Community-based approaches to improve tuberculosis services: observations from preintervention and postintervention surveys in a high TB burden disadvantaged community in India

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ABSTRACT

An alarmingly high prevalence of tuberculosis (TB) was reported among the Saharia tribe in Madhya Pradesh, India. A community-based intervention study was undertaken to improve TB case finding during 2018–2021. The interventions mainly comprised active case detection through village TB volunteers using advocacy, communication and social mobilisation activities. A preintervention and postintervention survey design was adopted to assess the impact of intervention. The prevalence declined from 1357 (95% CI 1206 to 1527) to 752 (95% CI 646 to 875) per 100 000 population (p<0.001). The study findings highlight the importance of innovative community-based approaches in controlling TB in high burden areas.

INTRODUCTION

India has the highest tuberculosis (TB) burden (26%) and accounts for 34% of the TB deaths in the world.[1] The recently conducted national TB prevalence survey reported the prevalence of pulmonary TB (PTB) as 316 per 100 000 population in the country and 386 per 100 000 population in the state of Madhya Pradesh, central India.[2] Though the indigenous people comprise <5% of the global population, the burden of TB among them is high and varies greatly.[3] The Saharia are one among the three particularly vulnerable tribal groups (PVTGs) in the state of Madhya Pradesh and work mainly as agriculture labourers. In contrast to the other two PVTGs, an extremely high TB prevalence of 3294 per 100 000 population is reported among them.[4] Though the National TB Elimination Programme (NTEP) is being implemented in the area, there are several challenges such as remotely located Saharia habitats, poor access to healthcare facilities, and their beliefs and practices related to TB, making the situation more complex.[5] Despite the high TB burden, the efforts to bring down the prevalence of TB seem to be inadequate in this key population.[6] NTEP, in addition to the Tribal Action Plan, has collaborated with the Ministry of Tribal Affairs, Government of India, for the Tribal TB initiative for vulnerability mapping and active case finding (ACF). Nine districts of the state of Madhya Pradesh have been identified for this activity based on predominance of the tribal population.[7] But the Saharia dominated districts are not included in this list as the Saharia tribe contributes to a small portion to the district's population. This again makes them more disadvantaged, and it becomes more important to put in special efforts for controlling TB in this disadvantaged population.

Our earlier study carried out in a defined geographical area adopting community-based approaches to reach the population and to improve access to services demonstrated a decline in TB prevalence in this community.[8] In view of this, an intervention study was conducted covering the total Saharia population of all seven Saharia-dominated districts during 2018–2021 to improve case finding and treatment outcomes through community-based approaches.

METHODS

Study area and population

The Saharia are one of the PVTGs in the central Indian state of Madhya Pradesh and have very poor socioeconomic indicators.[9] The intervention study was carried out among the Saharia population (more than 0.5 million) in seven Saharia-dominated districts, namely, Shivpuri, Sheopur, Ashoknagar, Gwalior, Bhind, Datia and Morena, in collaboration with state and district health authorities and NTEP (figure 1).

Study procedures and intervention

In addition to regular NTEP activities, we implemented an intervention package to improve TB case finding and treatment outcomes. The intervention package included symptom screening by trained village TB volunteers; mapping and strengthening of health facilities; training and capacity building of NTEP and project staff; sensitisation and involvement of Panchayati Raj institutions (rural local self-government in India) and advocacy, communication, and social mobilisation activities (details submitted as online supplemental file 1). Throughout the study period, monthly house-to-house visits were performed by the village TB volunteers to identify TB presumptive cases. Sputum specimens were collected from symptomatic individuals and transported to the nearest NTEP Gene Xpert/TrueNAT lab. Whenever required, an X-ray was done at the nearest health facility. Notification of TB cases,

