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Original Research Article

Trends and Determinants of Tuberculosis Treatment Outcome of Patients on Directly Observed Treatment in a University Teaching Hospital, South-South, Nigeria: A Five-Year Retrospective Study

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Abstract

Background: Tuberculosis (TB) a leading cause of death from a single infectious agent, continues to constitute a serious public health challenge in both developed and developing countries. Despite the implementation of the DOTS plan and the subsequent adoption of the End TB strategy, Nigeria continues to fall short of WHO targets especially TB treatment success rate (TSR).

Aim: This study aimed at identifying the trend of TB treatment outcomes and its determinants among patients on TB treatment at the University of Port Harcourt Teaching Hospital Directly Observed Therapy Short-Course (UPTH DOTS) Clinic.

Materials and Method: It was a cross sectional study. Data was collected retrospectively. Information was obtained from the medical records and TB registers at the facility's DOTS clinic covering a five-year period (2016-2020). All patients that were registered in the program whether transferred out or retained were included. The data was retrieved and analysed as needed.

Results: The cumulative results revealed that majority of the subjects were mainly new patients (93.0%), Pulmonary TB (85.2%), and HIV negative patients (65.1%), while the result of the treatment success rate was 61.1% (35.5% cured and 25.6% completed treatment), with treatment failure (0.7%), Lost To Follow Up (LTFU) (16.1%), death (13.4%), transfer out (5.0%), and 3.9% not assessed. However, younger age, being female, employed, having tuberculosis of the lungs (PTB) and being HIV negative were identified as contributors to good treatment outcomes.

Conclusion: The trend in the TB treatment outcome over the 5-year period under review showed that treatment success was highest in 2016 (71.3%) and had a major dip in 2020 (52.1%). This low TSR in 2020 cannot be unconnected with the Corona Virus pandemic which disrupted health and healthcare world-wide that year. Also, the result revealed that younger age, female sex, being employed, PTB, and negative HIV status were the major determinants of favourable TB treatment outcome.

Keywords: Tuberculosis, Treatment outcome, Determinant, DOTS centre, Port Harcourt.

Introduction

Tuberculosis (TB), an ancient disease, continues to constitute a serious public health challenge in both developed and developing countries despite well-coordinated global efforts over the decades.¹ Some of the earliest public health measures to

combat the spread of TB were identification of the tubercle bacilli by Robert Koch in 1882, BCG vaccination starting from 1921, discovery of streptomycin in 1944and use of isoniazid from $1952.^{2}$ The World Health Organization (WHO), never relented in the fight to drive down morbidity and mortality due to TB. With global partnerships, the trend was from declaring TB global emergency in 1993 to Stop TB Strategy in year 2006. The successes recorded together with the Millennium Development Goals gave the 67th World Health Assembly the impetus to adopt the 'End TB Strategy' in 2014 with the vision of making the world free of TB by the year $2035.^3$

A 2020 progress report by the UN Secretary General showed that global TB incidence is falling by about 2% per year so that between 2015 and 2020, the cumulative reduction was 11%⁴. The report showed progress but still fell short of the goal of the first 'End TB'' milestone of 2020, which benchmarked reduction of incidence rate by 20%.

The report further noted that the 30 high burden countries accounted for about 86% of new cases. Eight countries harboured two thirds of the total, with India leading, followed by China, Indonesia, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa. The common denominator here is that they are all developing countries with very large populations.^{4,5}

Several reports exist to show that the adoption of the DOTS strategy by most countries did yield many positive outcomes. Incidence of TB in Nigeria (per 100,000 people) has been steady at 219 from year 2000 to 2020, although with all the efforts, a decline was expected especially as global incidence was noted to be reducing by an average of 1.5% per year since 2000 and huge global actions to control HIV/AIDS the other epidemic that has been recognised as fuelling the TB epidemic. The WHO also reported a case detection rate for Nigeria (%, all forms) from 22% in 2015 to 30% in 2020, as well as the trend of Tuberculosis treatment success rate (%

cured/completed treatment) of 84% in 2015, rising consistently to 88% in 2019.^{6,7}

