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Assessment of Treatment Outcomes of Tuberculosis patients in a Rural Comprehensive Health Care Centre, Benue State, North Central Nigeria

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ABSTRACT

Despite the availability of effective intervention programs over the years, tuberculosis remains a major global health problem. It causes ill-health among millions of people each year and ranks alongside the Human immunodeficiency virus (HIV) as a leading cause of death worldwide. The aim of this study is to assess the outcome of tuberculosis treatment in a Rural Primary Health Care Centre, Benue State, North Central Nigeria. A three-year retrospective study was employed to review 150 tuberculosis cases treated from January 2014 - December 2016. Data were analysed using Statistical Package for Social Sciences (SPSS) version 20 and presented as tables and charts. The relationship between independent and outcome variables were tested with Chi-square test and P-value was set at 0.05. Of the 150 Tuberculosis patients treated, 84(56.0%) were males while 66(44.0%) were females. More than two-thirds (77.3%) of the patients had pulmonary tuberculosis. The successful treatment rate was 60.0% (32.7% treatment completed and 27.3% cured). Over twelve percent defaulted, 10.7% were lost to follow up, 6.7% were transferred out and 0.7% died. In this study, the successful treatment outcome was lower than the National target .The relationship between the disease sites; HIV status, Cotrimoxazole prophylaxis and the treatment outcome were statistically significant. Directly Observed Treatment Short Course (DOTS) providers should address issue of hindrances to adherence to treatment in order to improve the treatment success rate.

***Keywords**:Nigeria,Outcomes,Pulmonary,Tuberculosis*

INTRODUCTION

About 1.7 billion people are estimated to be affected with *Mycobacterium Tuberculosis* globally, out of which an estimated 1.3 billion lives in developing countries.[1] Tuberculosis (TB) has a global incidence rate of approximately 1% per year.[2] The disease kills approximately 5000 people daily, with 98% of the deaths occurring in the developing countries and in young adults.[3] Fifteen countries in the world are considered to have the highest burden of the disease, with thirteen of these countries being from the sub-Saharan region of Africa, accounting for 13% of the global prevalence of the disease.[3] The high incidence of the disease is

worsened by the high Human Immunodeficiency Virus (HIV) infection.[4] In 2010, Nigeria was ranked 10 th among the twenty two high burden counties in the world with Lagos, Oyo and Benue States having the highest prevalence rates.[5] In 2013, Africa had the highest proportion of new cases per population.[2,6] In 2014, the World Health Organization(WHO) projected Nigeria as having the highest burden in Africa and tenth in the world with prevalence rates of 616 cases per hundred thousand annually, as well as 150,000 deaths per year[5] No fewer than 460,000 new cases of TB were reported annually in Nigeria.[7] Tuberculosis prevalence in Nigeria varies across the States with 17.6% in Itu Local Government Area in Akwa Ibom State, 21.5% in Benue State, 37.9% in Enugu State and 38.5% in Ikot-Ekepene in Cross River State[4,8,9] Tuberculosis was declared a global emergency by WHO in 1999 and since then, several intervention programmes have been advocated to control the menace[5,7]In the year 2000, the Directly Observed Treatment short course (DOTs) strategy was introduced which focused on the political commitment, early diagnosis, standardised treatment, regular supply of drugs to aid it's, monitoring and evaluation[4,10] In 2006, the WHO lunched the Stop TB Strategy; the goal was to dramatically reduce the global burden of TB by 2015 in line with the Millennium Development Goal (MDG) and the Stop TB partnership targets.[1,11] The objectives of the strategy were targeted at achieving universal access to high quality care for all people living with TB, reduce the human suffering and socio-economic burden associated with, protect vulnerable populations from TB, HIV and Multi Drug Resistance Tuberculosis, support the development of new tools and enable effective and timely use, project and promote human rights in TB prevention, cure and control.[12,13]

