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Rubina Shiotani Date

Patient adherence to Directly Observed Therapy (DOT) for Tuberculosis in a rural community in Gujarat, India.

By

Rubina Shiotani

Degree to be awarded: Master of Public Health

Hubert Department of Global Health

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Dr. Monique Hennink

Committee Chair

_____

Dr. Philip Brachman

Committee Member

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By

Rubina Shitoani

B.A., Ohio Wesleyan University, 2004

Thesis Committee Chair: Dr. Monique Hennink, Ph.D

An abstract of a thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University in
partial fulfillment of the requirements for the degree of Master of Public Health
in Hubert Department of Global Health
2011

Abstract

Patient adherence to Directly Observed Therapy (DOT) for Tuberculosis in a rural community

in Gujarat, India.

By Rubina Shiotani

Background: India has one of the highest incidences of tuberculosis worldwide. The greatest impact of the disease is on the rural community, where poor adherence to treatment is a major constraint to prevention and control. Research assessing non-adherence to directly observed therapy (DOT) in India has often used a quantitative approach and has focused on urban areas; however, DOT-adherence among the most vulnerable (the rural poor) is not well understood.

Objective: This study examines patient adherence to DOT by assessing factors associated with DOT outcomes in a rural community, validating its treatment outcome reliability and understanding the details on socio-cultural influence, the different pathways of behavior and possible recommendation for strengthening adherence to the programme.

Methods: A mixed method study was conducted to measure factors associated with DOT outcomes and to explore the experience of DOT recipients and providers. Logistic regression analysis was employed for quantitative assessment on the 592 Tuberculosis patients registered for DOT from July 2007 through December 2009. For qualitative portion, in-depth interviews were conducted with 21 participants including both recipients and providers of DOT.

Results: In general, the treatment outcomes indicated relatively high cure rate under DOT. However, the reliability of the data are still questionable, and re-treatment due to relapse case has shown significant association with both default and failure patients. The key findings of the study reveal that barriers to DOT adherence stem from a multiple dimensions of socio-cultural influences, leading to a clash between cultural and public systems as well as a gap between patient and provider's perspectives. Both quantitative and qualitative studies indicated the importance of the tribal status in adhering to DOT.

Discussion: Despite high cure rate demonstrated by the tuberculosis registers, gender-specific stigma differentials, class/status inhibitions and traditional custom underline key dimensions of socio-cultural barriers to DOTS adherence. The findings of the study can be used to build on the existing interventions to further strengthen the efficacy of DOT in low-socioeconomic rural populations, contributing in an effort to positively modify TB epidemiology in future.

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Chapter 1: Introduction.

Tuberculosis (TB) is a disease caused by a bacterial agent: *Mycobacterium tuberculosis.* It is an infectious disease that is transmitted from person to person though the air via droplet nuclei. The spread of the agent is affected by multiple factors including duration of exposure, infectiousness of patient, host factors and environmental conditions (McGowan, 2011). Only those with active form of pulmonary TB are infectious, with the translation of latent to active form depending primarily on the host's weakened immunity. Although the asymptomatic latent form of TB is non-infectious, once progressed to an active form, it is said to kill more than 50% of patients if left untreated (Onyebujoh & Graham, 2004).

1.1. Global Epidemiology of Tuberculosis

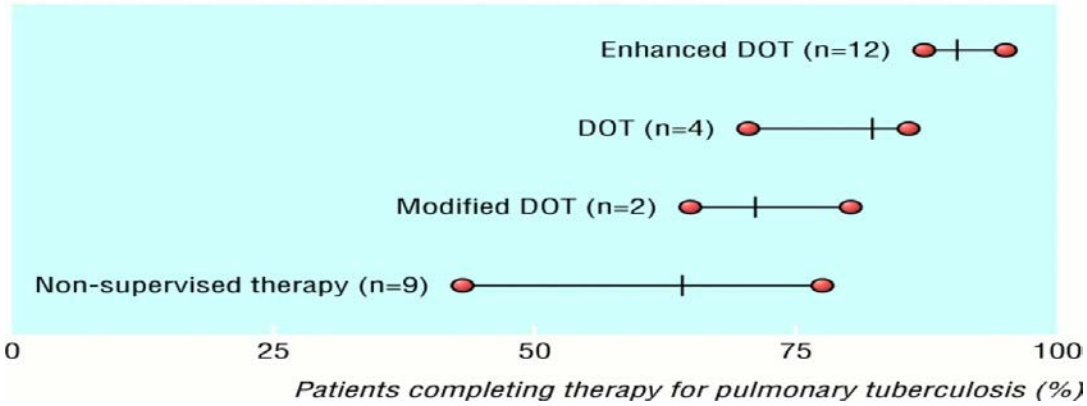
Tuberculosis is a global health concern with approximately 9 million people developing an active, contagious form every year (Selgelid, 2007). Despite the disease being curable, the 2007 World Health Organization reported an estimated 13.7 million infected with active TB worldwide and 1.8 million resulting in deaths (World Health Organization, 2008a). Tuberculosis kills around 5000 people a day, resulting in over 2 million deaths each year, of which 98% of them occur in the developing world (Wallace, 2008). It is considered one of the three primary diseases of poverty along with HIV/AIDS and malaria, and ranks fourth in terms of leading infectious cause of death after acute respiratory infection, AIDS and diarrhea (World Health Organization, 2002, 2006). Exacerbated by the increasing concern of HIV co-infection, the WHO has declared TB as a global health emergency since 1993 (World Health Organization, 2002). In an aim to achieve the millennium development goal for TB control, the 'Stop TB Partnership' was launched by the WHO in 2006 in collaboration with the World Health Assembly (WHA) (World Health Organization, 2002).

1.2. Intervention against Tuberculosis

Directly observed therapy (DOT) is one of the five key elements of the directly observed therapy, short-course (DOTS), an internationally recommended control strategy for tuberculosis. Although curable, treatment for TB requires a minimum of 6 months commitment to strict treatment regime, making completion difficult for many patients. To improve treatment completion, the WHO adopted DOT in 1994: the patient is directly observed while he/she swallows the medication in the presence of a health worker or another personnel who is not a family member, thereby encouraging treatment adherence through supervised therapy (Munro et al., 2007; World Health Organization, 2002). Studies (Chan & Iseman, 2002; Garner, Smith, Munro, & Volmink, 2007) indicate high treatment success rate of tuberculosis under DOT compared with non-DOT treatments, demonstrating the benefit of the intervention [Figure 1]. However, there is still debate about the role of directly observed therapy in low-resource countries and the impact it has on the overall epidemiology of TB (Volmink & Garner, 2006, 2007; Volmink, Matchaba, & Garner, 2000).

Regions with low-resources are the most impacted with TB. Africa has the highest estimated incidence rate of 345 per 100,000 annually, while Asia harbors the largest number of cases with countries including China, India, Bangladesh, Indonesia and Pakistan accounting for nearly half the cases arising each year (The World Bank, 2006). Evidence for directly observed therapy in these areas becomes critical in addressing the efficacy of DOTS in managing TB among low-resource countries. Generally, men have higher cases reported than women, and contrary to the trend indicating TB as the disease of the elderly in industrialized countries, the incidence rate is highest among young adults in the developing countries, most of which are caused by recent or re-infection (Dye & Floyd, 2006).

Figure 1. Rate of Treatment Completion for Various Directly Observed Therapy (DOT) for TB among Resource-Limited Country[1]



1.3. Tuberculosis in India

India has one of the largest TB incidences in the world, with estimated 2.0 million new cases and 500,000 deaths yearly owing to TB(Almeida et al., 2003) . Identified as the "disease of poverty," TB is one of the leading causes of mortality in the nation, killing approximately 2 persons every 3 minute (TBC India, 2010b). India first launched the WHO recommended DOTS strategy in 1997 after a series of pilot-tests from 1993-1996 (TBC India, 2010b). The strategy has been widely applied in the country, demonstrating its operational feasibility by curing about 8 out of 10 patients compared to 3 out of 10 in the previous programme (TBC India, 2010c). On-going TB control efforts by the Indian Government have led to a successful decrease in mortality from TB; however, India's DOTS programme is "the fastest expanding and the largest in the world in terms of patients initiated on treatment, placing more than 100,000 patients on treatment every month" (TBC India, 2010b). Like the rest of the world, high HIV co-infection and the development of multi-drug resistant TB hold great threat to the overall TB control and prevention in India.

Among the many states in India, Gujarat is one of the few states with previously reported multi-drug resistant TB (Ramachandran et al., 2009). Gujarat is a state in western India with an

[1] Edward D Chan. 2002. Current medical treatment for tuberculosis. *British Medical Journal* 325:1282.

area of 196,077 km² and a population that exceeds 50 million (Government of Gujarat) (Figures 2& 3).

Figure 2. Map of India[2]

[2] Map of India: http://www.indianchild.com/india_map.htm

Figure 3. Map of Gujarat[3]

Gujarat is one of the most industrialized states in India with the fastest growing economy in the nation; however, while the capital endures modern development, the rural communities still face severe socio-economic conditions leading to various health consequences, of which tuberculosis is among the most prevalent. Gujarat first implemented DOTS strategy in 1998, achieving state-wide coverage by April 2004 (TBC India, 2009). In India, involving private sectors in the overall TB management has been recognized as crucial, and the Government has been encouraging private-public partnership in carrying out DOTS (Dhotre, 2003). Among the 26 districts in Gujarat, Bharuch district uses such a partnership between the district TB Unit and SEWA-RURAL, a voluntary development organization involved in health and development activities in rural tribal area of South Gujarat since 1980 (SEWA-RURAL). DOTS has been implemented in Bharuch district since 2004. The overall process of examination to referral to DOTS is as follows:

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[3] Government of India, Ministry of Home Affairs

1. A physician or a medical officer examines a patient for a general check-up.
2. If suspected of TB, a lab investigation is carried out for one of the following: sputum, x-ray. (80% of lab registers are done for sputum check.)
3. If proved that the patient is TB positive, he/she is identified as category 1, 2 or 3 (see definitions below).
4. A patient is guided on the overall process and referred to the nearest Primary Health Center (PHC) for treatment.
5. The patient follows the government regime of TB treatment (6months) under DOT.
6. A patient returns at the end of the treatment for sputum check.

Although SEWA-RURAL serves as the primary referral center in the region, once referred to the TB Unit, the feedback on these patients is only partially obtained. In the hospital TB register 2009, out of the 396 patients referred to the DOTS programme by SEWA-RURAL, only 190 received feedback, leaving the outcome of the remaining 206 unknown. Additionally, it has been identified that there is a high number of missing cases on the district TB unit's DOTS register. The lack of adequate feedback and questionable accuracy of the report from the district TB Unit has been raised as an issue.

Because the majority of patients referred to DOTS are from lower socio-economic status of the population, in particular tribal groups (86%), their adherence to DOTS is an aspect that has not been explored previously. Previous literature indicates that those who identified difficulties with DOTS adherence often interrupt their treatment in between, these are known as the 'defaulters' (Waisbord). The needs of these default patients are often not being met by the delivery of DOTS.

SEWA-RURAL offers its patients a choice between DOT or non-DOT[4] treatment methods, but the majority of patients choose DOT predominantly because of the economic aspect of free medication. As tribes[5] contribute to a high portion of TB patients annually, considering their low socio-economic status, whether or not patients actually adhere to DOT becomes critical in addressing the overall TB epidemiology in the rural communities. Successful treatment

[4] Non-DOT: Self-supervised therapy where patients purchase medication from private clinics (source: SEWA-RURAL)

[5] Tribes: indicate a low socio-economic community of people who live in housings made of clay and straw

completion by adhering to DOT will be an important determinant to the overall TB control and management, especially for the most vulnerable.

The impact of non-adherence to DOT also holds great threat to the development of drug resistant strains. Studies indicate that although multi-drug resistant TB (MDR-TB) prevalence remains low for patients with new TB cases, it is more common among the previously treated patients (Ramachandran , 2009). Because patient's non-adherence to initial treatment may account for relapse as well as MDR-TB cases, complete adherence to DOT is essential in the control and prevention of TB. Yet, despite such recognition, patient adherence has not been previously documented in these regions.

Most research assessing patient adherence uses a quantitative approach. Although there has been an increasing demand for qualitative research on DOTS adherence to gaining a deeper understanding of the complex behavioral pattern, such studies remain limited (Volmink & Garner, 2006, 2007). Exploring the reasons behind poor adherence can indicate problems that require modifications; however, the mechanisms for successful intervention differs by context, and the essential features that make up such intervention are not well understood, especially among the population with the highest burden: the rural poor. Because poor adherence can lead to "prolonged infectiousness, drug resistance, increased replace case and even death," it poses a serious risk not merely for the individual but for the community as a whole (Munro, et al., 2007). Along with factors associated with treatment outcomes, a comprehensive understanding of the complex nature behind patient adherence to DOT is therefore crucial in the overall effort in TB elimination.

This study examined the patient factors associated with DOT outcomes (as a result of adherence), as well as the various barriers and facilitators that influence such adherence behavior in rural communities in the state of Gujarat, western India. A mixed method study was employed to assess these needs of DOTS patients, using both qualitative and quantitative methods. Additionally, the validation of outcomes was also assessed. The findings of the study offer

information essential for improving the delivery of DOT, providing public health implications for the overall control and prevention of TB especially among the rural communities who bear the highest burden of TB.

1.4. Background Information:

1.4.1. DOTS Strategy

The principal intervention against TB is the directly observed therapy, short-course (DOTS) strategy. The World Health Organization first introduced DOTS strategy in the mid-1990, centering its focus on diagnosis and treatment method (World Health Organization, 2002). DOTS is an internationally recommended control strategy for TB, which includes the delivery of a standard short course of first-line drugs, requiring a minimum 6 month treatment period for new patients and 8 months for retreatment patients (Munro, et al., 2007; Rouillon, 2010). The delivery of the treatment is administered by direct observation of therapy (DOT) provided by either a health worker or an individual nominated in the community, who cannot be a family member. During the intensive phase of DOTS (the first 2 months), the patient must swallow the medicine in the presence of the health worker or the assigned individual, followed by a continuous phase of one week (Tables 1&2). For the continuous phase, only the first dose is required to be observed; however, the consumption of the given medication must be ensured by the health worker in the following week by checking the patient's empty medication box. Various studies and reports (Chan & Iseman, 2002; Garner, et al., 2007; TBC India, 2010b; World Health Organization, 2006) indicate evidence supporting the effect of DOT, and the strategy has been promoted widely and implemented globally. In India, the Revised National Tuberculosis Program (RNTCP) applies the principles of DOTS in the Indian context and is described below.

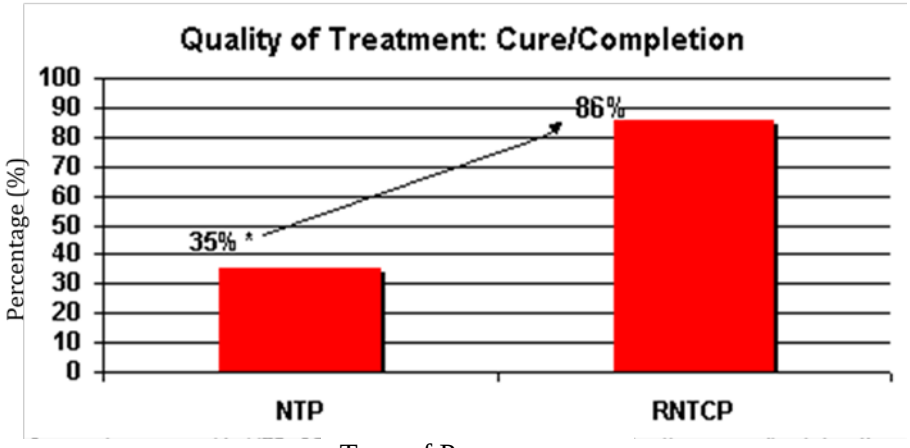
1.4.2. Revised National Tuberculosis Control Program, India

To address the high TB burden in the nation, the Revised National Tuberculosis Control Program (RNTCP) was first launched in India in 1993, implementing the WHO recommended

DOTS strategy(TBC India, 2010b). Beginning 1998, a rapid RNTCP expansion was initiated, covering about 30% of the country's population by the end of 2000. The expansion continued to flourish as 50% of the country was covered just two years later in 2002, quickly achieving 97% of the population by the end of 2005. By March 2006, the entire country was covered under DOTS (TBC India, 2010b).

Under the RNTCP, DOTS has five basic components: "political and administrative commitment, good quality diagnosis, good quality drugs, supervised treatment to ensure the right treatment given in the right way and systematic monitoring and accountability" (TBC India, 2010b).In continuous efforts to reach its goal in reduction of morbidity and mortality from TB, today, more than 15,000 suspects are examined daily for TB free of charge. As a result of the intensive examinations, about 3,500 patients are placed on treatment each day, demonstrating a significant increase from 35% to 86% treatment success rates compared to the previous programme (Figure 2). The definitions for diagnosis, treatment regime and outcomes are summarized below (Tables 1, 2 & 3).

Figure 4. Percentage of Treatment Success (Cure/Completion) in Current Strategy Acquiring DOT (RNTCP) Compared to Previous Strategy without DOT (NTP) in India[6]



6 TBC India

1.4.3. Definitions under the RNTCP[7]

Table 1. Diagnosis for Tuberculosis (WHO Guidelines).

Diagnosis:	
B:	*Smear-positive pulmonary cases:* Patients with at least 2 sputum samples positive for acid-fast bacilli (AFB) by microscopy or, patients with one positive sputum sample and radiological abnormalities consistent with active pulmonary TB.
X:	*Smear-negative pulmonary cases:* Patients with at least 3 sputum samples negative for AFB by microscopy, but radiological abnormalities and history/clinical evidence as determined by the physician is consistent with active pulmonary TB.
E:	*Extra-pulmonary TB cases:* Patients history/clinical evidence consistent with active TB as determined by the physician. Extra-pulmonary TB can be diagnosed for any part of a body including the pleura, lymph nodes, bones and joints, genito-urinary tract and central nervous system.

Table 2. Treatment Regimen Categories (WHO Guidelines).

Category	**Treatment**
Category I: New cases who are sputum-positive.	Treatment follows two phases. First, in the intensive phase, isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) are given under DOT 3 times a week on alternative days for 2 months (24 doses). In the continuous phase, isoniazid (H) and rifampicin (R) are given on alternative days for 4 months (54 doses). The first dose of each week is directly observed.
Category II: Re-treatment cases including patients with relapse, failure or default patients who return to treatment.	Treatment follows two phases. First, in the intensive phase, isoniazid (H), rifampicin (R), pyrazinamide (Z), ethambutol (E) and streptomycin (S) are given under DOT 3 times a week on alternative days for 2 months (24 doses). This is followed by one month of isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) 3 times a week on alternative days under DOT. In the continuous phase, isoniazid (H) and rifampicin (R) and ethambutol (E) are given 3 times a week on alternative days for 5 months (66 doses). The first dose of each week is directly observed.
Category III: Sputum-negative patients who possess signs and symptoms of TB, or have extra-pulmonary TB and are not seriously ill.	Treatment follows two phases. First, in the intensive phase, isoniazid (H), rifampicin (R), and pyrazinamide (Z) are given under DOT 3 times a week on alternative days for 2 months (24 doses). In the continuous phase, isoniazid (H) and rifampicin (R) are given on alternative days for 4 months (54 doses). The first dose of each week is directly observed.

