An analysis of recent trends of tuberculosis using drug sales data in a Shajapur district of Central India

Yogesh Shukla[1], Shobhana Yadav[2], Sanjay Agarwal[3], Anirudh Nayak[4]

[1]Associate Professor, Government Medical College, Satna, [2,4]Demonstrator, [3]Professor and Head, Department of Community medicine, Atal Bihari Vajpayee Government Medical College, Vidisha, Madhya Pradesh, India

ABSTRACT

Background: There is a pressing need for systematic approaches for monitoring how much tuberculosis (TB) treatment is ongoing in the public and private sectors in India, Both to shed light on the true scale of the problem and to help monitor the progress of interventions currently being planned to address this problem. **Aims and Objectives:** (1) To estimate the incidence of TB in 2021 by using drug utilization data in the public and private sectors of the Shajapur district. (2) To calculate the decline in patient months from the base year 2015 to 2021; (3) To find out the recent trends and volumes (patient months) using drug sales data in the public and private sectors. **Materials and Methods:** Secondary data verification was done from December 2021 to March 2022 in Shajapur district, Madhya Pradesh, India. The district-level data on drug consumption in the public was obtained from the drug store records of the district TB Center and drug sales in the private sector were obtained from the DTO, which was prepared by the drug inspector in compliance with the letter of the Directorate of Health services, Madhya Pradesh, Bhopal, and CMHO Shajapur for the review of drug sale data in the private sector for subnational certification. **Results:** The incidence of TB increased from 113.7/lakh population in 2015 to 151.5 lakh population in 2021. The patient month of the public sector is increasing from 2015 (patient months 3653.4) to 2021 (patient months 6064.84), which indirectly denotes that more patients are taking antitubercular treatment form the government sector as compared to the private sector in the current year. The private sector sale of the drugs is decreasing from 2015 (patient months:- 9507) to 2021 (patient months: 2012.61), but still 24.91% of antitubercular drugs are provided by the private sector. **Conclusion:** Subnational verification of claims by Shajapur district for progress toward TB-free status in India showed that the incidence of TB is increasing from the base year to the year 2021. So it was not recommended for an award in the silver category by the verification team.

Key words: Tuberculosis; Public sector; Private sector; India

INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by a Bacterium, *Mycobacterium tuberculosis*. It is spread through the air by a person suffering from TB. A single patient can infect 10 or more people in a year. The Government of India (GOI) has set an ambitious goal for ending TB by reducing the incidence of new TB cases by 80% by 2025 compared with 2015.[1] India has a high TB burden (1.80 million cases in 2020), with an incidence of approximately 256 cases/100000 population.[2] There is a wide variation in TB burden across the country. The efforts toward ending TB also vary across states, union territories (UTs), and districts in India. It is, therefore, crucial to monitor the progress toward the elimination goal at the subnational level. The central TB division (CTD) of the Ministry of Health and Family Welfare, GOI, decided to incentivize states, UTs, and districts for

Address for Correspondence:
Dr. Shobhana Yadav, Demonstrator, Department of Community medicine, Atal Bihari Vajpayee Government Medical College, Vidisha, Madhya Pradesh, India. **Mobile:** +91-9425089799. **E-mail:** shobhanay7@gmail.com

their progress toward TB-free status.[3,4] Under this initiative, the CTD sought claims from states, UTs, and districts for achievements in reducing TB incidence in 2021 compared with 2015. These achievements were considered under four categories: 20–39% (bronze), 40–59% (silver), 60–79% (gold), and ≥80% (TB-free). The claims received by the CTD were to be independently verified by an external agency. A national task force comprising experts in the field of TB epidemiology drafted the methodology for this verification. Shajapur district out of ten districts in Madhya Pradesh and who have submitted their claims for >40% reduction in incidence for the silver category toward TB-free status. Shajapur district was separated from Agar at the end of 2015. Its undivided population was 16.21 lakh in 2015. For the baseline calculation, we have considered the pre-divided population of 9.54 lakh according to the TU coming to Shajapur district.

