominantly agricultural country, and more than 80% of the population lives in rural areas. The capital city of Ethiopia, Addis Ababa, had an estimated population of 7.178 million in 2018. The city is the place where the African Union is based.

The Ethiopian health care delivery system has three stages (levels):

- The primary level health care system (Health posts, Health center and primary Hospitals)
- The secondary level (General Hospitals)
- The tertiary level (Specialized Hospitals)

At the primary health care level, each health post, health center and primary hospital serve populations of 3000-5000, 15000-25000 and 60,000-100,000 people respectively. Secondary level general hospital serve 1-1.5 million and tertiary level specialized hospital serve 3.5-5 million people (Argaw, Desta, Bele & Ayne, 2019:5).

The operation of the health system in Ethiopia has been decentralized to regional governments and district health offices below them. Each district has a primary hospital with multiple health centers, and every health center is administratively linked to five health posts which is the lowest level of Ethiopia's health care delivery system. Each neighborhood has its own health post with two health extension workers who provide a package of up to 16 basic services to rural populations, including tuberculosis prevention and treatment follow-up. Ethiopia's Federal Ministry of Health supervises a National Tuberculosis and Leprosy Control Programme that functions at national and regional levels with the goal of using the health extension workers program to ensure the equitable provision of tuberculosis control services (Randal and Sahil; 2016: 11).

1.3. AIM, OBJECTIVES AND RESEARCH QUESTIONS OF THE STUDY

1.3.1. Research purpose

The purpose of this study is to develop health education guide for improving understanding of the use, uptake and completion of Isoniazid preventive therapy, and reducing the burden of tuberculosis in HIV-positive patients.

1.3.2. Research objectives

The objectives of this study were to:

- Determine Isoniazid preventive therapy uptake and completion rate among HIV-positive patients on follow-up at Tikur Anbessa specialized Hospital.
- Identify determinants of the uptake and completion of Isoniazid preventive therapy among HIV-positive patients.

- Identify Isoniazid preventive therapy implementation challenges to health care providers.
- Assess understanding of the benefit of Isoniazid preventive therapy among patients who live with HIV.
- Develop health education guide on Isoniazid preventive therapy for health care providers use**.**

1.3.3. Research questions

1. What is the uptake and completion rate of Isoniazid preventive therapy among HIV-positive patients on follow-up at Tikur Anbessa specialized Hospital?
2. What are the determinants of the uptake and completion of Isoniazid preventive therapy among HIV-positive patients?
3. What are the isoniazid preventive therapy implementation challenges to health care providers?
4. Is there understanding of the benefits of Isoniazid preventive therapy among patients who live with HIV?
5. Is there developed health education guide on Isoniazid preventive therapy for health care providers use?

1.3.4. Significance of the study

Isoniazid preventive therapy (IPT) was found to be effective and one of the strategies of tuberculosis control to reduce incidence of TB. However, provision, uptake and completion of Isoniazid preventive therapy is facing a challenge in resource limited settings. As different studies indicated that lack of information, communication and health education were identified as barriers. Therefore, health education guide developed might help to increase patient's knowledge, awareness (understanding of the use of Isoniazid preventive therapy) and contribute to the improvement of uptake and completion of Isoniazid preventive therapy in patients living with HIV. Moreover, this study provided evidence-based information and input for implementers and policy makers to prevent incidence of tuberculosis in Ethiopia and hence this also contributed to the global end TB strategy which has the 2035 targets of a 95% reduction in TB deaths and a 90% reduction in the TB incidence rate, compared to levels in 2015.

1.4. DEFINITIONS OF KEY CONCEPTS

Isoniazid preventive therapy (IPT): Isoniazid preventive therapy in this study refers to the provision of Isoniazid treatment for the prevention of inactive (latent form) form of tuberculosis for HIV positive people to prevent further development of active form of tuberculosis after screening for the absence of symptoms indicating the occurrence of active TB.

Isoniazid preventive therapy initiation: HIV-positive people, eligible to take isoniazid preventive therapy, prescribed and initiated and who actually started to take IPT.

Isoniazid preventive therapy completion: HIV positive people who were started on isoniazid preventive therapy and completed within six to nine months of therapy initiation.

Latent tuberculosis infection (LTBI): It is the occurrence of in active TB infection without signs and symptoms of active form of TB. It is also the presence of immune responses to mycobacterium tuberculosis antigens without clinical evidence of active tuberculosis. Most people with latent (Hidden) tuberculosis infection have no signs or symptoms of TB disease and are not transmitting the disease. However, they are still at risk of developing active TB disease and becoming infectious.

Health personnel (Health care provider): refers to a person who provides health care services either as a member of an institution(s) or as an individual practitioner or people engaged in the promotion, prevention or improvement of the health of the population (example; nurses, health officers, doctors, pharmacist, counselors).

Isoniazid preventive therapy uptake (IPT): Acceptance to take Isoniazid drug provided by health care providers for the treatment of latent tuberculosis infection to prevent the occurrence of incidence tuberculosis.

1.5. THEORETICAL GROUNDING/THEORETICAL FRAMEWORK

The theoretical framework serves as the “blueprint” or “road map” for the whole research investigation. It serves as the guide for constructing and sustaining the research (Adom, Hussien, Agyem, 2018:438). A framework for research is defined by Kivunja (2018:46) as a structure that guides the researcher while study questions are adjusted, methods for measuring variables are chosen, and analysis is planned (Kivunja, 2018:45-46). After the data has been collected and processed, the framework is used as a mirror to see if the findings match the framework or if there are any inconsistencies; if there are any disparities, the question is whether the framework can be used to explain them. This study was guided by Anderson Behavioral Model (ABM) which is a health-care utilization model. The Anderson’s (1968; 1995) model of health care service use was primarily used in the 1960s (Hirshfield, Dowing, Harvath, Swartz & Chiasson 2018:789). The model was initially designed to explain how people use health services with the emphasis on the family level. It was later modified and adapted to anticipate personal consumption of wellbeing services at a personal level. The Anderson Behavioral Model elements such as predisposing factors, enabling factors and need factors have been utilized to direct the investigation of predictors related with different health outcomes, for example HIV medication use among PWHIV (SoleimanvandiAzar, Kamal, Sajjadi., 2020:405-420).

This model can also be used to investigate the relationship between predisposing factors, enabling factors and need factors in the use of health care (SoleimanvandiAzar, Kamal, Sajjadi., 2020:405-420; Li, Nong, Wei, Feng & Luo, 2016:2; Kim & Lee 2016:19-20; Andersen, 1968:14-16). The purpose of this study was to see how predisposing factors (intrinsic characteristics of the patient), enabling factors (resources or tools that encourage health-care usage), and need factors (perceived need based on a patient's own health-care beliefs and value system that affects a person's acknowledgement of need) affect tuberculosis preventive therapy (IPT) service utilization (SoleimanvandiAzar, Kamal, Sajjadi, 2020:405-420). The main purpose of using this Andersen’s Behavioural Model is because of its comprehensiveness in factor clasifications to identify various enabling factors, need factors and predisposing factors that lead to tuberculosis preventive therapy use and to understand how these different factors affect health behavior and outco

1.5.1. Predisposing Factors

Predisposing factors are characteristic variables that occur prior to disease which influence a person's attitudes toward using health care. Patients' well-being views (attitudes, values, and information about and in relation to the health-care system) are among these factors such as demographics (age, gender), social factors (education, occupation and ethnicity) and wellbeing beliefs of patients (attitudes, values, and information about and in relation to the health care system) influence the attitudes of a person towards the utilization of health care services (SoleimanvandiAzar, et al., 2020:409,416).

1.5.2. Enabling Factors

Enabling factors refers to personal causes (individual income and availability of health insurance), community causes (social support and a daily basis of treatment, availability of family network and suport, distance from health care sercice, degree, and quality of social relationships, availability of health workers and services, health and health care related literacy, and waiting time to get the required health care service) are all examples of resources that encourage or hinder the employment or use of health care (SoleimanvandiAzar, et al., 2020:416-418).

1.5.3. The Need Factors

This is what the individual understands the importance of receiving health care service by him self. Need factors reveal the situation of the person who has access to health care facilities. These consist of perceived need (perceptions of disease) and measured need (perception of disease), and the health condition of the sick person (Kim et al 2016:19-20). Need factors, on the other hand, are the most immediate cause of the use of health services, from a functional and health concern that produces the need for health care services SoleimanvandiAzar, et al., 2020:418).

The conceptual framework for the study assists research discussion and clearly indicates the primary issue to be investigated (Kivunja, 2018:45). This study was conducted using the conceptual framework of Andersen's Behavioral Model of Health service use as outlined below.

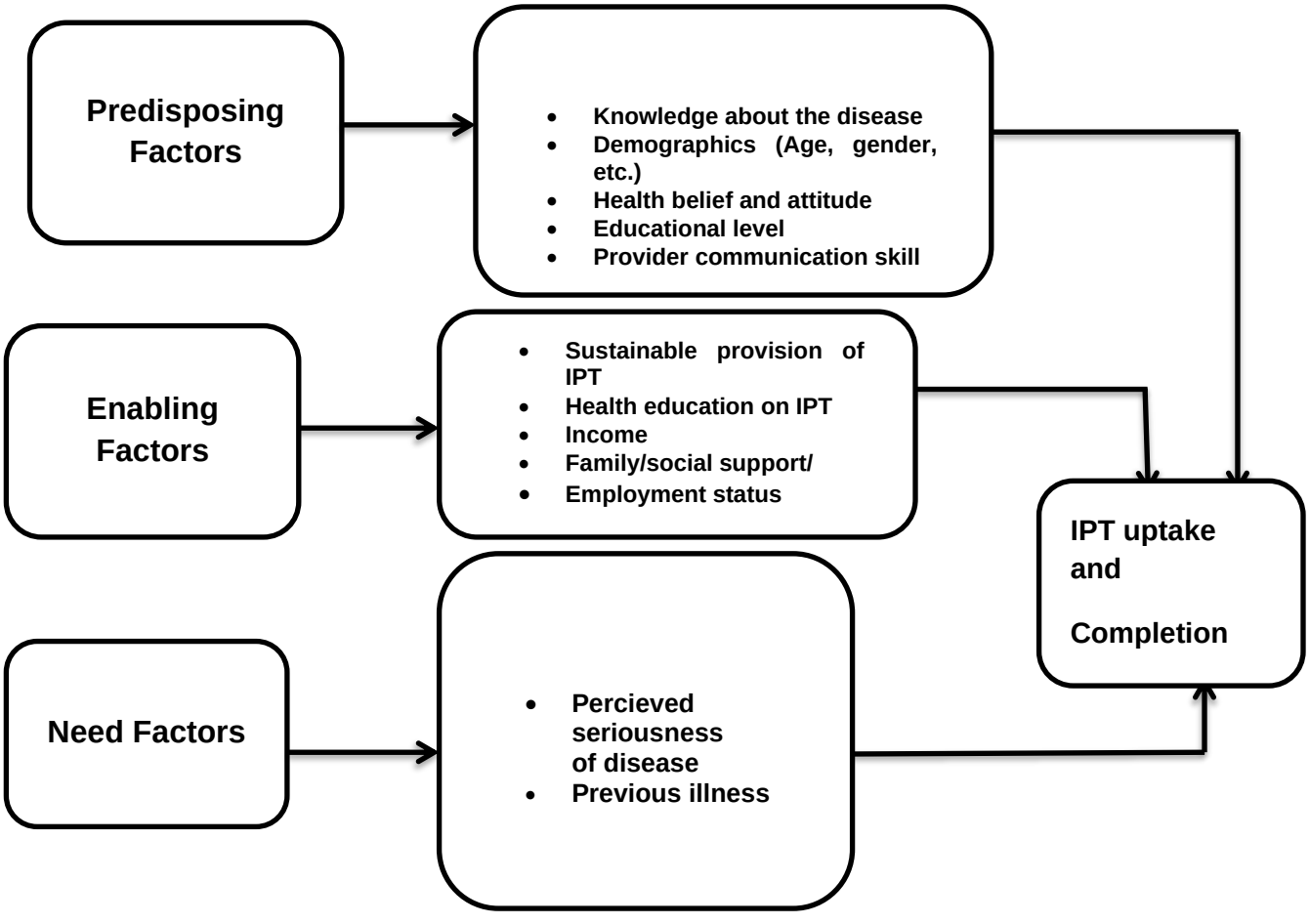


Figure.1.1: A conceptual framework adopted from Andersen's Behavioral Model of Health service use (Andersen, R.M., 1995).

1.6. Research paradigm

The research paradigm is defined as the researcher's fundamental set of beliefs that guide him or her through the process of the research (Kivunja and Kuyini, 2017: 26). It is a fundamental belief system and theoretical framework with assumptions about ontology, epistemology, methodology and axiology (Kivunja & Kuyini, 2017: 26; Shannon-Baker, 2016: 321). A research paradigm is defined as a set of beliefs, values, attitudes and assumptions that researchers have in common regarding the nature and conduct of research or how things function (Brown & Dueñas, 2019:2). Hence, paradigms are defined as a set of guidelines that a researcher might utilize to guide their research

(Shannon-Baker 2016:321). The word paradigm comes from Greek word paradigm which means pattern. In 1962, Thomas Kuhn, an American philosopher, used the term paradigm to describe a philosophical way of thinking. In educational research the term paradigm is used to explain a researcher's 'worldview'. This world view reflects the meaning or interpretation of research data through a perspective or way of thinking, a school of thought, or a collection of common beliefs (Creswell & Clark, 2018:95). The researcher's opinions about the world in which he or she lives and wants to live are reflected in the research paradigm. It comprises the abstract beliefs and principles that shape how a researcher understands the world, as well as how she or he interprets and acts within that world. As a result, when it is said that a paradigm shapes the researcher's worldview, it indicates that a paradigm is made up of abstract beliefs and principles that affect how a researcher perceives the world, as well as how s/he interprets and behaves in it (Creswell & Clark, 2018:54). It is a paradigm that defines the researcher's worldview (Creswell & Clark, 2018:54). It's the frame of reference through which a researcher examines the world. It is the conceptual prism through which a researcher evaluates the methodological parts of their research endeavor in order to determine how the research and data analysis methodologies will be applied (Kivunja and Kuyini, 2017: 26-27).

A paradigm, according to Creswell & Creswell (2018:46), is a basic set of beliefs or worldview that guides research action or enquiry. According to Kamal (2019:3), paradigms are human constructions that deal with first principles that indicate where the researcher is coming from in order to generate meaning from data and evidence. As a result, paradigms are significant because they provide principles and directives that impact what should be investigated, how it should be studied, and how the study's results should be interpreted by scholars in a particular discipline. The paradigm defines a researcher's philosophical orientation and has significant implications for every decision made in the during the research process, including selection of methodology and methods. Therefore, a paradigm outlines on how we will construct meaning from the data we collect based on our own experiences.

As a result, It is very important, that when developing research proposal, the paradigm that will be used to located the research be stated clearly (Kivunja & Kuyini 2017:26-27). A paradigm comprises of elements, namely, epistemology, ontology, methodology and

axiology (Dawadi, Shrestha, & Giri, 2021:26). It is critical to have a firm understanding of these elements because they include each paradigm's essential assumptions, beliefs, norms and values. As a result, when locating the study proposal within a particular research paradigm, investigator should keep in mind that the research should adhere to and be driven by the chosen paradigm's assumptions, beliefs, norms, and values (Brown & Dueñas, 2019:2-8). It is therefore important to demonstrate that we know what each of these elements mean. The researchers of this study believed that while some of the realities in health of PWHIV can be measured objectively (TB preventive therapy service access), others can be constructed. Therefore, both objectivists and subjectivists ontologies were applied as the researchers aimed to uncover various categories of reality in people with HIV. Health service use and implementation can be investigated objectively but realities related to the nature and cause for no service coverage, low uptake of IPT, low completion rate, can rather be constructed through providers and patients lived experiences which can not be investigated objectively.

1.6.1. Pragmatism

The current study used the paradigm type called pragmatist paradigm. Pragmatism worldviews derived from the work of Peirce, James, Mead, and Dewey (Creswell & Creswell, 2018:51). There are various forms of this philosophy, but many people believe that pragmatism as a worldview emerges through actions, situations, and consequences rather than antecedent conditions (Creswell, 2018:51). Action and change, as well as the link between knowledge and action, are central to pragmatism. This makes it suitable as a foundation for research approaches intervening into the world and not only observing the world (Creswell & Creswell, 2018:123). The use of pragmatism in this study is due to the fact that it is not committed to any one system of thought or reality. However,it applies to mixed methodologies research in that investigators or researchers use extensively a combination of both quantitative and qualitative assumptions when undertaking their study (Dawadi, Shrestha & Giri, 2021:25-27). Researchers are allowed to choose the study methodologies, strategies, and processes that best suit their needs and goals in this approach. Pragmatists do not believe the world as an absolute unity. In a similar way, mixed methods researchers use a variety methodologies and approaches to collect and analyzing data rather than sticking to a single method, such as quantitative or qualitative analysis (Dawadi, Shrestha & Giri, 2021:26). The underlying assumption of this type of

study is that combining qualitative and quantitative methods yields a more comprehensive grasp of a research problem than using either method alone (Creswell & Creswell, 2018:62; Dawadi, Shrestha & Giri, 2021:27-28). The researcher's choice of a research paradigm is therefore depended upon his or her ontological, methodological and epistemological assumptions. The literature revealed several paradigms such as post-positivism, pragmatism, transformative, constructivism, and many other paradigms to inform qualitative and quantitative research (Dawadi et al. 2021:25). This study adopted a pragmatist paradigm, as its assumptions are matching with the study's methodology, and methods of data collection and analysis. Below is an explanation of the paradigmatic assumptions' ontology, epistemology and methodology.

1.6.2. Epistemology

Epistemology gets its name from the Greek word episteme, which means knowledge. In research, epistemology is used to describe how we come to know something; how we know the truth or reality (Palermo, Reidlinger and Rees, 2021:252-253; Dawadi et al. 2021:26); or what constitutes knowledge within the world. It is concerned with the very foundation of knowledge, its nature, and forms as well as how it can be acquired, and how it can be communicated to other human beings. It focuses on the nature of human knowledge and understanding that the researcher may be able to obtain in order to extend, broaden and deepen understanding in their field of study (Rehman and Alharthi 2016:51 and Kivunja & Kuyini, 2017:27). The epistemological basis of research is intuitive knowledge if a researcher relies on kinds of knowledge such as beliefs, faith, and intuition. If a researcher depends on data obtained from experts, books, and business leaders, organizations then the epistemology is based on authoritative knowledge. If you put emphasis on reason as the surest way to knowing the truth, then this approach is called rationalist epistemology or logical knowledge. On the other hand, if some one puts emphasis on the understanding that knowledge is best derived from sense experiences, and demonstrable, objective truths, then the approach leans towards empirical epistemology.

Epistemology is important because, it helps in the establishment of the trust you put in your data (aids in the establishment of your data's trustworthiness). It has an impact on how you go about uncovering knowledge in the social settings that you are going to investigate (Kivunja & Kuyini 2017:27). Researchers who believe in positivism utilize

empiricist epistemology, whereas those who believe in interpretivism employ interpretivist epistemology. The researcher of this study believed that the determinants of tuberculosis preventive therapy nature, health service use and coverage are variable with time as policies and programmes evolved over time. The researcher believed that multiple methods of data collection methods are needed to best answer the determinant factors that affect tuberculosis preventive therapy service utilization. In addition, the researcher viewed that while sub-optimum utilization of tuberculosis preventive therapy at the time of the study can be known by empiricist epistemology, the current level magnitude and determinants could not be uncovered by holding this philosophical thought. Instead, a pragmatic worldview that mixed both empiricist and interpretivist epistemology at a time with multiple methods of data collection was used.

1.6.3. Ontology

Ontology is the building block of inquiry and refers to "the nature of our views about reality" or "the nature of reality" (Palermo, Reidlinger and Rees, 2021:253). Researchers have assumptions about reality, how it exists and what can be learned about it (Rehman and Alharthi 2016:51).

The nature of reality that researchers assume when conducting their inquiries or investigations is ontology, a branch of philosophy concerned with the assumptions we make in order to believe that something makes sense or is real (Creswell & Clark, 2018:89-91). It is the philosophical study of the nature of existence or reality, of being or becoming, as well as the basic categories of existing things and their relations. It investigates the researcher's fundamental belief system about the nature of being and existence (Creswell & Creswell, 2018:68). It is concerned about the assumptions we make in order to believe that something makes sense or is real, or about the very nature or essence of the social phenomenon we are investigating. It helps you in the conceptualization of the form and nature of reality and what you believe can be known about that reality. Philosophical beliefs regarding reality's nature are critical to comprehending how you interpret the evidence you gathered. These assumptions, concepts or propositions help to orientate your thinking about the research problem, its significance, and how you might approach it in order to contribute to its solution. Ontology is so critical to a paradigm because it helps to provide an understanding of the things that constitute the world. It aims to establish the real nature, or the basic concepts which

constitute themes that we analyse to make sense of the meaning embedded in research data. It makes some one to ask questions like: Is there any reality out there in the social world, or is it just a product of one's own mind? What is the nature of reality? In another way, Is reality of an objective nature, or the result of individual cognition? What is the nature of the situation being studied? As the researcher, Ontology allows you to examine your underlying belief system and philosophical assumptions, about the nature of being, existence and reality. Philosophical assumptions about the nature of reality are crucial to understanding how to make meaning of the data gathered. These assumptions, concepts or premises guide our thinking about the research topic, its importance, and how you could approach it in order to answer the research question, understand the subject under investigated, and contribute to its solution (Kivunja & Kuyini 2017:27).

The researchers of this study believed that while some of the realities in health of PLWHIV can be measure objectively (TB preventive therapy service access), others (why they are not accepting and taking or not completing) can be constructed. Therefore, both objectivists and subjectivist's ontologies were applied as the researchers aimed to uncover various categories of reality in people live with HIV. Health service use and implementation can be investigated objectively but realities related to the nature and cause for low service coverage, low uptake and completion of IPT can rather be constructed through providers and patients lived experiences which can not be investigated objectively.Therefore, both objectivist's and subjectivist's ontologies were applied as the researchers aimed to uncover various sorts of reality regarding implementation of TB preventive therapy service among people with HIV.

1.6.4. Axiology

Axiology refers to the ethical issues that must be considered while planning a research proposal. It considers the philosophical approach to making decisions correct or value decisions (Creswell and Plano Clark, 2018:89). It involves defining, evaluating and understanding concepts of right and wrong behavior in relation to the research. It considers what value we shall attribute to the various parts of our research, such as the participants, the data and the audience to which we shall report the results of our research. It attempts to answer the following question: What is the nature of ethics or ethical behavior? In answering this question, it is important to consider your regard for

human values of everyone that will be involved with or participate in your research study. This consideration is facilitated by the following questions which will help you think about it. As you undertake your research, what values will you live by or be guided by? What must be done to ensure that all participants' rights are respected? What are the moral concerns and features that must be taken into account? What are the cultural, intercultural, and moral difficulties that arise, and how will I deal with them? How will I ensure that individuals are willing to participate? How will I do the research in a way that is socially just, courteous, and peaceful? How can I avoid or reduce danger or injury, whether physical, psychological, legal, social, economic, or other? (Kivunja & Kuyini, 2017:28).

1.6.5. Methodology

A methodology is a set of methods or an approach that guides the usage of research design and research execution. It is the research approaches that occure in the study at a more practical level than the design. (Creswell & Creswell, 2018: 361; Creswell & Plano Clark, 2018:170). It is a research strategy or procedures that translate ontological and epistemological assumptions into guidelines that outline the steps how research is to be conducted (Creswell & Plano Clark, 2018:89). The relative importance of a research approach is determined by philosophical issues related to the question of ontology (the nature of reality) and epistemology (how the researcher gains knowledge). It is the broad term used to refer to the research design, methods, approaches and procedures used in an investigation that is well planned to find out or to discover anything (Creswell & Plano Clark, 2018:89). The broad topic of methodology includes data collection, participants, instruments employed, and data analysis. The methodology, in general, expresses the logic and flow of the systematic methods used to perform a research project in order to learn more about a study problem. It details the assumptions that were made, as well as the limits that were found and how they were mitigated or eliminated. It focuses on how we learn about the world or a specific area of it (Creswell, Plano & Clark, 2018:89).

When thinking about the technique for a research project, the researcher should ask himself or herself, "How will I go about getting the desired facts, information, and understandings that will enable me to answer my research question and therefor make a contribution to knowledge?" (Kivunja & Kuyini 2017:28). It guides the researcher in deciding what type of data is needed for a study and which data collection instruments

are best suited or appropriate for the purpose of a particular study's objectives. It is the methodological question that leads the researcher to ask how the world should be studied (Rehman & Alharthi 2016:52). The methodology chosen depends on what an individual wants to accomplish as well as the researchers' commitment to a specific paradigm (Dawadi, Shrestha & Giri, and 2021:26). This study takes a pragmatic approach or world view. According to pragmatic paradigm, the methodology and research design used must be focused on a specific topic or particular phenomenon of interest. Different phenomena may need the use of different techniques. Researchers can choose relevant procedures and research designs for their study's appropriate methodologies and research designs for their studies by focusing on the subject under investigation (Creswell & Plano Clark, 2018:63).

In this study researchers wanted to reveal the determinants and magnitude of tuberculosis preventive therapy uptake. Tuberculosis preventive therapy uptake and completion was the pheneomena of interest. Therefore, the methodogy used was mixed-method as the magnitude of uptake and completion clearly measured, underpinned by objectivist ontology and empiricist epistemology whereas the causes of sub optimal uptake and completion of IPT only be informed by interpretivist epistemology and constructivist ontology. Thus, the researcher adopted a pragmatic paradigm, and used both quantitative and qualitative data to develop an understanding of the research problem. For the quantitative data collection, the researcher used standardized questionnaire so that the varying perspective and experiences of people fitted into a limited number of predetermined responses catagories to which numbers were assigned and researcher constructed and administered the study instrument in a standardized manner according to predetermined procedures.

For the qualitative part of the study, the researcher used open-ended questions and conducted an interview with health care providers in their service delivery point or setting. The researcher assured all participants to establish trust and rapport during individual interviews. All the interviews were audio recorded, and the participants' meanings about the barriers and enablers of TB preventive therapy implementation were illustrated during the transcription and the analysis processes.

1.7. RESEARCH METHODOLOGY AND RESEARCH DESIGN

1.7.1. Research methods

This study used a mixed methods technique for its investigation. Mixed methods research requires gathering both quantitative and qualitative data, combining the two types of data, and employing different designs that may include philosophical assumptions and theoretical frameworks. The primary premise of this technique is that combining qualitative and quantitative approaches yields a more thorough understanding of a study subject than either approach alone (Dawadi, Shrestha, & Giri, 2021:25-26; Creswell & Creswell, 2018: 40-71).

In a research project, mixed methods entail blending or integrating qualitative and quantitative research and data. Quantitative data usually comprises closed-ended responses, but qualitative data is frequently open-ended with no predetermined responses (Dawadi et al., 2021:27; Creswell & Creswell, 2018: 70-71).

1.7.2. Research design

The design for this study was quantitative followed by qualitative research design.

This research was utilized explanatory sequential mixed methods approach; It is called sequential because the initial quantitative phase is followed by the qualitative phase. It is said explanatory as the initial quantitative data results are explained further with the qualitative data (Creswell & Creswell 2018:35-39). Following quantitative and qualitative data analysis; health education guide development done and validation of guide by mini-Delphi survey (sending the material prepaired to experts for comment and to add relevant points to the document) performed.

1.8. ETHICAL CONSIDERATIONS

According to Creswell and Creswell (2018:167-169), ethics is a set of moral principles concerned with the degree to which research procedures corresponds to professional, legal and social commitments to the study participants. Research that is conducted with human participants requires a careful consideration of ethical questions that may arise

during the conduct or execution of the study (Basil, 2021:17-18). The researcher was guided by ethical principles. To protect the participants' rights and keep them safe, the researcher followed and maintained ethical principles such as; beneficence, non-maleficence, autonomy and justice (Stadnick, Poth, Guetterman and Gallo, 2021:3; Basil, 2021:17-22).

The researchers obtained ethical clearance from the Ethics and Higher Degrees Committee of the Department of Health Studies in the College of Human Sciences at the University of South Africa (UNISA). In addition, ethical clearance was granted from Ethical Committee of Addis Ababa University College of health sciences and permission to conduct the study from Tikur Anbessa Specialized Hospital. The detail presented next in chapter three.

1.9. SCOPE AND LIMITATIONS

Scope and limitation of the study

In this study patient's treatment uptake and completion rate was determined using crossectional survey and review of their medical records. Qualitative study using in-depth interview was done on health care providers to identify determinants to implement Isoniazid Preventive therapy for latent tuberculosis in HIV patients.

Because the study is limited to one tertiary level teaching specialized hospital it might be difficult to generalize the findings of the study to other setups of the country. The study was cross-sectional, and the results obtained from this data were only to identify associations rather than causation between dependent and independent variables.

1.10. STRUCTURE OF THE THESIS

This thesis consistes consist of seven chapters as the chapter lay out of the thesis described below:

Chapter one

Chapter one outlines and presented the introduction and back-ground information about the research problem, the statement of the research problem, motivation of the study, aim

of the study, significance of the study, as well as the theoretical and conceptual frame works, research paradigms of the study and structure of the study.

Chapter two

This chapter presented the review of related literatures of the subject matter under study which discusses epidemiology of tuberculosis, Latent tuberculosis, tuberculosis and HIV co-infection, Isoniazid preventive therapy, predisposing, enabling and need factors in detailed approach.

Chapter three

This chapter discussed the research design and methods used in the study. It includes population, sampling, data collection, measures applied to ensure validity of data collection, integrity of data management and maintaining ethical principles, health education guide development and validation of the guide to be developed was presented.

Chapter four

In this chapter quantitative phase of data analysis and interpretation of research findings presented. The main objective of quantitative part to identify factors affecting IPT uptake and completion were presented.

Chapter five

In chapter five the findings of the qualitative phase of the research presented. The main objective of the qualitative phase was to gain a detail understanding of IPT implementation challenges and suggestions for improvement from the viewpoint of health care providers. The findings of the qualitative phase were presented and integrated with the findings of the quantitative phase to interpret and make meaning of the data.

Chapter six

This chapter presente the main findings of mixed methods research and provides an outline of the development of health education guid based on the research findings and recommendations to apply in our and similar setups and presented main findings of the study.

Chapter seven

In chapter seven conclusion of the study was presented and opportunities for further research suggested. In this chapter, conclusions, strengths, limitations and recommendations and contribution arised from the study presented.

1.11. SUMMARY

This chapter represented introduction, background information about the research problem, statement of the research problem, aim and objective and research questions of this study, significance of the study, design and methods, theoretical foundation, research paradigm and conceptual framework of the study, research design and methods, scope of the study and structure of the thesis. Review of related literatures was discussed in chapter two.

CHAPTER TWO

LITERATURE REVIEW

2.1. INTRODUCTION

The literature review is a summary of previous research on a certain topic of interest. The literature review examines scholarly articles, books, and other sources that are relevant to a particular area of research or interest topic. During the review, author describes, summarizes, and critically evaluates each source in the review (the strengths and weaknesses). The literature review can also identify and reveal gaps or controversies in the literature, topics needing further investigation and it saves time spent on investigating something that has already been done. A review of literature helps in understanding the research historical background for the research under study; describes concerns, controversies, theories, concepts and related research in the field; and it indicates how the research will extend or fill and address the gap (Creswell and Creswell, 2018:73). It also serves as a framework for determining the studies significance and benchmark for comparing the findings to those of other study findings. The foundation for writing the scholarly literature into a study could be any or all of these reasons. Studies must contribute to the body of literature on a topic, and literature sections are usually ordered from the larger problem to the narrower issue, which leads straight into the study's methods (Creswell and Creswell, 2018:73).

2.2. SCOPE OF LITERATURE REVIEW

This chapter discusses the literature review on tuberculosis, tuberculosis and HIV, latent tuberculosis, isoniazid preventive therapy uptake and completion in HIV patients. Key words used to search the literature include determinants, factors, barriers, isoniazid preventive therapy, tuberculosis, tuberculosis and HIV, latent tuberculosis, isoniazid preventive therapy uptake, isoniazid preventive therapy completion, isoniazid preventive therapy implementation, isoniazid preventive therapy adherence, tertiary hospital and Ethiopia.

2.3. TUBERCULOSIS OVERVIEW AND PATHOGENESIS

Tuberculosis (TB) is a communicable disease caused by bacteria from the mycobacterium tuberculosis complex, which is a rod-shaped, non-spore-forming, thin aerobic bacterium with measurements 0.5μm by 3μm. Mycobacteria belong to the family Mycobacteriaceae, the order Actinomycetales and of the pathogenic species belong to the mycobacterium tuberculosis complex. Tuberculosis is a chronic bacterial communicable disease that continues to be a major public health problem in the world. Most commonly, the disease attacks the lungs (pulmonary TB), and the lymph nodes, spine, brain or other (extra pulmonary TB). Pulmonary TB is the only type of TB that can be transmitted from person to person through droplets from the throat and lungs of people with active respiratory disease (active form of TB). If someone who is sick with TB disease of the lungs or throat coughs, speaks, laughs, sings, or sneezes; people near the sick person with TB disease can breathe the TB bacteria into their lungs, which causes infection (CDC, 2021:9, 15,16).