[7] ibid

Table 3. Treatment Outcomes (RNTCP).

Outcome	**Definition**
Cured	Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on two occasions, one of which was at the end of treatment.
Completed	Sputum smear-positive patient who has completed the treatment, with negative smears at the end of the intensive phase but none at the end of treatment.
Default	A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting the treatment.
Failure	Any TB patient who is smear positive at 5 months or more after starting a treatment.
Died	Patient who died during the course of treatment regardless of the cause.

Chapter 2: Review of Literature.

Despite various interventions aimed at improving the treatment completion suggested by directly observed therapy (DOT), poor adherence to treatment is still common especially among middle-to-low income countries (Munro, et al., 2007). Studies (Garner, et al., 2007; Volmink & Garner, 2007) indicate a lack of comprehensive and holistic understanding of barriers and facilitators to treatment adherence, considering it as a major obstacle in the current effort for TB control (Munro, et al., 2007). Because complete treatment is a major determinant to successful treatment outcomes (i.e. cured patients), patient adherence has been the key evidence for and against DOT especially among the high-burden low socio-economic population (Garner, et al., 2007). Previous literature indicates some of the important factors associated with treatment outcome as a result of patient adherence behavior, as well as the behavioral influences on DOTS adherence, especially among the vulnerable populations.

Quantitative assessments have indicated multiple factors associated with poor treatment outcomes, including non-adherence. A study conducted in the Southern region of Ethiopia indicated that being male (AOR 1.24, 95%CI 1.09-1.42), age >55 years (AOR 1.44, 95%CI 1.12-1.86) and having smear-negative pulmonary TB (AOR 1.62, 95%CI 1.4-1.86) were independent risk factors for poor outcomes (Munoz-Sellart, Cuevas, Tumato, Merid, & Yassin, 2010).In India, a similar result was obtained by a study conducted in Chennai, Tamil Nadu, which also indicated significant associations between default amongst men (AOR 3.4; 95%CI 1.5-8.2), history of previous treatment (AOR 2.8; 95%CI 1.6-4.9) and alcoholism (AOR 2.2; 95%CI 1.3-3.6) (Santha et al., 2002). In addition, patients with multidrug-resistant tuberculosis (MDR-TB) were more likely to fail treatment (33% vs. 3%; $P < 0.001$), while weight < 35kg was an independent factor associated with death (Santha, et al., 2002). Because unfavorable outcomes result in the decrease of treatment success rate, identifying the factors contributing to default would significantly improve programme outcomes. Studies (Munro, et al., 2007; Santha, et al., 2002) reveal that implementation of additional local strategies has led to positive outcomes, one of these strategies

is delivering DOTS via an Non-government organizations in the community to increase treatment adherence among their responsible communities (Santha, et al., 2002). As each region is unique, the need to consider the specific contexts in identifying the factors associated with patient adherence is critical in developing necessary modifications.

Among the studies conducted in low-resource countries, Thailand revealed that DOT was associated with lower odds of default during the treatment (Anuwatnonthakate et al., 2008). Such successful treatment completion and results have also been documented in rural Africa, where 89% of the study cohort completed 6 months of DOT under lay supervisors in the community (Volmink, et al., 2000). Likewise, in China, DOT has helped reduce TB prevalence by 40% from 1990 to 2000, and it "dramatically improved the cure rate in half of China's provinces" (Center for Global Development, 2007). With this high treatment success rate and the associated reduction in mortality, these results indicate a positive patient adherence pattern. Because various studies indicate that many patients in low-resource countries often discontinue the treatment process once their health condition starts improving (primarily due to lack of knowledge), DOT can emphasize the importance of continuing the treatment by constant reminders and compulsory attendance of patients under supervised therapy (Munro, et al., 2007; Singla et al., 2009).

While complete treatment by DOT is one of the most effective preventive measures against TB by reducing the infectious period and thus transmission, DOT also presents a range of challenges for both patients and providers especially in resource-poor countries. Studies (Munro, et al., 2007; Volmink & Garner, 2007) indicate that nearly 50% of all patients with TB do not complete treatment. With this in mind, some literature has questioned the importance of DOT for the success of TB treatment, with the "issue of contention [being] the extent to which DOT contributes to improved adherence to treatment" (Maher, 2003). A regression analysis conducted for a study in South India indicated that factors independently associated with default were having other commitments during treatment [AOR-3.22 (1.1–9.09)], inadequate knowledge of TB [AOR-1.88 (1.35–2.63)], and dissatisfaction with services provided [AOR-1.73 (1.14–2.6)]

(Vijay et al., 2010). Likewise, epidemiological studies and annual national reports indicate that unlike industrialized countries such as the United States where TB is mainly a disease of the elderly, in low-resource regions like Africa and India, younger age groups are those most at risk aged 15-59 (TBC India, 2010b; World Health Organization, 2010). Among this age group, men have higher reported cases of TB than women in general, and key findings of various articles indicate difficulty in adhering to DOT due to an inconvenient treatment schedule and access to health services providing DOT (Borgdorff, Nagelkerke, Dye, & Nunn, 2000; Dye & Floyd, 2006; Hamid Salim, Declercq, Van Deun, & Saki, 2004; Jaiswal et al., 2003; Jha et al., 2010; Radhakrishna, Frieden, & Subramani, 2003). These results illustrate the challenges in adhering to DOT in low-resource countries where patients' adherence depends largely on the convenience and quality of the service provided, which are difficult to be managed due to lack of adequate personnel and logistics while facing a large population in communities with multiple health issues.

Furthermore, although the medication is free of cost, many patients still have to cover the transportation costs (Jaiswal, et al., 2003). A study in India indicated that among the factors associated with default, difficulty in accessing a health facility and non-government DOT center due to cost of transportation comprised 57% and 43% of patients, respectively (Jha, et al., 2010). Likewise, in Pakistan, the additional cost required for patients to reach the nearest health facility for 2 months was equivalent to 6 days of wages (Walley, Khan, Newell, & Khan, 2001). Hence, studies indicate that while some countries preferred public health services, low-resource countries tended to prefer private doctors where the medication could be self-administered instead of DOT (Lienhardt & Ogden, 2004).

Similarly, although DOT is strongly advocated by the WHO and other international agencies, "controversy remains whether its benefits have been proven" (Volmink & Garner, 2007). As mentioned above on the preference of self-administration over DOT, the results of randomized controlled trials conducted in low-resource countries provided " no assurance that

DOT compared with self administration of treatment had any quantitatively important effect on treatment completion in people receiving treatment for tuberculosis" (Lienhardt & Ogden, 2004; Volmink & Garner, 2007; Walley, et al., 2001; Zwarenstein, Schoeman, Vundule, Lombard, & Tatley, 2000). Considering the additional financial burden and commitment required by both patient and providers, some studies suggest that these may worsen patient adherence to DOT in some countries (Anuwatnonthakate, et al., 2008; Volmink & Garner, 2006).

While these quantitative findings provide insightful information regarding the factors significantly associated with DOT adherence, a detailed understanding on the socio-cultural influences and possible interventions still remain unclear (Chowdhury, Chowdhury, Islam, Islam, & Vaughan, 1997; M. A. Khan, Walley, Witter, Shah, & Javeed, 2005; Lewis & Newell, 2009; Munro, et al., 2007; Newell, Baral, Pande, Bam, & Malla, 2006). Key findings from systematic reviews of qualitative research on patients' treatment adherence indicate that "lay conceptualizations of TB illness and its treatment are not well understood" (Munro, et al., 2007). These studies suggest that understanding "lay conceptualizations in social, economical and geographical context" (Cramm, Finkenflugel, Moller, & Nieboer, 2010) would help in further understanding the impact of traditional beliefs and comprehending the reason behind treatment interruption (Volmink & Garner, 2007).

The acceptability of DOT in low-resource countries is one such aspect related to poor adherence, which has been a much questioned concern (Nyblade, Stangl, Weiss, & Ashburn, 2009). Studies have suggested that fear and stigma associated with TB is "an obstacle to treatment and that DOT may aggravate this stigma especially in the presence of HIV infection" (Nyblade, et al., 2009). Studies conducted in Bangladesh showed that married women often worried about being divorced by their husbands; hence, once the symptoms subside, they may stop the medication in between, resulting in such default case (Connolly & Nunn, 1996). Previous literature revealed that factors such as social context and healthcare service play a significant role in influencing patients' health-seeking behavior, with social support being a positive influence

while stigma and inadequate service, including cost, access and side-effects of medication, often conflict with treatment adherence (A. Khan, Walley, Newell, & Imdad, 2000; Watkins & Plant, 2004). Studies indicate fear of infection to be the most common cause of TB stigma with serious socioeconomic consequences particularly for women (Courtwright & Turner, 2010). Hence, adherence to treatment is not merely influenced by patient factors, but it is framed by the physiological and psychological impacts of the disease as well as by social and cultural structures (Munro, et al., 2007). Other studies also demonstrate that a positive patient-provider relationship has a stronger link with compliance behavior than those of more acknowledged concepts such as knowledge of TB and health beliefs (Waisbord). Likewise, studies in other parts of India, Bangladesh, Nepal and Pakistan reveal that patient-provider relations are a key influence to DOT adherence, where poor communication and inconvenient treatment schedule hold significant impact on the patients' willingness to adhere to DOT (Chowdhury, et al., 1997; M. A. Khan, et al., 2005; Lewis & Newell, 2009; Munro, et al., 2007; Newell, et al., 2006).

Numerous countries have adopted DOT since its initial launch by the WHO, but the actual method of implementation differs by countries. Many countries offer support in terms of food, clothing, money and transport, while others have active tracing method to remind the patients of the treatment scheme (Volmink & Garner, 2007). An example in Bangladesh demonstrates a strategy where 5 days of wages is taken from a patient at the start of the therapy, of which half is returned to the patient upon completion while the other half is given to a community health worker involved in providing the therapy (Chowdhury, et al., 1997). Such a strategy demonstrates a means by which the patient is given agency and responsibility to adhere to treatment while also benefitting the provider.

Treatment adherence in India:

Studies (Chowdhury, et al., 1997; Weiss et al., 2008) indicate that many of the socio-cultural factors influencing patient adherence in India are similar to those demonstrated in other high-burden countries. In addition, a multi-site analysis using qualitative research indicates that

there is a gender disparity in terms of socio-economical factors influencing DOT adherence. While male patients focused more on the economical burden and financial concerns of the treatment, the concerns of the female patients were more diverse (Chowdhury, et al., 1997; Weiss, et al., 2008). However, these studies also indicate that "gender has not received adequate attention in social studies of TB," and indicate a greater need to further breakdown the complex influences attached to each gender (Weiss, et al., 2008). Likewise, another study in India provides a descriptive account of the cultural epidemiology in understanding the determinants of delayed diagnosis; yet, there remains a need for a qualitative account of relevant contexts and analysis of socio-cultural factors (Gosoniu et al., 2008; Weiss, et al., 2008). A deeper understanding of gender-specific issues and other socio-cultural influences on patients' treatment adherence behavior (post diagnosis) would further contribute to the practical impact of programme action that aims to improve DOT adherence.

Additionally, various studies indicate a high incidence of TB found among drug addicts, often resulting in non-adherence to DOT. In addition to the routine anti-TB treatment, an interventional prospective study involving drugs counseling was offered to drug addicts under the RNTCP in the capital, New Delhi. The results demonstrated that with the supplementary intervention, the overall treatment success rate in drug addicts improved to 83.3%, followed by 3.3% of default and 1.7% of failure, "both within the permissible range of RNTCP (<4%) (Dhingra, Lall, Aggarwal, & Vashist, 2008). Along with substance abuse, the key influences surrounding DOT adherence at a structural level are described primarily as duration of medication, unpleasant side-effects, distance to the clinic and inconvenient clinic timings (Addington, 1979; Cuneo & Snider, 1989; Jaiswal, et al., 2003). Lastly, various studies (Andersen, Lillebaek, Bang, & Prahl, 2011; Singla, et al., 2009) indicate that patients often discontinue the treatment process when they start feeling better. In relation to lack of knowledge and improper communication by the providers, this probably is one of the most highlighted behaviors for default patient. Consequently, the need for qualitative research has been increasing

in an effort to better understand patient adherence for improved treatment outcomes.

Validity of the Treatment Outcome:

Valid and complete TB surveillance data are essential in evaluating the success of TB control interventions such as DOT. The WHO and the Center for Disease Control and Prevention (CDC) stress the significance of monitoring and evaluating of TB program performance, as inadequate data quality can vastly influence the true epidemiology of TB and the treatment success rate, "undermining the ability to meet program objectives" (Sprinson, 2006). These data are the tool for local, national and global efforts to control and eliminate TB, although regional or country-wise disparities exist in the availability of accurate and complete TB surveillance.

While industrialized countries such as the U.S demonstrates as high as 90% validity of the data in the case report (Sprinson, Lawton, Porco, Flood, & Westenhouse, 2006), assuring the validity of reported cases and outcomes is more complex in the developing countries. Even within the industrialized countries, an evaluation of the monitoring system in Europe revealed that the treatment success rate of 85% was not achieved in 2002, partly due to missing outcome information for 21% of the cases (Antoine, French, Jones, & Watson, 2007). Among developing countries, a similar study assessing the quality of the DOTS strategy in Indonesia also revealed a high (54.3%) number of missing cases in hospital registers (Probandari, Utarini, & Hurtig, 2008). The study indicated the significance of ensuring the validity of information provided, as the proportion of cases with a successful outcome is a key indicator to assessing the efficacy of a national TB control programme.

Likewise, a WHO report emphasizes that in making policy recommendations, "it must be evidence-based, driven by accurate and representative data" (World Health Organization, 2008b). As required by the DOTS strategy, accurate reporting results from a valid diagnosis (WHO); however, a wide range of challenges exist for laboratories in resource-limited settings including laboratory management at all levels of the health care system, infrastructure and support systems along with inadequate laboratory equipments and technologies, human capacity development,

national laboratory referral and quality assurance programs, comprehensive monitoring systems and mobilizing resources to finance the strategic plans (Arora, 2004; Diaz, De Cock, Brown, Ghys, & Boerma, 2005). Although improving, the reliability of the treatment outcome reports still remains a concern especially among resource-poor rural settings (de Kantor & Barrera, 2007).

Nevertheless, studies also indicate that with dynamic public-private collaboration, management of TB report can improve. A study conducted in the Philippines showed that with the support of public-private collaboration, the treatment success rate improved from 64% in 1999 to 75% in 2005 (Quelapio et al., 2010). In India, a study conducted in Pune illustrated that close communication with a government sector and the NGO-run hospitals contributed to the success of the RNTCP(Dhotre, 2003) . Because treatment for patients in the RNTCP is decentralized (so that patients can receive the medication closest to their home), the treatment outcomes are collected from each district that the patient is registered under. The quality of these data is monitored so that attention can be given to the district units that are under performing (TB control in Tamil Nadu: Scope for improvement, 2003); however, such efforts are not well documented.

Likewise, a 2004 internal evaluation of RNTCP in Dhahod district in the state of Gujarat (India) revealed that in terms of reports and records, none of the primary health centers (PHCs) had sent the program management report to the district (TBC India, 2010a). Because this action is crucial in ensuring the drug supply and the overall treatment process, failure to meet the monthly report could inversely affect the patient outcome. Further, treatment cards at the PHCs were found to be incomplete and incorrect, as well as erasing and over-writing in the TB registers, lab registers and treatment cards were noted (TBC India, 2010a). Inconsistencies were also noted between the TB cards and number of medicine strips in the patient's medication boxes. Although there were very few inconsistencies between hospital and laboratory TB registers regarding cure rates, there have been inconsistencies between these TB registers and the district's TB Unit reports regarding the cure rates. This may be owing to the delayed follow-up sputum examination

reporting between the local and district levels. Because timely follow up of accurate results is crucial in the course of treatment and the final outcome, further collaboration between the local and district TB units should be strongly encouraged. Treatment success measured is one of the key programmatic output and the importance of strengthening treatment outcome monitoring has been recognized globally (Manissero, Hollo, Huitric, Kodmon, & Amato-Gauci, 2010).

Taken together, a need for a comprehensive understanding of patient adherence to directly observed therapy (DOT) and its resulting impact on the outcomes in a culturally specific context has been gaining more attention in the recent years. While complete treatment is one of the most effective preventive measures against TB, studies also highlight the difficulty in adhering to DOT (Cuneo & Snider, 1989; Munro, et al., 2007). Non-adherence to therapy holds significant impact both at individual and at public health levels and patient adherence to DOT therefore plays a significant role; however, little information is known from qualitative research about contextual influences on TB adherence among the community most impacted: the rural poor. Traditionally, research has focused on quantitative measures alone in addressing risk factors for treatment default and failure (unsuccessful treatment outcomes), but there has been little information regarding the complex net of influences that underline the treatment adherence behavior. Findings from the quantitative assessments have provided useful indicators for identifying the problems associated with non-adherence; however, the reasons behind these problems and the possible interventions that can lead to successful modification remain unclear (Volmink & Garner, 2007).Previous literature suggests the significance of the cultural context in influencing one's choice of treatment adherence, and there has been an increasing demand for studies that incorporate qualitative approach in understanding these influences (Munro, et al., 2007; Volmink & Garner, 2007). While quantitative studies can identify the factors associated with treatment adherence and hence the outcomes, qualitative approach can further explain the details of such behavioral pattern. Consequently, along with the quantitative approach offering statistical association of factors associated with treatment outcomes, an increasing emphasis has

been placed on the need for gaining a comprehensive understanding of the barriers and facilitators to DOT adherence, both from recipients and provider's perspectives. These findings can together contribute valuable information to the overall TB control and management, especially helpful among the less researched, yet vulnerable population.

This study aims to identify patient factors associated with DOT outcomes in a rural community, as well as to understand the details on socio-cultural influence, the different pathways of behavior and possible recommendation for strengthening adherence to the programme. The specific aims of the study are:

Quantitative: *1.What are the outcomes of all tuberculosis patients referred to the Government sponsored DOT in Jhagadia and Valia talukas (towns)?*

2. What is the reliability of the DOT outcome obtained from the Government register?

3.What are the factors associated with the treatment outcomes?

Qualitative: *4.What are the facilitators and barriers to DOT adherence from recipients and providers' perspectives?*

The findings of the study will contribute to an effort in further strengthening patient adherence for the existing programme and hence, the effectiveness of DOT in the control and prevention of TB.

Chapter 3:

3.1. METHODOLOGY

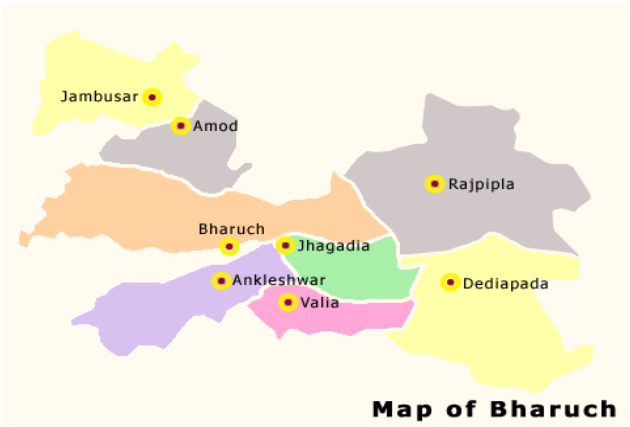
3.1.1. Introduction

To address these needs, a mixed method study was conducted in Jhagadia and Valia talukas (towns) in Bharuch district, Gujarat, India (Figure 5). The study assesses patient adherence and the efficacy of DOT in obtaining high treatment completion and hence, a high cure rate, using both quantitative and qualitative approaches. The specific goals of this study were to determine and validate the outcomes of suspected TB cases referred to district's DOT service by SEWA-RURAL, as well as to deduce factors associated or influencing the adherence behavior.

