A mixed methods evaluation of a differentiated care model piloted for TB care in south India

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Abstract

Background: India's National TB Elimination Program emphasizes patient-centered care to improve TB treatment outcomes. We describe the lessons learned from the implementation of a differentiated care model for TB care among individuals diagnosed with active TB.

Design and methods: Used mixed methods to pilot the Differentiated Care Model. Community health workers (CHWs) conducted a risk and needs assessment among individuals who were recently began TB treatment. Individuals identified with specific factors that are associated with poor treatment adherence were provided education, counseling, and linked to treatment and support services. Examined changes in TB treatment outcomes between the two cohorts of individuals on TB treatment before and after the intervention. We used qualitative research methods to explore the experiences of patients, family members, and front-line TB workers with the implementation of the DCM pilot.

Results: The CHWs were adept at the identification of individuals with risks to non-adherence. However, only a few provided differentiated care, as envisioned. There was no significant change in the TB treatment outcomes between the two cohorts of patients examined. CHWs' ability to provide differentiated care on a scale was limited by the short duration of implementation, their inadequate skills to manage co-morbidities, and the suboptimal support at the field level.

Conclusions: It is feasible for a cadre of well-trained front-line workers, mentored and supported by counselors and doctors, to provide differentiated care to those at risk for unfavorable TB treatment outcomes. However, differentiated care must be implemented on a scale for a duration that allows a change from the conventional practice of front-line workers, in order to influence the outcomes of population-level TB treatment.

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Introduction

India, with more than 2.9 million people with active tuberculosis (TB), accounts for 28% of the estimated global burden of 10.6 million TB cases.[1] The National TB Elimination Program (NTEP), under its National Strategic Plan (2017–2025), set the goal of eliminating TB as a public health problem in India by 2025.[2] The central pillar of the World Health Organization's post-2015 End TB strategy highlighted the importance of "patient-centered care" for all people with TB.[3] The patient-centered approach includes free diagnosis, treatment, follow-up care, and "direct benefit transfer (DBT)" of Rupees 500 per month for all patients while on treatment.[4] TB Health Visitors (TBHV) or public sector front-line TB workers, and integrated digital adherence technologies have been introduced in the NTEP to support treatment adherence.[5] Despite these efforts, the TB treatment cascades constructed for India and South Africa estimate that only 43% and 53% of the estimated 2013 TB burden complete treatment successfully.[6] Several studies have identified the reasons for nonadherence to treatment, namely lack of personalized attention and support in health facilities, poor interpersonal communication with health personnel, failure of public sector TB services to adequately prevent and manage side effects of TB medication, patients and family members who equate symptom reduction with cure of TB, the long distances patients have to travel to clinics, and the lack of attention to daily socioeconomic constraints of patients.[7–10]

Earlier, we have described certain categories of individuals living with TB who were identified to be at a higher risk of not achieving favorable treatment outcomes.[11] These categories include active TB individuals with coexisting morbidities such as HIV and diabetes, drug-resistant forms (DR-TB), previous treatment history, regular alcohol consumption, underweight at the beginning of treatment, elderly individuals (>60 years), and those living alone. Others have also described similar factors.[12–14]

Patient-centered approaches that incorporate the clinical and psychosocial needs of patients and provide care through compassion and dignity remain elusive in India.[15] Despite the evidence that family support and counseling improve treatment outcomes, the role of the family in ensuring patient treatment success has received little attention within TB programs.[16] To improve favorable TB treatment outcomes in India, the Karnataka Health Promotion Trust (KHPT) led Tuberculosis Health Action Learning Initiative (THALI) project funded by USAID, conceptualized, and piloted a Differentiated Care Model (DCM). The model aimed to achieve favorable treatment completion by addressing the unique, yet diverse needs of patients with high risks of non-adherence to TB treatment. The KHPT team developed a framework for service delivery that focused on patients and their families in their community contexts. The trained Community Health Workers (CHWs) used a risk and needs assessment tool (RANA) to first identify people with active tuberculosis who have risks for an unfavorable treatment outcome. They were expected to subsequently provide differentiated care, subject to the individual's consent. CHWs intensively followed-up individuals living with TB in their homes or at other convenient venues, provided individuals and families with TB information and counseling services, and facilitated access to social protection schemes and TB follow-up services. In this paper, we seek to understand the feasibility and effect of this differentiated care model on TB treatment outcomes among active TB patients. We also used both qualitative and quantitative methods to examine the enablers and barriers that CHWs faced while implementing this new approach.