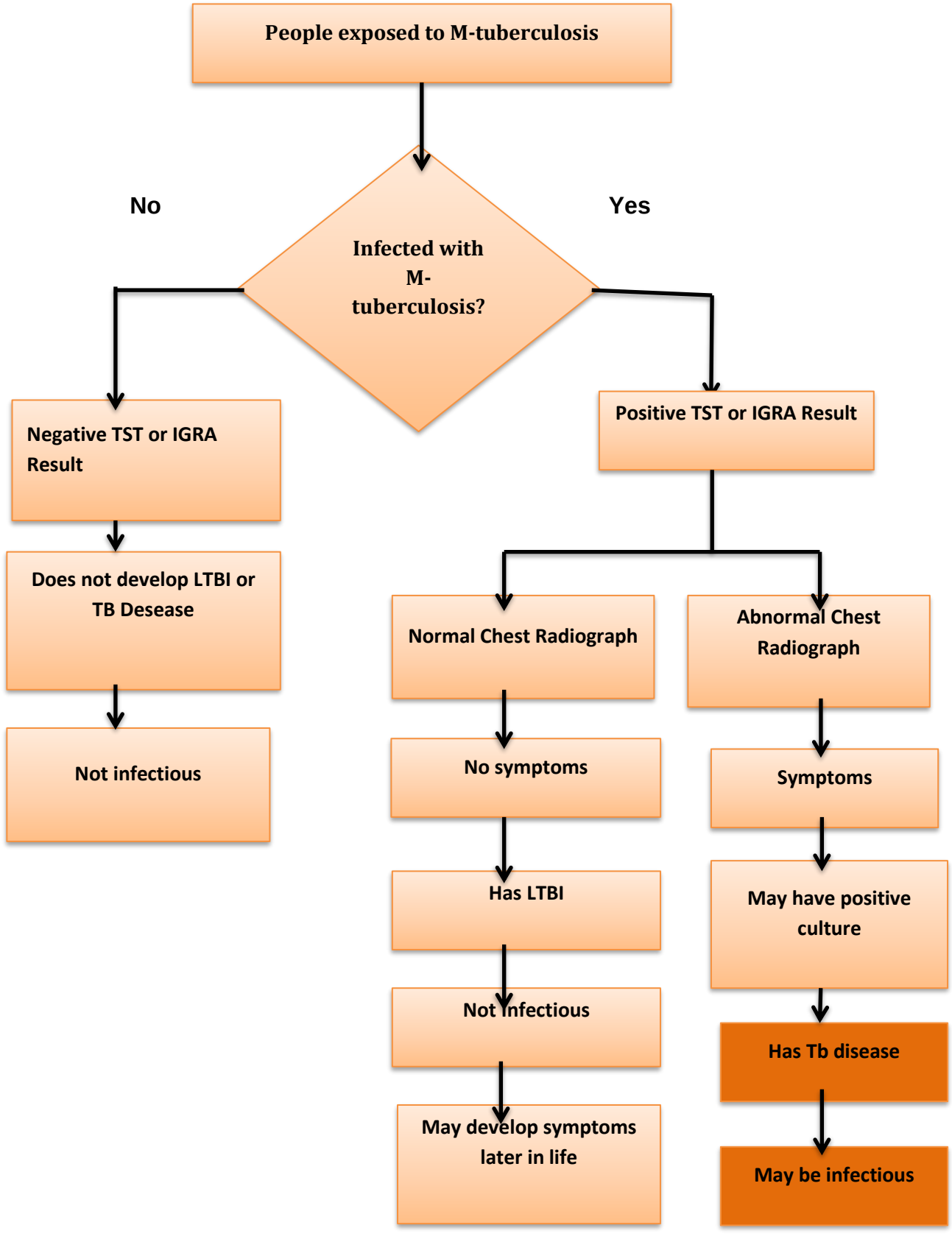


Figure. 2.1: Transmission and Pathogenesis of Tuberculosis (CDC 2018: 12-15).

2.4. TUBERCULOSIS EPIDEMIOLOGY

Until the covid-19 pandemic, tuberculosis (TB) remains a major public health concern and the biggest cause of infectious illness death worldwide (WHO, global TB report 2021:14). TB claimed around 4000 lives every day over the world (Ethiopian TB, TB/HIV guidline, 2021:15). By 2020, an estimated 10 million individuals would have been ill as a result of tuberculosis, with a quarter of the world's population being latently infected. People living with HIV have a substantially higher risk of developing tuberculosis than those who do not (Bunyasi, Schmidt, Abdullahi et al., 2017:1-2). Tuberculosis (TB) is a treatable and preventable infectious disease. A six-month anti-TB treatment regimen can treat about 85% of people who get the disease (WHO, global TB report 2021:14).

In 2019, the World Health Organization (WHO) recorded 7.1% million incidence cases, with 69% of notified TB patients having a documented HIV test result, up from 64% in 2018. In the WHO African Region, where the burden of HIV-associated TB is the highest, 86% of TB patients had a documented HIV test result, with 71% of them receiving TB treatment in 2019 (WHO global TB report 2020:71). In 2019, 86% of TB patients in the WHO African Region, which accounted for 73% of the global burden of HIV-associated TB, were aware of their HIV status. In 2019, 456 426 cases of TB among HIV-positive people were reported worldwide, accounting for 9.5% of the 4.8 million TB patients who had an HIV test result (WHO global TB report, 2020:85).

2.5. TB/HIV IN ETHIOPIA

Ethiopia is one of the world's high-TB, TB/HIV, and MDR-TB burden countries, with a TB incidence of 192 per 100,000 people. At national and PEPFAR-supported sites, 83% and 86% of recorded TB cases have their HIV status documented, respectively. HIV prevalence among tuberculosis patients is 8%, with regional variation ranging from 4.7% in SNNPR to 25% in Addis Ababa. At each follow-up appointment, PLHIV under care are routinely checked for tuberculosis. In Ethiopia, tuberculosis (TB) is one of the most common opportunistic illnesses (OIs) among PLHIV (Ethiopia, 2017, p. 39)

TPT for priority populations is still in short supply: 49% of newly enrolled persons living with HIV (PLHIV) and 22% of children under the age of five with household contacts with

bacteriologically proven TB infections were reported to have started TPT (Ethiopia TB report 2020: 23; Khatri & Davis, 2020: 23).

2.6. LATENT TUBERCULOSIS INFECTION (LTBI)

Persons with latent tuberculosis infection (LTBI) have M. tuberculosis in their bodies, but do not have TB disease and cannot spread the infection to other people. A person with LTBI is not regarded as having a case of TB. The process of LTBI begins when extracellular bacilli are ingested by macrophages and presented to other white blood cells. This triggers the immune response in which white blood cells kill or encapsulate most of the bacilli, leading to the formation of a granuloma which LTBI has been established. Latent tuberculosis infection may be detected by using the tuberculin skin test (TST) or an interferon-gamma release assay (IGRA). It can take 2 to 8 weeks after the initial TB infection for the body's immune system to be able to react to tuberculin and for the infection to be detected by the TST or IGRA. Within weeks after infection, the immune system is usually able to stop the multiplication of the tubercle bacilli, preventing further progression. Persons with LTBI have M. Tuberculosis in their bodies, but do not have TB disease and cannot spread the infection to other people (CDC 2021: 14). However, if these germs become active in the body and multiply, people will get sick with TB disease. When TB germs are active (multiplying in the body), this is called active TB disease.

2.7. TUBERCULOSIS INFECTION (TB DISEASE)

In some individuals, tuberculosis bacteria (the tubercle bacilli) overcome the immune system and multiply, resulting in progression from latent tuberculosis infection (LTBI) to active TB disease. Persons who have TB disease are usually infectious and may spread the bacteria to other people. The progression from LTBI to TB disease may occur at any time, from soon to many years later when their immune system becomes weak. Body fluid or tissue from the disease site should be collected for AFB smear and culture. Positive culture for M. tuberculosis confirms the diagnosis of TB disease (CDC 2021:14). The general symptoms of TB disease include unexplained weight loss, loss of appetite, night sweats, fever, fatigue and chills.

If a person has tuberculosis disease, the following are expected:

- Usually has a skin test or blood test result indicating TB infection
- May have an abnormal chest x-ray, or positive sputum smear, culture, or gen x-pert test for mycobacterium tuberculosis
- Has active TB bacilli in his/her body
- Usually feels sick and may have symptoms such as coughing, fever, weight loss and night sweats
- May transmit TB bacteria to other people
- Treatment is needed to treat TB disease (CDC 2021:15, 48).

2.8. HIV EPIDEMIOLOGY

Globally, in 2019, 38.0 million (31.6 million–44.5 million) people were living with Human immunodeficiency virus (HIV) and 1.7 million (1.2 million–2.2 million) people became newly infected with HIV. In the same year, 690 000 (500 000–970 000) people died from AIDS-related illnesses. As of the end of June 2020, 26 million (25.1 million–26.2 million) people were accessing antiretroviral therapy. Since the start of the epidemic, 75.7 million (55.9 million–100 million) people have become infected with HIV and 32.7 million (24.8 million–42.2 million) people have died from AIDS-related illnesses at the end of 2019 (UNAIDS 2019:1-2). According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), around one-third of the 36.9 million people living with HIV and AIDS worldwide are co-infected with TB. Sub-Saharan Africa is the hardest hit region, as it is home to 70% of all people living with TB/HIV co-infection in the world (UNAIDS 2018:1-3).

2.9. EPIDEMIOLOGY OF TB AND HIV CO-INFECTION

Tuberculosis (TB) and the Human Immunodeficiency virus (HIV) are strongly linked. People with healthy immune systems may not fall ill from latent TB infection. People living with HIV with low CD4 count are much more susceptible to active TB. Tuberculosis (TB) is one of the most common causes of death from an infectious disease globally. TB/HIV is the most common co-infection which carries high mortality and morbidity worldwide (WHO TB report, 2021:9). Tuberculosis (TB) remains the leading cause of death among people living with HIV, accounting for around one in three AIDS-related deaths. Globally, there were 9.9 million (8.9-11million) people who fell ill with TB in 2020 which is 127/100 000

population which shows a small decline from the 2019 report. Among the incident cases, 8% were people living with HIV (WHO, global TB report, 2021:9).

There is a synergy between HIV and TB in which Human Immune deficiency virus promotes progression of latent or recent infections of Mycobacterium tuberculosis to active disease and also increases the rate of occurrence of tuberculosis. People living with HIV may also be more susceptible to TB infection (Gunda, Maganga, Nkandala et al., 2018:2; Dawit, Abebe, Dessu, et al. 2021:2). Consequently, many national and global studies approved this synergy. For instance, the prevalence of TB/HIV co-infection among the studied population of Southwestern Saudi Arabia was reported 9.5% (Darraj, Abdulhaq, Yassin, et al., 2021:1571) and a study in Nepal also revealed TB/HIV prevalence 9.9% (Adhikari, Bhattarai, Basnet, et al.,2022: 5).

In studies done in different states of Nigeria also reported their findings as in Bayelsa State, among 600 TB suspected participants, the prevalence of TB by gen X-pert was nearly half(49%) and the prevalence of TB/HIV co-infection was found 32% (Enoch, Silas, Pius, and Nwozuke, 2021 :135) . In another Nigerian study in Plateau State also revealed the high prevalence of TB/HIV co infection (14.3%), among the age group of <20 years (Banda , Essien, Ebu, et al., 2021:209). In addition, the other study in Nigeria also revealed 15.1% of TB/HIV co-infection (Agbo, Banwat, Isichei, Chris, 2021:135). A study done in southern part of Ethiopia among ART clients was found 16.9% of TB/HIV co-infection and 84.3% of participants had not taken INH prophylaxis therapy(Ermeko, Lire, Lette, Lamore, Wordofa, 2021:3).

HIV/AIDS is accelerating the TB epidemic in Sub-Saharan Africa, with up to 70% of TB patients in some countries co-infected with HIV. Despite the overlapping epidemiology, efforts to combat tuberculosis and HIV have been mostly separate for many years. Improved collaboration between TB and HIV/AIDS programmers will result in more effective TB control among HIV-positive people and significant public health benefits. HIV-positive people can be easily tested for tuberculosis, and if they are infected, they can be given prophylactic medication to prevent the disease from developing or curative drugs if they already have it. Patients with tuberculosis can be offered an HIV test; in fact, evidence shows that TB patients are more likely than the general population to accept HIV testing. As a result, TB programs can play a significant role in identifying eligible individuals for ARV treatment (Anochie, Ajogwu, Kalu, Akpan et al., 2018: 10).

2.10. STRATEGIES TO REDUCE TUBERCULOSIS (TB) IN HIV PATIENTS

The treatment of latent tuberculosis infection (LTBI) is a crucial part of the WHO's End TB Strategy for preventing active tuberculosis disease. The efficacy of currently available tuberculosis prevention treatment ranges from 60% to 90% (WHO latent TB infection consolidated guideline, 2018:5). Early antiretroviral therapy (ART) for people living with HIV, in accordance with the Three I's for TB/HIV strategies: intensified case finding (ICF), isoniazid preventive therapy (IPT), and infection control for tuberculosis (IC), are among the interventions to reduce the burden of TB among people living with HIV (Ethiopian comprehensive HIV care guidline, 2018:90-101).

2.10.1. Eligible population for IPT (TPT)

Isoniazid preventive therapy (IPT) is a type of treatment given to people who are thought to be at risk of getting tuberculosis. In order to reduce the incidence of active tuberculosis; IPT also referred to as latent TB infection (LTBI) treatment or preventive therapy, needs to be provided for eligible population group (WHO latent TB guideline, 2018:1-3).

World health organization (WHO) recommended IPT (TPT) for:

- Adults and adolescents living with HIV who have an unknown or positive tuberculin skin test (TST) result and are unlikely to have active TB, as well as those on antiretroviral therapy (ART), those who have previously been treated for TB, and pregnant women (WHO latent TB guideline, 2018:2).
- Infants less than 12 months of age living with HIV who have contact with a case of TB and are investigated for TB should receive 6 months of isoniazid preventive treatment (IPT) if the investigation shows the absence of TB disease.
- Children above 12 months of age living with HIV who are considered unlikely to have TB disease on the basis of screening for symptoms and have no contact with a case of TB should be offered 6 months of IPT as part of a comprehensive package of HIV prevention and care if they live in a setting with a high prevalence of TB. All children living with HIV who have successfully completed treatment for TB disease may also receive TB preventive treatment three years later as part of a comprehensive package

of HIV care. These individuals should take TPT irrespective of the degree of immunosuppression (immune status), previous history of TB treatment and pregnancy (WHO latent TB guideline, 2018:3 & MacNeil, Glaziou, Sismanidis, Maloney and Floyd; 2019:264).

2.10.2. Tuberculosis preventive treatment options

Countries have diverse experiences and recommend different TPT (IPT) regimens based on their local HIV and TB epidemiology, and shorter regimens are likely to assist patients adhere to and finish treatment.

2.10.2.1. Recommended TPT regimens in Ethiopia

- ✓ Three months of weekly isoniazid plus rifapentine (3HP) is the preferred TPT regimen for all PLHIV > two years of age who are not receiving protease inhibitor or NVP based regimen, and who do not have any other contraindication for 3HP.
- ✓ Six months of isoniazid preventive therapy (6H) is the recommended regimen for children, adolescents and adults living with HIV who are receiving ART regimen with protease inhibitor or existence of another contraindication for 3HP.
- ✓ Three months of weekly isoniazid plus rifapentine (3HP) is also the preferred regimen for TPT in eligible HIV-negative children and adolescents (2-14 years of age).
- ✓ Three months of daily isoniazid plus rifampicin (3HR) is the preferred regimen for eligible HIV-negative children < 2 years of age.
- ✓ Six months of isoniazid preventive therapy (IPT) should be offered to HIV-exposed infants taking nevirapine-based prophylaxis who are also exposed to pulmonary TB case.
- ✓ IPT may be used for all eligible individuals if 3HP or 3HR are not available or contraindicated (Ethiopian TB, TB/HIV guideline, 2021:64 and WHO latent TB guideline, 2018:23-25).

There are some contraindications to be considered before initiating TB preventive therapy (IPT) i.e., Individuals with any one or more of the listed conditions should not be provided with IPT:

- Tuberculosis sign and symptoms such as fever, cough, weight loss, night sweating, and other presumptive symptoms even if the diagnosis is not yet confirmed.
- Active hepatitis (chronic or acute)
- History of regular and heavy alcohol consumptions
- Intolerance to TPT regimens or prior allergy

  Symptom's indicative of peripheral neuropathy such as tingling and numbness etc (Ethiopian comprehensive HIV care guidline, 2018:97).

N.B: Previous history of TB (treated TB) and current pregnancy should not be contraindications for starting Isoniazid preventive therapy (TPT).

According to the Ethiopian national policy recommendation, TPT should be administered:

- During enrolment to HIV care after screening out for the presence of active TB.
- It should be provided once and should not be repeated unless there is strong indication on its benefits and needs senior physicians decision.
- If IPT, it should be administered only for six months.
- It should not be administered right after completing a full course of TB treatment
- TPT can be administered for patients after three years of treatment for TB (Ethiopian TB, TB/HIV guideline, 2021:64).

2.10.3. Utilization of isoniazid preventive therapy among PLHIV

A systematic review of different studies showed that isoniazid preventive therapy (IPT) significantly reduced the relative risk of TB; the effect of IPT reported almost no risk of HIV disease progression and prior meta-analysis studies found IPT effective in tuberculin skin test (TST) positive participants in reducing risk of TB. Based on these findings, the World Health Organization (WHO) in 2004 recommended IPT for HIV-infected persons and most high TB/HIV burden countries have adopted antiretroviral therapy (ART) and the WHO recommended TB/HIV collaborative activities including IPT (WHO, global TB report,2020:10,85). In a study conducted in northwest Ethiopia regarding the effect of IPT on the incidence of active TB that concomitant use of ART and IPT among people living

with HIV revealed that there was a 96.8% reduction in TB incidence (Kebede, et al., 2021).

In a prospective cohort study conducted in Tanzania, it was discovered that providing isoniazid preventive therapy (IPT) to those who test negative to a symptom-based tuberculosis (TB) screening tool effectively prevents the development of active tuberculosis (TB) in both HIV-infected and HIV-uninfected at-risk populations, as well as being cost-effective, supports government policy to integrate IPT into HIV/AIDS care and treatment in the country (Shayo, Chitama, Moshiro, et al., 2018:1-2). Another study in Tanzania found that utilizing IPT reduced the incidence of tuberculosis in HIV-positive patients by 52% when compared to those who did not (Maokola, Ngowi, Mahande, et al., 2021:2-13).

2.10.4. Factors affecting utilization of isoniazid preventive therapy amongst PWHIV

Different studies in Ethiopian regions and systematic reviews revealed low or suboptimal implementation, uptake, and completion of isoniazid preventive therapy (Teklay et al. 2016:6), which supports WHO recommendations for providing IPT to PWHIV to reduce TB-related morbidity, with IPT found to significantly reduce the occurrence of TB among the IPT group compared to the non-IPT group, highlighting the need to strengthen IPT implementation (Mengesha & Ahmed, 2020:1). According to a study conducted in the Tigray region, the region's estimated isoniazid preventive therapy coverage was determined to be 20% (Teklay et al. 2016:6). According to a recent study, only 66.5% of HIV-positive people in south-west Ethiopia who were eligible for TPT supplied IPT (Aboma & Dida, 2021:5). According to a study conducted in Nigeria, the uptake of IPT is extremely low (7.1%), indicating a lack of awareness about the benefits of IPT (Aboma & Dida., 2021:4). Another study in Tanzania found that the uptake of IPT for PLWHIV is quite poor, with just 14.4% of clients ever receiving IPT (Maokola, Ngowi, Lawson et al.,2021: 563-564).

2.10.4.1. Patient related Factors

Several studies have revealed low implementation as a result of participants' lack of information and awareness regarding IPT. In addition, a study in Northwest Ethiopia

found that 62.10% of 383 participants (patients) had insufficient awareness of IPT (Woldeyohannes, Hailemariam, and Kalu 2017:3). Another study found that patient acceptance problems were a stumbling block to the introduction of isoniazid preventive therapy (Teklay et.al. 2016:6). In a study conducted in Rwanda, the main reason for not starting IPT was found to be a lack of awareness of the benefits to be gained (Birungi, Graham, Uwimana and van Wyk, 2018:4). Despite the WHO recommendation, a study in Nigeria found that tuberculosis preventive therapy (IPT) uptake or prevalence of beginning was exceedingly low, with only 7 out of every 100 eligible patients in a tertiary hospital receiving treatment. Lack of awareness of the benefit, according to the patient's perspective, was revealed to be an independent factor linked with this very low initiation level. As a result, it was suggested that healthcare providers raise their awareness and policy implementation of IPT (Abdulwasiu, Kazeem, Ifedolapo, et al. 2021:4-5).

2.10.4.2. Health care system related Factors

Studies showed different health system factors affecting uptake and completion of IPT. Isoniazid stock out, fear of isoniazid resistance, and lack of commitment of health managers to scale up the program were indicated by health providers as the main barriers hindering implementation of isoniazid preventive therapy (Teklay et.al., 2016:6). In a study conducted by Demelash, Belaynew and Yeshalem (2015: 830), factors such as explanation given from health professionals about advantages of IPT and length of time in which patients took HAART were significantly associated factors with uptake of IPT and counselling about IPT needs, attention and compliance of health care providers regarding IPT.

In a study conducted in Zimbabwe, researchers reported that the importance of training health care providers and distribution of IEC (information education communication) materials on isoniazid preventive therapy (IPT) to educate clients and the community at large; and insufficient advocacy and community sensitization was also identified as a factor for low uptake of TPT (Makoni et al., 2015:5; Ijeoma, Onuka, Uloaku, et al. 2015:267). A study conducted in rural South Africa to investigate factors associated with low rate of tuberculosis preventive therapy prescription for PLWHIV revealed the main factor associated with low rate was the belief of health care providers about their patients that they will not disclose about their TPT use (Amiya, Megan, Anthony,et al. 2021:4-5).

Another reason for not adopting IPT, according to the study, is the poor quality of healthcare services available in health care settings (Birungi et al. 2018:1, 4). In Ethiopia, a study indicated limited IPT implementation (only 18.2%) of eligible clients receiving tuberculosis preventive therapy, with INH supply interruption being the biggest barrier reported by 84.2% from selected health facilities (Belete, Demissie, Gebreegziabher., et al. 2017:4). In general, the evaluated research suggested the necessity for health education and IEC (information, education, and communication), which will help clients make informed decisions, commit to finishing their prescribed dose, and enhance overall uptake.

2.10.4.3. Therapy related

Concerns about the TPT's effectiveness, fear of potential side effects, and pill burden were among the barriers of TPT uptake highlighted in a Kampala study of persons living with HIV (Semitala, Musinguzi, Ssemata, et al., 2021:12). In a retrospective cohort study in Tanzania, only 14.4% of eligible patients were ever started on IPT. In the research area, being on ART, very malnourished, and being in WHO stage IV were all linked to low IPT uptake (Maokola, Ngowi, Lawson et al, 2021:562-565). For this study, researchers gathered primary data from HIV patients in the study institution, as well as reviewing their medical records to determine the completion rate by patient report and what is documented in their medical records. A similar investigation was not conducted in an Ethiopian tertiary health facility. During situational analysis in the study institution, investigators discovered that many eligible patients were not started on isoniazid preventive therapy (IPT) and that some of those who were started on IPT did not finish (discontinue) their recommended six-month dose, indicating that more research is needed.

As a result, the outcomes of this study may benefit participants and individuals living with HIV by increasing use of TB preventive medication, which will help to reduce TB incidence in the community. Furthermore, the research will contribute to scientific knowledge, and the findings will be useful to policymakers and TB control program managers who work in TB and TB/HIV programs.

2.11. HEALTH EDUCATION GUIDE DEVELOPMENT

Any document offering suggestions for clinical practice or public health policy is referred to as a guideline. A recommendation advises the health education guide intended end-user what he or she can or should do in specific situations in order to attain the best potential health outcomes, either individually or collectively. Evidence-based health education guide can improve clinical and public health outcomes by guiding health professionals in practicing in the most efficient manner and policymakers in establishing the best programs. As a result of this research, a health education guide to promote TB preventive therapy implementation is being developed. As a result, it may be used by health care practitioners to offer enough information before to TPT commencement. For the efficacy of TB preventive therapy, it is critical to provide enough health education and information to Patients. Furthermore, the findings of many studies, as well as the information and gaps revealed in our study data, demonstrated the necessity for a concise and precise health education guide (Wang, Norris and Bero ; 2018:1-2).

2.12. SUMMARY

Chapter two presented and discussed the introduction, scope of literature review, tuberculosis, tuberculosis overview, TB pathogenesis, HIV epidemiology, tuberculosis infection (TB Disease), latent tuberculosis infection, isoniazid preventive therapy uptake and completion in HIV patients. It further discussed what isoniazid preventive therapy is, Isoniazid preventive therapy utilization, the burden of TB and HIV co-infection, strategies to reduce Tuberculosis (TB), factors affecting utilization of isoniazid preventive therapy (therapy, health care system and therapy related factors), health education guide development and TB/HIV in Ethiopia.

CHAPTER THREE

RESEARCH METHODOLOGY AND RESEARCH DESIGN

3.1. INTRODUCTION

This chapter presented the comprehensive description of research design and research methods which was used to attain the goal and objectives of the study as well as to answer the research questions. It also describes in detail the study population, phases of research, sample size, sampling procedures, research instruments, data collection techniques, data analysis procedures and the overall research process. In addition, the strategies for validating the findings and the ethical considerations that were used during the conduct of research will also be described in detail.

3.2. STUDY SETTING

This study was conducted in Tikur Anbessa Specialized tertiary Hospital in Addis Ababa; Ethiopia. The hospital was founded in 1973 as a memorial hospital of Prince Mekonen. According to Ethiopian central statistical agency (CSA) report, the estimated total population of Ethiopia and capital city Addis Ababa; as of July 1, 2017, was 94,352,000 and 6.6 million consecutively. The total area of Addis Ababa city is 54,000 hectares and the mean annual rain fall is 1200mm.

Tikur Anbessa Specialized hospital is a tertiary level referral and specialized teaching public hospital found in the capital city Addis Ababa.The Hospital is located in lideta sub-city. Undergraduate and postgraduate medical students, dental medicine, medical laboratory technologists, pharmacists, midwives, nurses, and radio technologists have all received training at Tikur Anbessa Specialized Hospital.

This hospital offers a wide range of inpatient and outpatient specialist health care services, including HIV treatment and care. The hospital has roughly 630 beds available for inpatient care. Approximately 441785 patients were served by the hospital in the previous year. The hospital and college of health sciences employ 1204 health professionals (physicians and nurses, pharmacists, laboratory technologists, radiology technologists, and others), 913 academic employees, and 900 administrative workers. Tikur Anbessa Specialized Hospital was chosen at random from two federally funded

tertiary teaching hospitals: St. Paul and Tikur Anbessa. The hospital is a tertiary teaching and referral hospital run by Addis Ababa University. Since 2005, around 8000 adult HIV patients have received antiretroviral therapy (ART) at this hospital. Approximately 3500 adults living with HIV are currently undergoing active treatment. Patients with any illness condition, including HIV, are referred to this hospital from various health facilities across the country. The qualitative study included health care providers who worked at this hospital's HIV care unit. The information was gathered from an HIV follow-up out-patient clinic. All health care providers working at HIV care clinics who volunteered to participate were included in the study. Patients in care and follow-up were enrolled to participate in the study at their regular follow-up and ART drug refill appointment visits.

Figure 3.1: Study area Map (Map of Addis Ababa city), 2020

Above is a map of the study area in Addis Ababa. The city is divided into ten sub-cities, with the study hospital (Tikur Anbessa Hospital) in the Lideta subcity marked on the map with a star.

3.3. RESEARCH DESIGN

Research design is simply the framework or plan for a study that is used as a guide in collecting and analyzing the data. It is a blueprint that is followed in completing a study or for collecting measurements and analysis of data. It is also a map that is usually developed to guide the research (Asenahabi, 2019:77-78; Creswell & Creswell, 2018:42).

Research design allows for seamless scaling of research operations, as well as precise direction, resulting in research that is as efficient as possible, giving maximum information with the least amount of work, time, and money spent (Creswell & Creswell, 2018:392).

Furthermore, the study design aids in the organization of the investigator's ideas, which aids in the recognition and correction of his or her flaws, as well as providing a proper or specific direction to the other executives and others involved in the process (Creswell and Plano Clark, 2018:106,169). The three approaches in research are (1) Quantitative (2) Qualitative and (3) Mixed method approach (Creswell & Creswell, 2018: 304).

3.3.1. Phase I Quantitative component

Quantitative method is ideal for measuring of prevalence of a known phenomenon, patterns of association and interpretation of association. In addition, quantitative research is a means for testing objective theories by examining the relationship among variables. These variables, in turn, can be measured, typically on instruments, so that numbered data can be analyzed using statistical procedures. The final written report has a set structure consisting of introduction, literature and theory, methods, results, and discussion (Creswell & Creswell, 2018: 44 ; Asenahabi, 2019:79). For this section of the research, quantitative cross-sectional survey was employed to see the magnitude of the problem under study and to obtain data on specific factors or barriers for IPT (TPT) implementation and to determine the relationship between independent and outcome variables.

A cross-sectional study is defined as a type of observational research that analyzes data of variables collected at one given point in time across a sample population or a pre-defined subset (Asenahabi, 2019:80; Creswell & Creswell, 2018: 44).

3.3.2. Characteristics of cross-sectional studies

Some of the critical characteristics of a cross-sectional study are:

- Researchers can conduct a cross-sectional study with the same set of variables over a set period.
- Similar research may look at the same variable of interest, but each study observes a new set of subjects.
- The cross-sectional analysis assesses topics during a single instance with a defined start and stopping point, unlike longitudinal studies, where variables can change during extensive research.
- Cross-sectional studies allow the researcher to look at one independent variable as the focus of the cross-sectional study and one or more dependent variables (Creswell & Creswell, 2018: 44).

3.3.3. Phase II Qualitative component

Qualitative research is a technique for examining and comprehending the meaning that individuals or groups of people attach to a social or human issue (Asenahabi, 2019:81). As a result, we employed a phenomenological approach to investigate participants' lived experiences with the problem under study. Emerging questions and processes are part of the research process, as they are data acquired in the participant's environment, data analysis that builds inductively from specifics to broad themes, and the researcher's interpretations of the data. The structure of the final written report is customizable. People that engage in this type of research advocate an approach to research that values an inductive approach, an emphasis on individual meaning, and the necessity of rendering a situation's complexity (Asenahabi, 2019:86; Creswell & Creswell, 2018: 43). In this section, the researcher employed an exploratory approach to learn about the participants' perspectives on why there is such a poor uptake and completion of IPT in the study area. Exploratory research is defined as research used to investigate a problem which is not

clearly defined. It is conducted to have a better understanding of the existing problem (Creswell & Creswell, 2018: 43).

3.3.4. Characteristics of exploratory research

Exploratory research is described as research conducted to learn more about a problem that isn't well defined. It is carried out in order to gain a better knowledge of the current problem, but the results will not be conclusive. For this type of study, a researcher begins with a broad concept and uses the research to discover difficulties that can be the subject of future study. A key consideration here is that the researcher must be willing to shift course if new information or insight becomes available. When a problem is still in its early stages, such study is frequently conducted. It's also known as grounded theory or interpretative research since it's used to address questions like "what," "why," and "how."(Creswell and Plano Clarck, 2018:144-150)

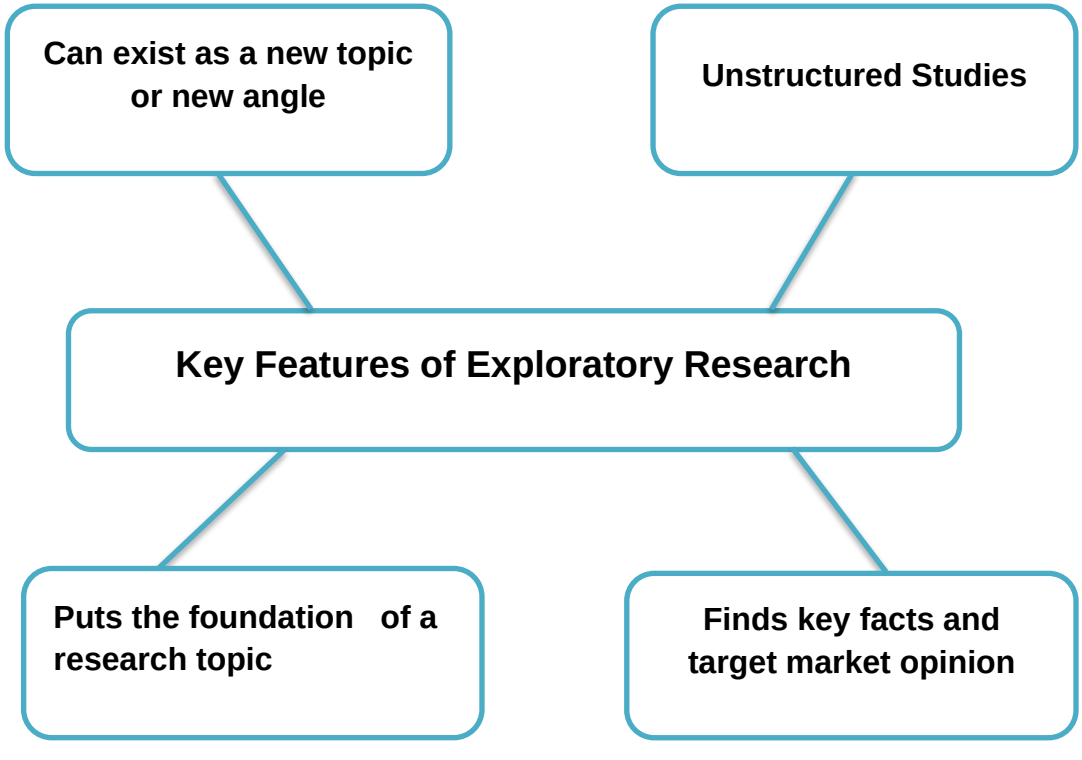


Figure 3.2: Main characteristics of exploratory study.

3.4. JUSTIFICATION FOR CHOOSING THE RESEARCH METHODOLOGY

3.4.1. Characteristics of Mixed Methods Research

Mixed methods research integrates quantitative and qualitative techniques in a single study. This method comprises of the collection and mixing or integration of both quantitative and qualitative data in a study (Asenahabi, 2019:84;Creswell and Plano Clark, 2018: 39-40; Dawadi et al., 2021:25-27). Mixed methods researchers use varied philosophical positions that fill the gap between positivists or post-positivist and social constructivist or interpretivist worldviews (Creswell and Plano Clark, 2018: 39-41). Researchers in social sciences and public health utilize mixed methods study. Problems most suitable for mixed methods research are those in which the quantitative approach or the qualitative approach alone is insufficient to develop multiple views and a comprehensive understanding of a research problem or question (Creswell and Plano Clark, 2018: 44).

Quantitative method is ideal for determining of prevalence of a known phenomenon, patterns of association and inference of association while qualitative methods allow for identification of previously unknown processes, and explanations of why and how phenomena occurred. Hence, the combination of both methods can help us to better and more comprehensive understanding of a research problem to answer questions about what, when, and how much a certain phenomenon occurs (Dawadi et al., 2021:25-27; Creswell and Plano, 2018: 593; Creswell & Creswell, 2018; 63).For this research, mixed methods approach was used. Since it combines elements of both qualitative and quantitative methodologies, mixed methods research sits in the middle of this spectrum. Closed-ended questions are common in quantitative data, whereas open-ended questions with no prepared interview questions are common in qualitative data (Dawadi et al., 2021:27; Creswell & Creswell, 2018; 43). Instead of collecting data concurrently and merging the results, a mixed methods researcher can gather quantitative and qualitative data in two periods, with one type of data collection preceding and informing the other, which is known as explanatory sequential mixed methods. Quantitative data is collected first, followed by qualitative data to assist explain or elaborate on the quantitative findings in an explanatory sequential mixed methods approach. This technique is justified by the fact that quantitative data and results provide a broad picture of the study topic; further

analysis, namely qualitative data collection, is required to refine, extend, or explain the broad picture. This study used an explanatory sequential mixed methods approach, which was so named because the quantitative phase was followed by the qualitative phase. It is explanatory because the qualitative data aids in the comprehension of the quantitative data (Asenahabi, 2019:86 ; Creswell & Creswell, 2018:355). In this study, the researcher used mixed methods was to explain the subject under study sufficiently by complementing quantitative and qualitative methods and to get comprehensive knowledge. Moreover, triangulating the data provides more valid result than utilizing either method alone.So first conducted was quantitative research in phase one and results analyzed. Result of the quantitative section about the magnitude of IPT utilization and implementation and determinant factors for low uptake and completion further explained by qualitative indepth interview in phase two and continued to expand the findings and explain them in greater depth. Phase three was the development of the guide, and Phase four the validation of the health education guide by a Mini Delphi survey.