In identifying determinants of TB treatment outcomes, a Nigerian South-Eastern study pinpointed category of treatment, sex and age of patients as main determinants.⁸ Another study from a contiguous state identified type of patients. regimen, not living alone treatment and educational status as determinants of good outcomes. An earlier review from our locality, Rivers state, Nigeria, reported younger age, female gender, retreatment cases, negative HIV status and positive sputum smear as factors related to good treatment outcome.⁹

Our study aimed at identifying the trend of TB treatment outcomes and its determinants among TB patients who assessed care in the DOTS Clinic, University of Port Harcourt Teaching Hospital (UPTH), in Rivers State, Nigeria, from year 2016 to 2020. This study is significant in that it is evaluating progress or otherwise at our centre by the first milestone of the 'End TB Strategy' (2015-2020). This will help provide information on the gaps in the TB control program as well as insights into the relationship between various determinants and TB treatment outcomes.

Materials and Methods

Study Design

Across-sectional study design was employed. Data was collected retrospectively using secondary data. It involved the review of folders and TB Registers at the Directly Observed Treatment Short course (DOTS) clinic of the UPTH, between January 2016 and December 2020.

Study Setting

The National TB and Leprosy Control Program opened a regional TB Reference Laboratory in the hospital for the South-South Zone of the country in 2013, one of Nigeria's six TB reference laboratories. This laboratory, together with the DOTS clinic at the hospital, has been primarily responsible for the diagnosis and treatment/ management of tuberculosis patients in Port

Harcourt and its surroundings under the National Tuberculosis and Leprosy Control Program (NTLCP). The hospital, a foremost referral centre for the whole of South-South and some parts of South-East geopolitical zones of the country, was excellently positioned for this research.

Study Population

The research population was made up of Tuberculosis patients who were enrolled for TB therapy at the UPTH's DOTS Clinic between January 2016 and December 2020. Every component of the patients' course of therapy from the moment of diagnosis was regarded an outcome, hence all patients who enrolled within the stipulated period were included, and none was omitted.

Study Instruments

Secondary data was extracted from the TB register of the UPTH DOTS clinic. A structured data collection format was developed for the purpose of collecting data from the TB patients' medical records. The extraction sheet contained sections which collected data regarding the sociodemographic details (age, sex, employment status, and place of residence), clinical details (type of TB infection, status of HIV infection, method of diagnosis), Registration details (year of registration, Patient type) and Treatment details at every visit (start and end date, smear result at two and five months and other follow up dates to determine treatment outcomes).

Operational Definitions

The following standard clinical case definitions and operational terms were used;

Pulmonary Tuberculosis (PTB): Patients with TB of the lung parenchyma or tracheobronchial tree who have been bacteriologically proven or clinically diagnosed.

Extra pulmonary tuberculosis (EPTB): Patients with TB affecting organs other than the lungs who were bacteriologically proven or clinically identified.

Cured: This reflects a patient who was formerly sputum smear-positive and is now sputum smear-negative as of the latest month of therapy and at least once before.

Treatment completed: A TB patient who finished therapy without showing signs of failure or cure. Patients who have had their therapy completed and their symptoms resolved, but whose sputum smear and culture results have not been available in the past month of treatment or on at least one earlier occasion.

Treatment failure: a positive smear patient who though on treatment persisted or became smear positive again five months or more after starting therapy.

Not evaluated: Patients with unassigned treatment outcome.

Transferred out: A patient who is being transferred to another medical facility.

Defaulted (interrupted patient): A patient who has been on treatment for at least four weeks and whose therapy was discontinued for two months or longer without physician clearance for whatever reason.

Died: The proportion (%) of patients who died before completing therapy for whatever reason.

New case: a patient who has never been treated for TB or has only been on anti-TB medication for less than four weeks.

Relapse: a TB patient who was previously treated and proclaimed cured or who finished a full course of therapy but now exhibits sputum smear positive TB.

Successful treatment outcome (treatment success): It is the total number of patients who have been cured or have finished therapy.

Unsuccessful treatment outcome: The total number of defaulters, deaths, and treatment failure patients.

Statistical Analysis

The data was verified for completeness, coded, and entered into a computer using a Microsoft Excel 2019 spreadsheet, which was then exported to the SPSS version 21 statistical program.

