Ejeta et al., General Med 2015, 3:2 DOI: 10.4172/2327-5146.1000176

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# Treatment Outcome of Tuberculosis Patients under Directly Observed Treatment of Short Course in Nekemte Town, Western Ethiopia: Retrospective Cohort Study

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Rec date: Nov 11, 2014 Acc date: April 04, 2015 Pub date: April 07, 2015

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#### **Abstract**

A retrospective study was conducted to assess the treatment outcome of tuberculosis patients enrolled in Directly Observed Treatment Short Course (DOTS) program over the course of five year (2009-2013) in six selected institutions providing DOTS program in Nekemte Town, Western Ethiopia from April to August, 2014. A total of 1175 tuberculosis patients were involved in the study: 14.5% were cured, 56.3% treatment completed, 0.2% was treatment failure, 8.1% were died during follow-up, 7.1% were reported as defaulters and 13.8% were transferred out to another health institution. The overall treatment success rate was 70.8% and show progressive increases over the course of the study. The associated predictors were enrolment years, HIV co-infection, and sputum smear follow up in second, fifth and seven months. Thus, continues follow-up of patients during the course of treatment and providing early detection and follow up for HIV infection need to be strength for improving treatment outcome.

Keywords: Treatment outcome; Tuberculosis; DOTS; Nekemte town

## Introduction

Research Article

Tuberculosis (TB) is one of the major public health problems worldwide. In 2012 alone, there were 8.6 million new cases and 1.3 million deaths globally [1]. It is continued to be the leading cause of death globally despite the availability of reliable diagnostic approaches and effective drugs for over decades [2]. The World Health Organization (WHO) declared TB a global emergency and introduced the Directly Observed Treatment of Short Course (DOTS) strategy for global TB control. In the face of this intensified effort to diagnose and treat TB, the rates in sub- Saharan Africa continue too low [3]. For effective TB control, it is very important to detect the disease as early as possible and to ensure that those diagnosed complete their treatment and get cured [4].

Ethiopia is one of high TB endemic countries in the world where the disease is the leading cause of mortality and morbidity. Ethiopia ranks 9<sup>th</sup> among 22 high TB burden countries and one of the top three in Africa. In 2012, the estimated annual incidence and prevalence of all forms of TB were 230 and 224 per 100,000 populations respectively [1]. A recent population-based survey showed that the prevalence of new sputum smear-positive TB was 174 per 100,000 populations [5].

In Ethiopia, a standardized TB prevention and control program incorporating DOTS was started as a pilot in 1992, at Arsi zone in Oromia region [6]. Then DOTS strategy has been subsequently scaled up and implemented at a national level. Currently, the DOTS geographic coverage has reached 90%, whereas the DOTS health facility coverage is 75% [6].

Understanding of the specific reasons for unsuccessful outcomes under DOTS program is important in order to improve treatment

strategy [7]. In this regard, studies in Ethiopia ranged from 26% to 94% [8-26]. The previous report of the TB defaulter, failure and death rates in Ethiopia ranged from 0.6% to 18.3% [8-18], 0.2% to 18.6% [8-15], and 2.6% to 10.1% [8-10,12,15,16,19,20], respectively. However, treatment outcomes of tuberculosis have not yet studied in western part Ethiopia. Therefore, this study was to assess the treatment outcome and its associated risk factors among TB cases attending DOTS clinics in the last five years (2009-2013) in Nekemte Town, Western Ethiopia.

# Methodology

#### Study design and setting

A five year (2009-2013) retrospective cohort study was conducted to investigate treatment outcomes among TB patients attending TB Clinic under DOTS program from April to May 2014. Study participants were all TB patients attending treatment in the last five year (2009 to 2013) in six randomly selected health institutions in Nekemte Town, Western Ethiopia. The selected health institutions were Nekemte Referral Hospital, Nekemte Health Center, Awash Higher Clinic, National Higher Clinic, Red Cross Clinic and Abdi Clinic. These health institutions were provided DOTS service for the people living in the area. The patients were diagnosed, registered, treated, and referred to other DOTS clinics following the National Tuberculosis and Leprosy Control Program (NTLCP) guideline which adopted from WHO [6].

