Original Article

Verification of Sub-national Claim for 'TB-free' Status of Rajsamand District, Rajasthan, India-2020

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Abstract

Background: Tuberculosis (TB) caused by Mycobacterium tuberculosis is an opportunistic infection that affects the lungs in humans. Caseload of TB has been deemed it endemic in various regions of the world and India is on top of that list. The Government of India has set out a goal to eliminate tuberculosis in India by the year 2025 with the help of the National Strategic Plan (NSP) 2017–25. The objective of the index study was to verify the claim of Rajsamand district in Rajasthan, that it witnessed a >20% reduction in TB incidence between 2015 and 2020. **Methodology:** This was a mixed-methods study. Quantitative component (cross-sectional study): Secondary data review (review of records from Nikshay notification systems and National tuberculosis elimination program (NTEP) reports, utilization of drugs in the public sector, and drug sales in the private sector). Primary data collection through survey. Qualitative component: nominal group technique and key informant interviews. **Result:** Percentage decline of a ≥ 20% incidence in 2020 compared to baseline 2015 was not seen. The number needed to test (increased by 18.26% in 2020 as compared to the baseline of 2015. TB Score of Rajsamand district for the year 2020 was 68.34 out of 100. **Conclusion:** Rajsamand district's claim of ≥20% reduction in TB incidence in the year 2020, was rejected.

Keywords: NTEP, Rajsamand, TB-free claim, TB score

Introduction

India has been engaged in fighting Tuberculosis (TB) for more than 50 years. Yet TB continues to be India's severe health crisis.[1] TB is a highly communicable disease that induces T cell response from the host's immune system. The bacteria responsible for the infection are Mycobacterium TB. The primary site of infection in humans is the lungs, however, extrapulmonary TB cases have been documented, despite being less frequently diagnosed.[2]

Standardized first-line treatment of TB comprises the administration of Rifampicin, Ethambutol, Isoniazid, and Pyrazinamide daily for 6–12 months after being diagnosed.[3] Lack of adherence to this treatment regimen has given rise to a few strains of drug-resistant TB. They are called multi-drug resistant T and extensive drug resistance.[4] Newer drugs such as Pretomanid in combination with Bedaquiline and Linezolid have been approved for treating a limited and specific population of adult patients with extensively drug-resistant, treatment-intolerant, or nonresponsive multidrug-resistant pulmonary TB.[5]

The World Health Organization (WHO) TB statistics for India for 2022 give an estimated incidence figure of 21.4 lakh cases. This is a rate of 210 per 1 lakh population.[6] TB has an estimated mortality rate of 37 per 1 lakh population of India as per the Global TB Report 2021.[7] India also has more than a million 'missing' cases every year that are not notified and most remain either undiagnosed or unaccountably and inadequately diagnosed and treated in the private sector.[8]

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Certification of Elimination of Disease is done by 'WHO' at the National Level currently. India has 28 States and 8 Union territories with vast diversity. The progress in reductions in TB incidence across states and within states varies widely, with some districts achieving greater declines in incidence than others. Because of different epidemiological scenarios across the country, this demands a differential strategy to reach the elimination targets and measurements at the sub-national level. The government of India started with the initiative of Sub National Certification in 2021 to incentivize and reward best-performing districts and states and motivate them to prioritize and undertake the implementation of a program to achieve milestones toward TB-free districts/States. This government of India initiative along with the WHO, Central TB Division (CTD), Indian Council for Medical Research (ICMR), and Indian Association for Preventive and Social Medicine (IAPSM) is called Sub National Certification (SNC) for TB-free status.[1,9] Criteria for Certification/Interim Recognition of Progress toward TB-free status is the achievement of a reduction in TB incidence as compared to 2015 of ≥20% for the Bronze medal, ≥40% for the Silver medal, ≥60% for the Gold medal, ≥80% for absolute TB-free status. The objective of the index study was to verify the claim of the Rajsamand district in Rajasthan, that if it witnessed a > 20% reduction in TB incidence between 2015 and 2020.

Methodology

Ethical approval was taken from ICMR NIE Chennai on 31st December, 2020. ICMR – National Institute of Epidemiology (NIE), had been entrusted by the CTD with the task of verification of the claims of reduction in incidence of TB and TB-free status made by districts and states. To verify the claims made by districts for their progress toward the elimination of TB, it was essential to estimate the incidence of TB in the community. It was done by calculating incidence from anti-TB drug sales in the private sector and anti-TB drug consumption in the public sector (a) Primary data collection through a survey was also done and data was analyzed using two methods: Direct (b) and Indirect (c). Incidence calculated from these 3 methods (a, b, and c) was then compared to the incidence of TB in 2015, and the percentage reduction in incidence was calculated.