Categorical variables such the socioas demographic and clinical characteristics were described in frequency and percentage, according to descriptive analysis. Inferential statistics: Chisquare was used to test the significance of the connection between socio-demographic characteristics, patient type, TB type, and HIV status with treatment outcome, with a P-value of 0.05 within a 95 percent confidence range. For this analysis, treatment outcomes were classified

as; treatment successful (cured and treatment completed) and treatment unsuccessful (treatment failure, died and defaulted).

Ethical Consideration

Ethical approval was obtained from the Ethical Review Committee of University of Port Harcourt. Confidentiality was ensured as patients' names were not extracted but numbers were given.

Results

Socio-demographic and clinical details of the TB Patients in DOTS Clinic, UPTH

Table 1: Socio-demographic and clinical details of patients on TB treatment in DOTS Clinic, UPTH

Variables	Frequency (n=614)	Percent
Age category (years)		
1-10 years	88	14.3
11 – 20 years	75	12.2
21 – 30 years	116	18.9
31 – 40 years	150	24.4
41 – 50 years	98	16.0
51 – 60 years	53	8.6
>60 years	34	5.5
Sex		
Male	335	54.6
Female	279	45.4
Employment status		
Employed	338	55.0
Unemployed	276	45.0
Place of residence		
Urban	511	83.2
Rural	103	16.8
Type of patients		
New	571	93.0
Retreatment	47	7.0
Year of enrolment		
2016	115	18.7
2017	125	20.3
2018	114	18.6
2019	141	23.0
2020	119	19.4
Type of TB		
PTB	523	85.2%
EPTB	91	14.8%
HIV status		
Positive	214	34.9
Negative	400	65.1

Table 1: Socio-demographic and clinical details showed majority were aged 31 - 40 years (24.4%), with a mean age of 31.92 ± 18.06 years.

Males were more (54.6%) while those employed were also more (55.0%) than the unemployed (45.0%). Most were living in the urban area

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(83.2%). New patients (93.0%) were in the majority than those for retreatment (7.0%), while most patients were enrolled into the clinic in 2019 (23.0%) and the least (18.6%) in 2017. Furthermore, 523 (85.2%) of the patients were

diagnosed with Pulmonary TB, 15% were extrapulmonary TB and 400 (65.1%) were noted to be HIV negative while 214 (34.9%) were HIV positive.



Distribution of Types of Patient (New or Retreatment)

Figure 1: Type of TB patient registered for TB treatment in DOTS Clinic, UPTH over a 5-year period

The trend in type of TB patients seen in the DOTS Clinic over a 5-year period is presented as in Figure 1. According to this result, types of TB patients seen in the clinic were similar over the period in review. The rate of new patients ranged from 90.4% to 96.0% while that of retreatment ranged from 4.0% to 9.6%.



According to the chart (figure 2), cumulative treatment success rate (TSR) for the period was 61.1%, of which 217(35.5%) were cured while 157 (25.6%) completed their treatment. Treatment failure was recorded for only 4 (0.7%) of the patients while 99 (16.1%) were lost to follow up (LTFU). Another 82 (13.4%) of the patients died during treatment while 31 (5.0%) were transferred out and 24 (3.9%) were not evaluated.

A look at the treatment outcome by years showed that the Treatment Success Rate was highest in 2016 (71.3%) hovering slightly lower thereafter until a major dip in 2020 (52.1%), while the cure rate was near steady from 2016 through 2019 again with a major dip in 2020 (22.7%). For completed treatment, 2016 had the highest percentage (31.3%), other years were slightly lower but the dip occurred in 2017 (17.6). Treatment failure was recorded for 2017 (1.6%) and 2019 (1.4%) there were no treatment failures recorded for 2016, 2018 and 2020. The rate of LTFU was highest in 2020 (33.6%) and lowest in 2016 (9.6%), while death rate was highest in 2017 (16.0%) and lowest in 2020 (10.9%). The rate of transfer of patients from the centre to other centres was highest in 2017 (11.2%) and lowest in 2020 (3.4%), while those who were not evaluated were more in 2018 (10.5%) and least in 2016 (0.9%). 2016 consistently showed better outcomes in indicators evaluated while 2017 had worst outcomes among pre-pandemic years. In finding explanations for the poorer indicators of 2017, there is need to look back at local and national events such as industrial actions during 2017 or even change in human resource structure at the clinic. We have already reasoned that the poor indicators noticed for 2020 was as a result of the pandemic.

