Study to Assess Factors Influencing Initiation, Adherence, and Completion of Tuberculosis Preventive Therapy Among Household Contacts of Pulmonary Tuberculosis Patients in Vijayapura District.

By

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Dissertation submitted to

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In

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I, Dr. Shanoon Sharaf Ali, hereby declare that this dissertation entitled **"Study to Assess Factors Influencing Initiation, Adherence, and Completion of Tuberculosis Preventive Therapy Among Household Contacts of Pulmonary TB Patients in Vijayapura District"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. Shailaja S. Patil**, **M.D.**, Professor, Department of Community Medicine, B.L.D.E.(DU), Shri. B. M. Patil Medical CollegeHospital and Research Centre, Vijayapura.

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Date: 28-06-2024 **Dr. Shanoon Sharaf Ali**

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LIST OF ABBREVIATIONS

TB	Tuberculosis
TPT	Tuberculosis Preventive Therapy
LTBI	Latent Tuberculosis Infection
TBI	Tuberculosis Infection
UN	United Nations
WHO	World Health Organization
NTEP	National Tuberculosis Elimination Programme
PMTPT	Programmatic Management Of TPT
IGRA	Interferon-Gamma Release Assay
MDR-TB	Multi Drug Resistant Tb
Mtb	Mycobacterium Tb
AFB	Acid Fast Bacilli
TST	Tuberculin Skin Test
TU	Tuberculosis Unit
SC	Scheduled Caste
OBC	Other Backward Class
ST	Scheduled Tribe
LPG	Liquid Petroleum Gas
BPL	Below Poverty Line

LIST OF ABBREVIATIONS

BCG	Bacillus Calmette-Guérin
INH	Isoniazid
DTO	District TB officer
NTM	Nontuberculous Mycobacteria
MTC	Mycobacterium Tuberculosis Complex
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
PLHIV	People Living with HIV
ART	Antiretroviral Therapy
SPSS	Statistical Package for the Social Sciences
AAY	Antodaya Anna Yojana
APL	Above Poverty Line
PUC	Pre-University Course
NGO	Non-Governmental Organization
GSDP	Gross State Domestic Product
NSDP	Net State Domestic Product
ISSS	Internalized Social Stigma Scale
PMJAY	Pradhan Mantri Jan Arogya Yojan
PMUY	Pradhan Mantri Ujjwala Yojana

ABSTRACT

Background:

India has the highest burden of Tuberculosis (TB) infection globally, nearly 35-40 crores of which an estimated 26 lakh are likely to develop active TB. Although early diagnosis and treatment of active TB remains a top priority in India, preventing TB by detecting and treating TB Infection (TBI) is an important step towards ending TB. Tuberculosis preventive treatment (TPT) is one of the key interventions recommended by the World Health Organization (WHO). The risk of developing TB disease is reduced by 60% after receiving TPT. In July 2021, NTEP issued new guidelines recommending TPT for all House-Hold Contacts (HHCs) of Bacteriologically confirmed pulmonary TB cases. There is very little literature on the initiation and completion rates of TPT. Knowledge about the current scenario and programmatic challenges would help in future improvision of the programme.

Objective:

1. To estimate the Proportion of HHCs (Household Contacts) of Bacteriologically confirmed Pulmonary TB who initiate and complete the TPT in Vijayapura district.
2. To explore the Factors influencing Adherence and Non-Adherence to TPT treatment.
3. To understand operational difficulties for non-initiation and non-completion of TPT by interviewing concerned health care providers and informing programme and policymakers.

Methodology:

This Cross-sectional study was conducted in a high burden district in Northern Karnataka by Interview Technique using a pre-tested semi-structured questionnaire. All HHCs of Bacteriologically confirmed Pulmonary TB cases registered from June 2022 to December 2022, who were eligible for TPT were enrolled in the study. The HHCs were interviewed From March 2023 to July 2023.

Out of 10 TB units, five units were selected using a simple random sampling method. TB patients were selected from these 5 TB units using the probability proportional to size sampling method to achieve the sample size. HHCs of those TB patients were interviewed after agreeing to participate in the study.

Results & Conclusion:

Total 565 HHCs interviewed in 119 households with average HH size of 5. 81% pf households were holding BPL card, 59% overcrowded and 78% Hindu by religion. We found that 22% of the HHCs/study participants told they were not screened for TB (even not for clinical symptoms) to start TPT and 21% of the study participants were not initiated on TPT, and 50% of those initiated did not complete the full course of TPT. The reasons for non-initiation were as follows: 56% lacked awareness about TPT, 32% told they were not approached by any healthcare provider regarding TPT, 6% were Unwilling, and another 6% had medical conditions that prevented them from being prescribed TPT. The most common reason for not completing the full course of TPT as told by 48% was it was not necessary to take complete TPT. Other reasons mentioned were: Unavailability of medicines (6%), not receiving drugs after 3 months (12%),

discontinuation due to adverse effects (15%), and some medical conditions and migration (9%). The study highlights the prevalent social factors and stigma associated with the TB disease, with a 55% non-response rate when approached for study participation. To address these factors and improve TPT outcomes, the study recommends several strategic interventions like introduction of shorter TPT regimens to enhance adherence, improved training for Health Care Personnels to ensure effective TPT delivery, addressing programmatic issues like ensuring steady drug supply, establishment of IGRA testing facilities, expanding health insurance coverage, and intensifying targeted IEC activities to reduce stigma and foster a stronger acceptance of TPT within communities.

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INTRODUCTION

Tuberculosis (TB) is a significant public health issue globally, leading to high morbidity and mortality. TB is a preventable and usually curable disease, yet in 2022, TB was the world's second leading cause of death from a single infectious agent, after coronavirus disease (COVID-19), and caused almost twice as many deaths as HIV/AIDS. More than 10 million people continue to fall ill with TB every year. [1]

According to the National TB Prevalence Study (2019-2021), the prevalence of microbiologically confirmed Pulmonary TB in ≥ 15 years of age was 316 per lakh population in the country and varied from 151 per lakh (Kerala) to 534 per lakh (Delhi). The prevalence of all forms of TB for all ages in India was 312 per lakh population (286 - 337) for the year 2021.[2]

According to the National TB prevalence survey, Karnataka bears a significant burden of tuberculosis (TB), with an estimated prevalence of 30.4 million cases annually. Notably, TB prevalence varies widely across different states, ranging from 13.7 to 74.7 million cases per year. In Karnataka, the percentage of notified TB cases was 58.86% in 2021, which increased to 80.4% in 2022. Unfortunately, the mortality rate associated with TB remained constant at 6% in both 2021 and 2022.[3]

India has the highest burden of Tuberculosis (TB) infection globally, nearly 35-40 crore[4], of which an estimated 26 lakh are likely to develop active TB. Several studies have shown that 5-10% of those infected will develop TB disease. The risk

is increased by >25% among contacts of bacteriologically confirmed TB patients compared to the general population.[5]

Although early diagnosis and treatment of active TB remain a top priority in India, preventing TB by detecting and treating Latent TB Infection (LTBI) is an important step toward ending TB.[6] Tuberculosis preventive treatment (TPT) is one of the key interventions recommended by the World Health Organization (WHO) to achieve the #EndTB Strategy Goals, as upheld by the United Nations (UN) high-level meeting on TB in September 2018.[7]

Programmatic Management of Tuberculosis Preventive Therapy (PMTPT) has been traditionally limited in extent and given low priority under National Tuberculosis Elimination Programme (NTEP) due to other competing and important priorities. In July 2021, NTEP issued new guidelines recommending TPT for all House-Hold Contacts (HHCs) of Bacteriologically confirmed pulmonary TB cases. Prevention of TB disease by treatment of TBI is a critical component of the National Strategic Plan (NSP) 2017-2025 for ending TB in India by 2025. The NSP proposes a Detect Treat-Prevent-Build approach. The risk of developing TB disease after TPT decreases by 60%.[8] Scaling up TPT would be key to hastening the rate of decline in TB incidence from 2.5% to the required 10% annually. [9]

As per the new guidelines issued in July 2021, TPT is advised for all HHCs of Bacteriologically confirmed TB cases after ruling out active TB infection clinically or by testing. All the HHCs are screened for symptoms of current cough, fever, weight loss, or night sweats. If they are found symptomatic, investigate for TB and manage accordingly. If found asymptomatic, TPT has to be started. HHCs

above the age of 5 years are advised IGRA/TST and chest X-ray if available before TPT, but the unavailability of facilities to do these tests should not prevent them from starting TPT[9]. Of the 32 NTEP districts of Karnataka, 22 have a "Test and Treat" approach, and 10 of the districts have a "Screen and Treat" approach. Vijayapura district has a "Screen and Treat" approach.

NTEP recommends two regimens for TPT among Household Contacts (HHCs) of drug-sensitive TB patients. One is daily Isoniazid for six months (6H), and the other is weekly one dose of Isoniazid + rifapentine for three months(3HP). According to the 2021 guidelines, states planning to roll out TPT are advised to provide a 6H Regimen until the 3HP is made available under NTEP. Under this regimen Isoniazid is given as daily dosage for 6 months. For individuals aged 10 years and older, the recommended dosage is 5 mg/kg/day, while for those younger than 10 years, the suggested dosage is 10 mg/kg/day, with a range of 7 to 15 mg. Maximum dose of Isoniazid if given daily would be 300 mg/day[9].

TPT has the potential to reduce overall annual TB incidence rates by approximately 8.3%. The efficacy of currently available TPT drugs ranges between 60% and 90%.[10] Preventing a case of TB through TPT is more cost-effective than treating an active TB case.[11] Additionally, preventing one case of TB disease can prevent up to 15 additional infections, yielding a substantial return on investment. Challenges of the program can be broadly divided into Adherence and operational. Adherence to TPT doses throughout the cause and treatment completion are important determinants of clinical benefit. Poor Adherence increases the risk of developing TB disease, including Drug-resistant TB. The efficacy of TPT is greatest if at least 80% of the doses are taken within 133% of the duration of the regimen. Operational challenge of the programme includes

enumeration and contact tracing of the target population by the health-care providers at the institutions providing care to the specific risk groups considered eligible for TPT. Our study aims to assess the proportion of household contacts (HHCs) of bacteriologically confirmed pulmonary tuberculosis (TB) patients who initiate and successfully complete treatment for TB preventive therapy (TPT) or drop out in the Vijayapura district. Additionally, it seeks to explore the sociodemographic, and programme factors influencing adherence and non-adherence to TPT among HHCs.

OBJECTIVES

1. To estimate the Proportion of Household Contacts of Bacteriologically confirmed Pulmonary Tuberculosis who initiate and complete the treatment or drop out from Tuberculosis Preventive Therapy in Vijayapura district.

2. To explore the Factors influencing Adherence and Non-Adherence to Tuberculosis Preventive Therapy.

3. To understand operational difficulties for non-initiation and non-completion of Tuberculosis Preventive Therapy by interviewing concerned health care providers and informing programme and policymakers.

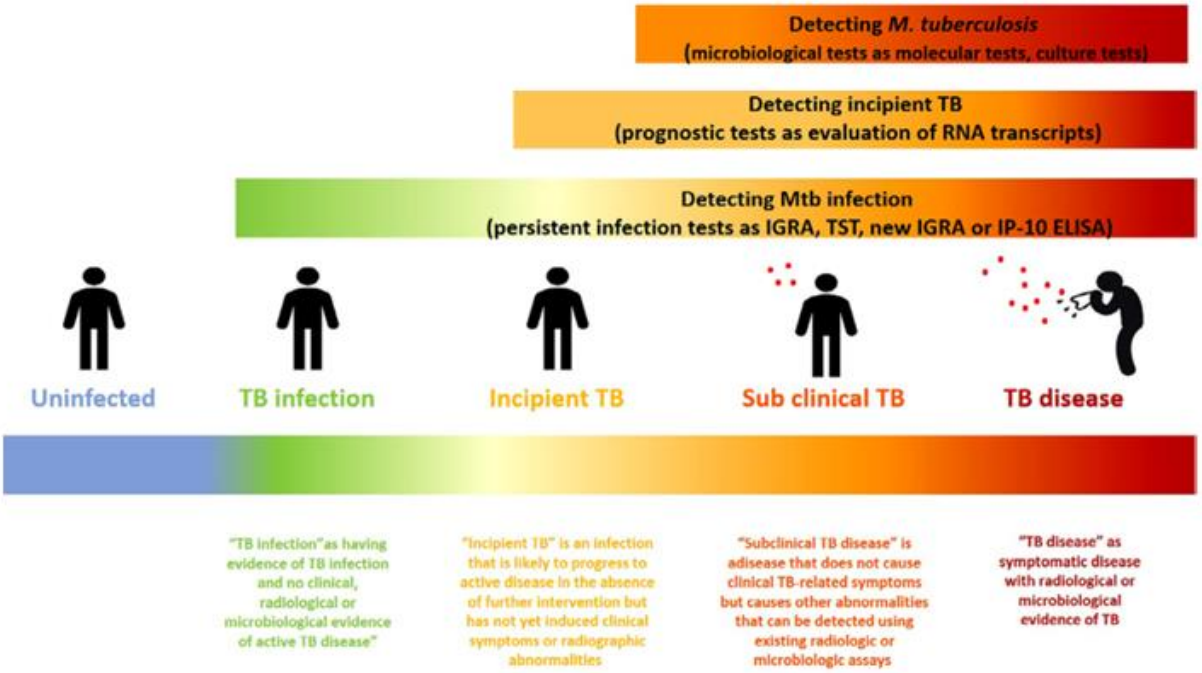
REVIEW OF LITERATURE

Pathophysiological basis of TPT

Connie A. Haley, in a review article, discussed that Latent tuberculosis infection (LTBI) occurs when an individual is infected with Mycobacterium tuberculosis without showing symptoms or having abnormal chest radiographs. While LTBI and active TB disease are used for clinical classification, the progression from exposure to active disease is more of a continuum. After exposure, the bacteria may be eliminated by the immune system, progress rapidly to primary TB disease, or enter a latent state with possible subclinical disease and undetected bacterial replication. Most individuals with LTBI remain asymptomatic for life, but about 8 to 10% may eventually develop active TB.[12]

S Kiazyk et.al., 2017 commented that the duration of LTBI can vary, with healthy individuals potentially carrying the infection for their entire lives. In about 5% to 15% of cases, LTBI can reactivate, often within the first 2 to 5 years after initial infection. Reactivation is when a latent infection progresses to active TB disease, making those with LTBI a significant source of new active TB cases. The exact reasons for LTBI reactivation are not fully understood but involve bacterial, host, and environmental factors. While the reactivation risk for healthy individuals with LTBI is around 5% to 15%, certain comorbidities and risk factors can increase this risk and lead to higher rates of developing active TB.[13]

Figure 1. The “continuum process” leading from TB infection to disease.[14]



Mtb infection is characterized by a dynamic equilibrium between the host and the microbe, which may result in different conditions spanning from: TB infection, with no overt signs or symptoms of disease; incipient TB, there is an increase in viable bacteria in the involved tissues due to the partial failure of the host to contain Mtb, but no signs or symptoms of disease; sub-clinical TB, with increase in bacterial burden and damage of the involved tissue detectable by radiological tests; TB disease, with classical signs and symptoms of disease. TB: tuberculosis; TST: tuberculin skin test; IP: IFN- γ inducible protein; IGRA: IFN- γ release assays.[14]

Jing-Wen Ai et.al., 2016 noted that several high-risk factors contribute to an increased rate of tuberculosis (TB) reactivation. These factors include human immunodeficiency virus (HIV) infection, organ transplantation, malnutrition, being a healthcare worker, being a prisoner, homelessness, diabetes, corticosteroid use, silicosis, smoking, tumor necrosis factor-alpha blocker use, close contact with TB patients, and kidney dialysis.[15]

Role of Household Conditions in TB Transmission

Deol AK et.al., 2022 commented that focused interventions on areas with low ventilation rates and high occupancy could be an extremely effective strategy for preventing TB infections.[16]

Ju-Yeun Lee et.al., 2022 conducted a systematic review to examine the impact of inadequate housing on TB and to classify TB exposure related to inadequate housing in terms of affordability and quality. Findings show that housing affordability has a greater impact on TB development and its consequences than housing quality. They also proposed that public health interventions should focus on enhancing housing affordability and simultaneously improving housing quality for residents in inadequate housing and the homeless.[17]

A prospective, single-arm, community-based study with historical controls was conducted comparing three groups by Hyunwoo Kim et al., 2019 aimed to evaluate the impact of a housing provision package on treatment outcomes for homeless South Korean TB patients they found that the housing provision package significantly improved treatment outcomes for homeless TB patients.[18]

Screening for LTBI

Daniel E. Jonas et.al., 2023 commented that when screening tests for LTBI come back positive, further evaluation is needed to rule out active tuberculosis disease before confirming LTBI and starting preventive treatment. This evaluation includes reviewing medical and social history, assessing symptoms, performing a physical examination, and conducting imaging tests, usually chest X-rays. Sometimes sputum samples and other lab tests are also required, as screening tests alone cannot distinguish between LTBI and active TB disease.[19]

