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Assessment of the Uptake of GeneXpert Technology for the Diagnosis of Tuberculosis in Rivers State between 2015 And 2017

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ABSTRACT

The global roll-out of Xpert MTB/RIF has changed the diagnostic landscape of tuberculosis (TB). Millions of tests have been performed and detection of multidrug-resistant TB has increased three- to eight-fold compared to conventional testing. The roll-out has galvanized stakeholders and paved the way for universal drug susceptibility testing. However, there are highlighted gaps that have constrained its scale-up and limited impact on patient outcomes. Consequently, this study was carried out to assess the uptake of GeneXpert technology for the diagnosis of tuberculosis in Rivers State, Nigeria. A retrospective gene Xpert program data from 11 sites (1 primary, 8 secondary and 2 tertiary health care facilities) of TB patients supported by USAID through KNCV Challenge TB and Global Fund projects in collaboration with other agencies in Rivers State was collected. Data generated from the service provided in the service sites between January 2015 and December 2017 was reviewed. Many testing sites were not adequately used and there is need for infrastructural support and capacity development. More reliable source of power with comprehensive training, strong referral systems, on-site supervision and regular monitoring should be implemented by the networks of authorized health service providers to ensure adequate and broader coverage and quality of Xpert MTB/RIF diagnostic services is achieved in Nigeria. A critical look into the performance profile of all the gene xpert machines in the state revealed that current average use rate stands at 41.02% in the State with the least being 11.30% at Abua xpert site and the highest being 136.88% at BMSH xpert site.

Keywords: Tuberculosis, Genexpert Technology, Diagnosis, MDR TB, TB Patients

1. INTRODUCTION

Tuberculosis, TB, is one of the major causes of preventable death in the world. TB is an infectious disease caused by Mycobacterium tuberculosis and most often affects the lungs but can also affect other parts of the body. TB infection is airborne and spread from person to person via droplets from person with lung infection through coughing, sneezing, talking or spitting. The infection causes serious damage to the lungs and other organs of the body. Tuberculosis is curable and preventable. Majority of those affected by TB can be cured; if rapidly and accurately diagnosed and treated. Tuberculosis (TB) is huge problem in most countries of low resource settings where TB diagnosis conventionally relies on microscopy. However, under field conditions TB microscopy has a sensitivity of only 40–60%, with the presence of HIV co-infection it falls to as low as 20% (Steingart et al., 2009). The regions with limited health care resources are responsible for the majority of the global burden of HIV-associated TB individuals and two-thirds of HIV infected people are found in the sub-Saharan Africa (WHO, 2014). The lunch of Global Laboratory Initiative gave high priority for global TB control by the strengthening and modernization of TB laboratories in low resource settings particularly in high HIV prevalence settings (Walusimbi et al., 2016). As a result, the array of diagnostics for TB has expanded enormously since 2007 and more than a few of them have been endorsed by the World Health Organization (WHO) (Pai and Pai, 2012; McNerney et al., 2012).

The most widely used test- the sputum smear microscopy has relatively low sensitivity (typically in the range 50%-70%), and cannot be used to identify paucibacillary TB, extrapulmonary TB or drug resistance (Steingart et al., 2006). The use of culture methods diagnosis requires a high level laboratory infrastructure which in reality is not widely available in most countries with a high burden of tuberculosis, add to the fact that test results take up to 3 months to become ready (Zetola et al., 2014).

There have been main constraints to progress in TB care and control globally. This was due to the fact that there are limitations in the diagnostic tests for tuberculosis (TB) that is conventional, as well as test for the detection of drug-resistant forms of TB and the diagnosis of TB in people living with HIV infection (Getahun et al., 2007; Small and Pai, 2010). The World Health Organization (WHO) in 2010 endorsed a new rapid molecular test, called Xpert MTB/RIF (Cepheid, Sunnyvale, CA, USA). This test can diagnose pulmonary TB and at the same time identify resistance to the most powerful first line anti-TB drug, rifampicin. In five different demonstration sites, studies carried out to determine the sensitivity and specificity indicated that the sensitivity of the test (compared with culture method) for TB was 91% and specificity 99%; while rifampicin resistance, sensitivity was 95% and specificity 98% (Boehme et al., 2011). One noteworthy thing about the MTB/RIF (Xpert) assay is that it has demonstrated capacity for quick TB detection and simultaneous assessment of rifampicin resistance with minimal technical expertise. The test takes two hours with minimal hands-on time (Helb et al., 2010; Nwokoye et al., 2014).

