

# Treatment Outcomes and Associated Factors of Tuberculosis Patients on Directly Observed Treatment (Short Course) in a Tertiary Hospital in Port Harcourt, Nigeria

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## Abstract

**Introduction:** Although concerted efforts have been implemented to achieve tuberculosis (TB) prevention and control, varying outcomes have been reported in several quarters, despite the implementation of the directly observed treatment short-course (DOTS) strategy in virtually all parts of the world. It was considered necessary to assess the treatment outcomes of TB patients on DOTS strategy and the associated factors against the World Health Organization (WHO) target at the University of Port Harcourt Teaching Hospital (UPTH) Port Harcourt, to stimulate improvements in efforts toward patients care in the hospital and elsewhere. **Methods:** A health facility-based review of patients' records (January 1, 2014–December 31, 2018) at the TB Clinic of UPTH was carried out using a validated data record sheet. Patients undergoing treatment were excluded. Data were analyzed with the SPSS software version 20. Outcome frequencies were summarized, and the Pearson's Chi-square test was used to determine the association between the outcome and independent variables at  $P \leq 0.05$  statistical significance level. **Results:** Overall, 174 (25.7%) had completed treatment, 181 (26.7%) were cured, 95 (14.0%) died, 70 (10.3%) transferred out, 45 (6.6%) defaulted, 49 (7.2%) were not evaluated, 44 (6.5%) were lost to follow-up, and 8 (1.2%) failed treatment. There was a 17.6% decline in the proportion of patients that completed treatment from 35.9% in 2014 to 18.3% in 2018. On the contrary, there was an increase in the proportion of patients that were cured, from 14.1% in 2014 to 26.1% in 2018. **Conclusions:** The treatment success rate for TB in the hospital was below the WHO benchmark of 85% cure rate throughout the period under review. Basic reforms in the service delivery processes that specifically targets groups at risk (male patients, sputum smear-negative TB patients, and patients with human immunodeficiency virus/TB co-infection) with drug adherence counselling, defaulter tracing arrangements, and emphasis on drug-susceptibility testing are recommended to improve treatment outcomes.

**Keywords:** Directly observed treatment short-course, Nigeria, Rivers State, tuberculosis treatment, tuberculosis outcomes

## INTRODUCTION

Tuberculosis (TB) is a serious worldwide health problem that can cause illness in millions of people.<sup>[1]</sup> It is a prominent cause of death in persons living with human immunodeficiency virus (HIV) infection and also a leading cause of death from a single transmissible disease agent.<sup>[1]</sup> In 2017, an estimated 10 million incident cases of TB (133 cases/100,000 populace) and 1.6 million TB deaths occurred. TB epidemiology varied by the World Health Organization (WHO) regions.<sup>[2]</sup> The African and South-East Asia regions accounted for nearly 70% of the overall global TB burden. Six countries, namely India, Indonesia, China, Nigeria, Pakistan, and South Africa account for 60% of all

new cases, and Nigeria was rated 4<sup>th</sup> among the countries with the greatest burden of the disease.<sup>[3]</sup>

Directly observed treatment short course (DOTS) is one of the globally endorsed control strategies for TB. It was initiated by the WHO to drastically reduce poor drug adherence, treatment dropout rates, and achieve a cure rate of at least 85%.<sup>[4,5]</sup> The

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primary objective of the strategy was to ensure that a patient takes the TB drug in the presence of a health worker or a designated treatment supporter, who might be a family or community member.<sup>[6]</sup> This is because in resource-limited settings such as Nigeria, despite the free treatment, daily medications for a minimum period of 6 months poses a challenge to many patients.

