Profiles and Treatment Outcomes of Patients with Tuberculosis: A Cross-Sectional Review of DOTS Patients in Delta State, Nigeria

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SUMMARY

Introduction: Tuberculosis (TB), the second leading cause of death among infectious diseases continues to be a major public health threat worldwide, more so in the developing world. Several strategies have been tried in the past decades to address the burden of the disease especially in low resource settings; namely: Directly Observed Therapy Short-course (DOTS), DOTS plus, and the Stop TB Strategy. Amid all these efforts, tuberculosis has developed multi-drug resistant strains (MDR) to various degrees and is now listed amongst the top re-emerging diseases in the world. The objectives of this study were to find out trend in TB case detection; age/sex distribution, new smear positive cases, identify the major type of TB, treatment outcomes, within the five-year period reviewed.

Methods: In this cross-sectional records review of years 2011-2015, secondary data was extracted from tuberculosis central registers at all sites in Delta State, Nigeria. The data was using win PEPI and EPIDATA software solutions and presented in tables and charts.

Results: There was a decline in case detection from 2011 to 2015, ages 25–34 years, was the largest proportion, while ages 0–4 years was the smallest proportion. Although males were generally more than females, the proportion of females was higher between ages 15-44. Treatment success rate improved from 68.7% in 2011 to 88.0 % in 2014. The sputum AFB positive rate was less than 60% for the first four years but spiked to above 70% in 2015. A decline in the proportion of patients lost to follow-up was observed from 2011 to 2015.

Conclusion: The Delta State Tuberculosis programme improved in case-holding. There is therefore a need for renewed public enlightenment and other strategies to improve patient compliance with the stipulations of the national tuberculosis control program.

Key Words: Tuberculosis, DOTS Treatment Outcomes, PTB, EPTB, AFB positive rate, Delta State, Nigeria

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Introduction

Mycobacterium Tuberculosis infection is a major infectious cause of deaths globally, mostly in developing countries.[1] It is a debilitating disease with a greater prevalence and severity in a background of reduced immunity. In more recent years, it has become even more complex due to a rise in its drug-resistant strains, among other issues.[2]

It is still the second leading cause of death among the infectious diseases and continues to be a major public health threat worldwide. Several tuberculosis control strategies were formulated through the mid-20th to the 21st century; namely: DOTS, DOTS plus and the Stop TB strategy intended to address the burden of the disease.[3,4]

Amid all the efforts to control TB, the tide is not abating; instead it is reappearing in almost epidemic proportions and now listed amongst the top re-emerging diseases, mainly because of increasing multidrug resistance and co-infection with HIV/AIDS. Till date, no other disease in history matches the sheer magnitude of the misery inflicted by TB on the human race in terms of morbidity and mortality. [5]

In a developing country like Nigeria, tuberculosis is one of the top public health problems almost everywhere, ranking fourth among the 30 high-burden TB countries in the world. [5] There were 90,447 TB cases notified in 2010 with 41,416 (58%) as new smear positive cases, and a case detection rate of 40% in Nigeria.[6] Although targets were set to reverse the incidence, half the prevalence and mortality, diagnose 70 percent of new smear-positive cases and cure 85 percent of tuberculosis cases by 2015, for many countries, these targets were not achieved despite the current existence of interventions.[7,8] New TB cases were estimated to be 10.6 million globally in 2016, with 1.4 million deaths and an additional 0.4 million deaths among the people co-infected with human immunodeficiency virus; 95 percent of these occurred in developing countries.[9]

The policy of the national programme in Nigeria is for all patients to be treated free of charge using DOTS strategy for six months in pulmonary TB cases, and twelve months for TB meningitis and spine. In many developing countries including Nigeria, Direct Sputum Smear Microscopy (SSM) is the most widely used test for the diagnosis of pulmonary tuberculosis in accordance with the *International Standards on Tuberculosis Care*.[10,11]

The implementation of DOTS, which has been long established in Nigeria, is practised through sites distributed in the various states of the country. This study therefore aimed to provide a summary description of patients who received DOTS for tuberculosis in Delta State, Nigeria in terms of prevalence of tuberculosis, age/sex distribution, new smear positive cases, identification of the major type of TB seen, and to assess treatment outcomes including cure rates, failure, loss to follow up (LTFU)

and death rates among tuberculosis patients managed at DOTS centres over a five–year period.

