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# The Effect of the Community Based Directly Observed Therapy on the Treatment Outcome of Tuberculosis Patients in Mitooma District, Western-Uganda

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### **ABSTRACT**

Tuberculosis (TB) is the leading cause of death among people living with HIV/AIDS (WHO, 2020). Sub-Saharan Africa has nearly all high TB burden countries including Uganda which contributes to the highest Tuberculosis related mortality globally. Poor adherence to Tuberculosis treatment can lead to prolonged infection and poor treatment outcomes. Directly Observed Treatment (DOT) seeks to improve adherence to TB treatment by observing patients while they take their anti-TB medications. Although Community based Directly Observed Therapy (CB-DOT) programs have been widely studied and promoted, their effectiveness has been inconsistent. The aim of the study was to determine the effect of the Community Based- Directly Observed Therapy on the Treatment Outcome of Tuberculosis Patients in Mitooma District, Western-Uganda. A cross-sectional survey research design was adopted and employed both quantitative and qualitative approaches for data collection. Data were collected from the TB patients. Descriptive statistics, Simple and multivariable logistic models were used to obtain summary statistics and examine associations between independent attributes and treatment outcome under CB-DOT program. Qualitative data were coded and analyzed using STATA version 13. Of the 191 TB patients that participated in the study, 143(74.9%) were males, the majority 156 (81.7%) were above 30 years, 144 (75.4%) were married and 176 (92.6%) were declared cured through sputum check after treatment completion. The multivariate analysis revealed that TB patients who were not educated were 9.01 times more likely to get cured compared to the educated patients (AOR=9.01; 95% CI (1.6-5.9); p=0.013). Duration or time spent on TB medication was associated with TB treatment outcome because the patients who had spent 6 months on TB medication (AOR=2.9; 95% CI (1.14 - 7.9); p=0.004) were three fold more likely to get cured compared to those who had spent less than one month. Similarly, patients who had spent six months and above (AOR=4.1; 95%CI (0.07 – 0.87); p=0.026) were more than four times more likely get cured compared to those who had spent less than one month. Results further showed that patients who were neutral in attributing their health state to the way they swallowed the TB medication (AOR = 0.33; 95%CI (0.12 - 0.9); p=0.001) were 67% less likely to get cured compared to patients who strongly agreed that their health status were attributed to the way they swallowed On the evaluation of the CB-DOTs program majority of the TB patients described the TB medication.

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program as vital in treatment of TB disease as health caregivers would deliver drugs at their home in time, share with health workers their challenges if any, reduce transport costs and monitoring the adherence of the TB medications through health education and regular visits. The study revealed that CB-DOT improved TB treatment outcomes. Monitoring the swallowing of TB drugs by health workers, health education and regular visits were highly recommended. Therefore, studies on policies for implementation of patient-centered and community-centered CB-DOT deserve further attention.

Key words: Community Based Directly Observed Therapy, Treatment Outcome, Tuberculosis Patients

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## **INTRODUCTION**

In Uganda, Directly Observed Treatment Short Course strategy based on 5 components, that is, political commitment, case detection by bacteriology, standardized treatment with supervision, effective drug supply, and treatment monitoring, recommended by World Health Organization was adopted by Ministry of health to eliminate tuberculosis [2]. The standardized treatment as recommended by WHO consists of 2-month intensive phase, in which patients take drugs directly under the observation of health care providers, and 4-month continuation phase for new TB cases while the retreatment cases have 3-month intensive phase and 5-month continuation phase [1].

Uganda is one of the 30 high burden TB/HIV countries in the world. On average, 88,000(maximum 130,000) people in Uganda fall ill with TB every year. Approximately 30 people in Uganda die from TB every day. More than half of the TB related deaths are among people living with HIV and TB is 4 times more common among men than in women [2]. The number of people with TB disease not diagnosed or started on the treatment (missed people of TB) reduced from about half to a quarter of the 88,000 people in 2020.

