# CHAPTER 5

# TB DRUG THERAPY CHALLENGES

This chapter discusses the socioeconomic and health policy challenges regarding availability, accessibility, and affordability of drug therapy among people living with TB. The study is conducted by utilizing a mixed-methods approach. The data is collected from a large set of sample participants across both public and private healthcare facilities and examined. This research highlights the implications of out-of-pocket expenditure (OOPE) burden on patients, and explores the significance of health policies in optimizing drug supply to the diverse socioeconomic patients. This research aims in understanding the barriers in effective TB treatment and offers targeted recommendations to policymakers in improving service delivery in India.

## 5.1 Background of the Study

Tuberculosis (TB) is one of the major infectious diseases affecting approximately one-third of the world's population (Sotgiu et al., 2014). With an incidence rate of 210 cases per 100,000 individuals and a mortality rate of 38%, tuberculosis is the leading infectious disease in India (Bagcchi, 2023; Sulis et al., 2014). As the most populous country, faces a healthcare system overburdened by its growing population. Private healthcare costs are out of reach for 3 million households, and drug prices continue to rise (Tripathi et al., 2019). In developing countries like India, impoverished households account for 85% of healthcare costs (Dash & Mohanty, 2019). As a result, many patients face financial barriers that hinder their access to effective treatment and care.

Rural and low-income populations in India face high out-of-pocket expenditures (OOPE), with the mean OOPE estimated at 14,660 INR and higher (Srinadh & Yadav, 2022), limiting access to quality healthcare services and affordable medicine (McIntyre et al., 2006). Consequently,

inadequate healthcare resources and the unaffordability of medicine for the people living with TB impede the achievement of universal health coverage (UHC) (Ranabhat et al., 2020). Moreover, less than 35% of the population has access to basic medical care, predominantly relying on private providers for treatment (Mathewos Oridanigo et al., 2021).

The Indian government spends 2.1% of GDP on health (Aggarwal, 2023), limiting the capacity and quality of healthcare services due to low spending. The public healthcare structure in the country is immensely burdened by the increasing population, perpetually diverting patients to private hospitals. Subsequently, there is a significant risk of pushing low-income patients into poverty. The private sector accounts major share of national health expenditure in India, with medicines being the largest component of OOPE. The government has initiated several health initiatives aimed at eradicating TB and reducing OOPE, including the Pradhan Mantri Bhartiya Janaushadi Pariyojna, the TB-DOT program, and the Ayushman Bharat health insurance scheme (Ranabhat et al., 2020). Nevertheless, household out-of-pocket healthcare expenditure has conventionally been a significant component of India's overall health expenditure. According to the National Health Accounts (NHA), the figure has improved over the years, to 47.1% in 2019-2020 from 62.6% in 2014-2015 (NHSRC, 2015, 2020).

In the view of all the above facts, this study aims to explore the socioeconomic and health policy challenges regarding the availability, accessibility, and affordability of drug therapy among the people living with TB in Agra district, Uttar Pradesh, India. By addressing these critical challenges, this research aims in understanding the barriers in effective TB treatment and to inform policy recommendations to enhance healthcare delivery and outcomes in the study region and beyond.

## 5.2 Methodology

### 5.2.1 Study Design

This study uses a mixed-method approach (quantitative and qualitative) that investigates the socioeconomic and health policy challenges regarding the availability, accessibility, and affordability of TB drug therapy. Major public and private sector healthcare facilities located in the Agra district of Uttar Pradesh, India, are the focus of the study. The study area comprises around 359 public and more than 500 private health facilities with a catchment population of around 3.1 million.

### 5.2.2 Data Collection Methods

The quantitative aspect of the research is undertaken by a facility-based cross-sectional survey using self-administered questionnaires. Complementing the quantitative study, the qualitative part again uses a facility-based cross-sectional survey study with self-administered questionnaires and semi-structured in-depth interviews to explore the reasons for the OOPE in medicines and service utilization issues. All the studies are conducted between October 2022 and March 2023.

### 5.2.3 Study Population

Both the quantitative and qualitative studies are undertaken in selected major public and private health facilities of the Agra district especially treating tuberculosis. All the health facilities treating tuberculosis found in the Agra district are considered to be the potential source facilities, while the patients, patient's relatives, and health professionals were considered sources of information. The people living with TB and their relatives, health professionals such as treating doctors, health officers, pharmacy professionals, pharmacy store managers, and frontline health workers in the sampled health facilities during the period from October 2022 and March 2023 are contemplated as the study population. Among the health facilities of the

Agra district, the major facilities which served more than three years in treating tuberculosis are included in the study. The facility administration that showed unwillingness for the conduct of the study is excluded from the study.

### 5.2.4 Sampling Methodology

The sample size of health facilities is determined by a multi-stage sampling technique comprising both public and private health facilities at a ratio of 1:1 between rural and urban populations. Accordingly, 20 major health facilities are selected with which public and private health facilities are 10 each. The study participants for the quantitative study are people living with TB from the sampled facilities. A total sampling of all 2244 people living with TB of these sampled health facilities between October 2022 and March 2023 is carried out.

For the qualitative part of the study, health professionals, patients, and patient relatives around the sampled facilities during the study period and those having a willingness to participate are chosen using the purposive sampling technique. A total of 49 participants are selected for the qualitative study. Additionally, they are also purposively designated as key informants for the qualitative semi-structured in-depth interviews

The purposive selection is critical in identifying key informants, who are invited to participate in qualitative semi-structured in-depth interviews. These interviews aim to delve deeper into the participants' experiences, revealing the perceived factors contributing to OOPE and service utilization challenges. The insights gained from the interview not only supplement the statistical findings but also provide a narrative that captures the complexities of accessing TB treatment in the Agra district.

