SCHOOL OF GRADUATE STUDIES

ASSESSMENT OF DOT IMPLEMENTATION IN TIGRAY, NORTHERN ETHIOPIA

BY

SEID ALI SANI (B.Pharm)

JULY 2009

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Abbreviations

AIDS	Acquired Immuno Deficiency Syndrome
BCG	Bacilli Calmette-Guérin
CBDOT	Community Based DOT
CDR	cased detection rate
CHWs	Community health workers
CSA	Central Statistical Agency
DOT	Directly Observed Treatment
DOTS	Directly Observed Therapy- Short Course
EC	Ethiopian Calendar
EPTB	extra pulmonary TB
FGD	Focus Group Discussion
Fig	Figure
FMOH	Federal Ministry of Health
HBDOT	Health facility Based DOT
HEWs	Health Extension Workers
HIV	Human Immuno Deficiency Virus
MDG	Millennium Development Goals
MDR-TB	multi drug-resistant tuberculosis
M. tuberculosis	*Mycobacterium tuberculosis*
NHC	Nucleus Health Center
NTP	National Tuberculosis Control Programme
PTB	pulmonary tuberculosis
SD	Standard deviation
TB	tuberculosis
TCTA	Tuberculosis Coalition for Technical Assistance
TBL	TB and Leprosy
THB	Tigray Health Bureau
TRC	TB Resource Centre
vs	versus
WHA	World Health Assembly
WHO	World Health Organization

Summary

Mycobacterium tuberculosis infects one third of the world's population. Ethiopia ranks seventh in the world & third in Africa with TB prevalence. TB is the leading cause of morbidity, the third cause of hospital admission and the second cause of hospital death in Ethiopia. TB patients take drugs for very long period of time. Hence, adherence is a major problem. To resolve this issue, the World Health Organization recommends the strategy of Directly Observed Therapy-Short Course (DOTS) which includes Directly Observed Treatment (DOT) to ensure a better patient adherence. The observer may be a health worker or a trained and supervised community member.

Studies elsewhere show varying results on the effectiveness of Community Based DOT (CBDOT) compared to Health Facility Based DOT (HBDOT) option. In Ethiopia, although attempts have been made to assess quality of DOT implementation, comparative effectiveness of CBDOT versus HBDOT programs has not yet been assessed.

This study was conducted to assess effectiveness of DOT implementation in CBDOT and HBDOT program areas in Tigray region. The study also aimed to compare implementation practice between the two DOT options and identify the factors affecting DOT implementation.

The study was a comparative cross sectional study conducted between October and December, 2008. Both quantitative and qualitative methods were used for data collection. The quantitative methods used were retrospective review of Unit TB Registers available in the health facilities, prospective observation of DOT observers' practice, exit interview of TB patients and self-administered questionnaire for health professionals. The qualitative method used was Focus Group Discussions (FGD) for both groups.

A total of 378 patients, 118 from Hintalo Wajirat (CBDOT) and 266 from Enderta (HBDOT) Woredas, registered from September 2005 to February 2008 treatment outcomes were reviewed retrospectively from Unit TB Registers. Effectiveness was measured by success rate. Treatment was successful for 101 (88.6%) and 181 (87.4%) new TB patients in CBDOT and HBDOT program areas, respectively. For new sputum smear positive pulmonary TB cases treatment was successful for 19 (90.5%) patients in CBDOT and 28 (84.8%) patients in HBDOT options. CBDOT option was as effective as HBDOT in treating TB patients and can achieve good treatment outcomes. CBDOT option also reduced transfer out of TB patients.

This study found out that DOT implementation as indicated by observation of DOT provider practice was comparable for CBDOT and HBDOT program areas. This indicated that CBDOT observers can practice DOT like HBDOT providers. Hence, CBDOT can complement HBDOT and could be a viable alternative in areas where people live faraway from health facilities.

The study also identified access, acceptability of DOT option and DOT providers, awareness of patients and providers, support to the patient, incentive to CBDOT providers, health improvement, documentation and supervision as factors that could affect DOT implementation.

Voluntary Community Health Workers are available in each and every village and are willing to render service to their villagers. National/regional policy should be adopted to equip them with proper training and provide supportive supervision so that they tremendously increase both access and quality of DOT. Mechanisms should be devised to ensure that health workers develop supportive attitude and facilitate wide scale deployment of voluntary Community Health Workers.

Key words: TB, DOT, CBDOT, HBDOT, Effectiveness, Treatment success and Tigray

1. Introduction

Mycobacterium tuberculosis (M.tuberculosis) infects one third of the world's population. Despite the availability of an affordable and effective treatment, the annual toll of 9 million new tuberculosis (TB) cases and nearly 2 million TB deaths worldwide represents an intolerable burden of human suffering, and an unacceptable barrier to socioeconomic development (WHO[a], 2006). TB remains a major cause of morbidity and mortality in many countries and a significant public health problem worldwide (WHO[b], 2008).

In Ethiopia, TB has been recognized as a major public health problem for more than five decades. The effort to control TB began in the early 1960s with the establishment of TB centers and sanatoriums in three major urban areas in the country and grown into National Tuberculosis Control Programme (NTP) in 1976. A standardized TB prevention and control programme incorporating Directly Observed Therapy-Short Course (DOTS) was started in 1992 (FMOH, 2008). Ethiopia is one of the twenty two countries where 80% of the world's TB cases occur. It ranks seventh in the world and third in Africa with TB prevalence (FMOH, 2008; WHO[a], 2009). In Tigray region, in 2006/07, the total notified cases of TB were 10,439 among which 10,268 (98.4%) were new cases (FMOH[b], 2007).

As a disease of poverty, TB is one of the priorities included in the Millennium Development Goals (MDG). The MDG target relevant to TB is to have halted and begun to reverse incidence by 2015 relative to 1990 and to eliminate TB as a public health problem by 2050 (WHO[b], 2006). World Health Organization (WHO) has declared TB as a global emergency, and the global plan to stop TB 2006-2015 aims to achieve MDG target with an investment of US $ 56 billion (WHO[a], 2007).

The MDG of reducing deaths from TB can be achieved if TB controls efforts approach the global goals for case detection rate (CDR) of smear positive pulmonary TB (PTB) 70% and success rate of 85% or above (WHO[a], 2007). However, neither the prevalence nor the mortality targets will be met in the African and European regions (WHO[a], 2009).

Patient adherence to self-administered treatment is a major challenge for a patient taking a number of drugs for long period of time (Harries *et al.*, 2004; Toman, 1979). WHO recommends the strategy of DOTS which includes Directly Observed Treatment (DOT) to ensure patient adherence to treatment (FMOH[a], 2007).

Conventional management of TB patients requires daily travel to a health facility or hospital admission during the intensive phase of treatment. However, the rapidly increasing number of TB incident cases due to the HIV/AIDS epidemic has made health services unable to cope with the increased case load. It is therefore necessary to explore ways of complementing government health service provision of TB care (FMOH[a], 2005). Moreover, treatment of TB must be organized with a primary consideration to the patients' convenience rather than to the convenience of healthcare delivery service. At the same time it should be noted that community involvement in supporting and supervising treatment, case detection and defaulter tracing is important (FMOH[a], 2007; Toman, 1979).

Community-based TB care has been shown to improve both access to service and adherence to treatment (Harris *et al.*, 2004). The implementation of community TB services calls for the introduction of trained and supervised community members to support TB patients and observe their drug intake. In these settings, TB patients will have the option of Community Based DOT (CBDOT) in addition to Health facility based DOT (HBDOT). The main purpose of community involvement is to make the service available as close to the people as possible (FMOH[a], 2005).

Different studies show varying results on the effectiveness of CBDOT compared to HBDOT (Harris *et al.*, 2001; Mezzabota *et al.*, 2004; Pangrassami *et al.*, 2004). In Ethiopia, although attempts have been made to assess quality of DOT implementation, comparative effectiveness of DOT implementation in CBDOT versus (vs) HBDOT programs has not yet been assessed. This study was aimed to identify factors affecting DOT implementation and asses the effectiveness of CBDOT compared to HBDOT in Tigray.

2. Literature review

2.1. Tuberculosis

TB is an infectious disease caused by *Mycobacterium tuberculosis (M. tuberculosis)* a rod shaped bacillus qualified as "acid fast" due to its staining characteristics in laboratory. The bacilli usually enter the body by inhalation (breathing). They may spread from the initial location in the lungs to other parts of the body via the blood stream, the lymphatic system, and the airways or by direct extension to other organs. Occasionally the disease can also be caused by *Mycobacterium bovis* and *Mycobacterium africanum* (FMOH, 2008; Harries *et al.*, 2004).

Natural history

In the majority (90-95%) of persons infected with *M. tuberculosis* the immunological defense either kills the inhaled bacilli or perhaps, more often, keeps them suppressed causing latent infection. Once infected with *M. tuberculosis*, a person can stay infected for many years, probably for life (Harries *et al.*, 2004). Only about 5-10% of such infected persons (primary infection) develop active disease. If untreated, TB leads to deaths within 2-3 years in at least half of the patients. Without treatment, about 20-25% would have natural healing and 25-30% would remain chronically ill, thus continuing to spread the disease in the community (FMOH, 2008).

Classification

TB cases are classified according to the site of the lesion as pulmonary or extra-pulmonary. PTB cases are further classified as either sputum smear-positive or sputum smear-negative. Extra pulmonary TB (EPTB) occurs in places other than the lungs (WHO, 1999).

Transmission

TB is most commonly transmitted by inhalation of infected droplet nuclei which are discharged in the air when somebody with untreated sputum positive PTB coughs or sneezes. Droplet nuclei can remain airborne in room air for many hours, until they are removed by natural or mechanical ventilation. Persons living in the same household or who otherwise are in frequent and close contact with an infectious patient are at risk of being exposed to the bacilli. A person who inhales one or more of the droplet nuclei can become infected with *M. tuberculosis* (WHO, 1999; FMOH, 2008).

Symptoms

The most important symptoms in the diagnosis of PTB are cough for more than 2 or 3 weeks, sputum production, and weight loss (Harries *et al.*, 2004). Patients with PTB may also have other symptoms. These may be respiratory (chest pain, haemoptysis, breathlessness) or constitutional (fever, night sweats, malaise, fatigue, loss of appetite, secondary amenorrhoea). These symptoms are even more indicative of TB if the patient has had contact with someone known to have the disease (WHO, 1999; Harries *et al.*, 2004; WHO[a], 2006). Symptoms of EPTB are related to specific extrapulmonary sites, such as lymph nodes, pleura, larynx, mening, genitourinary and intestinal tracts, bone, spinal cord, eye and skin (WHO[b], 2008).

Diagnosis

All suspects of any form of TB must be examined according to the standardized diagnostic procedures. By rank of importance the diagnostic methods to confirm/exclude TB are microscopic examination of sputum smears, radiological investigation, culture and histo-pathology. Sputum smear microscopy is the most efficient way of identifying sources of TB infection, and the primary tool for diagnosing TB; it is easy to perform at the peripheral laboratories, not expensive and specific. It can be used for diagnosis, monitoring and defining cure. Therefore this is the key diagnostic tool for case detection (FMOH, 2008).

2.2. Epidemiology of tuberculosis

2.2.1. Burden of tuberculosis

As a cause of human suffering, death and impoverhishment, TB ranks among the leading infectious diseases. TB has been with us for too long. An epidemic that should belong to the past is still increasing globally (WHO[a], 2006). TB is a major public health problem throughout the world, one-third of the world population is estimated to be infected with tubercle bacilli and hence at risk of developing active disease (WHO[a], 2007).

Globally, there were an estimated 13.7 million prevalent cases in 2007 (206 per 100,000 population) a slight decrease from 13.9 million in 2006. The estimated incident cases of TB for 2007 were 9.27 million (139 per 100,000 population). This is an increase from 9.24 million cases in 2006 (140 per 100,000 population) and 6.6 million cases in 1990. Most of the estimated

numbers of cases in 2007 were in Asia (55%) and Africa (31%), with small proportions of cases in the Eastern Mediterranean Region (6%), the European Region (5%) and the Region of the Americas (3%) (WHO[a], 2009).

The emergence of resistance to drugs used to treat TB, particularly multi drug-resistant TB (MDR-TB: TB that is resistant to at least Isoniazid and Refampicin) has become a significant public health problem in a number of countries and an obstacle to effective global TB control (WHO[e], 2006).

The global burden of TB is falling slowly, and at least three of six WHO regions are on track to achieve global targets for reducing the number of cases and deaths that have been set for 2015. Despite reductions in the global burden of TB, an estimated 37% of incident cases of smear positive TB are not being treated in DOTS programmes, up to 96% of incident cases with MDR-TB are not being diagnosed and treated according to international guidelines, the majority of HIV-positive TB cases do not know their HIV status and the majority of HIV-positive TB patients who do know their HIV status do not have access to treatment. Neither the prevalence nor the mortality targets will be met in the African and European regions. The gulf between prevalence and mortality rates in 2007 and the targets in these two regions make it unlikely that 1990 prevalence and death rates will be halved by 2015 for the world as a whole (WHO[a], 2009).

Burden of TB in Ethiopia

According to WHO estimates for 2007, the incidence of TB of all forms and smear positive TB in Ethiopia were 378 and 163 per 100,000 population respectively. The prevalence of all forms of TB was estimated to be 579 per 100,000 population far from the country's 2015 targets for prevalence (156 cases per 100,000). The mortality of all forms of TB is 92 per 100,000 population also far from the country's 2015 target for mortality, 20 deaths per 100,000 population (WHO[a], 2009).

In the year 2006/7, Ethiopia registered 129,743 cases of TB. TB is the leading cause of morbidity, the third cause of hospital admission and the second cause of death in Ethiopia (FMOH, 2008). The CDR in Ethiopia for the year 2006/7 was 32.1% (FMOH[b], 2007) but WHO reports CDR of 28% for the year 2007 (WHO[a], 2009). TB is an obstacle to socio-economic development; 75% of cases in developing countries are within the economically productive age

group, 15 and 54 years, and this leads to grave socio-economic consequence in a country with a very high prevalence of the disease (FMOH, 2008; Harries *et al.*, 2004).

2.2.2. Prevention and control of tuberculosis

The main interventions to prevent the spread of TB in the community are the detection of patients with infectious TB and providing them with effective treatment to ensure a rapid and lasting cure (TCTA, 2006). Primary prevention can be promoted through good public health practice to reduce the transmission of infection by adequate ventilation and isolation of infectious patients. Prevention of TB also includes Bacille Calmette–Guérin (BCG) vaccination and Isoniazid chemoprophylaxis for groups at risk (FMOH, 2008). In countries with high burden of TB, BCG vaccination should be given to all infants as soon as possible after birth (WHO[c], 2006).

The goals of TB control are to reduce mortality, morbidity and disease transmission (while preventing drug resistance) until TB no longer poses a threat to public health. The aim is also to reduce human suffering and the social and economic burden on families and communities as a consequence of TB. In order to achieve this, it is necessary to ensure access to diagnosis, treatment and cure for each patient (Harries *et al.*, 2004). A basic principle of TB control is that the health system, not the patient, is responsible and accountable for ensuring complete treatment of all patients who start treatment (Espinal and Frieden, 2004).

The global targets and indicators for TB control were developed within the framework of the MDG as well as by the Stop TB Partnership and the 1991 World Health Assembly (WHA). The impact targets are to halt and begin to reverse the incidence of TB and mortality by 2015 relative to 1990 levels and to eliminate TB as a public health problem (< 1 case per million population) by 2050. The outcome indicators are to achieve a case detection rate of new smear-positive cases of at least 70% and to reach a treatment success rate of at least 85% for such cases as first established by the WHA in 1991 (WHO[a], 2009) and also included in the global plan to stop TB (WHO[a], 2006; WHO[b], 2006).

TB control programs face many new and existing challenges. The challenges reach far into economic, societal and health infrastructure issues (WHO[a], 2006). Challenges of TB control include weak public health care system, poor access to health services, delays with TB diagnosis, limited access to good quality services, co-infection with HIV/AIDS, MDR-TB, poverty, stigma,

dissatisfaction with TB service, overcrowded and unsanitary environments, malnutrition, immigration, limited awareness of TB, and funding gaps in the context of a global financial crisis (WHO, 2005; WHO[a], 2006; WHO[a], 2008; WHO[b], 2008; WHO[a], 2009).

2.2.3. Case detection

Detection of the most infectious cases of TB-sputum smear-positive PTB cases- by case-finding in patients is an essential component of the control of TB. Its objective is to identify the sources of infection in the community, that is, individuals who are discharging large numbers of tubercle bacilli. Treatment of those infectious patients rapidly renders them non-infectious, there by cutting the chain of transmission. A secondary benefit of case detection is to minimize the delay in initiating treatment, there by increasing the probability of cure (Lulemo[a], 2004; FMOH, 2008).

Improved diagnostic setting (better diagnostic test and well trained staff) and procedures may yield little increase in case-finding without mechanisms to improve access to these services. In the developing world, many people with TB live and die with out the disease being diagnosed, or face delay in diagnosis and treatment. Studies from different areas have reported delays in case finding ranging from 6 days to 6 months (Chiang *et al.*, 2005; Golub *et al.*, 2005; Drabo *et al.*, 2006; Ouédrago[a] *et al.*, 2006; Shargie *et al.*, 2006).

2.2.4. Treatment of tuberculosis

Properly applied TB chemotherapy is effective in curing infectious cases, thereby interrupting the chain of transmission and recognized as one of the most cost-effective of all health interventions by the World Bank that recommended effective TB treatment to be a part of the essential clinical services package available in primary health care (WHO, 2003). The main objectives of TB treatment are to: cure the patient of TB (by rapidly eliminating most of the bacilli); prevent death from active TB or its late effects; prevent TB relapse or recurrent diseases (by eliminating the dormant bacilli); prevent the development of drug resistant (by using a combination of drugs) and decrease TB transmission to others (WHO[c], 2006; FMOH, 2008).

TB treatment regimens

TB treatment takes long time because it is difficult to kill the semi-dormant TB bacilli. Treatment regimens have an intensive phase and a continuation phase. The intensive phase of treatment is

designed for the rapid killing of actively growing bacilli and the killing of semi-dormant bacilli to prevent the emergence of drug resistance. DOT is essential in the initial phase to ensure adherence and protects the development of drug resistance. This phase uses greater number of drugs than the continuation phase since the risk of drug resistance is higher during the early stages of TB treatment when there are more TB bacilli (Harries *et al.*, 2004).

The continuation phase eliminates most residual bacilli that are still multiplying and reduces failures and relapses. At the start of the continuation phase, numbers of bacilli are low and there is less chance of selecting drug-resistant mutants: fewer drugs are therefore needed. The principles of treatment are the same in all TB patients (adults and children) (Harries *et al.*, 2004; WHO[c], 2006).

In Ethiopia, the intensive phase consists of three or more drugs for the first 8 weeks for new cases and 12 weeks for re-treatment cases. During the intensive phase, the drugs must be collected daily by the patient and must be swallowed under the direct observation. Continuation phase requires at least two drugs, to be taken for 4-6 months and the drugs must be collected every month and self-administered by the patient, except for the re-treatment cases and for regimens containing Refampicin. As a routine, all sputum-positive patients on TB treatment must have done sputum specimens examined at the end of the second, fifth, and seventh months. The drugs used as first line treatment of TB in Ethiopia are Refampicin, Ethambutol, Isoniazid, Pyrazinamide and Streptomycin (FMOH, 2008).

TB patients have an excellent chance of being cured, especially if they have not received anti-TB drugs in the past and are not infected with HIV. Short course treatment regimens can achieve more than 95% cure in previously untreated patients. In practice, however, this success rate is rarely achieved. The main reasons for failure are premature cessation of treatment (default) and irregularity in taking drugs, prescription of inadequate regimens, drug resistance, delay in starting treatment, death from AIDS, and drug toxicity. By far the most important causes of poor treatment outcome are early interruption of treatment and irregularity of drug intake. These are most commonly the result of: (Luelmo[b], 2004)

- poor accesses to health facilities (geographical, economic, limited or inconvenient hours, unfriendly service providers) and the resulting loss of income for the patient;

- poor patient orientation regarding the duration of treatment;
- the inevitable tendency of patients to forget drug intake and to stop treatment when they are feeling better;
- irregular supply of drugs, leading to monotherapy and loss of confidence in the health facility.

Importance of adherence to TB treatment

Poor treatment practices in any part of the health sector will increase the risk of drug resistance, spread of TB and death (Frieden[a], 2004). Adherence to treatment is the critical factor in determining treatment success. However, achieving adherence is not an easy task, either for the patient or the provider. Anti-TB drug regimens, consist of multiple drugs given for a minimum of six months, often when the patient feels well (except, perhaps, for adverse effects of the medications). Commonly, treatments of this sort are inconsistent with the patient's cultural milieu, belief system, and living circumstances. Consequently, it is not surprising that, without appropriate treatment support, significant proportions of patients with TB discontinue treatment before completion of the planned duration or are erratic in drug taking. Yet, failure to complete treatment for TB leads to prolonged infectivity; poor outcomes, and drug resistance (TRC, 2004; TCTA, 2006).

2.2.5. Directly Observed Therapy-Short Course (DOTS)

DOTS is the internationally recommended strategy to ensure cure of TB. A total of 37.3 million new and relapse cases, and 18.1 million new smear-positive cases, were notified by DOTS programmes in the 13 years between 1995 and 2007 (WHO[a], 2009).

The DOTS strategy is based around five key elements:

1. Sustained political commitment to increase human and financial resources and make TB control a nationwide activity integral to the national health system
2. Access to quality-assured sputum smear microscopy for case detection among persons presenting with, or found through screening to have, symptoms of TB (most importantly prolonged cough)
3. Standardized short-course chemotherapy (SCC) for all cases of TB under proper case-management conditions including DOT

4. Uninterrupted supply of quality-assured drugs with reliable drug procurement and distribution systems
5. A recording and reporting system enabling outcome assessment of all patients and assessment of overall programme performance (Harries *et al.*, 2004; WHO, 2004; WHO[b], 2007; Williams *et al.*, 2007).

Patient adherence to treatment is necessary to ensure that the treatment cures the patient. It may be difficult for a patient to adhere to anti-TB treatment for 6 to 8 months. It is difficult to predict which TB patients will adhere to self administered treatment. One certain way to ensure patient adherence is DOT. This means that someone supports the patient during the course of treatment and watches the patient swallow the tablets (Harries *et al.*, 2004).

The main advantage of DOT is that treatment carried out under program supervision. Only when a second person directly observes a patient swallowing the given medication can there be certainty that the patient is actually receiving the prescribed treatment regimen (Sbarbaro, 2004). DOT helps to reinforce patients' motivation to continue treatment and counters the tendency to interrupt treatment (WHO, 2003; TCTA, 2006).

DOT is always recommended for all smear-positive cases in the initial phase of treatment and when the continuation phase contains Refampicin (WHO, 2003). Properly implemented DOT ensures that drugs are taken at the right dosages, at the right intervals, and for the required duration (Frieden[b], 2004). A disadvantage of supervised intermittent chemotherapy is the rather high workload for the treatment service (Toman, 1979).

Recent data indicated that the DOTS coverage in Ethiopia was 100% in 2006 and 95% in 2007 (WHO[a], 2009). However, 100% DOTS coverage does not mean that all providers in a country are implementing the DOTS strategy and due to several factors, one being the low health service coverage, many patients in need of anti-TB treatment in the so called "DOTS-covered" areas are not yet treated with DOTS (FMOH, 2008). It is therefore necessary to explore ways of complementing government health service provision of TB. To that end, community involvement in TB contributes to effective TB control activities. This approach is cost-effective and responds effectively to the needs of communities, patients and health workers (FMOH[b], 2005).