With a successful DOTS strategy in place, the WHO estimates that the incidence of TB ought to be on the decline at a rate of 10% per year by 2025, and the proportion of people with TB who die from the disease will fall to about 6.5% by 2025.<sup>[7]</sup> Other possible treatment outcomes include treatment completed, treatment failure, died, lost to follow-up, not evaluated, moved to second-line for drug treatment, and treatment success rate. According to the Nigerian National TB and Leprosy Control Programme guideline,<sup>[8]</sup> the outcome categories are defined as follows:

- a. Cured: Initially, a smear-positive patient who completed treatment and had negative bacteriology result on at least two times, one of which is after treatment
- b. Completed treatment: Finished treatment, but without bacteriology result at the end of the treatment
- c. Treatment failure: Remaining smear-positive at five months despite the correct intake of medication
- d. Defaulted treatment: Patients who interrupted their treatment for two consecutive months or more of registration
- e. Died: Patients who died from any cause during the course of treatment
- f. Transferred-out: Patients whose treatment results are unknown due to transfer to another health facility
- g. Successfully treated: A patient who was cured or completed treatment
- h. Not evaluated: A patient whose laboratory assessment was not done at the end of treatment, and as such no outcome was assigned.<sup>[8]</sup>

Unsuccessful treatment outcome refers to the treatment of TB patients that resulted in treatment failure, i.e., remains smear-positive after five months of treatment, default (patients who interrupted their treatment for two consecutive months or more after registration), or died.<sup>[1,9]</sup> Although many local, regional, and international efforts have been implemented to achieve TB prevention and control, TB patients are still failing to complete treatment and be declared cured even with the institution of the globally recommended (DOTS) strategy in virtually all parts of the world. According to the WHO report of 2018, all over the world, a significant proportion of TB patients has not recovered after several courses of treatments. Some of the obstacles are relapsing after completion of the treatment, defaulting from treatment, and developing multi-drug-resistant TB (MDR-TB) among retreatment cases.<sup>[7,10]</sup> Nevertheless, a study done in Southern Ethiopia indicated that DOTS improved the TB treatment outcomes and service coverage thereby averting new infections and the emergence of drug resistance.<sup>[10]</sup> Some studies in Nigeria have shown varying outcomes and treatment success rates.<sup>[11]</sup>

Although the TB Clinic of the University of Port Harcourt Teaching Hospital (UPTH) has been operational for several decades, there has been no documented report on the outcome of services rendered to TB patients. It is against this background that it was deemed necessary to assess the treatment outcomes and the associated factors of TB patients on the DOTS strategy at the UPTH to weigh the clinic's performance against the WHO target of 85% cure rate or successful treatment rate. The outcome of the study is also expected to stimulate interests and improvements in efforts toward patient care in the hospital and elsewhere.

## METHODS

### Study area

The study was done at the DOTS Clinic of the UPTH, one of the two tertiary health-care institutions in Port Harcourt, the capital of Rivers State, South-south Nigeria. The hospital is a 950-bed health facility that offers tertiary health-care services, secondary and primary health care.<sup>[12]</sup> The TB clinic is domiciled in the Endemic Disease Unit of the Department of Community Medicine. The patients are generally referred from Port Harcourt and its environs, the Family Medicine Department, Accident and Emergency Department, referrals from the medical wards (male or female), children's ward, and the anti-retroviral clinic. The staff included the consultant community physicians, resident doctors, nurses, staff of voluntary agencies like the Family Health International and Health Assistants. Drug supply is from the Rivers State Ministry of Health. Diagnosis is made using patient history, medical examination, and laboratory finding (sputum acid-fast bacilli [AFB], culture, and GeneXpert). The patients are monitored with sputum samples taken at 2, 5, and 7 months, respectively, for AFB after the commencement of treatment and results recorded in a monitoring card.

### Study design

The study was a health facility-based, descriptive review of patient records at the TB Clinic of the UPTH, Port Harcourt.

### Study population

The present study was based on the facility records of all TB patients registered at the DOTS Clinic between the period under review.

### Inclusion/exclusion criteria

The records of all cases of pulmonary TB and extrapulmonary TB registered at the DOTS Clinic of UPTH between January 1, 2014 and December 31, 2018, as well as all cases transferred in and re-treatment cases were included in the study. Nevertheless, all patients undergoing treatment were excluded.

### Sampling and sample size determination

All case files of TB patients registered at the DOTS Clinic of UPTH from January 1, 2014, to December 31, 2018 that met the inclusion criteria were included in the study. The patient files/records were reviewed for completeness before inclusion. The minimum sample size was derived based on the Cochran's

formula for sample size calculation for the descriptive study,<sup>[13]</sup> using an estimate of the treatment success rate of 60.1%<sup>[1]</sup> and providing for a further 20% allowance to compensate for incompletely filled case files.

