

Tuberculosis Treatment Non-compliance Rate and Associated Factors at Public and Private Tuberculosis Follow up Clinics in Northeast Ethiopia: A Comparative Cross Sectional Study

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Received September 09, 2018; Revised October 23, 2018; Accepted November 09, 2018

Abstract Background: Non-Compliance to tuberculosis treatment is an important barrier for tuberculosis control programs because incomplete treatment may result in prolonged infectiousness, drug resistance, relapse, and death. **Objective:** This study was aimed at assessing treatment non-compliance rate and associated factors among registered tuberculosis patients at public and private directly observed therapy short course centers in Northeast Ethiopia. **Methods:** The study population was all individuals aged ≥ 18 years. Study subjects were selected using simple random sampling methods using patient's registration number as a sampling frame. Data was collected using standardized, well-structured and pre-tested questionnaire. Both bivariate and multivariate logistic regression techniques were applied to analyze the data using statistical package for social science version 21. **Results:** High rate of treatment non-compliance was found in both patients managed in private (32.2%) and public (27.6%) tuberculosis clinics. Forgetfulness, use of addictive substance and unavailability of drugs remained significant predictors of non-compliance both in public and private tuberculosis clinics. Herbal medication use was significantly associated with treatment non-compliance only among patients attending public tuberculosis clinics, AOR (95% CI) = 5.646(2.12, 15.05). Unlike patients at public tuberculosis clinics, monthly income, knowledge about tuberculosis, closure of tuberculosis clinics and health education showed significant association with non-compliance at private tuberculosis clinics. **Conclusions:** Forgetfulness, use of addictive substance and unavailability of drug were found to be the three most important factors, leading to treatment noncompliance both in public and private clinics. Integrating health education and counseling services with assigned particular personnel in all facilities and provision of alarming machines to all patients is recommended.

Keywords: noncompliance, public private Mix-DOTS, treatment interruption

Cite This Article: Melsew Getinet Tsegaw, and Yimer Seid Yimer, "Tuberculosis Treatment Non-compliance Rate and Associated Factors at Public and Private Tuberculosis Follow up Clinics in Northeast Ethiopia: A Comparative Cross Sectional Study." *American Journal of Epidemiology and Infectious Disease*, vol. 6, no. 1 (2018): 24-29. doi: 10.12691/ajeid-6-1-5.

1. Introduction

According to the World Health Organization (WHO), directly observed therapy short course (DOTS) ensures successful treatment of patients with tuberculosis [1]. DOTS program in Ethiopia has been implemented since the year 1992 GC. But it was limited to public health facilities until the year 2006. However, the FMOH had a strong interest in expanding DOTS services in collaboration with WHO global recommendations to involve the private sector in the delivery of TB treatment services [2]. Up until 2010, there were 213 public private mix (PPM) sites providing DOTS in Ethiopia and from these, 35 of the facilities were in Amhara region [3].

Despite a rapid expansion of TB health care facilities, tuberculosis remains the leading cause of morbidity, the third cause of hospital admission and the second cause of hospital death in Ethiopia [4].

Non-compliance with tuberculosis treatment has many adverse consequences, not only for patients and their families, but also for the society at large specially related to antimicrobial agents resistance. According to the recent national drug resistance report, 2.3% of new TB cases and 17.8% of previously treated TB cases were estimated to have MDR TB in Ethiopia. MDR-TB reflects the poor primary management of the disease. It is reported to be mainly the result of failure to ensure compliance, rather than the failure of the drugs to cure. The highest priority in fighting multi drug resistant tuberculosis (MDR-TB) must be directed towards prevention (5). A case control study in

Uganda conducted to determine the predictors of treatment failure among patients with sputum smear positive pulmonary TB showed that poor adherence to anti TB treatment was a significant predictor of treatment failure [6]. Another similar study carried out in Egypt showed, non-compliance was a significant risk factor for treatment failure [7]. Adversely, a research that aimed to identify associated variables with tuberculosis recurrence in patients treated with the short-course regimen in Brazil revealed a fact that non-compliance was positively independent associated factor with recurrence of tuberculosis [8].