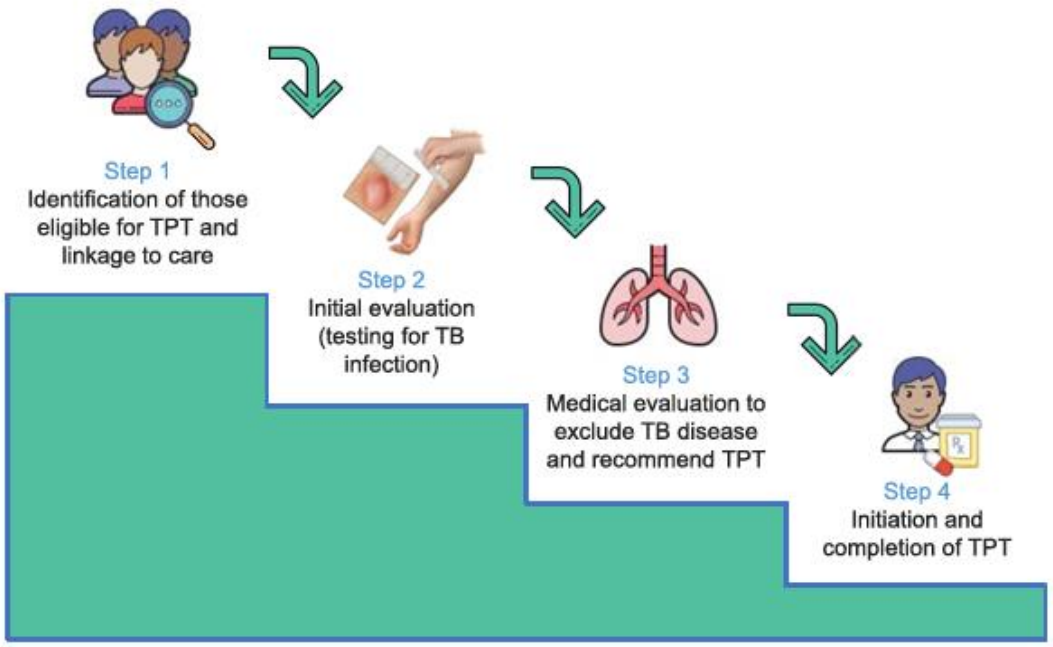
Yun-Gyoung Hur et.al., 2015 commented that the traditional tuberculin skin test (TST) often gives false positives in people who have had recent BCG vaccination or exposure to non-tuberculous mycobacteria (NTM). The interferon-gamma release assay (IGRA) is a quicker method that measures immune response to TB-specific antigens and avoids the cross-reactivity issues of the TST. However, IGRA cannot distinguish between LTBI and active TB. Its performance varies, sometimes providing false positives in high TB-incidence areas due to prevalent LTBI. This suggests that while IGRA is useful, it alone isn't enough for accurately diagnosing TB, LTBI, or NTM diseases. Therefore, additional biomarkers are needed to improve diagnosis and monitor treatment effectively.[20]

Delia Golett et.al 2016 discussed that Both IGRA and TST have limitations, including low accuracy in immunocompromised patients and inability to distinguish LTBI from active TB. Newer approaches, like using chemokine IP10, evaluating various cytokines, and identifying specific CD4+ T-cell signatures, show promise in better identifying and distinguishing LTBI stages, potentially enhancing risk stratification and guiding preventive therapy.[21]

Management of LTBI

WHO updated guidelines on LTBI in 2018 commented that Management of LTBI involves a comprehensive package of interventions: identifying and testing those individuals who should be tested, delivering effective, safe treatment in such a way that the majority of those starting a treatment regimen will complete it with no or minimal risk of adverse events, and monitoring and evaluation of the process.[22]

Figure 2: The cascade of prevention for the programmatic management of TB infection.[23]



Pranay Sinha et.al., 2022 commented that Over 5 years, augmented rations could avert 81% of TB cases and 88% of TB deaths among currently undernourished Indians. Correspondingly, this intervention could forestall 78% and 48% of TB cases and prevent 88% and 70% of deaths among undernourished HHCs and persons with HIV, respectively.[24]

Anurag Bhargava et.al., 2015 in a cluster-randomized controlled trial conducted in Jharkhand, India, also hinted towards the above observation that Nutrition to HHCs can improve the outcome of TB infection.[25]

Laura Muñoz et.al., 2018 commented that the Mycobacterium tuberculosis complex (MTC) bacteria can evade the immune system and remain dormant in the host for decades or even a lifetime. Antibiotic treatment can prevent this progression, typically involving a single drug for 6 to 9 months or a combination of two antibiotics for at least 3 months. However, using more drugs in the treatment regimen increases the risk of adverse side effects.[26]

Effectiveness of TPT

Patrick K Moonan et.al., 2018 commented that TPT will be crucial in reducing the TB burden in India, necessitating continuous innovation, locally-driven solutions, and rigorous program monitoring and evaluation to bend the epidemiologic curve effectively.[26]

Nicholas Winters et.al., 2023 in the meta-analysis comparing treatment outcomes between 3HP and 4R using individual patient data from six trials with 17,572 participants found that 3HP had about 5% higher treatment completion than 4R but also a 3% higher risk of treatment-related adverse events leading to permanent drug discontinuation and a 2% higher risk of grade 3-4 adverse events. There was no significant difference in efficacy for preventing tuberculosis between the regimens, although this conclusion was limited by the low number of disease occurrences. Treatment completion may be influenced by differences in regimen schedules and clinical practices.[27]

Delia Goletti et.al., 2018 commented that following thorough LTBI screening investigations, preventive TB therapy has been shown to be effective and well-tolerated in reducing the risk of TB reactivation in rheumatic patients requiring biological drugs.[28]

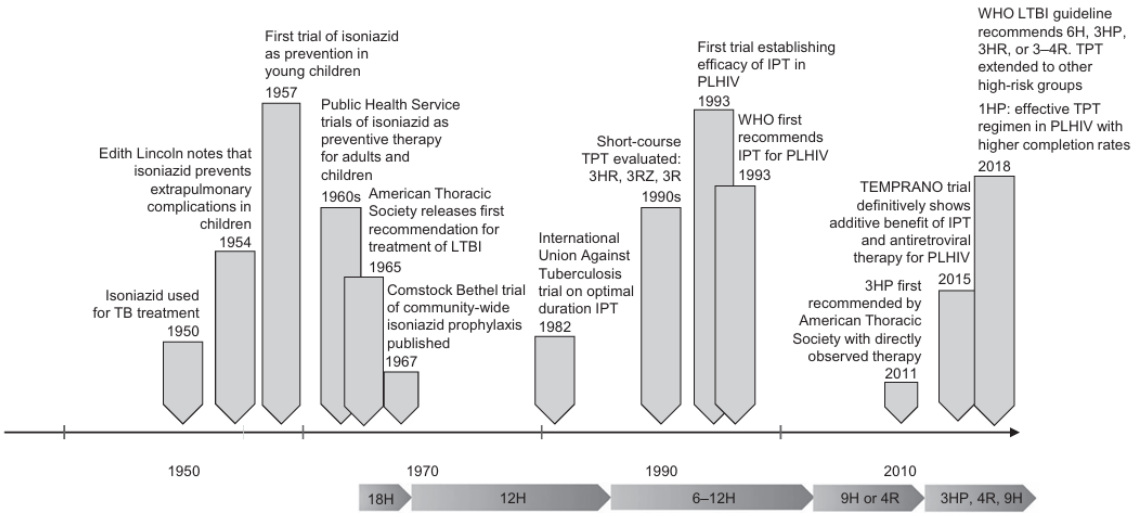
G.J. Fox et.al., 2017 discussed that preventive therapy targets LTBI to halt the progression to active TB by eliminating replicating mycobacteria. Unlike TB treatment, which utilizes multiple antibiotics to prevent drug resistance, LTBI treatment often involves just one or two antibiotics due to the low bacterial count, reducing resistance risks. This approach not only prevents individual morbidity but also curbs transmission. It significantly lowers the risk of active TB development and its complications for those infected.[29]

Dawit Getachew Assefa et.al., 2022 found that in Ethiopia, the incidence of TB and mortality is significantly lower among people living with HIV who receive IPT alone or in combination with ART compared to those who do not receive IPT.[30]

M. Mølhave et.al., 2020 commented that historical trials on preventive treatment for LTBI have demonstrated that large-scale treatment is both feasible and effective, even within high-burden populations in areas with high incidence. This underscores the relevance of incorporating preventive treatment as a strategic tool in efforts to eliminate the TB epidemic.[31]

History of TPT

Figure 3: History of Tuberculosis Preventive Therapy (TPT). [32]



18H, 12H, 9H, and 6H referto18, 12, 9, and 6 months of daily isoniazid, respectively, and 3R and 4R refer to 3 and 4 months of daily rifampin, respectively. 1HP,1 month of daily rifapentine and isoniazid; 3HP,3 months of weekly rifapentine and isoniazid; 3HR, 3 months of daily isoniazid and rifampin; 3RZ, 3 months of daily rifampin and pyrazinamide; IPT, isoniazid

preventive therapy; LTBI, latent tuberculosis infection; PLHIV, people living with human immunodeficiency virus; TB, tuberculosis; WHO, World Health Organization.[32]

The first recommendation of TPT by WHO came in the year 1993 for people living with HIV (PLHIV) despite concerns about toxicity, durability of protection, drug resistance, and adherence.[33]

In September 2018, during the first-ever UN High-Level Meeting on TB, country leaders committed to providing TPT to at least 30 million individuals at risk of TB disease between 2018 and 2022. That same year, the WHO, in collaboration with stakeholders, developed a regional action plan to help Member States adopt TPT and fulfill global commitments to protect individuals at high risk of TB disease.[34]

TPT Regimens

Figure 4: Duration of tuberculosis preventive therapy over time, as the American Thoracic Society recommended. Abbreviations: 1HP, 1 month of daily rifapentine and isoniazid; 3HP, 3 months of weekly rifapentine and isoniazid.[32]

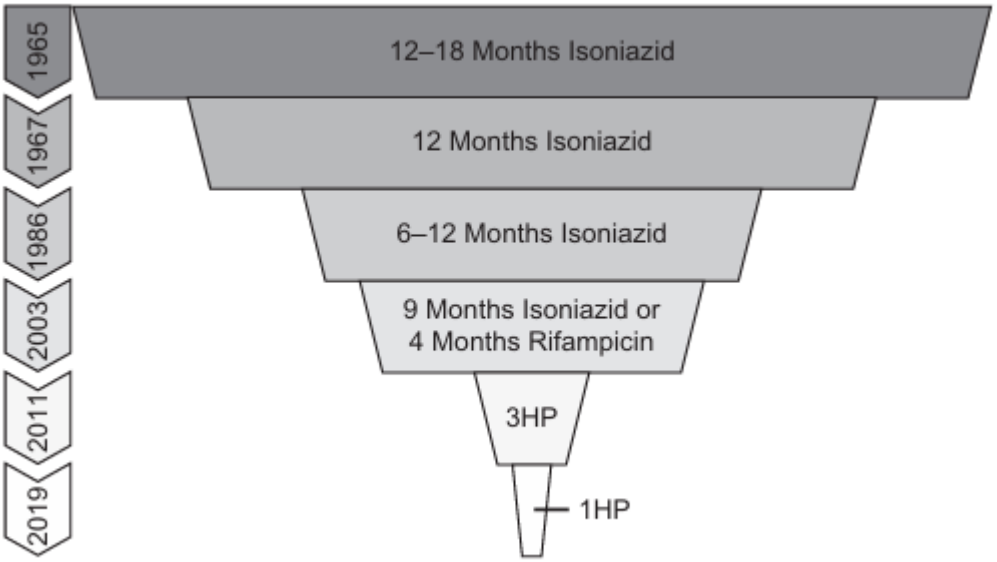


Table 1: TPT regimen options for HHCs according to 2021 NTEP guidelines on programmatic management of TPT. [35]

Regimen	Dose by age and weight band					
6 months of daily isoniazid monotherapy (6H)	Age 10 years & older: 5 mg/kg/day[d] Age <10 years: 10 mg/kg/day (range, 7–15 mg)					
Three months of weekly rifapentine plus isoniazid (12 doses) (3HP)	**Age 2-14 years[c]**					
	Medicine, formulation	10–15 kg	16–23 kg	24–30 kg	31–34 kg	>34 kg
	Isoniazid, 100 mg[a]	3	5	6	7	7
	Rifapentine, 150 mg	2	3	4	5	5
	Isoniazid + rifapentine FDC (150 mg/150 mg)[b]	2	3	4	5	5
	Age >14 years[c]					
	Medicine, formulation	30–35 kg	36–45 kg	46–55 kg	56–70 kg	>70 kg
	Isoniazid, 300 mg	3	3	3	3	3
	Rifapentine, 150 mg	6	6	6	6	6
	Isoniazid + rifapentine FDC (300 mg/300 mg)[b]	3	3	3	3	3

a. *300 mg formulation can be used to reduce the pill burden*
b. *Expected to become available in the near future*
c. *Dosage may differ among adults and children in overlapping weight-bands*
d. *Maximum dose of H if given daily would be 300 mg/day*

Susan Swindells et.al., 2019 found that, 1-month regimen of rifapentine combined with isoniazid was found to be just as effective as 9 months of isoniazid alone in preventing tuberculosis among HIV-infected patients. Additionally, a significantly higher percentage of patients completed the treatment in the 1-month group.[36]

The latest update on TPT guidelines by NTEP recommends the 1HP regimen for individuals aged 13 years and older. This regimen consists of 1 month of daily isoniazid and rifapentine, totaling 28 doses. [37]

MDR/Extra Pulmonary TB

Guozhong Zhou et.al., 2024 in their systematic review and meta-analysis, commented that TPT for contacts of patients with MDR-TB is linked to a decreased risk of TB disease advancement, with potential added benefits from tailoring the regimen based on the drug-resistance profile of the index patient.[38]

The guidelines from the American Thoracic Society, the U.S. Centers for Disease Control and Prevention, the European Respiratory Society, and the Infectious Diseases Society of America recommend using daily levofloxacin monotherapy for 6 to 12 months for HHCs of MDR TB patients.[39]

Household contacts of Extrapulmonary TB patients are not the target population for TPT according to the WHO guidelines on TPT. [40]

Review of Literature regarding programmatic challenges of TPT

Ben J. Marais commented that the challenges to preventive therapy encompass (1) concerns about accurately distinguishing active disease from latent infection, (2) apprehension regarding the development of drug resistance, (3) inadequate adherence to established guidelines without proper monitoring, and (4) difficulties in maintaining adherence to lengthy preventive therapy regimens.[41]

Alberto Matteelli et.al., 2023 in their review article, noted that the use of drugs in TPT, which are also included in TB therapeutic regimens, poses a risk of contributing to drug resistance if active TB disease is not adequately ruled out before initiating preventive treatment. [42]

Yousra Kherabi et.al., 2022 commented that further studies on shorter regimens are necessary, building on recent breakthroughs in TPT for drug-susceptible LTBI. Additionally, safety

concerns can hinder TPT implementation. Establishing a pharmacovigilance network, providing standardized follow-up for contacts starting on TPT, and offering counseling for both contacts and physicians may enhance the global adoption of TPT.[43]

Patrick K Moonan et.al., 2018 commented that challenges in TPT include High burden TB, accurately identifying individuals for treatment, developing and adopting new diagnostic tools, and ensuring acceptance, adherence, and completion, particularly in regions like India. These challenges encompass logistical, financial, and cultural barriers that must be addressed to enhance TPT efficacy and tuberculosis control efforts.[44]

Clay Roscoe et.al., 2021 based on a study in Namibia commented that Suboptimal programmatic implementation of TPT may result from various factors, including insufficient training, irregularities in TB screening and timing of TPT, unclear responsibilities in prescribing and recording, and clinical misperceptions. Addressing these challenges is crucial for effective TPT scale-up.[45]

METHODOLOGY

Background Details:

The study was conducted in Vijayapura, one of the northern districts of Karnataka. The ideal policy recommendation for TPT among HHCs of sputum-positive pulmonary TB patients is the "Test and Treat" approach, where they are tested using IGRA before initiating TPT, but due to lack of facilities for IGRA testing, the district follows the "Screen & Treat" approach, where they are only symptomatically screened and put on TPT if found asymptomatic for TB.

Figure 5: Map of Vijayapura District.[46]

Vijayapura, a mostly agricultural district, with an overall population of 21,77,331 and literacy rate of 57.46%. District has a high TB Burden, having an average incidence of 130-150 TB cases/month.

Study Population:

All the HHCs of Bacteriologically confirmed Pulmonary TB cases, diagnosed a minimum of six months prior to the data collection period to ensure the completion of TPT duration

Additionally, health care providers involved in the TB programme were also interviewed about TPT programme.