Methods

Study setting

The study setting included 14 districts in Karnataka and six districts in Telangana state in south India.

Study design

We used a quasi-experimental design, comparing treatment outcomes of 2-month cohorts of individuals living with TB, before and after the intervention. The cohorts of people living with TB were drawn from recently diagnosed and registered individuals with TB residing within the project areas. For operational feasibility, the qualitative study was limited to three districts Bengaluru and Koppal in Karnataka state and Hyderabad district in Telangana state. The qualitative study included in-depth interviews (IDI) with individuals living with TB and family members, TBHV and CHWs.

Study tools

The project team developed two tools in consultation with state TB officials and field staff; one for the assessment of patient risk and needs (RANA) and the second, a patient care and support card (PCS) that documented the information collected on follow-up visits and services offered. The RANA and PCS details are provided in a Supplemental Appendix. The DCM field level pilot was initiated in February 2019.

Study procedure

We merged data from the RANA and PCS cards, deidentified, and analyzed two cohorts of individuals with TB. The pre-intervention group consisted of the first cohort who began treatment in September–October 2018, and the post-intervention group comprised the second cohort who started treatment in February-March 2019 for quantitative analysis. We used IDI guides, developed separately for

each category, for the qualitative interviews. We conducted the qualitative study between October 2019 and March 2020, approximately 6–9 months after the initiation of the DCM field-level implementation. Separately trained field investigators conducted the face-to-face IDIs that were audio-recorded after obtaining written consent from all participants. Field investigators used probes to gather information on patients' knowledge and attitude to TB, barriers to TB treatment adherence, experiences and methods of coping with stigma and discrimination, and the nature of support received from family and community. They also interviewed the front-line workers including project-level CHWs and public sector TBHV.

Respondents for the in-depth interviews were purposively sampled from each of the three sites to ensure that at least one patient from each of the seven categories of the DCM, described in the introduction, was interviewed. Field researchers also interviewed four CHWs and four TBHV from the three sites. We transcribed and translated the data collected through in-depth interviews to English, reviewed data for accuracy and completeness, and imported the validated data to Nvivo 11.

Data analysis

We examined two outcome indicators, namely, the "death" and "unfavorable" outcomes that included death, failure or lost to follow-up (LFU), as defined by the NTEP. We estimate the extent of the difference in these two outcomes between the two cohorts of patients. To explore the changes in outcomes between the two cohorts of patients, we applied a univariate logistic regression model according to various risk categorization. We used only the univariate logistic regression model because there were no significant changes in the outcome variables between the two patient cohorts for any of the risk factors, and therefore we did not attempt a multivariate analysis.

We used qualitative analysis to examine the extent to which CHWs were able to implement the differentiated care model. We analyzed data thematically and coded data recursively to include initial themes from interview guides, as well as incorporate emergent themes from the subsequent analysis, until thematic saturation was achieved.

Ethical approval

The Institutional Ethics Committee of St John's Medical College and Hospital, Bengaluru, and the State TB office in the two states provided ethics and regulatory approvals for the study.

Results

The total number of individuals living with TB registered in the pilot was 2296 and 1947 in the pre-intervention and post-intervention cohorts. The proportion classified with some risk for an unfavorable treatment outcome increased from 46% in the pre-intervention cohort to 63% in the post-intervention cohort (Table 1). This increase in the post-intervention cohort was contributed by increased proportions of TB individuals with diabetes (8%–17%), co-existing HIV infection (2%–4%), and who regularly consumed alcohol (14%–25%). Similarly, the proportion of those with a single risk (32%–42%) and with more than one risk (14%–21%) also increased between the cohorts examined.

Treatment outcomes were available for 2228 (97%) and 1920 (99%) individual subjects in the "pre" and "post-intervention" cohorts, respectively (Table 2). About 94% of the subjects in the risk category had available treatment results, the exception being those with DR-TB (93%) and with more than one risk in the "pre-intervention" cohort. The treatment outcomes available were slightly higher in the second cohort for categories of elderly (95% vs 99%), DR-TB patients (93% vs 97%), HIV positive patients (94% vs 100%), and with more than one risk present (94% vs 99%).

