IMPROVING TUBERCULOSIS CASE FINDING AMONG HOUSEHOLD CONTACTS OF TUBERCULOSIS PATIENTS BY USING COMMUNITY BASED MODEL IN ADDIS ABABA, ETHIOPIA.

by

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Dedication

This study dedicated to my dear mother **TEJITU ABEBE**, who actually had the potential but could not pursue her academic career to the expected level and strived to fill this gap on her children

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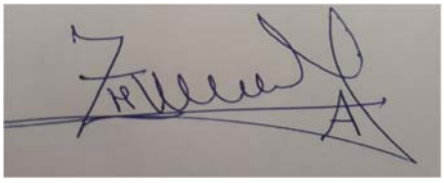
DECLARATION

I declare that **improving tuberculosis case finding among household contacts of tuberculosis patients by using community based model in Addis Ababa, Ethiopia** is my own work and that all resources 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 institutions.



Signature — June 2021

Zerihun Yaregal Admassu — Date

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Improving tuberculosis case finding among household contacts of tuberculosis patients by using community based model in Addis Ababa, Ethiopia

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ABSTRACT

Introduction: World Health Organization recommends screening of household contact as a key to improve detection of tuberculosis cases. Ethiopia's current tuberculosis household contact investigation strategies rely on symptomatic contacts attending health facilities for investigation. This approach has not led to the detection of additional tuberculosis (TB) cases; alternative approaches have to be considered. The purpose of the research was to develop guidelines in endorsing the implementation of a community based household contact investigation program in Addis Ababa.

Methods: A mixed method research using sequential exploratory design was conducted in Addis Ababa. In the first phase, qualitative data collection and analysis methods were used to formulate intervention approach and in the second phase, a quantitative random controlled trial was conducted, with the purpose of comparing the proposed intervention measures with routine household contact tuberculosis investigation. Frequencies and logistic regression analyses were used to determine the relative risk and associated factors. Thematic analysis was used for qualitative data analysis.

Results: The in-depth interview and focus group discussion findings identified themes namely household contact investigation (HHCI) implementation, misconceptions on HHCI, challenges with HHCI Approaches, opportunities for HHCI provision, contributing factors associated with household involvement, strategies for effective HHCI service and partnerships with health bureau. In phase two, the study reported that the prevalence of TB was 7.1% among the intervention group compared to 1.9% in the control groups at the end of first year follow-up. Nine guidelines were developed to support the household contact investigation system.

Conclusion: The passive case detection strategy of contact investigation did not find more cases, and tuberculosis patients and their family contacts were not satisfied with this method. However, the proposed community-based strategy shows that more TB cases can be detected by using existing medical staff. Therefore, an approach that makes the service more accessible is significant and the recommended community based TB household contact tracing approaches needs to be scaled up for its performance towards identified missed cases and enhance patient and their household contacts involvement.

Key words

Active case finding, community, contact investigation, household, passive, tuberculosis

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LIST OF ACRONYMS AND ABBREVIATIONS

AA	Addis Ababa
AACAHB	Addis Ababa City Administration Health Bureau
ACF	Active Case Finding
ACSM	Advocacy Communication Social Mobilization
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Anti-Retroviral Therapy
BCG	Bacillus Calmette-Guerin
BSC	Bachelor of Science
CBTC	Community Base TB Care
CDC	Centre for Disease Control and Prevention
CFR	Case Fatality Ratio
CI	Confidence Interval
CIs	Contact Investigation
CO	Central Office
CPT	Cotrimoxazole Prophylactic Therapy
CSA	Central Statistics Agency
CXR	Chest X-Ray
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short course
DST	Drug Susceptibility Testing
EFMOH	Ethiopian Federal Ministry of Health
ETB	Ethiopian Birr
FGD	Focus group discussion
HBC	High TB Burdened Country
HCO	Health care organization
HC	Health Center
HCP	Health Care Professional or Workers
HF	Health Facility

HH	Household
HHCI	Household Contact Investigation
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HO	Health officer
HTC	HIV Testing and Counselling
IDI	In-Depth Interview
IGRA	Interferon-Gamma Release Assays
IPT	Isoniazid Preventive Therapy
IUATLD	International Union against Tuberculosis and Lung Disease
LTBI	Latent tuberculosis infection
MD	Medical doctor
MDR-TB	Multi-Drug Resistance TB
MOH	Ministry of Health
MPH	Master in public health
MTB	Mycobacterium Tuberculosis
NR	Non-reactive
NTCP	National Tuberculosis Control Program
OAU	Organization of African Union
OPD	Outpatient department
OR	Odd ratio
PCF	Passive case finding
PHCU	Primary health care unit
PHD	Doctor of Philosophy
PLHIV	People Living with HIV and AIDS
PTB	Pulmonary tuberculosis
RHBs	Regional health bureaus
R	Reactive
RCT	Random controlled trial
RIF	Rifampicin
RR	Relative Risk

SD	Standard Deviation
SPSS	Statistical Package for Social Science
TB	Tuberculosis
TSR	Treatment success rate
TST	Tuberculin Skin Test
UHEP	Urban health extension program
UNISA	University of South Africa
WHO	World Health Organization
XDR-TB	Extensively drug-resistant TB

CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Tuberculosis (TB) is a chronic disease caused by different species of genus Mycobacterium. TB is usually caused by Mycobacterium tuberculosis. Mycobacterium tuberculosis affects the lungs (pulmonary tuberculosis), but it can also affect any part of the body (extra pulmonary tuberculosis). Mycobacterium tuberculosis is usually transmitted from person to person through coughing and sneezing by small droplets released into the air (WHO 2019:1).

Generally, a relatively small proportion of people infected with Mycobacterium tuberculosis will progress to tuberculosis. However, people living with HIV are much more likely to develop tuberculosis. Tuberculosis is also more common among men, and affects nearly adults in the most economically productive age groups (Narasimhan, Wood, Macintyre & Mathai 2013:6).

The most commonly used method for the diagnosis of tuberculosis in the world is sputum smear microscopy (it has been over 100 years old). Bacteria can be detected in sputum samples under a microscope. Following the latest discoveries in tuberculosis diagnosis, the application of rapid molecular testing in the diagnosis of tuberculosis and drug-resistant tuberculosis is increasing. In countries with more developed laboratory capacity, the current reference standard culture method is used to diagnose tuberculosis cases (MacLean, Broger, Yerlikaya, Fernandez-Carballo, Pai & Denkinger 2019:756).

Without treatment, the death rate from tuberculosis is high. In ten-year natural history study of sputum smear-positive diseases, 70% of HIV-negative tuberculosis died. Of culture-positive (but smear-negative) cases, 20% die within 10 years (Tiemersma , Vanderwerf, Borgdorff, Williams & Nagelkerke 2011:10).

Efficient drug treatment was first developed in the 1940s. Rifampicin is the most effective first-line anti-tuberculosis drug, which came out in the 1960s. Currently, for new cases of drug-sensitive tuberculosis, the recommended treatment is to treat with four first-line drugs for six months. Anti-tuberculosis medications are isoniazid, rifampicin, ethambutol and pyrazinamide. In the past decade, World Health Organization (WHO) member states have consistently reported that the success rate of tuberculosis treatment is 85% or higher (WHO 2017: 8).

Although the number of deaths from TB fell by 22% between 2000 and 2018, tuberculosis remains one of the top ten causes of death in the world in 2018. Globally, 10 million new (incident) TB cases were estimated in 2018 of which 57% were adult men, 32% were adult women and 11% were children. People living with HIV accounted for 8.6% of all new TB cases. It is estimated that 1.2 million of HIV-negative patients died of tuberculosis in 2018, and 250,000 people living with HIV died of tuberculosis (WHO 2019: 27).

Tuberculosis poses a threat to humans and remains a major public health problem in the world, but this is especially true among the 30 countries with a high burden of tuberculosis, accounting for 87% of estimated cases worldwide. According to the 2019 World Health Organization report, Ethiopia is one of the 30 countries with a high incidence of tuberculosis. In Ethiopia, 127,407 cases of TB were reported in 2018, and 29 cases per 100,000 people died of TB were reported (WHO 2019:202).

1.2 THE RESEARCH PROBLEM

Tuberculosis is identified as one of the major public health problems in Ethiopia for the past five decades. Efforts to control tuberculosis began in the early 1960s, when tuberculosis control centers and hospitals were established in the country's three major urban areas. The Central Office (CO) of the National Tuberculosis Control Program (NTCP) was established in 1976. From the very beginning, the Central Office has encountered serious problems in ensuring a sufficient budget and well-trained staff allocation (EFMOH 2017a: 9).

In 1992, a well-organized tuberculosis program was implemented in several pilot areas of the country, which included a standardized direct observation short-term treatment (DOTS). The Ministry of Health established an organized tuberculosis control plan in 1956. A detailed policy was proposed in 1969 (EFMOH 2017a: 10). According to the World Health Organization, "household contact management is one of the effective active case finding strategies widely implemented and given due attention in many countries" (WHO 2013: 26). The federal government of Ethiopia has included household contact tracing and management as a critical and important element in its tuberculosis program (EFMOH 2017a:38).

It is through household contact management that,

- Close contacts come to facilities to screen for TB
- Identify their TB status
- Recognize the impact of the status
- Make a well-versed choice for the future.

Household contact management offers an opportunity to detect TB cases early, deliver latent TB treatment, and prevent the occurrence of active TB, if TB is not diagnosed during screening (Beyanga, Kidenya, Gerwing-Adima, Ochodo, Mshana & Kasang 2018:6-8). Despite the implementation of household contact management in the study setting, the number of detected TB cases among TB patient's household contact could not exceed 0.05% for many years. In 2019, Addis Ababa has around 150 health institutions registered to deliver tuberculosis services (AACAHB 2020:10).

Addis Ababa (AA) notified 8,525 new cases of tuberculosis and registered 167 cases of drug-resistant tuberculosis in 2019. Although the majority of TB cases (85%) affected the productive age group, 363 (5%) cases were reported among children aged less than 15 years. HIV co-infection hinders tuberculosis control efforts, accounting for approximately 22% of reported tuberculosis cases each year (AACAHB 2020: 12).

In Addis Ababa, household contact TB tracing has been implemented by requiring all household contacts and other regular contacts, especially children under five years of

age and HIV-positive people, to be brought to the clinic for tuberculosis assessment. The health care worker will screen tuberculosis patients' household contact in tuberculosis clinic by conducting tuberculosis investigations, and if active TB is detects, they will initiate anti-tuberculosis drugs in accordance with national guidelines. In addition, for those children who are eligible for Isoniazid Preventive Treatment (IPT), they will receive IPT treatment, and medical staff working in tuberculosis clinics will monitor compliance with IPT and anti-tuberculosis treatment to ensure completion (EFMOH 2017b: 20).

The Ethiopian Federal Ministry of Health (EFMOH) is accountable for the management of the national tuberculosis program through the development of Ethiopian policy guidelines, strategies, and manuals. It has a contact person responsible for activities at the national level. The Regional Health Bureau (RHB) adopts the policies, guidelines, strategies, and manuals of the Ministry of Health to assume responsibility and implementation plans at the regional level. Each bureau has its own contact person to direct, supervise and monitor the tuberculosis program. Health facilities have program specific focal persons who are responsible to the medical director, and to provide the service to the clients according to the national guideline (EFMOH 2017a:9).

1.2.1 Addis Ababa city administration

The study was conducted in Addis Ababa, the capital and largest city of Ethiopia, where 4,851,253 people live. Females account 52.4% of the total population. A quarter of the population is under 15 years of age, 5% of the population is over 60 years old, and the population between 15 and 59 years old accounts for 70% of the total population (CSA of Ethiopia 2019:34).

As a chartered city, Addis Ababa enjoys a high reputation both in the city and in the region. This place is where the headquarters of the African Union is located. People of different races and religions from other parts of Ethiopia are all over the city. There are nearly 80 ethnic groups in the country, speaking at least 80 different religious languages (CSA of Ethiopia 2019:26).

The new administrative structure of Addis Ababa is based on the establishment of 10 sub-cities and 116 woreda. Addis Ababa health bureau, which was established in 1993, is accountable for the overall health care service delivery of the city. The health bureau of each sub-city is directly responsible to the administrative department of its sub-city. There are 52 hospitals in the city. Amongst them, the Addis Ababa Health Bureau owns 6 hospitals, the Federal Ministry of Health owns 5, 2 NGOs, 3 NGOs and police, and the remaining 36 are privately owned. There are also 98 public health centers administered by Addis Ababa health bureau. In addition, around 850 private clinics are providing services in order to achieve 100% medical coverage in Addis Ababa (AACAHB 2020:15).

The city had the highest TB case notification rate (252/100,000) in the country in 2019. The proportion of people living in slum areas is high and overcrowded, which is a problem in Addis Ababa. In total 24.8% of all households are overcrowded. Overcrowding has implications on people's health, especially in terms of spreading communicable diseases (AACAHB 2020:10).

According to the 2020 TB report of the Addis Ababa Health Bureau, 8,525 active TB cases were detected in the city, 95% of which were tested for HIV and 22% of them were found to be co-infected with HIV. In Addis Ababa, 104 government medical institutions and 52 private medical institutions provide anti-tuberculosis treatment (AACAHB 2020: 15).

1.3 STATEMENT OF THE RESEARCH PROBLEM

Although contact investigations have been a standard practice in most high-income countries for many years, they are rarely conducted in Ethiopia and most high-burdened countries. Ethiopia's TB household contact investigation policy usually focuses on passive case finding especially among high-risk contacts, such as children and people living with HIV (Adane, Damena, Weldegebreal & Mohammed 2020:7).

World Health Organization's recent TB contact investigation guidelines recommended that the intervention is to be in close contacts, in settings where adequate resources are

available (WHO 2013:9). Although many studies have shown a high incidence of tuberculosis among household contacts, few studies have evaluated its effectiveness compared to standard passive case finding. To date, limited randomized controlled trials of household contact studies have been published (Macpherson, Webb, Variava, Lala, Milovanovic, Ratsela, Lebina, Kinghorn & Martinson 2019:6).

Methods to improve missed TB cases detection in high-burden countries must be realistic and cost-effective, so that they are appropriate and affordable in the local context. It is essential that countries that allow contact investigations must have high DOTS coverage and continuously improve treatment completion rates to successfully treat other cases discovered through enhanced case detection (Kranzer, Afnan-Holmes ,Tomlin , Golub , Shapiro , Schaap , Corbett , Lonnroth & Glynn 2013:437).

In Ethiopia, there is no framework for TB household contact investigation implementation, and there is limited research on the recommendation of household contact investigations care model. Many health institutions try to improve this situation through passive case finding. However, these efforts are not based on systematic evidence to determine the possible determinants of the incidence of tuberculosis among household contacts. In order to provide information to health policy makers, this study aims to develop a guidelines in promoting the implementation of a community based household contact investigation program of the Addis Ababa healthcare system in Ethiopia.

Considering the barriers of household contact tuberculosis screening from the perspective of patients, their household contacts and health care workers, it is important to develop effective contact investigation strategies. This research aims to narrow the information gap and thereby increase notifications of tuberculosis cases in the study sites.

1.4 AIM OF THE STUDY

The overall aim was to provide guidelines and framework in promoting the implementation of a community based household contact investigation program in public health center in

Addis Ababa, Ethiopia. This section discusses the purpose and objectives of this research.

1.4.1 Research purpose

The purpose of this study was to develop guidelines in endorsing the implementation of a community based household contact investigation program in Addis Ababa.

1.4.2 Research objectives

The research objectives that led this research were to:

- Explore and describe the perception of tuberculosis experts, tuberculosis patients and tuberculosis household contacts on contact tracing strategies.
- Determine the yield of community based contact investigation in households of patients with bacteriological confirmed pulmonary tuberculosis in Addis Ababa compared with routine passive case finding.
- Develop guidelines to support household contact investigations in household contacts of TB patients.

1.5 SIGNIFICANCE OF THE STUDY

The findings of the study will increase the body of knowledge to improve the performance of contact investigation. This will not only help increase the existing knowledge on factors related to household contact investigations of TB patients, but will also bring new knowledge through the introduction of effective TB contact tracing models in the study area.

The research will benefit tuberculosis patients, families and communities, because the results of the research will help to endorse approaches to advance contact investigation methods. The ministry of health will also benefit, as the results of the study can be used as a basis for further generalizable research. This study developed guidelines to support

TB contact tracing, which will increase the rate of finding TB cases among TB household contacts.

The ministry of health will adopt the developed guidelines to enhance TB household contacts tracing implementation. These results also provide baseline evidence for scholars to continue or to conduct research on larger populations.

1.6 DEFINITION OF KEY CONCEPTS

The subsequent conceptual definition are used commonly in this research:

Active TB Case finding: It uses a sensitive algorithm based on tuberculosis symptoms to identify suspected active tuberculosis patients in a predetermined target population (EFMOH 2017b: 24).

Bacteriological confirmed pulmonary tuberculosis: A form of pulmonary is positive for biological specimens through smear microscopy, culture, or rapid diagnostic methods approved by the WHO (EFMOH 2017b: 24).

Case of TB: A definite case of TB or one in which a health worker has diagnosed TB and decided to treat the patient with a full course of anti-TB treatment (EFMOH 2017b:20).

Clinical evaluation of contacts: The systematic process of diagnosing or excluding active tuberculosis among contacts. If the results of contact identification and prioritization indicate tuberculosis or a risk of tuberculosis, a clinical evaluation should be performed (WHO 2012: 30).

Community based: In this study, TB focal and urban health extension workers will screen household contacts by visiting TB patients' homes.

Contact investigation: A systematic process intended to identify previously undiagnosed cases of TB among the contacts of an index case (WHO 2012:29).

Household Contact: People who share the same enclosed living space with the index case frequently or for a long time at one or more nights or during the day in the three months before the onset of the current treatment (WHO 2012: 28).

Index patients: In a specific family or other comparable environment, new or recurrent cases of tuberculosis that are initially detected in people of any age may have been exposed to other people (WHO 2012: 28).

Passive TB Case Finding: Screening of TB among individuals who are self-presented to health facility (EFMOH 2017b:25).

1.7 THEORETICAL FOUNDATIONS OF THE STUDY

The research paradigm is a series of basic assumptions and beliefs about how the world perceives, and then acts as a thinking framework that guides researchers' behavior. Different scholar have conducted the research prototype that was popularized by Kuhn (1962). It was included in one's opinion as per "nature of reality and knowledge" of its roots and institutions. Researchers accomplish this task by making certain assumptions about their memory and what they should do when conducting investigations. Thus, these can be called as paradigms (Creswell 2014:45).

In the implementation of the current study, the mixed method was utilized. The ontological, epistemological, axiological, rhetoric and methodological approaches were used. These approaches informed the researcher about the origin of research, its formation, its design and methodology. Philosophical researchers have claimed five dimensions to be what is knowledge (ontology's), how we know about it (epistemology), what values go into it (axiology), how we write about it (rhetoric) and methodology: the process of studying it (Creswell 2014:100).

Although TB case finding among TB patients household contacts has become a big issue recently, household contact screenings are not well operationalized in Ethiopia as well as in Addis Ababa region. Hence, the researcher believes that the stated gaps can be addressed from different perspectives in mixed approaches. In the execution of the current study, mixed method was used. The mixed approach uses both qualitative and quantitative methods that aim to produce findings that are objective, reliable, valid and reproducible.

1.7.1 Ontological assumptions

The hypothesis handle questions on the existing reality and what we know about a given phenomenon (Oppy 2019:70). This research presumes that there are many-constructed realities from different perceptions about TB household contact tracing strategies.

Tuberculosis ranks to be among the top killer infectious diseases in Ethiopia and still a major public health problem. Despite the remarkable progress since the 1990s by making TB services more accessible to the community, many people with TB remain undiagnosed or diagnosed only after long delays. The heavy burden of undiagnosed tuberculosis causes a lot of pain and financial hardship, and it continues to spread (Gashu, Jerene, Ensermu, Habte, Melese, Hiruy, Shibeshi, Hamusse, Nigussie, Girma, Kassie, Haile & Suarez 2016:5).

In the past few years, there has been heated discussion about using active case finding as a possible alternative to the conventional method of passive approach. Proactive household contact tracing is one of the active case-finding approaches to ensure early detection of tuberculosis, reduce the risk of poor prognosis and adverse social and economic consequences of the disease, and to help reduce the spread of tuberculosis (Blok, Sahu, Creswell, Alba, Stevens & Bakker 2015:3).

Contact tracing refers to “a set of interventions that may include, but not limited to, an active case finding in contacts with TB patients. The first step is to identify people who have been in contact with patients with infectious tuberculosis, and then proceed with specific interventions for those identified contacts.” These interventions include:
(1) Active TB screening in contacts with TB patients.
(2) Treatment of latent tuberculosis infection in contacts with TB patients.
The former is a prerequisite for the latter, because the treatment of latent tuberculosis infection cannot be performed without first excluding active disease (WHO 2012: 39-41).

In high-income countries where the burden of tuberculosis is low, both interventions are usually used. However, there are no strict guidelines for household contact tracing in high burden and low-income settings. Capacity constraints as well as the high burden, and the high rate of continued transmission in low-income countries make it an ideal effective intervention for proactively detecting cases. Many prevalence studies in high-burden countries have shown that contacts of TB patients have higher rates of latent and active disease (Beyanga et al 2018:4-6).

1.7.2 Epistemological assumptions

Epistemology is the basic philosophical assumption about the nature of knowledge or how we know it. Epistemological assumptions rely on questions about how we know, what we know, and the content of truth (Curtis & Drennan 2013: 20). This study evaluated the developed strategy, active case finding among contacts and compared it with passive case finding, and developed guidelines to support tuberculosis detection among household contacts of TB patients.

1.7.3 Methodological assumption

It deals with the enquiry of how to identify practices used to attain knowledge by the inquirer (Easterby-Smith et al 2013:465). This study uses quantitative and qualitative methods as a two- phase sequential research design, starting from the qualitative stage to explore the topic in depth. We used the results of a qualitative phase to build the second quantitative phase to test and generalize the initial exploratory results of the qualitative phase.

Interviews with TB patients and household contacts as well as Focus Group Discussion (FGD) with TB program managers were conducted. These enabled us to explore the best strategies for household contact tracing strategies model, the procedure needed for implementation, and the intervention impacts can provide detailed information about the research setting or context and emphasize the in-depth opinion from participants.

The main focus of quantitative methods is deductive reasoning, which tends to shift from general to specific. The deductive approach turns to hypothesis testing to verify the principles to be confirmed and/or modified. The purpose of the quantitative method was to evaluate the developed method and summarize the preliminary findings in the qualitative phase (Ivankova & Wingo 2018: 984).

1.7.4 Axiological assumptions

It is the role of values. The researcher's subjective values, intuition, and biases are important; they play a role in the dialog of social construction and inform his or her interpretation of the data (Easterby-Smith et al 2013:465). In this study, the researchers acknowledged that the research is valuable and that there are biases related to its role in the research environment. The researcher openly discusses values that shape the narrative and includes his own interpretation in concert with those participants.

1.8 RESEARCH METHOD AND DESIGN

1.8.1 Research design

According to Creswell and Plano-Clark (2011:59), a research design is a situational organization that collects and analyzes data in various forms, and aims to combine the relevance to the research purpose with the economy in the program.

It is the conceptual arrangement of research, used as a blueprint for data collection, measurement, and analysis. In this way, the design provides us with a picture of the overall study starting from writing hypotheses and their operational implications to the final analysis of the data (Tobi & Kampen 2018:1212). Research design is necessary because it helps various research operations to proceed smoothly, so that the research is as efficient as possible, to generate most information with the least energy, time and money (Rahman 2017:2).

An exploratory sequential study design were adopted in this study, in which a generic qualitative design (focused group discussion and in-depth interview) is followed by quantitative (patient interview) in a two phases study. During the first phase of the study, In-Depth Interview (IDI) and Focused Group Discussion (FGD) carried out to explore patients', household contacts, and health care providers' perception about household contact tracing strategies to augment and better understand the TB patients' household contact tracing and management care model, and finally to develop an effective approach.

Following the advice of patients, household contacts, and TB program health care workers, a community-based TB patient household contact tracing approach was developed. In the second phase of the research phase, a one-year follow-up randomized controlled trial was applied. Randomized controlled trials have allowed us to compare the yield of the developed community-based TB patient household contact tracing methods with conventional passive case finding methods.

Johnson, Onwuegbuzie and Turner (2007:115) describes, mixed method research as a type of research in which researchers or a group of researchers combine features of qualitative and quantitative research methods for the broad purposes of comprehensive understanding and collaboration.

Mixed method researchers emphasized the triangulation of descriptive and narrative data analysis. "Quantitative researchers are characterized by focusing on numerical data and analysis, while qualitative researchers focus on narrative data. In other words, the mixed method researcher explores and studies problems and issues based on the researcher's belief and are important to the scholarly community" (Fabregues & Molina-Azorin 2017:2855). The implementation of mixed methods is beneficial to strengthen the research through both quantitative and qualitative methods (Hayes, Bonner & Douglas 2013:10-12).

Therefore, in order to understand the detail of TB household contact tracing strategy implementation status, the strengths, challenges in Addis Ababa public health facilities, the researcher implemented mixed research method, using quantitative and qualitative methods. Therefore, this study benefited from both approaches.

The initial phase of this study was based on qualitative research. This paradigm was applied to explore TB experts, TB patients and TB household contacts perception on household contact TB tracing strategies. A quantitative research paradigm utilized in the second phase of the study is closely associated with positivist tradition. The quantitative paradigm was chosen because it described and examined the relationship between variables (Burns & Groove 2014:243). In this particular study, yield of contact tracing was compared between the groups.

The study was conducted in public health centers, providing tuberculosis services in Addis Ababa, Ethiopia. The research design, methods, sampling, data collection, data analysis and ethical consideration applied for this scientific study is described in chapter three in details.

1.8.2 Data analysis

The qualitative research data collection and interpretation were carried out simultaneously. In this research, thematic analysis was practiced. The researcher checked the collected quantitative data for completeness and consistency. Experienced data clerks used statistical Package for Social Science (SPSS) version 26 for data entry and analysis. Descriptive and inferential statistics were analyzed to estimate and determine the prevalence of TB and factors associated to the outcome. The details of the data collection, analysis of the qualitative and quantitative data are described in Chapter three.

1.8.3 Trustworthiness

Reliability of data is obtained from qualitative sources. Researchers in this study use credibility, transferability, dependability, and confirmability constructs to ensure trustworthiness. The details of these structures are discussed in Chapter 3.

1.8.4 Design validity and reliability of quantitative data

Validity and reliability are two important concepts to determine whether a research tool is applicable or not. The researcher properly handled these contents to check the applicability of study design, as described in Chapter 3.

1.9 ETHICAL CONSIDERATION

The research ethics and the higher degrees committee of University of South Africa and the scientific and ethics committee of Addis Ababa Health Bureau granted ethical clearance and authorization for the study (Annexure A and B). An official letter was written from the responsible institution to relevant health centers (Annexure B). Data collectors have received training in research ethics and procedures to ensure that the data collected meets ethical standards. By not collecting the identity names and numbers of study participants, the privacy and confidentiality of information in the data collection process was ensured. Participants' written consent was obtained before the start of the interview.

1.10 SCOPE OF THE STUDY

The study was conducted at the selected public Health Centers, which provide tuberculosis services in Addis Ababa, Ethiopia. The study used a mixed method approaches. The qualitative data collection methods were conducted to investigate the opinion of TB patients, their household contacts and TB program managers, while quantitative approach was used to determine the yield of community based contact investigation in households of patients with bacteriological confirmed pulmonary

tuberculosis in Addis Ababa compared with the routine passive case finding. The study formulates guidelines to strengthen the implementation of TB patients' household contact tracing and investigation services in order to optimize actions prioritized in the prevention of tuberculosis among household contacts.

1.11 STRUCTURE OF THE THESIS

The content of this thesis structured into six interrelated chapters. These chapters described below.

Chapter 1: Introduction and orientation to the study
Chapter 2: Literature review
Chapter 3: Research design and methods
Chapter 4: Analysis, presentation and description of findings
Chapter 5: Development of guideline
Chapter 6: Conclusion, limitation and recommendation

1.12 CONCLUSION

In this chapter, an overview of the study has been outlined. A brief introduction to tuberculosis case detection methods, passive and active case finding methods, which have been used to control tuberculosis for decades, were presented. The active case finding approaches have now attracted attention at national level and abroad.

Summarized background information about research issues. The research area specifically discusses the source of the research question. In addition, the aim, research purpose, research objectives and significance are also discussed. For subsequent chapters, important term definitions have been operationally defined, and the basis of research has been discussed. The research design and methods are briefly discussed. This study adopted a mixed method research design. Both quantitative and qualitative research methods were employed for data collection. Literature review will be discussed in the next chapter

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Chapter 1 presented an overview of the study that includes the statement of the problem, the research background, purpose, objectives, significance, the paradigm of the research and the methodology with more emphasis to the statement of the problem and TB control programs.

This chapter presents the review of the literature on tuberculosis situations in Ethiopia, TB case finding strategies, concepts of TB case finding approaches, mechanisms for the household contact investigation; the chapter describes also approaches for the implementation of household contact investigation.

To this end, this review comes from books, research journals, policies, and guidelines. Medline, PubMed and Google Scholar were used as searching database to search and retrieval of literatures. These keywords were used active case discovery, community, contact investigation, household, passive, and tuberculosis.

2.2 TUBERCULOSIS

Tuberculosis is a chronic disease mainly caused by the bacillus mycobacterium tuberculosis (MTB). There are five mycobacteria responsible for TB: mycobacterium tuberculosis, bovis, africanum, microti and Canetti. Tuberculosis usually affects the lung (pulmonary tuberculosis), but it may also affect other parts, extra pulmonary tuberculosis (WHO: 2019:1). Tuberculosis is transmitted from one person to a susceptible person through airborne particles, droplet nuclei (<5 microns). When a TB patient coughs, sneezes, speaks or sings, the bacteria are released into the air (Sharma, Sharma, Deo & Bisht 2018:280).

Tuberculosis is the most common, spreading from person to person through the air. Except for humans, there is no known animal reservoir of Mycobacterium tuberculosis. Mycobacterium bovis may penetrate the mucous membrane of the gastrointestinal tract or invade the lymphatic tissue of the oropharynx after ingesting the milk of sick cows. Owing to pasteurization in milk and effective tuberculosis control in cattle, human Mycobacterium bovis infections in developed countries have been greatly reduced. Infection by other organisms is relatively rare (Fernstrom & Goldblatt 2013:2-4).

A small percentage of people will develop tuberculosis in their lifetime, among the estimated 2 to 3 billion people who are infected with mycobacterium tuberculosis. After being exposed to cases of infectious tuberculosis, one-third of people can be infected with tuberculosis, but the infection will not progress to tuberculosis, and two-thirds of people will not be infected. In one-third of infected people, 5-10% will develop tuberculosis at some stage in their lives, with the highest risk in the first two years after exposure (WHO 2019:3).

For children under 5 years of age and HIV positive people or other immune-suppressing diseases, the risk of active tuberculosis is significantly higher (Silva, Muñoz-Torrico, Duarte, Galvão, Bonini, Arbex, Arbex, Augusto, Rabahi & Mello 2018: 150). Tuberculosis has existed for thousands of years and is still a biggest health challenge. It causes millions of people to suffer from diseases every year. In 2018, it was one of the top ten causes of death in the world, higher than HIV/AIDS, and one of the leading causes of death from infectious diseases (WHO 2019:45).