3.1.2. Study setting and design

Among all TB patients referred to DOT by SEWA-RURAL, 86.7% of them reside in either Valia or Jhagadia talukas (towns) in Bharuch district. Jhagadia and Valia talukas (towns) together make up a population of about 2.6 million (Government of Gujarat). The economy of these areas is mainly dependent on agriculture, in particular banana, sugar cane, cotton and wheat crops for export. Along with other local businesses, SEWA-RURAL also provides vocational training for the youth of low-socioeconomic population, who are then given employment opportunities. Overall, the two study sites represent typical rural communities in South Gujarat.

Figure 5. Map of Bharuch District[8]



[8] ibid.

3.1.3. Quantitative

3.1.3.1. Study setting and population

The study population included all tuberculosis patients residing in Jhagadia and Valia talukas (towns) in Bharuch district, who had been referred to the district TB Unit for DOT by SEWA-RURAL hospital from July 2007 to December 2009. The time frame for the study population chosen was between 2007 to 2009, in order to obtain the most recent years of a cohort that could best represent the current situation regarding the efficacy of DOT. The summary of the patient characteristics is shown in Table 5 of the Result section.

3.1.3.2. Factors and factor definitions

Standard international definitions following the WHO guidelines were used to classify the patients. The primary variable of interest was *Category*, dichotomized as "Category I" (C 1) or "Non-Category I" (Non C-1). Category I indicated new sputum positive patients. The "Non-Category I" group included patients of Category II and III; "re-treatment cases including patients with relapse, failure or default patients who return to treatment, [and] sputum negative patients." *Type of diagnosis* was classified into 'smear-positive pulmonary case' (B), 'smear-negative pulmonary case' (X), or 'extra-pulmonary case' (E). *PHC* stood for primary health center. *Tribal status* was divided into 'tribes' and 'non-tribes,' with 'tribes' indicating those who lived in a mud houses made of clay and straw, while 'non-tribes' lived in a concrete houses in the community. Additionally, all continuous variables were dichotomized into categorical variables: *age* was dichotomized into younger (less that 45 years) or older (equal to or more than 45 years) age groups, and *body weight* was dichotomized into less than 35 kg or equal to or more than 35 kg. The cut-off points for both variables were chosen based on the RNTCP report 2003 and literature review. The factors assessed in this study included: Age, Sex, Tribal status, Type of diagnosis, Occupation, Body weight, Category and Primary health center (PHC).

The referent group for each factor was selected accordingly:

Age and Body weight:

The national TB reports of India indicate association between lower weight and TB (TBC India). Additionally, TB in India is a disease of the younger generation (mostly between 15-45 years), unlike the industrialized countries where it is more commonly a disease of the older age group due to weakened immune system (RNTCP, 2003). Based on this, the referent groups for 'age' and 'body weight' were chosen as the older group (>=45 years) and the heavier group (>=35kg), respectively.

Sex:

Female was chosen as the referent group for 'sex' as various studies indicate significant association between TB and being a male (Anuwatnonthakate, et al., 2008).

Type of diagnosis, Occupation and PHC:

The referent groups for 'tribal status' and ordinal variables 'type of diagnosis,' 'occupation' and 'PHC' were chosen according to each outcome based on the lowest frequency [Table 5].

3.1.3.3. Data collection

The treatment outcomes of all TB patients referred to DOT from July 2007 to December 2009 were obtained from the district TB Unit outcomes register. The referred patients and their outcomes were identified via matching the patients' TB identification number on the official referral records by SEWA-RURAL hospital with the district TB Unit DOT outcomes register. Because DOT takes a minimum of a 6 months treatment period, patients whose initial register dating from December 2009 were excluded from the year 2009 as their outcome could not be obtained from the district TB Unit register during the research period in the month of June 2010. All patient characteristics were obtained from the SEWA-RURAL hospital register.

To confirm the treatment outcomes obtained from the district TB Unit, data were collected by visiting the patients identified on the hospital register, or by conducting a verbal autopsy with family members if the patient had already deceased at the time of field visit. Patients

were asked to show their follow-up sputum examination records. About 15% of the patients on the SEWA-RURAL hospital register was visited from June to August 2010.

3.1.3.4. Statistical Analysis

Univariate analysis between each factor and each of the individual and comparison outcomes (completed[9], default, cured, failure and died; completed vs. default, cured vs. failure) were assessed via simple logistic regression. Crude odds ratios (OR) and 95% confidence intervals (CI) were computed for the interpretation of univariate analysis. Taking *category* as the primary variable, all variables were assessed for interaction and confounding to build associative models. In addition, each model also included specific covariates considered significant in univariate analysis [Table 2]. For outcome "default," *sex* was forced in the model owing to literature reviews indicating significant association between males and default in South India (Anuwatnonthakate, et al., 2008). To identify factors that independently reduced or increased the odds for each outcome, stepwise logistic regression analysis was applied and the effects of backward elimination were examined to determine the most parsimonious model. Adjusted odds ratios (AOR) and 95% CI were computed for interpretation. The criterion for inclusion in the model was set at $p < 0.05$. All statistical analyses were conducted using SAS statistical software, Version 9.2 and $p < 0.05$ was considered to be statistically significant. Agreement on treatment outcome between district TB Unit and the study team was quantified using Cohen's Kappa coefficient statistic.

[9] According to the RNTCP (WHO guidelines), 'completed' indicates Sputum smear-positive patient who has completed the treatment, with negative smears at the end of the intensive phase, but none at the end of treatment. Refer to Table 3.

3.1.4. Qualitative

3.1.4.1. Study population

The qualitative part of the study was conducted in Jhagadia taluka (town) from June to August, 2010. A total of 21 participants were purposefully selected by identifying specific patients according to treatment outcomes form the SEWA-RURAL TB register record. These included patients who were categorized as ‘cured,’ ‘completed,’ ‘default,’ or ‘failure’. The selection criterion for age was between 20-50, based on the RNTCP report identifying this age-group as the most vulnerable to TB in India (RNTCP, 2003). All patients were married owing to traditional practice of early marriage.

The in-depth interview represented both recipients and providers of DOT service. This study was conducted in a total of seven different villages in Jhagadia taluka (town) within the catchment areas of six primary health centers (PHCs). The recipients of DOT comprised of tuberculosis (TB) patients who belonged to one of the following TB treatment categories: completed treatment, defaulted, cured or failed to be cured upon treatment completion. For the purpose of comparison and to facilitate a diverse sample, both male and female participants were recruited, tribe and non-tribe members, and those with various occupational backgrounds. Likewise, frontline community health workers and hospital staff who provided DOTS were selected; all frontline community health workers were female, while hospital staffs were male. Table 4 summarizes the participant characteristics recruited for the in-depth interviews.

Table 4. Summary of Participant Characteristics Recruited for In-depth Interviews

Age	Gender	Marital Status	Tribal Status	Occupation	TB Category	PHC (Village)
20's 30's 40's 50's	Male Female	Married Unmarried	Tribe Non-Tribe	Farmer Non-farm work Housewife	Completed Cured Default Failure	Avidha (Rajpardi) Dharoli (Gulfaliya) Gowali (Kapalsadi) Jhagadia (Limodra; Jhagadia) Jespor (Jespor) Panetha (Asha)

3.1.4.2. Participant recruitment

Participant recruitment involved visiting the houses of patients who were list selected from the TB register record according to their outcomes. This approach was appropriate for the non-tribes; however, the address recorded for tribes were found to be inadequate for tracing the patients. Hence, for each village listed under the TB register, all tribe patients were selected as 'potential' participants and recruited for the study on site upon field visit. Attempts were made to interview patients at their homes, and each 'potential' participant on the list was approached until the purposive sample had been achieved. If the desired patient was not traceable or already deceased at the time of field visit, the next patient on the list who matched the relevant TB treatment category, sex, age, occupation and PHC was recruited.

3.1.4.3. Data Collection

In-depth interviews were conducted with each patient at his or her place of residence. The interview guide was developed in collaboration with the SEWA-RURAL team consisting of community health physicians, training center coordinator, TB program supervisor and a senior internist. The initial guide was reviewed by Dr. Monique Hennink and changes were made accordingly. After a careful review, a total of four interview guides were prepared: one for the

completed and *cured* patients, one for *default*, one for *failure* and one for the *DOT providers*. Questions covered a range of socio-cultural and economic aspects including knowledge of TB, attitude towards TB, health-seeking behavior, family/social support, experience with the DOT recipient/provider, benefits and difficulties of the DOT, and possible suggestions or advice for the government for future TB patients. For DOT providers, default and failure patients, additional questions specific to each were added to the original guide. The interview guides were initially developed in English, which were then translated into Gujarati by a community health physician and the project supervisor. The Gujarati form was re-checked by the team for a final review and pilot tested prior to use. Because pilot-testing revealed some difficulties for patients in answering certain questions due to fear for judging the authority figures, the cultural context was taken into consideration and the changes were made to the introduction section to more strongly emphasize the security of the participant's identity as well as ensuring that there would be no penalization for any information that they revealed. Further, because there was an issue of insecurity and possibility of feeling intimidated by the mere presence of a doctor interviewer, all interviews on the participants other than the DOT providers were conducted by a medical intern rather than a doctor. Oral consent was received from each participant and the interview was tape recorded, transcribed verbatim and de-identified. They were then translated into English.

3.1.4.4. Data analysis

Data analysis followed a series of procedures. All documents were imported to MAXQDA10 software and read repeatedly. Any underlying issues noticed in a particular segment of the data were noted in a memo. The memo also included questions and reflections regarding the data, recording thoughts on the reason why one segment may be interesting, or to identify the context of the data, as well as what additional information may be desirable from the data. After annotating the data, all memos were read once again to identify themes across the data. Subsequently, core codes were developed based on their frequency of recurrence, the detail of the contents surrounding the issue and any other topics that stemmed out of the data. The codes

included both inductive and deductive codes. Once the core variables were developed, each of them was defined and a codebook was developed. Any modification to the code definition was made accordingly. The entire data set was then coded for analysis. Grounded theory analysis was used, which identified key issues and experiences from both recipients and provider's perspectives. These themes were subsequently compared by subgroups (i.e., gender, tribal status, TB treatment category,) using cross-case comparison strategy to further identify variations in attitudes and pathways of behavior. These data were then conceptualized by categorizing the main themes to identify relationships between codes and the meaning of these relationships in relation to the study objective.

3.1.5. Ethical consent

The study proposal was reviewed and excluded by the Institutional Review Board (IRB). All documents were de-identified to ensure that confidential information is protected. Additionally, due to a high illiteracy rate in the community, participant consent was obtained orally by SEWA-RURAL representative. All participation was voluntarily and any participants who refused or wished to stop the interview abruptly were granted.

3.2. RESULTS

The results obtained from quantitative and qualitative methods are described below.

3.2.1. Quantitative Results

Table 5. Characteristics of TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

Factor	Total n (%)	Completed n (%)	Default n (%)	Cured n (%)	Failure n (%)	Died n (%)	Missing n (%)
Total	**592 (100)**	**28 (4.7)**	**25 (4.2)**	**346 (58.4)**	**11 (1.9)**	**18 (3.0)**	**164 (27.7)**
Age (years)							
< 45	454 (76.69)	21 (4.6)	18 (4.0)	274 (60.3)	9 (2.0)	14 (3.1)	118 (26.0)
≥45	138(23.3)	7 (5.1)	7 (5.1)	72 (52.2)	2 (1.4)	4 (2.9)	46 (33.3)
Sex							
Male	410 (69.2)	17 (4.1)	19 (4.6)	239 (58.3)	7 (1.7)	11 (2.7)	117 (28.5)
Female	178 (30.0)	10 (5.6)	6 (3.4)	106 (59.6)	4 (2.2)	7 (3.9)	45 (25.3)
Tribal Status							
Tribe	513 (86.7)	19 (3.7)	22 (4.3)	312 (60.8)	9 (1.8)	17 (3.3)	134 (26.1)
Non-Tribe	79 (13.3)	9 (11.4)	3 (3.8)	34 (43.0)	2 (2.5)	1 (1.3)	30 (38)
Type of diagnosis							
B	505 (85.3)	0 (0)	24 (4.8)	335 (66.3)	11 (2.2)	16 (3.2)	119 (23.6)
X	51 (8.6)	17 (33.3)	10(20.0)	1 (2.0)	0 (0)	2 (4.0)	21 (41.2)
E	36 (6.1)	11 (30.6)	0 (0)	1 (2.8)	0 (0)	0 (0)	24 (66.7)
Occupation							
Farmer	399 (67.3)	16 (4.0)	20 (5.0)	238 (59.1)	5 (1.2)	13 (3.2)	107 (26.6)
Housework	158 (26.7)	11 (7.0)	4 (2.5)	89 (56.3)	4 (2.5)	5 (3.2)	45 (28.5)
Non-farm work	11 (1.9)	0 (0)	0 (0)	5 (45.5)	2 (18.2)	0 (0)	4 (36.3)
Study/other	21 (3.5)	0 (0)	1 (5.3)	14 (73.3)	0 (0)	0 (0)	6 (28.6)
Child	3 (0.5)	1 (33.3)	0 (0)	0 (0)	0 (0)	0 (0)	2 (66.7)
Body Weight							
< 35kg	176 (29.73)	13 (7.4)	9 (5.1)	90 (51.1)	5 (2.8)	10 (5.7)	49 (27.8)
≥ 35kg	416 (70.27)	15 (3.6)	16 (3.8)	256 (61.5)	6 (1.4)	8 (1.9)	115 (27.6)
Category							
C1	486 (82.1)	21 (4.3)	16 (3.3)	306 (63.0)	9 (1.9)	11 (2.3)	23 (4.7)
Non-C1	106 (17.9)	7 (6.6)	9 (8.5)	40 (37.7)	2 (1.9)	16 (15.1)	41 (38.7)
PHC (Valia)							
Chasvad	15 (2.59)	0 (0)	0 (0)	7 (46.7)	1 (6.6)	0 (0)	7 (46.7)
Delhi	25 (4.32)	0 (0)	0 (0)	16 (64.0)	0 (0)	0 (0)	9 (36.0)
Gundiya	26 (4.49)	2 (7.7)	2 (7.7)	17 (65.4)	0 (0)	0 (0)	5 (19.2)
Kara	25 (4.32)	1 (4.0)	0 (0)	14 (56.0)	0 (0)	0 (0)	15 (60.0)
Netrang	48 (8.29)	1 (2.1)	1 (2.1)	34 (70.8)	1 (2.1)	0 (0)	11 (22.9)
Thava	31 (5.35)	2 (6.4)	3 (9.7)	15 (48.4)	0 (0)	0 (0)	11 (35.5)
PHC (Jhagadia)							
Avidha	56 (9.61)	4 (7.0)	2 (3.5)	29 (50.9)	5 (8.8)	3 (5.3)	14 (24.6)
Bhalod	21 (3.63)	0 (0)	0 (0)	12 (60.0)	0 (0)	0 (0)	8 (40.0)
Dharoli	90 (15.54)	4 (4.4)	3 (3.3)	65 (72.2)	2 (2.2)	0 (0)	16 (17.8)
Gowali	58 (10.02)	4 (6.9)	3 (5.2)	31 (53.4)	0 (0)	1 (1.7)	19 (32.8)
Jespor	37 (6.39)	1 (2.7)	4(10.8)	21 (56.8)	0 (0)	3 (8.1)	8 (21.6)
Jhagadia	75 (12.95)	4 (5.6)	3 (4.2)	31 (43.1)	2 (2.8)	5 (6.9)	27 (37.5)
Moriyana	42 (7.25)	2 (5.1)	1 (2.6)	23 (59.0)	0 (0)	2 (5.2)	11 (28.2)
Panetha	30 (5.18)	2 (6.7)	2 (6.7)	24 (80.0)	0 (0)	0 (0)	2 (6.7)

3.2.1.1. Patient Characteristics

From July 2007 through December 2009, 592 tuberculosis patients were referred by SEWA-RURAL hospital and registered under district's DOT treatment. In general, most patients were males (69.2%), below the age of 45 years (76.7%), of tribe status (86.7%) or worked at a farm (67.3%). The majority were category I patients who were new sputum positive cases

(82.1%) and weighed more than 35 kg (70.3%). Among the various primary health centers (PHCs) in Valia and Jhagadia talukas (towns), Dharoli PHC had a higher portion of the patients (15.5%) compared to other PHCs, while Chasvad PHC had the lowest (2.6%). The baseline characteristics of TB patients for each outcome are shown in Table 5. Of the registered patients on DOT, 28 (4.7%) completed treatment, 25 (4.2%) defaulted, 346 (58.4%) were cured, 11(1.9%) failed to be cured by complete treatment (final sputum examination=positive) and 18 (3%) died. Additionally, 164 (27.7%) were missing.

3.2.1.2. Factors for treatment default

Table 6. Factors for 'default' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[§]

	Default			
	Crude OR*		AOR*	
Factors	(95%CI) [†]	P-Value[^]	(95%CI) [†]	P-Value[^]
Category		0.020		0.024
C1	0.37 (0.16-0.85)		0.38 (0.16-0.88)	
Non-C1	1.00		1.00	

[*]OR=Odds Ratio; AOR=Adjusted Odds Ratio; [†]95% C.I = 95% Confidence Interval; [^]*p <0.05*

[§] Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

Among the 592 patients, 25 (4.2%) were defaulters [Table 5]. Most were TB category I patient (5.1%), below the age of 45 years (4%), weighed more than 35kg (3.8%) and males (4.6%) of tribal status (4.3%) and worked at the farm (5%) [Table 5]. Among the PHCs, the distribution of the number of patients who defaulted were relatively equal, with the exception of Jespor PHC (10.8%) that showed slightly higher portion compared to the rest [Table 5]. Primary variable of interest (category) was the only factor that was significantly associated with treatment default; none of the other factors were significant both in unadjuted and adjusted analyses ($p<0.05$) [Table 6]. At the 5% significance level, there is sufficient evidence to conclude that TB category is independently associated with treatment default; the odds of treatment default for patients with TB category I is 0.38 times the odds of treatment default for patients other than category I (AOR: 0.38, 95%CI: 0.16, 0.88) [Table 6].

