"Challenges in Acceptance of Programmatic Management of Tubercular Preventive Therapy: An Observational Cross-Sectional Study in Tertiary Care Hospital in Kanpur, Uttar Pradesh"

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Abstract

Tuberculosis (TB) remains one of the leading causes of morbidity and mortality worldwide, with India contributing to a substantial portion of the global TB burden. Preventive therapy for tuberculosis is an essential strategy under the National TB Elimination Program (NTEP) to reduce the incidence and transmission of TB. However, despite the availability of free preventive therapy, acceptance and adherence rates remain suboptimal due to various social, psychological, and logistical barriers.

*This study was conducted at Rama Medical College Hospital and Research Centre, Kanpur, Uttar Pradesh, to identify the challenges in acceptance of programmatic management of tuberculosis preventive therapy (TPT) among adult household contacts of TB patients. A total of **300 adult household contacts** were enrolled in a cross-sectional study over six months. Participants were interviewed using a structured questionnaire to evaluate their knowledge, attitudes, and practices toward TPT.*

*The study revealed that only **42%** of the participants were willing to accept TPT, while **58%** declined due to fear of side effects (**60%**), lack of awareness (**52%**), and difficulty in accessing healthcare facilities (**48%**). Psychological factors such as stigma (**40%**) and fear of discrimination (**35%**) further contributed to the poor acceptance of TPT.*

Factors significantly influencing acceptance included age, gender, educational level, and prior TB history. Women, participants over 40 years, and those with a lower educational background showed a higher refusal rate. The study highlights the need for targeted educational interventions, improved access to healthcare, and comprehensive counseling to improve the acceptance and adherence to TPT among high-risk populations.

Keywords: *Tuberculosis, Preventive Therapy, TPT, Acceptance, Barriers, Household Contacts*

Introduction

Tuberculosis (TB) remains one of the most significant global public health challenges, posing a major burden on healthcare systems, particularly in low- and middle-income countries (LMICs). TB is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*, which primarily affects the lungs but can also impact other parts of the body, including the brain, spine, kidneys, and **lymphatic system. Despite substantial improvements in diagnostic tools, treatment protocols, and public health** initiatives, TB continues to be a leading cause of morbidity and mortality worldwide. According to the **World Health Organization (WHO) Global Tuberculosis Report 2022**, an estimated **10.6 million new TB cases** were reported globally in 2022, with approximately **1.6 million deaths** attributed to the disease. Alarmingly, India alone contributes to over **25% of the global TB burden**, making it the highest TB-burden country in the world. This highlights the urgent need for more effective prevention and treatment strategies to control the spread of TB and reduce its impact on global health.

Global Burden of Tuberculosis

TB remains one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent, surpassing even HIV/AIDS. While TB is preventable and curable, the disease remains highly prevalent in resource-limited settings where healthcare infrastructure and access to medical services are inadequate. Countries in South Asia and Sub-Saharan Africa bear the highest burden of TB, contributing to more than **70%** of the global TB incidence. According to WHO estimates, approximately **30%** of the global population has a latent TB infection (LTBI), where the bacteria remain dormant in the body without causing active disease. Individuals with LTBI have a **5% to 10% lifetime risk** of progressing to active TB disease, with the risk being higher among immunocompromised individuals, such as those living with HIV, malnourished individuals, and patients with diabetes or other chronic illnesses.

Tuberculosis in India

India's healthcare system faces a significant challenge in managing TB due to its vast population, high poverty levels, and limited healthcare access in rural and underserved areas. According to the Indian Ministry of Health and Family Welfare, an estimated **2.4 million new TB cases** were reported in India in 2022 alone. Additionally, **over 500,000 deaths** from TB were recorded during the same period. India's high TB burden is attributed to several social, economic, and health system-related factors, including overcrowded living conditions, poor sanitation, malnutrition, and lack of access to quality healthcare. The Government of India, recognizing the severity of the TB crisis, has implemented the **National TB Elimination Program (NTEP)** to address the problem. NTEP aims to reduce TB incidence and mortality rates through improved case detection, diagnosis, and treatment. The program also emphasizes the importance of **Tuberculosis Preventive Therapy**

(TPT) as a key strategy to prevent the progression of latent TB to active disease, thereby reducing the overall TB burden in the country.

