Frontiers in Health Informatics
ISSN-Online: 2676-7104
www.healthinformaticsjournal.com
2024; Vol 13: Issue 3
Open Access

Socioeconomic and health policy challenges to the availability, accessibility, and affordability of drug therapy among people living with tuberculosis towards public and private hospitals in Agra district, Uttar Pradesh, India: a cross-sectional study

Manikandan Arumugam[1], K M Noorulla[2], Mohd Yasir[2], Manish Kalwaniya[3], Swetlana Gautam[4], Hemalatha Siva[1*]

[1]Department of Pharmaceutical Engineering and Technology, Indian Institute of Technology (BHU), Varanasi, Uttar Pradesh, India.
[2]Department of Pharmacy, College of Health Sciences, Arsi University, Asella, Oromia, Ethiopia.
[3]School of Public Health, Indian Institute of Health Management and Research, Jaipur, Rajasthan, India.
[4]Department of Pharmacy, Dr Bhimrao Ambedkar University, Agra, Uttar Pradesh, India.
[*]Corresponding Author: Hemalatha Siva[*] Email: shemalatha.phe@iitbhu.ac.in

Cite this paper as: Manikandan Arumugam, K M Noorulla, Mohd Yasir, Manish Kalwaniya, Swetlana Gautam, Hemalatha Siva (2024) Socioeconomic and health policy challenges to the availability, accessibility, and affordability of drug therapy among people living with tuberculosis towards public and private hospitals in Agra district, Uttar Pradesh, India: a cross-sectional study. *Frontiers in Health Informatics, 13* (3),4624-4636

A B S T R A C T

India aims to achieve the goal of eliminating tuberculosis (TB) by the year 2025, five years ahead of the global target set for 2030. However, there are challenges in providing universal health coverage (UHC) for people living with tuberculosis (TB) due to inadequate resources and the unaffordability of medicine. This study aims to explore the socioeconomic and health policy challenges to drug therapy among people living with TB in the Agra district, Uttar Pradesh, India. A cross-sectional mixed-methods study was undertaken based on a facility-based survey and semi-structured interviews, involving 2244 participants from 20 major health facilities. The analysis focused on medical characteristics, OOPE, service utilization, and policy measures, with contributing factors and suggestions for improving service utilization and reducing OOPE on medicines. About 61% of 2244 participants were availing private healthcare services. Availability of medicines at public and private hospitals was reported by 98% and 48% of patients, respectively. Nearly 91% of private-sector patients couldn't afford the drugs. Government health policy implications for nutrition aid covered 92% of public sector patients, but only 21% of private sector patients. In both sectors, most patients spend their salaries and savings, which contributes to OOPE. Socio-economic and health policy challenges affect drug therapy availability, accessibility, and affordability. Addressing these challenges requires increased investment in infrastructure, drug supply chains, health insurance coverage, and coordination between public and private providers.

Keywords:*Tuberculosis, OOPE, Medicines, Health Policy.*

INTRODUCTION

Tuberculosis (TB) is one of the major infectious diseases threatening millions of lives worldwide and affecting approximately one-third of the world's population (1). 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 (2,3). Accordingly, 2021 witnessed a 19% increase from the previous year in people living with TB comprising 19,33,381 as opposed to 16,28,161 in 2020 (4). India ranks 36th globally in terms of incidence rates for tuberculosis, which has become a significant public health and social problem (2). India, the second 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 (5). In developing countries like India, impoverished households account for 85% of healthcare costs (6). Health insurance covers only a small portion of healthcare expenditure, leading to ineffective therapeutic regimes. The TB problem is particularly severe in developing countries, and cost-effectiveness considerations are aimed at prioritizing resource allocation for low-income

populations (7,8). 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 (9), limiting access to quality healthcare services and affordable medicine (10). Consequently, inadequate healthcare resources and the unaffordability of medicine for people living with TB impede the achievement of universal health coverage (UHC) (11). This socio-economic condition disrupts access to essential medicines and facilities. Ensuring the availability, accessibility, and affordability of essential medications is imperative for achieving universal health coverage (12). In India, less than 35% of the population has access to basic medical care, with most relying on private providers.

Treatment is hampered by a lack of affordability, which is especially problematic for those who need to use expensive medications (13). The Indian government spends 2.1% of GDP on health (14), 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.