World Health Organization (WHO) estimated 10 million incident cases (90% of adults; 57% of men; 10% of HIV-infected people) were diagnosed with tuberculosis in 2018, 44% of the estimated number of incidents occurred in Southeast Asia, followed by Africa and the Pacific, which accounted for 24% and 18% of the estimated number of incidents, respectively. The Mediterranean, Europe, and the Americas region accounted for a relatively small proportion of tuberculosis cases, at 8%, 2.6% and 2.9%, respectively (WHO 2019: 35). Thirty countries with a high burden of tuberculosis account for 87% of

all estimated global emergencies, of which eight countries account for 67% of the total cases. These countries were India, China, Indonesia, Philippines, Pakistan, Nigeria, Bangladesh, and South Africa (WHO 2019:21).

WHO adopted End TB Strategy during the 67th World Health Assembly conducted in 2014, a vision to make the TB free world, with no deaths, disease, and suffering due to the disease. To achieve this goal, the global incidence of tuberculosis should be reduced by about 4–5% per year, but globally, the incidence of tuberculosis reduced by about 2% per year between 2017 and 2018. From a regional perspective, the fastest decline in the incidence of tuberculosis occurred in the European region of the World Health Organization, which was 4.6% from 2015 to 2016 (WHO 2019:30-32).

Between 2015 and 2018, the cumulative decline in the incidence of tuberculosis was only 6.3%. From 2015 to 2018, the number of deaths from tuberculosis worldwide decreased by 11% (WHO 2019: 39). The cumulative incidence has fallen by 15% and the number of tuberculosis deaths has fallen by 24% between 2015 and 2018. The African region is struggling to achieve the 2020 milestone. The morbidity and mortality rates in the WHO African region have also declined relatively (4.1% and 5.6% per year, respectively), with a cumulative decline of 12% in morbidity and 16% in mortality between 2015 and 2018. “Seven high TB burden countries are on track to achieve the 2020 milestones for both incidence and deaths: Kenya, Lesotho, Myanmar, the Russian Federation, South Africa, the United Republic of Tanzania, and Zimbabwe” (WHO 2019:40).

In 2018, only 7 million new tuberculosis cases were notified reported to WHO by countries. Since 2013, the number of notified tuberculosis cases has increased, mainly due to a 34% increase in the number of notifications in India. However, globally, there was a 3.8 million gap between incident and expected TB Cases (WHO 2019:28).

Of the total estimated 484,000 MDR/RR-TB cases worldwide in 2018, only 39% were detected. To address the large number of missed cases, overall tuberculosis testing, the proportion of bacteriologically confirmed pulmonary cases, and DST coverage will need

to be improved. The latter two need to further strengthen laboratory capabilities and promote the wider use of rapid molecular detection diagnostic tools that are more sensitive than smear microscopes (WHO 2019:30).

With timely diagnosis and correct treatment, most people suffering from tuberculosis can be cured. However, the proportion of the global population who died of tuberculosis in 2018 was 16%. In order to reach the first milestone of the End of Tuberculosis Strategy, the target needs to be reduced to 10% by 2020 (WHO 2019: 45).

Overall, the death rate from tuberculosis is declining at a rate of about 3% per year, with the European and Western Pacific regions experiencing the fastest decline (6.0% and 4.6% per year respectively since 2010). Countries with high tuberculosis burden rates that have fallen by more than 6% annually since 2010 include Ethiopia, Russia , Tanzania, Vietnam, and Zimbabwe (WHO 2019: 46).

The case fatality rate varies greatly between countries, ranging from less than 5% in some countries in the WHO African region to more than 20% in most countries. This fact shows the inequality that countries need to address in accessing tuberculosis diagnosis and treatment. Between 2000 and 2018, tuberculosis treatment prevented about 44 million deaths among HIV-negative people. Among HIV-positive people, antiretroviral therapy-supported tuberculosis treatment prevented 9 million additional deaths (WHO 2019: 47).

2.3 TUBERCULOSIS SITUATIONS IN ETHIOPIA

Tuberculosis is one of the main public health problems in Ethiopia. It is posing significant deleterious health impacts by affecting the productive segment of the population and resulting serious burden to the health system and exploiting the individual's/household economy (Dasa, Roba, Weldegebreal, Mesfin, Asfaw, Mitiku, Teklemariam , Geddugo, Naganuri, Befikadu & Tesfaye 2019:3-5).

Despite 42% of the decline in the annual TB incidence from 369 cases in 1990 to 151 per 100,000 populations in 2018, Ethiopia remains one of the 30 countries reported with a high burden of TB, TB/HIV, and DR-TB for 2015 to 2020. Tuberculosis-related mortality is highlighted among the ten most reported causes of death in hospitalization, and the estimated annual mortality rate in 2018 was 29 per 100,000 people (WHO 2019: 202).

2.4 FINDING MISSED TB CASES IN ETHIOPIA

The World Health Organization estimates that the health system misses about 4 million people with tuberculosis every year. Of these missed cases, 75% are located in 12 countries, and Ethiopia is one of them (WHO 2019:15). Ethiopia accounts for 3% of the annually three million missed people with TB by global health system. In 2018, it is estimated that 35% (56,164) of incident TB cases were missed. Moreover, from the 5,800 people that was estimated to develop drug-resistant TB, 5,098 DR-TB was not detected, which not only has an epidemiological implication but also raises a human right and service equity issues (EFMOH 2019:21). An enhanced effort and integrated strategies much needed, especially for the vulnerable and high-risk populations for TB to accelerate the national TB control efforts towards TB control and elimination in Ethiopia (EFMOH 2019:7).

2.5 ADDRESSING THE DUAL TB AND HIV BURDEN

Despite the reported decline trends of HIV incidence rate in the country, there is a huge pool of HIV positive population directly driving the TB epidemic in Ethiopia, whereby in 2018, 8% of annually notified TB patients found to have HIV co-infection and the coinfection was 22% in the study setting area, Addis Ababa (EFMOH 2019:13).

The national responses in jointly addressing the TB and HIV epidemics begun in 2004 and have succeeded in saving the lives of hundreds of thousands of affected citizens. Despite this, Tuberculosis (TB) remains to be the leading cause of death among people

with HIV, accounting for around 40% of AIDS-related deaths. Both diseases together form a lethal combination, each speeding the other's progress (EFMOH 2017a:19).

In Ethiopia, 92% of reported tuberculosis patients were aware of their HIV status in 2018, and 82% of reported HIV-positive tuberculosis patients received an antiretroviral therapy (EFMOH 2019:22). “Even though more than 400,000 HIV positive populations enrolled in chronic HIV care with an annual enrolment of around 30,000 newly diagnosed HIV positives in 2018, only 0.4% of them diagnosed to have active Tuberculosis while only 40% of the newly enrolled HIV positives reported accessing preventative therapy as per national recommendation. This response implies a large segment of HIV-positive cases did not reach care for TB” (Adelman, Tsegaye, Kempker, Alebachew, Haile, Tesfaye, Aseffa, & Blumberg 2015:1200).

2.6. RISK GROUPS

Transmission is the result of the dynamics of four major factors: the susceptibility of the host; the degree of infectiousness of the source case, the level of exposure (proximity, frequency, and duration), and environmental factors mainly determined by ventilation (Mathema, Andrews, Cohen, Borgdorff, Behr, Glynn, Rustomjee, Silk & Wood 2017:650).

Tuberculosis is mainly spread through the inhalation of infected droplet nuclei. When an untreated sputum-positive tuberculosis patient coughs or sneezes, these droplets are emitted into the air. Coughing produces droplets containing Mycobacterium tuberculosis. When droplets are emitted into the air, some of them will form droplet nuclei, which are infectious particles of respiratory secretions, usually less than 5 mm in diameter, and contain one or more Mycobacterium tuberculosis (Nardell 2015: 1).

People who live in the same household or who are in close contact with patients with infectious diseases are at the greatest risk of exposure to bacteria (Turner & Bothamley 2015: 1370). In addition, consumption of raw milk containing Mycobacterium bovis is a possible way of getting a TB infection, though it is much less frequent (WHO 2019:39).

The risk of infection depends on the extent of an individual's exposure to droplet nuclei and on susceptibility to infection. Two factors, the concentration of droplet nuclei in contaminated air and the length of time-spent breathing that air, determine an individual's risk of exposure (Sloot, Schim van der Loeff, Kouw & Borgdorff 2014:1051).

The extent of an individual's exposure to droplet nuclei determined by the proximity and duration of contact with an infectious source case, since the concentration of droplet nuclei to which the person is exposed depends on proximity, and the length of time spent breathing the contaminated air depends on the duration of contact. The risk of infection of a susceptible person is therefore high with close, prolonged, indoor exposure to a person with bacteriologically confirmed pulmonary TB (Turner, Chiu, Churchyard, Esmail, Lewinsohn, Gandhi & Fennelly 2017: 642).

Tuberculosis affects men and women of all ages. However, some people are more susceptible to this disease: for decades, people have known that poverty, malnutrition and overcrowded living conditions increase the risk of this disease. (Shokri, Najafi, Niromand, Babazadeh, Javanian, Bayani, Afra & Ebrahimpour 2018:145). HIV infection has been identified as the main risk factor for the development of tuberculosis. The main age group affected is between 15 and 54 years old, which has serious socio-economic consequences in countries with a high incidence of the disease (Ahmed, Mekonnen, Shiferaw, Belayneh & Yenit 2018: 7).

2.7 TB CASE FINDING

The speedy identification of the tuberculosis presumptive and the detection of cases of tuberculosis disease in health facilities and communities is a basic and priority task of the tuberculosis control program. The main purpose of detecting TB cases is to interrupt the chain of disease transmission by starting treatment as early as possible (WHO 2013: 8). In this section, the following will be discussed; TB case finding strategies and approaches.

2.7.1 TB Case finding strategies

The finding of tuberculosis cases begins with presumptive identification, which involves screening patients for signs and symptoms of tuberculosis, especially coughs that last two weeks or longer. Fever, night sweats, and weight loss can be considered as other symptoms of tuberculosis (WHO 2017: 10).

The presumptive identification of tuberculosis can be performed at the community and health facility level. Health extension workers can conduct presumptive identification of tuberculosis at the community level. All confirmed tuberculosis cases should be immediately transferred to a nearby diagnostic medical institution for sputum smear examination and further clinical evaluation (Datiko, Yassin, Theobald, Blok, Suvanand, Creswell & Cuevas 2017:5).

In general, TB case finding activities follow either passive or active approaches. These are the common activities used to identify TB patients (EFMOH 2017b: 36):

- Awareness creation and social mobilization on TB
- Actively screen all clients visiting health institutions for tuberculosis
- Identify the suspect and conduct a bacteriological examination
- implements household and contact investigation for TB patients
- Intensified TB screening in high-risk groups
- Integrate tuberculosis screening activities into all service outlets
- Cooperate with all relevant health care providers

2.7.2 Approaches to tuberculosis case finding

There are several approaches to select individuals for tuberculosis testing, to identify tuberculosis presumptive. Health services can use

1. Passive case finding
2. Active case finding

2.7.2.1. Passive case finding

It is a case finding approaches where symptomatic patients self-present health facilities for assessment. The rationale for emphasizing passive case finding is that resources should focus on effectively treating patients who are symptomatic and most likely to be highly infectious to others (Golub, Bur, Cronin, Gange, Baruch, Comstock & Chaisson 2006:27).

This recommendation is based on the view that the cost of passively searching for cases is lower, and self-diagnosing patients are easier to complete treatment. However, the case detection rate in Ethiopia is estimated to be only 62% of the prevalence rate, indicating that this method has resulted in a considerable number of infectious cases that have not yet been diagnosed (Raviglione et al 2012:1910).

Passive case finding relies on four actions:

- People who have active tuberculosis recognize their symptoms.
- A person visiting an appropriate medical institution.
- The health worker correctly assessed whether the person met the criteria for suspected tuberculosis.
- The successful application of a complete diagnostic algorithm with sufficient sensitivity and specificity (Saunders, Tovar, Collier, Baldwin, Montoya, Valencia, Gilman & Evans 2019:520).

In each step, there are obstacles that may affect the early detection of cases. The poorest and disadvantaged people are at the highest risk of not completing or delaying each step. Since they have the least chance of obtaining high-quality services, they face the highest costs due to illness and medical care. Screening those who do not have access to medical services may help reduce delays (Ereso, Yimer, Gradmann & Sagbakken 2020:7-9).

Case detection is the foundation of the WHO-recommended tuberculosis control strategy, but the standard passive case finding (PCF) method has not been effective in detecting

all cases. Globally, it estimates that nearly one-third of new tuberculosis cases remain missed. Furthermore, the cases detected by the PCF experienced a long delay before diagnosis, so they continued to spread the disease while they were still in the community. Community Active Case finding (ACF) and household Contact Investigation (HHCI) have proven to be effective alternative strategies for case detection (Ho, Fox & Marais 2016:375).

2.7.2.2. Active case finding

Active case finding (ACF) refers to a strategy to actively search for tuberculosis in a specific population. Medical staff actively investigate populations through contact tracing, screening high-risk populations, sub-populations or a combination of both. This population may be contacts of patients with tuberculosis, other specific high-risk groups, or the general community. The purpose of active case finding is to detect and treat tuberculosis earlier than in other cases, thereby reducing the further spread of tuberculosis infection (WHO 2013:26).

2.8 HOUSEHOLD CONTACT INVESTIGATION

The World Health Organization (WHO) reported that the global detection rate of tuberculosis (TB) cases is below the WHO target. One of the proposed solutions is to actively and systematically screen all household contacts of tuberculosis patients to increase the case detection rate because the risk of tuberculosis infection and disease is high among contacts (WHO 2013: 11).

The systematic assessment of persons who may be exposed to tuberculosis patient can be an effective and targeted enhanced detection method for tuberculosis within the scope of the tuberculosis control plan. There are, however, no comprehensive global standard recommendations for these programs. WHO, the International Union Against Tuberculosis & Lung disease and the International Standards for Tuberculosis Care, all recommend that children less than 5 years of age and persons living with HIV who are

exposed to infectious cases of TB should be evaluated for active TB and considered for the treatment of latent tuberculosis infection if active TB is excluded (WHO 2013:15). With these exceptions, there are limited recommendations at the global level to:

- Define the epidemiological and program conditions under which contact investigation indicated.
- Describe TB index patients who should be contacted for investigation.
- Identify TB contacts who should be investigated (other than children less than 5 years of age and PLHIV); and
- Recommend the procedures to be used for identifying, screening, and tracking TB contacts.

Systematic reviews of published studies show that a pooled average of 2.1–4.5% (equivalent to the prevalence of 2,100–4,500 per 100,000 population) of household members or other close contacts with a person who has infectious TB are themselves found to have previously undiagnosed TB, although there is considerable heterogeneity in the results (Fox, Barry, Britton & Marks 2013:144). These findings suggest that contact investigations may lead to early detection of cases, which may reduce the severity of the disease and reduce the spread of Mycobacterium tuberculosis. Despite this potential benefit, only a few countries with high to medium TB prevalence have conducted active contact investigations (WHO 2013: 35).

TB Contact Investigation consists of three main steps:

1. TB contact identification
2. Notifying and evaluating the contacts for TB infection and disease.
3. Providing treatment

The goal of TB contact investigation is to identify infected people before they develop tuberculosis and ensure that they complete preventive treatment. The main purpose of screening is to detect active tuberculosis early. This can achieve two ultimate goals:

1. Reducing the risk of poor treatment outcomes, health sequelae, and the adverse social and economic consequences of TB for the individual. This reduces suffering, the prevalence of TB, and death from TB.

2. Reducing TB transmission by shortening of the duration of infectiousness. This reduces the incidence of TB infection and thus contributes to reduced incidence of TB disease.
A second objective is to rule out active disease in order to identify people who are eligible for the treatment of latent TB infection for example, among people living with HIV and contacts who are younger than 5 years (Kasaie, Andrews, Kelton & Dowdy 2014:850).

In addition, screening can help to determine who is most likely to have an active disease in the future, so screening may need to be repeated. For example, this group includes people who have abnormal chest X-rays and are compatible with tuberculosis. However, people with active disease have not been diagnosed at the time of screening. Combining screening for TB with screening for TB risk factors can also help to map individual or community's level of risk factors and socioeconomic determinants that need to be addressed to more effectively to prevent the disease (WHO 2013:45).

These investigations require partnerships and extensive resources. Although medical institutions and health authorities have made significant investments, the yield of contact investigations (CI) is usually low in terms of successfully locating, evaluating, and treating contacts. In light of these concerns, new methods are needed to perform CI more effectively and efficiently (Zellweger et al 2015:1178).

Studies have shown that, compared with passive cases finding, more tuberculosis cases can be detected by active cases finding among household contacts. Among household close contacts in low-income and middle-income countries, household contact TB screening found as many as 2.3% of tuberculosis patients (Fox et al. 2013: 145). A study in India showed that compared with passive case finding, home visits increased the number of tuberculosis cases by 63%. Standard procedures for conducting household contact investigations have found additional cases of tuberculosis in the community and provided an opportunity for isoniazid chemoprophylaxis for prevention of TB in children (Khaparde, Jethani, Dewan, Nair, Deshpande, Satyanarayana, Mannan & Moonan 2015: 3).

The various methods used for the TB screening among household contacts include symptom screening, chest radiography (CXR), sputum smear and culture examination, rapid molecular diagnostic tests Gene-Xpert, tuberculin skin test (TST), and interferon-γ release assay. Active screening can be carried out through symptom assessment, CXR, or symptom, assessment and CXR can be carried out concurrently or sequentially. The latest data shows that compared to screening by symptoms, CXR usually shows higher accuracy and less heterogeneity, but requires resources. When used alone, the overall sensitivity of chest X-ray readings (98%) is higher than the sensitivity of symptom screening (87%). Using chest X-ray as the second continuous screening algorithm for symptomatic tuberculosis screening provides 90% and 56% sensitivity and specificity, respectively (Kasaie et al 2014: 848).

2.9 MODELS OF HOUSEHOLD CONTACT INVESTIGATION

Tuberculosis screening and active case finding are increasingly seen as potential remedies that can address the stagnant rate of tuberculosis case detection and benefits the traditional passive detection method that rely on symptomatic patients to seek health facilities. Indeed, in some controlled trials, ACF has shown that it can detect more cases of tuberculosis (Dobler 2016:336). In addition, the effectiveness of screening for tuberculosis in certain key populations also implies potential benefits (Shah, Auld, Brust, Mathema, Ismail, Moodley, Mlisana, Allana, Campbell, Mthiyane, & Morris 2017: 245).

Tuberculosis screening either community based or health institutions based both bring opportunities and challenges to the health system. Active tuberculosis screening can usually identify different types of tuberculosis and different types of tuberculosis patients from traditional methods. Furthermore, TB screening can be very broad since it describes an intervention; target populations and diagnostic algorithms applied which are equally diverse and vary widely. Hence, it is a challenge to make simple conclusions about the value of tuberculosis screening (Blok et al 2015:4).

2.10 CONCLUSION

This chapter discussed the literature reviewed on the household contact investigation. Several aspects of the TB household contact investigation reviewed. The reviewed literature indicated that TB household contact investigation is a combination of several factors and each factor contributes to the overall program performance of the TB household contact investigation. The researcher tried to include all aspects of tuberculosis program including the tuberculosis situations, missed TB cases, TB case finding approaches, contact investigation, and models of HH contact investigation. Several countries' household contact investigation approaches as well as global TB program contact investigation performance indicators also exhaustively reviewed from researches conducted both in developing and developed countries. The WHO textbooks on tuberculosis and the national TB manuals, guidelines and reports were also reviewed.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

A literature review on tuberculosis (TB), tuberculosis case detection strategies, tuberculosis case detection approaches, household contact investigations and household contact investigation models were presented in Chapter 2. The review revealed that there is limited information on the implementation of active tuberculosis case detection among household contacts. In addition, the review also found that there is a lack of care models that support the TB detection among household contacts in the Addis Ababa. In this chapter, we will discuss in detail the research design, methods and data collection process of the guidelines used to develop guidelines to strengthen household contact screening and management of tuberculosis patients in Addis Ababa.

3.2 STUDY SETTING

The study was conducted in Addis Ababa (AA), Ethiopia. Owing to the high TB case notification rate and the high population density, this city was chosen. According to Ethiopian Ministry of Health 2018 report, Addis Ababa notified one of the high TB cases in the country (262 cases per 100,000 population), and the other two regions with high case notification were namely Dire dewa (348 per 100,000 population) and Harari (206 per 100,000 population) (EFMOH 2017:13).

Population density at the regional level varies from less than 10 persons per sq. km. to 4572 persons per sq. km. in Addis Ababa, the capital city. Overcrowding is a problem in all sub-cities of Addis Ababa and it is one of the associated factors for the incidence of TB among household contacts

In Addis Ababa, there are around 150 health facilities providing both TB diagnostic and treatment services. Health facilities are divided into public health centers, public hospitals, private clinics, private hospitals and non-profit non-governmental organizations. TB treatment services are decentralized to the health center, lower level of the health system while, diagnostic services are mainly implemented by hospitals. According to data from the regional health bureau, in 2019, 95% of tuberculosis patients in Addis Ababa received treatment and services in public health centers (AACAHB 2020: 13).

There are 98 public health centers administered by AACAHB and providing general medical services for the populations in their catchment area. In Addis Ababa, TB treatment is directly supervised on an outpatient basis (AACAHB 2020:10). In Ethiopia, the National Tuberculosis Control Program uses passive case finding as a standard strategy for contact investigations, usually focusing on particular high-risk groups, such as children and HIV positive people. In setting where no strong case detection system in place, community-based active case finding may provide an opportunity to fill the gap in detecting undiagnosed tuberculosis cases (EFMOH 2017b: 10).

3.3 RESEARCH APPROACH

Van den Berg and Struwig (2017:110) describe the research approach as a framework for the researcher tasks, through preparation of study problems to the presentation of data finding. Quantitative and qualitative research methods are the two research methods.

3.3.1 Quantitative research

Quantitative research is “a mode of inquiry, usually used in deductive research, to follow scientific methods to test theories or hypotheses, to collect descriptive information about variables or to examine the relationship between variables, or to determine the causal relationship between variables” (Burns & Grove 2014: 243).

Quantitative research uses of statistical data analysis to answer research questions. Key features include formal and systematic measurements and the use of statistics. Quantitative research produces statistical data. Through these statistical data, sample characteristics can be inferred from the entire research population (Zyphur & Pierides 2017:10). In this study, the quantitative approaches was used in phase two for 320 index cases enrolled in two groups of random control trail.

3.3.2 Qualitative research

Qualitative research constitutes research that does not attempt to quantify its results through statistical summaries or analysis. Qualitative research usually involves interviews and observations without formal evaluation. Qualitative research allows scholars to explore participant attitudes, behavioral experiences and in-depth insights (Austin & Sutton 2014: 437). Creswell (2014: 190) pointed out that qualitative research is an inquiry into the analysis of information conveyed through language and behavior in the natural environment, which can identify previously unknown processes and explain the causes and ways of phenomena and their influence.

Observation, in-depth interviews and group discussions are three main techniques commonly used in qualitative research. Researchers must choose which method is more suitable for answering research questions, or more than one techniques can be used. The researcher in these different designs acts as an observer, an interviewer, or group moderator (Nicholls 2017:115).

In this study, qualitative methods were used as the main part of the research, followed by quantitative methods for consensus building. In-depth interviews were conducted with tuberculosis patients, and their household contacts, and focus group discussions were conducted with tuberculosis clinicians and tuberculosis project managers to understand the obstacles to the implementation of household contact tracing and screening strategies.

3.3.2.1 In-depth interviewing

An in-depth interview is a loosely structured interview. It allows both the interviewer, and the interviewee to freely explore other points and ideas. In in-depth interviews, the interviewees are regarded as experts and the interviewers are regarded as students. Desire to learn the interviewees, and the interview ability to share information about research topics can determine the researcher's interviewing techniques (Baran & Jones 2016:188). Researchers asking questions in a neutral manner to engage with participants, listening attentively to the participants' responses, and asking follow-up questions and probes based on those responses. They do not lead participants according to any predetermined notions, nor do they encourage participants to provide particular answers by expressing approval or disapproval of what they say (Creswell & Poth 2016:46).

Different from quantitative research based on structured questionnaires, in-depth interviews are more like a kind of social dialogue. The question comes from the respondent's answer, as a follow-up to the answer or further exploration of the answer. Open-ended questions are a basic tool for qualitative research. In most cases, the interview may rely on informal conversations with little or no question preparation and sequencing. Alternatively, a topic guide or outline can be used to help participants to focus on the interview but there are no pre-structure questions. However, the most standardized approach for in-depth interviews is a pre-determined set of open-ended questions (Queiros, Faria, & Almeida 2017: 378).

3.3.2.2 Focus group discussions

Focus group discussions are a way to gain better information and insights from group interactions than in-depth interviews with individuals. A focus group discussion is not a group interview. The two methods can complement each other. It is based on the exchange of information, ideas and opinions between participants. The researcher is playing the role of a moderator, and not an interviewer (Tausch & Menold 2016:5).

Quantitative data is useful for obtaining general answers to research questions related to a large group of people. However, quantitative data alone is not enough to get a specific explanation related to the research problem. On the other hand, qualitative data can provide meaningful background information about the participants and the environment. However, due to the small number of participants and the narrow range, general conclusions cannot be provided. However, if the two methods are used together, they can be complementary (Ivankova & Wingo 2018: 987).

Therefore, in order to fully understand the current implementation status, advantages, challenges, and lessons of the TB household contact tracing strategy, to develop an effective care model, the researcher implemented mixed method designs using both quantitative and qualitative research methods to take benefit from both methods.

3.3.3 Mixed method research

Venkatesh, Brown, and Sullivan (2016: 440) define a mixed method study as a study that aims to collect and analyze quantitative and qualitative data in the same study for understanding and collaboration.

A mixed method researcher focuses on the systematic integration of numeric and narrative data in a single investigation. Quantitative researchers usually focus on numerical data, while qualitative researchers usually focus on narrative data. In other words, mixed method researchers are pragmatic, explore and examine problems based on narrative and numerical data, and analyzing their data through statistics and content analysis (Shannon-Baker 2016:324).

Mixed method research helps to build strength by using quantitative and qualitative approaches together to draw inferences that can lead to an increased understanding of the researched topic (Baran & Jones 2016:2). This study was guided by the mixed method research where both quantitative and qualitative approach were followed. The design that was followed was exploratory sequential by phases.

3.4 RESEARCH DESIGN

Research design is a conditional arrangement of data collection and analysis that aims to incorporate the different mechanisms of the research in a coherent and logical way, in order to effectively solve the research problem (Rahi 2017:2). Research design is the conceptual structure of research with an outline for data collection, measurement, and analysis. Hence, the design includes an outline of what the researcher will do from the preparation of the data collection and its operational implications to the final analysis of the data (Creswell 2014:43).

Research design is needed because it can promote the smooth progress of various research operations, so that the research is as efficient as possible, to generate the greatest information with the least energy, time, and money. Observational research and experimental research or interventional research are the two main categories of research design (Creswell 2014: 63).

3.4.1 Observational study

In the observational study, the researcher stands apart from events taking place in the study by simply observe and record.

3.4.2 Experimental study

In the experimental study, the researchers introduce an intervention and observe events that occur during the study. An experimental or intervention study may be controlled or non-controlled. For a more decisive answer, we need a “control” group who do not get the intervention under the study. In this design, groups are randomly selected and processed in the same way to control variables (Baran & Jones 2016: 96).

The True experimental study design must meet all the following conditions

1. Assignment based on random sampling
2. A viable control group.
3. It is preferable to intervene and test one variable.

3.4.3 Randomized controlled trials

A randomized controlled trial is an interventional study, which is characterize by dividing subjects into experimental groups and control groups by random methods. In a randomized controlled trial, the experimental group receive the interventions evaluated, while the control group receive a placebo without any treatment or standard care. Both groups are followed for the outcome(s) of interest (Deaton & Cartwrigh 2018:3).

Randomization is the most reliable way to ensure that the two participants are as similar as possible among all known or unknown factors that may affect the results of the study. With randomization, there is only a chance to determine the assignation of subjects to the study group (Spieth, Kubasch, Penzlin, Iligenss, Barlinn & Siepmann 2016: 1342).

Random allocation does not mean haphazard allocation. This idea is a well-thought planned technique used for assigning subjects to comparable groups. If the risk factors can be determined from the beginning, the subjects can be grouped or stratified before assignments. As long as it is ethical and practical, random design should be considered in controlled intervention studies (Nguyen, Collins, Lamy, Devereaux, Daurès, Landais, and Le Manach 2017: 110).

3.4.4 Exploratory, mixed method design

This research design is a two-phase sequential research design that characterized by an initial qualitative phase, followed by a phase of quantitative. In exploratory design, a researcher explores a topic and uses analysis of the results of a qualitative phase to construct a second quantitative phase to test or summarize the preliminary exploratory

results of the qualitative phase. In many cases, researchers use the results of the qualitative phase to develop research tools that can be used for data collection in the quantitative phase and quantitative follow-up design (Creswell 2014:37).

In contrast to the explanatory design, the exploratory research design begins with and lays great emphasis on a qualitative phase. After the quantitative phase is completed, the researchers will interpret the results to understand whether the results generalize or to provide more insights into the exploratory findings in the qualitative phase. The results of the qualitative phase can provide different research variables, and researchers can use these variables to develop research tools. Researchers can then use this research tool to assess the overall frequency of these variables in a large sample (Creswell 2014:72).The qualitative phase of the exploratory mixed method design involves few individuals while the quantitative phase involves a large sample of individuals.

In this study, a sequential exploratory design was adopted, which started from the qualitative phase, and then followed the specific results in the quantitative phase. (Berman 2017:15). Interviews and focus group discussions were conducted to explain and understand the different perspectives on the implementation of family contact tracing in the study area and to develop guidelines. A randomized controlled trial with a one-year follow-up was also conducted. This study design enables us to evaluate the yield of the developed community based TB screening approach among household contacts of bacteriologically confirmed pulmonary TB patients by using the existing health care staff and resources comparing with the routine passive case finding.

3.5 RESEARCH METHODS FOR PHASE I

A research method is a general structure guiding a research project and methods that are used to accomplish the goals and attributes of a study. It involves the collection, analysis and interpretation of data proposed by researchers for research. Methodological standards are followed in order to ensure that the evidence provided is reproducible and

reliable knowledge; it includes sampling, measurement validity, internal validity and external validity (Creswell 2014:17).

The first phase was used a qualitative data collection methods to collect data from tuberculosis patients, their household contacts and tuberculosis project managers in this study. The specific methods adopted are described as follows.

3.5.1 Objectives of phase I

The objective of phase I was to explore and describe the TB experts, TB patients and their household contacts' perception about TB patients' household contact tracing strategies in detail.

3.5.2 Population

Tuberculosis patients and their household contacts and tuberculosis experts who manage tuberculosis prevention and control activities in Addis Ababa were the two groups of study populations included in the first phase of this study.

3.5.3 Sampling

In the selected health center, TB patients and their household contacts who were on the continuation phase of TB treatment were randomly selected for interview. TB program managers were purposively selected from sub-city, regional and national health offices.