We examined the difference in the outcomes across the two cohorts according to different risk categories (Table 3). Case fatality rates reduced for most at-risk categories, including the elderly (8.2% vs 7.6%), previously treated individuals with TB (5.9% vs 5.1%), individuals with DR-TB (13.2% vs 11.5%) and TB with diabetes (6.1% vs 4.6%). Similarly, we noticed small reductions in unfavorable outcomes for the at-risk categories including individuals previously treated for TB (13.4% vs 12.4%), individuals with DR-TB (22.4% vs 21.3%), and individuals with TB-HIV (15.7% vs 11.3%). Among individuals with TB who had more than one risk present, case fatality rates reduced from 7.2% to 6.5% and unfavorable outcomes from 15.1% to 13.9%. However, none of these changes were statistically significant. Overall, the TB case fatality rates showed a marginal but insignificant increase between the two cohorts ("pre" 4.3; 95% CI: 3.4%−5.1% and "post" 4.8; 95% CI: 3.8%−5.8%). Similarly, the proportion with unfavorable treatment outcomes in the total population followed also increased marginally from 8.3% (95% CI: 7.2%−9.5%) for the "pre-intervention" cohorts to 9.8% (95% CI: 8.46%-11.12%) for the "post-intervention" cohort.

Among individuals living with TB, we qualitatively explored the influence of intensive in-person care. Often the patient's family members/caregivers would also respond. Individuals living with TB reported that CHWs played an important role in their treatment process. The CHWs had visited or telephonically communicated with them regularly. Visits ranged from once weekly to once a month. They reinforced the importance of adherence to TB treatment:

"They told me that if I stop taking tablets, I will get TB again. They used to speak to me for one hour or one and a half hours.

Table 1. Percentage distribution of TB patients according to cohorts of patients based on date of treatment initiation by selected risk characteristics.

Characteristics	TB treatment initiated on			
	September–October 2018		February–March 2019	
	Percent	Number of cases	Percent	Number of cases
Age				
Below 60	86.7	1991	83.7	1630
60 and above	13.3	305	16.3	317
Previously treated for TB				
No	81.0	1859	79.4	1546
Yes	19.0	437	20.6	401
DR-TB patient				
No	96.4	2214	96.8	1884
Yes	3.6	82	3.2	63
Living alone				
No	97.4	2236	98.4	1915
Yes	2.6	60	1.6	32
Diabetes Status				
No	92.0	2113	83.1	1618
Yes	8.0	183	16.9	329
HIV				
Negative	97.6	2242	95.9	1867
Positive	2.4	54	4.1	80
Drink alcohol				
No	86.0	1974	75.4	1469
Yes	14.0	322	24.6	478
Number of follow-up visits made				
<4	16.1	369	17.1	332
4–7	46.2	1060	38.8	756
8+	37.8	867	44.1	859
Number of risks present				
No risk	53.7	1233	37.0	720
Only one risk present	32.2	740	42.2	821
More than one risk present	14.1	323	20.9	406
Level of intervention exposure index (scale)				
Low	37.8	868	21.3	414
Medium	28.0	642	28.4	552
High	34.2	786	50.4	981
Initial weight (age 18 and above)				
Below median value	26.0	596	30.5	594
Median value or above	66.2	1519	67.4	1312
Unknown	7.9	181	2.1	41
Total	100.0	2296	100.0	1947

They even gave examples from patients of other localities. So after listening to them I continued the tablets." (Male; 35 years; Alcohol user, Koppal).

"My TB is fine now, I completed my course, and this [CHW] madam always reminded me to take medicines, so I never missed out" (Female, Elderly, Diabetic, previously TB treated; Hyderabad).

The CHWs explained the importance of a healthy and nutritious diet:

"She came, she gave information like 'eat like this, greens, grains, sprouts vegetables, eat everything you like, anything you need, ask us, I'll come to your house anytime'" (Male, 40 years; DR-TB, Bengaluru).

However, there were instances where the CHW was unable to influence lifestyle changes. Though CHWs ensured treatment adherence and consequent cure of TB for this individual, diabetes received scant attention, both for relevant dietary advice as well as assistance with access to affordable diabetes-related services:

Table 2. Percentage distribution of TB patients according to cohorts of patients based on date of treatment initiation, treatment outcome declared and selected risk characteristics.