Treatment outcome of Tuberculosis patients if not assessed it would lead to low rate of patient adherence to TB medications, high TB treatment failure, increase death rate due to TB, increase cases

of multi-drug resistant strains of Mycobacterium. This study seeks to assess Treatment outcomes of all TB patients on treatment over 1-year period by interviewing key respondents the Tuberculosis patients registered in TB health unit register. The study will determine the effect of Community Based-Directly Observed Therapy on both positive Treatment outcomes such as Cured(C), Treatment completed (CTD), and negative Treatment outcomes like Treatment failure, Death, lost to follow up and not evaluated [3]. Despite the discovery of Tuberculosis microorganisms, vaccines and effective TB medicines one hundred years ago, Tuberculosis remains a public health problem [4] The adoption of Community Based-Directly Observed Treatment is meant to increase the patient adherence to TB medications and reduce prevalence cases and improve the case detection rate at community level and especially in the high risk groups such as HIV/TB co-infection [8]. The program of CB-DOTs could still be facing a lot of challenges since in the whole world, the current state is that 789.000 Tuberculosis cases are HIV co-infected and estimated 1.7 million people died from tuberculosis and 231,000 were those co-infected with HIV [6]. Uganda remains one of TB high burden countries in the world despite the adoption and the practice of Community based directly observed treatments for Tuberculosis patients from 1998 up to date.

The Treatment outcomes in Mitooma district currently stands at a cure rate of 31percent and Treatment completion rate of 91 percent which is still low compared to the required national standards of 95 percent and 100 percent respectively [7]. Therefore, this study determined the effects of Community based directly observed Therapy to the Treatment outcomes of Tuberculosis patients in Mitooma district. Specifically, the study aimed at establishing the overall outcome of Community based-directly observed Therapy on the Patient adherence, Cure rate and Knowledge of patients on Tuberculosis. However, the effect of this community based program has been influenced by socio-economic factors such as lack of family support, poverty, and other context issues in ignorance implementation of this community based approach. Thus, there was a need to conduct the study to gain a deeper understanding of Treatment outcomes following the implementation of Community Based Directly Observed Therapy.

# **Purpose of the Study**

To determine the effect of Community Based-Directly Observed Therapy on the Treatment outcomes of Tuberculosis patients in Mitooma District.

#### THEORETICAL FRAMEWORK

The Theoretical framework is based on the Tuberculosis National Program framework. description, based on the National Tuberculosis program framework. The availability, accessibility and utilization of the health system of DOTs would improve patient adherence to tuberculosis which medications results into tuberculosis prevalence at community level. Based on the National TB program there are other factors which influence the program and in this research study, they have been referred to as independent factors. These factors include; socio-economic knowledge characteristics, Patient on importance of the **CB-DOTs** Program, Consistency of treatment supporters', Health

education sessions on TB disease, age of the Patients, Socio economic status of the TB Patient like Occupation, Follow up visits, Patient adherence to TB medication. It also includes moderating factors related to the health system and to individuals such as the policy implementation processes. You can see that the program is aiming to affect the health care system and knowledge of TB patients which will in turn affect the treatment outcomes of the tuberculosis patients such as success of the treatment and in this case the cure rate, the treatment completion and at worst the treatment failure and death [4].

#### **METHODOLOGY**

This study adopted a cross-sectional survey research design. The study was carried out in Mitooma district in Western Uganda. The study population consisted of Tuberculosis patients in MitoomaDistrict. The target population (N), 350 was the estimated patients in the health facilities then sample size (S) was 191 patients in TB unit register. Questionnaire: semi-structured questionnaires containing both open and closedended questions was administered to eligible participants. Structured face-to-face interviews were used to collect qualitative data from the Tuberculosis patients (P-BC) who had spent six months on TB treatment. Data analysis involved processing of the data which was done at three namely Univariate, bivariate Univariate multivariate analyses. analysis incorporated descriptive summary statistics for each variable. To study the characteristics of the respondents, techniques for summarizing data for continuous variables were used and these included: mean, variance and standard deviation while frequencies or proportions and percentages were used for categorical variables.

