“I lost my faith and stopped taking the medicines” – need for an intervention model based on health belief constructs for improving adherence to tuberculosis treatment

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Abstract

Background: India is reporting the highest number of tuberculosis (TB) cases worldwide. The health belief model has proved beneficial to understand health-related behaviors among patients with TB. We explored the reasons and solutions for non-adherence to the treatment of TB using the constructs of the health belief model. Methods: We conducted in-depth interviews among patients who were reported ‘lost to follow up’ (LFU) and among the service providers under the national TB program in the Patan district based on the constructs of the health belief model – perceived susceptibility, perceived severity, perceived benefits, and perceived barriers. All the interviews were audio-recorded and transcripts were analyzed using thematic analysis. Results: The analysis resulted in nine major reasons for LFU which were explained under the health belief model constructs. Perceived susceptibility was reflected by lack of support from health workers, losing faith in government, and dependence on alcohol. Negative counseling by quacks explained perceived severity, while improvement in symptoms corroborated with the perceived benefits. Side effects to anti-TB drugs, high pill burden, stigma, and financial constraints were the perceived barriers reported by the patients. Conclusions: The health belief model explains treatment non-adherence behavior among patients with tuberculosis in India. To eliminate TB, program managers in India need to design a comprehensive intervention model to counsel the patients on the benefits of completing treatment, generate awareness to dispel the myths surrounding the disease, and instill confidence through regular visits by health workers. Primary care physicians should try incorporating counselling of patients with TB in their routine care to reduce LFU.

Keywords: Constructivism paradigm, default, health behavior theory, lost to follow up, treatment outcome

Introduction

India reports the highest number of tuberculosis (TB) cases globally, nearly 1.5 million incident cases out of 5.8 million were reported in 2020.[1] Despite many efforts over the years, TB continues to be a major public health problem in India.[2] Relapse, treatment failure, loss to follow-up (LFU), and death are considered to be unfavorable treatment outcomes among...
patients with TB. Among these, LFU can be considered potentially preventable through focused efforts on the part of the program managers, primary care physicians, and front-line healthcare workers.

Existing evidence have reported several factors associated with LFU. Apart from lower socioeconomic status and HIV, alcoholism, drug use, side effect of drugs, lack of social support, and lack of counseling have been reported as important predictors. The importance of counselling through primary care providers has been adequately stressed upon for reducing LFU. Various theories have attempted to explain the patient behaviors of adherence to treatment among patients with TB and Human Immunodeficiency Virus (HIV). The health belief model has been successful in explaining the reasons for non-adherence to treatment for TB in various countries. There is, however, a paucity of literature for understanding the perspectives of LFU as construed in the HBM in the Indian context. This study explored the reasons and solutions associated with LFU among patients put on anti-TB treatment and program managers of the national TB program in Patan district (western part of India) through the constructs of the HBM.

Methods

Theoretical framework
This research was based on the conceptual framework described by the HBM. The HBM is based on the concept that health behavior is influenced by seriousness, susceptibility, benefits, and barriers as perceived by the individual. Although this concept was not explained to the patients with TB or the program managers, our interview tool was guided by the components of the HBM. The themes based on the health belief model only emerged at the time of thematic analysis.

Study setting and population
The study was conducted among program managers and adult patients with TB who were registered under the district TB office of Patan district and had lost to follow up (defaulted) from their treatment as defined in the national TB program. Lost to follow-up (LFU) was defined as “patients with TB who did not start treatment or whose treatment was interrupted for two consecutive months or more” and were previously called defaulters. The study was carried out in Patan district, located approximately 100 kilometers north of the capital city of Gandhinagar (Gujarat state in the western part of India). In the year 2019, 1858 patients were notified of TB in the public sector in the Patan district.

Study design
Our study, with a descriptive design, was conceptualized at a workshop organized by the State TB Cell Gandhinagar, who also funded the research. The theoretical underpinning used in the study was the constructivism philosophical paradigm, based on the idea that people understand and gain knowledge through experiencing events happening in their lives and by reflecting upon such experiences.

Data collection
The data were collected between January and June 2019 by the investigators themselves. All the authors are trained in qualitative research methods. We conducted in-depth interviews of 14 patients with TB who were reported as a loss to follow up under the program and that of the district TB officer of Patan district. Additionally, we conducted one FGD among the field staff working in the national TB program. The FGD was conducted in the first author’s department office where he works and was attended by 8 field staff. The FGD took nearly 30 min to complete (excluding the time for administering informed consent and briefing the group about the purpose of FGD). All the interviews as well as FGDs were conducted in the local language (Gujarati) and were audio-recorded with permission.