Methods

Secondary data from January, 2011 through December, 2015 from all ninety-eight TB-DOTS sites in the 3 senatorial zones of Delta State were collected and analysed in a cross-sectional records review to identify trends. Data was extracted from a standardized and updated State Tuberculosis Central Registry using a validated proforma and reanalysed using Microsoft Excel, winPEPI and Epidata software solutions. The results were represented using frequency tables and charts.

Results

The total number of TB patients seen at DOTS clinics in Delta State in the past five years is 13,635. Although there would have been overlaps, there was a consistent decline in numbers from 2011 to 2015. The total number in 2011 was 3076 while the total number in 2015 was 2349. The rate of decline slowed down between 2014 and 2015. Each year, age group 25–34 years made up the highest proportion of patients presenting for treatment at DOTS clinics while ages 0–4 years was the smallest proportion. Although the proportion of male patients was consistently more than that of females, for the ages 15-44 years, the collective proportion of females was consistently higher than that of males for all the years reviewed. **(Table 1)**

Table 1: Age/sex distribution of TB patients at DOTS centres in Delta State

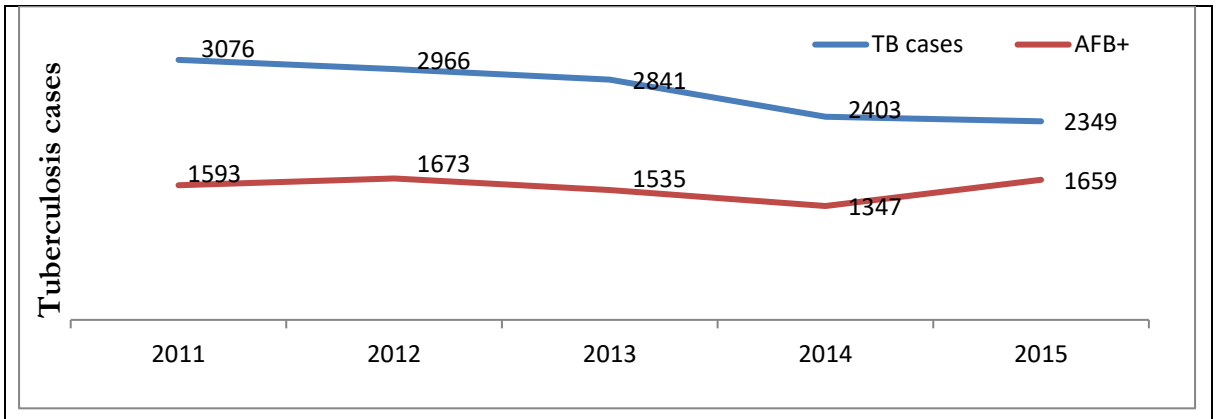
	Sex of patients Frequency (%)									
Age group	**2011**		**2012**		**2013**		**2014**		**2015**	
	M	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**
0-4	24(1.3)	16(1.3)	15(0.9)	14(1.1)	18(1.1)	18(1.5)	15(1.1)	13(1.30	8(0.6)	5(0.5)
5-14	38(2.1)	39(3.2)	43(2.5)	64(5.1)	32(2.0)	48(4.0)	22(1.6)	28(2.8)	33(2.4)	31(3.3)
15-24	220(12.0)	228(18.5)	243(14.3)	214(17.0)	222(13.8)	222(18.1)	203(14.4)	188(18.9)	183(13.1)	198(20.9)
25-34	517(28.0)	402(32.6)	425(25.0)	379(30.0)	395(24.5)	362(29.5)	351(24.9)	297(30.0)	279(21.2)	248(26.1)
35-44	419(22.7)	246(20.0)	396(23.2)	282(22.3)	396(24.5)	252(20.5)	337(24.0)	221(22.3)	337(24.1)	221(23.3)
45-54	290(15.7)	143(11.6)	265(15.6)	143(11.3)	264(16.4)	154(12.5)	227(16.1)	118(11.9)	270(19.3)	131(13.8)
55-64	172(9.3)	88(7.1)	165(9.7)	91(7.2)	140(8.7)	89(7.2)	133(9.4)	60(6.0)	161(11.5)	59(6.2)
≥65	164(8.9)	70(5.7)	152(9.0)	75(6.0)	146(9.1)	83(6.7)	122(8.7)	68(6.8)	129(9.2)	56(5.9)
Sub-total	**1844(60)**	**1232(40)**	**1704(57.5)**	**1262(42.5)**	**1613(56.8)**	**1228(48.2)**	**1410(58.7)**	**993(41.3)**	**1400(59.6)**	**949(40.4)**
Total	**3076(100)**		**2966(100)**		**2841(100)**		**2403(100)**		**2349(100)**	