2.2.6. Community contribution to TB care

TB is a serious public health problem with grave socio-economic consequences (Kumaresan et al, 1998). The human and social dimension of the TB epidemic cannot be adequately addressed without involving those most affected by the disease, by poverty and the resulting consequences of their sickness on their jobs and family lives. People directly affected by TB and their communities have to be involved in the planning, implementation and evaluation of health interventions (WHO[b], 2009).

A community consists of people living together in some form of social organization and cohesion. Although it may vary significantly in size and socio-economic profile, its members usually share social, cultural, economic characteristics as well as common interests, including health (WHO[a], 2008). The major implementers of community involvement in TB control are Health Extension Workers (HEWs), community members and community organizations (FMOH[b], 2005; FMOH, 2008).

Effective partnership between health services and the community may facilitate access by bringing the service to people's homes, and reducing the cost of care seeking for patients and health services as well as the cost of workload for staff. Effective community and patient involvement yields positive results, such as improved case finding and treatment outcomes, raised awareness concerning the nature of the disease and the availability of effective treatment free of charge, or general health promotion to be successful, community and patient involvement initiatives should be designed and implemented with community members involved as equal partners (WHO[b], 2008). However, community contribution to TB care should be seen as complementing and extending NTP capacity, not replacing NTP activity (WHO, 2003).

The "Community TB care in Africa" project carried out in Botswana, Kenya, Malawi, South Africa, Uganda and Zambia, showed that in a variety of settings the provision of community care, including the option of community DOT, was typically well received. Treatment out comes among patients cared for in the community were either equivalent to or (more frequently) improved, compared with patients treated through health facilities (WHO[d], 2006). The policy recommendations forwarded from the project were; NTPs should: (1) extend TB care to the community to improve access; (2) identify suitable community TB treatment supporters in

consultation with the community; (3) ensure that effective systems extend into the community for recording and reporting, and supply of drugs; (4) monitor contribution to TB care using standard indictors; (5) develop costly plans for expansion of the community approach (Maher, 2003).

Demissie *et al* (2003) demonstrated that organizing TB patients in a club significantly improves treatment completion rate. Decentralizing DOT using volunteer CHWs could also be a feasible option to improve treatment compliance (Mesfin[b] *et al.,* 2005). For DOT to be effective a treatment observer must be accessible and acceptable to the patient (Smith, 2004).

The implementation of community TB services calls for the introduction of trained and supervised community members to support TB patients and observe their drug intake. In these settings, TB patients will have the option of CBDOT, in addition to HBDOT (FMOH[b], 2005). Training of community care providers is essential and should focus on a limited number of activities (FMOH, 2008). Community volunteers also need regular support, motivation, instruction and supervision. Inspiring communities and obtaining their continued support in identifying and providing care for people with TB is essential to sustain community TB initiatives (WHO[b], 2006).

There are different factors that affect implementation of community TB care. A decentralized health care system, adequate community resources, community empowerment and a functioning health service extension programme favors implementation of community TB care. The disfavoring factors include poverty and household commitments which hinder participation of community members in the care of their own sick, difficulties to maintain motivation and awareness, and financial constraints faced by community organizations (FMOH[b], 2005).

Community Based DOT

CBDOT may be used to expand access to treatment for some underserved patient groups and to further improve treatment outcomes. DOT adapted to the needs of patients and to the working conditions of health care workers is certainly the best method of avoiding treatment interruption (WHO, 2003). CBDOT was associated with less costs per patient treated, better cost-effectiveness, shorter length of hospital stay, and good acceptability from patients especially as patients could stay with their families, continue to work and spend less money on care (Harries *et al.*, 2001). Kamolratanakul *et al* (1999) indicated that, no significant differences in outcomes

could be observed between patient groups receiving DOT under the various options (which include CBDOT) for treatment supervisors.

Studies showed that both CBDOT and HBDOT supervision generally performed effectively, with satisfactory rates of treatment success (Maher, 2003). Overall, there was no significant difference in conversion and cure rates between the two strategies, suggesting that CBDOT may be a viable alternative to HBDOT. CBDOT may be particularly useful in parts of the country where people live far from health facilities (Lwilla *et al.*, 2003). Studies carried out in different areas indicated that CBDOT is more cost effective than HBDOT (Floyd *et al.*, 1997; Islam *et al.*, 2002; Wandwalo *et al.*, 2005) and also acceptable (Wandwalo *et al.*, 2006). CBDOT has the potential of increasing the number of TB patients treated without significantly increase in resources (Wandwalo *et al.*, 2005).

In Ethiopia, although attempts have been made to assess quality of DOT implementation, comparative effectiveness of DOT implementation in CBDOT vs HBDOT programs has not yet been assessed. Hence, it is important to identify factors affecting DOT implementation and asses the effectiveness of CBDOT compared to HBDOT option in order to develop intervention strategies based on evidence and ensure proper DOT implementation.

3. Objectives

3.1. General Objective

Assess effectiveness of DOT implementation in CBDOT and HBDOT program areas and identify factors affecting DOT implementation in Tigray, Northern Ethiopia.

3.2. Specific objectives

- To compare effectiveness of DOT implementation in CBDOT vs HBDOT Woredas
- To asses DOT implementation practice in CBDOT and HBDOT Woredas
- To identify factors affecting DOT implementation

4. Methodology

4.1. Description of study area

Tigray is the northernmost region of the Federal Democratic Republic of Ethiopia. The region shares common borders with Eritrea in the north, the State of Afar in the east, the State of Amhara in the south, and the Republic of the Sudan in the west. The State of Tigray consists of 5 Administrative Zones, one special Zone, 35 Woredas and 74 towns. The capital city is Mekelle. A 2007 enumeration puts the population of Tigray at 4,314,456 with annual growth rate of 2.5%; of which 83.9% lives in rural areas. The ratio of males to females is approximately 1:1 (THB, 2007; CSA, 2008). Most of the population is concentrated in the highlands. The lowlands are more sparsely populated due to the prevalence of endemic and epidemic diseases. Infant mortality rate is 67/1000 live births, under five mortality rate is 106/1000 live births, and Maternal Mortality Rate is 756/100,000. Tigray has 113 Nucleus Health Centre (NHC) and health stations, 529 health posts, 42 health centers, 31 private clinics and 16 hospitals from which 1 is specialized referral hospital. The human resource in the health sector is about 5,265 comprising different professions (THB, 2007; FMOH[b], 2007).

The study Woredas were Hintalo Wajirat and Enderta from Southern Tigray Zone. Enderta has a population of 114,277 comprising 57,472 (50.29%) males and 56,805 (49.71%) females (CSA, 2008). According to the Woreda Health Bureau, there are 7 health centers and NHC and 13 health posts. The Woreda has 5 health officers, 25 nurses, 3 laboratory technicians, 4 pharmacy technicians, 34 HEWs and 12 trained treatment supporters/observers (Mehawir).

Hintalo Wajirat Woreda has a population of 152,219 comprising 75,262 (49.4%) males and 76,957 (50.56%) females (CSA, 2008). According to the Woreda Health Bureau, there are 6 health centers and NHC and 15 health posts. The Woreda has 5 health officers, 32 nurses, 3 laboratory technicians, 10 pharmacy technicians, 40 HEWs and 37 trained treatment supporters/ observers (Mehawir). TB treatment is given in the health facilities of both Woredas, but CBDOT service is also available in Hintalo Wajirat Woreda.

4.2. Variables

Independent variables

The independent variables of the study were DOT option, age, sex, TB category and type of TB.

Dependent variables

The dependent variables were cure rate, treatment completion rate, success rate, smear conversion rate, default rate, transfer-out rate and death rate.

4.3. Study design

A comparative cross sectional study involving a retrospective review of Unit TB Registers in the selected Woredas was carried out. Both quantitative and qualitative methods were used for data collection. Triangulation of the qualitative and quantitative methods was done to validate the data collected. The quantitative method used were retrospective review of Unit TB Registers available in the health facilities, prospective observation of DOT observers' practice, semi-structured exit interview of TB patients and self-administered questionnaire for health care professionals. The qualitative method used was Focus Group Discussions (FGD) from both CBDOT and HBDOT areas.

4.4. Study population

The source population for the study was all TB patients under treatment in Tigray region. The study population consisted of patients who were diagnosed with TB and treated under CBDOT treatment in Hintalo Wajirat Woreda and under HBDOT in Enderta Woreda.

4.5. Inclusion and exclusion criteria

TB patients under CBDOT treatment in Hintalo Wajirat Woreda and patients under HBDOT treatment in Enderta Woreda were enrolled in the study after they consented to participate. Patients diagnosed other than TB and those who refused to participate were excluded from the study. TB patients younger than 18 years of age were also excluded from the interview and FGD. Patients who were unable to respond because of any reason were not included. DOT providers participated in self-administered and FGD studies after they consented.

4.6. Sampling procedure and sample size

The study Woredas were selected based on the information obtained from Tigray Health Bureau (THB) considering the presence of HBDOT or CBDOT. CBDOT Woreda was selected considering the time when the Woredas started CBDOT service to get the maximum number of study participants for comparing CBDOT with HBDOT. The nearby Woreda with no CBDOT option was also selected for comparison. Unit TB Registers of patients registered from September 2005 to February 2008 were reviewed in Hintalo Wajirat (CBDOT) and Enderta Woredas (HBDOT). A total of 378, (118 patients' treatment outcome from Hintalo Wajirat and 266 from Enderta Woreda) were reviewed from Unit TB Registers.

In the exit interview 30 patients (15 from each group) from CBDOT and HBDOT Woredas were interviewed. A total of 20 patients (10 from each group) were observed during DOT service provision. FGD participants were purposively selected and the FGDs were conducted with TB patients, treatment observers and health workers. Forty two health professionals from both DOT options were involved in completing the self administered questionnaire.

4.7. Data collection and management

4.7.1. Data collection

Quantitative and qualitative data were collected using data abstraction format, non-participatory observation, exit interview, self-administered questionnaire and FGD.

Record review: Patients treatment outcomes were reviewed from Unit TB Registers retrospectively using data abstraction form for independent and dependent variables that were used to compare treatment effectiveness in HBDOT and CBDOT options (Annex 1).

Observation: Checklist (Annex 2) was used to conduct prospective non-participatory observation of TB DOT service providers' practice in both CBDOT and HBDOT Woredas.

Self-administered questionnaire: Self-administered questionnaires were administered and collected from 42 health personnel working in both Woredas. The goal of this questionnaire was to identify the possible causes for low case detection (Annex 3).

Exit interview: Short after receiving the routine service for which they were scheduled, CBDOT and HBDOT patients were interviewed using semi-structured questionnaire to compare their knowledge, satisfaction and perception towards the respective services (Annex 5 and 7).

Focus group discussion: Five FGDs were conducted in both CBDOT and HBDOT areas in order to get a more in-depth insight of the patients' and health care workers' view on factors affecting DOT implementation. Participants were purposively selected and the FGDs were carried out with TB patients, treatment observers and health workers. Interviews with the FGDs were tape recorded (Annex 8 and 9).

4.7.2. Data collectors

Ten data collectors were given three days theoretical and practical training using training guide. The training enabled data collectors to acquire knowledge and skill needed to get informed consent, ensure confidentiality of information given, review records, and conduct exit interview. Nurses were deployed as data collectors since the data collection involved reviewing medical records from Unit TB Registers. Data collectors involved in interviewing of patients were fluent in Tigringna (language predominantly spoken by people living in the study area). In order to improve the reliability of information obtained from patients, the exit interviews and observations were conducted by data collectors recruited from other Woredas. The FGDs were facilitated each by a moderator and note taker (recorder).

4.7.3. Data quality assurance

Data collectors were given training in order to ensure quality and consistency. The training had theoretical and practical sessions. During the training each and every question in the questionnaires was discussed to ensure clear and common understanding by all data collectors. The training was further enriched through role play.

In order to ensure validity of the study and maximize the response rate the checklist, exit interview and data recording forms were all pre-tested. The pre-test was used to rectify and revise data collection instruments. Guidelines were prepared and used for training. The guideline addressed procedures such as observation, exit interview and FGD (Annex 10-13). The quality of data collection was further ensured through daily review of data for completeness and

consistency. There was also spot checking of data collection. Moreover, the questionnaire used for interviewing was translated from English to Tigringna and back to English.

4.8. Data entry and analysis

Statistical Package for Social Sciences (SPSS) version 13.0 for windows program was used for quantitative data entry and analysis. All the data collected were checked for accuracy and completeness prior to entry into the database. Data entry clerk (computer literate and experienced in data entry) was recruited to enter all data collected from the field. After the data entry, the data base information was crosschecked with the data collection forms before commencement of analysis. Data from FGDs were transcribed, translated and analyzed after they were collected in the field. Chi-square test was used to detect statistically significant differences between the two DOT options. Descriptive statistics such as mean and standard deviation were calculated where appropriate. Frequency distribution and percentages were used to present findings. Presentation of data is in the form of descriptions, tables and graphs.

4.9. Ethical considerations

Ethical approval was obtained from Addis Ababa University, School of Pharmacy Ethical Review Committee. The proposal was also reviewed and accepted by THB TB and Leprosy (TBL) Division. Discussions were held with Woreda Health Bureau and health centers about the purpose of the study. Before patients were requested for consent they were informed well about the purpose of the study; the content of the questionnaire; confidentiality of the information collected from them and their right not to answer to questions if they do not want to respond as well as to stop answering and withdraw from the interview at any point in time. Patients were informed that they have the right to refuse to participate in the study without a retribution fear.

Data collectors also provide health education based on the responses obtained during exit interview to correct misconceptions, if any. Moreover, patients were informed three important points about TB to convey to others: a person having cough for more than 2 weeks should be diagnosed, TB is a curable disease if it is treated properly and TB treatment is given free of charge (Annex 5 and 7). Before starting the FGDs participants were informed about the study and group consent was sought. Moreover, the procedures of the discussion were explained and the confidentiality of the information given was notified.

4.10. Operational definitions

Cure rate: the percentage of TB cases that were registered in a specified period and were cured.

Death rate: the percentage of TB cases registered in a specified period that died during treatment, irrespective of cause.

Default rate: the percentage of TB cases registered in a specified period that interrupted treatment for more than two consecutive months.

Mehawr: members of the community who are trained to work in different health matters as health supporter (e.g. latrine building, TB/HIV etc).

Smear conversion rate: the percentage of new smear-positive PTB cases registered in a specified period that are converted to smear negative at the end of the initial phase of treatment.

Transfer-out rate: the percentage of TB cases registered in a specified period that were transferred to another basic management unit from which there is no treatment outcome information.

Treatment completion rate: the percentage of TB cases registered in a specified period that completed treatment.

Treatment success: the sum of patients who are declared "cured" and those who have "completed treatment", i.e. the sum of cure rate and treatment completion rate.

Woreda: the second lowest administrative unit in the government structure.

DOT providers' communication with patients was evaluated as:

Poor: if too busy to care, hasty, or not listening to the patient.

Fair: if the observer greets and gives attention to the patient while observing DOT.

Good: if the observer greets, asks and listen to the patient and observes DOT attentively.

Very good: if the observer asks questions and listens, demonstrate a caring respectful attitude, praises and encourages the patient to ask questions, asks checking questions and show sympathy.

5. Results

5.1. Quantitative results

The two study Woredas were selected based on the information obtained from the Regional TBL Department considering the practice of CBDOT to get the maximum number of patients for retrospective review of treatment outcomes. The Woredas selected for the study were comparable except for the presence of CBDOT in one of the Woredas, Hintalo Wajirat (Table 1).

Table 1: Health and Demographic profile of selected study Woredas, Tigray 2008.

	HintaloWajirat Woreda (CBDOT)	Enderta Woreda (HBDOT)
Population	152,219	114,277
Health officers	5	5
Nurses	32	25
Lab technicians	3	3
Health Extension Workers	40	34
Trained TB treatment supporters (observers)	37 (CBDOT observers)	12 (but not functional)
Health centers/NHC	6	7
Health posts	15	13

Sources: CSA, 2008; Woredas' Health office.

5.1.1. Record review

Data from a total of 384 TB patients record were abstracted from the two DOT options. Unit TB Registers were reviewed for 118 patients in Hintalo Wajirat Woreda (CBDOT) and 266 patients in Enderta (HBDOT) Woreda.

There were 67 (56.8%) and 133 (53.4%) males enrolled in CBDOT and HBDOT wings of the study, respectively. Females accounted 51 (43.2%) in CBDOT and 116 (46.6%) in HBDOT. Eighty four (72%) of patients from CBDOT and 195 (74%) of patients from HBDOT were in the age range of 15 - 54 years. New TB patients constituted 116 (99.1%) patients from CBDOT and 210 (94.6%) of HBDOT patients. PTB positive patients were 22 (18.6%) in CBDOT and 40 (15.4 %) in HBDOT. There were more EPTB patients in CBDOT and PTB negative in HBDOT option (Table 2).

Table 2: Characteristics of TB patients reviewed from Unit TB Registers in Enderta and Hintalo Wajirat Woredas; Tigray, 2008.

	CBDOT	HBDOT	X^2	p-value
Sex	N=118	N=249		
Male	67 (56.8%)	133 (53.4%)	0.366	0.545
Female	51 (43.2%)	116 (46.6%)		
Age (years)	N=117	N=265		
≤14	8 (6.8%)	40 (15.1%)	16.653	0.011
15 – 24	16 (13.7%)	56 (21.1%)		
25 – 34	28 (23.9%)	64 (24.2%)		
35 – 44	26 (22.2%)	43 (16.2%)		
45 – 54	14 (12.0%)	32 (12.1%)		
55 – 64	15 (12.8%)	12 (4.5%)		
65+	10 (8.5%)	18 (6.8%)		
Category	N=117	N=222		
New	116 (99.1%)	210 (94.6%)	4.365	0.113
Relapse	1 (0.9%)	10 (4.5%)		
Others	0 (0.0%)	2 (0.9%)		
Classification	N=118	N=258		
Pulmonary positive TB	22 (18.6%)	40 (15.4%)	8.204	0.017
Pulmonary negative TB	43 (36.4%)	134 (52.1%)		
Extrapulmonary TB	53 (44.9%)	84 (32.4%)		

5.1.1.1 Treatment outcomes for all categories of TB cases

Of all TB cases registered in the Unit TB Register with treatment outcome, treatment was successful for 103 (88.8%) and 231 (87.8%), CBDOT and HBDOT, respectively (X^2=0.071, P=0.790). Twelve (10.3%) patients from CBDOT died compared to 14 (5.3%) patients in HBDOT option. The transferred out patients from HBDOT option were 17 (6.5%) while it was zero from patients in CBDOT option (Fig 1).

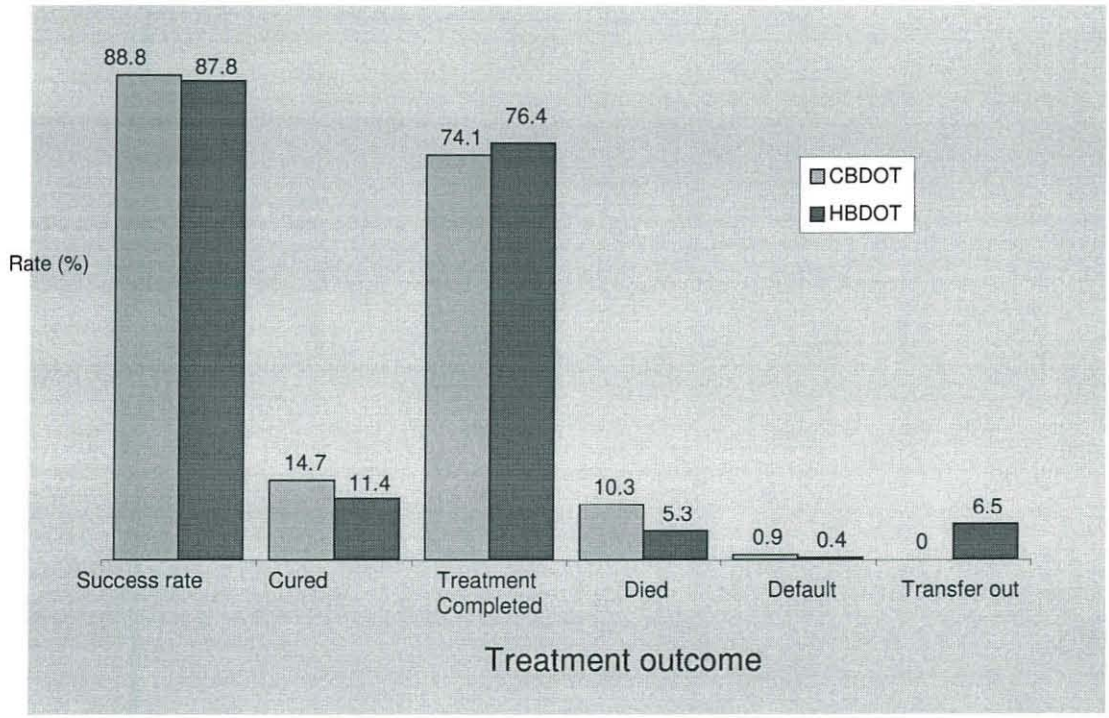

Fig 1: Comparison of treatment outcomes by DOT option for all category TB cases in Enderta and Hintalo Wajirat Woredas; Tigray, 2008.

5.1.1.2. Treatment outcomes for all new TB cases

As shown in figure 2 treatment was successful for 101 (88.6%) and 181 (87.4%) of all new TB cases under CBDOT and HBDOT options, respectively (X^2= 0.092, P=0.761). Eleven (5.3%) and 12 (10.5%) new TB cases died from HBDOT and CBDOT wings, respectively. The transfer out rate was 14 (6.8%) for HBDOT but zero for CBDOT option.

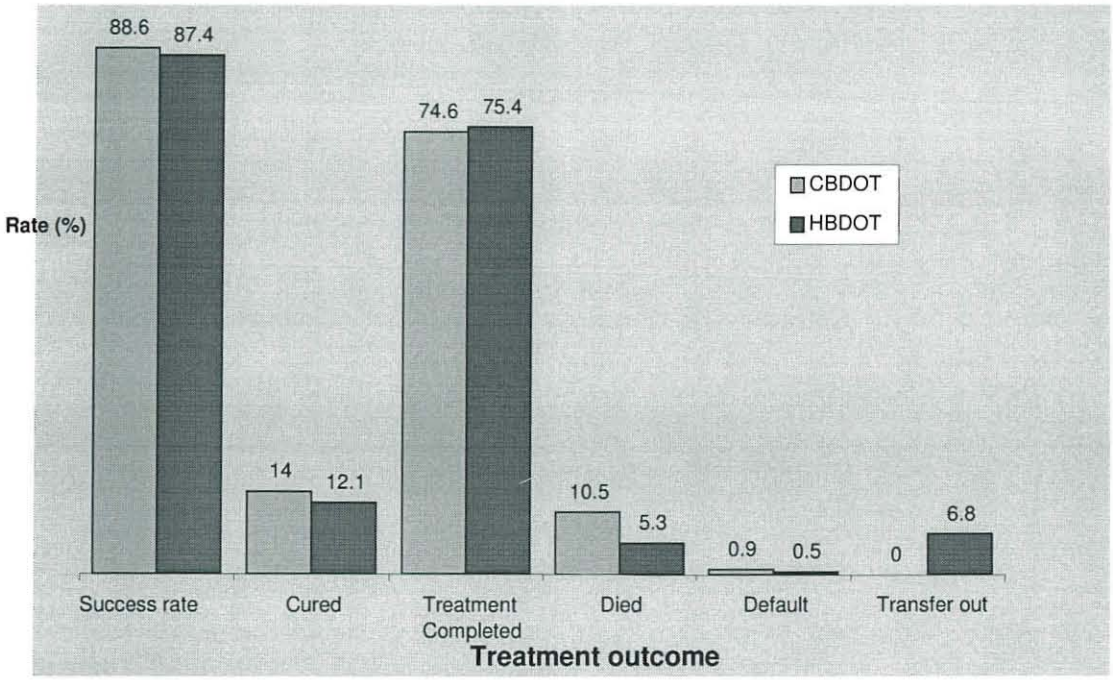

Fig 2: Comparison of treatment outcomes by DOT option for all new TB cases in Enderta and Hintalo Wajirat Woredas; Tigray, 2008.