Community-based Household Survey: For verification of the data submitted for the TB-free claim, a survey was conducted in the Rajsamand district. The supplementary file attached to the article has the details about the data collection and sampling process.

The district was divided into several TB units. Number of Survey Units was decided based on the number of TB units. Cluster sampling was conducted by each of the survey units. clusters were defined at the level of villages/wards. Probability proportionate to size sampling was done to select clusters sequentially. An inverse sampling method (a fixed number of bacteriologically positive TB cases were found by each team in the survey unit) was used. If the desired sample was not achieved, then the next nearest cluster was selected. When the desired sample was achieved, the STOP rule was applied. The STOP rule was applied if 30 bacteriologically confirmed pulmonary TB cases were detected, at least 10,000 households were surveyed, or at least 5% of the district population was surveyed.[10]

Data collection

Data collectors informed selected households about the purpose of the survey. Screening of all members for symptoms was done using a questionnaire which included household information, participant characteristics, symptoms suggestive of TB (persistent cough ≥2 weeks, fever ≥2 weeks, significant weight loss, blood in sputum any time during last 6 months, and chest pain in last one month), Current or past history of anti-TB treatment. Based on the questionnaire, those who were symptomatically suggestive of TB underwent one spot sputum sample testing.

Data collected from the survey was used to calculate the incidence of TB in Rajsamand in 2020 by two methods: Direct and Indirect.

In the direct method, patients who were newly found positive during the survey served as the numerator, the total population surveyed served as the denominator, and the direct incidence was calculated.

In the indirect method, we compared the incident cases from the survey to those notified in the Nikshay database.[11]

Secondary data review

The district verification team reviewed data from the schedule H1 register (Drug Inspector Register), and the data were already present on the Nikshay portal. Based on the reviewed data, the TB score, and number needed to test NNT were calculated.

NNT = [No. of patients tested by sputum microscopy and molecular test]/[No. of patients diagnosed positive for Mycobacterium TB]

TB score[9] was calculated based on the parameters: TB Notification, TB Notification with known HIV status, Universal Drug Susceptibility Testing Treatment Success rate, Beneficiaries paid under Nikshay Poshan Yojana, Drug Resistant-TB treatment initiation, Expenditure, Chemoprophylaxis for children, TB preventive therapy for People living with HIV/AIDS (PLHIV).

Qualitative research component

TB drug utilization data was also acquired. It was done by qualitative research techniques such as the Nominal Group Technique (NGT) and Key Informant Interviews (KII). For this data, Rifampicin was used as the indicator drug.

NGT sessions with chemists and private medical practitioners from clinics, nursing homes/hospitals, not for profit organizations were conducted. In addition, KIIs of the state drug controller, drug inspectors, and the Clearing and Forwarding (C&F) agency of the Rajsamand district were conducted.

The NGT/KII were conducted in a place and time convenient for the participants using a pre-designed topic guide with probes. The topics that were discussed during the NGT/KII included the probes to explore regarding drug sale data and assumptions for calculating patient treatment months, assumptions around coverage of drug sales, prescription for non-TB use of Rifampicin, treatment covered by each unit of product, treatment duration, and results in terms of decline or increase of drug sales among chemists and private providers selected at the district level by district TB officer and verification team. Trained members conducted 2–3 NGT sessions with chemists, private practitioners, and drug manufacturers and 5 KII with the state drug controller, drug inspectors, and C and F agency in the district. The data were collected in paper forms and uploaded to the web portal developed by the ICMR-NIE. For each NGT/KII, there were two data collectors, one of whom would take the role of a facilitator while the other would be the note taker. Information was provided to all the participants about the purpose of the NGT/KII.

Data quality assurance

The district verification team headed by the Faculty of Community Medicine, Ananta Institute of Medical Science and Research Center, trained and supervised the district survey teams.

The district verification team verified various data including TB score, NNT, Drug consumption data in the public sector, and Drug sale data in the private sector for the Nikshay portal.

Data analysis

Based on the drug consumption data collected from the public sector and drug sale data collected from the private sector, we calculated patient months. Then patient months were later converted to incidence.