3.5.4 Sample size

There is no predefined method to calculate the number of study participants in a qualitative research. Malterud, Siersma, and Guassora (2016: 1756) suggest that the sample for qualitative research should be based on the required information. Hence, data saturation is the guiding principle for sampling in qualitative research. The degree of data

saturation is sampled to the point where it is impossible to obtain new information and achieve redundancy. In this study, the recruitment of research participants was continued until the data was saturated. At this time, other research subjects or interviews did not produce any marginal changes to the core data concepts.

3.5.5 Data collection tools

The researcher used an organized in depth interview guide for TB patients and their household contacts and FGD guide for TB program managers during the qualitative phase of this study. Open-ended probing questions were used in the FGD and interview to probe the discussion of the participants. In turn, it helped to achieve the stated objectives of the study.

3.5.6 Data analysis

In the qualitative part of this study, thematic analysis was used to analyze in-depth interviews and FGD separately. Researchers carefully examine the data to identify common themes, ideas, and patterns of meaning that recur frequently. The detailed data analysis is described in chapter four.

3.5.7 Trustworthiness

Qualitative research focuses on data trustworthiness to answer how assertive the qualitative investigator is about the truth of research study's findings. Qualitative researchers often have different opinions on which criteria are best for assessing trustworthiness. However, the current consensus is that credibility, transferability, reliability, and confirmability are the most relevant terms to determine the trustworthiness of research (Kyngas, Kaariainen, & Elo 2020:45). Trustworthiness is all about establishing these four things, which are described in more detail below. In this study, different methods were used to make sure that the four qualitative expectations were verified and met.

3.5.7.1 Credibility

Credibility talk about the confidence that can be trusted in the authenticity of research results. It states the degree of reliability and appropriateness of the research report, especially with reference to the level of agreement between participants and researchers (Wood, Sebar & Vecchio 2020: 460).

In this study, the researchers stayed in the field until the end of data collection. Credibility enhancement activities include long-term participation, which means that sufficient time is allocated on-site throughout the study period to gain a deeper understanding of the information provider, eliminate misinformation or distortion and ensure saturation.

This is one of the key strategies for building trust, which in turn helps to obtain appropriate information from participants. In addition, enough time is allocated to each participant to build trust (Shufutinsky 2020:55). The investigator grabbed complete field notes, audiotaped and used participants' words in transcription of the interviews.

3.5.7.2 Dependability

Dependability refers to the consistency and reliability of research results and the degree to which research procedures are recorded, so that people outside the research can track, review, and criticize the research process. The researcher in this study enhance reliability by carefully recording the content of interviews, and by checking and rechecking the existence of phenomena (Korstjens & Moser 2018:124). In addition, dependability was assured by kept an 'audit trial'. Audit trials are all records that enable researchers and supervisors to track the research process to ensure that the research results can be confirmed by others. Research colleagues were consulted to determine whether the procedure used was acceptable and reliable.

3.5.7.3 Confirmability

Confirmability refers to the degree to which a result can be confirmed by others. The researcher can document the procedures for checking and rechecking the data throughout the study. Confirmability is concerned with providing evidence that the study's findings are based on the participants' narratives and words rather than potential researcher biases (Haven & Van Grootel 2019:234). The findings of this study were supported by evidence from literature, and the researcher acknowledged all the authors' viewpoints.

3.5.7.4 Transferability

Transferability is established by given readers with confirmation that the research study's findings could be pertinent to other contexts, situations, times, and populations. Researchers not only describe behaviors and experiences through detailed descriptions, but also describe their context to promote transferability judgments of potential users, so that behaviors and experiences are meaningful to outsiders. Applicability is also ensured by obtaining complete field records and ensuring that there are enough samples until the data is saturated (Schloemer & Schröder-Bäck 2018:15).

3.6 RESEARCH METHODS FOR PHASE II

In this study, for the second phase, a quantitative data collection method was used to collect data from tuberculosis patients and household contacts in their respective health institutions. The specific method used is described below.

3.6.1 Objective of phase II

The objective of phase II was to determine the yield of community based contact investigation in households of patients with bacteriological confirmed pulmonary tuberculosis in Addis Ababa compared with the routine passive case finding.

3.6.2 Setting

According to Streubert and Carpenter (2011:27), a setting is the physical, social or experimental environment in which research is conducted. The research results and their interpretation are highly dependent on it. The settings for this study were selected public health facilities.

3.6.3 Population

A population is a well-defined collection of people or objects known to have similar characteristics and a sample is a subset of the population. There are three closely linked types of population and these are target, study and sample population (Martínez-Mesa, González-Chica, Duquia, Bonamigo & Bastos 2016:328).

3.6.3.1 Target population

Target population is “a collection of items that have something in common for which we wish to draw conclusions at a particular time” (Otzen & Manterola 2017:230). In the current study, the target population to whom generalization is intended were all individuals on TB treatment and their household contacts, and medical care workers working on TB program at health facilities, sub-city, and regional level working in Addis Ababa, Ethiopia.

3.6.3.2 Study population

The study population is the subset of the target population available for the study (Elfil & Negida 2017:2). In the current study, the available population were the individuals who enrolled into TB treatment, and their household contacts, and TB clinic health care workers and TB program coordinators at sub-city and regional level working in Addis Ababa, Ethiopia.

3.6.3.3 Sample population

The sample population is a subgroup of the research population, and information about it is actually obtained (Otzen & Manterola 2017: 232). Owing to practical reasons and creditable data management, it will not be possible to study all the TB patients from selected health facilities. The research team recruited all tuberculosis patients identified during the study period until it reached the allocated number for that particular selected medical institution.

3.6.3.4 Sampling

Sampling is a procedure of picking samples from a larger population, used in statistical analysis, in which a predetermined number of observations are obtained from the target population (Curtis & Drennan 2013: 136). The researcher applies scientific sample design in the sample selection process, so that the researcher can collect the same answer from the sample as the target population. This is due to the different characteristics of each item in the target population (Rahi 2017: 3).

Probability sampling is considered to be the ideal choice for this study because it can ensure that each member of the population has a known non-zero probability to be included in the sample. Probability sampling involves the selection of a sample from a population, based on the chance that maximizes the likelihood of obtaining samples that are representative of the population. In a random sample, everyone in the target population has the same probability of selection. The reason for sampling is to choose a representative subset of the population, because it is impractical and it is very expensive to survey the entire population (Curtis & Drennan 2013: 180).

The study was conducted in Addis Ababa. The city health bureau manages 98 public health centers and provides general medical services to residents of the city. About 25% of the facilities were randomly selected by lottery method among the total public health centers to get the study site (Gebrekidan, Tesfaye, Hambisa and Deyessa 2014: 3).

Twenty-four public Health Centers (HC) were selected and for all selected HC, number of TB patients proportionally allocated based on their recent year annual caseload. From each health center, the newly diagnosed consecutive patients were randomly assigned into two groups either the intervention or the control group. The great value of this randomization is that it avoids the effects of confounding factors. Furthermore, the selection of this diverse range of health facilities maximizes the generalizability of the study findings. All people who met the eligibility criteria attended selected HC were approached for enrollment into the study.

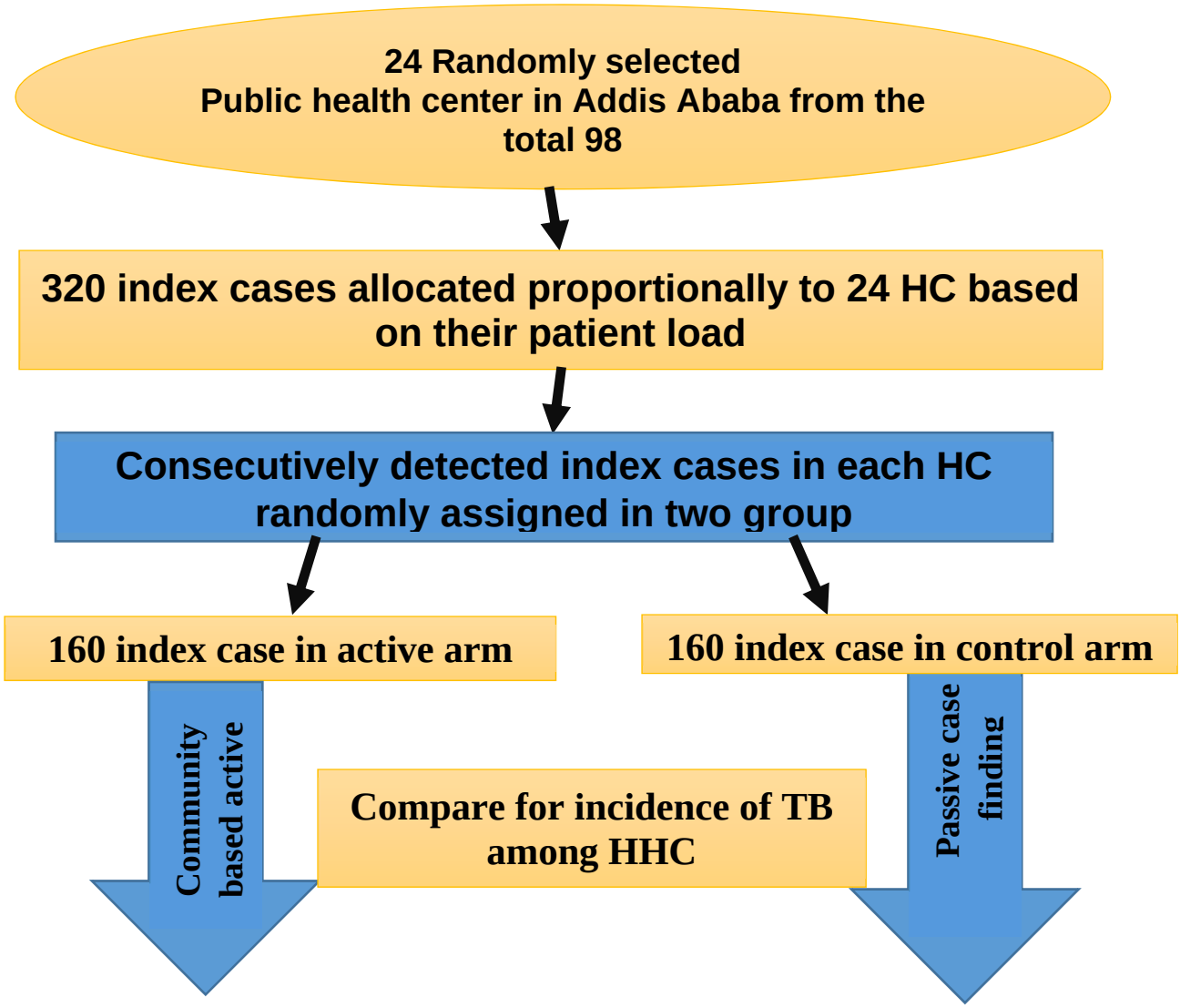

Figure 3.1: Schematic diagram of sampling procedure

According to Woo (2017: 338), eligibility criteria are criteria that specify the specific attributes of the target population to be selected for research.

This study used the following criteria to select the study population for the study site:

For TB Patients

- All patients aged 18 years and over with bacteriologically confirmed pulmonary TB.
- Patients who have eligible household contacts.
- Consented to the study

For TB patients contacts

- Household Consented to the study
- Contacts of 6-year age and above

The following exclusion criteria was applied for non-eligibility:

For TB patients contacts

- Pregnant women are eligible for inclusion, but a chest radiograph were not offered for known pregnant women

3.6.4 Description of intervention

A thorough explanation of the interventions conducted in this research will be discussed, including participant registration, follow-up, procedures, and results.

3.6.4.1 Recruitment of index cases

Bacteriologically confirmed pulmonary TB patients were selected from the participating health centers by TB staff working in tuberculosis units, and volunteered cases enrolled randomly into an intervention group and control group until the required sample size for the institution was reached. A participant information statement was given and asked to sign a consent form. The study intervention was only implemented for household contacts in the intervention group.

3.6.4.2 Recruitment of contacts

All members of the household occupied by the index case, six years of age and above, who were present during the period of recent infectivity that is three months up to the time of diagnosis were eligible for the study.

3.6.4.3 Intervention group

In the intervention group, TB clinic nurses and community health care workers contacted household contacts at home and provided information to explain the research. For those contacts who agreed to participate in the study, tuberculosis clinic nurses and community health care workers were conducted tuberculosis screening.

Using a home visit model at the time, they first identified, and then 3rd, 6th, 9th and 12th months post-exposure evaluated all household contacts in the active intervention groups. The procedures were free of charge to the participants. Consistently, the assessments include symptom based TB screening questions and physical examination. Contacts were defined as having possible TB if they had:

(a) two weeks Cough
(b) Fever that lasted for two weeks
(c) Night sweats
(d) Unexplained weight loss

Contacts meeting one or more of these criteria were asked to submit sputum specimens collected on spot for xpert examinations. Contacts with TB symptoms but with a negative sputum result had a chest X-ray at nearby radiology services and experienced physicians read X-ray films. All contacts were asked about their HIV status. Moreover, for contacts with unknown HIV status, testing and counseling (HTC) were offered. Treatment of latent and active TB were according to the policies of the NTCP.

3.6.4.4 Control group

At the time of enrollment, patients in the control group were asked to list all qualified household contacts and to obtain general information about the typical symptoms of tuberculosis. If any household contacts have these symptoms, they are also advised to report to the tuberculosis department of the health center. This approach is the standard for TB control programs in Ethiopia.

During the study, in addition to any routine diagnostic procedures, self-referring contacts with tuberculosis symptoms and can provide sputum, and the sputum sample were transferred to the Xpert reference laboratory. This allows a comparison of tuberculosis rates between the active group and the control group. Contacts diagnosed with TB in both groups were received standard treatment for TB through the NTCP guidelines.

3.6.5 Sample Size considerations

The reasons for the sample size calculation during the planning stage of the research are to:

- Ensure full confidence in the research results and conclusions
- Ensure that the research is sufficiently powered, as insufficiently powered research will waste resources, and take into account the ethical considerations of the research respondents, as they may not produce clinically meaningful results
- Achieves adequate power to enable the testing hypothesis testing
- Given that inadequate samples may produce results that cannot change clinical practice, it helps to provide reliable evidence for best practice guidelines.

The sample size for quantitative phase was calculated based on the following assumption:

- P1: The percentage of TB among Household contact by routine passive case finding approaches in the control group, 1% (AAHB 2019: 13).

- P2: The percentage of TB among Household contact in the intervention group, 7.8% (Adane et al 2020:4).
- The significance level is 5 percent,
- The power of the study. Here, 80 percent (or 0.8) power is chosen.
- Ratio of the number of unexposed to the number exposed is a 1:1 ratio.
- The non-response rate is 10%.

With this information, we calculated the number of people needed in each group (intervention and control) using the following formula (Pan, Liu, Miao & Yuan 2018:6).

Number n required per group is

$$n = \frac{(P1\,(100-P1) + P2\,(100-P2)) \times f\,(\alpha, \beta)}{(P1-P2)^2}$$

Where

P1 is the percentage with the characteristic in the control group and

P2 is the percentage we wish to detect in the intervention group with a power of 1− β at the significance level (p=0.05). By adding 10% non-response rate, the total sample size was 160 TB patients in each groups.

3.6.6 Data collection approach and method

Burns and Grove (2014:240) define data collection as the procedure of collecting, measuring and analyzing accurate insights for research using standard validated techniques. Scholars add that data collection is the process of collecting and measuring information on variables of interest, in an established systematic fashion to address the research problem (Saunders et al 2018:1899).

The data collection for this study was guided by sequential exploratory design where the qualitative data collection was followed by quantitative data. The data were collected from TB patients, their household contact using a pre-tested interviewer-administered questionnaire for the second phase of the study, while for qualitative data structured in depth interview, and FGD guide were used.

3.6.6.1 Intervention

A household contact investigation protocol was developed, which includes a household contact investigation form to be used by health care workers (HCW) in tuberculosis clinics. In selected public health institutions, participating medical workers and community health care workers received training on how to screen for tuberculosis and collect sputum.

The procedure stipulates that after all bacteriologically confirmed cases of tuberculosis index case identified, the medical staff and community health care workers should immediately conduct home visits for contact investigation.

In this study, the following interventions were implemented according to the protocol

1. Medical staff of health institutions and community health care workers conducted home visits and tuberculosis screening to all consenting household contacts, and recorded them in standard forms.
2. All the identified symptomatic household contacts during the visit were requested to give sputum samples, then collected by the medical staff and community health care workers and for those non-pulmonary presumptive, contacts were provided with a contact slip and counseled to present for evaluation at the nearest health facility.
3. A second home visit was conducted to identify contacts that were missed in the first visit.
4. If there are any missed contacts, a contact slip was left with instructions for follow-up and appropriate evaluation at the closest medical institution.
5. There was a follow up screening at the end of third, six, nine and 12 months after the first visit.

3.6.7 Data analysis

In this study, Epi Info and SPSS were used for data entry and analysis. The level of significance was set at $p < 0.05$, and 95% confidence intervals (CI) were used. The number of detected cases was standardized to a population of 100,000. The measures of risk was determined by relative risk (RR).

Characteristics of index patients and household contacts using simple frequencies and medians with interquartile ranges were described. The primary outcomes was the prevalence rate of disease. Relative risk comparing disease in the intervention study population to that of the control population was calculated and tested using chi test.

3.6.8 Reliability and validity

Quantitative researchers evaluate trustworthiness by how well the threats to internal validity have been controlled, and the validity of the instruments and measurements used in a study (Creswell 2014:55). The methods used to establish trustworthiness in this study include the following:

3.6.8.1 Reliability

The reliability of a research instrument is defined as the degree to which the instrument can obtain the same result through repeated measurements (Curtis & Drennan 2013:72). In order to ensure the reliability of the measuring instrument, standardized questionnaires were used, and pretest was carried out. The questionnaire was pre-tested on 15 PTB patients who were not included in the actual study by considering 5% of the total sample size, before the actual data collection and checked for the clarity and consistency. The data collectors received training on how to manage the questionnaire, and the main investigator handled all difficulties. The principal investigator rechecked the collected data once again on daily basis.

3.6.8.2 Content validity

Validity refers to whether a measurement instrument accurately measures what it is supposed to measure. An instrument is valid, if it truly reflects the concept it is supposed to measure. An instrument cannot validly measure the attribute of interest if it is erratic, inconsistent and inaccurate. Triangulation two or more data sources were used to ensure validity (Rahman 2017:5). In addition, qualitative and quantitative methods complement each other and improve effectiveness. In the current prospective cohort study, the main threat to validity was avoided by random assignment of participants into each groups.

3.6.8.3 External validity

External validity deals with possible problems of generalizability of the investigator's findings to additional populations and to other environmental conditions. External validity questions under what conditions and with what types of subjects, the same result can be expected to occur (Queiros, Faria, & Almeida 2017:380). In this study, this threat is minimized by using data from a number of sources and different perspectives, i.e. patients, care providers and household contacts. This method is very useful for ensuring the validity of health research, which involves exploring complex phenomena from different perspectives (Fabregues & Molina-Azorín 2017:2850).

3.7 OUTCOME MEASURES

The primary outcome for the quantitative study was the number of household contacts diagnosed with TB.

3.8 ETHICAL CONSIDERATIONS

Research ethics involves questions about how we formulate and articulate each research process in an ethical and responsible manner. The ethics of using human subjects for research must be carefully examined. Doody & Noonan (2016:805) define ethics as well

based standards of right and wrong that prescribe what humans ought to do usually in terms of rights, obligations benefits to society, fairness, or specific virtues. The researcher followed the following principles.

3.8.1 Protecting the right of institutions

After the research proposal met the ethical standards required by UNISA and AACAHB's institutional research and higher degree committees, the researchers obtained ethical permission. Consequently, received ethical permission, certification, and approval letter (see Annex A and B) for conducting research from UNISA and AACAHB, respectively. A permission letter was obtained from the city health office for facilitating the data collection process; and sub-city health offices wrote a letter to their catchment health facilities.

3.8.2 Protecting participants

Study participation was on a voluntary basis. Before collecting the data, the interviewees were well-versed of the purpose and objectives of the research, and the oral and written consent of each interviewee was obtained. They were told that they have the right to refuse or withdraw from the study at any time, and their refusal will not affect their right to tuberculosis treatment and services. Privacy and confidentiality of information during the data collection were ensured.

3.8.3 Scientific integrity

Researcher respects the work of others by acknowledging the source. In order to avoid plagiarism, all references are properly acknowledged. In order to ensure the objectivity of the research, the researcher adopts objective methods to collect, analyze and report the research results. The researcher followed the accepted standard of doing the research and was honest while collecting, analyzing, and reporting the study.

Methodological standards used to objectively interpret the data rather than researchers' opinion. The researchers wrote and reported the results of the research, and described the authenticity of the research by correctly explaining the methods and the reasons why used. There is no forgery in this process. The report was based on data collected by researchers.

3.9 CONCLUSION

In chapter three, the study methodology implemented in this research was described. Mixed research was implemented in this study, a qualitative study followed by a quantitative study. The study setting, sampling methods, data collection, research instruments used, and how the data analyses carry out were discussed. In addition, strategies to ensure trustworthiness were presented. Finally, ethical considerations were described. The researcher will present the analysis of data and the description of findings in the next chapter (Chapter 4).

CHAPTER FOUR

ANALYSIS, PRESENTATION AND DISCUSSION OF THE RESEARCH FINDINGS

4.1 INTRODUCTION

The research approach, methods of data collection, and analysis to achieve the stated objectives and rigor of the study were discussed in the previous chapter. Chapter 4 presents the finding of qualitative and quantitative data in the form of narratives, tables, and graphs in two sections.

Section one: Describes qualitative data analysis and presentation to explore and describe the perception of tuberculosis experts, TB patients, and TB household contacts on contact tracing strategies.

Section two: Describes quantitative data analysis and presentation to determine the yield of community-based contact investigation in households of TB patients in Addis Ababa compared with the routine passive case finding.

4.2 SECTION ONE

QUALITATIVE DATA ANALYSIS AND PRESENTATION

In this chapter, the results of the qualitative study are presented, interpreted, analyzed, and discussed in detail. This chapter starts with an introduction, and then describes how the various qualitative approaches were used. In addition, the qualitative findings were presented in themes and sub-themes. Finally, the findings of the qualitative data are described under sub-sections. The section is summarized by key findings from the qualitative research.

The objectives of the qualitative section of this research was anticipated to accomplish the following:

- Explore TB experts' perception about contact tracing strategies
- Explore TB patients' perception about contact tracing strategies

- Explore TB patients' household contacts perception about contact tracing strategies.

FGDs and in-depth interviews were used to achieve the mentioned objectives.

4.2.1 Introduction

Qualitative research is more subjective than quantitative research. It uses very different methods to gather open-ended data through in-depth interviews and focus group discussions. The general, open-ended questions asked during these interviews allow the participants to supply answers in their own words. In the case of limited knowledge of a topic, the initial collection of qualitative data will provide an opportunity to collect relevant information about the phenomenon, which will help researchers design quantitative tools (Bansal, Smith & Vaara 2018:1190).

Qualitative findings are presented in this chapter. The results of interviews with patients and their household contacts were discussed. Focus group discussions with health care providers and tuberculosis program coordinators are introduced and discussed in the following sections.

4.2.2 Data collection processes

In order to explore the factors that influence the implementation of household contact tuberculosis screening services at the Addis Ababa Public Health Center, this study used interviews and focus group discussions (FGD).

Data were collected by the researcher and his assistants and processed as follows:

Step 1: Data was collected from tuberculosis patients, and their household contacts through individual interviews.

Step 2: Through focus group discussions, data was collected from tuberculosis program officers in health centers and tuberculosis program managers at sub region, regional, and national levels. The people selected for the individual interviews and FGDs were selected based on predetermined eligibility criteria and willingness to participate in the study.

Generally, forty and twenty-four participants participated through in-depth interviews and focus group discussions consecutively. Since themes were saturated, it means adding more participants in the study will not lead to obtaining additional perspectives or information; it was not required to continue the discussion with the new individual and group.

Step 1: Individual interview

- In-depth interviews were conducted to forty individuals.
- The participants were TB patients and their household contacts.
- The interviews location were the respective health facilities TB Clinic
- Each interview lasted between 25-40 minutes.

Step 2: Focus group discussions

Three focus group discussions (FGD) were conducted. The participants were healthcare providers, including doctors, health officials and nurses who were directly involved in the treatment and follow-up of TB patients. Participants were selected from participating health center tuberculosis clinics. The inclusion criteria were health care providers who currently work at the TB clinic and have at least one and more years' experience in TB clinic.

Tuberculosis program officers from federal health office, Addis Ababa health bureau, and sub-city who manages the implementation of the TB program in the country and also in the study area were included in FGD. The inclusion criteria were health care providers who currently work on the TB program and at least have two and more years of TB program experience. The venue for the FGDs was Addis Ababa health bureau meeting hall. The focus group discussion had eight participants on average. The FGDs lasted between 45-60 minutes.

Before starting the interview, the participants were introduced to the ethical review of the academic institution, and the approval letter of the city health bureau to conduct the

research. After a detailed description of the determination and aims of the research, participants were required to sign consent paper. After obtaining the consent of the participants, all interviews in the two steps were recorded.

The researcher explained the purpose of the research, why the study needed, and why participants were selected to participate in both focus groups and in-depth interviews as indicated in the consent letter. Then, the researcher began the interview with the following welcoming statement:

"I am Zerihun Yaregal Admassu, a doctoral student at the University of South Africa. I am the principal researcher for this study as part of the academic program. It is an honor to invite you to participate in the in-depth interview and FDG; I appreciate your volunteering to participate in this study."

To maintain the credibility of the research, the researcher conducted the interviews. The researchers also used pre-planned interview guide. The probe follows the questions in the research guide in order to have a clear understanding and follow-up of the content of the narrative. In addition, number of the interview sequence identified the audio record.

A researcher and a trained assistant moderator conducted the focus group discussions using pre-planned interview guides. The researcher was responsible for presiding over the meeting to promote discussion, prompt members to speak, and encourage all members to participate, while the assistant takes down notes and further operated the tape recorder. In addition to taking notes, a tape recorder is also used to record discussions to capture most of the information. After each FGD meeting, the consistency of the recorded information and the notes taken by the note taker will be checked.

4.2.3 Data management and analysis

All audiotape records and transcripts from each interview and FGD were transcribed verbatim in the Amharic language, which is the local and official language of the country and then translated to English by the linguistic expert. During the transcription process, two professionals independently ensured that the views revealed during the discussion were perfectly represented.

In this study, a thematic analysis was used. Familiarize researcher with data, generate initial code, search for themes, review themes, define and name themes, and generate reports (Braun & Clarke 2006: 87). At first, the researcher acquainted himself with the data by listening to all audio recordings. Then read and re-read the transcript before translation. The understanding and familiarity of the data helps us to construct the code. This was followed by the extraction of themes from codes and emergent ideas during the interview.

The more the same code appears in the text and the more important it is relative to the research question, the more likely it is to be considered a theme. Finally, the narration written by the researcher serves as a written comment, describing and connecting various theme, and answering research questions. In general, qualitative analysis was performed on both steps independently.

4.2.4 Topic guide

Before the interview, interview guides were developed for in-depth interview and FGD. The in-depth interview questions are as follows: Ten short answer questions for TB expert, TB patients and their household contacts were present and their responses were noted in brief. The questions were:

Interview

- Did you feel at risk of contracting TB at home?
- What does TB contact tracing mean?
- Has screening household contacts of TB patients have benefited you?
- What may improve people's participation in the TB contact tracing?
- What is the favorite method of communication during TB contact tracing?
- How do you see the current TB contact tracing approaches?
- What would you like to add to make an improvement on the current TB contact tracing approaches?

FGD

- What do you understand by the term household contact tracing of TB patients?
- How do you describe the current tracing system, practice, strategies and rate in the country in general and in your facility in particular?
- How is TB patients household contact tracing done in your facilities?
- What mechanisms at individual/ health facility level are you doing to improve the household contact tracing system?
- How has that helped to improve contact-tracing system?
- In your experience, how do you trace TB patients' household contact?
- When do you trace household contact tracing to TB Patients ?
- What do you do after initial tracing? How do you follow your patient? Is there any follow up mechanism?
- How do you monitor your work?
- What challenges are you facing in the household contact tracing system?
- What do you suggest to improve the household contact tracing system? What do you think is the effective way to practice the household contact tracing system?
- Is there something, you want to say regarding household contact tracing which is not raised and is believed to be very important before concluding?

4.2.5 Data presentation and discussion of the interview

4.2.5.1 Composition of interview participant

Of the 40 in-depth interview participants who were randomly recruited, 17 (42.5%) were index tuberculosis patients and 23 household contacts. All index cases were in the continuation phase of anti-tuberculosis treatment. Eighteen of the participants' were male. The average age of the participants was 26.4 years old, and the youngest and oldest ages were 18 and 37 years old respectively.

4.2.5.2 Thematic presentation of results

As described in the data management and analysis in this chapter, in-depth interviews were conducted with tuberculosis patients and their household contacts. The findings from interviews of patients and their contacts are presented in the thematic areas as indicated in table 4.1.

Table 4.1: Major themes and sub-themes of TB patients and their household contacts interview responses in Addis Ababa

Major themes	**Sub-themes**
Household contact investigation (HHCI) implementation	Household contact tracing delivery system
	Patient belief and preferences
Opportunities for HHCI provision	Presence of Community health program at the community level
Challenges with HHCI Approaches	Approaches issues
	HCW-related
	Patients related
Misconceptions on HHCI	Non-health seeking behavior
Strategies for effective HHCI	Community involvement
	Integration of HEW with health center staff
	Patient preferences
	Service provision

4.2.5.3 Presentation and discussion of results

Thus, the major themes and sub-themes that were synthesized from the result are presented and discussed. The presentation of data was also supported by narratives from the participants and it is described with the support of literature in the discussion section.

4.2.5.3.1 Household Contact Investigation (HHCI) implementation

On the discussion of issues of HHCI Implementation, the two namely the household contact tracing delivery system and patient belief and preferences emerged.

4.2.5.3.1.1 Concept of household contact tracing delivery system

TB screening among household contacts is increasingly framed as a potential remedy for improving TB case early detection and successful control of the disease. Many studies in diverse setting has shown that the success of intervention depends on its implementation and its acceptability by the community (Badane, Dedefo, Genamo & Bekele 2018: 533).

In cognizant with household contact tracing delivery system, the in-depth interview participants were asked about the implementation of TB patient's household contact tracing strategies, and the participants described the concept of household contact tracing in different ways and also adding the benefit of the tracing. It was described as the process of identifying close contacts of a TB patient, conducting TB screening, and managing contacts based on the screening results. If qualified, it also enables clients to receive preventive treatment.

"Health care providers look for close contacts and advise patients to bring household contacts when they develop symptoms to evaluate and screen for TB; then clients are followed up by undertaking different tests to determine whether clients need TB treatment or not."

"When TB patients are diagnosed, then they are accompanied by community care workers to visit the household contacts to get screening service at home. If the close contacts show symptoms, they will be referred by using documented referral papers to health facilities."

On the other hand, some participants expressed broad views regarding the concept of household contact tracing by emphasizing that household contact tracing system is not only screening for tuberculosis, but also it includes a more compressive approach starting from screening to the treatment of tuberculosis prophylaxis.