Considering the whole scenario, India has implemented health initiatives to eradicate TB, reducing OOPE and providing free facilities for prevention and treatment. The government introduced the Pradhan Mantri Bhartiya Janaushadi Pariyojna in 2008, leading to numerous Janaushadi Kendras nationwide. In addition, the World Health Organization (WHO) recommended the Directly Observed Therapy-Short Course (TB-DOT) program, which provides effective and accessible treatments for rural populations. The Pradhan Mantri TB Mukt Bharat Abhiyan aims for mass movement and awareness campaigns to eradicate TB by 2025. Ayushman Bharat, a Central government health insurance scheme, aims to achieve universal health coverage (WHO-UHC) for all citizens (11). Additionally, the National Pharmaceutical Pricing Authority (NPPA) regulates bulk medicines' costs and accessibility under the Drugs Prices Control Order (DPCO) and Essential Commodities Act. It oversees drug production, availability, and procurement, preventing medicine scarcity. In 2022, a new National List of Essential Medicines of India (NLEM) list reduced drug prices by 20%.

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 (15,16), however, it is still on the higher side. Over the past two decades, despite the expansion of effective medication therapy for TB disease supported by government-funded healthcare services, impaired availability, accessibility, affordability, and consecutive high OOPE raised healthcare expenses. Considering all the above facts, this study aims to explore the socioeconomic and health policy challenges concerning the availability, accessibility, and affordability of drug therapy among people living with TB towards public and private hospitals in Agra district, Uttar Pradesh, India.

METHODS

Mixed-methods research comprising both quantitative and qualitative aspects on socioeconomic and health policy challenges to the availability, accessibility, and affordability of drug therapy was undertaken on people living with TB in some major public and private health facilities of Agra district, Uttar Pradesh, India. The study area comprises around 359 public and more than 500 private health facilities with a catchment population of around 3.1 million. Both qualitative and quantitative studies was conducted through a facility-based cross-sectional survey utilizing self-administered questionnaires. Additionally, the qualitative component was also supplemented by semi-structured in-depth interviews to investigate the factors contributing to the OOPE on medicines and service utilization issues. All the studies were conducted between October 2022 and March 2023. The qualitative and quantitative studies were conducted in selected major public and private healthcare settings especially treating people living with TB within the Agra district.

All the health facilities treating people with TB found in the Agra district were identified as 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 doctors who treat TB, 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 were contemplated as the study population. The study included major healthcare facilities in the Agra district that have been offering TB treatment for over three years, and the facility administration that showed unwillingness for the conduct of the study were excluded.

A multi-stage sampling approach was used to establish the size of the sample of health facilities comprising both public and private health facilities at a ratio of 1:1 between rural and urban populations. Accordingly, 20 major health facilities

were selected with which public and private health facilities were 10 each. The study participants for the quantitative study were people living with TB from the sampled facilities. A total sampling of all 2244 people with TB of these sampled health facilities between October 2022 and March 2023 was carried out. The qualitative part of the study involved selecting health professionals, patients, and patient relatives from the sampled facilities during the study period. Participants were chosen based on their willingness to participate, using the purposive sampling technique. Furthermore, they were specifically selected as key informants for the qualitative semi-structured in-depth interviews.

An in-house questionnaire (both quantitative and qualitative) was developed based on 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 our questionnaire for qualitative study have been thoughtfully designed and developed, ensuring their relevance in capturing the targeted qualitative aspects we aim to explore. Careful consideration was given to the response options to offer participants a sufficient level of granularity in expressing their opinions, experiences, or attitudes.

Each questionnaire (both quantitative and qualitative) has undergone rigorous 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 provided by 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 were 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 were identified and necessary adjustments were made to enhance the questionnaire's validity and consistency. By following this rigorous scientific approach, a robust foundation was established for our data collection. Moreover, using an in-house questionnaire provides several benefits, as it allows the researchers to maintain control over the research process, customize the questionnaire to specific research needs, and ensure a higher level of consistency and reliability compared to using third-party questionnaires.