In a policy guidance published in May 2011 by WHO, it was strongly recommended that Xpert MTB/RIF should be employed as the initial diagnostic test in two groups of people: individuals suspected of multidrug resistant (MDR)-TB, and people living with HIV who are suspected of having TB (WHO, 2011). Multidrug-resistant Tuberculosis (MDR-TB) test, or the Xpert MTB/Rif test (Xpert) is an automated rapid molecular test with high sensitivity for simultaneous detection of pulmonary TB (PTB) and resistance to Rifampicin with or without resistance to other first-line drugs (Ramsay et al., 2011).

Available data from studies conducted at different setting indicated that the test is effective and reliable for the rapid diagnosis of pulmonary tuberculosis especially in HIV positive individuals, and multi-drug resistant tuberculosis (MDR TB) in TB cases (Van Rie et al., 2010).

Xpert MTB/RIF testing is a point-of-care diagnostic test which made available a stage for the integration and scale-up of TB-HIV services especially in a situation with pervasive diagnostic delays and consequently reduce access to care services. Increased morbidity and mortality among HIV positive clients, and among TB cases infected with multi-drug resistant mycobacteria been recorded in setting with such delays. (Kawai et al.2006; Narasimooloo and Ross, 2012). Xpert MTBRIF; rapid tuberculosis and rifampicin resistance diagnostic technology has been implemented in different settings. In Nigeria, the program targets specific groups at risk of tuberculosis and tuberculosis cases at risk of resistance to one of the most powerful drugs that is presently in use for TB treatment (Mustapha et al., 2015).

Xpert program is principally implemented in Nigeria by the KNCV Tuberculosis Foundation in partnership with the government of Nigeria, with support from the United States agency for international development (USAID). The program implementation is supervised by the national TB control program (NTP) through an advisory committee of experts: the country GeneXpert advisory committee (C-GAT). However, there are few reports on the program outcomes and challenges presented following the massive deployment

of Xpert to some resource limited high burden settings (Mustapha et al., 2015).
Consequently, this work was carried out to assess the uptake of GeneXpert technology for the diagnosis of tuberculosis in Rivers State.

2. MATERIALS AND METHODS

2.1 Study Design

The study was retrospective and descriptive.

2.2 Study Area/Location

This study was carried out in the entire Gene expert facilities and sites in Rivers state. Rivers State was formed some fifty years ago is one of the 36 states of Nigeria. The state has a population of 5,185,400 according to census data released in 2006, making it the sixth-most populous state in Nigeria. Port Harcourt, the capital city is economically significant as the centre of Nigeria's oil industry. To the North, Rivers State is bounded by Imo, Abia and Anambra States, by the Atlantic Ocean on the South, to the West by Bayelsa and Delta states and to the East by Akwa Ibom State.

2.3 Study Population

Information about all the patients who sought screening on tuberculosis in the facilities and sites within Rivers State that offer TB diagnostics services using Xpert technology was retrieved. This includes patients who had HIV with presumptive tuberculosis or had poor response to 1st and 2nd line tuberculosis treatment regimen. Besides, information was also obtained about those who had relapsed after tuberculosis treatment; returned after treatment interruption; or had contact with a known case of MDR-TB. As part of the standard of care, documentation of patients' HIV status was required. All program report forms, monitoring and evaluation report sheets, site planning, preparations and take-off reports from the date a site was activated until December, 2017 were reviewed

2.4 Sample Size Determination

All the eleven (11) gene expert facilities and sites in Rivers State were visited.

2.5 Sampling Techniques/Procedure

All the eleven (11) gene expert facilities and sites in Rivers State were visited.

2.6 Data Collection Procedures

Secondary data about the patients test results from each site or facility from January, 2015 till December, 2017 was obtained from the record books/registers. Quantitative data on the number of patients enrolled at different sites including their Xpert test and HIV test outcomes was also abstracted. Xpert tests were reported valid if MTB and rifampicin resistance (RIFr) presence or absence were determined in addition to MTB presence. If only MTB presence was determined without RIFr status it's categorized as Indeterminate, and if the presence or absence of MTB cannot be determined (invalid) or there is test error or no result signals were shown, then it is reported failed test. HIV status was classified as either positive or negative and if not documented it classified as unknown.

The various sites were coded as S1 through S11 and these sites comprise of 1 primary, 8 secondary and 2 tertiary health care facilities.The genexpert annual use rate was calculated based on the National Tuberculosis and Leprosy Control programme estimate of 12 tests per day as the optimal test to be carried out in a gene expert site.