Determinants of TB Treatment outcomes in DOTS Clinic, UPTH

Various factors were analysed to identify determinants of TB treatment outcomes and presented in the Table 2. According to the findings, Treatment Success Rate was highest among those aged 21 - 30 years (71.6%), females (67.4%), employed (62.1%), urban residents (61.1%), retreatment cases (68.1), pulmonary TB patients (61.2%) and HIV negative patients (67.3%). When the results above were subjected to further analysis, it revealed statistically significant relationships between age $(X^2 =$ 87.934; p = 0.0001), sex (X² = 16.629; p = 0.011), employment status ($X^2 = 20.323$; p = 0.002), type of TB ($X^2 = 40.811$; p = 0.0001) and HIV status $(X^2 = 45.894; p = 0.0001)$ of the patients and the treatment outcomes. On the other hand, there was no statistically significant relationship between place of residence and type of patient (new and retreatment) with their treatment outcomes (p>0.05).

1 b treatment outcome					
Variables	Successful	Unsuccessful	Total		
	n (%)	n (%)	n (%)		
Age category					
0 - 10 years	48 (54.5)	40 (45.5)	88 (100.0)		
11 – 20 years	51 (68.1)	24 (31.9)	75 (100.0)		
21 – 30 years	83 (71.6)	33 (28.4)	116 (100.0)		
31 – 40 years	92 (61.3)	58 (38.7)	150 (100.0)		
41 – 50 years	55 (56.1)	43 (43.9)	98 (100.0)		
51 - 60 years	31 (58.5)	22 (41.5)	53 (100.0)		
>60 years	14 (41.2)	20 (58.8)	34 (100.0)		
Chi Square= 87.934; p-value = 0.0001*					
Sex					
Male	186 (55.5)	149 (45.5)	335 (100.0)		
Female	188 (67.4)	91 (32.6)	279 (100.0)		
Chi Square = 16.629: p-value = 0.011*					
Employment status	•				
Employed	210 (62.1)	128 (37.9)	338 (100.0)		
Unemployed	164 (59.4)	112 (40.6)	276 (100.0)		
	Chi Square = 20.323; p-value = 0.002*				
Place of residence	-				
Urban	312 (61.1)	199 (38.9)	511 (100.0)		
Rural	62 (60.2)	41 (39.8)	103 (100.0)		
	Fisher's exact test = 6.866 ; p-value = 0.307				
Type of patient					
New	342 (59.9)	229 (40.1)	571 (100.0)		
Retreatment	32 (68.1)	11 (31.9)	43 (100.0)		
Fisher's exact test = 15.604 ; p-value = 0.395					
Type of TB		-			
Pulmonary TB	320 (61.2)	203 (38.8)	523 (100.0)		
Extra pulmonary TB	54 (59.4)	37 (40.6)	91 (100.0)		
	Chi Squar	re = 40.811; p-value = 0.0001*			
HIV Status	-	_			
Positive	105 (49.1)	109 (50.9)	214 (100.0)		
Negative	269 (67.3)	131 (32.7)	400 (100.0)		
Chi Square = 45.894; p-value = 0.0001*					

 Table 2: Determinants of TB treatment outcome among patients on TB treatment in DOTS Clinic, UPTH

 TB treatment entreme

Discussion

Treatment outcomes

The cumulative treatment success rate (TSR) for TB in the DOTS centre for the period (2016-2020) was noted to be 61.1% (35.5% cured and 25.6% completed treatment) while the unsuccessful treatment outcome of 39.1% was composed of treatment failure 0.7%, LTFU (16.1%), death (13.4%), transferred out (5.0%) and 3.9% were not evaluated. This is similar to the findings of Pefura Yone, Kengne and Kuaban¹⁰ and Orji, Chime and Ossai ¹¹that reported a Treatment success rate (TSR) of 68.4% and 67.9% respectively. However, this is lower than the target of 85% for TSR set by the WHO.¹². Our finding is also lower than the report of Tweya et al.¹³, Hamusse et al.^{14.} Olarewaju et al.¹⁵, Zenebe and Tefera¹⁶ and Duru et al.¹⁷. They had treatment success rates of 86%, 83.6%, 85.5%, 81.8% and 81.4%, respectively. However, our result is much higher than the rate reported from two tertiary hospitals in Ethiopia^{18, 19} (29.5%, 26%) and another study also from a teaching hospital in south-east, Nigeria²⁰ (56.5%). During our review of literature, we noticed a trend towards lower rate of TSR in tertiary health facilities within Nigeria and outside compared with other tiers of the health service. This observation need to be investigated further. An earlier study (2014-2018) from our hospital reported a TSR of 52.4%⁹. The lower TSR in our study compared to the WHO target may also be linked to the high rates of transferred-out and patients not evaluated in the report as it is not easy to know the treatment