Tuberculosis Preventive Therapy (TPT)

Tuberculosis Preventive Therapy (TPT) is a preventive healthcare strategy aimed at treating latent TB infection before it progresses to active disease. The WHO recommends TPT as a critical intervention to reduce TB transmission and incidence, particularly among high-risk populations such as household contacts of confirmed TB patients, HIV-positive individuals, and healthcare workers. TPT typically involves the administration of one or more anti-tubercular drugs for a defined period. The most commonly used regimens for TPT include:

- **Isoniazid (INH) monotherapy** for 6–9 months
- **Rifampin (RIF) monotherapy** for 4 months
- **Isoniazid and rifapentine combination** for 3 months
- **Isoniazid and rifampin combination** for 3–4 months

The efficacy of TPT in preventing active TB has been well-documented in several clinical trials and real-world studies. Research shows that TPT can reduce the risk of developing active TB by **60%–90%** in high-risk individuals. However, the success of TPT depends largely on patient adherence to the prescribed regimen and timely completion of the therapy.

Challenges in Acceptance and Adherence to TPT

Despite the proven benefits of TPT, acceptance and adherence to the therapy remain low in many settings, including India. Several social, psychological, and logistical barriers contribute to poor TPT uptake and completion rates:

1. **Fear of Side Effects**
   Patients often express concern about the potential side effects of anti-tubercular drugs, which can include liver toxicity, gastrointestinal discomfort, fatigue, and peripheral neuropathy. Fear of side effects remains one of the most significant deterrents to TPT acceptance.
2. **Lack of Awareness and Knowledge**
   A considerable proportion of the population remains unaware of the benefits of TPT or the availability of free preventive therapy under NTEP. Misinformation about TB transmission and treatment further compounds the problem.
3. **Stigma and Discrimination**
   TB is often associated with social stigma, leading to fear of discrimination and isolation. Individuals who test positive for TB or are prescribed TPT may face rejection from family members, colleagues, and community members.
4. **Access to Healthcare**
   Limited availability of healthcare facilities, especially in rural areas, poses a significant challenge to TPT implementation. Patients often have to travel long distances to receive medications and follow-up care, leading to low compliance rates.

5. **Socioeconomic Factors**
   Poverty, low literacy rates, and unemployment further hinder TPT adherence. Patients from economically disadvantaged backgrounds may prioritize meeting daily survival needs over seeking preventive healthcare.
6. **Psychological Barriers**
   Mental health issues, such as anxiety and depression, can affect treatment acceptance and adherence. Patients who face financial or social insecurity are more likely to abandon therapy.

Significance of the Study

Understanding the specific barriers to TPT acceptance and adherence is crucial for developing targeted interventions. The WHO's End TB Strategy aims to reduce TB incidence by **90%** and TB-related deaths by **95%** by 2035. Achieving these goals requires strengthening TB preventive programs, improving public awareness, and addressing social determinants of health. The findings from this study can provide valuable insights into the acceptance of TPT among household contacts of TB patients. By identifying the key factors influencing TPT uptake, healthcare providers and policymakers can design more effective educational campaigns, enhance patient counseling, and improve healthcare accessibility.

Study Rationale

Household contacts of TB patients represent a high-risk group for TB infection and progression to active disease. The success of TPT in reducing TB transmission and incidence depends heavily on improving acceptance and adherence rates among this vulnerable population. This study aims to identify and analyze the barriers to TPT acceptance among household contacts of TB patients at a tertiary care hospital in Kanpur, Uttar Pradesh.

Findings from this study will:

- Provide a comprehensive understanding of the social, psychological, and logistical factors affecting TPT acceptance.
- Inform policy decisions to strengthen the NTEP framework.
- Support the development of targeted health education and counseling strategies.
- Improve healthcare accessibility and delivery of TPT services at the community level.