Study Period: March 2023 to April 2024 (1 year)

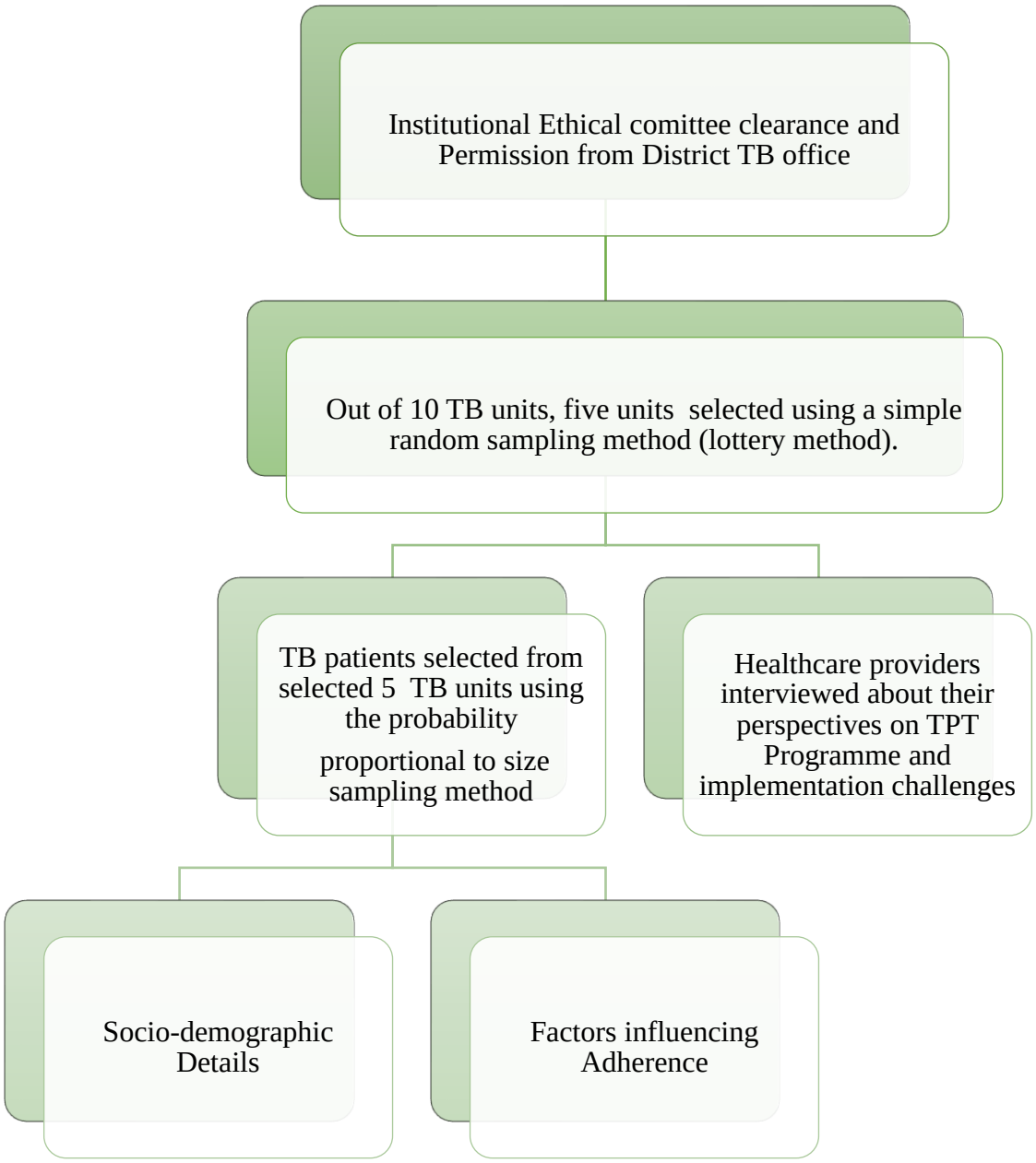
Study Design: Cross-Sectional Study

Study Technique:

A cross-sectional survey was conducted through in-person interviews with household contacts of the bacteriologically confirmed pulmonary TB cases in their households after acquiring their consent to participate. The semi structured questionnaire included socio-demographic variables of the Household (HH), TPT programme-related questions, reasons for non-initiation, and non-adherence.

All questionnaires were created in English and translated into the local language (Kannada), and administered after pilot testing. The head of the household or any adult male/female in the household was interviewed for basic HH information. A maximum of 3 visits were made to contact all the HHCs for one Household, if any members were not available for an interview, loss to follow up/locked.

Study Plan:



Definitions used to identify Cases and HHC's:

- Household contact (HHC): a person who shares the same enclosed living space as the index TB patient for one or more nights or for frequent or extended daytime periods during the three months before the start of current TB treatment.
- Bacteriologically confirmed TB: TB diagnosed in a biological specimen by smear microscopy, culture, or a WHO-endorsed rapid molecular test and adopted by NTEP such as Xpert MTB/RIF®/TrueNat®.
- Health care provider: All those medical and non-medical professionals who are involved in the implementation and monitoring of the TPT programme in the Vijayapura district.
- Initiation, Adherence, and Completion: It will be assessed according to data from NTEP, NGO firm, and also by asking the HHCs. households.

Inclusion Criteria

- All HHCs of newly diagnosed Bacteriologically confirmed Pulmonary TB cases who were eligible to be initiated on TPT.
- HHCs of TB patients registered in the previous six months.

Exclusion Criteria

- All HHCs of MDR TB cases.
- All HHCs of HIV Co-infected TB cases.
- All HHCs of Extrapulmonary TB cases.
- All HHCs of TB cases who are on Retreatment.
- HHCs where no Consent is given.

Sample size:

With an anticipated proportion of coverage of Isoniazid of TB contacts 53.8% [47], the study required a sample size of 383, with a 95% level of confidence and 5% absolute precision.[48] Formula used was

$$n = \frac{z2\ p*q}{d2}$$

Where Z= Z statistic at α level of significance

d2= Absolute error

P= Proportion rate

q= 100-p

On considering the Dropout rate/non-response rate at around 10% of the sample size (~ 38)

Total minimum Sample required (383 + 38) was: ~ 421.

Sampling Technique:

To conduct our study, we selected five out of the ten TB units in our district (Indi, Chadchan, Tikkota, Babaleshwar, Vijayapura Urban, Sindagi, Devar Hippargi, Basavana Bagevadi, Nidagundi, Muddebihal) using a lottery method. The chosen TB units are Basavana Bagevadi, Vijayapura Urban, Chadchan, Devar Hippargi, and Muddebihal. Within these selected units, we applied the probability proportional to size (PPS) sampling method to select number of TB patients who are bacteriologically confirmed to have pulmonary TB in last six months.

We identified the total number of TB cases fulfilling our study criteria from the selected TB units. Patients who are HIV positive, clinically diagnosed (only microscopically confirmed), have extra-pulmonary TB, multidrug-resistant TB (MDR-TB), or are undergoing re-treatment were excluded.

Table 2: Probability proportion to size sampling

TB Unit	Total Cases	Study Cases	Expected Number of Households (Multiplied By 3.2) *	Required Households (40%)
Basavana Bagewadi	105	43	138	55
Vijayapura Urban	1554	148	442	177
Chadchan	64	46	147	59
Devar Hippargi	45	17	54	22
Muddebihal	205	118	378	151
Total	**1973**	**372**	**1159**	**464**

Considering the average household size of 4.2 according to the Ministry of statistics[49], 3.2 household contacts (HHCs) for each eligible TB case was assumed by deducting the 1 index case. To meet the calculated minimum sample size of 421, 40% of the household contacts in each TU were selected by Probability proportion to size sampling (PPS) method (Table 1).

Study Tool:

A semi-structured, pre-tested questionnaire was developed referring to relevant articles and review of literature (Annexure I). This questionnaire covered various socio-demographic aspects including name, age, address, occupation, educational status, religious affiliation, caste, average monthly income, family type, size, housing and sanitary practices.

To assess the participants' socio-economic status, the Modified BG Prasad Classification socio-economic status scale (January 2022)[50] was used, as shown in Table 3.

Table 3: Modified BG Prasad's classification[50]

Social class	Original classification of 1961 per capita income (Rs/month)	Revised classification for January 2022 (Rs/month)
I (Upper class)	100 and above	8220 and above
II (Upper middle class)	50-99	4110-8219
III (Middle class)	30-49	2465 – 4109
IV (Lower middle class)	15-29	1230-2464
V (Lower class)	<15	<1230

Other sections included questions to assess the screening for TB disease, Prescription of TPT and completion of TPT. Reasons for not screening, prescribing TPT and completion of TPT also was elicited. An open-ended questionnaire was used to interview the Healthcare providers who consented to participate in the interview (Annexure-II).

Pilot Testing of Study Tool:

The semi structured questionnaire was developed on the basis of similar studies[6,47] and was translated to the local language Kannada. It was then pilot-tested by administering it to 20 HHCs each from rural and urban area. After pilot testing necessary modifications were made before starting data collection.

Study Variables:

Age: Age was recorded in completed years as told by the participants.

Type of family:

- Nuclear family: It consists of a married couple and their children while they are still regarded as dependents.
- Joint family: It consists of number of married couple and their children live together in the same household. All men are related by blood and women of household are their wives, unmarried sisters and their family kinsmen.
- Three Generation family: It is a family where representatives of three generation are living together. Young married couple continue to stay with their parents and have their own children as well.

Education:

- Illiterate: Not able to read, write and understand in any language.
- Primary school: Studied up to 7th standard.
- High school: Studied up to 8th standard to SSLC.
- PUC/Diploma: Studied up to PUC or any diploma.
- Graduate and above: Studied up to graduation and above.

Occupation:

- Unemployed: Those who are not employed
- Salaried Employees: Those who have a permanent salary every month.
- Agri Labor: Those who work on other's agricultural land.
- Non-Agri labour: e.g. coolies, domestic servants etc.
- Small Buisness: e.g. Businessman, Shop owners etc
- Farm Owners: Those who cultivate crops in their own land.

Substance use: Yes/ No:

- Yes: Person who at the time of the data collection had any habit of Smoking /uses tobacco in any form either daily or occasionally, Alcohol consumption or any other drugs.
- No: A person who at the time of the data collection does not smoke or use tobacco, alcohol or any other drugs for the past one year.

Screening for TB

- A HHC is said to be screened when he is asked about 4 symptoms (Cough, fever, weight loss and night sweats) of TB. If any symptom is present, the HHC is evaluated with other tests before initiating TPT.

Testing for TB

- The guideline recommends IGRA testing, but it is unavailable in the district.
- If IGRA is not available X-ray chest is the next mode of choice for testing.
- Tuberculin Skin Test (TST) is another screening test that can be effective for children under 5.
- History of X-ray and TST was asked in the study.

Outcomes

There are 5 outcomes according to the 2021 PMTPT guideline for an HHC; Treatment Not initiated, discontinued due to toxicity, Treatment completed, Treatment failed and Others.

- Initiation of TPT

An HHC is said to be initiated on TPT if she was at least screened symptomatically for TB and advised daily INH for 6 months.

- Completion of TPT

An HHC is said to be completed TPT if 80% (144) of the doses are taken within 133% (240 days) of the duration of the regimen.

- Discontinued due to toxicity

An HHC is said to be "discontinued due to toxicity" when she stops the TPT due to any adverse effect related to TPT. Common adverse effects are gastritis and peripheral neuropathy.

- Treatment failed

An HHC is said to be Treatment failed when he/she develops active TB disease during the course of TPT.

Statistical Analysis:

The collected data was initially entered into a Microsoft Excel spreadsheet. We cleaned the data carefully and checked for any missing information. SPSS Version 26 was used to analyze the data. Categorical data were summarized with frequencies and percentages and visually represented through diagrams and figures. The Chi-square test was used to explore associations between categorical variables. A p-value of less than 0.05 was considered statistically significant, and all tests were conducted using a two-tailed approach.

RESULTS

We interviewed 565 HHCs from the 5 selected TUs of the Vijayapura district to explore the initiation and completion rates of TPT among HHCs of smear positive Pulmonary positive TB patients and explored the factors affecting the adherence to TPT.

Table 4: Number of Index TB cases approached and not responded in selected TUs

Name of TB Unit	Number of TB cases Approached	Number of TB Households not participated in survey	Reasons for non-participation		
			Wrong Contact Numbers	Migration	Refused
Basavana Bagewadi	25	9 (36%)	-	4	5
Vijayapura Urban	140	94 (67%)	41	26	27
Chadchan	22	7 (32%)	3	-	4
Devar Hippargi	6	2 (33%)	1	-	1
Muddebihal	75	37 (49%)	9	9	19
Total	268	149 (55.6%)	54	39	56

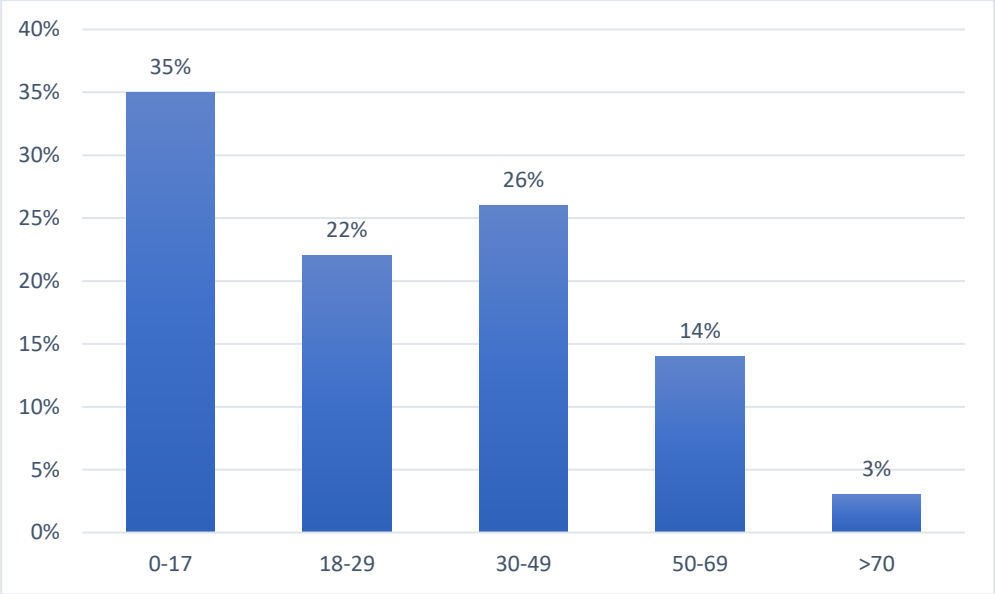
In this study, a total of 268 index cases were approached across 5 selected TB units. Out of these, 149 households were non-responsive, resulting in an overall non-response rate of **55.6%**. The reasons for non-responsiveness varied: 36% of households had wrong contact numbers, 26% of households had migrated, and 38% of households refused participation. To compensate for the non-respondent households of TB cases, we oversampled the households till we reached the minimum required sample size of 565 HHCs in order to get 40% representation from each selected TUs.

Table 5: Average Household size in Selected TUs

TB Unit	Households Surveyed	Number of HHCs	Average HHCs per Household
Basavana Bagewadi	16	68	4
Vijayapura Urban	46	205	5
Chadchan	15	63	4
Devar Hippargi	4	33	8
Muddebihal	38	196	5
Total	**119**	**565**	**5**

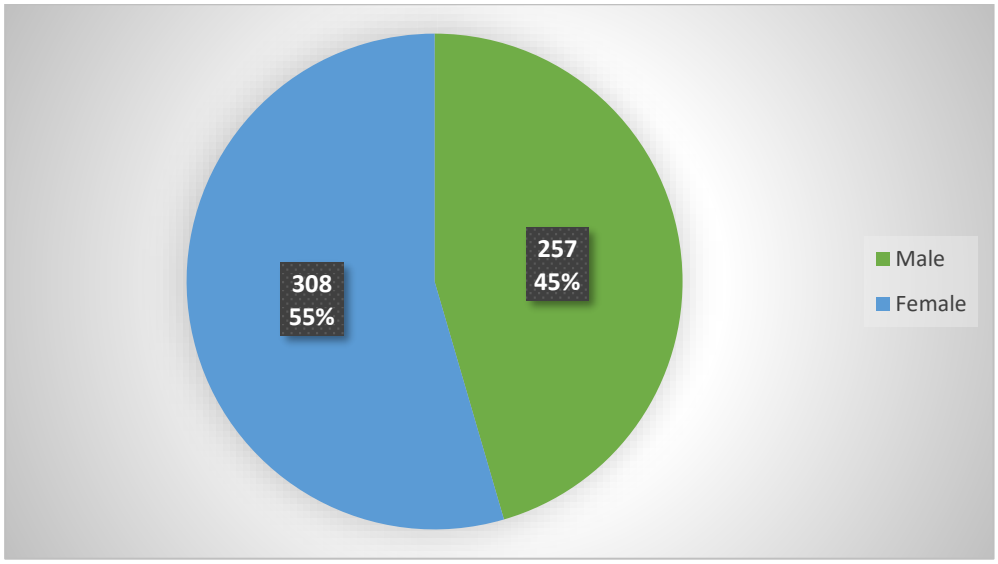
There are 10 TB units in Vijayapura, 119 households were selected from the 5 selected TUs resulting in 565 Household contacts. The TB units included were Basavana Bagewadi, Vijayapura Urban, Chadchan, Devar Hippargi, and Muddebihal. On average, the number of household contacts (HHCs) per house were 5.

Figure 6: Age distribution of the study population (n=565)



Most of the HHCs were children aged 0-17, comprising 35%. The 30-49 age group comprised 26%, followed by the 18-29 age group, 22%.

Figure 7: Gender distribution of the study population (n=565)



The study population comprised of 45% males and 55% females.