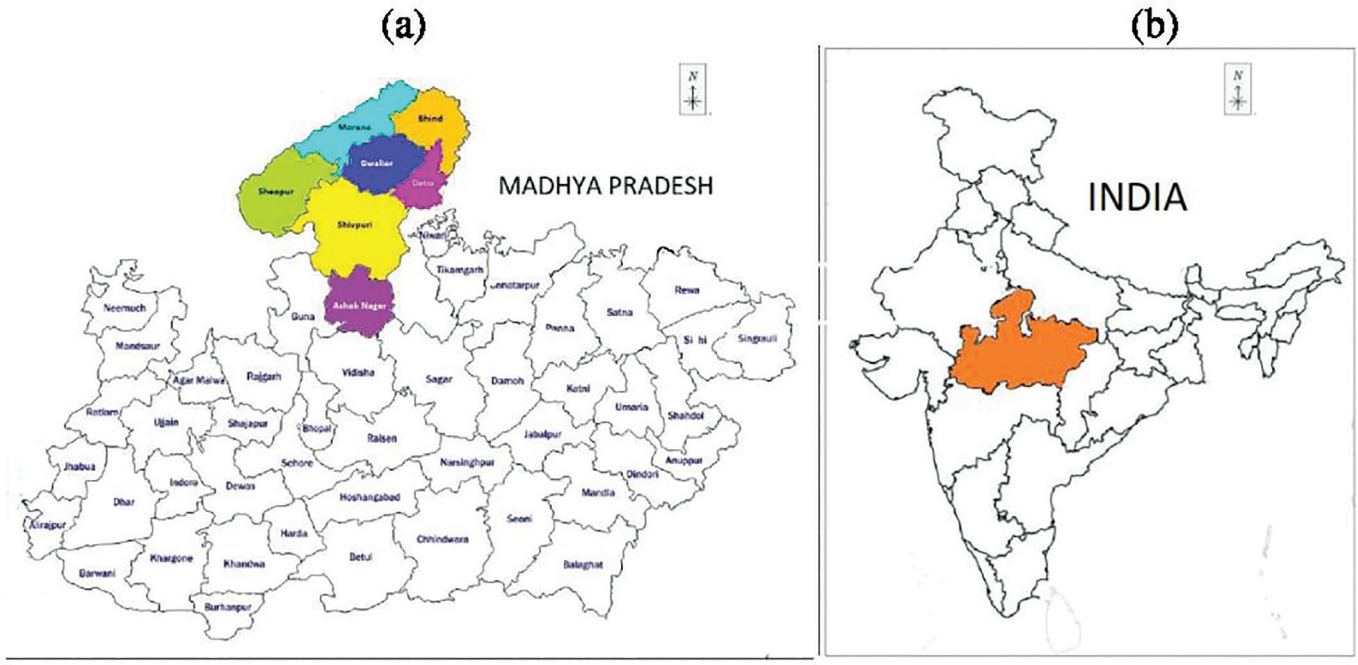

Figure 1 The study area.

treatment initiation, and follow-up were done as per NTEP guidelines by the project and NTEP supervisors.

Baseline and endline TB disease prevalence surveys

A preintervention and postintervention survey design was adopted to assess the impact of the intervention. The sample size to observe a reduction of 20% in the original prevalence (P_1=1500/100 000) to the assumed endpoint prevalence (P_2=1200/100 000), with a 95% confidence level and 80% power was estimated as 18 500 individuals. The baseline TB prevalence survey was carried out during January–May 2019 in 144 selected villages from all the seven districts. The detailed methodology is mentioned elsewhere.[10] The endline survey was carried out in 128 selected villages in these districts during September–November 2021. During both surveys, the estimated sample size was proportionally distributed in the Saharia population in each district and then in the administrative blocks. Villages were selected through the probability-proportional-to-size sampling technique from all blocks, and all households belonging to the Saharia tribe in the selected village were included in the survey. Every eligible individual aged ≥15 years in the selected village was screened for symptoms of TB. Two sputum specimens, one spot and one overnight, were collected from eligible individuals and were processed for microscopy and culture. Following the NTEP guideline and algorithm, the positive specimens were further subjected to drug susceptibility testing. An individual was labelled as a case of PTB if any one sputum specimen tested positive by microscopy/molecular testing and/or culture examination. All the detected cases were linked to the NTEP for anti-TB treatment.

