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A Prospective Study on Implementation of Long Term Follow-up of Cured Tuberculosis Patients and Barriers Faced by Health Care Workers at Ahmedabad City, Gujarat: A Mixed Method Approach

Tejas Shah [1], Venu Shah [2] *, Viral Dave [2]

1. Department of Health, Ahmedabad Municipal Corporation, Ahmedabad, Gujarat, India
2. Department of Community Medicine, Gujarat Cancer Society Medical College, Ahmedabad, Gujarat, India

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Corresponding Author:
Venu Shah
drvenushah@gmail.com

ABSTRACT

Background: Tuberculosis (TB) remains a major public health challenge in India. Efforts outlined in the National Strategic Plan (2017-2025) are committed to achieve targets towards eliminating TB. Early identification of recurrence among cured TB cases is a crucial strategy towards this goal. However, there are limited data on the implementation of long-term follow-up for cured cases.

Methods: A prospective mixed-method study was conducted to evaluate the implementation of long-term follow-up strategy among 180 cured TB patients. Quantitative assessment involved tracking follow-up visits at 6, 12, 18, and 24 months post-treatment success. Moreover, Focus Group Discussions (FGDs) with 46 TB Health Visitors (TB HVs) were conducted to identify barriers to the implementation of long-term follow-up strategies for cured TB cases.

Results: Quantitative analysis revealed a decline in follow-up visits over time, and only 16.89% of patients were followed up by TB HVs during fourth visit at 24 months post-treatment. Recurrent TB was identified in 22 cases, 13.7% of which were not followed up by health workers. Qualitative analysis highlighted patient-related factors like loss to follow-up due to migration and denial of sputum testing. Health workers cited workload issues and inadequate financial incentives as barriers to implementation.

Conclusion: The study underscores challenges in implementing long-term follow-up strategies for cured TB patients in India. Addressing barriers such as loss to follow-up and workload issues among health workers is crucial for improving recurrence detection and management. Efforts to enhance program effectiveness must prioritize overcoming these barriers to achieve the goal of TB elimination by 2025.

Keywords: Evaluation**,** Follow-up**,** Recurrence, Tuberculosis, Health worker, Mixed method research

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Introduction

Tuberculosis (TB) remains a major public health problem in many countries, including India (1). The Government of India has committed to achieving the Sustainable Developmental Goal of eliminating TB in the country by 2025, five years ahead of the Global Target. To support this mission and accelerate progress, the program has been renamed from the Revised National TB Control Program (RNTCP) to the National TB Elimination Program (NTEP). This change reflects the renewed focus on completely eliminating the disease (3).

In 2022, an estimated 10.6 million people developed TB globally, with an incidence rate of 133 cases per 100,000 people. The majority of cases were reported in the WHO regions of South-East Asia (46%), Africa (23%), and the Western Pacific (18%), and smaller shares in the Eastern Mediterranean (8.1%), the Americas (3.1%), and Europe (2.2%) (4). According to the WHO Global TB Report in 2023, the incidence arte of TB in India in 2021 was 210 per lakh of population, compared to 2015 when the incidence rate was 256 per lakh population (4). Under NTEP, infection prevention and control measures are identified as a critical strategy for eliminating TB (5). Based on programmatic guidelines, health workers are required to conduct follow-ups for all cured TB cases at the end of 6, 12, 18, and 24 months post-treatment completion (6). In the presence of clinical symptoms and/or a cough, sputum microscopy and/or culture should be performed to detect TB recurrence as soon as possible. Recurrence of TB is defined as the occurrence of active TB in a patient who has completed at least six months of anti-TB treatment and had a negative smear or sputum culture at the end of treatment, but later develops active TB again after initially being successfully treated (7).

Several studies have been conducted in countries including India focused on the early identification of TB recurrence through long-term follow-up of successfully treated TB cases (8-10). Despite an extensive literature search, there is a scarcity of data regarding the status of implementing long-term follow-up strategies in successfully treated TB cases in India. This gap underscores the need for further research and documentation to better understand the effectiveness and challenges of such follow-up programs. The current prospective study was conducted using mixed method approach for assessing the implementation status of long-term follow-up of cured TB cases along with identifying barriers associated with its implementation.