"In this health center, tuberculosis household contact tracing strategy is the process of identifying symptomatic contacts and letting them visit health facilities to evaluate them for tuberculosis and finally providing them preventive treatment if they don't have the disease tuberculosis."

"It is the way of diagnosing the disease early among contacts and additionally if the contacts have not developed the disease it also includes the provision of preventive treatment."

The benefits of the contact tracing strategy were stressed in the discussion of the concept of TB household contact tracing. The participants mentioned different benefits of household contact tracing strategy in the aspect of household contacts and for the benefit of the TB patients.

"During contact tracing, TB patients bring their household contacts to get screening service and also health education that will benefit the index cases by reducing stigma rising from the household contacts since they will acquire enough knowledge on the disease."

"TB is an infectious disease and household contacts have a high chance of acquiring the disease, so household contact tracing strategy enables us to detect TB early when

contacts screened for TB appropriately so, this is the main benefit of household contact tracing."

"As the health care worker gives preventive treatment to contacts this will prevent disease. And also when close contacts visit a health facility to get screening service they will also access better care and follow-up from TB Clinic, Moreover, they will get more knowledge on TB prevention."

Interestingly, few household contact participants indicated that they did not have any information regarding the concept of TB patient's household contact tracing.

"I don't know what TB Household contact tracing means."

In this study, the finding revealed that regarding the understanding of household contact tracing concept, the participants had relatively the same understandings despite a few who do not have any clue about the household contact-tracing concept. The participants' description of the concept of contact tracing ranges from screening and identifying case to more holistic meaning including the preventive treatment.

According to the Ethiopian Ministry of Health (EFMOH 2017b: 18), the systematic screening for active tuberculosis uses a sensitive algorithm based on tuberculosis symptoms to systematically identify people with presumptive tuberculosis among household contacts.

For patients who are screened positive, the diagnosis needs to be confirmed through rapid, sensitive diagnostic tests and other clinical evaluations. Moreover, Zellweger and his colleague remarks, these investigations require partnership and extensive resources and despite large investments by healthcare facilities and health departments, the yield of household contact investigations (HHCI) is often low in terms of successfully locating, evaluating, and treating contacts. Considering these issues, a new method of using HHCI more effectively and efficiently is needed (Zellweger et al. 2015: 1178).

There is also a huge difference in choosing effective methods between active cases and passive case finding methods for TB household contact tracing. Currently in sub-Saharan Africa, the tuberculosis epidemic is driven by HIV, which poses challenges for most tuberculosis control programs. In this case, actively looking for cases in the household contacts of tuberculosis patients known to be HIV-positive may be a method for early detection and treatment. In the end, this targeted strategy of proactively finding cases is more likely to be maintained in resource-limited national plans. The yield of case detection might also be higher and hence be of greater benefit to TB control (Adelman, Tsegaye, Kempker, Alebachew, Haile, Tesfaye, Aseffa & Blumberg 2015:1201).

4.2.5.3.1.2 Patient belief and preferences

In this study, respondents expressed numerous ideas about the household contact tracing delivery system. Unfortunately, 98.4% of the participated patients and their contacts stated that the delivery system of TB household contact tracing services should consider their situation.

"Sometimes I worry about getting the disease from my household contact (index case) and want to be screened but to get the service I have to go to the health facility which is relatively far from my home and they open on my working hours so it's difficult to go there and be tested since I have a job that is difficult to take a leave."

"My brother (Index case) told me to visit the health center to check my health status but it was difficult for me to go there because of transportation costs."

Previous studies identified patient-level preferences as one of the components for the successful implementation of household contact tracing approaches (Durlak & Dupre 2008:335). In this study, almost all of the interviewed TB patients and their household contacts said that the approaches should understand their preference.

"I desperately wanted to be screened but it's better for me to get the service here in my home because I can't go to the health facilities."

"I was not feeling good to bring my family for a checkup. They are all healthy so why I should put myself on extra cost for transportation and if it is a must I would love to get my family to be screened at my home."

Participants' perceptions and preferences were in contrast to the intervention approaches they got from the healthcare providers, which might affect the acceptance of the household contact tracing. In the study setting, the household contact tracing focused on passive case finding and the health care worker requested the symptomatic contacts to visit a health facility to screen for TB.

4.2.5.3.2 Opportunities for HHCI provision

4.2.5.3.2.1 Presence of Community health program at the community level

Majority of the respondents mentioned that the presence of Health Extension Workers (HEWs) at their respective woreda is a great opportunity for TB patients and their contacts that this can make health services more accessible. Participants considered that the presence of these cadres would let them to get TB screening service at their neighbors.

"The community members know HEWs in practicing mainly on health promotion and disease prevention activities so this makes it easy for the HEWs to do TB screening for TB patients' households at the community level."

In Ethiopia, the Health Extension Worker (HEW) model was created under the principle that if the right health knowledge and skills are transferred, households can take the responsibility of producing and maintaining their own health. Female nurses had been recruited at the woreda levels received training and become HEWs. They would receive one year of training on 16 health care packages. Their primary charge is to promote

health, including education, screening, prevention, and selective clinical interventions. HEWs are deployed in pairs, two for every kebele, receive mentoring and supervision from health officers stationed at the local health center. However, different studies conducted in this study area have shown that the involvement of HEWs in the TB program was weak (Getnet, Hashi, Mohamud, Mowlid & Klinkenberg 2017:8).

4.2.5.3.3 Challenges to effective HHCI

4.2.5.3.3.1 Approaches issues

World Health Organization (2013:87) recommends that household contacts of TB patients especially pulmonary TB patients should be screened and put on follow-up for at least a year by the health facility. However, in the study setting the assessment is only conducted at the baseline and depends on patients' voluntariness to bring their household contacts when they develop symptoms to the health facility (EFMOH 2017b:20). The participants mentioned the household contacts tracing implementation approaches in the study setting as a challenge.

"*I was told to bring my contacts as soon as they show TB related symptoms during the start of my treatment, but I fear my family would be infected after that also since I have been with them until now. And honestly I wasn't sure on the list of symptoms I should check for my family at that time."*

Moreover, the tracing of household contact approaches especially the passive case finding requires good knowledge of TB symptoms by patients and their household contact. In addition, many scholars agreed that the most vulnerable groups to acquire TB from contacts are children and elderly people but most of the time their manifestation is atypical which means it gives less chance to be identified early by TB patients or their contacts (Guirado & Schlesinger 2013:5).

"The nurse had told me to bring my children when they develop TB symptoms while I was on TB Treatment but I wasn't sure about the symptoms. After two months my younger child had a follow up for vaccination in the clinic and the nurse told me that my child shows TB symptoms. They requested laboratory and finally they diagnosed her with TB and put her on treatment. So I would recommend these approaches shouldn't rely on family or patients only."

4.2.5.3.3.2 HCW-related

In this study, the provisions of suboptimal service from health care workers were quoted as a challenge for HHCI effective implementation. The participants mentioned that, majority of the health institutions' tried to deliver quality of health care services however there were few complaints about the health education program and they recommend that it should be strengthened and given continuously.

"The service provided at this facility was good. However the time they spent on patient's education was not sufficient, timely monitoring and supervision are necessary."

Some of the participants said that the service given by medical staff in TB clinic was good and comprehensive and their HHCI was effective.

"I think there is no gap in providing household contact tracing at this health facility. I got good service and they follow my contacts health status. They also gave us an appointment for a check-up."

On the contrary, few participants said that the quality of household contact tracing services at health facilities is sub-optimal.

"They focus only on giving the tablets, and they don't give us enough information on the disease as well as contact tracing and the motivation of the health workforce is lacking passion."

4.2.5.3.3.3 Patients related

Participants explained that the effectiveness of passive household contact strategies is determined by the strength of health education and counseling process that is already discussed in the previous subthemes as well as TB patients and their household contacts commitments, as indicated in the following:

"If we conduct counseling properly for our household contacts as a health care worker said, we will control the disease by detecting cases early."

It was pointed out that despite the efforts of healthcare providers; few clients were reluctant to disclose their status to their household contacts. The reasons they cited were stigma and prejudice.

"The reason why I don't want to disclose my TB status is because of fear of stigma and discrimination from my household contacts. That is why I prefer to say nothing but I always keep my distance to prevent TB transmission to my household contacts."

The participants especially TB index cases also mentioned that even though they give information to their household contacts, the contacts had not volunteered to visit health facilities because of different reasons: Lack of awareness on the importance of HHCI, economic constraints, participants described some of the reasons for looking for alternatives such as holy water, stigma and discrimination. Studies revealed that external stigma, which is the social component had an impact on household contacts' motives to visit health facilities, which also, in turn affected the health seeking behavior. Misinformation or lack of information was found to be a possible reason for the lack of motivation to go to the medical facility. This is consistent with previous research, which pointed out that wrong information and insufficient information can affect clients' decisions about referral and care contact (Darko, Plange & Bator 2020:94).

4.2.5.3.4 Misconceptions on HHCI

4.2.5.3.4.1 Non-health seeking behaviour

The shortcomings of the national tuberculosis control plan, coupled with the common misunderstandings and misconceptions of tuberculosis patients, make the situation more complicated. These myths have turned TB into a social stigma. This stigma can play an important role in patients' reluctance to seek treatment. No tuberculosis control plan will be effective unless misconceptions among the community are detected and eliminated (Datiko, Habte, Jerene & Suarez 2019:11-13).

“My dishes and belonging were kept separate from rest of the family members this make me isolating from my households.”

“Majority of my community member and families were unaware that TB was not infectious after few weeks of treatment.”

Anxiety and isolation are the challenges of being diagnosed with tuberculosis. TB patients are exposed to a great deal of ostracism from the community and fear of social aversion. This stigma of tuberculosis patients in society may lead to their reluctance to seek treatment. In countries with a high burden of tuberculosis, studies have shown that many patients fail to disclose their condition to relatives and friends due to fear of discrimination (Sommerland, Wouters, Mitchell, Ngicho, Redwood, Masquillier, van Hoorn, van den Hof & Van Rie 2017:84). Health education must be based on existing scientific knowledge and conducted in a way that is easy for patients to understand and accept. Social and cultural factors must be considered because they play an important role in the compliance of TB patients.

4.2.5.3.5 Strategies for effective HHCI

4.2.5.3.5.1 Community awareness

Various researches in different countries have shown us a number of factors associated with improving the participation of household contacts on TB household contact investigation delivery. In this research, the interviewees voiced different thoughts on how to improve the participation of contacts during household contact tracing. Patients expressed their feelings concerning contributing factors associated with effective household contact tracing strategies as follows.

"It's all about community awareness toward TB. I remember when I advised my family to visit the clinic for TB screening. The first thing they fear was stigma and discrimination from the community; so community awareness creation plays a vital role to increase contact participation during contact investigation."

4.2.5.3.5.2 Patient preferences

As reflected in the discussion, the implementation of TB household contact tracing is fixed, especially after being diagnosed as a TB patients, it does not allow the flexibility to change the location of your contact tracing and follow-up. Once the patient registered and started treatment, they would be asked to bring symptomatic contacts to the facility without brief education and asking for their preferences and circumstance in the most all of the health facilities. This may hamper the relationship between the medical staff and the patient, thereby creating obstacles to one-on-one patient consultation, education, and comprehensive tracking of the prognosis of patients and their household contacts.

"The minute the patient starts the TB treatment in the health center, they will be asked to bring his or her household contacts for TB evaluation without enough explanation."

In order to improve these conditions, participants suggested that daily health education and contact tracing should be considered. Patients' preferences can progress the motivation of TB patients, and their contacts to participate in contact investigation.

“The health care workers should make the services more flexible like for example let us get the service in our home or rearrange their working time to fit our availability. If they do these I assure you that household contacts participation for contact investigation strategies will be improved.”

4.2.5.3.5.3 Service provision

Previous studies identified provider-level barriers for implementing TB patient's household contact tracing in developing countries and these include health care worker motivation, staff communication, increased workload and work-related stress (Darko et al 2020:94). In this study, interviewed TB patients and contacts listed the list of services they expected from a health care worker that could improve contact participation as follows.

“*They did not give us enough knowledge. They just told us to take our contact to the medical institution without sufficient advice. So, if they provided us detailed information about the concept and benefit, it would have enabled us to convince our contacts and to bring them to the clinic.”*

“*I have observed weakness in their advice and education; for example, I haven’t been informed of anything about my household contacts until now, I did not know that I have to bring my contacts for TB Evaluation.”*

4.2.6 Presentation and discussion of the focused group discussion (FGD)

4.2.6.1 FGD participant composition

As it has been described in the introduction section of this chapter, three FGDs were held with eight health care workers in each session.

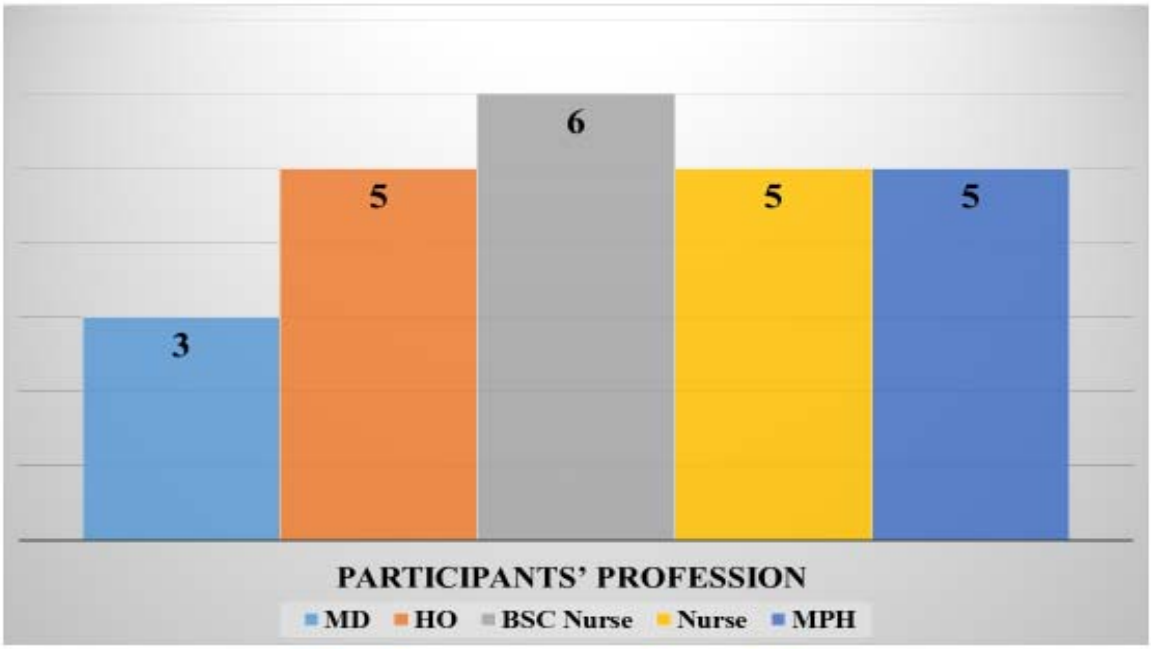

Figure 4.1: Participants' profession for Focused group discussion

Among the purposively recruited 24 FGD participants, 14 (58%) were female and all of the FGDs participants had TB related work experiences ranging from 2 to 35 years with an average of 10 years. Five (21%) of the FGD participants had Masters and 14 (58%) had a Bachelor's degree.

4.2.6.2 FGDs Themes

Six themes were identified in the FGDs, the themes were:

- Issues of household contact practice
- Issues of household contact tracing delivery system

- Issues of health care providers and clients role
- Issues of reasons for not seeking HHCI services
- Issues of partnerships and health bureau
- Strategies for effective HHCI service

Table 4.2: Major themes and sub-themes of FGDs participants in Addis Ababa

Major themes	**Sub-themes**
Household contact tracing practice	Concept of household contact tracing
	Current status of household contact tracing
Household contact tracing delivery system	Approaches
	Integration with community health program
Health care providers and clients role	Health care providers' responsibilities in household contact tracing
	Client issues
Reasons for not seeking HHCI services	Lack of awareness from patients and families
	Providers' knowledge
	Economic issue for Transportation
Issues of partnership and health bureau	Government commitment
Strategies for effective HHCI service	Capacity building of HCWs
	Community empowerment
	Integration of community and facility health care workers

4.2.6.3 Presentation and discussion of results

4.2.6.3.1 Household contact practice

In Ethiopia, systematic screening of active tuberculosis (TB) is recommended for household contacts. Household contacts are people who live in the same household with the tuberculosis patient, so they are at greater risk of contracting TB. A person who works

in a confined space with a TB patient, especially in a closed environment, may be considered a contact and is at an increased risk of TB infection (EFMOH 2017b:18).

According to a report by the World Health Organization (2012:13), many studies in countries with a high incidence of tuberculosis indicate that the prevalence of tuberculosis among contacts of tuberculosis patients may reach 5%, especially among household contacts. Hence, WHO recommends systematically and actively investigating tuberculosis infection and disease in household contact with tuberculosis patients.

The main requirement for the successful implementation of this policy is to change behavior at the level of the health system, healthcare providers, and contacts and their families. By considering this requirement, we discussed with the selected health care clinicians and program managers who monitor and supervise the TB program in the country as well as the study sites.

During the discussion of household contact practice issues with the FGDs participants in this study, the two subthemes emerged

- Concept of household contact tracing
- Current status of household contact tracing

4.2.6.3.1.1 Concept of household contact tracing

Participants described the concept of household contact tracing as the systematic process of identifying contacts exposed to cases of infectious tuberculosis disease then assess for infection with mycobacterium tuberculosis and tuberculosis disease in order to provide appropriate treatment either for latent tuberculosis or for tuberculosis disease.

"Household contact tracing is not only contacts identification; it also entails assessing contacts for Latent Tuberculosis *infection or TB disease, and following them through completion of treatment, as necessary."*

"The systematic identification of people with TB presumptive in household contacts and diagnose cases by using tests, examinations, or other procedures that can be applied rapidly."

The participants also discussed the objectives of household contact tracing focusing on individual, community, and at a country level.

"Household contact tracing and management ensure us early detection and initiation of appropriate treatment for the identified TB cases and I think these are the goals of the intervention at an individual level."

"Effective contact tracing strategy warrants that contacts with infectious TB cases can have access to medical evaluation and appropriate preventive treatment before they develop the active disease and hence reduce the burden of TB disease at community and country level."

Participants also have discussed on the core concepts and skills required to conduct TB contact investigations, mostly apprehended concepts by the participants included:

- Knowledge of TB transmission
- Knowledge of TB pathogenesis
- Difference between LTBI and TB disease

Additionally, participants also expressed their view on the choices of household contact approaches. The majority of participants said it should be an active search by health care workers in the targeted community to identify cases, whereas few said the patient's household contacts should come to health facilities to be screened when they develop symptoms. The World Health Organization defines household contact tracing as the process of finding cases of tuberculosis among people who are in close contact with the index case (WHO: 2019:1).

4.2.6.3.1.2 Status of household contact tracing

The discussion of the status of household contact tracing in the study setting includes its implementation approach in health facilities and the current practice by medical staff workers. Even though the majority of the participants recommend active case finding for household contact tracing, almost all of them have been implementing passive case finding.

“The household contact tracing program in our health center focuses on the process of screening household contacts for TB when they voluntarily present themselves in the clinic by having symptoms.”

“In our health facilities, we try to screen household contacts for active TB predominantly provider-initiated. It targets household contacts who do not seek health care because they do not have or recognize symptoms, or they do not perceive that they have a health problem that warrants medical attention, or because there are barriers to accessing care, or for other reasons.”

4.2.6.3.2 Household contact tracing delivery system

4.2.6.3.2.1 Approaches

The participants described their experience on the implementation and achievement of household contact tracing delivery, they all agreed that generally, household contact tracing in the health facilities was not yielding additional tuberculosis cases as expected, which was the main objective of TB contact tracing strategy among household contacts of TB patients. They agreed in principle that, passive case finding among contact is the main reason for the failure of this intervention.

"I don’t think the program is on the right path to the level of achieving its objective, particularly identifying cases early. The main reason is that the approaches we have been

implemented relying on patients' voluntariness to bring their families to facilities for screening."

It was further indicated that difficulty of attainment regarding improved case finding could be due to implementation of the passive case finding approaches that only focus on the baseline. It was a one-time activity and it obliged TB patients' household contact to attend health facilities for screening.

"It's known that the burden of undetected TB is high in household contacts. Many people with active TB do not experience typical TB symptoms in the early stages of the disease. These individuals are unlikely to seek care early, and may not be properly diagnosed when seeking care. Passive case-finding, therefore, leads to missed or delayed diagnoses for many people."

Additionally, concerning the implementation, the participants mentioned that not only using passive approaches renders its achievements but also the absence of a follow-up system for contact tracing makes the case finding approaches less effective.

"We have been screening household contacts for TB but it depends on patients' voluntariness and, we conducted the screening at the baseline only without any follow-up. I think this makes the yield of TB cases among contacts to be less, that is not in line with many of the research which shown us that a high number of TB cases can be identified early among contacts."

4.2.6.3.2.2 Integration with community health program

In most of the discussion with the health care workers, almost all of the participants stated that the presence and readiness of the community health care workers in the study setting area could have made it easy for narrowing a gap between the community and health facilities by bridging between the two stakeholders for most health-related activities. However, the FGDs participants complained, the Health Extension Workers (HEWs) did

not engage in TB related activities as expected and so the communities did not get the services they were meant to get.

“HEWs would have been a great opportunity if we had let them do their jobs. In our health center, the integration between health care workers and community health care workers is to implement TB patient's household contact tracing strategy has not been functional.”

“Most of the time the HEWs spend their time doing activities other than a health-related work. They spend their time on working on political mobilization. Because of this, they are now be unable to remember their skills.”

Loosen communication with health extension workers was one of the challenges mentioned by participants. This is said to be one of the reasons why proper contact investigations are not provided, especially the proactive. This finding is congruent with a study conducted in a different part of Ethiopia; where the results indicated that weak communication between TB clinic health care workers and HEWs let the planned task implemented less effective than expected especially in an urban setting (Getnet et al 2017:7).

“One of the big problems is providers’ gaps on communication with community health extension worker concerning household contact tracing. As a project, when health extension staff participated in contact tracing at a specific time in the pilot area, we have achieved a lot. However, for routine work, they have less communication with tuberculosis clinics and less participation. ”

4.2.6.3.3 Issues of health care providers and clients

During the discussion of health care providers and clients' issues, the concept of health care providers’ responsibilities in household contact tracing and the concept of client issues emerged.

4.2.6.3.3.1 Health care providers' responsibilities in household contact tracing

The participants listed some responsibilities that should be implemented by health care providers for an effective implementation of the TB case finding system among household contacts. Some of the duties that health care providers should perform are to counsel and educate patients about tuberculosis, identify close contacts, actively screen them, and manage symptomatic household contacts as guiding recommendations.

"Our responsibility is to inform TB patients to bring their symptomatic household contacts then we evaluate them for TB. If TB is diagnosed, we will put them on anti-TB treatment, and give them appropriate information about the follow-up and treatment."

"The good experience in our facility that recently we started for the health care workers is to accompany community health care workers when visiting patients' homes to screen household contacts and to link them to a health facility if they needed further investigation. By doing so, the household contacts and the TB patients had trust in the service, and their adherence to the service was also high since we bring the service to their home. In addition to this, we also provided detailed information about the methods of transmission and prevention of the disease."

The findings indicated that there are two different approaches practiced by a health care worker, majority of health care workers do contact investigation passively which relies on TB patients with bringing their symptomatic household contacts, and some health facilities conducted contact tracing by visiting household contacts at their homes. However, participants mentioned that healthcare providers encountered many challenges when conducting contact surveys.

4.2.6.3.3.2 Clients' issues

The findings showed that TB patients were a central part of household contact strategies since most of the facilities implement a passive approach, which depends on patients' voluntariness to identify their contact, give information to their contacts, advise them to visit health facilities and to get care treatment and support services. During the discussion, the health care workers put client issues as major issues for the effective implementation of household contact tracing strategies. Participants explained that the effectiveness of the household contact strategy depends on the intensity of the counseling process, the status of the patient and their household contacts, and the level of awareness, as shown below:

"If we counsel TB patients appropriately, we will not miss symptomatic contacts."

It shows that even if healthcare providers put some efforts, some contacts do not want to visit medical institutions. Issues of alternatives, economy, stigma, and prejudice were some of the reasons for not visiting health facilities.

"Contacts don't want to visit health facilities since they don't want to spend their time on checkup and some have financial constraints to afford transportation costs."

Participants mentioned that some TB patients are reluctant to reveal their TB status to their household contacts due to stigma, which has had a huge impact on the implementation of household contact tracing programs. The tuberculosis community has always recognized the stigma surrounding this disease, but little effort has been made to face this challenge. People who have tuberculosis or are considered to have tuberculosis continue to receive an abusive language (e.g., 'TB suspects', 'defaulters').

"Some TB patients declined to disclose their TB status to their contact due to fear of stigma and discrimination from their household member."

Patients' beliefs are a major factor effecting the tuberculosis intervention program. However, there has been little custom in shaping the pathway effect of patients' beliefs on the TB program.

"Household contacts sometimes prefer to get service from hospitals. Clients have a misperception that hospitals have high technology equipment's and qualified professionals to manage their problems."

4.2.6.3.4 Reasons for not seeking HHCI services

4.2.6.3.4.1 Lack of awareness from patients and families

Lack of awareness and enough knowledge on signs of tuberculosis, TB screening importance, the need of TB screening for the persons who had or have close contact with diagnosed TB patients were some of the encounters cited by the group of participants as factors for low utilization of the TB household contact tracing service. Sometimes people in close contact with TB patients refuse to go to a medical facility, even if the index case tells them to do so.

"There are problems from the community to visit facilities though they have close contact with TB patients."

"Patients don't disclose their health status to their household contacts because of fear, discrimination and isolation socially, particularly in families."

"While TB is one of the most common diseases in the country, it is also one of the most misunderstood diseases with many misconceptions surrounding it. It is therefore important to create awareness, and bust the myths surrounding the disease to tackle and prevent it."

Researchers have also shown that there is insufficient awareness or knowledge of tuberculosis and patient-centered services in areas with a high burden of tuberculosis (Huddart, Bossuroy, Pons, Baral, Pai & Delavallade 2018: 13). Knowledge and attitudes related to tuberculosis vary from place to place, ranging from the understanding of the cause of the infectious disease to misconception on the cause of the disease, from the support of the patients to the point of view that is seriously stigmatized. TB patients', adequate knowledge and positive attitudes are expected to contribute to improved healthcare-seeking behavior (Badane et al 2018: 536).

Fear of discrimination may mean that TB patients will delay or even completely refuse to inform their household contacts of their TB status, making their close contacts more likely to be infected. The stigma around TB can also make people reluctant to stick with their course of treatment over the many months this is due to fear of being 'found out'. By taking treatment irregularly, people may develop drug resistance (Cremers et al 2015: 10).

4.2.6.3.4.2 Providers' related

They mentioned the knowledge gap among care workers and the lack of clear service delivery manuals. Health care providers were busy with routine tasks; furthermore, participants mentioned the lack of health care providers' motivation to work, improper data recording and the high turnover of the staff as challenges.

"*We have faced multiple challenges and some of them are: low staff motivation, high staff workload; because of this, staff is usually providing suboptimal services."*

Again, the majority of health care workers reported the absence of a clear manual for contact tracing investigation as a major challenge for effective delivery of the program and recommend having such guidelines from the ministry of health. The lack of well-trained medical staff and the high turnover rate are common phenomena throughout the organization.

A study conducted in a high-burden country showed that despite regional differences, labor shortages, lack of qualified clinicians, and turn over of health care providers are the main challenges in implementing contact tracing activities (Ayakaka, Ackerman, Ggita, Kajubi, Dowdy, Haberer, Fair, Hopewell, Handley, Cattamanchi & Katamba 2017:11).

Evidence has shown that gaps in providers' knowledge about TB contribute to suboptimal care. In addition to that, inappropriate identification and selection of contacts can lead to incomplete CIs (Sima, Belachew & Abebe 2019:8). In order to obtain all the information from the index case during CI, the provider must establish trust and rapport. However, current national guidelines lack guidance on how tuberculosis control staff can establish rapport with cases during interviews.

4.2.6.3.4.3 Economic issue for transportation

As part of the reasons for not seeking HHCI services, the cost related to health facility visits were also discussed. The economic constraints of transportation were one of the challenges mentioned by the panelists as a factor that contributed to the low utilization of access services for TB patients.

"I had few patients who couldn't bring their household contact and the main reason was economical constraint."

It is generally believed that tuberculosis (TB) is mainly a disease of vulnerable groups. In the past few decades, the global tuberculosis program has been trying to meet the needs of poor and marginalized people by promoting poverty alleviation strategies in tuberculosis control programs (WHO 2005: 352). International standards insist on providing free tuberculosis diagnosis and treatment services. Nevertheless, TB patients and their families often face severe financial burden by spending a great deal of out-of-pocket expenses before and during treatment (Tanimura, Jaramillo, Weil, Raviglione & Lönnroth 2014:1770).

Free TB services help to reduce direct medical costs paid by the patients and their families. In reality, however, there are other hidden costs, such as direct non-medical costs, such as food, transportation, and accommodation costs, as well as indirect costs, loss of income and reduced productivity (Ukwaja, Alobu, Lgwenyi, and Hopewell 2013: 7).

A recent systematic review that involved 49 studies from 32 low and middle-income countries (African countries including Ethiopia and Asian countries with some Latin American countries) revealed, “indirect cost accounted for 60% of the total cost faced by patients across 25 surveys that provided the disaggregated data, constituting the largest financial risk for patients. The total of direct and indirect costs can significantly be equivalent to 39% of reported household income. The financial barriers to accessing TB services is often coupled with geographical and health system barriers, contribute to delayed diagnosis, leading to more advanced disease and continued transmission, and resulting in poor health outcomes and further aggravating poverty for the patient and affected household” (Tanimura et al 2014:1773).

4.2.6.3.5 Issue of partnership and health bureau

4.2.6.3.5.1 Government commitment

The participants pointed out that implementing partners were supporting the household contact tracing system through capacity building, mentoring, and logistics. However, with the phasing out of implementing partners, support was interrupted. It was indicated that the partners supported the provision of quality and standardized services in collaboration with regional health bureaus through building the capacity of health care providers by providing training, refresher training and mentoring, and supportive supervision of every quarter and providing them with feedback to improve their quality of services.

“The health bureau supports us, service is still provided although it is not as active as the time partners provided and limited provision.”

“The ministry of health in general and regional health bureau, in particular, did not give due emphasis on the contact tracing strategies.”

The WHO developed a guiding document for TB Contact investigation (CIs) to guide national TB program staff and all agencies and organizations involved in TB prevention, care, and control. Despite WHO’s (2013:1) strong recommendation on household contact investigation, in Ethiopia there is no clear guideline on how to implement and follow household contact tracing for tuberculosis patients. Different partners working on TB program had started implementing different contact investigation activities on selected sites and let the government system to take over it.

4.2.6.3.6 Strategies for effective HHCI

4.2.6.3.6.1 Capacity building of health care workers (HCW)

In order to implement and obtain effective results on the household contact-tracing program for TB patients, the medical staff should be equipped with the necessary knowledge and resources. The participants in focus group discussions mentioned frequently the need of guidelines on how, where, and when to implement HHCI is critical, but until now, health care workers try to solve these problems by themselves, resulting in a lack of uniformity and consistency throughout the study area.