Table 6: Socio-Demographic Variables and Household Characteristics

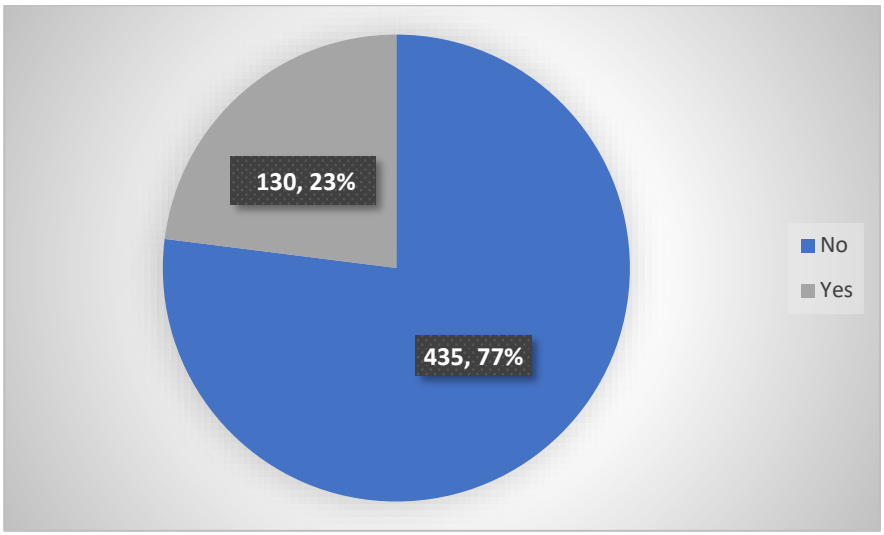
Socio-Demographic Variables and Household characteristics (n=119)			
		Frequency (n)	Percent (%)
Religion	Hindu	93	78%
	Muslim	26	22%
Caste	SC	22	19%
	ST	13	11%
	OBC	76	64%
	General	8	6%
Type of Family	Nuclear	57	48%
	Joint	44	37%
	3 Generation	18	15%
Income	Class 1	32	27%
	Class 2	21	18%
	Class 3	34	28%
	Class 4	30	25%
	Class 5	2	2%
Type of Cooking Fuel	LPG	36	30%
	Wood	21	18
	Both LPG and Wood	62	52%
Over Crowding	No	49	41%
	Yes	70	59%
Cross Ventilation	No	108	91%
	Yes	11	9%
Ration Card	AAY	7	6%
	BPL	96	81%
	APL	4	3%
	Not Available	9	8%
	Others	3	3%

The majority of the participants in the study were Hindu by religion, 79%, and 21% were Muslims. Most of the study participants belonged to the OBC caste (64%). Majority households were nuclear families (48%). In terms of income, more than 50% of the participant households belonged to Class 3, 4, and 5.

When looked at the household environmental characters, most of study households reported using both LPG and Wood for cooking and heating water for bathing purposes (52%).

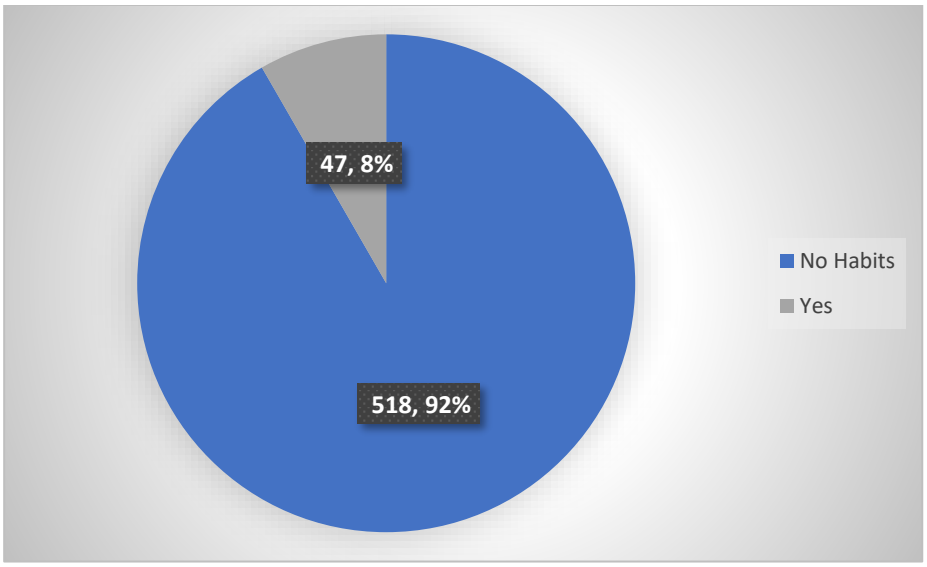
A large number of households experience overcrowding (59%), and lack cross ventilation (91%). Most households Below Poverty Line ration card (81%).

Figure 8: Health Insurance Coverage among HHCs (n=565)



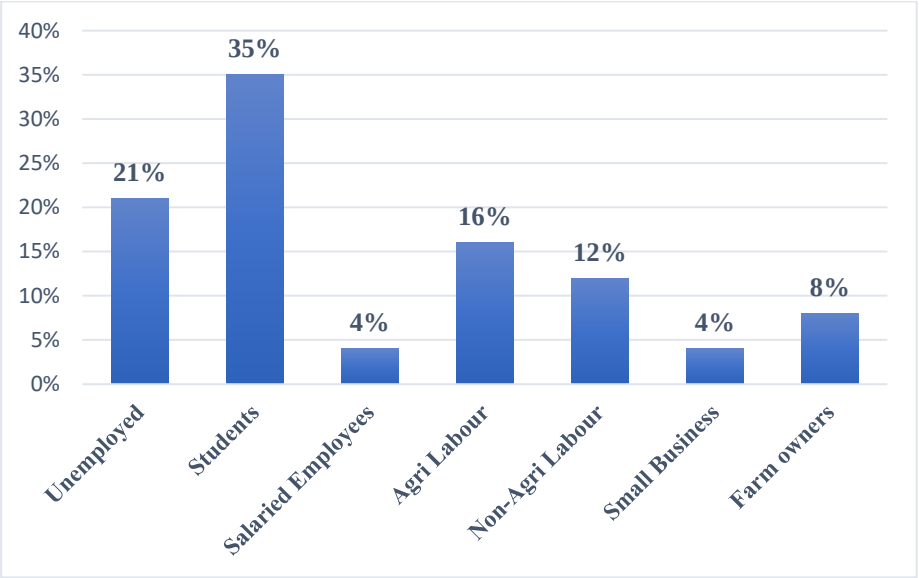
Only 23% of the HHCs had Insurance coverage, showing that most of the HHCs (77%) did not have any type of Health Insurance coverage.

Figure 9: Substance use among HHCs (n=565)



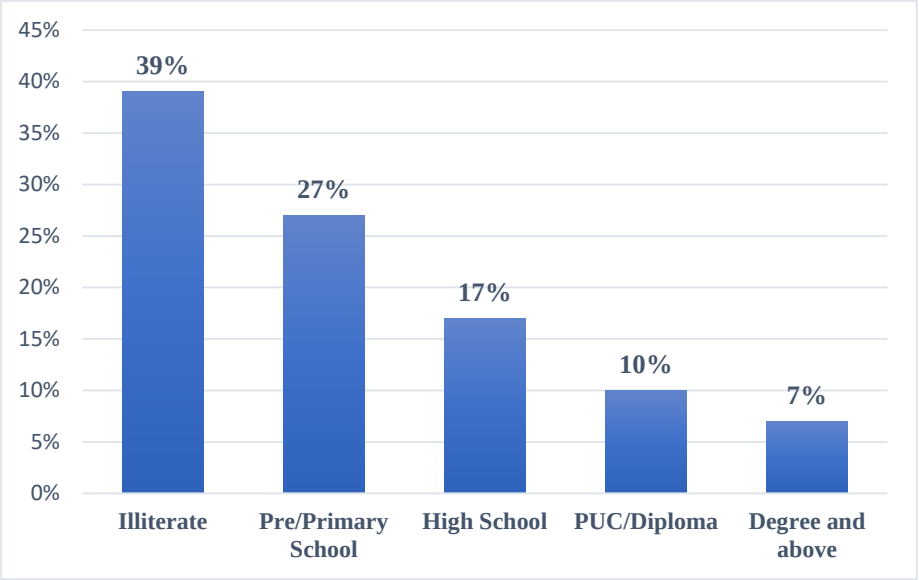
Only 8% of HHCs reported a history of Substance use. History of Tobacco chewing, smoking, consumption of alcohol or any other addictive substances were collectively considered as substance use.

Figure 10: Occupation of HHCs (n=565)



Most of the study participants were students comprising 35% of study population. 21% of the HHCs were unemployed and 28% of them were daily wage labourers. Only 4% of them were salaried employees.

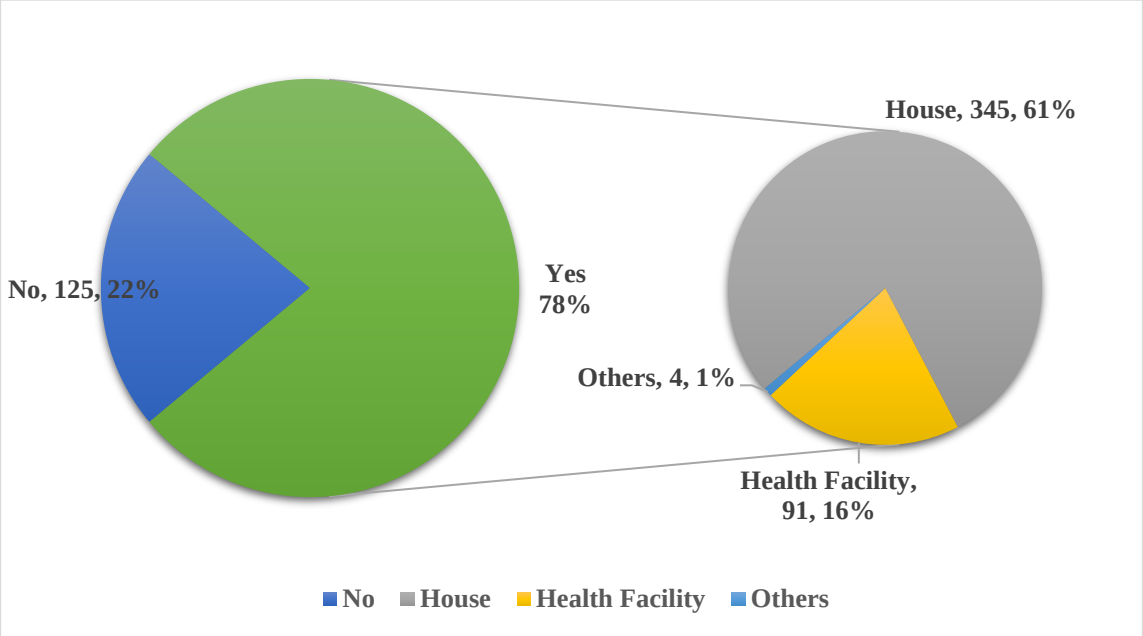
Figure 11: Educational Levels of HHCs (n=565)



Most of the study participants were illiterate comprising 39%. 27% of the HHCs had an educational level of primary school, and 17 % had a high school level. Only 7% of HHCs had a degree or above.

TB SCREENING

Figure 12: HHCs who underwent screening and the place of their Screening (n=565)



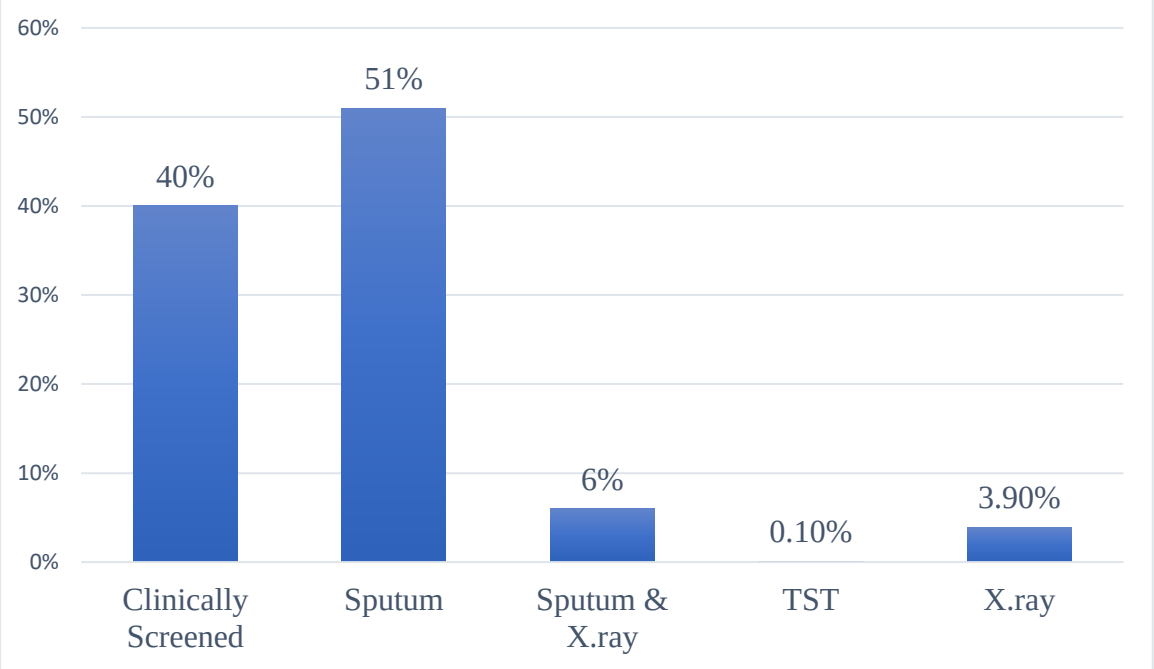
The majority of screenings were conducted in houses, accounting for 345 cases. Health facilities were the next most common location, with 91 screenings. There were 125 instances where no screening was conducted.

Table 7: Reasons for not Screening

Reasons for not Screening (n=125)		
	Frequency	Percent
Lack of Awareness	105	84
Don't Believe in TPT	10	8
Accessibility problem	10	8
Total	125	100

Among the 125 instances where TB Disease screening was not conducted, the primary reason was a lack of awareness about the need for screening, mentioned by 105 individuals (84%). Additionally, 10 individuals (8%) were not convinced that they or their child would benefit from the screening. Other reasons included the distance of their house from the screening location, mentioned by 5 individuals (4%), and the lack of money to facilitate screening, also mentioned by 5 individuals (4%).

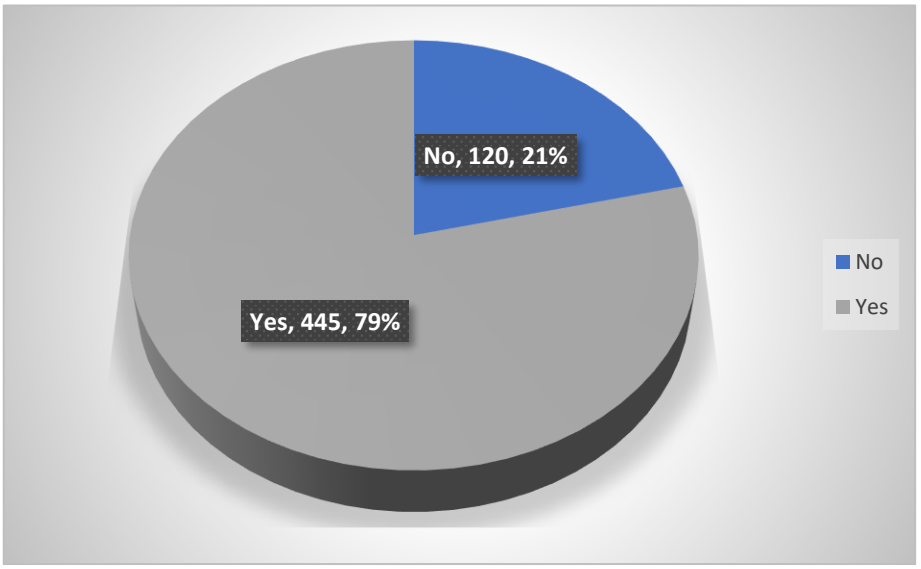
Figure 13: Various methods used to screen HHCs for TB (n=440)



Most of the HHCs were screened for active TB disease by testing the Sputum for AFB and 40% of HHCs were screened clinically asking history of fever, cough, weight loss or night sweats. Only 9% of HHCs were screened by X-ray chest.

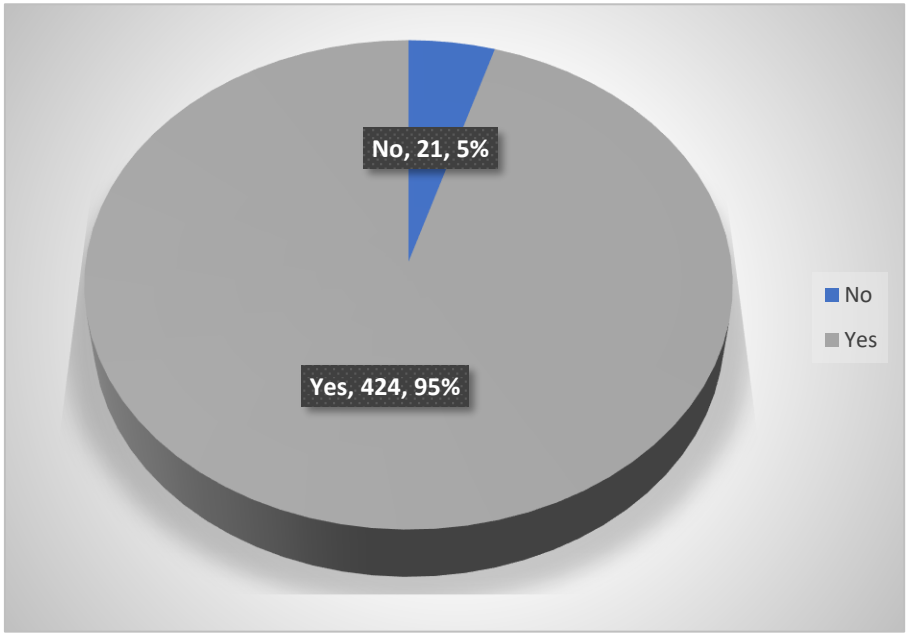
PRESCRIPTION OF TPT

Figure 14: HHCs Prescribed on TPT (n=565)



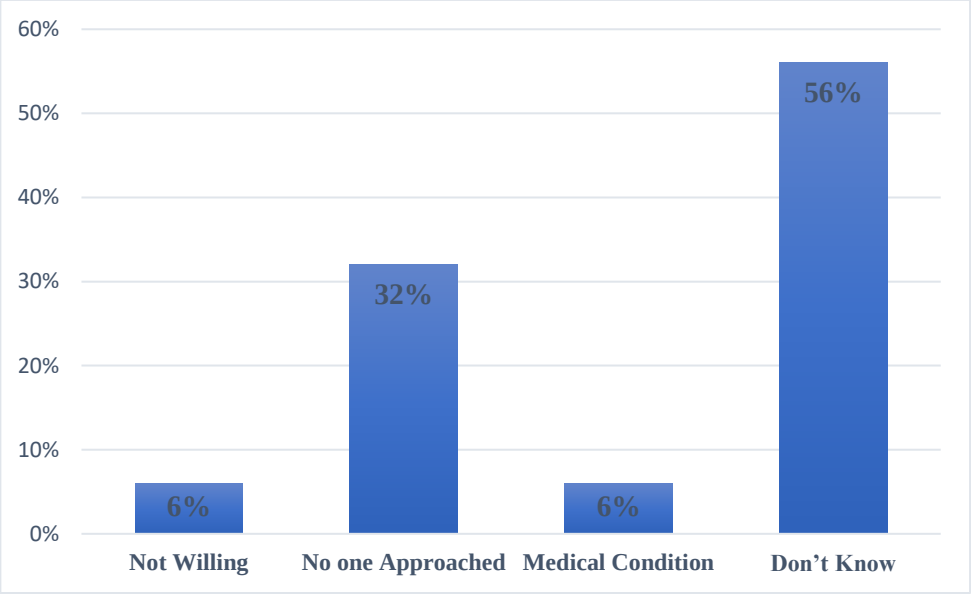
Out of 565 HHCs, 79% of HHCs were prescribed TPT, while 21% were not prescribed TPT. Five of the study participants were started on TPT without screening.