Cross tabulations was done to test any possible associations between each of the independent variables and the dependent variable. Statistical significance of the relationships will be determined for the p-value ( $p \le 0.05$ ) and all significant

variables at this level were considered for further analysis at multivariate level analysis. Multivariate analysis was performed to assess which factors were more associated with the dependent variable. Binary logistic regression analysis was used because the dependent variable is dichotomous or binary and it attempts to control for possible confounding effect of independent variables on each other and thus finds the independent **RESULTS** 

# Bivariate logistic regression analysis.

Logistic regression at a bivariate level revealed that the effect of the community based Observed Therapy on the treatment outcome of tuberculosis was significantly associated with age, level of education of the TB patients, marital status, duration/time spent on TB treatment, Adherence to TB treatment, attribution of health status to the way the patient swallowed the TB medication and knowledge On the importance of CB-DOT program due to health education and regular visits. The results in table4.2 revealed that age Unadjusted Odds Ratio (UOR); (UOR=3.80; 95%CI (1.23-11.8; p=0.021). The TB patients who were in the aged above 30 years were 4 fold more likely to get cured of TB under CB-DOTS program compared to their counterparts aged less than 30 years. The results further revealed that TB patients who were not educated were 4 times more likely to get cured under the community based directly observed therapy compared to their colleagues who were educated (UOR=3.51; 95%CI(1.14-10.8); p=0.029). Furthermore, Patients who were not married were 79% less likely to get cured under CB-DOT program compared to patients who were married The section focused on determining the association between treatment outcome of the tuberculosis patients and the socio-demographic, economic, adherence to medications, duration spent on TB treatment/cure rate of TB, knowledge of tuberculosis patients on the importance of the CB-DOTS program. It presents the bivariate

association for each independent/predictor variable with the dependent/criterion variable.

The qualitative data was collected through the use of open ended questions set in the questionnaire survey tool, interviewing the eligible tuberculosis patients and conducting focus group discussion (FGD) on the different eligible tuberculosis patient groups with different characteristics in Mitooma district.

(UOR=0.21; 95%CI (0.07-0.65); p=0.007). The results further show that the TB patients who have spent 6 months on TB medication were 3 fold more likely to get cured under CB-DOT program compared to those who have spent less than 1 (UOR = 2.6;95%CI(2.1-3.1);p=0.007). Similarly TB patients who had spent 6 months and above were 3.4 times more likely to get cured compared to those who had spent less than 1 month (UOR= 3.4; 95%CI(2.6-6.61); p=0.008. Results further revealed that TB patients who were not swallowing the TB medications according to the treatment supporter guide instructions were 99.98% less likely to get cured compared to those who adhered and swallow the TB medications according to the treatment supporter guide (UOR=0.02; instructions 95%CI(0.020.15);p<0.001). TB patients who reported that they had no knowledge about the importance of CB-DOT program were 99.78% less likely to get cured compared to their counterparts who were health educated, received regular visits and acquired knowledge on the importance of CB-DOT program (UOR=0.22; 95%CI(0.06-0.78); p=0.20).

# **Summary Bivariate analysis**

analysis results carried out using logistic regression analysis presenting the unadjusted/crude estimates. The bivariate analysis showed that the treatment outcome of the tuberculosis is associated with age, level education of the TB patients, marital status, duration spent on TB treatment, adherent to medication according to the

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treatment supporter guide instructions, opinion about the TB patients' health due to the way swallowed the TB medications and the Knowledge of on the importance of CB-DOT program as the **Multivariate logistic regression analysis** 

Multivariate analysis was performed to assess which factors were more associated with treatment outcome of the tuberculosis patients. The section presents the multivariate analysis results that were carried out using the multivariable logistic regression.

All factors which had p-values below the threshold of 0.05 at the bivariate analysis were included in the multivariate model (Table 4.5). A reference category was selected for each categorical variables.

The multivariate analysis showed that level of education of the TB patients under CB-DOT program statistically impacts the treatment outcome of the tuberculosis. TB patients who were not educated were 9 times more likely to get cured of TB disease compared to patients were educated Adjusted Odds Ratio (AOR) (AOR=9.01; 95%CI (1.6-5.9); p=0.013). Furthermore, duration or time

result of health education and regular visits. Other factors were not significantly associated with treatment outcome of the tuberculosis patients as demonstrated in (table 4.5).

spent on TB treatment was also associated with treatment outcome of the tuberculosis patients. Patients who had spent six months on TB treatment were 2.9 times more likely to get cured compared to those who had spent one month on Treatment (AOR=2.9; 95%CI (1.14 - 7.9); p=0.004). Similarly the multivariate analysis further revealed that patients who spent six months and above months on TB medication were 4.1 times more likely to get cured of TB disease compared to those who had spent one month on treatment (AOR = 4.1; 95%CI(0.07 - 0.87); Participants who were neutral in p=0.026). attributing their current health state to the way they swallowed the TB medication were 0.33 times less likely to get cured compared to those who strongly agree that their current health state is attributed to the way they swallowed the TB medication (AOR=0.33; 95% CI (0.12-0.9); P=0.001).