5.1.1.3. Treatment outcomes for new sputum pulmonary positive TB cases

Treatment was successful for 19 (90.5%) and 28 (84.8%) new sputum smear positive PTB cases for CBDOT and HBDOT options, respectively (Fisher's exact two tailed test P=0.693). Unlike HBDOT, there were no defaulters and transferred out patients in CBDOT (Fig 3).

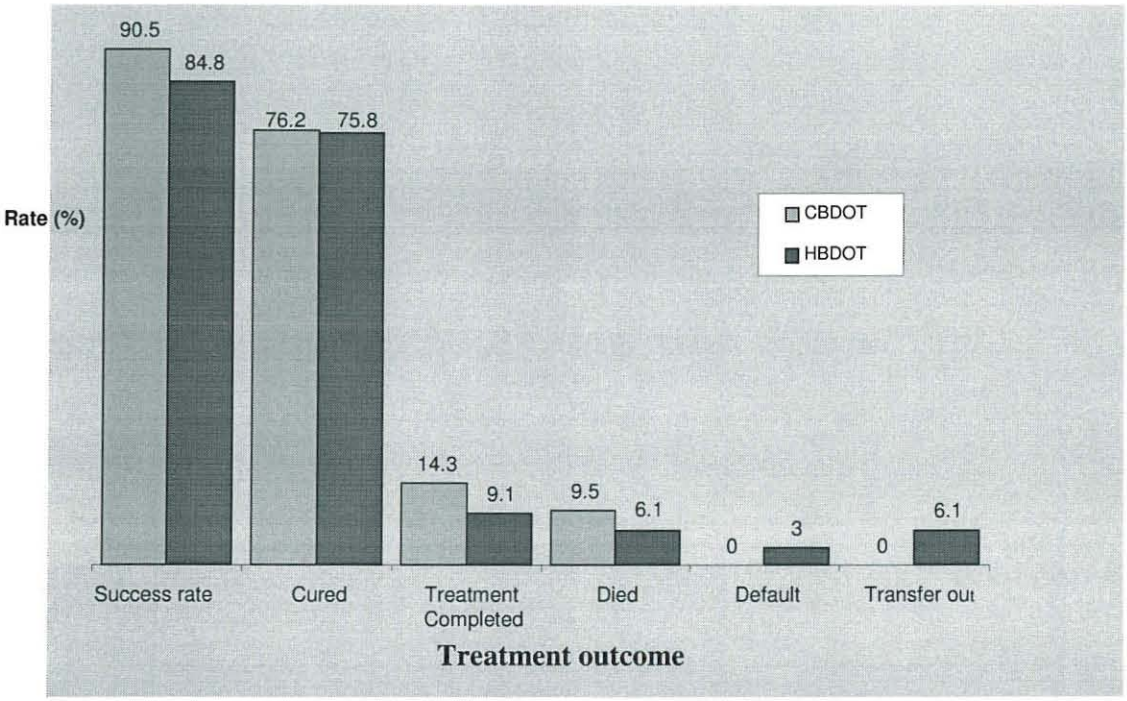

Fig 3: Comparison of treatment outcomes for new sputum pulmonary positive TB cases in Enderta and Hintalo Wajirat Woredas; Tigray, 2008.

5.1.1.4. Smear conversion rate

Positive sputum smear was converted to negative for 17 CBDOT and 26 HBDOT new sputum smear positive cases. The smear conversion rate was 81.0% and 78.8% for CBDOT and HBDOT options, respectively. Sputum test was not done or recorded for 2 (9.5%) CBDOT and 7 (21.2%) HBDOT patients upon completion of the intensive phase.

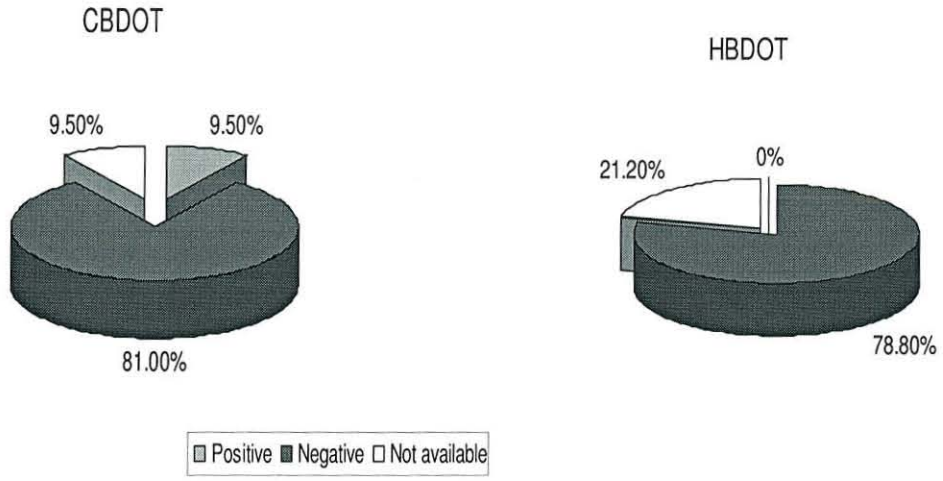

Figure 4: Smear results at the end of intensive phase for new sputum pulmonary positive TB cases in Enderta and Hintalo Wajirat Woredas; Tigray, 2008.

5.1.1.5. Data completeness

As indicated in Table 3, address of patients were not available in the Unit TB Registers for 6 patients (5.1%) in CBDOT and 24 (9.0%) in HBDOT wings. Name of contact persons were also not available for 13 (4.9%) patients in HBDOT registries. Pre-treatment body weight was recorded for 113 (95.8%) patients in CBDOT and 236 (88.7%) patients in HBDOT but missed in 5 (4.2%) CBDOT and 30 (11.3%) in HBDOT patients in the Unit TB Register. For 44 (16.5%) patients from HBDOT option and only 1 patient from CBDOT option, their TB categories were not recorded in the Unit TB Registers. Intensive phase monitoring charts were not complete for 12 (10.2%) patients from CBDOT area and 14 (5.3%) patients from HBDOT area.

Table 3: Completeness of Unit TB Registers in Enderta and Hintalo Wajirat Woredas; Tigray, 2008.

	CBDOT	HBDOT
	N=118	N=266
Sex		
Male	67 (56.8%)	133 (50.0%)
Female	51 (43.2%)	116 (43.6%)
Not available	0 (0.0%)	17 (6.4%)
Address of the patient		
Available	112 (94.9%)	242 (91.0%)
Not available	6 (5.1%)	24 (9.0%)
Name of contact person		
Available	118 (100.0%)	253 (95.1%)
Not available	0 (0.0%)	13 (4.9%)
Address of contact person		
Available	115 (97.5%)	260 (97.7%)
Not available	3 (2.5%)	6 (2.3%)
Pretreatment body weight		
Available	113 (95.8%)	236 (88.7%)
Not available	5 (4.2%)	30 (11.3%)
Category		
New	116 (98.3%)	210 (78.9%)
Relapse	1 (0.8%)	10 (3.8%)
Others	0 (0.0%)	2 (0.8%)
Not available	1 (0.8%)	44 (16.5%)
Classification		
Pulmonary positive TB	22 (18.6%)	40 (15.0%)
Pulmonary negative TB	43 (36.4%)	134 (50.4%)
Extrapulmonary TB	53 (44.9%)	84 (31.6%)
Not available	0 (0.0%)	8 (3.0%)
Intensive phase monitoring chart completeness		
Complete (2 months)	106 (89.8%)	252 (94.7%)
Not complete (<2 month)	12 (10.2%)	14 (5.3%)

5.1.2. Observation

Non-participatory observation of DOT implementation practice was done to evaluate how DOT is implemented and DOT observers practiced in CBDOT and HBDOT options. The observation was recorded using checklist (Annex 2). A total of 20 patients (10 from each group) were observed after getting the consent of both the patient and the DOT provider.

All patients recruited for the observation were registered in the Unit TB Registers. Their records in the Unit TB Registers were complete at the time of observation. All DOT observers greeted patients who came for DOT but there was no weight check in both groups. Eight CBDOT and six HBDOT patients were asked how they felt that day by DOT observers. All CBDOT centers (patients' home or CBDOT observers' home) but only one HBDOT centre had "drinking" water. However, water was available for patients to take their drugs (since patients bring water with them) and all patients were observed while swallowing their medicine.

As indicated in table 4, six CBDOT and seven HBDOT patients were advised about the importance of taking adequate and nutritious food along with treatment. The DOT observer communication with patients in both groups was rated as good by data collectors.

Table 4: Results for observation of DOT implementation practice in Enderta and Hintalo Wajirat Woredas, Tigray, 2008. (N=20)

	CBDOT	HBDOT
Number of observed patients	10	10
1. Treatment ID card	5	1
2. Registered in the Unit TB Register	10	10
3. Patient Unit TB Register complete	10	10
4. Observer greeted the patient	10	10
5. Weight check	0	0
6. Observer asked patients' feeling	8	6
7. Patient was asked about side effects	2	3
8. Provider encouraged the patient	5	2
9. Correct drugs provided to patient	10	10
10. Dose was recorded in the Unit TB Register	10	10
11. Correct dose based on weight was recorded	10	10
12. The observer filled attendance sheet	10	10
13. Water was available in the DOT center	10	1
14. Water was available to take drugs	10	10
15. Observer watched the patient swallow drugs	10	10
16. The patient was advised about food	6	7
17. The patient was advised about adherence	5	2
18. Observer communication	Good	Good
19. Total *	116/150	110/150

*excluding treatment ID card and water availability in the DOT center

5.1.3. Self-administered questionnaire

To identify possible reasons for low case detection rate self-administered questionnaires were distributed to and collected from 42 health staff working on TB. The questionnaire (Annex 3) had 14 possible causes for low case detection rate which were compiled and organized by reviewing different sources of information. Respondents were asked to select 5 important possible reasons for low case detection rate in Tigray region based on their experiences.

The respondents were 15 males and 27 females. The age of respondents range from 23 to 40 years, and the mean age was 31 years (SD=5.435). Majority of the respondents (61.9%) were nurses. They served in the health facilities from 3 - 25 years with mean of 11 years (SD=7.287) and TB related positions from 2-18 years with mean of 6 years (SD=4.011).

From the data collected through questionnaires it was noted that the five most important reasons for low case detection rate in the study area could be related to awareness and dissemination of information; intensified TB screening among high risk groups; utilization of health facilities; community involvement and delayed referral system for TB suspects (Table 5).

Table 5: Responses to possible causes for low case detection rate in Tigray region by health staff working on TB in Enderta and Hintalo Wajirat Woredas, Tigray, 2008.

Possible causes for low case detection rate (N=42)	**N**	**%***
Inadequate awareness and dissemination of information in the community, amongst medical staff and the community workers regarding respiratory symptoms notably persistent cough for more than two weeks	28	67
Absence of intensified TB screening among high risk groups	26	62
Limited utilization of health facilities	25	60
Inadequate/ absence of identification of suspects by HEWs and community volunteers	21	50
Delayed referral system for TB suspects to health facility providing DOTS service for examination and treatment	19	45

*Sum of percentage may exceed 100% as respondents may select more than one cause

5.1.4. Exit interview

The number of patients who participated in the exit interview was 30 (15 from each group) since no other patient was found fulfilling the criteria to be interviewed during the time of data collection. In each group 11 (73%) interviewees were males and 4 (27 %) were females. Majority of patients under HBDOT (80%) and 47% of CBDOT patients were illiterate. Majority of respondents i.e. 67% from CBDOT and 87% from HBDOT were farmers. Those patients who were married were 11 (73%) and 14 (93%) from CBDOT and HBDOT options, respectively (Table 6).

5.1.4.1. Knowledge about TB

Almost all respondents from both CBDOT and HBDOT categories knew that TB is preventable, curable and treatable. All patients knew that TB is not caused by witchcraft/sprit. However, 14 (93%) patients from both groups mentioned cold/wind blow as a cause for TB. Nine (60%) from CBDOT and 5 (33%) from HBDOT responded that TB is caused by consuming unhygienic food and water. Of the respondents under HBDOT category, 7 and 1 from CBDOT attributed tiresome work as a cause of TB. Only 5 patients from CBDOT and 1 patient from HBDOT mentioned germ as cause of TB.

Coughing for more than 2 weeks was mentioned by all respondents as a symptom of TB. Twelve (80%) CBDOT patients and 10 (67%) HBDOT patients mentioned weight loss as sign for TB. Other symptoms mentioned include night sweats (12 CBDOT and 8 HBDOT patients), loss of appetite (5 CBDOT and 7 HBDOT patients) and fatigue/chest pain (9 CBDOT and 11 HBDOT patients). Majority (93%) of CBDOT and 5 (33%) HBDOT respondents considered TB patients as source of TB. But 7 patients from HBDOT and only 1 patient from CBDOT program areas responded that they did not know the source of TB. Fourteen (93%) interviewees from each DOT option knew that TB is transmitted through respiration/sneezing and sharing drinking and eating utensils. Living in close contact with TB patients was mentioned by 12 (80%) respondents from each group as factor facilitating the transmission of TB.

Treatment of the sick (80% of each group), isolation of TB patients (80% CBDOT and 53% HBDOT patients), eating good foods (53% CBDOT and 60% HBDOT patients), avoiding concentrated living (60% CBDOT and 47% HBDOT patients) and avoiding direct coughing

(47% CBDOT and 40% HBDOT patents) were mentioned as TB prevention strategies. Vaccination and adequate ventilation were mentioned as TB prevention strategies by two patients from both DOT options.

Table 6: Exit interview respondents' socio-demographic characteristics, Enderta and Hintalo Wajirat Woredas, Tigray, 2008. (N=30)

	CBDOT	HBDOT
Number of respondents	15	15
Sex		
Male	11 (73.3%)	11 (73.3%)
Female	4 (26.7%)	4 (26.7%)
Age (years)		
20-24	3 (20.0%)	0 (0.0%)
25-34	2 (13.3%)	3 (20.0%)
35-45	5 (33.3%)	6 (40.0%)
45-54	3 (20.0%)	3 (20%)
55-64	1 (6.7%)	3 (20%)
65-74	1 (6.7%)	0 (0.0%)
Ethnicity		
Tigraway	15 (100%)	15 (100%)
Religion		
Orthodox Christianity	15 (100%)	15 (100%)
Education		
Can't read and write	7 (46.7%)	12 (80%)
Informal education	2 (13.3%)	1 (6.7%)
Grade 1-6	4 (26.7%)	2 (13.3%)
Grade 7-12	2 (13.3%)	0 (0%)
Marital status		
Never married	2 (13.3%)	0 (0%)
Currently married	11 (73.3%)	14 (93.3%)
Widowed	1 (6.7%)	1 (6.7%)
Cohabiting	1 (6.7%)	0 (0%)
Family size		
1-5	9 (60.0%)	5 (33.3%)
6-9	6 (40%)	10 (66.7%)
Mode	6 (4 times)	8 (6 times)
Having dependents (yes)	10 (66.7%)	13 (86.7%)
Occupation		
Farmer	10 (66.7%)	13 (86.7%)
Daily laborer	3 (20%)	2 (13.3%)
No job	2 (13.3%)	0 (0%)

5.1.4.2. Knowledge about TB treatment

Majority of the respondents in the exit interview said that TB if not treated would result in death and disability. Death (87% HBDOT vs 47% CBDOT respondents) and resistance to drug (80% CBDOT vs 47% HBDOT respondents) were mentioned as consequences of irregular treatment. Almost all patients from both groups (93%) knew that treatment helps to control TB and DOT is useful to ensure proper treatment with drugs (100% CBDOT and 93% HBDOT patients). All respondents in CBDOT implementation areas and 13 (87%) of the respondents in HBDOT areas indicated that TB treatment has to be taken for 8 months. Majority of patients knew the duration of intensive phase and continuation phase treatment. All respondents took their medicines daily and 14 (93%) from CBDOT and 9 (60%) from HBDOT would inform the health staff/ their DOT observer if they plan to travel. But five patients from HBDOT option indicated that they would never go away before completing their treatment.

5.1.4.3. Knowledge about side effects

Four interviewees (from each group) experienced side effects during their treatment. The side effects indicated were nausea and anorexia. Three of the four HBDOT patients had also joint pain. However, the side effects disappeared by themselves as reported by all CBDOT and HBDOT patients who experienced them. Majority of patients responded that if the side effects occur it would be minor and manageable and they would visit health facilities for management and care.

5.1.4.4. Attitude to diagnosis

Eleven (73%) patients from CBDOT and 7 (47%) from HBDOT accepted the diagnosis of TB when declared first time. Two patients from CBDOT and one patient from HBDOT options reported that they got relieved when they knew they had TB since their fear was HIV. But 7 (47%) HBDOT patients felt bad. Majority (87%) of TB patients' family accepted and 73% provided care and support to them.

5.1.4.5. Perception about DOT observer

Six patients from CBDOT and one patient from HBDOT area rated their DOT observer as very good, while 9 (60%) CBDOT and 13 (87%) HBDOT patients rated as good when they were asked their perception about their treatment observer. The approach of the DOT observers was accepted as helpful by all respondents.

5.1.4.6. Possible barriers to care

Ten (67%) of CBDOT and 12 (80%) of HBDOT respondents lived more than 1-hour walking distance from health facilities. All respondents from CBDOT walked less than 30 minutes to come to DOT centers but only five from HBDOT program areas. From these five patients in HBDOT area one patient lived with relative and another one lived in a rented house. No patient from each group reported use of alcohol, Chat chewing and cigarette smoking. Two patients (1 from each group) indicated that they were diagnosed with HIV/AIDS.

5.2. Qualitative result (Focus Group Discussions)

Five FGDs were conducted with health professionals, CBDOT observers and TB patients on selected discussion points (Annex 8 and 9). Topics relevant to the research questions were identified, sorted, analyzed and summarized to reflect on the objectives of the study.

Characteristics of FGD participants

FGD1. HBDOT health professionals: 3 males and 4 females; age range from 23-49 years; service 5-29 years in the health sector of which 5-14 years in TB related services; professional mix: 5 nurses, 1 pharmacy technician and 1 lab technician.

FGD2. CBDOT health professionals: 4 males and 5 females; age range from 26-40 years; service 3-25 years in the health sector of which 2-12 years in TB related service. Professional mix: 1 health officer, 6 nurses, 1 pharmacy technician and 1 lab technician.

FGD3. CBDOT observers: 4 males and 2 females; age range from 25-42 years and observe DOT for more than 6 months. They live 2-5 hours walking distance (round trip) from health facilities.

FGD4. CBDOT patients: 5 males and 1 female; age range from 24-51 years. They travel to DOT center 15-30 minutes. Three of them were in the intensive phase.

FGD5. HBDOT patients: 2 males and 3 females; age range from 29-63 years. They live 3-6 hours waking distance (round trip) from HBDOT. One lived rented near to HBDOT. Three of them were in the intensive phase.

Factors affecting DOT implementation

Five major themes regarding the factors affecting DOT implementation were identified as: access to DOT service; awareness and perception about TB treatment (DOT); acceptability of DOT option and DOT observers; support/incentive; and workload, supervision and documentation.

Access to DOT service

Majority of FGD participants from both groups indicated that health facilities that provide DOT are far away from patients' home. Moreover, patients were forced to travel 2-6 hours every day (round trip). That caused weakness and tiredness, initiated and aggravated cough and chest pain (*Wigat*).

In order to reduce treatment interruption, DOT providers in HBDOT areas advised patients to rent a house or live with relatives till they regain their strength to walk from their own home or complete the intensive phase. However, majority of participants noted that patients had neither the capacity to rent nor to cover cost of transport to come for DOT. As one elderly patient from HBDOT program area said:

> "*We are short of money even to manage the family, let alone to rent house.*"

When patients were asked "*Did you rent*?"; "*How could we rent?*" another male participant from HBDOT responded emotionally without asking permission to speak.

Patients were also asked why they did not live with their relatives who were living nearby the DOT center. All participants from HBDOT patients were eager to respond. The elderly patient (the same person mentioned above) responded:

> *"Forget the risk of disseminating the disease, what about the living expense? Shall we be burden to them at this time when the cost of everything is high like the sky?"*

Participants also mentioned transport problem as a barrier to DOT service access. Because of their geographical placement transport services may not be available even if patients are willing to pay for it. Female participant from HBDOT stated:

> *"Our treatment is every day, the vehicle is coming to our village once a week (market day), the distance from clinic is too long, and that is why I am forced to rent house nearby the clinic not because I can afford but not to die."*

Health professionals admitted that they sometimes delegated HEWs to provide and observe DOT. They also provide medicine to the care giver of patients if the patient is unable to come. Though HEWs were not trained to observe DOT and allowed to provide officially they were involved in both areas to provide DOT considering problem of patients that lived far away from DOT centers. Majority of participants argued that even CBDOT observers who are less trained than HEWs are involved so they couldn't see any problem in involving HEWs as the number of trained CBDOT observers is not enough.

Though some of the health professionals claimed that there would be schedule rearrangement for observing DOT during campaigns and trainings, majority of them admitted that sometimes patients would be provided with medicine for some days in advance with advice (based on the number of days they spend in the training or campaign). It is also noted that patients would not come on week ends and when the assigned person or focal person is absent (for example, on sick leave).

Moreover, in some health facilities patients request drugs for 2-3 days in advance in order not to come for DOT daily. This was described by the female DOT provider from HBDOT:

> *"It is always struggle; they request medicine for 2-3 days for different reasons like wedding, travel for trade, etc. It is difficult especially when they start feeling better."*

CBDOT observers go to patients home for observing DOT at early stage of treatment if patients are unable to come and if the patient does not appear to take medicine for any reason. Patients from CBDOT areas considered CBDOT as an important help, since it helps them to avoid long and tiresome trips to health facilities, save their time and avail treatment at home. As one male CBDOT patient praised,

"We don't have to worry for transport, beg the rich for mule or put burden on others (friends, neighbors) to carry us to health facilities. It is really a big help."

DOT providers from CBDOT areas also stressed the importance of CBDOT programme for DOT implementation. The following statement told by the head of one of the clinics supports this idea: *"CBDOT brings DOT to patients home."*

In CBDOT study areas when patients are assigned to CBDOT observers factors like distance traveled to DOT centre and patients' interest to be on CBDOT are considered.

Awareness and perception about TB treatment/DOT

Majority of patients emphasized that the awareness and perception about the importance of DOT in TB treatment affects its implementation. Male DOT provider from HBDOT areas stated:

"Some patients and health personnel do not know the danger of irregular intake and discontinuation of treatment. Due to their workload health personnel may not seriously follow patients who fail to show up."

Though majority of participants appreciated the importance of DOT one male participant from HBDOT patients group expressed that he would not need observer. He said:

"It is for ourselves, no one wants to kill himself/herself, we will not discontinue if we are provided in advance. But we will avoid the cumbersome daily trip to health facilities."

But most participants opposed this idea since they may get also advice and follow up from health workers. This is demonstrated by the expression of one female patient from HBDOT area.

