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Assessment of Tuberculosis Treatment Outcome and Its' Associated Factors Among Tuberculosis Patients Treated Under Directly Observed Treatment Short Course Service in Health Facilities at Adama Town, Central Oromia, Ethiopia

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ABSTRACT

Introduction: Tuberculosis is a serious public health problem in the developing countries. Assessment of tuberculosis treatment outcomes and its risk factors in directly observed treatment short course are among the major indicators of the performance of a national TB control program. Therefore; this study was undertaken to assess tuberculosis treatment outcome and its' associated factors among patients treated under Directly Observed Treatment Short Course in health facilities at Adama Town, Central Oromia, Ethiopia from March 1st 2016 G.C. to December 31/2016 G.C. Method: A cross sectional study was conducted in seventeen health facilities which initiated treatment and provided DOTs service at Adama Town. The data was collected using structured questionnaire and pre-developed data collection sheets by interviewing when the entire study participants were on treatment, then after the evaluation of patient by reviewing the record of TB treatment registration log book. A total of 281 study participants who fulfilled the inclusion criteria were included in the study. The data were entered and analyzed using SPSS 20 computer software. Result: A total of 227 (80.8%) patients had satisfactory treatment success rate in the study area. The odds of unfavorable treatment outcome was 81% (AOR: 0.19, 95% CI: 0.04 -0.87) less among patients 15-24 years of age compared to patients younger than 14 years of age. Females had 74% lower rates of successful treatment outcome (AOR: 0.26, 95% CI: 0.11-0.56) compared to male patients. However, patients who had lower distance than five kilometer for the health facilities had 3.87 times more likely to have favorable treatment outcome (AOR: 3.87, 95% CI: 1.83-8.29). HIV negative patients also had 20 times more likely to have favorable treatment outcome than HIV patients co-infected with TB (AOR: 20.35, 95%CI: 7.73-53.63). Patients with bacteriologically confirmed pulmonary TB infection had 55% less likely to have favorable treatment outcome than clinically diagnosed TB cases (AOR: 0.45, 95% CI: 0.21-0.98). Conclusion and Recommendation: Finally this study showed that treatment success rate is less when compared to WHO stated target to be achieved in End TB Strategy. Therefore; it is important to focus on treatment adherence to improve favorable TB treatment outcome and consider DOTs service which is accessible to all clients. Keywords: Cure rate, treatment complete, favorable treatment outcome DOI: 10.7176/JMPB/52-04

INTRODUCTION

Tuberculosis is caused by Mycobacterium Tuberculosis. It is transmitted from active cases to susceptible host through air when infectious person coughs or sneezes. Directly Observed Treatment of Short course (DOTs) is treatment strategy where the treatment is given under the direct supervision of a health worker. The treatment has now been standardized by putting patients into treatment regimen. The treatment of the patients in the program depend on patient category (new and retreated) (1, 2, 3, 5).

The World Health Organization defines that the TB treatment outcome of the patient can be cured, treatment complete, lost to follow up ,died, treatment failure, moved to DR TB register and not evaluated; the success rate is measured by number of cured and treatment complete (1,2).

The WHO has set a target for a treatment success rate of 90 % for all forms of TB cases for 2016 in end TB strategic plan (5). The main objective of TB treatment is to cure the patient of TB, prevent death from active TB or its late effects; prevent relapse of TB; decrease transmission of TB to others and prevent the development of drug resistance TB (1, 2, 6).

Different studies confirmed that comorbid with HIV, age, sex, residence area, distance from the treatment initiating center, and category of TB were associated factors for unsuccessful treatment success rate (3). On the other way poor standardized TB treatment and patient adherence are the other major contributing factors for development of drug resistant TB in the community (4). Hence, assessing favor factors for poor treatment outcome is a great important for success of TB infection control program in Ethiopia. Tuberculosis is one of the leading

infectious causes of death globally. Approximately one third of the world's population is infected with TB bacilli and at risk of developing active TB (9). According to WHO report 2015, worldwide, 9.6 million people are estimated to have fallen ill with TB in 2014: 5.4 million men, 3.2 million women, and 1.0 million children. Globally, 12% of the 9.6 million new TB cases in 2014 were HIV-positive. TB is one of the world's biggest threats, in 2014, TB killed 1.5 million people (1.1 million HIV-negative and 0.4 million HIV-positive). The toll comprised 890,000 men, 480,000 women and 140, 000 children. TB now ranks alongside HIV as a leading cause of death worldwide (7). Also it is the leading cause of morbidity, the third cause of hospital admission, and the second cause of death in Ethiopia (8, 9). According to WHO 2014 and 2015 report, the prevalence and incidence of all forms of TB are 211 and 224 per 100,000 of the population, respectively. Ethiopia is one of the 22 high burden countries (7).