## Data collection technique

The data were collected from the TB clinic unite registration book review. The Unit Registers reviewed contain basic information such as patient's age, sex, address, category, TB type, drug regimen, date

General Med ISSN:2327-5146 GMO Ejeta E, Chala M, Arega G, Ayalsew K, Tesfaye L, et al. (2015) Treatment Outcome of Tuberculosis Patients under Directly Observed Treatment of Short Course in Nekemte Town, Western Ethiopia: Retrospective Cohort Study. General Med 3: 1000176. doi: 10.4172/2327-5146.1000176

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treatment started, treatment follow-up, follow-up sputum result and treatment outcomes.

#### Definition of forms of TB and treatment outcome

The definition of forms of TB according to the standard definitions of the NLCP [6], adopted from WHO, there are three type of TB considered in this study and defined for the clinical case as follows: The first is Smear-positive pulmonary TB (SPPTB) and it is was identified if a patient had at least two initial sputum smear examinations positive for AFB by direct microscopy, or one initial smear-positive examination for AFB by direct microscopy and a positive culture, or a patient has one initial smear-positive examination for AFB by direct microscope and radiographic abnormalities consistent with active TB as determined by a clinician. The second type was smear-negative Pulmonary TB (SNPTB) and it was characterized by a patient having (1) symptoms suggestive of TB with at least three initial smear-negative examinations for AFB by direct microscopy and no response to a course of broad-spectrum antibiotics; (2) three smear-negative examinations by direct microscopy, and radiological abnormalities consistent with pulmonary tuberculosis, and decision by a clinician to treat with a full course of anti-tuberculosis; or (3) a diagnosis based on a positive culture for Mycobacterium tuberculosis after three initial smear-negative examinations by direct microscopy. The third type was Extra pulmonary TB (EPTB). In this case TB occurs in organs other than the lungs, proven by one positive-culture from specimens of an extrapulmonary site or histo-pathological evidence from a biopsy, or TB based on strong clinical evidence consistent with active EPTB and the decision by a physician to treat with a full course of anti-TB therapy.

Treatment outcome were categorized and defined according to NTLCP [6] guidelines as follows: Cured (a patient who was initial sputum smear-positive and who was finished treatment with negative bacteriology result at the end of treatment or sputum smear negative on two occasions at the end of treatment), Treatment completed (a patient completed treatment but did not meet the criteria for cure or failure. This definition applies to sputum smear-positive and sputum smear-negative patients with pulmonary TB and to patients with EPTB), Died (a patient died from any cause during treatment time), Failed (a patient was initially sputum smear-positive and when a

patient remained bacteriology or sputum smear-positive at month 5 or later during treatment), Defaulted (a patient whose treatment was interrupted for 2 consecutive months or more). Transferred out (a patient referred to another health facility for treatment in whom information on treatment outcome cannot be obtained), and successfully treated (a patient who was cured and/or completed treatment, or sum of cases that were cured and completed treatment).

### Data analysis

Statistical analyses were performed using SPSS version 20 statistical software where the results were presented using descriptive statistics tool in the tables and figures. The association and strength between the dependent (treatment outcome) and independent variables (address, age and sex of study participants, year of study, forms of TB, HIV test result and Patient categories) were assessed using binary and multiple logistic regression models at 95 confidence interval.

#### **Ethical consideration**

The study design and procedures were approved by the Institutional Research Ethical Review Board of Wollega University. Official permission was also obtained from respective institutions administration office. The anonymity was warranted for all record reviewed.

#### Results

A total of 1175 TB patients were registered in the last five years in our study area, of which 638 (54.3%) were males. Most of the patients were urban residents 1004 (85.4%) and within 15-44 ages range 898 (76.4%). The patients had a mean, standard deviation and median age of 29.9 13.99 and 26.00 respectively. In terms of patients' categories, 1070 (91.1%) patients were registered as new cases and (2%) as transfer in patients. In total, 239 (20.3%) patients were registered as pulmonary positive, 466 (39.7%) as pulmonary negative and 466 (39.7%) as EPTB patients. Two hundred one 201 (17.1%) of the TB cases were co-infected with HIV. The frequency of all form of TB is increasing from 82 to 276in the last five year with peak at 2011 (Table 1).