Risk characteristics	Treatment outcome declared				% for whom treatment outcome is declared	
	September–October 2018		February–March 2019		September–October 2018	February–March 2019
	Percent	Number of cases	Percent	Number of cases	Percent	Percent
Age						
Below 60	86.9	1937	83.6	1605	97.3	98.5
60 and above	13.1	291	16.4	315	95.4	99.4
Previously treated for TB						
No	81.0	1804	79.4	1525	97.0	98.6
Yes	19.0	424	20.6	395	97.0	98.5
DR-TB patient						
No	96.6	2152	96.8	1859	97.2	98.7
Yes	3.4	76	3.2	61	92.7	96.8
Living alone						
No	97.4	2170	98.4	1889	97.0	98.6
Yes	2.6	58	1.6	31	96.7	96.9
Diabetes Status						
No	91.9	2047	83.0	1593	96.9	98.5
Yes	8.1	181	17.0	327	98.9	99.4
HIV						
Negative	97.7	2177	95.8	1840	97.1	98.6
Positive	2.3	51	4.2	80	94.4	100.0
Drink alcohol						
No	86.4	1924	75.4	1447	97.5	98.5
Yes	13.6	304	24.6	473	94.4	99.0
Number of follow-up visits made						
<4	16.0	357	17.1	328	96.7	98.8
4–7	46.3	1031	38.9	746	97.3	98.7
8+	37.7	840	44.1	846	96.9	98.5
Number of risks present						
No risk	53.9	1200	36.8	707	97.3	98.2
Only one risk present	32.5	723	42.2	810	97.7	98.7
More than one risk present	13.7	305	21.0	403	94.4	99.3
Level of intervention exposure index (scale)						
Low	38.3	853	21.5	412	98.3	99.5
Medium	28.0	623	28.2	542	97.0	98.2
High	33.8	752	50.3	966	95.7	98.5
Initial weight (age 18 and above)						
Below median value	25.9	576	30.3	582	96.6	98.0
Median value or above	66.3	1477	67.6	1297	97.2	98.9
Unknown	7.9	175	2.1	41	96.7	100.0
Total	100.0	2228	100.0	1920	97.0	98.6

"For sugar tablets, the doctor suggested that I should take some 4 varieties of tablets. It cost around 1000 rupees. Here we have a medical shop, we showed him (pharmacist) the report and we told him that we cannot pay 1000/month, what do we do? Then he chose only one sugar tablet and asked me to take it. For 12 years I have been taking the same tablet. I told this once (to the CHW), she said, just continue taking medicines" (Male, Elderly and diabetes; Koppal).

Similarly, a lack of information regarding the need to conduct follow-up tests was also reported, as indicated in the following instances.

"No, they did not do any tests after [first] treatment [. . .] we learned that she was cured because she was feeling better and we could also see that in her behavior" (mother of a woman patient, 32 years; DR-TB; Hyderabad).

Table 3. Percentage distribution of TB patients according to experienced death, experienced unfavorable outcome and odds ratio from the univariate binary logistic model indicating the changes in the outcomes by cohort and risk characteristics.