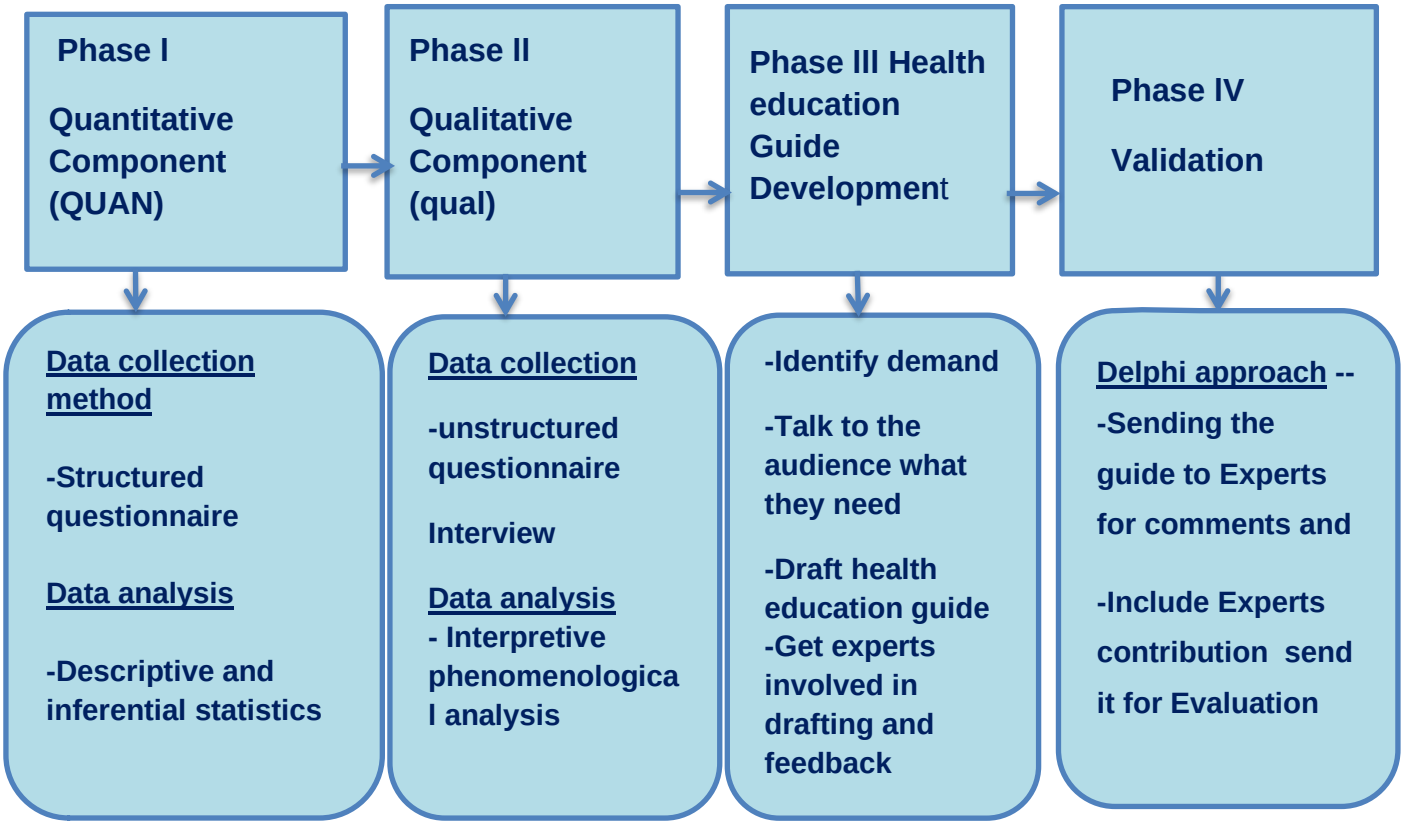


Figure.3.3: Phases of explanatory sequential mixed methods

3.4.2. Explanatory sequential mixed methods design

The sequential mixed methods design starts with a quantitative analysis that is explained by a qualitative follow-up (explanatory) or with a qualitative followed by a quantitative follow-up (exploratory). In the health sciences, the explanatory sequential mixed methods design is a prominent strategy in which qualitative data is used to assist explain quantitative findings in greater depth (Toyon 2021: 258; Creswell & Creswell 2018:355-359). Explanatory sequential mixed methods design was used in this study. In Phase one**;** the researcher used quantitative research and analysis to gather data on certain factors. In phase **two,** Following the quantitative data collection and analysis, a qualitative in-depth interview of participants was conducted and the research findings used to expand and explain them in greater depth. As a result, the quantitative findings of suboptimal IPT uptake and completion were expanded upon and supported by the qualitative in-depth interview part, with the results reported. In phase **three,** health education guide development was done according to the gap identified in the quantitative and qualitative analysis. In phase **four**, validation was done by sending the health education material prepaired for six experts in the field to evaluate and comment on it. Finally expert's comments incorporated and sent for their review and the final version of health eduction guide attached with the thesis.

3.4.3. Strengths and Limitations of Mixed Methods Research

Strengths of Mixed Method Research:

According to Creswell and Creswell (2018: 346-347), mixed methods research is an effective strategy for gaining a more comprehensive understanding of research problems or questions. Mixed methods research then:

- Provides an option for researchers to compare various perspectives drawn from both quantitative data and qualitative data.
- Explanatory sequential mixed methods design can be used to explain quantitative findings with a qualitative data collection and analysis.

- ❖ Exploratory sequential mixed methods design can be used to develop better measurement instruments by first collecting and analyzing qualitative data.
- ❖ Mixed methods research can be used to develop a more complete understanding of changes needed for a marginalized group (e.g., the poor) through the combination of the two qualitative and quantitative data.
- ❖ Mixed methods research can provide strong evidence to evaluate the impact of programs. Impact of programs in improving the health and wellbeing of populations can be better understood through collecting both qualitative and quantitative data over time.

Limitations of Mixed Methods Research:

Despite such a wide range of advantages, mixed methods research has its own limitations. According to Creswell and Plano Clark (2018:56-58) numerous challenges for researchers include the following:

- Mixed methods research needs extensive data collection. Researchers need to collect both quantitative and qualitative information that require a vigorous effort.
- It is time intensive to analyse both qualitative and quantitative data at a time. It requires extensive time to transcribe text data, code the transcripts and develop the analysis framework.
- Researchers need to be familiar with both quantitative and qualitative forms of research to conduct mixed methods research.

Mixed methods research is a complex undertaking, and it is difficult to understand for research users. The complexity of the design often demands for the use of clear, visual models in order to understand the details and the flow of research activities.

3.5. RESEARCH METHODOLOGY

Methodology is a set of procedures that guide the use of design. These procedures occur in the research at a more practical level than the design (Creswell & Creswell, 2018:361). Instruments used for data collecting, such as the questionnaire, interview, focus group, and so on, are examples of research methods. Research methods involve the form of data collection, analysis, and interpretation that the investigator proposed for his results

finding. The study setting, sample size determination and sampling techniques, the process of data collection and methods of data analysis that were employed in the findings are explained in the next paragraphs.

3.5.1. Population and Sampling

3.5.1.1. Study Population

Study population for quantitative study were people with HIV and registered at Tikur Anbessa Specialized Hospital and currently on ART care and follow-up and for the qualitative part are health care providers (nurses, physicians, pharmacists, and other ART providers) working at the hospitals HIV care and treatment unit were included.There were about 3100 people with HIV registered on follow-up in the hospital to take sample for quantitative study and there are twelve health care providers who were working in the unit for qualitative indepth interview.

The study population is termed as a large group of many cases from which the researcher draws a sample and can be stated in theoretical terms (Heavy, 2019:18). As Bhardwaj explained (2019:158), populations are human beings or other cases in which the investigator is interested in. Study population is the subset of the population included in the sample and a particular group in which the study is performed (Osuagwu, 2020:50). It is also known as the target population or the entire group of population that the researcher is interested and would like to generalize the study's findings. However, researchers do not have access to the whole population, and therefore must rely on the accessible population, which is often a non-random sample of the target group. According to Heavy (2019:137), the researcher also established eligibility or inclusion criteria, which are criteria that designate certain traits for admission into the target group. For the study, the following inclusion and exclusion criteria were used:

3.5.1.2. Eligibility Criteria

Inclusion criteria for quantitative study

- Patients living with HIV who are on HIV care and treatment follow up.
- Patients living with HIV willing to give written consent to participate.
- Patients living with HIV above 18 years of age were included in the study.

- Patients with HIV with more than 6 months of their diagnosis and follow up in care.

Exclusion criteria for quantitative study

- Patients with HIV less than 18 years of age.
- Patients with HIV in less than 6 months of diagnosis.
- Patients who are unable to give informed consent due to other medical co-morbidity such as hearing loss.
- Patients with transferred out to other health institution, lost to follow up and seriously sick.
- Patients on follow-up and refuse to participate due to their own reason.

Inclusion criteria for qualitative study:

- Health care providers such as Physicians, Pharmacists, Nurses and health officers etc who are working in ART clinic for six months and above and volunteer to participate.

Exclusion criteria for qualitative study:

- Health care providers (Physicians, Pharmacists, Nurses and health officers) who are working in ART clinic for less than six months.
- Health care providers (Physicians, Pharmacists, Nurses and health officers) who do not want to participate in this study.

3.5.1.3. Sampling

Sampling was done for quantitative as well as qualitative phases of the study. Sampling is defined as the procedure or technique of choosing study units from a well-defined study population. Sampling is important to reduce costs of the study, make the study practical, and increase the quality of the data (Bhardwaj, 2019:158; Creswell & Cresell, 2018:248). Bhardwaj (2019:158), further defined a sample as a smaller set or subsets a researcher selects from a larger pool and generalizes to the population and characterizes a sample as a group of participants in a study picked from the target population from which the researcher generalizes to the target population (Bhardwaj, 2019:158 Osuagwu, 2020:50).

The process of selecting study units from a specific research population is also known as sampling (Heavey, 2019:125-129).

In probability (random) sampling techniques, every element of the population has a greater than zero chance of being included in the sample. Probability samples are more likely to be representative of the population as compared to the non-probability samples. Most commonly, probability sampling techniques are used in quantitative studies or research. There are four categories of probability sampling techniques, namely: simple random sampling, stratified sampling, cluster sampling and systematic sampling (Heavey, 2019:128-129; Creswell & Cresell, 2018:248).

In this study, simple random sampling technique (SRS) was used to select participants from the population. In simple random sampling, the researcher selects participants (or units) for the sample so that any individual has an equal probability of being selected from the population. The purpuse of simple random sampling is to choose individuals to be sampled who will be representative of the population. Any bias in the population was equally distributed among the people chosen. Simple random sampling procedure often involves assigning a number to each individual (or site) in the population and then selecting individuals (or sites) for the sample using a random numbers table. For this method, you need to have a list of people from the target population, as well as a number for each of them. To use this random numbers table, first give each person in the population a unique number. Then, starting at any point in the random numbers table, match the numbers on your list to those in the table (Bhardwaj, 2019:159; Creswell & Cresewell, 2018:248; Heavey, 2019:128-129).

3.5.1.4. Sampling frame

The sampling frame is defined as the list of every member of the population from which the sample is taken (Creswell & Cresell, 2018:248). In this study, the quantitative sampling frame was ART patient register of all patients on follow up and for the qualitative part, the sampling frame includes all health care providers working at Tikur Anbessa Specialized Hospital ART unit.

3.5.1.5. Sampling technique

3.5.1.5.1 Quantitative sampling

Individuals who are HIV positive and on ART follow-up in the study institution were selected during their regular appointment for ART refill and participant's medical records also reviewed. To find eligible participants who met the inclusion criteria, the researcher used the ART register as a sample frame. Participants for this trial were identified using a simple random sample technique from patients who had their ART refill scheduled. Random sampling ensures that the sample is representative of the entire population because each person in the population has an equal chance of being chosen (Creswell & Cresell, 2018:291).

3.5.1.5.2. Sample size for quantitative data

A subset of the population elements with which the researcher works with is referred to as the sample size (Polit & Beck 2013:306). The sample size was calculated using the formula for single population proportion study with random sampling (Bordens & Abbott 2018: 296) for the quantitative section of the study. With a national average uptake of 18.2% (2015 report), a 95% confidence level, a 5% margin of error, and a 10% non-response rate were observed.

$$n = \frac{(Z_{\alpha/2})^2 \, p \, (1- p)}{d^2}$$

Where:

n= Sample size

d = margin of error = 5%

P= prevalence Assumption= 18.2%

$Z_{\alpha/2}$ = Z value corresponding to a 95% level of significance or is the value of normal distribution representing confidence level of 95% and its value is 1.96.

$n=(1.96)^2 x 0.182(1-0.182))/(.05)^2$

(3.8416 x .148876)/.0025=229

229+10% non-response rate

n= 252 Therefore the final sample size was = 252

3.5.1.5.3. Qualitative sampling

In a qualitative study, there are many sampling techniques that can be used when recruiting study participants, like, purposive and convenience sampling. In this study, all health care professionals (Physician, Pharmacists, Nurses) working in ART clinic of the study institution and agreed to participate were included. Participants were interviewed till we reached saturation of ideas generated or repeatation of responses. Sample size of participants used for in-depth interview has to be at least 10-12 and in this study all twelve health care providrs working on ART during the period of data collection were interviewed. In this qualitative research, the samples were chosen in a deliberate manner known as purposive sampling.The goal or purpose for selecting the specific study units is to have those that yield the most relevant and plentiful data in the topic of a study (Abuhamda, Ismail & Bsharat. 2021:77).

3.6. DATA COLLECTION

To measure the variables in the study, a quantitative data collection tool is used. A tool for measuring, observing, or recording quantitative data is known as an instrument. It includes specific questions and response options that you produced or constructed in advance of the research.Instruments like survey questionnaires, standardized tests, and checklists that might be used to observe a participant's behaviors. This instrument was given to participants, and data collected in the form of numbers (Creswell & Creswell, 2018:396).

3.6.1. Quantitative Data collection approach and method

Data source for this study was primary data source.Interview involving structured questionnaire was utilized for quantitative data collection. Patients with HIV on follow-up in the study institution were interviewed after patients signed the consent form. Information to be gathered includes patient's socio demographic characteristics, TB preventive therapy status, prevalence of IPT use, factors affecting IPT uptake and implementation.

3.6.2. Development of quantitative data collection instruments

Instruments to collect data were developed after extensive review of related literatures. Structured questionnaires which comprised of different sections were used to collect quantitative data.Instruments developed, adopted and customized after review of previous related studies by the researcher. The researcher translated the questions into local language in the study site, which is Amharic. To check the validity of the questionnaire, it was translated back into English to avoid its inconsistencies in the meaning and purposes. Then, one day training was given to data collectors on how to assure the quality of data, ethical issues, how to handle the challenges, effective communication strategies and some questions that need attention by the data collectors. After the tools developed, pre-testing done on twenty five participants and the instruments were reviewed to address deficits, unclear and ambiguous words. Accordingly, questiions asking participants ethnicity was excluded, questions like type of comorbidity, ART adherence level added and other unclear terms were revised.

3.6.3. Characteristics of quantitative data collection instruments

The survey questionnaire featured a cover sheet with patient information that the data collectors read and explained to those who were eligible and included in the study, as well as for those who wanted to learn more about the study. Those who accepted to participate in the study were then asked to sign an informed consent form after a thorough explanation. The survey questionnaire is divided into three sections. The first portion includes questions about the participants' socio demographic characteristics, such as their age, sex, marital status, ethnicity, religion, educational status, employment status, and monthly income. The second component dealt with the clinical, immunological, and virological statuses of those who took part in the study, and the third section dealt with IPT awareness, uptake, and completion among PLHIV on follow-up. The survey was also translated into Amharic, the native language..

3.6.4. Qualitative Data collection approach and method

For qualitative indepth interview part, open ended, non-leading and unstructured interview guide and probing questions were prepaired after review of different literatures. In addition, inputs from quantitative data collection and analysis were used to modify and develop

indepth interview instruments (questions). Sub optimal IPT uptake and low completion rate were leading to ask questions why the reason for low performance and how this occurred and to prob and explore more ideas about factors for the low finding. As the interview progressed, some of the questions might be modified in order to be for the appropriate purpose.

3.6.5. Characteristics of qualititative data collection instruments

Qualitative indepth interview questionnaires containing a cover page with participant information sheet attached. The data collectors provided for those who were volunteer to participate to read the information themselves and explained about the interview process as well as for those who wanted to learn more about the study. Health care providers who accepted to participate in the study were then asked to sign an informed consent form after a thorough explanation.Then partcipants (health care providers) who were working in ART at the time of data collection and based on the inclusion criteria were interviewed a series of questions. Data collectors were audio taped and took field notes.

3.6.6. Pre-testing of the data collection instrument

Pilot testing was undertaken for pre-testing the questionnaire. Unclear words and sentences from the questionnaire may be identified, removed (eg. Ethnic questions), added (eg. Comorbidity questions), corrected or edited in the light of the results of the pilot study (Bordens & Abbott, 2018 157-160). For quantitative study, the questionnaires prepaired were pre-tested before the actual data collection and participants selected to take part in the pilot study to complete the questionnaire were not included in the actual study analysis. The collected data from the pre-test was used to revise and modify data collection tool. The revised data collection tool was presented to the supervisor for corrections and comments and the final one used for the actual data collection.

3.6.7. Data collection process

The data collection procedure involves gathering information from study participants. In this study, quantitative data was collected by nurse data collectors in addition to the researcher. The lead investigator served as both a supervisor and a data collector. The data collector was a clinical nurse who worked in the same hospital and had previous experience in collecting data for several studies. On the participants' regular follow-up

and drug refill appointment dates, the researcher and study assistants collected data from the Hospitals' HIV care and treatment out-patient clinic. At the conclusion of the interview, the participants were given a structured and pre-tested questionnaire that was administered by the interviewer which may take about forty minuts (40 min). The survey was written in both English and Amharic. The questionnaires were developed from other related studies and tailored to the local context and study objectives. The information such as socio demographic characteristics including: age, sex, marital status, residence (urban versus rural), ethnicity, religion, education level, employment status and information given to patients regarding the benefits, adverse effects of Isoniazid preventive therapy and sources of information, their IPT uptake and completion status, number of months they took IPT, history of TB infection, comorbidities, immunological and virological markers and other information's were collected from participants and their medical records.

The role of the researcher was to supervise and oversee the overall data collection process and to resolve any problem encountered by research assistants. Orientation was provided and necessary logistics were availed by the researcher before the data collection date.

In addition to collecting data, the researcher was directing the research assistant to follow the data collection rules in order to ensure that the data collected was of high quality. On a daily basis, the researcher also gives technical assistance to the data collector. The researcher verified the filled instruments (questionnaires) for completeness and correctness at the conclusion of each day and discussed the day's performance with the data collector, including any issues encountered throughout the data collection process.

Face-to-face in-depth interviews with open-ended probing questions were used to acquire qualitative data. Health care providers working in HIV care and treatment units (counselors, physicians, coordinators, case managers, nurses, and pharmacists, among others) were included and interviewed for this section. The interviews were audio-taped with the participants' agreement and lasted roughly sixty minutes (1hr) each. The researcher made field notes as well.

The interview was performed in ART clinic private room at the participants' convenience and preferable time. Sample size for qualitative part was determined based on saturation

of ideas generated by participants. But in this study all twelve health care providers working in ART unit were included in the in-depth interview. Then based on the data finding health education guide prepaired and was issued by e-mail to professionals experts in the field to suggest, comment on, add ideas and information via the Delphi process of gathering expert opinion and input. All suggestions and comments were taken into account, and the amended information was returned to experts for review.

3.7. DATA AND DESIGN QUALITY

Quality concerns play a central role throughout all steps of a research process from the beginning of a research question and data collection to the analysis and presentation of research findings (Haradhan, 2017:11). Validity and reliability determine the quality of scientific study and the data gathering equipment or methods utilized. In this particular research, the researcher strictly followed the principles of both reliability and validity.

3.7.1. Reliability

The degree of consistency with which the instrument measures the trait it is supposed to measure is referred to as reliability. When a dependable research instrument or tool is utilized frequently, it produces the same value when used repeatedly (Creswell & Plano Clark, 2018:318). According to Peter (2016: 122,157), reliability refers to accuracy and precision of a measurement instrument or scale. Reliability in a quantitative study is the repeatability and independence of findings from the specific researchers generating those findings (Waltz et al., 2016:186).

Test score reliability is calculated using internal consistency measures, which can be expressed mathematically in a variety of ways. The coefficient alpha is the most widely used measure of internal consistency for composite scores (Bahariniya, Ezatiasar, & Madadizadeh, 2021:100), whereas Cronbach Alpha is the most widely used measure of internal consistency and can be used for three-, four-, or five-point likert scale items (Bahariniya, Ezatiasar, & Madadizadeh, 2021:100). (Bahariniya, Ezatiasar & Madadizadeh, 2021:1).

In this study, to ensure reliability of the questionnaires (instrument), the questionnaires were adopted from published in peer-reviewed journal articles such as those interviewd for pretesting (Abossie and Yohanes 2017:362-365; Teklay et al 2016:3-6; Abdulalim et

al 2017:1-5; Tiruneh, Getahun & Adeba, 2019:4-5; Thindwa, MacPherson; Choko, et al 2018:278), and questionnaires were pre-tested on patients enrolled in HIV care and treatment in the study institution; and those interviewed for pre-testing the tool were not included in the main study.

3.7.2. Validity

Validity is a measure of precision that relates to an instrument's ability to measure what it claims to measure or the degree to which it accurately measures what it intends to measure (Bahariniya, Ezatiasar & Madadizadeh and 2021: 101). Validity also refers to the extent to which the collected data actually tells us the truth (Creswell & Plano Clark, 2018:318; Peter, 2016: 121,152).

According to Patino and Ferreira (2018:183), validity of a research study refers to how well the results among the study participants represent true findings amongst similar individuals outside the study. This concept of validity applies to all types of clinical studies, including those studies of prevalence, associations, interventions, and diagnosis. In a research, validity includes two parts: internal and external validity.

3.7.2.1. Internal Validity

Internal validity is defined as the extent to which the research results are the true reflection or representation of reality rather than the effect of extraneous variables in the population we are studying and, thus, are not due to methodological errors. Internal validity refers to how accurate a studys' findings are for the population being studied (investigated) (Ruel, Wagner & Gillespie 2016: 187; Peter, 2016: 121&152).

The internal validity of a study can be threatened by many factors, including errors in measurement or in the selection of participants in the study, and researchers should think about and avoid these errors. In this study, to increase internal validity, investigators confirmed careful study planning and adequate quality control and implementation strategies including adequate recruitment strategies (develop consistency in administering the questionnaire), data collection, data analysis, and sample size. For this study, investigators established internal validity by maintaining consistency in administering the questionnaire throughout the data collection process**.**

3.7.2.2. External Validity

External validity refers to the extent to which a study's findings may be extended to other situations (Ruel, Wagner & Gillespie 2016: 188; Peter 2016: 121&152). External validity can be improved by employing broad inclusion criteria that result in a study population that more closely reflects real-life patients, and by selecting interventions that are possible to implement in clinical trials (Patino and Ferreira 2018:183).The selection of the sample, whether it is randomly selected from a broader population or not, poses a threat to external validity (Peter 2016:154). Since the objective of research is usually to extend findings beyond the unique sample of the experiment, external validity is crucial (Peter 2016:154). To ensure external validity, researchers in this study attempted to include a wide range of inclusion criteria, as indicated.

3.7.3. Objectivity

Objectivity refers to the findings related to the method of data collection and scoring of the responses. The research design should permit the measuring instruments which are fairly objective in which every observer or judge scoring the performance must precisely give the same report. In other words, the objectivity of the procedure may be judged by the degree of agreement between the final scores assigned to different individuals by more than one independent observer. This ensures the objectivity of the collected data which shall be capable of analysis and interpretation. Objectivity can also be defined as the degree to which the findings are free from bias i.e. addresses neutrality of the investigator (Forero, Nahidi and De Costa, et al., 2018:9). This is to address the question: how far the personal interests of the researcher influence the findings of the study? It is a measure of minimizing any possible bias due to the researcher's values or interests (Creswell & Creswell, 2018:48). In the present study, objectivity was attained by avoiding selection bias (selecting participants using randomization) and measurement bias (using tested instruments). The researcher avoided introducing any personal values and interests throughout the course of the study by assigning data collector.

3.8. DATA MANAGEMENT AND ANALYSIS

3.8.1. Quantitative data management

The quantitative data was cleaned and checked for completeness and consistency. Data will then be entered to EpiData version 3.1 and exported to Statistical Package for Social Sciences software (SPSS) version 25 for analysis. Descriptive summary statistics, bivariate and multivariate logistic analysis was done to present the findings and identify associated factors. Odds ratio also done to see strength of association between variables and results presented in graphs and tables.

3.8.2 Qualitative data management

Data from interviews of audio recored was transcribed and translated from Amharic to English by the research assistant and researcher. The overall data was looked, coded, and recoded, organized and qualitative thematic content analysis and framework analysis were used to study the data. Then after organizing and preparing the data for analysis, Coding and categorizing the data in themes, then description involving detailed interpretation of information and generating categories or themes for analysis made. Discussion and narrative passage to convey the findings of the analysis presented. Finally, Interpretation of the findings, lessons learned and identified gaps were reported. Thematic content analysis was utilized to investigate or describe factors that contributed to the poor use of isoniazid preventative therapy. The framework analysis assisted in classifying and summarizing the data within a thematic framework. Finally, the result interpreted concluded and reported. The researcher spent all the time during qualitative data collection.The final report was provided to peers to review and ask question about the qualitative research. Seven steps of qualitative data management used for analysis of data as described in this section.

3.8.3 Delphi data management

Delphi technique is a scientific method to organize and manage structured experts' communication processes with the purpose of creating understandings on either current or prospective challenges (Beiderbeck, Frevel, Gracht, et al., 2021:2) The objective of the Delphi method is to reach a consensus among the specialists (experts) on a specific

theme in order to create a scenario. It is important that each participant doesn't know the identity of other specialists during the method proceedings, purposely to keep the opinions completely formal and impersonal. Knowing the identity of respected specialist could be unapproachable and could interfere on the explanation of opinions. The Delphi technique is a way of obtaining a collective view from individuals about issues where there is no or little definite evidence and where opinion is important. Experts or group of panelists in the field with relevant knowledge were recruited anonymously to participate in the study (Niederberger & Spranger, 2020:1-2). For this study, six Delphi panelists experts working on TB, HIV, TB/HIV and infectious disease specialists, lecturers and experts of these programs patricipated. After recruiting experts and know the effectiveness of the group size and composition, health education guide developed were sent to gather appropriate knowledge and opinions from the experts, facilitate their creative thinking as individuals, collect, compose, synthesize and rearrange their varied responses (Niederberger & Spranger, 2020:1-2). Sugestions from Experts: sections like scope of the guide, target group for the guide and suggestions added. Inaddition, they suggested to add the current study finding evidences in to the introduction part of the guide and recommened the need to provide information on signs of hepatotoxicity during treatment to stop IPT.

3.8.4. Trustworthiness

Rigor is a key component of good qualitative research, which is set to ensure that findings from a particular study are accurate from the viewpoint of the readers, the participants and the study researchers (Tomaszewski, Zarestky, & Gonzalez, 2020:1-7). To ensure or maintain scientific accuracy when working with qualitative data, the concepts of trustworthiness such as dependability, transferability, and credibility were also used (Haradhan, 2018:22; Stenfors, Kajamaa and Bennett, 2020:597).

3.8.4.1. Credibility

Credibility is defined as the level of trust that may be placed in the accuracy of a study's findings or the study shows the real meanings of the study respondents, (Nowell, Norris, White & Moules, 2017:3).

In this study the researchers-maintained credibility by:

- Prolonged engagement: researcher spent adequate time with participants; to build good rapport (establish good communication) before initiating data gathering and persistent observation during data collection process.This allows the researcher to obtain a better understanding of the study's context, reducing the risk of information distortions caused by the researcher's presence in the field. Participants may volunteer in a variety of ways and often give more sensitive information. In addition, persistent observation helps to gain details and to discover participants' qualities and unusual characteristics. Researcher will always seek scholarly guidance from supervisor and other willing professionals.

- Triangulation: researcher collected data from health care providers as well as patient participants using both quantitative and qualitative data to ensure by using different data collection methods.

- Negative case analysis: reporting negative cases enhances the credibility of the study and helps to reformulate the research questions and increase the rigor of the study (Wallendorf and Belk, 1989). Researchers of this study believed to report any negative and unexpected responses during data collection.

- Member-checks: The voices of respondents must be included in the researchers' data analysis and interpretation. Member checks are intended to eliminate researcher bias while evaluating and interpreting study data. This means that the analyzed and interpreted data is handed back to the participants for them to examine and offer changes to the inquirer's interpretation if they are unhappy with it or believe it is incorrect (misreport). For a variety of reasons, informants may reject a researcher's interpretation, including social unacceptability or the researcher's general presentation style. Creswell and Creswell (2018), p. 321-323. We kept our credibility by reading the participant's comments at the end of the interview.

3.8.4.2. Dependability

Dependability refers to the consistency of findings over time (Connelly, 2016:1 & Nowell, 2017:3). If the results of the analyses are consistent, the investigation can be trusted (dependable). It is also the extent to which the study could be repeated by other researchers and the findings would be consistent over time. If another person wants to replicate the study, they should have enough information from the report to do so and obtain similar findings (Connelly, 2016:1& Nowell, 2017:3).

To ensure dependability:

- ❖ Code-recording of data: the researcher coding the same data twice, giving one or two weeks apart between each coding. The results from the two codings were compared to see if the results are the same (code agreement) or different (Forero, et al. 2018:1-7). In this study, the researcher coded the data twice, analyzed and compared the results.

- ➢ Stepwise Replication: is a method for evaluating qualitative research data in which two or more researchers analyze the same data separately and compare the results.

For this study, the researcher and one of the colleagues' analyzed the data and compared the results for similarity.

Audit trial: The research methods and protocol, inquiry process: raw data, interview and observation notes, documents and records collected from the field, test scores and others were evaluated by the supervisor (Tomaszewski, Zarestky & Gonzalez, and 2020:5). The data collected by the interview was checked and re-checked by the investigator on a daily basis.

3.8.4.3. Conformability

The degree to which the findings of an investigation could be validated or supported by other researchers is referred to as conformability. It refers to the findings of a research study's neutrality. This occurs when the conclusions are based on the responses of the participants rather than the researcher's potential bias or personal intentions (Connelly,

2016:1 & Nowell,2017:3). The researchers triangulated the research by collecting data from different populations (patients and health care providers) using qualitative and quantitative methods, and the supervisor evaluated all of the research methods and protocol, as well as the data collection process: raw data, interview documents, and field records.

3.8.4.4. Transferability

Research findings are transferable or generalizable only if they fit into new contexts outside the actual study context or applicable to similar conditions, population and phenomena (Connelly, 2016:1; Creswell & Plano Clark, 2018:393). Transferability is analogous to external validity, that is, the extent to which findings can be generalized. Generalizability refers to the extent to which one can extend the account of a particular situation or population to other persons, times or setting than those directly studied. In this research, to maintain transferability, participants were selected using purposive sampling method. Purposive sampling method allowed the researcher to select key informants who were knowledgeable about the issue under study. The research report should include a comprehensive set of details about methodology and context (Connelly, 2016:1& Nowell, 2017:3). This description helps other researchers in replicating the study with similar conditions in other settings.

3.9. ETHICAL CONSIDERATIONS

Ethical considerations are related to respondents' (patients') rights. Patients' rights were the center for ethical considerations. These respondents' rights were discussed in terms of informed consent, autonomy, anonymity, confidentiality, privacy, and justice, which included beneficence (or the absence of maleficence). Research that is conducted with human participants requires a careful consideration of ethical issues that may arise during the conduct of the study. The researcher shall observe and be guided by ethical principles explained in Creswell and Creswell (2018:167-169).

3.9.1 Informed consent

Informed consent to participation in research and evaluation is a vital element of health and social science research ethics (Thorley, 2019:14). It is the process of explaining potential research particpants about the main elements of a research study and what their

participation will include. The informed consent process is one of the important components of the ethical conduct of research with human participants. The consent process typically includes providing a written consent document containing the required elements of informed consent information and the presentation of that information to prospective participants (Grant, 2021:1; Stadnick, Poth, Guetterman and Gallo, 2021:5). Informed consent is agreement of participants to participate in research without any influence by the investigator. The researcher was accommodated to provide for participants with adequate information to make their own informed decision to participate in the study (Varkey, 2021:19; Creswell and Creswell, 2018:172).

According to Creswell & Clark (2018:267-268), informed consent includes agreement made by the participant to take part in the study during interview or audiotaped (Chesnay, 2015: 134) after being explained to about the purpose, benefits, risks and the process of data collection and confidentiality issues. Creswell and Creswell (2018:176) stated that informed consent is part of autonomy as the participants are supposed to make informed choices without being forced to participate in the study. For this study, participants were informed about voluntary participation, obtained voluntarily and without any form of pressure or unnecessary influence or promise for any special kind of remuneration. Participants were informed that they can resign at any time without giving reason and there was no disadvantage or sanction for withdrawal. Participants were provided with a consent form to write their names and sign.

3.9.2. Ensuring confidentiality

Confidentiality and anonymity of participants was ensured by participants choosing a pseudonym to be attached to the transcribed interviews and data analysis. Transcribed interviews and data were coded with the pseudonyms and maintained in a locked cabinet. They were informed that no one had access to the data and that the researcher kept quantitative data transcribed and interviews in a computer access by password protection with limited access to the researcher (Varkey, 2021:20). To ensure confidentiality of information provided by the participants, it was kept private and used only for the intended study purpose. The interview was conducted in a private room. Names were not used in the analysis of the data (only summarized information of the group appeared in the result). All audio recordings were transcribed, analyzed and modified to ensure that they cannot be linked to the study participant.

In addition, to ensure the rights of participants and protect them from any injury, the researcher maintained the ethical principles such as; beneficence, non-maleficence, autonomy and justice.

