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Assessment of Healthcare Providers Compliance with Standard of MDR TB Care and Treatment Outcome

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Abstract: The acquisition of MDR-TB results mainly from health system/service and patient-related factors. Previous studies showed that factors that affect health outcome can be human (patient, healthcare provider) and health system related. Poor quality of care provided to TB patients affects treatment outcome which could trigger development and spread of multidrug resistant TB. This study was conducted to assess treatment outcome of Multidrug resistant clients in Drug Resistant TB treatment centers in North Central Nigeria and assess also compliance of healthcare provider with the standard of MDR TB care and services they render. Data of 300 MDR TB clients were retrospectively collected after a review of the register and drug charts. Twenty-seven (27) participants were selected at random from the 3 states TB program and 18 health facility staff were also selected to answer questions related to compliance of facility and healthcare providers with MDR TB care/services. Response with scores zero (0) and 50% were seen as areas where compliance with the standard was lacking. Identification, training, supervision, and compensation for community treatment supporters, infection control, Socioeconomic and psychological support (including incentives, enablers), expert committee to routinely provide clinical/programmatic consultation prompt treatment initiation, use of electronic drug management system, support groups, adherence to standard operating procedures at facilities. The treatment outcome documented in the study were cured (61.7%), completed treatment (7.3%), still on treatment (17.7%), defaulted (1.3%), failed treatment (0.7%), Pre-XDR TB (4.7%), lost to follow up (1.3%), transferred out (0.7%) and died (9.7%). The study disclosed the treatment outcome of MDR TB clients and areas that compliance with standard is lacking. There is need for TB programmers to periodically assess their services and clients for continuous improvement of the program.

Keywords: Assessment of Healthcare Providers, Compliance, Predictor of Treatment Failure, Treatment Outcome, MDR TB, Nigeria

1. Introduction

In 2003, Directly Observed Treatment Short course (DOTS) was introduced in Nigeria and has resulted in significant progress in the management, prevention, and care of tuberculosis [17]. However, since the advent of MDR TB, the control of TB has been negatively impacted. Nigeria was identified by WHO as one of the 30 High TB Burdened Countries and TB is one of the leading causes of morbidity and mortality in Nigeria [18]. Multidrug-resistant tuberculosis (MDR-TB) is defined as tuberculosis that is resistant to at least isoniazid and rifampicin, the two most effective first-line anti-TB drugs. [19]. Patients on MDR TB treatment require prolonged and expensive treatment using second-line medications. [20]. Several mechanisms have been suggested to cause MDR-TB including poor adherence to anti-TB drug or previous TB treatment, poor/inadequate drug supply, direct transmission of MDR-TB from person to person, previous exposure to quinolones, use of inferior regimens, high human immunodeficiency virus (HIV) coinfection and others. [21-24]. It was projected that inappropriate use of second line anti-TB drugs in MDR-TB patients will lead to amplification of resistance and the increase of severe forms of multidrug resistance (Pre-XDR TB, XDR-TB) [1].

The key strategies employed by the National TB Program to control TB are early detection and appropriate treatment of patients. Complete administration of correct drug regimen and complete consumption of drugs by patients help in having a successful treatment outcome. TB programs are therefore increasing their efforts to improve the quality of TB diagnosis, care, and treatment as they also seek to improve access to TB services. National Tuberculosis and Leprosy Control Programme adopted a community-based treatment approach to the management of MDR/RR-TB to complement hospital-based treatment approach [2].

Ensuring that patients receive the care that they deserve and that care providers offer better services; improve adherence, diagnosis and treatment, reduce loss to follow-up will contribute to reducing TB burden [2].