Aims and objectives

Verification team verified secondary data of drug consumption in the public sector and drug sales data from the private sector with the objectives of: (1) estimating the incidence of TB in 2021 by using drug utilization data in the public and private sectors of the Shajapur district. (2) To calculate the decline in patient months from the base year of 2015 to 2021. (3) To find out the recent trends and volumes (patient months) using drug sales data in the public and private sectors. And verify the claim made by the Shajapur district for progress toward TB-free status.

MATERIALS AND METHODS

Subjects and methods

Under verification of claims for sub-national certification of progress toward "TB-free status," secondary data verification was done from December 2021 to March 2022 in Shajapur district, Madhya Pradesh, India.

Public Sector drug consumption data were extracted from the main stock register of the District TB Center (DTC) in Shajapur. Antitubercular drugs were supplied from time to time from state TB store to the district, which were received in the drug store of TB Center Shajapur and endorsed in the DTC drug store register. All TB Units in the district received anti-tubercular treatment (ATT) drugs from the DTC drug store only. DTC drug store registers for the years 2015 to 2021 were checked for all drugs received, issued, and balance. Information on rifampicine-containing drug consumption was abstracted and cross-verified randomly from stock registers of different TB units, and entries were made and Patient months were calculated. In year the 2015, 2016, and 2017, Intermittent drug regimes were in practice, and patients got treatment

in 2 categories: CAT 1 (2 months IP and 4 months CP), and CAT 2 (3 months IP and 5 months CP) and for each patient, a box of complete treatment was kept separated, and if needed for extension of treatment duration, separate 1-month prolongation pouches were provided. In 2018, fixed dose combination (FDC) daily drug regimes were introduced in both categories under the names PC1 and PC2 in 4 weight bands (D1, D2, D3, and D4), and for assurance of uninterrupted treatment, separate boxes were kept reserved for each patient. In mid-2018, a strip of 28 tablets with a fixed drug combination for adult and pediatric doses was introduced under the names 4 FDC adult and 3 FDC Pediatric for the intensive phase and 3 FDC adult and 2 FDC pediatric for the continuation phase. Private sector drug sale data of drugs used in the treatment of TB was collected from District TB Officer (DTO) Shajapur, which was collected by the drug inspector in compliance with the letter of the Directorate of Health services, Madhya Pradesh, Bhopal, and CMHO Shajapur for review of drug sale data in the private sector for subnational certification.

Drug data analysis

Drug sale data verification. Ti, Ci, and Xi values for each drug were finalized on the basis of the National Green Tribunal (NGT) and KII.

Calculation of patients based on drug sales[5]

Patient months = Si * Ti * Xi/Ci

Parameters	
Si	Number of units sold of Rifampicin containing product
Ti	Number of treatment months represented by a unit of drug sale (in this case tablet) for a given product
Ci	Coverage of sales data for a given product
Xi	Proportion of prescriptions intended for tuberculosis

For the assessment of Ci, Xi, and Ti, qualitative components, through NGT and KII with chemists and private medical practitioners from clinics, nursing homes, and not-for-profit organizations (IMA) were conducted. To ensure representativeness and attendance, a letter signed via CMHO was sent to all private medical practitioners and chemists who were notifying TB cases from the private sector and all chemists who were reporting TB drug sales in the district as well as members of chemist associations, about NGT at a predefined time and place. NGT and KII were held, and on the basis of thematic information about Ci and Xi, they were calculated. On basis of Ci, Xi and Ti for each drug (Rifampicin containing) were calculated separately. Patient months of consumption of drugs in the public and private sectors were calculated for each drug or category individually and on a yearly basis. Finally, drug

consumption in patients months for the year 2015–2021 was calculated, and on the basis of the number of patient months' drug consumption, it was divided via average months of drug consumption.

We calculated the drug-based TB incidence by dividing the total patient months (sum of patient months in the public and private sectors) by the average duration of treatment for TB and the district's population.

Shajapur district was separated from Agar at the end of 2015. Its undivided population was 16.21 lakh in 2015. For the baseline calculation, we have considered the pre-divided population of 9.54 lakh according to the TU coming to Shajapur district.