“I monitor and supervise six public health centers and all of them try to implement by themselves differently. There is no uniformity and it depends on the TB clinic focal person. This implement the program’s inconsistency since the TB focal person is changed every year. Hence there should be guideline on how to implement HHCI.”

Participants stated that it is indispensable to carry out continuous training and update on the latest development of TB HHCI. In addition to continuous exertions to advance the awareness and skills of medical staff, participants also pointed out that it is necessary to continuously monitor and supervise the implementation of HHCI services.

“By giving training, professionals can develop their knowledge and get timely information. But, there should also be a system to monitor and evaluate their implementation of HHCI according to WHO standard.”

4.2.6.3.6.2 Community empowerment

The participants expressed community empowerment as a critical component to ensure proper HHCI implementation.

“*To have a successful implementation of a program the endpoints should accept the program that will be implemented.”*

“What makes the community accept the intervention is their involvement in the identification and addressing of the problem by considering their situation.”

“To implement any household contact tracing strategy we must involve TB patients, their household contact, and finally the general community. “

Different studies have shown us that acceptance of the intervention has a positive impact on the desired outcome. To be accepted by the community, the intervention should be prepared with the involvement of the target population that maximizes their acceptance (Alipanah, Jarlsberg, Miller, Linh, Falzon, Jaramillo, & Nahid 2018:18). They also discussed the importance of social mobilization, which enables us to bring together all feasible and practical inter-sectoral allies to raise people’s knowledge and demand for good-quality TB care. It also helps to mobilize resources and services, and strengthen community participation to achieve sustainability.

“Social mobilization is important to create community commitment to participate in TB control and prevention within the context of the community. Major target audiences of social mobilization should be religious leaders, and social networks.”

4.2.6.3.6.3 Integration of community and facility health care workers

Respondents highly pointed that the presence of HEWs program in the community as an opportunity for effective HHCI strategies, but they also pronounced that the poor integration between TB clinic staff and community health care workers is a gap for the HHCI implementation. They highlighted that integration is mandatory between the two stakeholders to detect TB cases early among household contacts.

“Community health workers can play a pivotal role in community-based TB care. They can serve as a link between the patient, communities, and formal health systems.”

“Community health workers (CHWs) can conduct home-to-home visits for contact tracing, advocate for improved TB programs; serve as health educators, case detection, and following up on treatment interruptions.”

Community-based TB Care (CBTC) is a working partnership between the health sector and the community in the prevention and care activities of TB. Communities’ involvement in TB control aims at enabling the public to produce its own health through health extension program package (EFMOH 2017b:131). The implementation of CBTC is the collective responsibility of all stakeholders, including political and health managers, medical staff, health promotion staff, and the entire community. The CBTC package is one of 16 health extension packages implemented at the woreda level and in the community (EFMOH 2017b: 174).

4.3 SECTION TWO

QUANTITATIVE DATA ANALYSIS, PRESENTATION AND DISCUSSION

4.3.1 Introduction

In this section, the quantitative data findings are discussed in comparison with the two groups that participate in the study. The section starts with an introduction, subsequently the methods implemented during data collection, handling, and analysis are presented, and then describes the findings under sub-topics. This chapter summarizes the main findings of quantitative data. The goal of this study was to develop guidelines in endorsing framework of community-based TB patient's household contact tracing approaches in Addis Ababa.

The research objective for quantitative design was to determine the yield of community-based contact investigation in the households of patients with bacteriological confirmed pulmonary tuberculosis in Addis Ababa compared with passive case finding. In the following section, the quantitative findings that address the above-mentioned objective were presented.

4.3.2 Data collection and handling

The pre-tested questionnaire consists of closed questions and is used to collect data on tuberculosis patients and their household contacts. The questionnaire consists of four parts: socio-demographic, lifestyle, clinical, family characteristics and tuberculosis screening.

4.3.3 Data analysis

Data analysis is the process of checking, cleaning, transforming and modeling data to discover useful information, provide conclusions and support decision-making (Xia & Gong 2014: 310). Saunders et al. (2018: 1902) described data analysis as the ability to decompose data and clarify the nature of factors and their relationships. Therefore, the purpose of data analysis is to respond to research questions or research goals. According to Srivastava and Klassen (2016:16), a plan for data analysis comes from the research objectives, research design, methods of data collection used, and measurement of data. The following subsections introduce the principles of data analysis used in this study.

4.3.3.1 Statistical analysis program

Data were analyzed using the 26 version of statistical package of social science research using descriptive statistics and inferential statistics. A statistician was hired to assist the researcher in analyzing the data. A p-value of less than 0.05 was set as the level of statistical significance for the tests performed.

4.3.3.2 Data cleaning, checking for completeness and consistency

Zhang (2017:16) describes data cleaning as “the process including format checks, completeness checks, reasonableness checks, limit checks, review of the data to identify outliers (geographic, statistical, temporal or environmental) or other errors, and assessment of data by subject area experts.”

In this study, the data was cleaned manually and electronically during collecting, entering, and analyzing the data. Completeness and consistency of each of the questionnaires were checked before analysis. In the final analysis, all incomplete or inconsistent data in this field were discarded.

4.3.4 Participant enrolment

A two-year study was conducted from April 23, 2018 to March 30, 2020. This includes a one-year enrollment period and a one-year follow-up period. Between April 23, 2018 and March 30, 2019, 24 directly observed short-term treatment (DOTS) public health centers from the Addis Ababa region recruited 320 indexed cases and 610 household contacts.

After selecting twenty-four public health centers, a number of TB patients proportionally allocated based on the year 2017 annual bacteriologically confirmed pulmonary TB caseload. Then from each health center, the newly diagnosed consecutive patients were randomly assigned into two groups either the intervention or the control group. One hundred and sixty selected and volunteer index cases were enrolled in each group. Three hundred and fifty household contacts in the intervention group and 260 in the control group identified, eligible, and enrolled in the study. There were 350 household contacts in the intervention group, and 260 household contacts in the control group were identified, eligible, and participated in the study.

A total of 930 persons approached, of this number 320 were index TB patients from intervention and control groups, 350 and 260 were household contacts identified from intervention and control groups respectively. Of the 610 household contacts recruited, 596 (97.7%) completed the one-year follow-up. The completion rate of the two groups was almost the same, 97.7% among intervention group, compared with 97.6% among the control group over the same period. Three (0.5%) of the participants died during the one-year follow-up period, and 11 (1.8%) were lost to the follow-up. (See figure 4.2)

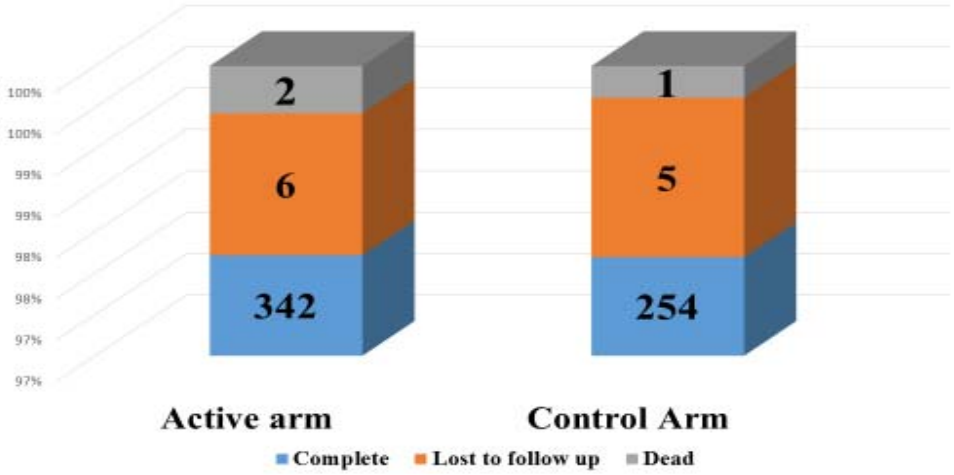

Figure 4.2: Follow up of the study patients

4.3.4.1 Recruitment Period

Participants were recruited between April 23, 2018 and March 30, 2019, and the one-year follow-up ended on March 30, 2020.

4.3.4.2 Procedures

A Household Contact was a person who shared the same enclosed living space for one or more nights, for frequent or extended periods during the day with the index case during the three months period before commencement of the current treatment episode (WHO 2012:28). If a contact is receiving or awaiting treatment for tuberculosis at the time of recruitment, the contact is not eligible. In the study area, in accordance with the national policy at the time, isoniazid preventive treatment was regularly provided for contacts aged 5 years and under. So, the researcher restricted the investigation to contacts aged 5 years or older because in this setting, younger contacts might receive preventive treatment and are often treated for tuberculosis empirically, which will confound the interpretation of tuberculosis diagnosis in children.

4.3.5 Outcomes

The primary outcome of the study was tuberculosis diagnosis among household contacts. All participating contacts underwent either intensified active case finding or the routine passive case finding; depends on their enrolled group. For patients and their contacts from interventional group, we did intensified active case finding while for clients from control group we implemented the routine programmatic passive case finding approaches.

4.3.6 Intensified active case finding

Nurses at the tuberculosis clinics worked with community health care workers to recruit volunteer tuberculosis patients. Nurses have conducted interviews using pre-designed questionnaires to collect basic information about address, age, education level, total number of houses, size of houses, household income and smoking habits. Based on the primary interview with the index patients, primary visits at their homes were carried out.

Nurses and community health care workers from the tuberculosis clinic visited the households during the recruitment period, and then again at the end of the third, sixth, ninth, and twelfth months. During these visits, the nurses educate the households on tuberculosis transmission and prevention methods, and provides active tuberculosis screening for all participating household contacts. This includes tuberculosis screening and free sputum examinations to check for any tuberculosis symptoms, such as two weeks of cough and cough type (not related to productivity), fever, night sweats, weight loss or chest pain. Collect sputum samples on the spot at their own home.

If the test was provided on the site, Xpert MTB/RIF will test the provided samples. For those health centers where the test were not available, the samples were referred to the nearest sites. The Xpert MTB/RIF tools is a new test that contributes to the rapid diagnosis of tuberculosis and drug resistance and is revolutionizing tuberculosis (TB) control. The

test can simultaneously detect resistance to Mycobacterium tuberculosis complex (MTBC) and Rifampicin (RIF) in less than 2 hours.

For a contact who was not present at the time of an active case-finding visit, a second home visit was made. If the contact missed for the second time, another family member on behalf of the person completed the screening question and sputum pots were left with instructions and were collected 24 hours later.

4.3.7 Routine programmatic passive case finding

During the study period, implementation guideline for tuberculosis activities in Ethiopia recommended passive TB case finding for household contacts, which principally involved clinical assessment and sputum Xpert MTB/RIF assay test. Investigation for tuberculosis typically was initiated among individuals presenting to health center with cough for longer than 2 weeks.

The national guidelines recommend collecting one spot sample from contacts with cough for longer than 2 weeks, chest radiography not recommended and was rarely and only done for contacts at the discretion of the assessing doctor (EFMOH 2017b:21). This programmatic passive case finding approach was not influenced by our study. Household contacts in the control group provided general information about the typical symptoms of tuberculosis. When they developed these symptoms, they were advised to report to the tuberculosis department of the nearest health center.

During the study period, self-referring contacts with TB symptoms, who were participating in the study, had one sputum specimens transferred to the laboratory for xpert, in addition to any routine diagnostic procedures. This allowed comparison of rates of confirmed TB between intervention and control groups. Contacts diagnosed with tuberculosis in both groups received standard treatment for TB through the NTCP.

4.3.8 Index Patients

Among eligible patients who attended the selected health facilities during the study period, 320 index TB patients were recruited 160 in the intervention and control group and the demographic profile of the index cases in the two groups is shown in table 4.3. There were more women in the index cases in the intervention group and more men in the gender distribution in the control group, although the difference was not significant. The mean and SD of TB patients age in the interventional group was 23.3 ± 8.9 years, the youngest was 18 years old and the oldest was 76 years old; where, in control group it was 26.8 ± 9.9 years with youngest and oldest age of 19 and 81 years respectively.

In the intervention group, index patients had cough for 38 days before diagnosed with PTB compared with 40 days in the control group. All index cases received HIV pre-test counselling; 98% underwent HIV testing and received post-test counselling. HIV status was not known for six patients who had refused HIV testing. In the control cohort, 32 of 160 tuberculosis patients (20%) were HIV-positive, while in the intervention cohort, 21% of tuberculosis patients were HIV-infected.

Table 4.3: Demographic profile of the index cases (N=320)

Characteristics		Intervention		Control	
		Index patients 160 Pt		Index patients 160 Pt	
		No	%	No	%
Age group in year					
	<18	0	0%	0	0%
	18-29	65	40.6%	57	35.6%
	30-44	43	26.9%	40	25%
	45-59	24	15%	36	22.5%
	>60	28	17.5%	27	16.9%
Sex	Male	73	45.6%	86	53.8%
	Female	87	54.4%	74	46.2%

HIV Status				
NR	127	79.4%	121	75.6%
R	30	18.8%	33	20.6%
Unknown	3	1.8%	6	3.8%
Religion				
Orthodox	61	38.1%	55	34.4%
Muslim	45	28.1%	42	26.2%
Protestant	46	28.8%	49	30.6%
Other	8	5%	14	8.8%
Marital status				
Unmarried	69	43.1%	72	45%
Currently married	73	45.6%	75	46.9%
Other	18	11.3%	13	8.1%
Income Yes	123	76.9%	118	73.8%
No	37	23.1%	42	26.2%

4.3.9 Household Contacts

4.3.9.1 Sociodemographic status

The 320 index patients reported 610 household members were living with them; 350 in the interventional group and 260 in the control group. The two groups were similar concerning the characteristics of the participants, which included age, sex, and educational status, as shown in table 4.4. The age distribution of household contacts between the two groups was almost similar. 51.7% of the household contacts in the active group were between 18 and 29 years old, while 56.9% of contacts in the control group were of the same age group.

In intervention group, there were more female respondents. Whereas in control groups the total number of females equals to the number of male respondents. Most of the respondents were educated (more than grade 12) with a proportion of 65.7%. Based on

the statistical test, the p-value of these variables was reported to be >0.05, which indicates that the distribution of respondents was similar in the intervention and control groups.

Table 4.4: Sociodemographic characteristics of the household contacts (N=610)

Characteristic		Group		P-Value
		Interventional 350	Control 260	
Age in years	5-18	34(9.7%)	20(7.8%)	0.70
	18-29	181(51.7%)	148(56.9%)	
	30-44	72(20.6%)	51(19.6%)	
	45-59	48(13.7%)	33(12.7%)	
	>60	15(4.3%)	8(3.1%)	
Sex	Male	162(46.3%)	130(50%)	0.364
	Female	188(53.7%)	130(50%)	
Educational level				
	None	2 (0.5%)	5(2%)	0.621
	Read & write	15(4.3%)	10(3.8%)	
	Grade 1-6	8(2.3%)	10(3.8%)	
	Grade 7-8	27(7.7%)	15(5.8%)	
	Grade 9-12	66(18.9%)	51(19.6%)	
	Grade 12+	232(66.3%)	169(65%)	
Income	Yes	281(80.3%)	201(77.3%)	0.372
	No	69(19.7%)	59(22.7%)	
Marital status				
	Never married	199(56.9%)	130(50%)	0.526
	Currently married	123(35.1%)	104(40%)	
	Divorced	3(0.8%)	5(1.9%)	
	Separated	7(2%)	4(1.6%)	
	Widowed	18(5.2%)	17(6.5%)	

4.3.9.2 Health Status

Health related factors did not differ significantly between the two groups. By observing whether there is a BCG scar in the left or right deltoid area of the arm, it was evaluated that nearly 94% of household contacts in the intervention group, and 95.4% of the control group received BCG vaccination p=0.548. HIV status was also found to be comparable between the two groups. More than 79% of household contacts did not know their HIV status in total, 81.7%, and 76.5% in interventional and control groups respectively. Based on the chi-square test, the diabetes status between the treatment and control groups were similar ($p > 0.05$)

Table 4.5: Health related characteristics of the household contacts (N=610)

Characteristic		Group		
		Interventional 350	Control 260	P-Value
HIV Status	Unknown	286(81.7%)	199(76.5%)	0.179
	Non-Reactive	53(15.1%)	46(17.7%)	
	Reactive	11(3.1%)	15(5.8%)	
BCG Vaccination	Yes	330(94.3%)	248(95.4%)	0.548
	No	20(5.7%)	12(4.6%)	
Smoking status	Current	36(10.3%)	25(9.6%)	0.865
	Former	5(1.4%)	6(2.3%)	
	Non	309(88.3%)	229(88.1%)	
Drinking status	Current	70(20%)	51(19.6%)	0.951
	Former	13(3.7%)	12(4.6%)	
	Non	267(76.3%)	197(75.8%)	
Diabetes Malthus	Yes	8(2.3%)	7(2.7%)	0.94
	No	342(97.7%)	253(97.3%)	
Previous history of TB	Yes	5(1.4%)	8(3.1%)	
	No	345(98.6%)	252(96.9%)	0.173

4.3.9.3 Household contact status

The average number of household contacts per household of index cases in the control and intervention groups was 1.6 and 2.2, respectively. In the interventional group, household contacts reported to have spent an average of 12.1 hours per day with the index patients during the index cases infectious period while the participants from the control group reported 11.6 hours. The infectious period for the index case is set at three months before the initiation of treatment rather than relying on index case recall from the time symptoms began. The 3-month period is a general WHO cutoff point (WHO 2012:28).

4.3.9.4. Outcome

The prevalence of tuberculosis among household contacts was the primary outcome. In the active contact-tracing group, 350 contacts from 160 TB index patients were screened for TB. In the one-year follow up on quarterly basis, among the 350 contacts, 342 completed the follow up and 185 symptomatic were identified through home-to-home visit, 170 provided a sputum sample for Xpert testing and 23 contacts tested positive for TB using Xpert. Two more additional cases were diagnosed by x-ray. However, in the control group, there were only 22 presumptive contacts self-present health facility for TB evaluation, and five of the TB cases were diagnosed by xpert. The yield of community based TB case finding versus the routine passive case finding among household contacts as shown in table 4.6.

Table 4.6: TB screening result of the respondents (N=610)

Period	Intervention sites 350		Control sites 260	
	Household contacts		Household contacts	
	Symptoms	TB diagnosed	Symptoms	TB diagnosed
Baseline	38	2	6	1
Third month visit	31	3	3	1
Six month visit	40	6	4	1
Nine month visit	39	7	5	0
12 month visit	37	7	4	2
Total	185	25	22	5

4.3.9.4.1 Outcomes of investigation at baseline

The prevalence of TB among household respondents at baseline were similar in the intervention and control groups ($p>0.05$), whereas the identification of TB presumptive in the intervention group at baseline was higher than that in the control group in this study.

At the baseline in the interventional group, 38 household contacts identified, met the criteria for TB presumptive who reported cough for two weeks and more: 35 were able to produce sputum for testing and two cases were diagnosed by a gene Xpert, and both of them had a bacteriological confirmed pulmonary disease. The prevalence of all forms of TB in contacts at baseline screening was 571 per 100,000 persons. However, in the control group, there were only six presumptive household contacts self-present health facility for TB evaluation, and one TB case diagnosed by xpert which is 384per 100,000 persons.

4.3.9.4.2 Outcomes of repeat screening and follow-up

At the end of the 12-month household contact follow-up period, 30 of the 610 contacts (4.9%) were diagnosed with tuberculosis. Among them, 25 cases (83%) were diagnosed through active case finding, and five cases (17%) were diagnosed through programmatic

passive case finding. Among the 340 contacts who underwent a 6-month interventional treatment follow-up, six cases of active tuberculosis were diagnosed. Among the 324 contacts who participated in the 12-month follow-up, seven new cases were detected. Five of them were tuberculosis confirmed bacteriologically, and the other two were clinically diagnosed tuberculosis patients.

Household contacts at control group had not screened actively but completed a questionnaire, and were asked to return to the clinic for an interview after 12 months. The staff of the tuberculosis clinic provided them with information about tuberculosis and instructed them advice tuberculosis clinic for treatment if they found typical tuberculosis symptoms. In each 6-month and 12-month follow-up of the control group, only 4 contacts visited an institution with symptoms of tuberculosis, and 1 case and 2 cases of active TB disease were diagnosed respectively.

In this study, 44% of the detected tuberculosis cases among household contacts were diagnosed during the first six months of follow up and 56% during the second six months of follow up.

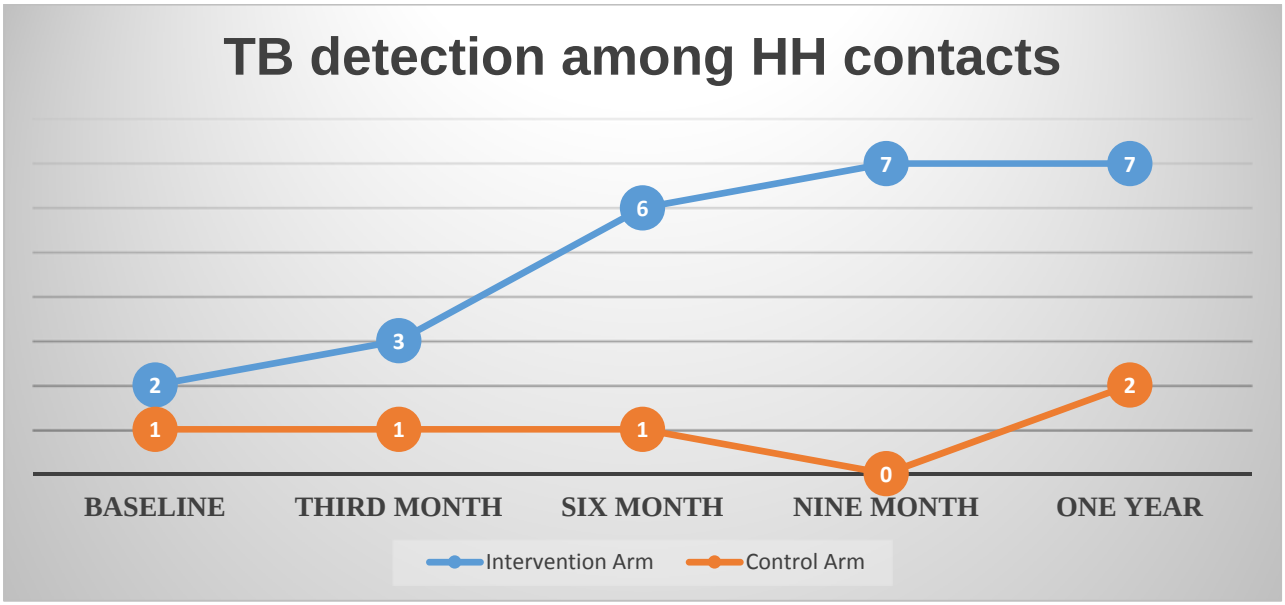

Figure 4.3: TB detection comparison between the two groups

The low proportion of TB presumptive and TB cases among household contacts in control group were likely a consequence of the passive nature of the strategy they used, which mainly relies on persons seeking appropriate health care on their own initiative when they have typical clinical symptoms.

The incidence of new TB cases is highest in the first year, and remains high for at least five years after exposure to TB patient. In this study, during the first year of follow-up, the prevalence of tuberculosis among household contacts in the active group was 7.1%, compared with 1.9% in the control group. After one year of follow-up, the relative risk of tuberculosis among household contacts in the intervention group was found 4.4 times higher than the control group.

Table 4.7: Relative risk on the incidence of TB among the groups

Sites	No of contacts	Identified TB Case	Cases per 100000contacts	RR CI 95%
Intervention	342	25	7142	4.422(2.919,6.698)
Control	254	5	1923	1

4.3.10 Discussion on quantitative data

In all cases, contacts with tuberculosis patients, especially those with tuberculosis confirmed by bacteriological have a significant risk of latent tuberculosis infection (LTBI) and active tuberculosis. The incidence of new cases is highest in the first year and remains high for at least five years after contact with TB patients (WHO 2012: 33). Many studies in countries with a high incidence of tuberculosis indicate that the prevalence among contacts, especially family members, may reach 5% or higher. Systematic assessment of people exposed to potentially infected cases of tuberculosis can be an effective and targeted method for detecting tuberculosis within the scope of tuberculosis control programs (Fox et al 2013:146).

Effective investigation of TB household contacts within national TB programs and other services can result in the detection of a significant number of cases. There are, however, no comprehensive recommendations for programmes in Ethiopia and specifically in the study setting of Addis Ababa. With this in mind, we implemented community based HHCI among household contacts of bacteriologically confirmed pulmonary TB patients.

The significant yield of active TB screening among household contacts with bacteriologically confirmed pulmonary TB index cases was shown in this study. This randomized trial for 610 household contacts of TB patients in Addis Ababa health centers shows a difference in TB case finding, comparing the current standard of care (facility-based screening) against community based feasibly delivered contact tracing based on active symptom screening and Xpert MTB/RIF testing. This study shows that integrated active HHCI can achieve high rates of screening and yield additional TB cases in the capital city of Ethiopia.

Consistent with other studies, results demonstrate that the integration of community health care workers with the health centers health care workers can successfully contribute to active case finding by screening HHCs and collecting samples for presumptive in their home, and this can improve access to TB services by screening and referring at the household-level (Datiko et al 2017:7).

It was pointed out that this study helps to recommend active HHCI for bacteriologically confirmed PTB index cases to produce the highest proportion of newly diagnosed TB cases (Tefera, Barnabee, Sharma, Feleke, Atnafu, Haymanot, Malley, and Feleke 2019: 7). In this study (Table 4.7), among the screened household contacts, community-based HHCI produced a high yield of 7.2% in all forms of TB (7,142 per 100,000 people). The finding was in-line with the practice level reported in Oromia region, eastern Ethiopia (Adane et al 2020:4); the finding is also comparable with the other studies in sub-Saharan Africa (Shah et al 2020:101), Pakistan (Javaid et al 2016:911) and Tanzania (Beyanga et al 2018:110).

In contrast, in this finding it was higher than the finding of a study by Tefera et al (2019:5) conducted in northern Ethiopia (4.3%). The possible explanations could be that our study focused not only at the baseline screening; we conducted a follow up screening among contacts on quarterly basis for one-year.

The use of dual reading of chest X-ray have enhanced the detection of tuberculosis in the present study. In future case-finding programs, supplementary procedures such as sputum generation is considered as an addition to spontaneous sputum production in people who cannot produce sputum (Biswas, Das, Sinha, Das & Bairagya 2013:201). It is expected that this will increase the yield of sputum samples and increase the sensitivity of screening methods, especially in early disease.

The incidence of TB remains high for several months after infection. Therefore, WHO (2013: 36) recommends regular screening within two years of exposure. This should be considered as part of the contact investigation plan. This method is routine in some high-income countries. Despite the presence of this guidance, the follow up screening is not practiced in developing and high TB burden countries. In our study, in intervention group, we detected 11 new cases at the first six-month follow-up assessment and 14 in the second six months. This is consistent with a recent meta-analysis that showed the incidence of TB among contacts was 1.5% (95% CI 0.9–2.4%) during the first year after exposure (Blok et al 2015:8).

Effective screening requires a high percentage of contacts to participate. In our research, we used the therapeutic relationship between patients and medical staff to improve compliance. Staff with community health care workers do household contact visits in contacts' home, which is a relatively effective and low-cost strategy, in combination with delivering education about the early symptoms and prevention of TB to household contacts. Increasing the detection of TB cases is a high priority for Ethiopia, a country in which one third of TB cases has missed annually for the last 10 years.

The most effective strategies to be implemented in high-risk populations are needed, and these strategies should be easily implemented. In this study, the implementation of community based TB patients household contact investigation have showed high TB yield among household contacts compared with the routine passive case finding in urban public health center. A significant prevalence of previously undiagnosed TB cases among household contacts were detected in this study. The findings suggest that household contacts are a high-yield population for efficient screening to enhance TB case detection.

A key feature of this intervention is its inclusion in the national tuberculosis control plan. Our strategy is implemented by existing health center employees, and the system works within the system that provides most of the TB care across the country. If the contact investigation program is to continue, it must be integrated with the existing tuberculosis control strategy. This integrated strategy, based on strong national and local leadership, is highly relevant to tuberculosis control programs in similar high-prevalence settings.

Another important aspect of our research is to involve community health care workers and index patients in recruiting their household contacts. This method has many practical advantages. First, the method uses the existing relationship between the patient and the medical staff to increase the possibility of cooperation with other family members. Second, our patient-centered approach ensures that patient consent is a prerequisite for household contact screening, which addresses some of the ethical concerns surrounding patient's confidentiality that arises in TB management.

4.4 SYNTHESIS OF QUALITATIVE AND QUANTITATIVE FINDINGS

The research background shows that very few researches has been conducted on the implementation of an effective household contact tracing approach, and the key contextual factors affecting the implementation. Exploring and identifying these contextual factors were needed to develop appropriate contact tracing approaches. Therefore, the goal of this research was to provide guideline on household contact investigation method. This study was performed through a mixed study approach using

exploratory sequential design. This design was conducted in two main phases with qualitative and quantitative approaches.

In the first phase of the study, there was no any hypothesis, because we wanted to explore the current HHCI implementation, limitations and strength to develop a new model, factors challenged the smooth implementation of HHCI in the research study setting were identified. These include application methods, lack of follow-up and poor integration between health facilities and community care workers. After that, the researcher defined an intervention based on the factors and relationships identified from the first stage, and then tested the developed approach through the second stage of the study.

The study begins with a qualitative exploration through interviews and FGDs with TB patients, household contacts and TB health care workers to assess what best approach should be implemented to effective TB case finding among contacts. One of the first steps in conducting household contact tracing is to identify all eligible household contacts. All household contacts need to be quickly found and evaluated. Over time, certain contacts may become more difficult to find. In the control group, the index cases mentioned that they had only 1.6 household contacts per household, which was lower than the 2.2 household contacts in the active group. This shows that the routine passive contact investigation method does not reach most household contacts.

In addition, the information collected in interviews with tuberculosis patients and household contacts indicated that contacts are reluctant to go to medical centers for services due to transportation costs and lack of clear information. Therefore, these mentioned gaps would render the identification of household contacts through passive case finding. However, the intervention group in this study shows that the most high-risk household contacts can be engaged in service by implementing patient's centered community based, household contact investigation approaches.

Presumptive identification is one of the core goals of household contact tracing, which is the basis for early identification of tuberculosis cases. During the intervention period in control group, only 22 contacts self-present to facilities for TB screening for having TB symptoms where as in active group 185 household contacts were identified with tuberculosis symptoms through home-to-home visit. This huge difference is related to the method used in the control group where the health care facilities rely on index cases to bring symptomatic household contacts. However, as shown in the interviews with patients and household contacts in this study, knowledge gaps, accessibility issues, and stigmatization are listed as challenges for visiting medical institutions for tuberculosis screening.

In terms of the follow up screening, the current routine implementation has no place for scheduled prospective follow up of household contacts. As shown in the study, during the first year of follow-up, the prevalence of tuberculosis among household contacts in the control group was 1.9%, while that in the active group was 7.1%. Receiving screening and educational care at home makes the service more accessible to those at high risk and vulnerable population for developing TB disease and reflecting on the detection of more TB cases in the intervention group. Patients and household contact interviews and FGD with care providers who support this finding explained that the integration of community and facility medical staff make services more accessible, affordable, and acceptable.