A high treatment defaulter rate (10-20%) was described in Ethiopia which unfavorably affected the national cure rate [9,10]. In an effort to reach the national as well as global target of 85% treatment success and non-compliance rates of lesser than 5% [1] within TB programs, patient compliance to anti TB medication needs to be improved both in private and public TB clinics. Conversely, the level of tuberculosis treatment non-compliance was not known, especially in private TB clinics.

Therefore, the aim of this project was to determine factors that predict treatment compliance among TB patients in public and private health institutions.

2. Methods

A facility based comparative cross sectional study between public and private DOTS clinics was conducted in Dessie and Kombolcha Cities, which are 380–400Km, Northeast of Addis Ababa from April 02 to May 04, 2016.

Tuberculosis patients age 18 years old and above were included in the study. Patients who had completed two weeks of treatment days or more were included, as we thought that they would have enough experience to answer the questions.

The required sample size for the study was determined using EPI INFO statistical package. In this regard, a minimum detectable odds ratio of 2, a 5% level of significance (two-sided), a power of 80% and a one to one allocation ratio of compliant group to non-compliant group were assumed. Moreover, some 5 % was also added for non-response. Accordingly, by taking 40 % proportion of non-compliant TB patients in public DOTS taken from a study done in North Wollo in 2009 [11] and the above assumptions, a minimum sample size of 152 for each of the two groups was used.

A total of 442 (272 in public and 170 in private) TB patients were registered at all 15 Health facilities (eight public and seven private) providing DOTS for tuberculosis during the time of data collection in the study area.

A simple random sampling technique and proportional allocation to size was used to select respondents from each clinic.

The main outcome variable was non-compliance to anti TB drug treatment. The predictor variables consisted of Patient related, health care and system related, treatment and disease related variables.

A patient was defined compliant to treatment if the proportion of actual doses taken of those prescribed was greater than 95%. Patients who missed 5% or more of the total prescribed dose of TB drugs were categorized as non-compliant.

The data was collected by accelerated midwife trainers at Dessie Health Science College, who were assigned for apprenticeships during the data collection period. Exit interview was conducted in a private nurses' room to maintain privacy. Moreover, the compliance status was ascertained by patients' medical record review and pill count. Data were entered in to computer using EPI-INFO and then exported to the Statistical Package for Social Sciences (SPSS) for Windows version 21 for analysis. Logistic regression modeling was used to calculate odds ratios for factors associated with treatment non-compliance. All variables independently associated with treatment non-compliance in the univariate analysis ($p < 0.2$) were considered in the multivariable model. The unadjusted (crude) and adjusted Odds ratios together with their corresponding 95% confidence intervals were computed. A P-value < 0.05 was considered statistically significant.

Ethical clearance was obtained from Institutional Review Board (IRB) of Gondar University. In addition, permission to conduct the study was obtained from Amhara Regional Health Bureau, South Wollo Health Department, and Woreda Health Office and from each Health Facilities prior to data collection. Objective of the study was clearly explained for participants before conducting the interview and written consent was obtained from each participant after voluntary participation feature of the study was explained.

3. Results

The study included 304 TB patients, age 18 years old and above, making a response rate of 100%. Of which, 158(52 %) were males and 146(48 %) were females.

The mean age at interview of participants was 32 years old (± 13 years standard deviations), ranging from 18 to 70 years. Majority of the patients 262(86.2%) were from the urban areas of Dessie and Kombolcha cities. Students constitute 15.1% of the respondents. Over two – third of the patients were from families with monthly household income of US \$26 to US \$51.

Overall, 93.8% of the patients were new cases of TB. Sixty percent of patients have pulmonary tuberculosis (smear positive 33% and smear negative 27%). The remaining (40%) were extra pulmonary tuberculosis patients.

About 40% of the respondents from both groups have a history of missing at least one dose of the prescribed treatment. Among all patients seen in both public and private DOTS clinics, the overall non-compliance rate of TB treatment was found to be 29.9%. Separately measuring, the rate of treatment non-compliance in private DOTS clinic and in public DOTS clinic was 32.2% and 27.6% respectively.

In the multivariate logistic regression analysis (Table 2 and Table 3); forgetfulness, use of addictive substance and unavailability of drugs during the scheduled visit showed significant association with treatment non-compliance both in public and private DOTS clinic. Herbal medication use was remained significantly associated with treatment compliance among patients attending public DOTS clinics. At private tuberculosis clinics; monthly income, knowledge about tuberculosis, closure of tuberculosis clinic and medical counseling showed significant association with treatment non-compliance after adjustment for possible confounders.