The formula was:  $n = Z^2pq/e^2$ , where  $n$  = minimum sample size for the study;  $Z$  = the normal curve, 1.96 at 95% confidence interval;  $e$  = margin of precision (5%);  $P$  = 60.1%, prevalence estimate of treatment success of 60.1%;  $q = 1 - p$ . After computation, a sample size estimate for the study of 461 was arrived at.

### Study instrument

Data were collected using a data extraction sheet which had the following sections: Section A: Sociodemographic characteristics of patients and year of treatment; Section B: Anthropometry attributes of patients (weights before commencement of treatment, at the end intensive phase of treatment, and at completion of treatment); and Section C: Laboratory results of patients (Type of TB by outcome of bacterial culture, Case type, Disease location, Patient categories during the start of treatment, HIV status and GeneXpert result). For type of TB bacterial culture status (smear), there were 1<sup>+</sup>, 2<sup>+</sup>, or 3<sup>+</sup>, negative or unknown. Those classified as unknown were those diagnosed based on clinical judgment of the physicians, WHO score for children, chest X-ray results, or computed tomography scan, or magnetic resonance imaging reports. The case types were either new or re-treatment cases. Disease location was either pulmonary or extrapulmonary TB. Treatment categories (CAT) were CAT1, CAT 2, R-6 (6 months regimen) or R-12 (12 months regimen). The HIV status of patients was either HIV positive on anti-retroviral therapy (ART), HIV positive, but not on ART, HIV negative or unknown HIV status. Gene Xpert results were rated as: Not detected, detected, or not done. Section D: Treatment outcomes (cured, treatment completed, treatment failure, died, lost to follow-up, not evaluated, moved to a second line, and treatment success).

### Study procedure/data collection process

Data were collected by the authors using a structured data extraction sheet designed for the study. The period under review covered from January 1, 2014, to December 31, 2018. Pertinent patient data from the year of treatment commencement, age, gender, residence, type of TB, smear results at baseline, HIV status, patient category during the start of treatment, and the outcomes of treatment were extracted from the case files and the treatment registers.

### Data analysis

Data were entered into MS Excel spreadsheet and then exported into SPSS software version 20. Descriptive statistics were used to generate and summarize the outcome frequencies. Pearson's Chi-square test was used to determine the association between treatment outcome and independent variables. The level of statistical significance was set at  $P \leq 0.05$ .

### Validity/reliability

Face validity of the data extraction tool was done to ensure that it measured what it intends to measure.

### Ethical considerations

Approval was sought and obtained from the Research and Ethics Committee of the University of Port Harcourt (UPH/CEREMAD/REC/MM61/054). Permission to conduct the study was also sought and obtained from the UPTH.

### Limitations of the study

This was based on the records of TB patients' case files and registers. It was not feasible to independently verify the accuracy of these records nor was it possible to collect additional data needed to confirm or refute the findings. However, since the findings were based on routine/regular data, it reflected the operational reality of the facility. Some information was missing from the case files.

## RESULTS

The number of cases that met the inclusion criteria and included in the study according to the year was as follows: 2014 (128 cases), 2015 (195 cases), 2016 (115 cases), 2017 (124 cases), and 2018 (115 cases), respectively, bringing the number to a total of 677. The present study included all age groups and ranged from 6 weeks to 83 years. The majority (70.2%) of the patients were adults, and with 29.8% in the pediatric age category. The mean age was 28.95 years  $\pm$  19.3 years, and the standard error was 0.74. The median age was 31.00 years, and the interquartile range was 31.00 years. Out of the 677 cases under review within the period, the greater part 371 (54.8%) were males, and 306 (45.2%) were females. By marital status: 127 (18.8%) were married, and 124 (18.3%) were widowed, 10 (1.5%) were divorced or separated from their partners. The marital status of 409 (60.4%) was not provided, and they were lumped along with children. Majority 465 (68.7%) of the patients lived in the urban areas of the state, whereas 212 (31.3%) lived in the rural areas. According to occupations, there were several missing records, especially for the years 2014, 2015, and some parts of 2016 totalling, 389. For those recorded, 110 (38.2%) of the patients were self-employed (as artisans, fishing, farming, trading, and business), whereas 102 (34.4%) were unemployed (mainly students and homemakers) and 76 (26.4%) were employed [Table 1].

