Tuberculosis Medication Nonadherence—A Qualitative Case Study

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Abstract

India is grappling with the problem of controlling tuberculosis nearly for the past 50 years. The problem of nonadherence to treatment regimen has also worsened the situation of multidrug resistant tuberculosis (MDR-TB) in India. This article explores the factors behind nonadherence among erstwhile TB defaulters in a rural district in India. In-depth interviews with seven chronic defaulters and with healthcare professionals were conducted at a government-run Chest Clinic. In addition to in-depth interviews with defaulters and healthcare professionals, medical records and government orders related to TB control were examined extensively. Participants were also observed to understand their interaction with healthcare professionals and fellow patients, especially during drug delivery time. Qualitative content analysis is the most appropriate method to analyze the transcribed text and archival records. Qualitative content analysis brought out five major themes responsible for their past nonadherence behavior, namely, (a) Awareness about tuberculosis and treatment, (b) Symptom recognition and self-medication, (c) Family support, (d) Accessibility, and (e) Stigma. Findings are documented according to the major themes and documenting direct quotes from participants and with healthcare professionals wherever appropriate. This case study also provided context-specific recommendations to the healthcare professionals as regards the nonadherence behavior among TB patients. It is hoped these focused recommendations, albeit known to the healthcare professionals, would be extremely useful in making modifications to the existing program to tackle the nonadherence behavior.

Keywords

Tuberculosis Control, Nonadherence Behavior, Rural India, Qualitative Content Analysis

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India is grappling with the problem of controlling tuberculosis nearly for the past 50 years. The problem of nonadherence to treatment regimen has also worsened the situation of multidrug resistant tuberculosis (MDR-TB) in India. This article explores the factors behind nonadherence among erstwhile TB defaulters in a rural district in India. In-depth interviews with seven chronic defaulters and with healthcare professionals were conducted at a government-run Chest Clinic. In addition to in-depth interviews with defaulters and healthcare professionals, medical records and government orders related to TB control were examined extensively. Participants were also observed to understand their interaction with healthcare professionals and fellow patients, especially during drug delivery time. Qualitative content analysis is the most appropriate method to analyze the transcribed text and archival records. Qualitative content analysis brought out five major themes responsible for their past nonadherence behavior, namely, (a) Awareness about tuberculosis and treatment, (b) Symptom recognition and self-medication, (c) Family support, (d) Accessibility, and (e) Stigma. Findings are documented according to the major themes and documenting direct quotes from participants and with healthcare professionals wherever appropriate. This case study also provided context-specific recommendations to the healthcare professionals as regards the nonadherence behavior among TB patients. It is hoped these focused recommendations, albeit known to the healthcare professionals, would be extremely useful in making modifications to the existing program to tackle the nonadherence behavior. Keywords: Tuberculosis Control, Nonadherence Behavior, Rural India, Qualitative Content Analysis

Introduction

According to Global TB Report, India accounts for a quarter of world's tuberculosis cases with approximately 2.8 million cases in 2016. India also accounts for 33% global TB deaths among HIV-negative population (WHO, 2017a). According to World Health Organization's high TB burden countries list, India along with China and Russia contribute to 47% of global Multidrug Resistant (MDR) TB cases.

Adherence is the extent to which patients follow the treatment recommendations of the healthcare providers (Osterberg & Blaschke, 2005). Poor adherence to drug regimen among TB patients results in disease progression without symptomatic relief. Poor adherence poses a significant public health crisis in the case of communicable disease such as pulmonary tuberculosis. Not only does the untreated individual remain symptomatic for a prolonged period of time, but also there exists a risk of spread.

According to WHO, poor adherence to the prescribed treatment increases the risks of morbidity, mortality and drug resistance at both the individual and community levels (WHO, 2003). Poor adherence to the long course of TB treatment is a major problem faced by TB control programs (Munro, et al., 2007).

Failure to adhere to tuberculosis drug regimen is one of the most serious barriers to tuberculosis control (Addington, 1979). The reasons for poor adherence are not only multifaceted and complex but range from characteristics of the individual patients to qualities of the social and economic environment that influence all tuberculosis prevention and control activities (Sumartojo, 1993). Nonadherence to drug regimen still persists despite the implementation of ICT-based (Central TB Division, 2017b) adherence protocol to obtain real-time adherence information.

