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An Ethnographic Study on the Factors Affecting Adherence to Directly Observed Treatment Short-Course in Typical Indian Settings

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Abstract

Efficient management of chronic illness remains a common clinical problem. Non-adherence to a prescribed medical regimen remains a tremendous barrier to the effective medical management of chronic diseases and is considered one of the most serious problems that the medical world faces in the present. Tuberculosis is one such chronic disease which has been a prevalent problem in most of the developing nations, including India. In this paper, we describe an ethnographic study conducted in the state of Assam, with the objective of deciphering the multiple factors that are associated with the failure of the treatment regimen of Tuberculosis, viz. the DOTS (Directly Observed Treatment Short course) programme under RNTCP (Revised National Tuberculosis Control Programme).

Keywords

Adherence, Tuberculosis Treatment, Risk Factors

1. Introduction

Directly Observed Treatment, Short-course (DOTS) strategy, implemented as a part of Revised National Tuberculosis Control Program (RNTCP), is a systematic comprehensive package introduced in India in 1993 for TB control. The principal components of DOTS are political will, diagnosis by microscopy, regular supply of drugs for short-course treatment, Direct Observation of Treatment (DOT), and systematic monitoring [1].

In spite of the efforts taken under the DOTS program, India still contributes significantly to the global TB

burden. The total number of TB cases in India that were notified in 2013 sums up to 1,415,617, the highest in the world (WHO Global Tuberculosis report, 2014) [2]. Modern anti-TB drugs are capable of curing virtually all patients. But it is imperative for the patients to take these medicines in prescribed dosages regularly for a minimum of six months for successful treatment in the direct observation of a DOTS provider. Adherence to such a long term treatment is often found to be a major issue which hinders the DOTS program from achieving the desired efficiency [3]. Adherence is defined as the extent to which a patient's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice [4]. Poor adherence is one of the primary reasons behind suboptimal clinical benefit which causes medical and psychosocial complications of the disease, reduces patient's quality of life and results in wastage of health care resources [5] [6].

In spite of access to free anti-TB medications in India under a strategy which involves treatment under direct observation, poor patient adherence is often noticed which can be attributed as a major cause of treatment failure and of the emergence of drug-resistant TB. Previous research has found travel expenses, traveling to treatment centers, male sex, poor patient information and communication, alcoholism and homelessness as the primary causes for the non-adherence to anti-TB treatment [7]-[15]. Patient adherence to the standard anti-TB therapy in developing countries has been estimated to be as low as 40% [16]. It has also been found that a significant population of patients does not receive DOTS in the true sense [17].

This paper aims at eliciting a study conducted in areas of Assam to understand the factors behind poor patient adherence to DOTS in typical Indian settings so that proper interventions can be developed or modified to promote adherence and thus bridge the gap between clinical efficacy of these interventions and their effectiveness when used in the field, and thus increase the overall effectiveness and efficiency of tuberculosis treatment. Adherence interventions are not being able to achieve complete efficiency because these interventions address risk factors independently. These risk factors are of inter-related to each other and it is imperative to assess the risk factors on a holistic level to design proper systems-level adherence interventions. Policy makers could take into consideration the cited risk-factors to develop a better DOTS program with appropriate strategies to counter the reasons for non-adherence. This would lead to a program with higher rates of adherence and thus, a better treatment rate.

2. Method

An ethnographic study was conducted in two socio-economic settings, rural and urban, to get a better understanding of the factors behind poor adherence to DOTS in the Indian scenario. The study was undertaken with forty patients and the assigned health workers across two districts (Kamrup and Dhubri) in Assam.

2.1. Site of Study

For the rural setting, rendezvous points for the workers and the patients in Agomaani Tehsil of Dhubri district were visited. These meeting points were, in most cases, the homes of the patients. There were also a few cases where the patients visited the workers' residences. In the urban context, majority of the cases comprised of patients who visited the assigned health centers to get their medicines. The study was conducted in Fatashil PHC, RNTCP Nodal Center for North-East Zone (GMCH) and the District Tuberculosis Center, in the Kamrup district.