Data management and analyses

All completed forms and laboratory reports were scrutinised and checked at the block/district level. The data entry operators entered data in a predesigned and pretested data entry software developed on the CSPro V.7.0 platform. TB prevalence was calculated as TB cases tested positive by microscopy/molecular testing and/or culture per 100 000 population. The extended Mantel-Haenszel χ^2 for linear trend with a value of $p<0.05$ at 1 degree of freedom was used to study the decline in TB positivity during the intervention period. The z-test was used to measure the differences in disease between the two disease surveys. IBM SPSS V.26.0 was used for carrying out different statistical analyses.

RESULTS

Coverage and registration

The Saharia population in all the 1814 Saharia villages of 32 administrative blocks in seven districts of Madhya Pradesh was covered under the study. TB case positivity was recorded as 41.3% in November–December 2018, which declined to 15.0% in 2019, 11.27% in 2020 and 9.3% in January–March 2021. This shows a significant linear decline (extended Mantel Haenszel Chi Square for linear trend=459.43, $p<0.001$ at 1 degree of freedom) in TB positivity during the intervention period. Overall, during the study period a total of 68862 presumptive cases were tested, and among them 8797 TB cases were detected with a case positivity of 12.8%. Of these, 371 cases were drug-resistant, including 302 multidrug-resistant TB, 12 extensively drug-resistant TB and 57 H-mono-resistant TB cases. The treatment success rate remained above 90% throughout the study period (table 1).

TB prevalence during the baseline and endline surveys

During the baseline survey (January–May 2019), of the 21828 registered eligible individuals (≥15 years of age), 20114 individuals (92.1%) were screened for PTB. Of these, 2893 (14.4%) were symptomatic and 273 were microbiologically confirmed PTB cases. The baseline prevalence was 1357 (95% CI 1206 to 1527) per 100 000 population.[10] In the endline survey (September–November 2021), of the 22 805 registered individuals, 21946 individuals (96.2%) were screened, 1631 (7.4%) were symptomatic and 165 were microbiologically confirmed. The prevalence in the endline survey was 752 (95% CI 646 to 875) per 100 000 population. The reduction in the prevalence of PTB was statistically significant ($p<0.001$) (figure 2). The prevalence in both baseline and endline disease surveys increased with age and was significantly higher among men

Table 1 Yearwise tuberculosis (TB) cases and resistance detected

Variables	Years				
	2018 (November–December) n, (%)	2019 (January–December) n, (%)	2020 (January–December) n, (%)	2021 (January–March) n, (%)	Total
Presumptive TB tested	757	24769	37271	6065	68862
Microbiologically confirmed TB	276 (36.4)	3344 (13.5)	3361 (9.0)	451 (7.4)	7432 (10.79)
Chest X-ray	37 (4.8)	373 (1.5)	841 (2.2)	114 (1.8)	1365 (1.98)
Total active TB cases	313 (41.3)	3717 (15.0)	4202 (11.2)	565 (9.3)	8797 (12.77)
Positivity (95% CI)*	41.3 (37.8 to 44.9)	15.0 (14.6 to 15.5)	11.3 (10.9 to 11.6)	9.3 (8.6 to 10.1)	12.77 (10.8 to 13.8)
DS-TB (%)†	294 (93.9)	3520 (94.7)	4049 (96.3)	563 (99.6)	8426 (95.78)
XDR-TB (%)‡	3 (0.9)	8 (0.2)	1 (0.02)	0 (0.0)	12 (0.14)
MDR-TB (%)§	15 (4.8)	165 (4.4)	121 (2.9)	1 (0.18)	302 (3.43)
H-Mono-resistant TB (%)¶	1 (0.3)	24 (0.6)	31 (0.7)	1 (0.18)	57 (0.65)

Table presents the number of presumptive TB cases and confirmed TB cases detected during November 2018 to March 2021. Values in parenthesis are percentages.
*[1]Percentage of total active cases out of the total presumptive TB cases tested.
†Percentage of drug-sensitive TB (DS-TB) cases out of the total active TB cases.
‡Percentage of extensively drug-resistant TB (XDR-TB) cases out of the total active TB cases.
§Percentage of multidrug-resistant TB (MDR-TB) cases out of the total active TB cases.
¶Percentage of H-mono-resistant TB cases out of the total active TB cases.

than women. In the endline survey, men were about 2.8 times more likely to have TB compared with women, similarly, older individuals (55+ years and above) were about 5.7 times more likely to have TB positivity compared with younger individuals (15–24 years).