Application of information and communication technology (ICT) in the healthcare field has resulted in overall better performance and delivery of healthcare services. RNTCP's reliance on information and communication technology to ensure adherence among TB patients is based on WHO's recommendation. Despite India's growth in the ICT domain, the rural population has still not caught up with the development. Technical illiteracy (Gupta & Gautam, 2017) is one of the factors that leave rural population incapable of using the services provided by government.

The first author has also observed that many patients who visited the DOTS Center also sought help to attend or make calls from others (including the researcher) and did not seem capable of reading or sending SMSs.

RNTCP is currently doing a small-scale evaluation of its ICT-based adherence protocol 99DOTS and results are expected by the end of 2018 (WHO, 2017b).

Though the healthcare staffers at the DOTS Centre seem to have a fair idea about the reasons for nonadherence in specific cases, they attributed this to the individual's lack of "seriousness." To this end, I briefly interacted with TB patients and their family and decided to explore the factors responsible for nonadherence among TB patients. RNTCP, by principle, assumes that it is individual's responsibility to complete the full course of antibiotics. India TB report 2018 extensively discusses about community inclusion element in TB control, but none seems to exist in the rural district where the study was undertaken.

Aims and Rationale behind the Study

The inspiration to conduct the current study culminated from the fact that the first author has lost two of his close relatives to tuberculosis, particularly due to their nonadherence behavior. This behavior was not only puzzling but ironical in that anti-tuberculosis medicines are distributed through DOTS Centers free of cost. This piqued the author's interest in studying more about nonadherence behavior especially in a rural setting where awareness about health conditions remain poor. Being a full-time research scholar in a public university provided the author with the unique opportunity to study and explore this nonadherence behavior and to understand some of the factors responsible. Aside from research work, the author also provides health education to local population to create awareness and to stress the importance of following healthcare professionals' guidelines be it with diet, exercise or drug regimen.

Research Design

Qualitative case studies are useful in an in-depth understanding of a bounded system; data generation usually happens through multiple sources of information (Creswell & Poth, 2016). According to Robert Stake, a case can be a program while keeping the boundaries of

inquiry in focus (Stake, 2000). Nonadherence behavior is a complex, multidimensional construct (Martin & DiMatteo, 2013), which warrants in-depth interviews and observation as the psychological characteristics are best analyzed by multiple data gathering techniques (Spielberger, 2004).

The current inquiry utilizes an exploratory qualitative case study as it attempts to identify the causal factors behind nonadherence behavior among TB patients in a RNTCP-run DOTS Center in a rural district of India.

Research Sample

The focus of this inquiry was to explore and obtain information (Flyvbjerg, 2001) from a single group of defaulters to arrive at an understanding of their nonadherence behavior. Deviant case sampling strategy was found to be the most appropriate strategy since the case study sought to understand the nonadherence phenomenon from information-rich cases (Patton, 2014).

Seven chronic defaulters currently re-registered for DOTS in the in-patient ward of Chest Clinic were identified and selected as respondents.

Criteria for inclusion as respondents:

a) Tuberculosis confirmed patients registered for DOTS either in this treatment center or elsewhere.
b) Tuberculosis patients who had defaulted on their treatment more than once, but re-registered for treatment.

Also, TB medical officer and staff nurses were interviewed multiple times to get their viewpoint. These interviews were recorded with their verbal consent. This helped the researcher in getting a holistic picture of the nonadherence behavior.

Data Generation

Semi-structured interviews were conducted to generate data concerning the nonadherence behavior among TB defaulters. Semi-structured interviews are used when researchers set limits on what topics to be covered (Green & Thorogood, 2004).

Since a qualitative case study entails data collection from multiple sources for triangulation purposes (Green & Thorogood, 2004), healthcare providers from the district treatment center were also interviewed to understand the DOTS protocol for defaulters. Medical records as well as pertinent Government Orders (GOs) and documents were also examined.

Initially, participants were observed in the Chest Clinic for their interaction with fellow patients and healthcare providers and recorded as field notes with a view to provide contextualized insights (Mills, Durepos, & Wiebe, 2010) during interpretation.