Each year, age group 25–34 years made up the modal age group of new smear positive cases presenting at DOTS clinics while ages 0–4 years made up the smallest proportion. The next highest frequencies/proportions were seen in age groups 35-44 years, and 15-24 years. Males were consistently more in the 35-44 years age group than in the 15-24 years group throughout the 5 years reviewed but females were more in age group 15-24 years than in the 35-44 years group for years 2011, 2013 and 2015. In 2012 and 2014, females aged 15-24 years were at par with ages 35-44 years. **(Table 2)**

Table 2: Age/Sex Distribution of New Smear Positive Cases from 2011 - 2015

	Sex of patients Frequency (%)									
	2011		**2012**		**2013**		**2014**		**2015**	
Age Group	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**
0-4	1(0.1)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	2(0.20	0(0)
5-14	9(1.0)	21(3.4)	13(1.3)	20(3.0)	8(1.0)	13(2.0)	11(1.4)	10(1.8)	14(1.4)	16(2.4)
15-24	147(15.1)	163(26.3)	175(17.3)	148(22.5)	132(14.9)	158(24.4)	136(17.0)	121(22.2)	143(14.3)	160(24.2)
25-34	307(31.6)	219(35.3)	282(27.8)	215(32.6)	260(29.3)	204(31.5)	209(26.1)	181(33.2)	225(22.6)	189(28.5)
35-44	231(23.7)	120(19.4)	258(25.4)	154(23.4)	229(25.8)	137(21.2)	205(25.6)	121(22.2)	253(25.4)	154(23.3)
45-54	155(16.0)	54(8.7)	158(15.6)	63(9.6)	134(15.1)	72(11.1)	121(15.1)	62(11.4)	192(19.3)	76(11.5)
55-64	68(7.0)	23(3.7)	72(7.1)	32(4.9)	72(8.1)	37(5.7)	68(8.5)	28(5.1)	103(10.3)	35(5.3)
≥65	55(5.6)	20(3.2)	56(5.5)	27(4.1)	53(5.9)	26(4.0)	51(6.3)	23(4.2)	66(6.6)	32(4.8)
Sub-total	**973(61.1)**	**620(38.9)**	**1014(60.6)**	**659(39.4)**	**888(57.9)**	**647(42.1)**	**801(59.5)**	**546(40.5)**	**997(60.1)**	**662(39.9)**
Total	**1593 (100)**		**1673 (100)**		**1535 (100)**		**1347 (100)**		**1659 (100)**	

There was a consistent decline in the total number of TB cases seen in each year for the 5 years reviewed but the number and proportion of AFB positive cases fluctuated during the years in review. The proportion of AFB positive cases detected among TB patients was consistently less than 60% for years 2011 through 2014; but in 2015 the proportion of AFB+ cases detected increased steeply to over 70% **(Figure 1)**



AFB+/N Ratio (%)	51.8	56.4	54.0	56.1	70.6

N refers to the total number of tuberculosis patients seen each year consecutively for the 5 years reviewed

Figure 1: Comparison of total no. of tuberculosis patients with no. of AFB+ Cases