Data analysis
The audio recordings were transcribed into English. Thematic analysis (codes based on constructs of the health belief model) was done from the transcription.

Ethics considerations
The study was approved by the Institutional Ethics Committee of GMERS Medical College Patan (Gujarat, India). Written informed consent (including consent for audio recording) was taken from all the study participants before conducting the in-depth interviews. At the end of the interviews, all patients were counseled to re-initiate their treatment and not to stop their treatment again.

Results

For exploring the perspectives of the patients who were ‘lost to follow-up’, we enrolled 14 patients with TB – 12 male and 2 female; aged 26–65 years. Among the 14 patients, 10 resided in an urban area, while 4 were from rural areas; 13 patients were married and one was unmarried. For exploring the providers’ perspective, we enrolled 6 service providers in the study – all were male; aged 35–55 years. Four service providers were from an urban area and two were from rural areas. Among the service providers, one was the district TB officer of Patan district, one was Medical Officer and four were TB health visitors.

Loss to follow up and the health belief model
The thematic analysis brought forth nine codes that explained the various constructs of the health belief model [Figure 1].

Perceived susceptibility
Lack of support from health workers
Some of the patients perceived that a lack of counseling and support from healthcare workers was one of the reasons for their LFU.

Figure 1
There is, however, a
“One fine day, the health worker took all my medicine and did not return it to me ever, so then after I didn’t get my medicine back and I stopped it.” (45 years, male patient)

The healthcare workers, on the other hand, complained about overburden in work mainly due to the shortage of staff at the health facilities. A 48-year-old female service provider who works in a primary health center expressed her frustrations: “I have to work for immunization programs, maternal health, health survey, nutrition, and everything. How much time can I give? Some patients were coming in the evening, I scolded them - I have to prepare food, I too have to look after my family. How can I give time during the evening or night?”

Lost faith in government
Faith in the government system was also a concern with adherence to anti-TB treatment. A few patients responded they do not have trust in government hospitals and then referred themselves to a private hospital.

“I was referred to Dharpur Civil Hospital, but I didn’t want to go there as I had a bad experience with this hospital previously. My two family members died in Dharpur Civil Hospital. So I did not go there.” (45 years Male patient).

Alcohol addiction
A majority of patients denied alcohol abuse as a reason for not adhering to treatment, however, it was perceived as a major barrier to treatment adherence by the service providers. Alcohol abuse resulted in not only missed TB treatment doses and other scheduled appointments but also in patients being unreceptive to counseling and treatment adherence messages.

“Most of the patients are addicted to alcohol consumption. In addition, most are inflexible, they do not pay attention while counseling. They are not listening to anyone.” (30 years, male service provider)

“I am an alcoholic for a long time. After taking medicines for a few months, I did not feel good. So, I continued to take alcohol and stopped my medicines.” (55 years, male patient)

Perceived severity
Negative counseling by quacks
Some service providers felt that lack of awareness of TB and its treatment also influenced treatment adherence. Myths and misbelief among patients were also important factors for LFU, especially in rural areas.

“Some patients went to ‘Bhuva’ and ‘Maharaj’ [quacks] for the cure of TB. ‘Bhuva’ and ‘Maharaj’ asked them to stop treatment and use their local remedies for TB. Some patients died after stopping treatment.” (40 years, male service provider)

Perceived benefits
Improvement in symptoms
Feeling symptomatically better after taking treatment for two to three months was perceived as a critical reason for non-adherence to anti-TB treatment by a few patients. Out of the 14 patients, 3 felt that once they get relieved of all symptoms, there was no need of taking the medicines anymore.

“I was not aware and no one informed me that I need to take the medicines for 6 months. So, whenever I feel better, I stop the treatment” (30 years, male patient)

Perceived barriers
Side effects
Most of the patients perceived that adverse drug reaction after taking the medicines was the primary reason for stopping the treatment. Nausea, vomiting sensation in the abdomen, rashes, itching, headache, vertigo, restlessness, and diarrhea were the major symptoms reported.
“For the first 6 months, I did not have any side effects, but, after starting treatment for the second time after 4 to 5 days, I passed blood from my stool and cough. I ask about the same to my doctor, but, the doctor did not give any satisfactory response. I lost my faith and stopped taking the medicines.” (33 years, male patient)

“I feel weak after taking the medicines. I also had heavy bleeding from stools and gums, so I stopped taking the drugs.” (23 years, female patient)

“Drug is very heavy and it causes a burning sensation in abdomen and when I stop I feel good. So I quit treatment” (65 years, male patient).