Character		Type of TB n (%)	Total n (%)		
		SPPTB	SNPTB	ЕРТВ	
Address	Urban	216 (18.4)	401(34.1)	387(32.9)	1003(85.4)
	Ruler	27(2.3)	65(5.5)	79(6.7)	171(14.6)
Sex	Male	143(12.2)	263(22.4)	232(19.7)	637(54.3)
	Female	100(8.5)	203(17.3)	234 (19.9)	537(45.7)
Age	0-14	3(3.6)	24(2.0)	57(4.9)	84(7.2)
	15-24	107(26.0)	150(12.8)	155(13.2)	411(35.0)
	25-34	74(24.7)	107(9.1)	119(10.1)	300(25.6)
	35-44	35(18.9)	78(6.6)	72(6.1	185(15.8)
	45-54	12(11.8	55(4.7)	35(3.0)	102(8.7)

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	55-64	9(15.5	30(2.6)	19(1.6)	58(4.9)
	>=65	3(8.8)	22(1.9	9(0.8)	34(2.9)
TB Patient category	New	213(18.1)	435 (37.1)	436(37.2)	1071(91.1)
	Relapse	9(.8)	2(0.2)	0(0.0)	11(.9)
	Treatment failure	1(0.1)	0(0.0)	0(0.0)	1(.1)
	Default	0(0.0)	4(0.3)	1(0.1)	5(.4)
	Transfer in	9(0.8)	8(0.7)	7(0.6)	24(2.0)
	Unknown	11(0.9)	17(1.4	22(1.9)	63(5.4)
HIV test result	Reactive	44(3.7)	95(8.1)	62(5.3)	201(17.1)
	Non-reactive	188(16.0)	348(29.6)	388(33.0)	924 (78.6)
	Unknown	11(0.9)	23(2.0)	50(1.4)	84(4.3)
Total		243(20.7)	466 (39.7)	466(39.7)	1175(100)

**Table 1:** Characteristics of TB patients in in the selected health institutions providing DOTs services in Western Ethiopia from 2009-2013. SPPTB: smear positive pulmonary TB, SNPTB: Smear negative pulmonary TB, EPTB: Extra pulmonary TB, n: frequency.

## **Treatment outcomes**

Out of 1175 TB patients registered in the last five years, 170 (14.5%) were cured, 662 (56.3%) were treatment completed treatment, 95 (8.10%) during follow-up died, 2 (0.20%) were treatment failure, 84 (7.1%) were defaulted, and 162 (13.8%) transferred out to another health institutions. The trends of cure case has shown steady increased from 2 (0.20%) to 43 (3.70%) in the last five year, and also the death

rate has shown a remarkable increased (0.30%) to (1.70%). However, the defaulters' rate was declined from 37% to 8% in 2009-2013 with exception of 2011 that were exhibited 26.2% (Table 2).

On the other hand, transfer out rate of TB patients progressively increases from 14 (1.20%), 28 (2.40%), and 62 (5.30%) in 2009, 2010 and 2011 respectively. And then declining from 45 (3.80%) to 13 (1.10%) in 2012 to 2013 (Table 2).

Character		Treatment outcome n (%)						
		Cured	Treatment Completed	Died	Treatment failure	Default	Transferred out	
Address	Urban	155(13.2)	558(47.5)	82(7.0	2(0.2)	68(5.8)	139(11.8)	1003(85.4)
	Ruler	15(1.3)	104(8.9)	13(1.1)	0(0)	16(1.4)	23(2.0)	171(14.6)
Sex	Male	101(8.6)	339(28.9)	52(4.4	1(0.1)	51(4.3)	94(8.0)	637(54.3)
	Female	69(5.9)	323(27.5)	43(3.7)	1(0.1)	33(2.8)	68(5.8)	537(45.7)
Age	0-14	2(0.2)	65(5.5)	3(0.3)	0(0)	9(0.8)	5(0.4)	84(7.2)
	15-24	75(6.4)	211(18.0)	23(2.0)	1(0.1)	24(2.0)	78(6.6)	411(35.0)
	25-34	49(4.2)	168(14.3)	18(1.5)	1(0.1)	24(2.0	40(3.4)	300(25.6)
	35-44	24(2.0)	106(9.0)	27(2.3	0(0)	14(1.2)	14(1.2)	185(15.8)
	45-54	9(0.8)	62(5.3)	15(1.3	0(0)	5(.4)	11(0.9)	102(8.7)
	55-64	8(0.7)	31(2.6	7(0.6)	0(0)	3(0.3)	9(0.8)	58(4.9)
	>=65	3(0.3)	19(1.6)	2(0.2)	0(0)	5(0.4)	5(0.4)	34(2.9)
TB Patient	New	151(12.9)	612(52.1)	88(7.5	2(0.2)	74(6.3)	144(12.3)	1071(91.1)
category -	Relapse	7(0.6)	0(0)	1(0.1)	0(0)	1(0.1)	2(0.2)	11(.9)
	Treatment failure	0(0)	0(0)	0(0)	0(0)	0(0)	1(0.1)	1(.1)