Objective

3. To assess the implementation of a two-year post-treatment follow-up among cured TB patients.
4. To identify the perceived barriers in implementation of a two-year post-treatment follow-up using focus group discussion (FGD) with TB Health visitors (TB HVs).

Methods

This prospective study was conducted to assess the implementation of long term follow-up among cured TB patients. The mixed method approach was used to assess long term follow-up of total 180 cured TB patients. FGD method was used to identify the barriers of implementing a two-year post-treatment follow-up, in which total 46 health workers were participated. Sample size for quantitative aspect was calculated using formula 4 pq/l^2. Considering the recurrence rate of TB as 10% with 5% margin of error, within 95% confidence limits, sample size was calculated to be 139 (11). With an expected response rate of 75%, adjusted sample size was 174, which was rounded up to 180. The TB unit is a sub-district level supervisory unit based on the NTEP. It is the nodal point for TB elimination activities. There are a total of 23 TB units in Ahmedabad Municipal Corporation (12), 12 TB Units of which were randomly selected for the study. Fifteen TB cases declared as cured during July-September 2021 were randomly selected from each TB unit. Selected cases were followed up for two years. For conducting FGD, two TB HVs from

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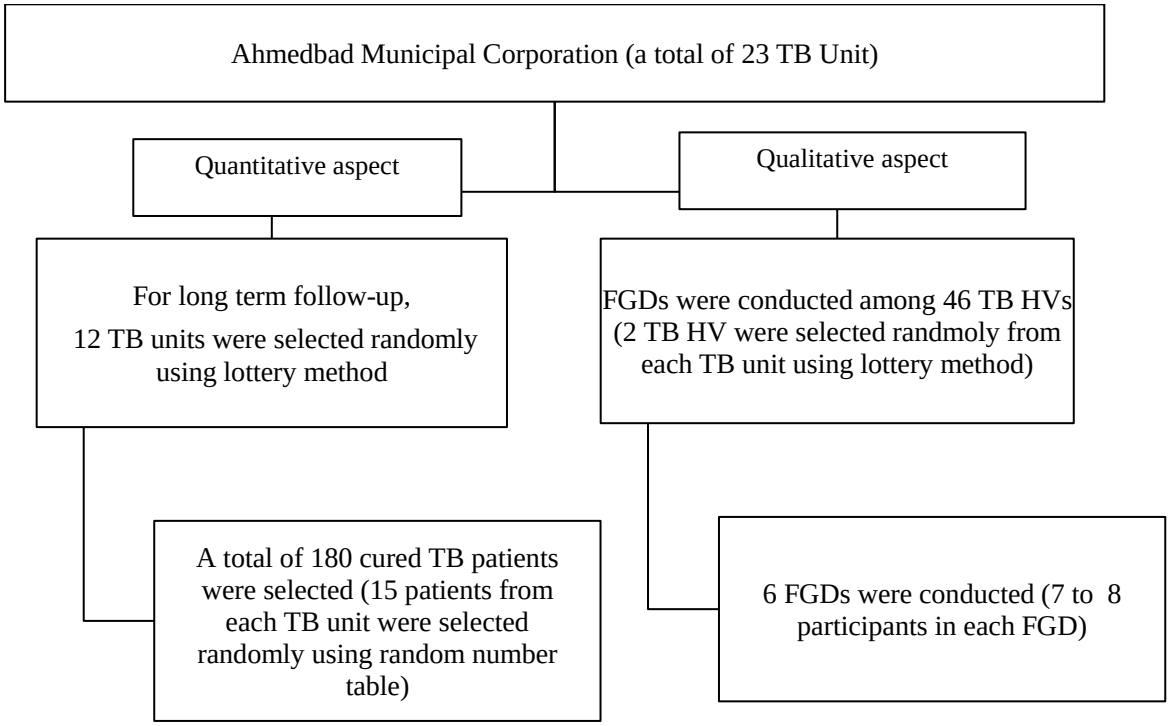
each 23 TUs were selected randomly. A total of 6 FGDs were conducted including 7 to 8 participants in each FGD. Flow diagram for sample selection is given in Box 1.



Box 1. Sampling frame of study participants

Study Methodology

After obtaining ethical approval from institutional ethics committee, data collection was initiated. Pre designed questionnaire was used for data collection. Piloting was done at one of the TB units and questionnaire was validated. Data collection was carried out by a team of faculties, medical residents, and medical social workers of Community Medicine Department who were given prior training. Written informed consent of each patient was taken during the first visit. In case of paediatric patients, consent of their guardian was taken.