Multidrug resistant TB essential element checklist extracted from the MDR TB Planning toolkit was developed to help countries achieve the goals of providing universal access to high-quality care for people with drug resistant TB and halting the transmission of drug-resistant TB. The tool describes accepted level of care and services that direct and indirect service providers should provide during planning and implementation of Programmatic Management of Drug resistant Tuberculosis cases [3]. The standards provide a reference point for assessing provider or system performance and quality of care, and help to identify levels of quality in healthcare delivery. By identifying the current and expected levels of quality, compliance or adherence with such standards can be measured easily [4].

According to the Institute of Medicine [5], majority of medical errors result from faulty systems and processes, not individuals. Processes that are inefficient and variable, changing case mix of patients, health insurance, differences in provider education and experience, and numerous other factors contribute to the complexity of health care. [25]. Health facilities functions at a lower level than it can and should put forth effectiveness, safety, patient-centeredness, timeliness, efficiency, and equitability as the six aims of healthcare. Majority of these aims are targeted through process-of-care measures, assessing whether providers of health care perform processes that have been demonstrated to achieve the desired aims. [25]. Adequate TB treatment is important both for the recovery of the patient and prevention of transmission. Long duration of treatment results in non-adherence to medications and this increases the risk of unsuccessful treatment outcomes. Treatment outcome is influenced by many factors ranging from patient, healthcare provider to health system related [6, 16].

The specific aim of this study was to identify areas where there are gaps in the health system as bridging the gaps would help to improve healthcare outcome including treatment outcome.

2. Methods

2.1. Study Setting

The study was conducted in six drug resistant TB treatment centres in North Central Zone of Nigeria. Three treatment centres were hospital based while three centres were community-based. All data reporting at the drug resistant treatment centres are channeled to the Drug resistant TB Officers who report to the State TB Program.

2.2. Data Collection Methods

This is a qualitative study which involved retrospective collection of Multidrug resistant TB patients' data after review of the register and drug charts. The period of data collection was from July 2020 to December 2020. Healthcare providers and the systems were prospectively assessed with MDR TB Essential Element checklist. The checklist was used by trained research assistants to interview healthcare providers and observation made were also documented. Questions in the checklist covered healthcare providers and health system/program related elements.

2.3. Study Participant

Twenty seventy (26) participants were selected at random from the 3 states TB program and 18 health facility staff were also selected to answer questions related to compliance of facility and healthcare providers with MDR TB care/services, structure and processes. Data was collected retrospectively for three hundred (300) MDR-TB patients based on purposive sampling.

2.4. Ethical Considerations

Ethical approval for the study was obtained from the States' Ministry of Health Research Ethical Committee. Permission to conduct the study at the facilities was granted by the institutions. All participants gave their informed and written

consent before participating in the study, and their anonymity, privacy and confidentiality was respected.

2.5. Data Analysis

Data were entered in Microsoft Excel, coded and later imported into IBM SPSS (Version 16) for analysis. Descriptive statistics were used to analyze categorical variables which were presented as frequencies and percentages in tables and charts. Inferential statistics were applied depending upon the nature of data and variables. Chi square was used to test association between variables as appropriate.

3. Results

The state TB Program officials included Medical doctors (22%), DR TB officer (11%, Pharmacist (22%), M & E Officer (22%) and Laboratory Scientist (22%). Health facility service providers included Medical doctors (27.8%), Nurse (16.7%), M& E officer (16.7%) and DR TB Officer (5.6%). About 50% of the treatment centers used for the study are facility based and 50% are community treatment centers. About 50% of the health facilities are located in urban and 50% located in rural area (Table 1).