Estimation of patient months:-

Public sector:

Total number of patient months in the public sector for a given product = Total number of Rifampicin tablets consumed in one year x Number of treatment months represented by a unit of drug

Private sector:

Total number of patient months in the private sector for a given product =

Σi [Ni(Si/Ci)(Ti)]

Total number of packs of Rifampicin sold **(N)**

Percentage of Rifampicin-containing products covered in the drug sale

data used by the District **(S)**

Number of Treatment Months Represented by a unit of drug sale (usually pack) for a given product **(C)**

The proportion of Prescriptions Intended for TB **(T)**

Total number of patient months = patient months in the public sector + patient months in the private sector.

Based on the total number of patient months, a percentage decline in the patient months was calculated.

% Decline = (No. of total patient months in 2015 – No. of total patient months in current year)/No. of patient months in 2015.

The results of the study were obtained from data collected and computed by Nodal Officers of the Department of Community Medicine at the Ananta Institute of Medical Sciences and Research Center, Rajsamand.

Participant's rights

The participant could choose to leave the focus group at any time. The focus group conversations were audio-recorded to ensure accuracy. The participant could ask to pause the recording at any time.

Confidentiality

All the information of the participants was kept confidential, the anonymity of the participants will be maintained in the future. The audio recordings of the discussion information of the participants, opinions, and suggestions were kept secured in a password-protected electronic device. The information was accessed only by the Principal Investigator of the study.

Results

Annual TB notification rates were taken as per data on the Nikshay Portal for the Rajsamand District. From Figure 1, we can infer that the annual TB notification rate was highest in the year 2016 and reduced to a significant amount in the year 2020. The reason could be the COVID-19 pandemic.

Community-based Household Survey results:

Data collected of TB patients in Rajsamand is as follows, the number of households registered in Rajsamand district was 3141. The number of participants covered was 12,238. Number of people who consented to participation were 10807 [N]. The number of people who were symptomatic eligible (Cough for more than 2 weeks, Fever for more than 2 weeks, and History of significant weight loss) was 192 [1.7%]. Number of people that were already on Anti-tuberculosis treatment

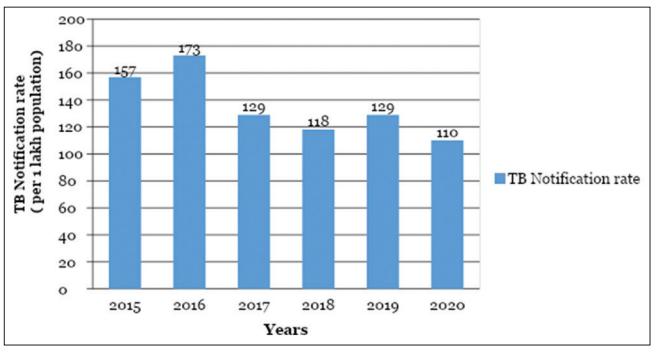

Figure 1: Annual TB notification rate

(ATT) was (a) 10 [0.09%]. The number of people who had a past history of TB were (b) 32 [0.29%]. The number of sputum tests conducted was 191 [1.7%]. The number of people who were found positive after the sputum test was (c) 31 [0.29%]. The total of the three lists (a+b+c) was 73 [0.67%]. STOP rule (Population of Rajsamand District were tested until 30 Positive cases of TB were found from the symptomatically eligible people. After 30 cases the survey was stopped.) was applied after 31 cases were found. People who participated, till the STOP rule was applied, were 12,238. Current and past TB patients (a+b) not found in the Nikshay district notification register were 1 [0.009%]. Microbiologically confirmed current and past TB patients (a+b) that were not found in the Nikshay portal were 0. Of the patients that tested +ve during the survey, those who were found in Nikshay were 14 [0.12%].

NNT is the number of individuals that must be tested with a bacteriological test to identify one person with TB during the reporting period. From Figure 2, we could make out that NNT was highest in the year 2019.

From Figure 3, it can be seen that TB drug sales reduced after the year 2018.

Table 1 shows various parameters used in calculation of TB score and their values in the Rajsamand district.

As per Table 2, Rajsamand district's claim of a ≥20% reduction in TB incidence in the year 2020 in comparison to 2015 was rejected.

Discussion

As nations, across the world are aiming to eliminate TB by the year 2030; Indian officials have decided to jump on a plan to reach the goal earlier than planned, by 2025. To put the aforementioned goals in effect, various government bodies (MoHFW, National Health Mission, CTD, etc.) and organizations (WHO, ICMR, and IAPSM) volunteered as the workforce for SNC for TB-free status.

