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Estimation of tuberculosis incidence at subnational level using three methods to monitor progress towards ending TB in India, 2015–2020

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ABSTRACT

Objectives We verified subnational (state/union territory (UT)/district) claims of achievements in reducing tuberculosis (TB) incidence in 2020 compared with 2015, in India.

Design A community-based survey, analysis of programme data and anti-TB drug sales and utilisation data.

Setting National TB Elimination Program and private TB treatment settings in 73 districts that had filed a claim to the Central TB Division of India for progress towards TB-free status.

Participants Each district was divided into survey units (SU) and one village/ward was randomly selected from each SU. All household members in the selected village were interviewed. Sputum from participants with a history of anti-TB therapy (ATT), those currently experiencing chest symptoms or on ATT were tested using Xpert/Rif/TrueNat. The survey continued until 30 *Mycobacterium tuberculosis* cases were identified in a district.

Outcome measures We calculated a direct estimate of TB incidence based on incident cases identified in the survey. We calculated an under-reporting factor by matching these cases within the TB notification system. The TB notification adjusted for this factor was the estimate by the indirect method. We also calculated TB incidence from drug sale data in the private sector and drug utilisation data in the public sector. We compared the three estimates of TB incidence in 2020 with TB incidence in 2015.

Results The estimated direct incidence ranged from 19 (Purba Medinipur, West Bengal) to 1457 (Jaintia Hills, Meghalaya) per 100 000 population. Indirect estimates of incidence ranged between 19 (Diu, Dadra and Nagar Haveli) and 788 (Dumka, Jharkhand) per 100 000 population. The incidence using drug sale data ranged from 19 per 100 000 population in Diu, Dadra and Nagar Haveli to 651 per 100 000 population in Centenary, Maharashtra.

Conclusion TB incidence in 1 state, 2 UTs and 35 districts had declined by at least 20% since 2015. Two districts in India were declared TB free in 2020.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This was the first and largest exercise of its kind to verify subnational progress towards TB-free status in a country.
⇒ Incidence of TB was calculated by three methods—direct method from a community-based survey, indirect method by correcting the notification rate for under-reporting of cases in the notification system, and using drug sales and utilisation data
⇒ Global Positioning System coordinates captured at every surveyed household, in-the-field supervision, real-time data monitoring through state and national dashboards, random review of audio and written transcripts of nominal group technique and key informant interviews, ensured quality of the data.
⇒ Though we tested only one spot sputum sample and did not perform chest radiography, we are less likely to have missed patients with TB since we tested all participants currently on anti-TB therapy, with a history of TB or currently experiencing any TB symptoms.

BACKGROUND

The Government of India (GoI) has set an ambitious goal for ending tuberculosis (TB) by reducing the incidence of new TB cases by 80% by 2025 compared with 2015.[1] India has a high TB burden (2.69 million cases in 2019), with a notification rate of approximately 159 cases/100 000 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 of India. It is, therefore, crucial to monitor the progress towards the elimination goal at the subnational level.

The Central TB Division (CTD) of the Ministry of Health and Family Welfare, GoI decided to incentivise states/UTs/districts for their progress towards TB-free status.[3 4] Under this initiative, the CTD sought claims from states/UTs/districts for achievements in reducing TB incidence in 2020 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 methodology for this verification. The objective of the verification process was to estimate the incidence of TB in 2020, calculate the decline in the incidence of TB between 2015 and 2020 and verify the claim made by the respective state/UT/district for progress towards TB-free status. We describe the methodology of the verification process and the challenges faced during its implementation.

METHODS

The verification process included a community-based survey and review of programme data and anti-TB drug utilisation data in each district. Incidence of TB for each district was estimated by three methods: (1) through a community-based survey (direct method), (2) by correcting the notification rate for under-reporting of cases in the notification system (indirect method) and (3) using drug sales and utilisation data.