Figure 15: Reasons for not prescribing TPT (n=120)



Among the 120 HHCs who were not prescribed TPT, 56% lacked awareness about TPT and 32% were not approached by any healthcare provider regarding TPT. 6% were not willing and 6% had medical conditions which prevented from prescribing TPT.

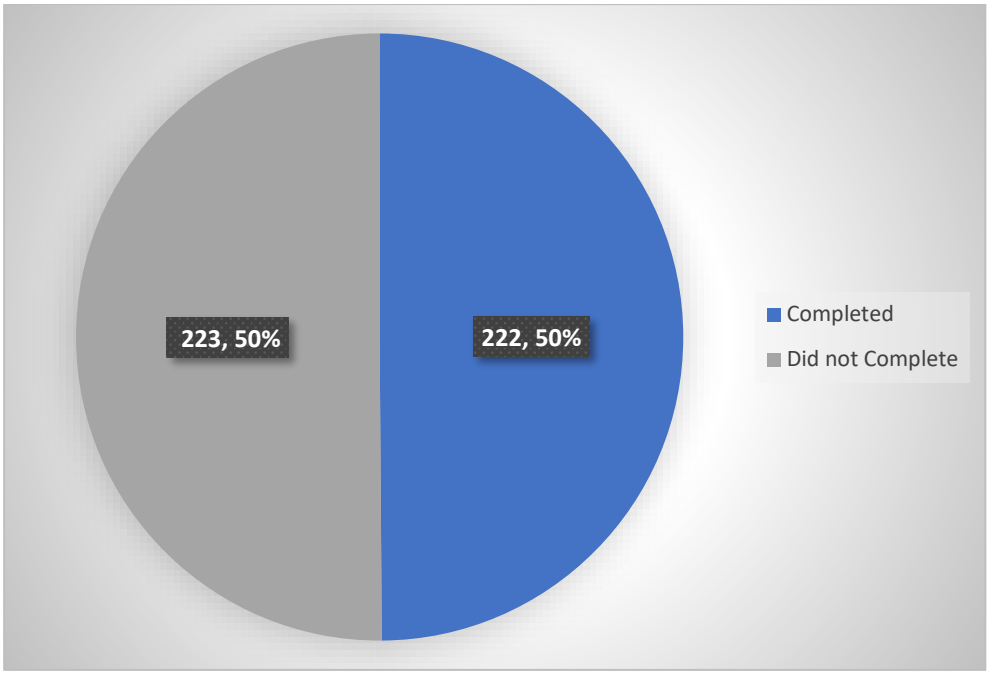
Figure 16: Counselled Regarding TPT (n=445)



Out of the 445 HHCs prescribed TPT, 95% of individuals received counselling regarding the necessity of TPT, potential side effects, and other relevant information from the healthcare workers. 5% told that they didn't receive any counselling before prescribing TPT.

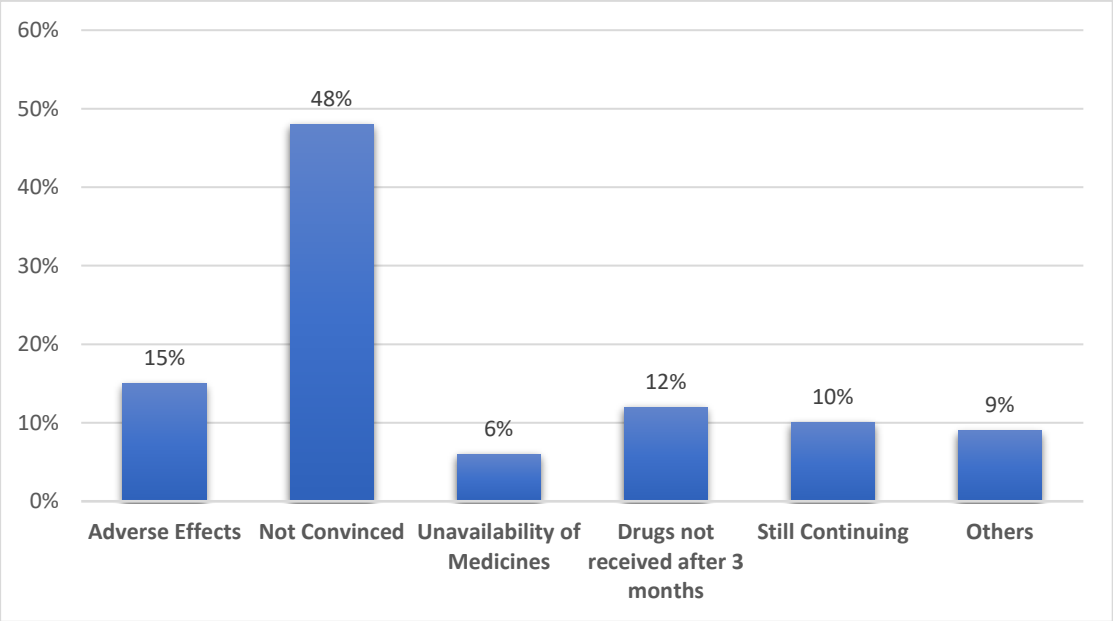
COMPLETION OF TPT

Figure 17: Completion of TPT among HHCs (n=445)



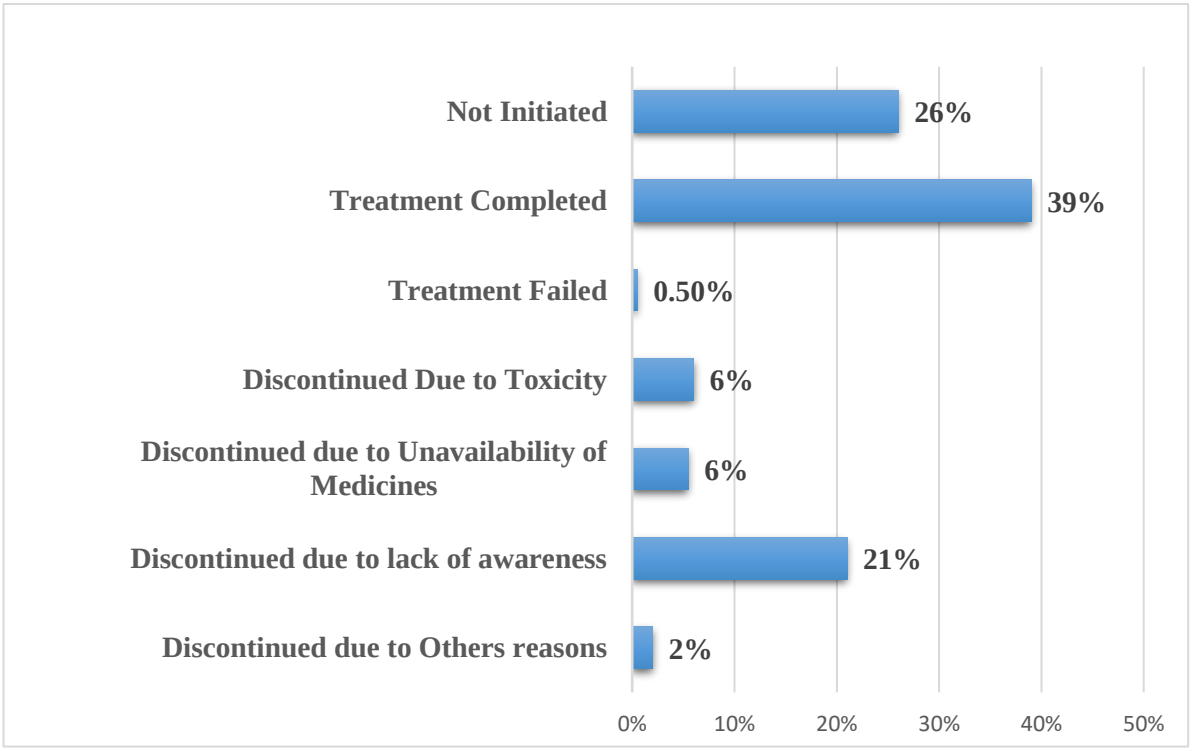
Completion rate of TPT among those who were initiated was found to be 50%.

Figure 18: Reasons for not completing TPT (n=223)



The most common reason for not completing TPT was the belief that it was not necessary, with 48% participants mentioning this reason. 6% of the participants mentioned unavailability of medicines and 12% told that they didn't receive drugs after 3 months. 15% of the participants discontinued due to adverse effects. Gastritis was the commonest adverse effect mentioned by the participants. 9% of other reasons included medical conditions and migration.

Figure 19: Outcome of TPT among study population (n=565)



The study population had an overall 39% completion rate and 26% of the study population were not initiated with TPT treatment. 21% of the participants discontinued TPT due to lack of awareness, 6% discontinued due to toxicity and another 6% due to unavailability of Medicines.

Table 8: Association of Gender and Age of HHCs with Screening Status

Gender and Age of HHCs V/s Screening for TB				
Gender of household contacts		**Underwent Screening**		**Total**
		No	**Yes**	
Male	Count	60	197	257
	% within Gender	23%	77%	100%
Female	Count	65	243	308
	% within Gender	21%	79%	100%
Total	Count	125	440	565
	% within Gender	22%	78%	100%
Chi- Square Value: 0.409 P Value: 0.523				
Age group of HHCs				
0-30	Count	63	258	321
	% within Screening	20%	80%	100%
31-60	Count	50	157	207
	% within Screening	24%	76%	100%
>60	Count	12	25	37
	% within Screening	32%	68%	100%
Total	Count	125	440	565
	% within Screening	22%	78%	100%
Chi- Square Value: 3.940 P Value: 0.139				

The study found that 77% of male and 79% of female HHCs were screened for TB disease before initiating TPT. 23% of the male HHCs and 21% of female HHCs were not screened for TB. Among the age group less than 30 years, 80% were screened for TB and 29% were not screened. 24% among the age group between 30 and 60 years and 32% among age group above 60 years were not screened for TB. There was no statistically significant association of Gender and age with screening status.

Table 9: Association of Occupation of HHCs with Screening for TB

Occupation of HHCs Vs Underwent Screening for TB				
Occupation		**Underwent Screening**		Total
		No	Yes	
Unemployed	Count	61	254	315
	% within Occupation	19%	81%	100%
Salaried Employees	Count	6	14	20
	% within Occupation	30.0%	70.0%	100%
Agri Labour	Count	25	67	92
	% within Occupation	27%	73%	100%
Non Agri Labour	Count	3	65	68
	% within Occupation	4%	96%	100%
Small Buisness	Count	5	18	23
	% within Occupation	22%	78%	100%
Farm owners	Count	25	22	47
	% within Occupation	53%	47%	100%
Total	Count	125 (22%)	440 (78%)	565
Chi- Square Value: 42.187 P Value: 0.000*				
*Statistically Significant				

The study found that 81% among unemployed and around 70% among labourers (Agri and non-agriculture labourers) underwent screening for active TB disease before initiation of TPT. 53% among farm owners and 30% among salaried employees were not screened for TB. Occupation was found associated statistically significant with the screening status. Out of the total not screened for TPT majority were unemployed which included students and adults not having any job.

Table 10: Association of Education Level and Substance use of HHCs with Screening for TB.

Educational level and Substance use status Vs Underwent Screening for TB				
		Underwent Screening		Total
		No	Yes	
Illiterate	Count	45	178	223
	% within Education	20%	80%	100%
Pre/Primary	Count	37	115	152
	% within Education	24%	76%	100%
High School	Count	24	74	98
	% within Education	24%	76%	100%
PUC	Count	15	40	55
	% within Education	27%	73%	100%
Degree and above	Count	4	33	37
	% within Education	11%	89%	100%
Total	Count	125 (22%)	440 (78%)	565
Chi-Square Value: 4.837 P Value: 0.304				
Habits/Substance Use				
No	Count	114	408	522
	% within Substance use	22%	78%	100%
Yes	Count	11	32	43
	% within Substance use	26%	74%	100%
Total	Count	125	440	565
	% within Substance use	22%	78%	100%
Chi- Square Value: 0.323 P Value: 0.570				

The study found that 89% among of the HHCs who had an educational level Degree and above were screened for active TB disease before initiation of TPT. 20% among Illiterate and 24% among primary level of education were not screened for TB. Educational level was not statistically associated with level of education.

Out of the 43 HHCs, who had an history of substance abuse, 74% were screened for active TB disease before initiation of TPT. Substance use status was not statistically associated with screening status.

Table 11: Association of Gender with Outcome of TPT

Gender of HHCs Vs Outcome of TPT treatment							
Gender		**Outcome of Treatment**					**Total**
		Not Initiated	Completed	Failed	Discontinued due to Toxicity	Discontinued due to other reasons	
Male	Count	74	102	1	13	67	257
	% within Gender	29%	40.5%	0.5%	5%	26%	100%
Female	Count	72	121	1	21	93	308
	% within Gender	23.7%	39%	0.3%	7%	30%	100%
Total	Count	146	223	2	34	160	565
	% within Gender	26%	40%	0.5%	6%	27.5%	100%
Chi- Square Value: 3.176 P Value: 0.529							

Among the 257 male HHCs around 40% completed TPT treatment and 29% were not initiated on treatment. Among the 308 female HHCs 39% completed the completed TPT treatment and around 24% were not initiated on treatment. 31% among male HHCs and 37% among female HHCs Discontinued the TPT due to various reasons. Gender was not statistically significant with outcome of TPT treatment.

Table 12: Association of Age of HHCs with Outcome of TPT

Age Vs Outcome of TPT treatment							
Age Groups (in years)		**Outcome of Treatment**					**Total**
		Not Initiated	Completed	Failed	Discontinued due to Toxicity	Discontinued due to other reasons	
0-30	Count	86	126	2	22	85	321
	% within Outcome	27%	39%	0.6%	7%	26.4%	100%
31-60	Count	49	84	0	10	64	207
	% within Outcome	24%	41%	0%	5%	30%	100%
>60	Count	11	13	0	2	11	37
	% within Outcome	30%	35%	0%	5%	30%	100%
Total	Count	146	223	2	34	160	565
	% within Outcome	26%	40%	0.5%	6%	27.5%	100%
Chi- Square Value: 4.254 P Value: 0.834							

Out of the 321 HHCs who were in the age group less than 30 years, 39% completed TPT treatment and 27% were not initiated on treatment. Among the 207 HHCs who belonged to age group between 30 and 60 years, 41% completed TPT treatment and 24% were not initiated on treatment. Around 35% of HHCs from each age group discontinued the TPT due to various reasons. Age was not found to be statistically significant with outcome of TPT treatment.

Table 13: Association of Occupation with Outcome of TPT

Occupation Vs Outcome of TPT treatment							
Occupation		**Outcome of Treatment**					**Total**
		Not Initiated	Completed	Failed	Discontinued due to Toxicity	Discontinued due Other Reasons	
Unemployed	Count	82	126	1	19	87	315
	% within Outcome	26.0%	40.0%	0.3%	6.0%	27.6%	100%
Salaried Employees	Count	6	7	0	2	5	20
	% within Outcome	30.0%	35.0%	0.0%	10.0%	25.0%	100%
Agri Labour	Count	24	31	0	7	30	92
	% within Outcome	26.1%	33.7%	0.0%	7.6%	32.6%	100%
Non Agri Labour	Count	19	25	1	3	20	68
	% within Outcome	27.9%	36.8%	1.5%	4.4%	29.4%	100%
Small Buisness	Count	4	14	0	3	2	23
	% within Outcome	17.4%	60.9%	0.0%	13.0%	8.7%	100%
Farm owners	Count	11	20	0	0	16	47
	% within Outcome	23.4%	42.6%	0.0%	0.0%	34.0%	100%
Total	Count	146	223	2	34	160	565
	% within Outcome	26%	40%	0.5%	6%	27.5%	100%
Chi- Square Value: 18.211 P Value: 0.574							

Among the 315 HHCs who were unemployed, 40% completed the treatment, 26% were not initiated and around 34% discontinued due to various reasons. Among the labourers (Agri and non-agriculture labourers), around 35% completed the treatment and 27% were not initiated on TPT. 61% of HHCs who had small business and 43% of HHCs who were farm owners completed the treatment. Occupation was not statistically significant with outcome of TPT treatment.