RESULTS

Public Sector drug consumption data were extracted from the main stock register of DTC Shajapur. Antitubercular drugs were supplied from time-to-time from the state TB store to the district, which were received in the drug store of TB Center Shajapur and endorsed in the DTC drug store register. All TB units in the district received ATT drugs from the DTC drug store only. DTC drug store registers for the years 2015 to 2021 were checked for all drugs received, issued, and balance. Information on rifampicine-containing drug consumption was abstracted and cross-verified randomly from stock registers of different TB units, and entries were made and Patient months were calculated.

In the years, 2015, 2016, and 2017, Intermittent drug regimes were in practices and patients got treatment in 2 categories: CAT 1 (2 months IP and 4 months CP) and CAT 2 (3 months IP and 5 months CP), and for each patient, a box of complete treatment was kept separated, and if needed for extension of treatment duration, separate 1-month prolongation pouches were provided. In 2018, FDC daily drug regimes were introduced in both categories under the names PC1 and PC2 in 4 weight bands (D1, D2, D3, and D4), and for assurance of uninterrupted treatment, separate boxes were kept reserved for each patient. In mid-2018, a strip of 28 tablets with fixed drug combinations for adult and pediatric doses was introduced under the names 4FDC adult and 3FDC Pediatric for the intensive phase and 3FDC adult and 2FDC pediatric for the continuation phase.

Table 1 depicts that the patient month of the public sector is increasing from 2015 to the current year 2021, which indirectly denotes that more patients are taking ATT form the government sector as compared to the private sector in the current year.

Private sector drug sale data of drugs used in the treatment of TB were collected from DTO Shajapur, which were collected by the Drug Inspector in compliance with the letter of the Directorate of Health services, Madhya Pradesh, Bhopal, and CMHO Shajapur for the review of drug sale data in the private sector for subnational certification. Drug sale data verification T_i, C_i, and X_i values for each drug were finalized based on NGT and KII. Two NGTs were performed with a mix of participants from different groups. The first NGT group, which was a group of the pharmacist and doctors, has come to the conclusion that C_i is 0.85 and X_i is 0.96, while the other group has come to theconclusion that C_i is 0.20 and X_i is 0.85. The first group was closer to the real assumption as it was heterogeneous and accepted the present scenario of sales of drugs both in the public and private sector.

X_i (Proportion of Prescriptions intended for TB) - Was also calculated on the basis of NGT and KII which suggest that all drugs in FDC s of more than one drug were being used only in the prescription of treatment of TB only so

Table 1: Yearly distribution of patient months by public drug consumption

S. No.	Year	Patient months
1.	2015	3653.4
2.	2016	4890.4
3.	2017	2932.44
4.	2018	10826.4
5.	2019	8581.57
6.	2020	2430.90
7.	2021	6064.80

Table 2 : Yearly distribution of patient months by private sector drug sale

S. No.	Year	Patient months
1.	2015	9507.38
2.	2016	8108.04
3.	2017	6829.55
4.	2018	3848.84
5.	2019	6660.12
6.	2020	1913.22
7.	2021	2012.61

Table 3: Total patient months combined in public and private sector

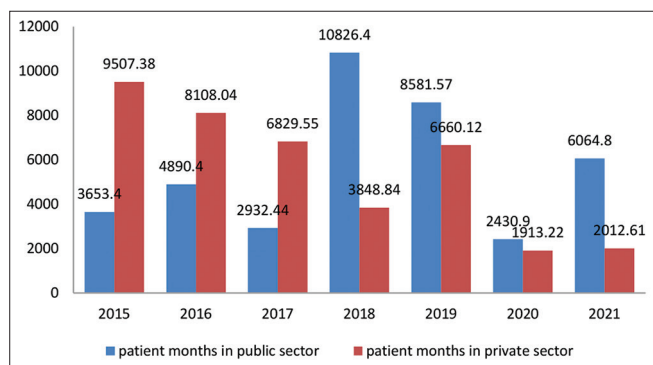| S. No.	Year	Patient month public	Patient month private	Total
1.	2015	3653.4	9507.38	13160.78
2.	2016	4890.4	8108.04	12998.44
3.	2017	2932.44	6829.55	15752.99
4.	2018	10826.4	3848.84	14675.24
5.	2019	8581.57	6660.12	15241.69
6.	2020	2430.90	1913.22	4344.12
7.	2021	6064.80	2012.61	8077.41