3.2.1.3. Factors for not giving final sputum check at treatment completion (i.e.'completed')

Table 7. Factors for 'completed' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[ϕ]

	Completed			
	Crude OR*		AOR*	
Factors	(95%CI)[†]	P-Value[^]	(95%CI)[†]	P-Value[^]
Tribal Status		0.005		0.006
Tribe	0.30 (0.13-0.69)		0.31 (0.13-0.72)	
Non-Tribe	1.00		1.00	
Body Weight		0.052		0.293
<35kg	2.13 (0.99-4.58)		3.41 (1.45-6.21)	
≥35kg	1.00		1.00	
Category		0.319		0.019
C1	0.64 (0.26-1.54)		0.78 (0.32-0.83)	
Non-C1	1.00		1.00	

[*]OR=Odds Ratio; AOR=Adjusted Odds Ratio; [†]95% C.I = 95% Confidence Interval; [^]*p <0.05*

[ϕ] Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

Twenty eight (4.7%) of the 592 patients did not give a final sputum check at the completion of treatment [Table 5]. Twenty one patients (4.6%) were below the age of 45 and of tribal status (3.7%). The sex and occupation were reflective of one another as there were 17 males (4.1%) and 16 (4%) farmers, while there were 10 females (5.6%) and 11 housework (7%) reported [Table 5]. A majority of patients belonged to TB category I (new sputum positive case); however, unlike the rest of the demographic, there was no smear positive pulmonary cases among these patients (0%) [Table 5]. Among the various PHCs, these patients were found in a total of 4 PHCs in Valia taluka [Gundiya (7.7%); Kara (4%); Netrang (2.1%); Thava (6.4%)] while they were found in all but Bhalod PHC in Jhagadia taluka [Table 5]. At the 5% significance level, tribal status was independently associated with not giving the final sputum check at treatment completion (AOR: 0.31; 95%CI: 0.13, 0.72) [Table 7]. Further, although non-significant in univaraite analysis (OR: 0.64; 95%CI: 0.26, 1.54), TB category demonstrated significant association when adjusted for all other covariates in the model [weight (p=0.045); tribal status (p=0.006)] (AOR: 0.78; 95%CI: 0.83) [Table 7].

3.2.1.4. Factors for cured patients

Table 8. Factors for 'cured' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[§]

	Cured			
Factors	Crude OR* (95%CI)[†]	P-Value[^]	AOR* (95%CI)[†]	P-Value[^]
Tribal Status		0.003		0.199
Tribe	2.05 (1.27-3.32)		1.46 (0.82-2.60)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		<0.0001		<0.0001
B	8.08 (3.95-16.52)		7.95 (3.74-16.87)	
E	0.12 (0.01-0.96)		0.09 (0.01-0.78)	
X	1.00		1.00	
Body Weight		0.019		0.044
<35kg	0.65 (0.46-0.93)		0.65 (0.43-0.99)	
≥35kg	1.00		1.00	
Category		<0.0001		<0.0001
C1	2.81 (1.82-4.33)		3.11 (1.89-5.12)	
Non-C1	1.00		1.00	
PHC		0.007		0.012
Valia Taluka (town)				
Chasvad	1.00		1.00	
Delhi	2.03 (0.55-7.47)		1.97 (0.49-7.84)	
Gundiya	2.16 (0.59-7.90)		2.93 (0.72-11.89)	
Kara	1.46 (0.40-5.26)		1.78 (0.45-7.10)	
Netrang	2.78 (0.84-9.12)		3.25 (0.91-11.57)	
Thava	1.07 (0.31-3.68)		1.35 (0.37-4.99)	
Jhagadia Taluka (town)				
Avidha	1.23 (0.39-3.85)		1.68 (0.50-5.66)	
Bhalod	1.86 (0.49-7.12)		2.33 (0.55-9.84)	
Dharoli	2.97 (0.98-9.06)		3.88 (1.19-12.53)	
Gowali	1.31 (0.42-4.10)		1.78 (0.53-5.99)	
Jespor	1.50 (0.45-5.01)		1.86 (0.52-6.65)	
Jhagadia	0.81 (0.26-2.45)		0.92 (0.28-2.96)	
Moriyana	1.86 (0.57-6.11)		2.23 (0.63-8.05)	
Panetha	4.57 (1,18-17.68)		7.23 (1.61-32.54)	

[*]OR=Odds Ratio; AOR=Adjusted Odds Ratio; [†]95% C.I = 95% Confidence Interval; [^]*p <0.05*

[§] Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

Among the total of 592 patients, 346 (58.4%) patients were cured, comprising the highest proportion of patients in this study. The distribution of the patients was almost identical to the rest of the outcomes, except with much higher portion in each case [Table 5]. Among the PHCs in Valia taluka, Netrang PHC consisted significantly higher portion of patients cured compared to

the rest (70.8%), while Dharoli PHC was the highest among Jhagadia taluka (72.2%) [Table 5]. The rest distributed almost equally. At the 5% significance level, factors independently associated with cured patients were TB category (primary variable) (AOR: 3.11, 95%CI: 1.89, 5.12) and weight (AOR: 0.65, 95%CI: 0.43, 0.99) [Table 8]. Of the factors assessed, type of diagnosis, PHC and tribal status demonstrated significant associations with cured patients, either independently or in a univariate analysis. Taking diagnosis X as the reference level, type of diagnosis was independently associated with cured patients when patients were diagnosed as category B (AOR: 07.95, 95%CI: 3.74, 16.87) [Table 8]. Likewise, taking Chasvad PHC as the reference, at the 5% significance level, PHC was independently associated with cured patients when patients belonged to Dharoli (AOR: 3.88, 95%CI: 1.19, 12.53) or Panetha PHCs (AOR: 7.23, 95%CI: 1.61, 32.54) [Table 8]. At the 5% significance level, tribal status was significantly associated with cured patients in unadjusted analysis (AOR: 2.05, 95%CI: 1.27, 3.32); however, once adjusted for other covariates in the model [weight (p=0.045); PHC (p=0.012); type of diagnosis (p<0.0001); TB category (primary)], it was no longer significant (AOR: 1.46, 95%CI: 0.82, 2.60) [Table 8]. At the 5% significance level, no other variable were significantly associated with cured patients (p<0.05) [Table 8].

3.2.1.5. Factors for failure

Table 9. Factors for 'failure' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[§]

	Failure			
	Crude OR*		AOR*	
Factors	(95%CI)[†]	P-Value[^]	(95%CI)[†]	P-Value[^]
Occupation		0.039		0.039
Farmer	0.06 (0.01-0.34)		0.06 (0.01-0.36)	
Housework	0.12 (0.02-0.73)		0.12 (0.02-0.73)	
Non-Farm work	1.00		1.00	

[*]OR=Odds Ratio; AOR=Adjusted Odds Ratio; [†]95% C.I = 95% Confidence Interval; [^]*p <0.05*

[§] Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

Eleven (1.9%) patients of the total of 592 were 'failures' (patients whose final sputum examination was positive, hence failing to be cured even after completing the treatment) [Table

5]. This group consisted the lowest numbers of patients in the study; however, patient factors were similar to the rest of the groups. All patients who failed to be cured by complete treatment were diagnosed as sputum positive cases [Table 5]. Occupation was the only variable that was significantly associated with treatment failure; no other variables were significant both in unadjuted and adjusted analyses ($p<0.05$) [Table 9]. Taking non-farm work as the reference, at the 5% significance level, there is sufficient evidence to conclude that occupation is independently associated with 'failed' patients whose occupation is a farmer (AOR: 0.06, 95%CI: 0.01, 0.34) or a housewife (AOR: 0.12, 95%CI: 0.02-0.73) [Table 9].

3.2.1.6. Factors for death

Table 10. Factors for 'death' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[§]

	Died			
Factors	Crude OR* (95%CI)[†]	P-Value[^]	AOR* (95%CI)[†]	P-Value[^]
Body Weight		0.020		0.027
<35kg	3.07 (1.19-7.92)		2.92 (1.13-7.58)	
≥35kg	1.00		1.00	
Category		0.024		0.035
C1	0.33 (0.12-0.87)		0.35 (0.13-0.93)	
Non-C1	1.00		1.00	

[*]OR=Odds Ratio; AOR=Adjusted Odds Ratio; [†]95% C.I = 95% Confidence Interval; [^]*p <0.05*

[§] Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

Eighteen (3%) of the 592 patients died while being on DOTS treatment [Table 5]. There was no patients diagnosed with extra-pulmonary cases, and the occupation of the patients were clustered among farmers (3.2%) or house work (3.2%) [Table 5]. Interestingly, all patients who died belonged solely to the PHCs in Jhagadia taluka, as no patient who died were identified among PHCs in Valia taluka. Among those in Jhagadia taluka, most belonged to Jhagadia PHC, but this was likely owing to the large numbers of patients in Jhagadia PHC. At the 5% significance level, factors independently associated with death were TB category (primary variable) (AOR: 0.35, 95%CI: 0.13, 0.93) and weight (AOR: 2.92, 95%CI: 1.13, 7.58) [Table 10]. No other variable was significantly associated with death ($p<0.05$) [Table 10].

3.2.1.7. Factors for non-defaulting vs. default

Table 11. Factors for 'non-default vs. default' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[§]

	Non-Default VS Default			
	Crude OR*		AOR*	
Factors	(95%CI)[†]	P-Value[^]	(95%CI)[†]	P-Value[^]
Category		0.002		0.002
C1	3.86 (1.62-9.21)		3.86 (1.62-9.21)	
Non-C1	1.00		1.00	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio; †95% C.I = 95% Confidence Interval; ^*p <0.05*

§ Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

In order to further assess the effect of each factor for adherence, patients who completed treatment were compared to those who defaulted. Among the 592 patients in total, 385 (65%) of them completed treatment while 25 (4.2%) of them defaulted. Those who completed treatment (non-defaulting) included patients who 'completed' (did not give last sputum examination) (4.7%), got cured (58.4%), and completed treatment but failed to be cured (1.9%). Of the variables assessed, TB category was the only factor significantly associated with non-defaulting. At the 5% significance level, there is sufficient evidence to conclude that TB category is independently associated with patients non-defaulting (AOR: 3.86, 95%CI: 1.62, 9.21) [Table 11].

3.2.1.8. Factors for being cured vs. not cured upon treatment completion

Table 12. Factors for 'cured vs. failure' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India[§]

	Cured by complete treatment VS Failure			
	Crude OR*		AOR*	
Factors	(95%CI)[†]	P-Value[^]	(95%CI)[†]	P-Value[^]
Occupation		0.022		0.017
Farmer	2.14 (0.56-8.14)		2.37 (0.61-9.28)	
Housework	1.00		1.00	
Non-Farm work	0.11 (0.02-0.77)		0.11 (0.02-0.72)	
Body Weight		0.162		0.072
<35kg	0.42 (0.13-1.42)		0.31 (0.08-1.18)	
≥35kg	1.00		1.00	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio; †95% C.I = 95% Confidence Interval; ^*p <0.05*

§ Factors with *p >0.05* are not presented. Refer to tables and figures for the full result.

Lastly, to assess the benefit of complete treatment adherence, among those who completed the treatment, patients who were cured were compared to those who failed to be cured. Of the 592 patients in total, 346 (58.4%) were cured while 11 (1.9%) failed to be cured upon completion of treatment. Between the two groups, occupation was independently associated with being cured by complete treatment. Taking house work as the reference, at the 5% significance level, there is sufficient evidence to conclude that occupation is independently associated with being cured by complete treatment for patients whose occupation is non-farm work (AOR: 0.11, 95%CI: 0.02, 0.77) [Table 12]. Further, at the 5% significance level, weight was not significantly associated with being cured by complete treatment in unadjusted analysis (AOR: 0.11, 95%CI: 0.02, 0.77); however, once adjusted for other covariates in the model [occupation (0.02); TB category (primary variable)], weight demonstrated a significant effect (AOR: 0.31, 95%CI: 0.08, 0.96) [Table 12]. At the 5% significance level, no other variable indicated significant association with being cured by complete treatment ($p<0.05$) [Table 12].

At the 5% significance level, sex and age were not associated with any of the treatment outcome in this study.

3.2.1.9. Validation of treatment outcomes identified by district TB Unit

Table 13. Agreement between District TB Unit (DTU) and Study Team (ST) for Each Outcome (n=68).

	Cured	Completed	Default	Failure	Died
DTU+/ST+ (n)	18	2	1	1	6
DTU+/ST- (n)	16	2	4	3	1
DTU-/ST+(n)	4	0	1	1	14
DTU-/ST- (n)	10	16	27	27	22
Agreement, %	58.3	90	84.9	87.5	65.1
Kappa*	0.19	0.62	0.22	0.27	0.27
95% C.I. †	-0.08, 0.46	0.11,1.12	-0.41, 0.85	-0.39, 0.94	-0.03, 0.57

†95% C.I = 95% Confidence Interval
*Kappa Coeffient

To validate the outcomes reported by the district TB Unit, the Government registered outcomes were compared with the outcomes deduced by the study team. For “cured” patients, number of observed agreement (NOA) were 28 (58.3%) [Table 13]. Based on the Kappa interpretation, the strength of agreement was considered ‘poor.’ However, the strength of

agreement was considered to be ‘good’ for “completed” patients (NOA: 90%; Kappa: 0.62; 95%C.I: 0.11,1.12), and ‘fair’ for patients categorized as “default” (NOA: 84.8%; Kappa: 0.22; 95%C.I:-0.41, 0.85), “failure” (NOA: 87.5%; Kappa: 0.27; 95%C.I: -0.39, 0.94) and “died” (NOA: 52.4%; Kappa: 0.27; 95%C.I: -0.03, 0.57) [Table 13].

3.2.2. Qualitative Results

3.2.2.1. Characteristics of Tuberculosis Patients and DOT Providers

The socio-demographic characteristics of the tuberculosis patients who participated in the in-depth interviews and providers are shown in Table 13. The patients represent four TB categories: Cured, Completed, Default and Failure. The age-range of the patients was within 22 to 55, while that of the providers were within 30-50. This age-range of the patients (below 60) is reflective of the national reports by Tuberculosis Control India (TBC India) that identified below 60 age groups as the highest TB distribution group in India. Owing to the tradition of early marriage in rural India, all patients were married; one third were tribes and the rest were non-tribes. All patients belonged to the lower income groups with majority being below the poverty line, with an exception of a few non-tribes who were not. There were equal numbers of female and male participants, and the predominant occupations of the patients were farmers or non-farm work (i.e. auto-rickshaw drivers) for men, and housewives for women. The patients and providers together were linked to six primary health centers (PHCs) in Jhagadia taluka (town).

Most TB patients and providers interviewed in this study belonged to Jhagadia (24%) PHC. Jhagadia PHC is located in the capital of Jhagadia taluka (town) where SEWA-RURAL hospital, the town’s primary DOT referral Center is located. The findings of the study are broadly divided into three aspects; 1) socio-cultural influences on patient adherence behavior 2) economical issues and 3) provider’s perspectives on DOTS system and delivery, including

patient-provider relationship. Each aspect holds its specific subgroups of issues and these are described below.

Table 14. Summary of Sample Distribution for In-depth Interviews

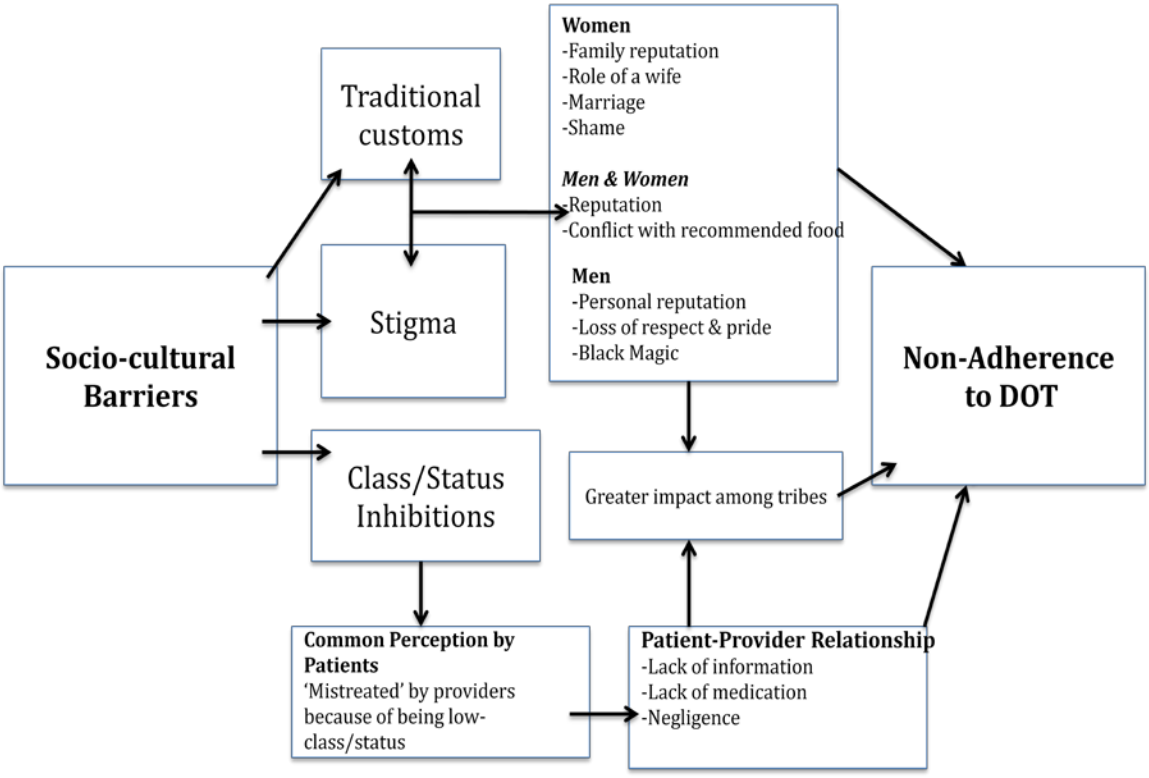
Characteristics	Percentage	Number
Age		
20's	19%	4
30's	24%	5
40's	33%	7
50's	19%	4
Gender		
Male	52%	11
Female	48%	10
Marital Status		
Married	100%	21
Unmarried	0%	0
Tribal Status*		
Tribe	33%	7
Non-Tribe	43%	9
Occupation		
Farmer	33%	7
Non-farm work	19%	4
Housewife	24%	5
DOT provider	24%	5
TB Category		
Completed	19%	4
Cured	24%	5
Default	9%	4
Failure	9.5%	2
PHC		
Avidha	24%	5
Dharoli	4.8%	1
Gowali	4.8%	1
Jhagadia	24%	5
Jespor	4.8%	1
Panetha	4.8%	1

* *DOT provider excluded*

3.2.2.2. Socio-cultural Influences on patient adherence behavior

Three key dimensions of socio-cultural influences were identified and are shown in the conceptual framework (Figure 5), these include: 1) stigma, 2) class/status inhibitions and 3) traditional customs. Some of these dimensions of socio-cultural influences vary by gender. Although the key issues are similar for both tribe and non-tribes, tribes expressed a greater burden in terms of stigma and class/status inhibitions.