Table 1. *Participants' Characteristics for assessment of HCP compliance.*

Characteristics	Frequency	Percentage
State TB Program officials:	27	100
Medical doctor	6	22
DR TB Officer	3	11
Pharmacist	6	22
Monitoring & evaluation officer	6	22
Lab Scientist	6	22
Health facility staff:	18	100
Medical doctor	5	27.8
Nurse	6	33.3
Monitoring & evaluation officer	6	33.3
DR TB Officer	1	5.6
Facility	3	50
Community	3	50
Urban	3	50
Rural	3	50

Table 2. *Areas of Improvement identified from assessment.*

BENUE		PLATEAU		KADUNA	
Assessment variable	Response	Assessment variable	Response	Assessment variable	Response
Identification, training, supervision, and compensation for community treatment supporters' infection control.	No-0%	Use of rapid test to detect MDR – TB	Partial= 50%	Supportive supervision improves MDR-TB services at each level	Partial=50%
Socioeconomic and psychological factors identified and addressed (including incentives, enablers).	Partial-50%	Recording and reporting by facility and treatment supporter	Partial= 50%	Analysis of delays in treatment initiation, deaths while waiting.	Partial=50%
Expert committee routinely provides clinical and programmatic consultation	Partial -50%	Identification, training, supervision, and compensation for community treatment supporters infection control	No= 0%	Key staff recently trained on drug – resistant TB.	No=0%
MDR-TB center of Excellence.	No= 0%	Socioeconomic and psychological factors identified and addressed (including incentives, enablers).	Partial=50%		
Electronic drug management system	No=0%	Patients who miss appointments are promptly retrieved.	Partial=50%		
HR development plan for MDR – TB scale – up is monitored. TB infection control (IC)	Partial=50%	Expert committee routinely provides clinical and programmatic consultation	No=0%		
Supervision of IC measure at the community and household levels.	No=0%	Accurate forecasting of SLD needs.	Partial= 50%		
		Supportive supervision improves MDR-TB services at each level.	Partial= 50%		
Community-based DOTS providers support MDR-TB patients via reimbursement for transportation cost and food package.	Partial=50%	Electronic drug management system	No= 0%		
Opportunities to participate in support groups	No= 0%	Surveillance of drug resistance in previously treated patients	Partial=50%		
Access to income-generating activities.	No=0%	Plan for staffing, supervision, and support at each level.	No=0%		
		Key staff recently trained on drug – resistant TB.	No=0%		
		Health workers and treatment supporters use approved respirators when caring for MDR – TB patients during the time the patients are known or thought to be infectious.	Partial=50%		
		opportunities to participate in support groups	No=0%		
		Involvement of community leaders to address community-wide issues such as stigma toward drug-resistant TB patients.	Partial=50%		

In Benue State, the table 2 showed that the result was not satisfactory as it ranged from 0 to 50% for the elements

-Identification, training, supervision, and compensation for community treatment supporters' infection control, Socioeconomic and psychological support (including incentives, enablers), Expert committee not routinely provides clinical/programmatic consultation and others.

In Plateau state, unsatisfactory results ranging from 0 to 50% were observed for the variables- Use of rapid test to detect MDR – TB, Recording and reporting by facility and treatment supporter, Electronic drug management system and others.

In Kaduna state, unsatisfactory results ranging from 0 to 50% were observed for the variables- Supportive supervision improves MDR-TB services at each level, Analysis of delays in treatment initiation, deaths while waiting, Key staff recently trained on drug-resistant TB.

Table 3. *Sociodemographic characteristics of Drug Resistant TB patients N=300.*

Variable	Frequency	Percentage
Age (years)		
0-14	8	2.7
15-24	34	11.3
25-34	91	30.3
35-44	90	30.0
45-54	51	17.0
55-64	16	5.3
65-74	7	2.3
>74	3	1.0
Gender		
Female	88	29.3
Male	212	70.7
Occupation		
Applicant	26	8.7
Business	38	12.7
Civil servant	17	5.7
Clergy	1	0.3
Farmer	146	48.7
Student	42	14.0
Healthcare worker	1	0.3
Others	29	9.7
Marital status		
Single	75	25.0
Married	224	74.7
Not applicable	1	0.3
HIV status		
Negative	244	81.3
Positive	55	18.3
Unknown	1	0.3
DR TB Type		
MDR TB	284	94.7
Pre-XDR TB	14	4.7
XDR TB	2	0.7
History of TB treatment		
New	225	75.0
Retreatment	75	25.0

A total of 300 DR-TB patients were assessed. Majority of the patients were in the age group 25-34 years (30.3%), males were 212 (70.7%) and females were 88 (29.3%). Majority of the patients were farmers 146 (48.7%), married 224 (74.7%), HIV negative 244 (81.3%). Pre-XDR TB cases were 14 (4.7%) while XDR TB cases were 2 (0.7%). New cases were 225 (75%) while retreatment cases were 75 (25%). (Table 3).