### 5.2.5 Questionnaire Development

To effectively address the research objectives of this study, an in-house questionnaire is developed for both quantitative and qualitative components based on the extensive research

needs assessment and with valuable inputs from various experts, including government health officials, administrative officials, hospital administration, and public health officers.

The quantitative study questionnaires are designed with clear research objectives in mind and aim to gather specific observations and insights that are crucial for informing decision-making processes.

The Likert scale questions and interview questions in the questionnaire for qualitative study are thoughtfully designed and developed, ensuring their relevance in capturing the targeted qualitative aspects that this study aims to explore. Careful consideration is given to the response options to offer participants a sufficient level of granularity in expressing their opinions, experiences, or attitudes. It is firmly believed that the in-house questionnaires are the most appropriate and effective approach for this study's objective. The English version of questionnaires used for both quantitative and qualitative studies are included as supplemental material (**Appendix B**).

### 5.2.6 Pre-testing and Validation

Each questionnaire (both quantitative and qualitative) is subjected to pre-testing and quality checks in a sample of 5 healthcare facilities to ensure reliability and effectiveness. A separate set of 5 healthcare facilities (3 Public and 2 Private) was intentionally selected, which were not included in the main study. This approach allowed to validation and refinement of the questionnaire, ensuring its optimal performance before implementing it in the main study.

The expertise and diverse perspectives of various professionals have greatly contributed to the questionnaire's content and design, ensuring that it elicits the necessary information accurately and comprehensively. In testing the questionnaire, the responses from the sample facilities are analyzed and critically examined for their performance in terms of clarity, relevance, and data reliability. Through this improvement and quality check process, potential ambiguities or issues

are identified and necessary adjustments are made to enhance the questionnaire's validity and consistency. By following this rigorous scientific approach, a robust foundation is established for the data collection. Moreover, using an in-house questionnaire provides several benefits, as it allows to maintain the control over the research process, customizes the questionnaire to specific research needs, and ensures a higher level of consistency and reliability compared to using third-party questionnaires.

### 5.2.7 Data Collection Process

The authors/data collectors collected the data using data abstraction formats and self-administered questionnaires, and the principal investigator conducted the qualitative semi-structured in-depth interviews. The data collection sheets included self-administered questionnaires, which contained questions about socio-demographic characteristics (area of residence, age, sex, level of education, occupation, and monthly income), medical characteristics, OOPE, and perceived contributing factors on OOPE and service utilization. Key informants are interviewed using a semi-structured approach designed to elicit their perspectives on the problem's causes and present initiatives to address them. Data collectors are trained for four days on the data collection instruments and processes before data collection. Two experts from the TB department of the district administration are invited to review the interview guide for an in-depth interview to ensure its face and content validity.

### 5.2.8 Analysis and Statistics

Medical characteristics and OOPE of the study participants, service utilization, and policy measures among public and private hospital patients are the critical components of the analysis. The analysis is performed in aggregate and descriptive parameters such as Frequency, Mean, and Standard Deviation (SD) are calculated for different variables. To investigate the potential association between sociodemographic variables and the choice of availing healthcare services

from either public or private providers, a bivariate chi-square test is conducted in GraphPad Prism® Version 5.01 statistical software. The sociodemographic variables considered in this analysis included (area of residence, age, sex, level of education, occupation, and monthly income). The associated *p-value* is reported and the *p-value* ≤ 0.05 is considered statistically significant.

In the Likert scale method employed in the qualitative study, respondents are asked to rate their level of agreement or disagreement with each statement (total of 17 factors) using a 5-point scale from 1 to 5. The scale ranged from "1 - Strongly Disagree" to "5 - Strongly Agree", and "0 – Not Applicable" is additionally included because of different respondent's role existence. Participants are instructed to select the response option that best represents their viewpoint. Based on the specific values of each response, the mean scores and standard deviation for each factor are computed based on the provided ratings. The analysis and interpretation of participant responses are used to evaluate the factors contributing to impaired public service utilization and out-of-pocket expenditure.

Data from an in-depth interview is subjected to a thematic analysis approach. Key themes such as contributing factors, and suggestions for improving the service utilization and reducing the OOPE on medicines are manually reviewed and handled.

## 5.3 Results

### 5.3.1 Quantitative Findings

#### *5.3.1.1 Characteristics of the Study Sample*

Among the 2244 participant patients in this study, approximately 61% opted for healthcare services from the private sector. This inclination towards private healthcare highlights significant trends regarding patient preferences and accessibility dynamics within the Agra district. The demographic characteristics of patients, differentiated by their choice of public

versus private healthcare sectors, are shown in **Table 5.1**, along with the p values for differences between the public and private sectors.

**Table 5.1: Descriptive statistics on the socio-demographic characteristics of People Living with TB in the study facilities (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=2244)**

| Variables | Type of Hospital for Availing Health Service | | Bivariate Statistics – Chi-Squared test |
|---|---|---|---|
| | Public N (%), n=886 | Private N (%), n=1358 | *P* value* |
| **Residence** | | | |
| Urban | 515 (58.1) | 777 (57.2) | 0.6699$^{ns}$ |
| Rural | 371 (41.9) | 581 (42.8) | |
| **Sex** | | | |
| Male | 482 (54.4) | 740 (54.5) | 0.9666$^{ns}$ |
| Female | 404 (45.6) | 618 (45.5) | |
| **Age** | | | |
| <15 Years | 58 (6.6) | 65 (4.8) | 0.0052$^{ns}$ |
| 15-30 Years | 423 (47.7) | 574 (42.3) | |
| 31-45 Years | 240 (27.1) | 410 (30.2) | |
| >45 Years | 165 (18.6) | 309 (22.7) | |
| **Level of Education** | | | |
| None | 282 (31.8) | 434 (31.9) | **<0.0001** |
| High School or Below | 473 (53.4) | 658 (48.5) | |
| Higher Secondary or Diploma | 101 (11.4) | 249 (18.3) | |