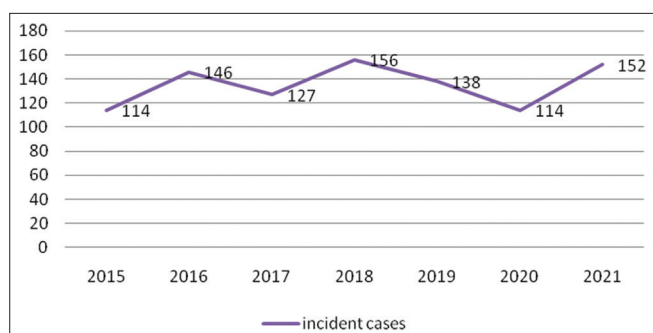**Figure 1:** Total patient months in the public and private sector

Figure 2: Incident cases per lakh population

Xi for those drugs were taken as 1 while only Rifampicin as single drug is also being used in treatment of old cases of Leprosy and percentage of contribution in treatment of other drugs was only 1–3% so Xi for such drugs were taken as 0.96 into consideration.

Table 2 denotes that the above table denotes that the private sector's sale of the drugs is decreasing from the year 2015 to the current year 2021, but still represents 24.91% of antitubercular drugs provided by the private sector.

Table 3 denotes that the drug sale data for patient months shows that during the year from 2015 to 2016, there was more drug sale in the private sector as compared to the public sector. After the year 2018 onward, public sector consumption of antituberculars was higher as compared to the private sector.

Figure 1 denotes comparison of the patient months between public and private sectors.

Percentage of decline of patient months in the current year as compared to the baseline year 2015

= No. of patient months in 2015–No. of patient month in the current year 2021/No of patient months in 2015×100
= 13160.78–8077.41/13160.78×100
= 5083.37/13160.78×100
= 38.62%.

The percentage of the decline of total patient months in the current year 2021 as compared to the baseline year 2015 is 5083.37 patient months (38.62%). 9.54 lakh (58.85% of the total population) is the baseline population of the district. The patient months of 2015 are the combined patient months (60+40%) of the undivided district. Hence, this decline cannot be taken as a proxy for the decline of incident cases in the district.

Figure 2 shows that the above diagram shows that incident cases as per drug utilization data increased from 113.7/lakh population in 2015 to 151.5 lakh population in 2021. So there is an increasing trend of TB cases in the district in the current year as compared to the baseline year of 2015. The fall during 2019 and 2020 may be due to the underreporting of cases during the COVID pandemic.

DISCUSSION

For verification of the claim by the district for subnational certification under "TB-free India," this study was conducted in the Shajapur district of Madhya Pradesh (India) from December 2021 to March 2022 through secondary data verification from the base year 2015 to 2021. Under this study, the public and private sectors were assessed by drug consumption data and drug sales data. We found in our study that the incidence of TB increased from 113.7/lakh population in 2015 to 151.5 lakh population in 2021. So there is an increasing trend of TB cases in the Shajapur district in the current year as compared to the baseline year of 2015. The fall during 2019 and 2020 may be due to underreporting of cases during the COVID pandemic.