The retreatment patients were 3.48 times more likely to have MDR-TB than newly diagnosed patients (X^2 P (0.003). Chi square analysis of 300 MDR TB cases showed that History of previous treatment, non-adherence to treatment and age were factors associated with MDR TB cases among HIV positive patients (p=0.003, 0.000 and 0.001 respectively) while non-adherence was significantly associated with MDR TB among HIV negative patient. Development of MDR-TB was not associated with gender, State (location), marital status, occupation and educational status. (Table 4).

Of the 300 MDR TB patients whose data were retrospectively collected, 185 had smear negative within 1-2 months and were declared cured while the remaining included patients still on treatment, defaulters and others. Predictors of treatment failure by regression analysis included a positive sputum smear at the end of month 2 of TB treatment (OR 6.15, 95%CI 3.051-9.342) and poor adherence to treatment (OR 3.01 95%CI 1.368 – 6.643) as shown in Table 5.

Table 4. *Factors associated with MDR TB.*

Type of DR-TB	MDR (%)	PrexDR (%)	XDR (%)	χ^2 (P-Value)	MDR (%)	Pre-XDR (%)	XDR 9%)	χ^2 (P-Value)
Variable								
Marital Status:								
Single	12 (12.4)	1 (1.8)	0. (0.0)	0.475 (0.789)	58 (23.8)	4 (1.6)	0 (0.0)	1.100 (0.894)
Married	40 (71.4)	2 (3.6)	1 (1.8)		173 (970.9)	7 (2.9)	1 (0.4)	
Divorced	0 (0.0)	0 (0.0)	0 (0.0)		1 (0.4)	0 (0.0)	0 (0.0)	
History of RX								
New case	24 (75.0)	1 (1.8)	1 (1.8)	4.088 (0.131)	170 (69.7)	9 (3.7)	1 (0.4)	0.753 (0.686)
Retreatment	10 (17.9)	2 (3.6)	0 (0.0)	0.003	62 (25.4)	2 (0.8)	0 (0.0)	
Nonadherence to Treatment								
No	46 (82.1)	0 (0.0)	1 (1.8)	16.650 (0.000)	210 (86.1)	8 (3.3)	0 (0.0)	11.910 (0.003)
Yes	6 (10.7)	3 (5.4)	0 (0.0)		22 (9.0)	3 (1.2)	1 (0.4)	
Frequency of Non Adherence								
More than 3 times	46 (82.1)	1 (1.8)	0 (0.0)	47.015 (0.000)	209 (85.7)	9 (3.7)	0 (0.0)	29.383 (0.000)
3 times	2 (3.6)	0 (0.0)	0 (0.0)		1294.9)	0 (0.0)	1 (0.4)	
2 Times	4 (7.1)	0 (0.0)	1 (1.8)		7 (2.9)	1 (0.4)	0 (0.0)	