Study settings

The District Tuberculosis Centre functions as the nodal point for all TB control activities under the National Tuberculosis Elimination Program (NTEP) in the district through a tuberculosis unit (TU) at the subdistrict level. The first points of contact with the community where TB diagnosis and treatment initiation happens are peripheral health institutions manned by at least one medical officer and Health and wellness centres equipped to provide comprehensive Primary healthcare. TB is a notifiable disease in India since 2012. TB diagnosis and treatment are offered free of cost under the NTEP. Nikshay is the standard notification system that also captures patients diagnosed in the private sector.

Community-based household surveys

Sampling procedure

Sixty-seven districts, one state and two UTs had filed claims under different categories of achievement. For verifying the claim from the state, we selected four districts using probability proportionate to size (PPS) sampling. The probability of selection of the district was proportional to the size of the population of the district. The districts with a higher population had a higher probability of selection into the sample. Thus, we verified the claims in a total of 73 districts. We divided each district into survey units (SU) based on the number of TUs in it to represent the entire district in the household survey. We divided the districts with <5 TUs into 5 SU, districts with 6–10 TUs into 10 SU and districts with >10 TUs into 15 SU. We selected one village/ward from each SU by PPS sampling (probability of selection of cluster proportionate to its population size) from the 2011 census list of villages and wards.

Sample size

We used the inverse sampling method to detect a predetermined number of bacteriologically positive TB patients in each district. Inverse sampling is a sampling technique to estimate a proportion (P) for rare events.[5] In this method, the survey is continued until a predetermined number of rare events (m) are detected in the surveyed population. The required sample size (n) is not known in advance, contrary to the conventional cluster sampling. We decided to detect 30 bacteriologically confirmed TB cases in a district, assuming an expected proportion of TB of 274 cases/100 000 population and a coefficient of variation of 18.5.

Survey procedure

In each selected cluster, the survey teams started from a randomly selected household and moved sequentially. Using an android application developed by the WHO India, the trained survey teams interviewed participants of any gender, and all ages, residing in the selected village/ward for at least 1 year. Those who reported any symptoms (persistent cough for ≥2 weeks, fever for ≥2 weeks, significant weight loss, presence of blood in sputum any time during last 6 months, chest pain in last 1 month), or were currently on anti-TB treatment (ATT) or had a history of ATT, were eligible for sputum collection. The teams obtained written informed consent from those eligible and collected one spot sputum sample, which was transported according to NTEP Guidelines. The nearest NTEP testing centre performed a rapid molecular test (CBNAAT or TrueNat) for *Mycobacterium tuberculosis* (MTB).[6 7] The teams uploaded the results to the web page of the application within 24–48 hours of collection.

The survey continued until 30 cases of TB were detected from each district. If the desired number of bacteriologically positive TB patients were not achieved within the selected cluster, we selected the next geographically adjacent cluster and repeated the process. The survey was stopped once the target of 30 TB cases were detected. We considered additional stop rules for districts that could not detect 30 TB cases—either covering 10 000 households or 5% of the total population, whichever they met first.

Data analysis

We used the survey data to calculate the incidence of TB in 2020 by two methods—direct and indirect. The direct method used incident MTB cases detected during the survey (defined as those with a history of ATT between April 2020 and March 2021, those currently on ATT on the date of survey with a date of diagnosis between April 2020 and March 2021 and those newly testing positive during the survey) as the numerator and total population surveyed as the denominator. In the indirect method, we matched the incident cases detected among the surveyed population with those notified in Nikshay database. We calculated an under-reporting factor for each district using the number of TB cases that could not be matched with Nikshay database. We adjusted the Nikshay-based TB notification rate for 2020 using this factor.

Secondary data verification

We verified the programmatic data and TB drug utilisation data from the public and private sectors using rifampicin as the indicator drug.