Figure 6: Conceptual Diagram of Socio-cultural barriers to DOT Adherence



3.2.2.2.1. Stigma

Because DOT is a public system where one is directly observed, all patients showed concern over their TB status being made public within their own community. There was a common anxiety among both male and female patients regarding their reputation in the community, but the nature of this concern differed by gender. Male patients of any occupation worried about their personal reputation, many explained the close-knit community and its impact

on one's reputation in the community. Many men took pride in working to support their family, as they considered this act as being acknowledged as the "pillar" of the household. Such acknowledgement indicated one's strong position in the household and the community, which could be damaged if their TB status was known in the community. Although more apparent among the tribes than non-tribes, most associated loss of respect and pride with TB status, expressing shame for the incapability to work. For example,

> "I couldn't work anymore after I got TB.. my wife had to run the family, and people used to talk about us. I felt so ashamed" (male patient: completed: tribe).
>
> "We all live so close with one another. Here, what you do, what others do, it affects our everyday life. The community is so close that everyone knows everything about you, or they come to find out. I need to maintain my reputation, but when I got TB, that was lost" (male patient: completed: tribe).
>
> "My neighbor took everything away when I became sick with TB. Now.. I'm sure they want me to just die because they took over everything that I used to own because I couldn't work anymore. My respect was lost, and my pride was so hurt" (male patient: completed, non-tribe).
>
> "Some people used to say, oh he has TB, now he can't do anything. So I couldn't get involved in anything that they did. I was no longer respected" (male patient: completed: tribe).

While male patients seemed to focus more on their personal reputation within the community, female patients expressed a wider range of concerns including being judged by the wider society, as well as the reputation of her family. Female patients would often "hide the matter" from their neighbors and fear that they will be treated differently: silence was the means by which they faced the situation, as well as by asking the provider not to tell anyone she was on DOTS treatment.

> "We hide the matters (TB status) from neighbors and society, we did not tell anyone.. so the interview has to be done in secret, noone can come to know about this" (female patient: failure: non-tribe).
>
> "Here, rumors spread like fire… if someone knows that I have TB, everyone will talk about me badly" (female patient: cured: tribe).
>
> "I asked the lady [provider] not to tell anyone.. I didn't want anyone to know, but I was afraid she might tell.. so I asked her in the beginning" (female patient: completed: tribe).

A few female patients explained that there is a type of curse associated with having TB, so to be told that she has TB by others implied that she is no longer a member of the family or the community; she would be seen as an outcast. As TB is a communicable disease, women expressed that to tell someone she/he has TB indicates a type of punishment where one is to be segregated from the rest of the society.

> "There is a heavy curse that says 'let you have TB!' the meaning of the word is so heavy.. so burdensome and painful.. so when my mother-in-law told me that she thinks I have TB, I cried, I felt really bad.. I thought she was just saying that to punish me" (female patient: failure: non-tribe).

Although such shame seemed to be common in both genders, the reason and depth of shame were worse for women. Female patients complained about not being able to touch kitchenware while on DOTS treatment, which was especially difficult for married women as they "failed to carry out the role of a housewife" (patient). Many female patients believed that one should not touch kitchenware as this may pass on the bacteria to others in the family. Yet, because most women tended to hide that they had TB, not being able to stand in the kitchen to make food appeared as being of no use, described by the neighbors as, "she does nothing, not from a good house."

> "I kept everything separately.. all the dishes and utensils. No one used the same utensil I used. I tried not to go to kitchen..I was doing this for my family.. but people outside don't

know that.. we didn't want them to know I had TB.. so we didn't tell.. But they come to our house and say she does nothing.. her parents didn't teach and all.. (sobs)" (female patient: completed: non-tribe).

Not being able to carry out the "role" of a wife did not merely affect her alone, but also her parents as well as siblings especially if they were also females. This was considered one of the most painful situations for female patients when they were told that their sisters cannot get married because of their failure to demonstrate the role of a wife.

"They..they [neighbors] used to say.. don't marry a girl from their house.. [the female patient's house] they are not brought up nicely.. (sobs)" (female patient: completed: tribe).

Although both tribes and non-tribes were concerned about being judged by the society in terms of not being able to marry the younger sisters, this was more apparent among the tribes with lower caste. The lower the caste, the more conscious they were about their status and concerned over marrying a person of higher caste than their own. Hence, for these female patients, the overall socio-cultural barrier revolved around not merely herself, but more so about her entire family and her future marriage prospects.

"They [the neighbors] point fingers at us.. They don't let us live" (female patient: completed: tribe. *She does not say "me", but says "us").

As a consequence, there were two patterns in treatment adherence behavior resulting primarily for her family: one that would try to hide and stop the medication as soon as she started to feel better, and the other, who was motivated to get cured as soon as possible. Female patients who stopped the medication in between (default patients) were typically from tribes who were concerned about being ostracized from family and society.

"I didn't want them to throw me.. I don't want the neighbors to judge me.. say that I have TB.. don't go to her.. " (female patient: default: tribe).

3.2.2.2.2. Class/Status Inhibitions

All patients, regardless of their adherence outcome, gender, occupation and tribe/non-tribe status, expressed a wide range of issues regarding the patient-provider relationship with DOTS providers. Many believed that they were not provided adequate information regarding the service of the program due to lack of care from the provider's side towards people of low-class. There was a common pattern among the patients in referring to themselves as the 'illiterate,' 'poor' or 'blind.' Yet, all three terms were used when explaining a provider's attitude towards them, as many patients used these terms as a metaphor to describe their neglected social status rather than the literal meanings. Patients strongly felt that their low-class/status in a society was tied to the way the providers treated them. This concept of being 'mistreated' by the providers owing to their low social class and status was primarily dominant in two aspects of communication: 1) communication regarding information about the DOTS treatment and 2) interpersonal communication.

All patients mentioned the lack of information provided by the DOT provider about the treatment program; however, the majority blamed their low-class/status as the reason why the information was not provided properly. Patients complained about the lack of adequate information given regarding the DOTS treatment process, leaving them confused about the duration of the treatment as well as the number of medicines provided to them per week and the monetary incentive received at the completion of treatment. Patients also complained about being made to "run here and there" for reasons that were unclear to them, reflecting their confusion with the treatment process. There was a sense of frustration associated with this lack of information, as patients expressed being helpless and not having the agency to control the situation.

> "The workers don't give full information. They give medicine but give incomplete medicine. No one gives complete information. If it's six months course.. they give five

months, or four months course..don't give full medicine.. and it's their duty to tell us that at what month we should go for sputum examination.. the people in charge don't tell to the patients. The person who gave medicine also didn't come to see me even once.. Even he didn't tell whom to take medicine..and at what interval should I take..or when to go for sputum check up.. No one came to tell this. We didn't even know about the money at the end of treatment..! I was very upset.. This is their biggest mistake. It's better not to keep them as the providers. We are blind [low-class status] people, so they don't care about us. They have information, but they don't bother to tell" (male patient: completed: tribe).

"If someone makes you run here and there for no reason, then it's not called a good behavior. If an illiterate person doesn't understand something about the treatment, they should be explained in detail rather than making them run here and there without reason. They think we are illiterate, so they don't care about us. You should fulfill your duty what's expected from you. Now, if you make us run for a reason, then it's fine but for a wrong or no reason then that's not fair. It's not just for me but any person. Because we are illiterate people we do not understand anything. Then you only should make us understand it and send. But if you send us back in the midst of everything and make us run here and there just because we are illiterate, then it's wrong" (male patient: cured: non-tribe).

"There are several people who believe that once they have got the disease, they are going to die. They do not take medicines. Do not listen to the family members. But if the Government people care about them and take care of them, they may take medicines. We are poor so some of us only listen to Government people, but they don't care enough about us because we are low-class.." (male patient: completed: non-tribe).

Inter-personal communication between a patient and provider of DOTS was another aspect that was criticized. When asked what is positive about the provider, all patients focused

solely on the medication being provided and very few mentioned the behavior and the interactions they had with the provider.

> "In talks…nothing much. We [with provider] did not talk much" (male patient: completed: tribe).

There was a sense of distance between the patient and the provider, as patients complained about the ego of the provider and the discomfort they faced while adhering to DOT. While male patients expressed anger when discussing a provider's behavior, female patients expressed sadness in lack of attention and personal care they were receiving.

> "They should fulfill their duties properly. In the hospital, there should not be any ego. Good people should be kept at work who could treat people well.." (male patient: completed: non-tribe).
>
> "The medicine, that they gave…but their behavior……..I really didn't like.. They are not doing their duty. They ignore who we are.. So strict steps should be taken for them" (male patient: completed: non-tribe).
>
> "They just give medicine and went away.. they don't care about us.." (female patient: default: tribe).

Many patients held a fixed perception that being a low-class had a significant tie to being ignored by the DOTS providers. Such sense of negligence by the providers reflected in the lack of trusted relationship they shared with the provider. This was particularly common among the tribes, both males and females, who expressed doubt about the DOT service and often thought that the doctors and providers were not telling them the truth regarding their health status. Although not mentioned directly, there was a sense among these patients that not being told "honestly" by the doctors and providers was due to the patients' low-literacy level.

> "I told the doctor to tell the truth, not just that it will be cured. They think we are poor, so they think what do they [patients] know? They don't know anything. So tell them it will be cured and the matter finishes. But I kept going to clinic so he [doctor] used to say it's

better if you go up [to heaven], not to come there to harass him" (female patient: completed: tribe).

"I stopped taking the medicine when I started to feel better. The providers came to remind me, but I didn't go back. I didn't listen. They think we are illiterates, that we don't know anything. So why listen to them?" (male patient: default: tribe).

While some patients attempted to question the system, the majority felt they had no provider to whom they could regard to or to express their thoughts, once again reflecting the issue of class and status inhibitions. This was particularly of a concern in providing adequate supply of medicine to the patients. Although DOT requires that the patients receive the medication from the provider, some patients complained of not being provided the medicines regularly. This was common among the default patients, who belonged to the category of having more than 2 months of interval in taking medicine. When being asked why they had stopped the medication in between, a default male patient expressed anger and frustration as he pleaded that it was not his fault, rather, the provider's. Similarly, a female patient who was categorized as "default" on the hospital register cried while her family told the difficulty they had to go through in trying to get medicine from a private doctor instead, regardless of the unaffordable cost. There was a common trend that among the default patients, it was not the patient's will to stop the medication in between; instead, they were not adequately provided the medicine by the provider. Yet, despite the situation, many patients expressed that they did not report this as they believed their status did not allow anyone to listen to them, while others felt they had no right to voice the truth.

"R: The workers did not give medicine so I stopped, how would I get medicine? When they would give medicine, then we would take.. We don't make medicines at home..

I: Didn't you go and tell anyone about this?

R: Whom to tell ?! Whom will the poor people tell to??! Who will listen to us??" (male patient: default: tribe).

> “We went over and over to the facility.. we asked we need medicine.. they [provider] said ‘no we don’t have.’ So we waited.. then our daughter became very sick.. she kept getting worse and worse.. so we went again, they said again ‘no.’ They said ‘don’t tell anyone we don’t have medicine..!’ so we kept quiet.. we didn’t know we could tell you [the interviewer].. we were scared.. we have no right so if we tell they might do something to us.. so we went to private doctor.. there we ended up paying more than what we can afford.. we collected money from everywhere.. we just wanted our daughter to live.. but we really don’t have money.. we didn’t know our daughter was put into ‘default’.. it was not her fault, she wanted to get cured, they didn’t have the medicine for her but they told us not to tell anyone about it, we just did what they told us to (cries)” (default female patient’s family: tribe).

Similarly, male patients, both tribe and non-tribe, complained that the schedule of DOT did not take into consideration of the patients’ need, but once again they felt they did not have anyone they could regard to for this matter. Unlike female patients who were housewives or occasionally helped the husbands on the farm, male patients carried other responsibilities that required them to move around such as selling the vegetables out in the market. Patients explained that DOT was scheduled regardless of their convenience, which made it highly difficult for them to adhere to. This was seen even among the patients who completed the treatment.

> “No difficulties in taking medicines..but in getting medicine, we had difficulty. The workers didn’t give us medicine according to our need.. but who do we tell to? We are poor people.. we have noone to tell to..” (male patient: completed: non-tribe).

For many patients, they did not express the system of DOT as beneficial in continuing the treatment, but rather, expressed previous TB patients’ recovery as the motivation to adhere to DOT. This pattern was more apparent among males, both tribes and non-tirbes, who tended to seek comfort and assurance that he, too, can be cured, by conversing with a previous TB patients who were also registered on DOT and got cured.

> "First of all, the driver of the clinic only told me that he had TB and took medicine for 6 months and now he is cured. So I thought I can get cured too" (male patient: cured: tribe).
>
> "I knew this person who had TB. He told me don't worry, I also had but I took medicine and it's cured. I thought TB doesn't get cured. I thought I was going to die. So when he told me that I also wanted to take medicine fully" (male patient: cured: tribe).
>
> "I heard from my uncle that he got cured after taking the medicine. Now I took fully and I'm also cured. So I also tell people with TB they can be cured if they take medicines properly. They just have to continue and take properly" (male patient: completed: non-tribe).

Many patients expressed that talking to someone of their same class/status such as a relative or community member offered greater sense of trust as they have experienced the same feelings and shares understanding of the existing stigma. Hence, patients described that talking to previous TB patients offered emotional support, both in terms of facing stigma as well as giving hope that they can also be cured. These aspects also led to other healthy behavior and mindset, such as quitting substance abuse and appreciation of the improvement in health.

> "I talked to this person who had TB. I thought now noone will care about me. But he was nice and talked to me. He said he knows my feelings. Then I felt I can also be cured. I can go talk to him. I myself also stopped smoking. I used to smoke earlier. He said it's not good. So I stopped. I also took medicines regularly after that" (male patient: completed: non-tribe).
>
> "I went to talk to him [a community member] because I heard he also had TB and got cured. I felt good. I felt I can also improve. So I continued, and my health improved, the effect was seen. So I felt good and wanted to continue fully. I learnt that if you want to get cured, you have to complete the medicine, even if you feel better" (male patient: cured: tribe).

In contrast to the directly observed treatment at a facility, majority of the patients showed appreciation if the provider visited them at home to provide the treatment. Provider's visit did not merely mean convenience for the patients, but patients also expressed a sense of personal care, which allowed them to develop a deeper relationship with the provider. Building a trusted relationship also indicated that the patients were more likely to listen to the provider, as majority of the cured patients expressed positive interaction with their provider.

> "If a person comes to my house to see how I'm doing it's a great pleasure to me. I feel like they [providers] actually care, and I want to listen to them. If they came to my house and asked about my health and say complete the treatment, I would have definitely listened" (male patient: default: tribe).
>
> "My children were small and my mother was aged…so I had to do service in the school in nursery. So I used to go in morning and around 12 the clinic used to close. And I reach at 11:30, I used to come back and there was no one at home. My son used to go to school, so she [provider] herself told not to take any hardship, she herself would come and give. I liked her very much. I trusted her so I continued medicine regularly" (female patient: cured: non-tribe).
>
> "She [provider] was good. I used to go there [to facility] many times but due to weakness, I couldn't walk much…I walked a little and then would sit down…so 2-3 times she [provider] saw this, so she said not to worry about it, she herself would come to my house and give here. I felt she cared about me, so I also listened to her" (male patient: cured: tribe).

Similarly, many patients expressed that they preferred to be treated at home, even if they were to be directly observed. Although some male patients preferred self-supervised therapy, others expressed that they preferred to be taken care by the wife or sister: a female member of the family other than the mother. In general, there was a pattern that male patients felt a female member of the family other than the mother can better remind them and follow the treatment

process than the provider, as many male patients believed it is the wife or sister's duty to take care of the husband or the brother, reflecting the cultural perception of the role of women in the house. The male patients, however, did not mention their mother, as they felt it is their duty to look after and take care of the mother.

> "I: did you take tablets in their presence?
>
> R: no…actually they told me to drink the tablets in their presence but I only told them to give me at home and I told them to have faith in me." (male patent: completed: tribe)
>
> "My wife can remind me and give me medicine. It is better if she does so. It's her duty to take care of me, and I know she will do a good job. So medicine should be given at home by her" (male patient: completed: non-tribe).
>
> "I asked my sister to talk to the provider so that she can get the medicine from her and give me at home. She has done it before, and that way I felt better because I know she will take care of me nicely" (male patient: cured: tribe).

Interestingly, female patients did not mention their husband, but tended to prefer other women to observe their treatment, such as a lady provider or mother-in-law, while some preferred to be directly observed by their sons. Just as the male patients did not mention their mother, female patients did not mention daughter, once again reflecting the cultural perception of *paraya dan*, which translates into "other's wealth." Female patients explained that daughters are considered the property of others, as one day they will leave the house for marriage and become other's wealth. Likewise, they described that because of this teaching, the only other powerful women figure in the house is the mother-in-law; hence, they tended to prefer the help from them. Although not all, some mother-in-law also expressed that they knew their responsibility, so they did not inform the parents of the daughter-in-law regarding her TB status, instead, took full responsibility to take care of her. Similarly, those who preferred to be directly observed by the sons stated that unlike daughters, sons are the "walking stick for parents" that one can rely and lean on, expressing their strong trust in them.

> “I told my mother-in-law first when I first found out that I have TB. I didn’t tell my husband then. Mother-in-law first, then husband came to know later. I went to the health clinic to get medicine, but I had to be very careful and hide.. so it would have been better if my mother-in-law could watch me when I took the medicine at home” (female patient: failure: non-tribe).

“It was getting difficult for me to go to clinic, so I asked my son for help. I asked him to go and get the medicine and come home and give it to me, so that he can take the empty strip (medicine case) back to the provider and tell her he watched me eat the medicine. I asked him because he is the ‘stick’ for me” (female patient: completed: tribe).

3.2.2.2.3. Traditional Customs

Although not directly related to the public system of DOT, food recommended while being on treatment conflicted with the age-old customs of patients. A majority of patients explained that the providers constantly told them to eat eggs and milk (high-protein food) to support the medication. Yet, conservative by nature, many showed concern over going against personal will to do what is against their custom and beliefs such as fasting. All patients mentioned that their daily diet did not include eggs as they were vegetarian, but they were strongly advised by the DOT providers to eat these foods. Both male and female patients demonstrated ritual-oriented perspectives and expressed that they had a hard time accepting and doing things that went against their traditional customs.

> “Daughter in law: We did not tell my other in law’s mother in law that I have TB. We used to hide these medicines and eggs from her. I used to get up early in the morning at 4:00 to 5:00 AM and eat eggs. Like that my treatment went on. We did not talk to grandmother in law because she believed in age-old customs.
>
> Mother in law: I used to tell this man for eggs. He regularly provided country special big eggs for my daughter in law. My mother in law often asked me why this man comes every day? But I did not tell her. She will be very upset, both for TB and for going

against our custom. We also hid the matter from our neighbors and society" (female patient: non-tribe, and her mothering law)

"There was time I wanted to fast. But the lady [provider] kept insisting that I have to eat eggs. Now, I don't eat eggs usually. But she kept telling me so it was very difficult for me. I didn't want to eat it, so sometimes I ate, but sometimes I didn't" (male patient: completed: tribe).

Further, only among tribe farmers, they also mentioned black magic rather than adhering to DOT. Some of these patients described that they have always been regarding black magic and did not feel the need to adhere to DOT schedule; instead, they preferred to follow black magic in their spare time when they were off the farm.

"I always did this [black magic]. I know it works and it will cure me. I don't want to go to clinic. When I have time, I will try to follow that [black magic] instead" (male patient: completed: tribe).

3.2.2.3. Economic Issues:

There were three main economic issues that influenced DOTS adherence, including 1) cost of transportation to DOTS facilities and 2) opportunity cost (loss of time and energy to earn money). These issues were more commonly discussed among tribes, for both male and female patients. The third aspect was cost for food, which was common among both tribes and non-tribes, as all patients demonstrated a request for additional financial support as part of the DOT adherence.