"I had traveled even on Kidusyohannes" to underline her every day journey. She also added, *"All of us are not the same, some of us may discontinue if we are provided with the medicine in advance."*

Health improvement could also affect DOT implementation. Majority of FGD participants (DOT providers) noted that patients may decline from regular DOT when they start to feel better and may discontinue treatment thinking they are cured. Side effects and improper use of medicines were also mentioned as a cause for discontinuation of treatment. Female CBDOT observer said:

"Some patients complained that TB medicines caused dryness of throat and nausea. And sometimes they may discontinue treatment; some of them were used to drink alcohol (Areki and Tela) which may lead to non adherence."

Acceptability of DOT option and DOT observers

In general, DOT observers in both DOT options were accepted by their respective patients. However, there were some concerns about CBDOT observers especially from HBDOT participants. The reasons mentioned were: perception about the knowledge and dedication of CBDOT observers, drug handling problems and fear of drug resistance.

Almost all participants believed that DOT observers in HBDOT area have good knowledge and provide better care and follow-up than CBDOT observers. Some of the participants also noted that, health workers are always available for the patient to take medicine because they are paid. Moreover, if DOT observers are not around another health professional may replace them, but this may not be easy in CBDOT resulting in treatment interruption as they are not paid hence couldn't work as health professionals. If CBDOT observer go somewhere and provide medicine to the patient in advance, the patient may forget to take or use it improperly. But others argued that this is also the case in HBDOT since health personnel provide 2-3 days treatment (for example, when they go for training).

Patients from CBDOT area preferred CBDOT at their village despite the possibility of better care in HBDOT programme. However, patients in HBDOT area did not accept the idea of CBDOT by trained community observers. Even though they would be glad to get the service nearby, they prefer if it is given by health professionals. This strong opposition is highlighted by the following quote from a male patient in HBDOT area:

"Community members are forgetful; they are busy by their own business to win life so that they will not follow us properly and provide medicine at the right time. They may also keep the medicines in their pockets and may go to every grocery (Be-ye-tela-betu) to drink; the medicine may not work properly since it is not handled properly (Yinefsbetal)."

Majority of participants from HBDOT and some from CBDOT believed that medicine handling and storage is better in HBDOT. In CBDOT, medicines may be misused and mistakes may be

done during handling and provision of DOT. But some argued that handling of medicine will not be a problem as far as medicines are blister packed and observers are trained. There was also less confidence on CBDOT observers among health professionals and patients in HBDOT program areas. This was demonstrated by one of the participants from HBDOT program area who opposed CBDOT approach. He stated:

> *"It is difficult to handle TB with HBDOT let alone CBDOT."*

Most of them believed that drug resistance will emerge if CBDOT observers are involved. This is reflected by the following quote from female health professional in HBDOT areas:

> *"Drug resistance for anti-malarial drug, Fansider came as a result of community involvement. Community members may provide drug inappropriately by delegating their spouse, hence drug resistance may also emerge in TB if CBDOT observers provide medicines to others with similar symptoms."*

But majority of health professionals from CBDOT area and one from HBDOT area argued against. They said, that would not happen since community members are not involved in diagnosis of TB and they just provide medicine and observe drug intake. Male DOT provider from HBDOT area who strongly argued for CBDOT option responded as:

> *"If CBDOT providers are trained and supervised nothing will hinder them from doing the work like the health professionals. Whether we accept CBDOT or not, sizeable number of patients will not come to health facility for a number of reasons and hence it will be very difficult to control TB."*

Though there was strong debate among DOT providers in HBDOT area initially, at the end of discussion almost all FGD participants agreed that CBDOT can be implemented if the observer is well trained. And CBDOT acceptance will increase because of its advantages like easy access, comfort, treatment while living in the community and cost reduction.

HBDOT area participants also suggested that trained treatment supporters should be selected carefully and trained well; better to select females since they are usually around home and from those who are not busy with their own business and have good knowledge; better to involve

elders than young ones for reasons related to stability and acceptance by community; CBDOT observers should be given incentives to develop interest and commitment (could be clothes, per diem etc); and provided with KIT for medicine handling.

Patients from both areas were also asked whether they were satisfied or not with the care provided to them. HBDOT patients expressed that they were satisfied with the care they are provided. But one elderly male patient complained:

> *"Their follow-up is only providing medicine what else do they have?"* followed by murmurings.

But CBDOT area patients expressed their satisfaction. A male patient from CBDOT witnessed:

> *"Nowadays, we are treated at home while lying on our beds."*

One Woreda supervisor recalled what one of the patients said to him.

> '*Now, they came to home, provide medicine and observe while we swallow, now we say Eff-foy…y…y'*, the supervisor added, *"This shows which option is better…."*

But most FGD participants from health professionals group in both DOT areas on the other hand believed that patients may be psychologically satisfied when they are treated at health facilities.

Support/incentive

FGD participants from both DOT areas complained about shortage of food to take with their TB medicine. They are unable to feed themselves due to poverty, drought, and weakened ability to work. They believed and were taught by health professionals that when some one is on TB treatment, he/she should get enough food especially milk, egg and meat. Otherwise, it will not be possible to be cured as medicines may not work if they are taken short of food. The believed that the disease may even come back after completing treatment. Food was a serious issue raised in all FGDs.

Most FGD participants suggested that patients should be provided with nutritious food. The following speech by one of the patients from CBDOT area may reflect the problems of patients related to food. He said:

"TB is a disease of the rich. Poor couldn't withstand it! It can't be cured without meat, egg and milk." Another patient from the same group added, *"Those cured are those who have money, those who do not have money did not."*

All FGD participants unanimously emphasized the importance of family support for the patient to adhere to DOT in addition to the advice and follow-up from the DOT observer.

CBDOT observers were trained for one day about TB: how it is transmitted, signs and symptoms, causes, transmission and prevention, how they could help TB patients, and how to send TB suspects (especially those who cough for more than two weeks) for diagnosis. Reading materials were also provided to them. They also got follow-up and education from HEWs and the Woreda.

CBDOT observers work on their own willingness. They do not get any wages but they are assigned to do jobs for free. Their benefits are the satisfaction they get by helping others and the respect they get from cured patients and the society, as they described.

"There was TB in my family. Now we couldn't see any reason for not giving this (DOT observing) sacred service to others...," said female CBDOT observer.

Workload, supervision and documentation

Lack of adequate training among health care workers and high turnover of staffs were enumerated by health professionals from both DOT areas as factors affecting DOT implementation. Some of the participants also complained that TB treatment service is usually considered as the sole responsibility of focal persons as they are the ones who attend all TB related trainings. The other health workers, therefore, are not that willing to provide the service and do not care much for documentation even though they provide DOT.

As mentioned by health professionals from CBDOT areas; when the number of patients observed in HBDOT center increases, the DOT service may be compromised due to increased workload. Workload to health facilities would reduce when patients are assigned to CBDOT thereby improving the quality of DOT.

Most of the participants from CBDOT area identified that CBDOT improves community involvement in health and community satisfaction: patients reduce cost for transport and house

rent, and get treatment at their home/village that saves money for the patient and the family. Community members would also be involved in observing DOT; hence belongingness to the programme and participation would be increased.

Some of the CBDOT observers complained that some patients' homes are far from the DOT observers' and it took much of their time. Moreover, they have overlapping commitment in the community and responsibilities at home. CBDOT observers are also involved in other health related works (they are meant not only for TB but also family planning, HIV, latrine building, health education, etc).

HEWs follow and supervise CBDOT observers; and HEWs are followed and supervised by Woreda supervisors. CBDOT observers used to report DOT follow-up weekly. Currently, this practice is discontinued because reporting forms are out of stock and not supplied. In HBDOT, focal persons follow and supervise the practice and report. Unit TB Registers also may not be completed due to lack of adequate training of observers and carelessness (not giving attention).

Possible causes for low case detection

Three major themes were also identified for possible causes for low case detection rate as: access and limited utilization of laboratory services; awareness and perception about TB; and inadequate referral of TB suspects and absence of intensified screening.

Access and limited utilization of laboratory services

TB suspects were forced to visit private clinics in Mekelle (away from their village) for better diagnosis since they couldn't get appropriate service from the government health facilities easily and the fear associated with high expenses discouraged others. Long walking distance to diagnostic centers makes screening tiresome and costly for TB suspects.

Majority of health professionals also complained laboratory related problems that include shortage of trained manpower, reagents, instruments and faraway lab facilities. And suggested that labs should be strengthened in terms of trained and skilled human resource as well as equipment and reagents

FGD participants from CBDOT areas mentioned that though a number of TB suspects were screened (above 1000 in 3 months) by collecting sputum samples by HEWs and CHWs and brought to lab for smear test, negativity rate was very high. To improve this they suggested proper training to sample collectors. This was evidenced by the following quote from health professionals in CBDOT area. He said:

> *"Community workers need to be trained on how to take sputum samples (instead of saliva) and should also consider 'cardinal TB signs' instead of cough for more than two weeks only."*

Moreover, there is limited utilization of labs as patients did not expect reliable results from nearby health centers. Most believed that the nearby health centers had no capacity to diagnose TB.

Awareness and perception about TB

Health professionals from HBDOT area admitted that there is less community involvement in the identification of suspect cases. Majority of participants recommended active involvement of treated patients (based on their experience), CHWs, HEWs, CBDOT observers, women and youths associations and political leaders.

Almost all Health professionals in both groups agreed that CBDOT option provides an opportunity to expand the service through training and deploying selected community members (Mehawrs) in identification of suspects and observing DOT.

> *"CBDOT improves case detection rate since the community would be encouraged by looking the patients treated at their home or village as they would also get treatment if they are diagnosed as TB patient. It also helps to detect a number of TB suspects earlier than HBDOT since patients came to HBDOT when they are very ill."*

Participants stressed the need to strengthen and continue the approach explained by health worker from CBDOT area:

"In CBDOT area we have a system called 1 to 50, one person is assigned for fifty households and if there is someone who coughs for more than two weeks, he/she would be referred and/or brought to health facilities for check-up."

FGD participants suggested that to improve awareness health education related to TB should be given continuously through all opportunities, such as in schools, churches, markets, clinics, campaigns like polio and mass media. People with high risk of TB exposures, patients, and other community members should be educated on signs and symptoms of TB as cough is usually associated with cold and Kafia (small rain). Some of the TB suspects were also not willing to be tested for fear that they might have HIV.

"We need to create awareness among the community as we did for polio...," said male CBDOT observer strongly.

Absence of intensified screening in high risk groups and inadequate referral of TB suspects

Health professionals in the FGDs admitted that screening among high risk groups was not enough and agreed on the importance of intensified screening in high risk groups. This was demonstrated by the saying of female health worker from CBDOT group. She stated:

"All departments of the health facilities (antenatal, OPD, etc) should be used as an opportunity to identify suspect TB cases and HIV positive TB patients should be smear tested."

Moreover, health professionals considered that inadequate referral of TB suspects by health professionals, HEWs, and CHWs to diagnostic centers contribute to low case detection rate.

6. Discussion

This study was conducted to assess effectiveness of DOT implementation in CBDOT and HBDOT Woredas in Tigray region. The study also aimed to compare implementation practice between the two DOT options and identify factors affecting DOT implementation.

TB treatment success rate, smear conversion rate and complete data reporting can be used among others to evaluate and monitor DOT programmes (WHO, 2004). Treatment effectiveness of DOT programmes were measured by treatment success rate. Treatment success rate is the sum of patients who are declared "cured" and those who have "completed" treatment. Traditionally, success rate is considered for a cohort of smear PTB cases (Maher *et al.*, 2003; Wandwalo *et al.*, 2005) but it can also be used for all TB cases (WHO, 2004; FMOH, 2008; Wandwalo *et al.*, 2005).

In this study, treatment success rate for all category TB cases was 88.8% for CBDOT and 87.8% in HBDOT option but no significant difference was observed. Similar results were also reported in other studies (Islam *et al.*, 2002; Maher *et al.*, 2003).

This study also found out that the success rate for all new TB cases was 88.6% for CBDOT and 87.4% for HBDOT but no significant difference was observed. A study conducted in Tanzania also reported that treatment success for all new TB cases in CBDOT was 85% and for that of HBDOT 83% (Wandwalo *et al.*, 2004; Wandwalo *et al.*, 2005).

In the present study, the success rate for new sputum positive PTB cases was found to be 90.5% for CBDOT and 84.8% for HBDOT program areas. In Ethiopia, treatment success rate for new smear positive patients for cohort treated under DOTS was 74% in 1994 and increased to 84% in 2006, a little short of the global target (> 85%) (FMOH[b], 2007; WHO[a], 2009).

Most studies carried out in different countries have also shown that the success rate in CBDOT option was found to be higher than HBDOT option for new sputum positive PTB patients. Treatment success rate for patients from CBDOT and HBDOT program areas in Kenya were: 88% vs 85% (Kangangi *et al.*, 2003), in Malawi: 68% vs 58% (Maher *et al*, 2003), in Senegal: 88% vs 76% (Thiam *et al.*, 2007), in South Africa: 83% vs 65% (Clarke *et al.*, 2006), in Tanzania: 88 vs 76% (Lwilla *et al.*, 2003), in Uganda: 74% vs 56% (Adatu *et al.*, 2003), in

Zambia: 60% vs 48% (Maher *et al.*, 2003) and in India: 77% vs 78% (Singh *et al.*, 2004). These studies indicated that treatment success for CBDOT was higher or at least equal to HBDOT.

The present study revealed that there is difference between the two DOT options with regard to death rate and transfer out rate. In this regard, higher proportion (10%) of CBDOT patients died compared to 5% of patients in HBDOT area. However, in CBDOT program areas the transfer out rate was zero while about 7% HBDOT area patients were transferred out to other health facilities/ DOT centers. The higher proportion of death among CBDOT program might be due to the fact that CBDOT is appropriate for patients who could not attend health facilities and might attract patients who are severely ill and hence with higher risk of dying (Lwilla *et al.*, 2003).

Most interestingly the transfer out rate in all patient groups (all category TB cases, all new cases and sputum positive PTB cases) were higher for HBDOT compared to CBDOT option which had no transferred out patients. This difference might arise for the reason that patients are getting treatment from nearby facilities in their village but HBDOT patients might seek transfer after they start therapy to reduce the burden and inconvenience caused by daily travel to DOT center and associated costs with treatment.

A proxy indicator for the cure or treatment completion outcome is the proportion of smear-positive cases that have negative smears after receiving intensive phase treatment (sputum conversion rate). This indicator reflects the capacity of the programme to maintain patients on treatment, obtain follow-up smears, and reduce patients' bacterial population through treatment (Lulemo and Frieden[a], 2004).

The smear conversion rate for Tigray and Ethiopia in 2007/2008 (1999 E.C.) were 76.7% and 71%, respectively (FMOH[a], 2007). In this study the smear conversion rate for new smear positive PTB patients was found to be 81% for CBDOT program areas and 78.8% for HBDOT program areas. Studies conducted in Malawi (75% in CBDOT and 89% in HBDOT) and Tanzania (76% in CBDOT and 69% in HBDOT) also indicated that there was no significant difference in sputum conversion rates between patients treated under CBDOT and HBDOT strategies (Lwilla *et al.*, 2003; Maher *et al.*, 2003).

Several of the evaluation strategies reviewed indicated that treatment programs using DOT that are comprehensive, community-based and patient-centered achieve the highest treatment completion rates (Chaulk *et al.*, 2008). The fact that there was no significant difference in successes rate and comparable conversion rates between CBDOT and HBDOT strategies suggests that CBDOT may be a viable alternative to HBDOT. CBDOT may be particularly useful where people live far away from health facilities (Lwilla *et al.*, 2003).

In most countries including Ethiopia, TB is a reportable disease. A system of recording and reporting information on TB cases and their treatment outcomes is one of the key elements of the DOTS strategy. Good recording practices are necessary for effective patient management. Assessment of performance and epidemiological trends provides the basis for programmatic and policy development. Effective monitoring depends on appropriate recording and reporting systems. These systems are essential to ensure high-quality TB care and information sharing (WHO[a], 2008).

The present study however revealed that Unit TB Registers in some places were not properly handled i.e. they were either incomplete or deleted or torn and damaged. It seems that the importance of proper handling of Unit TB Registers is underestimated. In order to have proper patient follow-up for DOT and effective evaluation programme in place in both CBDOT and HBDOT program areas, it is important to have complete data recording, reporting and proper handling of the Unit TB Registers. Bond *et al* (2005) also indicated that limited supervision of care givers and poor record keeping undermined the quality of TB management. NTPs and all TBL Divisions at different level should work to ensure continuous reporting and follow-up in both DOT program areas.

HBDOT is not always convenient and accessible to TB patients. A study conducted in Tanzania compared CBDOT with a short-course treatment regimen with HBDOT strategy, and indicated that it is not necessary that a health worker supervises the patient: a trained community observer can perform this task at least as effectively as a health worker (Lwilla *et al.*, 2003).

Similarly, this study found out that the DOT implementation practice in CBDOT and HBDOT program areas was comparable. It is worth mentioning that water unavailability in the DOT center did not affect DOT practice. This is because though water was not available at the DOT

center in HBDOT Woreda patients were able to take their medicine in front of the DOT observer since the trend is that patients bring water to the treatment center. But one could ask what will happen if the patient did not bring water for some reason.

Regarding to treatment ID card, the difference arose because CBDOT patients were treated at their home or DOT observers' home and it would be easy for them to show their treatment ID card. But HBDOT patients who traveled more than 1-hour walking distance may not consider the importance of having treatment ID card with them since they were in treatment daily in the health center and did not affect their treatment as their list is available in the Unit TB Register. However, the importance of treatment ID card could not be underestimated especially in HBDOT areas where many health professionals are involved in providing DOT.

Though it is important for monitoring progress and adjustment of drug dose, in both areas weight checking was not practiced during DOT service provision except at the start of treatment in both DOT options. Significant portion of patients from both DOT options were not advised about the importance of adherence, and were not encouraged to continue their treatment. However, it may be difficult to have a meaningful observation of practice in one day.

This study demonstrated that CBDOT option implemented more DOT components than HBDOT option. One of the reasons could be the less number of patients (1-3, usually one) per CBDOT observer. Hence, CBDOT strategy can complement HBDOT strategy at least equally and if support from health facilities is strengthened through supervision, training and support better result could be obtained.

The global target for case detection is to detect 70% of new sputum positive PTB cases, but some personnel working on TB in Tigray, believed that the 70% target is exaggerated and unachievable in addition to other reasons that may cause decrease in case detection. The same finding was reported by Yassin *et al* (2006) from southern Ethiopia. This will have significant effect in TB control since it may reduce the efforts to reach to the target. The CDR of Tigray in 2006/07 was 27.4% (FMOH[b], 2007). Case finding in Ethiopia as well as in Tigray is far less than the global target of 70% (FMOH[b], 2007; FMOH, 2008). Hence, it is important to identify the possible causes for such low achievements since it ultimately affects treatment success.

One of the possible reasons for low case detection identified in this study was inadequate awareness and dissemination of information in the community, amongst medical staff and the community workers regarding respiratory symptoms notably persistent cough more than two weeks.

Wahyuni *et al* (2007) indicated that significant portion of nurses and TB workers did not know cough greater than 3 weeks can be a symptom of TB. Moreover, Xu *et al* (2007) found that majority of patients sought care for cough in the general health system rather than in the special TB dispensary. Therefore, it is vital to involve the health workers deployed to the general health system in the DOTS programme. If all health care workers know that cough more than two weeks more likely to be associated with TB rather than other respiratory diseases they would rather refer patients to diagnostic centers than trying to treat their cough by themselves.

Analysis of data generated from exit interviews showed that most respondents in both CBDOT and HBDOT program areas knew that TB is preventable, treatable and curable. However, majority of patients from both groups mentioned cold/wind as a cause for TB. Almost half of HBDOT area patients mentioned exhaustion as a result of hard work as the cause of TB. The real cause of TB, germ was mentioned by only some of the patients. That indicates inadequate awareness among TB patients and hence the need to educate both patients and their care takers (family and DOT observers).

According to Cambanis *et al* (2005), most people know that TB is dangerous and curable. However, they did not know what caused TB and only a few cited TB as an infectious agent. People believed that TB is the result of every day life; hard work, cold air and exposure to dust.

Raising public awareness and decentralizing DOT TB treatment at village level using volunteer community members could reduce prolonged delays in seeking care and improve compliance to TB treatment (Mesfin[b] *et al.*, 2005). Golub *et al* (2005) also indicated that education of the patient population about TB symptoms might reduce delays. Improvement in TB control through training and supervision of staffs and TB information campaigns targeted at the population was also reported by Ouérdraogo[a] *et al* (2006).

Absence of intensified screening among high risk groups was identified as the second most important possible cause for low case detection in the survey. Studies have found that contact investigation is a valuable means of identifying new TB cases. It is recommended that all NTPs screen household contacts for symptoms of disease and offer preventive therapy to children (WHO[c], 2006). Shargie *et al* (2006) also indicated that intensified case finding among household members of infectious TB cases is an effective approach to increase case detection.

The study also indicated that limited access and utilization of health facilities could contribute to low case detection rate in the study areas. Limited utilization might have resulted from the fact that patients do not expect reliable result from the nearby health centers as they believe that they had no capacity to diagnose TB. Short distance from home to TB clinic and perceived barriers in reducing adherence to household screening were also reported by Tornee *et al* (2005). Kemp *et al* (2007) also indicated that patients and household costs faced during diagnosis were prohibitively high even where services are provided free of charge.

Inadequate/absence of identification of suspects by HEWs and community volunteers was also mentioned as a reason for low case detection. CBDOT program areas involve community members (birth attendants, CHWs, CBDOT observers and other community members) in detecting new cases and undergo mass screening campaigns for TB suspects. For those who could come to health facilities (weak patients, transport problem, etc), sputum samples will be taken by CHWs (Mehawrs) and brought to lab for smear test and occasionally lab department go to their village for check-up.

This study indicated that CBDOT option provides an opportunity to expand the service through training and deploying selected community members (Mehawrs) trained in identification of suspects and observing DOT. Chowdhury *et al* (1997) also indicated that involving CHWs in screening villagers for chronic cough and collecting sputum samples for smear microscopy resulted in high rates of case detection. To reduce the reported high negativity rate in the FGD, CHWs who collect sputum sample should be trained about why and how to produce good sputum samples and provide information to TB suspects. Wahyuni *et al* (2007) reported that such information was provided by few DOT providers.

Delayed referral system for TB suspects to health facility providing DOTS service for examination and treatment contribute to low case detection. According to Mesfin (2005) there was delayed health care seeking behavior in Tigray as a result of lack of awareness and access to appropriate diagnostic facilities. Hence, case finding strategies must be sensitive to patient delay and health system must become more accessible in rural areas.

Dembele *et al* (2006) also indicated that PTB case detection was low due to losses of cases at each stage leading to diagnosis of TB. Hence, case detection depends on the operational effectiveness of the staff working in the health services as well as the referral of suspects to the TB diagnosis and treatment centers.

DOT requires patients to take their daily medication under the supervision of health workers for the first two months and a monthly visit to health institutions for self-treatment during the subsequent 6 months (FMOH, 2008). In Ethiopia this arrangement places huge burden on rural patients who will be forced to stay away from home during the intensive phase and travel long distances to get medication (Mesfin[c] *et al.*, 2005). Hence, it is important to identify factors affecting proper implementation DOT to pave the way to improve treatment effectiveness.

