INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH

QUALITY AND TREATMENT OUTCOMES OF DIRECTLY OBSERVED TREATMENT OF SHORT-COARSE OF TUBERCULOSIS (DOTS) IN SOUTH WEST ETHIOPIAN: A COHORT STUDY

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ARTICLE INFO	ABSTRACT
	Background: TB is one of the world's leading causes of death and of the global burden of disease. It is estimated that at 36 million will die of TB if proper control measures are not instituted. Assessing the quality of Directly Observe Short-Course Treatment of Tuberculosis can have significant importance in evaluating Tb control activities and in identifying area of improvements for better and effective Tb control strategies. Objective: To assess the quality and treatment outcome of directly observed Treatment Short Course (DOTS) of Tuberculosis in south West Ethiopian in Public Health facilities. Methods: Prospective cohort study was employed using both semi-structured and structured questionnaires and phase to phase observation and interview. The study populations were all Tb patients who enrolled during study period until they finished their treatment, drop out and or death. Treatment outcome was obtained from patients' charts and direct clinical examination. Results: From 324 patients enrolled and followed for treatment outcomes, 279(87.45%) of the patients were completed their treatment, 45(13.8%) were transferred out to other health facilities by referral system and none of the patients were defaulted from the treatment or discontinued the treatment. From the total patients who completed the treatment 221(68.8%) were totally cured, 45 (13.8%) were failed to cure and the death rate were 4% (13) Conclusion and Recommendation: The overall quality of TB care indicated that 26.1% of the patients received poor quality of care. The finding of this study indicated that there was a weak supervision pattern and the supervision pattern was also unplanned, inconsistent and lack feedback. Finally the outcomes of DOTS cure rate is only 68.8%.

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INTRODUCTION

About one third of the world's population is infected with Mycobacterium tuberculosis. More than 80% of all TB patients in 2005 lived in Asia and Sub-Saharan Africa. Today, TB is still one of the world's leading causes of death and of the global burden of disease. It is estimated that at 2020, approximately 1,000 million people will be newly infected, over150 million will become sick and 36 million will die of TB if proper control measures are not instituted. Poverty, HIV and multidrug-resistant tuberculosis (MDR-TB) are key factors driving the TB epidemic (1-5)

The Stop TB Strategy, launched in 2006, builds upon and enhances the achievements of DOTS. New objectives include universal access to patient-centered treatment and protection of populations from TB/HIV and multidrug-resistant TB (MDR-TB). To reach the target of 85% treatment success globally, DOTS: the internationally recommended approach to TB control, which forms the core of the Stop TB. The five components of DOTS are political commitment with increased and sustained financing, case detection through quality-assured bacteriology, standardized treatment with supervision and patient support, an effective drug supply and management system and monitoring and evaluation system, and impact measurement. In countries which have adopted the DOTS strategy, it may be implemented in all or some parts of the country, and by all or some health-care providers. Only those TB patients notified by health-care facilities providing DOTS services are included in this indicator. Each year national TB control programs report to WHO the number of cases of TB diagnosed in the preceding year, and the outcomes of treatment for the cohort of patients who commenced treatment a year earlier.(6-8)

Ethiopia ranks third in Africa and 8th among the 22 highest tuberculosis (TB) burdened countries in the world. The prevalence of all forms of TB is estimated at 261 per 100 000 population, leading to an annual mortality rate of 64 per 100 000 population. The incidence rate of all forms of TB is estimated at 359 per 100 000 population, while the incidence rate of smear-positive TB is 108 per 100 000 population. The TB case detection rate, treatment success rate and TB cure rate are 74%, 82.5% and 67%, respectively Multidrug-resistant TB (MDR-TB) is a challenge. A countrywide survey between 2003 and 2006 showed that the prevalence of MDR-TB was 1.6% in new TB cases and 11.8% in retreatment cases. In addition, there was a high TB/HIV co-infection rate, with 25% of registered TB cases also testing positive for HIV Ethiopia is one of the 22 HBCs. According to the WHO global TB report 2011, there were an estimated 220,000 (261 per 100,000) incident cases of TB in Ethiopia in 2010. According to the same report the prevalence of TB was estimated to be 330,000 (394 per 100,000). There were an estimated 29,000 deaths (35 per 100,000) due to TB, excluding HIV related deaths, in Ethiopia during the same period (9-15).