3.9.3. Ensuring autonomy

Autonomy: refers to the patients' right to choose and the professionals' obligation to respect their choices. This principle of autonomy is only respected when the professional fulfills the responsibility to guarantee the patient's right to direct the course of their own life and make decisions about their own care (Nora & Junges, 2021:6).

Participants in the study were treated with respect, their privacy was respected, and their right to self-determination was protected (Varkey, 2021:19 & Nora & Junges, 2021:6).

To maintain participant autonomy, the researcher gave study participants the required information about the research protocol and methods and obtained their informed consent.

The participants' privacy and confidentiality were protected throughout the research procedure in this study. Participant's names were replaced by codes, and the interview was done in a secret private room. Throughout the study, the researcher also respects the participants' right to self determination (Varkey, 2019:19).

3.9.4. Ensuring beneficence

Beneficence: The word beneficence refers to the ethical obligation to maximize benefits, avoid or minimize harms, promotion of wellbeing by maximizing benefits to participants (Varkey, 2021:18; Bordens & Abbott, 2018:203; Nora & Junges, 2021:5). Beneficence also described as acting for the benefit of others and one of the most essential ethical principles in research which encompasses a duty on the investigator to take advantage and minimize risk (Thorley, 2019:6).

Researcher would be responsible to ensure the wellbeing of the study participants by maximizing the benefits of the participants and avoiding any physical discomfort, emotional disturbance, and economic crisis of the study participants. Prior to the interview of study participants, the researcher and assistants were clearly explained to about the

aim and objective of the study, confidentiality of the information and the right of each participant to participate or decline from the study at any interview or data collection period. By this technique investigator and research assistants minimize all kinds of harm and distress and to get a possible balance between the possible benefits and threat of being participated.

3.9.5. Ensuring non-maleficence

Non-maleficence: This refers to not causing harm to participants through acts of intentional action or omission. It is the researcher's responsibility to keep the participants safe. It is a moral imperative not to injure others. Participants were told to decline from participating at any stage of interview if they are not feeling comfortable to partipate. The study participants were protected from potential physical, psychological, financial, and social dangers or harm by the researcher (Varkey, 2021:18; Bordens & Abbott, 2018:203 & Nora & Junges, 2021:5). A Study should ensure that the real benefits to be derived by the study respondents or community clearly outweigh possible risks and the study respondents are subjected to only those chances that are clearly necessary for the conduct of the research. This section of the study clearly described the steps undertaken to avoid the possible side effects with respect to psychological, physical and social which could be mentioned by respondents in the study. First, the data collectors communicated with each study respondent before the actual data gathering process took place about no discomfort could be posed due being involved in the study. At the second step, each study respondent was informed that no psychological problem can be manifested to them on rational of the study participants. At the finally, each study respondents was informed about ethicality of the research. Moreover, the respondents were also clearly informed about confidentiality and privacy of all responses completed by them.

3.9.6. Justice

It refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. The principle refers primarily to equitable distribution of both the burdens and the benefits of participation in research (Creswell and Cresell 2018:173-174; Varkey, 2021:20 and Bordens & Abbott, 2018:203). According to Nora & Junges (2021:6), justice refers to equitable distribution of benefits (the patient’s right to receive a fair share of benefits, burdens, and risks). It is an

unbiased equal distribution of goods and services and responsibility for the quality of care. Hence, every patient would have the right to fair, equitable, and adequate care. In this study, the researchers ensured the rights of participants in that individuals were treated equally by using the same sampling procedure and applying the same types of assessment instruments to all participants. Participants were informed about having an equal chance to participate and equal benefit from the output of this research. After obtaining ethical clearance from ethical committees of both universities of South Africa higher degrees committee and Addis Ababa University College of health sciences Ethical review board, researcher recruited the data collector and gave a one-day orientation and training about the data collection process. Data collector took informed consent from all participants before the interview. To obtain informed consent, the participants were given all the relevant information related to the study which includes the purpose of the study, benefits and any potential risks. Participants had the opportunity to ask questions freely. The researcher emphasized that participation is based on willingness and participants can decline from the research at any time or stage of research without any impacts on their health care service. The contact details of the researcher and relevant ethics committees were provided to the participants on the consent form which is attached.

Risk: Regarding risks that the participants may suffer and the level of risk; this study had very minimal risk and does not involve any physical harm, social discrimination, psychological trauma and economic loss. To prevent extra economic loss, interview was done on their regular and scheduled visit at the clinic. To avoid their psychological harm, interview was performed at separate rooms with confidentiality. The whole interview process was explained to the participants assuring that names are not mentioned in the research. The risk might be spending about 20 minutes for survey questions and about 40 minutes for in-depth interviews of health care providers.

The patients' medical records were used as data source with permission of the hospital officials and their records which were kept locked and confidential. After obtaining the necessary data from the record, it was returned back to the record room with safety and confidentiality. All participants' information obtained from their records was kept confidential and names were not used to identify participants; instead codes were used to identify participants.

After obtaining approval from University of South Africa College of health sciences higher degrees committee and Institutional Review Board (IRB) of Addis Ababa University College of health sciences; the data collector was trained on how to keep participants safety, respect, confidentiality, how to protect them from stigma and in all aspects of ethical issues. In addition, data collector was a nurse who has experience on HIV care and treatment. The data collector was collecting data on daily basis and researcher supervised the process to ensure the implementation of ethical principles and follow the data collection procedures and check for data completness. There was no incentive or compensation provided for the study participants during the survey as well as in-depth interview of health care providers.

3.10. SUMMARY

This chapter presented and discussed the research design and methodology, the sequential use of two approaches, namely, qualitative and quantitative, which together constitute mixed methods approach. The mixed method design discussed in detail and justified why this approach was selected. Simple random sampling and purposive sampling techniques, structured interview schedule and in-depth interview issues discussed and justified. The features of the data gathering instruments were described. Methods of data analysis and justification for choosing a particular data analysis, Delphi data management, reliability and validity of the instruments were discussed. Finally, the ethical procedures that were followed to protect the rights of respondents were explained, the balance of risks and benefits and as well as the IRB review process were discussed.

CHAPTER FOUR

QUANTITATIVE RESEARCH FINDINGS AND DISCUSSION

4.1. INTRODUCTION

This section presents and discusses the findings of quantitative section inline with the research questions. The quantitative part comprises of socio demographic information of the participants (people living with HIV), knowledge about TB preventive therapy (IPT) uses amonge participants, clinical, immunological, virological status, uptake and completion of IPT among PLHIV.

4.2. QUANTITATIVE RESEARCH RESULTS

4.2.1. Response rate

All of the 252 people who were approached and interviewed agreed to participate in the study, resulting in a 100% response rate. Despite the fact that a ten percent non-response rate was taken into account, all eligible clients who were requested to participate were doing so voluntarily. Participants that were not included were those who were not eligible for the study. A flow diagram of the total number of people on HIV care and treatment, as well as the initiation and completion status of participants in the study area, is shown in Figure 4.1.

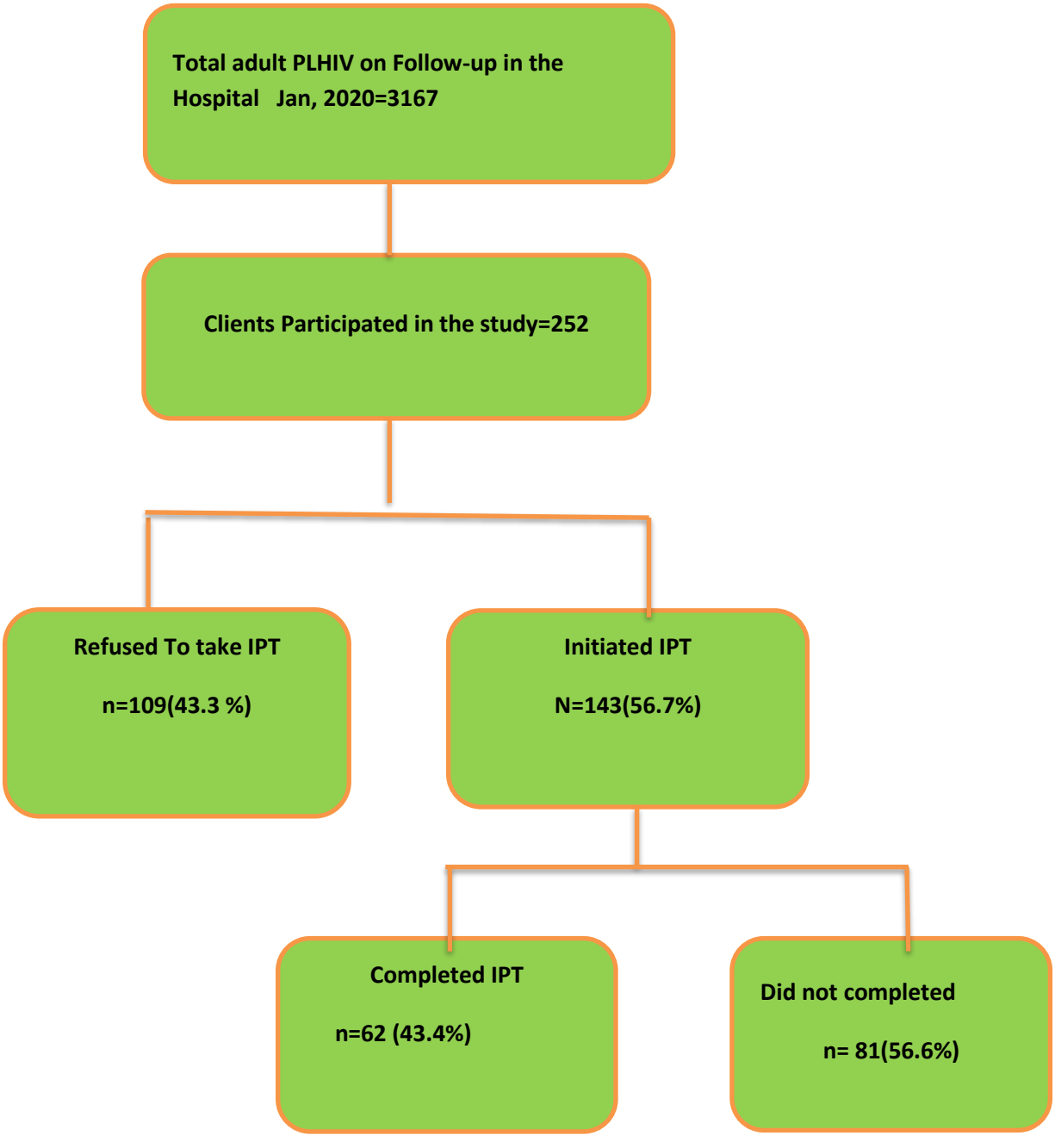


Figure 4.1: Flow diagram showing participant selection initiation and completion status of study participants in a tertiary hospital (N=252).

4.2.2. Socio-demographic characteristics of the participants

A total of 252 people living with HIV (PLWHIV) eligible for TB preventive therapy (TPT) were included. In addition, their medical records were reviewed and appointment schedule, viral load and CD4, their ART regimen, whether they have taken IPT or not, TB treatment history and other variables were included in the analysis. Table 4.1. Below simply showed the list of variables and their frequency and percentage distribution. Some of the characteristics were further presented and discussed separately in different forms.

TABLE 4 .1 FREQUENCY DISTRIBUTION OF VARIBLES OF PEOPLE LIVE WITH HIV ON FOLLOW-UP IN A TERTIARY HOSPITAL, ADDIS ABABA, ETHIOPIA, (n=252).

Variables	Categories	Frequency	Percent (%)
Age	**18-29**	**21**	**8.3**
	30-29	**63**	**25.0**
	40-49	**75**	**29.8**
	50-59	**60**	**23.8**
	60 plus	**33**	**13.1**
Gender	**Male**	**102**	**40.5**
	Female	**150**	**59.5**
Residence	**Addis Ababa**	**238**	**94.4**
	Out of Addis	**14**	**5.6**
Monthly Income	**<1000**	**30**	**11.9**
	1000-3000	**35**	**13.9**
	3001-5000	**112**	**44.4**
	5001-10,000	**45**	**17.9**
	>10,000	**30**	**11.9**
Nutrition	**Malnourished**	**27**	**10.7**
	Normal	**212**	**84.1**
	obesity	**13**	**5.2**
Current ART regimen	**1st Line**	**185**	**73.4**
	2nd Line	**62**	**24.6**

	3rd Line	**5**	**2.0**
Initial CD4 count	**<200**	**166**	**65.9**
	201-349	**48**	**19**
	350-500	**24**	**9.5**
	>500	**14**	**5.6**
Recent CD4 count	**<200**	**38**	**15.1**
	201-349	**35**	**13.9**
	350-500	**72**	**28.6**
	>500	**107**	**42.5**
Recent viral load count	**<1000**	**228**	**90.5**
	>1000	**24**	**9.5**
Attended health education on IPT	**Yes**	**145**	**57.5**
	No	**107**	**42.5**
Have Information and understanding on IPT	**Yes**	**159**	**63.1**
	No	**93**	**36.9**
Awareness on r/n between TB and HIV	**Yes**	**170**	**67.5**
	No	**82**	**32.5**
Awareness on IPT reduce TB risk	**Yes**	**191**	**75.8**
	No	**61**	**24.2**
Awareness on the importance of regular evaluation for TB	**Yes**	**190**	**75.4**
	No	**62**	**24.6**
Ever treated for TB	**Yes**	**113**	**44.8**
	No	**139**	**55.2**
Current use of Cotrimoxazol	**Yes**	**49**	**19.4**
	No	**103**	**80.6**
Presence of comorbidity	**Yes**	**57**	**22.6**
	No	**195**	**77.4**

4.2.2.1. Participants Age

In our study, participants' age was not found associated with IPT uptake and completion and below is Figure 4.2. The graph showing the age distribution of participants on ART follow up.

Figure .4.2. The age distribution of participants on ART follow-up in a tertiary hospital, Addis Ababa (n=252).

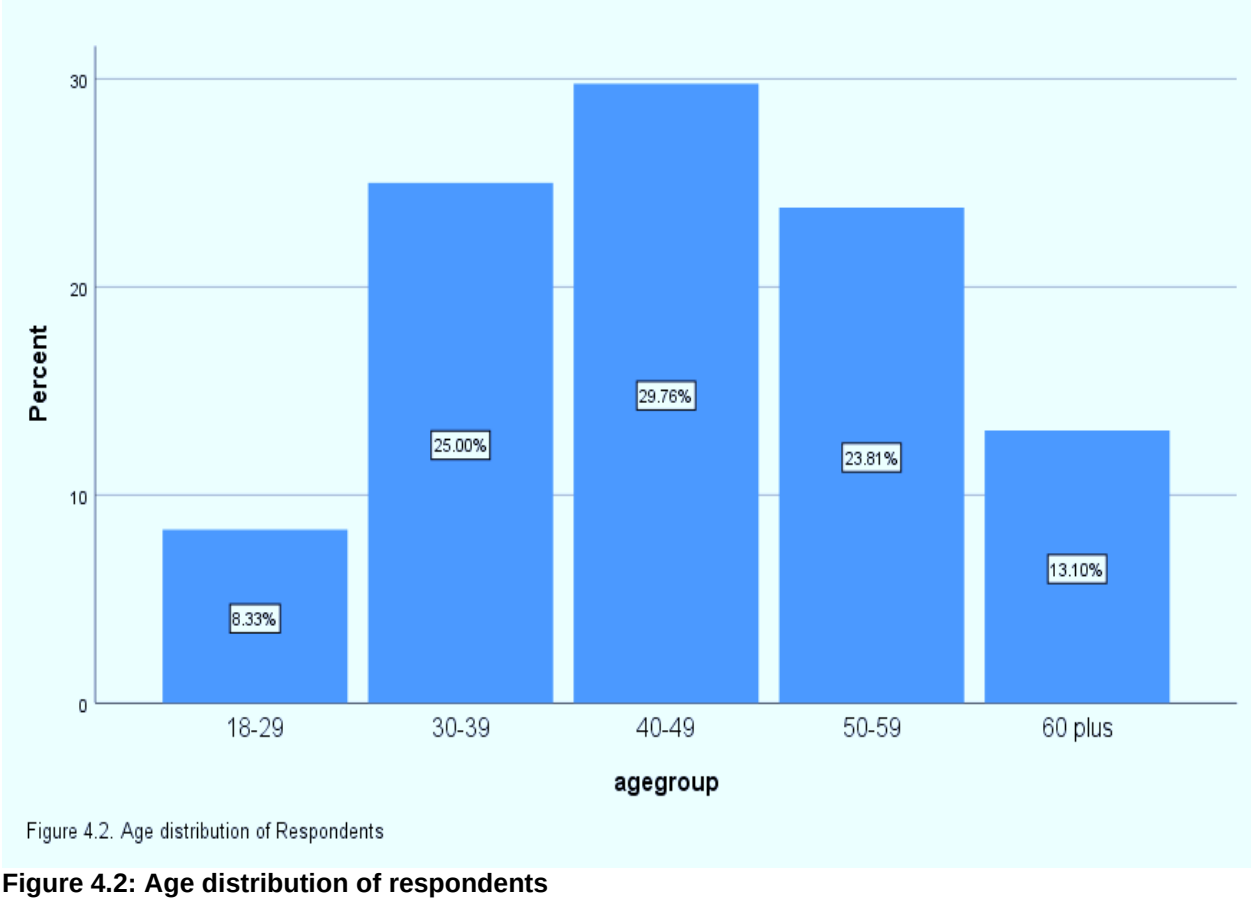


Figure 4.2: Age distribution of respondents

The mean age of respondents was 45 years and maximum and minimum age was 80 and 18 consecutivelly. The age distribution as it is displayed in Figure 4.2. Indicates that 29.8% (n=75) of the participants were in the age group 40-49, 25% (n=63) were in the age group 30-39, 23.8% (n=60) were between 50-59 and the rest, 8.33% (n=21) were between 18-29 and 13.1% (n=33) were 60 years and above. As it is shown in the above, it indicates that most of the participants (about 79%) age lies between 30-59 years. In our study participants, age had no significant association with uptake of tuberculosis reventive therapy (IPT).

4.2.2.2. Partcipants gender

In terms of gender, as indicated in table 4.2 below, 150 (59.5%) of the 252 participants were female clients, and the average age of the participants was 45 years.

TABLE.4.2. GENDER DISTRIBUTION OF STUDY PARTICIPANTS BY IPT INITIATION (N=252).

Variable		IPT Initiation		Total	P-value
		Yes	No		
sex	Male	49	53	102	0.021
	Female	94	56	150	
Total		143	109	252	

During cross tabulation, gender was found associated with IPT initiation and it was added to the final model of logistic and found associated with initiation of IPT. The final model and analysis were presented in bivariate logistic regression table.

4.2.2.3. Partcipants Marital status

Concerning marital status of the partcipants, 46% were married and the rest 21%, 16.7% and 15.9% were widowed, divorce and single consecutively. In this study, there was no association found between marital status and IPT uptake.

TABLE. 4.3. MARITAL STATUS OF PARTICIPANTS (2020), N=252

		IPT Initiation		
		Yes	No	Total
Marital Status	Single	26	14	40
	Married	67	50	117
	Widowed	28	25	53
	Divorced	22	20	42
Total		143	109	252

4.2.2.4. Partcipants residence

As it is shown in the table 4.4, about 238 (94.4%) participants were residents of Addis Ababa and the rest were coming out of Addis Ababa up on their schedule appointment.

Participants' residence was found associated with IPT uptake in bivariate analysis and found significantly associated in the final model of logistic analysis too. Hence, those who came from out of Addis Ababa for their care and treatment were found with better uptake than those residing in Addis Ababa.

TABLE 4.4: PARTCIPANTS RESIDENCE (N=252)

		IPT Initiation		Total	P-value
		Yes	No		
Residence	Addis Ababa	131	107	238	0.024
	Out of Addis	12	2	14	
Total		143	109	252	

4.2.2.5. Participants Religion

In terms of religion, 191 (75.8%) of the participants were Orthodox Christians, followed by 11.5% protestants and 8.3% Muslims, respectively. Religion had no effect on IPT uptake in this study.

TABLE 4.5: PARTCIPANTS RELIGION (N=252).

Religion by IPT Initiation				
		IPT Initiation		Total
		Yes	No	
Religion	Muslim	13	8	21
	Orthodox	106	85	191
	Protestant	18	11	29
	Catholic	6	5	11
Total		143	109	252

4.2.2.6. Participants Education status

TABLE 4.6: PARTICPANTS EDUCATIONAL STATUS (N=252).

Education by IPT Initiation				
		IPT Initiation		Total
		Yes	No	
education	No formal education	16	14	30
	Primary education	44	27	71
	Secoondary education	54	39	93
	Tertiary education	29	29	58
Total		143	109	252

Participants' educational status was summarized in table 4.6: as 11.9% have no formal education (can not read and write) and 28.2%, 36.9% and 23% were completed primary, secondary and tertiary education consecutively. In our analysis, education had no association with IPT uptake and completion.

4.2.2.7. Particpants substance use behavior

Patients with HIV who used substances were the most likely to fail to take their medication. In the current study, 39.7% of respondents said they use various substances, with the majority (37.3%) consuming alcohol while on ART. However, there was no link between substance usage and IPT absorption in this study.

TABLE 4.7: PARTICIPANTS SUBSTANCE USE BEHAVIOR (N=252)

Substance use by Initiation IPT				
		Initiation IPT		Total
		Yes	No	
Substance use	Alcohol	52	42	94
	Cigaret	0	1	1
	Chat	1	1	2
	No substance use	89	63	152
	Alcohol+chat	1	1	2
	Alcohol, chat, Cigarette	0	1	1
Total		143	109	252

According to the findings, 67.1% of the total participants arrived on time for their scheduled appointment, while the rest arrived unannounced throughout the study period (during the time of data collection). Keeping their planned appointments is usually a symptom of poor adherence to ART and IPT.

4.2.2.8. Nutritional status

In terms of the participants' nutritional condition, 10.7% were found to be severely and moderately malnourished, with supply interruptions for nutritional intervention (nutritional supplement) being widespread in the study institution. This data cross tabulation shows that there is no link between participants' nutritional status and IPT uptake.

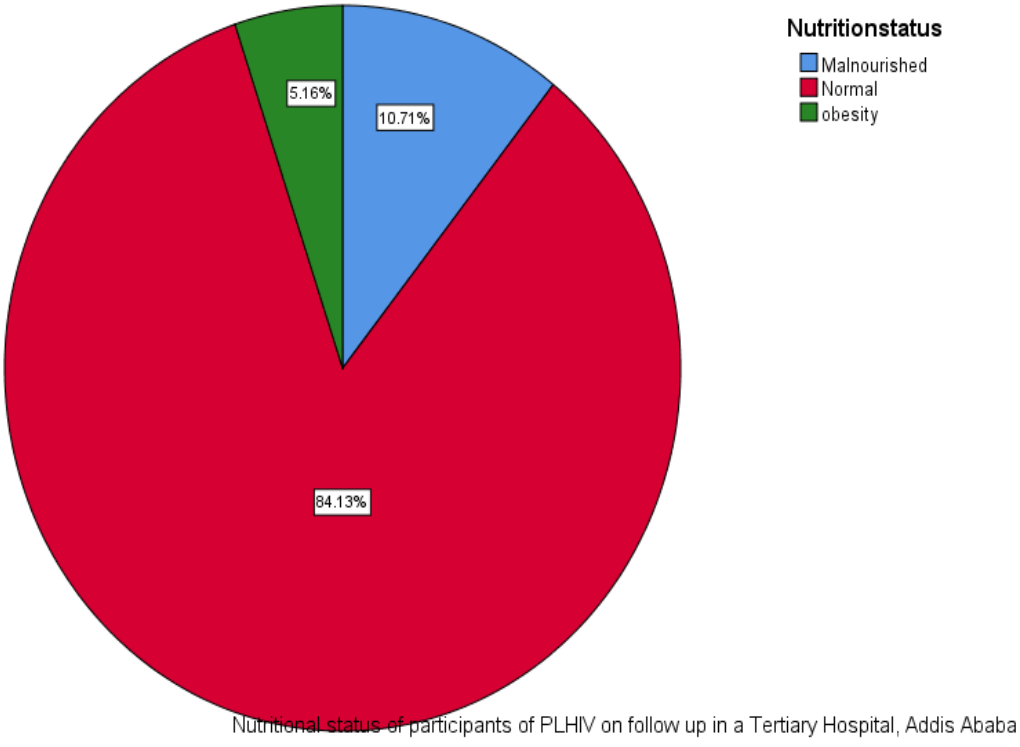


Figure. 4.3. Participant's nutritional status, 2020 n=(252)

4.2.2.9. Participant's eployment status and monthly income

At the time of data collection, 70.6% of the participants were employed by the government, private sector, or self-employed, 18.7% were unemployed, and the rest were retired and students. Their monthly earnings ranged from no income to 25000 birrs, with an average of 3199.4 eth birr per month. The presence of an association between participants' income and treatment initiation was revealed by cross tabulation of predictor factors with IPT treatment initiation. However, it did not show up in the final regression analysis model.

TABLE. 4.8. PARTICIPANTS MONTHLY INCOME, (N=252).

Income by IPT Initiation					P= value
		IPT Initiation		Total	
		Yes	No		
Income	<1000	10	20	30	
	1000-3000	23	12	35	0.012
	3001-5000	64	48	112	
	5001-1000	32	13	45	
	>1000	14	16	30	
Total		143	109	252	

4.2. 3: Clinical, immunological and virological statuses of people live with HIV

Different immunological and virological characteristcs of partcipants were presented in this section. Concerning duration on ART, 227 (90.1%) of the participants have been taking their ART drug for longer than 60 months (>5 years) and based on WHO clinical staging at ART initiation, only 16.7% of participants were on stage I of HIV disease where as currently, at the time of data collection, 95.6% of them were on treatment stage I.

Clients' antiretroviral therapy (ART) regimens were examined, and it was discovered that 73.4% of them were on separate first-line regimens, 24.6% were on second-line regimens, and 2% were on third-line regimens consecutively. During the study of the clients' review, it was discovered that the majority of the participants (66%) had a CD4 count of less than 200 at the time of their ART commencement, and that 42.5% had a recent CD4 count of more than 500 at the time of data collection. The majority of the patients were found to be virally suppressed (90.5%), while 9.5% had a high viral load of

>1000 copies/l, which could indicate treatment failure or poor adherence to their treatment at the time of data collection.

As shown in table 4.9, participant's initial CD4 count, and viral load status were associated with IPT initiation during cross tabualtion. Later in the final model of analysis, only viral load status was found significantly associated with IPT treatment initiation which is explained in detail in the analysis section

TABLE.4.9.IMMUNOLOGICAL AND VIROLOGICAL STATUSES OF PARTICIPANTS BY IPT INITIATION (N=252).

	Innitiation of Treatment			P=value
Variables		No	Yes	
Current ART regimen	1st Line	72	113	0.068
	2nd Line	34	28	
	3rd Line	3	2	
Initial CD4 count	<200	80	86	0.022
	201-349	16	32	
	350-500	5	19	
	>500	8	6	
Recent viral load count	<1000	93	135	0.015
	>1000	16	8	

TABLE 4.10: PARTICIPANTS' AWARENESS ON IPT, (n=252).

Variables	Participants awareness on IPT			P=value
Attended health education on IPT	Yes	39	106	0.000
	No	70	37	
Have Information and understanding on IPT	Yes	41	118	0.000
	No	68	25	
Awareness on IPT reduce TB risk	Yes	65	126	0.000
	No	44	17	
Awareness on the importance of regular evaluation for TB	Yes	75	115	0.034
	No	34	28	
Awareness on PLWHIV without S/S of TB can get IPT	Yes	47	98	0.000
	No	62	45	

During assement of participants, 57.5% replied that they had attended TB preventive therapy related health education and 42.5% of them didn't attend. Among the participants, 63% responded and indicated that they have awareness and understand what TB preventive therapy (IPT) is and 56.7% of them got information from health professionals. About 67.5% had and 32.5% of the participants had no appropriate understanding and awareness about the relationship or link between TB and HIV. When asked if IPT might be used to minimize the risk of tuberculosis, 75.8% said yes, while the remainder said no. About 75% agreed that routine testing for the existence of tuberculosis should be done at every clinic visit, while the remaining 25% disagreed. When asked if an HIV positive person (PLHIV) without signs or symptoms of tuberculosis can receive TB preventive therapy, 42.5% said no, owing to erroneous ideas that IPT is used to cure tuberculosis. As a result, health care practitioners must give detailed individual and mass health education and awareness creation.

4.2.4. Partcipants awareness on Isoniazid preventive therapy

Information provision, health education or awareness creation on TB preventive therapy is crucial for the succees of the treatment. In this study, participants who had information and awareness on IPT were found having high uptake compared to those who had no awareness, information and understanding.

4.2.5. Uptake and completion of IPT among PLHIV

IPT eligible patients received TB preventive therapy in 56.7% of the 252 interviews, while 43.3% did not. When asked when they started TB preventive therapy, almost all of them said it was years or months after they started ART. Refusal to take, fear of drug side effects, providers refusing to prescribe, refusal due to pill burden, and perception that they are not a TB case were the most common reasons for not taking TB preventive therapy, with 22.2%, 7.9%, 7.1%, 3.2% and 3.2% respectively.

Patients must take TB preventive medication with good adherence and complete the prescribed dose within the stipulated month to achieve a favorable and expected outcome and protection from TB disease. The results of this quantitative section analysis, on the other hand, revealed a different scenario. Despite the fact that 143 out of 252 participants agreed to take IPT, the majority of them, 81 (56.6%), did not complete the six-month treatment. According to the data, they just take the drugs from the pharmacy and some of them discared it to the dust bin before leaving the hospitals' compound and others discard the medication at their homes.

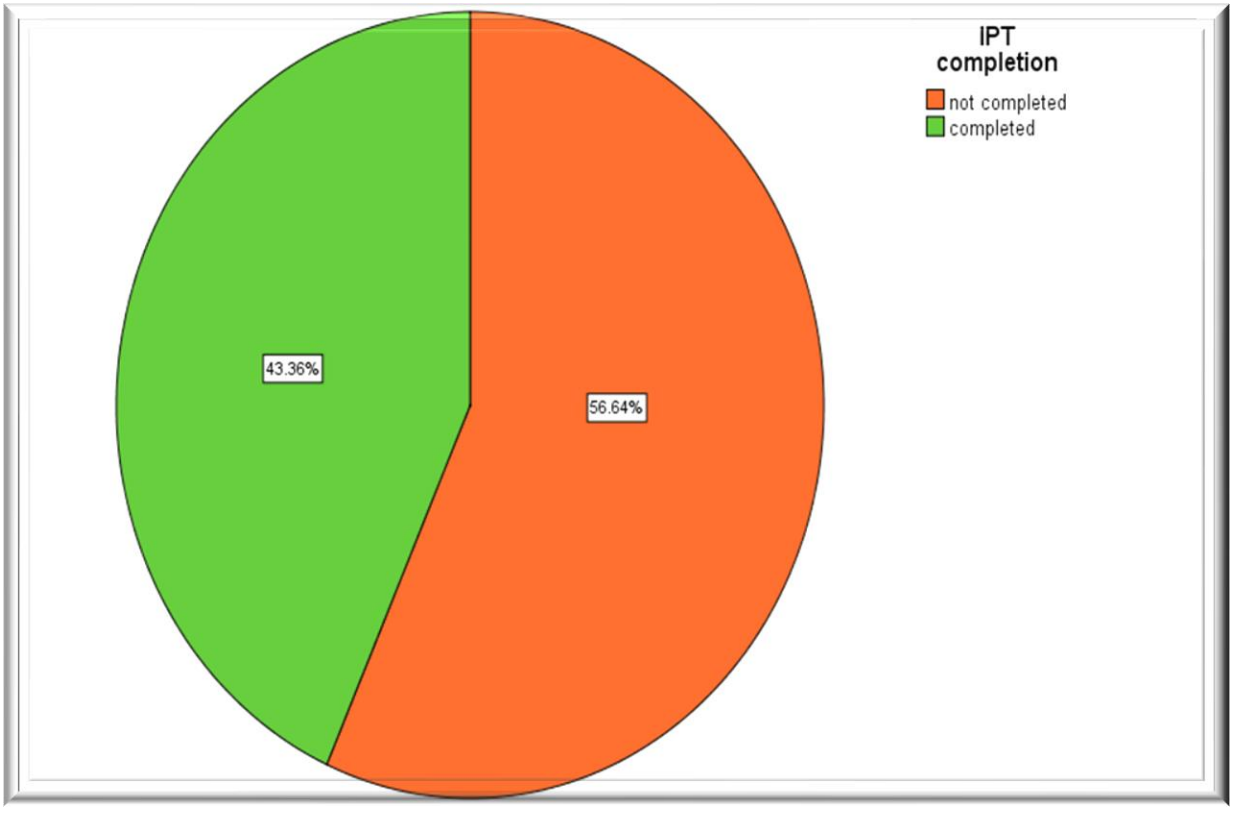


Figure 4.4: IPT completion status of participants on ART in a tertiary Hospital.

TABLE 4.11: CROSS TABULATION OF VARIABLES BY INITIATION OF ISONIZID PREVENTIVE TREATMENT (N=252)

Variables		Initiation of treatment Number (%)		P-value
		No	Yes	
Age	18-29	11	10	0.518
	30-39	24	39	
	40-49	29	46	
	50-59	28	32	
	60 plus	17	16	
Gender	Male	53	49	0.021
	Female	56	94	
Residence	Addis Ababa	107	131	0.024
	Out of Addis	2	12	
Monthly Income	<1000	20	10	0.012
	1000-3000	12	23	
	3001-5000	48	64	
	5001-10,000	13	32	
	>10,000	16	14	
Nutrition Status	Malnourished	17	10	0.090
	Normal	87	125	
	obesity	5	8	
Current ART regimen	1st Line	72	113	0.068
	2nd Line	34	28	
	3rd Line	3	2	
Initial CD4 count	<200	80	86	0.022
	201-349	16	32	
	350-500	5	19	
	>500	8	6	
Recent viral load count	<1000	93	135	0.015
	>1000	16	8	

Attended health education on IPT	Yes	39	106	0.000
	No	70	37	
Have Information and understanding on IPT	Yes	41	118	0.000
	No	68	25	
Awareness on r/n between TB and HIV	Yes	72	98	0.678
	No	37	45	
Awareness on IPT reduce TB risk	Yes	65	126	0.000
	No	44	17	
Awareness on the importance of regular evaluation for TB	Yes	75	115	0.034
	No	34	28	
Awareness on PLWHIV without S/S of TB can get IPT	Yes	47	98	0.000
	No	62	45	
Ever treated for TB	Yes	59	54	0.010
	No	50	89	
Current use of Cotrimoxazol	Yes	29	20	.012
	No	80	123	
Presence of comorbidity	Yes	31	26	0.054
	No	78	117	

Management of opportunistic infections with cotrimoxazol for eligible clients is one of the services given to PLWHIV. During the time of data collection, 19.4% of the participants were taking cotrimoxazol. About 17.5% clients were not adherent to their antiretroviral therapy and missed from one dose to more than five doses in the past seven days. The main reasons for non-adherence to their ART drugs were 10.7% due to forgetfulness followed by negligence with 3.2% and others.