Table 2.1: Facilities and Codes

S/N	Name of facility	Site Code
1	UPTH	S1
2	BMSH	S2
3	General Hospital Degema	S3
4	General Hospital Abua	S4
5	General Hospital Okrika	S5
6	General Hospital Bori	S6
7	General Hospital Ahoada	S7
8	Chest Clinic Rumuigbo	S8
9	Military Hosplital PH	S9
10	Gbeye Clinic Omoku	S10
11	General Hospital Terabor	S11

Data Processing

The Microsoft Excel spreadsheet package 2010 and Statistical Package for

Social Sciences (SPSS, version 20) were used in analysing the data; as data was described in categorical form using frequencies and percentage.

3. RESULTS AND DISCUSSION

3.1 RESULTS

The data generated from the service provided in the service sites between January 2015 and December 2017 was reviewed. Patients were offered Xpert tests at these sites if they had HIV with presumptive tuberculosis or if they had poor response to 1st and, or 2nd line tuberculosis treatment regimen; relapsed after tuberculosis treatment; returned after treatment interruption; or had contact with a known case of MDRTB.

Table 3.1: Demographic profile of patients' data retrieved at heath facilities

Variables	Frequency	Percentage
Age of patients		
<1 Year	73	0.3
1- 4 Years	822	3.9
5- 20 Years	2264	10.8
21-30 Year	3787	18.1
31- 40 Years	4898	23.3
41- 50 Years	4624	22.0
51 and Above	4512	21.5
Total	20980	100
Sex		
Male	9790	46.7
Female	11190	53.3
Total	20980	100
Pregnant	141	1.3
Non- Pregnant	11041	98.7
Total	20	100.0

Table 3. 2: Prevalence of tuberculosis (TB) among Xpert testing clients by site

Site	Type of Facility	No of MTB Test	MTB Cases	
			Freq	%
S1	Tertiary	3040	721	23.72
S2	Tertiary	6983	1141	16.34
S3	Secondary	727	62	8.53
S4	Secondary	613	52	8.48
S5	Secondary	664	93	14.01
S6	Secondary	1004	176	17.53
S7	Secondary	3146	610	19.39
S8	Primary	1975	330	16.71
S9	Secondary	1157	243	21.00
S10	Secondary	938	83	8.85
S11	Secondary	733	235	32.06
Total		20980	3746	17.86

Table 3.3: Sensitivity and resistance to rifampicin (RIF) based on MTB cases among Xpert testing clients by site

Site	MTB Cases	MTB+ RIF Sensitive		MTB+RIF Res	
	Freq	Freq	%	Freq	%
S1	721	664	92.09	57	7.91
S2	1141	1063	93.16	78	6.84
S3	62	56	90.32	6	9.68
S4	52	49	94.23	3	5.77
S5	93	85	91.40	8	8.60
S6	176	155	88.07	21	11.93
S7	610	596	97.70	14	2.30
S8	330	289	87.58	41	12.42
S9	243	225	92.59	18	7.41
S10	83	81	97.59	2	2.41
S11	235	223	94.89	12	5.11
Total	3746	3486	93.06	260	6.94

Table 3.4: Rate of indeterminate to rifampicin (RIF) based on MTB cases among Xpert testing clients by site

Site	MTB Cases	RIF Indeterminate	
	Freq	Freq	%
S1	721	11	1.53
S2	1141	12	1.05
S3	62	9	14.52
S4	52	0	0.00
S5	93	1	1.08
S6	176	0	0.00
S7	610	5	0.82
S8	330	32	9.70
S9	243	12	4.94
S10	83	1	1.20
S11	235	10	4.26
Total	3746	93	2.48

Table 3.5: MTB cases by HIV status and their Rifampicin responses

Site	MTB Cases	MTB+ HIV Pos		MTB+ HIV Neg		MTB+ HIV Unknown		MTB+ HIV Pos with RIFs		MTB+ HIV Pos with RIFr	
	Freq	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%
S1	721	242	33.6	441	61.2	38	5.3	232	95.5	11	4.5
S2	1141	333	29.2	607	53.2	201	17.6	291	87.4	32	9.6
S3	62	26	41.9	28	45.2	8	12.9	23	88.5	1	3.8
S4	52	8	15.4	39	75.0	5	9.6	8	100	0	0.0
S5	93	14	15.1	26	28.0	53	57.0	13	92.9	1	7.1
S6	176	64	36.4	112	63.6	0	0.0	53	82.8	11	17.2
S7	610	231	37.9	348	57.0	31	5.1	223	96.5	8	3.5
S8	330	85	25.8	193	58.5	52	15.8	75	88.2	10	11.8
S9	243	101	41.6	121	49.8	21	8.6	93	92.1	8	7.9
S10	83	35	42.2	38	45.8	10	12.0	33	94.3	1	2.9
S11	235	87	37.0	145	61.7	3	1.3	83	95.4	4	4.6
Total	3746	1226	32.7	2098	56.0	422	11.3	1126	91.8	87	7.1