Despite known aetiology and availability of anti- tuberculosis drugs, TB treatment outcome still remains an issue of public health importance.[14,15] Inadequate and incomplete treatment, including poor treatment adherence had led to newer forms of drug resistance.[4,16] Global prevalence of multi drug resistance TB is 7.0% and distributed into the various regions as follows: 6.5% in industrialized countries, 13.6% in Russia and Eastern Europe, 1.5% in Asia and 6.6% in Africa and the Middle East while that of extensively drug resistance TB is 6.6%.[2,15] The WHO has set an internal target value for favourable treatment outcome at 85% and published recommendations for accessing TB outcomes in the nineties, with a revised version published in 1998.[8,13] However, in many highly developed countries with good treatment facilities, outcomes have still not reached the targets set by WHO.[9,15] The treatment success rate among new smear positive cases enrolled for treatment during 2009 was pegged at 88% by WHO in the whole regions.[7,15] The overall case fatality rates (CFR), default and failure rates were 4%, 5% and 2% respectively amongst new smear-positive cases registered for treatment in 2009[3,15] In 2015, the success rate of pulmonary tuberculosis (PTB) was 57.6% in Poland.[5,19]

Amongst the six WHO regions, the highest treatment success rates were recorded in Western Pacific Region 79% and in Africa 75%.[5,8] Most of the 22 high burden countries have reached or exceeded the treatment success rate of 85%. In Ethiopia, a standardized TB prevention and control programmes incorporating DOTs was started in 1992.[15,19] The success rate of TB treatment in Lagos state, Nigeria was estimated to be 89.4%, with 12.5% lost to follow-up, 3.3% dead and 2.5% treatment failure.[2,3] The outcomes of TB treatment has not been very impressive across the world . Several factors such as level of education, income statues, access to TB treatment centres, marital status, HIV status and treatment category have been implicated.[17,18]Other factors responsible for unfavourable TB treatment outcomes reported were inadequate supervision, improper policies, low grade diagnostic and therapeutic facilities, individual differences in drug metabolism, inadequate knowledge about TB and little caution towards handling of TB cases among health personnel. This study assessed the treatment outcomes of tuberculosis among TB patients receiving treatment in a rural comprehensive health centre at Ugbokolo, Okpokwu Local Government Area, Benue State, Nigeria.

MATERIALS AND METHODS

Study Area

Ugbokolo is a rural settlement of about 140 kilometres at Makurdi- Enugu road. It has a population of 120,000 people (based on 2.8% fertility rate projection from 2006 National population figures). The rural comprehensive health centre was established by Benue State government 22 years ago and serves about thirteen other satellite communities. It has bed occupancy for 45 patients and handles cases in basic surgeries, paediatrics, obstetrics, internal medicine and has a theatre. The facility has staff strength of one doctor, six nurses, four community health extension workers, two midwives and four porters. It also has well developed HIV clinics and DOTs facility for sputum microscopy and Gene xpert machine for TB and rifampicin resistance detection. It

has referral linkages with General hospital Okpoga, the local government headquarter, Federal Medical Centre, Makurdi and Benue State University Teaching Hospital, Makurdi. The annual average presumptive TB cases seen in the facility is 800.

Study Design

A retrospective document review was conducted to assess the outcomes of TB patients' documents registered from January 5, 2014 to December 4th 2016.

Study Population

All documents of tuberculosis patients that were registered for treatment at the rural comprehensive health care centre constituted the study population.

Inclusion and Exclusion Criteria

The documents of all the registered TB patients were included. All registries in which treatment outcomes were not completed and patients transferred to other health facilities or did not consent were excluded from the study.