Once	0 (0.0)	2 (3.6)	0 (0.0)		3 (1.2)	0 (0.0)	0 (0.0)	
State								
Benue	27 (48.2)	1 (1.8)	0 (0.0)	3.789 90.435)	88 (36.1)	3 (1.2)	1 (0.4)	8.036 (0.090)
Kaduna	11 (10.6)	1 (1.8)	1 (1.8)		87 (35.7)	8 (3.3)	0 (0.0)	
Plateau	14 (25.0)	1 (1.8)	0 (0.1)		57 (23.4)	0 (0.2)	0 (0.1)	
Age								
0 – 14	0 (0.4)	0 (0.3)	0 (0.4)	1.897 (0.764)	8 (3.3)	0 (0.6)	0 (0.8)	2.845 (0.827)
15 – 24	5 (8.9)	1 (1.8)	0 (0.1)	0.06	24 (11.5)	0 (0.1)	0 (0.0)	
25 – 64	46 (82.1)	2 (3.6)	1 (1.8)	0.08	187 (76.6)	11 (4.5)	1 (0.4)	
Above 64	1 (1.8)	0 (0.1)	0 (0.3)		9 (3.7)	0 (0.0)	0 (0.0)	
Sex								
Male	35 (62.5)	3 (5.4)	1 (1.8)	1.878 (0.391)	162966.4)	10 (4.1)	1 (0.4)	2. 679 (0.263)
Female	17 (30.4)	0 (0.4)	0 (0.4)	1.897 (0.764)	70 (28.7)	1 (0.4)	0 (0.2)	
Occupation								
Students	6 (10.7)	1 (1.8)	0 (0.3)	20.370 (0.060)	33 (13.5)	1 (0.4)	1 (0.4)	7.113 (0.850)
Farmer	26 (46.4)	0 (0.2)	1 (1.8)	0.010	113 (46.3)	6 (2.5)	0 (0.2)	
Civil Servant	2 (3.6)	2 (3.6)	0 (0.1)		14 (5.7)	1 (0.4)	0 (0.1)	
Business	7 (12.5)	0 (0.2)	0 (0.1)		30 (12.3)	1 (0.4)	0 (0.1)	
Craft	5 (8.9)	0 (0.4)	0 (0.1)		12 (4.9)	1 (0.4)	0 (0.3)	
House Wife	2 (3.6)	0 (0.1)	0 (0.1)		5 (2.2)	0 (0.2)	0 (0.2)	
Unemployed	4 (7.1)	0 (0.1)	0 (0.2)		25910.2)	1 (0.4)	0 (0.3)	
Treatment Category								
Shorter regimen	52 (92.9)	0 (0.3)	0 (0.1)	62.222 (0.07)	220 (90.2)	2 (0.8)	1 (0.4)	$1.3x10^2$ (0.090)
ITR	0 (0.1)	2 (3.6)	1 (1.8)		2 (0.8)	8 (3.3)	0 (0.1)	
LOTR	0 (0.1)	1 (1.8)	0 (0.1)		10 (4.1)	1 (0.4)	0 (0.4)	

Significant at P<0.05.

Table 5. *Predictors of Tuberculosis treatment failure in the three states.*

Variables	Odd Ratio (OR)	95%CI	P-Value
Sex			
Male	1		
Female	1.939	1.030 – 3.652	0.040
Marital status			
Single	1		
Married	4.630	2.057 – 10.421	0.060
Widowed/widower	-	-	-
State			
Benue	1		
Kaduna	4.257	2.176 – 8.325	0.000
Plateau	0.721	0.304 – 1.710	0.458
Adherence to treatment			
Yes	1		
No	3.014	1.368 – 6.643	0.003
Smear conversion			
Smear negative within 1-2 months	1		
Smear positive after 2 months	6.512	3.051-9.342	0.030

Significant at P<0.05.