Directly observed therapy (DOT) is a widely recommended and promoted strategy to manage tuberculosis (TB), however, there is still disagreement about the role of DOT in TB control and the impact it has on reducing the acquisition and transmission of drug resistant TB. In many countries globally, the adoption of Directly Observed Treatment (DOT) has been associated with reduced rate of treatment failure, relapse and drug resistance. However, its impact in reducing TB incidence has been limited by non-compliance to DOT, which occurs when patients do not turn up for treatment at the health facility or community DOT point. In countries where DOT has had little impact on TB control, poor or non-compliance to self-administered TB treatment is common and has been identified as an important cause of failure of initial treatment, leading to relapse (16 - 20)

Of the six WHO regions, five have Tb incidence that is falling or stable, but Africa has an incidence that keeps increasing at almost 10% per year, offsetting the gains in the rest of the world Tuberculosis is presenting new challenges as a global public health problem, especially at a timeof increasing threats due to HIV infection, multi-drug-resistant and extensively drug-resistant strains of Mycobacterium tuberculosis. Besides, there has been poor performances achieved in Tb control activities in,(case detection and Treatment success rate below the WHO standard). Drug-resistant TB has emerged as a major challenge facing TB prevention and control efforts. In Ethiopia, the extent/trend of drug resistance TB is not well known. Multidrug-resistant TB (MDR-TB) is a challenge. A countrywide survey between 2003 and 2006 showed that the prevalence of MDR-TB was 1.6% in new TB cases and 11.8% in retreatment cases. According to the WHO global TB report 2011, there were an estimated 220,000 (261 per 100,000) incident cases of TB in Ethiopia in 2010. According to the same report the prevalence of TB was estimated to be 330,000 (394 per 100,000). There were an estimated 29,000 deaths (35 per 100,000) due to TB, excluding HIV related deaths, in Ethiopia during the same period. The rationale for conducting this study was to provide the base line information on quality of DOTS and its outcomes in study areas, The finding can be the input for policy makers on revision of TB treatment strategies

OBJECTIVES

General Objective

To assess the quality and treatment outcome of Directly Observed Treatment Short Course (DOTS) of Tuberculosis in south West Ethiopian Public Health facilities.

Specific Objectives

To assess the qualities of DOTS in South West Ethiopian public health institution as per National and International standards.
To describe the treatment outcomes of DOTS in South West Ethiopian public health institution
To explain factors affecting quality of DOTS in South West Ethiopian public health institution

METHODOLOGY

Study Area

The study area was south West Ethiopian Health facilities in both selected Ilu Aba Bor Zone Public health facilities.

Study Design
The study was prospective cohort study among all TB patients enrolled between January 2016 and August 2016 and followed until treatment completion, death and transfer to another health institution.

Upon enrollment, field workers was interviewed each patient to collect demographic, social, and medical information with a structured questionnaire. There were no interference with routine patient management and treatment. Treatment outcome was obtained from patients' charts and clinical examination. The last enrolled patient was followed at least for six months.

Sampling techniques
One referral hospital, one district hospital and six health centers was selected randomly from public health facilities.

Data Collection Procedures
Donabedian's quality assessment model in Health care and FMOH's-TLCP manual was used for the development of questionnaires for structural and process quality assessment

Data Quality Control
To evaluate the data collection instrument for its validity of reliabilities and consistency a pilot study was done on 5% of study in both cases. Training was given for data collectors
The data collected was checked for the completeness, accuracy, by the principal investigator every day and correction was made soon if any fault done.

Data Analysis and Interpretation
All the data was entered, compiled and analyzed by using SPSS version 20 of statistical software package. A frequency of descriptive statists was presented by using percentages and table. Logistic regression analysis was performed to assess the relation of each cause of drug miss use. Statistical significance was defined at a level of 0.05 and data was described with a confidence interval of 95%.

Ethical Consideration
Letter was written by University research review board to Zonal health department and to each health institutions   and patient willingness also was asked

RESULTS
Socio Demographic Characteristics of TB Patients
A total of 324 TB patients were included in this study with a response rate of 100 %, of which 183 (56.5%) patients being female. These patients had a standard deviation and mean age of 7.7 and 31.6 years, respectively and the mean (SD) of family size was 5.2(1.4). Among the study participants, 139 (42.9%) were in the age group of 15-34. Two hundred forty seven (76.2 %) were married; 194 (59.9%) were Orthodox Christian; 140 (43.2%) were farmers by occupation and 156 (48.1%) of the study participants monthly income was greater than one thousand Ethiopian Birr.