4.5 CONCLUSION

This chapter introduced the analysis, interpretation and discussion of qualitative and quantitative data. The presentation began with an introduction to the chapter and review of research questions of the study. In the first section, the main findings of qualitative data were introduced and discussed, and all emerging themes were analyzed, discussed and confirmed in conjunction with the literature.

This chapter introduced the explored views of tuberculosis patients and their household contacts on household contact tracing strategies. In addition, the first section introduced the views of tuberculosis experts on household contact tracing and investigation, as well as the factors related to implementation in the qualitative analysis method.

In section two, the findings of the descriptive statistics and inferential statistics were presented and discussed using tables and graphs. Inferential statistics were used to draw inferences (causality) from the correlation of dependent variables to various independent variables. Compared with similar studies conducted elsewhere, those variables with significant correlations had analyzed and explained.

CHAPTER FIVE

DEVELOPMENT OF HOUSEHOLD CONTACT TB TRACING AND INVESTIGATION GUIDELINES FOR THE PREVENTION OF TB

5.1 INTRODUCTION

The purpose of this research is to support the implementation of household contact tracing and investigation services for tuberculosis patients in Ethiopia. The ultimate goal of this study is to develop guidelines to optimize priority actions for the prevention of tuberculosis among household contacts. In this chapter, the developed TB patients' household contact tracing investigation guidelines for health workers in Ethiopia is presented.

The guidelines were grounded on the study of the main finding, the theoretical framework of research, related literature review**,** it is also in line with the updated WHO policy on household contact TB tracing strategies, national guidelines and insights of the researcher considered.

5.2 PROCESS OF COMPILING THE GUIDELINE

The suggested guidelines were framed after reviewing the available WHO guidelines and recommendations for investigating contacts of persons with infectious tuberculosis in low and middle-income countries, different literature and the national tuberculosis guideline (WHO 2014: 45)**.** The important key point in the preparing of these guidelines was the consideration of the theoretical framework. Then there was analysis of the current understanding on the study question, in specific the literature review and the researcher professional experience.

Finally, identification of key points from the research findings and integrating them into the available literature and recommendations was done.

5.3 APPLICATION OF THE THEORETICAL FRAMEWORK TO THE DEVELOPMENT OF THE GUIDELINES

According to Moleki (2008:162), purpose, the agent, a recipient, framework (context), dynamics and the procedures are the core component blocks of a guideline. Each of these building blocks will be described below.

5.3.1 Purpose

The purpose of the developed guidelines is to assist the country's national and regional tuberculosis control program to develop and implement effective strategies to detect tuberculosis cases among household contacts who have been exposed to tuberculosis cases.

5.3.2 Agent

In agreement with Young and Ryan (2020:697), an agent refers to a person who has knowledge or skills to perform activities or solve problems, and actively participates in or produces a specific result. In this study, an agent is a health care worker who can provide quality TB care. Health care worker include doctors, health officers, nurses, and community health care workers.

5.3.3 Recipient

The recipient is the inheritor of the activity planned by the agent. Tuberculosis patients and their household contacts treated at the public health center in Addis Ababa, Ethiopia were the beneficiaries of tuberculosis care services in this study.

5.3.4 Framework

Framework is described as the setting or situation where the events happen. In this study, the framework is a public health institution that provides tuberculosis care services (Varpio, Paradis, Uijtdehaage & Young 2020:989).

5.3.5 Dynamics

Dynamics provide motivation or driving factors for the quality of care services (Moleki 2008:165). In this study, the dynamics embrace strategies, guidelines, training, supplies, organization, practices, and documentation. Better performance of the dynamics results in better patient satisfaction and better health service outcomes.

5.4 APPLICATION OF THE EXISTING RECOMMENDATIONS FOR INVESTIGATING CONTACTS OF PERSON WITH INFECTIOUS TUBERCULOSIS IN LOW AND MIDDLE INCOME COUNTRIES TO THE COMPILATION OF THE GUIDELINE

Tuberculosis contact tracing and management are rarely and incoherently implemented in majority of the high burden countries. In most less developed countries with high TB incidences, it is contained within in the national program to tackle TB; however, in most of the countries, it is either not undertaken or is employed based on low standards because of the absence of clear definitions of index cases, household contacts and techniques (WHO 2013:35).

In order to reduce the burden of tuberculosis on the household contacts of tuberculosis patients who are at risk of affected by the disease severely, the WHO has formulated and issued this recommendation (WHO 2012:8-9). The purpose of this WHO policy document was to guide national tuberculosis planners, all institutions and organizations involved in tuberculosis prevention, care and control to develop reasonable strategies to investigate, and practice tuberculosis household contacts investigations (WHO 2012:8).

The document was carefully prepared after extensive literature review and expert opinions from all over the world. It is hoped that these evidence-based guidelines will be translated into national policies and practices based on local conditions and findings, so that other neglected interventions can be implemented and ultimately contribute to the elimination of tuberculosis. The developed guidelines are guided by these existing recommendations. (Table 5.1)

Table 5.1: WHO recommendations for conducting contact investigations

No	Recommendation
1	It is recommended that contact investigation be conducted for household and close contacts when the index case has any of the following characteristics: • has sputum smear-positive pulmonary TB, • has multi-drug-resistant TB (MDR-TB or extremely-resistant TB (XDR-TB) (proven or suspected), • is a PLHIV or • is a child < 5 years of age. Strong recommendation, very low-quality evidence
2	It is suggested that contact investigation be conducted for household and close contacts of all other index cases with pulmonary TB, in addition to the index cases covered in Recommendation 1. Conditional recommendation, very low-quality evidence
3	Clinical evaluation of household and close contacts for active TB is recommended as a priority on the basis of their risk for having or developing active TB or for the potential consequences of the disease if it develops. Priority should be given to: • people of all ages with symptoms suggestive of TB, • children < 5 years of age, • People with known or suspected immunocompromising conditions (especially PLHIV) and contacts of index cases with MDR-TB or XDR-TB (proven or suspected). Strong recommendation, very low-quality evidence

4	In settings of high HIV prevalence, it is recommended that all household and close contacts be counselled and tested for HIV. Strong recommendation, very low-quality evidence
5	It is recommended that all household contacts of an index case who is a PLHIV should be counselled and tested for HIV. Strong recommendation, very low-quality evidence
6	It is recommended that all household and close contacts of people with TB who have symptoms compatible with active TB should receive counselling and testing for HIV as part of their clinical evaluation. Conditional recommendation, very low-quality evidence
7	PLHIV who are household or close contacts of people with TB and who ,after an appropriate clinical evaluation, are found not to have active TB should be treated for presumed LTBI as per WHO guidelines. Strong recommendation, high-quality evidence
8	Children < 5 years of age who are household or close contacts of people with TB and who, after an appropriate clinical evaluation, are found not to have active TB should be treated for presumed LTBI as per WHO guidelines. Strong recommendation, high-quality evidence

5.5 PROCESS OF DEVELOPING GUIDELINES

This section discusses the steps to develop guidelines for investigating household contacts of patients with infectious tuberculosis. A guideline on guideline development model (Ansari & Rashidian 2012:6) influenced the process of developing guidelines. The detailed development process of the guideline will be described below.

The steps for the guidelines development process is outlined below:

1. Defining the purpose and scope of the guidelines
2. Review of the study findings
3. Review of a literature
4. Development of the first draft of the guidelines
5. Seek inputs from key stakeholders on the revised guidelines produced

6. Validate the guidelines

5.5.1 Defining the purpose and scope of the guidelines for the household contact TB tracing and investigation strategies

5.5.1.1. Purpose of the guidelines

The main purpose of this guideline is to develop an effective method that focuses on solutions for early detection of tuberculosis among household contacts of tuberculosis patients. Support health care providers and implementers on the improvement of household contact tracing strategy; and programme owners such as the ministry of health and regional health bureau to facilitate the TB patient household contact tracing investigation system through evidence based decision-making.

5.5.1.2 Potential users of the guideline

The guidelines are mainly aimed at

- Medical professionals involved in the management of TB patients, such as nurses, doctors and community health care workers (HEW).
- The health service program managers who are working in tuberculosis program
- Patients who receive tuberculosis treatment

5.5.1.3 Objectives of the guidelines

The overall goal of the guidelines is to enable TB programmes to:

- Improve TB case detection rate by focusing on screening of households exposed to infectious TB cases.
- Stop transmission of tuberculosis by identifying and treating persons with previously undetected TB cases.
- Provide guidance on techniques used in the assessment of TB household contacts.

- Ensure that household contacts with infectious TB cases have access to medical evaluation before they develop active disease and hence reduce the burden of TB disease.

5.5.1.4 Expected benefits

Effective use of this guideline aims at producing the following benefits:

- Availability of standard guidelines for prevention, early identification of TB among household contact with TB patients using community based health care approaches.
- Awareness creation for the TB patients' household members in the early detection, and prevention of TB.
- Improve the capacity of the medical community to ensure better care in early detection, management, and prevention of TB among household contact with TB patients.

5.5.2 Review of the findings of the empirical study

According to this study, the generation of current evidence on TB household contact tracing provides a framework for contextualized the guidelines. In Chapter 4, this study showed that TB household, family contacts, and medical staff working in TB programs recommend active case finding for TB household contacts. In this study, the in-depth interview and focused group discussion finding shows us that active case finding focuses on community based household contact tracing for TB preferred by TB patients and household contacts. Regarding the implementation of the TB household contact tracing, the presence of regular follow up was highly recommended during the focused group discussion with TB program managers in the study setting.

The randomized controlled trial finding, using community-based team for household contact tracing as an intervention in active group compared with the routine passive case finding, showed increased case detection in active cohort for both at the baseline and

follow up period. The overall TB incidence of tuberculosis in the active cohort was 7288 cases per 100,000 contacts, while 1923 cases per 100,000 contacts among a control cohort.

5.5.3 Review of the literature

The literature reviewed shows that the TB household contact investigation is a combination of several factors, each of which contributes to the overall plan performance of the TB household contact investigation. Studies have shown that there are more cases of tuberculosis detected by active detection of cases among household contacts than passive detection of cases. Household contact investigations detect as many as 7.3% of patients with pulmonary TB among close contacts in TB high burden countries (Fox et al 2013:145).

In some controlled trials, Active Case Finding (ACF) has shown that it can detect more cases of tuberculosis. Moreover, the effectiveness of active TB screening among certain key populations is also suggestive of potential benefits (Kranzer et al 2013:442). “Various methods used for contact screening include symptom screening, chest radiography, sputum smear and culture examination, and rapid molecular diagnostic test Gene-Xpert, tuberculin skin test (TST), and interferon-γ release assay“ (WHO 2013:44).

5.5.4 Development of the first draft of the guidelines

The Researcher extracted the evidence for the formulation of the guiding principles from the summary and conclusions of these research findings. Then, the researchers laid the foundation for the development of guidelines based on the summary and conclusions recommended by the World Health Organization and other documents specifically aimed at high tuberculosis burden and low-income countries. The guidelines are summarized in the below tables as follows:

Table 5.2: Summary of the guidelines and application of the evidence

Recommended guidelines	Study finding
Guideline 1: TB DOTs public health center should establish a community based TB household contact tracing system program.	Low interest to use a routine passive case finding by TB patients and their household contacts. Baseline assessments showed that the low yield of TB among household contacts by routine passive case finding.
Guideline 2: Both health care workers and community health care workers should have defined roles and responsibilities for implementing TB household contact tracing investigation program.	This study showed that there was no standard guidelines about TB household contact tracing investigation as part of quality care. No guidelines for roles and responsibilities
Guideline 3: Clinical assessment of all household contacts for active TB is recommended at their house by TB clinic health care workers and their catchment community health care worker	Community based household contact tracing approaches was preferred by TB patients and their household contacts, which revealed by the study finding.
Guideline 4: All household contacts should receive regular, scheduled quarterly TB screening during the first one year of follow up. Urgent assessment should be arranged whenever a patient develops symptoms	More than quarter of household contacts who developed TB were diagnosed during the second six months of follow up.
Guideline 5: All health care workers should be trained in documentation and record keeping of TB screening follow up for TB patients' household contacts.	In this study, we witnessed the absences of clear guidelines on household contact tracing documentation
Guideline 6: Revise the tuberculosis register and include necessary variables that the current register missed.	In this study, we witnessed the absences of clear guidelines on household contact tracing documentation

Guideline 7: Health center should develop and include TB mentoring indicators in the supervision tool for community health care workers.	We observed poor integration between medical staff of health center and community health worker in this study
Guideline 8: Appropriate evidence-based documentation and clear guidelines should be provided to health workers for early detection of tuberculosis among household contacts	In this study, we witnessed the absences of clear guidelines on household contact tracing
Guideline 9: Information and educational materials should be used to provide correct and accurate information on TB for communities	We saw some misconception about TB from patients and household contact

The role of health care workers and other stakeholder is vital for the successful implementation of the intervention, in order to achieve the desired goal the role and responsibilities' of the key stakeholders should be clearly mentioned

Table 5.3: Roles and responsibilities of health Care workers

STAKEHOLDER	ROLES AND RESPONSIBILITIES
Policy makers	▪ Carry out advocacy, communication and social mobilization (ACSM) to bring about policy reforms and the development of institutional structures to support community based TB screening for TB patients household contact ▪ Prepare guidelines or SOP on household contact tracing investigation
Health center head and technical management team	▪ Establish joint team of TB clinic staff and community health care worker. ▪ Implement on-site surveillance to ensure health care facilities are adequately detecting and managing TB among household contacts

	▪ Health care facilities mangers should conduct ongoing supervision and evaluations of TB patients' household contact tracing investigation. ▪ Develop a facility-specific plan for the early detection of TB among household contacts ▪ Ensure sufficient and appropriately trained health care workers employed.
TB clinic staff	▪ Interviewing index TB cases; ▪ Determining whether the TB patient is a Priority Index Case for household screening ▪ Recording patient information on the TB treatment card and the unit TB register (if not yet started TB treatment); ▪ Listing/recording all TB contacts with the priority index cases; ▪ Communicating/sharing the list of all TB contacts of the priority index cases with the responsible HEW. ▪ Conduct TB screening as early possible for eligible household contacts with community health care worker at their house ▪ Conduct follow up screening in quarterly interval for at least one year ▪ Manage the identified cases as the national recommendation
Community health care worker	▪ Collecting the list of all TB contacts in their catchment area of the health center; ▪ Copying list of TB contacts into the HP TB contact registration form; ▪ Identify contacts of the priority index cases. ▪ Educate patients and household contacts on early detection of TB and prevention of TB, through health education talks and community awareness campaigns. ▪ Conduct baseline and follow up TB screening for eligible household contact with TB clinic staff according to the health center schedule

Table 5.4: Household contact investigation procedures

Step	**Description**	**Responsibility**
1	Conduct TB knowledge assessment for index TB patients	TB clinic staff
2	Educate the index TB patients about the purpose of a contact screening, the basics of transmission, the risk of transmitting tuberculosis to others, and the importance of medical evaluation, treatment and follow up	TB clinic staff
3	Patient counselling and consent to commence their household contact tracing	TB clinic staff
4	Initiate contact tracing as soon as the index case is registered to receive TB treatment	TB clinic staff & Community HCW
5	Conduct baseline and quarterly based follow up TB screening for household contact at their home at least for one year	TB clinic staff & Community HCW
6	Maintain the confidentiality and obtain oral consent before starting the screening of the contacts.	TB clinic staff & Community HCW
7	Document the necessary information about TB contacts in the contact tracing register	TB clinic staff & Community HCW
8	Inform TB contacts to go to the nearest health facilities for evaluation if any of the contacts develop any of the TB symptoms any time in the future.	TB clinic staff & Community HCW
9	Collect sputum sample from eligible TB presumptive contacts during home to home visit	TB clinic staff & Community HCW
10	Refer complicated TB contacts eligible for future examination to the nearest health facility	TB clinic staff & Community HCW

5.5.5 Seek inputs from key stakeholders on the revised guidelines produced

Finally, researchers consulted key stakeholders through a meeting, and introduced the results of these studies and literature reviews during the meeting, and their feedback was incorporated into the final draft. The key stakeholders includes those working on TB program at regional level and clinician working on TB specialized hospitals.

5.5.6 Validation of the guidelines

According to scholars, analysis is the deliberate decomposition of a statement into its components (Li, Xie, Wang, Xie, Deng & Lu 2018:5). This is done to determine the relationship between the statements contained in the guidelines and the relative levels of thought. Similarly, as stated by Benzon, Joshi, Gan, and Vetter (2019: 1775), evaluation is a judgment on the value and logical structure of the criterion. It also determines the extent to which the guideline meets certain external criteria and/or standards. In addition, the evaluation of the criteria allows users or evaluators to make judgments and conclusions about its effectiveness.

Experts in the field of tuberculosis household contact tracing and investigation services validated the above guidelines for clarity, simplicity, generality, rational structure and operational adequacy by using Likert scale as shown in table 5.5.

Table 5.5: Criteria for validating each guidelines

Criteria	**Strongly disagree (1)**	**Disagree (2)**	**Neither agree nor disagree(3)**	**Agree (4)**	**Strongly agree (5)**
Clarity The guidelines is simple and easily understandable					

Specificity The guidelines is specifically focusing on household contact tracing					
Reliability The guidelines can be used consistently by other health care facilities/ settings					
Flexibility The guidelines can be flexible in a unique setting or facilities					
Effectiveness The guidelines is able to achieve the objective					
Validity The guidelines is justifiable or evidence based.					
Relevance Guidelines is appropriate for the strengthening house contact tracing					
Applicability The target users are clearly defined, as described in the scope of the guidelines					
Acceptability The guidelines is realistic and acceptable by MOH/RHB and stakeholders					
Achievability Can be executed by MOH/RHB on the implementation of house contact tracing					

5.5.6.1 Clarity and relational structure

The guideline was validated for trustworthiness, semantic clarity and structural clarity. Seven persons working in the field of tuberculosis were selected as reviewers of the guidelines. The review team consists of technical experts, a tuberculosis program coordinator and a researcher working in the field of tuberculosis control programs.

Table 5.6: Biographic information of experts for guideline validation

No	Qualification	Occupation	Work experience
1	Medical doctor	TB Program advisor	18 years
2	Medical doctor	TB researcher	12 years
3	MD + MPH	TB researcher	11 years
4	Medical doctor	TB Clinic head	13 years
5	MPH + PHD	Lecturer	10 years
6	PHD	Lecturer	17 years
7	MD + PHD	TB Program advisor	20 years

Prospective reviewers were individually contacted and invited to work as reviewer for the developed guidelines on TB household contact tracing and investigation program. A brief description of the guidelines and procedures was followed by the submission of the developed guidelines to each reviewer in paper format. Summary of the study was attached with the guidelines along with the ethics clearance certificate, and letter of permission. In addition, all participating experts are required to provide consent forms.

Each reviewer had one month to respond to feedback. Participants were also provided with criteria for evaluation and verification criteria as described in Table 5.5. The participants were expected to evaluate each recommendation and were requested to

score using Likert scale as indicated in table 5.7. The experts requested to score each recommendation from 50 by using the criteria in table 5.6 and the researchers considered that the recommendation would be an acceptable level if the mean score was 40 (80%) and above. All experts sent their feedback to the researcher based on the criteria provided. The researcher then compiles an assessment based on this (see Table 5.7). Almost all of the experts provided equivalent scores.

Table 5.7: Average scores of evaluators on each recommendation

Evaluators (Eva.)								
Recommendation	**Eva.1**	**Eva. 2**	**Eva. 3**	**Eva.4**	**Eva. 5**	**Eva. 6**	**Eva. 7**	**Average score**
Recommendation 1	48	47	47	49	46	48	47	**47**
Recommendation 2	45	47	46	48	47	49	46	**47**
Recommendation 3	49	48	47	47	49	47	48	**48**
Recommendation 4	46	49	48	47	47	48	47	**47**
Recommendation 5	48	49	47	48	46	47	48	**48**
Recommendation 6	48	46	46	49	48	47	49	**48**
Recommendation 7	47	46	48	48	49	48	47	**48**
Recommendation 8	45	47	48	49	48	47	48	**47**
Recommendation 9	48	46	47	49	48	47	49	**48**

5.5.6.2 Simplicity

The guidelines were appraised to determine its rightness and applicability for providing household contact tracing and investigation services for tuberculosis in public medical institutions in Ethiopia. To make the guidelines simple and easy to use for primary health care workers, it is necessary to summarize all specific activities of the TB household contact tracing and investigation service in concise and clear language and provide easy-to-use summaries.

5.5.6.3 Generality

Moleki (2008: 177) defines generality as the extensiveness of the scope and determination of the guidelines. The guidelines aims to support the staff who provide TB household contact tracing and investigation services to use supported, scientifically effective and suitable approaches and implementations.

5.6 CONCLUSION

In Addis Ababa, Ethiopia, there were limited and inconsistent contact investigation practices for tuberculosis. Awareness on household contact TB screening importance among TB patients and their contacts were low, and there were no national guidelines for TB household contact tracing investigation to assist health care workers. This guideline for TB household contact tracing investigation in Addis Ababa provides a comprehensive guide of the procedures, the detailed flow of activities to be performed by persons involved in TB patients household contact tracing and management.

In this chapter, guidelines for tracing and managing household contacts of tuberculosis patients were developed. This chapter detailed the implementation of the guidelines. Draft guidelines related to each topic have been developed. In total, nine guidelines were formulated and submitted to experts in the field for review and confirmation. In the next chapter, conclusions and recommendations will be presented.

CHAPTER SIX

CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

The preceding chapter presents the development of the guidelines; this chapter presents the research summary, the conclusion of the findings, and limitations of the study in agreement with the aim of the study. Further, the researcher summarizes applied recommendations for endorsing the execution of community based TB patient's household contact tracing investigation in the study area, as well as areas for further research were recommended.

6.1.1. The aim of the study

The overall aim was to provide guidelines and framework in promoting the implementation of a community based household contact investigation program in the public health center in Addis Ababa, Ethiopia.

The objectives of this study were to:

- Describe the current implementation status of contact investigation in households of patients with bacteriological confirmed pulmonary tuberculosis in AA.
- To describe and explore the TB experts, TB patients and TB household contacts perception on contact tracing strategies.
- Determine the yield of community based contact investigation in households of patients with bacteriological confirmed pulmonary tuberculosis in Addis Ababa compared with passive case finding.
- Develop guidelines to support household contact investigations in household contacts of TB patients.

6.1.2 Research summary

A mixed method of collecting and analyzing qualitative and quantitative data, were adopted. A sequential exploratory design was conducted to address to the purposes of the research. The study participants were tuberculosis patients, household contacts, and health care workers, who consent to participate in individual interviews and focus group discussions. Obtained the ethics license from the university of South Africa and the Addis Ababa health bureau (please refer to the attachment annex A and B), and agreed to conduct research from Addis Ababa health bureau.

From the findings of phase one, experiences of TB patients, household contacts and health care providers' on TB patients household contact tracing investigation, different recommendation were identified and emerged as themes. Based on the identified themes and sub-themes, we develop a community based accessible active case finding approaches. In phase two, through the implementation of a community based accessible active case finding approaches among household contacts using home visits, identifies additional TB cases beyond the routine passive contact screening (waiting for household member to advance symptoms and present on their own to health facilities) signifying an encouraging approach towards improving access to early detection of TB.

By considering the findings of the two phases, interim guidelines were developed and supported by the literature. Therefore, the guidelines were drafted from the interim and submitted to experts for evaluation based on criteria. Finally, guideline developed as presented in chapter five.

6.2 CONCLUSIONS

The research findings are summarized agreeing to the study objectives as follows.

6.2.1 Describe implementation status of contact investigation

In general, a passive case finding was implemented in the study setting predominantly. The findings indicated that the implementation of passive case finding regarding TB patients household contact tracing investigation lacked patients and household members' satisfaction, and health care worker motivation. Moreover, the routine passive case finding strategy was deficient in regular follow up, which only focused at baseline and relied on patients' willingness to bring their household contacts to health facilities.

It proposed that setting clear guidelines and strategies focusing on patients and their household contacts preference, an active case finding among household contact using community health care worker, with follow up was suggested.

6.2.2 Describe the TB experts, TB patients and TB household contacts perception

Health care workers are usually the driving force of health institutions. According to reports, their attitude towards household contact investigations of tuberculosis patients is very good. However, in terms of implementation methods, limited knowledge and skills in tracing and counseling, over-burdened work, and low employee motivation are some of the challenges encountered.

With regards to index cases and household contacts, the index cases reported that they had low motivation to bring their household contacts to health facilities, as well as the household contacts were not volunteering to visit health facilities. Rather, they propose community based approaches that they claimed made brought the health system more accessible to the community.

6.2.3 Issues of health care system

The Ethiopian government launched an innovative plan in 2009, the Urban Health Extension Program (UHEP), which aimed at using urban health extension experts as the main implementers of the plan to bring good health to urban residents. The purpose of the program is to ensure the provision of services to urban communities and enhance the quality of services.

Community health care workers minimized the workload of health care providers and supported the community by moving the health system into the community level. However, as witnessed in this study, respective health care facilities did not use the catchment community health care workers' potential wisely to involve them in the counseling, referral, tracking and feedback of TB patients' household contact tracing investigation.

One main factor that affected accuracy and enhanced implementation of household contact tracing was lack of standard guidelines for health care workers. On its implementation, the routine passive case finding approaches relied on patients' voluntariness that makes low patients motivation to bring their contacts to health facilities. We acknowledged potential gaps to bring household contacts who were at risk for TB to care. The presence of standard household contact investigation protocol will facilitate regular monitoring of this activity by the supervisors and programme managers.

The problem of properly recording data on registers was one of the challenges for proper monitoring of recommendations and link services. Moreover, the TB program registration sheet missed some variables. Furthermore, integrating TB patients household contact investigation information into routine national surveillance activities would further improve programme performance at health facilities, regional, and national levels and elevate Ethiopia's contribution for the detection of missed cases to the global End TB Strategy.

6.2.4 Determine the yield of community based contact investigation in households of patients with compared with passive case finding.

In the study setting, the household contact investigation has been inconsistently practiced for decades. It only involves passive methods, waiting for contacts to visit medical institutions when they develop symptoms of tuberculosis. The detection of TB cases among household contacts were insignificant for many years. To address this gap, we evaluated the developed active community based contact tracing approaches with the routine approaches in this study.

We found that community based contact-tracing implementation of household contact yielded more TB cases compared with the routine passive finding. At the end of 12 months follow-up period, 4.9% of contacts were diagnosed with tuberculosis. Of these, 83% were diagnosed through active case finding and 17% were diagnosed through the routine passive case finding.

6.2.5 Develop guidelines to support household contact investigations in household contacts of TB patients.

6.2.5.1 Guideline development summary

The purpose of developing the guideline was to recommend ways to strengthen the implementation of TB patients' household contact tracing. The researcher has developed a preliminary guideline based on the themes identified in the first phase, and the results of randomized controlled trial conducted in the second phase, which were supported by literature.

This interim guideline was reviewed and operationalized to formulate nine recommendations. The guideline was submitted to experts in the field for review and validation for the final strategy inputs.

6.2.5.2 Final guideline

The final guidelines were based on the formal consensus of experts in the TB programme. After verification, the researcher discussed with the study supervisor and approved the following final guidelines:

6.2.5.3 Recommended guideline

Guideline 1: TB DOTs public health center should establish a community based TB household contact tracing system program.
Guideline 2: Both health care workers and community health care workers should have defined roles and responsibilities for implementing TB household contact tracing investigation program.
Guideline 3: Clinical assessment of all household contacts for active TB is recommended at their house by TB clinic health care workers and their catchment community health care worker
Guideline 4: All household contacts should receive regular, scheduled quarterly TB screening during the first one year of follow up. Urgent assessment should be arranged whenever a patient develops symptoms
Guideline 5: All health care workers should be trained in documentation and record keeping of TB screening follow up for TB patients' household contacts.
Guideline 6: Revise the tuberculosis register and include necessary variables that the current register missed.
Guideline 7: Health center should develop and include TB mentoring indicators in the supervision tool for community health care workers.
Guideline 8: Appropriate evidence-based documentation and clear guidelines should be provided to health workers for early detection of tuberculosis among household contacts
Guideline 9: Information and educational materials should be used to provide correct and accurate information on TB for communities

6.3 LIMITATIONS OF THE STUDY

- The findings may not be generalized to the entire country because it was only conducted in Addis Ababa and may not mirror the circumstances in other regions.
- The study did not include private health facilities; therefore, the findings may not be generalized to the entire health facilities in the city administration.
- This study was restricted to household contacts of bacteriologically confirmed pulmonary TB.
- Even with these limitations, the results of the study are reliable and valid. The use of triangulation methods and a sufficient number of research participants increase the reliability of the research results.

6.4 RECOMMENDATIONS

The researcher recommends the following recommendations for endorsing the community based TB patients' household contact tracing strategy in Addis Ababa built on the findings of the research. In addition, the researcher recommends specific areas for further research in this section.

6.4.1 Recommendation for programme owners

Ministry of health (MOH), regional heath bureau (RHB) and sub-city health bureau are the leading program implementers.

- MOH/RHB should give attention to the community based TB patients' household contact tracing approaches and it should be counted as a vital performance indicator. This will enable them to follow the program regularly.
- The implementation manual for TB program should be reviewed and updated**.** This will support the integration of the community based TB household contact tracing investigation strategies in the tuberculosis guideline.
- Orientation for medical staff and programme managers should be given regularly for any new advances.

- Strengthen the communication system between medical staff of health facilities and community health care workers.
- Strengthen the monitoring and evaluation system, which will bring changes on the improvement of services.

6.4.2 Recommendation for health care providers' practice

The health care providers' include those health care workers working in TB patients' diagnosis and management area; and the recommendations are that health care providers should:

- Adhere to guidelines, manuals and SOPs while implementing contact-tracing programmes.
- Educate the index case and contacts about the purpose of a contact screening, the basics of transmission, the risk of transmitting tuberculosis to others, and the importance of medical evaluation, treatment and follow up.
- Maintain confidentiality and obtain oral consent before starting the screening of the contacts.
- Conduct detail clinical/medical evaluation and laboratory examination for all bacteriologically confirmed pulmonary TB contacts at their home with community health workers. Initiate as soon as the index case is registered to receive TB treatment.
- Conduct scheduled a quarterly TB screening for all the bacteriologically confirmed pulmonary TB household contacts during the first one year of follow up.
- Document the necessary information about TB contacts in the contact tracing register.
- Work closely with HEW to expedite contact-tracing activities.

6.4.3 Recommendation for further research

Further research recommended on the following area:

- The cost effectiveness of a community based household contact approaches.
- The need of household contact investigation for clinically diagnosed TB patients.
- Evaluation of a TB case finding through systematic contact investigation with large sample size in large scale.

6.5 CONTRIBUTION OF THE STUDY

The key contributions of the study can be summarized as a generation of local evidence; we identified a potential missed opportunities to detect more TB cases among household contacts, which is integrating health center medical staff and a community health care worker to conduct TB screening among contacts at their homes.