According to Global TB report 2016, the incidence of TB is estimated to 192/100K population, mortality rate (HIV negatives) is 26/100K populations, HIV co-infection rate among notified TB patients is 8% and TB is among top ten leading causes of inpatient mortality, also the drug resistant TB cases diagnosed was 2.7% among new cases and 14 % among previously TB cases (8).

Drug-resistant TB is a growing challenge in response to TB. It is a man-made problem, largely as a result of individual or combination of factors related to management of drug supply, patient management, prescription of chemotherapy, and patient adherence that causes poor treatment success rate (10).

Generally a good treatment outcome is an indicator for the quality of TB treatment provided by a health care system. Ideally, treatment outcome in all patients should be routinely monitored by the epidemiological surveillance system. However, most studies done on treatment outcome of TB patients shows age, sex ,knowledge of TB, family size, residence area, distance from the treatment indicating center and HIV Co-morbid were the major contributing factors for poor treatment outcome. But most of these studies methods were only retrospective in Ethiopia. Hence, this study is needed to assess TB treatment outcome and its' associated factors among TB patients treated under DOTs services prospectively. The finding of this study will help program implementers to improve the prevention and control of TB to achieve the global target and national set in End TB Strategy. And will have significant implications for strengthening favorable treatment outcome. In addition, it will also assist the regional TB control program coordinators, Adama Town Administration Health Office and health institutions in decision-making and planning for future time. To conceptualize this study socio demographic, patient factor and disease factors are framed as follows:-



Figure 1: Conceptual framework of factors associated with TB treatment outcome.

METHODS AND MATERIALS

The study was conducted at Seventeen health facilities located in Adama Town which is found in central Oromia

Regional State, Eastern Ethiopia. An institutional based cross sectional study was conducted to assess TB treatment outcome and its' associated factors among TB patients treated under DOTs services. The sample size was determined by considering all Patients registered at the beginning of the study in 4 Hospital, 5 Health center and 8 private clinics were included during the study period which was 281.

A cross sectional institutional based data were collected using checklist by seventeen diploma /level IV nurses (focal person of TB assigned on TB clinic) after one day training on the objective of the study and data collection instrument and procedure. The socio demographic data which was not on TB unit register book (Educational status, occupation, distance from treatment center, income family size, religion) was collected from the study participant when they are on treatment and the record review was collected after the evaluation of the patient from TB unit register book. Two supervisors were assigned for checking the completeness and consistency of the collected data and corrected the problem if occurs during the time of data collection.

The data were entered into SPSS statistical software for analysis. The distribution of the variables was explored and data cleaning was performed to identify outliers/inconsistence, errors and missing values. Descriptive statistics were computed to get summary values. Variables found statistically significant under bivariate analysis at a p value less than 0.25 were identified and the candidate variables were entered into multivariate logistic regression analysis to the see independent effect of the variable on the outcome variable and Odds ratio (OR) with 95% confidence interval (CI) for each variables of interest was reported and p value less than 0.05 was considered as statistically significant for all the independent variables in the model.

Definition of terms:

DOT strategy: It is a new WHO protocol treatment regimen that put the patients under direct observation for the treatment of TB.

Extra pulmonary TB: TB which involve other organ except the lungs.

Pulmonary TB smear positive: A patient with at least one sputum specimens which are positive for AFB by microscopy.

Bacteriological Confirmed: - A patient with at least one sputum specimens which are positive for AFB by microscopy or positive for AFB in Genxpert or culture test.

Pulmonary TB- smear negative: A patient with symptoms suggestive of TB with at least two sputum specimens who were negative for AFB by microscopy and no improvement after tried by broad spectrum antibiotic and with chest radiographic abnormalities consist with active PTB.