Risk characteristics	Experience death				Experienced unfavorable outcome			
	Sep–Oct 2018	Feb–Mar 2019	Unadjusted odds ratio (95% CI)	p-value	Sep–Oct 2018	Feb–Mar 2019	Unadjusted Odds Ratio (95% CI)	p-value
Age								
Below 60	3.7	4.3	1.18 (0.84–1.66)	0.336	7.7	9.2	1.21 (0.95–1.54)	0.117
60 and above	8.2	7.6	0.92 (0.51–1.65)	0.775	12.7	13.0	1.03 (0.64–1.65)	0.912
Previously treated for TB								
No	3.9	4.8	1.25 (0.89–1.74)	0.199	7.2	9.1	1.30 (1.01–1.67)	0.038
Yes	5.9	5.1	0.85 (0.46–1.56)	0.602	13.4	12.4	0.91 (0.61–1.37)	0.658
DR-TB patient								
No	3.9	4.6	1.18 (0.87–1.60)	0.291	7.9	9.4	1.22 (0.98–1.52)	0.079
Yes	13.2	11.5	0.86 (0.31–2.40)	0.767	22.4	21.3	0.94 (0.42–2.13)	0.882
Living alone								
No	4.3	4.8	1.12 (0.83–1.50)	0.464	8.2	9.6	1.19 (0.95–1.47)	0.123
Yes	3.4	9.7	3.00 (0.47–19.00)	0.243	13.8	22.6	1.82 (0.59–5.62)	0.296
Diabetes status								
No	4.1	4.9	1.20 (0.88–1.65)	0.250	8.4	10.0	1.21 (0.96–1.52)	0.101
Yes	6.1	4.6	0.74 (0.33–1.65)	0.467	7.7	8.9	1.16 (0.60–2.26)	0.660
HIV								
Negative	4.2	4.7	1.12 (0.83–1.52)	0.448	8.2	9.7	1.21 (0.97–1.50)	0.085
Positive	7.8	8.8	1.13 (0.31–4.06)	0.855	15.7	11.3	0.68 (0.24–1.90)	0.463
Drink alcohol								
No	4.0	4.4	1.11 (0.79–1.56)	0.560	7.6	8.6	1.13 (0.88–1.45)	0.326
Yes	6.3	6.3	1.02 (0.56–1.84)	0.959	12.8	13.5	1.06 (0.69–1.63)	0.778
Number of follow-up visits made								
<4	16.2	11.0	0.64 (0.41–0.99)	0.046	24.1	18.6	0.72 (0.50–1.04)	0.081
4–7	2.3	5.9	2.63 (1.58–4.36)	<0.001	5.6	11.5	2.19 (1.54–3.09)	0.000
8+	1.5	1.5	0.99 (0.46–2.15)	0.985	5.0	4.8	0.97 (0.62–1.50)	0.884
Number of risks present								
No risk	2.3	2.4	1.03 (0.56–1.90)	0.921	5.3	6.2	1.20 (0.81–1.78)	0.373
Only one risk present	6.2	6.2	0.99 (0.65–1.50)	0.967	10.7	10.9	1.02 (0.74–1.41)	0.893
More than one risk present	7.2	6.5	0.89 (0.49–1.60)	0.690	15.1	13.9	0.91 (0.60–1.39)	0.656
Level of intervention exposure index (scale)								
Low	5.7	5.6	0.97 (0.58–1.62)	0.907	10.4	11.9	1.16 (0.80–1.68)	0.436
Medium	4.8	6.5	1.36 (0.83–2.25)	0.225	8.8	11.3	1.31 (0.89–1.92)	0.169
High	2.1	3.6	1.73 (0.95–3.15)	0.073	5.6	8.1	1.48 (1.01–2.19)	0.046
Initial weight (age 18 and above)								
Below median value	5.4	7.6	1.44 (0.89–2.31)	0.134	11.1	15.1	1.43 (1.01–2.01)	0.044
Median value or above	3.2	3.5	1.09 (0.72–1.66)	0.673	6.4	7.2	1.14 (0.85–1.53)	0.395
Unknown	9.7	9.8	1.00 (0.32–3.16)	0.994	15.4	14.6	0.94 (0.36–2.45)	0.899
Total	4.3	4.8	1.14 (0.85–1.53)	0.371	8.3	9.8	1.19 (0.96–1.47)	0.106
Total cases	2228	1920			2228	1920		

The counseling efforts of a few CHWs aided in reducing alcohol consumption for a short duration, but the combined efforts of the CHW and the family members ensured that, despite the continued alcohol dependency, the patient consumed tablets correctly until treatment completion.

"They asked him to leave alcohol for life. [. . .] After he contracted TB, he left consuming alcohol for some three months [. . .] Still he takes the alcohol, but he has become better than before." (Uncle of the male patient; Alcohol user; Koppal).

Usually, if family members were themselves invested in the patient's health, the task of the CHW was easier to facilitate. A diabetic TB mother explained how the CHW would guide her son to take care of her:

"If I call [CHW] madam, she will tell my son 'go get her the injection.' . . . 'take care of your mother', this is (TB) dangerous, give her healthy food, give her something to eat in a timely manner, you should take care of her not only now but also in the future." (Female, 45 years; Diabetes; Bengaluru)

However, there were cases where the individual with TB did not have a primary caregiver or a strong available support network of this kind. In such instances, CHWs were reported to have minimal or no interaction with family, friends or neighbors.