Though there is no significant difference among interviewed patients regarding the distance from health facilities, they differ regarding to distance from DOT centers. All CBDOT respondents lived in areas which were less than 30 minutes walking distance from DOT centers; while only 5 patients from HBDOT. Even from these 5 patients, 1 patient lived with relative and 1 in a rented house. This shows that CBDOT is an option that brings TB DOT services near to patients home.

The health service DOT coverage in Ethiopia currently is 95% (WHO[a], 2009). However, it must be emphasized that DOTS population coverage does not measure access to care. It only measures the presence or absence of DOTS service in a given administrative area; it does not provide information on geographic distance or financial or other barriers to care (WHO, 2004). The mere existence of services in a certain administrative area does not prove that they are used or used correctly. Services have to be accessible to be used. This implies that organizing a supply of care that is geographically, financially and culturally accessible is vital (WHO[a], 2008).

According to Khan *et al* (2002) the high costs of attending health facilities for DOT may be deterring patients, and in particular, economically active patients who have most to lose from the time taken by direct observation. DOT centers situated faraway from patients home discourage not to adhere due to their weakened health status, family illness, harvesting times, etc. However, CBDOT option reduces distance traveled for DOT. Thiam *et al* (2007) also indicated that access to drugs would be improved through decentralization of treatment. Daily travel, long distances and high transportation costs were identified as the main obstacles to DOT (Ouédraogo[b] *et al.*, 2006). Shargie and Lindtjørn (2007) from their study in Southern Ethiopia reported that the main determinants for defaulting were related to physical access to treatment center. A study by Wong *et al* (2005) also reported that the commonest reason stated for switching from DOT to non-DOT was geographical inconvenience.

A study from Nepal reported that travel cost to reach the TB treatment facility was significantly associated with non-adherence to anti-TB treatment. Although medicines are provided free the burden of cost to travel to the treatment facility can be a disabling factor in completing treatment (Mishra *et al.*, 2005). A study from Gambia also reported that defaulting rate was high among those who incurred significant time or money costs traveling to receive treatment (Hill *et al.*, 2005). Michael *et al* (2004) also indicated that lack of money for transportation contributed to poor compliance and defaulting.

Even for those bedridden patients CBDOT brings the service to them and hence reduces risk of defaulting. It also helps to trace defaulters early. A study conducted in South Africa indicated that community involvement in TB care can improve the affordability and cost effectiveness of TB treatment (Sinanovic *et al.,* 2003). It is interesting to note that CBDOT observers would go to patients' home for observing DOT if the patient did not appear to show for any reason. That reduced the risk of treatment discontinuation.

Awareness to TB treatment was another factor that could affect DOT implementation. In this study, though interviewees from both groups have comparable knowledge about the consequence of failure to get treatment, they differed regarding consequence of irregular treatment (incomplete adherence) of TB which may affect treatment outcome. Nearly half of the patients from HBDOT areas and one-fifth of CBDOT area did not mention resistance to drug as a possible consequence of irregular treatment, hence there is an urgent need to inform patients when they start treatment

since it may affect adherence to their treatment. If they do not know that irregular treatment results in development of drug resistance, their inadequate knowledge will result in incomplete treatment, and finally death; patients could be reluctant to adhere to their treatment regimen. The contribution of knowledge to compliance was also reported by Lertmahrit *et al* (2005).

This study also showed that almost all patients from both groups knew the importance of DOT and duration of treatment in the two phases, intensive and continuation phases. If patients and those who are involved in their treatment do not know and accept the importance of DOT and the risks attached to discontinuation, this will negatively affect DOT implementation. Hence, before initiation of treatment patients, their families and DOT observers should be educated and accept the importance of adherence. A study conducted in Swaziland also indicated that all relevant staff must be trained on TB programme and patient education need to be reinforced throughout TB treatment. Health education of the wider community is also needed (Escott and Walley, 2005). Lagrada *et al* (2008) also indicated that helping the patients understand the importance of DOT can increase TB treatment completion.

Compliance to the prescribed regimen is influenced by factors like social and economic background, the patient's acceptance of health care providers and the social support received by them (TRC, 2004). This study also identified acceptability of DOT and DOT observers as an important factor affecting DOT implementation. Both DOT and DOT observers should be accepted by the patient, the community and health facilities for proper implementation of DOT. DOT observers should be selected carefully and the patient should be convinced before they are being assigned to a particular CBDOT.

This study showed that almost all interviewees and patient FGD participants accepted their respective DOT observers and consider their approach as helpful. A study carried out to compare the acceptability of CBDOT and HBDOT options in Tanzania indicated that the majority of patients were satisfied with the DOT options they received and both DOT options were acceptable (Wandwalo *et al.*, 2006). The acceptances of CBDOT observers by TB patients might help to expand the service to more underserved areas of the country through creating opportunities to have more DOT observers and additional DOT option. The same finding was also reported from Kenya (Kangangi *et al.*, 2003).

In this study almost all participants believed that DOT observers in HBDOT area have good knowledge and provide better care and follow-up than CBDOT observers. Patients from CBDOT area preferred CBDOT at their village despite the possibility of better care in HBDOT programme. However, it was noted that one day training given to CBDOT observers may not be enough considering the responsibility they are going to play. Hence, there should be a mechanism for CBDOT observers to update their knowledge and skill through refresher trainings.

This study further revealed that HBDOT program areas though they do not practice CBDOT formally, they are forced to involve CHWs and patients care takers (that are not trained to observe DOT) when patients are unable to attend DOT at health facilities. Moreover, they sometimes violate DOT by providing medicines to non-trained DOT observers and patients. Despite this fact, HBDOT patients and health professionals do not accept CBDOT as a viable option. They challenge the quality of service rendered by DOT observes deployed to run CBDOT. The reasons mentioned include CBDOT may contribute to drug resistance and there may be medicine handling problem and improper use. But this can be tackled through continuous training and supervision. Of course, CBDOT observers should be trained on TB and its management prior to their involvement in TB treatment supervision (Mesfin[c] *et al.*, 2005).

Community involvement means a shared responsibility for individual and public health by the people and the health services. Health services can strengthen the community's capacity to act, and foster long-term sustainability of such participation, through educating people on the problems and discussing their possible solutions, and by encouraging community self-reliance and ownership of health initiatives (WHO[b], 2009). CBDOT is an example of shared responsibility between health services and communities in tackling major public health priorities (Adatu *et al.*, 2003). From the FGDs carried out with patients and HBDOT health professionals, there was no awareness raising program and promotion done regarding CBDOT though some CBDOT observers were trained in HBDOT areas. But it is very important to consult, communicate and involve health workers, patients and the community about CBDOT because CBDOT programme will only be successful if there is support and acceptance from health professionals, patients and the community.

It is also worth mentioning that there was strong debate among DOT providers in HBDOT area initially. Nevertheless, at the end of discussion almost all FGD participants agreed that CBDOT can be implemented if the observer is well trained. Though there was consensus about CBDOT observers' capability of observing DOT among FGD participants they suggested that trained treatment supporters should be selected carefully and trained well. They indicated that it is better to select females (since they usually do not move faraway from their village), those who are not busy with their own business and those with good knowledge, elders than young (for reasons related to stability and acceptance). CBDOT observers should also be given incentives to develop interest and commitment and provided with KIT containing appropriate medicines.

This study also indicated that CBDOT is widely accepted for the following reasons; easy access, comfort, treatment while living with the family and cost reduction. Adatu *et al* (2003) also reported that in Uganda the acceptability of CBDOT was very high mainly because CBDOT improved access to TB care, decreased costs and enabled patients to stay with their family.

Studies carried out in different areas reported that CBDOT is more cost effective than HBDOT (Floyd *et al.*,1997; Islam *et al.*, 2002; Willkinson *et al.*, 2003; Wandwalo *et al.*, 2005; Clarke *et al.*, 2006) and also acceptable (Mesfin[b] *et al.*, 2005; Wandwalo *et al.*, 2006; Cavalcante *et al.*, 2007). Other studies also indicated that there is strong economic case for decentralization and CBDOT option (Floyd *et al.*, 2003; Nganda *et al.*, 2003; Okello *et al.*, 2003).

This study also identified the importance of support extended to the patient and the DOT provider for proper implementation of DOT. Though majority of interviewed patients in CBDOT area accepted their TB diagnosis, almost half of HBDOT area respondents felt bad. If they felt bad about their diagnosis they may not disclose and that may hinder them from getting support. Stigma is a major problem for TB patients and health care providers. Stigma may prevent persons with symptoms from coming forward for diagnosis and impair their ability to access care and comply with the prescribed treatment (TRC, 2004).

In this study from both DOT options majority of patients had got acceptance, care and support by their family. The acceptance of TB patients by their families may help them to adhere to their treatment. TB patients and their family members are burdened a lot by the disease. TB patients have to make a lot of adjustments and rearrangements to cope with the disease physically,

emotionally, economically and socially (TRC, 2004). Tekle *et al* (2002) indicated that family support can also alleviate patients' economic and social problems and provide encouragement to patients to continue their treatment. Lertmaharit *et al* (2005) also reported that social support is significantly associated with compliance.

TB affects mostly the poor. Patients are unable to feed themselves and their family as TB weakens their productivity. Poverty and shortage of food may add fuel to their disease and complicate their treatment. Food was a serious issue raised by all FGDS. Hence, TB patients should be provided with food or ways should be developed to support them. It was indicated that the nutritional status of the patient improves as a consequence of reduced bacterial load during treatment. Food (for the patient and the family) can be a highly effective incentive to improve treatment adherence (Lulemo and Frieden[b], 2004).

Baldwin *et al* (2004) also indicated that nutritional incentives may reduce diagnostic delay and enhance treatment adherence. Bond *et al* (2005) also reported that food was highly valued by patients and patients reported that their situation had improved due to the food they received. A study by Sagbakken *et al* (2008) highlighted the importance of encouragement and support of patients for food and transport to continue on TB treatment.

Motivating CBDOT observers is vital for the sustainability of the program. The modalities may vary from place to place; in a study conducted by Lwilla *et al* (2003) a feeling of prestige related to helping a fellow villager, a good relationship with nearby health facility workers, refresher training and respect from the community were cited as some of the motivating factors of CBDOT observers. Similarly, in the present study CBDOT observers mentioned that helping others is the source of their satisfaction and on top of that the respect they would get from treated patients considered as a reward to their services.

A study carried out in Tigray by Mesfin (2005) indicated that most CHWs were willing to be TB treatment supervisors in their respective village. In this study also CBDOT observers in the FGD expressed their willingness. However, DOT observers complained that some patients' home is far from the house of DOT observers so that it takes more of their time. Hence, there is a need to train other more DOT observers at nearby.

Moreover, they have overlapping commitment in the community and at home. In the village they are involved not only in TB but also family planning, HIV, latrine building, health education activities. These overburden the observers and hence require serious attention. Involving more CHWs (mehawr) for observing DOT may reduce the burden. Mesfin[c] *et al* (2005) also indicated the importance of reducing CHWs multiple responsibilities in order to ensure continuity of their support to the health service.

Patients complain of daily travel and discontinue DOT when they start to feel better before completing treatment. Kaona *et al* (2004) also indicated that patients failed to comply with TB treatment once they started feeling better. Bock (2004) also noted that after 1 or 2 months of effective treatment, the patient feels symptom-free. From that moment onwards it seems pointless to the patient to take the medication that may be unpleasant and give rise to more adverse effects and discomfort than the disease itself. It is only natural to enjoy the recovery and stop taking medication. Hence, it is important to educate and prepare patients in advance before starting treatment about the importance of 8 months full treatment to ensure cure than suffer the consequences of incomplete treatment. Similarly, the present study found out that patients would likely discontinue treatment once they started feeling better.

Control of TB depends on effective strategies to support the process of care from detection of disease through the completion of appropriate treatment. Sustained supervisions of CBDOT observers by the district health team is needed to ensure the continuity of CBDOT strategy through ensuring appropriate supply and safe storage of medication in distant places, and regular checks of recorded data. This intensified supervision certainly has a cost and requires appropriate managerial capacity but appears essential for improved TB control (Thiam *et al.*, 2007).

It was indicated that CBDOT is a viable option and can complement and strengthen the existing HBDOT (Adatu *et al.*, 2003; Wandwalo *et al.*, 2006). The main challenge of the CBDOT was to ensure effective supervision and monitoring of patients and treatment supporters in the community (Wandwalo *et al.*, 2006). Hence, a routine supervision system to monitor and support the services and care provided at community level should be established. Motivation of the involved community member is encouraged by regular support (WHO[b], 2008).

This study has used both qualitative and quantitative methods; the use of several data collection methodologies complement to answer the objectives of the study. However, during observation of DOT provision the presence of third person (data collectors) might have affected the behavior of the patient and the DOT provider and subsequently the findings. Nevertheless; data collectors were trained and guideline for observation was used. This may reduce their influence. The study has also used data collectors from areas outside the study area to maximize the reliability of collected data.

7. Conclusion

- CBDOT option was as effective as HBDOT in treating TB patients and can achieve good treatment outcomes. CBDOT option also increased access and reduced transfer out of TB patients.
- CBDOT observers can practice DOT like HBDOT observers. Hence, CBDOT can complement HBDOT and could be a viable alternative in areas where people live far away from health facilities.
- It is important to identify factors affecting DOT implementation for better success of DOT programs since finding these important factors may pave the way to improve treatment effectiveness.
- Patient related data recording and handling of Unit TB Registers should be improved for proper management of TB patients and overall assessment of DOT program performance. Hence, recording and handling of Unit TB Registers require urgent attention and intervention.
- Both DOT options were acceptable by their respective patients. However, CBDOT option faced strong opposition from HBDOT area patients and health care personnel.

8. Recommendations

From the findings of this study the following recommendations are forwarded:

- Voluntary CHWs are available in each and every village and are willing to render service to their villagers. National/regional policy should be adopted to equip them with proper training and provide supportive supervision so that they tremendously increase both access and quality of DOT. Mechanisms should be devised to ensure that health workers develop supportive attitude and facilitate wide scale deployment of voluntary CHWs.
- It is important to do awareness creation and involvement of health professionals, patients and the community in advance before implementing CBDOT programme.
- Incentive mechanism for CBDOT observers should be sought for continued existence of their willingness.
- Data recording and handling of Unit TB Registers should be improved as they are the main sources of information for patient follow up and program evaluation. TBL Divisions at different level should work to ensure proper documentation, continuous reporting and supervision in both DOT program areas.

References

Adatu F, Odeke R, Mugenyi M, Gargioni G, McCray E, Schneider E, Maher D. (2003) Implementation of the DOTS strategy for tuberculosis control in rural Kiboga District, Uganda, offering patients the option of treatment supervision in the community, 1998-1999. *Int J Tuberc Lung Dis.* 7(9 Suppl 1):S63-71.

Baldwin MR, Yori PP, Ford C, Moore DA, Gilman RH, Vidal C, Ticona E, Evans CA. (2004) Tuberculosis and nutrition: disease perceptions and health seeking behavior of household contacts in the Peruvian Amazon. *Int J Tuberc Lung Dis.* 8(12):1484-1491.

Bock N. (2004) What is the significance of default (treatment interruption) in the treatment of tuberculosis? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 263-266.

Bond VA, Tihon V, Muchimba M, Godfrey-Fausett P. (2005) 'Kuyendella odwala TB'-Visiting TB patients: The widening role of home-based care organizations in the management of tuberculosis patients in Lusaka, Zambia. *Int J Tuberc Lung Dis.* 9(3):282-287.

Cambanis A, Yassin MA, Ramsay A, Bertel Squire SB, Arbide I, Cuevas LE. (2005) Rural poverty and delayed presentation to tuberculosis services in Ethiopia. *TM and IH.* 10(4):1–6.

Cavalcante SC, Soares EC, Pacheco AG, Chaisson RE, Durovni B. (2007) Community DOT for tuberculosis in a Brazilian favela: comparison with a clinic model. *Int J Tuberc Lung Dis.* 11(5):544-549.

CSA (Central Statistical Agency). (2008) Federal Democratic Republic of Ethiopia population census commission, summary and statistical report of the 2007 population and housing census; population size by age and sex, Addis Ababa, Ethiopia, pp. 113.

Chaulk PC, Kazandjian VA, Guterrez PV. (2008) Measurment in public heath: what pulmonary tuberculosis management has thought us? *Gac Sanit.* 22(4):362-370.

Floyd K, Skeva J, Nyirenda T, Gausi F, Salaniponi F. (2003) Cost and cost-effectiveness of increased community and primary care facility involvement in tuberculosis care in Lilongwe District, Malawi. *Int J Tuberc Lung Dis.* 7(9 Suppl 1):S29-37.

FMOH[a]. (2005) TB/HIV Implementation Guideline, Addis Ababa.

FMOH[b]. (2005) TB and Leprosy Manual, Addis Ababa.

FMOH[a]. (2007) Tuberculosis, TB/HIV and Leprosy Prevention and Control, Strategic Plan 2007/8-2009/10, Addis Ababa.

FMOH[b]. (2007) Planning and Programming Department, Health care and Health Related Indicators (2006/07), Addis Ababa.

FMOH. (2008) Tuberculosis, Leprosy and TB/HIV Prevention and Control programme Manual,4th edn, Addis Ababa.

Frieden[a] T. (2004) How can public and private sectors cooperate to detect, treat, and monitor tuberculosis cases? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 92- 95.

Frieden[b] T. (2004) How can emergence of drug resistance be prevented? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 209-210.

Golub JE, Bur S, Ornin WA, Gange S, Baruch N, Comstock GW, Chaisson RE. (2005) Patient and health care system delays in pulmonary tuberculosis diagnosis in low incidence state. *Int J Tuberc Lung Dis.* 9(9):992-998.

Harries A, Kenyon T, Maher D, Floyd K, Nyarko E, Nkohoma W. (2001) Community TB Care In Africa: Report on lessons learned meeting in Harare, Zimbabwe, September 2000. URL: http://www.WHO community care for tuberculosis.htm (Last accessed on September 9 /2008).

Harries A, Maher D, Graham S. (2004) TB/HIV- A Clinical Manual, WHO, Geneva, 2nd edn, China,pp. 210.

Hill PC, Stevens W, Hill S, Bah J, Dankor SA, Jallow A, Lienhardt C. (2005) Risk factors for defaulting from tuberculosis treatment: a prospective cohort study of 301 cases in Gambia. *Int J Tuberc Lung Dis.* 9(12):1349-1354.

Islam Md A, Wakai S, Ishikawa N, Chowdhury AMR, Vaughan JP. (2002) cost-effectiveness of community health workers in tuberculosis control in Bangladesh. *Bull World Health Organ.* 80(6):445-450.

Kamolratanakul P, Sawert H, Lertmaharit S, Kasetjaroen Y, Akksilp S, Tulaporn C, Punnachest K, Na-Songkhla S, Payanandana V. (1999) Randomized controlled trial of directly observed treatment (DOT) for patients with pulmonary tuberculosis in Thailand. *Trans R Soc Trop Med Hyg*. 93(5):552-557.

Kangangi JK, Kibuga D, Muli J, Maher D, Billo N, N'gang'a L, Ngugi E, Kimani V. (2003) Decentralization of TB treatment from the main hospitals to the peripheral health units and in the community within Machakos district, Kenya. *Int J Tuberc Lung Dis*. 7(9 Suppl 1):S5-13.

Kaona FA, Tuba M, Siziya S, Skaona L. (2004) An assessment of factors contributing to treatment adherence and knowledge of TB transmission among patients on TB treatment. *BMC Public Health*. 4:68.

Kemp JR, Mann G, Simwaka BN, Salaniponi FM, Squire SB. (2007) Can Malawi's poor afford free tuberculosis services? Patient and household costs associated with a tuberculosis diagnosis in Lilongwe. *Bull World Health Organ*. 85(8):580-585.

Khan MA, Walley JD, Witter SN, Imran A, Safdar N. (2002) Cost and cost effectiveness of different DOT strategies for the treatment of tuberculosis in Pakistan. Directly observed treatment. *Health policy plan*. 17(2):178-186.

Kumaresan JA, Ahsan Ali KMd, Parkkail LM. (1998) Tuberculosis control in Bangladesh: success of the DOTS strategy. *Int J Tuberc Lung Dis*. 2(12): 992-998.

Lagrada LP, Uehara N, Kawahara K. (2008) Analysis of factors of treatment completion in DOTS health facilities in metro Manila, Philippines: a case-control study. *Kekkaku*. 83(12):765-772.

Lertmaharit S, Kamol-Ratankul P, Sawert H, Jittimanee S, Wangmanee S. (2005) Factors associated with compliance among tuberculosis patients in Thailand. *J Med Assoc Thai.* 88 (Suppl 4):S149-156.

Lulemo[a] F. (2004) what is the role of case detection in tuberculosis control? In:Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 3-4.

Luelmo[b] F. (2004) Why does treatment fail and what can be done to avoid poor treatment outcome? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 185-188.

Lulemo F and Frieden[a] T. (2004) What are the indicators of an effective tuberculosis control programme? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 315-317.

Lulemo F and Frieden[b] T. (2004) What are the relative priorities for a tuberculosis control programme, and what activities should not be undertaken? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 322-325.

Lwilla F, Schellenberg D, Masanja H, Acosta C, Galindo JA, Egwaga S, Njako B, Ascaso C, Tnner M, Alonso P. (2003) Evaluation of efficacy of community based vs. institutional-based direct observed short-course treatment for the control of tuberculosis in Kilombero District, Tanzania. *TM and IH.* 8(3):204-210.

Maher D. (2003) The role of the community in the control of tuberculosis. *Tuberculosis (Edinb)* 83(1-3):177-182. Stop TB department, WHO, Geneva Switzerland. Elsevier Science Ltd. URL:

http://www.tuberclosisjournal.com/article/S1472-9792(02)00066-5/abstract (Last accessed on September 9/2008).

Maher D, Floyd K, Sharma BV, Jaramillo E, Nkhoma W, Nyarko E, Wilkinson D, Raviglione M. (2003) Community contribution to TB care: Practice and policy, Stop TB department, WHO, Geneva. WHO/CDS/TB/2003.312.

Mesfin MM (2005) Community-Based directly Observed Treatment Short course strategy in pilot districts of Tigray: Overview of baseline studies. *Ethio J Health Dev*. 19 (special issue):3-6.

Mesfin[a] MM, Tasew TW, Richard MJ. (2005) The quality of tuberculosis diagnosis in districts of Tigray region of northern Ethiopia. *Ethiop J Health Dev*. 19 (special issue):13-20.

Mesfin[b] MM, Tasew TW, Tareke IG, Mulugeta GWM, Richard MJ. (2005) Community knowledge, attitudes and practices on pulmonary tuberculosis and their choice of treatment supervisor in Tigray, northern Ethiopia. *Ethiop J Health Dev*. 19 (special issue):21-27.

Mesfin[c] MM, Tasew TW, Tareke IG, Richard MRJ. (2005) Community health workers: their knowledge on pulmonary tuberculosis and willingness to be treatment supervisors in Tigray, northern Ethiopia. *Ethio J Health Dev*. 19 (special issue):29-34.

Mezzabotta G, Inaba KT, Zarabi A, Tacconi E, Seita A, Baghdadi S. (2004) Comparison between treatment outcome of TB patients Treated in DOTs centers and in the community in Afghanistan. In proceedings: Second International Conference On Improving Use of Medicines, Chang Mai, Thailand, p. 192.

Michael KW, Belachew T, Jira C. (2004) Tuberculosis defaulters from the "DOTS" regimen in Jimma zone, South West Ethiopia. *Ethiop med J*. 42(4):247-253.

Mishra P, Hansen EH, Sabroe S, Kafle KK. (2005) Socioeconomic status and adherence to tuberculosis treatment: a case-control study in a district of Nepal. *Int J Tuberc Lung Dis.* 9(10):1134-1139.