Drug-resistant TB (DR-TB): It is a general term used to describe a strain of MTB that is resistant to one or more first line anti-TB drugs.

New case (N): A patient who has never had treatment for TB or has been on ant-TB treatment for less than four weeks.

Relapse (R): A TB patient who have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB.

Treatment after Failure (F): Treatment after failure patients are those who have previously been treated for TB and whose sputum was positive at the end of five or later.

Treatment after loss to follow-up (L): Patients who have previously been treated for TB for more than one month and stops treatment for more than eight weeks and were declared lost to follow-up at the end of their most recent course of treatment.

Transfer in (T): A patient who started treatment in one reporting unit and transferred to another reporting unit to continue the treatment.

Other previously treated patients (O): Are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

Treatment outcome: It is the result obtained after the initiation of the treatment of TB (cured, treatment complete, treatment failure, died, Lost to follow up, Not evaluated, Moved to MDT –TB Register).

Treatment completed: A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.

Cured: A patient whose sputum smear or culture was positive at the beginning of the treatment but who was smear or culture-negative in the last month of treatment and on at least one previous occasion

Treatment success: Defined as cure or A patient whose sputum smear or culture was positive at the beginning of the treatment but who was smear- or culture-negative in the last month of treatment and on at least one previous occasion plus treatment completion without confirmation by smear microscopy cured or complete treatment.

Treatment failure (F): A patient whose sputum smear or culture is positive at 5 months or later during treatment or Patients found to harbor a drug-resistant (DR) strain at any point of time during the treatment, whether they are smear-negative or -positive.

Died: A TB patient who dies for any reason before starting or during the course of Treatment

Lost to follow up: A TB patient who was treated at least for one month and whose treatment was interrupted for

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two consecutive months or more and declared lost follow up in their recent treatment out-come.

Not evaluated: A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.

Moved to DR: A patient who has been diagnosed as having DR-TB as per the national guideline prior to being declared as' Failure' and is placed on MDR-TB TB treatment.

Favorable treatment outcome: Cured and treatment completed.

Unfavorable treatment outcome: Lost to follow up, Died, Treatment Failure, moved to DR, Not evaluated

RESULTS

Socio-Demographic Characteristics: A total of 281 TB patients were registered at Adama Town in 6 public,10 private and 1 NGO health facilities among which 157(55.9%) were males and 124 (44.1%) were females; and 171(60.9%) were urban residents. More than one third (39.9%) of the patient were in the age group 25-34 with the mean age of 32.4 years. Nearly half (48.8%) were daily laborers, more than half (59.4%) earn a monthly income of less than 600 ETB. Nearly two-third (62.5%) of the respondents was at a distance of 5km or more from the Health facilities. About half (47.7%) respondents attended primary education. Concerning contact person 272 (96.8%) of the respondents have contact person from which 256 (91.1%) of them register their family members as contact person (Table 1).

Socio demographic variables	Characteristics	Frequency	Percent
Age	>5yrs	4	1.4
	>14yrs	13	4.6
	15-24	102	36.3
	25-34	112	39.9
	≥35year	50	17.8
Sex	Male	157	55.9
	Female	124	44.1
Residence	Urban	171	60.9
	Rural	110	39.1
Occupation	Employed	31	19
1	Merchant	68	24.2
	Farmer	34	12.1
	Daily laborer	137	48.8
	Others	11	1.1
Income per month	Less than 600	167	59.4
1	600-1000	21	7.5
	1001-15000	29	10.3
	1501-2000	42	14.9
	2001-25000	12	4.3
	2501-3000	1	0.4
	3001-3500	5	1.8
	3501 and above	4	1.4
Distance from treatment center	\leq 5km	121	43
	5km above	160	57
Educational status	No formal education	67	23.8
	Primary school	134	47.7
	Secondary & Above	80	28.5
Family size	< 5	79	32.2
<u>,</u>	Above 5	202	71.9
Contact person	HEW	7	2.5
<u>r</u>	Health care worker	4	1.4
	Family member	256	91.1
	Self	5	1.8

Table 1: Socio demographic characteristics of TB	patient who completed treatment at Adama Town health
facilities, Central Oromia, Ethiopia from March 1st to	o December 31/2016.