Data collection

TThe data were collected using a pretested structured data extraction format. The main data source were the routine NTBLCP standardized facility reporting and recording forms. Information on the socio-demographic variables, type of TB patient, site of diagnosis, date of diagnosis, sputum smear results, HIV status, Co-trimoxazole presumptive therapy, ART regimen, CD4 count (baseline and the most recent), duration of TB treatment and treatment outcome were extracted from the records. Data collection was done manually. Where there was incomplete information, LGA TB registers, TB suspects registers, patient's sputum follow up registers and ART clinic laboratory records register were used as supportive registers.

Operational Definitions

The Nigerian NTLCP guideline (2), adopted from WHO, was used for the operational definitions. These outcomes include:

a) **New Case**: Diagnosed patient who had never had treatment or had treatment for less than four weeks

b) **Cured**: TB patient who was smeared positive at diagnosis, who completed 6 or 8 months of treatment and who is smear negative at the end of 6th or 7th month of treatment and at least one previous occasion.

c) **Treatment completed**: TB patient who was smeared positive at diagnosis and who completed treatment but in whom smear examination results are not available at the end of treatment, or all smear negative and extra-pulmonary TB patients who completed treatment.

d) **Failure**: A smear positive patient who while on Category 1 treatment remained, or became smear positive again five months or later after commencement of treatment.

e) **Defaulted**: A patient who has been on treatment for at least four weeks and whose treatment was interrupted for eight or more consecutive weeks.

f) **Transfer Out**: A TB patient already registered for treatment in one LGA/State who is transferred to another State and whose treatment is not known.

g) **Died**: TB patient who dies for any reason during the course of anti-tuberculosis chemotherapy.

h) Successful Outcome: The sum of cured and treatment completed.

I) **Unsuccessful Outcome**: Treatment Failure, defaulted, and or died

Data Analysis

Data were analyzed using SPSS Version 20 for windows. Independent variables considered were age, sex, year of treatment, type of TB and HIV status. Descriptive statistics were used to summarize the independent variables and chi square ($\chi 2$) test was used for test of association between the independent variables and the main outcome of the study, with statistical significance set at p-value of 0.05.

Ethical Issues

Ethical approval for the study was obtained from the Ethical Committee of BSUTH, written consent from the chairman Okpokwu Local Government Area and verbal consent from the medical superintendent in-charge.

RESULTS

Majority of the patients treated in 2014 and 2016 were males, accounting for 62.0% and 59.6% respectively, while in 2015 females were in the majority (55.8%). Most of the respondents 31.3% were between the ages 21-30 years old while 14.7% were between 41-50 years. Six (4.0%) of the patients were less than ten years. The mean age of the respondents was 37.4 years. The prevalent treatment regimen offered to the patients was directory observed treatment short course (87.3%). Other regimens offered were eight months (4.0%) and twelve months (8.7%). Most of the patients

(77.3%) were managed as pulmonary TB, extra-pulmonary TB constituted (19.3%), while disseminated TB amounted to (3.3%). Of the total cases reviewed, most (92.0%) were new cases, while the remaining cases were relapse (6.0%), failure (1.3%) and transferred in (0.7%) respectively.

Of the 150 total cases reviewed, majority 60.7% had positive sputum smear at baseline. For the repeat sputum smear at two or three months, 50.7% of the cases were not done while 36.7% tested negative. At five months, most 60.7% of the cases were not done while 38.0% tested negative. At seven months, majority 78.0% of the cases did not have their sputum done while 22.0% tested negative.

Majority (70.2%) of the successfully treated patients under review at the centre fell within the ages of 21-30 years. Over fifty percent (54.8%)of those that were treated were males and 69.7% were females while 65.5% had pulmonary TB. Majority of those treated were new cases (61.6%) and 61.8% HIV negative while 57.6% were HIV positive. Slightly below two thirds were on CPT. The relationship between the site, HIV status and cotrimoxazole prophylaxis and the outcome were statistically significant. However, the relationship between the rest of the socio-demographic variables and clinical status of the patients with the treatment outcome were not statistically significant.