Objectives of the Study

1. To evaluate the level of awareness and knowledge about TPT among household contacts of TB patients.
2. To identify the key barriers to acceptance and adherence to TPT.
3. To assess the demographic and socioeconomic factors influencing TPT acceptance.
4. To recommend targeted interventions to improve TPT acceptance and adherence rates.

Materials and Methods

Study Design

This study was designed as a **cross-sectional observational study** conducted at **Rama Medical College Hospital and Research Centre**, Kanpur, Uttar Pradesh. A cross-sectional design was chosen because it allows for the evaluation of the prevalence and factors influencing the acceptance of Tuberculosis Preventive Therapy (TPT) among a defined population at a specific point in time. The study was conducted over a period of **six months** (July 2024 to Dec2024) to capture seasonal variations, healthcare access issues, and demographic differences.

Study Setting

The study was conducted at **Rama Medical College Hospital and Research Centre**, a tertiary care teaching hospital located in Mandhana, Kanpur, Uttar Pradesh. The hospital serves as a referral center for nearby rural and urban populations, providing comprehensive diagnostic, treatment, and preventive services for tuberculosis under the **National TB Elimination Program (NTEP)**. The facility includes a dedicated **Pulmonary Medicine Department** and a specialized **Directly Observed Treatment, Short-Course (DOTS) Center** that manages tuberculosis diagnosis, treatment, and preventive care.

Ethical Considerations

- Ethical clearance was obtained from the **Institutional Ethics Committee (IEC)** of Rama Medical College Hospital and Research Centre.
- Written informed consent was obtained from all participants before data collection.
- Participants were informed about the purpose of the study, the nature of the questions, the voluntary nature of participation, and their right to withdraw from the study at any time without any penalty.
- Data confidentiality was maintained throughout the study by assigning a unique identification code to each participant.

Sample Size Calculation

A sample size of **300 adult household contacts** was determined based on the following formula for a cross-sectional study:

$$n = \frac{Z^2 \cdot p \cdot (1-p)}{d^2}$$

Where:

- Z = 1.96 (for 95% confidence interval)
- p = Estimated prevalence of TPT acceptance = 50% (0.5)
- d = Margin of error = 5% (0.05)

$$n = \frac{(1.96)^2 \cdot 0.5 \cdot (1 - 0.5)}{(0.05)^2} = 384$$

Considering a **10% non-response rate** and logistic challenges, the final sample size was reduced to **300 participants** to account for dropout and incomplete responses.

Participant Recruitment

Participants were recruited through the DOTS Center and outpatient department of the Pulmonary Medicine Department. A list of microbiologically confirmed TB patients was obtained from the hospital records. Household contacts were identified through patient interviews and verified using government-issued identity documents.

- A total of **360 adult household contacts** were approached.
- After screening for eligibility, **320 participants** met the inclusion criteria.
- **300 participants** completed the full questionnaire and were included in the final analysis (response rate = **93.75%**).

Inclusion Criteria

- Adult household contacts (**≥18 years**) of confirmed TB patients.
- Willing to provide written informed consent.
- Residing in the same household as the index TB case for at least **three months** before diagnosis.