Category of TB: - In case of category of TB 121 (43.1%) were bacteriologically confirmed pulmonary TB, 86 (30.6%) were clinically diagnosed Pulmonary Negative TB and the rest 74 (26.3%) were Extrapulmonary TB. **HIV Status of the respondents**: - From the total patients registered during the study period, 276 of were tested for HIV and greater part (86.8%) of the respondents were non-reactive for HIV. Thirty five (12.4%) were TB/HIV co-infected.

Treatment outcome:-The treatment outcome of TB patients was assessed. Accordingly, 90 (74.4%) were Cured,

137(48.8%) have completed the treatment, 4(1.4%) were treatment failure, 14(5%) were lost to follow up, 14(5%) were died and 22 (7.8%) were not evaluated. The overall treatment success rate was (80.8%). Also when evaluated by category of TB, Bacteriologically confirmed TB patient 90(74%) were Cured, 13(10.8%) treatment their complete, 4(3.3%) were treatment Failure, 2(1.6%) were lost to follow up, 2(1.6%) were died and 9 (3.3%) were not evaluated. From clinically diagnosed Pulmonary Negative 66(76.7%), complement their treatment, 7(8%) were lost follow up, 6(6.9%) were not evaluated, and Extra pulmonary TB 57(77\%) complement their treatment 5 (6.8%) were lost to follow up, 6(5.4%) were died, 4(5.4%) were not evaluated.

Factors associated with treatment outcome: - Logistic regression was employed to assess socio-demographic variables including age, sex, Residence, distance from treatment center, HIV status, Educational status, occupation, category of TB.

In bivariate analysis, sex, distance from health from the treatment center, residence, knowledge of TB, category of TB and HIV status were associated with treatment outcome. Females had 67% lower rates of successful treatment outcome (COR: 0.33, 95% CI: 0.17, 0.65) compared to male patients. Patients from urban area were about 2 times more likely to have favorable treatment outcome than patients from rural area (COR: 1.90, 95%CI: 1.05, 3.47). Patients who walked for less than five kilometers to the treatment center are 3.71 times more likely to have favorable treatment outcome than those who are far from the treatment center for more than five kilometers (COR: 3.71, 95% CI: 1.97-6.99). HIV negative patients were about 16 times more likely to have favorable treatment outcome than HIV patients co-infected with TB (COR: 15.71, 95%CI: 6.99, 35.29). Patients with bacteriologically confirmed pulmonary TB infection had 51% less likely to have favorable treatment outcome than clinically pulmonary TB and extra pulmonary TB (COR: 0.49, 95%CI: 0.26, 0.93).

Table 2. Bivariate Logistic regression analysis of factors associated with treatment outcome among TB patients at Adama Town health facilities, Central Oromia, Ethiopia from March 1st to December 30/ 2016

Characteristics	TB Treatment outcome		COR	P-Value
	Favorable	Unfavorable	95% CI	
	N (%)	N (%)		
Age				
< 15	12(70.6)	5(29.4)	1.00	
15 - 24	90(88.2)	12(11.8)	0.32(0.09,1.07)	0.06
25 - 34	87(77.7)	25(22.3)	0.69(0.22,2.14)	0.52
\geq 35	38(76.0)	12(24.0)	0.76(0.22,2.59)	0.66
Sex				
Male	116(73.9)	41(26.1)	1.00	
Female	111(89.5)	13(10.5)	0.33(0.17,0.65)	0.001
Residence				
Urban	145(84.8)	26(15.2)	1.00	
Rural	82(74.5)	28(25.5)	1.90(1.05,3.47)	0.035
Distance from HF				
>5 Kms	84(69.4)	37(30.6)	3.71(1.97,6.99)	< 0.001
≤5 Kms	143(89.4)	17(10.6)	1.00	
Education				
No formal Education	53(79.1)	14(20.9)	1.36(0.59,3.14)	0.47
Primary Education	107(79.9)	27(20.1)	1.30(0.63,2.69)	0.48
Secondary & Above	67(83.8)	13(16.2)	1.00	
Occupation	. ,	· · ·		
Employee	28 (93.3)	2(6.7)	1.00	
Merchant	54(85.7)	9(14.3)	2.33(0.47,11.54)	0.29
Farmer	22(78.6)	6(21.4)	3.18(0.70,20.79)	0.12
Daily laborer	114(76.0)	36(24.0)	4.42(1.00,19.47)	0.04
Others*	9(90.0)	1(10.0)	1.55(0.13,19.24)	0.73
Category of TB				
Bacteriological	105(86.6)	16(13.2)	0.49(0.26,0.93)	0.028
Clinical	122(76.2)	38(23.8)	1.00	
HIV Status		· /		
Reactive	11(31.4)	24(68.6)	15.71(6.99,35.29)	< 0.001
Non-reactive	216(87.8)	30(12.2)	1.00	
* Students, Daily laborers	. ,	· · /		