Of the total number of patients commenced on anti TB, 60% were successfully treated, 32.7% completed treatment and 27.3% cured, 12.7% defaulted, 10.7% were lost to follow up, 9.3% died and 6.5% were transferred out.

The failure among the respondents was the least outcome

Table I: Sex, age, treatment regimen, site of infection, and treatment category distributions (2014 -2016)

Sex Distribution of Tuberculosis Patients Treated (2014 -2016)					
Year	**Sex Male Frequency**	**Percent**	**Female Frequency**	**Percent**	**Total**
2014	31	62.0	19	38.0	50
2015	19	44.2	24	55.8	43
2016	34	59.6	23	40.4	57
Age distribution					
Age Group (Years)		**Frequency**		**Percent**	
<10		6		4.0	
11-20		10		6.7	
21-30		47		31.3	
31-40		36		24.0	
41-50		22		14.7	
51-60		18		12.0	
61-70		8		5.3	
>71		3		2.0	
Mean 37.4(SD=16.5)					
Total		150		100.0	
Distribution by Treatment Regimen					
Treatment Regimen		**Frequency**		**Percent**	
6 months		120		87.3	
8 months		6		4.0	
12 months		13		8.7	
Total		150		100.	
Distribution by Treatment Category					
Treatment Category		**Frequency**		**Percent**	
New		138		92.0	
Relapse		9		6.0	
Failure		2		1.3	
Transferred-In		1		0.7	
Total		**150**		**100.0**	

Table 1I: Summary of sputum smear result of pulmonary tuberculosis cases (n=150)

Smear result at Baseline	Frequency	Percent
Positive	91	60.7
Negative	25	16.7
Not done	34	22.7
Smear result at 2 or 3 months		
Positive	19	12.7
Negative	55	36.7
Not done	76	50.7
Smear result at 5 months		
Positive	2	1.3
Negative	57	38.0
Not done	91	60.7
Smear result at 6 or 7 months		
Negative	21	22.0
Not done	117	78.0

Table III : Sociodemographic and Clinical Characteristics of Patients by Treatment Outcome

Characteristics	Treatment Outcome Successful freq(%)	Not successful freq (%)	Total freq (%)	X^2	P-value
Age Group					
≤10	4(66.7)	2(21.3)	6(100)	51.403	0.152
11-20	7(70)	3(30)	10(100)		
21-30	33(70.2)	14(29.8)	47(100)		
31-40	17(47.2)	19(52.7)	36(100)		
41-50	14(63.6)	8(36.4)	22(100)		
51-60	5(27.8)	13(72.2)	18(100)		
61-70	4(50)	4(50)	8(100)		
›70	0(0)	3(100)	3(100)		
Sex					
Male	46(54.8)	38(45.2)	84(100)	12.189	0.058
Female	46(69.7)	20(30.3)	66(100)		
Disease site					
Pulmonary	76(65.5)	46(34.5)	116(100)	39.936	0.000
Extra pulmonary	14(48.3)	15(51.7)	29(100)		
Disseminated	0(0)	5(100)	5(100)		
Treatment Category					
New	85(61.6)	53(38.4)	138(100)	17.858	0.465
Relapse	0(0)	9(100)	9(100)		
Failure	0(0)	2(100)	2(100)		
Treatment interrupted	0(0)	1(100)	1(100)		
HIV Status					
Positive	34(57.6)	25(42.4)	59(100)	22.052	0.037
Negative	55(61.8)	34(38.2)	89(100)		
Unknown	0(0)	2(100)	2(100)		
Cotrimoxazole (cpt)					
On CPT	27(20.8)	16(37.2)	43(100)	12.420	0.053
Not on CPT	2(12.5)	14(87.5)	16(100)		

Table IV: Overall treatment outcomes and HIV status

Overall Treatment Outcome of Tuberculosis Cases		
Treatment Outcome	**Frequency**	**Percent**
Treatment completed	49	32.7
Cured	41	27.3
Defaulted	19	12.7
Loss of Follow up	16	10.7
Died	14	9.3
Transferred out	10	6.7
Treatment Failed	1	0.7
Total	150	100.0