Process Attributes of Quality of DOTS
Regarding to provider patient interaction, 324 patients were observed while they were receiving their drugs. The results from this study showed that 223 (68.8%) patients were greeted by provider and 208 (64.2 %) patients participated in part of decision making processes of service delivery. Of the total observed patients 197(60.8%) patients were advised how to take drugs, 195 (60.2%) patients were told when the next follow up will be, 193(59.6%) were advised on the need to comply with treatment, 170(52.5) patients were told when the next AFB will be done and 194 (59.9%) asked providers about TB drug treatment conditions. Regarding to the facility level, 309 (95.4%) patients were given treatment while providers having tables and chair, almost all patients wait stand to receive treatment and bring water to swallow drug in the TB clinic (Table 1).

Table 1 Provider –patient interaction and pattern of services provision in Ilu Aba Bor zone, 2016.

Variables		Frequency	Percentage
Patients greeted by health professionals	Yes	223	68.8
	No	101	31.2
Patients participated in decision making	Yes	208	64.2
	No	116	35.8
Health workers properly explained about how to take drugs	Yes	197	60.8
	No	127	39.2
Health workers advised patients when to return for follow up	Yes	195	60.2
	No	129	39.8
Health worker advised patients on the need to comply with Rx	Yes	193	59.6
	No	131	40.4
Health worker explained patients when follow up AFB done	Yes	170	52.5
	No	154	47.5
Health worker advised patients to bring person with Sign and Symptoms of TB	Yes	194	59.9
	No	130	40.1
Provider ask pt for any concern regarding TB treatment	Yes	194	59.9
	No	130	40.1
Patients who asked health professional for any concerns	Yes	185	57.1
	No	139	42.9
Provider having chair and table, while treating patients	Yes	309	95.4
	No	15	4.6

Patient Satisfaction as an Outcome Indicator for Quality of DOTS

Thirteen satisfaction questions were used to assess satisfaction of clients in the service they received, cronbach's alpha was tested and the result showed that that its alpha value of 0.781. According to the satisfaction of clients with the different aspects of services provided the finding of this study declared that: 257(79.3%) were satisfied; in adequacy and appropriateness of working hours; with respect to waiting time 252(77.8%) were satisfied; 252 (77.8) were satisfied by the time spent to them by care providers; Satisfaction with regard to cleanliness and Comfortableness of waiting area weren 237(73.2%) and 233 (71.9%) respectively; satisfaction with cleanliness of TB room and equipments /instruments where TB pts get service were 233 (71.9%) and 232 (71.6%) respectively. Meanwhile, 220 (67.9%) and 193 (59.6%) were satisfied with the respect offered by health professionals and measures taken to assure privacy respectively. (Table 2)

Table .2 Patient's satisfaction level in the given service in I/A/Bor Zone, 2016.

Variables	Satisfaction level		
	Satisfied	Neutral	Dissatisfied
Satisfaction with adequacy and appropriateness of working hours	257(79.3)	0(0)	67(20.7)
Satisfaction with the waiting time	252(77.8)	5(1.5)	67(20.7)
Satisfaction with the time spent by health worker	252 (77.8)	3 (0.9)	69 (21.3)
Satisfaction with Cleanliness of waiting area	237(73.2)	0(0)	87 (26.8)
Satisfaction the overall comfort of the waiting area	233 (71.9)		91(28.1)
Satisfaction with the cleanliness of the place where pts received service	233 (71.9)		91(28.1)
Satisfaction with the cleanliness of instrument /equipment used by the health professional	232 (71.6)	25 (7.7)	67 (20.7)
Satisfaction of pts with the respect offered by Health professionals	220 (67.9)		104 (32.1)
Satisfaction with measures taken to assure privacy	193 (59.6)	27 (8.3)	104 (32.1)
Satisfaction with service provider's competence and ability	202 (62.4)	8 (2.5)	114 (35.2)
Satisfaction with the completeness of the information given to pt	197 (60.8)	8 (2.5)	119 (36.7)
Satisfaction with Cost incurred	319 (98.5)	0	5 (1.5)
Satisfaction with the effectiveness of the service pts received	186 (57.4)	5 (1.5)	133(41.1)
Overall satisfaction	194 (59.8)	5 (1.5)	8.6)

Treatment out comes

From 324 patients enrolled and followed for treatment outcomes, 279(87.45%) of the patients were completed their treatment, 45(13.8%) were transferred out to other health facilities by referral system and none of the patients were defaulted from the treatment or discontinued the treatment. From the total patients who completed the treatment 221(68.8%) were totally cured,45(13.8%)were failed to cure and the death rate were 4%(13) (Table 3).