outcomes for patients who were transferred out or those not evaluated due to incomplete records during the study period. Assigning patients transferred out as unsuccessful outcome is a misclassification of outcome. A tertiary hospital receives referrals from far and wide. What usually happens is that patients are investigated, diagnosed, stabilized, placed on treatment or referred to a DOTS Centre of closer proximity to the patient for drug taking. This is done to improve accessibility of care and increase treatment adherence. Furthermore, the category of patients listed as not evaluated are those patients that have missing or incomplete documentation such as test results in the DOTS register which results in final treatment outcome being unknown. It is not unlikely that results or other documents may miss from the patients' folder since they use the same folder to access care in other clinics within the hospital.

The TSR in this study is lower than the observed trend of Tuberculosis treatment success rate (% of new cases cured/completed treatment) in the recent past years in Nigeria. The WHO and the FMOH reported TSR of 84% in 2015, rising steadily to 88% in 2019.^{6,7,12, 21.}

The trend in the TB treatment outcome over a 5year period in our DOTS clinic showed that treatment success was highest in 2016 and least in 2020. However, cure rate was highest in 2019 and lowest in 2020, while 2016 and 2017 represented the year with the highest and lowest rates of completed treatment, respectively. Treatment failure (TF) was highest in 2017 and was lowest (0%) in 2016, 2018 and 2020, while the rate of LTFU, death and transferred out (TO) was highest in 2020, 2017 and 2017, respectively and least in 2016, 2020 and 2020 respectively. Similarly, Moges et al²² and Worede and Abitew²³ reported yearly swinging variation of treatment success rate. However, the trend in the results showed 2020 to consistently record unfavourable outcomes. 2020 was unique in world history with reference to SARS-COV2 (COVID-19) pandemic that produced astronomically high morbidity and

mortality and impacted gravely on the practice of public health so that all other health conditions received much less attention.

Among the different categories of patients in the DOTS centre, new patients formed the vast majority (93.0%) and ranged from 90.4% to 96.0% over the 5-year period under study. The between association patient category and showed no statistical treatment outcomes significance (p > 0.05) as both new and retreatment patients had competitive outcomes. In separate studies, Olarewaju¹⁵ and two Umeokonkwo²⁰ corroborated our finding. They had 95.1% and 91.2% new TB cases, respectively. Olarewaju et al.¹⁵ differed slightly in reporting that higher TSR was significantly associated with being a new case of TB. The continuous increase in the enrolment of patients with TB in the clinic on a yearly basis could have dual explanations in the sense that it could be a pointerto a continuous spread of the disease amongst the populace or it signified improved case finding, screening and enrolment into the treatment programme.

Determinants of TB Treatment outcomes

In this study, the association between the sociodemographic characteristics of the patients and the treatment outcome showed that age (21 - 30)years), sex (females) and being employed have a statistically significant relationship with positive treatment outcomes. This is in agreement with the finding of Tessema and Muche¹⁸ thatshowed patients aged more than 40 years old were more likely to have unsuccessful treatment outcome, while Worede and Abitew²³ reported that age (<14years, 15 - 24 years and 25 - 34 years) and area of residence (urban) were likely to have a successful treatment outcome. In Worede's report, gender had no significant input on treatment outcome. Zenebe and Tefera¹⁶ also reported that age and sex (females) were significantly associated with treatment success. Further credence to our report came from Biadglegne et al.^{19.} In their study, they observed that being of older age, and a rural resident were associated with a lower treatment