| | | | |
|---|---|---|---|
| Degree/Graduates or Above | 30 (3.4) | 17 (1.3) | |
| **Occupation** | | | |
| Casual Labour | 219 (24.7) | 307 (22.6) | **<0.0001** |
| Cultivator | 111 (12.5) | 146 (10.8) | |
| Home Maker | 192 (21.7) | 401 (29.5) | |
| Employed (Salaried) | 70 (7.9) | 155 (11.4) | |
| Employed (Self) | 93 (10.5) | 97 (7.1) | |
| Student | 201 (22.7) | 252 (18.6) | |
| **Monthly Income** | | | |
| <5000 INR | 344 (38.8) | 409 (30.1) | **<0.0001** |
| 5001-10000 INR | 382 (43.1) | 551 (40.6) | |
| 10001-15000 INR | 107 (12.1) | 297 (21.9) | |
| >15000 INR | 53 (6.0) | 101 (7.4) | |

**P value ≤ 0.05 was considered statistically significant, ns – non-significant*
*N-Frequency, %-Percentage, n-total respondents in the respective category, INR-Indian Rupee currency.*

The analysis revealed no statistically significant differences in healthcare sector choice based on residence area, age, or sex. This suggests that these factors do not heavily influence whether patients choose public or private healthcare facilities. On the other hand, significant associations are observed concerning the level of education, occupation, and monthly income. These variables are significantly linked to the choice of healthcare sector, indicating that socio-economic factors play a pivotal role in determining healthcare preferences. Patients with higher educational attainment or income levels, and those in specific occupational categories, exhibited a tendency to utilize private healthcare services more frequently.

#### *5.3.1.2 Healthcare service utilization and Health policy benefits*

Healthcare service utilization and health policy benefits among people living with TB are studied under the categories of hospital, active TB stage, family screening, preventive treatment for families, and frontline health worker intervention, and the related data are shown in **Table 5.2**.

In terms of hospital category utilization, the findings indicate a distinct pattern in patient preferences within both the public and private healthcare sectors. A significant proportion of patients, 50.4% (n = 886), utilized community health centres within the public sector. In contrast, 45.6% (n = 1358) of patients sought treatment from tertiary care hospitals within the private sector. This distribution highlights the differing roles and capacities of public versus private facilities in delivering TB treatment.

In both healthcare sectors, a majority of the people living with TB are found to be in the pulmonary infection stage during the study period (74.2% in the public sector and 81.7% in the private sector). This underscores the critical need for ongoing, aggressive TB detection and management strategies, especially considering the contagious nature and public health implications of pulmonary TB.

Upon further evaluation regarding family screening practices and preventive treatments, this study reveals significant disparities between the healthcare sectors. In the public sector, nearly 79% of patients (n = 886) underwent family screening for TB, but a contrast to only 25% (n = 1358) is seen in the private sector. Moreover, preventive treatment to the families in the public healthcare sector is successful for 71% of the patients, but a very low number (10%) concerned the private hospital patients. These differences highlight potential gaps in private sector engagement with broader public health strategies like family screening and preventive care.

Another policy implication such as the Frontline health workers intervention during treatment is notably higher among public-sector hospital patients, with an 80% intervention rate, compared to 35% among private-sector patients. This significant involvement in the public sector aligns with health policy efforts prioritizing community-based interventions and support structures that are essential for comprehensive TB management.

**Table 5.2: Medical characteristics of the study participants, service utilization and policy measures among public and private hospital patients (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=2244)**

| Variables | Type of Hospital for Availing Health Service | |
|---|---|---|
| | **Public N (%), n=886** | **Private N (%), n=1358** |
| **Category of Hospital** | | |
| Primary Health Care | 223 (25.2) | 283 (20.8) |
| Community Health Care | 447 (50.4) | 360 (26.5) |
| Medical College Hospital/Tertiary Care | 36 (4.1) | 619 (45.6) |
| District Hospital/Quaternary Care | 180 (20.3) | 96 (7.1) |
| **Active TB Stage** | | |
| Primary Infection | 23 (2.6) | 47 (3.5) |
| Pulmonary Infection | 657 (74.2) | 1110 (81.7) |
| Extra Pulmonary | 146 (16.5) | 197 (14.5) |
| MDR TB | 57 (6.4) | 4 (0.3) |
| Active TB with Comorbidities | 3 (0.3) | 0 (0) |
| **Family Screening** | | |
| Yes | 703 (79.3) | 336 (24.7) |
| No | 183 (20.7) | 1022 (75.3) |

| | | |
|---|---|---|
| **TB Cases in the Family after Screening (Public n=703, Private n=336)** | | |
| 0 Case | 556 (79.1) | 250 (74.4) |
| 1 Case | 100 (14.2) | 77 (22.9) |
| 2 Cases | 29 (4.1) | 8 (2.4) |
| 3 Cases | 6 (0.9) | 1 (0.3) |
| 4 Cases | 12 (1.7) | 0 (0) |
| **Preventive Treatment to Family** | | |
| Yes | 631 (71.2) | 137 (10.1) |
| No | 255 (28.8) | 1221 (89.9) |
| **No. of Monthly Hospital Visits** | | |
| One | 415 (46.8) | 336 (24.7) |
| Two | 294 (33.2) | 911 (67.1) |
| Three | 83 (9.4) | 106 (7.8) |
| Four & above | 94 (10.6) | 5 (0.4) |
| **Frontline Health Worker (ASHA/AWW) contacted during the Treatment Period** | | |
| Yes | 709 (80) | 480 (35.3) |
| No | 177 (20) | 878 (64.7) |
| **Frontline Health Worker Visit to Patient Home** | | |
| None Visited | 188 (21.2) | 878 (64.7) |
| TB Health Visitor | 323 (36.5) | 336 (24.7) |
| Asha Worker | 104 (11.7) | 64 (4.7) |
| Senior Treatment Supervisor | 205 (23.1) | 19 (1.4) |
| Any Other from the Health Department | 66 (7.4) | 61 (4.5) |