Overall, during the 5-year period under review, 174 (25.7%) had completed treatment, 181 (26.7%) were cured, 95 (14.0%) died, 70 (10.3%) transferred out, 45 (6.6%) defaulted, 49 (7.2%) were not evaluated, 44 (6.5%) were lost to follow-up, and 8 (1.2%) failed treatment. There was a 17.6% decline in the proportions of patients that completed treatment from 35.9% in 2014 (46 of 128 patients) to 18.3% in 2018 (21 of 115 patients). On the contrary, there was an increase in the proportions of patients that were cured, from 14.1% in 2014 to 26.1% in 2018. There was no significant change in the proportion of patients that met the criteria for treatment failure over the years under review. Although there appeared to be a decline in the proportions of patients who defaulted in receiving treatment, there was also an increase in the proportion of those that were

not evaluated at the end of the treatment period (none in 2014, but 37.4% in 2018). There was also an overall increase in the proportions of patients that were lost to follow-up from none in 2014 to 12.1% in 2017, but this figure dropped to 4.3% in 2018 [Table 2].

From the evaluation, 355 (52.4%) had a successful treatment outcome in the hospital, against 322 (47.6%) unsuccessful treatment outcome. At no point during the period under review did the treatment success rate, meet or exceed the WHO recommendation of 85%. The highest rate of treatment success (67%) was achieved in 2016 [Table 3].

There was a significant relationship between age, gender, and treatment outcomes. In the age category of 21–40 years, 163 (61.0%) of the patients had a successful treatment outcome,

compared to the rest age categories ( $P = 0.002$ ). The female gender, 174 (56.9%) more successful treatment outcome when compared with the male 181 (48.8%) ( $P = 0.036$ ). Other sociodemographic variables such as residential area and marital status did not show any significant association [Table 4].

Disease-related factors such as the case type (new or retreatment case), sputum smear (positive or negative), and HIV status (positive or negative) had a significant relationship with treatment outcomes. Patients who underwent re-treatment for TB, 48 (65.8%) had successful treatment outcomes compared to new cases 307 (50.8%) ( $P = 0.016$ ). The smear-positive TB (PTB) cases 136 (68.0%) had better treatment outcomes compared to smear-negative TB cases 219 (45.9%) ( $P = 0.000$ ). Patients with HIV-negative status, 238 (59.6%) had more successful treatment outcomes compared to those with HIV-positive status 114 (43.5%)  $P < 0.01$  [Table 5].

**Table 1: Sociodemographic profile of study participants**

Variable	Frequency (n=677), n (%)
Age group (years)	
0-20	222 (32.8)
21-40	267 (39.4)
41-60	153 (22.6)
61-80	34 (5.0)
81-100	1 (0.2)
Mean age (years), median age (years), interquartile range (years)	29.0±19.3, 31.0, 31
Gender	
Male	371 (54.8)
Female	306 (45.2)
Marital status	
Unknown/child	409 (60.4)
Married	127 (18.8)
Widowed	124 (18.3)
Divorced/separated	10 (1.5)
Single	7 (1.0)
Residential area	
Urban	465 (68.7)
Rural	212 (31.3)
Occupation (n=288)	
Self-employed	110 (38.2)
Unemployed	102 (35.4)
Employed	76 (26.4)

## DISCUSSION

The cumulative successful treatment outcome rate for all TB types of 52.4% reported in this study was very low compared to what has been reported in several studies in Nigeria and elsewhere<sup>[1]</sup> and also fell far short of the WHO recommended a target of 85%.<sup>[14]</sup> This poor outcome represents a huge challenge for patient survival and severe implication for the emergence and spread of MDR-TB in the state and its environs. The huge disparity in the outcomes could be partly attributed to the higher prevalence of TB/HIV co-infection in the index study of 38.7% when compared to a TB/HIV co-infection rate of 19.1% in a similar study in Ethiopia.<sup>[15]</sup> Nevertheless, the result calls for an urgent, focussed intervention to reduce defaulter rates, loss to follow-ups, and the proportion of patients not evaluated, as well as take a second look at the service delivery processes and programme contents of the TB clinic of the hospital.