Table 1: Bivariate and multivariable analysis results of factors associated with Treatment Outcome of Tuberculosis Patients under Community Based- Directly Observed Therapy in Mitooma District (n = 191)

		Treatment outcome of TB patients					
		Cured Not cured		Bivariate analysis		Multivariable analysis	
Variables		n(%)	n(%)	UOR(95%CI)	p-value	AOR(95%CI)	p-value
Gender	Male	134(76.14)	9(64.29)	1			
	Female	42(23.86)	5(35.71)	0.56( .18- 1.78)	0.328		
Age group	Less than 30 years	29(16.48)	6(42.86)	1		1	
	Above 30 years	147(83.52)	8(57.14)	3.80( 1.23- 11.8)	0.021*	2.8(0.47-16.6)	0.252
Level of Education	Educated	31(17.61)	6(42.86)	1		1	
	Not educated	145( 82.4)	8( 57.14)	3.51(1.14- 10.8)	0.029*	9.01(1.6-5.9)	0.013**
Employment Status	Employed	9(5.11)	2(14.29)	1			
	Not employed	167(94.89)	12(85.71)	3.1(0.6-15.9)	0.177		
Marital Status	Married	137(77.84)	6(42.86)	1		1	
	Not married	39(22.16)	8( 57.14)	0.21(0.07- 0.65)	0.007*	0.2(0.02-1.1)	0.064
	Health worker	49(27.84)	7(49.9)	1			
Which TB Treatment supporter were you given?	Village health team	17( 9.66)	1(0.1)	1.05(0.30- 3.70)	0.936		
	The relative	104(59.09)	7(49.9)	2.12(0.71- 6.38)	0.180		

## **Presentation of Qualitative Results**

## **Success of CB-DOTS Program**

Regarding the success of the program, it was revealed that the CB – DOTs program was very successful because patients got cured and more so it was easy and convenient for them to obtain drugs and treatment from their home areas. Accordingly, a patient responded by saying that: "This program was helpful in the treatment and curing of the disease because medications were brought at home hence reducing transport costs involved and the TB treatment supporters would observe/monitor the swallowing of medications hence lead to good adherence" (TB patient #75).

# **Benefit of CB-DOTS Program**

Another emerging theme from the participants was the benefit of the program. Patients revealed that other than benefiting from treatment, the program helped them to improve the relationship among their family members and together with the health care providers. One participant revealed that; "CB -DOTS helped me build good relationship with my health care provider and my family was given enough information about TB disease" (TB patient #48).

Such good relationship was built because as part of the program, the service providers would give additional support to the patients and caregivers in form of counseling and therapy that were targeting

at promoting social support of family members for the patients.

### DISCUSSION

#### **Socio-economic Factors**

This research study found that Treatment outcome the Tuberculosis was associated with participants' level of education. Patients who were not educated were more than 9 times more likely to get cured of the TB disease. This is because according to previous study done by Court Wright &Turner, 2010.it was found out that TB status is sometimes hidden because it may result in divorce or reduced prospects of marriage and people encounter TB stigma in many settings and considering those settings being the institutions the educated people occupy for formal employment then its most likely that in educated people TB stigma is higher than in uneducated people hence better adherence of the uneducated people.