TB drug utilisation data

We obtained data about rifampicin consumption in the public sector for 2015–2020 from NTEP drug consumption registers. We collected sales data of rifampicin-containing drugs in the private sector from Clearing and Forwarding (C&F) agencies, drug manufacturers, distributors, chemists, drug commissioners, drug inspectors and private practitioners. All formulations, paediatric and adult, fixed-dose combinations, and separate tablets were included. Besides the incomplete nature of recording and maintaining data in the private sector, certain issues challenged the validity of private sector drug sale data. In some districts where the private sector was non-existent, people were purchasing drugs from nearby districts. Some patients notified from the private sector were being treated under the public sector. Also, some rifampicin-containing drugs were used for conditions other than TB, and the number of drug formulations were many; each being prescribed in a multitude of dosing regimens. We obtained this information through qualitative research techniques. Trained members conducted 2–3 nominal group technique (NGT) sessions with chemists, private practitioners and drug manufacturers and 5 key informal interviews (KII) with state drug controller, drug inspectors, and C&F agency in the district. The data were collected in paper forms and uploaded to the web portal developed by Indian Council of Medical Research-National Institute of Epidemiology (ICMR-NIE).

Data quality assurance

We formed verification teams at the central, state and district levels and trained them to standardise data collection and analysis. The district verification teams trained and supervised the district survey teams. Central and state teams supervised the secondary data verification performed by district verification teams.

Data analysis: For a given drug (i), based on the quantity of drug consumed in the public sector, we calculated patient months treated for TB, using the following formula:

$$\text{Patient months in the Public sector for drug (i)} = \text{Number of Rifampicin} - \text{containing drug (i) packs solds in 1 year} \times \text{Ti}$$

where Ti is the number of treatment months represented by each unit of that drug i.

We calculated Ti of a given formulation, the strength of rifampicin in it, and its dosing regimen, based on the inputs from qualitative interviews.

We adjusted private sector drug sale data for rifampicin usage for non-TB conditions and coverage of drug sales data.

$$\text{Patient months in the private sector for drug i} = \frac{\text{No. of packs sold}}{\text{Ci}} \times \text{Ti} \times \text{Xi}$$

Ti—the number of treatment months represented by each unit of sale of drug i.

Xi—the proportion of sale of drug i intended for tuberculosis.

Ci—the proportion of sales of drug i that has been reported.

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

Comparison of TB incidence between 2015 and 2020

We estimated the incidence of TB for 2020 for each district based on direct, indirect and drug data-based methods.[8 9] We compared these estimates with the baseline TB incidence for 2015. This baseline incidence was calculated based on TB notification under the programme, presumptive TB examination rate, presence of private sector facilities in the district, drug sales data (for state-level incidence) and local intelligence. For district-level TB incidence estimations, state-level estimations were divided into districts with district-level weights for public sector notification rates, the number of private health facilities, private sector notification rates and presumptive examination per bacteriologically positive case. The criteria for recommending a district for subnational claims for progress towards TB-free status are summarised in table 1.

Patient and public involvement

Patients and members of the community were not part of the conception and design of the study. Volunteers from the community were involved in community mobilisation/sensitisation and survey data collection.

RESULTS

TB incidence: direct method

Survey teams (n=645) visited 355 171 households across 73 districts and interviewed 1 184 106 (86.4%) individuals who consented to participate in the survey. Of the total participants, 52% (n=617 500) were females, 28%

Table 1 Criteria for the recommendation of recognition for achievements in progress towards TB-free status in India, 2020

Criteria	Recommendation for certification/award
Any of the three incidence estimates* higher than 10% of the baseline estimate	Not recommended under any category
At least two of the three-point estimates of decline in incidence support claimed category and none of the incidence estimates shows an increase from baseline incidence	Recommended under eligible/claimed category
At least two of the three-point estimates of decline in incidence support claimed category and the other point estimate of incidence shows an increase of up to 10% from baseline incidence	If lower bound of the incidence estimate is more than 10% of the baseline estimate, then not recommended for any category. Else recommended under claimed category
At least two of the three-point estimates of decline in incidence support higher than the claimed category	If lower bounds of CIs of those estimates of decline in incidence are found to support higher category, recommended under higher category
All three incidence estimates are <44/100 000 population	Tuberculosis (TB)-free status for that year

*The three estimates refer to the decline in the incidence of TB between 2015 and 2020 calculated using the TB incidence in 2020 calculated by direct, indirect and drug data-based methods.