Although the DOTS medication is free of cost, the patients still have to cover the transportation to the DOTS facility. The additional cost required for patients to reach the nearest health facility was equivalent to feeding at least one of the children in the family, and it also reflected in the difficulty in accessing the health facilities.

"I have to feed the children.. but where would I get the money..? If they provided some vehicle, I can save that money to feed my children.." (female patient: default: tribe).

> "I have no land…no govt job…nothing. This, my boy was studying at that time, so even he didn't have any income. Even I didn't have any income. That on working as a peon…we get 800-900 rupees pay. Only this much. The rickshaw fare [vehicle equivalent to taxi] for going and coming..that will cost only. It was about 400 rupees.. This difficulty was faced" (female patient: completed: tribe).

> "To go Jhagadia…sometimes…some difficulty was faced…in matter of money, difficulty in walking…till the cross road…weakness was so much that I couldn't walk…on walking little, I had to sit. There was no money…and to go by walking was a bit difficult and we can't call rickshaw cause of no money. So…it was difficult. There was nothing like calling a car and going by it…so it took me one hour to reach the crossroad. Had these problems…at least for around 1-1 1/2 month. And there while going to Seva Rural, we had to walk again from Jhagadia crossroad till seva rural…due to no money. This was the problem for 1-2 months" (male patient: completed: tribe).

In addition to the cost of transportation, both male and female patients showed concern over the loss of time and energy to earn money. Once again, this concern was only apparent among the tribes who work together especially in the farm to earn for the family. For these patients, the distance and difficulty in accessing to clinic not merely indicate the burden of transportation cost, but they also result in time and effort lost to travel, affecting the amount of work they can engage at work, which consequently impacts the living of the entire family. While patients showed appreciation over the free medication provided by DOT, many tended to initially regard private doctors due to access and services, where the location was closer and the medication could be self-administered instead of DOT.

> "I am the pillar of the house.. if I don't earn, then who will? But to get to Sewa-rural takes time.. I can't work then.. so I said give me the whole medication, trust me, I will take [instead of going to the health facility to be directly observed]" (male patient: default: tribe).

For both tribes and non-tribes, regardless of gender, one economic issue that was mentioned by all was the cost of food required while being on the medication. Although non-tribes have higher income than tribes, this was no exception for those whose occupation included work other than being farmer (such as auto-rikishaw driver). The food recommended while being on treatment include dairy products high in protein such as eggs and milk; however, there was a common perspective among the patients that these items are too costly to afford regularly. Although the patients appreciate the free cost of medication, they also request further support from the government in terms of these food items to better adhere to DOT.

> " If the person is poor, then it would be good if they (the government) give some more relief…like if a person don't have any money, then it will be better if they provide money for food then it would be good. If the person has no money, then there is no facility for food, milk, eggs, etc. then how would he take all this…even I had the same difficulty, I also didn't get milk much. Now, we had no income, so we can't buy the "desi [big] eggs" as they are costly. Even the milk is costly. Now, as you also know..so sometime when we could buy milk, I took it also. So for poor people, whatever we get we have to adjust. So it would be good if the govt gives some more relief, for TB patients. When they are giving so expensive med free of cost then if some more help in matter of food if they can give. Now I am cured, but in future if some poor person gets TB, then from where will he buy egg and milk? The doctor advice to eat as much egg and milk as possible but from where should we bring? So…one or twice a week, I used to have. That too costs 12-15 rupees per 2 days when we got money, we bought milk and had it. So if some relief is given then it's good." (male patient: completed: non-tribe)
>
> "If the government can give the money for milk, I would have definitely followed the treatment fully. I couldn't afford these food, so I stopped the medicines" (male patient: default: tribe).

3.2.2.4. Provider's Perspectives on DOT system and Patient-Provider Relationships:

There were mixed perspectives among the providers in terms of the DOT treatment. However, when it came to attitudes towards the patients, a majority expressed confidence in patient satisfaction and believed that they were carrying out the treatment process properly.

4.2.2.4.1. DOT System

Most providers expressed satisfaction with the DOT system, and believed that their supervision was done properly. Many felt that directly observing patients can properly monitor patients to complete the treatment, which they felt reflected the numbers of patients they had cured. Yet, there were a number of concerns with the service of DOT, primarily in the availability of medicines and follow-up examination.

Although most stated that they believe DOT service is beneficial for the patients, many felt that availability of medicine was an issue in terms of initiation of treatment and weight of patients. Some providers expressed that often times the medicines do not reach on time for the medication to begin, which becomes critical especially for patients experiencing severe case. Likewise, due to the nature of the disease and exacerbated by malnutrition, many patients lose weight quickly. Providers worried that some of these patients become extremely under weight that the available medication do not suit them, causing severe side effects. Providers explained that once the side-effects become problems, patients no longer adhere to treatment.

> "Once the primary health center [PHC] receives the information of a new TB patient, they request the Government to send them the box of medication. But sometimes the medication does not reach on time to the PHC for the TB patient to start his/her medication. If the TB patient is weak, not being able to start the treatment on time becomes a huge concern.
>
> "Medication is not available for all weight. Hence, for some patient, the dose is high for their weight and side effects become a problem. The non-tolerant rate is about 5-10%."

At every treatment phase interval, follow-up sputum test is conducted to monitor patient's health progress. Yet, some providers showed concern that patients don't understand why they are being called back to the hospital and generally associate fear with the process.

> "Every 2, 4 and 6 months, a patient is asked to return to the hospital for a follow-up where he/she is tested for sputum check. But about 20% of patients feel afraid of being called back into the hospital. They don't know why, so not everyone comes for this check up, which is highly important for monitoring the treatment progress."

3.2.2.4.2. Attitude towards Patients

While patients expressed a number of issues with respect to patient-provider relationships, most providers felt that they had formed a good relationship with the patients and believed that patients had a strong trust in them. Many providers also seemed to take pride in their work, often stating that it is their "duty" to ensure that the patients are cured.

> "I know that the private people [private clinic staff] cover their face with cloth when they talk to the patient. Here, we don't do that. We talk to them directly. So patients like that. They feel closer to us."

> "It's our duty to make sure the patient gets cured. We do our jobs properly, so patients like us."

> "And if they [patients] have any questions they come home to ask it (laughs). They think I am someone who they can talk to. So if they have any problems like diarrhea, vomiting, cough, anything, even if they have spot on their body, they come to us."

> "At our clinic, things go according to their [patients'] timing. We take care of them nicely, so that they will be cured. It's our duty to treat them."

Stigma relating to TB was also well acknowledged among the providers as almost all of them mentioned that they have been asked by the patients to hide their TB status. Providers expressed that they are willing to keep it secret, while some strongly stated that it is their duty to do so. Interestingly, the perspective on stigma slightly differed by gender. Although generally

acknowledged, female providers considered stigma as greater burden while males providers believed stigma has become much less of an issue due to the increase in TB in the community.

> "They [the patients] always say, don't tell anyone, they are scared that people will mistreat them."
>
> "It's our duty to keep it secret. It's part of what we have to do to allow patient adherence to DOT."
>
> "Patients ask me to keep secret especially for young girls.. if they [community] comes to know then they might refuse to marry her."
>
> "One of my patients, she was pregnant.. I told her to take the medicines regularly, but she said she has to go back to the village to give delivery to a baby. Her relatives and in-laws were there, so she told me she doesn't want to take medicines in front of them.. she expired [died]from TB then.."
>
> "Earlier there was a lot of misunderstanding. It's better now, but people know the stigma associated with it. For example if there is a young unmarried lady who got it, then people refuse to get her married in their families. So relatives tell us don't tell anyone. Now, why would I tell anyone? They come home silently and take medicines. No-one comes to know about it. "

However, for most providers, they felt it was patients' own motivation that had a greatest influence upon their adherence behavior. One tactic that all providers mentioned in encouraging patient adherence was to talk to them about survival. Some expressed that the fear tactic, by telling them that they would not survive otherwise, worked for some patients, while others mentioned that they continuously asked them if they wanted to live.

> "We always tell them, if you want to live, you have to take medicines. So people who care about their lives, they take regularly. We also explained that people who don't take medication often die. So if you wish to live, you have to take medicines."

> “I always ask, do you want to live?? If you do, you have to continue with us and you can be cured.”

Some providers also expressed frustration with the patients that do not come to receive the treatment. Many did not seem to understand the reason behind patient’s irregular DOT adherence, and often linked it back to the influence of one’s own motivation for survival.

> “Some people just don’t come regularly. I told this one person why not continue? For that he said he doesn’t have problem now so why take the medicines without reason, again and again? I told him that the medicines are ready, but he is not taking it. I reminded him too but he doesn’t listen. There is no other problem, but the only problem is those who do not come to take medicines.. I don’t know why they don’t listen to us..”

> “we do our work. We want to help. But if they don’t care about themselves, how much can we help?”

Likewise, while some explained that the patients appreciated the close distance to clinic, some also acknowledged that it may not matter for certain patients.

> “They [patients] feel good that they get medicines from nearby PHC. They don't have to go very far. If they had to go far, they will not come.”

> “This man, he lived close from the clinic, there was even a direct bus from his place to my place. But he said he still did not get time to come. He became a defaulter.”

Most providers also expressed a number of concerns for patients with substance abuse such as drinking and smoking. Some of these were associated with frustration, as providers complained about not being able to cure such patients. There was a common pattern that the providers desired some intervention for these patients.

> “There is a lot of addiction in our communities, so if someone drinks and gets TB, they only leave it if they are very ill. And when they improve a bit, they again start it, it has become a habit. I just say, take drugs and you will be cured. But some of them just take medicines whenever they wish. So there’s no point to give them any medicine.”

> "If the Government can do something to teach them, to stop them, some kind of intervention would be good.. Because if one has addictions, it's really difficult for them to adhere to the treatment and get cured.."

Similarly, some providers also showed concern over medication issue, which includes long duration and several large medicines. Along with substance abuse, many felt they were barriers to patient adherence; yet, these were not mentioned by many patients, although some indicated that the long treatment duration was "boring" and that "big medicines were annoying." There was also relatively few complaints regarding the side-effects of the medicine from the patient's side, which providers believed to be the reason for patient defaulting.

Interestingly, while all patients expressed the free cost of medication as the most beneficial of the DOT that separated public system from private clinics, some providers felt that this may be the reason for non-adherence. Providers worried that without having to pay for them, the patients may consider the medication "worthless," hence failing to take them regularly. Although majority felt that the monetary incentive at the end of the treatment may be a motivation for patients to adhere to DOT, some felt patients did not take advantage of the free cost of medication.

> "The medicines are given free of cost. If you look at other medicines, they are expensive. Nowadays everyone has to pay for everything, you don't get free medicine. So some of them may be thinking oh it's worthless because it's free, they are giving for free so how can this work? Some might be thinking, oh I didn't have to pay for it, so I don't need to bother, it's not my loss if I don't go to get the medicine."

> "Patients always want money, so the incentive at the end may be attractive to them. They think oh they can get money, so they should adhere to treatment. But when it comes to something being free, like medicines, they might lose their responsibility to continue properly. Some might think, oh it's free, so why care? I know people think like that."

Chapter 4:

4.1. DISCUSSION

Overall, this study provides greater understanding of the complex context in which patients of low-class and low-income adhere to DOT in a closely-knit rural community. This contextual information provides valuable information on the key in social-cultural barriers to DOT adherence, some supporting and some adding to the findings from previous studies. Despite the high cure rate of DOTS demonstrated by the TB registers, the in-depth interviews reveal that a range of barriers still plague the minds of patients in adhering to the public system of DOTS.

Perhaps the most striking feature of this study is the complex dimensions of the socio-cultural barriers to DOT adherence. Results from quantitative assessments indicated that patients were more likely to default if their TB category did not belong to category I. Given that categories other than I are categories II and III which include retreatment cases, this may explain why these patients tended to default more compared to the newly diagnosed group. Studies indicate most retreatment cases as the result of previous default experience or treatment failure due to resistant strains (Chiang, 2004;Becerra, 2000). Considering this, the result indicating significant association between defaulting and TB category holds great threat in the already high burden communities. In order to prevent these initial defaults, the difficulty of DOT adherence needs to be viewed from multiple aspects including the socio-cultural structures that influence gender-specific stigma differentials, class and status inhibitions and age-old customs. These influences underline the roots of their culture that reflect the adherence behavior of this particular community. While patients seemed to prefer DOT over private clinics primarily owing to the cost associated with the treatment, there is a clash between cultural and public systems.

Because current DOT has less privacy that require the patient to swallow the medication in front of the frontline community worker, stigma was identified as one of the key issues most directly related to the concern of being made public. This finding is compatible with the earlier studies; however, in contrast to the earlier studies indicating stigma associated with the

infectiousness of the disease, the findings of this study identified stigma in terms of reputation in the community exacerbated by one's incapability to carry out certain roles. Although gender was not statistically significant for any of the treatment outcomes in the quantitative assessments, the in-depth interviews reveal that there are definitely different influence on adherence by gender; men showed concern over personal reputation such as pride and respect, while women expressed greater extent of social judgment and family reputation. An interesting gender difference in the perspective of stigma also existed among the providers; stigma was considered as a greater issue by female providers than male providers. This difference is perhaps reflective of the patient behavior in which male patients openly seek comfort through conversing with other male patients, while such was not mentioned among the female patients. In addition to what has already been identified by previous literatures, these findings offer a greater detail regarding the specific roles men and women have in society and its impact on adherence behavior by each gender. With close-knit community underlining the basis of how the communities functions, such forms of stigma hold great threat to both men and women in their daily life, but women need greater support to avail treatment.

Similarly, this study also reflected the perspectives of tribes, which has not been addressed previously. The results from quantitative assessments demonstrated non-tribes as the group more likely to complete treatment than tribes, thereby indicating lower DOT adherence among the tribes. Interestingly, the results also indicated that patients are less likely to be cured by complete treatment if they are farmers or housewives than those whose occupation is non-farm work. This is likely a reflective of the socio-economical influence in part, as non-farm work generally indicates higher social stand than farmers for men, and housewife for women. These findings are perhaps explained by the patterns observed in in-depth interviews, as tribes (farmers) presented greater extent of burden in adhering to the system, although both tribes and non-tribes expressed their concerns. Given that patients of higher social stand may have greater access, knowledge and financial support for health care services, these factors may explain such

differences. Tribes often relied on assistance from the Government, and expressed that they felt helpless otherwise. Hence, this study indicates the importance of understanding patient dynamics, and suggests the need for formative evaluation to further assess community needs for this particular group. Identifying what additional support may be necessary from the Government could further strengthen adherence among the most (86%) impacted group.

Likewise, although studies underlined the effect of culture on adherence behavior, traditions such as age-old custom was not identified previously. Conservative by nature, religious practices held great importance among the community, as regular prayers and fasts are practiced and custom is strictly maintained. The age-old custom is handed down from one generation to the next, including the strict vegetarian diet. Both men and women expressed hesitancy in complying with the suggested food items such as eggs, and while many confessed that they did not eat, those who ate did so secretly. Most of patients who ate eggs explained the difficulty in hiding the eggs out of the fear to be judged by the society, as some revealed certain strategy such as waking up early in the morning to take them. Despite being explained by the provider that it is for a health benefit, the majority expressed hesitancy in altering the traditional custom that they are used to. Because many patients indicated the difficulty in adherence due to such tradition, these aspects should be taken into consideration when suggesting the type of food recommended while being on treatment.

Given such perspectives, interventions that take into account of the socio-cultural context becomes highly crucial in encouraging patient adherence to DOT; however, what and how they should be offered were less understood by previous studies. Earlier studies have suggested interventions for education and constant reminders in stressing the patients to continue treatment regime; yet, these results indicate that the problem does not reflect mere lack of knowledge, but it more strongly reflects the patients' attitude about themselves and their helplessness or unwillingness to comply with the public treatment system. The findings of the study showed that provider's visit to patient's home, or being provided the treatment at home by a family member,

(even if they were to be directly observed), have a positive response among the patients. Provider's visit to home highlighted positive interactions, indicating not merely the convenience of the patients but also a sense of personal care. Patients felt they were treated sincerely if the provider visited their houses, which largely influenced their decision in adhering to DOT. For supervision at home by a family member, the preference differed by gender; men preferred wife or sister while women preferred mother-in-law or the son. These were reflective of the cultural understanding of the perceived role of a wife from men's point of view, as well as being the 'daughter' of the husband's house and the strong trust mothers had in their sons rather than the daughters. Hence, these findings offer details of the patient preferences, which can be regarded specific to gender. Further, as noted earlier, in some cases, conversing with previous TB patients who were cured by DOT seemed highly influential for male patients undergoing the treatment. Previous studies indicated strong association between substance abuse and default, as well as temporal improvement in health leading to misconception that they are fully cured. The results of this study revealed that the majority of male patients acknowledged such aspects of treatment process via conversing with the previous TB patients, which seemed more effective than speaking with the providers. Many of them expressed trust and hope for cure by speaking to someone who is of similar class that shares an experience and understanding of their situation. This did not merely encourage treatment adherence, but also led patients to take initiatives to stop risky behavior such as substance abuse. Hence, these results suggest that when offering supplementary counseling, involving previous TB patients may further encourage patient adherence especially among men.

A second finding of the study was the gap between patients' perceived perception of the providers and the actual perspectives of the providers. Previous literatures (Chowdhury, et al., 1997; Gosoniu, et al., 2008; Hamid Salim, et al., 2004) had identified a parallel relationship between the way patients felt and the way providers treated them. These studies had shown that while patients complained about poor personal care and communication from the provider, the

providers also admitted to giving little care about whether or not the patient was being cured. As a result, the patients' complaints about poor personal care by the providers directly reflected the providers' behavior as most providers revealed that they were simply following their work routine, and did not bother to communicate with the patients. However, this study showed that the providers indicated no intension to degrade or mistreat the patients; instead, class and status inhibitions were another dimension of socio-cultural influence that affected multiple aspects of patient-provider relationship. A majority of providers took pride in their profession and felt responsible in assisting patients get cured. Most also acknowledged the difficulties in adhering to DOT such as stigma, and were willing to keep it secret from the community upon patients' request. Although some patients complained of the ego of the providers, poor patient-provider relationship did not merely rise from the behavior of the providers; instead, it was deeply reflected in patients' understanding of the social status in the community that led to poor interaction between the two, consequently resulting in non-adherence. As reflected by the terms such as 'poor' and 'illiterate' used to describe their low-class in the society, (rather than their literal implications), there is a common perception among patients that they consider themselves as the 'neglected' group of the society, ignored by those who they consider as the 'higher class' group: the Government providers and doctors at the health facilities. Patients often victimized themselves for being a low-class, and expressed a strong association between being a low-class and the treatment received by DOTS service. Despite the providers expressing commitment in assisting the patients, this perception that the providers and the Government do not "care enough" for the patients in realty consequently led to an issue of doubt and lack of trust in the providers and the service offered by them. This attitude perhaps explains why some patients did not adhere to the treatment, despite accessible facility and constant reminders sent from the providers to continue the treatment.

Yet, unlike the negative perception held by the patients, the providers generally expressed satisfaction in patient-provider interaction, and believed that the patients had strong trust in them.