Our study results suggest that patient months in the public sector are increasing from 2015 (patient months 3653.4) to 2021 (patient months 6064.84), which indirectly denotes that more patients are taking ATT from the government sector as compared to the private sector. The private sector sale of drugs is decreasing from 2015 (patient months: –9507) to 2021 (patient months: –2012.61), but still 24.91% of antitubercular drugs are provided by the private sector. Though an efficient national TB elimination program is in place in India, offering free diagnosis and treatment for TB, a sizeable proportion of TB patients are diagnosed and treated in the private sector.[6] With the availability of many anti-TB drug formulations over the counter, compounded by the varying prescription practices for TB treatment, and with an average duration of treatment of 2–6 months, counting the number of patients treated for TB in the private sector is challenging.[7] This complex heterogeneity in private sector TB diagnosis and care makes the usefulness of drug sale data in burden estimation and

monitoring apparent. The data from the private TB drug market also have some limitations, such as its lack of organized and complete recording and reporting. A study conducted by Wells et al. and Arinaminpathy et al.,[8,9] also suggests that in India there may have been a minimal decline in recent years in TB treatment volumes in the private sector. According to a study conducted by Wells et al., and Menzies et al.,[10,11] about a third of the TB patients had incurred debts in order to bear the expenses of their treatment. This must be taken seriously given the fact that the government provides treatment for TB through the DOTS program free of charge. The amount of drug dispensing without prescriptions was not investigated, as it was felt that a true picture would not emerge given that this was against the interests of the private pharmacies. In addition, the treatment of TB patients by private practitioners is not satisfactory. A study conducted by Mehra, Ananthakrishnan, and Sreedharan[12,13] showed a lack of awareness among doctors who treated TB patients in their own clinics about the standard drug regimens for the treatment of TB recommended by national and international agencies. These doctors prescribed eighty different regimens, most of which were inappropriate and expensive. In a study conducted by Uplekar and Shepard and Lambert et al.[14,15] In a country with a high TB incidence, it was found that 25% of pharmacies sold at least one anti-TB drug. The study documented a small market for TB drug sales in private pharmacies and provided the opportunity to start the collaboration with pharmacies. Another study by Lonnroth et al.,[16] estimated that between 1100 and 3400 people buy anti-TB drugs each month in the 1814 registered private pharmacies in the city, and a quarter of them do so without a prescription, and that at least 40% of all anti-TB drug dispensing occurs in the private sector. A similar result from a study by Hurtig et al. and Islam et al.[17,18] showed a substantial amount of anti-TB drugs being sold through private pharmacies. The limitation of this study is that true TB burden is measured in terms of numbers of patients, not patient months.

Limitations of the study

There is a limitation of our study is that it was a simple descriptive record based study. For further more of the the analysis of the data we need to do analytical study.

CONCLUSION

Subnational verification of claims by Shajapur district for progress toward TB-free status in India showed that the incidence of TB is increasing from the base year to the year 2021. So it was not recommended for an award in the silver category by the verification team. It is widely recognized that there will remain major challenges for TB control in India as long as TB treatment is dominated by such a large and fragmented private sector. Together with currently available surveillance tools, approaches such as those presented here could contribute to a comprehensive picture of the state of the public and private sectors; how they change over time, and where interventions are most needed. The decreasing trend of TB treatment in the private sector over the past 6 years while the drug consumption rate increased in the public sector highlightings specific states that the government's approach to fight against TB will be successful if both sectors work together.

REFERENCES

1. National Strategic Plan for Tuberculosis Elimination 2017–2025. New Delhi; 2017. Available from: https://tbcindia.gov.in/writereaddata/nspdraft20.02.20171.pdf [Last accessed on 2022 Nov 15].

2. India TB Report 2020. New Delhi; 2020. Available: https://www.tbcindia.gov.in [Last accessed on 2021 Apr 19].

3. Pardeshi G, Wang W, Kim J, Blossom J, Kim R and Subramanian SV. TB notification rates across parliamentary constituencies in India: A step towards data-driven political engagement. Trop Med Int Health. 2021;26(7):730-742.
   https://doi.org/10.1111/tmi.13574

4. Golandaj JA, Naikar SK and Hallad JS. Trends and sub-national disparities in TB notifications in India: Insights from HMIS data. Indian J Tuberc. 2022;69(2):141-150.
   https://doi.org/10.1016/j.ijtb.2021.04.005

5. Arinaminpathy N, Batra D, Maheshwari N, Swaroop K, Sharma L, Sachdeva KS, et al. Tuberculosis treatment in the private healthcare sector in India: An analysis of recent trends and volumes using drug sales data. BMC Infect Dis. 2019;19(1):539.
   https://doi.org/10.1186/s12879-019-4169-y