(n=333 569) were aged between 15 and 30 years and 79% (n=935 256) were Hindu by religion. Overall, 24 410 (2.06%) reported one or more symptoms, 6371 (0.5%) had a history of ATT and 1041 (0.1%) were currently on ATT. Of the total 24 422 samples tested, survey detected 998 MTB cases.

Among the 73 districts surveyed, the criteria of stop rule was achieved in 25 districts (30 active cases with TB detected in 11 districts, 10 000 households surveyed in 6 districts, 5% of the district population surveyed in 8 districts). The remaining 48 districts did not meet any of the three stop rules. The estimated incidence of TB using the direct method ranged from 19 (Purba Medinipur, West Bengal) to 1457 (Jaintia hills, Meghalaya) per 100 000 in different Indian districts (table 2, online supplemental table 1, figure 1).

TB incidence: indirect method

Of the 1507 incident cases (currently on ATT and history of TB between April 2020 and March 2021), excluding those newly diagnosed during the survey, 358 (23.8%) cases could not be verified with Nikshay. In 25 of the 73 districts, all incident TB cases could be matched within Nikshay indicating that there was no under-reporting. The under-reporting was <20% in 18 districts, between 21% and 40% in 18 districts, 41% and 60% in 8 and 61% and 80% in 4 districts (table 3). Adjusting the TB notification rate in 2020 from Nikshay for the level of under-reporting observed, the estimated incidence of TB ranged between 19 (Diu, Dadra and Nagar Haveli) and 788 (Dumka, Jharkhand) per 100 000 population (table 2, online supplemental table 1, figure 1).

TB incidence: drug consumption/sale data-based method

Overall, 1329 individuals including 475 (35.7%) private providers, 679 (51.1%) chemists, and 175 (13.2%) drug inspectors, assistant drug controller, president of chemist association or Stockists participated in NGT/KII. In the private sector, the median (IQR) duration of treatment given to patients treated in the private sector in different districts was 6 (6, 6) months, a median (IQR) 100% (99%–100%) of the drug sale was intended for TB and the median (IQR) coverage of sales data was 95% (80%, 100%). The incidence of TB using drug sale data ranged from 19 per 100 000 population in Diu, Dadra and Nagar Haveli to 651 per 100 000 population in Centenary, Maharashtra (table 2, online supplemental table 1, figure 1).

The agreement between the three estimates is presented in figure 2. Based on the verification criteria enlisted in table 1, we recommended certifying Lakshadweep (UT) and Budgam district, Jammu & Kashmir as TB free (≥80% reduction in TB incidence). We recommended Diu district for award under the gold category (60%–79% reduction in TB incidence) and four districts under silver (40%–59% reduction in TB incidence). Twenty-eight districts, one UT and one state were recommended for the bronze category (20%–39% reduction in TB incidence).

DISCUSSION

We conducted a nationwide exercise in India in 2020 to verify the subnational claims submitted by different states/districts/UTs for various levels of progress towards TB-free status. In 2 of the 73 districts, the incidence was less than the national target for 2025 of 44 per 100 000 population. Compared with the incidence in 2015, the incidence in 2020 declined by 60%–80% in 1 district, 40%–60% in 4 districts and 20%–40% in 28 districts, 1 UT and 1 state.