success. The determinants keep getting varied as Mengistu et al.²⁴ and Olarewaju et al¹⁵, in separate studies, identified no significant association between sex, age, residence, type of TB. HIV status, and successful TB treatment outcome. The association of unsuccessful outcome with increasing age, which could be explained by a tendency to more chronicity, delayed TB diagnosis due to interests in other common cough differentials which are commoner with age such as COPD, bronchitis, bronchiectasis (Karo et al.)²⁵. It could also be due to higher loss to followup, more death rates and worsened TB morbidity in the elderly, alongside other co-morbidities and general physical frailty associated with advancing age. Anecdotally, the elderly are likely to prefer to do things their way, refusing to follow directions, become non-adherent to medications and followup visits especially when they feel better. This significant negative treatment outcome associated with old age, males and the unemployed presents a serious challenge in the treatment of TB. The elderly are more likely to present with severe symptoms and may even transmit it easily to the young ones (children, grandchildren) who may be around them. For the unemployed, their financial challenges will impact on their care seeking behaviour, resulting in delays and the continued spread of the TB bacilli.

The result of this study also showed that majority of the patients presented with PTB (85.2%) but Biadglegne et al.¹⁹ revealed in their report that EPTB cases (56.2%) were more than PTB cases (43.8%). Olarewaju et al. ¹⁵also reported that PTB was noted amongst 89.74% of the cases, while the relationship between TB type and treatment outcome showed a statistically significant (p<0.05) relationship as PTB patients recorded higher treatment success rate. Worede and Abitew²³ also discovered that PTB patients were three times more likely to have successful treatment outcome compared to EPTB patients. Biadglegne et al.¹⁹ Orji, Chime and Ossai¹¹ reported that PTB was a predictor of good treatment outcome. Studies at primary, secondary and tertiary levels of care of some Nigerian hospitals by Ibrahim et al.²⁶ and Oyefabi et al. ²⁷reported higher treatment success rates for PTB. It was Umeokonkwo et al.²⁰ that provided a contrary report. They found no difference in treatment outcome for PTB and EPTB.

The duo of TB and HIV constitute a lethal combination of diseases that significantly impact the public health system individually and collectively. HIV infection is considered the main risk factor for the increase in the number of TB patients and poor treatment outcomes due to weakened immune system.²⁸ The result from this study showed that about two thirds of the patients (65.1%) were HIV negative while the relationship between HIV status and treatment outcome is statistically significant (p<0.05) as there was higher treatment success (67.2%) among the HIV negative TB patients. This finding is tallies with those of Biadglegne et al.,¹⁹ Babatunde et al., ²⁸and Orji, Chime and Ossai ¹¹ where 75%, 66.3% and 67.2% of the patients were HIV negative and recorded a higher treatment success which was seen to be statistically significant. Furthermore, Worede and Abitew²³ reported that HIV negative TB patients were about four times more likely to have successful treatment outcome than TB patients with unknown HIV sero-status. Umeokonkwo et al.²⁰ also posited that HIV coinfection was a significant predictor of poor TB treatment outcome. They observed that negative patients were 1.7 times more likely to experience successful treatment outcomes than those who were HIV positive.

Conclusion and Recommendation

The results from this study have shown that new TB patients, PTB cases and HIV negative TB patients formed majority of the TB patients across the years under review. Furthermore, the trend of the TB treatment outcomes at the UPTH DOTS clinic during the period under review showed.TSR was highest in 2016 hovering slightly lower thereafter until a major dip in 2020, while the cure rate was near steady from 2016 through 2019

again with a major dip in 2020. For completed treatment, 2016 had the highest percentage, other years were slightly lower but the dip occurred in 2017. Treatment failure was recorded for 2017 and 2019 there were no treatment failures recorded for 2016, 2018 and 2020. The rate of LTFU was highest in 2020 and lowest in 2016, while death rate was highest in 2017 and lowest in 2020. In general, this study revealed that younger age, female sex, being employed, PTB, and negative HIV status were the major determinants of favourable TB treatment outcome.

We recommend more attention in terms of supervision of the DOTS centres, training and retraining of frontline staff. Also, seeing that the vast majority of the patients are new cases, more effort should be made by the state ministries of health and other public health agencies to properly sensitize the populace about the disease and its preventive measures. Furthermore, the government and non-governmental agencies can go further to establish and equip DOTS centres in rural areas to ensure that TB patients living in such areas get adequate care and support.

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Author's contribution

Conceptualization: IO Data analysis: IO Drafting of manuscript: INO, IO Review and editing of manuscript: INO

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