As put in action, different states in India followed up with the registered patients. With the verification obtained, many districts went on to declare themselves on track to being TB-free (i.e., at least a 20% reduction in the incidence of TB in 2020 compared to baseline 2015). Therefore, these districts were invited to a survey that was aimed at confirming their claims.

Rajsamand being one of the districts claiming a decrease in incidence of TB of more than 20% in 2020 as compared to baseline 2015 and on track of being TB-free was invited for the Survey.

Based on the data available on the Nikshay portal, the baseline TB incidence of Rajsamand district in 2015 was 266 per 1 lakh population. Based on the index study, the incidence came out to be 287 per 1 lakh population when calculated by the direct method. This shows an increase of 8% in the incidence when compared to 2015. Data on drug sales in patient months (both private and public) also showed a 4.5% increase in patient months. Another criterion for the claim was a TB score >80, which was also not fulfilled based on the data available on the Nikshay portal. Rajsamand's TB score came out to be 68.34. However, while calculating NNT, an increase of 18.6% was seen in comparison to 2015.

For the survey to verify the secondary data, over 3000 households were registered. From those households, over ten thousand people gave consent to participate in the survey. The data collected throughout this project reflects only 1.77% of the target population showed symptoms of TB. Further, upon testing, only 16.7% of them tested positive. What these percentages show is out of 191 people who were symptomatic for TB only 31 patients tested positive. Out of those, only 10 patients were already on ATT as many were not aware of the symptoms of TB or that the government provides free treatment as well as monetary benefits to those who are diagnosed.

Sub National verification of claims for progress towards TB-free status in India showed that the incidence of TB in 1 state, Union territory (2 UTs), and 35 districts has declined by at least 20% since 2015 and Rajsamand was not one of them.[10] Major facets that hindered Rajsamand from achieving its goal were

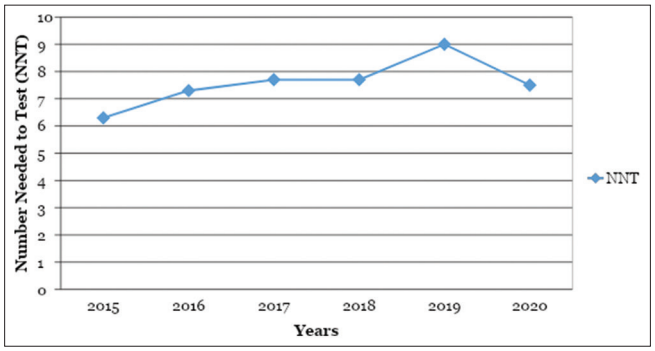

Figure 2: Number Needed to Test (NNT)

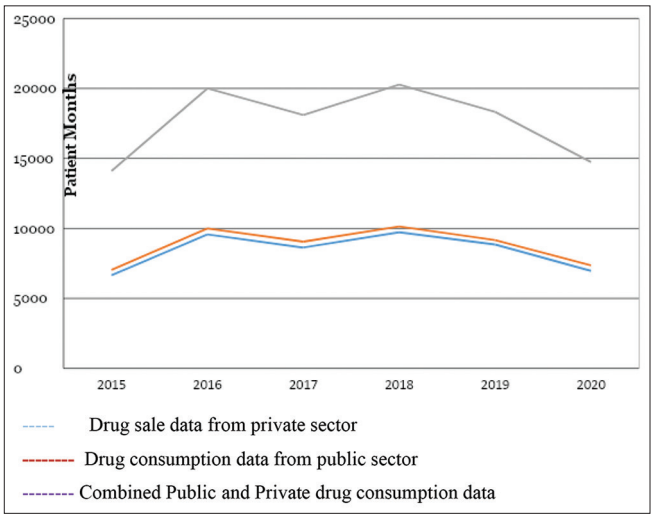

Figure 3: TB drug sale data in patient months

Table 1: TB score calculation for Rajsamand district

TB score calculation for Rajsamand District										
Components for TB score* as per Nikshay portal	**TB notification *n*=20**	**Screened for HIV *n*=10**	**UDST *n*=10**	**Success rate *n*=15**	**Beneficiaries paid *n*=10**	**DRTB *n*=15**	**Expenditure *n*=10**	**Chemo prophylaxis *n*=5**	**PLHIV *n*=5**	**Total *n*=100**
Scores for Rajsamand District after Survey	12.33	9.44	9.23	13.27	1.97	13.61	3.37	2	3.12	68.34

*TB score tells about the performance of the district based upon 9 criterias mentioned in the table