Table 2 Decline in tuberculosis (TB) calculated using the direct, indirect and using drug data based methodsin 2020, compared to baseline TB incidence in 2015

State	District	Incidence: indirect (per 100 000 population)	Incidence: direct (per 100 000 population)	Incidence: drug data (per 100 000 population)	Baseline incidence (per 100 000 population)	Decline: indirect (%)	Decline: direct (%)	Decline: drug data (%)
Andhra Pradesh	Srikakulam	121	151	139	177	32	15	21
	Vizianagaram	167	229	113	227	26	–1	50
Arunachal Pradesh	East Kameng	299	175	82	360	17	51	77
	East Siang	139	201	52	342	59	41	85
	Tirap	328	278	54	245	–34	–13	78
	West Siang	252	184	26	141	–79	–30	82
Dadra Nagar Haveli, Daman, Diu	Dadra Nagar Haveli	137	75	99	171	20	56	42
	Daman	118	147	78	222	47	34	65
	Diu	19	48	19	102	81	53	81
Gujarat	Botad	112	69	76	154	27	55	51
	Devbhumi Dwarka	58	40	64	128	55	69	50
	Mehsana	191	181	233	347	45	48	33
	Porbandar	86	144	150	213	60	32	30
	Rajkot	100	127	91	242	59	48	62
	The Dangs	107	166	74	157	32	–6	53
Himachal Pradesh	Hamirpur	153	111	140	237	35	53	41
	Kangra	119	152	129	220	46	31	41
	Kinnaur	159	198	243	263	40	25	8
	Lahul–Spiti	102	62	174	219	53	72	21
	Una	101	147	140	237	57	38	41
Jammu	Kathua	101	294	114	224	55	–31	49
	Udhampur	93	136	102	157	41	13	35
Jharkhand	Dumka	788	579	264	321	–145	–80	18
	Palamu	186	439	135	197	6	–123	31
	Pashchimi Singhbhum	213	1029	65	262	19	–293	75
	Saraikela-Kharsawan	163	545	181	228	29	–139	21
Kashmir	Budgam	20	37	30	104	81	64	71
Kerala	Ernakulam	67	69	82	120	44	43	32
	Kasargod	47	29	48	112	58	74	57
	Kollam	64	107	50	147	56	27	66
	Malappuram	47	37	49	99	53	63	51
Lakshadweep	Lakshadweep	27	28	27	36	25	22	25

Continued

Table 2 Continued

State	District	Incidence: indirect (per 100 000 population)	Incidence: direct (per 100 000 population)	Incidence: drug data (per 100 000 population)	Baseline incidence (per 100 000 population)	Decline: indirect (%)	Decline: direct (%)	Decline: drug data (%)
Madhya Pradesh	Alirazpur	132	184	66	109	−21	−69	39
	Betul	169	98	94	177	5	45	47
	Harda	104	359	64	357	71	−1	82
	Narsinghpur	165	291	190	219	25	−33	13
	Sehore	150	414	170	182	18	−127	7
	Umaria	248	586	134	175	−42	−235	23
Maharashtra	Kolhapur	43	61	45	158	73	61	72
	Nashik	43	60	40	112	62	46	64
	Ratnagiri	75	128	119	203	63	37	41
	Satara	67	49	85	179	63	73	53
	Sindhudurg	79	80	86	143	45	44	40
	Bhiwandi Nizampur	694	310	296	346	−101	10	14
Mumbai	Centenary	400	572	651	686	42	17	5
	Ghatkopar	269	512	273	583	54	12	53
	Grant Road	314	55	130	351	11	84	63
	Parel	324	149	224	671	52	78	67
	Prabhadevi	336	158	99	338	1	53	71
Meghalaya	East Khasi Hills	408	491	188	344	−19	−43	45
	Jaintia	341	1457	188	292	−17	−399	36
	West Khasi Hills	231	267	102	166	−39	−61	39
Mizoram	Mamit	95	112	62	101	6	−11	39
Nagaland	Kiphire	208	308	NA	150	−39	−105	–
Odisha	Dhenkanal	122	136	75	121	−1	−12	38
	Sonapur	94	286	54	87	−8	−229	38
Puducherry	Puducherry	115	49	86	185	38	74	54
Punjab	Fatehgarh Sahib	69	35	97	152	55	77	36
	Kapurthala	50	101	97	169	70	40	43
	Nawanshahr	98	87	50	252	61	65	80
Rajasthan	Bhilwara	198	456	140	366	46	−25	62
	Rajsamand	184	287	95	266	31	-8	64
Tamil Nadu	Thiruvannamalai	64	66	70	135	53	51	48
Telangana	Bhadradri Kothagudem	285	281	172	425	33	34	60
	Khammam	227	160	232	251	10	36	8
	Nizamabad	146	77	162	269	46	71	40
	Kamareddy	144	139	167	136	−6	−2	−23