Semi-structured interviews were conducted by the bedside to elicit responses from the respondents and transcribed verbatim (Wolcott, 2005). Four specific questions were posed to the defaulters a) How did you get this disease? b) Who/What brought you to Chest Clinic? c) Why did you stop taking medicine in the past? d) How do you feel with the current treatment? Several spontaneously constructed, non-directional questions (Paget, 1983) were also asked to extract narration from the defaulters. Subsequent interviews were conducted at venues places chosen by participants whenever deemed necessary.

Data Analysis

Interviewed responses from each defaulter were transcribed verbatim in Tamil, translated from Tamil to English by the first author. The translated material was crosschecked by other authors for errors and discrepancies. Final version of transcribed report was carefully examined individually by all the authors looking for relevant information pertaining to the research questions that were posed. Qualitative content analysis was found to be the appropriate method for transforming transcribed texts and literal content into latent meanings (Erlingsson & Brysiewicz, 2017). First and third authors carried out the first level coding and development of categories independently. This step greatly reduced the humongous transcribed material to a manageable level. Themes that highlighted the nonadherence behavior were given to the second author by paraphrasing pertinent responses given by defaulters and healthcare providers for contrasting of categories (Schreier, 2012).

Informed Consent

Prior to conducting interviews, the researcher explained his academic motives to the Medical Officer, Chest Clinic, DOTS Centre. Administrative consent was obtained from him to conduct interviews and observe the respondents in the in-patient ward. Before the start of interview, verbal consent was obtained from all the interviewees explaining the strict academic intentions and recordings would be used only for academic purposes. They were encouraged to ask questions related to interviews and were answered to their satisfaction.

Findings

The first research question that was posed to the defaulters gave rise to the category, poor "awareness about tuberculosis and its treatment." Second question gave rise to the category, "symptom recognition and self-medication." Third question brought forth, "Family Support," "Accessibility Issues," "Drug Toxicity," and "Stigma."

Awareness about tuberculosis and treatment

Defaulters could not describe how they got tuberculosis or how it is transmitted. Earlier studies conducted in the neighboring state also reveal poor knowledge about the cause and mode of spread (Kar & Logaraj, 2010). One of the participants noted, "nobody told me [how I got TB], I drank lot of ice water, I think I got because of that." Health awareness building measures taken by the district administration seem clearly inadequate which was corroborated by a healthcare provider, "Awareness building measures are not enough, just advising them will not help; we get a huge number of patients every day, how can we give counseling to all?" Outpatient nurse attributed poor awareness about the treatment process for discontinuation of treatment after IP (intensive phase), "They stop medicine after IP (intensive phase) because symptoms will reduce after a few doses of IP. They think they are cured. Symptoms will reduce, they will also gain weight. Many patients stop treatment after IP."

It was also observed that safe practices like cough hygiene and masks were not worn either by the patients or the attendants. Plastic covers and uncovered mugs were used to spit out phlegm which goes against the guidelines of National Institute of Tuberculosis and Respiratory Diseases (Director, 2018).

Patients collecting cough syrup in used liquor bottles from the pharmacy was observed by this researcher on many occasions.

RNTCP formulated ACSM (Advocacy Communication & Social Mobilization) strategy to create awareness and bring about attitudinal change to encourage seeking of treatment and completion of treatment (Central TB Division, 2017b).

While RNTCP advocates TB treatment monitoring platforms like Nikshay and 99DOTS for improving adherence among patients, there is no availability of data to measure their success at a rural level.

Healthcare provider commented that many patients do not disclose their past TB treatment when they seek treatment, "they will not tell you whether they took DOTS earlier from elsewhere, really difficult to treat these cases."

Symptom recognition and self-medication

Defaulters were vague in describing the initial onset of symptoms and admitted to have tried treatment initially by either self-medication by buying over-the-counter medicines or traditional healers. One defaulter, "initially cheeked dried galangal to control cough. I started running fever and had chest pain, so went to pharmacy, took them for some time."

Despite the onset of symptoms, none of the respondents sought allopathic treatment, another defaulter voiced, "English medicine will generate lot of heat, for cold I tried crab soup. I myself prepare herbal concoction; country medicines are safe."

Outpatient nurse opined that some of the TB symptoms are also the symptoms of common cold or some other ailment, which is why rural population gives less importance to them or at best ignore them, "They can't differentiate [symptoms], they will be vague when they come here. Some will try everything, when they do not work, they will come here at the last stage."