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	Default	0(0)	3(0.3)	0(0)	0(0)	0(0)	2(0.2)	5(.4)
	Transfer in	5(0.4)	17(1.4)	0(0)	0(0)	0(0)	2(0.2)	24(2.0)
	Other	7(0.6)	20(1.7)	4(0.3)	0(0)	8(0.7)	11(0.9)	63(5.4)
HIV test result	Reactive	32(2.7)	90(7.7)	35(3.0)	19(0.1)	20(1.7)	23(2.0)	201(17.1)
	Non-reactive	133(11.3)	551(46.9)	54(4.6)	1(0.1)	57(4.9)	128(10.9)	923(78.6)
	Unknown	5(0.4)	21(1.8)	6(0.5)	0(0)	7(0.6)	11(0.9)	50(4.3)
Treatment	NRH	38(3.2)	173(14.7)	37(3.1)	1(0.1)	9(.8)	49(4.2)	307(26.1)
centers	NHC	101(8.6)	339(28.9)	46(3.9)	1(0.1)	59(5.0)	85(7.2)	631(53.7)
	nhc	13(1.1)	66(5.6)	5(0.4)	0(0)	8(0.7)	19(1.6)	110(9.4)
	AHC	12(1.0)	59(5.0)	6(0.5)	0(0)	1(0)	6(0.5)	84(7.2)
	RCC	0(0.0)	6(0.5)	0(0)	0(0)	2(0.2)	1(0.1)	9(0.8)
	Abdi Clinic	6(0.5)	19(1.6)	1(0.1)	0(0)	5(0.4)	2(0.2)	33(2.8)
Year	2009	2(0.2)	26(2.2	3(0.3)	0(0)	37(3.1)	14(1.2)	82(7.0)
	2010	39(3.3	91(7.7)	19(1.6)	1(0.1)	6(0.5)	28(2.4)	184(15.7)
	2011	40(3.4)	177(15.1)	26(2.2)	1(0.1)	22(1.9)	62(5.3)	328(27.9)
	2012	46(3.9)	176(15)	27(2.3)	0(0)	11(0.9)	45(3.8)	305(26.0)
	2013	43(3.7)	192(16.3)	20(1.7)	0(0)	8(0.7)	13(1.1)	276(23.5)
Total	Total		662(56.3)	95(8.1)	2(0.2)	84(7.1)	162(13.8)	1175(100)

**Table 2:** Treatment outcomes of TB patients in from 2009-2013. NRH: Nekemte Referral Hospital, NHC: Nekemte Health Center, AHC: Awash higher clinic, nhc: National Higher Clinic, RCC: Red Cross Clinic, n: frequency.

## Treatment success rate and its predictors

The overall treatment success rates in the last five year were 70.8%. The success rate shows progressive increases in the last five years. On other hand, the unsatisfactory treatment success showed slight increase from 15.7% to 32.4% from 2009 to 201 but exhibited dramatic decline in 2012, and 2013.

In bivariate analysis, forms of TB, patient category, year of treatment, and smear result and follow up at second, fifth and seventh

month were significantly associated with treatment success rate. However, addresses, sex, age range, form of TB and treatment center were not significantly associated. Controlling the effect of confounding factors, HIV sero status, year of treatment, and sputum conversion rate and follow up at second, fifth and seventh month is predicator factor that affect the treatment success rate (Table 3).

Variables		Treatment Outcon	ne, n (%)	Crude odd ratio (95% CI)  Adjusted odd ratio (95%		
		Success	Un-success		-	
Patient categories	New	762(64.9)	308(26.2)	0.574(0.342-0.965)*	.676(.373-1.22)	
	Relapse	7(0.6)	4(0.3)	0.813(0.216-3.065)	3.12(.56-17.30)	
	Return after default	3(0.3)	2(0.2)	0.949(0.148-6.083)	.805(.118-5.493)	
	Transfer in	22(1.9)	2(0.2)	0.129(.028599)*	.261(.052-1.304)	
	other	37(3.1)	26(2.2)	1.00	1.00	
HIV test result	Reactive	122(14.7)	79(23)	1.845(1.341-2.539)*	1.986(1.398-2.822)*	
	Un recorded	26(3.1)	24(7)	2.631(1.482-4.670)*	2.236(1.191-4.199)*	