Regarding disclosure status, majority of participants 65.9% disclosed to their spouses, 19% disclosed to their own child/children and 8.3% to their parent(s), 6% to their brothers/sisters consecutively. Results showed that disclosing to other than immediate family like friends, neighbors and to the community is not practical due to still persisting stigma and discrimination. The main reasons mentioned for not disclosing their status other than to their spouses and immediate family, one hundred eighty (180) of them were particularly due to fear of stigma and discrimination which indicates the existence of awarenes gap in the community.

Participants (people with HIV) were asked about the presence of comorbidity. Hence, 21.4% of them had different comorbidities or diseases. Among those 9.1% were diabetic cases and 9.2% had hypertention. Due to these diseases, participants have been taking treatment in addition to anti retroviral therapy. Taking multiple tablets for different diseases including HIV caused participant to have poor adherence for treatment and also not to accept TB preventive therapy.

Regarding previous tuberculosis treatment, history of participants showed that 44.8% of them were treated for TB either for pulmonary or exta pulmonary. In addition, our data during cross tabulation to see the relationship between history of TB treatment and IPT use showed the presence of association with (P=0.010). Participants previously treated for TB found to have with better uptake compared to those not treated previously. This might be because those with history of TB disease know the seriousness of the disease. The figure below shows the percentage of (occurrence of TB among participants life time until the date of data collection).

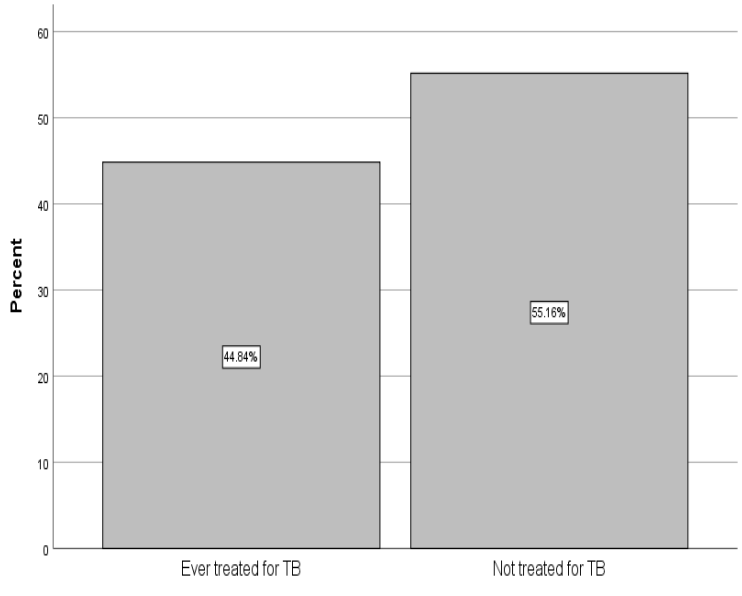
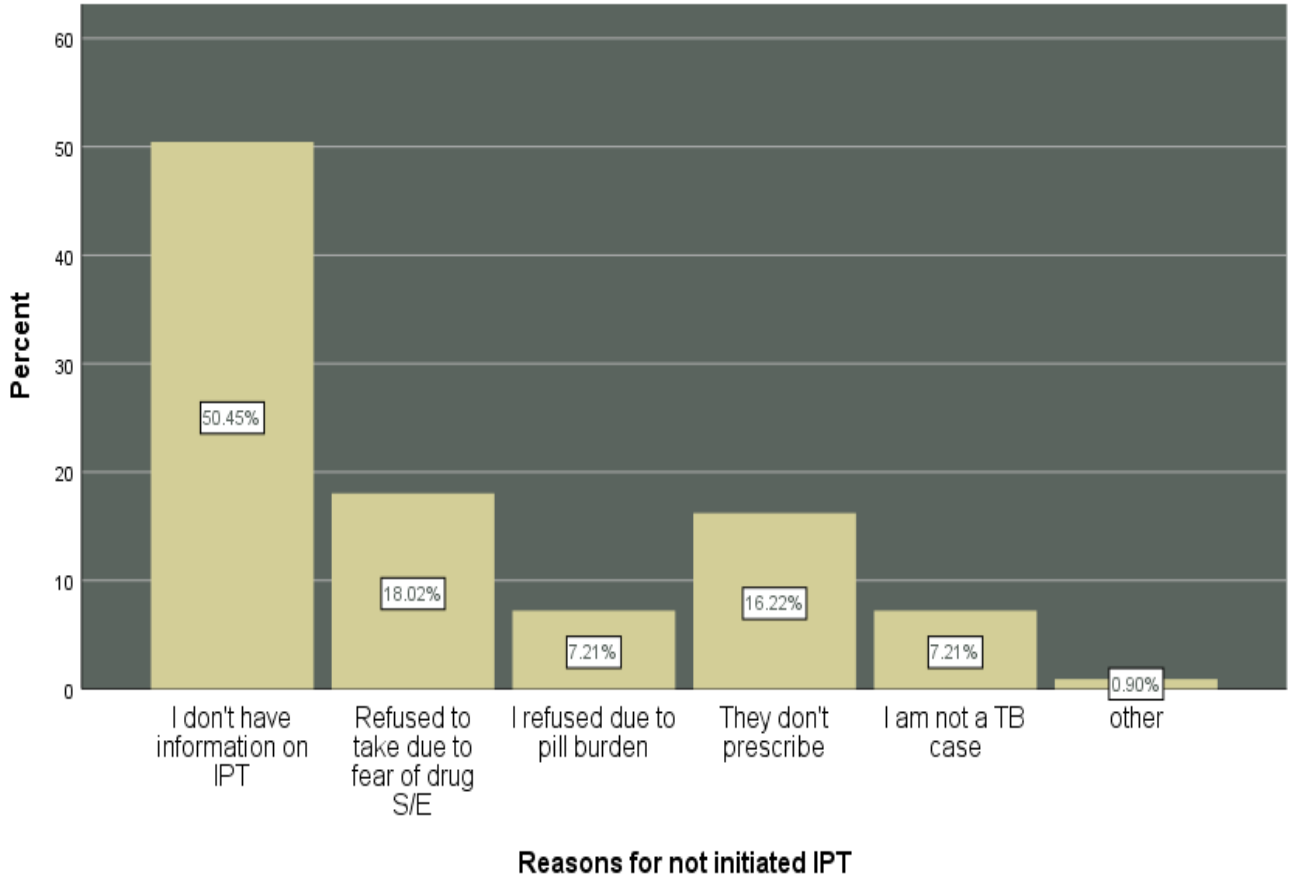


Figure 4.5: Showing ever treated and not treated for tuberculosis among patients on ART in a tertiary hospital, 2020 (n=252).

Many participants (PLHIV) on follow-up in the study institution were not initiated on tuberculosis preventive therapy. During the interview, they mentioned different reasons for not being initiated on IPT and the main reasons were presented in figure 4.6 below.

Figure. 4.6. Showing reasons for not initiated IPT among patients on ART in a tertiary hospital (n=252)



During cross tabulation of factor variables with the dependent variables, many factors showed significant association with the outcome variable (Table 4. 4). Then, binary logistic regression model was used to identify independent variables which are significantly associated with the outcome variable for further analysis and interpretation.

TABLE 4.12: LOGISTIC REGRESSION ANALYSIS OF EXPOSURE VARIABLES BY INITIATION OF TREATMENT (N=252), 2020

Variables	Crude Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)	P-value
Gender (Male) Female reference	0.551(.331,.917)	.514 (0.280, 0.943)	0.032**
Residence (Addis Ababa) Out of Addis reference	0.204(.045,.932)	.126 (0.022,723)	0.020**
Recent Viral load result (<1000) >1000 reference	2.903(1.194,7.062)	3.057(1.072,8.716)	0.037**
Awareness on TB/HIV relationship (Yes) No reference	5.017(2.660,9.465)	.543 (0.270,1.091)	0.086
Have information and understanding (Yes) No reference	7.828(4.383,13.92)	6.941(3.385,13.82)	0.000**
Awarenesson IPT reduce TB (Yes) No reference	5.017(2.660,9.465)	2.694(1.195,6.073)	0.017**

***significant at 95%*

4.2.6. Association of different predictor variables with IPT treatment initiation

Different independent varibles were computed with the outcome variable to see their association. Participants mean, age, and income were compared using anova test and there was no statistically significant difference in taking IPT across their age and there was no statistically significant difference across their income level. Multivariate logistic

regression analysis was conducted to determine the presence of association between variables using odds ratio with 95% confidence interval and association was declared with the level of significance at P ≤ 0.05.

Among the predictor variables such as participant's gender, current residence, recent viral load count, and their awareness on IPT benefit, having information and understanding on IPT were found significantly associated with initiation of IPT among people living with HIV who participated in the study.

4.3. DISCUSSION: UPTAKE, COMPLETION AND DETERMINANTS OF TB PREVENTIVE THERAPY

Isoniazid prevention therapy is an effective intervention strategy in reducing the TB incidence, mortality and morbidity in PWH by preventing the occurrence of Tuberculosis co-infection. Currently, the recommended dose of IPT for adults is 300 mg of isoniazid (INH) per day for 6 months, and according to the local prevalence of TB.

This study aimed to determine the prevalence of IPT performance and to identify determinant factors for IPT uptake, completion and implementation. The degree of IPT uptake among patients with HIV and on follow-up was found to be sub-optimal in the current study at Tikur Anbessa Tertiary Specialized Teaching Hospital, and hence 56.6% of interviewed eligible clients were discovered to have begun IPT during the study period. Furthermore, only 43.3% of those who were given (started) IPT finished the required six-month dose within the time frame stated.

4.3.1. Uptake of Isoniazid preventive therapy

In our present study, isoniazid preventive therapy uptake and completion as it is presented above were suboptimal, accounting for 56.6% and 43.3% consecutively. Isoniazid preventive therapy coverage varied across the globe and nation. Different studies in Ethiopia and Africa revealed different levels of prevalence or uptake level with their range of completion rates. Our study's IPT uptake was higher than a study in Northwest region of Ethiopia which reported 37% prevalence (Wasie&Tigabu,2018:237) and it was found comparable to studies in North East Ethiopia, which indicated a 50%

initiation rate (Mengesha & Ahmed, 2020:131), and a study in Zimbabwe, which reported a 52% prevalence of IPT use (Nyathi, Dlodlo, Satyanarayana, et al. 2019:9).

On the other hand, our findings are lower than those of studies in Ethiopia's Gambela region, which reported a 66.5% initiation rate (Aboma & Dida, 2021:8); 62% IPT utilization in Tigray, Ethiopia (Legese, et al. 2020:4-5); and 68% isoniazid preventive therapy initiation in a study on HIV-positive children in Kenya (Aboma & Dida, 2021:8). (Ngugi, et al. 2020:7). When compared to the findings of a study conducted in Tanzania, findings revealed a 45% initiation rate, where the results of this study were found better (Festo& Gasto, 2020:1-8).

4.3.2. Completion Rate of Isoniazid preventive therapy

Adherence to full completion of the given dose is required for tuberculosis treatment to be effective. The completion rate of those provided (started) with IPT was relatively low in this study, at 43.3 %, which was lower than studies conducted in North East Ethiopia, which reported a better completion rate of IPT at 61.8% (Mengesha & Ahmed, 2020:131), 67.9% in North west Ethiopia (Wasie&Tigabu,2018:237), 94 % in Zimbabwe (Nyathi, et al. 2019:9), and 82% in a a study conducted in Kenya (Ngugi,et al. 2020:7). In general, the findings fell significantly short of the WHO's goal of giving TPT to 30 million PWH over a five-year period from 2018 to 2022 (WHO, global TB report 2020:116). Gender, participants' residence, current viral load level and awareness of IPT lowers TB recurrence and having information and understanding on IPT were identified as variables that were substantially associated with IPT uptake in this study, as indicated in table 4.3 above.

4.3.3. Gender

The initiation of TB preventive medication was found to be substantially linked with gender. As a result, when compared to female PLHIV participants, male PLHIV participants were found to be 1.9 times less likely to begin INH TB preventive therapy (Males were found with low uptake and completion of IPT compared to female gender).

Coefficient= -.666, adjusted AOR= .514, CI= (0.280, 0.943) and (P=0.032).

Similar findings on the role of gender in this regard have been reported in other countries' studies. According to a study conducted in rural Malawi, male participants and females under the age of 25 had poor IPT completion rates (Little et al. 2018:5). Furthermore, a retrospective cohort study on isoniazide preventive therapy coverage in Tanzania found that being female was associated with increased IPT uptake and low in males (Maokola, Ngowi, Lawson, Robert et al, 2021:564-565), and other studies found that female participants initiated IPT more than male participants (Maharaj et al. 2018:6; Ngugi, et al.,2020:4-5). The implications of the fact that men are less likely to start IPT (TPT) need to be investigated further, however the WHO global TB report stated that TB affects more men than women, which could be related to their poor IPT uptake as one cause (WHO, Global tuberculosis report, 2021:9).

4.3.4. Residence

The participants' residency was also found to be strongly associated with treatment initiation in this study. Residents of Addis Ababa were 7.9 times more likely to participate. Residents who came from and live outside of Addis Ababa were less likely to start TB preventive treatment, Coefficient= -2.075, AOR=.126, CI (0.022, 723), P= 0.020. Distance was not a barrier to IPT commencement or completion in this study. Those who traveled from afar, on the other hand, had a higher rate of acceptance.

In contrast, a study of children in North West Ethiopia indicated that those who traveled less than 30 minutes to the health care facility were more likely to complete IPT than those who traveled one hour or more (Wasie&Tigabu, 2018:237). Furthermore, a study conducted in Tanzania to identify barriers to suboptimal implementation of IPT found that distance from health care facility and cost of transportation were among the patient factors preventing IPT uptake in the study area, which providers were unable to force for their referral to a nearby health care facility and close to their residence (Festo & Gasto, 2021:5).

4.3.5. Recent Viral load result

Another association was discovered with the most current viral load result. Patients with a recent viral load result of less than 1000 (those who have viral suppression) were 3.057 times more likely to start INH TB preventive therapy than patients with a recent viral load

result of more than 1000 (those who have high viral load or may have treatment failure), Coefficient= 1.117, AOR= 3.057, 95% CI (1.072, 8.716), P= 0.037. The explanation for this could be that those with high viral loads are more likely to have poor antiretroviral adherence, and these people may also have poor adherence to Isoniazid TB preventive therapy, while others may refuse to start at all.

4.3.6. Patients Information and understanding on IPT

The fourth associated variable was participants' initiation of TB preventive therapy (INH), which increased by 6.9 (6.9 times more likely to initiate IPT) in patients with information and understanding compared to patients with no information and understanding about TB preventive therapy, Coefficient= 1.937, AOR= 6.9, 95% CI (3.385, 13.827), P= 0.000. In research conducted in Ethiopia and Africa, patients' misinformation, misunderstanding, lack of awareness, and low level of knowledge about the benefits of IPT were revealed to be important contributors in low IPT uptake and completion (Abdulalim et al, 2017:1-4; Semitala et al., 2021:6-7; Grace, 2019: 278).

4.3.7. Patients' awareness on benefits of IPT

The patient's awareness of the benefits of IPT was also associated to IPT uptake.

The likelihood of participants starting TB preventive therapy (INH) increased by 2.69 when compared to individuals who did not know IPT can reduce the occurrence of TB: Coefficient=.991, AOR= 2.69, with 95% CI (1.195, 6.073), P=0.017.

Patients who were not informed about the reasons for taking IPT by their health care professionals had a very low uptake of IPT, with only 7.1% of eligible clients participating. The key factor linked with low tuberculosis preventive therapy uptake was a lack of awareness of the benefits of TPT (Busari, Oshikoya, Adejumo, 2021:4-5). In addition, a study conducted in another region of Ethiopia found that unclear information provided by health care providers was one of the factors contributing to poor adherence to IPT among people living with HIV who were receiving Tb preventive therapy (IPT), and researchers from the same study suggested that patients should receive clear and targeted health education (Abdulalim et al, 2017:1-4). These findings of misinformation, awareness, and knowledge gaps could be attributable to a lack of patient counseling, insufficient time for a

provider-patient visit due to (staffing shortages), and insufficient provider training, to name a few. Recommendations were made based on the identification of deficiencies in this area.

4.4. SUMMARY

Chapter four presented the quantitative findings of the research and discussed the response rate, socio demographic characteristics of participants, clinical, immunological and virological status of people living with HIV, awareness on isoniazid preventive therapy among people living with HIV**,** uptake and completion of IPT among PLHIV and association of different predictor variables with IPT treatment initiation and finally, discussion of associated factors were presented.

CHAPTER FIVE

QUALITATIVE RESEARCH FINDING AND DISCUSSION

5.1. INTRODUCTION

This chapter represents the results from the qualitative design which explores barriers to uptake and completion of tuberculosis preventive therapy among patients living with HIV. The study focuses on TB preventative therapy (TPT) implementation issues and determining factors that health care workers encounter when providing IPT to PLWH (service delivery, medication, and patient factors). The Andersen's Behavioral Model of Health Service Use (ABM), which focuses on enabling, predisposing, and need factors affecting IPT uptake, was discussed using the study's themes and subtopics. In-depth interview questions based on literature reviews were created to address barriers to IPT adoption and implementation. The process of data analysis and interpretation of research findings has already been described, and qualitative data was acquired through in-depth interviews, with the results provided in tables and texts.

The purpose of this qualitative part of the study was to gain detail understanding of barriers to IPT uptake and completion from the health care provider’s point of view.

There are five sections in these qualitative findings chapter (in-depth interviews with 12 health care workers). The first section depicts the socio-demographic characteristics of in-depth interview participants. The second section includes health-care workers' experiences on administering IPT to HIV-positive persons. The third section discusses the factors that influence IPT uptake and completion among HIV-positive people (including implementation challenges), the fourth section discusses ways to improve providers' knowledge, and the final section offers suggestions for improving tuberculosis preventive therapy (TPT) implementation.

5.2. THE QUALITATIVE DATA MANAGEMENT AND ANALYSIS

Qualitative data analysis includes production of data, utilization of notes, and codes emphasis on presenting data (Edmonds and Kennedy 2016:321). In addition, Creswell and Plano Clark (2018:311) argued that qualitative interpretation of data from an interview

might result in the researcher asking further questions in successive interviews to approve or disprove the meaning of any primary data.

The researcher transcribed the audio files, re-read the expanded field notes and transcripts of every interview and remained focused on the knowledge and context of the study. This helped the researcher to revise and refine the subsequent in-depth interview sessions. The qualitative data generated and analyzed were expanded field notes, audio recorded files and their transcripts. The audio recordings of the semi-structured in-depth interviews were transcribed verbatim. The research assistant read the interview transcripts for analysis. Therefore, the interview transcripts were generated from both the transcription of the audio recordings and expanded field notes. The researcher translated the Amharic transcriptions into English language. The research assistant who was proficient in both English and Amharic checked the consistency between the Amharic transcripts and its translation to English version. This action has helped the researcher to have an in-depth understanding regarding the data on IPT uptake determinants and challenges.

The data was interpreted across the participants and common ideas were grouped into categories so that the concepts and relations were explored and constructed. The analysis followed thematic analysis approach in which main themes and categories were identified and analyzed manually. Initial analysis of the interviews began during the fieldwork using field notes report by the researcher. Coding was conducted through reading and re-reading the compiled transcripts. Finally, main themes and sub-themes were extracted from the data and presented by narratives created from direct quotes.

5.3. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS OF IN-DEPTH INTERVIEW

Socio-demographic characteristics of participants included in the qualitative in-depth interview were presented below.

Table 5.1 presented demographic data of health care providers who participated in qualitative in-depth interviews. Twelve health care providers working on ART participated in this qualitative section of the study. Individual face-to-face in-depth interviews were performed with health care providers. The age range of care providers who participated in

the qualitative section was from 30-60 years of age. Majority (66.7%) of the participants were professional nurses followed by pharmacists and a medical doctor. All participans have been working for more than five years in their profession and from 3-16 years on HIV care and treatment as ART provider, coordinator and counselor.

TABLE 5.1: DEMOGRAPHIC CHARACTERISTICS OF HEALTH CARE PROVIDERS AT ART CLINIC, TIKUR ANBESSA HOSPITAL, ADDIS ABABA, ETHIOPIA, 2020 (N=12).

Demographic characteristics of Health care providers (n=12)		
Variables		Number (%)
Age	< 35 ≥35	2(17) 10(83)
Sex	Male Female	4(33) 8(67)
Profession	Nurse Medical Doctor Pharmacist	8(66.7) 1(8.3) 3(25)
Marital status	Single Married Divorced Widowed	2(17) 8(66.7) 1(8.3) 1(8.3)
Work experience on HIV care	3-5 years >10years	6(50) 6(50)

As indicated in table 5.2, the qualitative section's themes and issues emerged following an in-depth interview with health care providers. These themes were presented as the participants described their experiences and challenges.

TABLE 5.2: THEMES AND SUB THEMES APPEARED AFTER DATA ANALYSIS, TIKUR ANBESSA HOSPITAL, ADDIS ABABA, ETHIOPIA, 2020

Themes	Sub-themes
1. Experiences in providing isoniazid preventive therapy for HIV patients	
2. Determinants of IPT uptake	1. Patients' refusal and non-completion 2. Provider's counseling and patient education practices 3. Misconceptions and misunderstanding of Patients on IPT
	4. Fear of drug resistance, Pill burden and drug side effect
	5. Drug shortage
3. Improving providers knowledge on IPT(TPT)	1. Training on IPT for care providers 2. IPT guideline and Health education guide
4. Best practices to improve uptake and completion of isoniazid preventive therapy in HIV patients	1. Adequate counselling and Health education to patients 2. Time of Isoniazid preventive therapy initiation

5.4. EXPERIENCES IN PROVIDING ISONIAZID PREVENTIVE THERAPY FOR HIV PATIENTS

5.4.1. Health care providers experiences in providing isoniazid Preventive therapy

In addition to current ART treatment regimens, health care practitioners confront hurdles in initiating isoniazid preventive therapy for PLWHIV. Almost all providers mentioned that patients prefer to have TB therapy rather than TB prophylaxis if they develop TB disease. This points to an issue with understanding whether TB treatment is given after a person becomes ill or as a preventative measure before the disease develops.

A female physician ART provider explained her experience as:

> *"We provide IPT for people living with HIV after screening for TB, investigating them including chest x-ray if possible. Explaining about the side effects of the drug like fever, rash, numbness and jaundice for patients who are planning to start IPT. If sever side effects occur like Jaundice, we discontinue the drug. Patients need to have monthly follow-up and blood tests. Previously, we used to provide IPT every three years and immediately after completed TB treatment. But currently changed to once and three years after TB treatment is completed."*

Fourty six years old professional nurse provider replied:

> *"Studies show that IPT has good outcomes regarding prevention of TB. But in our case, there is resistance in both providers and clients of not accepting the medication. Providers were not happy to prescribe because of fear of side effects and pill burden. Currently, due to the repeated motivation from the program implementer's side and convincing that side effects are not common, and patients should benefit from taking IPT. Therefore, we are providing IPT (TPT) for eligible patients."*

Therty five years old female professional nurse provider answered:

> *"We provide IPT to prevent TB among HIV patients including TB treated patients three years post treatment. But there is a problem in accepting TPT on the patient's side. But currently we insist that they take treatment and due to this, they accept to take IPT even though there are patients who still are not voluntering to take it."*

Therty one year old Pharmacist clarified:

> *"The service is intermittent and previously it was given as a campaign, and it was good then the service becomes slow. Providers always need pressure from the programmers and supporters' side. Currently, it started to be initiating again".*

5.4.2. Determinants of uptake and completion of IPT

It is known that patients living with HIV are prone to tuberculosis infection. Most of the providers believe that all eligible PLHIV have to take TB preventive therapy and agree on the benefit of IPT to prevent the development of active TB and prescribe the drug. On the other hand, there are many factors that hinder the uptake and completion of tuberculosis preventive therapy (IPT).

5.4.2.1. Patient's refusal and non-completion problems

Many factors that affect Isoniazid preventive therapy uptake and completion were mentioned by providers. Health care providers express the reasons or barriers to uptake and completion of IPT. These are mainly related to patients' unwillingness, refusal to take and poor adherence.

Female professional nurse provider (36 years old) replied:

> *"Mostly patients refuse to take IPT when they discuss with other patients (with each other) about the occurrence of side effects during their clinic visit for drug refill and they*

misunderstand as side effects which occurred rarely in one patient will happen to everyone if there are misconceptions of taking the drug INH."

Fifty-eight years old male senior professional nurse responded:

"There is no checking mechanism whether they completed or not. Negligence and poor adherence are observed in young clients. In addition, patients refuse due to pill burden, negligence, resistance to our advice, fear of becoming sick due to pill burden (particularly those with low economic status and small business workers for daily living) strive just for their daily living so these patients have poor adherence and less chance of acceptance."

Therty one years old Pharmacist working in the unit explained:

"Usually, pateints refuse to take IPT because they thought that they are healthy and not important to them and only sick people should take it coupled with the service not focused on preventive aspect of medicine, rather it focused on clinical aspect which caused lack of understanding and refusal of patients to take IPT."

Therty five-year-old female professional nurse explained:

"There is a problem in accepting TB preventive therapy on the patient's side. But currently we insist that they treatment take and due to this, they accept to take IPT even though there are patients who still refuse to take. The main reasons for the problem were misconception and misinformation heard from other clients who said IPT can cause nerve problem for all patients. So that, patients prefer TB treatment if they develop

TB disease instead of taking TB preventive therapy and patients are not willing for clinic visits to pick IPT monthly. The other problem is when new drug program initiated there is always resistance to accept."

Fourty six years old professional nurse Provider replied:

"Studies showed that IPT has been beneficial for people living with HIV in the prevention of TB. But in our case, there is resistance in both providers and clients of not accepting the medication. Providers were not happy to prescribe because of fear of side effects and pill burden. The main barrier is clients lack of understanding and negative attitude about TPT, misinformation and misunderstanding of clients (If they hear or see side effect of other patients then they discuss each other and refuse to take. Currently due to repeated motivation and convincing we are providing IPT for eligible patients.)"

Fourty years old female nurse ART provider explained:

"We provide TB preventive therapy after explaining to them. But some of the patients respond as "I will take when I develope Tb disease" and some refuse to take and others discontinue by complaining about simple gastritis and burning sensation and some of them complete IPT."

In this study, among 250 IPT eligible patients approached and interviewed, only 56.6% initiated and among those initiated, less than half (only 43.3%) completed the six months dose within the specified period. Patients' refusal to take INH and non-completion was found to be a major determinant of IPT uptake.

The findings were similar to those of research conducted in Zimbabwe among HIV patients, in which 52% of eligible patients were started on IPT and the rest rejected (Nyathi, Dlodlo, Satyanarayana, Takarinda, Tweya, Hove, et al. 2019:4-10). Furthermore, in another study conducted in one part of Ethiopia, the overall IPT implementation

coverage was determined to be 20%, with the reasons for this being patients' non-acceptance (Teklay et al., 2016:6).

Incontrary to popular belief, research conducted elsewhere in Africa found that more than 99% of eligible patients began IPT, with a 75% completion rate, and that patient rejection was not an issue in their study (Little, Khundi, Barnes, et al., 2018:1).

5. 4.2.2. Providers counseling and patient education practices

Patients must have proper counseling, awareness, and understanding about their care and treatment in order to accept, be convinced, and agree on their own care. This will enable patients in making an informed and voluntary decision to participate in their own treatment, as well as persuade them to take their medication as prescribed. The majority of the unit providers agree with this viewpoint and explain their own experiences.

Thirty-year-old male Pharmacist described:

> *"Health education and preventive aspect of health care is not common here in our setting. Patients refuse to take IPT due to lack of awareness and understanding. Short patient–provider contact, and counseling time resulted from shortage of providers. This lack of knowledge, information and not providing appropriate counselling will make them to discontinue INH medication plus vit-B6. When patients discontinue vit-B6 (pyridoxine), they might develop peripheral neuropathy, this deficiet of awareness and information resulted from the occurrence of side effects because they discontinued vit-B6 by themselves and with the presence of side effects (PNP,) they can not continue taking IPT.*

Fifty-eight years old female physician replied:

> *Provider's communication, counseling skill and knowledge may affect the patient's acceptance of any medical care. Before*

initiating IPT, providers should teach, explain advantages of taking and problems of not taking IPT and adequate time and privacy need to be given for counseling. If not counseled effectively, the result will be discontinuing the medication and poor adherence.To provide effective care in this regard, providers need to be well trained and commited."

Thirty-six years old female nurse provider explained:

"Patients need detail counseling on advantages and possible side effects of the drug and both mass and individual health education has to be provided. But currently we are not practicing health education as part of routine work. Advise them to come back and seek medical advice if any side effect occurs. Providers should assess their adherence and convince them with every visit. We need to give time for counseling because some of them understand easily and others need more time. So, giving time for counseling is the best practice. But our current practice is not as needed due to shortage of providers and lack space for counseling."

Fifty-eight years old male nurse provider replied:

"There is a gap in counseling techniques; if they resist taking IPT during counseling and those we have been giving them against their interest or without convincing that they do not want to take TB preventive therapy medication or they will take the drug and discard it away. Negligence and poor adherence is observed in young clients and refusal is common particularly in older patients. On the other hand, patients simply accept during counseling that they will take the drug and possibly tolerate simple side effects."

In line with our current study, a study done in southern region of Ethiopia reported low utilization of isoniazid prophylaxis therapy. Consequently, to improve implementation and uptake of IPT; activities like creating awareness to patients through health education and counseling was suggested to improve adherence (Legese, Degefa, Gebrewahd, Gebremedhin and 2020:5). Similarly, studies in Africa found related findings, adequate IPT-related health education and counseling were mentioned by both caregivers and health care providers as the key facilitators of IPT uptake and completion whereas inadequate caregivers' knowledge on IPT and, inadequate counseling regarding the duration of IPT was found a barrier to IPT uptake and completion respectively (Ngugi, Muiruri, Odero, and Gachuno; 2020:6-7). In addition, a study elsewhere also revealed low patients' awareness of IPT and inadequate time needed to counsel patients on IPT were among the main barriers mentioned for IPT implementation which was reported by health care providers (Van Ginderdeuren, Bassett, Hanrahan, Mutunga, Van Rie; 2019:8). A study in Zambia on challenges for IPT implementation in PLWHIV reported policy level determinants, health care providers' misconception, drug supply, and limited information and communication on IPT, limited demand creation activities and monitoring and evaluation as reasons for low scale up of IPT in the study area (Kagujje, Mubiana, Mwamba and Muyoyeta, 2019:2-3).

Therefore, findings of this study and other related studies indicated lack of awareness or clients' knowledge deficit on IPT or TPT and lack of proper counseling of patients on TPT benefits and adherence issues resulted with low acceptance, low uptake, poor adherence, and low uptake and implementation challenges.

5.4.2.3. Misconceptions and misunderstandings of patients on IPT

Almost all interviewed providers in our study setting agreed and mentioned that IPT uptake has been affected by different misconceptions and misunderstandings of clients which indicate that patients need to have appropriate and correct information from reliable source or from health care providers.

Thirty six years old female professional nurse explained:

> *"Patients refused to take TB preventive therapy due to misunderstanding and inappropriate information which is shared among clients. Misinformation from other patients about the side effect of IPT and by generalizing as it will happen to everyone who is going to take IPT. In addition, clients responded as they are not TB cases or as they have no TB disease, and they explain as it is better and prefer to be treated if they develop TB since both TB preventive and treatment are to be taken for six months."*

Sixty years old male nurse provider responded:

> *"Clients refused by responding "I have no TB, I don't want to take TB preventive therapy, "I will protect myself" and they are thinkinking as it is better to be treated if developed TB than taking prophylaxis. In addition, patients consider this program as it is for research purposes and misunderstand as it is not for their benefit. Patients do not want to take drugs except antiretroviral therapy. These responses indicate patients' misconception about IPT."*

Similarly, a study conducted elsewhere indicated that patients were given insufficient information about IPT's advantages and side effects. As a result, there were rumors and misconceptions concerning IPT among patients, leading to some patients refusing to be initiated or discarding the prescription after being educated. Concerns about agreement and support for patient education efforts were expressed by health care providers (Wambiya, Atela, Eboreime, Ibisomi, 2018:7). Misconception was highlighted as one of the difficulties in another comprehensive evaluation of data on the use of isoniazid preventive treatment (Grace, 2019: 278). Health workers perceived inadequate knowledge about TB as a potential challenge for PLHIV to accept and complete TPT. They also explained that there are people who still have misconceptions and perceive TB

as a hereditary disease or misunderstand transmission through smoking cigarettes and drinking alcohol which led them to not accept and complete TPT. In addition, many patients also reported they are unaware that TB could be prevented, did not understand the importance of TB preventive therapy which indicates the existence of knowledge and information gap (Semitala et al., 2021:6-7).

5.4.2.4. Fear of drug resistance, Pill burden and drug side effect

Fear of drug resistance when using the drug as monotherapy if patients develop active TB while on prophlaxis, pill burden when Isoniazid (IPT) is given with antiretroviral therapy (ART), and fear of side effects if patients are taking IPT alone or multiple therapy for other comorbidity were also reported on the provider's side, all of which hampered TPT implementation in the study area. Adding Isoniazid preventive therapy to existing ART medication, according to health care practitioners, increases pill burden among patients, leading to poor adherence or stopping and discarding the drug away while claiming "I am taking it properly" or declining to take medication due to pill burden. Patients' non-adherence was thought to be due to their fear of adverse effects and pill burden.

Thirty-six years old female nurse provider answered:

> *"Regarding isoniazid preventive therapy resistance, I had a belief that it can cause resistance and hesitate to prescribe. But after realizing and understanding that it is recommended based on studies; I advise and provide it to patients to take INH."*

Fifty-eight years old male nurse provider explaind:

> *"In my opinion, there is fear and no question that there will be drug resistance when a drug used as prophylaxis and as treatment in combination if they develop TB. But personally, I didn't face a patient developing TB while taking TB preventive therapy in our setting."*

Thirty-one-year-old male Pharmacist responded:

"Since providing isoniazid preventive therapy is a mono-therapy; resistance might happen. Therefore, providers should do skin test before giving TPT. In-addition, these patients also may have pill burden when it is provided with antiretroviral therapy (ART)."