DISCUSSION

This is the first large-scale intervention study covering the entire Saharia tribal population residing in the seven Saharia-dominated districts in the central Indian state of Madhya Pradesh. The study results show high TB case detection and a significant reduction in TB prevalence in this vulnerable population. Reducing TB burden requires preventing its transmission in the community. The best way to achieve this is by searching actively for cases, testing with good diagnostic methods, initiating patients promptly on treatment, and supporting and following them till the completion of the treatment.[11] The present study demonstrated a significant decline in the prevalence of PTB from 1357 to 752 per 100000 population. This might be due to innovative community-based approaches introduced in the study area during the study. The intervention package provided diagnostic and treatment services closer to the tribal community through the active involvement of village TB volunteers from the same community. The high treatment success rate achieved in the present study could be due to regular follow-up for treatment adherence by village TB volunteers and the project staff. A study in an urban Ugandan community in 2019, involving an intensive case finding campaign, showed that the burden of prevalent TB as measured by systematic screening had decreased by 45% in 2021.[12] Another study by Marks *et al* in Vietnam also showed a similar finding.[13]

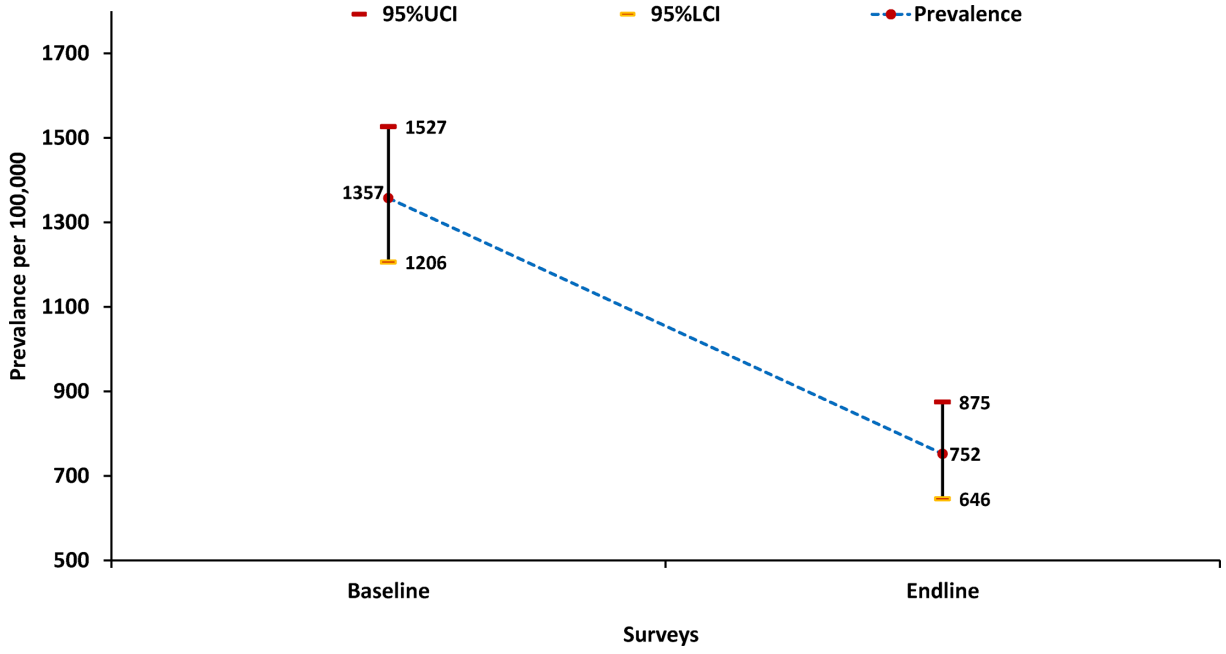

Figure 2 Prevalence in baseline and endline surveys.