Table 14: Association of Educational Level with Outcome of TPT

Educational Level Vs Outcome of TPT treatment							
Educational Level		**Outcome of Treatment**					**Total**
		Not Initiated	Completed	Failed	Discontinued due to Toxicity	Discontinued due to other reasons	
Illiterate	Count	56	66	0	12	89	223
	% within Education	25%	30%	0.0%	5%	40%	100%
Pre/Primary	Count	39	70	0	9	34	152
	% within Education	26%	46%	0.0%	6%	22%	100%
High School	Count	24	46	1	7	20	98
	% within Education	25%	47%	1.0%	7%	20%	100%
PUC	Count	18	22	0	3	12	55
	% within Education	33%	40.0%	0.0%	5%	22%	100%
Degree and above	Count	9	19	1	3	5	37
	% within Education	24%	51%	3%	8%	14%	100%
Total	Count	146	223	2	34	160	565
	% within Education	26%	40%	0.5%	6%	27.5%	100%
Chi- Square Value: 38.554 P Value: 0.001*							
*Statistically Significant							

Out of the 223 HHCs who were illiterate, 30% completed the treatment, and around 45% discontinued due to various reasons. Among the HHCs who had a degree or above level of education, 51% completed TPT and 22% discontinued due to various reasons. Educational level was found to be statistically significant with outcome of TPT treatment.

Table 15: Association of Substance use with Outcome of TPT

Substance Use Vs Outcome of TPT treatment							
Substance Use		**Treatment Outcome**					**Total**
		Not Initiated	Completed	Failed	Discontinued due to Toxicity	Discontinued due to other reasons	
No Habits	Count	138	212	1	32	139	522
	% within Outcome	26%	40%	0.1%	6%	27.9%	100%
Yes	Count	8	11	1	2	21	43
	% within Outcome	19%	26%	2%	5%	48%	100%
Total	Count	146	223	2	34	160	565
	% within Outcome	26%	40%	0.5%	6%	27.5%	100%
Chi- Square Value: 15.392 P Value: 0.004*							
*Statistically Significant							

Out of the 43 study participants who had history of substance abuse 53% discontinued due to various reasons and 26% completed the treatment. Out of the 522 study participants who did not have any history of substance abuse, 40% completed the treatment and 35% discontinued due to various reasons. History of substance use was found to be statistically significant with outcome of treatment.

Table 16: Association of Type of screening with Outcome of TPT

Type of Screening Vs Outcome of TPT treatment							
Type of Screening		**Treatment Outcome**					**Total**
		Not Initiated	Completed	TPT failed	Discontinued due to Toxicity	Discontinued due to other reasons	
Not Screened	Count	146	21	0	1	11	179
	% within Outcome	82%	11.5%	0.0%	0.5%	6%	100%
Clinically Screened	Count	0	43	0	16	45	104
	% within Outcome	0.0%	41%	0.0%	16%	43%	100%
Sputum	Count	0	134	0	17	86	237
	% within Outcome	0.0%	57%	0.0%	7%	36%	100%
Sputum & x-ray	Count	0	18	2	0	9	29
	% within Outcome	0.0%	62%	7%	0.0%	31%	100%
X-ray	Count	0	7	0	0	9	16
	% within Outcome	0.0%	43%	0.0%	0.0%	57%	100%
Total	Count	146	223	2	34	160	565
	% within Outcome	26%	40%	0.5%	6%	27.5%	100%
Chi- Square Value: 484.46 P Value: 0.00*							
*Statistically Significant							

Out of the 104 HHCs who were screened clinically, 41% completed and 59% discontinued due to various reasons. Among the 237 HHCs who were screened with sputum examination, 57% completed the TPT and 43% discontinued due to various reasons. Among the Individuals who were screened with both Sputum and X-ray, completion rate was even higher at 62%. Method of screening was found to be statistically significant with outcome of TPT treatment.

Interview with Healthcare Providers for perspectives on TPT Programme and implementation challenges

Health care workers interviews were conducted using open ended questionnaire with 5 healthcare providers (HCP) who gave consent to participate in the interview. 2 Senior TB Supervisors and 3 TB Health Visitors were interviewed regarding their perspectives and challenges on TB Preventive Treatment (TPT).

1. General understanding regarding TPT

When enquired about their attitude on treating HHCs they mentioned that they have concerns about TPT potentially causing drug resistance and its overall efficacy.

2. Role and Responsibilities in TPT

When the STSs were asked about the functioning of TPT programme they mentioned their role in overseeing TB control but mentioned that they have limited involvement in TPT due to the presence of an NGO managing TPT in the district.

3. Drug Supply

When asked about drug supply, they mentioned that, initially there was a significant challenge of drug shortage, which was exacerbated during the COVID-19 pandemic. However, this issue has been resolved.

4. Trainings for TPT

When asked about training regarding TPT, HCPs pointed out the lack of formal training on TPT.

5. Challenges of TPT programme

When asked about the challenges both supervisors and health visitors identified stigma as a major challenge, with patients often afraid to take medication due to fear of being labelled and misconceptions about TPT. They also mentioned MDR cases pose additional challenges in administering TPT due to complexity and patient fear.

DISCUSSION

The study aimed to evaluate the socio-demographic characteristics, TB screening processes, and the completion of Tuberculosis Preventive Therapy (TPT) among household contacts (HHCs) of TB patients in the Vijayapura District of Karnataka. Vijayapura, a mostly agricultural district, faces significant developmental challenges, with an overall literacy rate of 57.46%, comprising 68.10% for males and 46.19% for females.[51] The district contributes 1.9% to Karnataka's Gross State Domestic Product (GSDP) and 1.8% to the Net State Domestic Product (NSDP), with a per capita income of Rs. 104,190 in 2018-19.[52] Despite the seemingly high per capita income, there is a significant disparity between the rich and the poor. District has a high TB Burden, having an average incidence of 130-150 TB cases/month. TPT initiative was started here in September, 2021.

Non-Response and Stigma

The study encountered a significant non-response rate, with 149 out of 268 approached households being non-responsive to participate in the study, resulting in an overall non-response rate of 55.6%.

A significant number of households (54) had incorrect contact numbers, indicating potential issues with data accuracy and record-keeping in the Nikshay Portals. This underscores the necessity for regular verification of contact information to ensure effective follow-up and communication with patients and their households. Reema Arora et al., 2021 also identified similar challenges in maintaining accurate information in the Nikshay portal in their study.[53]

Migration accounted for 39 non-responsive households, with many relocating back to their original village after being diagnosed at their workplace. There is a high prevalence of seasonal migration in the district and suggests that migration can significantly affect TB and TPT services. Woldesemayat EM noted in his review article published in 2021, that migrants often face a high prevalence of TB risk factors, such as exposure to TB, HIV, malnutrition, substance use, delayed diagnosis, low education, poor health-seeking behavior, stigma, and marginalization.[54] Additionally social barriers, including language, cultural issues, and unfriendly health services, may further contribute to the burden among this population.

56 Households refused to participate in the study interview at their household, stating they don't want to be identified as having TB case in their house by neighbours, friends or relatives as the reason, these highlighted features of TB-related stigma. S. Atre et al., in their study conducted in Maharashtra, found that concealment of the disease was often driven by fears of losing social status, facing marital problems, and experiencing hurtful behavior from the community.[55] Gargi Thakur et.al 2020, also found that social stigma remains a significant issue, often leading families to hesitate in sharing that a member has contracted TB disease.[56] Anmol Pradhan et.al., 2022 in a study using Internalized Social Stigma Scale (ISSS) found that stigma negatively affected treatment adherence of TB patients.[57]

Socio-Demographic Characteristics

In our study, we found an overall average of 5 household contacts (HHCs) per TB patient, suggesting that health workers should plan for higher medication needs. Rural areas typically have a higher number of HHCs, indicating the need for adjustment in these regions to ensure adequate provision of TPT medications.

Most of the study population belonged to Socioeconomic class 3 or lower (4,5) according to the modified BG Prasad classification, indicating that lower socioeconomic status (SES) remains a significant determinant of TB. This finding aligns with numerous studies suggesting that TB is more prevalent among lower socioeconomic groups.[58,59] People with low SES typically face poor housing and environmental conditions, greater food insecurity, and limited access to quality health care compared to those from higher SES groups.[60] These adverse conditions are interrelated and collectively increase the risk of TB by influencing various stages of the pathogenetic pathway. Poor living conditions and food insecurity weaken the immune system, while limited access to health care leads to delays in diagnosis and treatment, creating an environment where TB can thrive and disproportionately affect those in lower socioeconomic classes.

39% of our study population never attended school. A cross-sectional study using the NFHS 4 data found a high prevalence (0.4%) of TB among the Uneducated.[61]

The benefit package of PM-JAY can cover patients with pulmonary TB, inpatient evaluation for other forms of TB, and enhance the allocation for treatment.[62] It also covers the management of comorbid conditions such as severe undernutrition, anemia, HIV, and diabetes. However, only 23% of our study population had Ayushman Bharat health cards.[63]

A study in Haryana found a 29% prevalence of smoking among household contacts (HHCs) of TB patients.[64] In contrast, we found a lower prevalence of substance use among the households in our study. This discrepancy may be attributed to self-reporting bias. Substance use, which includes tobacco chewing and alcohol, though prevalent in this region, was not reported when asked, probably due to stigma. Additionally, the fact that 38% of the study population were students could also contribute to the lower reported prevalence of substance abuse.

Household Characteristics

Indoor air pollution is common in TB households and has been identified as a risk factor for TB mortality and morbidity.[60] 90% of the houses in our survey lacked cross ventilation, and 59% of the households were overcrowded and 52 % used Wood along with LPG for cooking and heating water. These can cause indoor air pollution, which is a significant risk factor in TB mortality and morbidity.[65]

A study done in Pune by Jessica L Elf et.al., 2019 discovered a link between kerosene use and tuberculosis.[66] Another study conducted in Nepal by Amod K Pokhrel et.al., 2010 also provides evidence that using kerosene stoves is associated with TB.[67] In our study we had not found any households using kerosene as a cooking fuel. They responded by saying we are not getting any kerosene from the public distribution system anymore. The Government's Ujjwala program has significantly changed the type of cooking fuel in the households. The 'Pradhan Mantri Ujjwala Yojana' (PMUY) is a flagship scheme with the objective to make clean cooking fuel such as LPG available to the rural and deprived households, which were otherwise using traditional cooking fuels such as firewood, coal, cow-dung cakes etc.[68] Most of our study households used Wood (mainly twigs and small wood pieces) along with LPG, citing high cost of LPG.

TB Screening for starting TPT;

The ideal policy recommendation for TPT among HHCs of sputum-positive pulmonary TB patients is the "Test and Treat" approach, but due to lack of facilities for IGRA testing, our district follows the "Screen and Treat" approach, where they are only

symptomatically screened for 4 symptoms of TB (Fever, cough, weight loss and night sweats). If they are found asymptomatic, TPT is prescribed.

In the absence of facilities to perform IGRA, the key question is whether the absence of symptoms in adults or children is sufficient to rule out active TB, or if a chest X-ray should also be performed.[69] While systematic chest X-ray use is not mandatory in resource-limited settings[70], WHO states that the absence of chest X-ray abnormalities combined with the absence of TB-related symptoms has the highest negative predictive value for ruling out TB.[71] Only 8% of the study population was screened using X-rays. Mobile vans equipped with digital chest X-ray machines are increasingly being piloted and could be used in these settings. A study in Zimbabwe by T Sengaiet.al.,2019 found that nearly 10% of asymptomatic individuals with chest X-rays indicative of pulmonary TB were diagnosed and treated for TB, with 13% of them having bacteriologically confirmed disease.[72] A similar study in India confirmed the operational and economic value of chest X-rays in asymptomatic individuals.[73]

Our study further demonstrates that the type of screening method employed was statistically linked to the outcome, revealing that selecting the appropriate screening method could significantly impact the completion of Tuberculosis Preventive Treatment (TPT). Studies have shown that clinical symptom screening is inferior to any modality of tests.[74]

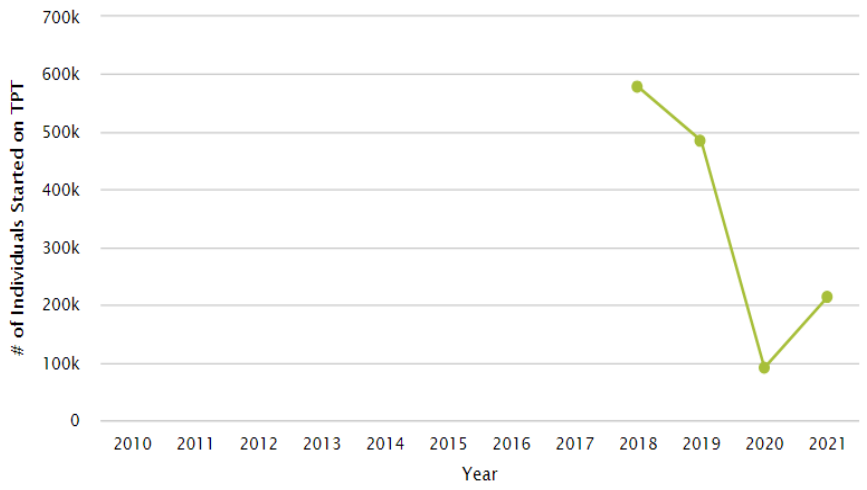
Most of the study participants were students comprising 35% of study population. 21% of the HHCs were unemployed and 28% of them were daily wage labourers. Our study found a statistically significant association between screening and Occupation. The reason could be the influence of occupation type on screening accessibility. For instance, occupations like farming, where individuals typically depart early in the morning and return late, present challenges for screening implementation.

The results indicate that screening for TB among household contacts (HHCs) is not a felt need. This could be attributed to the generally low educational levels of many HHCs or the ineffectiveness of proper information, education, and communication (IEC) activities in reaching the broader population. Studies have shown that educational or counselling interventions can enhance the likelihood of successful treatment completion.[75,76] Studies in developed countries emphasize the necessity of correlating biomarkers with IGRA to confirm latent TB infection (LTBI)[77], but we found a failure to screen the HHCs using X-ray or IGRA. X-ray was used only among 10% of those who underwent screening and IGRA was not available at all.

Prescription of TPT

Initiation of TPT is major indicator for monitoring TPT.[78] The figure below shows the trend of TPT initiation in India. Covid-19 had a brought a major dip in the graph.

Figure 20: Number of Individuals Started on TPT in India[79]



Our study has shown that 79% of the study participants were prescribed on TPT and 74% Initiated the TPT. Our study was conducted in the recovery phase of the Pandemic and this reflects on the results. There is limited data on TPT-initiation rates among household contacts in Indian scenario, while studies on TPT among children shows suboptimal rates of TPT initiation in India (19–33%) [80,81,82] and varied rates in other countries (32–89%).[83,84,85,86] Most of these Indian Studies are prior to the expansion and strengthening of TPT services launched in 2018, which could be the reason for very low initiation rates compared to our study.

One of the households in our study told that 5 HHCs were initiated on TPT (Tuberculosis Preventive Therapy) without any screening, not even clinically. Although recall bias could have influenced this finding, if this discrepancy is real, it raises serious concerns about potential drug resistance[87] and the overall effectiveness of the TB control program. Initiating TPT without proper screening contradicts established guidelines and could lead to improper treatment and increased risk of drug-resistant TB strains. This highlights an urgent need to review and strengthen screening protocols and ensure strict adherence to guidelines. Interviews with healthcare providers revealed a lack of specific training on TPT, which could also contribute to this issue.

Completion of TPT/Outcome

Out of the total participants who were prescribed TPT, 50% of individuals did not complete TPT. According to WHO, completion of TPT among household contacts who started treatment in 2021 reported by 83 countries; the median completion rate was 89%,

but rates varied widely.[88] A study in Namibia showed a 48% completion rate of TPT among PLHIV which is similar to our study.[89]

In our study, the most common reason for not completing TPT was found to be the belief that it was not necessary. 46% of those not completed conveyed the same message through different wordings. This attitude could be a reason of multiple worries, especially longer duration of the regimen for an apparently healthy individual and fear of side-effects of the drugs. A study in Indonesia showed that Completion of TPT among contacts on short regimens was over 90%.[90] The latest guidelines released by Ministry of Health and family welfare in May 2024 have recommended 1HP Regimen (1 month of daily INH and Rifapentine).[91] This step will be a game changer in TPT adherence and completion. The challenge will be to make the newer drug supply available in all the districts.

Some of the participants conveyed that they discontinued the medication due to the unavailability of the drugs. The interview with the STS also revealed that there was a shortage of medication in the initial phases of TPT. Studies have reported that scaling up of TPT has led to drug shortages worldwide.[92] Another interesting finding in the reasons for not completing TPT was that 7% of the participants who failed to complete the treatment conveyed that drugs were not given to them after 3 months. Even though initially we thought it might be due to reduced supply, in Interviews with the health care providers, they suggested it could be due to frequent staff changes done by the Private organization (NGO) which is looking after implementation of TPT in the district. When the field staff are changed frequently, the patients followed by them are lost, and new staff cannot follow the new list of patients. Dedicated staff recruitment is crucial for

effective contact tracing, screening, improving adherence, follow-up, and program execution.[83]

Adverse effects or side effects of the drugs was another reason reported for discontinuing TPT by 15% of the HHCs. INH can cause minor gastric irritation, and the recipient can have symptoms like vomiting and nausea.[93] Peripheral neuropathy is another major common adverse effect, and Hepatitis is a fatal adverse effect.[94] Out of the 34 Individuals who discontinued TPT due to adverse effect, only 1 of them had Peripheral Neuropathy symptoms, and all others had only gastritis. None of them had Hepatitis. All of the HHCs who had gastritis discontinued the drugs at their own discretion without consultation with a healthcare provider, adequate counselling by health care persons and follow up can decrease such drop outs.