Sensitization of policy makers and managers about TB household contact tracing, guidelines developed to facilitate household contact tracing implementation in delivering improved TB prevention among household contacts and to make decisions consistent with scientific knowledge.

After presenting the research results to regional health bureaus, partners and health care providers. The research results will be distributed to relevant parties through EFMOH and RHB. Publications will be done in accredited journals.

REFERENCES

Adane, A., Damena, M., Weldegebreal, F. & Mohammed, H. 2020. Prevalence and associated factors of tuberculosis among adult household contacts of smear positive pulmonary tuberculosis patients treated in public health facilities of Haramaya district, Oromia region, eastern Ethiopia. *Tuberculosis Research and Treatment* 2020 (2020):1-7.

AACAHB See Addis Ababa City Administration Health Bureau

Addis Ababa city administration health bureau. 2020. *Annual TB activity report.* Addis Ababa: AACAHB.

Adelman, MW., Tsegaye, M., Kempker, RR., Alebachew, T., Haile, K., Tesfaye, A., Aseffa, A. & Blumberg, HM. 2015. Intensified tuberculosis case finding among HIV-infected persons using a WHO symptom screen and Xpert MTB/RIF. *International Journal of Tuberculosis and Lung Disease* 19(10):1197-1203.

Ahmed, A., Mekonnen, D., Shiferaw, AM., Belayneh, F. &Yenit, MK. 2018. Incidence and determinants of tuberculosis infection among adult patients with HIV attending HIV care in northeast Ethiopia: a retrospective cohort study. *British Medical Journal Open* 8(2):1-14.

Alipanah, N., Jarlsberg, L., Miller, C., Linh, NN., Falzon, D., Jaramillo, E. & Nahid, P. 2018. Adherence interventions and outcomes of tuberculosis treatment: A systematic review and meta-analysis of trials and observational studies. *PLoS medicine* 15(7):1-44.

Ansari, S. & Rashidian, A. 2012. Guidelines for guidelines: are they up to the task? A comparative assessment of clinical practice guideline development handbooks. *PLoS One* 7(11):1-9.

Austin, Z. & Sutton, J. 2014. Qualitative research: Getting started. *The Canadian Journal of Hospital Pharmacy* 67(6): 436-440.

Ayakaka, I., Ackerman, S., Ggita, JM., Kajubi, P., Dowdy, D., Haberer, JE., Fair, E., Hopewell, P., Handley, MA., Cattamanchi, A. & Katamba, A. 2017. Identifying barriers to and facilitators of tuberculosis contact investigation in Kampala, Uganda: a behavioural approach. *Implementation Science* 12(1):1-13.

Badane, AA., Dedefo, MG., Genamo, ES. & Bekele, NA. 2018. Knowledge and healthcare seeking behaviour of Tuberculosis patients attending Gimbi general hospital, west Ethiopia. *Ethiopian Journal of Health Sciences* 28(5):529-538.

Bansal, P., Smith, WK. & Vaara, E. 2018. New Ways of Seeing through Qualitative Research. *Academy of Management Journal* 61(4):1189-1195.

Baran, M.L. & Jones, J.E., 2016. *Creating and Implementing a Mixed Method Research Study. In Mixed Methods Research for Improved Scientific Study.* USA: IGI Global.

Benzon, HT., Joshi, GP., Gan, TJ. & Vetter, TR. 2019. Development, reporting, and evaluation of clinical practice guidelines. *International Anaesthesia Research Society* 129(6):1771-77.

Berman EA. 2017. An Exploratory Sequential Mixed Methods Approach to Understanding Researchers' Data Management Practices at UVM: Integrated Findings to Develop Research Data Services. *Journal of eScience Librarianship* 6(1): 1-24.

Beyanga, M., Kidenya, BR., Gerwing-Adima, L., Ochodo, E., Mshana, SE. & Kasang, C. 2018. Investigation of household contacts of pulmonary tuberculosis patients increases case detection in Mwanza City, Tanzania. *BMC Infectious Diseases* 18(110):1-8.

Biswas, S., Das, A., Sinha, A., Das, SK. & Bairagya, TD. 2013. The role of induced sputum in the diagnosis of pulmonary tuberculosis. *Lung India* 30(3): 199–202.

Blok, L., Sahu, S., Creswell, J., Alba, S., Stevens, R. & Bakker, MI. 2015. Comparative meta-analysis of tuberculosis contact investigation interventions in eleven high burden countries. *PLoS ONE* 10(3): 1-18.

Braun V. & Clarke V. 2006. Using thematic analysis in psychology. *Qualitative Research in Psychology* 3(2):77-101.

Burns, N. & Groove, SK. 2014. Research method. *Ergonomics* 32(3):237-248.

Central Statistical Agency of Ethiopia and Inner City Fund International 2020. Ethiopia demographic health survey. Addis Ababa, Ethiopia and Calverton, Mary Land, USA: CSA and ICF.

Cremers, AL., de Laat, MM., Kapata, N., Gerrets, R., Klipstein-Grobusch, K. & Grobusch, MP. 2015. Assessing the consequences of stigma for tuberculosis patients in urban Zambia. *PLoS ONE* 10(3):1-16.

Creswell, JW. 2014. *Research Design: Research Design: Qualitative, Quantitative and Mixed Methods Approaches*. 4th edition. Thousand Oaks, CA: Sage.

Creswell, JW. & Plano Clark, V. 2011. *Designing and conducting mixed methods research*. 2nd edition. Thousand Oaks, CA: Sage.

Creswell, JW. & Poth, CN. 2016. *Qualitative inquiry and research design: Choosing among five approaches.* Thousand Oaks, CA: Sage.

Curtis, E. & Drennan, J. 2013. *Quantitative Health Research: Issues and Methods*. Thousand Oaks, CA: Sage.

Darko, S., Plange, ED. & Bator, ET. 2020. Factors contributing to low tuberculosis case detection in west Akim municipality of the eastern region of Ghana: A Community and Health Facility Based Study. *Journal of Health, Medicine and Nursing* 72(1):85-102.

Dasa, TT., Roba, AA., Weldegebreal, F., Mesfin,F., Asfaw,A., Mitiku, H., Teklemariam, Z., Geddugo,BJ., Naganuri, M., Befikadu, H. & Tesfaye, E. 2019. Prevalence and associated factors of depression among tuberculosis patients in Eastern Ethiopia. *BMC Psychiatry* 19(82):1-7.

Datiko, DG., Yassin, MA., Theobald, SJ., Blok, L., Suvanand, S., Creswell, J. & Cuevas, LE. 2017. Health extension workers improve tuberculosis case finding and treatment outcome in Ethiopia: a large-scale implementation study. *BMJ Global Health* 2(4):1-8.

Datiko, D.G., Habte, D., Jerene, D. & Suarez, P. 2019. Knowledge, attitudes, and practices related to TB among the general population of Ethiopia: Findings from a national cross-sectional survey. *PloS one 14*(10):1-16.

Deaton, A. and Cartwright, N., 2018. Understanding and misunderstanding randomized controlled trials. *Social Science & Medicine* 2109(1):2-21.

Dobler, CC. 2016. Screening strategies for active tuberculosis: focus on cost-effectiveness. *ClinicoEconomics and Outcomes Research* 8(1):335-347.

Doody, O. & Noonan, M. 2016. Nursing research ethics, guidance and application in practice. *British Journal of Nursing* 25(14):803-807.

Durlak, JA. & DuPre, EP. 2008. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American Journal of Community Psychology* 41(3-4):327-50.

Easterby-Smith, M. & Senior, E. 2013. The cultural production of natural knowledge: contexts, terms, themes. *Journal for Eighteenth-Century Studies* 36(4): 471-476.

Elfil, M. & Negida, A. 2017. Sampling methods in Clinical Research; an Educational Review. *Emergency* 5(1): 1-3.

Ereso, BM., Yimer, SA., Gradmann, C. & Sagbakken, M. 2020. Barriers for tuberculosis case finding in Southwest Ethiopia: A qualitative study. *PLoS ONE* 15(1): 1-20.

EFMOH see Ethiopian Federal Ministry of Health.

Ethiopian Federal Ministry of Health. 2017a. *National strategic plan tuberculosis and leprosy control 2013/14 – 2020.* Addis Ababa, Ethiopia: EFMOH.

Ethiopian Federal Ministry of Health. 2017b*. National guideline for TB, DR-TB and leprosy in Ethiopia.* Sixth edition. Addis Ababa, Ethiopia: EFMOH.

Ethiopian Federal Ministry of Health. 2019*. Annual TB activity report*. Addis Ababa, Ethiopia: EFMOH.

Fabregues, S. & Molina-Azorín, J.F. 2017. Addressing quality mixed methods research: A review and recommendations for a future agenda. *Quality & Quantity* 51(6): 2847-2863.

Fernstrom, A. & Goldblatt M. 2013. Aerobiology and its role in the transmission of infectious diseases. *Journal of Pathogens* 2013(1):1-14.

Fox, GJ., Barry, SE., Britton, WJ. & Marks, GB. 2013. Contact investigation for tuberculosis: a systematic review and meta-analysis. *European Respiratory Journal* 41(1):140-156.

Gashu, Z., Jerene, D., Ensermu, M., Habte, D., Melese, M., Hiruy, N., Shibeshi, E., Hamusse, SD., Nigussie, G., Girma, B., Kassie, Y., Haile, YK. & Suarez, P. 2016. The

yield of community-based retrospective tuberculosis contact investigation in a high burden setting in Ethiopia. *PLoS ONE* 11(8): 1-14.

Gebrekidan, G., Tesfaye, G., Hambisa, MT. & Deyessa, N. 2014. Quality of tuberculosis care in private health facilities of Addis Ababa, Ethiopia. *Tuberculosis Research and Treatment* 2014:1-9.

Getnet, F., Hashi, A., Mohamud, S., Mowlid, H. & Klinkenberg, E. 2017. Low contribution of health extension workers in identification of persons with presumptive pulmonary tuberculosis in Ethiopian Somali Region pastoralists. *BMC Health Services Research* 17(193): 1-9.

Golub, JE., Bur, S., Cronin, WA., Gange, S., Baruch, N., Comstock, GW. & Chaisson, RE. 2006. Delayed tuberculosis diagnosis and tuberculosis transmission. *International Journal of Tuberculosis and Lung Disease* 10(1): 24-30.

Guirado, E. & Schlesinger, L. 2013. Modelling the Mycobacterium tuberculosis granuloma–the critical battlefield in host immunity and disease. *Frontiers in Immunology* 4(1): 1-7.

Haven L., & Van Grootel, DL. 2019. Preregistering qualitative research. *Accountability in Research 26*(3):229-244.

Hayes, B., Bonner, A., & Douglas, C. 2013. An introduction to mixed methods research for nephrology nurses. *Renal Society of Australasia Journal* 9(1):8-14.

Ho, J., Fox, GJ. & Marais, BJ. 2016. Passive case finding for tuberculosis is not enough. *International Journal* of Mycobacteriology 2016(5):374-8.

Huddart, S., Bossuroy, T., Pons, V., Baral, S., Pai, M. & Delavallade, C. 2018. Knowledge about tuberculosis and infection prevention behaviour: A nine city longitudinal study from India. *PLoS One* 13(10):1-15.

Hunter RL. 2015. Tuberculosis as a three-act play: A new paradigm for the pathogenesis of pulmonary tuberculosis. *Tuberculosis* 97(2016): 8-17.

Ivankova, N. & Wingo, N. 2018. Applying mixed methods in action research: Methodological potentials and advantages. *American Behavioural Scientist* 62(7): 978-997.

Javaid A., Khan MA., Khan MA., Mehreen S., Basit A., Khan RA., Ihtesham M., Ullah I., Khan A., & Ullah U. 2016. Screening outcomes of household contacts of multidrug-resistant tuberculosis patients in Peshawar, Pakistan. *Asian Pacific Journal of Tropical Medicine* 9(9):909-912.

Johnson, RB., Onwuegbuzie, AJ. & Turner, LA. 2007. Toward a Definition of Mixed Methods Research. *Journal of Mixed Methods Research* 3(9):112-133.

Kasaie, P., Andrews, JR., Kelton, WD. & Dowdy, DW. 2014. Timing of tuberculosis transmission and the impact of household contact tracing. An agent-based simulation model. *American Journal of Respiratory and Critical Care Medicine* 189(7):845-52.

Khaparde, K., Jethani, P., Dewan, PK., Nair, SA., Deshpande, MR., Satyanarayana, S., Mannan, S. & Moonan, PK.2015. Evaluation of TB case finding through systematic contact investigation, Chhattisgarh, India. *Tuberculosis Research and Treatment* 2015 (2015):1-5.

Korstjens, I. and Moser, A., 2018. Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing. *European Journal of General Practice 24*(1):120-124.

Kranzer, K., Afnan-Holmes, H.,Tomlin, K., Golub, JE., Shapiro, AE., Schaap, A., Corbett, EL., Lönnroth, K. & Glynn, JR. 2013. The benefits to communities and individuals of screening for active tuberculosis disease: a systematic review. *International Journal of Tuberculosis and Lung Disease* 17(4):432–446.

Kyngas, H., Kaariainen, M. and Elo, S., 2020. The trustworthiness of content analysis. In The application of content analysis in nursing science research. Cham: Springer nature.

Li, H., Xie, R., Wang, Y., Xie, X., Deng, J. & Lu,C. 2018. A new scale for the evaluation of clinical practice guidelines applicability: development and appraisal. *Implementation Science* 13(61): 1-9.

MacLean, E., Broger, T., Yerlikaya, S., Fernandez-Carballo, BL., Pai M. & Denkinger, CM. 2019. A systematic review of biomarkers to detect active tuberculosis. *Nature Microbiology* 4(5):748-758.

MacPherson, P., Webb, EL., Variava, E., Lala, SG., Milovanovic, M., Ratsela, A., Lebina, L., Kinghorn, A. & Martinson, NA. 2019. Intensified household contact tracing, prevention and treatment support versus enhanced standard of care for contacts of tuberculosis cases in South Africa: study protocol for a household cluster-randomised trial. *BMC Infect Dis* 19(839):1-10.

Malterud, K., Siersma, VD. & Guassora, AD. 2016. Sample size in qualitative interview studies: guided by information power. *Qualitative Health Research* 26(13):1753-1760.

Martínez-Mesa, J., González-Chica, DA., Duquia, RP., Bonamigo, RR. & Bastos, JL. 2016. Sampling: how to select participants in my research study? *Anais Brasileiros de Dermatologia* 91(3):326-330.

Mathema, B., Andrews, JR., Cohen, T., Borgdorff, MW., Behr, M., Glynn, JR., Rustomjee, R., Silk, BJ. & Wood, R. 2017. Drivers of Tuberculosis Transmission. *Journal of Infectious Diseases* 216(6): 644–653.

Moleki, MM. 2008. *Critical care nursing students' experience of clinical accompaniment in open distance learning (ODL): A phenomenological perspective.* D Litt et Phil (Health Studies) thesis. University of South Africa, Pretoria.

Nardell, EA. 2015. Transmission and Institutional Infection Control of Tuberculosis. *Cold Spring Harb Perspect Med* 6(2):1-12.

Narasimhan, P.,Wood, J., MacIntyre, CR. & Mathai, D.2013. Risk Factors for Tuberculosis. *Pulmonary Medicine* 2013(1):1-12.

Nicholls, D. 2017. Qualitative research. Part 3: methods. *International Journal of Therapy and Rehabilitation* 24(3):114-121.

Nguyen, T.L., Collins, G.S., Lamy, A., Devereaux, P.J., Daurès, J.P., Landais, P. and Le Manach, Y. 2017. Simple randomization did not protect against bias in smaller trials. *Journal of Clinical Epidemiology* 84(1):105-113.

Oppy, G. 2019. Ontological arguments. *The Philosophers' Magazine* 86(1):66-73.

Otzen, T. & Manterola, C. 2017. Sampling techniques on a population study. *International Journal of Morphology* 35(1):227-232.

Pan, H., Liu, S., Miao, D. & Yuan, Y. 2018. Sample size determination for mediation analysis of longitudinal data. *BMC Medical Research Methodology* 18(1):1-11.

Queiros, A., Faria, D. & Almeida, F. 2017. Strengths and limitations of qualitative and quantitative research methods. *European Journal of Education Studies* 3(9): 369-387.

Rahman, MS. 2017. The Advantages and Disadvantages of Using Qualitative and Quantitative Approaches and Methods in Language Testing and Assessment Research: A Literature Review. *Journal of Education and Learning* 6(1):1-11.

Rahi, S. 2017. Research Design and Methods: A Systematic Review of Research Paradigms, Sampling Issues and Instruments Development. *International Journal of Economics & Management Sciences* 6(2): 1-5.

Raviglione, M., Marais, B., Floyd, K., Lonnroth, K., Getahun, H., Migliori, GB., Harries, AD., Nunn, P., Lienhardt, C., Graham, S., Chakaya, J., Weyer, K., Cole, S., Kaufmann, SH. & Zumla, A. 2012. Scaling up interventions to achieve global tuberculosis control: progress and new developments. *Lancet* 379 (9829):1902-13.

Saunders, MJ., Tovar,MA., Collier,D., Baldwin, MR., Montoya,R., Valencia,TR., Gilman,RH. & Evans, CA. 2019. Active and passive case finding in tuberculosis-affected households in Peru: a 10-year prospective cohort study. *The Lancet Infectious Diseases* 19(5): 519-528.

Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., Burroughs, H. & Jinks, C. 2018. Saturation in qualitative research: exploring its conceptualization and operationalization. *Quality & quantity* 52(4):1893-1907.

Schloemer, T. & Schröder-Bäck, P. 2018. Criteria for evaluating transferability of health interventions: a systematic review and thematic synthesis. *Implementation Science* 13(1):1-17.

Shah, NS., Auld, SC., Brust, JC., Mathema, B., Ismail, N., Moodley, P., Mlisana, K., Allana, S., Campbell, A., Mthiyane, T. & Morris, N. 2017. Transmission of extensively drug-resistant tuberculosis in South Africa. *New England Journal of Medicine* 376(3): 243-253.

Shah, L., Pena, MR., Mori, O., Zamudio, C., Kaufman, JS., Otero, L., Gotuzzo, E., Seas, C. & Brewer, TF. 2020. A pragmatic stepped-wedge cluster randomized trial to evaluate the effectiveness and cost-effectiveness of active case finding for household contacts within a routine tuberculosis program, San Juan de Lurigancho, Lima, Peru. *International Journal of Infectious Diseases* 100(1): 95-103.

Shannon-Baker, P. 2016. Making paradigms meaningful in mixed methods research. *Journal of Mixed Methods Research* 10(4): 319-334.

Sharma, D., Sharma, J., Deo, N. & Bisht, D. 2018. Prevalence and risk factors of tuberculosis in developing countries through health care workers. *Microbial Pathogenesis* 124(1):279-283.

Shokri, M., Najafi, R., Niromand, J., Babazadeh, A., Javanian, M., Bayani, M., Afra, ZG. & Ebrahimpour, S. 2018. The frequency of risk factors for pulmonary tuberculosis in tuberculosis patients in Babol, Northern Iran, during 2008-2015. *Current Issues in Pharmacy and Medical Sciences* 31(3):144-147.

Shufutinsky, A., 2020. Employing use of self for transparency, rigor, trustworthiness, and credibility in qualitative organizational research methods. *OD Practitioner* 52(1):50-58.

Sima, BT., Belachew, T. & Abebe, F. 2019. Health care providers' knowledge, attitude and perceived stigma regarding tuberculosis in a pastoralist community in Ethiopia: a cross-sectional study. *BMC Health Services Research* 19(1):1-11.

Silva, DR., Munoz-Torrico, M., Duarte, R., Galvão, T., Bonini, EH., Arbex, FF., Arbex,MA., Augusto,VM., Rabahi, MF. & Mello, FCQ. 2018. Risk factors for tuberculosis: diabetes, smoking, alcohol use, and the use of other drugs. *J Bras Pneumol* 44(2):145-152.

Sloot, R., Schim van der Loeff, MF., Kouw, PM. & Borgdorff, MW. 2014. Risk of Tuberculosis after Recent Exposure A 10-Year Follow-up Study of Contacts in

Amsterdam. *American Journal of Respiratory and Critical Care Medicine* 190(9): 1044-1052.

Spieth, PM., Kubasch, AS., Penzlin, AI., Illigens, BMW., Barlinn, K. & Siepmann, T. 2016. Randomized controlled trials–a matter of design. *Neuropsychiatric Disease and Treatment* 12(1):1341-49.

Sommerland, N., Wouters, E., Mitchell, EMH., Ngicho, M., Redwood, L., Masquillier, C., van Hoorn, R., van den Hof, S. & Van Rie, A. 2017. Evidence-based interventions to reduce tuberculosis stigma: a systematic review. *The International Journal of Tuberculosis and Lung Disease* 21(11):81-86.

Srivastava, A. & Klassen, EP. 2016. *Functional and shape data analysis (Vol. 1).* New York: Springer.

Streubert, HJ. & Carpenter, DR. 2011. *Qualitative research in nursing*. 4th edition. Philadelphia: Lippincott.

Tanimura, T., Jaramillo, E., Weil, D., Raviglione, M. & Lonnroth, K.2014. Financial burden for tuberculosis patients in low-and middle-income countries: a systematic review. *European Respiratory Journal* 43(6): 1763-1775.

Tausch, A.P. & Menold, N. 2016. Methodological aspects of focus groups in health research: results of qualitative interviews with focus group moderators. *Global Qualitative Nursing Research* 3(1):1-12.

Tefera, F., Barnabee, G., Sharma, A., Feleke, B., Atnafu, D., Haymanot, N., Malley, GO. & Feleke, G. 2019. Evaluation of facility and community-based active household tuberculosis contact investigation in Ethiopia: a cross-sectional study. *BMC Health Services Research* 19(234): 1-9.

Tiemersma, EW., van der Werf, MJ., Borgdorff, MW., Williams, BG. & Nagelkerke, NJD. 2011. Natural History of Tuberculosis: Duration and Fatality of Untreated Pulmonary Tuberculosis in HIV Negative Patients A Systematic Review. *PLoS ONE* 6(4): 1-13.

Tobi, H. & Kampen, JK.2018. Research design: the methodology for interdisciplinary research framework. *Qual Quant* 2018 (52):1209–1225.

Turner, RD. & Bothamley, GH. 2015. Cough and the transmission of tuberculosis. *Journal of Infectious Diseases* 211(9):1367-72.

Turner, RD., Chiu, C., Churchyard, GJ., Esmail H., Lewinsohn, DM., Gandhi, NR. & Fennelly, KP. 2017. Tuberculosis Infectiousness and Host Susceptibility. *Journal of Infectious Diseases* 216(6): 636-643.

Ukwaja, KN., Alobu, I., Lgwenyi, C. & Hopewell, PC. 2013. The High Cost of Free Tuberculosis Services: Patient and Household Costs Associated with Tuberculosis Care in Ebonyi State, Nigeria. *PLoS ONE* 8(8): 1-10.

Van den Berg, A. & Struwig, M. 2017. Guidelines for Researchers Using an Adapted Consensual Qualitative Research Approach in Management Research. *Electronic Journal of Business Research Methods* 15(2):109-119.

Varpio, L., Paradis, E., Uijtdehaage, S. & Young, M. 2020. The distinctions between theory, theoretical framework, and conceptual framework. *Academic Medicine* 95(7): 989-994.

Venkatesh, V., Brown, SA. & Sullivan, YW. 2016. Guidelines for Conducting Mixed-methods Research: An Extension and Illustration. *Journal of the Association for Information Systems* 17(7):435-495.

Woo, K., 2017. *Polit & Beck Canadian Essentials of Nursing Research*. Fourth edition. Ontario: Lippincott Williams & Wilkins.

Wood, L.M., Sebar, B. and Vecchio, N., 2020. Application of Rigour and Credibility in qualitative document analysis: Lessons Learnt from a case study. *The Qualitative Report 25*(2): 456-470.

World Health Organization.2012. *Recommendations for investigating contacts of persons with infectious tuberculosis in low- and middle-income countries*. Geneva: WHO.

World Health Organization.2013. *Systematic screening for active tuberculosis. Principles and recommendations.* Geneva: WHO.

World Health Organization.2017. *Guidelines for treatment of drug-susceptible tuberculosis and patient care.* Geneva: WHO.

World Health Organization.2019. *Global tuberculosis report 2019.* Geneva: WHO.

Xia, BS. & Gong, P. 2014. Review of business intelligence through data analysis. Benchmarking. *An International Journal* 21 (2):300-311.

Young, ME. & Ryan, A. 2020. Post positivism in health professions education scholarship. *Academic Medicine 95*(5): 695-699.

Zellweger, JP., Sotgiu, G., Block, M., Dore, S., Altet, N., Blunschi, R., Bogyi, M., Bothamley, G., Bothe, C., Codecasa, L., Costa, P., Dominguez, J., Duarte, R., Fløe, A., Fresard, I., García-García, JM., Goletti, D., Halm, P., Hellwig, D., Henninger, E., Heykes-Uden, H., Horn, L., Kruczak, K., Latorre, I., Pache, G., Rath, H., Ringshausen, FC., Ruiz, AS., Solovic, I., Souza-Galvão, ML., Widmer, U., Witte, P. & Lange, C. 2015. Risk Assessment of Tuberculosis in Contacts by IFN-γ Release Assays. A Tuberculosis

Network European Trials Group Study. *American Journal of Respiratory and Critical Care Medicine* 191(10):1176-84.

Zhang, A. 2017. Data Analytics: Practical Guide to Leveraging the Power of Algorithms, Data Science, Data Mining, Statistics, Big Data, and Predictive Analysis to Improve Business, Work, and Life. *Create Space Independent Publishing Platform* 1 (1):1-280.

Zyphur, MJ. & Pierides, DC. 2017. Is quantitative research ethical? Tools for ethically practicing, evaluating, and using quantitative research. *Journal of Business Ethics* 143(1):1-16.

ANNEXURES

ANNEX A: ETHICAL CLEARANCE CERTIFICATE

UNISA university of south africa

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

6 December 2017

Dear Zerihun Yaregal Admassu

HSHDC/781/2017
Zerihun Yaregal Admassu

Student:6210-348-2
Supervisor: Prof ZZ Nkosi
Qualification: PhD
Joint Supervisor: -

Decision: Ethics Approval

Name: Zerihun Yaregal Admassu

Proposal: Improving tuberculosis case finding among household contacts of tuberculosis patients by using community base model

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.*

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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
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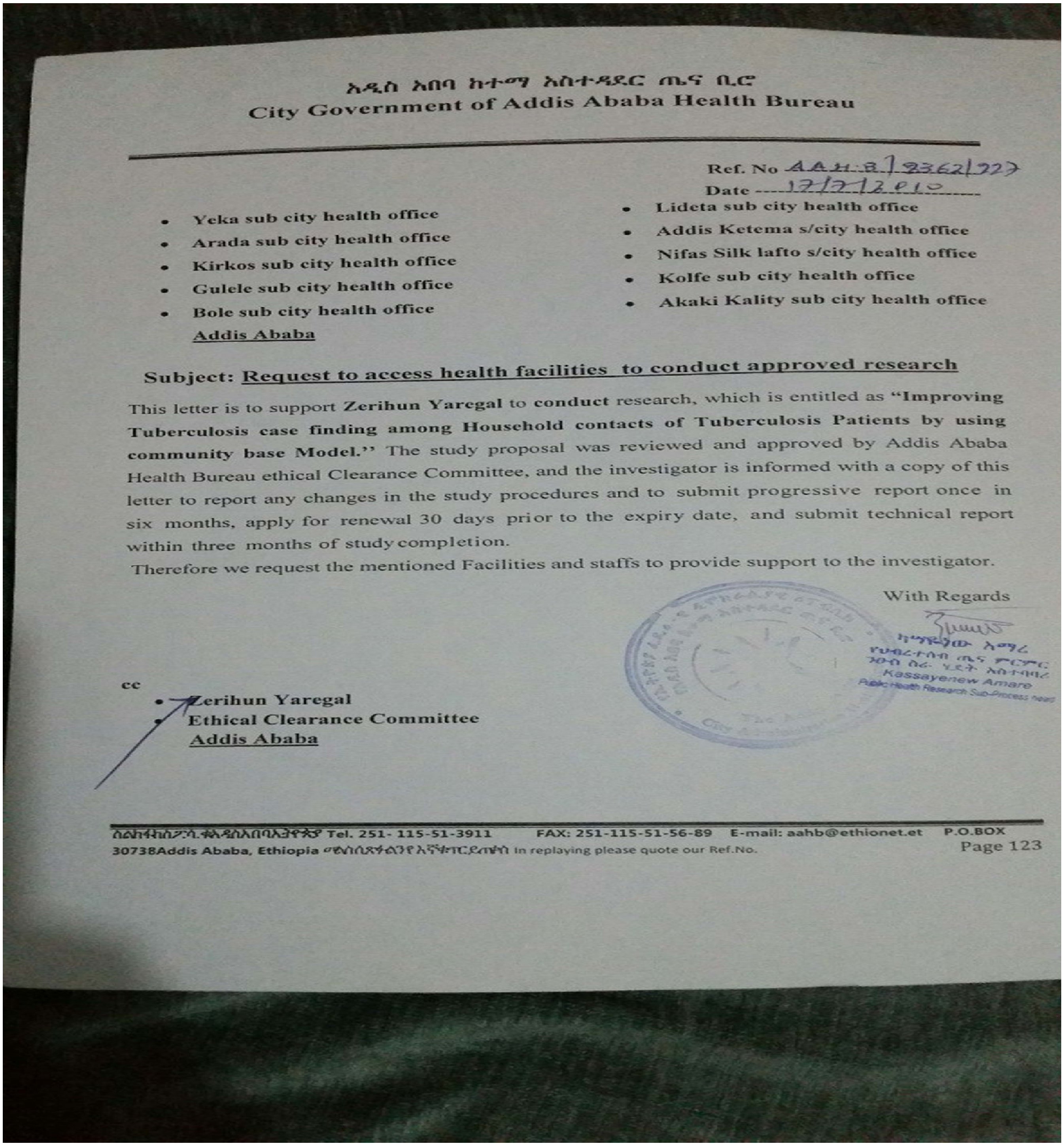
ANNEX B: LETTER OF PERMISSION FROM ADDIS ABABA HEALTH BUREAU



አዲስ አበባ ከተማ አስተዳደር ጤና ቢሮ

City Government of Addis Ababa Health Bureau

Ref. No AAH:B/ 9362/227

Date 17/7/2010

- **Yeka sub city health office**
- **Arada sub city health office**
- **Kirkos sub city health office**
- **Gulele sub city health office**
- **Bole sub city health office**
- **Lideta sub city health office**
- **Addis Ketema s/city health office**
- **Nifas Silk lafto s/city health office**
- **Kolfe sub city health office**
- **Akaki Kality sub city health office**

Addis Ababa

Subject: Request to access health facilities to conduct approved research

This letter is to support **Zerihun Yaregal** to **conduct** research, which is entitled as **"Improving Tuberculosis case finding among Household contacts of Tuberculosis Patients by using community base Model.''** The study proposal was reviewed and approved by Addis Ababa Health Bureau ethical Clearance Committee, and the investigator is informed with a copy of this letter to report any changes in the study procedures and to submit progressive report once in six months, apply for renewal 30 days prior to the expiry date, and submit technical report within three months of study completion.