Continued

Table 2 Continued

State	District	Incidence: indirect (per 100 000 population)	Incidence: direct (per 100 000 population)	Incidence: drug data (per 100 000 population)	Baseline incidence (per 100 000 population)	Decline: indirect (%)	Decline: direct (%)	Decline: drug data (%)
Tripura	Dhalai	48	286	64	122	61	−134	48
	North Tripura	67	411	68	156	57	−163	56
	South Tripura	38	217	48	113	66	−92	58
	West Tripura	76	145	83	238	68	39	65
West Bengal	Nadia	90	200	60	173	48	−16	65
	Purba Medinipur	36	19	38	145	75	87	74

Strengths

To the best of our knowledge, this is the first and largest exercise of its kind to verify subnational progress towards TB-free status in a country. The use of anti-TB drug sales and consumption data available in the programme or primary data collected from multiple sources to estimate incidence was used on such a large scale for the first time, including both public and private sectors.[8 10] Three different methods of estimation of TB incidence were employed so that the strengths of one method shall overcome the limitations of another. We used the underreporting factor calculated from the survey to adjust the incidence derived from the Nikshay notification portal to obtain a more realistic estimate. Similarly, the drug data from the private sector was adjusted using correction factors obtained from qualitative research techniques. Quality assurance of this process was multipronged and at multiple levels. We captured Global Positioning System coordinates at every household included in the survey process. Besides, we ensured in-the-field supervision, real-time monitoring of the data through state and national dashboards, review of audio and written transcripts of NGT and KIIs, and the quality of the data at every level. The web application developed by the WHO and ICMR-NIE as a one-time effort is now available for efficient and quality implementation of future rounds of this exercise.

Limitations

We tested eligible participants identified from the survey using only one spot sputum sample. Though we screened for 'any TB symptom', and tested all persons reporting symptoms, currently on ATT or reporting history of consumption of ATT, the survey might have missed patients with new onset extrapulmonary TB. We did not use chest radiography (CXR) to screen the survey participants. Though CXR has higher accuracy than symptom screening alone, screening for 'any TB symptom' had a high sensitivity of 90% on par with the 94% sensitivity of CXR.[11] Further, we included participants currently on ATT and those with a history of TB who are likely to have been the people who would have been captured by CXR. Chadha *et al* have reported a significant additional yield (3.3%–21.3%) of cases when screening for a history of ATT.[12] Hence, we might not have missed a substantial number of eligible participants to have influenced our incidence estimates.

Though we used the inverse sampling technique, since most districts did not attain the target number of cases, we proceeded with the calculation variance and 95% CI consistent with random sampling. Thus, the survey could have ended up studying a larger sample than would have been required had an appropriate sample size calculation been performed based on the incidence of TB in that region.[13] In the light of this experience, for the future rounds of this exercise, we recommend recalculation of the target number of cases to be achieved by the districts based on their baseline incidence and population.