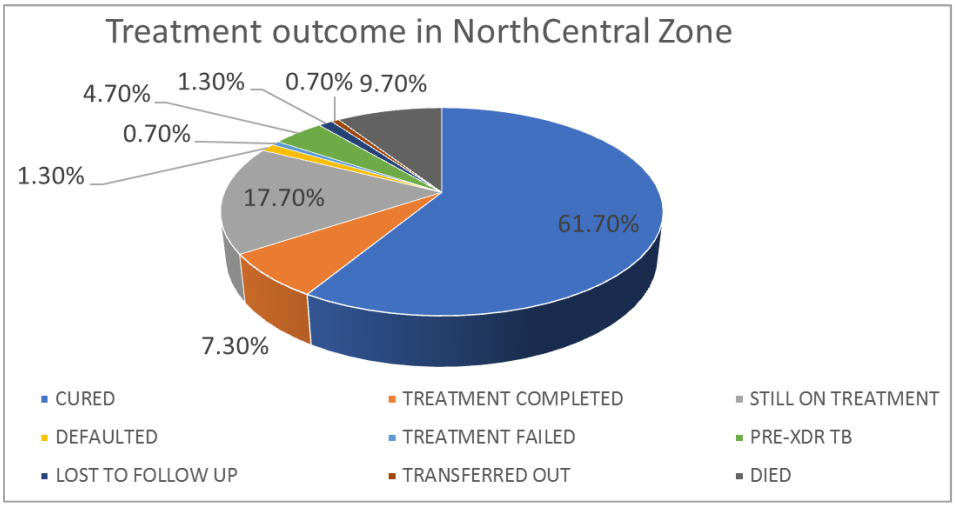

Figure 1. *Percentage of treatment outcome.*

Out of 300 MDR TB cases whose details were retrieved from the register, 185 (61.7%) were cured, 22 (7.3%) completed treatment, 53 (17.7%) were still on treatment, 4 (1.3%) defaulted, 2 (0.7%) failed treatment, 14 (4.7%) were Pre-XDR TB, 4 (1.3%) were lost to Follow up, 2 (0.7%) were transferred out and 29 (9.7%) died. (Figure 1).

4. Discussions

The study was carried out in 3 states representing the North Central zone of Nigeria. MDR TB Essential Element Checklist was used to assess the States TB Program, healthcare providers at MDR TB treatment centers [3]. The trained research assistants asked the service providers questions as contained in the checklist, audited registers/charts/documentations and made other observations. The questions in the checklist were taken as elements/variables during analysis with responses represented on a scale of 2, where No=0, Partial=1 and Yes=2. The responses were converted to percentages. Healthcare service providers at the State TB Program and treatment centers were selected at random to participate in the interview. The selection had a good representation of the healthcare providers from the different thematic areas (clinical, M & E and laboratory) as at the time of data collection. Involving equal number of community and facility-based treatment centres was to get robust information because it is believed that more activities happen in the community and also to have a good representation of workers for checklist application and interview.

From the checklist applied, all the variables scored 100% in the treatment centers assessed in 3 states except the few which were shown in table 2. The variables scoring 0 to 50 were identified as areas that would need to be improved on and for Benue the areas include Identification, training, supervision, and compensation for community treatment supporters' infection control, Socioeconomic and psychological factors identified and addressed (including incentives, enablers); Expert committee routinely provides clinical and programmatic consultation; MDR-TB center of Excellence; Electronic drug management system; HR development plan for MDR TB scale up is monitored & TB infection control (IC); Supervision of IC measure at the community and household levels; Community-based DOTS providers support MDR-TB patients via reimbursement for transportation cost and food package; Opportunities for patients to participate in support groups; access of patients to income-generating activities.

For Plateau State, the areas for improvement include use of rapid test to detect MDR-TB; Recording and reporting by facility and treatment supporter; Identification, training, supervision, and compensation for community treatment supporters infection control; Socioeconomic and psychological factors identified and addressed (including incentives, enablers); Patients who miss appointments are promptly retrieved; Expert committee routinely provides clinical/programmatic consultation due to inadequate fund; Accurate forecasting of SLD needs; Supportive supervision improves MDR-TB services at each level; Electronic drug management system; Surveillance of drug resistance in previously treated patients; Plan for staffing, supervision, and support at each level; Practice of infection control by workers & treatment supporters; opportunities for patients to participate in support groups and Involvement of community leaders to address community-wide issues such as stigma toward drug-resistant TB patients.