Nganda B, Wang'ombe J, Floyd K, Kangangi J. (2003) Cost and cost-effectiveness of increased community and primary care facility involvement in tuberculosis care in Machakos District, Kenya. *Int J Tuberc Lung Dis.* 7(9 Suppl 1):S14-20.

Okello D, Floyd K, Adatu F, Odeke R, Gargioni G. (2003) Cost and cost-effectiveness of community-based care for tuberculosis patients in rural Uganda. *Int J Tuberc Lung Dis*. 7(9 Suppl 1):S72-79.

Ouédraogo[a] M, Kouanda S, Boncoungou K, Dembélé M, Zoubga ZA, Ouédraogo SM, Coulibaly G. (2006) Treatment seeking behavior of smear positive tuberculosis patients diagnosed in Burkina Faso. *Int J Tuberc and Lung Dis*. 10(2):184-187.

Ouédraogo[b] M, Kouanda S, Dembélé M, Ouédraogo SM, Badoum G, Ouédraogo G, Bambara M, Yaogho MG, Drabo YJ. (2006) Obstacles to the implementation of directly observed treatment in Ouagadougou, Burkina Faso. *Int J Tuberc and Lung Dis*. 10(2):188-191.

Pungrassami P, Johnsen SP, Chongsuvivatwong V, Olsen J, Sorensen. (2004) The practice of directly observed treatment (DOT) for tuberculosis in Southern Thailand: Comparison between different types of DOT observers. In proceedings: Second International Conference On Improving Use of Medicines, Chang Mai, Thailand, p. 190.

Sagbakken M, Frich JC, Bjune G. (2008) Barriers and enablers in the management of tuberculosis treatment in Addis Ababa, Ethiopia: a qualitative study. *BMC Pubic Health*.8:11.

Sbarbaro J. (2004) What are the advantages of direct observation treatment? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 183-184.

Shargie EB, Mørkve O, Lindtjørn B. (2006) Tuberculosis case-finding through a village out reach programme in a rural setting in southern Ethiopia: community randomized trial. *Bull World Health Organ*. 84(2):112-119.

Shargie EB and Lindtjørn B. (2007) Determinants of Treatment adherence Among Smear-Positive Pulmonary Tuberculosis Patients in Southern Ethiopia. *PLOSMed*.4(2):e(37).doi:10.137 1/J.pmed0040037. URL: http://www.plosmedicine.org (Last accessed on December 2/2008).

Sinanovic E, Floyd K, Dudley L, Azevedo V, Grant R, Maher D. (2003) Cost and cost-effectiveness of community-based care for tuberculosis in Cape Town, South Africa. *Int J Tuberc Lung Dis*. 7(9 Suppl 1):S56-62.

Singh AA, Parasher D, Shekhavat GS, Sahu S, Wares DF, Granich R. (2004) Effectiveness of urban community volunteers in directly observed treatment of tuberculosis patients: a field report from Haryana, North India. *Int J Tuberc Lung Dis*. 8(6):800-802.

Smith I. (2004) What is the health, social, and economic burden of tuberculosis? In: Toman's Tuberculosis case detection, treatment and monitoring Question and Answer, Frieden T (ed), 2nd edn, WHO, China, pp. 233-237.

TCTA (Tuberculosis Coalition for Technical Assistance). (2006) International Standards for Tuberculosis Care (ISTC). The Hague: Tuberculosis Coalition for Technical Assistance.

Tekle B, HaileMariam D, Ali A. (2002) Defaulting from DOTS and its determinants in three districts of Arsi Zone in Ethiopia. *Int J Tuberc Lung Dis*. 6(7):573-579.

THB. (2007) Tigray health profile, 1998 EFY. URL:http://www.trhb.gov.et/index.htm (Last accessed on December 8/2008).

Thiam S, LeFevre AM, Hane F, Ndiaye A, Fielding KL, Ndir M, Lienhardt C. (2007) Effectiveness of a strategy to improve adherence to tuberculosis treatment in a resource-poor setting. *Int J Tuberc Lung Dis*. 297(4): 380-386.

Toman K. (1979) Tuberculosis, case finding, treatment and Chemotherapy Question and Answer, WHO, Geneva, pp. 239.

Tornee S, Kaewkungwal J, Fungladda W, Silachamroon U, Akarasewi P, Sunakorn P. (2005) Factors associated with the household contact screening adherence of tuberculosis patients. *Southeast Asian J Trop Med Public Health.* 36(2):331-340.

TRC (TB Resource Centre). (2004) DOTS and Adherence Support: Assessment of community DOTS. URL:http://TB-hiv.com (Last accessed on December 2/2008).

Wahyuni C, Budiono X, Rahariyani LD, Sulistyowati M, Rachmawati T, Djuwari X, Yuliwati S, van der Werf MJ. (2007) Obstacles for optimal tuberculosis case detection in primary health centers (PHC) in Sidoarjo district, East Java, Indonesia. *BMC Health Serv Res*. 7(1):135.

Wandwalo E, Kaplata N, Egwaga S, Morkove O. (2004) Effectivness of community-based directly observed treatment for tuberculosis in an urban setting in Tanzania: a randomized controlled trial. *Int J Tuberc Lung Dis*. 8(10):1248-1254.

Wandwalo E, Robberstad B, Morkve O. (2005) Cost and cost-effectiveness of community based and health facility based directly observed treatment of tuberculosis in Dar es Salaam, Tanzania. In: *Cos Eff Resour Alloc*, BioMed Central.3(6): doi:10.1186/1478-7547-3-6. URL: http://www.resource-allocation.com/conent/3/1/6 (Last accessed on December 2/2008).

Wandwalo E, Makundi E, Hasler T, Morkove O. (2006) Acceptability of community and health facility- based directly observed treatment of tuberculosis in Tanzanian urban setting. 78(2): 284-294.Elsevier Ireland Ltd. URL: http://www.journals.elsvierhealth.com/periodicals/heap/article/S0168-8510(05)00269-1/pdf. (Last accessed December 2/2008).

WHO. (1999) Tuberculosis infection control in the era of expanding HIV care and treatment, Addendum to WHO, Guidelines for the Prevention of Tuberculosis in Health Care Facilities in Resource-Limited Settings, TB infection control-WHO_TB_99.269_ADD_eng.

WHO. (2003) Treatment of Tuberculosis: Guidelines for National Programs, 3rd edn. World Health Organization, Geneva. WHO/CDS/TB/2003.313.

WHO. (2004) Compendium of indicators for monitoring and Evaluating National Tuberculosis Programs. WHO/HTM/TB/2004.344.

WHO (WHO-Regional Office for Africa). (2005) Communicable disease in the Africa region 2004, Harare.

WHO[a]. (2006) The global plan to stop tuberculosis, 2006-2015, WHO, Geneva. WHO/HTM/STB/2006.35.

WHO[b]. (2006) Stop TB strategy final, WHO, Stop TB partnership.WHO/HTM/STB/2006.37.

WHO[c]. (2006) Guidance for national tuberculosis programmes on the management of tuberculosis in children. WHO/HTM/TB/2006.371 WHO/FCH/CAH/2006.7.

WHO[d]. (2006) Community contribution to TB care: practice and policy. The communication initiative network. URL:http://www.comminit.com/en/node/221284/36 (Last accessed on December 8/2007).

WHO[e]. (2006) Guidelines for the programmatic management of drug-resistant tuberculosis, WHO. WHO/HTM/TB/2006.361.

Annex 1: Data abstraction form

01. Name of Health institution/ DOT center_____
02. Zone/Woreda: _____
03. Kebele/Tabia: _____
04. Date of data collection: _____ (DD/MM/YY)
05. Data collector's name: _____ Sig. _____
06. Supervisor's name: _____ Sig. _____

Instruction:
Data abstraction form should be completed on all patient lists in the Unit TB Register which are selected for the study.

Unit TB No. _____Woreda TB No._____

Subject	Options	Coding
101. Name of the patient available	01. Yes 02. No	[__|__]
102. Complete address of the patient available	01. Yes 02. No	[__|__]
103. Sex	01. Male 02. Female 03. Not available	[__|__]
104. Age	01. _____ (years) 02. Not available	[__|__]
105. Name of contact person available	01. Yes 02. No	[__|__]
106. Address of contact person available	01. Yes 02. No	[__|__]
107. Name and address of community treatment supporter available	01. Yes 02. No 03. Not applicable	[__|__]
108. Category of patient	01. New (N) 02. Treatment after failure (F) 03. Relapse (R) 04. Treatment after default(D) 05. Transfer in (T) 06. Others (O) 07. Not available	[__|__]
109. Pretreatment body weight	01. _____ Kg 02. Not available	[__|__]
110. Sputum smear result	01. Positive 02. Negative 03. Not available	[__|__]
111.Types (classification) of TB	01. Sputum-positive Pulmonary TB (P/POS) 02. Sputum-negative Pulmonary TB (P/NEG)	

	03. Extra pulmonary TB (EP) 04. Not available	[__|__]
112. Sputum results recorded At 2nd month	01. Positive 02. Negative 03. Not available	[__|__]
113. Sputum results recorded At 5th month	01. Positive 02. Negative 03. Not available	[__|__]
114. Sputum results recorded At 7th /11th month	01. Positive 02. Negative 03. Not available	[__|__]
2. Intensive phase		
201. Frequency	01. Daily 02. 3 times/week 03. Not available	[__|__]
202. *Drugs taken and dose* NB. R=Refampicin H=Isoniazid Z=Pyrazinamide E= Ethambutol S= Streptomycin	Drug Dose	
203.Intensive phase monitoring chart completeness	01. Complete (2 months) 02. Partially complete (1< X<2 months) 03. Not complete (≤1 month)	[__|__]
3. Continuation phase		
301. Frequency	01. Daily 02. 3 times /week 03. Not available	[__|__]
302.*Drugs taken and dose* NB. R= Refampicin H= Isoniazid Z=Pyrazinamide E= Ethambutol S= Streptomycin	Drug Dose	
303. Continuous phase monitoring chart completeness	01. Complete (>5 months) 02. Partially complete (3-5 months) 03. Not complete (≤3 months)	[__|__]
4. Treatment out come		
401.Date of decision available	01. Yes 02. No	[__|__]
402. Treatment out come	01. Cured 02. Treatment completed 03. Died 04. Default 05. Failure 06. Transfer Out 07. Not recorded	[__|__]

Annex 2: Observation checklist

01. Zone/Woreda :_____
02. Kebele/Tabia: _____
03. Health facility/ DOT center: _____
04. Date of observation: (dd/mm/yy)_____
05. Observer's name: _____
06. Supervisor's name:_____

Observe treatment of TB patients who come into the health facility/community DOT observer and record observation here.

	Questions for observation	Yes	No
1.	Does the patient have a TB Treatment ID Card?		
2.	Does the patient registered in the Unit TB register?		
3.	Examine the Unit TB register. Is it complete so far?		
4.	Did the observer greet the patient?		
5.	Was the patient checked his or her weight?		
6.	Was the patient asked how he or she is feeling today?		
7.	Was the patient checked/asked for side effects?		
8.	Was the patient encouraged based on his improvements?		
9.	Was the patient given the correct drugs?		
10.	Was the dose recorded in the Unit TB register for the patient?		
11.	Was it recorded correctly?		
12.	Did the observer fill the patient's attendance sheet?		
13.	Was water available at the health facility/ DOT center?		
14.	Was water available for the patient to take the drugs?		
15.	Did the observer watch the patient swallow the anti-TB drugs?		
16.	Was the patient advised about food?		
17.	Was the patient advised about the importance of adherence?		
18.	Observe the DOT observer's communication with the patient. Did the observer communicated? (Circle based on your observation)	1. Poorly* 2. Fair 3. Good 4. Very Good	

*__Poor__ communication includes: too busy to care, hasty, or not listening to the patient

__Fair__: if the observer greets and gives attention to the patient while observing DOT.

__Good__: if the observer greets, asks and listen to the patient and observes DOT attentively.

__Very good__: if the observer asks questions and listens, demonstrate a caring respectful attitude, praises and encourages the patient to ask questions, asks checking questions and show sympathy.

Annex 3: Self-administered questionnaire for health professionals (English and Tigringna)

1. Name of Health institution/ DOT center_____
2. Zone/Woreda: _____
3. Date of data collection: _____DD/MM/YY
4. Data collectors name: _____ Supervisor: _____

Dear colleague;
I am prospective graduate of School of Pharmacy, Addis Ababa University. For the fulfillment of MSc program in Pharmacoepidemiology and Social Pharmacy, I have planned to assess provision of Directly Observed Therapy (DOT).

Despite great efforts for long period of time, TB is still a major cause of morbidity and mortality in Ethiopia. Ethiopia is one of the 22 high burden countries globally. Moreover, case detection rate of new smear positive cases stands very low at 32%. In 2006/07 the case detection rate in Tigray was 27.4%. In that regards, this study aims to identify possible causes for low case detection rate.

Please, be assured that the information you provide is strictly confidential. Your name will not be recorded and the information obtained also will not be used in any way that will identify you. You are not obliged to answer any question you don't feel comfortable. However, your genuine response helps a lot for the completion and success of the study.

Part I: Demographic information of respondents

Sex M/F	Age	Profession	Qualification (Speciality)	Service year	TB related Service Year

Part II: Read the following list carefully and select and rank the 5 most important reasons for low case detection rate in Tigray region.

1. Lab staff are not sufficiently trained to identify a positive smear _____
2. Limited utilization of health facilities _____
3. Insufficient clinical suspicion _____
4. Insufficient referral of TB suspects for diagnosis _____

5. Lack of coordination and incomplete reporting among parallel disease reporting system ___
6. Delayed referral system for TB suspects to health facility providing DOTS service for examination & treatment_____
7. Limited access of health facilities _____
8. Inadequate use of smear microscopy services (sufficient samples may not be obtained/smear examination may not be requested on sputum samples submitted for culture_____
9. Insufficient promotion and awareness in the community, amongst medical staff & the community workers regarding respiratory symptoms notably persistent cough for more than 2 weeks or more _____
10. Inadequate functioning of smear microscopy services _____
11. Incomplete implementation of DOTS _____
12. Laboratories are not equipped with all reagents to perform the smear _____
13. Absence of intensified TB screening in high risk group _____
14. Inadequate/ absence of identification of suspects by health extension workers & community volunteers _____

Part 2: ካብዚ ንታሕቲ ተዘርዚሮም ንዘለው ነጥብታት ተጠንቂቅካ(ኪ) ኣንብቦም(ኣንብብዮም)። ብድሕሪኡ፣ ኣብ ትግራይ ኣገዮም ጠቕምቲ ዝኾኑ 5 ምኽንያታት ትሑት መጠን ምልላይ ዓባይ ሰዓል ብቐደም ሰዓብ ኣቐምጥ(ጢ)።

1. ሰብ ሙያ ላብራቶሪ ውዕኢት smear ብግቡእ ንምልላይ ዘኽእል እኹል ስልጠና ዘይምውሳዱም_____
2. ቀረብ ጥዕና ምጥቃም ውሱንነት _____
3. ንሕማም ዓባይ ሰዓል ዘሎ ጥርጣረ እኹል ስለዘይኮነ (ብሰብ ሙያ ጥዕና) _____
4. ንጥርጡራት ሕማም ዓባይ ሰዓል ምርመራ ክግበረሎም ሪፈር ዕሒፍካ ምልኣኽ እኹል ስለዘይኮነ _____
5. ኣብ ሞንጎ ተመዓደውቲ ሜላታት ምዕብዓብ ሕማም ጥምረት/ዘይትግልእ ፀብዓብ ስለየዘለ_____
6. ጥርጡራት ሕማም ዓባይ ሰዓል ናብ ግልጋሎት ምርመራን ሕክምናን DOT ቀረብ ጥዕና ሪፈር ዝባሃሉ ደንጉዩ ስለዝኾነ_____
7. ቀረብ ጥዕና ናይ ምርካብ ውስንነት _____
8. ጉድለት ኣጠቓቕማ ግልጋሎት smear microscopy (እኹል ናሙና ዘይክርክብ ይኽእል /ንካልቸር ዝተወሰደ ናይ ዓኽታ ናሙና ንsmear ምርመራ ዘይክእዘዝ ይኽእል) _____
9. ኣብቲ ሕብረተሰብን ሰብ ሙያ ጥዕናን ካብ ሕብረተሰብ ዝተመልመሉ ሓገዝቲ ግልጋሎት ጥዕና ብዛዕባ ምልክታት ሕማም ስርኣተ ምስትንፋስ ብፍላይ ዘይቀርዕ ሰዓል ንልዕሊ ክልተ ሰሙን ውስን ዝኾነ ኣፍልጦን ሓበሬታን_____
10. ግልጋሎት smear microscopy ብግቡዕ ዘይምስራሕ_____
11. ዝተግልአ ትግበራ DOT ስለዘየለ _____
12. ግቡእ ግልጋሎት smear ንምሃብ ዘድልዩ ናይ ላብራቶሪ ሪኤጀንታት ዘይተግልኡ ምኻኖም_____

13. ሕማም ዓባይ ሰዓል ብቐሊሉ ክተሓዙ ንዝኽእሉ ኣካላት ብዝተጠንቀረ መልክዑ ዝፍለይሉ መንገዲ ዘይምህላው_____
14. ብሰራሕተኛታት ጥዕና ኤክስቴንሺንን ፍቃደኛታት ወሃብቲ ግልጋሎት ኣባላት ማሕበረሰብን ንጥርጡራት ሕማም ዓባይ ሰዓል ኣለሊኻ ምፍላጥ እኹል ዘይምኻኑ/ዘይምህላው_____

Annex 4: Informed consent form (English)

My name is _____. I am working on a study designed to assess DOT (Directly Observed Therapy of TB treatment) implementation in Tigray. For the purpose of obtaining the necessary information, I am interviewing TB patients. And I would like to ask some questions about your disease and related things.

Your participation is purely voluntary. Information you provide will be kept completely confidential, only the research team will have access for it. Moreover, your name will never be written and your responses are identified only by codes.

You have the right not to answer any question. However, your honest and genuine response to the questions is of paramount importance for the successful completion of the study. You have also right to get clarification if you have any doubt and you can stop the interview at any time.

Moreover, your participation, non participation or refusal to answer questions will have no effect now or in the future on services that you or member of your family may receive from health service providers.

Would you be willing for the interview?

1. Yes. Thank you lets begin.
2. No. Thank you.

Signature of the data collector certifying that informed consent has been given verbally by the respondent _____

Annex 5: Questionnaire for exit interview of TB patients

01. Name of Health institution/ DOT center_____
02. Woreda: _____
03. Kebele/Tabia:_____
04. Unit TB No. _____
05. Woreda TB No._____
06. Date of interview: _____
07. Interviewer's name: _____Sig. _____
08. Supervisor: _____Sig. _____

Objective: To determine the patient's awareness on TB and TB medication and his/her attitude and perception about CBDOT or HBDOT

Part I- Socio demographic characteristics of respondent

Subject	Response	Coding	Skip pattern
101. Sex	01. Male 02. Female	[__|__]	
102. Age	_____years	[__|__]	
103. Educational status	01. Can't read & write 02 Informal education 03.Grade 1-6 04.Grade 7-12 05.Grade 12^{+}	[__|__]	
104. What is your ethnic group?	01. Tigraway 02. Afar 03. Amhara 04. Other (Specify)_____	[__|__]	
105. Place of residence	_____		
106. What is your religion?	01. Orthodox 02. Muslim 03. Catholic 04. Protestant 05. Other (specify)_____	[__|__]	
107. What is your occupation?	01. Farmer 02. Daily laborer 03. Merchant 04. Government employee 05. Private employee 06. Not employed 07. Other (specify)_____	[__|__]	

108. What is your marital status?	01. Never married 02. Currently married 03. Divorced/Separated 04. Widowed 05. Cohabiting 06. Other (specify)_____	[__|__]	
109. What is your family's monthly income? (Birr/kind; no income write "0")	01. _____ 02. Dependent on others 88. Don't know 99. No response	[__|__]	
110. Family size		[__|__]	
111. Do you have any dependents? (Young children, elderly, or sick relatives)	01. Yes 02. No 03. Not applicable	[__|__]	
Part II Knowledge about TB and TB treatment			
Knowledge about TB			
201. Have you ever been caught by TB before?	01. Yes 02. No	[__|__]	If No go to Q203
202. How many times have you been diseased?	01._____ times 02. I do not remember exactly	[__|__]	
203. Was there any one who had TB from your family/friends/neighbors?	01. Yes 02. No	[__|__]	
204. Is TB curable disease?	01. Yes 02. No 88. I do not know	[__|__]	
205. Is TB treatable disease?	01. Yes 02. No 88. I do not know	[__|__]	
206. What is the cause of TB?	01.Germ 02. Sprit/witchcraft 03. Sexual intercourse 04. Unhygienic food and water 05. Cold 06. other (specify)_____ 99. No response	[__|__] [__|__] [__|__] [__|__] [__|__] [__|__]	
207. When do you suspect that a person has TB (symptoms of TB)?	01.Coughing(> 2 weeks) 02.Weight loss 03. Loss of appetite 04. Night sweats 05. Fever 06.Fatigue/Chest pain/ shortness of breath 07. localized pain/swelling 08 Others (specify)_____	[__|__] [__|__] [__|__] [__|__] [__|__] [__|__]	

	99. No response		
208. How do you think people get TB? /from where someone get TB?	01. TB patients 02. health person/ health unit 03.Others(specify) _____ 99. No response	 [__|__] [__|__] [__|__]	
209. How it is transmitted?	01.Respiration/sneezing/coughing/spitting 02. Kissing 03. Sharing utensils 04.Consumption of raw milk 05.lives in close contact with TB patents 06. Being HIV positive/AIDS 88. I don't know 99. No response	 [__|__] [__|__] [__|__] [__|__] [__|__] [__|__]	
210. Is TB preventable?	01. Yes 02. No 88. I don't know	 [__|__]	If No go to Q 212
211. If yes, how?	01. Vaccination for kids 02. Isolation of infectious patients/reducing having contact with TB patients 03. Treating the sick 04. Eating good food 05. Proper hygiene 06.Adequate ventilation 07. Avoiding direct coughing & sneezing 08.Avoiding concentrated living 09. Others (specify)_____ 88. I don't know 99. No response	[__|__] [__|__] [__|__] [__|__] [__|__] [__|__] [__|__] [__|__] [__|__] [__|__]	
Knowledge about TB treatment			
212. Have you ever interrupted /discontinued your treatment?	01. Yes 02. No 99. No response	 [__|__]	If No go to Q 214
213. If yes, why?			
214. What will happen if you are not treated?	01. Cure 02. Die 03. Disability 04. Improvement 05. Others(specify)_____ 88. I don't know	 [__|__] [__|__] [__|__] [__|__]	
215. What is the consequence of irregular treatment to TB?	01. Cure 02. Death 03. Chronic suffering	[__|__] [__|__] [__|__]	