Revised National Tuberculosis Control Programme (RNTCP) in 2017 revised its technical and operational guidelines and made it compulsory for private sector doctors to notify any TB cases through an amendment in year 2015 (Central TB Division, 2017b). Despite government's notification, percentage of annual notification of TB patients from private sector remains zero in Puducherry Union Territory (Central TB Division, 2017b). This unaccommodating stand from private health sector poses an additional challenge to its current early case detection strategy. In India, people equate quality healthcare with private healthcare providers. Standalone pharmacies are one of the neglected links in the fight against the control of TB (Samal, 2016), whose cooperation could not only help curb self-medication behavior but also help in case detection and early diagnosis. Every respondent of this study had more or less indulged in self-medication, either allopathic or alternative medicines, before finally enrolling themselves for DOTS. Department of Drug Control, Government of Puducherry, on 02/01/2018, issued a directive to local authorities to take stock of anti-TB drugs available with all local pharmacies, quantity purchased in the last one year, quantity sold in the last 5 years (Licensing Authority, DoDC, 2018). Despite the government's directive, this researcher could buy two of the first line anti-TB drugs over the counter.

Folk healing methods are prevalent and majority of our respondents had utilized their services one way or the other. Misconceptions about allopathic treatment were common and one particular respondent branded allopathic medicines as heat producing; this common misperception has been documented in earlier studies too (Sujatha, 2003).

Healthcare as well as scientific community has always remained skeptical about these traditional healing practices (Dalal, 2015).

Family Support

Lack of family support seems to be a big barrier in adhering to the treatment regimen. Many respondents expressed feelings of despair during their discussion about family. Statements like, "I am like an orphan," "Nobody visits me," and "I am treated like a leper" demonstrate poor family support that these defaulters receive.

Senior Treatment Supervisor (STS) commented that some families do not want TB patients to get better for lot of reasons, "in some cases, wife will discourage us from following up, no use...drinking is a big problem for husbands not getting support from wives."

Abandonment of spouse is another problem, outpatient nurse cited a particular case, "He [husband] left her because of her TB. Her parents took care of her during treatment."

Assistance and support from friends and family have been implicated in promoting patient adherence by encouraging optimism and self-esteem (DiMatteo, 2004).

In a cross-sectional survey conducted in Kampala, Uganda, it was found that the prevalence of self-referral to the NTLP Centre was 33% and family members were seen to be an important source of influence in seeking treatment in 53% of the cases (Kiwuwa, 2005). As the results of this study points out, family support has an influential role in improving adherence among TB patients (Deshmukh et al., 2017). The current DOTS treatment under RNTCP does not empower the patient in managing their own treatment (Atkins, Biles, Lewin, Ringsberg, & Thorson, 2010) nor does it actively solicit family involvement or support in the treatment process. RNTCP has successfully launched projects like Project Axshya and Counsellors' [sic] Project to counsel not only patients but also family members with an aim to create awareness about tuberculosis, but their presence is restricted to only few states (Central TB Division, 2017b).

Accessibility issues

National Strategic Plan for Tuberculosis Elimination report acknowledges the existence of accessibility issues particularly in rural areas, which prevent patients from seeking or continuing tuberculosis treatment (Central TB Division, 2017a).

Many respondents voiced complaints about having to travel long distance for receiving treatment or having to bring someone to accompany them after receiving treatments, which cause dizziness. One of the defaulters, "how can I come 3 days in a week, cannot get up after taking medicine, I sometimes miss treatment because of dizziness." Another defaulter, "I cannot bring someone every time, they [nurses] will shout if I do not."

RNTCP advocates roping in government school teachers, auxiliary health workers, ASHA (Accredited Social Health Activist), and community-level health workers to optimize outreach activity (Central TB Division, 2017a) and drug distribution, but lack of accountability and no clear role definitions seem to complicate the situation. This was voiced by the Senior Treatment Supervisor: "we have distributed medicines to them, but when they do not show up, patients miss treatment."

Outpatient nurse commented, "These workers [community health] they cannot explain about drugs or its side effects, they just deliver them without telling what is what, some patients they come to us with complaints about the way they were treated by those workers."