HIV Status of Tuberculosis Patients on Treatment

HIV Status Before Treatment	Frequency	Percent
Positive	59	39.3
Negative	89	59.3
Unknown	2	1.3
Total	150	100.0

Age, Sex Distribution of TB Patients by HIV Status

Variables Age Group	Positive Freq.	%	Negative Freq.	%	Not done Freq.	%	Total Freq.	%	X^2	P- Value
≤10	3	5.3	2	2.2	1	50.0	6	4.0	40.175	0.000
11-20	0	0.0	10	11.0	0	0.0	10	6.7		
21-30	11	19.3	35	38.5	0	0.0	46	30.7		
31-40	20	35.1	16	17.6	0	0.0	36	24.0		
41-50	13	22.8	9	9.9	0	0.0	22	14.7		
51-60	6	10.3	10	11.0	1	50.0	17	11.3		
61-70	4	7.0	6	6.6	0	0.0	10	6.7		
>70	0	0	3	3.3	0	0.0	3	2.0		
SEX										
Female	24	42.1	39	42.9	1	50.0	64	42.7	0.448	0.799
Males	33	57.9	52	57.1	1	50.0	86	57.3		

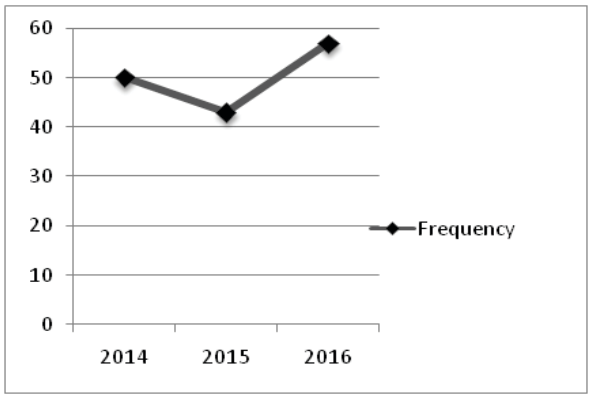

Figure I: TB trends

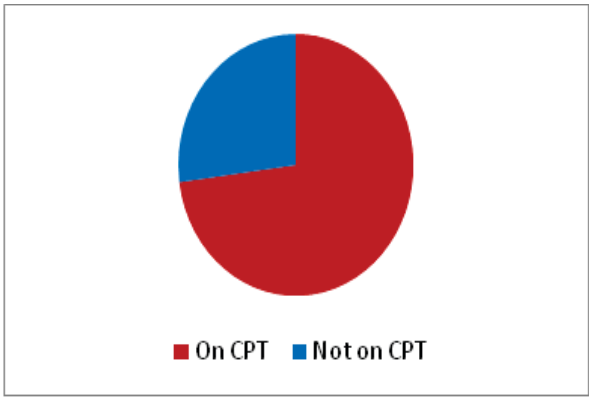

Figure III:TB/HIV co-infected patients on ART (n-59)