	04. Disability 05. Improvement 06. Resistance to drug 07. Others (specify)_____ 88. I don't know		
216. Does treatment of TB help in the control and prevention of TB?	01. Yes 02. No 88. I don't know	[__|__]	
217. What is the use of DOT?	01. To ensure taking of drugs 02. To prevent sell of the drug by the patient 03. Others _____	[__|__] [__|__]	
218. Duration of treatment of TB total course	01. _____months 88. I don't know	[__|__]	
219. Duration of treatment of Intensive phase (DOT)__(months)	01. <2 months 02. > 3 months 03. 2-3 months 88. I do not know	[__|__]	
220. Duration of treatment of continuation phase(self-administered) _____(months)	01.< 5 months 02. >6months 03. 5- 6 months 88. I do not know	[__|__]	
221. How frequent should drugs be taken during the intensive phase?	01. daily 02. weekly 03. three times weekly 04. Other (specify)_____	[__|__]	
222. How many drugs are you taking?	_____	[__|__]	
223. When do you take your drugs?	01. Every day 02. Every other day 03. 3 days/week 04. Others _____	[__|__]	
224. What will you do if you plan to travel/move to another area?	01. Inform the staffs 02. Taking transfer 03.Take drugs when I return 04. Others_____	[__|__] [__|__] [__|__]	
Knowledge about side effects			
225. Have you ever suffered any side effect when taking medication?	01. Yes 02. No	[__|__]	If No go to Q228
226. If yes what were the side effects?	01. Anorexia 02. Nausea 03. Abdominal pain/ Joint pain 04. Burning sensation in feet 05. Orange/red urine	[__|__] [__|__] [__|__] [__|__]	

	06. Deafness 07. Hepatitis 08. Visual impairment 09. Renal failure 10. Dizziness 11. Others(specify)_____	[__|__] [__|__] [__|__] [__|__] [__|__] [__|__]	
227. What action was taken to manage the side effects?	01. Drugs stopped 02. Drugs dose reduced 03. Drugs changed 04. Disappear by it self 05. Others(specify)_____	[__|__] [__|__]	
228. What do you know about the side effects if they occur?	01. Manageable 02. Minor 03. Severe 04. Others(specify)_____	[__|__]	Read the options
229. What will you do if you have the side effects?	01. Discontinue treatment 02.Visiting health facility 03.Discontinue treatment & Visiting health facility 04. Others(specify)_____	[__|__]	
Attitude to diagnosis			
230. How do you feel being diagnosed with TB?	01. Good 02. Acceptable 03. Bad 04. Not bad	[__|__]	
231. What will family and close friends think?	01. Accepted 02. Provide care & support 03. Stigma/discrimination 04. Feel bad	[__|__] [__|__]	
Possible barriers to care			
232. Do you have any other health problem at the moment?	01. Yes 02. No	[__|__]	If No go to Q23
233. If yes what?			
234.Distance between the nearest health facility and house	_____(Km, minutes/hours/days walk)		
235. Distance between DOT center and house	_____(Km, minutes/hours/days walk)		
236. How do you go to the health facility/ DOT center?	01.Private car/ Animals 02. Taxi 03. Walking 04. Others (Specify)	[__|__]	
237. How much does the transport cost? (if no cost Put "0")	01. _____Birr 88. I do not know		

Life style factors			
238. Do you drink alcohol?	01. Yes 02. No	[__|__]	If No go to Q240
239. If yes, how frequent?	01. Daily 02. Sometimes 03. Occasionally 99. No response	[__|__]	
240. Do you smoke cigarettes?	01. Yes 02. No	[__|__]	If No go to Q241
241. If yes, how frequent?	01. Daily 02. Sometimes / not daily 99.No response	[__|__]	
242. Do you regularly take drugs or chew chat?	01. Yes 02. No	[__|__]	If No go to Q301
243. If yes, how frequent?	01. Daily 02. Sometimes 03. Occasionally 99. No response	[__|__]	

Part III Perception about DOT observer

301. How do you find DOT observer in giving the service	01. Very good 02. Good 03. Fair 04. Poor	[__|__]	
302. How the DOT observer approaches you?	01. Busy to care/hasty 02. Helpful 03. Friendly 04. Not attractive	[__|__]	

Important notes for the interviewee:

1. A person having cough for more than 2 weeks should be referred to DOT center to be diagnosed for TB.
2. TB is a curable disease if it is treated properly.
3. TB treatment is given free of charge.

Thank you very much for your willingness and cooperation for the interview by taking your precious time. As promised at the beginning, your responses remain strictly confidential.

Annex 6: Informed consent form (Tigringna)

<u>ናይ ስምምዕ ቅጥዒ</u>

ሽመይ_____ ይበሃል አብ ትግራይ ዘሎ ቀጥታዊ ክትትል ሕክምና ቲቢ ንግምጋም ዝተደለወ መዕናዕቲ አብ ምስራሕ ይርከብ። ዘድሊ ሓበሬታ ንምርካብ ድማ ንሕሙማት ዓባይ ሰዐል ቃለ መሕተት ይገብር አለኹ። እና በዛዕባ ሕማምጃ (ኒ) ን ካልኦት ተዘመድቲ ነገራትን ዝተወሰኑ ሕቶታት ክሓተት ደልየ አለኹ።

ተሳትፎኻ (ኺ) ሙሉእ ብሙሉእ ብፍቓድ ዝፍፀም እዩ። ካባኻ (ኺ) ዝርከብ ሓበሬታ ሙሉእ ብሙሉእ ብምሽጣር ዝተዓቀበ እዩ። አካል ጉጅለ ናይዚ መዕናዕቲ ጥራሕ ነዚ ሓበሬታ ክረክብ ይኽእል። ብተወሳኺ ሽምካ (ኒ) ብፍፁም አይጥቀሰን። እትህቦ (ብዮ) መልሲ ዝልለ ብኮድ ጥራሕ እዩ።

ንዝቐረበልካ (ኒ) ሕቶታት ብኽፋል ኮነ ብምሉእ ናይዘይምምላስ መሰልካ (ኒ) ዝተሓለወ እዩ። ይኹን'ምበር ብዛዕባ እዚ መዕናዕቲ ንዝዳለው ሕቶታት እትህቦ (ብዮ) ትኽክለኛን ቅንዕን መልሲ እዚ መዕናዕቲ ዝተማልአ ስክዒት ንኽህልዎ አዝዩ ጠቓሚ እዩ። ግልፂ ዘይኮነልካ (ኒ) ነገር መብርሂ ናይ ምርካብ መሰልካ (ኒ) ዝተሓለወ እዩ። አብ ዝኾነ እዋን ቃለ መሕተት ምቁራፅ ይካአል እዩ።

ብተወሳኺ አብዚ ቃለ መሕተት ብምስታፍካ (ኒ) ይኹን ብዘይምስታፍካ (ኒ) ወይ ሕቶ ንምምላስ ብምእባይካ ካብ ወሃብቲ ግልጋሎት ጥዕና ንእትረኽቦ (ብዮ) ወይ አባል ስድራኻ (ኺ) ንዝረኽብዎ ግልጋሎት ጥዕና ሕዚ ኮነ አብ ቕዳሊ ምንም ዓይነት ተፅዕኖ አይህልዎን።

ቃለ መሕተት ንምግባር ፍቓደኛ ዲኻ (ኺ)?

1. እወ ፤ የቕንየለይ፡ በል (ሊ) ንጀምር።
2. አይኮንኩን ፤ የቕንየለይ ።

ፊርማ አቕራቢ ቃለ መሕተት እዚ ሓበሬታ ብስምምዕ ወሃቢ መልሲ ብቓል ከምዝተዋህበ ንምምስካር_____

Annex 7: Questionnaire for exit interview of TB patients (Tigringna)

1. ሽም ጥዕና ጣብያ/ ማእኸል DOT:_____
2. ዞባ/ወረዳ: _____
3. ቀበሌ/ ጣብያ: _____
4. ቐዕሪ ክፍሊ ዓባይ ሰዓል: _____
5. ቐዕሪ ወረዳ ዓባይ ሰዓል: _____
6. ቃለ መሕተት ዝተገበረሉ ዕለት: _____
7. ሽም ቃለ መሕተት ዝገበረ አካል:_____ ፈርማ _____
8. ተቐፃሪ አካል:_____ ፈርማ _____

ዓላማ: ሕሙማት ዓባይ ሰዓል አብ ሕማም ዓባይ ሰዓልን ሕክምና ዓባይ ሰዓልን ዘለዎም ግንዛበ ክምኡውን አብ CBDOT ወይ HBDOT ዘለዎም ቅዋምን፣አርኣእያን፡ አረዳድኣን ንምፍላጥ፡፡

Part I: Socio demographic characteristics of respondent

Subject	Response	Coding	Skip pattern
101. ዖታ	01. ተባዕታይ 02. ኣንስታይ	[_|_]	
102. ዕድመ	_____ ዓመት	[_|_]	
103. ኩነታት ደረጃ ትምህርቲ	01. ኣየንብብን ኣይጽሕፍን 02. ዘይስሩዕ ትምህርቲ 03. 1-6 ክፍሊ 04. 7-12 ክፍሊ 05. 12+(ልዕሊ 12 ክፍሊ)	[_|_]	
104. ብሄርካ (ኺ) እንታይ እዩ?	01. ትግራዋይ 02. ዓፋር 03. ኣምሓራይ 04. ካሊእ (ጥቐስ)_____	[_|_]	
105. ትነብረ(ር)ሉ ቦታ	_____		
106. ሃይማኖትካ (ኺ) እንታይ እዩ?	01. ኦርቶዶክስ 02. እስልምና 03. ካቶሊክ 04. ፕሮቴስታንት 05. ካሊእ (ጥቐስ)_____	[_|_]	
107. ስራሕኻ እንታይ እዩ?	01. ሓረስታይ 02. መዓልታዊ ሰራሕተኛ 03. ነጋዳይ 04. ናይ መንግስቲ ሰራሕተኛ 05. ናይ ግሊ ሰራሕተኛ 06. ስራሕ የብለይን 07. ካሊእ (ጥቐስ)_____	[_|_]	
108. ኩነታት መርዓ?	01. ዘይተመርዓወ(ት) 02. በዓል ሓደር 03.ዝፈትሐ(ት) 04.በዓል(ቲ) ቤት ዝሞተቶ(ዝሞታ) 05. ብዘይመረዓ ብሓደ ዝ(ት)ነብር 06. ካሊእ (ጥቐስ)_____	[_|_]	
109. ናይ ስድራኻ (ኺ) ወርሓዊ እቶት ክንደይ እዩ? (ብብር/ብዓይነት፣ኣታዊ ተዘይብሎም "0" ፀሓፍ)	01._____ 02. ኣብ ካልኦት ዕማዕተኛ 88. ኣይፈልጠን 99. መልሲ ኣይተወሃበን	[_|_]	
110. በዝሒ ስድራ	_____	[_|_]	
111.ናይባዕሉ (ላ) ኣታዊ ዘይብሉ (ላ) ስድራ ኣለካ(ኺ) ዶ? (ህፃናት፣ ቆልዑ፣ ዓበይቲ፣ ሕሙም ዘመድ)	01.እወ 02.የብለይን 03.ኣይምልከቶን	[_|_]	

Part II Knowledge about TB and TB treatment			
Knowledge about TB			
201. ቅድሚ ሕዚ ብሕማም ዓባይ ሰዓል ተታሒዝካ(ኪ) ትፈልጥ(ጢ) ዶ?	01. እወ 02. ተታሒዘ ኣይፈልጥን	[_|_]	መልሱ ተታሒዘ ኣይፈልጥንእንተኾይኑ ናብ ሕቶ 203 ሕለፍ
202. ክንደይ ግዜ ብሕማም ዓባይ ሰዓል ተታሒዝካ(ኪ) ትፈልጥ(ጢ?	_____ ግዜ	[_|_]	
203. ብሕማም ዓባይ ሰዓል ዝተጥሓዘ(ት) ስድራ፡ ዓርኪ፡ ወይ ጐረቤት ነይሩ(ራ) ዶ?	01. እወ 02. ኣይነበረን	[_|_]	
204. ሕማም ዓባይ ሰዓል ክድሕን ይኽእል ዶ?	01. እወ 02. ኣይድሕንን 03. ካሊእ (ጥቐስ)_____ 88. ኣይፈልጠን	[_|_]	
205 ሕማም ዓባይ ሰዓል ክሕክም ይኽእል ዶ?	01. እወ 02. ኣይሕክምን 88. ኣይፈልጠን	[_|_]	
206. መልዓሊ ሕማም ዓባይ ሰዓል እንታይ እዩ?	01.ጀርም/ባክቴርያ 02.መንፈስ/ጥንቆላ 03. ዖታዊ ርክብ 04.ዕርየት ዝጐደሎ ማይን ምግብን 05. ቁሪ/ንፋስ 06. ካልኦት (ጥቐስ)_____ 99. መልሲ ኣይተዋሃበን	[_|_] [_|_] [_|_]	
207. ሓደ ሰብ ሕማም ዓባይ ሰዓል ክምዘለዎ ብኽመይ ይፍለጥ (ምልክታት ሕማም ዓባይ ሰዓል)?	01. ሳዓል (ልዕሊ 2 ሰሙን) 02. ምቕናስ ክብደት/ምቕጣን 03. ናይ ምግቢ ድልየት ምቕናስ 04. ለይቲ ምርሃዕ 05. ምንቅጥቃጥ 06. ድኻም / ኣፍልቢ ምሕማም/ሕዕረት እስትንፋስ 07. ኣብ ውሱን ክፋል ሰውነት ስምዒት ሕማም ወይ ሕበጥ ምህላው 08. ካልኦት (ጥቐስ)_____ 99. መልሲ ኣይተዋሃበን	[_|_] [_|_] [_|_] [_|_] [_|_]	
208. ሰባት ብኽመይ ሕማም ዓባይ ሰዓል ይሕዞም?	01 ካብ ካልኦት ሕመማት ዓባይ ሰዓል 02.ካብ ሰብ ሞያ ጥዕና/ክፍሊ ጥዕና 03. ካልኦት (ጥቐስ) _____ 99. መልሲ ኣይተዋሃበን	[_|_] [_|_]	
209. ሕማም ዓባይ ሰዓል ብኽመይ ይመሓላለፍ?	01.ብትንፋስ/ብምህላስ/ብምስዓል/ብዓኽታ 02. ብምስዕዓም 03. ኣቐሑ ሓቢርካ ብምጥቃም 04.ዘይፈልሐ ፀባ ብምስታይ 05. ምስ ሕመማት ዓባይ ሰዓል ተቐራራብካ ብምንባር 06. ካልኦት (ጥቐስ)_____ 88. ኣይፈልጠን 99. መልሲ ኣይተዋሃበን	[_|_] [_|_] [_|_] [_|_] [_|_]	
210. ሕማም ዓባይ ሰዓል ምክልኻል ይከኣል ዶ?	01. እወ 02. ኣይከኣልን 88. ኣይፈልጠን	[_|_]	መልሱ ኣይከኣልን/ኣይፈልጠን እንተኾይኑ ናብ ሕቶ 212 ሕለፍ
211. መልስኻ (ኺ) እወ እንተኾይኑ ብኽመይ?	01. ሕፃናት ብምኽታብ 02.ሕመማት ዓባይሰዓል ብምፍላይ /ቅርርብ ምስ ሕመማት ብምቕናስ 03. ንሕመማት ዓባይ ሰዓል ብምሕካም	[_|_] [_|_] [_|_] [_|_]	

	04. ፅቡቕ መግቢ ብምምጋብ 05. ፅሬት ብምሕላው 06.እኹል ንፋስ ብምርካብ 07.ቀጥታ ዝኾነ ምስዓልን ምህጣስን ብምግዳፍ 08. ተቐራሪብካ ምንባር ብምግዳፍ 09. ካልኦት (ጥቐስ)_____ 88. ኣይፈልጠን 99. መልሲ ኣይተዋሃበን	[_|_] [_|_]	
Knowledge about TB treatment			
212. ሕክምናኻ (ኺ) ኣቋሪፅካ (ኪ) ትፈልጥ (ጢ) ዶ?	01. እወ 02. ኣይፈልጥን 99. መልሲ ኣይተዋሃበን	[_|_]	መልሱ ኣይፈልጥን/ መልሲ ኣይተዋሃበን እንተኾይኑ ናብ ሕቶ 214 ሕለፍ
213. መልስካ (ኪ) እወ እንተኾይኑ ንምንታይ?			
214. እንተዘይተሓኪምካ (ኪ) እንታይ ይኸሰት?	01. ይድሕን 02. ይመውት 03. ተሓጋዚይ ክሳብ ዝኾን ይደክም 04. የማሓይሽ 05. ካልኦት (ጥቐስ)_____ 88. ኣይፈልጠን	 [_|_] [_|_] [_|_]	
215.ሕክምና ዓባይ ሰዓል ብዘይ ስሩፅ (ብምቁርራፅ) እንተወሲድካ (ኪ) እንታይ ይኸሰት?	01. ምድሓን 02. ሞት 03. ተኸታታሊ ስቃይ 04. መጉዳእቲ ኣካል 05. ምምሕያሽ 06. መድሓኒት ዘይሰርሕ ይኸውን 07. ካልኦት (ጥቐስ)_____ 88. ኣይፈልጠን	 [_|_] [_|_] [_|_] [_|_]	
216. ሕክምና ሕማም ዓባይ ሰዓል ንምቁፅፃርን ምክልኻልን ሕማም ዓባይ ሰዓል ይሕግዝ ዶ?	01. እወ 02. ኣይሕግዝን 88. ኣይፈልጠን	 [_|_]	
217. መድሓኒት ዓባይ ሰዓል ኣብ ቅድሚ ሰብ ሞያ (ተኸታተልቲ) ጥዕና ምውሳዱ ዘለዎ ጥቕሚ እንታይ ዩ?	01. መድሓኒት ብትኽክል ምውሳዱ ንምርግጋፅ 02. እት ሕሙም ነቲ መድሓኒት ከይሸጦ ንምክልኻል 03. ካልኦት (ጥቐስ) _____	 [_|_] [_|_] [_|_]	
218. ሕክምና ዓባይ ሰዓል ዝወስዶ ጠቅላላ ግዜ	01_____ኣዋርሕ 88. ኣይፈልጠን	 [_|_]	
219. ኣብ ቅድሚ ሰብ ሞያ (ተኸታተልቲ) ጥዕና ዝውሰድ ሕክምና ዓባይ ሰዓል ክንደይ ኣዋርሕ ይውሰድ?	01. < 2 ኣዋርሕ 02. > 3 ኣዋርሕ 03. 2-3 ኣዋርሕ 88. ኣይፈልጠን	 [_|_]	
220. ኣብ ገዛኻ (ኺ) ወሲድካ(ኪ) ትወስዶ(ድዮ) መድሓኒት ዓባይ ሰዓል ክንደይ ኣዋርሕ ይፀንሕ?	01. < 5 ኣዋርሕ 02. > 6 ኣዋርሕ 03. 5-6 ኣዋርሕ 88. ኣይፈልጠን	 [_|_]	
221. ኣብ ቅድሚ ሰብ ሞያ (ተኸታተልቲ) ጥዕና ዝውሰድ መድሓኒት ዓባይ ሰዓል በብክንደይ ግዜ ይውሰድ?	01. በብመዓልቱ 02. በብሰሙን 03. ኣብ ሳልስቲ 04. ካሊእ (ጥቐስ)_____	 [_|_]	
222. ኣብ መዓልቲ ክንደይ ዓይነት መድሓኒት እናወሰድካ (ኪ) ኢኻ (ኺ)?	_____	[_|_]	
223. መድሓኒት መዓዝ ትወስድ	01. በብመዓልቱ		

(ዲ)?	02. አብ ሳልስቲ 03. ሰለስተ መዓልቲ ኣብ ሰሙን 04. ካሊእ (ጥቐስ) ____	[_|_]	
224. ናብ ካሊእ ቦታ ንምኽድ ትልሚ እንተሃልዩካ እንታይ ትገብር?	01. ንሰብ ሞያ ጥዕና ይሕብረለይ 02 ቅያር ጣብያ ጥዕና ይወስድ 03. ምስተመለስኩ መድሓኒት ምውሳድ ይቅዕል 04. ካሊእ (ጥቐስ)_____	[_|_] [_|_]	
Knowledge about side effects			
225. መድሓኒት ዓባይ ሰዓል ዘመፀኣልካ (ኪ) ፀገም ኣሎ ዶ?	01. እወ 02. የለን	[_|_]	መልሱ የለን እንተኾይኑ ናብ ሕቶ 228 ሕለፍ
226. መልስኻ (ኺ) እወ እንተኾይኑ እንታይ ዓይነት ፀገም ነይሮም?	01. ምቕናስ ድሌት ምግቢ 02. ዕዉልውል ምባል 03. ቀንዛ ከብዲ 04. ኣብ እግሪ ናይ ምቅፃል ስምዒት 05. ብጫ/ቀይሕ ሕብሩ ሽንቲ 06. ናይ ምስማዕ ፀገም 07. ፀገም ፀላም ከብዲ 08. ናይ ምርኣይ ፀገም 09. ፀገም ኩላሊት 10. ምፍዛዝ 11. ካልኦት (ጥቐስ)____	[_|_] [_|_] [_|_] [_|_] [_|_] [_|_]	
227. ነቶም ፀጋማት ንምእላይ እንታይ ፍታሕ ተወሲዱ?	01. መድሓኒት ተቋሪፁ 02. መጠን ዝውስድ መድሓኒት ቀኒሱ 03. መድሓኒት ተቐይሩ 04. እቲ ስምዒት ባዕሉ ጠፊኡ 05. ካሊእ(ጥቐስ)_____	[_|_] [_|_] [_|_]	
228. ፀጋማት መድሓኒት ዓባይ ሰዓል እንተሃልዮም በዛዕቦኦም እንታይ ትፈልጥ (ጢ)?	01. ክእለ ይኽእል እዩ 02. ከቢድ እዩ 03. ቀሊል እዩ 04. ካሊእ(ጥቐስ)_____	[_|_] [_|_]	እቶም ምርጫታት ይነበበሉም
229. እዞም ፀጋማት እንተ ተሰሚያሙኻ (ኺ) እንታይ ትገብር (ሪ)?	01. ሕክምና የቋርፅ 02. ናብ ግልጋሎት ጥዕና ይኸይድ 03. ሕክምና ኣቋሪፀ ናብ ግልጋሎት ጥዕና ይኸይድ 04. ካልኦት (ጥቐስ)____	[_|_]	
Attitude to diagnosis			
230. ዓባይ ሰዓል ኣለካ(ኪ) ምስቶባሃልካ(ኪ) እንታይ ተሰሚዑካ (ኪ)?	01. ፅቡቕ 02. ቅቡል 03. ሕማቕ 04. ሕማቕ ኣይኮነን 05. ካሊእ (ጥቐስ)____	[_|_]	
231. ቤተሰብን ናይ ቀረባ ኣፅርኽትን/መሓዙት ንመይ ተቐቢሎሞ?	01. ቅቡል ይገብርዎ 02.ሓገዝን ክንክንን ይገብሩለይ 03. የዳልው/የግልሉ 04. ሕማቕ ስሚዒት የሕድሩ	[_|_] [_|_]	
Possible barriers to care			
232. ሕዚ ካሊእ ፀገም ጥዕና ኣለካ (ኪ) ዶ?	01. እወ 02. የብለይን	[_|_]	መልሱ የብለይን እንተኾይኑ ናብ ሕቶ 234 ሕለፍ
233. እወ እንተኮይኑ እንታይ?			
234.ናብ ገዛኻ(ኺ) ዝቐረበ ጥዕና ጣቢያ ዘለዎ ርሕቀት	_____ (ኪ.ሜ/በደቂቃ/ሰዓት/መዓልቲ)		
235. ማእኸል ሕክምና (DOT) ካብ ገዛኻ(ኺ) ዘለዎ ርሕቀት	_____ (ኪ.ሜ/በደቂቃ /ሰዓት/መዓልቲ)		
236. ናብ ግልጋሎት ጥዕና (ማእኸል	01. ብእንስሳ ዘቤት		