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		T	I		
	Nonreactive	684(82.2)	240(70)	1	1
Year	2009	28(3.4)	54(15.7)	11.05(6.28-19.434)*	11.06(6.048-20.24)*
	2010	130(15.6)	54(15.7)	2.381(1.504-3.768) <sup>*</sup>	2.54(1.576-4.10)*
	2011	217(26.1)	111(32.4)	2.932(1.960-4.387)*	2.637(1.734-4.012)*
	2012	222(26.7)	83(24.2)	2.143(1.413-3.251)*	2.16(1.407-3.324)*
	2013	235(28.2)	41(12)	1.00	1.00
Sputum smear results	Positive	2(0.2)	2(0.2)	8.76(1.172-65.47) <sup>*</sup>	4.278(.104-176.6)
at 2nd month	Not done	646(55.0)	320(27.2)	4.34(2.71-6.951)*	.399(.178892)*
	Negative	184(15.7)	21(1.8)	1	1
Sputum smear results	Positive	0(0)	1(0.1)		
at five month	Not done	661(56.3)	334(28.4)	10.8(5.25-22.213)*	4.75(1.052-21.495)*
	Negative	171(14.6)	8(0.7)	1	1
Sputum smear results	Positive	0(0)	1(0.1)		
at seven month	Not done	662(56.3)	337(28.7)	17.3(7.044-42.526)	9.66(2.04-45.745)*
	Negative	170(14.5)	5(0.4)	1	1
Address	Urban	713(85.7)	291(84.8)	0.934(0.656-1.330)	
	Rural	119(14.3)	52(15.2)	1.00	
Sex	Male	440(52.9)	198(57.7)	1.217(0.944-1.568)	
	Female	392(47.1)	145(42.3)	1.00	
Age rang	0-14	67(8.1)	17(5.0)	0.465(0.193-1.124)	
	15-24	286(34.4)	126(36.7)	0.808(0.388-1.683)	
	25-34	217(26.1)	83(24.2)	0.701(0.332-1.481)	
	35-44	130(15.6)	55(16)	0.776(0.359-1.677)	
	45-54	71(8.5)	31(9)	0.800(0.352-1.818)	
	55-64	39(4.7)	19(5.5)	0.893(0.66-2.179)	
	>=65	22(2.6)	12(3.5)	1.00	
Forms of TB	PTB+	182(21.9)	57(16.6)	0.157(0.014-1.759)	
	PTB-	321(38.6)	146(42.6)	0.227(0.020-2.528)	
	ЕРТВ	328(39.4)	138(40.2)	0.210(0.019-2.339)	
	Un recorded	1(0.1)	2(0.6)	1.00	
Treatment center	NRH	211(25.4)	96(28)	1.422(0.619-3.267)	
<del></del>	NHC	440(52.9)	191(55.7)	1.357(0.601-3.062)	
	nhc	79(9.5)	32(9.3)	1.266(0.517-3.100)	
	AHC	71(8.5)	13(3.8)	0.572(0.212-1.542)	
	RCC	6(0.7)	3(0.9)	1.562(0.316-7.726)	

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Abdi Clinic	25(3.0)	8(2.3)	1.00	

**Table 3:** Factors associated with treatment success rate of TB patients in Western Ethiopia, 2009-2013. \*Statistical significance (P<0.05), 1:00: Reference group, NRH: Nekemte Referral Hospital, NHC: Nekemte Health Center, AHC: Awash higher clinic, nhc: National Higher Clinic, RCC: Red Cross Clinic, n: frequency.

## Discussion

The present retrospective cohort study assesses the treatment outcome and its associated risk factors of TB patient in the last five year (2009-13) in Western Ethiopia. A total of 1175 TB patients were registered in DOTs program of which 637 (54.3%) were males. This consistent with other studies at South Ethiopia [10] and Gambella Regional Hospital [24] in which 55.8% and 54.5% patients were males respectively, but in contrary to study done in Kolla Diba Health

Center and Addis Ababa, 51.3% [16] and 53.2% [25] of the registered TB patients in these studies were females, respectively.