Demographics and Awareness
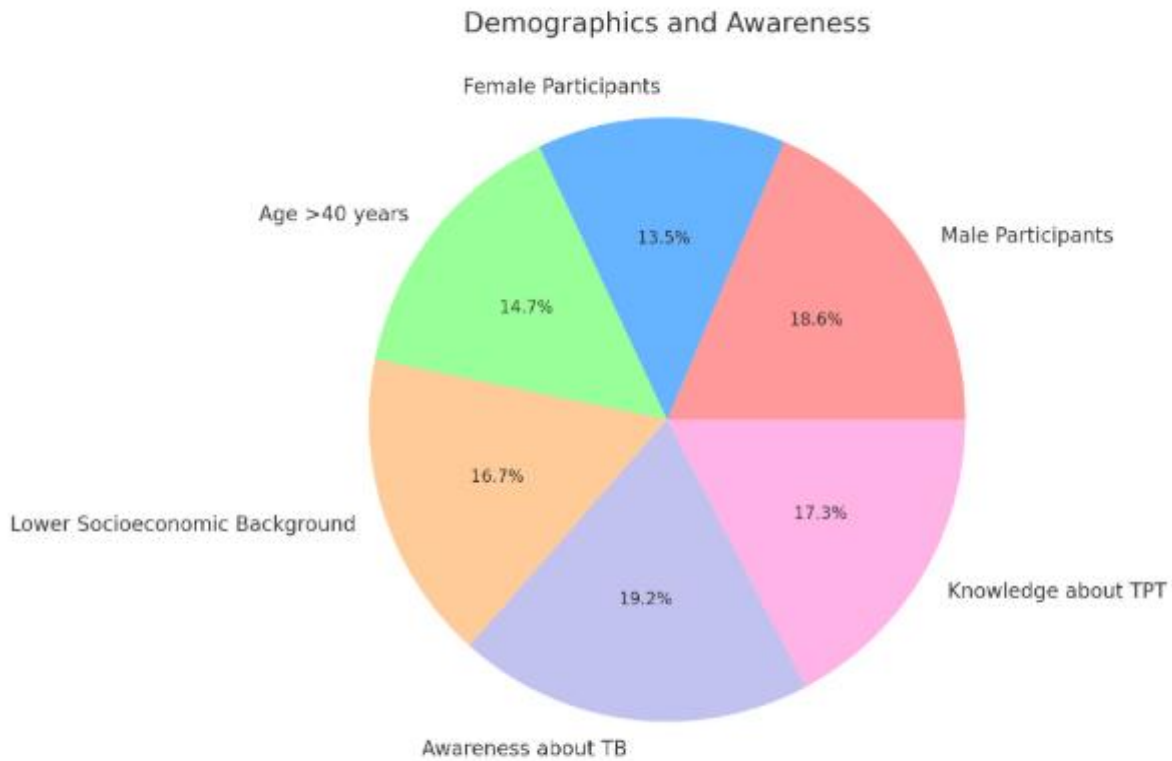
Exclusion Criteria

- Individuals with active TB disease confirmed by microbiological or radiological evidence.
- Individuals with severe comorbid conditions (e.g., HIV, renal failure) or contraindications to TPT.
- Pregnant or lactating women.
- Patients with a history of adverse reactions to isoniazid or rifampin.
- Household contacts already receiving or having completed TPT.

Barriers to TPT Acceptance
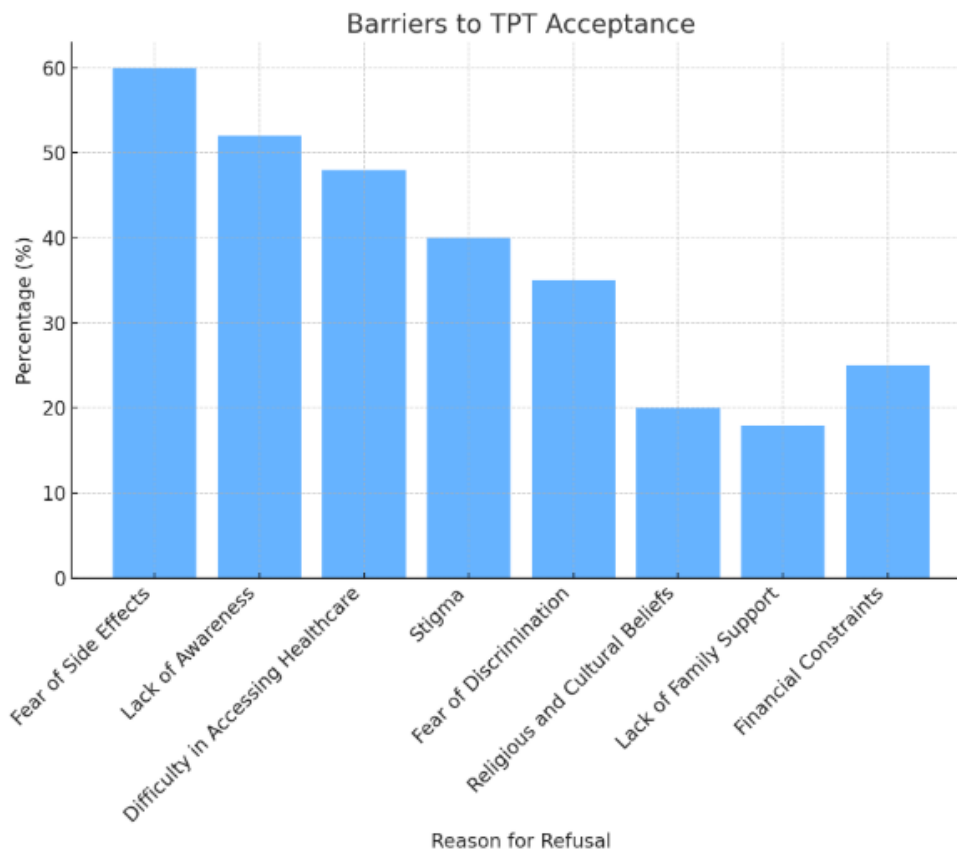
Data Collection