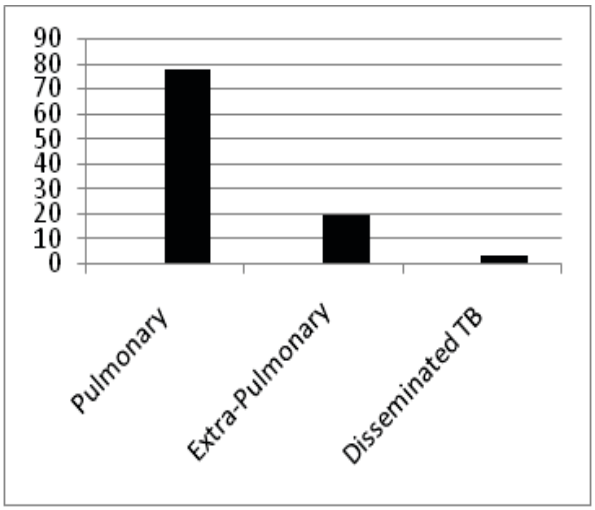

Figure II: Diagnosis

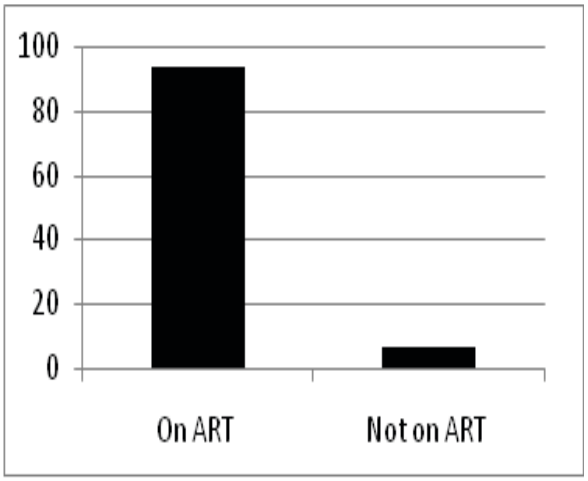

Figure IV: TB/HIV co-infected patients on cotrimonazole preventive therapy

0.7%. Out of the total case reviewed, 39.3% were HIV co-infected, 59.3% were negative and 1.3% were not screened for HIV. All the co-infected patients were referred to the HIV clinic for ant-retroviral therapy. In the sex distribution of respondents by HIV status, majority (35.1%) were within the age group of 20-40 years, followed by those within the age group 41-50 (22.8%). Majority (57.9%) of the confirmed positive cases were males, while 42.1% were females. The relationship between the age groups and HIV status was statistically significant while the relationship between the sex and the HIV status was not statistically significant.

In the Figures above, a total of 150 patients were treated at the clinic in the period under review. Of these, the highest number of patients were seen in 2016, representing 57 (38.0%), while 50(21.3%), and 43(28.7%) were seen in 2014 and 2015 respectively. At baseline, most of the patients 77.3% were diagnosed as pulmonary TB, extra- pulmonary constituted 19.3% and disseminated 3.3%. Out of the 59 co-infected respondents, referred to HIV clinic for treatment, 93.2% commenced treatment. Of the 59 patients co-infected with TB/HIV, 43 (72.9%) were placed on cotrimoxazole.

DISCUSSION

This study assessed treatment outcomes of tuberculosis patients from 2014 to 2016 in a rural comprehensive health care facility in North Central Nigeria. Majority of TB patients seen in this facility had a mean age of 37 years and most fell within the age bracket of 21-30 years. Males also constituted the majority in this study. This is similar to studies done in

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Ibadan, and Ebonyi state in Nigeria.[2,4] Similar findings were observed in Egypt and Ethiopia.[15,18,19]The predominance of males compared to females could be due to the fact that males been the head of the family are exposed more to the disease as a result of their economic activities to source for revenue for their family. Out of pocket expenses for health care in Nigeria are very high and because males have a higher economic power have a greater health seeking behaviour.[3,4,5]

Furthermore the age ranges of 21-30 years that are mostly affected by TB infection are the most productive age group economically in Nigeria. Over two-thirds of the respondents in this study had pulmonary TB. This is far higher than some studies done in Metema in South Africa.[11] majority of the patients were infected with pulmonary TB is not surprising. Environmental factors such as high humidity and substandard housing are high risk factors for pulmonary TB. In a developing country like Nigeria that has high population and insufficient housing, its citizens are prone to pulmonary TB. Most houses in Nigeria are over crowed and lacked sufficient windows for cross ventilation. There is lack of health education for observing cough etiquettes.[10,11]The category of cases seen in this study showed that new cases predominate 87.3%. This is slightly lower than the study done in Southern Sudan and Jinka General Hospital in Southern Ethiopia.[5,15] The relapse and failure rates in this study were slightly higher than that reported in the above study. This could be due to differences in drug compliance and TB/HIV co-infection.