Such contradiction perhaps reflects why many providers failed to understand the reason behind patients "just not listening" to them. As a result, most believed that patient's own will for survival was the most influential determinant to adherence rather than the providers' care towards them, thereby emphasizing survival as the primary strategy to encourage treatment adherence. Although will for survival may be a significant motivation for adherence among the patients, such patterns clearly reflect a difference between the perspectives of the patients and providers. The inconsistency in the attitudes towards one another highlight the need to diminish the existing gap in order to better understand patients' standpoint among providers as well as to reflect on the common perception held by the patients.

Hence, contrary to the perception that non-adherence resulting in default is due to poor patient care by providers, many patients already held negative perception (that they are being looked down on) about the 'higher class' even prior to treatment, which was highly influential to their adherence behavior. Overall results indicated that in general, the groups of people who comprise the majority of patients (i.e. tribes) in this study are highly conscious of their social status in the society. While previous studies in Bangladesh indicated the issue of marriage among women with TB, this study revealed that the lower the caste, the more conscious they were about marrying someone from the higher caste. For this reason, the issue of having TB and the prospective of future marriage for this particular community did not simply end at whether or not one (or one's family member) can be married, but it held a deeper value of whether one can progress more in the society as a higher caste. Although societal image about the 'low-class vs. high-class' cannot be easily altered, because providers indicate strong commitment and willingness to provide service that most benefits the patients, efforts need to emphasize on diminishing the stereotype of providers held among the patients to further encourage their health-seeking behavior. Interventions may include ensuring the patients of the provider's commitment at the initiation of the treatment regimen, in addition to encouraging the providers to converse more with the patients or to visit their households occasionally.

Lastly, an interesting finding from the provider's perspective also included the free cost of medication actually hindering patient adherence due to the perception that these medicines are 'worthless' or that the patients did not feel responsible enough to take them; however, this aspect was not mentioned by patients as all expressed appreciation of the free treatment provided.

In terms of structural issues, the findings of the study was compatible with the earlier studies conducted in developing countries that indicated difficulty in access to healthcare and lost opportunity cost, mainly owing to the cost of transportation and distance to facility. This was important, but not a surprising finding given the low-income population and scattered residents in the community. However, the high demand of request for additional financial support for food was a new finding. Many patients expressed willingness to adhere to DOT if they were provided the money for such food. Because many patients expressed not knowing about the monetary incentive at the end of the treatment, or did not receive the incentive even after completion of the treatment, the distribution and use of monetary incentive may be reviewed to offer them the financial support during the treatment. Lastly, from providers' standpoint, the centralized medicine delivery leading to inadequate supply was acknowledged, which was reflective of the situation mentioned by many default patients. Because some patients chose not to report the situation out of hopelessness while others felt they had no right to voice the truth, the actual number of patients being categorized as 'default' due to such consequence is also worrisome.

4.2. CONCLUSION

Overall, the results from quantitative assessments indicated relatively high treatment cure rate with the strength of agreement on treatment outcomes between the district TB Unit and the study team being fairly good for all outcomes except for “cured” patients. Although this indicates some positive aspect regarding the effectiveness of DOTS in achieving successful treatment outcome, considering that “cured” patients make up the highest portion (58.4%) among all treatment outcomes identified by the district TB Unit register, the overall reliability of the cure rate is questionable. One hypothesis to explain this finding may be that due to the large numbers of patients placed on DOT annually, proper follow-up of these referred patients may not been carried out by the district TB Unit. Studies also suggest that inadequate trained personnel in developing countries adversely affect the administrative side of DOTS (Enarson, 2001). However, this hypothesis has not been documented previously, and further investigation needs to be done to evaluate this idea.

The key findings of the study indicate that the barrier to DOT adherence stem from a range of socio-cultural influences, leading to a clash between the cultural and public health systems as well as a gap between patient and provider’s perspectives on patient-provider relationships. Attention needs to be paid to tribal status and occupation in understanding patient dynamics of those who may be more likely to result in unfavorable outcomes. Additionally, factors such as TB category must be taken into consideration to encourage treatment adherence especially among the retreatment cases to prevent further development of multi-drug resistant TB. Supplementary interventions that take into consideration of these factors as well as additional research that investigate the perspectives of patients with retreatment cases may further reduce default rate and strengthen DOT adherence. Such efforts will not merely improve the efficacy of DOT in these communities, but they are also likely to contribute to the nation’s overall effort in meeting the aim of the National Tuberculosis Control in India.

4.2.1. Limitation and Interesting note

Interestingly, in contrast to the various literatures indicating significant association of sex and age with defaulting, this pattern was not identified in this study. Further assessment in these two areas may provide insight into understanding their roles in patient adherence for these particular communities.

Among those who were cured, based on the highest significant point estimates, Panetha PHC is likely to be the best at yielding successful treatment outcomes (cured) among its patients, although the reliability of the argument is questionable due to the narrower confidence intervals indicated by Dharoli PHC. Similarly, it is interesting to note that none of these dead patients belonged to any of the PHCs in Valia taluka; instead, all were identified in Jhagadia taluka. These may be owing to the number of patients placed on DOT in each PHC or taluka with less numbers of patient placement benefiting more from the treatment, but further investigation between the two talukas may yield an interesting find (e.g. differences in management, quality of care, etc.).

For both unadjusted and adjusted analyses, some outcomes resulted in a wide confidence intervals, most likely due to an inadequate sample size (sample size<30), which may have affected the reliability of these results.

4.3. PUBLIC HEALTH IMPLICATIONS

By successfully adhering to DOT, it can not merely cure the patient, but also further prevent the spread of TB, moving a step closer towards elimination. Because TB is air-borne disease and if untreated, smear-positive patient can infect around 10-15 persons a year(Center for Disease Control and Prevention, 2011), adherence to therapy is a major determinant of their outcomes and the overall epidemiology of TB. The positive effect of DOT is clear; however, reducing the rates of TB incidence, prevalence and mortality among the low-resource countries with a high burden of TB remains the ongoing focus of international efforts to control and prevent TB. Previous literature has indicated the importance of practical and emotional support for patient needs, but what, how and where they can be obtained (e.g. households and communities) were less understood. This study provides a clearer understanding of the core social and cultural issues influencing DOT adherence and patient preferences, which can be built upon the existing interventions to allow treatment management most suited to the patients' daily lives. Although some of the barriers are focused on patients who default DOTS, a majority of the difficulties are relevant for any patient regardless of their treatment outcomes (cured, completed, failure, default). Failure to diminish these problems indicates risk for increased default rate, relapse case and drug resistant strains due to non-adherence. Continuous efforts to understand patient dynamics (especially tribes,) gender-specific stigma differentials, and patients' as well as providers' attitude and beliefs are critical in improving treatment adherence. These influences must be taken into consideration in specific context that underline the efficacy of DOT, hence being a positive influence for adherence.

The finding of the study is slightly different from previous studies that indicate poor patient-provider relationship as an influence to treatment default. Instead, this study highlights the strong perception of being neglected due to low-class held by the patients, which consequently affects the patient-provider interaction. While its results cannot be easily generalized, considering that TB is a poverty-related disease more prevalent in rural settings, such aspect offers insight

into the complex socio-cultural structures that underline the core issue of all other aspects of barriers that hinder treatment adherence in the low-class, low-income context. Although the study was conducted in India, the findings may also benefit patients of villages among other South Asian countries that demonstrate similar cultures.

Because women and tribes are affected to a greater extent than non-tribe men, special attention is needed for them in terms of social support and information and knowledge acquisition. Although merits of education are highlighted by various literatures, the adoption of such strategy may have little impact especially on the tribe community due to their high-illiteracy rate as well as the general rejection to listen to the providers. Many patients hold a perception that DOTS providers "don't care enough," blaming their low-class as the reason for the "mistreatment." This holds a range of consequences primarily leading to lack of information regarding the treatment process (duration, follow-up examination, number of medicine) and lack knowledge on the disease (misconception that TB is not curable, or that temporal improvement in health means fully cured). These factors are often tied to frustration among the patients, increasing risk for non-adherence. Although the monetary incentive at the completion of treatment may evoke motivation for those who are aware of it, the study revealed that many patients did not acquire information on this. The results also indicated some positive aspects reflected in the follow-up process of the treatment.

Hence, in addition to structural issues including economical aspects, minimizing the class/status inhibitions and taking into consideration of the perception of patients may be the key to improving patient adherence to DOT in this particular community. Possible recommendations for both socio-cultural and economic aspects are highlighted below: 1) offering supplementary support in terms of emotional and information acquisition, 2) providing the opportunity for the patient to choose who he/she wants as their treatment supervisor, 3) improving quality of patient-care, 4) consistent monitoring and evaluation at each PHC and 4) offering support for nutritious food and transport.

Offering supplementary counseling for support

One possible intervention that can be initiated is to offer supplementary counseling for support, both in terms of information acquisition and emotional understanding. The findings of this study demonstrate that among male patients, patient support structure and networks lies between current and previous TB patients of similar social stand (e.g. relatives; community member) who were placed on DOT. Through securing emotional support and ensuring that one can be cured, possibilities in developing supplementary intervention around the trusted relationship between current and previous patients may further strengthen program effort. A successful counseling can encourage treatment adherence, as well as lead to imparting information regarding treatment process and knowledge about the disease itself, including risky behaviors for defaulting. The quantitative assessments demonstrated that the overall demographic characteristics of TB patients in Jhagadia and Valia talukas (towns) are comprised mostly of new sputum positive pulmonary TB case, who is a tribe male below 45 years of age and works at a farm. Hence, allowing such intervention may greatly reduce the overall default patients, thereby increasing treatment success.

As stigma may more strongly affect female patients than male patients, an alternative for female patients might be to offer private counseling by a female provider, or additional family support. Because female patients are often dependent on their husbands and in-laws, special attention needs to be considered for them to avail of treatment.

Allowing the patient to choose who they want as the supervisor for the therapy

As DOT is a supervised as opposed to self-administered therapy, allowing the patient to choose who they want as the supervisor for the therapy may provide greater comfort in adhering to DOT. Although DOT is currently carried out mostly by female frontline community health workers, a high preference of DOT by family member exists in the community. Gender difference in the preference note that male patients wish to be taken care by wife or sister, while female patients prefer mother-in-law or son, owing to cultural perceptions of the role each holds.

Allowing the patients to choose the supervisor has mainly two implications; on stigma and class/status inhibitions. Patients can ask the supervisor to "keep matters low" to avoid stigma, as well as to be treated at a personal level rather than simply as a patient. By having the agency to freely communicate with the supervisor of their own choice, it is likely to diminish the issue of class/status inhibitions and further prevent issues such as not reporting when there is no adequate supply of medicine.

Improving patient-provider relationship

Findings of the study indicate inconsistency between patients' perceived perception of providers and the actual perspectives of the providers. Patients desired personal attention and this was easily conveyed by simple conversation from the provider asking about the patient's health as well as by visiting the patient's house. As majority of providers acknowledged the existence of stigma and were willing to help, support and keep it secret, encouraging them to treat the patients at a personal level may further diminish the exiting gap. These may include ensuring the patients that the providers are committed and are willing to serve the patients the best they can for them to be cured. Further, the providers should also be encouraged to converse with the patients for at least a few minutes prior to giving the medication, or making it a habit to simply ask the patients how they are doing rather than just carrying out DOT. Provider's visit to patient's home is tied to patient satisfaction, which is a key influence to DOT adherence, where lack of care and attention as well as inconvenient treatment schedule hold significant impact on the patients' motivation and willingness to adhere to DOT. (Although the issues of stigma as well as management difficulty due to lack of personnel must be taken into consideration.) To treat the patients at a personal level and building rapport with them may be more effective in earning their trust and hence complying with the treatment process.

Consistent monitoring and evaluation at each PHC

Because inadequate supply of medicine is highlighted by both patients and providers, a system of monthly monitoring and evaluation of drug supply at each primary health center is

recommended. Lack of adequate supply can lead to patient defaulting, severe side effects and increased risk for death; hence, it is critical to ensure that the patients under DOT are receiving the adequate treatment needed. Although a small portion (1.9%) of the overall patients, the result also indicated a group of patients who failed to be cured upon complete treatment. This perhaps indicates that among the sputum positive cases, some may have been a carrier, or acquired resistance during the treatment, which is of concern as it underlines the ineffectiveness of the traditional medicine (first line drugs) to combat TB for this particular group. Hence, close attention must be paid to the supply of adequate and appropriate medication required for each patient.

In addition, the evaluation may also assess patient-provider relationship to encourage providers' personal interaction with the patients such as house visit or asking about their health conditions as mentioned earlier. Likewise, evaluation can examine whether or not adequate feedback has been reported to the SEWA-RURAL hospital. This may also have an impact on the validation of treatment outcome reported by the district TB Unit and increase the reliability of the data recorded.

Offering support for nutritious food and transport

The significant association of weight and not being cured or dying was compatible with various literatures, and additional nutritional support should be considered especially for patients who weigh below 35 kg. Due to the high demand for financial support in purchasing recommended food items, minimum food items (either milk or egg) may be offered as an incentive to adhere to DOT at least for the first quarter phase of treatment (approximately 2 months). An alternative is to review the distribution of monetary incentive given at the completion of treatment, as most patients did not know or complained of not receiving them. Perhaps a formative evaluation that investigates patient preference in the use of monetary incentive may suggest whether or not they prefer to receive it at the end, or to be distributed

during the treatment (to purchase the food items) and how (at every treatment phase; every week; every visit to the clinic for DOT, etc.)

Likewise, to minimize the burden of transportation cost, transportation may be offered to the facility as requested by patients every Monday, Wednesday and Friday for DOT services, although feasibility remains questionable especially for the tribes and farmers.

The barriers to DOT adherence in rural communities indicate two levels, one at 1.) personal and societal levels, and the other at 2.) structural level. The findings of the study demonstrate that both these levels are intertwined with one another through a range of complex socio-cultural dimensions influencing the overall decision of patient adherence to DOT. Taking these findings into account in the design of intervention may further allow practicality of local delivery, improving TB treatment adherence and hence the provision of TB treatment.

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Tables and Figures:

Table 6. Factors for 'default' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Default			
Factors	Crude OR* (95%CI)†	P-Value^	AOR* (95%CI)†	P-Value^
Age		0.572		0.509
<45 years	0.77 (0.32-1.89)		0.74 (0.30-1.82)	
≥45 years	1.00		1.00	
Sex		0.786		0.852
Male	1.39 (0.55-3.55)		1.31 (0.51-3.36)	
Female	1.00		1.00	
Tribal Status		0.84		0.92
Tribe	1.14 (0.33-3.88)		1.07 (0.31-3.68)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		0.675		0.649
B	2.50 (0.33-18.83)		2.62 (0.34-19.96)	
E	N/A		N/A	
X	1.00		1.00	
Occupation		0.803		0.901
Farmer	1.06 (0.14-8.27)		0.85 (0.11-6.89)	
Housework	0.52 (0.06-4.88)		0.48 (0.05-4.55)	
Non-Farm work	N/A		N/A	
Study / Other	1.00		1.00	
Child	N/A		N/A	
Body Weight		0.485		0.403
<35kg	1.35 (0.58-3.11)		1.46 (0.60-3.55)	
≥35kg	1.00		1.00	
Category		0.020		0.024
C1	0.37 (0.16-0.85)		0.38 (0.16-0.88)	
Non-C1	1.00		1.00	
PHC		0.829		0.843
Valia Taluka (town)				
Chasvad	N/A		N/A	
Delhi	N/A		N/A	
Gundiya	3.92 (0.34-25.40)		3.75 (0.32-43.98)	
Kara	N/A		N/A	
Netrang	1.00		1.00	
Thava	5.04 (0.50-50.78)		5.17 (0.51-52.81)	
Jhagadia Taluka (town)				
Avidha	2.66 (0.27-26.46)		2.44 (0.24-24.51)	
Bhalod	N/A		N/A	
Dharoli	1.62 (0.16-16.02)		1.67 (0.17-16.57)	
Gowali	2.56 (0.26-25.48)		2.49 (0.25-24.59)	
Jespor	5.70 (0.61-53.30)		5.25 (0.55-49.74)	
Jhagadia	1.96 (0.20-19.39)		1.81 (0.18-18.16)	
Moriyana	1.15 (0.07-18.91)		1.08 (0.07-17.97)	
Panetha	3.36 (0.29-38.73)		2.98 (0.25-34.96)	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio

†95% C.I = 95% Confidence Interval, ^*p <0.05*

Table 7. Factors for 'completed' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Completed			
Factors	Crude OR* (95%CI)†	P-Value^	AOR* (95%CI)†	P-Value^
Age		0.827		0.984
<45 years	0.91 (0.38-2.18)		1.01 (0.41-2.49)	
≥45 years	1.00		1.00	
Sex		0.191		0.593
Male	0.73 (0.33-1.62)		1.08 (0.44-2.66)	
Female	1.00		1.00	
Tribal Status		0.005		0.006
Tribe	0.30 (0.13-0.69)		0.31 (0.13-0.72)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		0.786		0.694
B	N/A		N/A	
E	0.92 (0.49-1.72)		1.23 (0.45-3.37)	
X	1.00		1.00	
Occupation		0.251		0.824
Farmer	0.08 (0.01-0.97)		0.21 (0.02-2.89)	
Housework	0.15 (0.01-1.78)		0.27 (0.02-3.75)	
Non-Farm work	N/A		N/A	
Study / Other	N/A		N/A	
Child	1.00		1.00	
Body Weight		0.052		0.293
<35kg	2.13 (0.99-4.58)		3.41 (1.45-6.21)	
≥35kg	1.00		1.00	
Category		0.319		0.019
C1	0.64 (0.26-1.54)		0.78 (0.32-0.83)	
Non-C1	1.00		1.00	
PHC		0.867		0.854
Valia Taluka (town)				
Chasvad	N/A		N/A	
Delhi	N/A		N/A	
Gundiya	2.00 (0.17-23.56)		1.59 (0.13-19.49)	
Kara	1.00		1.00	
Netrang	0.51 (0.03-8.53)		0.49 (0.03-8.54)	
Thava	1.65 (0.14-19.39)		1.07 (0.09-13.11)	
Jhagadia Taluka (town)				
Avidha	1.85 (0.20-17.41)		1.22 (0.12-12.11)	
Bhalod	N/A		N/A	
Dharoli	1.12 (0.12-10.46)		0.85 (0.09-8.16)	
Gowali	1.78 (0.19-16.76)		1.05 (0.10-10.54)	
Jespor	0.67 (0.04-11.18)		0.60 (0.04-10.21)	
Jhagadia	1.71 (0.19-15.42)		0.97 (0.10-9.37)	
Moriyana	1.20 (0.10-13.95)		0.89 (0.07-10.93)	
Panetha	1.71 (0.15-20.10)		1.26 (0.10-15.74)	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio
†95% C.I = 95% Confidence Interval, ^*p <0.05*