According to the programmatic guidelines, four follow-up visits have to be carried out by health workers once the patient is declared cured (6 month, 12 months, 18 months, and 24 months) (6). Therefore, to assess long term follow-up status, investigators have conducted interviews with patients at the end of 7, 13, 19 and 25 months post-treatment success. Lists of treated patients during July, August, and September 2021 were procured from the District TB Office, AMC. Fifteen patients from each TB unit were randomly selected from the list using random number table.

Inclusion criteria

Any case of pulmonary TB treated according to the NTEP guidelines was included in the study.

Exclusion criteria

- Participants not willing to give consent,
- Treated TB cases not traceable either due to migration or change in contact details,
- Patients found to have recurrence during any of the visit were excluded from subsequent visits.

Case definitions *(2)*

1. Pulmonary TB (Pulmonary TB): Pulmonary TB refers to TB that involves the lung parenchyma. Patients with pulmonary TB can be categorized as follows.

- Bacteriologically confirmed: A case of TB in which at least one biological specimen is positive

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for Mycobacterium TB by smear microscopy, culture, or molecular methods.

• Clinically diagnosed: A case of TB in which no bacteriological confirmation is available, but a clinician has diagnosed TB based on clinical symptoms, radiological findings, or other supportive evidence, and the patient has been prescribed a full course of anti-TB treatment.

2. Recurrent TB: Recurrent TB, also called post-treatment TB, occurs when a patient who was previously treated for TB and declared as "treatment success" or "cured" develops active TB again. Recurrent TB may result from relapse (reactivation of the original infection) or reinfection (new infection with a different strain of Mycobacterium TB).

3. Relapse TB: Relapse TB refers specifically to the recurrence of TB in a patient who was previously declared as "cured" or having completed anti-TB treatment, and developed bacteriologically or clinically confirmed TB again. Relapse TB is considered a form of recurrent TB but explicitly linked to the reactivation of the initial infection rather than a new infection.

4. Cured TB case: A patient with bacteriologically confirmed TB who treated by fulfilling the following criteria.

• Completed a full course of anti-TB treatment based on the prescribed regimen and had a negative sputum smear or culture in the last month of treatment and on at least one previous occasion.

Data entry and analysis

Data entry was done in Microsoft Excel and data analysis was carried out using Jamovi software version 2.3.28, an open-source statistical platform designed for comprehensive analysis. Quantitative data were analyzed using frequency and percentages whereas thematic content analysis was carried out for qualitative aspects by the interviewers.

Results

A total of 180 patients were interviewed during first visit. Patients who developed recurrence or who were lost to follow-up were excluded from subsequent visits. Therefore, number of patients interviewed during the second, third, and fourth visits were 173, 160 and 148, respectively. Implementation status by health care workers is given in Table 1.

Table 1. Implementation status of long term follow-up of cured TB cases by health workers (N = 180)

Follow-up visits	Long term follow-up conducted by Health workers	
	Yes N (%)	No N (%)
First (N = 180)	127 (70.55)	53 (29.45)
Second (N = 173)*	94 (54.33)	79 (45.64)
Third (N = 160)*	57 (35.62)	103 (64.38)
Fourth (N = 148)*	25 (16.89)	123 (83.11)

*A total of 12 patients lost their life during entire follow-up period at different time intervals. Around 22 (13.8%) and 39 (26.3%) patients were lost to follow-up during third and fourth follow-up, respectively.

It was noticed that maximum number of follow-up visits (70.55%) were carried out by health workers at 6 months post-treatment completion, i.e. first follow-up. Only 16.89 % of patients were followed up by health workers at 24 completed months (Table 1). Twenty two cases were found to have recurrent TB during all the follow-up visits. Maximum number of recurrent cases (54.5%) was identified during 6 to 12 months post-treatment period (Figure 1).

Out of 22 cases in which recurrence was found, 3 (13.7%) cases were not followed up by health workers. These three patients referred health centers as they developed the symptoms (Table 2). Rests of the cases were identified by health workers during their follow-up visits.