*N-Frequency, %-Percentage, n-total respondents in the respective category, MDR TB-Multidrug-resistant tuberculosis, ASHA-Accredited Social Health Activist, AWW-Anganwadi worker.*

### *5.3.1.3 Availability, Accessibility, Affordability, OOPE on Medicines, and Health Policy Benefits*

The out-of-pocket expenditures (OOPE) among people living with TB are assessed and the effectiveness of policy measures related to the availability, accessibility, and affordability of medicines are evaluated. These findings are shown in **Table 5.3**.

In the context of public hospitals, it is well-established that consultations and diagnostic services are provided free of charge. However, all patients utilizing private hospitals faced charges for these services, which varied depending on the hospital type and nature of the diagnosis. This unpreventable imposition of fees in the private sector presents significant financial barriers for patients and underscores a critical difference in the economic impact of healthcare access between the sectors.

**Table 5.3: OOPE of the study participants, and policy measures among public and private hospital patients (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=2244)**

| Variables | Type of Hospital for Availing Health Service | |
|---|---|---|
| | Public N (%), n=886 | Private N (%), n=1358 |
| **OPD Visits/Consultation Charges Per Visit** | | |
| Free of Charge | 872 (98.4) | 0 (0) |
| <500 INR | 12 (1.4) | 885 (65.2) |
| 501-1000 INR | 2 (0.2) | 426 (31.4) |
| >1000 INR | 0 (0) | 47 (3.5) |
| **Diagnosis Expenses** | | |
| Free of Charge | 854 (96.4) | 0 (0) |

| | | |
|---|---|---|
| <500 INR | 16 (1.8) | 531 (39.1) |
| 501-1000 INR | 8 (0.9) | 369 (27.2) |
| 1001-2000 INR | 1 (0.1) | 288 (21.2) |
| >2000 INR | 7 (0.8) | 170 (12.5) |
| **Medicine Availability in the Treating Hospital** | | |
| Yes | 867 (97.9) | 647 (47.6) |
| No | 19 (2.1) | 711 (52.4) |
| **Affordability on Medicines** | | |
| Yes | 816 (92.1) | 123 (9.1) |
| No | 70 (7.9) | 1235 (90.9) |
| **Monthly Medicine Expenses** | | |
| Free of Charge | 796 (89.8) | 0 (0) |
| <500 INR | 41 (4.6) | 106 (7.8) |
| 501-1000 INR | 5 (0.6) | 528 (38.9) |
| 1001-2000 INR | 22 (2.5) | 321 (23.6) |
| >2000 INR | 22 (2.5) | 403 (29.7) |
| **Expenses of Vitamins & Supplements** | | |
| Free of Charge | 636 (71.8) | 0 (0) |
| <2000 INR | 228 (25.7) | 911 (67.1) |
| 2001-4000 INR | 20 (2.3) | 319 (23.5) |
| 4001-10000 INR | 2 (0.2) | 114 (8.4) |
| >10000 INR | 0 (0) | 14 (1.0) |
| **Expenditure on Hospitalization on MDR TB** | | |
| Free of Charge | 875 (98.8) | 0 (0) |

| | | |
|---|---|---|
| <3000 INR | 7 (0.8) | 543 (40.0) |
| 3001-5000 INR | 2 (0.2) | 306 (22.5) |
| >5000 INR | 2 (0.2) | 509 (37.5) |
| **Other Expenses** | | |
| <500 INR | 755 (85.2) | 851 (62.7) |
| 500-1000 INR | 118 (13.3) | 317 (23.3) |
| 1001-2000 INR | 9 (1.0) | 157 (11.6) |
| >2000 INR | 4 (0.5) | 33 (2.4) |
| **Patients Received 500 INR/Month for Nutrition from the Government as Aid** | | |
| Yes | 819 (92.4) | 289 (21.3) |
| No | 67 (7.6) | 1069 (78.7) |
| **Source of Money on Expenditure** | | |
| Daily Wages | 46 (5.2) | 104 (7.7) |
| Family Dependent | 101 (11.4) | 15 (1.1) |
| Farming | 35 (4.0) | 36 (2.7) |
| Government Aid | 169 (19.1) | 4 (0.3) |
| Insurance | 3 (0.3) | 3 (0.2) |
| Loan | 2 (0.2) | 2 (0.1) |
| Salary | 289 (32.6) | 967 (71.2) |
| Savings | 241 (27.2) | 215 (15.8) |
| Business | 0 (0) | 12 (0.9) |

*N-Frequency, %-Percentage, n-total respondents in the respective category, INR-Indian Rupee currency, OPD-Out Patient Department, MDR TB-Multidrug-resistant tuberculosis.*

In the case of medicine availability in the treating hospital, around 98% (n = 886) of patients from public hospitals reported the availability, whereas 48% (n = 1358) only reported the availability in private hospitals. This significant disparity highlights ongoing challenges in pharmaceutical supply chain management and accessibility in private healthcare settings.