In the multivariate analysis, the treatment outcome was varied with age, sex, distance from HF, category of TB and HIV status. The odds of unfavorable treatment outcome was 81% (AOR: 0.19, 95% CI: 0.04, 0.87) times less among patients 15-24 years of age compared to patients younger than 14 years of age. Females had 74% lower

rates of successful treatment outcome (AOR: 0.26, 95% CI: 0.11, 0. 56) compared to male patients. Patients were 3.87 times more likely to have favorable treatment outcome if they had to walk for less than five kilometers to the treatment center than those who are far from the treatment center for more than five kilometers (AOR: 3.87, 95% CI: 1.83,8..29). HIV negative patients were about 20 times more likely to have favorable treatment outcome than HIV patients co-infected with TB (AOR: 20.35, 95% CI: 7.73, 53.63). Patients with bacteriologically confirmed pulmonary TB infection had 55% less likely to have favorable treatment outcome than clinically pulmonary TB and extra pulmonary TB (AOR: 0.45, 95% CI: 0.21, 0.98) (Table.4).

Table 3. Multivariable logistic regression analysis of predictor variables of treatment outcome among TB patients at Adama Town Health facilities, Central Oromia, Ethiopia from March 1st to December 30/ 2016.

Characteristics	TB Trea	TB Treatment outcome		P-Value
	Favorable	Unfavorable	95% CI	
	N (%)	N (%)		
Age				
< 15	12(70.6)	5(29.4)	1.00	
15 - 24	90(88.2)	12(11.8)	0.19(0.04,0.87)*	0.032
25 - 34	87(77.7)	25(22.3)	0.50(0.12,2.03)	0.334
\geq 35	38(76.0)	12(24.0)	0.83(0.19,3.59)	0.800
Sex				
Male	116(73.9)	41(26.1)	1.00	
Female	111(89.5)	13(10.5)	0.26(0.12,0.59)*	0.001
Distance from HF				
>5 KMs	84(69.4)	37(30.6)	1.00	
≤5 KMs	143(89.4)	17(10.6)	3.87(1.83,8.29)*	0.001
Category of TB				
Bacteriological	105(86.6)	16(13.2)	0.45(0.21,0.98)*	0.043
Clinical	122(76.2)	38(23.8)	1.00	
HIV Status	. /	. /		
Reactive	11(31.4)	24(68.6)	1.00	
Non-reactive	216(87.8)	30(12.2)	20.35(7.73,53.63)*	< 0.001

DISCUSSION

Assessment of anti-tuberculosis treatment outcome as well as analysis of factors responsible for unfavorable treatment outcome is one of the major indicators for the evaluation of the performance of a national TB program. In facilities based cross sectional study, information on the treatment outcome of all types of TB patients across the study period were assessed in Adama Town health facilities. This overall treatment success rate for all cases of tuberculosis in our study was 80.8%. This supports previous studies in Ethiopia with success rates of 85.6%, in North West Ethiopia (25), 85% success rate according to FMOH five years TBL, TB/HIV program analysis (23).

This result showed a slight improvement when compared with retrospective cross-sectional survey done on TB treatment outcomes at Adama hospital medical college (AHMC) which showed 63.7% treatment success (31), at Gimbi Town with success rate of 74% (15) and at Gambella Hospital which trend of TB treatment outcome showed 63.4% (15). Other studies that in consistence with this study are the retrospective study that was conducted in Sagamu, Nigeria (13), prospective study done in South Africa which shows only 70% success fully treated (28) & in Brazil that shows unsuccessful was 24.6% (12).