The other important aspect of this study is the economic benefit of ACF through community-based interventions. A study carried out in the state of Tamil Nadu during October 2016 to March 2018 showed that there was a 78% reduction in out-of-pocket expenditure for treatment by patients detected through ACF as compared with passive case finding in public health facilities (₹255 vs ₹1163).[14] Thus, ACF significantly averted catastrophic costs due to TB among patients and it could ensure financial protection of TB patients and limit their risk of poverty.[15] In our study the estimated cost for screening a population of more than 0.5 million for about two and half years was just ₹212 ($2.6) per person, but it was ₹1547 ($18.9) for identification of a presumptive TB case and ₹3268 ($39.8) to detect a confirmed PTB case in a tribal community scattered in the seven districts. In interventions such as the ACF, understanding incremental benefits and costs is challenging. In addition, the ACF is basically a provider-initiated activity with the primary objective of detecting TB cases early in targeted groups and initiating treatment promptly. It is expected to increase coverage and to prioritise by focusing on clinically, socially and occupationally vulnerable populations. The ACF remains one of the key approaches that can address the challenges of TB among tribal communities.

The findings of the present study have immense potential to improve case detection and treatment outcomes, reducing TB burden and financial burden in remote hilly and tribal areas. Working closely with the existing health system and linkage with the TB control programme in the study area are key to the success of this intervention package. This should promote sustainability and has the potential for scale-up in other resource-poor and high TB burden areas.

Limitations

The lack of a control group is a major limitation of the study. As the study was carried out in one of the PVTGs, taking some tribal villages as the control group was not feasible. Hence, a preintervention and postintervention survey design was adopted. The high case detection and subsequent decline in TB prevalence from this study could be due to improved access and utilisation of TB services. However, the study design does not establish causality. Furthermore, the roles of confounding factors and seasonality have not been considered while interpreting the results. The intervention package was comprehensive, and it is not possible to pinpoint specific interventions for the observed impact. Despite the above limitations, the study has robust strength to show high TB case detection and subsequent decline in TB prevalence using community participatory approaches and would be useful in TB programmes, especially in vulnerable and disadvantaged populations.

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Contributors RKS, RY, MM, VGR and JB contributed to the concept, design and implementation of the study, and drafted and revised the manuscript. PM, SN and MAL contributed to the execution of the study, collection of data and monitoring. RKS and JB verified the data. JB, RKS, MM, VGR and RY decided to submit the manuscript.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. The Institutional Ethics Committee of ICMR-NIRTH, Jabalpur, approved the study (NIRTH/IEC/2273/2016). Participants gave informed consent to participate in the study before taking part.

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Supplementary File

Community-based approaches to improve tuberculosis services: Observations from pre- and post-intervention survey in high TB burden disadvantaged community in India

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METHODS

Study Setting

The state of Madhya Pradesh in the central part of India is home to the largest tribal population inthe country. The state has 46 identified Scheduled Tribes (ST) whilethree tribes namely Bharia, Baiga, and Saharia, are classified as PVTGs. Of these, the Saharia, also known as Sahar, Sehariya, or Sahariya, have very poor socio-economic indicators.[8] The majorityof them earn their livelihood as agricultural labourers. Usually, their residencesareon the outskirts of the main village and their hamlets/clusters of houses are called '*Saharana*'. They are vulnerable to TB with risk factors such as poor living conditions, malnutrition,tobacco smoking, and alcohol consumption behaviour.