Table 3.6: Uptake of Gene Xpert test by site (2015-2017)

	Year 2015			Year 2016			Year 2017		
Sites	Total Test Done	Annual Use Rate	% Annual use Rate	Total Test Done	Annual Use Rate	% Annual use Rate	Total Test Done	Annual Use Rate	% Annual use Rate
S1	353	0.119	11.91	766	0.258	25.84	1921	0.648	64.81
S2	1306	0.441	44.06	1620	0.547	54.66	4057	1.369	136.88
S3	0	0.000	0.00	79	0.027	2.67	648	0.219	21.86
S4	0	0.000	0.00	278	0.094	9.38	335	0.113	11.30
S5	0	0.000	0.00	0	0.000	0.00	664	0.224	22.40
S6	121	0.041	4.08	462	0.156	15.59	421	0.142	14.20
S7	38	0.013	1.28	849	0.286	28.64	2259	0.762	76.21
S8	91	0.031	3.07	697	0.235	23.52	1187	0.400	40.05
S9	199	0.067	6.71	492	0.166	16.60	466	0.157	15.72
S10	0	0.000	0.00	38	0.013	1.28	899	0.303	30.33
S11	38	0.013	1.28	178	0.060	6.01	517	0.174	17.44

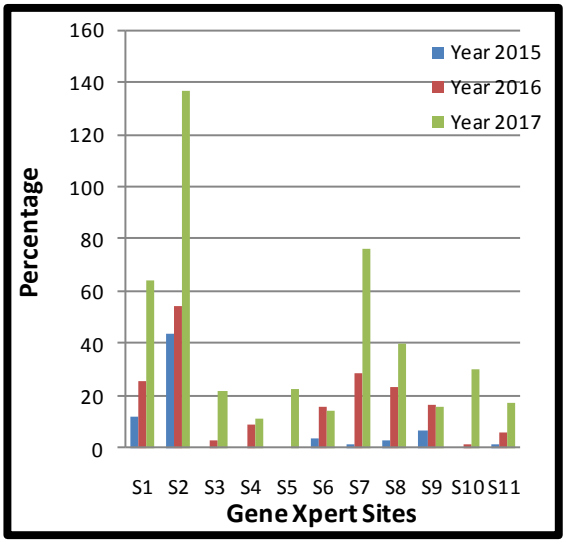

Figure 1: Uptake of Gene Xpert test by site (2015-2017)

From January, 2015 to December, 2017, 20945 presumptive cases of TB and presumed TB in HIV infected patients were offered single Xpert tests at the 11 sites. The number of tests and yields of MTB, RIF sensitive and RIF resistance at the 11 different sites were summarized in table 4.5 to 4.8. The demographic profile of patients' data retrieved at heath facilities from the 11 gene Xpert test sites indicated that out of the 20,980 patients tested, 9790 (46.7%) were male and 11,190 (53.3%) were female. Of the female patients that came to the sites, 141 (1.3%) were pregnant and 11,049 (98.7%) were not pregnant.

Total number with valid Xpert test recorded in this study is almost double the total number with valid Xpert test reported by Mustapha et al., (2015) in a study on assessment of GeneXpert MTB RIF program implementation carried out in 22 Xpert laboratories covering a period between September 2011 and December 2013 in Nigeria. This may be due to the growing effort and improvement in knowledge gaps on gene xpert usage. The gender distribution of the patients in this study was almost equally shared and not significantly different across the study sites. Nwokoye et al., (2014) similarly reported 48.0% male and 52.0% female in a study on performance and biosafety implications of GeneXpert MTB/RIF assay conducted in Nigerian institute of Medical Research (NIMR), Lagos, between January and December 2012. The slight higher female representation in this study may be due to what was observed by Okinyi et al (2010) who cited that the health seeking behavior of females could be a contributing factor as females take health issues more serious than males.