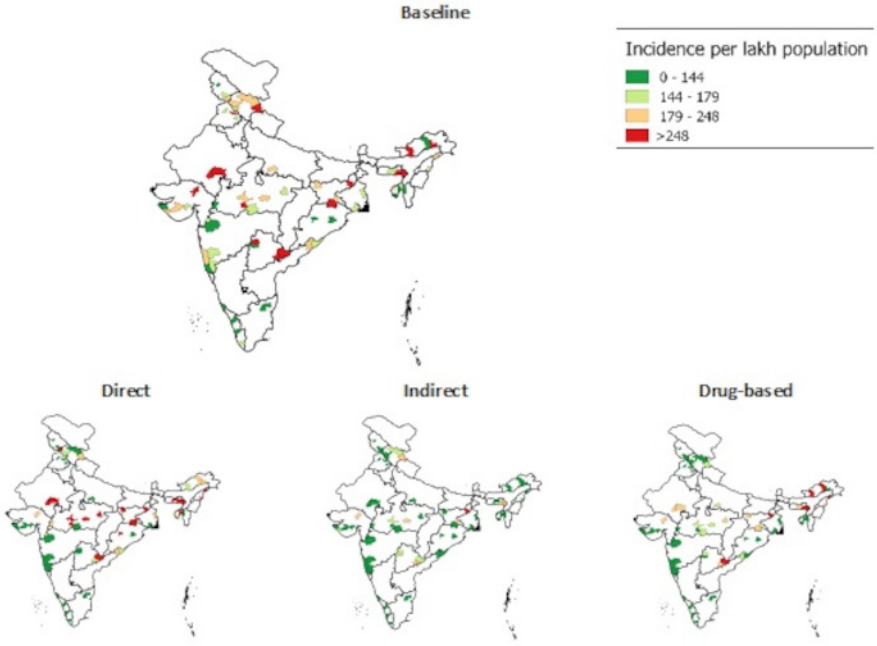

Figure 1 Comparison of baseline tuberculosis (TB) incidence with direct, indirect and drug data based TB incidence for subnational verification of TB claims in India, 2020.

We could not adjust the private sector drug data-based incidence calculation for the proportion of private sector patients taking treatment from the public sector in some districts. Thus, we could have overestimated the incidence based on drug data calculation in those districts. But we do not anticipate this might have influenced our recommendations as the drug data-based incidence estimates were the lowest of the three estimates in most districts. Though drug sale and utilisation data-based incidence estimation posed challenges, we have established a baseline estimate through this exercise against which estimates from future rounds can be compared.

Anti-TB drug sale data for incidence estimation

A comprehensive estimation of the burden of TB, especially in a high Tb burden country, should account for all patients with TB irrespective of their place of diagnosis and compliance with treatment. Though an efficient national TB elimination programme 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.[14] 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,[8 15] counting the number of patients treated for TB in the private sector is challenging.[16 17] This complex heterogeneity in the 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 organised and complete recording and reporting.[15 18]

It was challenging to enlist all drugs available in the market and calculate the number of treatment months represented by each unit of sale of drug (Ti) for each of them, given the various formulations and dosing regimens. Through multiple rounds of training, hands-on sessions, and field visits to interview chemists, programme staff and private practitioners, we standardised the list of the drugs and their Ti. We recommend using this list with modifications in the future rounds without repeating the exercise in its entirety. Our study captures the incomplete reporting of TB drug sales data in the private sector, and we have corrected the private sector drug sale volume for the issues mentioned above.

Individual district divisions under metropolitan cities had applied separately for TB-free status. It was challenging to obtain drug sales data at the disaggregated level as the data are usually available at the level of metro city only.

Table 3 Under reporting of active tuberculosis (TB) cases in Nikshay portal calculated as part of verification of subnational claims for progress towards TB-free status in India, 2020

Under-reporting	Districts, n
Nil	25
≤20%	18
21%–40%	18
41%–60%	8
61%–80%	4
>80%	None