In terms of affordability, almost 91% (n = 1358) of private-sector patients could not afford the medicines. Furthermore, about 30% of these patients reported monthly spending on medicines exceeding 2000 INR, highlighting a substantial economic burden that threatens their ability to sustain essential treatment regimens.

***Government Policy and Nutritional Aid***

Government policy aimed at mitigating these financial constraints includes provisions such as the Central government's nutritional aid of 500 INR per month for people living with TB. This benefit is effectively extended to 92% of patients within the public healthcare sector. However, access is notably restricted in the private sector, reaching only 21% of patients. The limited reach of this aid into private care sectors highlights a potential policy review/enhancement to ensure equitable support for all people with TB, regardless of their healthcare provider choice.

***Sources of OOPE***

The study also reveals that patients predominantly rely on personal resources to cover their healthcare expenses. Specifically, 60% of patients in the public sector and 87% in the private sector report their source of expenditure as their salary and savings. This reliance not only underscores the prevalent financial burden faced by people with TB but also reflects the issues in healthcare financing and the need for policies aimed at reducing OOPE through enhanced insurance coverage and subsidies.

### 5.3.2 Qualitative Findings

#### *5.3.2.1 Socio-Demographic Characteristics of Respondents*

In total, 49 participants aged between 20 and 62 years are engaged as respondents in this qualitative study. The diverse roles of these respondents are carefully selected to provide comprehensive insights into the study objectives. Among the 49 respondents, respondent's roles such as treating doctors, and health officers are engaged in providing valuable perspectives on the intricacies of TB treatment, healthcare service delivery, and the implementation of health policies. For the remaining participants, which include people with TB and their relatives, the focus is primarily on their experiences and interactions with healthcare services. The length of service in the respondent's role is also gathered, except for the patients and their relatives. The inclusion of various respondent roles enriches the data and contributes to a multifaceted understanding of the factors impacting TB care and support in the Agra district.

The demographic characteristics of the qualitative study participants are summarized in **Table 5.4**. This table presents important data, allowing for a clearer understanding of the diversity and backgrounds of those involved in this qualitative component study.

**Table 5.4: Socio-demographic characteristics of health professionals, patients, and patient relatives around the study facilities for the qualitative findings (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=49)**

| Variables | N (%), n=49 |
|---|---|
| **Sex** | |
| Male | 34 (69.4) |
| Female | 15 (30.6) |

| | |
|---|---|
| **Age** | |
| 20-30 Years | 6 (12.3) |
| 31-40 Years | 22 (44.9) |
| 41-50 Years | 13 (26.5) |
| >50 Years | 8 (16.3) |
| **Respondent's Role** | |
| Doctor | 14 (28.5) |
| Health Officer | 5 (10.2) |
| Store Manager | 4 (8.1) |
| Pharmacist | 8 (16.3) |
| Frontline Health Worker | 6 (12.3) |
| Patient Relatives | 6 (12.3) |
| Patients | 6 (12.3) |
| **Length of Service on Respondent's Role (n=37)** | |
| <5 Years | 3 (8.1) |
| 5-15 Years | 26 (70.3) |
| 16-25 Years | 6 (16.2) |
| >25 Years | 2 (5.4) |

*N-Frequency, %-Percentage, n-total respondents in the respective category*

### *5.3.2.2 Perceived factors contributing to the impaired public service utilization and OOPE on medicines*

In this study, a total of 17 factors are identified as potentially influential in determining service utilization and the out-of-pocket expenditure (OOPE) burden associated with tuberculosis (TB) therapy. These factors are circulated as questionnaires administered to all respondents, whose

insights are evaluated using a 5-point Likert scale to quantify perceptions regarding their impact.

Among the factors assessed, several factors are found to be particularly significant in the context of TB therapy. The most commonly perceived contributors are as follows,

- **Delayed Diagnosis and Poor Treatment Adherence**: Respondents indicated that delays in diagnosis and non-adherence to prescribed treatment plans significantly exacerbate both the disease burden and OOPE. This factor received a mean score of 3.76 ± 1.15 (Mean ± Standard Deviation), highlighting its critical role in influencing patient outcomes.
- **Low Monthly Disposable Income**: Another key factor identified is the limited real monthly disposable income per patient, which is rated with a mean score of 3.71 ± 1.18 (Mean ± Standard Deviation). This underscores the financial challenges faced by the patients, which can hinder their ability to access necessary treatments.
- **Lack of Health Insurance**: The majority of patients do not possess health insurance. This factor is rated with a mean score of 3.69 ± 1.33 (Mean ± Standard Deviation), indicating that insufficient insurance coverage is a significant barrier to financial protection and access to healthcare services.
- **Insufficient Government Incentives**: Respondents also expressed concern over the insufficient government incentives. This factor is rated with a mean score of 3.61 ± 1.16 (Mean ± Standard Deviation).

The mean scores of all responses concerning the various contributing factors are presented in **Table 5.5**.