Gender norms appeared to decide the extent to which interaction was possible between the patient and the CHW, and sometimes acted as a barrier to building a relationship:

"Sometimes I felt awkward, you never know what people will think and doubt. What is this, he (CHW) comes so often to my home, who is this man, so, people may start thinking bad things about me and wonder what the reason for it is. . .so I have told him that I will call him if I need the medicines or anything" (Female, 30 years; previously TB treated; Koppal).

Respondents spoke of their fear of sharing the news of their illness with relatives or neighbors due to the perceived threat of discrimination.

"Here people would not allow me to sit near their houses, not even near shops, they will ask me to get up and go. It is so humiliating and that is why I have completely stopped going out. What to do, to whom to tell all our feelings" (Male, 40 years; DR-TB; Bengaluru).

"No, we didn't tell anyone[. . .] even when somebody comes to ask about her (for the proposal to the marriage).. people in our area, if we tell them one thing, they will add something and say ten more things and spread rumors, that is why we have not told anyone [. . .] Even to these ASHA workers we have informed not to reveal this (TB) in front of others [. . .] now we are in a rented home, so if they get to know then they would not let us stay [. . .] They will doubt us, they say: you don't come because you have TB, we have children at home" (Female, 21 years; Diabetes; Koppal)

In certain instances, individuals with TB expressed that staff at health facilities also demonstrated a discriminatory attitude. At the same time, there were some examples of overcoming discrimination with the help of health workers, notably, in the case of this HIV-TB respondent from Koppal, who had consequently become a social worker herself. In her words:

"She took me to one office and there they said that they would give me a job as a community worker for HIV work. I faced a lot of emotional trauma, on one side I was carrying a baby, and no Mangalsutra (chain with black beads worn to signify married status) was there, so I face discrimination everywhere, including during fieldwork. During fieldwork, many said many bad words, but this madam [CHW] kept motivating me, she said I am no less, and I deserve a better life. Today I go around and talk to patients with TB and HIV. I am better now and somewhere I feel I can influence people" (Female, 35 years; HIV positive; Koppal)

In addition to the patient and family members' experiences, the qualitative study also explored the understanding of the frontline workers on the differentiated care approach. As described by a CHW, differentiated care includes counseling on treatment adherence and nutritional needs, with the primary objective of improving treatment outcome among high-risk groups.

The CHW's understanding of the specific risk categories for unfavorable treatment outcomes among TB patients was found to be adequate.

"When I joined, I did the same follow-up for all of them. Only once in a month follow up. As time passed by, I understood that some patients are more likely to stop taking their medicines. Because of being diabetic, already a lot of medicines need to be taken, Alcohol drinking; once drunk they then don't want medicines or anything else. . . . . Then the elderly; they may forget. They may not have any caretakers. . . they have poor memory. Previously treated; they are afraid of side effects. Earlier also they have stopped medication midway. . . MDR patients; we have a follow-up every 15 days, it is because they have many medicines. They are fed up with injections. . . . many are like. . . . 'This way or that way we will die. . . leave it (medication). Let us see what happens. So, we follow these patients every 15 days" (Male, CHW; Bengaluru).

CHWs see their role as providing counseling and raising awareness about TB treatment adherence for individuals with TB and their families.

"Counseling is very important. . . why is counseling needed?. . .the patients ask, 'Do we need to take so many tablets'? '(Why) should this disease happen to me only? No

one else got it'. . . when we speak to them, they get some acceptance of the situation." (Female, CHW; Bengaluru).

Apart from this, they provided information on diets, nutrition, testing, cleanliness, hygiene, and cash incentives during treatment.

However, CHWs lacked sufficient knowledge to manage patients who had comorbidities or who qualified for multiple risk categories. The CHWs were also under-equipped to deal with alcohol-dependent patients and commonly reported having difficulty in ensuring their treatment adherence:

"Now I go to (their)home, do some counseling, 'you shouldn't drink, I am not asking you to quit, but at least not to consume while on drugs(medication). When I say so 'ok madam' (they would reply). I would sit there for one hour and tell you it's a lot of trouble for your family. Your wife and children suffer. You will be fired from your job. No one will respect you. . . when told so. . . they (the patient) listen carefully and say 'Ok madam! Ok, madam!' Then after I leave. . .. in the evening, the wife would call and tell me 'he is drunk and sleeping. You were saying so much. Now what do we do? Will we be told a bit more about this, can something be done?" (Female, CHW; Bengaluru).