Thirty-five years old female nurse provider explained:

"Yes, previously my understanding was as it can cause drug resistance. But later on, I accepted that it is suggested based on studies. But I am still resistant to prescribe for patients with co-infections and comorbidity like hematological cases due to lack of detail knowledge on how to screen for eligibility for those with another comorbidity. Now I changed the situation to some extent."

Fifty-eight years old female provider reported:

"There may be drug resistance if they develop active TB disease while patients are taking IPT prophylaxis. There were patients who developed TB while on IPT and later discontinued and started on regular full course tuberculosis treatment."

In agreement with our study, there was provider's reluctance to prescribe due to fear of Isoniazide drug resistance. A study done by Wambiya, et al. (2018:6) informed that fear of providers to prescribe IPT their concern about the patient's poor adherence which leads to the development of INH drug resistance and in the future resulting in the development of multi drug resistance TB or extensively drug-resistance TB.

On the other Hand, other studies found no drug resistance form of tuberculosis observed due to IPT use. Instead, in the same study report, IPT was found to decrease TB incidence by four-fold among PLWH (Juszkiewicz, Jarosz, Włoszczak-Szubzda &

Głowacka, 2020:5-6) and also found no increase in isoniazid resistance as compared to the estimated rate in HIV-infected patients.

In this study, all interviewed health care providers mentioned pill burden and drug side effect as a barrier for IPT uptake and completion. Due to these factors, providers hesitate to prescribe as well as most patients do not accept, and they are also non-adherent to the drug.

Similarly, different studies revealed drug toxicity as a barrier for IPT implementation. In addition, in a study done in Tanzania, drug side effect and pill burden were among the identified barriers by health care providers hindering utilization or implementation of Isoniazid preventive therapy (Festo & Gasto, 2021:6; Johan van Griensven, Kimcheng Choun, Bopha Chim, et al. 2015:5-6).

5.4. 2.5. Drug shortage

Regarding shortage of INH drug in this study, almost all health care providers reported that there was no shortage in their institution and only one provider responded that there was shortage of IPT i.e., temporary stockout from the hospital pharmacy not from the central store and there were occational stockouts of pyridoxine (vitamin B-6).

In contrast to this study, different studies elsewhere reported that drug stock out, frequent interruption of Isoniazide drug and unavailability of single INH drug were found as a major challenge for IPT implementation (Mahendra, Reddy, Pruthu, Nagesh, Prasanna, et.al., 2020:12; Teklay et al., 2016:7 and Fox, et al., 2017:6). In addition, in other study, clinical care providers mentioned that INH drug supply inconsistency (stock out and poor supply) were mentioned as a major factor which indicated that lack of support to IPT program implementation (Wambiya, et al. 2018:7). Studies in Zambi and South Africa reported that stock out of IPT and vitamin B-6 and insufficient Isoniazid supply were the main challenges for implementation of TPT in their study area (Kagujje et al. 2019:1-2; Amiya, Megan, Anthony, et al. 2021:4-5). In a recent study done in Tanzania, health care providers identified similar problems of which insufficient, irregular drug supply, drug stock out of IPT and pyridoxine were among the reported barriers affecting full scale implementation of tuberculosis preventive therapy (Festo & Gasto, 2021:5). Therefore, IPT shortage was not found a problem in our study institution.

5.4.3. Improving providers knowledge on IPT (TPT)

For the success of the TPT programe and implementation of IPT in this case; providers need to be well trained and equipped with the necessary information and knowledge. During in-depth interviews, health care providers reported inadequacy of specific training opportunities as well as unavailability of guidelines regarding IPT. They believe that training should be provided adequately prior to the introduction of a program, it should be continued thereafter for untrained new staff plus refresher training for every new updates. Majority of the providers said that they have no appropriate training on IPT. They also replied as no separate IPT (TPT) guideline at the clinical service site and they are using the information on national HIV care and treatment guidline and others are using desktop references. They also noted that they provide information for patients individually and differently. Hence availability of health education guide may help them to provide comprehensive and consistent information to all patients. Therefore, they revealed the need for health education guide or health education material.

5.4.3.1. Provider's training

Fifty-eight years old male nurse provider replied:

> *"Concerning trainings, we did not take specific training on isoniazid preventive therapy (IPT) or any other TB preventive therapy. We have been trained within the antiretroviral therapy (ART) training package and we don't have separate IPT guidelines, and we don't have health education guide or material. We are using the information on HIV care and treatment guideline."*

Thirty-one-year-old Male Pharmacist reported:

> *"I was trained with ART training package, there was no separate detail training on IPT and there is no separate guidline for IPT provision. Patients need to be provided with mass and individual health education but in our hospital this practice is weak, and the*

setup is not convenient. In addition, there is no health education guide or health education material in place."

In agreement with our study in a study done in Tigray region of Ethiopia; lack of training opportunities and updates on IPT was found among the main barriers for low IPT implementation. The importance of special training on IPT prior to the launching of the program and timely update on IPT (TPT) for newly assigned staff was suggested (Teklay et al., 2018:6). A study in Kenya also revealed lack of training and not adequately trained as factors hindering IPT implementation and health care providers need to be empowered and equipped with knowledge and training (Wambiya, Atela, Eboreime, Ibisomi, 2018: 6).

Similarly, research in Namibia found that TPT uptake among PLHIV was extremely poor (below 50%), with only one in every five eligible patients starting TPT. The main reason for this was a lack of provider training. Furthermore, a study in rural South Africa indicated that poor TPT provision was substantially associated with insufficient TPT training of health care personnel (Amiya, Megan, Anthony, et al. 2021:4-5).

5.4.3.2. Isoniazid preventive therapy (IPT) guideline

Particpants replied in two catagories:

"Regarding the availability of IPT (TPT) guidline; participants answered differently. Two thirds of them confirmed and reported the presence of IPT guidlines in their working unit either separate or with ART guidelines; the rest three replied as there is no guideline at all and one provider participant answered as there is no guideline for TPT but they only use desktop references and job aids."

This might indicate lack of consistency in the providers' orientation especially for those newly assigned staffs as well as to all staff every time when new programs introduced.

A study done in one of the regions of Ethiopia reported unavailability of IPT guideline as a barrier for isoniazid preventive therapy implementation (Teklay et al., 2018:6). In addition,

a study done in Kenya revealed that existence of unclear IPT guideline and standard operating procedure were among the barriers identified for effective implementation and acceptance of IPT and due to this reason, health care providers asked for clarity and revision (Wambiya et al. 2018:5).

5.4.4. Best practices to improve uptake and completion of IPT in HIV patients (Health care providrs suggestions)

Health care providers interviewed were forewarded and recommended best practices they identified which would help to hasten the IPT implementation and improve uptake and completion of IPT in HIV patients. Most of the providers had similarity in their explanation and recommendation in this regard.

5.4.4.1. Adequate counselling and Health education to patients

Providers gave diferent explanations and opinions on counselling and health education which needed to improve plus practiced currently:

Thirty-six years old nurse female provider explained:

> *"Best thing to improve is strengthen counseling of clients on advantage of TB preventive therapy and possible side effect of the drug in detail and counsel them properly; because some of them understand easily and others need more time. So allocate time for counseling is best solution. Providing both mass and individual education is important. We also need to advise and teach patients to come back to seek medical advice if any side effect occur. In addition, providers should assess their adherence and convince them every visit.*

Fifty-eight years old male nurse provider for replied:

> *"Best experience to improve is providing better counseling service with good approach of dealing with clients. Privacy during counseling (env't), since they are afraid of stigma, and they need secured area. In addtion reduce work load up on providers and*

motivation of staff who prescribe IPT to patients. Explain the risk, benefit of IPT to patients and their family and training of providers who are working on ART clinic; they should be well trained, equipped and knowledgeable on IPT which plays a great role on the service. Avail health education guide so that all staff can provide consistent and full package of information to all patients following the guide."

Thirty-one years old male pharmacist recommended:

"The best practices to improve uptake and completion of isoniazid preventive therapy is the practice of skin test or to do skin test as a screening method to identify whether patients are latently infected or not. When patients are screened and know, they are positive; might better accept and complet TPT."

Fifty-two years old female nurse provider suggested:

"Best practice to improve uptake and completion of IPT is Initiating at the same time with ART; this will help clients not to consider TPT as additional (extra) drug and they will have good adherence and outcome. Moreover, update staff with training, avail and use IEC materials on TPT, improve counseling skill of providers as better counseling improves acceptance of clients, provide adequate time and convenient room for counseling and health education."

There are studies who reported similar findings. In a qualitative study done in resource constrained settings, lack of patient information, lack of understanding of the benefits of (TPT) were reported as TPT implementation barriers (Semitala, Musinguzi, Ssemata, et al., 2021, 5-10).

Likewise, adequate IPT-related health education and counseling were cited by both caregivers and health care providers as the two key enablers of IPT uptake and completion which means inadequate knowledge of IPT and, inadequate counseling regarding IPT was found a barrier to uptake and completion respectively (Ngugi, Muiruri,

Odero, and Gachuno., 2020:6-7). A study in South Africa revealed IPT implementation identified by health care workers, low patient awareness of IPT and inadequate time to counsel patients on IPT were among the main barriers mentioned. (Van Ginderdeuren, Bassett, Hanrahan, Mutunga, Van Rie 2019:8). Another study also presented supporting results indicating the importance of assisting patients to know about IPT which revealed the need for appropriate education and counseling of patients as the main facilitator for uptake and completion of TPT so that they understand the benefit of IPT and could ask their providers to prescribe (Ngugi, Muiruri, Odero et al., 2020:6-7).

5.4.4.2. Time of initiation of Isoniazid preventive therapy

Fourty six years old female nurse provider explained:

> *"The best practice I observed from other health institutions was initiating IPT with ART at the same time for newly diagnosed HIV patients. So that they accept as it is part of their HIV care and will take TPT without adherence problem. Otherwise, when initiated some time after ART initiation, they consider it as not as such important if they take their ART appropriately."*

Fifty-two years old female nurse provider replied:

> *"She suggested that it is better to initiate IPT or other TB preventive therapy with ART at the time of ART initiation; this will help clients not to consider IPT (TPT) as extra drug and by prescribing concurrently they will have good adherence, completion rate and outcome of therapy."*

In agreement with the above providers' suggestions in our study about the time of IPT initiation, studies in rural Malawi reported that IPT provision at the time of initial HIV diagnosis was found highly acceptable with three fourth completion rates (Little , Khundi, Barnes, Ngwira, Nkhoma, Makombe, Corbett, Chaisson, Dowdy, 2018:1, 5).

In contrast, another study reported that concurrent initiation of isoniazid with antiretroviral therapy resulted in high discontinuation rate than without concurrent initiation due to

increased drug toxicity (Johan van Griensven, Kimcheng, Bopha, Sopheak, Natalie, and Lutgarde, 2015:5-6).

CHAPTER SIX

6.1. PRESENTATION OF MAIN QUALITATIVE AND QUANTITATIVE FINDINGS AND GUIDLINE DEVELOPMENT

Double burden of tuberculosis and HIV are the major heath problems in many parts of the world particularly in resource limited countries like Ethiopia (Tesfay et al, 2018:2). Active Tuberculosis among PLWH can be prevented either by protecting them from being exposed to Mycobacterium Tuberculosis bacteria or by providing TB preventive therapy for those already exposed to the bacteria to prevent the progression of latent TB to active disease (Tesfay et al, 2018:3; Dawit et al. 2021:2).

Even though Isoniazid preventive therapy has been one of the WHO recommended key strategies of tuberculosis prevention in HIV positive, and Ethiopia adopted and integrated with HIV care and treatment guidline (FMOH 2018: 89-99; WHO Global tuberculosis report, 2021:20), its implementation encountered many challenges.

6.2. PRESENTATION OF MIXED METHOD FINDINGS

The study was intended to assess uptake and completion of Isoniazid preventive therapy (IPT) among people with HIV in Ethiopia Tertiary Hospital. According to the study, implementation was found low. In this study among two hundred fifty-two (252) participants interviewed, 56.7% were provided with TB preventive therapy and the rest accounting for 42.3% were not offered at all. More than half (56.6 %) of those initiated with IPT did not complete the prescribed dose of IPT with the specified six months of time or else within nine months duration.

The main factors hindering implementation of IPT (not initiating and not completing) identified in this study were mainly patients' refusal to take, fear of drug side effect, providers didn't prescribe, refusal due to pill burden, and patients perceiving that they are not a TB case (lack of awareness and understanding) consecutively. As it was noted from the participants response; they just take the drug from the pharmacy and some of them discard it to the dustbin before leaving the hospitals' compound. This may indicate lack of knowledge, counseling and informed decision of patients. In order for this program of tuberculosis preventive therapy to be successful, patients have to be educated,

counselled, agree to take medication and always need to have well informed decisions on their care and treatment.

Logistic regression analysis was done to identify independent variables which have significant association to the outcome variable. Hence, variables such as participants' gender, residence, and having high viral load level, having information and understanding on IPT, having awareness on IPT can reduce the occurrence of tuberculosis.

Accordingly, in this analysis, male participants were found to be less likely to initiate TB preventive therapy (IPT) compared to female participants. In addition, participants who have high viral load levels were found to be with low levels of IPT initiation compared to participants who have good viral load suppression. Regarding residence of participants, those who came from out of Addis Ababa were most likely to initiate IPT as compared to participants who live in Addis Ababa town. Participants who have information and understanding on IPT plus those who have awareness of IPT that can reduce the occurrence of tuberculosis were found with high level of IPT initiation compared to participants with no awareness, information and understanding about IPT.

In the qualitative part of this study, during health care provider's interview, the identified reasons affecting IPT implementation in the study area were mentioned in detail. These were mainly patient's refusal, non-completion and adherence problems, inadequate counselling and patient education practices, misconceptions and misunderstandings of patients about IPT, providers fear of drug resistance, pill burden and drug side effect and lack of training and guidelines. These explanations imply and showed the gaps mainly on the patients, providers and organization. Participants refuse simply by sharing wrong information from their neighbours and other patients. This could be due to lack of appropriate health education and counseling. On the other hand, organizations and program implementers need to train providers and put necessary guidlines at every delivery site for reference. In addition, as part of this study, we developed mini health education guide for health care providers use.

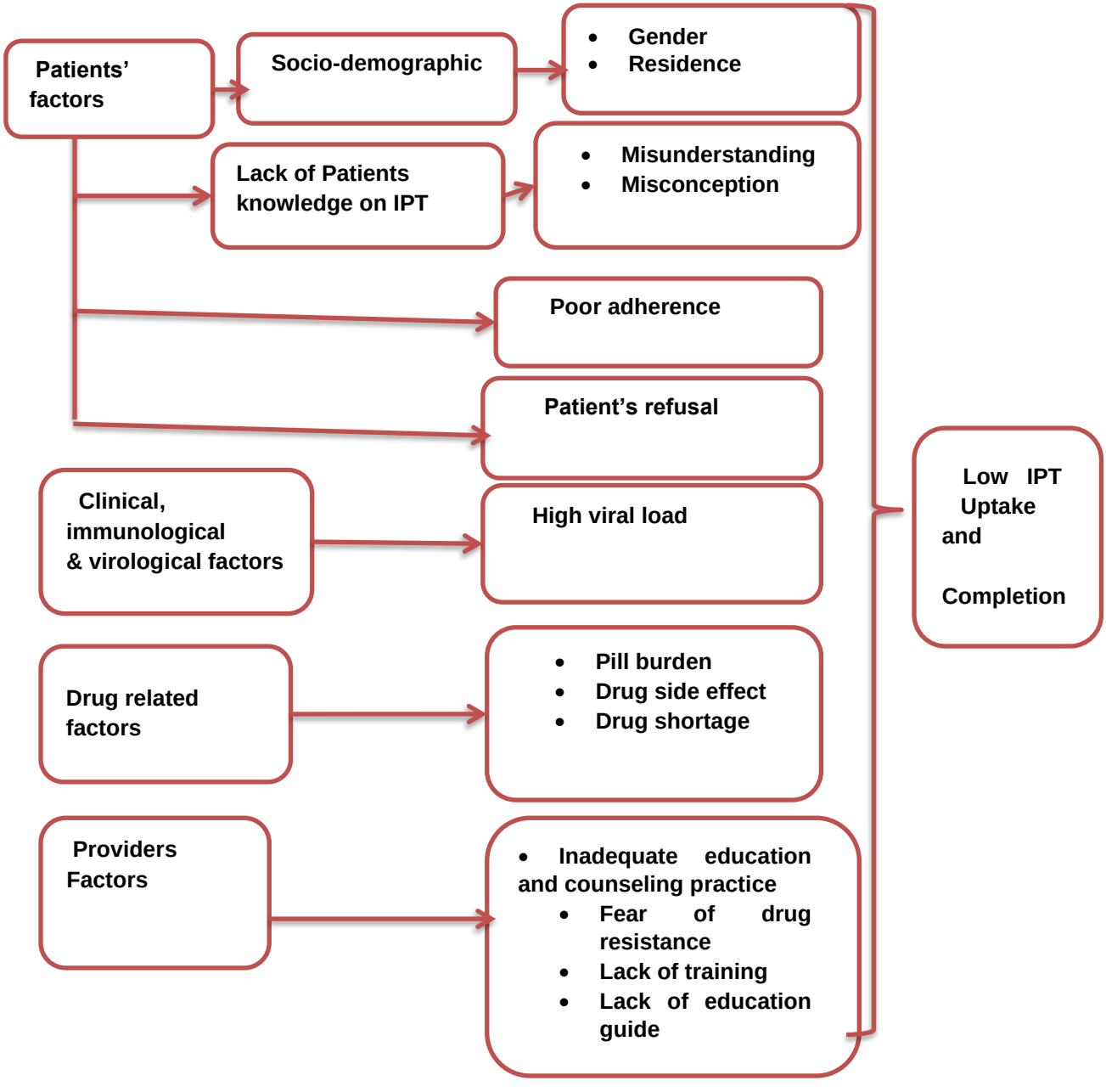


Figure 6.1: A conceptual model showing contributing factors for low implementation of IPT in the study (2020).

This conceptual model is according to the findings of the present study. It consists of four main catagories. Patient related, drug related, provider related factors and clinical, immunological, virological factors. Contributing factors for low uptake and completion of IPT as it is shown in (Figure 6.1.) were the findings from both quantitative and qualitative sections such as patients' socio-demographic factors (gender, residence) and lack of Patients knowledge on IPT (Misconception and Misunderstanding); Clinical, immunological & virological factors (high viral load);

drug related factors (Pill burden, Drug side effect, Drug shortage) and provider related factors (Inadequate education and counseling practice, Fear of drug resistance, Lack of training, Lack of guideline). Combination of these factors resulted in low uptake and completion of tuberculosis preventitve therapy (IPT) in the study institution and each catagory described in the analysis sections.

6.3. HEALTH EDUCATION GUIDE DEVELOPMENT

Health education guide was developed and presented as section 6.3. It was developed based on the the information and gaps identified using our data analysis. Based on our findings as explained above, patients misunderstanding, misconception, misinformation and knowledge gap on TB preventive therapy were among the main determinants for low uptake, implementation and completion. Hence this short health education guide was prepared for health care providers use when they provide counseling and education before TPT administration. The process of preparation as it is mentioned in the methods section; was shared to different experts in the field and they commented on it. Then experts' comments and additional points added were incorporated and sent for review again and after they returned the final material, included with this thesis.

6.4. HEALTH EDUCATION GUIDE

Health Education Guide to perform a thorough assessment before starting patient education and provision of tuberculosis preventive therapy to PWHIV

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HEALTH EDUCATION GUIDE CONTENTS

Tuberculosis Preventive Therapy

Contraindications to IPT

Monitoring of TB preventive therapy

Treatment interruption management

The national algorithm for TB screening

ACRONYMS	
ALT	**Alanine aminotransferase**
AST	**Aspartate aminotransferase**
ART	**Antiretroviral therapy**
DST	**Drug sensitivity test**
GGT	**γ-glutamyl transpeptidase**
HIV	**Human immune-deficiency virus**
HEW	**Health extension workers**
IGRA	**Interferon-gamma release assay**
IPT	**Isoniazid preventive therapy**
LTBI	**Latent tuberculosis infection**
OI'S	**Opportunistic infections**
PLHIV	**people living with HIV**
TST	**Tuberculin Skin Test**
TB	**Tuberculosis**
TPT	**Tuberculosis preventive therapy**
WHO	**World health organization**

KEY NOTES:

- **Isoniazid Preventive Therapy is the provision of INH to persons with latent TB infection to prevent the development to active TB Disease.**
- **Many studies concluded the benefit of providing TB preventive therapy to people living with HIV (PLHIV)**.

  - **Adults and adolescents living with HIV should be screened using a clinical algorithm; those who do not have a current cough, fever, weight loss, night sweats, or poor weight gain in children are unlikely to have active TB and should be provided IPT.**

- **People with HIV should also be screened for active hepatitis (acute or chronic), history of jaundice, regular and heavy alcohol consumption, and symptoms of peripheral neuropathy. Therefore, IPT work up is essential before initiating IPT**

  - **IPT should be given to all eligible PLHIV regardless of the degree of immune status, ART status, previously been treated for TB and pregnancy status**
  - **Providing IPT to HIV-positive people does not increase their likelihood of developing INH-resistant tuberculosis. As a result, worries about the development of INH resistance should not prevent IPT provision.**
  - **Tuberculin Skin Test (TST) is not a requirement for initiating IPT in people living with HIV (PLHIV)**

  - **Administration of IPT immediately after completion of full course of TB therapy is not recommended, It could be administered after three years.**
  - **If a patient develops symptoms of TB during TPT treatment; evaluate the patients for TB and do drug sensitivity test and treat according to resistance pattern.**

  - **IPT should be given at a dose of 10 mg/kg/day (maximum 300 mg) for duration of 6 months.**
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- **If the patient stops taking IPT for less than three months, re-start the course with the missed doses added at the end. If the client misses more than three months of treatment: Start a new 6-month IPT course.**

- **Arrange ARV refill with INH refill appointments and patients should be counselled on adherence and monitor for side effects at every visit.**

- **Health education should be provided adequately so that clients will have awareness and informed decision for uptake and completion of TPT** (Dugdale, D**.,2019:1)**

6.5. INTRODUCTION

In 2019, an estimated ten million people worldwide contracted tuberculosis. HIV-negative persons died from TB at a rate of 1.2 million per year, while HIV-positive people died at a rate of 208 000 per year (Ethiopia TB, TB/HIV guideline, 2021). Despite advancements in access to antiretroviral therapy (ART), tuberculosis (TB) is the leading cause of HIV-related deaths globally. In 2019, global data showed that HIV-positive people were 20 times more likely than HIV-negative people to have active tuberculosis (WHO, consolidated Latent TB guidline, 2020:9). According to 2020 global TB report, Ethiopia is among the 30 High TB/HIV and MDR-TB Burden Countries, with annual estimated TB incidence of 144/100,000 populations and mortality rate of 19 per 100,000 populations (Ethiopia TB, TB/HIV guideline, 2021). Not all individuals infected with mycobacterium develop active tuberculosis (TB). Latent tuberculosis infection (LTBI) is described as a condition of persistent immunological response to stimulation by mycobacterium tuberculosis antigens with no evidence of clinically manifest active TB disease. It is estimated that a person with LTBI has a 5–10 percent lifetime risk of developing active TB (Kagujje, Mubiana, Mwamba, and Muyoyeta, 2019:1). The risk is especially high in children under the age of five and in adults who have weakend immune systems including people with HIV. Treatment of latent TB infection (LTBI) to prevent active TB disease is an important part of the World Health Organization's (WHO) End TB Strategy, and the efficacy of currently available treatments ranged from 60% to 90%. Therefore, Adults, adolescents, and children living with HIV, regardless of their immunological state or antiretroviral drug therapy status, should receive tuberculosis prevention treatment. Isoniazid preventive therapy (IPT) is one of the three I’s globally recommended strategy for prevention of incident TB among HIV infected individuals in addition to intensive case finding and infection control. IPT is a critical public health intervention for preventing tuberculosis in HIV-positive patients, and the WHO has recommended it as part of a comprehensive HIV care and treatment plan. To check for the presence of latent tuberculosis infection (LTBI), either a tuberculin skin test (TST) or an interferon-gamma release assay (IGRA) can be utilized. However, it is not required criteria for people living with HIV or child household contacts aged < 5 years to begin preventive treatment.

People with HIV who presented negative for any of the four symptoms and whom active TB is excluded by investigations are eligible for TB preventive therapy. The four-

symptoms are cough, fever, night sweating, weight loss and failure to gain weight in children. These screening methods are recommended for all people with HIV at every visit to a health facility or visit a health care worker.

In our current study done in Tikur Anbessa specialized teaching tertiary Hospital, 252 adult participants on HIV care and treatment were interviewed and the uptake of IPT among these participants was found to be 56.7% but only 43% of those initiated were found completed the prescribed dose. Among the contributing factors for low uptake and completion of IPT; health service and provider related factors (lack of adequate health education on TB and IPT, inappropriate information and misunderstanding about IPT benefits, misconceptions about IPT side effect and lack of dedicated time for counseling) were mentioned by clients. Therefore, this health education guide may help to improve provision of health education which will help to increase uptake and completion of IPT.

6.5.1. Purpose

The purpos of developing this health education resource (guide) is to provide appropriate information to clients in order to promote TB preventative therapy (TPT) uptake and completion, and thereby contribute to the end of the TB pandemic.

6.5.2. Intended Audience

This material is intended to contribute to health care providers who are working on TB/HIV, HIV care and treatment and TB services at any level of health service setting. It also uses as a quick reference for health care practitioners and clinicians to give health information, education and counseling for clients, thereby influencing individuals' and communities' health care seeking and health care utilization behavior.

6.5.3. Health education

6.5.3.1. Health education definition

Health education is a process in which people learn how to take care of their own health and the health of their community. Health education is the main and essential element of health promotion. Education is an interactive process that focuses on the desired patient behavior and patient's stated priorities to achieve health goals. Patients must be educated about diseases and treatments as part of the healthcare process. Patients need to understand the disease, as well as the benefits, disadvantages of different interventions and how to interact with the local service (Walker, Adebajo and Bukhari, 2020:1-2). In addition, it is to raise awareness, expand knowledge, gain skills and shape a health-oriented attitude of particular individuals who are also perceived as elements of a society. The process concentrates on making people realize the relation between one's health, their lifestyle, physical and social setting. It does not solely mean transferring the knowledge, but it allows the learner to apply the knowledge effectively i.e. consider, think, make decisions and take actions concerning their health, gain skills which help to improve it. As a result of health education, awareness increases, an ability to make decisions concerning health enhances knowledge and skills connected not only with health and sickness but also the prevention and coping with difficult situations improve.

6.5.3.2. Communicating with patients

Patient education empowers patients to take a more active role in their own health care. It also corresponds to the growing trend of patient- and family-centered treatment. Health care providers must be able to assess patient needs and communicate clearly and effectively. Physicians (health care providers) must spend more time with patients in order to enhance health care results. Time is crucial in any educational process. The interaction between the teaching health care providers and the patient must be motivated, and attentive to the needs of the individual patient. The development of patient health literacy is critical to the success of our tried-and-true health-prevention strategies. A physician-patient relationship necessitates a shared duty. Physicians have a responsibility to inform patients about how to achieve health and wellbeing, and patients have a responsibility to act on that information in their own best interests. The physician's ability to diagnose and treat patients, as well as the patient's right to accept or refuse clinical evaluation, therapy,

or both, are all dependent on medical informed consent (Paterick, Patel, Tajik, and Chandrasekaran, 2017:112-113).

6.5.3.3. Assessment of clients

The success of patient education is mainly determined by how well you assess the needs of the patients. A learning needs assessment is the foundation for effective patient education. Health care professionals assess by interviewing the patient and family, communicating with the medical team and/or observing the patient. Assessment of barriers that impact delivery of care is the key to developing of a personalized plan to match the patient needs, abilities and preferences of the patient. Patients are empowered to modify their behaviors, and this type of care is referred to as "patient-centered" care.

- Assess socio-demographic information as well as support system, culture/values/beliefs and barriers to learning.
- Assess learning needs based on current health issues, knowledge and concerns.
- Assess patient engagement in learning process (patient's goals and priorities, motivation, and rediness to learn).
- Determine learning preferences (verbal, written, visuals, multi-media and technology).
- Consider specific assessment tools (teach back of the patients, return demonstration or evaluat patient adherence to self care plan, out come or behavioural change).

6.5.3.4. Guide to perform a thorough assessment before patient education

- **Gather clues:** speak with members of the health-care team and observe the patient. Make sure you don't make any assumptions. Patient instruction based on incorrect assumptions which may be ineffective and time-consuming.
- **Know your patient (Client):** Introduce yourself to your patient and explain your role in their care. Review their medical records and ask simple questions to get to know them.

- **Establish a rapport:** take the time to get to know one another and establish good relationship. When it's appropriate, make eye contact with your patient and make them feel at ease with you. Conduct a thorough examination and give attention to the individual's problems. It will be worthwhile since your patient education initiatives will be more successful**.**
- **Gain trust of clients:** Show respect for others and treat them with kindness and without prejudice.
- **Determine whether your patient is ready to learn or not:** Inquire about your patients' perspectives, attitudes, and motives.
- **Know the patient's perspective:** Discuss the patient's concerns, fears, and probable misconceptions. The information you obtain can assist you in training your patients.
- **Asking the right questions:** Find out whether the patient has any concerns rather than simply asking questions. To get more information from the patient, use open-ended questions. Pay close attention. The patient's responses will assist you in determining what the person's core beliefs are. This will enable you to gain a better understanding of the patient's motivation and build the most effective teaching techniques.
- **Know about the patient's knowledge:** Find out what information your patient already has. To figure out what the patient may have learnt from health care providers, you could use the teach-back method (also known as the show-me method). The teach-back method is a strategy to make sure you've conveyed everything to the patients in a way they understand. Find out if the patient has any skills that need to be developed.
- **Involve others:** Ask if the patient wants other people involved with the care process. It is possible that the person who volunteers to be involved in your patient's care may not be the person your patient prefers to be involved. Learn about the support available to your patient.
- **Identify barriers and limitations:** You may perceive barriers to education, and the patient may confirm them. Some factors, such as low health literacy may be harder to recognize (Dugdale, 2019:1).

6.5.3.5. Choosing effective patient education materials

Once health care provider have assessed the patient's needs, concerns, readiness to learn, preferences, support, and possible barriers to learning, you will need to:

- Make a plan with your patient and his or her support person
- Agree with the patient on realistic learning objectives
- Select resources that fit the patient

The first step is to assess the patient's current knowledge about their condition. Some patients need time to adjust to new information, master new skills, or make short- or long-term lifestyle changes.

Your patient's preferences can guide your choice of education materials and methods.

- ✓ Find out how your patient likes to learn
- ✓ Be realistic; Focus on what your patient needs to know, not on what is nice to know
- ✓ Pay attention to the patient's concerns. The person may have to overcome a fear before being open to teaching
- ✓ Respect the patient's limits. Offer the patient only the amount of information they can handle at one time
- ✓ Organize the information for easier understanding
- ✓ Be aware that you may need to adjust your education plan based on the patient's health status and environmental factors (Dugdale, 2019:1).

6.5.3.6. Basic Priorities during patient education

When educating patients, you need to cover:

1. Explain or introduce the main subject. What is TB, TB/HIV, causes, symptoms, diagnosis, treatment or prevention, risks
2. What your patient needs to do and why
3. When your patient can expect results (if applicable)
4. Warning signs (if any) your patient should watch for
5. What your patient should do if a problem occurs
6. Who your patient should contact for questions or concerns (Dugdale, 2019:1).

6.5.3.7. Patient Education Resource Options

There are many ways to deliver patient education. Examples include one-on-one teaching, demonstrations, and analogies or word pictures to explain concepts.

You can also use one or more of the following teaching tools:

- Printed materials or brochures
- videos or DVDs
- Power Point presentations
- Charts or Posters
- Models
- Group educations
- Involve trained peer educators (Dugdale, 2019:1)

When selecting health education materials:

- The type of resources that a patient or support person responds to varies from person to person. Using a mixed media method often works best.
- Keep your assessment of the patient in mind. Consider factors such as knowledge and culture as you develop a plan.
- Avoid fear strategies. Focus instead on the benefits of education. Tell your patient what to pay special attention to.
- Be sure to review any materials you plan to use before sharing them with the patient.

NB: There is no education material or resource which substituts one to one patient education (teaching).

In some cases, it may not be possible to get the right materials for your patients' needs. For example, it may be hard to find materials on new treatments in certain languages or on sensitive topics. Instead, you may try having a discussion with the patient on sensitive topics or creating your own tools for the patient's needs.

6.5.4. Health care providers' advice for clients

Patients should be advised to see their doctor or nurse on a frequent basis once they begin therapy for latent tuberculosis infection. It's also crucial to remind them to take all of their medications exactly as advised by their doctors. The health-care providers will monitor their progress. These medications might have serious adverse effects or negative effects for some people. If the patient on IPT has any of the following side effects, advise them to call or visit their doctor or health care provider right away:

- Color change of urine that becomes dark or brown
- Epistaxis (nasal bleeding)
- Nausea and/or Vomiting and Poor or no appetite
- Easy skin bruising, skin rash
- Yellowish skin or eyes

- Bleeding from gums
- Fever for 3 or more days
- Lower chest pain or heartburn
- Dizziness
- Abdominal pain
- Tingling sensation over fingers and toes and aching type of joint pain

(Ethiopian TB, TB/HIV, DR-TB guidline, 2021:74)

In addition to giving awareness on side effects, people with latent TB infection and on TB preventive therapy have to be advised on the need to know symptoms of TB disease and if developed they should see a doctor with out delay. Clients who drink alcoholic beverages (wine, beer, and liquor) while on treatment for latent tuberculosis can be dangerous for their health and treatment adherence. As a result, patients should be informed about this issue (Ethiopian, national HIV care guideline, 2018:97).

6.5.5. Patient's eligibility assesement for IPT (TPT)

Before TPT initiation for people with HIV, health care providers need to evaluate for eligibility to take a given regimen of TB preventive therapy. Hence, taking history and assessing for the presence of TB, check for any one of TB symptoms, History of peripheral

neuropathy, alcohol abuse and dependence, history of jaundice and for any contra indication vital. Investigations needed to evaluate the patient such as liver function testing has an advantage.

6.5.5.1. Evaluation of Liver Function Tests

A set of enzymes or chemicals related to the way the liver functions are measured in liver function tests. Liver function tests are a set of blood tests used to assess the liver's health. Changes in liver function tests indicate as to whether the liver is strained, inflamed, infected, or diseased, as well as the severity of the condition. The pattern of the tests can reveal the cause and allow for early detection of unknown problems as well as ongoing monitoring of existing issues (Sarah Jarvis, 2021).

The elevation of a given enzyme activity in the serum is thought to primarily reflect its increased rate of entrance into serum from damaged liver cells. Tests, such as the alkaline phosphatase and aminotransferases are used to detect liver cell damage or bile flow interference.