ሕክምና DOT) ብኽመይ ትኽይድ (ዲ)?	02. ብታክሲ 03. ብእግረይ ተጓዒዘ 04. ካሊእ (ጥቐስ)_____	[_|_]	
237. ወፃኢ መጓዕዝያ ክንደይ ይኽውን? (ወፃኢ እንድሕር ዘይብሉ "0" አቕምጥ)	01._____ብር 88. ኣይፈልጦን		
Life style factors			
238. ናይ አልኮል መስተ ትሰቲ (ይ) ዶ?	01.እወ 02. ኣይሰትን	[_|_]	መልሱ ኣይሰትን እንተኾይኑ ናብ ሕቶ 240 ሕለፍ
239. መልስኻ (ኺ) እወ ተኾይኑ በብኽንደይ?	01. መዓልታዊ 02. ሓድሓደ ግዜ 03.ኣብ ግዜ በዓላት፣ ጉዳያት... 99.መልሲ ኣይተዋህበን	[_|_]	
240. ሽጋራ ተትክኽ (ኺ) ዶ?	01. እወ 02. ኣየትክኽን	[_|_]	መልሱ ኣየትክኽን እንተኾይኑ ናብ ሕቶ 242 ሕለፍ
241. መልስኻ (ኺ) እወ ተኾይኑ በብኽንደይ?	01. መዓልታዊ 02. ሓድሓደ ግዜ 99.መልሲ ኣይተዋህበን	[_|_]	
242. ጫት ወይ ካልኦት ሱስ ዘትሕዙ ነገራት ትጥቀም ዶ?	01. እወ 02. ኣይጥቀምን	[_|_]	መልሱ ኣይጥቀምን እንተኾይኑ ናብ ሕቶ 301 ሕለፍ
243. መልስኻ (ኺ) እወ ተኾይኑ በብኽንደይ?	01. መዓልታዊ 02. ሓድሓደ ግዜ 03.ኣብ ግዜ በዓላት፣ ጉዳያት... 99.መልሲ ኣይተዋህበን	[_|_]	
Part III Perception about DOT observer			
301. ተኽታተልቲ ሕክምና DOT ዝህብዎ ግልጋሎት ከመይ ረኺብካዮ (ኺዮ)?	01. ብጣዕሚ ዕቡኾ 02. ዕቡኾ 03. ደሓን 04. ትሑት	[_|_]	
302. ኣቀራርባ ተኽታታላይ ሕክምና DOT እንታይ ይመስል?	01.ዝተጨናነቐ/ህውኽ 02. ተሓባባራይ 03. ምሕዝነታዊ 04. ኣይስሕብን	[_|_]	

<u>ጠቐምቲ ሓበሬታታት</u>

1. ሓደ ሰብ ልዕሊ ክልተ ሰሙን እንተስዒልዎ እቲ ሕማሙ ሕማም ዓባይ ሰዓል ክኽውን ስለዝኽእል ናብ ጥዕና ጣቢያ ከይዱ ክምርመር ከምዘለዎ ሓበሬታ ምሃብ የድሊ
2. ሕማም ዓባይ ሰዓል ብኣግባቡ እነተሓኪሙ ክድሕን ዝኽእል ሕማም ምኻኑ ሓበሬታ ምሃብ የድሊ
3. ሕክምና ዓባይ ሰዓል ብነፃ ከምዝወሃብ ሓበሬታ ምሃብ የድሊ

<u>ናይ መጨረሻ!</u>

ወርታዊ ግዜኻ (ኺ) ስዒእኻ(ኺ) ነዚ ቃለ መሕተት ንምግባር ፈቓደኛ ኮይንካ (ኪ) ብምትሕብባርካ (ኪ) ኣዝየ የመስግን፡፡ ኣብ መእተዊ ከምዝተጠቐሰ መልስኻ (ኺ) ብምስጢር ዝተዓቀበ እዩ፡፡ የቐንየለይ !!!

Annex 8: Focus group discussions topics (English)

I. Discussion topics for health professionals under HBDOT and CBDOT

1. Case detection

- As it is known our country has low case detection rate; is there any thing done so far to improve case detection rate? If yes what was done? Why not?
- What do you think should be done to improve case detection?
- A number of patients in the Unit TB Register are empty of smear results at 2nd, 5th, and 7th months. What do you think is the reason?

2. Community participation

- What kind of TB related community participation did you observe so far? What kinds of activities could be carried out by involving the community? What should be done to ensure community participation?

3. DOT implementation

- What do you think are the factors that affect proper implementation of DOT?How do you compare HBDOT and CBDOT in implementing DOT?

4. What are the opportunities and challenges of HBDOT/CBDOT?

- For the community? For the patient? For the health professionals/ Treatment supporters? The health system?

5. Service accessibility

- What will you do if the patient not came to you to take medicine during holiday, Saturday and Sunday; s/he is diseased and stayed in bed, rain, harvesting time, etc?
- Considering existing local situation what do you think if patients are provided with CBDOT? Why?

6. CBDOT option

- What are the criteria to refer patients to CBDOT? What kind of patients is referred to CBDOT? What kind of supervision and help you provide to CBDOT observers?

II. Discussion topics for treatment observer under CBDOT

1. Case detection
   - Do you encourage and teach household contacts of TB patients to be screened for TB irrespective of duration of cough? Why? Why not?
   - What do you think will attract suspect TB patients to seek care?
2. DOT implementation
   - What do you think are the factors affecting proper implementation of DOT?
   - What do you think are the roles and responsibilities of treatment observer for effective DOT program?
3. Support
   - What kind of supervision and help you get from the health facility? Woreda? Region? What kinds of training you get to be treatment observer? What kind of incentive you get from observing treatment for TB patients?
4. Challenges
   - What kind of challenges you encounter as treatment observer? How observing treatment affects your daily life?
5. Service accessibility
   - What will you do if the patient not came to you to take medicine during holiday; s/he is diseased and stayed in bed, rain, harvesting time, etc?

III. Discussion topics for patients under CBDOT/HBDOT

1. Case detection
   - Have your household members screened for TB? Why? Why not?
   - What do you think will attract suspect TB patients to seek care?
2. Service acceptability and satisfaction
   - Do you think you are getting appropriate service from the treatment observer? Why? Why not?
   - Could you tell us what kind of services you wish to get from the treatment observer?

3. CBDOT option

- What do you think if your treatment observer (who provides and watches while you swallow your medicine) is a trained community member? Why?
- What kind of benefits you are getting from CBDOT (having treatment observer from the community)?

4. Service accessibility

- How far the health facility from your permanent residence? What kind of problem this creates to you? What did you do to manage your daily treatment?
- What do you do about your treatment if you stay in bed, during holidays, on Saturday and Sunday? What will the treatment observer did for you?

5. Perception

- What do you think if your treatment observer (who provides and watches while you swallow your medicine) is a health professional and you are expected to come daily to the health facility? Why?

Annex 9: Focus group discussions topics (Amharic and Tigringna)

I. Discussion topics for health professionals under HBDOT/CBDOT

1. Case detection

- እንደሚታወቀው በአገራችን Case detection rate አነስተኛ ነው። Case detection rate ለመጨመር ከአሁን በፊት ምን የተሰራ ስራ አለ? ከሌለ ለምን?
- Case detection ለመጨመር /ለማሻሻል/ ምን መደረግ አለበት ብላችሁ ታስባላችሁ?
- Unit TB Register ሲታይ የብዙ ታካሚዎች የ2ተኛ ፣5ተኛ ና 7ተኛ smear results (ውጤት) ተመዝግቦ አይታይም? የዚህ ምክንያት ምን ይመስላችኋል?

2. Community participation

- ከTB ጋር የተያያዘ ሕብረተሰቡን ያሳተፈ ምን አይነት ስራ/ እንቅስቃሴ ከአሁን በፊት ታዝባችኋል? ሕብረተሰቡን በማሳተፍ ምን አይነት ስራዎች ሊሰሩ ይችላሉ ብላችሁ ታስባላችሁ? የሕብረተሰቡን ተሳትፎ ለማረጋገጥ ምን መደረግ አለበት?

3. DOT implementation

- DOT በአግባቡ ተግባር ላይ እንዲውል /እንዳይውል የሚያደርጉ ምክንያቶች ምንድን ናቸው ብላችሁ ታስባላችሁ?
- ከ DOT አተገባበር/አፈፃፀም አንፃር Community DOT እና Health facility DOTን እንዴት ታነፃፅራቸዋላችሁ? የትኛው የበለጠ ውጤታማ ነው ብላችሁ ታስባላችሁ? ለምን?

4. የcommunity DOT/ Health facility በጎ ጎኖች/ጠቀሜታዎች እና ችግሮቹ ምንድን ናቸው?
   - ለሕብረተሰቡ? ለታማሚው/ለታካሚው? ለጤና ባለሙያው? ለህክምና ደጋፊው (Community treatment supporters)? ለጤና አገልግሎቱ?
5. የአገልግሎት ቅርበት
   - የ ቲቢ ታካሚዎች በበዓላት ወቅት፡ቅዳሜ ወይም እሁድ፤ በመዳከማቸው የተነሳ አቅም አንሳቸው ከቀሩ/ታመው ከተኙ፤ ዝናብ ወይም የእርሻ ወቅት ወይም የመሳሰሉት ችግሮች አጋጥማቸው ሲቀሩ ምን ታደርጉ ነበር ወይም ምን ታደርጋላችሁ?
   - ከአካባቢያችሁ ነባራዊ ሁኔታ አንፃር ታካሚዎች Community DOT አገልግሎት ቢያገኙ ምን ታስባላችሁ/ ምን ይመስላችሓል? ለምን?
   - ታካሚዎች Community DOT እንዲያገኙ የሚላኩት በምን መስፈርት ነው? ምን አይነት ታካሚዎችስ ናቸው ወደ Community DOT የሚላኩት?
   - Community DOT ላይ ለሚሰሩ DOT observer (ተመልካቾች) ምን አይነት እርዳታ/እገዛና ቁጥጥር ይደረጋል?

II. Discussion topics for treatment observer under CBDOT

1. ኩነታት ምልላይ
   - ምስ ሕሙማት ዓባይ ሰዓል ምትእስሳር ንዘለዎም ስድራታት ኩነታት ግዜ ሰዓል ብዘየገድስ ምርመራ ዓባይ ሰዓል ክገብሩ ተታባብዕዎምን ተምህርዎምን ዶ? ንምንታይ እዙይ ትገብሩ? ንምንታይ እዙይ አይገበርኩምን?
   - ሕማም ዓባይ ሰዓል አለዎም ተባሂሎም ዝጥርጠሩ ሰባት ሕክምና ናይ ምርካብ ድልየት ንኽሕድሩ እንታይ ክግበር አለዎ ትብሉ?
2. ትግበራ DOT
   - DOT ብግቡእ ንምትግባር ዝፀልው ረቓሒታት እንታይ ይመስልኹም?
   - መርሃ ግብሪ /ፕሮግራም/ DOT ወሊኢታዊ ንክከውን ተግባርን ሓላፍነትን ተኸታተልቲ ሕክምና እንታይ ክኸውን አለዎ ትብሉ?
3. ድጋፍ
   - ካብ ትካል ጥዕና እንታይ ዓይነት ሱፐርቪዥን /ክትትል/ ትረኽቡ? ወረዳ? ክልል?
   - ተኸታተልቲ ሕክምና ንኽትኮኑ እንታይ ዓይነት ስልጠና ወሲድኩም?
   - ንሕሙማት ዓባይ ሰዓል ክትትል ሕክምና ብምግባርኩም እንታይ ዓይነት ጥቕማ ጥቕሚ/መበራቲትዒ ትረኽቡ?
4. አፀገምቲ ተግንፎታት
   - ክም መጠን ተኸታተልቲ ሕክምና እንታይ ዓይነት አፀገምቲ ተግንፎታት አጋጢሞምኹም?
   - ክትትል ሕክምና ንዕለታዊ መነባብሮኹም ብኽመይ ዕልዋ ይገብረልኩም?

5. ረኽቢ ግልጋሎት

- ሓደ ሕሙም ብዝተፈላልየ ምክንያታት [ባዓል ስለዝኾነ፣ ሓሚሙ ደቂሱ(ሳ)፣ ብዝናብ ምክንያት፣ ናይ ምህርቲ እዋን ኮይንዎ(ዋ) ወዘተ] መድሓኒት ክወስድ እንተዘይ መሊኡ(ኣ) እንታይ ትገብሩ?

III. መዛተይ ነጥብታት ኣብ CBDOT/HBDOT ንዘለው ሕሙማት

1. ኩነታት ምልላይ
   - ኣባላት ስድራኹም ሕማም ዓባይ ሰዓል ከም ዘለዎምን ዘይብሉምን ንምፍላጥ ተመርሚሮም ዶ? ንምንታይ ተመርሚሮም? ንምንታይ ኣይተመርመሩን?
   - ብሕማም ዓባይ ሰዓል ዝጥርጠሩ ሰባት ክንክን ሕክምና ክረኽቡ ንምትብባዕ እንታይ ክግበር ኣለዎ ትብሉ?
2. ተቐባልነትን ዕግበትን ግልጋሎት
   - ቀረብ መድሓኒት ኣትረኽብሉ ቦታ ካብ መንበሪ ገዛኹም ዘለዎ ርሕቐት ክንደይ ይኾን? እዙይ እንታይ ዓይነት ጥቕሚ ፈጢሩልኩም?
   - ብወሃብቲ /ተኽታተልቲ/ ሕክምና ግቡእ ግልጋሎት ንረክብ ኣለና ዶ ትብሉ? ረኺብና ዘበለኩም ምኽንያት? ኣይረኽብናን ዘበለኩም ምኽንያት?
   - ካብ ወሃብቲ /ተኽታተልቲ/ ሕክምና እንታይ ዓይነት ግልጋሎት ክትረኽቡ ከምትዕበዩ ክትገልፁልና ትኽእሉ ዶ?
3. መማረፅታት CBDOT
   - ካብ CBDOT (ኣብ ቀረባኹም ሕክምና ዓባይ ሰዓል ምውሳድ) እንታይ ዓይነት ጥቅሚ ትረኽቡ ኣለኹም? ቀረብ ጥዕና ኣትረኽብሉ ቦታ ካብ መንበሪ ገዛኹም ዘለዎ ርሕቐት ክንደይ ይኾን? እዙይ እንታይ ዓይነት ፀገም ፈጢሩልኹም?
   - ብመንፅር እዞም ፀገማት ዕለታዊ ንምክትታል እንታይ ገርኩም?
4. ረኽቢ /ምርካብ/ ግልጋሎት
   - ሓሚምኩም ደቂስኩም እንተነይርኩም፣ ኣብ ጊዜ በዓላት ፣ ኣብ ቀዳምን ሰንበትን ሕክምናኹም ኽመይ ትገብሩ ኔርኩም ? ተኽታተልቲ ሕክምናኽ እንታይ ገይሮመልኩም?
5. ኣረደድኣ
   - ተኽታታሊ ሕክምናኹም (መድሓኒት ክትውሕጡ እንተለኹም ዘቕርበልኩምን ዝሪኢኹምን) ካብ ሰብ ሞያ ጥዕና እንተዝኸውን እሞ በብማዕልቱ ናብ ሰብ ሞያ ጥዕና ዘለዎ ትካል ጥዕና እንተመሃኹም እንታይ ይመስለኩም? እዚ ዝበልኩምሉ ምኽንያት?
   - ክትትል ሕክምና ዝገብርልኩም [መድሓኒት ክትወስዱ ዝሕግዝኹም] ካብ ዝስልጠኑ ኣባላት ሕብረተሰብ እንተኾነ እንታይ ይመስለኩም? እዚ ዝበልኩምሉ ምኽንያት?

Annex 10: Guideline for observing DOT provider practice

1. The forms should be accessible only to research staffs.
2. Informed consent; It is essential to get the consent of both the patient and the provider before observing the interaction.
3. You should have informed consent for every participant in the study and those patients unable to give informed consent shouldn't be included in the study.
4. Allow providers and patients to refuse observation or to discontinue the observation at any time.
5. Explain to provider that the purpose of the observation is not to assess his/her personal performance, nor will information obtained/gathered through the observation be provided to his/her superiors to be used during performance appraisal.
6. Inform that the purpose of the study is to get a sense of how DOT treatment services are provided overall at the health care facilities/DOT centers and community found in Tigray.
7. Before the session begins, find a place to sit/stand so that the patient and provider interaction can be seen clearly.
8. During the session you should remain quite and still so as not to disrupt the patients and provider and try to minimize disruptions during the DOT process.
9. Writing in the forms should be done as discretely as possible.
10. Do not discuss your observation with any one other than the study staff/ principal investigator or without the knowledge and consent of the principal investigator
11. Be sure to thank the patient and providers for allowing you to observe DOT.
12. Try to be accustomed with the existing condition/situation; do not be much differentiated than the DOT observer in terms of clothing, style etc. Always dress white coat if your observation is in the health facility.
13. Do not interfere or comment on the DOT observer practice.
14. Do not be judgmental on the patient and observer appearance/condition. Just follow carefully and record all the necessary data.
15. Try to complete all the necessary information before leaving the room.

Annex 11: Guideline for reviewing Unit TB Registers

1. Approach the person who is expected to provide Unit TB Register in a friendly, polite manner and try to create a welcoming atmosphere.
2. Discuss the objectives of the study (if necessary) with Unit TB Register holder (person responsible to authorize data access) and inform him/her that it is not to report how they did rather it is used for the study purpose only.
3. Care should be taken when you abstract data from the main document, be sure that you are looking to the required information before writing on the form.
4. Before abstracting detailed information complete the general information required.
5. Be sure that you are completing all important information from the Unit TB Register before looking for the next sample.
6. When you use the recorded data try to keep it as it is and take care not to damage since it is an important record; and don't write anything on it nor delete from it.
7. Data abstraction form should be completed for all patients in the Unit TB Register selected for the study.
8. Write only what is available there, do not guess or try to fill data which was not initially completed by DOT observers.
9. Do not miss the information on the remark side of the main document as it may indicate site of EP disease, HIV status if known, change of drugs and most importantly DOT options.
10. Follow instruction on the abstraction form.
11. Thank the person (s) who provides (s) you the Unit TB Register.
12. When you write the name of the drug and dose (regimen) use the standard notation as:
    - 2HRZES/1HRZE/5HRE; 2ERHZ/6EH; 2HRZ/4RH; 2S(ERHZ)/1(ERHZ)/5 $E_3(RH)_3$; 2HRZE/4RH; 2S (HRZ)/4(RH)
        - ➢ The numbers indicate the months of treatment
        - ➢ The letters indicate the drugs for both intensive & continues phase
        - ➢ The sub-script number indicates (e.g. no. 3) as in E_3 $(RH)_3$ it is given 3/week.

Annex 12: Interviewer's guide

1. When you meet patients, please
   - Great warmly and try to create a welcoming and friendly atmosphere
   - Introduce yourself
   - Ensure the patient is comfortable and try your best to keep privacy for the respondent
2. Inform the objective of the study to the patient briefly i.e. to assess DOT implementation in Tigray in order to improve the service rendered by providers for the patient
3. Ask the willingness of the patient and obtain consent.
4. Discuss confidentiality issues with the patient:
   - Assure the interviewee that the information collected from him/her will be kept strictly confidential and will not be accessed to any one other than the research team.
   - The respondent should be informed that his/her name will not be written
5. Inform the respondent that the participation in the study is only voluntary and with full consent and the respondent has the right not to respond (answer) questions if he/she does not want to answer and the service he/she obtain from the health service will not be affected by his refusal
6. Inform the respondent /patient that they do not have to answer any questions that they don't want to answer and may end the interview at any time when they want to.
7. Inform the respondent that reliability and accuracy of information given by him/her is very much important to achieve the objectives of the study
8. After discussing the above information with respondent and obtained his/her full consent continue to complete the questionnaire
9. If the respondent (patient) refuses to respond (participate), discontinue the interview but do not forget to thank him/her and wish good luck.
10. If the respondent (patient) refuses to respond (participate) in the interview at the middle of the interview thank him/her and wish good luck, and discontinue the interview
11. Try to fill all necessary data before departing from the patient
12. Respect the religion, belief and attitude of the patient. Respect the responses given by the patient

Annex 13: FGD guideline

Focus groups are used to learn about the experiences and perceptions of groups. Focus group interview address a single topic in depth. Because the comments of each respondent can stimulate reactions from the other respondents, focus groups can yield rich insights. Ideally, the focus group is conducted by a team consisting of a moderator and assistant moderator. The moderator facilitates the discussion; the assistant takes notes and runs the tape recorder

The ideal focus group moderator should have the following traits:

- Can listen attentively with sensitivity and empathy
- Is able to listen and think at the same time
- Believes that all group participants have something to offer no matter what their education, experience, or background
- Has adequate knowledge of the topic
- Can keep personal views and ego out of facilitation
- Can appropriately manage challenging group dynamic

The assistant moderator must be able to do the following:

- Run a tape recorder during the session
- Take notes in case the recorder fails or the tape is inaudible
- Note/record body language or other subtle but relevant clues
- Allow the moderator to do all the talking during the group

- Both moderator and assistant moderator are expected to welcome participants, ensure consent of participants to participate in the FGD, offer them soft drinks, help them make their name tents, and direct them in completing pre-group paperwork.
- Name tents should identify participants with a number written largely for anonymous identification of individuals as they make comments
- The moderator has a responsibility to adequately cover all prepared questions within the time allotted. S/he also has a responsibility to get all participants to talk and fully explain their answers.

- It is good moderator practice to paraphrase and summarize long, complex or ambiguous comments. It demonstrates active listening and clarifies the comment for everyone in the group.
- Because the moderator holds a position of authority and perceived influence s/he must remain neutral, refraining from nodding/raising eyebrows, agreeing/disagreeing, or praising/ denigrating any comment made.

When conducting focus groups:

- Participants should have fun and feel good about the session
- Make sure every participant is heard
- Get full answers
- Monitor time closely ***(N.B. The maximum time allowed for FGD is 90 minutes)***
- Keep the discussion on track
- Please do a lot of listening- attendees want to give their input

  -It is critical that all members participate as much as possible, yet the session should move along while generating useful information

  -Ensure even participation. If one or two people dominating the meeting, then call on others. Give each person a minute to answer the question. If the domination persists, note it to the group and ask for ideas about how the participation can be increased. Do every thing you could to equalize voices with in the group.
- Get permission from all respondents to audiotape the discussion. Also let them know that you will stop the tape any time if they ask. They have the right to object to the session being taped.
- Ensure equal participation. Provide opportunities to speak by creating ground rules and encourage every one to speak.

Ground rules

1. We want you to do the talking
   - We would like every one to participate
   - I may call on you if I haven't heard from you in a while
2. There are no right or wrong answers

- Every person's experiences and opinions are important
- Speak up whether you agree or disagree
- We want to hear a wide range of opinions

3. What is said in this room stays here
   - We want participants to feel comfortable sharing when sensitive issues come up
4. We will be tape recording the group
   - We want to capture every thing you have to say
   - We don't identify anyone by name in our report, you will remain anonymous

- Strategies to deal with challenging participants:
  - The dominator: "let's have some other comments."
  - The rambler: stop eye contact: look at your watch; jump in at their inhale
  - The shy participant: make eye contact; call on them; smile at them.
  - The participant who talks very quietly: ask them to repeat their response more loudly.
- When the focus group is complete the moderator thanks all participants.
- Immediately after all participants leave, the moderator, the assistant moderator and the principal investigator debrief while the recorder is still running and label all tapes and notes with the date and name of the group.

DECLARATION

I, the undersigned, declare that this thesis is my original work and has not been presented for a degree in any other university.

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Signature: 

This thesis has been submitted for examination with our approval as university advisors

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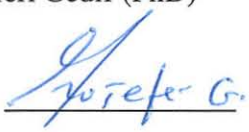
Signature: 

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