The CHWs also faced practical implementation challenges to counter the stigma and discrimination associated with TB among the patients.

"Door to door [visits], we don't do because patients don't feel comfortable to have us inside, for some it affects their family honor" (Female, CHW; Hyderabad).

A CHW encountered instances of stigma even within her own family when she informed them about having taken up the job that involved working with TB patients:

"Then I also discussed at home, that I have this kind of job. We come from a village. . . they say. . . Oh! This disease! No, no. . . we will also catch it . . . You can search for some other job, right?' I did not listen to them. I attended training, attended classes, participated in workshops, and learned that it does not attack us immediately. When I became aware I became more confident" (Female, CHW; Bengaluru).

Interviews with TBHVs revealed that they perceived their role as being a support to all individuals living with TB for all medical procedures such as TB diagnosis, testing, and counseling regarding treatment adherence as given below:

"Success rate is more important to us so, when we provide them the treatment they have to utilize it. .. they should get

cured and the disease should not spread, that is the more important thing that we inform the patient during counseling. We can't talk much about their personal things, but we can talk about the treatment and facilities that we provide here" (Male, TBHV; Bengaluru).

Differentiated care for the at-risk individuals thus appeared to remain outside the ambit of their responsibilities. They did note however that the presence of CHWs reduced their workload:

"CHWs were very supportive to us as they do follow-ups after we do the data-entry. I must spend my whole day in PHC sometimes looking after online work like HIV status and some such cases. So, I will take the CHW's help for follow-ups. I used to give the details to CHW then they used to visit patients to give feedback. They do their work well" (Male, TBHV; Bengaluru).

The limited involvement with the community in part seemed to be a result of limited manpower, which was cited as one of the challenges.

Discussion

We designed and piloted a differentiated care model, using CHWs to complement the work of public health sector TBHV. The model aimed to improve the outcomes of TB treatment among TB patients who are at increased risk of unfavorable outcomes. The results demonstrate that the differentiated care model is feasible for implementation by well-trained CHWs. Their knowledge and skills in identifying risk categories and providing them with follow-up care improved. While the pilot implementation showed some improvement in the case fatality rates and unfavorable outcomes for individuals with specifically identified risk factors, these changes were not statistically significant. There could be multiple reasons for this. Our qualitative research findings suggest that it does take time for CHWs to internalize and practice a differential approach. The duration of pilot implementation was short, and the evaluation was conducted shortly thereafter. Due to project closure, a phased withdrawal of CHWs began in May 2019 and was complete by October 2019. Perhaps a longer period of intervention and a scaled-up approach may have resulted in improved treatment outcomes at the population level. Our previous study found that frontline workers, such as CHWs, are effective and crucial in augmenting the cascade of care through the provision of information, adherence counseling, and psycho-social support to individuals and families living with TB.[17] The augmentation in the cascade was evident 18–24 months after the intervention. Furthermore, the number of patients available for analysis, particularly for risk categories, was not sufficient to detect statistical significance in the results, although we covered a large geographic area for the implementation of

the project. Finally, a higher proportion of individuals with risk characteristics were identified in the "post-intervention" cohort as compared to the "pre-intervention" cohort. In other words, the cohort of patients analyzed was not balanced in terms of risk characterization. The high proportion of individuals who were followed up and had their treatment outcomes documented is a positive indicator of improved program function and more complete reporting, which may have contributed to better TB treatment outcomes.

The qualitative component of this study revealed that CHWs knew how to provide individuals living with TB with standard information on TB, nutrition, and adherence to treatment. However, they lacked specific information and skills to manage those with comorbidities and to influence behavior change communication for alcohol-related behaviors. They were able to convince patients to accept their diagnosis and treatment of TB, but were unable to counteract TB related stigma and discrimination at the family and community level. Their ability to provide differentiated care was thus limited. Implementation challenges and resource constraints prevented the full implementation of the differentiated care pilot. Not all the CHWs were able to grasp and practice the intensive training package that they received, though few were more efficient, effective, and dedicated in the education, counseling, and facilitation of services for individuals with TB. The inability of the project to translate this efficiency of a few CHWs to scale could have contributed to the lack of desired change in population-level TB outcomes, especially in a context where individuals living with TB continue to regularly face discrimination within their families and occasionally from the health care facility staff. Initially, we conceptualized that the differentiated care model would be delivered by a three-tiered team of a CHW, a counselor, and a medical doctor. Unfortunately, counselors were not recruited and the two-project level medical doctors were inadequate to cover all at-risk patients.