Table 8. Factors for 'cured' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Cured			
Factors	Crude OR* (95%CI)†	P-Value^	AOR* (95%CI)†	P-Value ^
Age		0.089		0.119
<45 years	1.40 (0.95-2,05)		1.44 (0.91-2.28)	
≥45 years	1.00		1.00	
Sex		0.439		0.076
Male	0.95 (0.66-1.4)		0.58 (0.36-0.94)	
Female	1.00		1.00	
Tribal Status		0.003		0.199
Tribe	2.05 (1.27-3.32)		1.46 (0.82-2.60)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		<0.0001		<0.0001
B	8.08 (3.95-16.52)		7.95 (3.74-16.87)	
E	0.12 (0.01-0.96)		0.09 (0.01-0.78)	
X	1.00		1.00	
Occupation		0.766		0.931
Farmer	1.77 (0.53-5.91)		1.35 (0.35-5.15)	
Housework	1.55 (0.45-5.28)		1.37 (0.35-5.34)	
Non-Farm work	1.00		1.00	
Study / Other	2.40 (0.54-10.69)		2.15 (0.38-12.05)	
Child	N/A		N/A	
Body Weight		0.019		0.044
<35kg	0.65 (0.46-0.93)		0.65 (0.43-0.99)	
≥35kg	1.00		1.00	
Category		<0.0001		<0.0001
C1	2.81 (1.82-4.33)		3.11 (1.89-5.12)	
Non-C1	1.00		1.00	
PHC		0.007		0.012
Valia Taluka (town)				
Chasvad	1.00		1.00	
Delhi	2.03 (0.55-7.47)		1.97 (0.49-7.84)	
Gundiya	2.16 (0.59-7.90)		2.93 (0.72-11.89)	
Kara	1.46 (0.40-5.26)		1.78 (0.45-7.10)	
Netrang	2.78 (0.84-9.12)		3.25 (0.91-11.57)	
Thava	1.07 (0.31-3.68)		1.35 (0.37-4.99)	
Jhagadia Taluka (town)				
Avidha	1.23 (0.39-3.85)		1.68 (0.50-5.66)	
Bhalod	1.86 (0.49-7.12)		2.33 (0.55-9.84)	
Dharoli	2.97 (0.98-9.06)		3.88 (1.19-12.53)	
Gowali	1.31 (0.42-4.10)		1.78 (0.53-5.99)	
Jespor	1.50 (0.45-5.01)		1.86 (0.52-6.65)	
Jhagadia	0.81 (0.26-2.45)		0.92 (0.28-2.96)	
Moriyana	1.86 (0.57-6.11)		2.23 (0.63-8.05)	
Panetha	4.57 (1,18-17.68)		7.23 (1.61-32.54)	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio
†95% C.I = 95% Confidence Interval, ^*p <0.05*

Table 9. Factors for 'failure' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Failure			
Factors	Crude OR* (95%CI) †	P-Value ^	AOR* (95%CI) †	P-Value ^
Age		0.686		0.667
<45 years	1.38 (0.29-6.49)		1.42 (0.29-6.93)	
≥45 years	1.00		1.00	
Sex		0.907		0.911
Male	0.76 (0.22-2.61)		0.74 (0.19-2.93)	
Female	1.00		1.00	
Tribal Status		0.636		0.855
Tribe	0.69 (0.15-3.24)		1.17 (0.21-6.42)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		0.959		0.992
B	N/A		N/A	
E	N/A		N/A	
X	1.00		1.00	
Occupation		0.039		0.039
Farmer	0.06 (0.01-0.34)		0.06 (0.01-0.36)	
Housework	0.12 (0.02-0.73)		0.12 (0.02-0.73)	
Non-Farm work	1.00		1.00	
Study / Other	N/A		N/A	
Child	N/A		N/A	
Body Weight		0.258		0.111
<35kg	1.99 (0.60-6.64)		2.96 (0.78-11.29)	
≥35kg	1.00		1.00	
Category		0.981		0.949
C1	0.98 (0.21-4.61)		1.05 (0.22-5.16)	
Non-C1	1.00		1.00	
PHC		0.969		0.997
Valia Taluka (town)				
Chasvad	1.00		1.00	
Delhi	N/A		N/A	
Gundiya	N/A		N/A	
Kara	N/A		N/A	
Netrang	0.30 (0.02-5.08)		0.28 (0.02-5.02)	
Thava	N/A		N/A	
Jhagadia Taluka (town)				
Avidha	1.08 (0.11-10.42)		0.83 (0.08-8.48)	
Bhalod	N/A		N/A	
Dharoli	0.32 (0.03-3.75)		0.29 (0.02-3.51)	
Gowali	N/A		N/A	
Jespor	N/A		N/A	
Jhagadia	0.38 (0.03-4.52)		0.24 (0.02-3.22)	
Moriyana	N/A		N/A	
Panetha	N/A		N/A	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio

†95% C.I = 95% Confidence Interval, ^*p <0.05*

Table 10. Factors for 'death' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Died			
Factors	Crude OR* (95%CI) †	P-Value ^	AOR* (95%CI) †	P-Value ^
Age		0.912		0.813
<45 years	1.07 (0.35-3.29)		1.15 (0.37-3.61)	
≥45 years	1.00		1.00	
Sex		0.724		0.968
Male	0.67 (0.26-1.77)		0.87 (0.39-2.46)	
Female	1.00		1.00	
Tribal Status		0.343		0.363
Tribe	2.67 (0.35-20.35)		2.57 (0.34-19.82)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		0.959		0.992
B	0.80 (0.18-3.59)		0.91 (0.2-4.14)	
E	N/A		N/A	
X	1.00		1.00	
Occupation		1.000		1.000
Farmer	1.03 (0.36-2.94)		1.04 (0.36-3.03)	
Housework	1.00		1.00	
Non-Farm work	N/A		N/A	
Study / Other	N/A		N/A	
Child	N/A		N/A	
Body Weight		0.020		0.027
<35kg	3.07 (1.19-7.92)		2.92 (1.13-7.58)	
≥35kg	1.00		1.00	
Category		0.024		0.035
C1	0.33 (0.12-0.87)		0.35 (0.13-0.93)	
Non-C1	1.00		1.00	
PHC		0.975		0.992
Valia Taluka (town)				
Chasvad	1.00		1.00	
Delhi	1.22 (0.10-14.69)		1.92 (0.15-25.53)	
Gundiya	0.56 (0.03-9.66)		0.58 (0.03-10.52)	
Kara	N/A		N/A	
Netrang	0.30 (0.02-5.08)		0.42 (0.02-7.53)	
Thava	N/A		N/A	
Jhagadia Taluka (town)				
Avidha	0.52 (0.04-6.14)		0.56 (0.05-6.99)	
Bhalod	N/A		N/A	
Dharoli	N/A		N/A	
Gowali	0.25 (0.01-4.17)		0.29 (0.02-5.14)	
Jespor	1.24 (0.12-12.92)		1.18 (0.12-13.13)	
Jhagadia	1 (0.11-9.23)		1.19 (0.12-11.66)	
Moriyana	0.70 (0.06-8.33)		0.92 (0.07-11.51)	
Panetha	N/A		N/A	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio

†95% C.I = 95% Confidence Interval, ^*p <0.05*

Table 11. Factors for 'non-default vs. default' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Non-Default VS Default			
	Crude OR*		AOR*	
Factors	(95%CI) †	P-Value ^	(95%CI) †	P-Value ^
Age		0.414		0.359
<45 years	1.46 (0.59-3.61)		1.53 (0.61-3.86)	
≥45 years	1.00		1.00	
Sex		0.444		0.584
Male	0.69 (0.27-1.78)		0.76 (0.29-1.99)	
Female	1.00		1.00	
Tribal Status		0.962		0.795
Tribe	1.03 (0.30-3.58)		1.18 (0.33-4.18)	
Non-Tribe	1.00		1.00	
TB type of diagnosis		0.833		0.251
B	0.53 (0.07-4.10)		0.30 (0.04-2.34)	
E	1.00		1.00	
X	N/A		N/A	
Occupation		0.812		0.873
Farmer	0.49 (0.16-1.49)		0.58 (0.19-1.78)	
Housework	1.00		1.00	
Non-Farm work	N/A		N/A	
Study / Other	0.54 (0.06-5.16)		0.45 (0.05-4.35)	
Child	N/A		N/A	
Body Weight		0.396		0.433
<35kg	0.69 (0.30-1.62)		0.71 (0.30-1.68)	
≥35kg	1.00		1.00	
Category		0.002		0.002
C1	3.86 (1.62-9.21)		3.86 (1.62-9.21)	
Non-C1	1.00		1.00	
PHC**	N/A		N/A	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio
†95% C.I = 95% Confidence Interval, ^*p <0.05*
*** Not statistically computable due to inadequate sample size.*

Table 12. Factors for 'cured vs. failure' among all TB Patients registered for treatment in a DOT programme from July 2007 through December 2009, Jhagadia & Valia Talukas (towns), Bharuch district, Gujarat, India

	Cured by complete treatment VS Failure			
Factors	Crude OR* (95%CI)†	P-Value^	AOR* (95%CI)†	P-Value^
Age		0.833		0.782
<45 years	0.81 (0.18-4.00)		0.81 (0.16-3.97)	
≥45 years	1.00		1.00	
Sex		0.924		0.811
Male	1.29 (0.37-4.50)		1.25 (0.32-4.94)	
Female	1.00		1.00	
Tribal Status		0.374		0.721
Tribe	2.04 (0.42-9.83)		1.23 (0.21-7.52)	
Non-Tribe	1.00		1.00	
TB type of diagnosis				
B	N/A		N/A	
E				
X				
Occupation		0.022		0.017
Farmer	2.14 (0.56-8.14)		2.37 (0.61-9.28)	
Housework	1.00		1.00	
Non-Farm work	0.11 (0.02-0.77)		0.11 (0.02-0.72)	
Study / Other	N/A		N/A	
Child	N/A		N/A	
Body Weight		0.162		0.072
<35kg	0.42 (0.13-1.42)		0.31 (0.08-1.18)	
≥35kg	1.00		1.00	
Category		0.507		0.291
C1	1.70 (0.35-8.15)		2.42 (0.46-12.5)	
Non-C1	1.00		1.00	
PHC				
Valia Taluka (town)		0.890		0.821
Chasvad	1.00		1.00	
Delhi	N/A		N/A	
Gundiya	N/A		N/A	
Kara	N/A		N/A	
Netrang	4.86 (0.27-87.24)		4.51 (0.24-83.27)	
Thava	N/A		N/A	
Jhagadia Taluka (town)				
Avidha	1.04 (0.10-10.77)		1.49 (0.13-17.27)	
Bhalod	N/A		N/A	
Dharoli	4.64 (0.37-57.93)		5.23 (0.40-68.72)	
Gowali	N/A		N/A	
Jespor	N/A		N/A	
Jhagadia	2.21 (0.18-27.98)		4.22 (0.27-65.6)	
Moriyana	N/A		N/A	
Panetha	N/A		N/A	

*OR=Odds Ratio; AOR=Adjusted Odds Ratio

†95% C.I = 95% Confidence Interval, ^*p <0.05*

Appendicies:

Appendix A: Patient Interview Guide for Cured and Completed

Introduction:

Hi, I want to thank you so much for agreeing to meet with me today. My name is -------- (appropriate person from SEWA-RURAL) and I want to talk to you about your experience of the TB treatment by the Government (DOTS treatment). This interview is going to take about 40 minutes and because I don't want to miss any information, I want to tape-record this session. May I have your consent on the recording?
(If "yes,") Thank you.
Even though it will be recorded, please feel at home, I really appreciate you for sharing your information. I want to remind you that everything discussed here is confidential. This means that your responses will only be shared with my study team and at no time will I record any names or other identifying information about you. There are no right or wrong answers, and you can also refuse to answer any question. Remember, you don't have to talk about anything you don't want to and you will not be penalized in any way if you decide not to participate or want to end the interview. Are there any questions about what I just explained? May I continue?

Warm-up/Opening:

Are you working?
How far do you live from the nearest health clinic or hospital?
How do you feel about your health now in terms of TB?

Knowledge on TB

What do you know about TB and its treatment?
What could a person do that would reduce his or her chances of a cure?
Before you visited any facilities, how expensive did you think TB diagnosis and treatment was?
Before you visited any facilities, how long did you think TB treatment lasts?

Attitude towards TB

What was your reaction, when you found out that you have TB?
What was the first thing you did, when you learned that you have TB?
What worried you the most, when you thought about your TB status?
How serious a problem do you think TB is in your community?

Health-seeking behavior

When or if you had symptoms of TB, at what point did you go to the health facility?
If you did not go to the health facility at first, what was the reason?
If you went to a private practioner first, what was your experience with them compared to the DOTS treatment?

Family/social support

Who did you talk to about your illness when you were diagnosed with TB? Why?
Who did you not talk to about your illness when you were diagnosed with TB? Why?
How did your family respond to your TB diagnosis and treatment?
How did your community react to your status of TB?

Experience with the DOTS worker

How did the DOTS worker react to your status of TB?
Did the DOTS worker directly observe your medication at all times?
Probe: If not at all times, ask how then the treatment was received.
What did you like about the DOTS worker?
What did you dislike about the DOTS worker?

Benefits/Difficulties of DOTS treatment

What do you find is the most beneficial about the DOTS treatment?
Probe on: free of cost, availability of the treatment, weight gain
What were the difficulties of the DOTS treatment?
Probe on: side effects of medication, duration of the treatment, number of pills, burden if injection

If you smoke or drink, how do you think your behavior affected your adherence to DOTS treatment?

Closing:

What advice would you give to others who may be considering seeking TB treatment from the Government? (DOTS)
In your opinion, what can Government do to increase TB patients' adherence to the DOTS treatment?
Is there anything else you would like to tell us?

-END of INTERVIEW-

Appendix B: Patient Interview Guide for DOT Default Group

In addition to Appendix A,

What bothered you the most when you were on treatment?
Why did you stop the medication in between?
How did your relationship with your family change while on medication and after you stopped taking the medication?
Probe: what about with close friends?
If your symptoms arose again, how long would you wait before seeking treatment again? why?

Appendix C: Patient Interview Guide for DOT Failure Group

In addition to Appendix A,

What worried you the most when you heard that you were not cured after completing the treatment?
What help would you or did you seek when you found out that you were not cured after completing the treatment?
Probe: Did you switch your treatment to something else (e.g govt. to private)? Why?

Appendix D: DOT Provider Interview Guide

(Provider's experience on administering the DOTS program)

Warm-up/Opening:

What is your level of health profession education?
Where is the health facility you work in located?
How long have you been working at this health-care facility/unit?

Delivery by DOTS worker

How many TB patients do you currently provide DOTS treatment to?
How often do you provide DOTS treatment to the patients?
What materials/ways do you find useful in guiding your TB patients when providing the DOTS treatment?
Probe: Why?

Benefits & Difficulties of the DOTS program

What do you find is the most beneficial about the DOTS treatment?
What do you find is difficult about providing the DOTS treatment to the TB patients?
What are the most common complaints about the DOTS treatment that you hear from your TB clients?
What are the most common positive aspects about the DOTS treatment that you hear from your TB clients?

Family/social support

Who are the treatment supporters most often proposed by your TB clients?
Probe: In your opinion, what role do these supporters play to the patient's adherence to the treatment?
How is a person who has TB usually regarded/treated in your community?

Patients with substance abuse

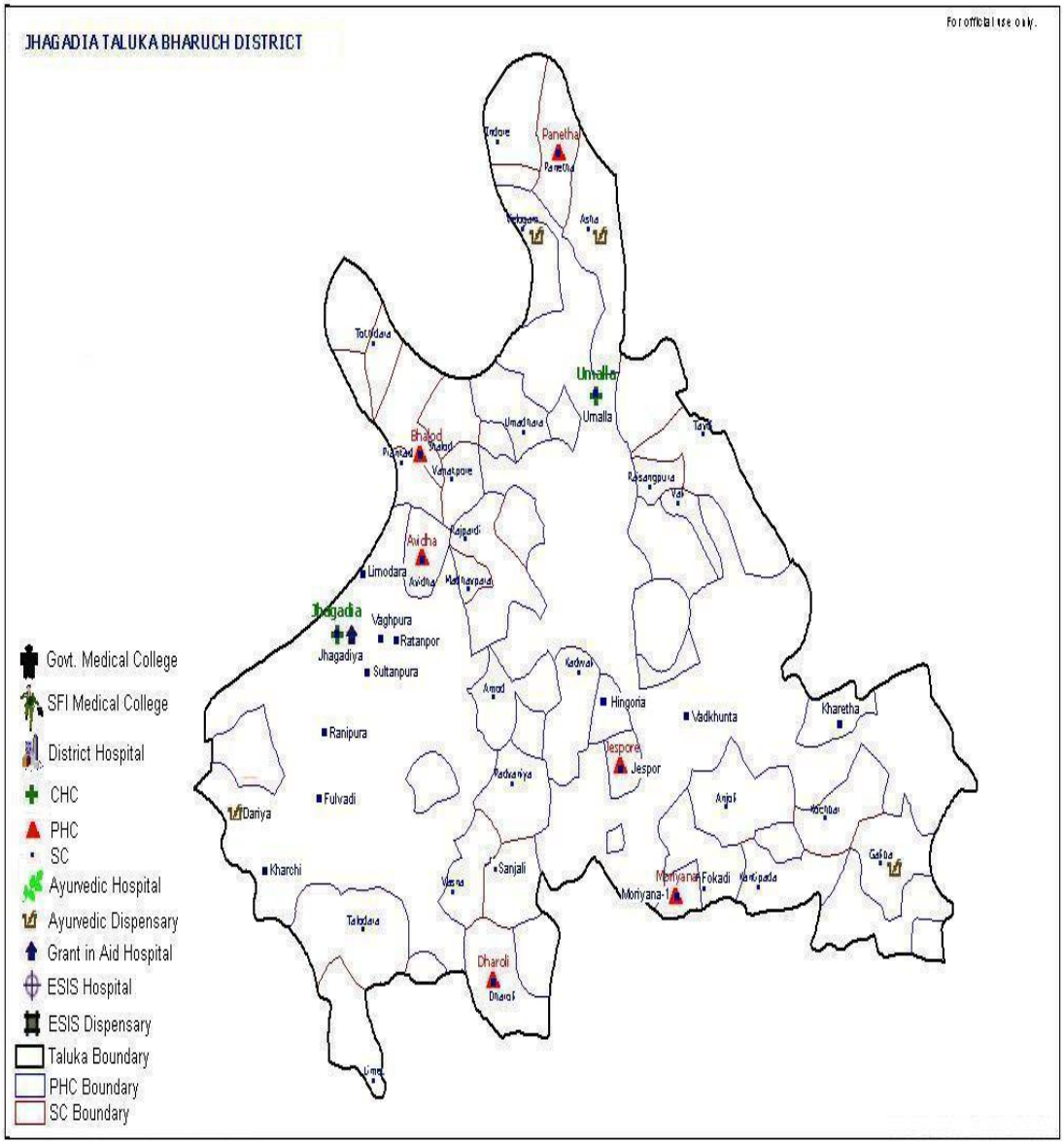
What was your experience with patients of substance abuse and their adherence to the treatment?

Closing:

In your opinion, what can Government do to increase TB patients' adherence to the DOTS treatment?
What communication channels do you think the health workers can use to encourage TB prevention practices in your community?
Is there anything else you would like to tell us?

-END of INTERVIEW-

Appendix E: Map of Study Site (Qualitative): Primary Health Centers in Jhagadia



*Missing PHC: Gowali PHC (*source: Map of Health Facilities: http://images.aarogya.com/ahmedabad/images/jhagadia.JPG)