The retrospective study done in Afar Region in December 2016 shows that female patient were more likely to have successful treatment out come when compared to male patients (21). Also the other study conducted with in Specialty Health center and Jericho University College indicate male had high risk of poor treatment outcome than females (13). This finding is inconsistent with the finding of this study that showed females had lower rates of successful treatment outcome. This difference could be attributed to the cultural differences in the study societies (21). But it is similar with study conducted in 2013 at Debra Tabor Health Facilities that showed female had lower rate of successful treatment outcome (19).

The result of this study indicated that HIV/AIDs has statistically significant impact on TB treatment outcome means from co-infected individuals have unfavorable treatment outcome whereas from non-reactive patients. This study is similar with study done in Cameroon Baptist convention health board tuberculosis treatment centers BBH (Banso Baptist Hospital) that showed better for treatment out come to be HIV negative while on treatment because HIV is the main reason for death and treatment failure (21).

The other studies consistence with this result is the retrospective study done at Gimbi Town Health Facilities that reveals HIV status, treatment regimen and place of residence have significant impact on treatment outcome of TB patient (15). But the other retrospective study done from 2000 to 2011 in Tigray Region shows HIV status didn't show any statically significant (22).

The patient near to the treatment center (less than 5km) had good treatment success when compared to those greater than 5km from the facility. It consistence with study done at Gondar university in July 2016 that shows successful treatment outcome was 66% lower among TB/HIV co-infected patient who have been residing outside living Gondar Town as compared those who have been living in Gondar (25). Also it agrees with national community care guide line which was papered in 2006 according to E.C.

But the other retrospective and cross sectional study conducted on smear positive Tuberculosis cases in Tigray Region shows distance from the treatment center didn't show any statistically significant (22).

This study revealed that Patients with bacteriologically confirmed pulmonary TB infection had 55% less likely to have favorable treatment outcome than clinically pulmonary and extra pulmonary. This finding agrees with the finding of Tigray Regional Health Bureau report (24), also it is consistence with the retrospective study done in March 2016 at Dabra Tabor, that shows to being smear negative PTB and EPTB had higher probability of being unsuccessful treatment outcome (19). Also the study conducted at Dilla University support this result that showed unsuccessful treatment outcome was also observed in PTB negative patients and EPTB compared to the PTB positive patients (24).

CONCLUSION AND RECOMMENDATION

The treatment outcome of all forms tuberculosis patient in Adama Town was unsatisfactory when compared with national target that sated in stop TB strategy (85%) in previously time and stated recently in End TB strategy (90%). The factors associated with this treatment outcome were Age, sex, distance from the treatment center, co-infection with HIV and category of TB.

This might be because of poor adherence patient with treatment regimen, poor lost to follow up tracing, poor practice of DOTs strategy and pill burden of the treatment. From unsatisfactory treatment there are 14 not evaluated cases this may slightly affect the result. On the other hand the most potentially infectious or (bacteriologically confirmed) TB case the cure (75%) is very low which is the serious public health problem that should be addressed urgently.

Finally as recommendation; female TB patient and those age between 15-24 should get additional social support to decrease the lost follow up rate by health facilities TB focal person and the management commute and strengthen early tracing with catchment area health extension workers. And all health facilities TB focal person and management committee should arrange HIV exposed TB patient to enroll in chronic HIV care or refer to chronic HIV care center. As organization; being with Adama Town Administration Health Office; health facilities should decentralize DOTs service to the lower health facility to make convenient for the patient those should go greater than five Kilo meter for treatment. And also Adama Town Administration Health Office should arrange feedback mechanism for TB patient that started treatment in the facility and registered on log book, then referred to other health facility to exchange patient evaluation among their TB focal person and others.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Tariku Tesema participated in Conceptualized the study, designed the study instrument and conducted the data analysis.

Abdulkerim Abate and Eyasu Ejeta are participated in approved the research proposal with some revisions, participated in data analysis, revised subsequent drafts of the paper and involve in manuscript preparation and critical review of the manuscript. All authors read and approved the final manuscript.

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