Serum enzyme tests can be divided into two catagories:

- Enzymes whose elevation in serum reflects damage to hepatocytes and
- Enzymes whose elevation in serum reflects cholestasis

(Daniel, 2018:2338-2340).

Enzymes that Reflect Damage to Hepatocytes

Aminotransferases (transaminases) are sensitive indicators of liver cell injury that can help diagnose acute hepatocellular diseases like hepatitis. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are two among them (ALT). In decreasing order of concentration, aspartate aminotransferase (AST) is present in the liver, cardiac muscle, skeletal muscle, kidneys, brain, pancreas, lungs, leukocytes, and erythrocytes. Alanine aminotransferase (ALT) is a more specific indicator of liver injury since it is present predominantly in the liver. Aminotransferases are normally found in low

concentration in the serum. When the liver cell membrane is damaged, resulting in increased permeability, these enzymes are released in greater amounts into the bloodstream. The release of aminotransferases does not need liver cell necrosis, and there is a poor link between the degree of liver cell damage and the level of aminotransferases. As a result, the absolute rise of aminotransferases in acute hepatocellular diseases has no prognostic significance. The normal range for aminotransferases varies by laboratory, however it usually falls between 10 and 40 IU/L.Technical reasons account for the difference in normal range between laboratories; there are no reference standards for establishing upper boundaries of normal for ALT and AST. Small increases in serum aminotransferases can be caused by any type of liver cell damage. Levels of up to 300 IU/L are nonspecific and can occur in any form of liver disease (Daniel, 2018:2338-2340).

A little increase in ALT in asymptomatic blood donors is rarely a sign of serious liver disease; studies have found that fatty liver disease is the most likely cause. To put it another way, stunning elevations: >1000 IU/L aminotransferases—occur mainly in diseases associated with significant hepatocellular damage, such as:

- Viral hepatitis,
- Ischemic liver injury (prolonged hypotension or acute heart failure),
- Toxin-or drug-induced liver injury.

Some illnesses (diseases) can be diagnosed by the pattern of aminotransferase rise. The ALT is usually higher than or equivalent to the AST in most acute hepatocellular diseases. While the AST:ALT ratio is often less than one in individuals with chronic viral hepatitis and nonalcoholic fatty liver disease, several studies have found that as cirrhosis progresses, the ratio climbs to greater than one. A AST: ALT ratio of >2:1 is suggestive of alcoholic liver disease, but a ratio of >3:1 is highly suggestive. In alcoholic liver disease, the AST is rarely greater than 300 IU/L, whereas the ALT is frequently normal. An alcohol-induced pyridoxal phosphate shortage causes a low level of ALT in the blood (Daniel, 2018:2338-2340).

Enzymes that Reflect Cholestasis

In cholestasis, the activities of three enzymes are frequently elevated: alkaline phosphatase, 5'-nucleotidase, and -glutamyl transpeptidase (GGT). Alkaline phosphatase and 5'-nucleotidase are found in or near the bile canalicular membrane of hepatocytes, whereas GGT is located in the endoplasmic reticulum and in bile duct epithelial cells. GGT increase in serum is less selective for cholestasis than alkaline phosphatase or 5'-nucleotidase elevations; owing to its more diffuse location in the liver (Daniel, 2018:2338-2340).

6.5.5.2. Assessment for peripheral neuropathy

Peripheral neuropathy (PN) is a serious nerve disorder that is frequently encountered in HIV patients. It's a peripheral nerve problem that causes a variety of signs and symptoms such as pain, paresthesia (a subjective sensation of tingling, numbness, or crawling), poor sensitivity, weakness, and gait changes. The involvement of sensory fibers, motor fibers, and autonomic fibers within the peripheral nerves can cause a variety of neuropathy symptoms (Motiwala, 2021:197,200). Administration of pyridoxine with isoniazid protects against the development of peripheral neuropathy in these individuals (WHO, handbook on TPT, 2020:44). Administration of pyridoxine 50mg/d with isoniazid protects against the development of peripheral neuropathy in these individuals (WHO, handbook on TPT, 2020:44). Patients with the above symptoms of peripheral neuropathy should be investigated and not be administered with IPT.

6.5.5.3. Alcohol intake assessment

The history should also focus on whether alcohol abuse or dependency is present while analyzing alcohol use. Behavioral patterns and effects of alcohol consumption, rather than the amount consumed, are commonly used to define alcoholism. A pattern of drinking alcohol in a way that has negative social, family, occupational, or health consequences is referred to as abuse. Dependence is defined by alcohol-seeking behavior, despite its adverse effects. Many alcoholics exhibit both reliance and abuse, with dependency being the more serious and mature form of alcoholism (Daniel, 2018:2338-2340).

6.5.6. Tuberculosis preventive therapy options

Different tuberculosis preventative therapy (TPT) regimens were suggested by the World Health Organization. However, in Ethiopia, INH for six months (6H) is commonly used at the national level. INH daily for six (6H) or nine months (9H), INH and Rifampicin (3RH) daily for three months, Rifampicin for four months (4R), INH and Rifapentin weekly for three months, or one-month daily isoniazid plus Rifapentin are among the alternatives available. TPT is given to those who have latent Mycobacterium TB infection. Isoniazid preventative therapy (IPT) is used to keep TB infection from becoming active disease. Screening for active TB in HIV-positive individuals is the single most important step before initiating IPT.

So far, the evidence strongly suggests that IPT is beneficial to those who are eligible. According to studies, giving IPT to HIV-positive patients does not enhance the chance of acquiring INH-resistant tuberculosis. The dose of INH is 300mg/day for adults and 10mg/kg for children. The duration of IPT is for six months. It is also required to provide vitamin B6 (50 mg/day) to prevent side effects (INH-induced peripheral neuropathy).

6.5.6.1. Contraindications to IPT

Individuals with any one or more of the following conditions should not receive IPT (TPT):

1. Symptoms suggestive of active tuberculosis disease even if the diagnosis isn't yet confirmed.
2. Active hepatitis (chronic or acute); examine the patient for jaundice and tenderness in the right upper quadrant of the abdomen.
3. Consumption of alcoholic beverages on a regular and heavy basis.
4. Previous isoniazid allergy or intolerance
5. Peripheral neuropathy symptoms (persistent numbness and burning sensation in the feet and hands. However, past history of treated TB and current pregnancy should not be contraindications for initiating of TPT (WHO handbook on TPT, 2020:46).

According to the national policy for TB preventive therapy for people infected with HIV:

- ❖ After active TB has been ruled out, TB preventative treatment (TPT) should be given at the time of enrolment to HIV care and treatment.
- ❖ TB preventative therapy should only be given once and should not be repeated unless there is strong suggestion on its benefits, which should be decided by a senior physician.
- ❖ TB prevention therapy (IPT) should only be used for six months.
- ❖ TB preventative therapy should not be started right after full course of TB treatment has been completed.
- ❖ Patients who have had TB treatment in the last three years can receive TB preventive therapy (Ethiopian, consolidated HIV care guideline, 2018:98).

6.5.6.2. Monitoring of TB preventive therapy

Health extention workers (HEWs) or a family supporter should provide assistance to patients at home level. Isoniazid should be given to patients in one-month supply and appointment for six months. The client's monthly scheduled follow-up should be integrated with the client's other treatment services. At each follow-up appointment, the health care worker should: Educate the patient about the importance of going to the health facility if symptoms suggestive of tuberculosis occur. Evaluate and counsel patients on the importance of treatment adherence, check for drug toxicity (including hepatitis, peripheral neuropathy, and rash), and check for signs and symptoms of active tuberculosis or other OIs. If active tuberculosis is discovered, preventive therapy should be discontinued immediately and a full course of anti-TB treatment should be started (Ethiopian, consolidated HIV care guideline, 2018:97).

6.5.6.3. Treatment interruption management

If a patient stops taking isoniazid preventative therapy against medical advice, the patient should be traced down (through adherence case managers/supporters, Health extension workers (HEW), or the index person) and treatment should be restarted after identifying and addressing the adherence issues. If a patient completes the full course of therapy (six months dosage) within six to nine months, they are said to have finished IPT (WHO, handbook on TPT, 2020:6).

- If the client stops IPT for a period of less than three months: Resume the same course by adding for the missed doses at the end
- If the client discontinues treatment for a period of more than three months: Re-initiate new course of IPT for six months again.

Concerning repeat administration of IPT; there are different recommendation in different countries considering the local HIV and TB epidemiology. Administering IPT immediately after completing a full course of TB treatment is not suggested currently in Ethiopia (Ethiopian, consolidated HIV care guideline, 2018:98-99).

TABLE 6.1: TOXICITY GRADING OF SOME OF THE LIVER FUNCTION TESTS (ETHIOPIAN CONSOLIDATED HIV CARE GUIDELINE, 2018:199,204)

Test Type	Mild	Moderate	Sever	Sever–life threatening
ALT (SGPT)	1.25 – 2.5 x ULN	2.6 – 5.0 x ULN	5.1 – 10.0 x ULN	>10.0 x ULN
AST (SGOT)	1.25 – 2.5 x ULN	2.6 – 5.0 x ULN	5.1 – 10.0 x ULN	>10.0 x ULN
Bilirubin (>2 weeks of age)	1.1 – 1.5 x ULN	1.6 – 2.5 x ULN	2.6 – 5.0 x ULN	>5.0 x ULN
Lipase	1.1-1.5xULN	1.6-3.0xULN	3.1-5xULN	>5 xULN

- Signs of hepatotoxicity during treatment; **Stop IPT if:**

- Patient is symptomatic and ALT levels are increased by ≥ 3x from baseline (day 0 of IPT).
- Patient is asymptomatic and ALT levels are increased by ≥ 5x from baseline (day 0 of IPT) (Bethesda 2018:3)

TABLE.6.2: GRADING OF PERIPHERAL NEUROPATHY TOXICITY IN ADULTS AND ADOLESCENT (ETHIOPIAN CONSOLIDATED HIV CARE GUIDELINE, 2018:199,204)

Problem	Mild Toxicity	Moderate toxicity	Sever toxicity	Sever–life threatening Toxicity
Peripheral Neuropathy	Transient or mild discomfort, no limitation of activity	-Moderate limitation of activity, some assistance might be needed -Non-narcotic analgesia required	-Moderate limitation of activity, some assistance might be needed -Non-narcotic analgesia required	-Life-threatening, extreme limitation in of activity, Significant assistance required, -significant medical intervention/therapy required, Hospital/hospice care. -Debilitating or not responsive to narcotic analgesia. -Sensory loss involves extremities and trunk.

6.6. The national algorithm for TB screening

The Figure 6.2. Below is self explanatory algorism which shows the process of assesement and screening for TB and IPT therapy.

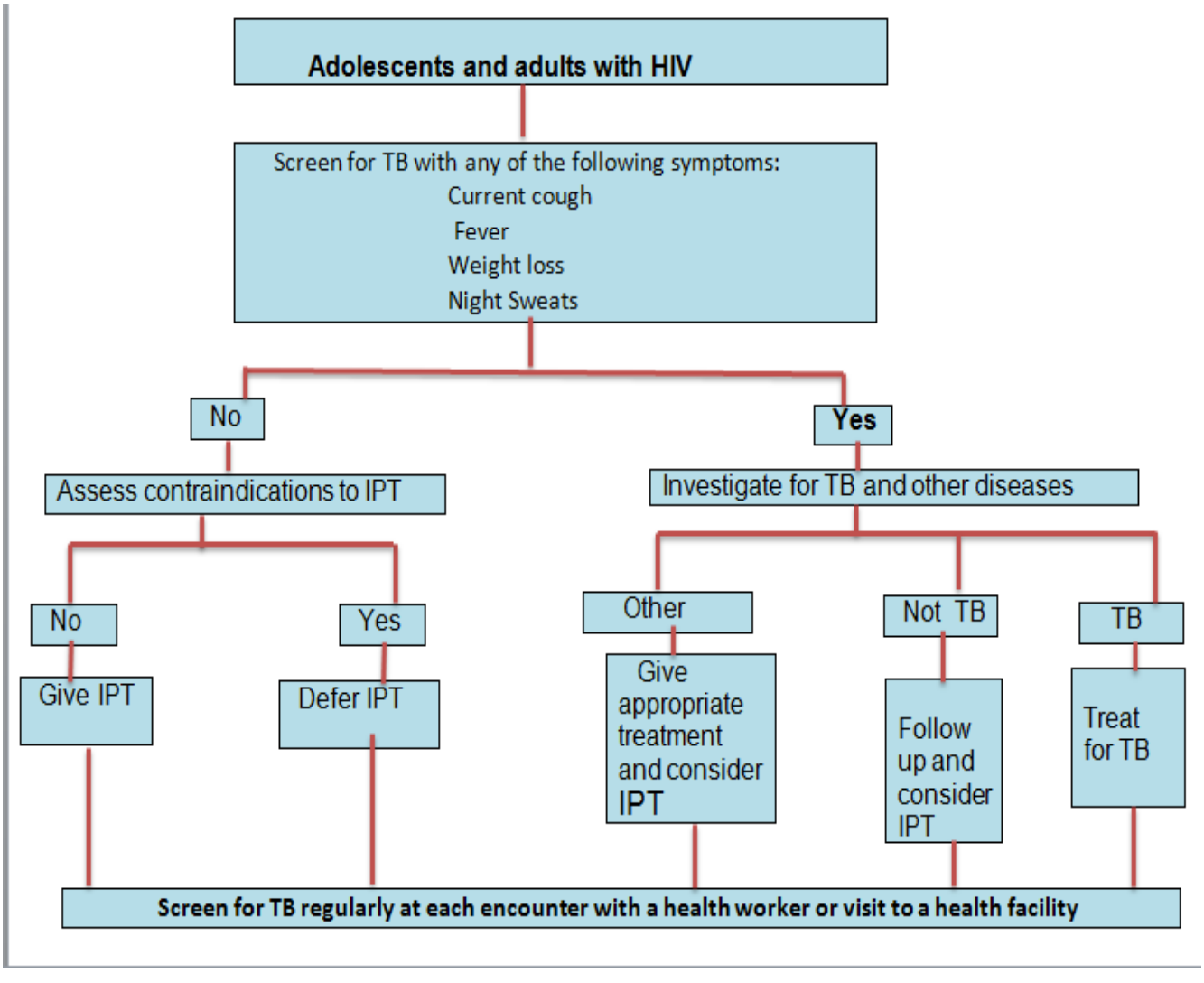

Figure 6.2: The national TB screening and TPT provision algorithms for adults and adolescent PLWH in Ethiopia, (Ethiopian, TB, TB/HIV Guideline, 2021:65).

6.7. Resources for health education guide

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CHAPTER SEVEN

CONCLUSION, RECOMMENDATION, LIMITATION AND CONTRIBUTIONS OF THE STUDY

7.1. CONCLUSION

In this study, uptake of tuberculosis preventive therapy in Addis Ababa in a Tertiary health care institution was found sub-optimal and completion rate among those who were initiated was alarmingly low. The main implementation barriers identified were client's refusal to take tuberculosis preventive therapy, inadequate education and counselling of patients, providers attitude and knowledge, providers fear of development of drug resistance when given as a single drug, inadequate training of staffs on TB preventive therapy, lack of guidelines, inconsistency of information given to patients, sharing of wrong information about TPT among clients. Health care providers need to be well trained and availing IPT guidelines, strengthen patient education and counselling before initiating TB preventive therapy. For effective counselling and good communication, it is important to maintain patients' privacy, adequate space and favourable working environment. Therefore, adequate manpower allocation is needed so that providers could spend the time needed to counsel and educate patients appropriately till they understand and accept to take IPT and assessing of patient's adherence at every visit. Attention needs to be given not only for initiation but also for completion status of patients.

7.2. RECOMMENDATIONS

Based on the findings of this research we recommend the following:

- Strengthening health education sessions on TB preventive therapy benefit by heath care providers as well as through different medias.

- Introduce shorter duration of TB preventive therapy regimen types like Rifampicin with isoniazid daily for three months ("3RH") or Rifapentin with isoniazid ("1HP")

daily for one month or Rifampicine alone (“4R) for four months which is not practiced in Ethiopia nationally except few places.

- Strengthen counselling services by increasing provider’s number so that they can have adequate time for counselling each patient.
- Avail separate, and comprehensive TB preventive therapy guidelines.
- Avail health education guide: so that health care workers may provide information which is consistent to avoid misconceptions about INH preventive therapy and help clients to make informed decisions.
- Provide appropriate formal training for health care providers on TB preventive therapy.
- Continious supportive supervision and mentorship on TB preventive therapy implementation.
- Needs further multicentered further research, possibly at national level study.
- Tuberculin skin test (TST) or interferon-gamma release assay (IGRA) test for screening the presence of latent infection before initiation of preventive therapy.

7.3. CONTRIBUTIONS OF THE STUDY

The study revealed the level of TB preventive therapy implementation in a Tertiary Hospital and their completion status among those who initiated on IPT in Addis Ababa, Ethiopia. The study also exposed multiple barriers for sub optimal uptake and completion of TB preventive therapy in the study area.

The study findings can be used for health care providers to better understand the reason for low uptake and implementation of TB preventive therapy (IPT) and to realize the gap between initiation and completion of IPT. Hence, health care providers working on HIV care and treatment need to provide health education individually so that patients could understand and be aware about tuberculosis preventive therapy and take commitment for their own health care intervention. The study identified the reasons why patients refuse to take IPT and why they didn’t want to complete after initiation.

In addition, based on the findings of this study and as an intervention; short health education guide was developed to be used by health care providers. The material is to be used as a guide when providing health education to patients and it might help to improve

quality of services provided regarding TB preventive therapy. The health education guide is presented in chapter six.

The findings of this study can contribute to the development of programmes, strategies and policies regarding tuberculosis prevention in people living with HIV. The study also revealed some of the research gaps that require further studies which contribute towards the improvement of the health of people living with HIV

7.4. STRENGTH AND LIMITATIONS OF THE STUDY

This study has a number of strengths. Firstly, this study was done in the country's largest referral and teaching Hospital in which many cases from different areas have been sent to the hospital by referral. Secondly, the study used a mixed methods approach, which allowed data to be collected from differing viewpoints. Participants in the qualitative phase of the study were health care providers who had worked in an ART clinic for years and had a lot of experience and knowledge about the challenges of TB prevention therapy implementation. After the quantitative data was collected and analyzed, the qualitative interview guide was created and amended. As a result, the interview guide was created in such a way that the quantitative data could be clarified. Despite its many advantages, the study had some flaws. Firstly, there was no regular number of patients flow due to the appointment spacing model of HIV care, which took longer than expected and planned data gathering time. Secondly, communication with senior students for experience sharing and consultation was impossible owing to the present COVID-19 pandemic.

7.5. SUMMARY

The results and analysis section presents the findings of the study. The first section presents the findings of the quantitative phase of the study. It contains socio-demographic characteristics of participants, awareness and information on TB preventive therapy, uptake and completion status of participants on TB preventive therapy and other variables. Variables were presented in relation to IPT uptake and completion. The second section presents the findings of the qualitative phase of the study. In depth interview of health care providers on IPT implementation barriers, factors affecting completion and uptake and providers best experiences explained. Finally, Delphi survey was employed to

collect expert’s ideas and comments to develop health education guide and the process explained.

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ANNEXURES

ANNEXURE A: ETHICAL CLEARANCE CERTIFICATE OBTAINED FROM UNISA

UNISA university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES
REC-012714-039 (NHERC)

6 December 2017

Dear Silenat Biressaw Workneh

HSHDC/776/2017
Silenat Biressaw Workneh
Student:6211-105-1
Supervisor: Prof PT Sandy
Qualification: PhD
Joint Supervisor: -

Decision: Ethics Approval

Name: Silenat Biressaw Workneh

Proposal: Determinants of the uptake of isoniazid preventive therapy among the human immunodeficiency virus positive patients in Ethiopia

Qualification: **DPCHS04**

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted from 6 December 2017 to 6 December 2022.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on. 6 December 2017

The proposed research may now commence with the proviso that:

1) *The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*

2) *Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department of Health Studies. An amended application could be requested if there are substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.*

Open Rubric

University of South Africa
Preller Street, Muckleneuk Ridge, City of Tshwane
PO Box 392 UNISA 0003 South Africa
Telephone: +27 12 429 3111 Facsimile: +27 12 429 4150
www.unisa.ac.za

3) *The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study.*

4) *[Stipulate any reporting requirements if applicable].*

Note:
The reference numbers [top middle and right corner of this communiqué] should be clearly indicated on all forms of communication [e.g. Webmail, E-mail messages, letters] with the intended research participants, as well as with the Research Ethics Committee: Department of Health Studies.

Kind regards,

Prof JE Maritz
CHAIRPERSON
maritje@unisa.ac.za

Prof MM Moleki
ACADEMIC CHAIRPERSON
molekmm@unisa.ac.za

Prof A Phillips
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ANNEXURE B: ETHICAL CLEARANCE OBTAINED FROM ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCE

ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES (IRB)
አዲስ አበባ ዩኒቨርስቲ፡ ጤናሳይንስ ኮሌጅ
Institutional Review Board

ANNEX 3
Form AAUMF 03-008

IRB's Decision

Meeting No: 07/2019 Date: 14/08/2019
Protocol number: 052/19/IM

Protocol Title: Determinants of uptake of isoniazide preventive therapy among HIV-positive patients	
Principal Investigator:	Silenat Biressaw Workneh
Institute:	College of Health Sciences, AAU
Elements Reviewed (AAUMF 01-008)	☑ Attached ☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:
Decision of the meeting:	☑Approved ☐Approved with Recommendation ☐Resubmission ☐ Disapproved

I. Elements approved-
1. Protocol Version No: 2
2. Protocol Version Date:
3. Informed consent Version No. 2
4. Informed Consent Version Date:

II. Obligations of the PI-
1. Should comply with the standard international & national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs IRB approval
3. The PI should report SAE within 10 days of the event
4. End of the study, including manuscripts and thesis works should be reported to the IRB
5. The PI should report non-compliance and unanticipated events

III. TO NERC ☐

Institution Review Board (IRB) Approval: Period from: November 18, 2019 to November 17,2020

Follow up report expected in

3 Months ___ 6 months __✔__ 9 months_____one year____

Chairperson, IRB
Dr. Adamu Addissie

Signature
Date: 08/11/2019

ADDIS ABABA UNIVERSITY Institutional Review Board Office (IRB) Faculty of Medicine

ANNEXURE C: PARTICIPANTS INFORMATION DOCUMENT

Title: Determinants of the uptake of isoniazid preventive therapy among the human immunodeficiency virus-positive patients in Ethiopia

Hello, my name is _____.

Introduction

We are conducting research on the uptake of isoniazid preventive therapy among the human immunodeficiency virus-positive patients. The study is part of the PhD dissertation of Mrs Silenat Biressaw. Research is just the process of investigation to learn the answer to a question. In this study, we want to know the determinants of uptake and completion of isoniazid preventive therapy. The purpose of the study is to determine uptake and completion rate of IPT which can be used to develop heath education guide to improve adherence and completion rate of IPT to reduce the incidence of tuberculsis among patients with HIV.

Invitation to participate we are inviting you to participate in this research. All HIV patients on follow up at this hospital and started on isoniazid preventive therapy will be included in this research. If you agree to participate in this study and give written informed consent, interview will be conducted which will take 20 minutes for survey questions on patient participants. **Confidentiality:** The information you give is confidential and will be used only for the intended study purpose. The interview will be conducted in private room, all notes from the interview and audio-records with your permission will be kept locked in the filing cabinet or on a computer that only the researcher can access. Names are not used in the analysis of the data (only summarized information of the group will appear in the result). All audio recordings will be transcribed, analyzed and modified to ensure that they cannot be linked to you as the study participant. **Risk:** There is only minimal risk to the participants. **Benefit:** there is no immediate benefit except the outcome of this research associated to this study. **Participating in this research is voluntary**, that refusal to participate will involve no penalty or loss of benefits or you may refuse to answer questions or stop the interview at any time. Your refusal will not have any effects on the services that you or any member of your family receives.

Contact details of researcher/s - If you have questions, reporting of study related adverse events regarding the study or related issues you can call to researcher- 251-911-68 74 04,

Thank you for your participation in this study.

ANNEXURE D: CONSENT FORM

INFORMED CONSENT

Title: Determinants of the uptake of isoniazid preventive therapy among the human immunodeficiency virus-positive patients in Ethiopia

I confirm that I have been informed by Mrs._____ about the nature of the study. I have also read/it was read to me, and I understood the information sheet and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I understand that sections of any of my medical records may be looked at by Mrs_____ and authorized parties. I am aware that I will undergo interviews. Data will be kept for two years if published or six years if not published, after this period the data will be destroyed.

Should you wish to contact us at any stage regarding consent, contact Mrs. Silenat or supervisor, 0911687404 .

I agree to take part in the above-mentioned study. I hereby give consent for my records to be used as per the above-mentioned conditions and for the purposes of research and also to do interviews.

Name and Surname of Patient/Participant	Signature/Mark or Thumbprint	Date:

Translator/Other Person Explaining Informed Consent (Designation)……

Printed name	Signature	Date:

Witness (If applicable):

Printed name	Signature	Date:

ANNEXURE E: QUESTIONNAIRE: ENGLISH VERSION

Research title: Determinants of the uptake of isoniazid preventive therapy among human immunodeficiency virus-positive patients in Ethiopia.

INSTRUCTIONS

1. All information here with provided will be treated confidentially. It is not necessary to indicate your name in this questionnaire
2. Please answer all questions by providing a circle in the corresponding alternative or by writing your opinion in the space provided

3. Please answer all questions as objectively as possible.

4. Answer according to your own personal opinion and experience.

Questionnaire's code_____ Medical record number _____

Section I. Socio demographic characteristics of people live with HIV and on follow-up in a tertiary Hospital in Ethiopia.

Code	Questionnaire (Please circle your response)	Responses
101	Age in years____	1.18-30 2.31-40 3.41-50 4. >50
102	Sex_____	1. Male 2. Female

104	What is your religion?	1. Muslim 2. Orthodox 3. Protestant 4. Catholic 5. Other, please specify_____
105	What is your highest level of education?	1. No formal education 2. Primary school 3. Secondary school 4. Tertiary education
106	Employment status	1. Government /Private employee 2. Self-employed 3. Retired 4. Unemployed 5. Student
107	Monthly income of participant	1.<500 birr 2. 500-1000 birr 3. 1001-3000 birr 4. >3000 birr 4. other, please specify _____
108	Residence of the participant	1. Addis Ababa region 2. Out of Addis
109	Nutrition Status at the time of data collection	1. SAM 2. MAM

		3. Normal 4. Overweight
110	Substance use behavior of participant	1. Alcohol 2. Cigarette 3. Chat 4. None 5. Other, specify_____
111	Appointment schedule at the time of data collection	1. Scheduled 2. Unscheduled

Section II. Clinical, immunological and virological statuses of people live with HIV and on follow-up in a tertiary Hospital, in Ethiopia.

Code	Questionnaire (Please circle your response)	Responses
201	Current ART Regimen_____	1. First line 2. Second line
202	Duration on ART in months _____	1. <12 months 2. 12-36 months 3. 37-60 months 4.>60 months
203	WHO clinical stage of HIV disease at the time of ART initiation	1. I 2. II 3 III 4. IV
204	Current WHO clinical stage of HIV disease at the time of data collection	1. I 2.II 3. III 4. IV
205	CD4 count at ART initiation _____	1. <200 2. 200-349

		3. 350-500 4. >500
206	Most recent CD4 count_____	1. <200 2. 200-349 3. 350-500 4. >500
207	Most recent viral load result_____	1.<1000 2. >1000

Section III. Knowledge on Isoniazid preventive therapy among people live with HIV (PLHIV) in a tertiary Hospital, Ethiopia.

Code	Questionnaires (Please circle your response)	Responses
301	Have you attended TB and IPT related health education and counseling session/s from your health care providers?	1. Yes 2. No
302	Do you have information and understanding of isoniazid preventive therapy?	1. Yes 2. No
303	Source of Information_____	1. Health education by health care workers 2. Television/Radio 3. IEC materials 4. Others, specify
304	What is the relationship between TB and HIV infections?	1. HIV causes TB

		2. TB causes HIV 3. TB is common in HIV+ patients 4.Other, specify_____
305	IPT reduces the risk of TB infection	1. Yes 2. No
306	Do you think people living with HIV should get regular evaluation for TB?	1.Yes 2.No
307	An HIV positive person (PLHIV) without sign and symptom of TB Infection can get TB preventive Treatment (INH)	1. Yes 2. No

Section IV. Uptake and completion of IPT among PLHIV on Follow - up in a tertiary Hospital, Ethiopia.

Code	Questionnaires (Please circle your response)	Responses
401	Have you ever been provided with isoniazid preventive therapy?	1. Yes 2. No

402	If yes, to no-401, what was the time you initiated on isoniazid preventive therapy?	1. Before ART started 2. with ART at the same time 3. Months or years After ART initiation
403	If not provided with isoniazid preventive therapy, Reason?	1. I don't have information on IPT 2. I refused to take due to fear of drug side effect 3. I refused due to pill burden 4. Other, specify _____
404	Duration of isoniazid preventive therapy you have taken?	1. Six months 2. Nine months 3. Twelve months
405	Completion status of HIV patients started on isoniazid preventive therapy	1. Completed 2. Did not complete
406	If not completed, reasons for not completing isoniazid preventive therapy	**1.** Refused to continue treatment **2.** Pill burden (High number of tablets) **3.** Loss to follow-up **4.** Drug shortage **5.** Developed toxicity/adverse reaction 6. Referred to other institution 7. Forgetfulness 8. Developed TB

		9.Other, specify _____
407	What measures do you think may help improve your uptake adherence and completion of TB preventive therapy (IPT)?	1. Adequate counseling and health education 2. Incentives (transport fee) 3. Reminders (Clock) 4. Family support (Relative, friend) 5. Others, specify_____
408	Type of tuberculosis preventive therapy taken;(drugs used for prophylaxis)	1. Isoniazid 2. Rifampicin 3. Isoniazid + Rifampicin 4. Unknown
409	Screening for TB using Intensified Case Finding (ICF) tool	1. Yes 2. No
410	Have you ever been treated for TB in the Past?	1. Yes 2. No
411	If yes, site of TB treated in the past	1. Pulmonary 2. Extra pulmonary
412	Are you currently on tuberculosis treatment?	1. Yes 2. No
413	Are you currently on cotrimoxazol prophylaxis therapy?	1. Yes 2. No
414	Have you missed your ART treatment dose in the last one week?	1. Yes 2. No

415	If yes to no-414, how many doses have you missed in the last one week?	1. One dose 2. Two doses 3. Three doses 4. Four doses 5. More than four doses
416	Reason for missing the dose_____	1. Negligence 2. Forgetfulness 3. Drug finished 4. Sickness 5. Transportation problem 6. Lack of food 7. Drug adverse reaction 8. Other (specify_____
417	To Whom have you disclosed your HIV status?	1. Spouse 2. Own child / children 3. Parent(s) 4. Brothers/Sisters 5. Relatives/Friends 6. No one 7.Others, specify____
418	If you do not disclose your HIV positive status, why?	

		_____
419	Do you have any disease (comorbidity) other than HIV?	7. Yes 8. No
420	If yes to no-319, type of comorbidity	_____

Thank you for your participation!!

ANNEXURE F: INFORMATION SHEET FOR IN-DEPTH INTERVIEW (ENGLISH VERSION)

Title: Determinants of the uptake of isoniazid preventive therapy among the human immunodeficiency virus-positive patients in Ethiopia

Hello, my name is _____.

Introduction: We are conducting research on the uptake and completion of isoniazid preventive therapy among the human immunodeficiency virus-positive patients. The purpose of the study is to determine uptake and completion rate of IPT which can be used to develop heath education guide to improve adherence and completion rate of IPT

Invitation to participate: we are inviting you to participate in this research. All health care providers working on HIV care and treatment in this hospital will be included. If you agree to participate in this study with written informed consent, interview will be conducted which will take 40 minutes for in-depth interview of health care providers. **Confidentiality:** The information you give is confidential and will be used only for the intended study purpose. The interview will be conducted in private room, all notes from the interview and audio-records with your permission will be kept locked in the filing cabinet or on a computer that only the researcher can access. Names are not used in the analysis of the data (only summarized information of the group will appear in the result).All audio recordings will be transcribed, analyzed and modified to ensure that they cannot be linked to you as the study participant. **Risk:** There is only minimal risk to the participants like taking time for interview. **Benefit:** there is no immediate benefit except the outcome of this research may benefit in the prevention of TB incidence to the individual and community. **Participating in this research is voluntary**: that refusal to participate will involve no penalty or loss of benefits or you may refuse to answer questions or stop the interview at any time.

Contact details of researcher/s - If you have questions, reporting of study related adverse events regarding the study or related issues you can call to researcher- 251-911-68 74 04, and **-**IRB telephone +251118961396.

Thank you for your participation in this study.

ANNEXURE G: CONSENT FORM FOR HEALTH CARE PROVIDERS

Title: Determinants of the uptake of isoniazid preventive therapy among the human immunodeficiency virus-positive patients in Ethiopia

I confirm that I have been informed by Mrs._____ about the nature of the study. I have also read, and I understood the information sheet and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

I am aware that I will undergo interviews. Data will be kept for two years if published or six years if not published, after this period the data will be destroyed.

I agree to take part in the above-mentioned study. I hereby give consent to do interviews.

Name and Surname Signature Date:

ANNEXURE H: INTERVIEW GUIDE QUESTIONS: ENGLISH VERSION

Name_____ Age_____ Sex _____

Marital status_____ Profession _____Year of service_____

Signature_____ Date_____

Questions:

- ❖ Please tell me your experiences in providing isoniazid preventive therapy for HIV patients.
- Please tell me more about isoniazid preventive therapy.
- What else?
- You mean isoniazid preventive therapy can cause drug resistance?
- ❖ In your view, what are the barriers/determinants/ of providing isoniazid preventive therapy to HIV patients in your service area?
    - You mean drug shortage?
    - Patient willingness/Refusal
    - Elaborate It
- ❖ What do you think would improve your knowledge on IPT provision?
    - What about having health education guide for isoniazid preventive therapy provision?
    - Formal training on IPT provision and lack of IPT guideline?
    - What other?
- ❖ Can you please tell me about the best practices you think to improve uptake and completion of isoniazid preventive therapy in HIV patients?
    - In your view, is there anything else that can be done to improve uptake and completion?
- ❖ Do you have anything else to add on this topic?

Thank you for participating and spending your precious time.