Table 1. Socio-demographic characteristics of TB patients at public and private DOTS clinics Northeast Ethiopia, 2016

Variable		Health Facility		Total (304) Count (%)
		Public(n=152) Count (%)	Private(n=152) Count (%)	
Sex	Male	84(55.3)	74(48.7)	158(52)
	Female	68(44.7)	78(51.3)	146(48)
Age	18-29	83(54.6)	69(45.4)	152(50)
	30-41	38(25)	48(31.6)	86(28.3)
	42+	31(20.4)	35(23)	66(21.7)
Residence	Urban	131(86.2)	131(86.2)	262(86.2)
	Rural	21(13.8)	21(13.8)	42(13.8)
Religion	Islam	91(59.9)	71(46.7)	162(53.3)
	Orthodox	56(36.8)	74(48.8)	130(42.8)
	Protestant	5(3.3)	7(4.6)	12(3.9)
Ethnicity	Amhara	147(96.7)	135(88.8)	282(92.8)
	Others	5(3.3)	17(11.2)	22(7.2)
Marital status	Married	65(42.8)	70(46.1)	135(44.4)
	Single	68(44.7)	63(41.4)	131(43.1)
Educational status	Divorced/separated	19(12.5)	19(12.5)	38(12.5)
	No formal schooling	34(22.4)	26(17.1)	60(19.7)
	Primary	45(29.6)	19(12.5)	64(21.1)
	secondary	41(27.0)	56(36.8)	97(31.9)
	12+	32(21.1)	51(33.6)	83(27.3)
Occupational status	Gov't Employee	26(17.1)	27(17.8)	53(17.4)
	Self employed	49(32.2)	43(28.3)	92(30.3)
	Unemployed	42(27.6)	37(24.3)	79(26.0)
	Housewife	14(9.2)	20(13.2)	34(11.2)
Monthly household income	Student	21(13.8)	25(16.4)	46(15.1)
	≤500	61(40.1)	31(20.4)	92(30.3)
	501-1000	52(34.2)	53(34.9)	105(34.5)
	1001-1499	21(13.8)	35(23.0)	56(18.4)
	≥1500	18(11.8)	33(21.7)	51(16.8)

Table 2. Factors associated with TB treatment compliance among TB patients (n=152) attending public health facilities, Northeast Ethiopia, 2016

Variables	Compliance level		COR(95%CI)	AOR(95%CI)
	Compliant	Noncompliant		
Forgetfulness				
No	91	20	1	1
Yes	19	22	5.27(2.41,11.51)	4.752(1.966,11.48)
Substance Abuse				
No	97	27	1	1
Yes	13	15	4.15(1.76,9.76)	3.54(1.336,9.37)
Availability of Drug				
Always Available	95	29	1	1
Not Always Available	15	13	2.839(1.21,6.65)	3.084(1.141,8.33)
Herbal Medication Use				
No	98	26	1	1
Yes	12	16	5.026(2.12,11.93)	5.646(2.12,15.05)

Accordingly, patients at public DOTS clinics who were forgetful in taking daily dose of their treatment were 4.75 times more likely to be non-compliant as compared to those who were no forgetful in taking their daily treatment (AOR = 4.75, 95%CI: 1.96, 11.48). However, the difference in the level of treatment compliance between patients at private DOTS clinics who forget and recollect taking daily dose of their drug showed marginal significance (AOR=2.39, 95% CI: 0.91, 6.24).

Those patients who currently use addictive substance were more likely to be non-compliant both in patients attending public and private DOTS clinics (AOR, 95%CI):

3.54, 1.34 -9.37), (AOR, 95%CI):2.61, 1.11 - 6.24) respectively.

Patients who reported unavailability of drug during the schedule days were more likely to be treatment non-compliant; their risk of being non-compliant was 3 times higher than those who reported availability of drugs in times of their schedule both in public and private DOTS clinics.

Herbal medication use was significantly and independently associated with noncompliance among patients attending public DOTS clinics (AOR=5.65, 95%CI=2.12, 15.05) but not in patients at private DOTS clinic. The difference is significant between public and private DOTS clinics (P=0.042).