Furthermore, the experience from our study shows that there was an inverse relationship with age and successful treatment outcomes because as the age of the patients increased, the proportion with successful treatment outcomes declined. This finding may be due to a higher loss to follow-ups, mortality, and

**Table 2: Treatment outcomes by year**

Variable	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	Total (%)
Completed treatment	46 (35.5)	50 (25.6)	35 (30.4)	22 (17.7)	21 (18.3)	174 (25.7)
Cured	18 (14.1)	45 (23.1)	42 (36.5)	46 (37.1)	30 (26.1)	181 (26.7)
Treatment failure	2 (1.6)	4 (2.1)	0	2 (1.6)	0	8 (1.2)
Defaulted	35 (27.3)	10 (5.1)	0	0	0	45 (6.6)
Transferred	15 (11.7)	33 (16.9)	7 (6.9)	15 (12.1)	0	70 (10.3)
Died	12 (9.4)	33 (16.9)	17 (14.8)	19 (15.3)	14 (12.2)	95 (14.0)
Loss to follow up	0	12 (6.1)	12 (10.4)	15 (12.1)	5 (4.3)	44 (6.5)
Not evaluated	0	4 (2.1)	0	2 (1.6)	43 (37.4)	49 (7.2)
Removed from treatment register	0	4 (2.1)	2 (1.7)	3 (2.4)	2 (1.7)	11 (1.6)
Total	128 (18.9)	195 (28.8)	115 (17.0)	124 (18.3)	115 (17.0)	677 (100)

**Table 3: Two categories treatment outcome by year of treatment**

Variable	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)	Total (%)
Successful treatment	64 (50.0)	95 (48.7)	77 (67.0)	68 (54.8)	51 (44.3)	355 (52.4)
Unsuccessful treatment	64 (50.0)	100 (51.3)	38 (33.0)	56 (45.2)	64 (55.7)	322 (47.6)
Total	128 (18.9)	195 (28.8)	115(17.0)	124 (18.3)	115 (17)	677 (100)

**Table 4: Association of between sociodemographic factors with treatment outcomes**

Variable	Treatment outcome		Total	$\chi^2$	P
	Successful (%) (n=355) (52.4)	Unsuccessful (%) (n=322) (47.6)			
Age					
0-20	109 (49.1)	113 (50.9)	222 (100.0)	17.307	0.002*
21-40	163 (61.0)	104 (39.0)	267 (100.0)		
41-60	72 (47.1)	81 (52.9)	153 (100.0)		
61-80	11 (32.4)	23 (67.6)	34 (100.0)		
81-100	0 (0.0)	1 (100.0)	1 (100.0)		
Gender					
Male	181 (48.8)	190 (51.2)	371 (100.0)	4.385	0.036*
Female	174 (56.9)	132 (43.1)	306 (100.0)		
Total	355 (52.4)	322 (47.6)	677 (100.0)		
Occupation					
Unemployed	65 (63.7)	37 (36.3)	102 (100.0)	3.370	0.185
Self-employed	63 (57.3)	47 (42.7)	110 (100.0)		
Employed	38 (50.0)	38 (50.0)	76 (100.0)		
Residential area					
Rural	108 (50.9)	104 (49.1)	212 (100.0)	0.276	0.599
Urban	247 (53.1)	218 (46.9)	465 (100.0)		
Total	355 (52.4)	322 (47.6)	677 (100.0)		
Marital status					
Married	77 (52.7)	69 (47.3)	146 (100.0)	5.444	0.352**
Single	77 (60.6)	50 (39.4)	127 (100.0)		
Divorced/separated	4(57.1)	3 (42.9)	7 (100.0)		
Widowed	5 (50.0)	5 (50.0)	10 (100.0)		
Not recorded/child	192 (49.6)	195 (50.4)	387 (100.0)		
Total	355 (52.4)	322 (47.6)	677 (100.0)*		

\*Statistically significant, \*\*Fisher's exact; level of significance for this study was set at  $P < 0.05$

severe morbidity associated with aging as has been reported in previous studies.<sup>[10,16]</sup> Again, this once more underscores the need to critically appraise and perhaps review the role of treatment supporters in the DOTS programme initiative of the hospital, which is designed to ensure that patients, especially the vulnerable ones get additional home and community-based support that could enhance their full recovery.