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Table .3 Treatment out comes of DOTS in I/A/Bor Zone, 2016.

S.N	Treatment out comes	Frequency	Percentage
1	Treatment completed		
1.1	Cured	221	68.8
1.2	Treatment failure	45	13.8
1.3	Death	13	4.0
	Sub total	279	87.4
2	Transferred out	45	13.8
3	Defaulter	0	0
Total		324	100

Determinant factors for treatment out comes

According to logistic regression analysis of adjusted odd ratio of determinant factors for DOTS outcomes like socio economic characteristics, morbidity TB category health facility and base line drugs, age and sex did not have any significant relationship with outcomes. The significant factors from socioeconomic factors were marital status, patient educational level and residents of the patients.

The Odds of having good treatment outcomes for DOTS of married patient was 6.7(5.72-8.92) times than divorced patient with p-0.286 and 2.93(2.4-3.205) times than unmarried/ single patients with p-0.045.

The Odds of patients educated until college level have more chance to be cured from TB by DOTS 5.0(3.57-8.66) times than un educated patient (p-0.0001) and the patient reside in urban have good out for DOTS 1.75(1.58-1.96)times rural resident patients with p-0.175.

Smear positive pulmonary TB patients show good outcomes for DOT 5.18(2.28-11.73) times smear negative pulmonary TB patients (P-025). The Odds of treatment failure of DOTS with old regimen (HRZE/HE) was 10(4.46-13.361) times the patiens treated by new regimen (HRZE/HR) with P-0.001(Table 4).

Table4: Determinant factors for DOTS qualities ant treatment outcomes in Ilu Aba Bor zone, 2016.

S.No	Associates causative factors (N=324)		F/%	AOR(95%CI)	P-values	Intercept
1	Age	15-24	59/18.2	1.34(1.5-8.3)	0.930	0.98
		25-34	139/42.9	1.85(1.74-2.03)	0.94	
		35-44	103/31.8	1		
		> 45	23/7.1	1.94(1.09-2.01)	0.97	0.893
2	Sex	Male	141/43.5	1		
		Female	183/56.5	0.239(0.125—0.309)	0.909	
3	Marital status	Single	60/18.5	2.93(2.41-3.205)	0.045	5.27
		Married	247/76.2	6.7(5.72-8.92)	0.0286	
		Divorced	8/2.5	1		
		Widowed	9/2.8	2.025(1.97-3.74)	0.000	
4	Pt. Educational status	Can't read and write	57/17.6	1		0.457
		Read and write	51/15.7	2.14(0.185-3.25)	0.936	
		Primary(1-8)	128/39.5	3.018(2.738-4.47)	0.671	
		Secondary(9-12)	63/19.4	3.018	0.23	
		Collage and above	25/7.7	5.000(3.75-8.66)	0.0001	
5	Residence	Urban	129/39.8	1.75(1.58-1.976)	0.172	0.16
		Rural	195/60.2	1		
	Clinical TB morbidity classification	Smear positive PTB	246/76	5.18(2.28-11.73)	0.021	0.3043
		Smear Negative PTB	48/14.8	1		
		EPTB	30/9.2	0.39(1.42-8.09)	0.605	
	TB pt. category	New	314/97	2.74(0.92-3.31)	0.039	0.06
		Relapse	10/3	1		
	Base line drugs	2HRZE/6HE(old recommendation)	36/11	1		0.00
		2HRZE/4HR(new recommendation	318/89	10.00(4.46-13.36)	0.0001	
	Health facility	Hospital		3.21(1.02-5.77)	0.046	
		Health center		1		0.107

DISCUSSION

According to this study quality of DOTS was assessed by different quality parameters in structural, process and as an outcome ,thus the overall quality of TB care indicated that 26.1% of the patients received poor quality of care. The result of our study was better than study in Jimma 66.0%, Bahir Dar city 52.2% and Egypt 49.8% patients received poor quality of care (1,2,3).