**High pill burden**

One 40-year-old male patient who was co-infected with HIV felt that the number of pills was too much to bear with: “I am HIV positive. So, HIV and TB medicines are too much in number. I feel exhausted by taking so many medicines. One day I stopped taking all the medicines.”

**Stigma**

A few patients felt that the fear of stigma was an important barrier to completing TB treatment. Patients did not want health workers to visit their homes for any counseling and did not want to attend the local health facilities due to fear of disclosure of their disease. According to a male service provider aged 55 years, social stigma among unmarried women with TB was a challenge: “Stigma and discrimination are major concerns in young adolescent girls. If in a society someone comes to know that about their TB, no one prefers to marry them.” While a 30-year-old male patient said, “What will people think of me when they come to know that I have TB? I am afraid. I cannot tell this to anyone. What kind of girl would marry someone with TB? I am not married yet.”

**Financial constraints**

Financial constraints were faced by most of the patients during their treatment. TB is a debilitating disease, leading to severe weakness and makes patients incapacitated to work. Also, it most commonly affects the working population, that is, the primary earning members of the families. Most of the patients stopped the treatment once they were out of money to pay the bills of private hospitals.

“I spent [Indian Rupees] 9000 to 10000 per month for my TB treatment for 6 months in a private hospital. In total, I spent [Indian Rupees] 50000 to 60000 in a duration of 6 months. Then the doctor told me that treatment needs to be continued for 12 months. I didn’t have more money for treatment. So I stopped it.” (33 years, male patient).

“Because of illness, I lost my daily wages for 2 months. I had financial problems. So I stopped treatment.” (45 years, male patient).

A 65-year-old male patient said, “I did not take the injections because the hospital is far away from my home and I don’t have money for transportation. So after taking 2-3 injections I stopped taking injections. I also didn’t get 500 rupees [cash benefit] every month because of lack of a bank account in my name and an Aadhaar card [unique identification card].”

**Issues with reporting in online portal**

The service providers reported a few issues with updating details of the patients in the online portal (NIKSHAY) which led to losses to follow-up. This happened when the patients migrate from the district under which they are registered to another district. Being linked to the patient’s mobile number, the NIKSHAY software does not have an option to track the patients in the absence of a mobile number – thus patients transferred to another district are lost to follow-up.

“TB notification in the NIKSHAY software is a major issue, as the software is linked with the mobile numbers of the patients. Many poor patients do not have a mobile or provided a wrong mobile number or a relative’s mobile number. So if a patient is reported as transfer-out to another district, it becomes very difficult to locate the patients and have to be reported as lost to follow up.” (30 years, male service provider)

The second issue reported by the service providers was when the patients shift from the public sector to the private sector for their treatment.

“There is an issue of shifting the patients from the public system to the private for treatment. There is no option to change the ID of the patients in the NIKSHAY software. So, once the patients stopped their medicine from the government system and continued it from a private doctor, our software showed these patients as LFU, although they were on treatment [from a private provider].” (55 years, male service provider)

**Solutions for reducing LFU**

A few solutions were suggested by the patients as well as the service providers for reducing the loss to follow-up among the patients with TB.

**Addressing side effects**

Some of the patients felt that as the major detriment for completion of treatment was side effects to anti-TB drugs, it would be beneficial if the government works on it by providing sufficient supportive drugs for the same.

“If side effects do not occur, I will continue the medicines. Government must ensure that minimal side effects occur during the treatment.” (33 years, male patient)

“If my treatment for the side effects was satisfactory, I would have completed my treatment.” (55 years, male patient)

**Frequent health worker visits**

One patient felt that they have to travel long for getting the medicines and if the medicines are delivered at the doorstep, it would have been possible to complete the treatment. The patient said, “I have travel long for taking treatment and I don’t have..."
any accompany person. If I can get my medicine at my doorstep it would be better.” (65 years, male patients)

Better counseling interventions
A service provider himself believed that in the rural areas of the district, the counseling provided by the health workers is suboptimal and stressed the need for counseling of patients with TB who are addicted to alcohol.

“Counselling is an issue in the rural parts of Patan district. Few patients are alcoholic and they are under the influence all the time.” (45 years, male service provider)

Better implementation of cash-transfer program
Most of the patients believed that the cash transfer program was not being implemented. With financial constraints forcing them to stop their medicines, the monetary benefits would help them to take the medicines along with some nutritious food purchased from the cash benefit.