**Table 5.5: Perceived factors contributing to the impaired public service utilization and OOPE on medicines by the health professionals, patients, and patient relatives in the study facilities (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=49)**

| S. No | Contributing Factors | Frequency (%) | | | | | | Mean | SD* |
|---|---|---|---|---|---|---|---|---|---|
| | | NA | SD | D | N | A | SA | | |
| 1 | TB disease prevalence or incidence itself is a major cause | 0 (3) | 1 (5) | 2 (3) | 3 (3) | 4 (24) | 5 (11) | **3.49** | 1.47 |
| 2 | Rising drug prices on medicines | 0 (0) | 1 (14) | 2 (1) | 3 (8) | 4 (21) | 5 (5) | 3.04 | 1.41 |
| 3 | Rising inflation | 0 (1) | 1 (8) | 2 (4) | 3 (13) | 4 (22) | 5 (1) | 3.02 | 1.20 |
| 4 | Govt spending on medicines is low | 0 (4) | 1 (13) | 2 (7) | 3 (6) | 4 (9) | 5 (10) | 2.67 | 1.68 |
| 5 | Govt not providing medicines free of cost in govt facilities | 0 (7) | 1 (16) | 2 (8) | 3 (4) | 4 (10) | 5 (4) | 2.12 | 1.59 |
| 6 | Medicines availability in govt hospitals is low | 0 (4) | 1 (17) | 2 (6) | 3 (4) | 4 (8) | 5 (10) | 2.51 | 1.73 |
| 7 | High-cost branded drugs are prescribed | 0 (0) | 1 (10) | 2 (8) | 3 (10) | 4 (11) | 5 (10) | 3.06 | 1.42 |
| 8 | Govt medical service utilization by the public is poor | 0 (3) | 1 (14) | 2 (6) | 3 (10) | 4 (12) | 5 (4) | 2.53 | 1.47 |
| 9 | Govt facility/infrastructure is poor & patients depend on private | 0 (2) | 1 (11) | 2 (6) | 3 (3) | 4 (21) | 5 (6) | 2.98 | 1.52 |
| 10 | Govt schemes in addressing OOPE are not adequate | 0 (1) | 1 (14) | 2 (8) | 3 (6) | 4 (10) | 5 (10) | 2.82 | 1.57 |
| 11 | Govt schemes in addressing OOPE are not reaching the public | 0 (0) | 1 (13) | 2 (8) | 3 (4) | 4 (12) | 5 (12) | 3.04 | 1.56 |
| 12 | Govt incentives on people living with TB are not sufficient | 0 (0) | 1 (5) | 2 (4) | 3 (4) | 4 (28) | 5 (8) | **3.61** | 1.16 |
| 13 | The majority of patients have not taken health insurance | 0 (0) | 1 (5) | 2 (6) | 3 (5) | 4 (16) | 5 (17) | **3.69** | 1.33 |
| 14 | Private medical service is good | 0 (2) | 1 (8) | 2 (3) | 3 (16) | 4 (12) | 5 (8) | 3.06 | 1.41 |
| 15 | Private medical service/Private medical store is the only cause | 0 (0) | 1 (6) | 2 (15) | 3 (13) | 4 (11) | 5 (4) | 2.84 | 1.15 |
| 16 | Real monthly disposable income per patient is very low | 0 (0) | 1 (3) | 2 (8) | 3 (1) | 4 (25) | 5 (12) | **3.71** | 1.18 |
| 17 | Delayed diagnosis and patient not following treatment plan lead to the increased burden on disease and OOPE | 0 (1) | 1 (2) | 2 (5) | 3 (3) | 4 (27) | 5 (11) | **3.76** | 1.15 |

*NA-Not Applicable, SD-Strongly Disagree, D-Disagree, N-Neutral, A-Agree, SA-Strongly Agree.*
*Response scores-Strongly Disagree (1), Disagree (2), Neutral (3), Agree (4), Strongly Agree (5), and Not Applicable (0).*
*TB-Tuberculosis, Govt-Government, OOPE-Out-of-Pocket Expenditure, SD*-Standard deviation.*

### 5.3.3 Qualitative Semi-Structured In-Depth Interview Findings

In-depth interviews are conducted with all 49 study participants, to explore their perspectives based on their specific roles within the healthcare framework. The interviews are structured around three primary patterns of responses, such as

- ✓ Factors that contribute to impaired public service utilization
- ✓ Self-strategies for improving the burden of OOPE on medicines
- ✓ Suggestions to the government/policymakers for improving service utilization and reducing OOPE

#### *5.3.3.1 Factors that Contribute to Impaired Public Service Utilization*

The key informants mentioned several critical factors that contribute to impaired public healthcare service utilization among the people living with TB in the Agra district.

***Identified Factors***

- ➢ **Long Wait Times**: The long waiting periods at the OPD and medication counters are among the most common issues mentioned by the key informants. They mention that "these delays cause frustration and discourage people from seeking timely care", which underscores the high patient volumes and inadequate staffing.

- ➢ **Centralization of TB Treatment Services**: Key informants mention that the centralization of TB treatment services in specific facilities creates accessibility challenges for those in rural areas. They say that "have to travel considerable distances to specific treatment centres", which can also contribute to non-adherence to treatment regimens.

- **Poor Infrastructure**: The infrastructure of government hospitals is another concern mentioned by the key informants. They say that "Inadequate facility, lack of essential medical equipment, and lack of hygienic condition", as factors challenging the quality of care.

- **Lack of Branded Medicines**: Informants say that "branded medicines are not available in government hospitals", leading to the perceptions of poor treatment options and loss of trust in public health services.

- **Misconceptions about Public Health Services**: Majority of the key informants pointed about the misconception of the quality of services in public health facilities. Many patients perceive these services as subpar compared to private options, which can deter them from utilizing available resources. This stigma, combined with the above factors, creates an impaired public health services utilization within the community.

#### *5.3.3.2 Self-Strategies for Improving the Burden of OOPE on Medicines*

Key informants in the study are asked for their opinions on the effective strategies that could be implemented at the facility level to alleviate the burden of out-of-pocket expenditures (OOPE) on medications for tuberculosis (TB) treatment. Their insights highlight several key approaches that may significantly enhance patient access to treatment and reduce financial constraints.

***Recommended Strategies***

- **Orientation and Awareness Programs**: A predominant recommendation from key informants is to conduct orientation and awareness programs about the services provided by the government. These initiatives should focus on informing the

public/patients about the services available in the government healthcare facilities through the following modes,

- ✓ **Frontline Health Workers**: Utilizing community health workers to engage directly with the public, providing information and support regarding available services and navigating the healthcare system.