The probable reason could be time gap between the studies. Geographical difference and health care delivery system might be the possible reasons for the differences.

According to our study structural attribute pertaining to quality assessment showed that all health institutions had trained health professionals in DOTS assigned as full time staff 100%; all anti TB dugs were available for a minimum stock for 3 months (100%); trained laboratory professionals on AFB (100%). Similar findings were reported from the study done in Jimma (1).

In line with the study conducted in Tigray all health facilities had TB drugs supply without interruption (4). This might be due to the government give emphasis and different stake holders support with drug supply to control and prevent the disease.

Provider- Patient interaction had pivotal role in quality of DOTS service. Patient- provider interaction with reference to DOTS service among many includes greeting politely, involving patients in decision making, providing advice and others play important role. Our observational result showed that while 68.8% of patients were greeted politely by their health care providers, about two third three and six in ten of the patients were participated in parts of decision making and were advised to comply with their treatment respectively. These interactions were inadequate to provide quality services as a witness studies conducted in West Africa, western and Eastern Europe showed that inadequate communications between providers and patients could lead to rejection of public health facilities and acting as a barrier for TB control activities and its quality of services. (5)

The finding of this study indicated that there was a weak supervision pattern and the supervision pattern was also unplanned, inconsistent and lack feedback. This was against WHO and national recommendations where they recommend strong supportive supervision as part of program communication and quality improvement. (6, 7)

More than half of respondents, 57.4.%, were satisfied in the effectiveness of the treatment provided and 40.2% were dissatisfied with the overall services they received but satisfaction in cleanliness of waiting area, comfortableness of waiting area, waiting time, and adequacy of working hours, in 73.2%, 71.9%, 77.8%, 79.3%, respectively. Different literatures showed that these were among the major areas of dissatisfaction which can lead to service rejections by the patients and defaulting, treatment failure and drug resistances. (14-17).

Finally this study revealed the outcomes of DOTS cure rate is 68.8%, treatment failure is 13.8% the death rate is 4.0%; it is less than Indian and Nigerian study and greater than Tigray and Addis Abeba study and overall First Ethiopian National Population Based Tuberculosis Prevalence Survey. This discrepancy is may be due to sample size and study time deference (8, 11, 12 , 17- 24).

CONCLUSIONS

Input and process quality parameters which were the main determinants of output quality of a program were poor in relative to the 100% requirement of world health organization. Thus, overall quality DOTS was remained low. Availability of AFB trained laboratory professionals, laboratory reagent, use of registration books, flow chart for TB diagnosis, and availability of waiting room for TB patients and accessibility of service were graded poor in quality. Provider- patient interaction, keeping privacy, and supervision of TB clinic were poor. Additionally there was long waiting time observed which can lead to patients' dissatisfaction and failure to adhere to treatment which in turn can lead to service rejection and program failure.

Patients were dissatisfied regarding in cleanliness, comfortableness of waiting area, duration of waiting time, and adequacy of working hours of TB clinic. It is recommended that: The respective health institutions need to provide periodic refreshments on job trainings and develop mechanisms to improve the qualities of staffing. The regional health Bureau, Zonal health office, and health institutions need to facilitate accessibility, and construct TB clinic with standards like having proper waiting room. Regular supervision and follow up of TB programme with proper schedule and feedback need to be practiced by each health institution, zonal health office, and Regional health Bureau as their own concerns. Health professional working in TB clinic should treat TB patients by keeping their own privacy and health professionals working in rural health institutions should be stable and provide quality service. Further advanced researches should be done on the area.

Acronyms and Abbreviations

DOTS   : Directly Observed Treatment Short Course
EPTB   : Extra Pulmonary Tuberculosis
FMOH   : Federal Ministry of Health
FDRE   : Federal Democratic Republic of Ethiopia
GLRA   : German Leprosy &Tuberculosis Control and Relief Association
HC   : Health Center
HW   : Health Worker
ISTC   : International Standards for Tuberculosis Care
PTB   : Pulmonary Tuberculosis
TB/Tb   : Tuberculosis
TLCP   : Tuberculosis and Leprosy Control Program
WHO   : The World Health Organization

Competing interests

The authors declare that they have no competing interests

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