

Assessment of GeneXpert MTB/RIF Performance by Type and Level of Health-Care Facilities in Nigeria

Mustapha Gidado, Nkiru Nwokoye, Chidubem Ogbudebe, Bassey Nsa, Peter Nwadike, Prisca Ajiboye, Rupert Eneogu, Sani Useni, Emeka Elom¹, Adebola Lawanson¹

KNCV Tuberculosis Foundation/Challenge TB Project, Abuja, Lagos, ¹National TB and Leprosy Control Program, Abuja, Nigeria

Abstract

Setting: Nigeria adopted GeneXpert MTB Rif as a primary diagnostic tool were available and accessible since 2016. The current geographical coverage of GeneXpert machines by LGAs stands at 48%, with a varied access and utilization. **Objectives:** To assess the association between the type and level of health facilities implementing GeneXpert MTB/Rif and performance outcome of the machines in Nigeria. **Study Design:** Retrospective secondary data analysis of GeneXpert performance for 2017 from GXAlert database. The independent variables were type and levels of health care facilities, and dependent variables were GeneXpert performance (utilization, successful test, error rates, MTB detected, and Rifampicin resistance detected). **Results:** Only 366 health care facilities are currently implementing and reporting GeneXpert performance, the distribution is 86.9% and 13.1% public and private health care facilities respectively, and only 6.3% of the facilities are primary health care. Of 354,321 test conducted in 2017, 91.5% were successful, and among unsuccessful test 6.8% were errors. The yield was 16.8% MTB detected (54,713) among which 6.8% had Rif resistance. The GeneXpert utilization rate was higher among private health care facilities (55.8%) compared to 33.3% among public health care facilities. There was a statistically significant difference in the number of successful test between public and private health facility-based machines as determined by one-way ANOVA ($F(1,2) = 21.81, P = 0.02$) and between primary, secondary and tertiary level health facility-based machines ($F(1,2) = 41.24, P < 0.01$). **Conclusion:** Nigeria with very low TB coverage should rapidly scale-up and decentralize GeneXpert services to the private sector.

Keywords: GeneXpert utilization, private health facility, public health facility

INTRODUCTION

Tuberculosis (TB) is the ninth leading cause of death worldwide and the leading cause of a single infectious agent, ranking above HIV/AIDS, with the estimated burden of 10.4 million TB cases and 600,000 new cases of drug resistance. In 2016, only 61% and 25% of drug-susceptible and drug-resistant TB were notified, respectively.¹ Nigeria is ranked 4th among high-burden TB countries, with an estimated incidence of 219/100,000 population, and notified only 24% of the estimated cases in 2016, contributing 8% of the global missed TB patients.^{1,2}

The World Health Organization in December 2010 recommended the use of GeneXpert *Mycobacterium tuberculosis*/Rifampicin (MTB/RIF) for TB diagnosis and detection of drug resistance, especially among people living with HIV/AIDS and persons suspected to have multidrug-resistant TB.^{3,4} This was considered a breakthrough

for TB control by bringing a near point-of-care test for TB; GeneXpert MTB/RIF is an automated, real-time nucleic acid amplification technology, with sensitivity and specificity higher than that of microscopy and chest X-ray.⁵⁻⁷ After years of implementation, it was observed that many countries using GeneXpert MTB/RIF as the first diagnostic tool recorded a decrease in microscopy/GeneXpert ration, signifying an increased use of GeneXpert MTB/RIF.⁸

Nigeria adopted GeneXpert as the first diagnostic tool in 2016, and currently has 390, four-module GeneXpert machines (1560 modules) installed throughout the 36 states of the federation

Address for correspondence: Dr. Nkiru Nwokoye,
Plot 564/565 Independence Avenue, Central Business District,
Abuja FCT, Nigeria.
E-mail: nkiru.nwokoye@kncvtbc.org

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and the federal capital territory; despite the large number of GeneXpert machines in the country, the average utilization rate is 27%.⁹ The performance challenges in the field were weak enabling environment for optimal utilization of the machine (infrastructure and human resource [HR]) and programmatic issues related to identification, referral, and sample transportation; appropriate placement of the machine; and maintenance.¹⁰⁻¹² Therefore, this study aims to conduct a retrospective secondary data analysis of the performance of GeneXpert MTB/RIF in different types and levels of health-care facilities in Nigeria.