Table 2: Eligibility Criteria for "TB free claim"

Eligibility Criteria for "TB Free status" as per WHO/ICMR/NTEP	Data for Rajsamand district in 2015	Data for Rajsamand district in 2020	Percentage decline or increase as per survey [%]	Criteria fulfilled or not fulfilled
TB Score for latest year [Table 1] ≥80%	61.1%	68.3%	<80%	Not fulfilled
Increase in NNT ≥20%	6.35	7.51	Increased by 18.2%	Not fulfilled
Percentage decline in patient months ≥20% [based on drug sale data]	7048	7366	Increased by 4.5%	Not fulfilled

poverty, lack of education, and the stigma about TB. Because of a scattered population, there was insufficient access to medical care, testing facilities, and trained personnel.

In this TB-free verification process nationwide, as per The Hindu, [22 March, 2022] Kerala was the only state as a whole to receive a medal as the state recorded a 37.5% reduction in the incidence of TB between 2015 and 2020. Barring a few districts all districts in Kerala received a medal. In 2017, Kerala revamped its TB elimination drive as "People's Movement Against TB", with the active involvement of the local community and panchayats.[11]

Although India has made great strides in treating the huge numbers of TB patients and in controlling the spread of TB, it is ambitious to think that a country with a population of almost 1.4 billion people can easily eliminate a disease as infectious and as easy to spread as TB.

Although districts have claimed at least a 20% decrease in incidence taking 2015 as the baseline and being TB-free, there still is inconsistency in the data put forward to the MoHFW. This lack of progress stems from unawareness of symptoms in the population. In addition, to get the correct treatment, they should have access to basic medical care which is insufficient at the primary levels. This is evident from the index study that only 10 patients were on ATT out of 32 who tested positive for TB. The scenario must be worse for extra-pulmonary TB patients because they are more difficult to identify.

Nonetheless, the results of this study do bring hope as it is evident that we are headed in the right direction. If we are to believe the data put forward to the Nikshay portal, it suggests there is a decrease in the incidence and prevalence of TB in India. However, we as a nation are far from declaring ourselves TB-free.

To leap in building a TB-free country national health mission needs a more robust system of active case finding for TB. Although the index study did not account for extrapulmonary TB cases, these cases need more intensive case-finding strategies at the field level. A molecular laboratory that can carry out Cartridge based nucleic acid amplification test (CB-NAAT) tests needs to be set up at every Primary Health Center. In some districts, the presence of private clinics and chemists is almost none, to rectify this medical professionals should be encouraged by the government to provide their services in the hinterland. Second, awareness should be spread regarding the symptoms, treatment of TB, and available government schemes through popular media and social media channels. Third, private practitioners and private chemists should be encouraged to be more proactive in TB notification. However, private practitioners can be actively involved in the nationwide "TB Mukt Panchayat initiative".

The strengths of this study were the active participation of the target population in this survey. All who were symptomatically eligible underwent the sputum examination, apart from that, the patients proven positive microbiologically for TB were already registered under the Nikshay protocol except one. In addition, agencies of international repute such as WHO, IAPSM, ICMR, and NIE were actively involved in this study, as monitoring of the study was conducted by personnel sent by these agencies. They also visited the survey sites and supervised the whole journey of the 1st cycle of TB-free claim verification.

Sources of bias in the study may include **Selection bias:** 1) Sampling bias: Asymptomatic pulmonary TB cases may have been missed in the community-based survey. 2) Incidence prevalence bias: Patients treated long-time ago or cured patients may have been missing. 3) Extra-pulmonary TB cases were not accounted for.

Information bias: 1) Recall bias: Patients treated long-time ago or cured patients may have been missed. 2) Interviewer Bias: In households with asymptomatic TB patients, interviewer bias may have occurred.

Limitations of this study were not all villages/wards under the Rajsamand district were covered in the survey. A stop rule was applied which prevented survey teams from finding more cases once 30 microbiologically positive TB cases were found. Only one spot sputum sample test was used to confirm the presence of TB in symptomatically suggestive people. The main focus of the survey was to find cases of pulmonary TB; this might have led the survey teams to miss cases of extrapulmonary TB in the survey population.

Conclusion and Recommendations

The results that came out of Rajsamand district were not to the level expected of a district claiming a ≥20% reduction in incidence since 2015. Hence, district Rajsamand from Rajasthan, could not achieve any award in the first cycle of Sub National Certification for TB-free claim.

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Conflicts of interest

There are no conflicts of interest.

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