The 10.7% in this study due to loss to follow up is lower than the study done in Pakistan, but it is higher than some studies done in Nigeria and a teaching hospital in East Africa.[4,15,18]The differences observed above could be due to difference in patients' attitude towards health seeking behaviour and also the fear of stigmatization.

The death rate of 9.3% obtained in this work is higher than studies done in South Eastern Asian countries and Ibadan, Nigeria.[16,17] It is however lower than the study done in East Africa and Egypt.[15,19]The 12.5%obtained in this work for defaulting is far higher than the 2.4% in some African countries, and lower than 30.8% in South Western Nigeria.[6,7]Reducing the rate of defaulters in Tb programme requires effective monitoring of various aspects of DOTS such as contact tracing of defaulters, adequate supervision and good communication with patients.

In this study the success rate was 60%. This is higher than some studies done in East Africa.[20,21] It is however lower than that of NTBLCP and WHO target of 85%.[13,20] This rate is also lower than that recorded for studies conducted in South East Asia and South Western Nigeria where 88% and 85.5% were recorded as successful treatment rates respectively. Effective implementation of DOTs strategy has positive correlation with success rates in TB management.[5,13,18] Studies have shown that efficient management of DOTs reduces drug resistance and poor drug compliance.[22] The total number of TB/HIV co infected patients placed on cotrimoxazole in this study is 72.9%. This is far higher than the study done in Soweato in South Africa were the coverage was 54%.[5,6,11]

In Nigeria the national coverage of the use of cotrimoxazole in TB/HIV co infection is not well established but in children is as small as 4%.[2,4] It has been shown that there is slow uptake of cotimoxazole in developing countries including Nigeria in the management of TB/HIV co infection. This had being associated with delays in the dissemination of recommendations on its use , problems with drug procurement and supply, poor health care infrastructure for managing patients before ART and inadequate systems for monitoring and evaluation.[5,9,10] The number of adults receiving cotrmoxazole could also be increased by raising awareness of its benefits and by using indicators to monitor its uptake both globally and at the level of individual treatment programmes. The major uses of cotrimoxazole in TB/HIV co infection are boosting patients' immunity and reducing opportunistic infections such as pneumocystis pneumoniae[12,13,19]

The prevalence of TB/HIV co infection in this study is 17.3%. This is lower than the study done in Ethiopia were the prevalence was 22.8%.[7,15] It is also lower than the national prevalence recorded in Nigeria as 19.1%.[8,10] It is however higher than 5.6% recorded in Benue State North Central Nigeria.

That the prevalence of TB/HIV co infection in this study is lower than the national average is not surprising. This is because this study was done in a rural health centre and it is believed that there is lower prevalence of HIV in rural areas than in urban settings. More than 17% of the patients had extra pulmonary TB in this study. This is lower than 38.8% recorded in East Africa and 34.7% recorded in Ghana.[15, 16, 17] The differences could be due to differences in HIV burden, over diagnosis or misclassification.

CONCLUSION

This study concluded that the major determinants that had significant associations with successful treatment outcomes were treatment site, HIV status, and cotrimoxazole prophylaxis. The lower rate of loss to follow up in this study than the national average was unexpected. A true picture regarding loss to follow up could be obtained using a larger sample size in future studies.

Recommendation

Contact tracing must be strengthened to have a successful TB programme. The whole process of TB programme should be reviewed in Nigeria with the aim of improving DOTs, supply of quality drugs and mandatory appointment of treatment supporters.

Furthermore, ancillary important drug like cotrimoxazole supply must be promptly done, monitored and evaluated.

Conflict of Interest

None to declare.

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