“I don’t have money to purchase food and milk. With an empty stomach, it’s difficult to take medicines. [Indian Rupees] 500 rupees per month was too little for my family.” (65 years, male patient)

Online portal update
A few service providers suggested adding an option to the online portal for patients shifting from the government sector to a private doctor for their treatment.

“We don’t have an update option in the NIKSHAY software. If patients are highlighted as LFU in the software, we visit the patients at their homes for counseling. However, during their home visit, we come to know that they are taking medicines from a private hospital. So, patients who are reported as LFU in the software, are actually on medication from a private doctor.” (35 years, male service provider)

Discussion
This qualitative inquiry generated pathways that were explained by the health belief model towards patients’ behavior of non-adherence to anti-TB treatment. The perceived susceptibility and severity related to TB explained the patient’s belief that a threat existed and they needed to take anti-TB medicines to overcome the threat. Also, that their perceptions regarding the benefits and barriers acted toward their behavior of non-adherence to the treatment. Our findings were supported by investigators from Iran. [12,13]

Our study reported side effects to anti-TB medicines, social stigma, lack of faith in government, and financial constraints as the major reasons for loss to follow-up among patients with TB. Multiple evidence has reported side effects to TB drugs as the leading cause for loss to follow up.[14-16] This highlighted the need for adequate counseling about the expected side effects of the medicines along with the provision of supportive treatment for the minor side effects. The pathway to LFU due to side effects was reinforced by the lack of support from health workers as perceived by the patients in the present study. Some of the patients in our study complained about the infrequent home visits by the health workers during the course of their treatment. This lack of support from the health workers and the lack of accessibility was also reported in another study from North India.[119]

The unaddressed side effects also prompted the patients to shift their care-seeking to a private practitioner, thereby increasing their financial burden. The direct medical costs of care for TB have been reported to be higher for patients with multi-drug resistant TB (MDR-TB) due to its longer dose schedule.[20] Patients in this study also mentioned that they had to leave their employment due to the severe weakness experienced during the debilitating phase of the disease. This forced unemployment led to the loss of their wages and added to the indirect costs incurred by the patients. A qualitative study in Central India among MDR-TB patients also reported the same findings.[20]

Patients in the current study reported receiving the initial financial benefit, under NIKSHAY Poshan Yojana, after 3-4 months of starting treatment. Timely cash benefit transfers are pertinent to purchase nutritious food like milk/fruits during the course of the treatment.[20] Also, the benefit acts as a financial cushion during the initial debilitating months of weakness when they are not able to go to work. The pathway to LFU due to financial constraints was in turn supported by the fact that some patients did not have a bank account and other necessary documents to open a bank account, which led to the non-receipt of the monetary benefit.[20]

Alcohol consumption has been implicated as one of the major risk factors for failure to complete treatment among patients with tuberculosis,[20] and is specifically associated with loss to follow-up among MDR-TB patients.[21,24] In our study, the service providers suggested developing linkages between the national TB program and the alcohol addiction program; the need for such collaborative activities has been highlighted previously.[25]

In the present study, the stigma surrounding their apprehension of disclosure of their disease status was prominently highlighted. The fear of disclosure was directly related to the fear of potential rejection by suitable matches for marriage in the community. In other studies, the impact of stigma among men was more due to their economic prospects, which included loss of income-generating employment,[26,27] while among women the stigma was due to the impact on their marriage prospects.

Summary
The HBM explains loss to follow-up among patients with TB in India. A comprehensive intervention model comprising of creating awareness regarding the benefits of completing TB therapy and explaining the disease severity and transmission potential; mass media campaigns dispelling myths surrounding
the disease and for allaying fears surrounding any ineffectiveness of anti-TB drugs; reducing apprehension through adequate counselling on the supportive medicines to be consumed in case of side effects to anti-TB drugs; and instilling confidence (self-efficacy) on the government health system through regular visits by health workers would be helpful in improving adherence to anti-TB medicines. Counselling of patients with TB on these aspects by the primary care physicians would further reduce the LFU rates.

**Key take-home message**

Primary care physicians and program functionaries of TB can play an important role in ensuring adherence to treatment by adequate counselling based on the constructs of the HBM.

**New knowledge/novelty**

Patients with TB have a tendency to stop the treatment once they are relieved of their symptoms. Primary care physicians in their out-patient department and TB health workers during their home visits should utilize patient interactions as an opportunity to administer counselling interventions for improving their compliance to treatment.

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**Conflicts of interest**

There are no conflicts of interest.

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