The educational level of the HHCs was found to be associated statistically significant with the outcome of TPT. Individuals with higher education levels, such high school, and above degree exhibited higher rates of treatment completion, ranging from 46% to 51%, compared to 30% to 46% in Illiterate and Primary level. This could be attributed to the knowledge about TB and a better understanding of the need for TPT among the educated class. Educational level has been the major factor associated with TB mortality for both sexes and all age groups according to a study in Colombia by Salomé Valencia-Aguirre et.al., 2020.[95]

SUMMARY

A Cross-sectional study conducted in Vijayapura district to estimate the proportion of household contacts (HHCs) of bacteriologically confirmed first-time diagnosed pulmonary tuberculosis (TB) patients, who were initiated, completed, or dropped out from tuberculosis preventive therapy (TPT). It also aimed to explore the factors influencing adherence and non-adherence to TPT treatment. Health care personnels were interviewed for operational difficulties in implementing TPT.

Major findings of the study are:

- A total of 119 houses were surveyed across 5 TB units, involving 565 HHCs.

- A total of 268 index cases were approached, and 149 households were non-responsive, resulting in an overall non-response rate of 55.6%. Non-response rate was higher in Urban areas.

- The sample population is predominantly Hindu (79%) with a Muslim minority (21%); the majority are of Other Backward Caste (69%); most fall into lower socioeconomic class (3, 4 and 5); a significant portion lacks health insurance (77%); a substantial portion never attended school (39%); and 8% reported substance use.

- The surveyed households (n=119) include primarily nuclear families (48%), with the highest cooking fuel usage being a combination of LPG and wood (52%), 59% experiencing overcrowding, 81% holding below-poverty line (BPL) ration cards, and only 23% covered by Ayushman Bharat health insurance.

- The majority of TB screening (345 cases) were conducted in households, and 22% were not at all screened for TB; among these, the primary reason was lack of awareness (105 individuals, 84%), followed by disbelief in the benefit of screening (10 individuals, 8%); the highest number of household contacts (HHCs) screened for tuberculosis (TB) was through Sputum Testing (225 HHCs), followed by clinical screening (174 HHCs).

- A total of 445 household contacts (HHCs) were prescribed Tuberculosis Preventive Therapy (TPT), and 21% were not; of those prescribed TPT, 424 received counselling about its necessity and potential side effects.

- The study showed that the initiation of TPT was around 75 %, and the completion rate was only 50% among them.

- The major reason for not completing full TPT, was no belief in long term preventive treatment, and it was not a felt need. Unavailability of medicines and discontinuation due to toxicity were other reasons.

- Statistical significance was found between those who underwent screening and occupation of HHCs, Treatment outcome with educational level and Type of screening method. Those who had higher educational levels and were screened using sputum or X-ray rather than clinical screening were found to have a higher TPT completion rate.

- The study underscores the need for improved screening protocols, dedicated staff, and shorter treatment regimens to enhance TPT adherence and completion.

CONCLUSION

This was a community-based cross-sectional study conducted in a high TB burden district to assess the initiation and completion rates of Tuberculosis Preventive Therapy among Household contacts of microscopically confirmed first-time diagnosed Pulmonary TB patients and identify the factors influencing the outcomes.

The research encompassed five randomly selected TUs out of a total of ten in the district and involved interviews with 565 Household Contacts residing in 119 households.

We found that social factors like poverty, stigma, and illiteracy are still major factors which influence TB care service utilization. Most of our study participants were Hindu by religion, and belonged to other backward caste and nuclear in nature. The majority of households were overcrowded and used both LPG and biofuel mass, posing a risk factor for TB transmission. We also found that the majority households lacked health Insurance (PMJAY) and held BPL public distribution cards (PDS).

The findings revealed a high initiation rate of TPT in 79% of HHCs and a completion rate of only 50%. The major barriers identified for non-completion were lack of awareness about TPT, not being approached by healthcare personnel, unavailability of medicines and adverse effects.

RECOMMENDATIONS

- Introduction of Shorter Regimen:

  The implementation of shorter TPT regimens presents a promising avenue for improving treatment adherence and outcomes.

- Capacity building /training:

  The competence of healthcare providers is paramount in ensuring the successful delivery of TPT services. Our study brought issues related to training like lack of clarity about TPT and its benefits. Hence, capacity-building workshops for primary care workers can be organized.

- Maintaining a Steady and ample Drug Supply:

  During our interviews with healthcare providers, we found that there was shortage of drugs in the initial phase of TPT. This has been addressed nowadays according to them. Proper indenting and maintaining good supply chain is an important step towards TPT outcome.

- Enhancing Data Accuracy and Reliability on the Nikshay Portal:

  Implement verification processes to ensure accurate entry and regular updating of phone numbers and addresses on the Nikshay Portal. Maintaining precise and current information is crucial for effective follow-ups and the efficient delivery of TB services to patients.

- Quicker screening and initiation:

  There is a delay in the screening and initiation of TPT; in some cases, 3 months after the Index case is diagnosed. This should be addressed through proper follow-up of the HHCs as quickly as possible.

- Establishing IGRA Testing Facility and Mobile X-ray as Alternative:

  The establishment of IGRA testing facilities should be done quickly, and interim solutions such as mobile X-ray units may be considered for screening.

- Increasing Health Insurance Coverage:

  Health Insurance coverage was found to be very low, and steps should be taken to increase enrolment of PMJAY, which can reduce the financial burden associated if necessary.

- Addressing Concerns about Drug Resistance:

  Even healthcare providers raised concern about possible resistance due to TPT, lack of proper information is evident in their concerns. This should be addressed through proper trainings.

- Involvement of Private practitioners in TPT:

  Involvement of private practitioners in TPT is limited, and in a country with more than 50% private healthcare utilization rate, we need to bring them into confidence about the effectiveness of TPT.

- IEC Activities

  Our study found that the stigma associated with TB is very high. IEC activities should be targeted to make TPT a felt need among the households. Understanding the underlying causes of refusal is critical, as it could stem from mistrust, lack of perceived benefit, or stigma associated with TB.

STRENGTHS

1. In 2021, the district initiated TPT for all household contacts of TB patients. This study is the first of its kind to assess the program's initiation rate, completion rate, and the factors influencing them and is funded by the State NTEP-Karnataka as part of its operational research initiatives.

2. There are very few studies on the initiation and adherence rates of TPT among adult household contacts of Pulmonary TB patients.

3. Our study suggested that screening for TB among household contacts should be more objective, moving beyond clinical symptom screening to include IGRA and X-rays at larger scales.

4. Our study also revealed that stigma and low socioeconomic status continue to play a significant role in the social factors affecting TB.

5. Our study found that training healthcare workers and gaining their trust are pivotal in advancing toward the END TB goal.

LIMITATIONS

1. Since this was a cross-sectional interview-based study, whatever study participants reported about TPT was noted and analysed, so the self-reporting bias of treatment initiation, adherence and completion cannot be ruled out.

2. Only a few healthcare providers could be contacted and agreed to be interviewed regarding the TPT Implementation. A larger sample including the NGO partner working in the district would have given more details about Programme performance and challenges.

3. Although the study is community-based, the findings might be context-specific to Vijayapura District or similar settings.

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ANNEXURE-1

QUESTIONNAIRE

Factors Influencing Initiation, Adherence, and Completion of Tuberculosis Preventive Therapy Among Household Contacts of Pulmonary TB Patients.

Socio-demographic questionnaire (To be answered by the head of the household or any adult (M/F) who lives and knows about the family matters)

Date: Household Code: ☐☐☐☐☐

1. Name:	
2. Address:	
3. Phone number:	
4. Nikshay ID of Index case (From Excel):	
5. Designated Health Centre:	
6. Religion**:**	Hindu ---------- 1 Muslim ---------- 2 Christian ----------3 Jain/Buddhist ---------- 4 Others ----------5
7. Caste	SC ---------- 1 ST ---------- 2 OBC ----------3 General ---------- 4 Others (specify _____) ---------5 Refused ----------999
8. Average monthly income of the family (In Indian Rupees)	>8220----------1 4110-8219----------2 2465-4109----------3 1230-2464----------4 <1230----------5
9. Size of the family:	___ ___
10. Date on which relative was found TB positive (Index case) (From Excel):	..../...../.....
11. Did he/she (relative) complete treatment?	Yes ---------- 1 No ---------- 0 Refused ---------- 999

12. If No, why?	6 months not completed------1 Side effects----------2 Not Interested----------3 Expired----------4 Other_____5 Refused ----------999
13. Digital Adherence Tools if any using	Yes ---------- 1 No ---------- 0 Don't know ----------88
14. Did you receive 500/month as part of Nikshay Poshan Yojana?	Yes ---------- 1 No ---------- 0 Don't know ----------88 Refused ---------- 999
15. If No, why?	
16. Health Insurance (Ayushman Bharat,PMJAY)	Yes specify _____) ---------- 1 No ---------- 0 Refused ----------999

A. Household Roster

A.1. code	**A.2 Name of the household member**	**A.3 Relation to Index Case***	**A.4 Sex** *Male ------1 Female----2 Others----3*	**A.5 Age** *(Incompleted years)*	**A.6 Education** *Never attended----------0 Pre/Primary School----------1 High School----------2 PUC/Diploma----------3 Degree and above----------4*	**A.7 Occupation***	**A.8 Substance Abuse** No Habits---1 Tobacco chewing ----2 Smoking bidi/ cigarettes---3 Alcohol------4 Others -------5 Refused ----------999	**A.9 Marital Status** Currently Married--1 Unmarried----2 Divorced---4 Widow----5 Separated--6 Refused---999
A1.1								
A1.2								
A1.3								
A1.4								
A1.5								

***Relation to Index case:** Index Case-01, Wife/husband-02, Son/daughter-03, Daughter/son-in-law-04, Grandchild-05, Parent-06, Grandparent-07, Sibling-08, Parent-in-law-09, Nephew/niece-10, Sibling-in-law-11, other relative-12, others-13

B. Screening (Symptomatic Screening for COUGH, FEVER, WEIGHT LOSS AND NIGHT SWEATS)						
Code	**B.1 Did anyone approach you for TB screening ?** Yes ----- 1 No ----- 0 Refused ---------999	**B.2 If yes, who did?** HCW at OPD----------1 HCW at TB clinic --2 Other HCW in the health facility (specify) ----------3 Community health worker----------4 Heard it from media: e.g., radio / TV/ etc.----------5 Other (specify) ---6	**B.3 Did you Undergo screening for TB?** Yes ----------1 No ----------0 Refused ---999	**B.4 Where Did you Undergo Screening?** House----------1 Health Facility (Specify) ----------2 Other (specify) ----------3 Refused -------999	**B.5 Why didn't you go for screening?** I don't know the need for screening----------1 I am not convinced that I/Child will benefit ----------2 I don't think I/child will get TB----------3 My house is far----------4 I don't have money--------5 I don't have time----------6 Other (specify) ----------7 Refused ----------999	**B.6 Date of Screening (or month at least)**
A1.1						
A1.2						
A1.3						
A1.4						
A1.5						

Code	**C.1 Did you undergo x-ray?** Yes ----- 1 No ----- 0 Refused--999	**C.2 Did you undergo TST (skin Test)?** Yes ----------1 No ----------0 Refused ---999	**C.4 Did you undergo Sputum Examination?** Yes ----- 1 No ---------- 0 Refused --999
A1.1			
A1.2			
A1.3			
A1.4			
A1.5			

D. TPT-1						
Code	**D.1 Did they prescribe TPT for you?** Yes -----1 No ----- 0 Refused --------- 999	**D.2 If no, why?** Contra-indication for TPT----------1 Not Willing----------2 Don't Know----------88 Other (specify) ----------4 Refused ----999	**D.3 Were you counseled regarding TPT?** Yes ----- 1 No ----- 0 Refused ----------999	**D.4 Date of starting TPT?**	**D.5 Did you Complete TPT for the full duration?** Yes ----- 1 No ----- 0 Refused ----999	**D.6 Why Not?** Side Effects (specify) ----------1 I am not convinced that I/Child will benefit ----------2 I don't think I/child will get TB----------3 Difficulty in Getting Medicines----------4 Medicines not available in the Health Facility----------5 I/Guardian felt not necessary to complete--6 Other (specify)-----7Refused ----------999
A1.1						
A1.2						
A1.3						
A1.4						
A1.5						

E. TPT-2				
Code	**E.1 Date of completion of TPT?**	**E.2 Outcome** Treatment not Initiated----1 Treatment completed------2 Treatment failed----------3 TPT discontinuation due to toxicity ----------4 Other (specify) ----------5	**E.3 Where Do you Collect your Medicines?** Delivered at Home-------1 Health Facility (Specify)----2 Others (Specify)----3	**E.4 Do you use any transport means to come to the HF?** Yes----------1 (Please specify which & amount of cost/day) No ---------- 0 Refused ----999
A1.1				
A1.2				
A1.3				
A1.4				
A1.5				

F. Past History						
Code	**F.1 Past h/o of TB?** Yes ---1 No ----0 Dk-88 Refused ----999	**F.2 Are you having Diabetes?** Yes ----- 1 No ----- 0 Dk-88 Refused ----999	**F.3 Are you having Hypertension?** Yes ----- 1 No ----- 0 DK-88 Refused --999	**F.4 Are you having HIV/AIDS?** Yes ----- 1 No ----- 0 DK -88 Refused ----------999	**F.5 Are you having Any other long-term ailment (>2 months)?** Yes (Specify) ---------- 1 No ----- 0 Refused --------999	**F.6 Did you see any IEC activities related to TB disease/prevention /Treatment?** Yes (Specify) ----- 1 No ----- 0 DK-88 Refused ----------999
A1.1						
A1.2						
A1.3						
A1.4						
A1.5						

Household Conditions:

1. House:	Own---------- 1 Rented---------- 2 Refused ----------999
2. Type of House:	Kutcha---------- 1 Pucca---------- 2 Mixed----------3
3. Number of Rooms excluding Kitchen:	___ ___
4. Tap Water Supply:	Yes ---------- 1 No ---------- 0 Refused ----------999
5. Toilet Facility Inside House:	Yes ---------- 1 No ---------- 0 Refused ----------999
6. Ration Card**:**	AAY---------- 1 BPL---------- 2 APL----------3 Not Available----------4 Others ----------5
7. Type of cooking Fuel (Can tick multiple)	LPG Gas ---------- 1 Wood---------- 2 Both----------3 Kerosene ----------4 Others (specify _____) ---------5 Refused ----------999
8. Disposal of Household waste	Vehicle----------1 Throw Outside----------2 Other_____3

9. Does anyone smoke inside house? (Bidi / cigarette)	Yes ---------- 1 No ---------- 0 Refused ----------999
10. Cross-Ventilation/Window area >20%Floor area	Yes ---------- 1 No ---------- 0
11. Cattle inside living area	Yes ---------- 1 No ---------- 0
12. Sources of IAP in everyday use	Agarbathi-/ Dhoop ----------1 Mosquito coil--/ liquidator ----------2 Pooja/ Camphor ??----------3 Lighting (Candle, Kerosene) ----------4
13. Damp Roofs/Walls (Observe all walls, roof)	Yes ---------- 1 No ---------- 0
14. Floor Material	Clay----------1 Mud----------2 Cement----------3 Tile----------4 Others----------5
15. Wall Material	Thatch----------1 Mud----------2 Stone----------3 Brick----------4 Cement----------5 Painted----------6 Others----------7
16. Roof Material	Thatch----------1 Asbetos----------2 Tiles----------3 Iron----------4 Concrete----------5 Others----------6
17. Over-crowding (Room/Person)	Yes ---------- 1 No ---------- 0
18. Separate Kitchen with smoke vent	Yes ---------- 1 No ---------- 0
19. Smoke from Neighbourhood	Yes ---------- 1 No ---------- 0
20. Burns waste near House	Yes ---------- 1 No ---------- 0
21. ARI Episodes Under 5 in last 6 months	

ANNEXURE-II

OPEN ENDED QUESTIONNAIRE FOR HCP

1. How do you think the programme for TB is functioning?

2. New scheme of TPT was added to the programme since around 2 years; what do you think about treating all household contacts of TB Patients?

3. Did you receive any training regarding TPT?

4. Are you facing any challenges in drug supply?

5. What are other challenges you encounter in TPT programme?

ANNEXURE-III

ETHICAL CLEARANCE

BLDE
(DEEMED TO BE UNIVERSITY)
Declared as Deemed to be University u/s 3 of UGC Act, 1956
Accredited with 'A' Grade by NAAC (Cycle-2)
The Constituent College
SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

BLDE (DU)/IEC/ 697/2022-23 30/8/2022

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on **Friday, 26th August, 2022 at 3.30 p.m. in the Department of Pharmacology** scrutinizes the Synopsis of Post Graduate Student of BLDE (DU)'s Shri B.M.Patil Medical College Hospital & Research Centre from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "STUDY TO ASSESS FACTORS INFLUENCING INITIATION, ADHERENCE AND COMPLETION OF TUBERCULOSIS PREVENTIVE THERAPY AMONG HOUSEHOLD CONTACTS OF PULMONARY TB PATIENTS IN VIJAYAPURA DISTRICT".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR SHANOON SHARAF ALI

NAME OF THE GUIDE: Dr. Shailaja S. Patil, Professor , Dept. of Community Medicine

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA

Chairman,
Institutional Ethical Committee,
BLDE (Deemed to be University)
Vijayapura

Dr.Akram A. Naikwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA

MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103, Karnataka

Following documents were placed before Ethical Committee for Scrutinization

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-263303, Website: www.bldedu.ac.in, E-mail: [illegible]
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

ANNEXURE-IV
PERMISSION LETTER

BLDE
(DEEMED TO BE UNIVERSITY)
Declared as Deemed to be University u/s 3 of UGC Act, 1956Accredited with 'A' Grade by NAAC (Cycle-2)
The Constituent College
SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA
DEPARTMENT OF COMMUNITY MEDICINE

Ref. No.: DCM/22/23/1376 **Date 5-08-2022**

To
The District Tuberculosis Officer
Vijayapura District.