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. Self-administered questionnaires with questions about medical characteristics, OOPE, and perceived contributing factors to OOPE and service utilization were included in the data collection sheets. The questionnaires additionally included questions about socio-demographic characteristics (area of residence, sex, age, level of education, occupation, and monthly income). Key informants were interviewed using a semi-structured approach designed to elicit their perspectives on the problem's causes and present initiatives to address them. Prior to data collection, four days of training were provided to data collectors about the tools and procedures used in data collection. Two experts from the TB department of the district administration additionally reviewed the interview guide for an in-depth interview to ensure its face and content validity.

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. Descriptive parameters like Frequency, Mean, and Standard Deviation (SD) were determined for each variable in the aggregate analysis. 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 was 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 was reported and the p-value ≤ 0.05 was considered statistically significant. In the Likert scale method employed in the qualitative study, respondents were 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” was additionally included because of different respondent’s role existence. Participants were instructed to select the response option that best represented their viewpoint. Based on the specific values of each response, the mean scores and standard deviation for each factor were computed based on the provided ratings. The analysis and interpretation of participant responses were used to evaluate the factors contributing to

impaired public service utilization and out-of-pocket expenditure. Data from an in-depth interview was subjected to a thematic analysis approach. Thematic issues, including contributing factors and suggestions for enhancing service utilization and reducing the OOPE on medicines, were manually reviewed and handled.

QUANTITATIVE FINDINGS

3.1.1. Characteristics of the study sample

Out of 2244 participants, around 61% were seen distributed towards the private health care sector. The demographic characteristics of patients in the two sectors in Table 1, along with the p values for differences between the public and private sectors. There were no statistically significant differences in the residence area, age, and sex towards the choice of availing the services from the healthcare sector, while the level of education, occupation, and monthly income was significantly associated with the differences in the choice of availing the public and private healthcare sector services.

3.1.2. Healthcare service utilization and Health policy benefits

Healthcare service utilization and health policy benefits among people living with TB were 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 Table 2. Regarding the category of the hospital, the majority of the patients availed themselves of community health centers (50.4%, n = 886) and tertiary care hospitals (45.6%, n = 1358) in the public and private sectors, respectively. In both sectors, the majority of the patients were found to be in a stage of pulmonary infection during the study period (74.2% in the public sector, and 81.7% in the private sector).

Out of those utilizing public sector hospitals, family screening for TB was done on about 79% (n = 886) of the patients, but the percentage for private sector patients is only 25% (n = 1358). Moreover, preventive treatment in the family of government hospitals was successful for 71% of the patients, but a very low number (10%) concerned the private hospital patients. Another policy implication is that the intervention of frontline health workers during the treatment period is found to be high (80%) in public-sector hospital patients when compared to private-sector patients (35%).

3.1.3. Availability, Accessibility, Affordability, OOPE on Medicines, and Health Policy Benefits

The OOPE of the study participants and policy measures of the availability, accessibility, and affordability of medicines were studied, and the data are shown in Table 3. As it is well known that the public hospitals have no charges for consultations and diagnostic aspects, the private hospitals in the sampled facilities impose charges on 100% of the patients in different aggregates according to the hospital types and the type of diagnosis, which can't be prevented. 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. In terms of affordability, almost 91% (n = 1358) of private-sector patients could not afford the medicines. Even the monthly expenditure on medicines for private sector patients is high, above 2000 INR for about 30% of patients (n = 1358).

Central government health policy implications in terms of government aid for nutrition as 500 INR every month for people living with TB was seen as almost covered for 92% of patients in the public sector, while this benefit reaching the private sector patients is low at 21%. The majority of patients in both sectors report their source of expenditure as their salary and savings (60% in the public sector, 87% in the private sector), which contribute largely to OOPE.

3.2. QUALITATIVE FINDINGS

3.2.1. Socio-Demographic Characteristics of Respondents

A total of 49 participants aged 20–62 years were included in the study. Among the 49 respondents, different respondent's roles were engaged in gaining more insights into the study objectives. The length of service in the respondent's role was also gathered, except for the patients and their relatives. The majority of the respondents were doctors and health officers. The demographic data of the qualitative study participants are shown in Table 4.