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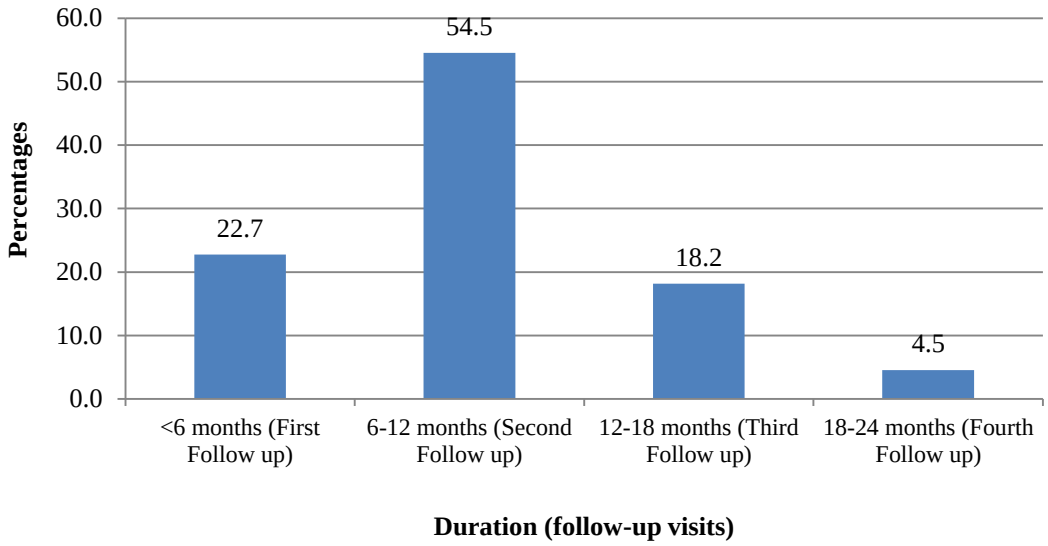

Figure 1. Recurrence TB cases identified during each follow-up visits (N = 22)

Table 2. Implementation of "long-term follow-up visit policy" by health care workers based on the duration of recurrence (N = 22)

Duration of development of Recurrence post-treatment completion	Implementation of "long-term follow-up visit policy" Yes N (%)	No N (%)	Total
< 6 months	5 (100)	0	5
6-12 months	10 (83.3)	2 (16.7)	12
12-18 months	3 (75)	1 (25)	4
18-24 months	1 (100)	0	1
Total	19 (86.3)	3 (13.7)	22

Focused group discussion was carried out among health workers involved in long term follow-up visits of cured cases. Based on the thematic analysis, themes pertaining to perception of health workers involved in implementation of long term follow-up strategies were identified. One of the themes was obstacles encountered from successfully treated TB patients that impede the execution of long-term follow-up (Table 3) and issues experienced by healthcare workers themselves that affect their ability to carry out long-term follow-up (Table 4).

Loss to follow-up due to changes in contact details and patient denial for sputum testing were the most common issues for beneficiaries, whereas overburdening with many tasks and monetary issues were perceived by health care workers in implementing long term follow-up visits.

Table 3. Findings from FGDs regarding health workers' perspectives on patient-related factors influencing long-term follow-up

Sub-theme	Patients related factors influencing long term follow-up
Loss to follow-up	There is an issue of migration of patient or change in address/contact details of the patient (46 years, male) Change in mobile number of patient or relative whose mobile number was given at the time of registration (38 years, male) Patients block our number when we call them frequently for follow-up (34 years, female)

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Sub-theme	Patients related factors influencing long term follow-up
Denial of sputum testing by patients	Patients deny for sputum testing, saying they are better now so there is no need for the same (51 years, male) Patients do not give sputum sample as they were afraid if sample comes positive they need to take treatment again for 6 months (28 years, female) Patients who are working or doing job, they do not have time to visit the facility for sputum testing (34 years, female) Repeated home visit after treatment of a patient raise the issue of stigma among them specially from their neighbors (40 years, male)

Table 4. Barriers in implementation of long term follow-up perceived by health workers

Sub-theme	Issues perceived by healthcare workers
Work load related issues	'We are all over burden with many tasks, so cannot complete all follow-up visits' (36 years, male) 'We have to focus on treatment of current TB patients, so we get less time to conduct follow-up visits of cured cases' (45 years, male) 'If patients have problems, they will refer to the health center for checkup on their own' (29 years, female)
Monetary issues	'Salary provided to us is very low. We should be paid as per our work load' (38 years, male) 'We do not receive get travel allowance or any incentive for follow-up of cured TB cases' (28 years, male)

Discussion

The study presents a comprehensive analysis of the implementation of long-term follow-up visits for cured TB cases by health workers, shedding light on various challenges pertaining to patients and the healthcare system.