In agreement with the previous studies conducted in South Ethiopia [10], KollaDiba Health Center [16], Gambella Regional Hospital [24] and Addis Ababa [25], 76.4% of the registered TB patients in this study were from the productive age group. This might indicated the negative impact of TB on the socio-economic condition of the society.

In this study, EPTB patients constituted the prevailing form of TB (39.7%). It is also the dominate (66.1%) form of TB among HIV sero-reactive patients which is similar with the study done in Addis Ababa [25] where 40.5% was reported and different part of the countries [27,28]. In the present study, the prevalence of HIV among TB patients was 17.1% which is higher than previous study which was done in Northern part of Ethiopia, KollaDiba Health Center, North Gondar Zone Prison, and Enfraz Health Center, 11.5% [14], 10.9% [16], 12.4% [22] and 11.7% [23] were reported respectively. However, the present study TB-HIV co-infection was lower than previous reports from different health centers in Addis Ababa, Gondar University Hospital, and Felege Hiwot Referral Hospital, 27.2% [21], 52.1% [26], and 25% [15], respectively. The present observation difference between TB-HIV co-infection was partly due to local HIV prevalence difference in different parts of the country.

The overall treatment success rate was 70.8% that is higher than the studies done in southern Ethiopia and Gambella Regional Hospital, 49% [10] and 63.4% [24] respectively, but lower than study done in Addis Ababa (82.7%), Kolla Diba Health Center (85.6%), Enfraz Health Center and nationwide success rate in Ethiopia, 82.7% [25], 85.6% [16], 94.8% [23] and 85% [6], respectively. As well as the average treatment success (83%) rate of 22 high burden countries [29]. This difference elucidated by high unrecorded rate in south Ethiopia and, high rate of transfer out and unrecorded rate in the present study. The observed progress in the trend of treatment success from 2009 through 2013 in the current study was similar to the findings of the study in South Ethiopia [10], Addis Ababa [25], and Enfraz Health Center [23]. This progress may be partly explained by the improvement in the diagnosis of the diseases and expansion of health institution.

The overall default rate in the current study was 7.1% which was higher than the average (6.20%) observed among the 22 high burden countries [25] but lower than previous study done in Gambella Regional Hospital and the rural households in Northwest Ethiopia, 22.9% [24] and 10% [30], respectively. The default rate of TB patients

decreasing across years in this study was in contrary to study done in Gambella Regional Hospital [24]. The observable difference in default rate and trend in the study area might be due to the valuable effect of DOTs, increasing of patients' awareness on infectious diseases, satisfaction with the health provider and expansions of health institutions in the country which can alleviate the effects of distance on treatment outcomes as illustrated by pervious study on determinate of defaulter [30-33].

The overall death rates were 8.10% in this study. This was higher than the study done in Addis Ababa and Gambella Region Hospital, 3.70% [25] and 3.60% [24] respectively. In addition, the death rate had shown a progressive increased 0.30% to 1.70% over the study period. The observable difference might be due to weak smear result follow up and defaulter tracing mechanism where 44.5% patient had not smear result follow up record in second, fifth and seventh months.

In the study, the controlling effect of confounding factors, HIV sero status, year enrolment and sputum conversion rate and smear result follow up at second, fifth and seventh month is predator factor that affect the treatment success rate. This could be observed by effect of smear result follow up on treatment success and effect of HIV on clinical presentation and prognosis of the TB disease treatment.

Apart from such important findings, this study is not without limitation. As common for secondary data studies, important variables had not been recorded for about 44.5% and 4.30% for smear result follow up and treatment outcome, respectively.

# Conclusion

The present study showed that treatment outcome of TB patients that attended TB treatment at the study area was unsatisfactory as they didn't meet the target success rate set by WHO. The predictors identified for unsuccessful rate were HIV sero status, year enrolment and smear result follow up at second, fifth and seventh month. These predictors are in line with WHO recommendation for DOTs program. Thus, continuous follow-up of patients with frequent supportive supervision during the course of treatment and providing early detection and follow up for TB-HIV co-infection need to be strengthened for effective treatment outcome.

## Acknowledgements

The authors would like thank the Teams of TB clinic at Nekemte Referral Hospital, Nekemte Health center, Awash Higher Clinic, National Higher Clinic, Red Cross Clinic and Abdi Clinic for the help rendered during the study period. Wollega University is also gratefully acknowledged for logistic support for the data collection and process.

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