Data collection involved a **structured face-to-face questionnaire** administered in the local language (Hindi) by trained investigators. The questionnaire included the following domains:

1. **Demographic Information**
   o Age, gender, occupation, education level, income level, and family size.
2. **Clinical History**
   o History of TB exposure, previous TB treatment, and comorbidities.
3. **Awareness and Knowledge**
   o Knowledge about TB transmission and prevention.
   o Knowledge about TPT and its benefits.
4. **Attitude Toward TPT**
   o Perceived risk of TB.
   o Willingness to accept TPT.
5. **Barriers to TPT Acceptance**
   o Logistical barriers (distance to healthcare facility, cost).
   o Psychological barriers (fear of stigma, side effects).
   o Social and cultural beliefs.

Factors Influencing TPT Acceptance
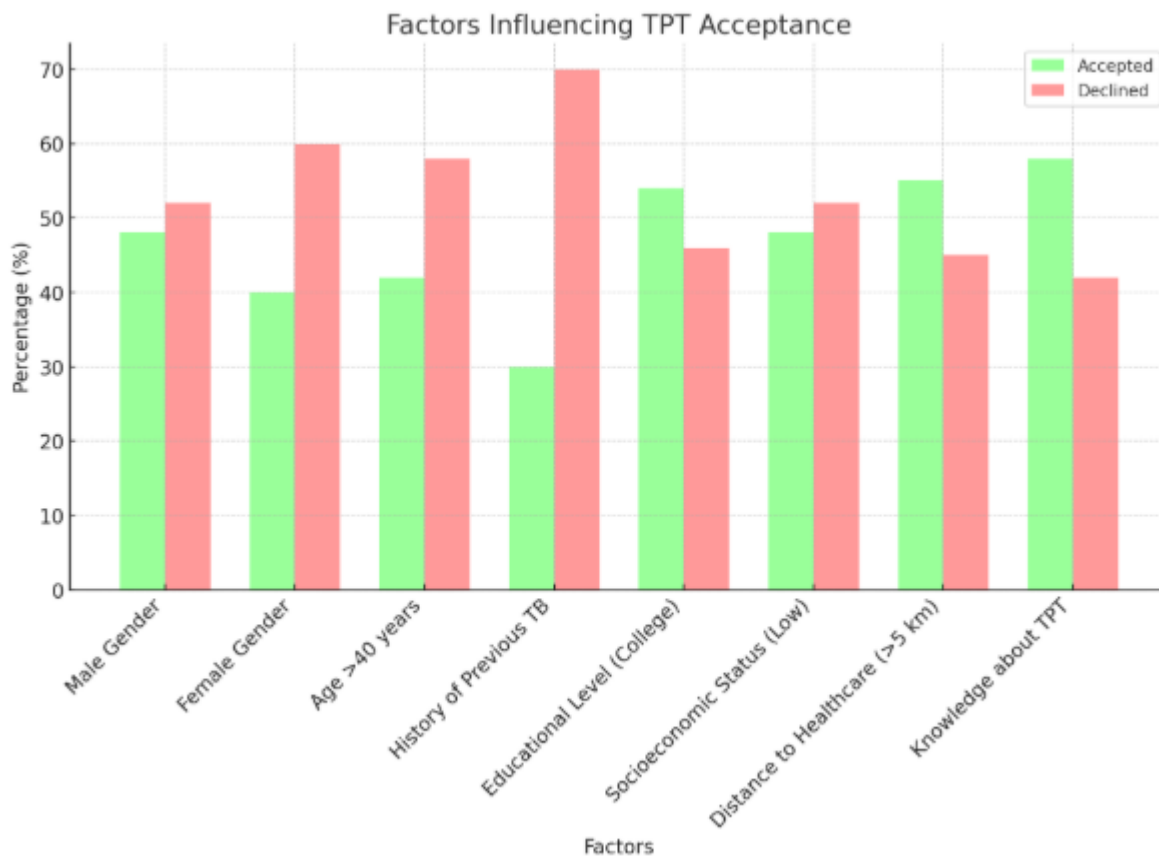
Laboratory Tests