Study Area and Population

The intervention study was carried out amongst the Saharia population in all sevenSaharia-dominated districts of the central Indian state of Madhya Pradesh viz. Shivpuri, Sheopur, Ashoknagar, Gwalior, Bhind, Datia, and Morena.The survey included all 500,000+ residents of Sahara tribes living in these districts.The study was conducted in collaboration with State andDistrict health authorities and NTEP officials.

Sample Size

A pre- and post-intervention survey design was adopted to assess the impact of the intervention. It was anticipated that our intervention would reduce the TB prevalence by at least 20% at the end of the study period. The estimated sample size to observe a reduction of 20% in the original

prevalence (P_1=1500/100,000) to the assumed endpoint prevalence (P_2=1200/100,000), with a 95% confidence level and 80% power was estimated as 18,500 individuals. However, to have robust estimates of prevalence of TB, the sample size were also estimated separately for baseline and endline TB prevalence surveys. The estimated sample size for baseline survey (assuming a prevalence of 1,500 per 100,000[5], 20% relative precision, 95% confidence level, design effect of 3, and coverage of at least 90%) was 21,900 adults (≥15 years of age)..In the case of endline survey, the estimated sample size (based on the baselineprevalence of 1,357 per 100,000population[5] and all other assumptionsof the baseline survey) was 22,300 adults.

Study procedures

Mapping and listing of households

All the households in Saharia villages/hamlets were mapped and numbered. A house-to-house census was carried out in all the villages and all individuals in the household were registered. Data on age, sex, and marital status were included in the register. A unique identification number (ID) was generated for all the registered individuals. **Sampling and strategies adopted for baseline and endlineTB prevalence surveys**

A baseline survey to estimate the prevalence of TB in Saharia population was carried out during January to May 2019 in 144 selected villages from all the seven districts. Endline TB prevalence survey was carried out in 128 selected villages in these districts at the end of the study using the same methodology (September- November 2021). The detailed methodology is given in earlier publication (Bhat J et al, Trans R Soc Trop Med Hyg. 2022;116(6):564-570).. Briefly the estimated sample size was proportionally distributed to the Saharia population in each district and then blocks. Villages were selected by PPS sampling technique, and within a selected village, all households belonging to Saharia tribe were included in the survey. In the household, all eligible individuals ≥15 years of age were screened for the symptoms of TB. Individuals who were not residing in the household, refused to participate, or not willing to give written consent were excluded from the study. The information was collected on a pre-coded and pre-tested individual questionnaire. All registered individuals were asked about the symptoms of pulmonary TB including cough for two weeks or more, chest pain for one month or more, fever for one month or more, haemoptysis in six months. A person with any one of the symptoms was considered as a presumptive pulmonary TB case and individuals with a history of previous anti-tubercular treatment were considered eligible for sputum collection. Two sputum specimens; one spot and one overnight were collected from them in sterile containers. The specimens collected from the participants were sent to the laboratory at ICMR–NIRTH in cold conditions. In the laboratory the specimens were treated by the standard NALC NaOH method and inoculated on

Lowenstein-Jensen (LJ) medium. The media were observed for the growth of *M.tuberculosis*weekly for eight weeks. The growth was confirmed using a rapid diagnostic kit (SD Bioline, Republic of Korea). Following the NTEP guideline and algorithm, the positive specimens were further subjected to drug susceptibility testing.

Case definition and treatment: An individual was labeled as a case of pulmonary TB if any one sputum specimen tested positive by microscopy/molecular testing and/or culture examination. All the detected cases were linked to NTEP for anti–TB treatment.

Intervention

In addition to NTEP regular activities we provided the intervention package to improve TB case finding and treatment outcomes in the study area. This intervention package mainly focused on improving access and utilization of TB services in Saharia tribal population. The components of the intervention package were as follows-.