Although CHWs and TBHVs broadly self-described their roles in helping people with their TB treatment process, their scope of work was conceptualized differently. Because of the large number of individuals with TB under their care, TBHV's time is spent on case notification, ensuring an uninterrupted supply of medicines and regular TB follow-up services, constraining their ability to focus on individual patient-centered education and counseling services. CHWs appear to be well placed to focus on patient-centered education and counseling services when backed up by counselors and doctors within the health care delivery system.

This study represents one of the first attempts to assess the impact of a community-level intervention for a differentiated TB care model at scale across two states and multiple districts. The mixed methods used provide valuable insights into what worked and what didn't, as well

as probable explanations for these outcomes. However, limitations of the study include its short duration of implementation, inadequate sample size to demonstrate significant impact, and the use of univariate binary regression instead of multivariate logistic regression.

Despite these limitations, there are program implications that this differentiated care pilot has demonstrated. CHWs can identify individuals at risk of unfavorable treatment outcomes. They can provide standard information on adherence to treatment and nutrition and leverage family support for those who lived with families. The proportion of individuals followed up until treatment outcome is declared was high, as indicated by reduced proportions of TB patients lost to follow-up. Future interventions can focus on addressing the inadequacies identified in this study. CHWs cannot independently find solutions for migrant workers who live without their families. CHW interventions in urban TB programs could explore migrant-specific strategies. A deeply internalized sense of stigma among people living with TB and their family members was a predominant factor that hindered effective communication of the CHW about treatment outcomes. Programs can assess, design, implement and evaluate how TB-related stigma can be identified and appropriately addressed at the individual, family, and community level.[18–21] Future programs can evaluate the cost-implications of the three-tiered team for the delivery of differentiated care.

National TB programs could benefit from ensuring that all individuals with TB are assessed for risks of poor treatment adherence and unfavorable outcomes, by integrating and scaling up differentiated care approaches. Since many of the variables that determine risk for an unfavorable outcome are captured in India's Nikshay (End TB patient-data platform), Artificial Intelligence or Machine Learning can be in-built to communicate to front-line workers, who need an intensive follow-up intervention package. Even within the existing health system, a cadre of front-line workers who supervise ASHA (Accredited Social Health Activist) could be trained to provide counseling and support to individuals and families living with TB. The community-level intervention should have strong links to health-facility services. This could play a role in improving TB treatment outcomes among vulnerable communities. India's Central TB Division recently released a guideline for differentiated care of individuals living with TB.[14] The guideline is focused on clinical protocols and could be complemented by enhancing the skills of a cadre of health workers to identify and manage patients who require this intensive support.

Conclusion

The differentiated care pilot was designed to provide specific care interventions to improve treatment outcomes among people living with TB at risk of poor treatment

outcomes. The pilot implementation demonstrated that these individuals within certain risk categories can be easily identified by a trained CHW, who is supported by the health system. However, for interventions to be successful, quality at scale is important. Rapid scaling, a longer duration of the intervention, and more intensive field mentoring on site may address some of the implementation gaps identified in this study.

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Author contributions

RW, KK, and PBS were involved in the designing of the differentiated care model. RW, RSP, KK, PBS, SR, AM, AP, and VP supported the development and finalization of the study tools. RSP, PBS, BKM, SR, AM, and AP trained the field staff. KK, VP, BKM, SR, AM, AP, and PBS coordinated and supervised the data collection and data entry. VP and HLM administratively supported the project and data collection. RSP did the statistical analysis and interpreted the results. SR, AM, and AP supported in the data analysis of qualitative data. RW and RSP wrote the first draft of the manuscript. SR, KK, PBS, RA, RCR, AS, RS, AM, AP, BKM, VP, and HLM offered comments on the draft and critically revised the manuscript. All authors read and approved the final manuscript.

Data availability

Some restrictions will apply with sharing the data. Data cannot be shared publicly without approval from the donor agency and the concerned NTEP office. The de-identified data used for the paper can be obtained from the corresponding author with permission from KHPT, the donor agency, and the concerned State TB officer.

Declaration of conflicting interests

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Supplemental material

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