ANNEXURE I: INFORMATION SHEET AMHARIC VERSION

የተሳታፊዎች መረጃ ሰነድ

ርዕስ፡ የአይሶኒያዚድ ቲቢ መከላከያ የኤች አይ ቪ ህክምና ክትትል ባላቸው ህሙማን መካከል ያለው አቀባበል ወሳኝ ምክንያቶች ጥናት

ሰላም, ስሜ _____.ይባላል።

መግቢያ ፡ የአይሶኒያዚድ ቲቢ መከላከያ ህክምና በኤች አይ ቪ ህሙማን መሃከል ባለው አቀባበል ዙርያ አንድ ጥናት እየሰራን ነው። ይህ ጥናት የስለናት ቢረሳው የፒ.ኤች ዲ ጥናት አካል ነው፡፡ ጥናት ማለት የአንድን ጥያቄ መልስ ለማግኘት ምርምር የምናደርግበት ሂደት ማለት ነው። በዚህ ጥናት የአይሶኒያዚድ ቲቢ መከላከያ ህክምና በኤች አይ ቪ ህሙማን መሃከል ያለው አቀባበል ወሳኝ ምክንያቶችን ለማወቅ የታሰበ ነው፡፡ የጥናቱ ዓላማም የቲቢ መከላከያ ህክምናውን ተቀባይነት እና አጠቃቀም በማጥናት የጤና ትምህርት መመሪያዎች ለማዘጋጀት እና የታካሚዎችን የመድሃኒት አወሳሰድ ልምድ በማሻሻል በኤች አይ ቪ ህሙማን የሚከሰተውን የቲቢ በሽታ ቁጥር ለመቀነስ የሚያስችል መረጃ ማቅረብ ነው።

የተሳታፊነት ግብዣ: እርስዎ በዚህ ጥናት ላይ ተሳታፊ እንዲሆኑ እንጋብዝዎታለን። በዚህ ሆስፒታል የኤች አይ ቪ ህክምና ክትትል ላይ ያሉ ታካሚዎች በዚህ ጥናት ውስጥ ይካተታሉ። በዚህ ጥናት ለመሳተፍ ከተስማሙ እና ይህንንም በፅሁፍ በተዘጋጀው የስምምነት ቅፅ ላይ ካረጋገጡ ለታካሚዎች 20 ደቂቃ፣ ለጤና ባለሞያዎች ደግሞ 40 ደቂቃ የሚፈጅ ቃለመጠይቅ ይደረግልዎታል። **ሚስጥራዊነት:** የሚሰጡን መረጃ በሚስጥር የሚያዝ እና ለጥናቱ ግብዓትነት ብቻ የሚያገለግል ይሆናል። ቃለ መጠይቁ ፀጥታው በተጠበቀ ክፍል ውስጥ የሚከናወን ሲሆን በእርስዎ ፈቃድ በቃለ መጠይቁ ወቅት በፅሁፍ እና በድምፅ መቅረጫ የሚያዙ ማስታወሻዎች በተቆለፈ የማስቀመጫ ሳጥን እና ተመራማሪው ብቻ ሊጠቀምበት በሚችል የግል ኮምፒተር ይቀመጣሉ። የመረጃ ትንታኔ በሚሰራበት ጊዜ የተሳታፊዎችን ስም አንጠቀምም (በጥናቱ ውጤት ላይም የግል ሳይሆን የሁሉም ተሳታፊዎች የተጠቃለለ መረጃ የሚቀመጥ ይሆናል)። ሁሉም የድምፅ ቅጂዎችም ወደ ፅሁፍ ተገልብጠው እና ተተንትነው እርስዎ የጥናቱ ተሳታፊ እንደሆኑ በማይገልፅ መልኩ የሚቀመጡ ይሆናል። **የአደጋ ስጋት:** ተሳታፊዎቹ የጥናቱ አካል በመሆናቸው ሊያጋጥማቸው ይችላል ተብሎ የሚጠበቅ የአደጋ ስጋት በጣም ዝቅተኛ ነው። **ጥቅም:** ተሳታፊዎቹ የጥናቱ አካል በመሆናቸው ወዲያውኑ የሚያገኙት ጥቅም ባይኖርም የጥናቱ ውጤት ግን ወደፊት በህክምና ክትትላቸው ላይ በጎ ተፅዕኖ ሊኖረው ይችላል። **የዚህ ጥናት ተሳታፊነት ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሠረተ ነው፤** በጥናቱ ላለመሳተፍ መወሰን በእርስዎ ላይ የሚያስከትለው ምንም አይነት ቅጣት ወይም የጥቅም ክልከላ የለም። በጥናቱ ከተሳተፉም በማንኛውም ሰዓት ጥያቄዎችን ላለመመለስ ወይም ቃለመጠይቁን ለማቋረጥ መወሰን ይችላሉ። ላለመሳተፍ መወሰንዎ ወይንም ማቋረጥዎ እርስዎ ወይም የቤተሰብዎ አባል ከሆስፒታሉ በሚያገኙት አገልግሎት ላይ ምንም ተፅዕኖ አይኖረውም። **ተመራማሪውን ለማግኘት-** በጥናቱ ዙሪያ ጥያቄ ካለዎት፣ በጥናቱ ወቅት የተፈፀሙ ድርጊቶችን ለማሳወቅ ወይንም ለተመሳሳይ ምክኒያቶች ተመራማሪውን ማግኘት ከፈለጉ ይህንን ስልክ ቁጥር ይጠቀሙ። - 251-911- 68 74 04, +251118961396.

በጥናቱ ላይ ለመሳተፍ ስለፈቀዱ እናመሰግናለን።

ANNEXUREJ: CONSENT FORM AMHARIC VERSION

የጥናት ተሳትፎ ስምምነት ቅፅ

ርዕስ፡ በኢትዮጵያ በሚገኙ የኤች አይ ቪ ህሙማን የአይሶኒያዚድ ቲቢ መከላከያ ህክምና አቀባበል ወሳኝ ምክንያቶች

ስለ ጥናት ይዘት በ _____ አማካኝነት በቂ መረጃ እንደተሰጠኝ አረጋግጣለሁ። የመረጃ ጽሁፉን አንብቤ (ወይንም በሌላ ሰው ተነብቦልኝ) እንዲሁም ጥያቄዎችን በመጠየቅ ስለ ጥናቱ ለመረዳት ችያለሁ።

በጥናቱ መሳተፌ በእኔ ፈቃደኝነት ላይ የተመሠረተ እና በማንኛውም ሰዓትም ምንም ምክንያት ሳልሰጥ ማቋረጥ እንደምችል፤ ይህም የማገኘው የህክምና እንክብካቤ እና ህጋዊ መብቴ ላይ ምንም ተፅዕኖ እንደማያሳርፍ ለማወቅ ችያለሁ።

የጥናታዊ ቡድኑ አባል የሆነው/የሆነችው _____ እና ፈቃድ ያላቸው አካላት የህክምና መዝገቤን ሊያዩ እንደሚችሉ ተረድቻለሁ። ቃለ መጠይቆች እንደሚደረጉልኝም አውቄያለሁ። ለጥናቱ የሚሰበሰበው መረጃ ጥናቱ በመፅሄቶች ከታተመ ለሁለት ዓመታት፣ ካልታተመ ደግሞ ለ6 ዓመታት ከተቀመጠ በኋላም የሚደመሰስ ይሆናል።

በጥናቱ ለመሳተፍ ባለው ስምምነት ዙሪያ በማንኛውም ሰዓት ከእኛ ጋር ለመነጋገር ከፈለጉ ሲ/ር ስለናትን ወይንም አስተባባሪውን ለማግኘት ይችላሉ።

ከላይ በተገለፀው ጥናታዊ ፅሁፍ ላይ ለመሳተፍ ፈቃደኛ ነኝ። ቃለመጠይቅ ለመስጠት እና የህክምና መዝገቦቼም ከላይ በተገለፀው መልኩ ለጥናቱ ግብዓት እንዲሆኑ መስማማቴንም አረጋግጣለሁ።

የጥናቱ ተሳታፊ ሙሉ ስም ፊርማ/የጣት አሻራ ቀን:

አስተርጓሚ (ስምምነቱን ለተሳታፊው ያስረዳው ሌላ ሰው) .....:

የታተመ ስም ፊርማ ቀን:

ምስክር (ካስፈለገ):

የታተመ ስም ፊርማ ቀን:

ANNEXURE K: AMHARIC VERSION QUESTIONNAIRE

የአማርኛ መጠይቅ

የጥናቱ ርዕስ

በኢትዮጵያ በሚገኙ የኤች አይ ቪ ህሙማን የአይሶኒያዚድ ቲቢ መከላከያ ህክምና አቀባበል ወሳኝ ምክንያቶች

መመሪያዎች

1. በዚህ መጠይቅ የሚሰበሰበው መረጃ በሙሉ ሚስጥራዊነቱ የተጠበቀ ይሆናል። በመጠይቁ ላይም ስምን መግለፅ አስፈላጊ አይደለም።
2. ከተሠጡት ምርጫዎች ውስጥ በማክበብ ወይም በተሠጠው ክፍት ቦታ ላይ ሃሳብዎትን በመፃፍ ትክክለኛ የሚሉትን መልስ ይስጡ።
3. በተቻለ መጠን ሁሉንም ጥያቄዎች በግልፅ ለመመለስ ይሞክሩ።
4. በግል ሃሳብዎ እና ልምድዎ ላይ ብቻ ተመስርተው መልስ ይስጡ።

የመጠይቁ ኮድ _____ የህክምና ሪኮርድ ቁጥር _____

ክፍል 1. በሶስተኛ ደረጃ ሆስፒታል ውስጥ ክትትል ያላቸው የኤች አይ ቪ ህሙማን ስነ-ህዝባዊና ማህበራዊ ሁኔታ፤ ኢትዮጵያ

ኮድ	መጠይቅ (እባክዎትን ትክክለኛውን ምላሽ ያክብቡ)	
101	ዕድሜ ____	1.18-30 2. 31-40 3. 41-50 4. >50
102	ፆታ _____	1. ወንድ 2. ሴት
104	ሃይማኖት	1. ሙስሊም 2. ኦርቶዶክስ 3. ፕሮቴስታንት 4. ካቶሊክ 5. ሌላ ከሆነ ይግለፁ _____
	የትምህርት ደረጃ _____	1. መደበኛ ትምህርት ያልተከታተለ

105		2. አንደኛ ደረጃ ትምህርት 3. ሁለተኛ ደረጃ ትምህርት 4. ሶስተኛ ደረጃ (ኮሌጅ፣ ቴክኒክ)
106	የስራ ሁኔታ	1. የመንግስት/ የግል ተቀጣሪ 2. የግል ስራ 3. ጡረታ ላይ 4. ስራ የሌለው 5. ተማሪ 6. ሌላ ከሆነ ይግለፁ _____
107	ወርሃዊ ገቢ	1.<500 ብር 2. 500-1000 ብር 3. 1001-3000 ብር 4. >3000 ብር 4. ሌላ ከሆነ ይግለፁ _____
108	የመኖሪያ አድራሻ	1. አዲስ አበባ ክልል 2. ከአዲስ አበባ ውጭ
109	የስነምግብ ሁኔታ	1. በጣም የተነዳ 2. የተነዳ 3. ጤናማ 4. ከመጠን በላይ ውፍረት
110	የእጽ አጠቃቀም ባህሪ	1. አልኮሆል 2. ሲጋራ 3. ጫት 4. የለም 5. ሌላ ካለ _____
111	የህክምና ቀጠሮ ሁኔታ	1. በቀጠሮ የመጡ 2. ያለቀጠሮ የመጡ

ክፍል 2. በሶስተኛ ደረጃ ሆስፒታል ውስጥ ክትትል ያላቸው የኤች አይ ቪ ህመማን ክሊኒካል (clinical) ፣ የቫይረስ (virological) እና በሽታ የመከላከል (immunological) ደረጃና ሁኔታ፤ኢትዮጵያ

ኮድ	መጠይቅ (እባክዎትን ትክክለኛውን ምላሽ ያክብቡ)	
201	አሁን እየወሰዱት ያለው የፀረ ኤች አይ ቪ መድሀኒት _____	1. የመጀመሪያ ደረጃ 2. ሁለተኛ ደረጃ
202	የፀረ ኤች አይ ቪ መድሀኒት ለስንት ጊዜ ወሰዱ ፣	1. <12 ወር 2. 12-36 ወር 3. 37-60 ወር 4.>60 ወር
203	የፀረ ኤች አይ ቪ ህክምና በተጀመረበት ወቅት የነበረው የአለም ጤና ድርጅት (WHO) የኤች አይ ቪ በሽታ ደረጃ	1. I 2. II 3 III 4. IV
204	አሁን ያለው የአለም ጤና ድርጅት (WHO) የኤች አይ ቪ በሽታ ደረጃ	1. I 2.II 3.III 4. IV
205	የፀረ ኤች አይ ቪ ህክምና በተጀመረበት ወቅት የነበረው የሲዲ4 መጠን_____	1. <200 2. 200-349 3. 350-500 4. >500
206	ለመጨረሻ ጊዜ የተሰራው የሲዲ4 መጠን_____	1. <200 2. 200-349

		3. 350-500 4. >500
207	ለመጨረሻ ጊዜ የተሰራው በደም ውስጥ የታየ የቫይረስ መጠን (Viral Load) ምርመራ ቁጥር _____	_____

ክፍል 3. በሶስተኛ ደረጃ ሆስፒታል ውስጥ ክትትል ያላቸው የኤች አይ ቪ ህሙማን ስለ አይሶኒያዚድ የቲቢ መከላከያ ህክምና ያላቸው ዕውቀት፣ ኢትዮጵያ

ኮድ	መጠይቅ (እባክዎትን ትክክለኛውን ምላሽ ያክብቡ)	
301	ስለ ቲቢ በሽታ እና የአይሶኒያዚድ የቲቢ መከላከያ ህክምና ዙሪያ የጤና ትምህርት ተሰጥቶት ያውቃል?	1. አዎ 2. አይደለም
302	ስለ የአይሶኒያዚድ የቲቢ መከላከያ ህክምና መረጃው እና መረዳቱ አለዎት?	1. አዎ 2. አይደለም
303	የመረጃው ምንጭ _____	1. በጤና ባለሞያ የተሠጠ ትምህርት 2. ቴሌቪዥን/ ራዲዮ 3. መርጃዎች የትምህርት(IEC materials) 4. ሌላ ከሆነ ይግለፁ_____
304	ቲቪ እና የኤች አይ ቪ ግንኙነት ምንድነው ?	1. ቲቪ ለኤች አይ ቪ መንስኤ ነው 2. ኤች አይ ቪ ለቲቪ መንስኤ ነው 3. በኤች አይ ቪ ህሙማን ላይ ቲቪ በብዛት ይታያል(ከሌላው ህብረተሰብ በበለጠ) 4. ሌላ ካለ፣_____
305	አይሶኒያዚድ የቲቢ መከላከያ ህክምና በቲቪ የመያዝ ሁኔታን ይቀንሳል	1. አዎ 2. አይደለም

306	ኤች አይ ቪ በደማቸው ውስጥ ያለባቸው ሰወች በየጊዜው ለቲቪ መመርመር አለባቸው ብለው የስባሉ	1. አዎ 2. አይደለም
307	ኤች አይ ቪ በደማቸው ያለባቸው ሰወች የቲቪ ምልክት ከሌላቸው አይሶኒያዚድ የቲቢ መከላከያ ህክምና መውሰድ ይችላሉ	1. አዎ 2. አይደለም

ክፍል 4 በሶስተኛ ደረጃ ሆስፒታል ውስጥ ክትትል ያላቸው የኤች አይ ቪ ህሙማን ስለ አይሶኒያዚድ የቲቢ መከላከያ ህክምና ያላቸው ዕውቀት፣ ኢትዮጵያ

ኮድ	መጠይቅ (እባክዎትን ትክክለኛውን ምላሽ ያክብቡ)	
401	ከዚህ በፊት የአይሶኒያዚድ የቲቢ መከላከያ ህክምና እንዲጠቀሙ ታዘልዎት ያውቃል?	1. አዎ 2. አይደለም
402	ለ ጥያቄ ቁጥር 401 አዎ ብለው ከመለሱ ህክምናው የቀረበልዎት መቼ ነበር?	1. ፀረ ኤች አይ ቪ መድሃኒት ከመጀመሬ በፊት 2. ከፀረ ኤች አይ ቪ መድሃኒት ጋር አንድ ላይ 3. ፀረ ኤች አይ ቪ መድሃኒት ከጀመርኩኝ ከወራት ወይም ከዓመታት በኋላ

403	ለ ጥያቄ ቁጥር 401 አይደለም ብለው ከመለሱ ህክምናውን ያልወሰዱበት ምክንያት	1. ስለ ቲቪ መከላከያ መረጃ አልነበረኝም 2. ተጓዳኝ ችግር ይኖረዋል ብየ ስለፈራሁ ፈቃደኛ አልነበርኩም 3. መድሃኒት ስለበዛብኝ መውሰድ አልፈለግሁም 4. ሌላ ካለ፤ይግለጹ
404	የኢይሶኒያዚድ የቲቢ መከላከያ ህክምና የወሰዱት ለምን ያህል ጊዜ ነው?	1. ስድስት ወር 2. ዘጠኝ ወር 3. አንድ አመት
405	ታካሚው የወሰዱት የኢይሶኒያዚድ የቲቢ መከላከያ ህክምና አጠቃቀም	1. ህክምናው ጨርሰዋል 2. ህክምናው አቋርጠዋል
406	የኢይሶኒያዚድ የቲቢ መከላከያ ህክምናውን ካልጨረሱ ያልጨረሱበት ምክንያት	**1.** ህክምናውን ለመቀጠል ፈቃደኛ ባለመሆናቸው **2.** የሚወስዱት የመድሃኒት ብዛት ከፍተኛ በመሆኑ (Pill Burden) **3.** የህክምና ክትትል በማቋረጥ **4.** የመድሃኒት እጥረት **5.** በመድሃኒቱ የጎንዮሽ ጉዳት **6.** ወደሌላ የጤና ተቋም በሪፈር በመላካቸው **7.** በመርሳት **8.** ሌላ ከሆነ ይግለፁ _____
407	የቲቢ መከላከያ ህክምናውን በትክክል ለመውሰድና ለመጠቀም ምን መደረግ አለበት ይላሉ ?	1. በቂ ትምህርትና ምክር 2. ለትራንስፖርት ገንዘብ 3. አላርም(Reminders፣clock) 4. የቤተሰብና የጓደኛ ድጋፍ 5. ሌላ ----------
		1. አይሶኒያዛይድ 2. ሪፋምፒሲን

408	የተጠቀሙት የቲቢ መከላከያ ህክምና (የመድሃኒቱ ስም)	3. አይሶኒያዛይድ + ሪፋምፒሲን 4. ያልታወቀ
409	Intensified Case Finding (ICF) በመጠቀም የቲቢ ምርመራ ተደርጓል?	1. አዎ 2. አይደለም
410	ከዚህ በፊት የቲቢ ህክምና ወስደው ያውቃሉ?	1. አዎ 2. አይደለም
411	ከላይ ላለው ጥያቄ መልስዎ አዎ ከሆነ የምን ቲቢ ነበር የያዝዎት?	1. የሳንባ 2. ከሳንባ ውጪ
412	በአሁኑ ሰዓት የቲቢ ህክምና እየወሰዱ ነው?	1. አዎ 2. አይደለም
413	በአሁኑ ሰዓት ኮትሪሞክሳዞል የበሽታ መከላከያ መድሃኒት ይወስዳሉ?	1. አዎ 2. አይደለም
414	ባለፈው አንድ ሳምንት ውስጥ የጸረ ኤች አይ ቪ መድሀኒት ያልወሰዱበት ቀን ነበረ?	1. አዎ 2. አይደለም
415	ለ ቁጥር 414 መልስዎ አዎ ከሆነ ያልወሰዱት ስንት ጊዜ ነው?	1. አንድ 2. ሁለት 2. 3. ሶስት 4. አራት 5. ከአራት በላይ
416	የጸረ ኤች አይ ቪ መድሀኒት ያልወሰዱበት ምክንያት	1. ቸልተኝነት 2. መርሳት 3. መድሀኒቱ ስላለቀ 4. ህመም 5. የትራንስፖረት ችግር 6. ምግብ አልነበረም 7. የመድሀኒት የጎንዮሽ ችግር 8. ሌላ ካለ ይግለፁ_____

417	ኤች አይ ቪ በደምዎ ውስጥ እንዳለ ለማን ተናግረዋል ?	1. የትዳር አጋር 2. ልጅ / ልጆች 3.ወላጅ 4. ወንድም/እህት 5. ሌላ ዘመድ/ ጓደኛ 6. ማንም አያውቅም 7. ሌላ ከሆነ ይግለፁ _____
418	ኤች አይ ቪ በደምዎ ውስጥ እንዳለ ለማንም ካልነገሩ ለምን ?	_____
419	ከኤች አይ ቪ ውጪ ሌላ ያለብዎት ህመም አለ?	9. አዎ 10.አይደለም
420	ለቁጥር 419 አዎ ካሉ የህመሙን አይነት ይግለጡ	_____

በጥናቱ ላይ ስለተሳተፉ እናመሰግናለን!!

ANNEXURE L: INFORMATION SHEET FOR IN-DEPTH INTERVIEW: AMHARIC VERSION

የቃለ መጠይቅ መመሪያ፡ የግል ቃለመጠይቆች

የጥናቱ ርዕስ፡ በኢትዮጵያ በሚገኙ የኤች አይ ቪ ህሙማን የአይሶኒያዚድ ቲቢ መከላከያ ህክምና አቀባበል ወሳኝ ምክንያቶች

ለዚህ ጥናታዊ ፅሁፍ የሚውለው መረጃ በከፊል የተዋቀረ መርሃግብር (semi-structured interview schedule) ያላቸው የግል ቃለ መጠይቆችን በመጠቀም ይሰበሰባል። የቃለ መጠይቁ መመሪያ በውስጡ ጥያቄዎችን ይዟል። ተሳታፊዎች በአይሶኒያዚድ የቲቢ መከላከያ ህክምና ዙሪያ ያላቸውን ተሞክሮ ያስረዱ ዘንድ በተቻለ መጠን ዝቅተኛ ቁጥር ያለው ጥያቄዎችን ይጠየቃሉ።

ስሜ _____ ይባላል። የዚህ ጥናት ዓላማ በኤች አይ ቪ ህሙማን ውስጥ ያለውን የአይሶኒያዚድ ቲቢ መከላከያ ህክምና አቀባበል እና አጠቃቀም ወሳኝ ምክኒያቶችን ለማወቅ ሲሆን ውጤቱም የጤና ትምህርት መመሪያዎችን ለማዘጋጀት እና የህመምተኞችን የመድሃኒት አወሳሰድ ልምድ በማሻሻል በኤች አይ ቪ ህመምተኞች የሚከሰተውን የቲቢ በሽታ ቁጥር ለመቀነስ ሊጠቅም ይችላል። የሚሰጡት መረጃ በሚስጥር የሚያዝ እና ለጥናቱ ግብዓትነት ብቻ የሚያገለግል ይሆናል። ቃለ መጠይቁ ፀጥታው በተጠበቀ ክፍል ውስጥ የሚከናወን ሲሆን በእርስዎ ፈቃድ በቃለ መጠይቁ ወቅት በፅሁፍ እና በድምፅ መቅረጫ የሚያዙ ማስታወሻዎች በተቆለፈ የማስቀመጫ ሳጥን እና ተመራማሪው ብቻ ሊጠቀምበት በሚችል የግል ኮምፒተር ይቀመጣሉ። የመረጃ ትንታኔ በሚሰራበት ጊዜ የተሳታፊዎችን ስም አንጠቀምም። ሁሉም የድምፅ ቅጂዎችም ወደ ፅሁፍ ተገልብጠው እና ተተንትነው እርስዎ የጥናቱ ተሳታፊ እንደሆኑ በማይገልፅ መልኩ የሚቀመጡ ይሆናል።

ANNEXURE M: QUESTIONNAIRE FOR IN-DEPTH INTERVIEW: AMHARIC VERSION

ለጤና ባለሞያዎች መጠይቅ

ስም _____ ዕድሜ _____ ፆታ _____

የትዳር ሁኔታ_____ ስራ _____የአገልግሎት ዘመን_____

ፊርማ_____ ቀን_____

ጥያቄዎች:

- ❖ እባክዎትን የአይሶኒያዚድ የቲቢ መከላከያ ህክምናን ለኤች አይ ቪ ህመምተኞች በማቅረብ ዙሪያ ያለዎትን ተሞክሮ ይንገሩኝ?
- እባክዎትን ስለ የአይሶኒያዚድ የቲቢ መከላከያ ህክምና ተጨማሪ ነገር ይንገሩኝ?
- ሌላስ?
- የአይሶኒያዚድ የቲቢ መከላከያ ህክምና መድኃኒት መለማመድ እና መቋቋም ችግርን ያመጣል እያሉኝ ነው?

- ❖ በእርስዎ እይታ የአይሶኒያዚድ የቲቢ መከላከያ ህክምናን ለ ኤች አይ ቪ ህመምተኞች ለማቅረብ የሚያስቸግሩ መሰናክሎች እና አቀባበሉንም የሚወስኑ ምክኒያቶች ምንድን ናቸው?

    - የመድሃኒት እጥረት?
    - እባክዎትን ተጨማሪ ነገር ይንገሩኝ።
    - ሌላስ? እባክዎትን ያብራሩልኝ።

- ❖ በአይሶኒያዚድ የቲቢ መከላከያ ህክምና አቅርቦት ዙሪያ ያለዎትን አውቀት እንዴት ማሻሻል የሚችሉ ይመስልዎታል?
    - በአይሶኒያዚድ የቲቢ መከላከያ ህክምና ዙሪያ የጤና ትምህርት መመሪያ ማዘጋጀትስ?
    - ስለ አይሶኒያዚድ የቲቢ መከላከያ ህክምና መደበኛ ስልጠና እና የአተገባበር መመሪያ አለመኖሩ ምክኒያት ነው እያሉኝ ነው?
    - ሌላስ?

- የኢይሶኒያዚድ የቲቢ መከላከያ ህክምና በኤች ኢይ ቪ ህሙማን ያለውን ተቀባይነት እና ትክክለኛ አጠቃቀም ለማሻሻል የሚረዱ ጥሩ ልምዶችን ሊነግሩኝ ይችላሉ?
    - እባክዎትን በደንብ ያብራሩልኝ።
    - በእርስዎ አስተያየት አቀባበሉን እና መድሃኒት አወሳሰዱን ለማሻሻል ሌላ መደረግ የሚቻል ነገር አለ?

- በዚህ ርዕስ ዙሪያ ሌላ የሚጨምሩት ነገር አለ?

ውድ ጊዜዎን ሰውተው በዚህ ጥናት ላይ ስለተሳተፉ አመሰግናለሁ።

ANNEXURE N: TURNITIN ORIGINALITY REPORT

Turnitin Originality Report

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ANNEXURE O: LETTER FROM LANGUAGE EDITOR

ROSEMARY'S PROOFREADING
& EDITING SERVICES

+27 83 215 6445
Rosemarys.pes@gmail.com
1 Richards drive
Midrand, 1684

24 DECEMBER 2021

To Whom It May Concern:

RE: LANGUAGE EDITING

This letter serves as confirmation that language and technical editing was conducted by Rosemary's Proofreading and Editing Services. Further details of the study and the researcher have been provided below.

TITLE OF THE STUDY: "HEALTH EDUCATION GUIDE FOR PROMOTION OF UNDERSTANDING AND USE OF ISONIAZID PREVENTIVE THERAPY UPTAKE AMONGST HIV POSITIVE PATIENTS".

Researcher: **SILENAT BIRESSAW WORKNEH**

Student number: 62111051

Kind Regards

R MALULEKE (CODER & LANGUAGE EDITOR)

ANNEXURE P: CURRICULUM VITAE

Curriculum vitae: Silenat Biressaw Workneh

E-Mail: silenatbw@yahoo.com

Personal data

Surname: Workneh

First Names: Silenat Biressaw

Date of Birth: 23 February 1970

Nationality: Ethiopian

Language: English, Amharic

Home/work Adress: Addis Ababa University, Addis Ababa, Ethiopia

Ethiopia Mobile Phone Number: +251-911 68 74 04

Educational Background

Name of institution	Degree	Date of completion
Addis Ababa University	MSc. In Tropical and infectious disease	July 5,2012
Addis Ababa University	BSc. Nursing	31 July, 2008
Addis Ababa University	BA in Sociology	July 24,2009
Awi zone, Dangil Town	Certificate of completion 9-12	July 7, 30, 1984

Awi zone, Dangil Town	Certificate of completion 1-8	June 30, 1981

Work Experience

Job Title	Employer	Town	Region	Year
Expert public health professional	Addis Ababa University, College of Health science	Addis Ababa	Addis Ababa	2013-2021(to date)
Research assistant, Folate project	Addis Ababa University, CHS, department of Psychiatry	Addis Ababa	Addis Ababa	2013-2014
Oncology department coordinator nurse	Addis Ababa University, CHS, Tikur Anbessa Hospital	Addis Ababa	Addis Ababa	2010-2012
Clinical nurse	SOS infants Ethiopia	Addis Ababa	Addis Ababa	2005-2006

Training

Title	Provider	Date of issues
Training of trainers (TOT) on HIV Counseling and testing (certificate of completion	Ministry of health & Adama medical college	August 2- 14, 2021
Training of trainers (TOT) on	Ministry of health &	September 16-27,

Comprehensive HIV prevention, care and treatment. (Certificate of completion)	Adama medical college	2019
Training of trainers (TOT) on Clinical mentorship Of HIV services(certificate of completion)	Ministry of health & CDC	September 16-20, 2018
Training of trainers (TOT) on Psycho-social support for children and adolescents (certificate of completion)	Clinton health access initiative	September 14-19, 2020
Training of trainers (TOT) on Syndrome Management of Sexually Transmitted Infections (certificate of completion)	ICAP with Ministry of health	April 30-May 5,2018
Life skill training of trainers (TOT) (Certificate of completion	Addis Ababa University, HICT project	Oct 31-Nov 5, 2016
Safe motherhood for African nurses (certificate of completion)	Egypt, Alexandria	August 23-Sept 8,2010
Good clinical practice and laboratory practice (GCP & GLP) and research Ethics (certificate of completion)	Addis Ababa University, CHS, department of psychiatry	Oct, 2013
HIV program management (certificate of completion)	ALERT training center with AAU, HICT project	Dec,24-29,2018
Health sector response to gender-based violence (certificate of completion)	AAU, HICT project	September 15-18,2017

SPSS and EPidata statistical soft wares (certificate of completion)	Virtual computer engineering	January 23-March 23,2012
• Competency base national comprehensive MNCH/PMTCT training (certificate of completion)	AAU, HICT project	Oct 2-13, 2018
Health sector response to gender-based violence (certificate of completion)	AAU, HICT project	Sept 15-18,2017
Comprehensive TB/HIV training (certificate of completion)	AAU, HICT project	March 4-9,2019

Publications

- Adherence to antiretroviral therapy and associated factors among HIV infected children in Ethiopia: unannounced home-based pill count versus caregivers' report. *BMC Pediatrics 2013, 13:132 http://www.biomedcentral.com/1471-2431/13/132.* Author
- A Placebo-controlled Trial of Folate with B12 in Patients with Schizophrenia with Residual Symptoms in Ethiopia Using a Sequential Parallel Comparison Design. *British Journal of Medicine & Medical Research 4(23): 4090-4104, 2014 international www.sciencedomain.org (Protocol)*, Co-author

ANNEXURE Q: INTERVIEW TRANSCRIPT

Participant code I

Sex- Female, Age-36 , Marital status- Married, Professional Experience- 13 years

Participants' Profession-Nurse

Theme 1 Quesions

- **What are your experiences in providing isoniazid preventive therapy for HIV patients?**

  Answer: Due to the fact that patients live with HIV are susceptible to tuberculosis infection, they have to take isoniazid preventive therapy. Patients who are eligible for isoniazid preventive therapy should be free from TB disease with syptom screen, and they should be volunteer to take the drug and take daily for six months continuously.

- **About isoniazid preventive therapy? What you belief about IPT provision?**

  Answer: In the current practice of test and treat clients, when providing ART and INH preventive therapy and if side effect or toxicity happened it will be difficult to differentiate the sideffect of which drug . So I believe that it is better to provide INH preventive therapy 2-3 months after ART initiation.

- **Do you think providing isoniazid preventive therapy can cause drug resistance?**

  Answer: Regarding isoniazid preventive therapy resistance, I previously had a belief that it can cause resistance. But recently I understanding that it is based on studies; and I advise them and provide INH for clients.

Theme 2 Questions

- **What are the barriers/determinants/ of providing isoniazid preventive therapy to HIV patients in your service area?**

  Answer: Most of the time clients do not accept to take the drug due to other comorbidity and pill burden. They take additional medications for other diseases.
  Clients refuse to take when they hear and discuss about the occurrence of side effect on another Patients. Mis-informed as it will happen to everyone who take the drug INH.
  -Clients simply refuse to take the drug
  - They might take the drug and discard it at their home or before leaving the hospital compound.
  -If they have peripheral neuropathy we will not prescribe at all.

- **Do you have drug shortage in your pharmacy?**
  - I didn't face drug shortage.

- **Why are patients not willing/Refuse to take or not completing IPT?**
  - Refusal, due to their own reason
  - Lack of appropriate information (Incorrect-information), myths from othr patients, their friends, community.
  - If not counseled appropriately

Theme 3 Questions

- **What do you think would improve your knowledge on IPT provision?**

  -Reading and self-updating
  -Discussion with Experienced staffs
  - Experience sharing with others
  -Training on TB preventive therapy

- **Do you have Formal training on IPT provision?**
  - Training was with ART training, no separate and detail training on IPT provision.
  - We need to have special training on IPT, how to counsel and provide, how to asses and manage the side effect.
- **What about having health education guide for isoniazid preventive therapy provision? Do you have It?**
  - We need to have health education material or guide it will be easy for providers to communicate and discuss with patients individually and in a group.
  - Will be easy for clients to understand and decide for themselves. If they have informed decision; they will not blame the providers when side effect of the drug occurs.
  - Some of the clients provided with IPT did not complete, discontinue after few days which indicates the presence of information gap and the need for strengthening health education and counselling.
- **Do you have IPT guideline?**

  No we don't have, I only use desk top references and Job aids.

Theme 4 Questions

- **How about the best practices you think to improve uptake and completion of isoniazid preventive therapy in HIV patients?**

  Best thing is counsel clients on advantage of INH preventive therapy and possible side effect of the drug in detail and counsel them properly; because some of them understand easily and others need more time. So giving time for counseling is best.

- **In your view, is there anything else that can be done to improve uptake and completion?**
  - Provide Detail counseling on advantage
  - Both mass and individual health education

- Advise them to come back and seek medical advice if any side effect occurs.
- Providers should assess their adherence, counsel and convince them every visit.
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Theme 5 Question

- **Anything else to add on this topic?**

Health care professional's attitude should be changed: sometimes we providers hesitate to provide INH when patients have pill burden, fear of adherence problems and lost to followups.