With respect to gender, a greater proportion of females compared to their male counterparts had better treatment outcomes. This finding corroborates that by Oyefabi *et al.* in Zaria, Nigeria.<sup>[17]</sup> This is expected as females are known to exhibit better health-seeking behaviors than males and adhere better to medications and advice of health-care providers.<sup>[18,19]</sup> There was also a significant relationship that reveals that re-treated TB cases had better treatment outcomes than new cases. This finding was very reassuring because it was a pointer that the adherence counseling of the TB clinic was possibly yielding the desired results. It might also be partially influenced

by the drug-susceptibility testing which became commonly conducted to inform the choices of treatment regimens. However, the finding was at variance with some other studies that demonstrated unsuccessful treatment outcome among re-treated cases compared to new cases.<sup>[11]</sup>

There was also a significant relationship between sputum smear-PTB patients at presentation and treatment outcome, as smear-PTB patients had better treatment outcomes compared to sputum smear-negative TB patients. This finding is in agreement with that conducted in Ethiopia where smear-PTB patients had 3.204 times more successful treatment outcomes compared to smear-negative TB cases.<sup>[1]</sup> This is because many smear-negative patients might live with a false sense of recovery since their sputum test was negative results and become complacent with their medications, which might compromise their health outcome. In other situations, many smear-negative cases could be severely ill, with co-morbidities or immunocompromised with HIV, which

**Table 5: Association between disease-related factors and treatment outcomes**

Variable	Treatment outcome		Total	$\chi^2$	P
	Successful (n=355; 52.4), n (%)	Unsuccessful (n=322; 47.6), n (%)			
Treatment category					
CAT 1	106 (54.6)	88 (45.4)	194 (100.0)	3.030	0.382
CAT 2	21 (53.8)	18 (46.2)	39 (100.0)		
R-6	222 (52.1)	204 (47.9)	426 (100.0)		
R-12	6 (33.3)	12 (66.7)	18 (100.0)		
Case type					
New case	307 (50.8)	297 (49.2)	604 (100.0)	5.817	0.016*
Retreatment	48 (65.8)	25 (34.2)	73 (100.0)		
Sputum smear at presentation					
Negative	219 (45.9)	258 (54.1)	477 (100.0)	27.566	0.000*
Positive	136 (68.0)	64 (32.0)	200 (100.0)		
Positive sputum smear					
1+	69 (67.0)	34 (33.0)	103 (100.0)	0.212	0.899
2+	40 (67.8)	19 (32.2)	59 (100.0)		
3+	27 (71.1)	11 (28.9)	38 (100.0)		
Total	136 (68.0)	64 (32.0)	200 (100.0)		
HIV status (n=661)					
Negative	238 (59.6)	161 (40.4)	399 (100.0)	16.545	0.000*
Positive	114 (43.5)	148 (56.5)	262 (100.0)		
HIV positive (n=262)					
On art	112 (43.4)	146 (56.6)	258 (100.0)	0.070	0.792
Not on art	2 (50.0)	2 (50.0)	4 (100.0)		

\*Statistically significant

could result in despair and subsequent reluctance in taking their medications.

With regard to HIV status and association with treatment outcomes, more HIV-negative patients had better treatment outcomes than HIV-positive patients. This finding corroborates similar findings by other researchers.<sup>[15]</sup> This is probably because the HIV/TB co-infection, like most co-morbidities can be very emotionally tasking, and associated with additional pill burden/load, which could possibly negatively affect their medication adherence, thus leading to poor treatment outcomes.

## CONCLUSIONS

It was obvious from the study that the treatment success rate for TB in the DOTS clinic was below expectation and the global standard as represented by the WHO benchmark. In light of this, there is a compelling need to institute some basic reforms in the service delivery processes, specifically targeting male patients, patients with HIV/TB co-infection, and sputum smear-negative patients with drug adherence counseling, defaulter tracing arrangements, and emphasis on drug-susceptibility testing for all patients are highly recommended.

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## Conflicts of interest

There are no conflicts of interest.

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