2.2. Interviews

Semi-structured interviews were conducted with the patients and their health providers in their natural settings with the objective of finding out the reasons behind poor adherence to the program. The interviews were conducted in vernacular languages (Assamese and Bengali). Health workers/ASHA workers were involved in the study to get a better idea about the background of the patient and to overcome any kind of social barrier that might have affected communication with the patients due to unfamiliarity with the interviewers. The questionnaire, developed to ascertain PRFs consisted of a combination of open and close-ended questions that elicited information on patient-related (socio-demographic, knowledge and attitude about TB), worker-related (prior training and experience, issues in the present system, awareness of TB), travel-related (concerns related to traveling by the patient to health center to collect the medicines or travelling by the worker to the patient's home to deliver the medicines), system related factors (flexibility of the system, incentives from the system, recording, monitoring and reporting mechanisms) and patient/health care provider related factors (communication with

health care staff).

2.3. Analysis

The data was then analyzed to find out the risk factors which had high association with the defaults in the studied cases. These ascertained factors can be attributed as the primary reasons behind poor adherence to DOTS in Indian settings.

3. Observations

The potential risk factors behind non adherence have been summarized in the following **Table 1**.

Risk factors contributing to poor adherence were assessed for the urban and rural settings. In rural areas, it was observed that in 20 of the interviewed cases, medicines were delivered on a weekly basis. Thus the maintenance (accuracy) of records (treatment card) in such cases is questionable. Also 9 treatment cards were found where the records had been tampered or manipulated. This ascertained the need to focus on the risk factors that might have contributed to poor adherence rather than on poor adherence itself because outcome or process related adherence measurement is rendered unreliable in such cases by poor record maintenance. The data obtained from analysing the risk factors found relevant in the studied 20 rural cases and 20 urban cases is summarised in the following **Figure 1**.

Thus, it was observed that side effects caused by the anti TB medicines are the primary reason behind patient's poor experience with the program. This reason becomes a potential risk factor for poor adherence because the
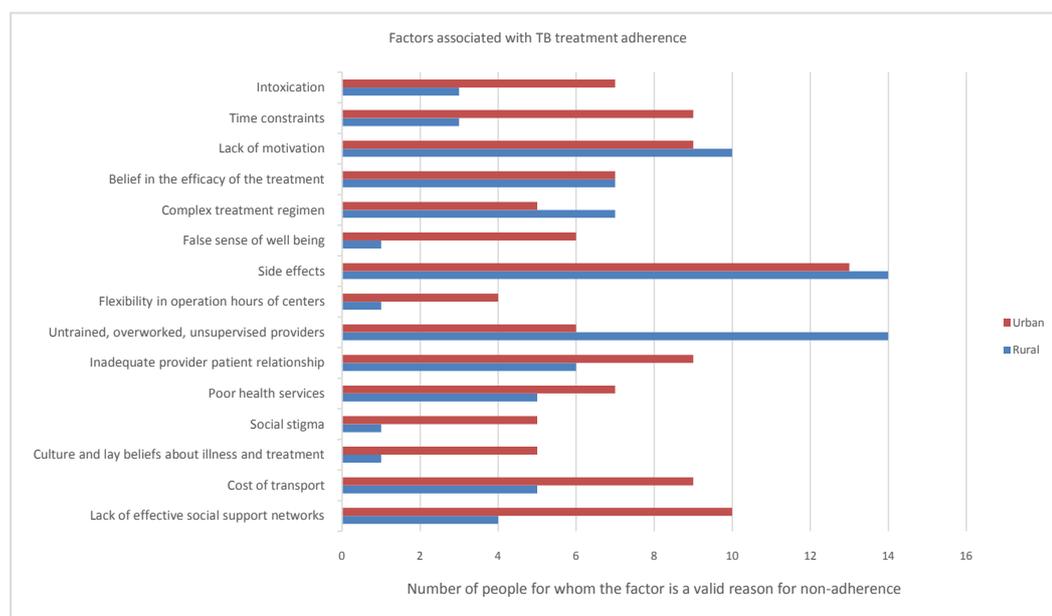

Figure 1. Bar graph highlighting the various factors and the No. of people that associate with those factors.

Table 1. Potential risk factors associated with tuberculosis treatment.

Socioeconomic related factors	Lack of effective social support networks and culture and lay beliefs about illness and treatment; high cost of transport, social stigma
Health care related factors	Poorly developed health services; inadequate patient-provider relationship; health care providers who are untrained, overworked or inadequately supervised; flexibility in operation hours
Condition related factor	False sense of well-being, intoxication
Therapy related factors	Complex treatment regimen; adverse side-effects of treatment
Patient-related factors	Belief in the efficacy of treatment; motivation

patient does not receive in-time care to these side effects. They mostly suffer from weakness and fatigue which poses problems in their work and thus their livelihood. Moreover, most of the rural patients are not monetarily strong enough to afford vitamin and other supplements to maintain their health. This results in decreased motivation to adhere to the course. The main problem, as was observed in the interviews, lies in the negligence of the health provider to report these side effects to the designated medical officers. Also most of the times if any default occurs, it is not reported. There is a lack of proper training, reporting and supervising mechanisms for these health providers. This is also the reason why the risk factor of "untrained, overworked, inadequately supervised providers" has high potential in the studied rural cases.