The proportion of new tuberculosis patients notified each year was generally on the increase from 2011 through 2015 although 2012 was an exception. This implies that the cases of relapse, treatment failures, and return after loss to follow-up were generally on the decline through the years. The newly registered cases were 85.5% in 2011 and gradually rose to 97.8% in 2015 except for 2012 when newly registered cases constituted 93.9% which was higher than the newly registered cases in 2013. **(Figure 2)**

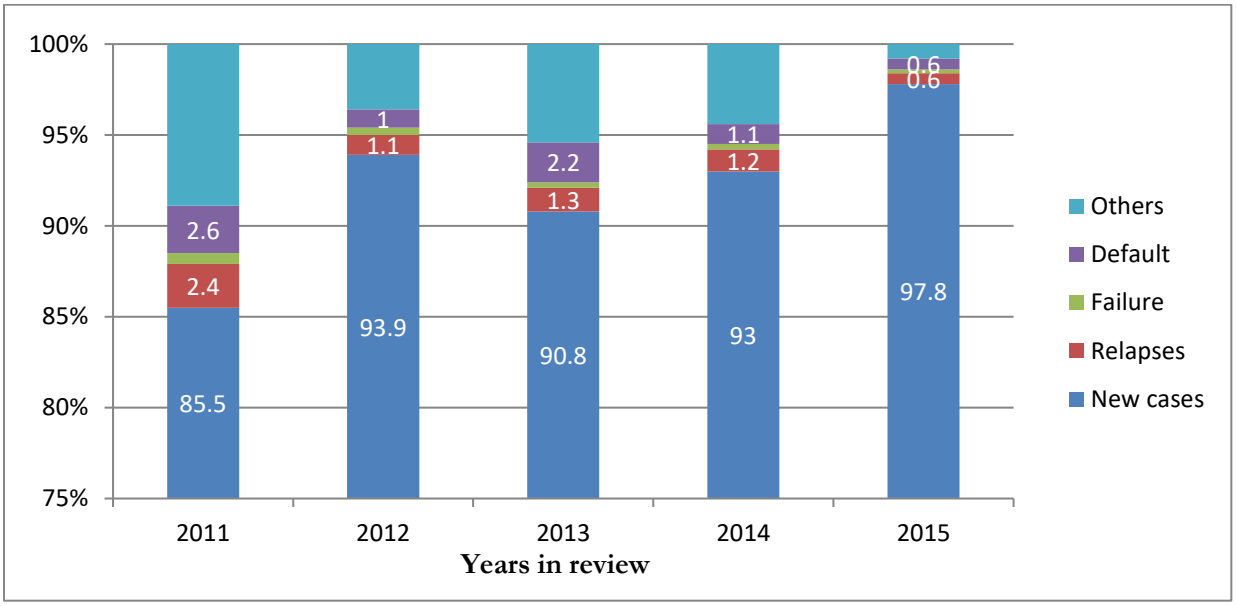


Figure 2: Categories of patients registered for TB-DOTS treatment in Delta State

The relative proportion of PTB and EPTB that presented at DOTS centres in Delta State was nearly constant for the 5 years reviewed. Extra pulmonary TB was about 2% of patients for all the years with a small variation in 2013. **(Figure 3)**