6. Sreeramareddy CT, Qin ZZ, Satyanarayana S, Subbaraman R and Pai M. Delays in diagnosis and treatment of pulmonary tuberculosis in India: A systematic review. Int J Tuberc Lung Dis. 2014;18(3):255-266.
   https://doi.org/10.5588/ijtld.13.0585

7. Satyanarayana S, Nair SA, Chadha SS, Shivashankar R, Sharma G, Yadav S, et al. From where are tuberculosis patients accessing treatment in India? Results from a cross-sectional community based survey of 30 districts. PLoS One. 2011;6(9):e24160.
   https://doi.org/10.1371/journal.pone.0024160

8. Wells WA, Ge CF, Patel N, Oh T, Gardiner E and Kimerling ME. Size and usage patterns of private TB drug markets in the high burden countries. PLoS One. 2011;6(5):e18964.

    https://doi.org/10.1371/journal.pone.0018964

9. Arinaminpathy N, Batra D, Khaparde S, Vualnam T, Maheshwari N, Sharma L, et al. The number of privately treated tuberculosis cases in India: An estimation from drug sales data. Lancet Infect Dis. 2016;16(11):1255-1260.

    https://doi.org/10.1016/S1473-3099(16)30259-6

10. Wells WA, Uplekar M and Pai M. Achieving systemic and scalable private sector engagement in tuberculosis care and prevention in Asia. PLoS Med. 2015;12(6):e1001842.

    https://doi.org/10.1371/journal.pmed.1001842

11. Menzies D, Benedetti A, Paydar A, Martin I, Royce S, Pai M, et al. Effect of duration and intermittency of rifampin on tuberculosis treatment outcomes: A systematic review and meta-analysis. PLoS Med. 2009;6(9):e1000146.

    https://doi.org/10.1371/journal.pmed.1000146

12. Mehra C and Ananthakrishnan R. Why Free Medicines can Transform TB Management. India: The Hindu; 2015. Available from: https://www.thehindu.com/opinion/openpage why-free-medicines-can-transform-tb management/article7862511.ece [Last accessed on 2023 Feb 27].

13. Sreedharan J. Sale of anti-tuberculosis drugs through pharmacies: A cross sectional study in Kerala, India. Italian J Public Health. 2011;8:12-16.

    https://doi.org/10.2427/5639

14. Uplekar MW and Shepard DS. Treatment of tuberculosis by private general practitioners in India. Tubercle. 1991;72(4):284-290.

    https://doi.org/10.1016/0041-3879(91)90055-w

15. Lambert ML, Delgado R, Michaux G, Vilz A and Van der Stuyft P. Tuberculosis control and the private health sector in Bolivia: A survey of pharmacies. Int J Tuberc Lung Dis. 2004;8(11):1325-1329.

16. Lonnroth K, Lambregts K, Nhien DT, Quy HT and Diwan VK. Private pharmacies and tuberculosis control: A survey of case detection skills and reported anti-tuberculosis drug dispensing in private pharmacies in Ho Chi Minh City, Vietnam. Int J Tuberc Lung Dis. 2000;4(11):1052-1059.

17. Hurtig AK, Pande SB, Baral SC, Porter JD and Bam DS. Anti-tuberculosis treatment in private pharmacies, Kathmandu valley, Nepal. Int J Tuberc Lung Dis. 2000;4(8):730-736.

18. Islam T, van Weezenbeek C, Vianzon R, Garfin AM, Hiatt T, Lew WJ, et al. Market size and sales pattern of tuberculosis drugs in the Philippines. Public Health Action. 2013;3(4):337-341.

    https://doi.org/10.5588/pha.13.0094

Orcid ID:
Yogesh Shukla - https://orcid.org/0000-0003-4146-2204
Shobhana Yadav - https://orcid.org/0000-0002-4992-5173
Sanjay Agarwal - https://orcid.org/0009-0006-7841-8441
Anirudh Nayak - https://orcid.org/0009-0005-3309-5856