Kaduna State was observed to have very few areas for improvement which include Training, Supportive supervision improves MDR-TB services at each level and analysis of delays in treatment initiation, deaths while waiting.

It was few areas on the checklist that the TB Program officials recommended for improvement which include expert committee not routinely providing clinical/programmatic consultation due to inadequate funding for their meetings & plans and absence of MDR TB center of excellence in the country. Assessing the factors associated with the development of MDR TB becomes vital in curbing the MDR TB threat in North Central of Nigeria. Retreatment was found

to be associated with MDR TB in this study. Many studies have also reported retreatment to be associated with MDR TB [7-9, 26]. The reason could be attributed to high relapse rate of TB leading to prolonged treatment and increase the chance of developing MDR TB. Age was another factor associated with MDR TB in this study which is consistent with studies of [10]. In addition, age group with highest number of MDR TB cases was 25-44 years which is the age group where the Pre-XDR TB cases were found. The Pre-XDR TB cases were enrolled into treatment as MDR TB but later progressed to Pre-XDR TB. The age groups most affected from this work also conform with global trend in which the middle age groups are most at risk of being infected with tuberculosis. The findings revealed that non-adherence was associated with development of MDR TB in both HIV and non-HIV patients with emphasis on the frequency of the non-adherence. Patients who had more than 3-4 missed appointments every month were more likely to develop MDR TB as this was observed among patients who progressed to Pre-XDR TB stage.

Smear positive at the end of month 2 and poor adherence were predictors of treatment failure. A positive smear at the end of month 2 as observed in this study is consistent with studies of [11, 12]. Smear microscopy has been helpful in TB program for identification of those at risk for early intervention. Rapid killing of actively dividing bacilli happens at the first two months of treatment and this is the time majority of sputum smear positive patients convert to negative. Non-adherence to treatment was a predictor for treatment failure in this study and this does not appear to be different the study where it was reported that living further from clinic was associated with treatment failure which indirectly means non-adherence resulted from living far from clinic [12].

Kaduna State had cases of defaulted (3.7%) and treatment failure (1.9%). Treatment failure was observed among patients that progressed to Pre-XDR TB. Defaulted and treatment failure might be the reason for having MDR TB cases that progressed to Pre-XDR TB. Total Treatment failure (0.7%) reported in this study from the pooled analysis for North Central Zone is not different from what other studies reported in Ethiopia (0.3-0.8%) [13]. However, this is not similar with 8.3% that was reported in Southwest Nigeria [14]. The variation in figures could be attributed to large sample size, location and study population used in the previous Nigerian study.

A previous study showed higher level of non-adherence (24.7%-25%), different from the findings of this study [15]. The low figure obtained in this study might be due to a system put in place by the Nigeria TB Program to monitor patients on treatment closely.

5. Conclusion

The present study carried out in North Central Nigeria exposes the areas where healthcare providers are not fully complying with the set standard of MDR TB services. The areas include, not adhering to standard, inadequate training, inadequate social support packages for patients, weak supportive supervision and others. The level of adherence from this study was high, however the few cases of non-adherence and poor treatment outcome which are caused by human and system factors need to be addressed. MDR Essential toolkit was developed for healthcare providers to adopt and use it for delivering quality services. This tool serves as a checklist which was used in this study to assess health facilities and healthcare providers. Poor quality services can negatively impact treatment outcome which is why it is vital to continuously monitor the quality of care & services in order to maintain standards.

6. Limitations of the Study

There are seven states in North Central zone of Nigeria, however only three states were used for this study. There is need to use a larger data set to include all the states for the same population (multidrug resistant TB patients).

7. Recommendations

From the findings of this study, it is recommended that:

1) State specific gaps identified in this study be addressed by the TB Program.
2) TB program devise strategic means of having effective supervision where assessment of healthcare providers, processes and systems is conducted periodically for continuous improvement.

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