# The Tuberculosis patient adherence to medications while enrolled under the CBDOTS program care

The study found out that the duration or the time spent on TB treatment had an impact on the Treatment outcome. Patients who had spent 6 months on TB treatment were three fold more likely to get cured, this is because Tuberculosis patients who have spent during a period of 6 months of enrolment on TB medication usually have improved counselling, good communication skills and patient choice of DOT supporter with reinforcement of supervision activities. In similar study done by Thiam, 2007 described the main reason of poor adherence to TB treatment as it remains a major obstacle to efficient TB control in developing countries by the example of Senegal and noted that CB-DOTs intervention package is based on decentralization of treatment, patient choice of DOT and reinforcement of supervision activities.

Similarly, Patients who had spent six and more months on the TB medication were more than 4 fold more likely to get cured compared to their counterparts who had spent one month on treatment. This is attributed to the reasoning that direct observation of treatment is integral and essential component of directly observed therapy and the observation of treatment time increases with the number of months enrolled on the drugs for TB. This is similar to study done by [8] that discovered that some of the particular issues of promotion of adherence to treatment for tuberculosis were direct observation and some other specific strategy based factors such as political commitments by governments, improved laboratory services and reporting system of documentation. In the same study it was found out that direct observation is integral and essential component of CB-DOTs.

# The cure rate of TB among the Tuberculosis patient (P.BC) who have spent 6 or more months on treatment.

Patients who were neutral in attributing their current health state to the way they swallowed the TB medication were 99.7% less likely to get cured compared to those who strongly agreed that their current health state is attributed to the ways they swallowed the TB medications. This is attributed to by the fact that factors that influenced adherence to TB treatment positively were beliefs in curability of TB, beliefs in severity of TB in presence of HIV and support from the families and health professional and in congruent to other researchers such as [1]. The qualitative study done by [1] in Ethiopia on the barriers and facilitators of adherence to TB treatment in patients co-infected of HIV/TB found out that factors that influenced adherence to TB treatment positively were beliefs in the curability of TB, beliefs in the severity of TB in presence of HIV infection and support from families and health workers. The same study established that barriers to TB treatment were the

experience of side effects, pill burden, economic constraints, lack of food, stigma with lack of disclosure and lack of adequate communication with the health care workers.

# The knowledge of Tuberculosis patients on the importance of Community Based Directly Observed Therapy.

TB patients who reported that they had no knowledge about the importance of CB-DOT program were 99.78% less likely to get cured compared to their counterparts who were health educated, received regular visits and acquired knowledge on the importance of CB-DOT program

(UOR=0.22; 95%CI(0.06-0.78); p=0.20) and according to the some research study done by Dimitrova et al.,2006 in Russia which explored the existing barriers to access to TB services in urban and rural areas of samara Oblast and more clearly barriers associated with patients' personal characteristics like the level of knowledge and awareness on the significance of the treatment intervention by the patients which usually modifies the personal behavior. In the health care system were seen both as cause of TB and major obstacle to access to care.

The qualitative component in this research study of the 48 tuberculosis patients found out that CB - DOTS helped TB patients build good relationship with the health care provider and their families were given enough information about TB disease. This is similar to the qualitative study of medication-taking behavior in primary care by [2] that investigated factors influencing medication intake patterns in general not TB specific based on interviews with 44 patients in a UK general hospital.

It was found out that patients show different disease and treatment backgrounds in which it explains the mechanisms of understanding, acceptance, skepticism and rejection with in the treatment cycle and proposes new approaches to enhance treatment adherence, safe medication and patient satisfaction.

## **CONCLUSIONS**

The findings of this study indicated that treatment outcome of the tuberculosis patients enrolled under CB-DOTS program in Mitooma district was associated with socio-economic factors (level of education), adherence to medications and the way Patients swallow their TB medication. The study further concludes that CB-DOT did improve TB treatment outcomes according to the study results. Monitoring the swallowing of TB drugs by health workers/relatives, health education and regular visits were highly described and recommended by the patients. Therefore studies on policies for implementation of patient-centered community-centered CB-DOT deserve further attention.

#### RECOMMENDATIONS

TB patients stated that CB-DOT improved their TB treatment outcomes through the monitoring while swallowing their TB drugs, health education and regular visits by health workers.

Therefore, this research study's recommendations are based on policies for implementation of patient-centered and community-centered CB-DOT.

There should be improved funding capacity of government or most agencies managing Tuberculosis in order to improve on progress of most of practical steps in the implementation science processes of CB-DOTs.

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