MATERIALS AND METHODS

Study design

The study design was a retrospective secondary data analysis from GxAlert database. The target was all GeneXpert machines connected to GxAlert web-based nationwide; this included both private and public health-care facilities and the different health facility levels (primary, secondary, and tertiary). Data review was from January to December 2017. The GxAlert software (SystemOne, Northampton, MA, United States) connects GeneXpert machine to the Internet, allowing transfer of results to a central, secure database in real time.¹³ The automated database was developed for different reporting indicators across all machines and was monitored by a designated individual. Primary data from patients were uploaded into the individual computers connected to the GeneXpert machine by laboratory staff. All results from the machine were captured in the database based on the unique identification number assigned to individual patients. The GxAlert database provides information on the following performance indicators: utilization rate of the machine (number of tests conducted per day/month); proportion of successful tests conducted; error rates; invalid results; MTB detected and Rif resistance detected; and type and level of health-care facilities disaggregated into private, public, primary, secondary, and tertiary health-care facilities.

Exclusion criteria were Xpert MTB/RIF installed in the last quarter of 2017, machine offline for more than a quarter, and machines primarily used for research activities.

The private health facilities were either hospitals or stand-alone laboratories; the facilities could be private for-profit or faith-based (nonprofit) facilities; whereas the status of primary, secondary, and tertiary is based on designation by the government. Utilization rate of the machine was calculated based on a 2-h turnaround time of the machine, assuming an average of 6-h working period per day within the laboratory (i.e., for a four-module machine, it should run 12 tests per day); for an average of 200 working days per year (excluding weekends and public holidays), it should be 2400 tests per year. Successful test rate was the proportion of tests with appropriate results (all results minus errors, invalid, and indeterminate); error rate was the proportion of the sample tested with an error result as determined by the machine;

invalid rate was a proportion of all tests with invalid results; and lastly, indeterminate rate was the proportion of all sample results with indeterminate results as an outcome.

The GxAlert system was designed with a quality control mechanism to ensure validity and reliability of the data. Quality control measures employed included the use of computer barcode Scanner to reduce transcription errors, automatic generation of all outcome indicators (test results including errors, invalid, indeterminate, MTB detected, and rifampicin detected) by GeneXpert machine and direct upload of indicators to GxAlert platform.

Statistical analysis

The database from January to December 2017 was reviewed to identify facilities that meet inclusion criteria which included functional connectivity to the Internet, minimum of the three-quarter report, and facilities with complete identification variable on level and type. Data cleaning, validation, and quality improvement were done by exporting GxAlert data to Statistical Package for the Social Sciences v16 software (SPSS Inc., Chicago, IL, USA). Each variable was checked for accuracy and consistency, and frequency tables were generated to check for outliers and errors. The level and type of health-care facilities were double checked with the National Health-Care Facilities directory.

Strength and limitation of the study design

The strength of this method is the use of an existing database. Variables within the database were automatically uploaded from the GeneXpert machines, thereby reducing recording and transcription error if data were to be collected manually by the staff. All GeneXpert machine performance variables were generated by the machine, eliminating errors from human interpretation and documentation of the results.

Limitation of the design is that analysis was restricted to only variables generated from the machines and other important variables on overall facility utilization (general outpatient utilization), turnaround time for maintenance, logistics supply management of cartridges, and other information for GeneXpert test documented on sample request form were not captured in the analysis. The database had no information on the number of staff performing the GeneXpert assay, staff competency, training and supervision to the facility, and if the laboratory was a TB stand-alone laboratory or integrated with other laboratory services.

Selection/information bias

A likely inherent selection bias for the performance outcome is that machines in primary health-care facilities are likely to have more infrastructure and HR challenges than that of secondary and tertiary health facilities; utilization rate of GeneXpert machines in private health facilities could equally be influenced by service charges (cost). The interpretation of the association between performance and type of health-care facilities should not be described in isolation; it is critical to describe some general context of the different types of

health-care facilities. The fact that biodata of patients or the health-care workers at the facility were not captured reduced the chances of information bias.

Ethical consideration

There are three critical ethical considerations in this study: the overall ownership of the database is with the national TB program; multiple partners are responsible for procurement, installation, and maintenance of the GeneXpert nationwide; and different health-care facilities including the private sector are involved in providing the services. Permission and consent to use the database was granted by the national TB program, while data analysis was done without unique identification of facility's name or partner's name supporting the facility. The only identification that was used was the designation of health-care facilities as public, private, primary, secondary, or tertiary. Patient-level details were excluded during the analysis.