- ✓ **Media Outreach**: Campaigns such as television advertisements and local newspapers could be instrumental in raising awareness about TB treatment options, eligibility for support programs, and the availability of essential medications.

- ✓ **Community Engagement**: Collaborating with religious leaders and community preachers to incorporate health education in community gatherings. This approach can effectively communicate critical health messages and encourage individuals to seek services without stigma.

- ➢ **Availability of Branded Medications**: Some key informants raised the issue of the availability of branded drugs in public sector hospitals. They suggested that making these medications accessible could improve the quality of care and enhance patient trust in government facilities.

- ➢ **Direct Benefit Transfers (DBT)**: Majority of key informants recommended the timely provision of direct benefit transfers (DBT) to patients. They said that timely DBT would not only enhance the affordability but also encourage adherence to prescribed regimens.

#### *5.3.3.3 Suggestions to the Government/Policymakers for Improving Service Utilization and Reducing OOPE*

Key informants are asked for their suggestions to the government and the policymakers to enhance service utilization and mitigate out-of-pocket expenditure (OOPE). Their insights reveal a comprehensive set of proposed strategies in addressing existing challenges of the healthcare system.

***Key Recommendations***

1. **Employment of Additional Health Professionals**: A common suggestion made is to increase the number of health professionals across all healthcare settings. This would not only alleviate the burden on existing staff but also improve patient care and reduce wait times.

2. **Decentralization of TB Treatment Services**: Respondents strongly support the decentralization of TB treatment services. By making these services more accessible at the community level, patients would not face barriers to receiving care, ultimately leading to improved adherence to treatment and better health outcomes.

3. **Extension of Free Medicine Schemes**: There is a strong suggestion for extending free medicine schemes to private hospitals. This measure aligns with the vision of completely eradicating TB by reducing financial burdens on patients, which is believed to be a critical step towards ensuring that all individuals have access to effective treatment options.

4. **Compensability of Tuberculosis**: Respondents made suggestions that tuberculosis could be classified as a compensable disease. Implementing such a policy could provide additional financial support for those affected, helping to cover the costs associated with treatment and care.

5. **Public Insurance Coverage for Private Treatment**: Another notable recommendation made is for the establishment of public insurance programs that include coverage for all treatments in private hospitals. This could enhance patient choice and access to a broader range of treatment options, ensuring that individuals do not face financial hardship when seeking necessary care.

6. **Travel Allowance for people living with TB**: Respondents suggest the travel allowance of 300 INR for all people living with TB. Currently, this allowance is provided only to people with multi-drug resistant (MDR) TB. Extending this support to all people with TB would address the travel-related challenges and could facilitate better access to necessary care.

7. **Full Implementation of Current Policies**: All respondents suggest the necessity of fully implementing existing health policies. There is an urgent need to ensure that policies intended to improve healthcare access and TB support programs are executed effectively, optimizing their intended impact.

## 5.4 Discussion

In this study, around 61% of the people living with TB avail private sector healthcare facilities in the study area. This result is in line with the study by Guy Stallworthy et al. 2020, in which they compare the private TB treatment coverage in 10 countries by using the WHO data, which shows India at 74%, Indonesia at 74%, and Philipines 70%, Pakistan 85%, Nigeria 67%, Bangladesh 84%, and Myanmar 74% (Stallworthy et al., 2020). The same study also reports the private TB drug sales of 54% and a private % of total health expenditure (2017) of 72% in India.

There is growing evidence that the private sector's TB care falls short of international standards and needs urgent improvement (Cazabon et al., 2017). Private healthcare providers have low

tuberculosis (TB) testing rates, rarely send patients to the national TB program, and prefer empirical antibiotic treatment. Chest radiography is used often, sputum testing seldom, and medication susceptibility testing rarely. A "know-do gap" exists between healthcare providers' knowledge and actions. They also struggle with patients' poor compliance and high care expenditures, with 50% of these costs incur before a medical diagnosis (Cazabon et al., 2017; Daniels et al., 2017; Hanson et al., 2017; Tanimura et al., 2014). A study from Mumbai and Patna cities of India by Kwan et 2018 shows that only 37% of symptomatic people living with TB are correctly managed by private healthcare providers, and only 15% are referred to the national TB program (Kwan et al., 2018).

Around 70% of the private patient's monthly income falls below 10000 INR, irrespective of the financial burden the patients choose the private healthcare sector may be due to a lack of awareness of public schemes regarding national TB programs. This can be well addressed by creating health campaigns, advertising, and orientation to the public by the government and the same is supported by the current qualitative findings. TB treatment often requires long-term drug therapy, which can impose a significant financial burden on patients and their families. Public hospitals generally offer TB treatment at subsidized or free rates, but these facilities are overburdened and may lack adequate resources. Private hospitals, on the other hand, charge high fees for consultations, diagnostics, and medications, making TB treatment unaffordable for many patients (Viney et al., 2019).

Regarding the non-availability of medicines, 2% of patients in public sector hospitals and 52.4% of patients in private sector hospitals report the non-availability of medicines, respectively. This shows that the private hospitals are not well prepared for TB treatment services, irrespective of having branded costly medicines on their premises. Inadequate drug supply and stockouts can hinder patients access to crucial TB medications. This issue is more prevalent in public hospitals that often struggle with procurement and distribution

inefficiencies. Private hospitals face drug shortages, particularly if they do not have robust supply chains or if the drugs are expensive (Shukar et al., 2021). When it comes to affordability around 8% of public sector patients reported unaffordable, which could be a reason for some unavailable medicines in the public sector hospitals and force the patients to obtain from private medical stores. In the case of private sector patients, around 91% of them reported the unaffordability of the medicines, this is believed to be a major impact on achieving the vision of TB eradication at the country level.