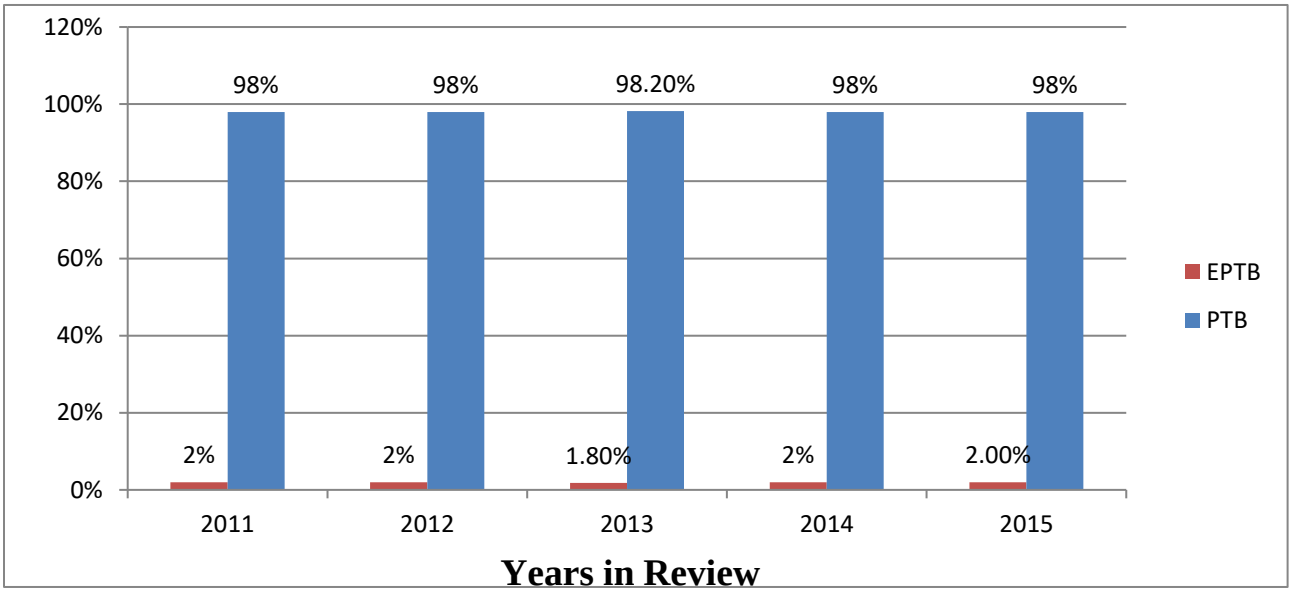


Figure 3: Proportions of Pulmonary and Extra-pulmonary Tuberculosis at DOTS Clinics

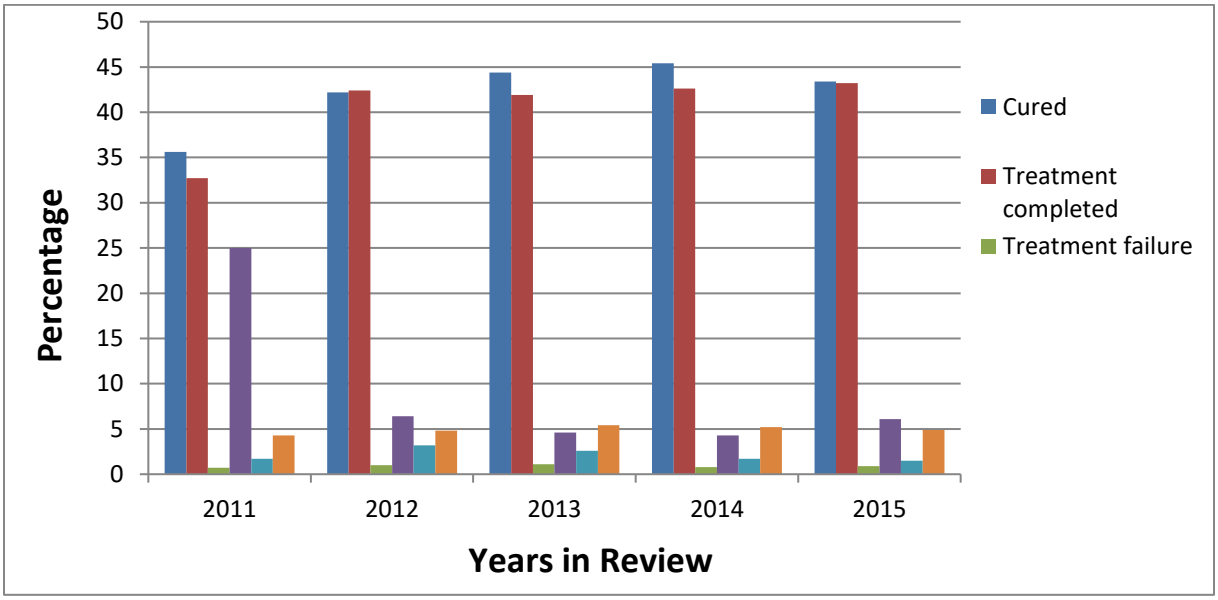


Figure 4: Trends in treatment outcomes of tuberculosis patients in Delta State

The treatment completion rate fluctuated between 32.7% and 43.2% between 2011 and 2015. Cure rate for patients ranged from 35.6% to 45.4%; it was highest in 2014. Loss to follow-up rate was disproportionately high in 2011 at 25% compared to the other years – all of which were below 10%. Death rate was similar for the 5 years reviewed; it ranged from 4.3% to 5.4%.