Table 3. Factors associated with TB treatment compliance among TB patients (n=152) attending private health facilities in Northeast Ethiopia, 2016

Variables	Compliance level		COR(95%CI)	AOR(95%CI)
	Compliant	Noncompliant		
Monthly household income*				
≤500	15	16	1	1
500-1000	37	16	0.405(0.16,1.01)	0.196(0.06, 0.64)
1001-1499	26	9	0.325(0.12,0.91)	0.272(0.08, 0.92)
≥1500	25	8	0.300(0.104,0.87)	0.199(0.05, 0.73)
Forgetfulness **				
No	86	28	1	1
Yes	17	21	3.794(1.76,8.18)	2.39(0.91,6.24)
Substance abuse *				
No	75	22	1	1
Yes	28	27	3.287(1.62,6.69)	2.60(1.108, 6.24)
Knowledge of TB*				
Adequate	89	28	1	1
Not Adequate	14	21	4.768(2.15,10.59)	3.460(1.37, 8.75)
Availability of Drug*				
Always Available	96	35	1	1
Not Always Available	7	14	5.486(2.04,14.71)	3.45(1.08,10.95)
Closure of TB clinic*				
No	92	36	1	1
Yes	11	13	3.020(1.24,7.36)	3.077(1.01, 9.40)
Medical counseling *				
Yes	71	21	1	1
No	32	28	2.958(1.46,5.97)	2.742(1.14, 6.57)

* remained significant at a 0.05 level of significance.

Patients attending private DOTS clinics who had better monthly income were 81% less likely to be non-compliant as compared to low-income groups (AOR=0.19, 95%CI=0.05, 0.73).

Patients' Knowledge regarding TB did not show significant difference at public DOTS clinics. However, those patients at private DOTS with inadequate knowledge were 3.46 times high risk for non-compliance (AOR=3.601, 95%CI = 1.37, 8.75).

Closure of TB clinic at private DOTS was significantly associated with non-compliance, but not at public DOTS clinics. The difference was significant between the two groups ($p = 0.04$). Private DOTS service providers which close their clinics during the scheduled days contribute a three-fold increase in the risk of non-compliance for their patients.

A significant number of patients attending private DOTS clinics reported that they were not receiving regular counseling and health education concerning their treatment regimen and DOTS services. These patients were 2.74 times more likely to be non-compliant as compared to those who got medical counselling from health workers (AOR=2.74, 95%CI=1.14, 6.57).

4. Discussions

High rate of treatment non-compliance was found among patients managed both in the private (32.2%) and the public DOTS (27.6%) clinics. This may be due to the fact that DOTS clinic did not strictly adhere to the guidelines recommended in the DOTS strategy. This finding was higher than similar reports carried out in Southern Ethiopia and Arsi Zone; which revealed a non-compliance rate of 20% and 11.3% respectively

[9,10]. This may be due to the use of higher cut of point used to declare non-compliance in those studies. In another study, non-compliance rate of the current study was lower in comparison with a study done in India, which described a non-compliance rate of 56.27% in private DOTS clinics and 34.25% in public DOTS clinics [19]. However, a comparative cross-sectional study comparing the public facilities with private facilities providing DOTS services in Nigeria showed a higher defaulter rate in public hospitals, which was 29.3 % compared to only 10.78% in private hospitals [12].

In the Multivariate analysis of this study, forgetfulness to take drugs was found to be significantly associated with non-compliance. This finding was in accordance with the study conducted in Gondar, Ethiopia [11]. This may be attributed from the passive participation of treatment supporters.

Substantially, the current study established a fact that non-compliance rate was higher in those tuberculosis patients who were addictive substance users; which was in keeping with previous different studies [12,24,27,28]. This may be due to the reason that addicted patients are highly likely to have decreased interest and sleep pattern disturbance, which would eventually affect their daily adherence to treatment regimen, in turn ending up with missing of daily doses. The other factor associated with non-compliance both in public and private DOTs clinics was drug unavailability at every visit. This finding was not in agreement with the study from Nepal that unavailability of drugs at every visit in the treatment centers was not able to statistically show a difference between compliant and non-compliant groups [26]. This may be because of sociocultural, economic and demographic variations of the study settings.