The government of India's National Tuberculosis Elimination Programme (NTEP) initiative, ensures the direct benefit transfer scheme "Nikshay Poshan Yojana" to all people with active TB for their nutritional benefits by providing 500 INR every month until the disease progression irrespective of both public and private sector patients. This study shows that there are around 8% and 79% of public and private sector patients, respectively not receiving the said amount. This gap needs to be urgently addressed by the program administration to ensure the DBT reaches 100%. The large number of private patients who are not receiving the amount may be also due to non-registration of patient profiles by the private sector hospital administration in the Ni-Kshay (End Tb) web portal. This is supported by a qualitative TB care study by Guy Stalworthy et al. 2020, in which non-reporting to the national TB programs is evidenced (Stallworthy et al., 2020). The government should ensure the identification of people living with TB and ensure the standards and policies maintained for TB eradication.

According to the WHO Global TB Report data, in India alone, there are 696 thousand missing patients from private TB providers (Stallworthy et al., 2020). The qualitative component of this study also recognized that delayed diagnosis and patients not following treatment plans can lead to an increased burden on disease and OOPE as a major perceived contributing factor. Also, this study identifies that real monthly disposable income per patient is very low, indicating the mandate of a cost-effective approach to treating TB disease. Economic research

reports the costs and cost-effectiveness of two Indian prototype Public-Private Mix (PPM) projects using public-sector DOTS and private-sector non-DOTS treatment. Public sector DOTS and PPM DOTS cost about half as much as non-DOTS private therapy (Floyd et al., 2006). Therefore, it is evident that the public-private mix could be more appropriate when it comes to including private sectors in national TB programs.

Access to healthcare facilities, including hospitals, is not evenly distributed across India. Rural areas and economically disadvantaged regions have limited access to quality healthcare facilities, including hospitals providing TB treatment. This lack of accessibility affects patients' ability to access drug therapy conveniently. Moreover, India's healthcare system is fragmented, with a mix of public and private hospitals providing TB treatment. This fragmentation poses challenges in coordinated efforts for identifying, treating, and monitoring TB cases. Lack of coordination between public and private sectors can result in gaps in treatment, difficulties in monitoring adherence to drug therapy, and uneven distribution of resources.

In terms of health insurance, the quantitative and qualitative findings of this study show a very low portion of patients on health insurance, which is 3% in both healthcare sectors and it is a notorious perceived contributing factor in escalating the OOPE issues. The government should prioritize advancing the promotion of comprehensive health insurance schemes and advocate to reduce disparities in reimbursement for TB care (Pan et al., 2016).

The key informants highlight the lack of awareness regarding the availability and quality of services in government hospitals. This unawareness and misconception in quality, diverts general public to seek healthcare services from private facilities, resulting in a strain on their financial resources. Additionally, the key informants mention that the perception of inadequate medical staffs and long waiting times causes frustration and discourages individuals from utilizing public health facilities. This gap should be addressed and adequate human resources

are to be ensured. The need for efficient and transparent mechanisms to ensure the timely delivery of direct benefit transfer (DBT) to the intended beneficiaries should also be deemed necessary.

There is an urgent need to address the challenges related to the infrastructure and the logistics to improve the accessibility and availability of government services in remote areas. The study noted the importance of increasing awareness campaigns and education programs to promote early detection and treatment of TB. Moreover, it is well known that TB is associated with social stigma in many communities, impacting patient willingness to seek treatment or disclose their condition. This can further hinder access or delays in seeking healthcare or opting for private hospitals over public facilities to avoid social stigma (Tadesse, 2016).

## 5.5 Limitations and Strengths of this Study

The limitations of this study include that it covered only service utilization and OOPE burden on TB medicines in public and private sector hospitals. This study did not assess the quality and outcome of the private sector hospitals. The strength of this study include the use of both quantitative and qualitative methods to supplement each other.

## 5.6 Conclusions

This study finds a high extent of TB service utilization in private sector hospitals in the Agra district. Among the sampled patients, around 61% avail of private sector healthcare services both in rural and urban areas of Agra. Several socio-economic and health policy challenges impact the availability, accessibility, and affordability of drug therapy among TB treatment in India. These challenges include limited availability of drugs, unequal distribution of healthcare system, finance, limited health insurance, and fragmented healthcare. Addressing these challenges requires a multi-faceted approach, including increased investment in healthcare

infrastructure, strengthening drug supply chains, expanding health insurance coverage, reducing out-of-pocket expenses for patients, and improving coordination between public and private healthcare providers. Additionally, awareness campaigns aimed at reducing stigma and discrimination can help encourage more people living with TB to seek timely treatment.

Similar issues regarding TB treatment are also prevalent in various regions across India. Therefore, while direct applicability may not be guaranteed due to regional differences in demographics and policies, the study's findings may serve as a reference for understanding broader trends in TB management both nationally and potentially in similar contexts internationally.

## 5.7 Ethical Considerations

The study complies with the declaration of Agra district hospitals. The Chief Medical Officer (CMO) of the Agra district administration has given approval for the study protocol, and the permissions are obtained from all the study facilities to conduct the study. Participants are informed that their personal information will remain confidential and will only be used for the study purpose. The consent process includes a clear explanation of the study's objectives, and the participants are given the privilege to withdraw from the study at any time. Written informed consent is obtained from each study participant for their participation and publication of the results. All data collected from participants is kept confidential by not using personal identifiers. For confidentiality and ethical considerations, the names of sampled health facilities are identified only by codes throughout the study.