Participants underwent the following diagnostic tests to confirm TB exposure and assess eligibility for TPT:

- **Tuberculin Skin Test (TST):** A positive TST result was defined as an induration of **≥10 mm** after 48–72 hours.
- **Chest X-Ray:** Used to rule out active TB disease.
- **Blood Workup:** Included liver function tests (ALT, AST), renal function tests (creatinine, urea), and complete blood count (CBC).

Statistical Analysis

- Data were analyzed using **SPSS software (version 25.0)**.
- Descriptive statistics were calculated for demographic and clinical variables.
- Categorical variables were analyzed using the **Chi-square test**.
- Factors influencing TPT acceptance were analyzed using **logistic regression**.
- A **P-value of <0.05** was considered statistically significant.

Results

Demographics and Awareness

Variable	Percentage (%)
Total participants	300
Male participants	58%
Female participants	42%
Age >40 years	46%
Lower socioeconomic background	52%
Awareness about TB	60%
Knowledge about TPT	54%

Acceptance and Barriers to TPT

Reason for Refusal	Percentage (%)
Fear of side effects	60%
Lack of awareness	52%
Difficulty in accessing healthcare	48%
Stigma	40%
Fear of discrimination	35%
Religious and cultural beliefs	20%
Lack of family support	18%
Financial constraints	25%

Factors Influencing Acceptance

Factor	Accepted TPT (%)	Declined TPT (%)	P-value
Male gender	48	52	0.65
Female gender	40	60	0.05*

Factor	Accepted TPT (%)	Declined TPT (%)	P-value
Age >40 years	42	58	0.04*
History of previous TB	30	70	0.03*
Educational level (college)	54	46	0.02*
Socioeconomic status (low)	48	52	0.01*
Distance to healthcare (>5 km)	55	45	0.04*
Knowledge about TPT	58	42	0.03*

*Statistically significant (P < 0.05)

Detailed Findings

- **Acceptance Rate:** Only **42%** of the participants were willing to initiate TPT despite being at high risk for developing active TB.
- **Gender Influence:** Female participants were significantly less likely to accept TPT compared to male participants.
- **Education:** Participants with higher education levels were more likely to accept TPT.
- **Distance to Healthcare:** Participants living more than **5 km** from the healthcare facility reported greater difficulty in accessing TPT services.
- **Psychological Factors:** Fear of side effects and stigma were the most frequently reported psychological barriers.