Discussion

The control of tuberculosis continues to be topical as the burden and complexity of the disease is still a source of much concern both globally and locally.

This study of TB patients in Delta State has shown a steady decline in the total number of TB patients seen at DOTS centres over the 5 years reviewed. It is not immediately obvious why this is so but this finding is consistent with that of a similar study in United States, and it is not surprising as control efforts have been consistent in the last decade. [12]

Sex distribution in this study was similar to that from a previous study conducted within the state13 and in other studies in western and eastern Nigeria where the prevalence of tuberculosis amongst males was generally greater than that of females.[14–16] This finding is also consonant with that from studies from outside Nigeria where male predominance has been observed.[17,18] However, the findings contradict the assertion that prevalence of tuberculosis is higher in females in countries like Nigeria where the prevalence of HIV is above 1%.[19] The reason for this dissimilarity is not clear especially as the prevalence of HIV in Nigeria is 3.2% and 4.1% in Delta State.[20] However, a closer observation reveals that although the total number of male patients was more than that of females for each year, for ages 15-44 years, the collective proportion of females was consistently greater than that of males for the 5 years reviewed. This is more consistent with the WHO assertion of a female preponderance in high burden HIV countries.19 This could truly be the effect of HIV and due to the fact that transgenerational sex and marriage are somewhat common in this environment.[21,22]

The patients who presented for treatment at DOTS centres were mostly new TB cases ranging between 85.5% and 97.8%; a finding similar to that from a study at Nnewi, Anambra state where the rate of new cases was 80.8%.[23]Belete et al also showed a similar percentage of new cases in a study on treatment outcome of tuberculosis patients under directly observed treatment in Addis Ababa, Ethiopia.[24] The loss to follow-up rate in this review was mostly around 5% and similar to studies which revealed a loss to follow-up rate of 3%,16 but less than 8.93% reported in another study conducted in south-west.[25] These findings were however a far cry from the loss to follow-up rates of 18.3% and 15.7% reported from previous studies conducted in Nigeria and

India.[23,26] Though there was an improvement in loss to follow-up rates within the last year reviewed in this study, it could be attributed to the patient's knowledge and beliefs about their illness, motivation to manage it, and awareness of consequences of poor adherence all interacting to influence adherence behaviour. However, loss to follow-up rate in 2011, was disproportionately higher than for the rest of the years. This could have been to the introduction of tracking of patients that were lost to follow-up. This was introduced in the programme in the year 2010 and continued till 2015. This suggests that extra effort by the DOTS providers to track loss to follow-up significantly reduced this programmatic challenge and case-holding in Delta State.

The decline in TB cases as well as the trend of AFB positive cases over the five years was unlike findings from a similar study in Enugu state which showed a rising trend of TB cases despite a decline in the proportion of AFB positive cases.[14] AFB positive cases in this study were disproportionately higher in 2015 and did not align with the decreasing trend. This may have been due to the recent introduction of Xpert MTB Rif in the diagnosis of TB. The findings of this study with respect to sex and age patterns of sputum smear positive PTB correlate with reports from a recent study in southern Nigeria,[27]and are consistent with the documented global epidemiology of the disease.28

A predominance of pulmonary tuberculosis, as seen in this study (98%), was also reported by studies of patients treated at DOTS centres in South-Western Nigeria, Eastern Nigeria, and Europe where 94.8%, 97%, 86.5% and 80.3% of the patients had pulmonary tuberculosis.[23,25,29] Hospital wide infectious disease profiles have shown PTB to be quite common in a couple of settings: A review in North-West Ethiopia saw a prevalence of 43.8%; Kano, Nigeria with a prevalence of 14.7%, and Saudi Arabia with a prevalence of 10.3%.[30–32] These findings show that the burden of tuberculosis is still high in a lot of settings – especially in settings like ours or may be due to over diagnosis of PTB due to a greater use of chest X-ray reports, case definitions and clinical findings instead of the standard AFB or Xpert MTB Rif tests.