Most of the interviewed DOTS providers were found to be inexperienced in providing the required clinical and motivational support to their patients. The workers mostly learnt from their experience. Training was found lacking in maintaining of records and reporting of issues to higher authorities or even properly counselling the patients and their family. Lack of awareness about the significance of each feature of DOTS is a major reason behind their negligence in counselling the patients according to situations. For example, few workers did not know about the importance of the sputum test after the end of Intensive Phase of CAT I and so most of the treatment cards lacked this data. The presence of this data on time is essential for ensuring DOTS. Moreover these providers are often found to be overworked as they have been assigned the DOTS work as a side responsibility. This adds to the risk factor of "time constraint" in overall risk assessment. The workers receive their payment only after the patient completes the course which does not happen generally. A meagre payment added to high work-load often serves as a major factor for decrease in their motivation in providing adequate support to their patients. Cases were stated where the providers were devoid of payment even after 2 years of completion.

Many patients complained about the complex medication regimen which involves taking 7 tablets together during Intensive Phase of CAT I, as taking these medicines together makes them feel sick-nausea, headache, vomiting, etc. So the workers have been seen to have adapted accordingly and the medicines are given with a gap of 5 - 10 minutes between two consecutive doses. Thus the patients had to stay near the workers for nearly an hour to ensure medication compliance. This time factor proves costly to workers and patients who have high work load or are bound by temporal factors, beyond their control (like standing in a queue for work). Tuberculosis is generally prevalent among the poorer and malnourished sections of the population [18]. In urban areas, patients who are involved in occupations like daily wage labour can find it difficult to travel to the DOTS center to undergo treatment due to time constraints that are a part and parcel of their occupation. The health workers assigned for implementing DOTS program are mostly females belonging to ASHA. They are generally assigned their patients on the basis of their locality. In cases where the patient's home is far away from the worker's house, the medicines are provided on a weekly basis to avoid regular visits. Most of the interviewed cases belong to this category where regular visits are not possible due to patients living far away or in inaccessible or remote areas (poor road conditions, lack of mode of transport, etc.). Those patients living near medical subcenters or the health worker's houses can actually benefit from the human bonding established on regular meetings for ensuring medication compliance.

Cases were also found where the patients defaulted because they could not get access to medicines when migrated (temporarily or permanently). Without a referral letter from the corresponding center responsible for the patient's medications, it becomes almost impossible to get these medications in the place where the person has migrated, which results in default. The problem is aggravated if the displacement is permanent as one needs to start the treatment all over again, independent of the previous treatment regimen.

It was observed that the supervision of records taking place is temporally discontinuous. The damage is already done before records get to the higher authorities. TB being a chronic communicable disease needs a real-time check as any let-up in the treatment often has long term repercussions on the entire health system.

Social stigma associated with TB also has negative repercussions. Cases included patients affected by TB generally who reported of finding themselves surrounded by social prejudices and taboo, which can be detrimental in the treatment. They tend to feel apprehensive about the prospect of visiting a DOTS center or being visited by a health worker. Health workers reported of having to lie about their intentions of visit while asking around for addresses. Two cases were found in the rural interviews where women poorly adhered to the DOTS program due to the lack of proper family and social support. Patients have also been found to come under a false sense of well-being after a certain period of time (two months generally) which can divert them from undergoing the full cycle of treatment. This in turn leads to further complications and conversion of CAT I to CAT II or sometimes even MDRTB (Multi Drug Resistant TB), XDRTB (Extensive Drug Resistant TB) or in certain cases

TDRTB (Total Drug Resistant TB). The chances of survival get slimmer with each progression in level and the cost of medications rises exponentially.

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4. Discussions

The ethnographic study conducted across the two districts in Assam helped develop an understanding of the DOTS programme and the problems it faces across various socio-economic settings. The study produced several key findings that not only gave weightage to prior research work but also provided some new insights regarding the problem of adherence to the programme. These have been categorized under numerous heads, which have been identified as the potential risk factors. The potential risk factors were clubbed under five distinct groups, viz. Socioeconomic related factors, health care related factors, condition related factors, therapy related factors and patient related factors., most of which have been covered by the observations from the study. These factors need to be considered on a holistic level to tackle the problem of non-adherence to the tuberculosis treatment programme. Certain implications can be drawn from the factors that have been cited, which could help devise a better treatment program for tuberculosis.