3.2.2. Perceived factors contributing to the impaired public service utilization and OOPE on medicines

A questionnaire with a total of 17 factors, which were believed to influence service utilization and the OOPE burden, especially on TB therapy, were given to the participants. The responses were evaluated using a 5-point Likert scale. The most common perceived factors contributing were "delayed diagnosis and patients not following treatment plans lead to

increased burden on disease and OOPE" – 3.76 ± 1.15 (Mean ± SD), "Real monthly disposable income per patient is very low" – 3.71 ± 1.18, "The majority of patients have not taken health insurance" – 3.69 ± 1.33, and "government incentives for people living with TB are not sufficient" - 3.61 ± 1.16. The mean score of all the responses on different contributing shown in Table 5.

3.3. QUALITATIVE SEMI-STRUCTURED IN-DEPTH INTERVIEW FINDINGS

In-depth interviews were conducted with all the qualitative study participants (n = 49), and the interview responses were obtained according to the respondent's role. The interview was held with three patterns of responses: factors that contribute to impaired public service utilization, self-strategies for improving the burden of OOPE on medicines, and suggestions to the government or policymakers for improving service utilization and reducing OOPE.

3.3.1. Factors that contribute to impaired public service utilization

In terms of contributing factors, the key informants mentioned several reasons, such as the long waits outside OPD and drug counters, the centralization of TB treatment services, the poor infrastructure of government hospitals, and the fact that branded medicines are not available in government facilities. As per the key informants, the misconception of poor services in public health facilities is a major contributor to impaired service utilization.

3.3.2. Self-strategies for improving the burden of OOPE on medicines

Key informant's opinions were asked on the strategies to be undertaken at the facility level to improve the burden of OOPE on medicines. Orientation and awareness programmes to the public about the services provided by the government should be undertaken periodically through frontline health workers, television advertisements, local newspapers, making use of religious preachers for awareness programmes, etc., which were mostly mentioned by the key informants. Also, some of the key informants mentioned making branded drugs available in public sector hospitals. The majority of the key informants shared their concerns about providing direct benefit transfers (DBT) on time.

3.3.3. Suggestions to the Government/policymakers for improving service utilization and reducing OOPE

The respondents were asked to provide suggestions to the government or policymakers on how to improve service utilization and reduce the OOPE. Employing additional health professionals in all health care areas, decentralization of TB treatment services, extending the free medicine scheme with all medicines available to private hospitals in the vision of complete eradication of TB, making tuberculosis a compensable disease, providing public insurance that also covers private hospital treatment, and reimbursement of all kinds of health services were some of the suggestions made. Additionally, they suggested that there need to be an extension of 300 INR as a travel allowance for all people living with TB, which is currently provided for MDR TB only. All respondents suggested the full implementation of the current policies.

Table 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 *P* value*
	Public N (%), n=886	**Private N (%), n=1358**	
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

Table 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.

Table 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

Table 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

Table 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.

DISCUSSION

In this study, around 61% of the people living with TB avail the healthcare services towards private sector facilities in the study area. This result is in line with the study by Guy Stallworthy et al. 2020, in which they compared the private TB treatment coverage in 10 countries by using the WHO data, which showed India at 74%, Indonesia at 74%, and Philipines 70%, Pakistan 85%, Nigeria 67%, Bangladesh 84%, and Myanmar 74% (17). The same study also reported 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 (18). Private healthcare providers have low tuberculosis (TB) testing rates, rarely send patients to the national TB programme, 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 incurred before a medical diagnosis (18-21). A study from

Mumbai and Patna cities of India by Kwan et 2018 showed that only 37% of TB symptomatic patients were correctly managed by private healthcare providers, and only 15% were referred to the national TB programme (22).

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 programmes. This can be well addressed by creating health campaigns, advertising, and orientation to the public by the government and the same was supported by our 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; however, these facilities are overburdened and may lack adequate resources. Private hospitals, on the other hand, may charge high fees for consultations, diagnostics, and medications, making TB treatment unaffordable for many patients (23).

Regarding the non-availability of medicines, 2% and 52.4% of the patients reported in public and private sector hospitals, respectively. This shows that the private hospitals were not well prepared for the 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 (24). 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 towards 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 living 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. Our 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 programmes is evidenced (17). 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 were 696 thousand missing patients from private TB providers (17). Our qualitative 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, our study identified that real monthly disposable income per patient is very low, indicating the mandate of a cost-effective approach to treating TB disease. Economic research investigated 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 (25). Therefore, it is evident that the public-private mix could be more appropriate when it comes to including private sectors in national TB programmes.