1. Village TB Volunteer: One Village TB Volunteer per 1000 population was selected from the same locality, preferably from the same community. They were initially given one-week orientation and then periodically re-oriented for symptom screening of individuals and different aspects of NTEP.
2. Mapping and strengthening of health facilities: All government health facilities were mapped, especially TB laboratory and X-ray diagnosis facilities. All the districts had one CBNAAT (Gene Xpert) facility at district headquarter. Additional facilities for molecular diagnosis were established in two districts. The Gene Xpert facility in these districts was also strengthened by posting additional laboratory technicians.
3. Training and capacity building of NTEP and project staff: Periodically, training and capacity building workshops for NTEP block and district level staff and project staff were organized to orient and reorient them on symptoms and screening, sputum collection and quality testing, DOT and TB treatment, and patient counseling. Separate training sessions were organized for local traditional healers, ASHA, *Anganwadi* Workers (AWWs), and other community representatives to orient them about the TB situation in the area, study objectives and *modus operandi* of the study.
4. Sensitization and involvement of Panchayati Raj Institutions (PRIs): The elected heads and members of local PRIs at district (Zila Panchayat), administrative blocks (Kshetra

Panchayat), and village (Gram Panchayat) were also involved in the study. These members motivated the community to participate in the project activities.

5. TB case detection and treatment: Throughout the study period, monthly house-to-house visits were performed by the village TB volunteers to identify TB presumptive cases. The visits were performed in the early morning/ evening to ensure availability of the participants. All available individuals were questioned for symptoms relating to TB. If the individuals were not available on the first instance, the volunteer visited again at a convenient time for three consecutive days.Two sputum samples (spot and overnight) were taken from the patients revealing TB symptoms, and were sent to the closest TrueNAT or NTEP Gene Xpert lab. The results were communicated to the individuals by Village TB Volunteer. Chest X-rays were done in microbiologically negative individuals having persistent symptoms.
6. Case notification, treatment initiation, and follow-up: Notification of TB cases, treatment initiation, and follow-up were doneas per NTEP guidelines by the project and NTEP supervisors. All presumptive cases were registered on the NIKSHAY portal with the help of NTEP staff. The project staff visited each TB case to persuade them to initiate treatment promptly as possible and to comply with it All the non-respondents were personally visited by the supervisors to convince them ofearly diagnosis and treatment.
7. Advocacy, communication, and social mobilization (ACSM): VariousACSMactivities were periodically carried out in the study villages with the help of village volunteers, schools, and community-based organizations (CBOs). Awareness lectures and video clips were used to create awareness among schools and quizzes were also organized in schools. Students from these schools were also involved in carrying out rallies in nearby villages. Health camps were organized in local markets (*haat bazaars*) to create awareness about the symptoms of TB, available diagnosis, and treatment facilities. Public gatherings at the religious programme (*Bhajan/Kirtan/Pravachan* - reading of religious scripture, chanting of mantras) were also addressed through TB messages by religious leaders, and TB pamphlets/flyers were distributed. Successfully cured TB individuals were also involved as a messenger (*TB-doot*) in these ACSM activities and their success stories were used as a tool to motivate individuals to come forward for screening and completion of treatment.
8. Contact Screening: All household contacts were screened for symptoms of TB by village volunteers and project staff. Isoniazid preventive therapy (IPT) forchildren was

also provided with the help of district health authorities. Sputum was collected from symptomatic individuals for molecular testing. All individuals with negative results were followed-up periodically by Village TB Volunteers and project staff.

Data management and Analyses

A centralized data management unit (central unit) was established at ICMR-NIRTH, Jabalpur. All completed forms (symptomatic& patients) and laboratory reports were scrutinizedand checked at the block/district level by field staff before sending it to ICMR-NIRTH for data entry. The data entry operators entered data in a pre-designed and pre-tested data entry software developed on CSPro 7.0 platform. The TB prevalence was calculated as TB cases tested positive by microscopy/molecular testing and/or culture per 100,000 screened population. In case of multiple testing by microscopic examination, culture, and CBNAAT, a positive case was counted once only. Extended Mantel Haenszel Chi Square for linear trend with p-value at one degree of freedom was used to study the trend in the decline in TB positivity during intervention period.The z-test was used to measure the differences in disease between the two disease surveys. Statistical software IBM SPSS-26.0 was used for carrying out different statistical analyses.