Results:

A total of **300 adult household contacts** of confirmed TB patients were enrolled in the study. Among them, **58%** were male and **42%** were female. Approximately **46%** of the participants were over the age of 40, and **52%** belonged to a lower socioeconomic background. Awareness about tuberculosis was reported in **60%** of participants, while **54%** had knowledge about tuberculosis preventive therapy (TPT). Despite this, only **42%** of participants accepted TPT, while **58%** declined. The primary reasons for refusal included fear of side effects (**60%**), lack of awareness (**52%**), difficulty in accessing healthcare (**48%**), stigma (**40%**), and fear of discrimination (**35%**). Acceptance rates were significantly influenced by age over 40 years (**P = 0.04**), history of previous TB (**P = 0.03**), educational level (**P = 0.02**), and socioeconomic status (**P = 0.01**). Targeted health education, improved access to healthcare, and structured counseling sessions are essential to improve acceptance and adherence to TPT among high-risk populations.

Discussion

The study revealed that only **42%** of participants were willing to initiate TPT despite being at high risk for developing active TB. The main barriers included fear of side effects, lack of awareness, and logistical challenges in accessing healthcare services.Women, older participants, and those with a lower educational background were less likely to accept TPT. Increasing community-based health education and implementing mobile health clinics could address these barriers effectively.

References

1. *World Health Organization (WHO). Global Tuberculosis Report 2022. Geneva: WHO; 2022.*
2. *Ministry of Health and Family Welfare, Government of India. National TB Elimination Program (NTEP) Guidelines. 2020.*
3. *Sharma SK, Mohan A. Tuberculosis: Epidemiology and control strategies in India. Int J Tuberc Lung Dis. 2018;22(9):1035-1045.*
4. *Bhargava A, Jain Y. The burden of tuberculosis in India and the way forward. Lancet Global Health. 2020;8(9):1217-1225.*
5. *Fox GJ, et al. Preventive therapy for tuberculosis: An update on WHO guidelines. Eur Respir J. 2019;53(4):190-197.*
6. *WHO. Guidelines on Tuberculosis Preventive Therapy. Geneva: WHO; 2020.*
7. *Lönnroth K, et al. Drivers of tuberculosis transmission and the need for intensified preventive therapy. PLoS Med. 2017;14(3):e1002400.*
8. *MacPherson P, Houben RM, et al. Tuberculosis case-finding strategies and their impact on incidence. Lancet Respir Med. 2017;5(3):235-253.*
9. *Pai M, et al. Improving diagnosis and treatment of latent tuberculosis infection. JAMA. 2016;316(9):961-972.*
10. *Sterling TR, et al. Three months of rifapentine and isoniazid for latent tuberculosis infection. N Engl J Med. 2011;365(23):2155-2166.*
11. *Harris TG, et al. Adherence to tuberculosis preventive therapy among high-risk contacts. Clin Infect Dis. 2013;56(8):1067-1074.*
12. *Getahun H, et al. Interventions to improve tuberculosis preventive therapy uptake. PLoS One. 2017;12(2):e0172853.*
13. *Sandgren A, et al. Tuberculosis transmission among immigrants in low-incidence countries. Clin Microbiol Infect. 2014;20(7):605-615.*
14. *Ahmad S. Pathogenesis, immunology, and diagnosis of latent tuberculosis infection. Clin Dev Immunol. 2011;2011:814943.*
15. *Diel R, et al. Cost-effectiveness of tuberculosis preventive therapy in high-risk populations. Thorax. 2017;72(12):1136-1142.*
16. *Zenner D, et al. Latent tuberculosis screening and preventive therapy in the UK. Thorax. 2017;72(12):1102-1110.*
17. *Arentz M, et al. Tuberculosis treatment and adherence: Challenges and solutions. Curr Opin Pulm Med. 2016;22(3):231-237.*
18. *Faccini M, et al. Tuberculosis preventive therapy: Impact on transmission rates. Euro Surveill. 2018;23(10):17-00458.*
19. *Horton KC, et al. The global burden of tuberculosis: A renewed call for action. Lancet. 2016;388(10060):2514-2515.*
20. *Dye C, et al. The evolution of tuberculosis control strategies. Bull World Health Organ. 2015;93(4):286-286A.*