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, our quantitative and qualitative findings showed 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. Concerning the issue of financial inequality, individuals diagnosed with TB who had lower incomes were subject to higher financial burdens. The government should prioritize advancing the promotion of comprehensive health insurance schemes and advocate to reduce disparities in reimbursement for TB care (26).

The key informants highlighted the lack of awareness among the general public about the availability and quality of

services in government hospitals. The misconception of quality leads people to seek healthcare services from private facilities, resulting in a strain on their financial resources. Additionally, the key informants mentioned that the perception of inadequate medical staff and long waiting times further 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 is of the utmost importance.

There is an urgent need to address the challenges related to infrastructure and logistics to improve the accessibility and availability of government services in remote areas. The respondents emphasized 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 patients' willingness to seek treatment or disclose their condition. This can further hinder access to drug therapy, as patients may delay seeking healthcare or opt for private hospitals over public facilities to avoid social stigma (27).

Strengths and Limitations of the Study

The strengths of this study are attributed to the utilization of both quantitative and qualitative methods, which serve to complement one another. The limitations of this study is that it focused only service utilization and OOPE burden on TB medicines in public and private sector hospitals, and it did not study the quality and outcome of the private sector hospitals.

CONCLUSION

The study identified that the extent of private-sector TB healthcare service utilization in the Agra district was high. 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 people living with TB in India, specifically concerning public and private hospitals. These challenges include limited availability of drugs, unequal distribution of healthcare, financial, 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.

Ethical Considerations

The study complied with the declaration of Agra district hospitals. The Chief Medical Officer (CMO-Office) of the Agra district administration approved the study protocol (Ref No: CMO/AGRA HO/08/2022/01). Permission from each study facility's administration to conduct the study was obtained. Participants were assured that their personal information would remain confidential and would only be used for the study. The consent process included a clear explanation of the study's objectives and the privilege was given to withdraw from the study at any time. Each participant in the study provided written informed consent for participation and publication. The data gathered from participants was maintained in a confidential manner by not including any personal identifiers. To maintain confidentiality and to take care the ethical concerns, the sampled health facilities were designated by codes throughout the study.

Acknowledgements

The authors acknowledge the Department of Pharmaceutical Engineering and Technology, IIT-BHU, Varanasi, UP, India, for their support and encouragement in completing this project. The authors also acknowledge the study participants, including health professionals, study facility administrations, and the Agra district administration, for their necessary support.

Funding

There was no funding source at any level of the project. So, the project was entirely non-funded. All expenses were borne by the authors themself.

Conflict of Interests

All authors declare that they have no competing interests.

Data Availability

The data used and analyzed in this study are available upon reasonable request.