The current study reveals a concerning trend in the decline of follow-up visits over time, with a substantial drop observed from the first visit (70.55%) to subsequent visits (16.89% at the fourth visit). This decline raises questions about the sustainability and consistency of follow-up efforts, potentially impacting the detection and management of recurrent TB cases. Moreover, the identification of recurrent TB cases predominantly during the second visit (54.5%) suggests the critical importance of regular follow-up in detecting and addressing disease resurgence. Youn et al. (13), in their study, mentioned that the majority of recurrence cases (89%) occurred within the first 2-year period. The current study noted the development of recurrence in five (3.2%) cases during follow-up visits carried out within 12-24 months of completed treatment. Therefore, it is very important to carry out the follow-up of cured cases for at least a two-year post-treatment.

Early detection of recurrence is paramount for prompt intervention and preventing further transmission, emphasizing the need for sustained follow-up efforts beyond the initial treatment phase. Mathur et al. (8) reported that long-term follow-up of treated and new smear-positive TB cases reinforces the effectiveness of anti-TB treatment based on the RNTCP assessed by improved health outcomes in more than two-thirds of cases.

In the current study, around 61 (33.8%) patients were lost to follow-up during third and fourth follow-up visits either due to changes in address or contact numbers. Similar findings were noted by the study conducted by Varma et al. (14). The study also highlighted significant patient-related factors contributing to loss to follow-up, including migration and changes in contact details. These issues underscore the importance of patient education, community engagement, and innovative strategies to overcome barriers to follow-up, such as utilizing alternative communication methods. Qualitative assessment on implementation challenges in conducting long term follow-up visits was carried out in the study. Based on the thematic analysis, most of health workers perceived

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workload-related challenges as a prominent obstacle hindering effective follow-up of cured TB cases. Overburdened healthcare systems may struggle to allocate sufficient resources and time for comprehensive follow-up, particularly among competing priorities. Financial constraints, including low salaries and lack of incentives for follow-up activities, further exacerbate the challenges faced by healthcare workers, potentially compromising the quality and continuity of care. Patients' related factors affecting effective implementation were loss to follow-up due to changes in contact details and patients' reluctance to undergo sputum testing due to fear of reinfection and a perceived lack of necessity. These issues require improved communication and counseling strategies.

The study findings underscored the need for multifaceted interventions to enhance the implementation of long-term follow-up visits for cured TB cases. Strengthening healthcare infrastructure, improving healthcare worker capacity and motivation through better remuneration and incentives, and implementing patient-centered approaches are crucial steps toward addressing the identified barriers.

Conclusion

The study noted successful implementation of long-term follow-up for cured TB cases during the first year post-treatment period, with the majority of patients being contacted by workers during the initial two follow-up visits, occurring at 6 and 12 months post-treatment. As most of the recurrent cases occurred within one year post-treatment, they were effectively identified by health workers during their follow-up visits. However, ensuring appropriate follow-up visits throughout the second year is essential to effectively implement the long-term follow-up strategy.

The study provides valuable insights into the complexities of long-term follow-up for cured TB cases, highlighting both patient-related challenges and healthcare system constraints. Addressing these challenges requires a holistic approach, encompassing policy reforms, resource mobilization, and community engagement to ensure sustained follow-up and effective TB control strategies.

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Conflict of Interest

No conflict of interest is declared.

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Ethical considerations

Permission from Institutional Ethics Committee was sought prior to data collection. Written informed consent was obtained from each participant, with guardian consent sought for paediatric patients.

Code of Ethics

GCSMC/EC/Research Project/APPROVE/2021/319

Author Contributions

Conceptualization, T. S, V. S, V. D; Data Curation, V. S; Formal Analysis, V. S, V. D; Investigation, V. S; Methodology, V. S, V. D; Supervision, V. S, T. S, V. D; Writing - Original Draft, T. S, V. D, V. S; Review Editing, V. S, T. S, V. D.

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