One of the strongest predictive factors of treatment non-compliance at public DOTs centers was herbal medicine use. Similarly, a study in South Africa had also described the fact that seeing a traditional healer during TB treatment was a significant predictor of non-compliance (14). Nevertheless, the current study has shown that there was no statistically significant association between herbal medication use history and treatment non-compliance among patients at private DOTs centers. The result of this study indicated, herbal medication use history was a significant risk factor of non-compliance. This may be due to educational and economic level differences of patients seeking services across the public and private DOTs clinics. This finding was in consistent with a report in Nairobi [13].

Noticeably, this study found that inadequate knowledge regarding tuberculosis at private clinics was able to significantly increase the risk of non-compliance as it is evidenced with a finding that the considerable proportion 35 (23%) of the patients were unaware of their disease and treatment regimen. This finding might be due to the reason that patients at private DOTs clinics did not get regular counseling and health education by the health care workers about TB and treatment adherence. This would be due to lack of independent and responsible health workers for DOTs services in private health facilities. In line with this, health care workers might have been busy with other activities. Thus, this would be a challenge for them to provide regular counseling services to their patients. Steadily, other studies in Ethiopia, Kenya, India, and Nepal [10,23,26,28] showed that having adequate knowledge ascribed to TB disease was a possible protector of patients' treatment non-compliance. But, a study in Malaysia showed no statistically significant difference between compliant and non-compliant groups with the knowledge element [15]. The current study also confirmed that lack of health education was an important determinant of non-compliance in private DOTs. This was supported with a finding that the chance of non-compliance was 2.74 times more likely in patients not counseled in the health care settings than those patients who had been counseled by healthcare workers. This finding was in keeping with a similar study carried out in Nepal [26].

Considerably, the follow up length of patients in the compliant group was variable. Thus, it is impossible to provide a conclusion that currently compliant groups may later be non-compliant. This would have biased the evidences obtained across the two comparative groups.

5. Conclusions

The study has documented a high level of non-compliance rate both in public and private DOTs clinics. Nonetheless, there was no statistical association between the DOTs services provision setting (In this case, Private and Public settings) and compliance outcome. Forgetfulness, use of addictive substance and unavailability of drug at each scheduled day were found to be significant and independent factors affecting the level of treatment non-compliance both in patients attending public and private DOTs clinics. Separately examining, monthly income, knowledge about TB, closure of DOTs clinics and

absence of health education service were important determinants of non-compliance in the private DOTs clinics. On the other hand, in the private DOTs service settings, herbal medicine use was the strongest predictor of non-compliance.

Strengthening the supervision of both the public and private DOTs service settings would improve the commitment of addressing all required components of the DOTs strategy and in turn increase the TB treatment compliance rate

A treatment social supporter and alarming machines donations to all patients are highly recommended to assist patients in reminding their daily doses

It is mandatory to assign a responsible health care worker to coordinate DOTs and audit available anti-TB drugs regularly at the clinics. Routine health education for patients, their family, and the general population may also improve compliance.

Acknowledgements

Firstly, we would like to forward our deepest gratitude to Amhara National Regional State Health Bureau for partially funding the research. Secondly, we would like to say thanks for all DOTs center staffs in the study area for their genuine cooperation during data collection. Finally, we would like to forward our heartfelt thanks to the study participants of this project.

Funding

Amhara National Regional State Health Bureau supported the study.

Competing Interests

Authors would like to declare that we have no competing interests.

List of Acronyms

ANRSHB	Amhara National Regional State Health Bureau
AOR	Adjusted Odds Ratio
CI	Confidence Interval
COR	Crude Odds Ratio
DOTS	Directly Observed Therapy Short- course
DST	Drug Sensitivity Test
FMOH	Federal Ministry of Health
HBS_s	High Burden Countries
RR	Risk Ratio
INH	Isoniazid
MDR	Multi Drug Resistance
PPM	Public Private Mix
PI	Principal Investigator
RHZE-	Rifampicine Isoniazid Pyrazinamide Etambutol
S	Streptomycin
TB	Tuberculosis
UoG-IERB	University of Gondar Institutional Ethical Review Board
WHO	World Health Organization

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