It was also observed in this study that 41.4% of the patients were within the ages of 20 and 40 years, which are generally considered to be the most active age groups. Similar finding was reported by Adegboyega et al., (2014) in a review work on sustaining the fight against drug resistant tuberculosis (DR-TB) in Nigeria. Of those, 10,023 (47.8%), 8982 (42.8%) and 1975 (9.4%) were enrolled at tertiary, secondary, and private level health facilities (sites) respectively. The tests were valid in 3746 patients. Hence, the prevalence of Mycobacterium tuberculosis (MTB) infection was 17.86%, with the lowest prevalence of 8.48% in site 4th and highest prevalence of 32.06% in Site 11th. And of those MTB cases, 3486 (93.06%) had Mycobacterium tuberculosis (MTB)

infection with sensitivity to rifampicin (RIFs), 260 (6.94%) had Mycobacterium tuberculosis (MTB) infection with rifampicin resistance (RIFr) and 93 (2.48%) were RIF indeterminate.

The prevalence of TB in this study is less than less than 29.2% reported by Obioma and Ngozika, (2018) in a study carried out in two government owned hospitals in Port Harcourt, Rivers State. One reason that could make the prevalence in this study less may be due to the fact that this study involved all Gene Xpert sites in Rivers State including those that may not be adequately used because as shown above, the two tertiary facilities have the highest patronage in the State. This may also have indicated that many cases did not report for MTB diagnosis in some of the diagnostic sites. Besides Obioma and Ngozika's study was conducted in the two tertiary hospitals in Rivers State with guaranteed large influx of patients. The findings on prevalence in this study is also less than 27.2%, 23.5% and 33.5% reported in Nigeria (Nwokoye et al., 2014), South Africa (Ligthelm et al., 2014) and Nigeria (Mustapha et al., 2015).respectively.

The prevalence of DR-TB in this study was 6.94%. this finding is similar to Rasaki et al., (2014) who reported 7.1% DR-TB in a study on the pattern of rifampicin resistance tuberculosis in Ilorin, North-Central, Nigeria, but this result is much lower compared to 22.0% and 41.5% rifampicin resistance reported by Mustapha et al., (2015) and Nwokoye et al., (2014). This difference must have been brought about by increased and innovative effort geared into DR-TB services such as PMDT, community management of DR-TB cases, improved services at treatment centres, increased numbers of GeneXpert machines etc, with improved services. It should be noted that the WHO (2011) reported that Nigeria has an estimated MDR-TB rate of 2.2% and 9.4% among new and re-treatment TB cases, respectively, and is consequently ranked 15th among the 27 High Burden Countries for MDR-TB.

Out of the 3746 MTB cases, 1226 (32.7%) were HIV positive, 2098 (56.0%) were HIV negative and 422 (11.3%) HIV status was unknown. Among the MTB cases, patients that were HIV positive and sensitive to rifampicin were 1126 (91.8%) and those resistant to rifampicin (RIFr) were 87 (7.1%).

According to Tuberculosis Fact Sheet, (2012), it was reported that the prevalence of HIV among TB patients increased from 2.2% in 1991 to 25% in 2010. And now in this study 32.7% was found. This indicated that the TB situation in Nigeria is HIV-driven. Similarly, in a pilot study conducted in Abuja by Lawson et al (2010), it observed a high co-infection of HIV with TB. This reiterates the need to fortify the linkage between TB and HIV services in Nigeria.

The MTB detection by Xpert based on patients' HIV status in this study is similar to 32.9% MTB-HIV co-infection reported by Nwokoye et al., (2014). But the MTB-HIV positive who were resistant to rifampicin (RIFr) in this study is lesser than 14.6% (Mustapha et al., (2015) and 18.5% (Nwokoye et al., 2014). It appears that many testing sites were not adequately used as patients do not report for test. This indicates there is need to strengthen the networks of authorized service providers to ensure adequate and broader coverage and quality of Xpert MTB/RIF diagnostic services.

4. CONCLUSION

It must be said at this time that Gene-Xpert MTB RIF program implementation for enhanced tuberculosis diagnosis in Nigeria, has shown no or fair impact from what it used to be before now in the study location. The prevalence of MTB cases in this retrospective study was low even when compared to study carried out in the two government owned tertiary health centers in the state during same periods. Hence, it appears that many testing sites were not adequately used as patients do not report for test. This indicates there is need to strengthen the networks of

authorized service providers to ensure adequate and broader coverage and quality of Xpert MTB/RIF diagnostic services

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