Extra-pulmonary tuberculosis was more prevalent in other studies in Ibadan, Oyo state, and Nnewi, Anambra State, Nigeria and another study in Europe with a prevalence of 15.6%, 13.5% and 19.3% respectively,23,29,33 than in this review where only 2% had EPTB within the five years reviewed. The reason for this could be over diagnosis or higher co-infection with HIV in those studies. A higher prevalence of 51.2% and 56.2% of EPTB, have been recorded in studies in north-west Ethiopia.[31,34]The reasons for this are not immediately obvious.

This study revealed that over a period of five years, the proportion of patients who had completed their TB

treatment gradually increased from 32.7% to 43.2%. This finding was in contrast to a study conducted in Southern Ethiopia where there was a decline in the proportion of patients who completed TB treatment from 68% to 50 % over a period of ten years.[35] The cure rate for patients in this review fluctuated between 35.6% and 45.4% which was rather inconsistent and low compared to the WHO recommended TB cure rate of 85%. [36] However, this corroborated findings from a study conducted in Eku, Delta State, Nigeria where the cure rate was 45.7%.[13] This finding is probably a result of the inconsistencies in the system of provision of DOTS services in Delta State. These inconsistencies could include drug stock-outs; lack of, or poor follow-up services and reminder systems, and possibly, inconsistencies with timing of clinics. Several studies from India, Pakistan, Iraq and Mexico reported varying cure rates; 42.9%, 55%, 63.5%, 69.6% and 82.7% respectively.[18,37–40] Though there was an improvement in the treatment success rate observed in this study.

The loss to follow-up rate of patients attending DOTS clinics observed in this study, steadily declined from 25% to 4.3% for the first four years. However, there was a slight increase to 6.1% after one year. This finding was mostly lower than values obtained from Eku, Delta State where loss to follow-up rate was observed to be 12.9% over a five-year period. The reason for this difference could be attributed to the fact that the study conducted in Eku assessed only one DOTS centre compared to this study that assessed twenty-six centres in Delta State. However, results from this study were worse compared to those observed in North-West Ethiopia where loss to follow-up rate among TB patients was reportedly low at 2.5%.[35] The differences observed between these studies may be from challenges observed in the delivery of general health care services, including DOTS in Nigeria.

The treatment failure rate in this study was below 3% for the years reviewed and similar to 2.7% reported from a previous study conducted by Echendu et al in eastern, Nigeria.[23] This suggests that TB drug resistance may be low in Delta State even though it is among the high burden States for TB in Nigeria.[41]

The death rate among TB patients observed in this study ranged from 4.3% to 5.4%. These rates were similar to those from studies conducted in Abuja, Nigeria and Felige, Ethiopia where death was reported to be 4.9% and 5.8% respectively. [31,42] Slightly lower mortality rates of 3%, 2.7%, and 3.6% recorded from previous studies in Mexico and India indicate a likely generally better outcome of treatment for patients in those countries.[39,40,43]However, this finding were in contrast to reports from a study in Saudi Arabia where TB mortality rate was 18%.[32]Although death rate in this study was markedly lower than that compared to the Saudi

Arabian study, the probable reason for this could be because more than half of the patients in the Saudi study had associated co-morbidities. It also needs to be kept in mind that the treatment outcomes of patients who loss to follow-up are unknown.

Conclusion

Tuberculosis is common in all age groups in Delta State but most prevalent in the second and third decades of life. Its prevalence has been on the decline since 2011 in Delta State. Extra- pulmonary Tuberculosis rate has been stable at about 2%. Treatment outcomes in Delta State do not meet the WHO recommendations

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