Sub: Regarding permission to collect data for conducting study on "Factors Influencing initiation, adherence and completion of tuberculosis preventive therapy among house –hold contacts of TB Patients in Vijayapura district".

Respected Sir,

With reference to the above cited subject I seek your permission to collect data on basic statistics, demographic and contact information of TB patients in our District from DTC for conducting study on "Factors Influencing initiation, adherence and completion of tuberculosis preventive therapy among house –hold contacts of TB Patients" in 5 TB Units (Vijayapura urban, Babaleshwar, Dever Hipparagi, Chadachan & B Bagewadi) of Vijayapura district by Dr. Shanoon Sharaf Ali, PG student in the department of Community Medicine Shri B M Patil Medical College Vijayapura.

At the end of the study, research findings will be shared with you and confidentiality of Subjects will be maintained.

Kindly do the needful.

Thanking you

Yours faithfully

10/08/22
District TB Officer,
District TB Centre,
Vijayapura-586 102
Karnataka, (India)
10/8/2022

Prof. & HOD
Dept. of Community Medicine
BLDE (Deemed to be University)
Shri B. M. Patil Medical College,
VIJAYAPURA-03.

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
BLDE (DU): Phone: +918352-262770, Fax: +918352-261303, Website: www.bldedu.ac.in, E-mail: office@bldedu.ac.in

ANNEXURE-V
FUNDING

GOVERNMENT OF KARNATAKA
HEALTH & FAMILY WELFARE SERVICE
OFFICE OF THE JOINT DIRECTOR (TB), LADY WILLINGDON STATE TB CENTRE, 2nd FLOOR, AROGYA SOUDHA, 1st CROSS, MAGADI ROAD, BENGALURU-560023

No: LWSTC/NTEP/PPM/64/2022-23 Date: 17/10/2022

Minutes of State OR Committee meeting held on 22nd September 2022 at State TB Office, Arogya Soudha, Bengaluru

The state OR committee meeting was held at the State TB Office, Arogya Soudha, Bengaluru on 22nd September 2022 and the esteemed OR committee members had attended the meeting physically and virtually. The list of OR committee members who were present during the meeting is listed in Annexure 1.

The following are the points and decisions taken during the meeting:

(1) The state had received 25 (twenty-five) post-graduate thesis on the area of tuberculosis from various medical colleges of Karnataka and MPH/PhD thesis from institutes affiliated to medical colleges. The committee had obtained priory approval from Central TB Division (CTD) to fund thesis for non-medical PG courses. However, as per the CTD directives, it was envisaged that the medical college PG thesis should always be prioritised under any circumstances. The OR committee recommended all the thesis for funding. (Annexure 2)
(2) The three multicentric OR studies which were supposed to be undertaken discussed during the last State OR committee meeting were dropped as few administrative issues were foreseen.
(3) The state had received 20 Operational Research Protocols from various medical colleges and one dental college across the state. The protocols were reviewed by internal and external experts. Based on the merits and discussions, the committee selected eight (8) proposals for funding from the programme (Annexure 3). The select Principal and one Co-Investigator shall mandatorily undergo 'State level protocol development workshop' at National TB Institute, Bengaluru from 7th – 11th November 2022.
(4) The three approved protocols which were selected in the previous OR cycles and had not received funding shall we included in the current financial year.

The meeting ended with vote of thanks.

Annexure 1

1. Dr Sharath BN, Chair, State OR Committee, Karnataka
2. Dr Anil S, State TB Officer, Member Secretary
3. Dr Ashok Dorle, Member (Virtual mode)
4. Dr Raveendra Reddy, Member (Virtual mode)
5. Dr Ravichandra, Member (Virtual mode)
6. Dr Ashwini, Member (Virtual mode)
7. Dr Akshay, Member (Virtual mode)
8. Dr Shazia Anjum, Ex-officio member

Joint Director (TB)

S.No	Name	Topic	Department	College	Year
10	Dr Mary Mathews	Pathways and time to treatment initiation in people with drug resistant tuberculosis in Bengaluru city – a mixed method study.	MD, Community Medicine	St Johns Medical College, Bengaluru	2022
11	Dr Sandhya Reddy	Evaluation of tuberculosis preventive treatment in household contacts of pulmonary tuberculosis cases in Bagalkot taluk: A cross sectional study	MD, Community Medicine	SN Medical College, Bagalkot	2022
12	Dr Kruthi P	Detection Of Latent Tuberculosis in Patients with Chronic Kidney Disease on Renal Replacement Therapy Using Interferon Gamma Release Assay	MD, General Medicine	Sri Devaraj Urs Academy Of Higher Education And Research, Kolar	2022
13	Dr Sreenath Menon P K	Assessment Of Notified Tuberculosis Patients for High Risk of Severe Illness Using a Programmatic Screening Tool In Bengaluru City- A Cross Sectional Study	MD, Community Medicine	ESIC Medical College and PGIMSR, Bengaluru	2022
14	Dr Balakrishnan R	Comparison of Quality of Life between Drug Sensitive and Resistant Tuberculosis patients during and after treatment in Bengaluru city: A Cross-sectional Study	MD, Community Medicine	ESIC Medical College and PGIMSR, Bengaluru	2022
15	Mr Vishwa Rajakumar Byakod	Role of Pharmaceutical Care Management Among MDR-Tuberculosis Patients: A Prospective Interventional Study.	Master of Pharmacy in Pharmacy Practice	KLE College ff Pharmacy, JNMC Campus, Belagavi	2021
16	Dr Bandaru Yeswanth Raja	Role of clinical pharmacist to improve tubercular patient's compliance referred to NTEP centre attached to a tertiary care hospital: a randomised controlled study	Doctor of Philosophy (Ph.D.)	KLE College of Pharmacy, JNMC Campus, Belagavi	2020
17	Dr Shanoon Sharaf Ali	Study to assess factors influencing, adherence and completion of tuberculosis preventive therapy among household contact of pulmonary tuberculosis patients in Vijaypura district	MD, Community Medicine	Sri BM Patil Medical College, Vijaypura	2022

ANNEXURE-VI
PARTICIPANT INFORMATION SHEET

PURPOSE OF RESEARCH:

I have been informed that this study will help in improving TPT programme and hence lead to preventing TB in India.

I have been explained the reason for doing this study and selectingme/my ward as a subject for this study. I have also been given the free choice of either being included or not in the study.

PROCEDURE:

I understand that relevant history will be taken, and I will undergo a detailed clinical examination and will also be explained the requiredinvestigations as per standard protocol.

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain and discomfort during the examination or during any intervention. This is mainly the result of my condition and the procedure of this study is not expected to exaggerate thesefeelings which are associated with the usual course of diagnosis and treatment.

ALTERNATIVES:

Even if you decline in participation, you will get the routine line of management.

BENEFITS:

I understand that I/my ward's participation in this study will help Analyze the operational difficulties and factors associated with Adherence to TPT Programme.

CONFIDENTIALITY:

I understand that medical information produced by this study will becomea part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time.

Dr. Shanoon Sharaf Ali is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course ofthis study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. And that a copy of this consent form will be given to me to keep it andfor careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the studyat any time without prejudice to my present or future care at this hospital.

I also understand that Dr. Shanoon Sharaf Ali will terminate my participation in this study at any time after she has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____

the purpose of this research, the procedures required and the possible risks andbenefits, to the best of my ability in patient's own language.

Date:

(Guide) (Investigator)

ANNEXURE-VII

INFORMED CONSENT FORM FOR HHCs

I confirm that Dr. Shanoon Sharaf Ali has explained the research's purpose, the study procedure, and the possible discomfort and benefits that I may experience during the study. Dr. Shanoon Sharaf Ali has explained all the above in detail in my own language and I have understood the same. Therefore, I agree to give consent for my participation as a subject in this research project.

Date:

_____

(Name of Study Participant)

_____

(Signature of Study Participant)

CONSENT STATEMENT FROM PARENTS / LOCAL GUARDIAN:

I confirm that Dr. Shanoon Sharaf Ali has explained the research's purpose, the study procedure that my son/daughter will undergo & the possible discomfort and benefits that he/she may experience in my own language. I have been explained all the above in detail in my language and understand the same. Therefore, I agree to give consent for my ward's participation as a subject in this research project.

_____

(Signature of the Parent / Guardian) Date:

_____

(Signature of witness)

ASSENT FORM

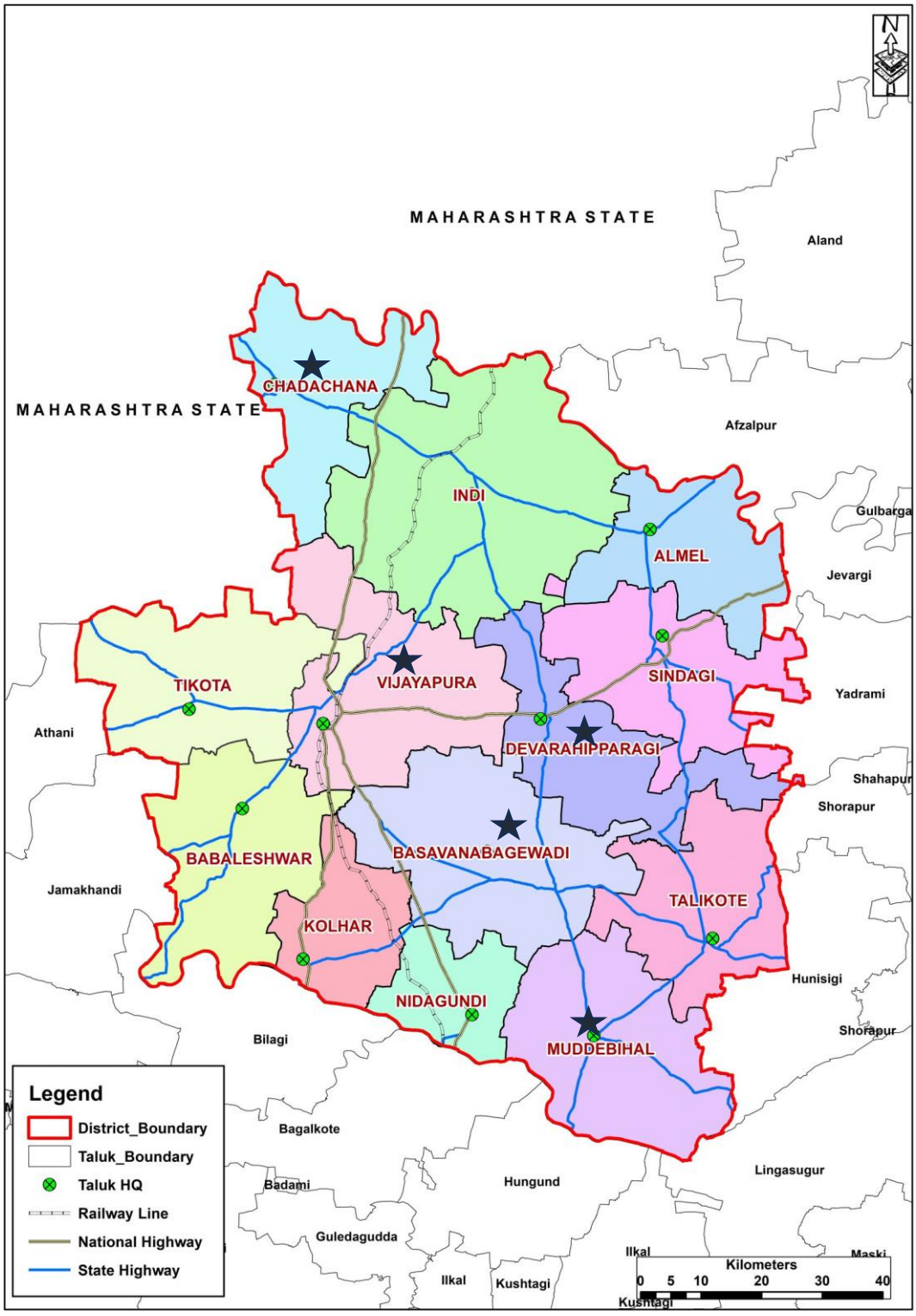
I have been asked to participate in a study on the topic "Study to Assess Factors Influencing Initiation, Adherence, and Completion of Tuberculosis Preventive Therapy Among Household Contacts of Pulmonary TB Patients in Vijayapura District" done by Dr. Shanoon Sharaf Ali under the guidance of Dr. Shailaja S Patil. By participating in this research, I will be asked a series of questions by the researcher regarding the topic. I have understood that the information about me will be kept secret, and I have the right to ask questions about my information and the result of the study. I have been informed that I will be able to leave the research at any time I want without any prejudice. I agree to be a part of this research.

Participants full Name:

Date:

ANNEXURE-VIII

STUDY AREA MAP



★ TB units selected for study

ANNEXURE-IX

PLAGIARISM REPORT

iThenticate

Similarity Report ID: oid:3618:61862689

PAPER NAME	AUTHOR
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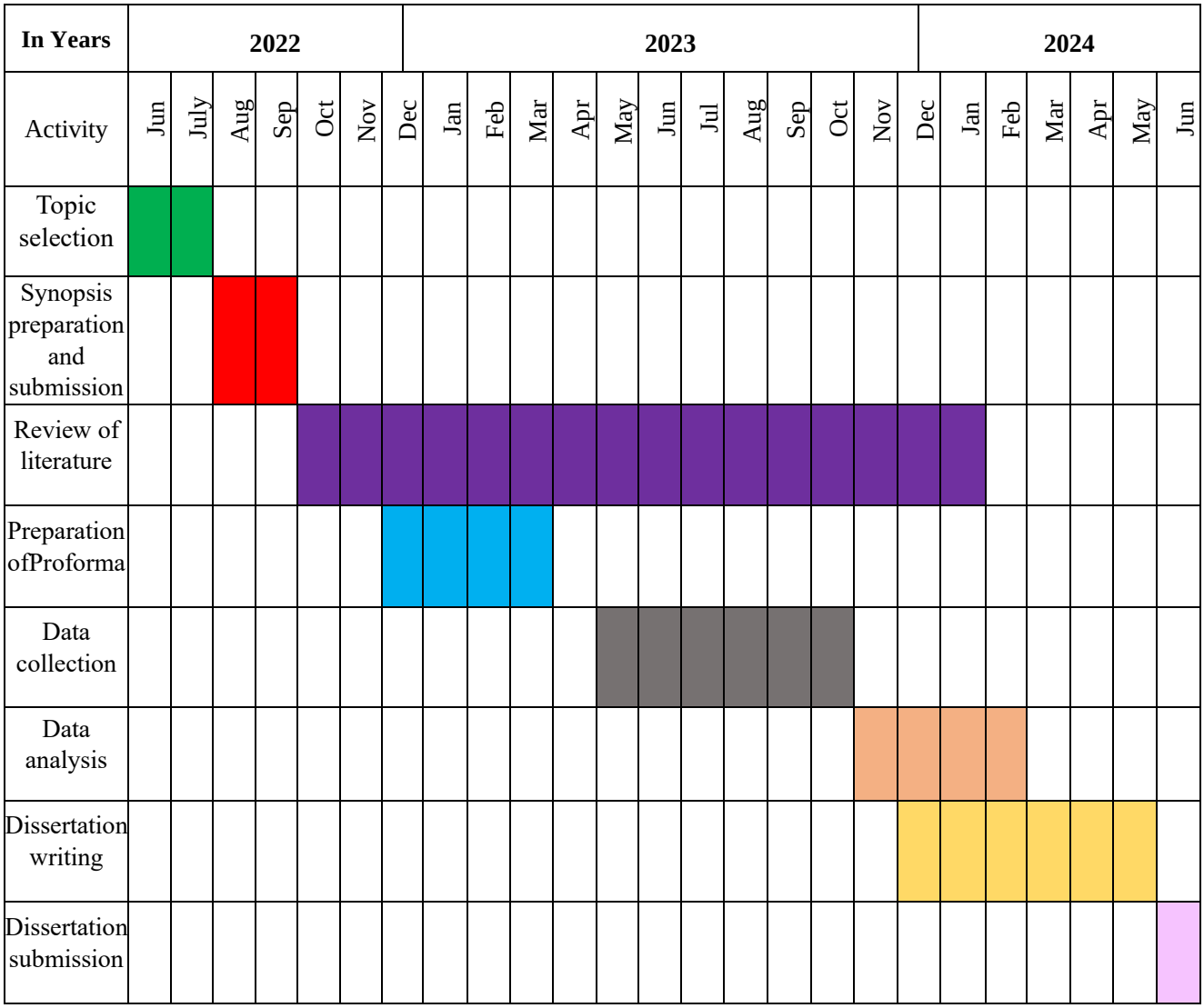
ANNEXURE-X

Gantt Chart



ANNEXURE-XI

SURVEY PHOTOGRAPHS