A proper social support system needs to be developed which caters to the social needs of the patients and helps counter social stigma and myths associated with the disease. People who have recovered successfully from TB can provide mentoring services to the ones currently under treatment. Providing incentives in the form of food tokens, transport facilities to treatment setting or reimbursements for travelling etc. could have a positive impact. Occupational constraints limit the regularity in attendance to the health care facilities which results in defaults. This reinforces the need of flexibility in operation hours of the DOTS centers. Operation ASHA has initiated a system in certain regions where providers travel from home to home on scooters/motorbikes to deliver the medicine. This ensures a proper medication delivery system which tackles several risk-factors such as time constraints, flexibility in operation hours and cost of transportation. This model could be scaled up slowly and steadily to cover other regions as well. Such a model also necessitates a dedicated and trained team of providers which would help reduce awareness issues and ensure quality care for patients.

A significant lack of information flow has been found in the current scenario between health service providers and patients. The information flow needs be enhanced in both directions. Cases of missed doses, problems caused due to side-effects, information regarding proper diet etc. needs to be conveyed appropriately without delays. In other words, reporting and supervision mechanism of the programme needs to be addressed. The problem of side-effects has been found to be highly relevant in both the urban and rural sectors which indicates the exigency of solving the issue of unreported and unaddressed side-effects. Technological interventions could be made which would lead to a smooth and reliable data flow across the various stakeholders in the system. Interactive voice response facilities could be considered to ensure that all concerns related to side-effects are dealt with efficiently with professional help as soon as possible.

Another change that needs to be employed is the replacement of the alternate day regimen with the every-day regimen currently being followed in most parts of the world including developing nations like Pakistan, Bangladesh and Nepal. International Union against Tuberculosis and Lung Disease (IUATLD) has itself stated in no uncertain terms that alternate day treatment could lead to resistance against Rifampicin. Also, MDRTB tests need to be done as early as possible to avoid the ineffective course of the first line of drugs. The drug susceptibility test would eliminate the chances of undergoing an unproductive course of medication.

Education on use of medications needs to be improved. Studies have revealed a lack of knowledge when it comes to dispensation of medicines, which is a serious concern for a disease like tuberculosis where the bacteria tends to develop resistance to the medications if not taken according to the standards that have been set. This leads to complications in the form of development of resistance to TB medications. Besides this, the importance of the adhering properly to the entire treatment process also needs to be imparted, especially in the backward areas. Appropriate IEC activities, keeping in mind the cultural connotations, could result in success.

Timely reminders to patients regarding defaults in the form of messages and telephone calls could help recover cases of forgetfulness and carelessness. As the entire treatment cycle is significantly lengthy, it needs to be

ensured that the patient does not come under depression and get demotivated. A strong patient-provider relationship becomes crucial in overcoming this problem. Patients troubled by intoxication need special care and attention, not only from the family members but also from the providers.

Technology has proved successful in myriad settings across the globe in attempts to tackle the conundrum of non-adherence. Smart pillboxes like uBox [19] for timely reminders of medication have been developed. Microsoft's eCompliance [20] project in collaboration with Operation ASHA has also seen significant success in this regard. It uses a biometric system in the form of a fingerprint machine which ensures regular attendance of patients to the DOTS centers. Supervisors are notified regarding default cases via SMS. Parichaya [21], an interactive medi-kit, helps patients in utilizing their idle time during medication to create awareness about the TB and the DOTS therapy. The device aims to motivate the patients to adhere to DOTS therapy and in taking informed health decisions. In a study conducted in the US, the use of videophones has been found to be effective and reliable and less costly as compared to DOTS, thus reducing economic burden on the government [22]. It cannot be denied that there might exist some other reasons which might not befit the context in which the study was conducted. Factors such as corruption [23] and shortage of medicine [24] supply have also been reported.

Although the DOTS programme has seen significant success in many parts of India, the problem of adherence continues to persist due to a variety of reasons. The potential risk-factors need to be carefully analysed to understand the existing loop-holes in the system and come up with strategies and interventions in the existing DOTS program to ensure better adherence rates. These risk-factors are not mutually exclusive, they are inter-related. Thus, it is essential to connect all the dots of the system while developing interventions which can promote adherence to a systems-level programme like DOTS in India.

Acknowledgements

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