Microbiologist in the treatment center commented, "there is no facility to sputum culture here; we will have it to send it to state headquarters. When we refer patients to state headquarters, they do not go, citing long distance as one reason."

In India, community-centric programs aim to detect, fight, and control diseases while giving less consideration to public requirements or patient perspectives. In this study, accessibility issues were voiced by not only respondents but also other patients. Travel distance

to reach hospital, complexity of the regimen, adverse effects from anti-TB drugs were pointed out as accessibility issues both by respondents as well as healthcare providers. During fieldwork, it was observed that there were no proper waiting facilities for patients or attendants.

The patients spend a significant time waiting in a queue before they could see the doctor. As earlier experiments around the world point out that DOTS treatment work better with enablers like arranging transportation facilities, outreach, financial and social incentives (Chaulk & Kazandjian, 1998) and home delivery of drugs.

Stigma

Three out of seven respondents were found to be profoundly stigmatized and other two expressed fear of loss of livelihood. Some of the comments signifying stigma among respondents were,

> "They [relatives] should not see me here in this ward."
> "Already no respect from my relatives, if they come to know TB, it's over."
> "I do not want to die here."
> "I already lost job because of this [TB]"

Medical Officer acknowledged the presence of stigma among TB patients, "stigma is there...if they live in a rented place, they do not want even house owners to know...workplace, even when people like you [researchers] visit them with questions."

> "I always tell them there is no shame" (outpatient nurse, DOTS Center)
> "It is difficult when I visit them to give medicines, workplace or home. They react… they do not want others to know they are taking medicine." (Senior Treatment Supervisor, DOTS Center)

A sense of despair and self-stigmatization has been observed during the fieldwork and many patients, who did not partake in this study, also disclosed being the recipient of discriminatory treatment by the healthcare providers (Baral, Karki, & Newell, 2007). Earlier studies note that discriminatory treatment suffered in the hands of healthcare providers force patients to not adhere with the treatment regimen (Casagrande, Gary, LaVeist, Gaskin, & Cooper, 2007).

Recommendation

The purpose of this study is to identify some of the factors behind treatment nonadherence that is hampering the DOTS strategy in a district hospital setup. The study was begun with the underlying assumption that TB is a disease of poverty along with lack of health education policy that Revised National Tuberculosis Control Programme [sic] is suffering from. The fact that none of the attendants spotted in the vicinity was seen wearing a mask is proof enough of the lack of awareness about the disease and its transmission. Equally disturbing finding is the vague symptom recognition by patients despite their earlier defaulter status. Self-medication is a huge problem, either by way of over-the-counter medications (usually antibiotics) or folk medicine, which results in delay in seeking appropriate treatment. The fact that tuberculosis is too recalcitrant to all these alternative modes of treatment and delay could prove fatal is not completely understood by the public. Private medical practitioners' not notifying the local TB medical officer further complicates the adherence problem. Strangely enough, Chest Clinic of in this district does not have a Culture and Sensitivity laboratory, for which patients are being referred to state headquarters which is 130 kilometers away. Recent

steps announced by the Ministry of Health and Family Welfare that imposes jail term for doctors and pharmacists who do notify the local TB medical officer in a prescribed format. The drug toxicity itself poses a big threat to adherence. The daily drug regimen program had not yet been implemented in Karaikal when the interviews were conducted but is in force now. RNTCP should make necessary steps to include family members in the treatment process, which should promote adherence behavior of TB patients. This state government promotes liquor tourism and around 68 liquor shops are operating and doing brisk business in this district. Alcohol abuse is quite rampant, and it is not an uncommon sight to notice drunkards lying on the road or entering into a brawl. Abject poverty is another reason why adherence behavior is not what it should be. This researcher has seen people smuggling liquor and other banned chewable tobacco into the ward, which hinders with the treatment process. "A bottle of brandy is cheaper than a full meal here" is a comment voiced by one of the attendants of a TB patient during fieldwork. The local government has to realize the fact that liquor and communicable diseases are a deadly combination and quietly bring down the control efforts of healthcare professionals. Anti-TB medicines work well along with proper diet. Lack of nutrition is a major problem, which should be handled simultaneously while attempting to control tuberculosis in India.

RNTCP's disease-only approach should become people-centered approach. Tuberculosis might respond to drugs when healthcare providers respond to patients' needs.

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