Therefore we request the mentioned Facilities and staffs to provide support to the investigator.

With Regards

Kassayenew Amare

Public Health Research Sub-Process head

cc

- **Zerihun Yaregal**
- **Ethical Clearance Committee**

Addis Ababa

Tel. 251- 115-51-3911 FAX: 251-115-51-56-89 E-mail: aahb@ethionet.et P.O.BOX 30738Addis Ababa, Ethiopia In replaying please quote our Ref.No.

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ANNEX C: CONSENT FORM

Part 1: Information sheet and Consent Form

STUDY TITLE: Improving tuberculosis case finding among household contacts of tuberculosis patients by using community base model in Addis Ababa, Ethiopia.

Zerihun Yaregal Admassu, a public health expert currently pursuing a doctoral degree from the University of South Africa and conducting a study as titled above in the fulfilment of the requirements for the degree of doctor of literature and philosophy degree in public health (DLitt et Phil). This study will be conducted in all ten sub-cities of Addis Ababa city administration at selected public health facilities.

The purpose of this study is to provide guidelines and frameworks to facilitate the implementation of a community-based household contact program at the Public Health Center in Addis Ababa, Ethiopia. The researchers intend to use the results of this study to endorse new interventions, methods of tracing and managing services for household contacts of tuberculosis.

I the undersigned individual being oriented about the relevance of this study In terms of improving service delivery in medical facilities for TB patients, family contact tracing health care services are widely known. It is very important for me to participate in this research. All my information should be kept confidential and used only for this research. In addition, I have been well informed that my name will not be asked. I have the right not to discuss issues that I do not want to discuss. If I want to withdraw from the study at any time during the discussion, I have no obligation to continue to do so or give reasons.

If you need any clarification, you can contact the researcher at the address below.

Zerihun Yaregal:

Tel:+251911539178 e-mail: 62103482@mylife.unisa.ac.za.

I have read this form and voluntarily consent to participate in this study.

Participant's Signature:_____ Date:

I have explained this to the above participant and have sought his/her understanding for informed consent.

Researcher/ research assistant's Signature:_____Date:

Part 2: Focused group Discussion Confidentiality Binding Form.

Improving Tuberculosis case finding among Household contacts of Tuberculosis Patients by using community based Model in Addis Ababa, Ethiopia.

Thank you for taking the time to discuss with me today. My name is Zerihun Yaregal Admassu, PhD student at UNISA on public health. Today I would like to discuss with you about your experiences with tuberculosis case finding programme among household contacts of tuberculosis patients in Addis Ababa, we are developing a community base model in order to capture lessons that can be used in future interventions.

The interview doesn't talk long. I will take some notes and recording the session in order to capture the complete conversation. All responses will be kept confidential. This means that your interview responses will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the respondent. Remember, you don't have to talk about anything you don't want to and you may end the interview at any time.

Are there any questions about what I have just explained?

Are you willing to participate in this interview? Yes No

Participant signature _____ Date_____

ANNEX D: INTERVIEW GUIDE

Part 1: Focus group discussion guide

Guide for focus group discussion with TB Program Manager

Once again, thank you for participating for FGD.

1. What do you know about the term family contact tracing of TB patients?
2. How do you describe the current tracing system, practice, strategies, and rate in the country in general and in your facility in particular?
3. How to track family contacts of TB patients in your institution?
- What mechanisms at individual/ Are you improving the family contact tracking system for medical institutions?
-How can this help improve the contact tracking system?
4. Based on your experience, how do you track the family contact of a TB patient?
5. When did you trace family contacts to TB patients6. What do you do after first tracing? How do you follow your patient? Is there any follow up mechanism?
7. How do you monitor your work?
-Documents and reports-Communication with other health care providers
-Comments from partners who support the program
8. What challenges does the family contact tracking system face?
9. What do you suggest to improve the Household contact tracing system? What do you think is the best way/most effective way to practice the family contact tracking system?
10. If you have anything to say about family contact tracking, it is important to not mention it before closing.

PART 2: In-depth interview guide

Guide for key informant interview with TB patients and their household contacts

Name of data collector: _____

Name of Supervisor: _____

Respondent's unique identifier: _____

Date: _____

1. Did you feel at risk of contracting TB at home from household member?
2. What is TB household contact tracing according to your understanding?
3. What is the immediate benefit of contact tracing to a TB contact?
4. What may best improve people's participation in the TB household contact tracing?
5. Which TB household contact tracing actions could the HCWs use best in the clinic?
6. How do you describe the current TB Household contact tracing system?
7. What shall be done to improve TB Household contact tracing system?
8. If you have something you want to say regarding TB Household contact tracing system which was not raised and believed very important before concluding.

ANNEX E: QUESTIONNAIRE ENGLISH VERSION

Part 1: Questionnaire for TB patients

Name of Health Facility

Name of interviewer

Code of Index case

Part One: Sociodemographic Characteristics

S.No	Question	Response	Remark	Code
101	Sex	1.Male 2.Female		
102	Age in year.			
103	What is your religion?	1. Orthodox 2. Muslim 3. Protestant 4. Catholic 77. Others, (specify) --------		
104	What is your marital status?	1. Never married 2. Currently married 3. Divorced 4. Separated 5. Widowed		
105	What is your level of education?	1.None 2.Read & write 3.Grade 1 -6 4.Grade 7 -8 5.Grade 9-12 6.Grade 12 +		
106	What is your occupation?	1.Civil servant 2.Daily labour 3.Employed in private sector		

		4.Has private business 5.Housewife 6.Maid servant 7.No job 8.Student 77.Others, (specify) -----		
107	Do you have your own income?	1.Yes 2.No Skip to 109		
108	What is your monthly income?	1.< 200 ETB 2.200-400 ETB 3.401-600 ETB 4.601-1000 ETB 5.> 1000 ETB		

Part Two: Life Style characteristics

S.No	Question	Response	Remark	Code
201	Do you smoke cigarette?	1.Yes skip to 204 2. No If no to 202		
202	Have you ever smoked?	1.Yes If yes to 203 2.No skip to 207		
203	How long time ago did you smoke (months/years)?	1.During the past year 2.More than 1 year previously		
204	If yes to 201/202, how many per day?	1.<=5 cigarette 2.6-10 cigarette 3.11-15 cigarette 4.>15 cigarette		
205	If yes to 201/202, for how many years?	1.<5 2.5-10 3.10+		
206	Smoking status	1.Current smokers	1. Smoke cigarette within the past year.	

		2. Former smokers 3.Non-smokers	2. Stopped smoking more than 1 year previously. 3. Never smoke throughout their life.	
207	Do you take alcohol?	1.Yes skip to 210 2. No skip to 208		
208	Have you ever drunk?	1.Yes skip to 209 2. No skip to part 3		
209	How long time ago did you drunk (months/years)?	1.During the past year 2.More than 1 year previously		
210	If yes to 207/208, how often?	1.<1d/week 2.1-3d/ week 3.4-6d/ week 4.daily		
211	If yes to 207/208, for how many years?	1.<5 2.5-10 3.10+		
212	Drinking status	1.Current drinkers 2. Former drinkers 3.Non-drinkers	1. Drink during the past year. 2. Stopped drinking more than 1 year previously. 3. Never drink throughout their life.	

Part Three: Physical Examination & Anthropometric measurement

S.No	Question	Response	Remark	Code
301	BCG-scar (examine the participant)	1. Present 2. Absent		

302	Baseline Weight	_____ kg		
303	Height/measure their height.	_____ m		
304	BMI: (calculated by P.I)	1.≥18.5kg/m^2 2. ≥17-<18.5kg/m^2 3.< 17 kg/m^2		

Part Four: Clinical characteristics

S.No	Question	Response	Remark	Code
401	HIV status	1. Non-Reactive 2. Reactive 3.Refuse		
402	ART	1.Yes 2.No		
403	CPT	1.Yes 2.No		
404	Do you have Diabetes?	1.Yes 2.No		
405	Do you have any of the following conditions?	1.kideny failure 2.cancer 3.high blood pressure 4.heart disease 77.Others, (specify) ----- 88.no		
406	Do you take any medication?	1.Yes 2.No If yes, specify----------		
407	For how long?			
408	Previous self-history of TB	1.Yes 2.No		
409	Duration of symptom before diagnosis			
410	Chest X-ray	)Normal)Abnormal		
411	Cavitary disease on CXR	1.Yes 2.No		

Part Five: Household Characteristics

S.No	Question	Response	Remark	Code
501	Have you ever lived together with a TB patient?	1. Yes 2. No		
502	If yes to Q 501, when?			
503	Family/ Household Size			
504	No of person/room			
505	Do/did you suspect that someone is/was at risk of getting TB from you?	) Yes, in the household) Yes, at workplace) No) I do not know		

Part Six: LABORATORY RESULTS FORM

S.No	Question	Response	Remark	Code
601	Xpert Result			
602	Culture Result			

Name of interviewer _ _ _ _ _ _ _ _

Time finished _ _ _ _ _ _ _ _ _ _ _

Signature _ _ _ _ _ _ _ _ _ _ _ _ _

Part 2: Interviewer administered questionnaire for TB patients household

Code of Index case_____Code of patient household contact

Name of interviewer Time started

Part One: Sociodemographic Characteristics

S.No	Question	Response	Remark	Code
101	Sex	1.Male 2.Female		
102	Age in year.			
103	What is your religion?	1. Orthodox 4. Catholic 2. Muslim 77. Others, (specify) 3. Protestant		
104	What is your marital status?	1. Never married 4. Separated 2. Currently married 5. Widowed 3. Divorced		
105	What is your level of education?	1.None 4.Grade 7 -8 2.Read & write 5.Grade 9-12 3. Grade 1-6. 6. Grade 12 +		
106	What is your occupation?	1.Civil servant 5.Housewife 2.Daily labour 6.Maid servant 3.Employed in private sector 7.No job 4.Has private business 8.Student 77.Others, (specify) -----		

107	Do you have your own income?	1.Yes 2.No Skip to 109		
108	What is your monthly income?	1.< 200 ETB 2.200-400 ETB 3.401-600 ETB 4.601-1000 ETB 5.> 1000 ETB		

Part Two: Life Style characteristics

S.No	Question	Response		Remark	Code
201	Do you smoke cigarette?	1.Yes skip to 204 2. No If no to 202			
202	Have you ever smoked?	1.Yes If yes to 203 2.No skip to 207			
203	How long time ago did you smoke (months/years)?	1.During the past year 2.More than 1 year previously			
204	If yes to 201/202, how many per day?	1.<=5 cigarette 3.11-15 cigarette 2.6-10 cigarette 4.>15 cigarette			
205	If yes to 201/202, for how many years?	1.<5 2.5-10 3.10+			
206	Smoking status	1.Current smokers 2. Former smokers 3.Non-smokers	1. Smoke cigarette within the past year. 2. Stopped smoking more than 1 year previously. 3. Never smoke throughout their life.		
207	Do you take alcohol?	1.Yes skip to 210 2. No skip to 208			

208	Have you ever drunk?	1.Yes skip to 209 2. No skip to part 3		
209	How long time ago did you drunk (months/years)?	1.During the past year 2.More than 1 year previously		
210	If yes to 207/208, how often?	1.<1d/week 3.4-6d/ week 2.1-3d/ week 4.daily		
211	If yes to 207/208, for how many years?	1.<5 2.5-10 3.10+		
212	Drinking status	1.Current drinkers 2. Former drinkers 3.Non-drinkers	1. Drink during the past year. 2. Stopped drinking more than 1 year previously. 3. Never drink throughout their life.	

Part Three: Physical Examination & Anthropometric measurement

S.No	Question	Response	Remark	Code
301	BCG-scar (examine the participant)	1. Present 2. Absent		
302	Weight	_____ kg		
303	Height	_____ m		
304	BMI: (calculated by P.I)	1. ≥18.5kg/m^2 2. ≥17-<18.5kg/m^2 3.< 17 kg/m^2		

Part Four: Clinical characteristics

S.No	Question	Response	Remark	Code
401	HIV status	1. Non-Reactive 2. Reactive 3.Refuse		

402	Do you have Diabetes?	1.Yes 2.No		
403	Do you have any of the following conditions?	1.kideny failure 2.cancer 3.high blood pressure 4.heart disease 77.Others, (specify) -----88.no		
404	Do you take any medication?	1.Yes 2.No If yes, specify----------		
405	For how long?			
406	Previous -history of TB	1.Yes 2.No		

Part Five: Household Characteristics

S.No	Question	Response	Remark	Code
501	Have you ever lived together with a TB patient?	1. Yes 2. No		
502	If yes to Q 501, when?			
503	Family/Household Size			
504	No of person/room			
505	How many hours in a day do you spend with your household members?			
506	Have you ever lived/worked with someone with TB?	Yes, I am living/working with now Yes, I lived/worked with before No, I have never lived/worked with		
507	What do you think is the cause of TB?	1. Eating bad food 2. Devine punishment 3. Witchcraft 4. Bacteria 5. Other (specify.....)		

		6. I do not know		
508	Did you feel at risk of contracting TB at home or work environment?	1.Yes: a household member with cough has/had not been tested 2. Yes. member has/had cough 4. No: no workmate has/had cough 5. Other (specify…….....) 6. I do not know		

Part Six: TB Screening

S.No	Question	Response	Remark	Code
601	Cough with a duration of 15 days	1. Yes duration 2. No		
602	Fever	1. Yes 2. No		
603	Night sweating			
604	Weight loss			
407	Chest X-ray	1. Normal 2.Abnormal		
408	Cavitary disease on CXR	1.Yes 2.No		

Part Seven: Laboratory Results

S.No	Question	Response	Remark	Code
601	Xpert Result			
602	Culture Result			

Name of interviewer _ _ _ _ _ _ _

Time finished _ _ _ _ _ _ _ _ _ _

Signature _ _ _ _ _ _ _ _ _ _ _ _

ANNEX F: AMHARIC VERSION OF THE QUESTIONNAIRE

Part 1: Interviewer administered questionnaire for TB patients

ለሳንባ በሽታ ታካሚዎች የተዘጋጀ ቃለ-መጠይቅ

የጤና ተቋም ስም

ቃለ-መጠይቅ የሚያደርገው ስም

የህክምና መከታተያ መለያ ቁጥር

ክፍል አንድ: ማህበራዊ ሁኔታ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
101	ጾታ	1.ወንድ 2.ሴት		
102	እድሜ			
103	ሀይማኖት?	1. ኦርቶዶክስ 2. ሙስሊም 3. ፕሮቴስታንት 4. ካቶሊክ 77. ሌላ, -------		
104	የጋብቻ ሁኔታ?	1. ያላገባ/ች 2. ያገባ/ች 3. የፈታ/ች 4. የተለያየ/ች 5. የሞተባት/ችበት		
105	የትምህርት ሁኔታ መግለጫ?	1.ምንም ያልተማረ/ች 2.ማንበብ እና መጻፍ የሚችል 3.ከ 1- 6 ክፍል ያጠናቀቀ 4.ከ 7-8 ክፍል ያጠናቀቀ 5.ከ 9-12 ክፍል ያጠናቀቀ 6.ከ12ኛ ክፍል በላይ		
106	የስራ ሁኔታ መግለጫ?	1. የመንግስት ስራ 2.የቀን ሰራተኛ 3.የግል ድርጅት ተቀጣሪ 4.የግል ስራ		

		5.የቤት እመቤት 6.የቤት ሰራተኛ 7.ሥራ አጥ 8.ተማሪ 77ሌላ, -----		
107	የራስህ/ሽ የሆነ ገቢ አለህ/ሽ ?	1.አዎ 2.የለም ከሆነ ወደ ተ.ቁ 109		
108	ወርሀዊ ገቢህ ምን ያክል ይሆናል?	1.< 200 ብር 2.200-400 ብር 3.401-600 ብር 4.601-1000 ብር 5.> 1000 ብር		

<u>ክፍል ሁለት: የኑሮ መገለጫ</u>

ተ.ቁ	ጥያቄ	መልስ		ማብራሪያ	ኮድ
201	ሲጋራ ታጨሳለህ/ሻለሽ?	1.አዎ ከሆነ ወደ ተ.ቁ 204 2.የለም ከሆነ ወደ ተ.ቁ 202			
202	ሲጋራ በየትኛውም ጊዜ አጭሰህ ታውቃለህ?	1.አዎ ከሆነ ወደ ተ.ቁ 203 2.የለም ከሆን ወደ ተ.ቁ 207			
203	ምን ያህል ጊዜ ይሆናል ካጨስክ/ሽ(በወር/በአመት)?	1.ባለፈው አንድ አመት ውስጥ 2.ከአንድ አመት በላይ አልፎታል			
204	የ ተ.ቁ 201/202 አዎ ከሆነ, በቀን ምን ያህል?	1.<=5 ሲጋራ 2.6-10 ሲጋራ 3.11-15 ሲጋራ 4.>15 ሲጋራ			
205	የ ተ.ቁ 201/202, ለስንት አመት?	1.<5 2.5-10 3.10+			
206	የማጨስ ሁኔታ	1. አሁን ላይ አጨሳለው 2. በፊት አጨሳለው 3.አላጨስም	1. ባለፈው አንድ አመት አጨሳልው. 2. ማጨስ ካቆምኩኝ አንድ አመት አልፎኛል.		

			3.በፍጹም አጭሼ አላውቅም.	
207	መጠጥ ትጠጣለህ?	1.አዎ ከሆነ ወደ ተ.ቁ 210 2. የለም ከሆነ ወደ ተ.ቁ 208		
208	መጠጥ ጠጥተህ ታውቃለህ?	1.አዎ ከሆነ ወደ ተ.ቁ 209 2. የለም ከሆነ ወደ ክፍል 3		
209	ምን ያህል ጊዜ ሆኖሃል ጠጥተሃል (ወራት/አመታት)?	1.ባለፈው አንድ አመት ውስጥ 2.ከአንድ አመት በላይ አልፎታል		
210	መልሱ ለ207/208 አዎ ከሆነ, በስንት ጊዜ?	1.<1 ቀን በሳምንት 2.1-3 ቀን በሳምንት 3.4-6 ቀን በሳምንት 4.በየቀኑ		
211	ለ ተ.ቁ 207/208 አዎ ከሆነ መልሱ, ለስንት አመት?	1.<5 2.5-10 3.10+		
212	መጠጥ የመጠጣት ሁኔታ	1.አሁንም እጠጣለው 2. ከዚህ በፊት እጠጣ ነበር 3.ጠጥቼ አላውቅም	1. ባለፈው አመት ውስጥ ጠጥቻለው. 2. መጠጣት ካቆምኩኝ አንድ አመት በላይ ሆኖኛል. 3. በፍጹም ጠጥቼ አላውቅም.	

<u>ክፍል ሶስት: አካላዊ ምርመራ እና ልኬት</u>

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
301	የሳንባ በሽታ መከላከያ ክትባት (በምርመራ ይረጋገጥ)	1. አለ 2. የለም		
302	መነሻ ክብደት	_____ ኪ.ግ		
303	ቁመት	_____ ሜ		
304	ቢ.ኤም.አይ: ይሰላ	1. ≥18.5ኪ.ግ/ሜ^2 2. ≥17-<18.5ክ.ግ/ሜ^2		

		3.< 17 ኪ.ግ/ሜ^2		

ክፍል አራት: የህክምና ሁኔታ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
401	የኤች.አይ.ቪ ሁኔታ መግለጫ	1. ኤች.አይ.ቪ ነጻ 2. ኤች.አይ.ቪ ያለበ/ባት 3.ለመመርመር ያልፈለገ		
402	ጸረ-ኤች.አይ.ቪ መድሀኒት ተጠቃሚ	1. አዎ 2.የለም		
403	የተጉአዳኝ በሽታ መከላከያ ተጠቃሚ	1.አዎ 2.የለም		
404	የስኩአር በሽታ አለ?	1.አዎ 2.የለም		
405	ከተዘረዘሩት ውስጥ ያለብዎት ካለ?	1.የኩላሊት ስራ ማቆም 2.ካንሰር 3.ከፍተኛ የደም ግፊት 4.የልብ በሽታ 77.ሌላ, ----- 88.የለም		
406	ማንኛውም የሚወሰድ መድሀኒት ካለ?	1.አዎ, ---------- 2.የለም		
407	ለምን ያህል ጊዜ?			
408	ከዚህ በፊት የሳንባ በሽታ ታክመህ ታውቃ/ቂለህ/ሽ	1.አዎ 2.የለም		
409	በሽታው መኖሩ ከመረጋገጡ በፊት ለስንት ጊዜ ምልክት አሳየህ/ሽ			
410	የደረት ራጅ ውጤት	1.ጤናማ 2.ጤናማ ያልሆነ		
411	የሳንባ ክፍል ጉዳት በራጅ እይታ	1.አለ 2.የለም		

ክፍል አምስት: የመኖሪያ ቤት ውስጥ ያለ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
501	የሳንባ ህመም ታካሚ ጋር አብሮ የመኖር ሁኔታ ነበር?	1. አዎ 2. የለም		

502	ለ ተ.ቁ 501 መልሱ አዎ ከሆነ, መቼ?			
503	የቤተሰብ ብዛት ቁጥር			
504	የሰዎች ቁጥር ብዛት በአንድ ክፍል			
505	ባንተ/ቺ ምክንያት የሳንባ በሽታ ተይዞ ሊሆን ይችላል ብለህ የምትገምተው ሰው አለ?	1.አዎ, መኖሪያ ቤት 2.አዎ, ስራ ቦታ 3.የለም 4.አላውቅም		

<u>ክፍል ስድስት: የላብራቶሪ ውጤት ቅጽ</u>

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
601	የኤክስፐርት ውጤት			
602	የከልቸር ውጤት			

ቃለ-መጠይቅ ያደረገ ሰው ስም

መጠይቁ ያለቀበት ጊዜ

ፊርማ

Part 2: Interviewer administered questionnaire for TB patient's household contacts

ከህመምተኛው ጋር አብሮ ለሚኖር ሰው የተዘጋጀ መጠይቅ

የታማሚው ህክምና መለያ ቁጥር _____

ከህመምተኛው ጋር አብሮ የሚኖር ሰው መለያ ቁጥር

ቃለ-መጠይቅ ያደረገው ስም መጠይቁ የተጀመረበት ጊዜ

ክፍል አንድ: ማህበራዊ ሁኔታ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
101	ጾታ	1.ወንድ 2.ሴት		
102	እድሜ.			
103	ሀይማኖት?	1. ኦርቶዶክስ 2. ሙስሊም 3. ፕሮቴስታንት 4. ካቶሊክ 77. ሌላ, --------		
104	የጋብቻ ሁኔታ?	1. ያላገባ/ች 2. ያገባ/ች 3. የፈታ/ች 4. የተለያየ/ች 5. የሞተባት/ችበት		
105	የትምህርት ሁኔታ መግለጫ?	1.ምንም ያልተማረ/ች 2.ማንበብ እና መጻፍ የሚችል 3.ከ 1- 6 ክፍል ያጠናቀቀ 4.ከ 7-8 ክፍል ያጠናቀቀ 5.ከ 9-12 ክፍል ያጠናቀቀ 6.ከ12ኛ ክፍል በላይ		
106	የስራ ሁኔታ መግለጫ?	1. የመንግስት ስራ 2.የቀን ሰራተኛ 3.የግል ድርጅት ተቀጣሪ 4.የግል ስራ 5.የቤት እመቤት		

		6.የቤት ሰራተኛ 7.ሥራ አጥ 8.ተማሪ 77ሌላ, -----		
107	የራስህ/ሽ የሆነ ገቢ አለህ/ሽ?	1.አዎ 2.የለም ከሆነ ወደ ተ.ቁ 109		
108	ወርሀዊ ገቢህ ምን ያክል ይሆናል?	1.< 200 ብር 2.200-400 ብር 3.401-600 ብር 4.601-1000 ብር 5.> 1000 ብር		

ክፍል ሁለት: የኑሮ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
201	ሲጋራ ታጨሳለህ/ሻለሽ?	1.አዎ ከሆነ ወደ ተ.ቁ 204 2.የለም ከሆነ ወደ ተ.ቁ 202		
202	ሲጋራ በየትኛውም ጊዜ አጭስህ ታውቃለህ?	1.አዎ ከሆነ ወደ ተ.ቁ 203 2.የለም ከሆን ወደ ተ.ቁ 207		
203	ምን ያህል ጊዜ ይሆናል ካጨስክ/ሽ(በወር/በአመት)?	1.ባለፈው አንድ አመት ውስጥ 2.ከአንድ አመት በላይ አልፎታል		
204	የ ተ.ቁ 201/202 አዎ ከሆነ, በቀን ምን ያህል?	1.<=5 ሲጋራ 2.6-10 ሲጋራ 3.11-15 ሲጋራ 4.>15 ሲጋራ		
205	የ ተ.ቁ 201/202, ለስንት አመት?	1.<5 2.5-10 3.10+		
206	የማጨስ ሁኔታ	1. አሁን ላይ አጨሳለው 2. በፊት አጨሳለው 3.አላጨስም	1. ባለፈው አንድ አመት አጨሳልው. 2. ማጨስ ካቆምኩኝ አንድ አመት አልፎኛል. 3.በፍጹም አጭሼ አላውቅም.	
207	መጠጥ ትጠጣለህ?	1.አዎ ከሆነ ወደ ተ.ቁ 210		

		2. የለም ከሆነ ወደ ተ.ቁ 208		
208	መጠጥ ጠጥተህ ታውቃለህ?	1.አዎ ከሆነ ወደ ተ.ቁ 209 2. የለም ከሆነ ወደ ክፍል 3		
209	ምን ያህል ጊዜ ሆኖሃል ጠጥተሃል (ወራት/አመታት)?	1.ባለፈው አንድ አመት ውስጥ 2.ከአንድ አመት በላይ አልፎታል		
210	መልሱ ለ207/208 አዎ ከሆነ, በስንት ጊዜ?	1.<1 ቀን በሳምንት 2.1-3 ቀን በሳምንት 3.4-6 ቀን በሳምንት 4.በየቀኑ		
211	ለ ተ.ቁ 207/208 አዎ ከሆነ መልሱ, ለስንት አመት?	1.<5 2.5-10 3.10+		
212	መጠጥ የመጠጣት ሁኔታ	1.አሁንም እጠጣለው 2. ከዚህ በፊት እጠጣ ነበር 3.ጠጥቼ አላውቅም	1. ባለፈው አመት ውስጥ ጠጥቻለው. 2. መጠጣት ካቆምኩኝ አን አመት በላይ ሆኖኛል. 3. በፍጹም ጠጥቼ አላውቅም.	

ክፍል ሶስት: አካላዊ ምርመራ እና ልኬት

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
301	የሳንባ በሽታ መከላከያ ክትባት (በምርመራ ይረጋገጥ)	1. አለ 2. የለም		
302	መነሻ ክብደት	____ኪ.ግ		
303	ቁመት	_____ ሜ		
304	ቢ.ኤም.አይ: ይሰላ	1. ≥18.5ኪ.ግ/ሜ2 2. ≥17-<18.5ኪ.ግ/ሜ2 3.< 17 ኪ.ግ/ሜ2		

ክፍል አራት: የህክምና ሁኔታ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
401	የኤች.አይ.ቪ ሁኔታ መግለጫ	1. ኤች.አይ.ቪ ነጻ 2. ኤች.አይ.ቪ ያለበ/ባት 3.ለመመርመር ያልፈለገ		

402	ጸረ-ኤች.አይ.ቪ መድሀኒት ተጠቃሚ	1. አዎ 2.የለም		
403	ከተዘረዘሩት ውስጥ ያለብዎት ካለ?	1.የኩላሊት ስራ ማቆም 2.ካንሰር 3.ከፍተኛ የደም ግፊት 4.የልብ በሽታ 77.ሌላ, ----- 88.የለም		
404	ማንኛውም የሚወስድ መድሀኒት ካለ?	1.አዎ, ---------- 2.የለም		
405	ለምን ያህል ጊዜ?			
406	ከዚህ በፊት የሳንባ በሽታ ታክመህ ታውቃ/ቂለህ/ሽ	1.አዎ 2.የለም		

ክፍል አምስት: የመኖሪያ ቤት ውስጥ ያለ መገለጫ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
501	የሳንባ ህመም ታካሚ ጋር አብሮ የመኖር ሁኔታ ነበር?	1. አዎ 2. የለም		
502	ለ ተ.ቁ 501 መልሱ አዎ ከሆነ, መቼ?			
503	የቤተሰብ ብዛት ቁጥር			
504	የሰዎች ቁጥር ብዛት በአንድ ክፍል			
505	በቀን ምን ያህል ሰዓት ከቤት ውስጥ አባል ጋር ታሳልፋ/ፊለህ/ሽ?			
506	ቲቢ ካለበት ሰው ጋር አብረህ ኖረሃል/ኖረሻል?	አዎ አሁንም እየሰራው/እየኖርኩኝ ነው አዎ ከዚህ በፊት ኖሬ/ሰርቼ አውቃለሁ የለም፣ ኖሬም/ሰርቼም አላውቅም		
507	ቲቢ በሽታ ምንስኤው ምን ይመስልሀል?	1.የተበላሹ ምግቦች መብላት 2. የፈጣሪ ቅጣት 3. አስማት 4. ባክቴሪያ		

		5. ሌላ (ግለጽ.....) 6. አላውቅም		
508	በመኖሪያ ቤት ወይም በስራ ቦታ ቲቢ ይዞኝ ሊሆን ይችላል ብለህ ታስባለህ?	1.አዎ: አብሮኝ የሚኖር ሰው ሳል ነበረው ግን አልተመረመረም 2. አዎ: አብሮኝ የሚሰራ ሰው ያስለው ነበር ግን አልተመረመረም 3. የለም: ቤትም ሆነ ስራ ቦታዬ ማንም የለም		

ክፍል ስድስት: የቲቢ በሽታ ግምገማ

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
601	ሁለት ሳምንት እና ከዛ በላይ ሳል ያለው	1. አዎ ከሆነ ምን ያህል ጊዜ 2. የለም		
602	ትኩሳት	1. አዎ 2. የለም		
603	ላብ			
604	ክብደት መቀነስ			
605	የደረት ራጅ ውጤት	1.ጤናማ 2.ጤናማ ያልሆነ		
607	የሳንባ ክፍል ጉዳት በራጅ እይታ	1. አዎ 2. የለም		

ክፍል ሰባት: ላብራቶሪ ውጤት

ተ.ቁ	ጥያቄ	መልስ	ማብራሪያ	ኮድ
701	የኤክስፐርት ውጤት			
702	የከልቸር ውጤት			

ቃለ-መጠይቅ ያደረገ ሰው ስም

መጠይቁ ያለቀበት ጊዜ

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ANNEX G: LANGUAGE EDITOR CERTIFICATE

ALEM
ALEM Translation & Secretarial Services

CERTIFICATE OF LANGUAGE EDITING

This document certifies that the manuscript listed below was edited for proper English language grammar, spelling, punctuation, sentence structure and phrasing by one of the highly qualified editors at Aleme Abera Translation Secretarial and Other Related Services.

Manuscript Title

IMPROVING TUBERCULOSIS CASE FINDING AMONG HOUSEHOLD CONTACTS OF TUBERCULOSIS PATIENTS BY USING COMMUNITY BASED MODEL IN ADDIS ABABA, ETHIOPIA.

Author: Zerihun Yaregal Admassu

Date issued: February 06/2021 GC

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