REFERENCES

1. Sotgiu G, Falzon D, Castiglia P, Migliori GB, Raviglione M. Tuberculosis and the strategy for the New Millennium: not simply "more of same." Epidemiol Biostat Public Health. 2014;11(2).
2. Bagcchi S. WHO's global tuberculosis report 2022. Lancet Microbe. 2023;4(1):e20.
3. Sulis G, Roggi A, Matteelli A, Raviglione MC. Tuberculosis: epidemiology and control. Mediterr J Hematol Infect Dis. 2014;6(1).
4. Khanna A, Saha R, Ahmad N. National TB elimination programme - What has changed. Indian J Med Microbiol. 2023;42:103-107. doi:10.1016/j.ijmmb.2022.10.008
5. Tripathi VVR, Tripathi A, Jaiswal S. Health welfare system in modern India revitalizing Indian Healthcare-Its potential and challenges. ZENITH International Journal of Multidisciplinary Research. 2019;9(2):178-193.
6. Dash A, Mohanty SK. Do poor people in the poorer states pay more for healthcare in India? BMC Public Health. 2019;19(1):1020. doi:10.1186/s12889-019-7342-8
7. Castelo A, Mathiasi PA, Iunes R, et al. Cost effectiveness of antituberculosis interventions. Pharmacoeconomics. 1995;8:385-399.
8. Organization WH. Guidelines on the Management of Latent Tuberculosis Infection. World Health Organization; 2015.
9. Srinadh R, Yadav J. Paying Out of One's Own Pocket: How the Poor in India Are Facing Hardship to Treat Their Kids. Niti Ayog Annual Report 2020–21. 2022. https://www.niti.gov.in/paying-out-ones-own-pocket-how-poor-india-are-facing-hardship-treat-their-kids
10. McIntyre D, Thiede M, Dahlgren G, Whitehead M. What are the economic consequences for households of illness and of paying for health care in low-and middle-income country contexts? Soc Sci Med. 2006;62(4):858-865.
11. Ranabhat CL, Jakovljevic M, Dhimal M, Kim CB. Structural factors responsible for universal health coverage in low-and middle-income countries: results from 118 countries. Front Public Health. 2020;7:414.
12. Mathewos Oridanigo E, Beyene Salgedo W, Gebissa Kebene F. Affordability of essential medicines and associated factors in public health facilities of Jimma Zone, Southwest Ethiopia. Adv Pharmacol Pharm Sci. 2021;2021:1-9.
13. Cameron A, Ewen M, Auton M, Abegunde D. The world medicines situation 2011. Medicines prices, availability and affordability. 2011;3.
14. Aggarwal V. Health Budget 2023: Highlights. Indian Journal Of Clinical Practice. 2023;33(9):5-6.
15. National Health Systems Resource Centre (NHSRC) Work Report 2019-20, Ministry of Health and Family Welfare, Government of India.; 2020. https://nhsrcindia.org/about-us/annual-report
16. National Health Systems Resource Centre (NHSRC) Work Report 2014-15, Ministry of Health and Family Welfare, Government of India.; 2015. https://nhsrcindia.org/about-us/annual-report
17. Stallworthy G, Dias HM, Pai M. Quality of tuberculosis care in the private health sector. J Clin Tuberc Other Mycobact Dis. 2020;20:100171. doi:10.1016/j.jctube.2020.100171
18. Cazabon D, Alsdurf H, Satyanarayana S, et al. Quality of tuberculosis care in high burden countries: the urgent need to address gaps in the care cascade. Int J Infect Dis. 2017;56:111-116. doi:10.1016/j.ijid.2016.10.016
19. Tanimura T, Jaramillo E, Weil D, Raviglione M, Lönnroth K. Financial burden for tuberculosis patients in low-and middle-income countries: a systematic review. Eur Respir J. 2014;43(6):1763-1775. doi:10.1183/09031936.00193413
20. Daniels B, Dolinger A, Bedoya G, et al. Use of standardised patients to assess quality of healthcare in Nairobi, Kenya: a pilot, cross-sectional study with international comparisons. BMJ Glob Health. 2017;2(2):e000333. doi:10.1136/bmjgh-2017-000333
21. Hanson C, Osberg M, Brown J, Durham G, Chin DP. Finding the Missing Patients With Tuberculosis: Lessons Learned From Patient-Pathway Analyses in 5 Countries. J Infect Dis. 2017;216(suppl_7):S686-S695. doi:10.1093/infdis/jix388

22. Kwan A, Daniels B, Saria V, et al. Variations in the quality of tuberculosis care in urban India: A cross-sectional, standardized patient study in two cities. PLoS Med. 2018;15(9):e1002653. doi:10.1371/journal.pmed.1002653
23. Viney K, Islam T, Hoa NB, Morishita F, Lönnroth K. The Financial Burden of Tuberculosis for Patients in the Western-Pacific Region. Trop Med Infect Dis. 2019;4(2). doi:10.3390/tropicalmed4020094
24. Shukar S, Zahoor F, Hayat K, et al. Drug Shortage: Causes, Impact, and Mitigation Strategies. Front Pharmacol. 2021;12:693426. doi:10.3389/fphar.2021.693426
25. Floyd K, Arora VK, Murthy KJR, et al. Cost and cost-effectiveness of PPM-DOTS for tuberculosis control: evidence from India. Bull World Health Organ. 2006;84(6):437-445. doi:10.2471/blt.05.024109
26. Pan Y, Chen S, Chen M, et al. Disparity in reimbursement for tuberculosis care among different health insurance schemes: evidence from three counties in central China. Infect Dis Poverty. 2016;5(1):7. doi:10.1186/s40249-016-0102-4
27. Tadesse S. Stigma against Tuberculosis Patients in Addis Ababa, Ethiopia. PLoS One. 2016;11(4):e0152900. doi:10.1371/journal.pone.0152900