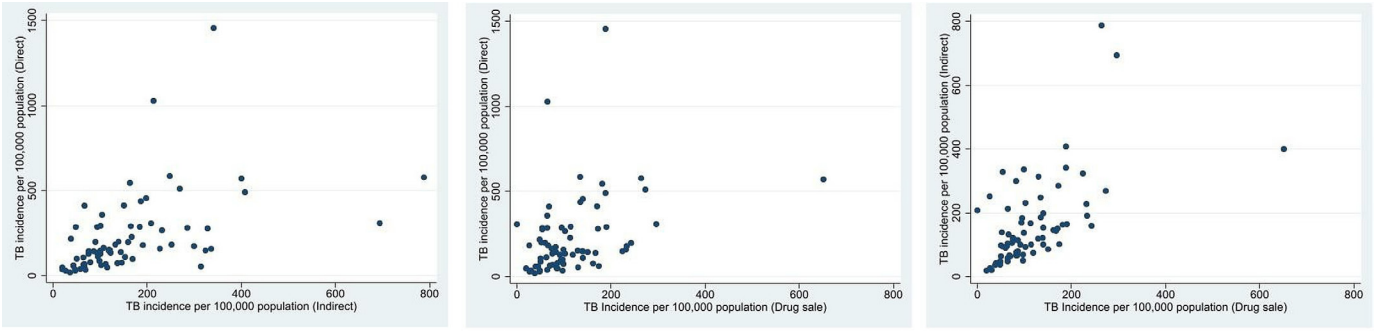

Figure 2 Estimates of tuberculosis (TB) incidence per 100 000 population by three methods, India, 2020.

Agreement between incidence estimates

In 45 districts, all three estimates of TB incidence suggested a decline in the incidence of TB. An efficient Tb notification system with minimal or no under-reporting and diligent maintenance of drug sales and utilisation data ensured that all three estimates agreed. In 17 districts, the indirect and drug data-based estimates pointed toward a decline, while the direct estimate pointed an increase in TB incidence since 2015. National TB Elimination Programme misses 10% of estimated drug-sensitive TB and 50% of estimated drug-resistant TB cases. (India TB report 2020). Even after the adjustment for the under-reporting, indirect estimates were lower than the direct estimate in these districts, as the under-reporting factor might not have captured the full extent of under-reporting.[19] This could have been due to the sampling error induced variations in the direct estimate and the under-reporting factor used to calculate the indirect estimate.

In 11 districts where 2 estimates pointed towards an increase in incidence, the only estimate pointing towards a decline in incidence was the drug data-based estimate. It is likely that the drug data from these districts could be incomplete, leading to a very low estimate of the incidence by this method. This might be because, in some districts, the private sector does not exist and people migrate to nearby districts to buy ATT. Though we tried to capture this proportion through NGT/KIIs, it is still likely to be an underestimate. Rifampicin is a Schedule H1 drug that cannot be sold in retail without a prescription from a registered medical practitioner and the details of the supply shall be recorded in a separate register, maintained for 3 years, and be available for inspection. Despite this fact, chemists' reporting of rifampicin sales is incomplete, leading to missing drug sales data. In such cases, the drug data-based incidence might show a trend opposite the other two estimates. To avoid decisions based on an apparent steep decline in one incidence estimate, we had framed the verification criteria based on reduction suggested by at least two of the three estimates.

The possible impact of COVID-19

Given that we carried out the exercise during the pandemic, we would like to describe its possible impact on our estimates. The pandemic and the control measures instituted might have led to under notification of TB due to the constraints under which the general healthcare system of the country functioned during this period.[19] In September 2020, the NTEP announced a Rapid Response Plan to mitigate the impact of the COVID-19 pandemic on TB epidemic and NTEP activities, which called for bidirectional TB–COVID screening.[20] It is likely that TB notification might have increased after implementation of this plan.

Implications for policy and future research

Based on the experience of subnational verification of progress towards TB-free status in India in 2020, we make the following recommendations. First, yearly monitoring of progress towards TB-free status is to be carried out at subnational level by setting up a standardised mechanism for periodic aggregation and reporting of data at the TU and district level. Second, it is essential to ensure universal and complete reporting of Schedule H drug sale data providing details of the prescriber, patient, indication, name of drug and quantity sold. Third, there is a need to refine the methodology of drug data-based incidence estimation and ensure better quality of drug data required for incidence estimation. This can be done by sensitisation of all the stakeholders including the drug controllers, drug inspectors, C&F agencies and private practitioners regarding recording and reporting of drug sale and utilisation data.

CONCLUSION

Subnational verification of claims for progress towards TB-free status in India showed that the incidence of TB in 1 state, 2 UTs and 35 districts has declined by atleast 20% since 2015. Two districts in India were TB free in 2020.

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