RESULTS

Of 366 GeneXpert MTB/RIF machines uploading data during January–December 2017, 318 (86.9%) were public and

48 (13.1%) were private health-care facilities. Among these, 23 (6.3%) were categorized as primary-level, 287 (78.4%) as secondary-level, and 56 (15.3%) as tertiary-level health-care facilities [Table 1]. The overall number of tests performed was 354,321 in 2017, out of which 91.5% had successful test outcome. The proportion of tests performed was highest among GeneXpert MTB/RIF machine in the secondary health-care facilities. The mean age of patients tested was 35 years. Among 64,389 patients with known HIV status, HIV positivity rate was 23.1%. Of 90,783 patients with documented gender status, 49.1% were female.

The distribution of GeneXpert MTB/RIF machine by type and level of health-care facilities and their performance outcomes are shown in Table 2. There were significant differences in proportions of tests performed by the level of health facility (primary, secondary, and tertiary) implementing GeneXpert MTB/RIF machine regarding error, invalid, and indeterminate outcomes. The proportion of error test outcomes was higher in private health facility GeneXpert machines than those in public health facilities, but this difference was not statistically significant [Table 2]. However, machines in primary health facilities have the lowest (89.3%) proportion of successful test outcomes compared to 91.6% in secondary-level and 92.2% in tertiary-level facilities ($P < 0.01$). Tertiary health facility-based machines had the lowest proportions of MTB-positive ($P < 0.01$) and unsuccessful ($P < 0.01$) test outcomes compared to those in primary- and secondary-level health-care facilities [Table 2]. Among 64,389 patients with known HIV status, positivity rate was higher among patients tested in the private health facility-based machines compared to the public health facility-based machines ($P < 0.01$).

GeneXpert machine utilization rate by type and level of health-care facilities is shown in Table 3. The overall machine utilization rate was 33.6. Machine utilization rate among secondary health facility-based machines was worse than those in primary-level and tertiary-level health-care facilities. GeneXpert utilization rate was higher in private health facilities compared to those in public health facilities [Table 3].

One-way between-groups analysis of variance (ANOVA) was conducted to explore the association of type and level of health-care facilities implementing GeneXpert MTB/RIF machine and performance outcomes [Tables 4 and 5]. There was a statistically significant difference in the number of successful test outcomes between public and private health facility-based machines as determined by one-way ANOVA ($F(1,2) = 21.81, P = 0.02$) and between primary-, secondary-, and tertiary-level health facility-based machines ($F(1,2) = 41.24, P < 0.01$) [Table 4]. *Post hoc* comparisons using the Tukey's honestly significant difference (HSD) test revealed that the mean difference in the number of successful test outcomes in secondary health facility-based machines ($1.83 \pm 0.37, P < 0.01$) was significantly different from those in primary ($1.84 \pm 0.36, P < 0.01$)- and tertiary ($1.84 \pm 0.36, P < 0.01$)-level health-care facilities. There

Table 1: GeneXpert *Mycobacterium tuberculosis*/rifampicin machine distribution, and demographic and clinical characteristics of patients

Variables	Frequency (%)
Type of health facility ($n=366$)	
Public	318 (86.9)
Private	48 (13.1)
Level of health facility	
Primary	23 (6.3)
Secondary	287 (78.4)
Tertiary	56 (15.3)
Utilization, test outcomes ($n=354,321$)	
Successful	324,248 (91.5)
Unsuccessful	30,073 (8.5)
Bacteriology and drug resistance profile	
MTB not detected	270,225 (83.2)
MTB detected	54,713 (16.8)
MTB detected, RIF resistance negative	50,292 (91.9)
MTB detected RIF resistance positive	3731 (6.8)
MTB detected RIF resistance indeterminate	690 (1.3)
Unsuccessful test outcome category	
Invalid	5207 (1.5)
Error	24,176 (6.8)
Indeterminate	690 (0.2)
Age, years, median (IQR)	33 (24-48)
Gender ($n=90,783$)	
Male	46,230 (50.9)
Female	44,553 (49.1)
HIV status of patients tested ($n=64,389$)	
Positive	14,901 (23.1)
Negative	49,488 (76.9)

MTB – *Mycobacterium tuberculosis*; RIF – Rifampicin; HIV – Human immunodeficiency virus; IQR – Interquartile range

Table 2: GeneXpert *Mycobacterium tuberculosis*/rifampicin machine distribution by type and level of health-care facilities and test performance outcomes

Variables	Type of facility		<i>P</i> [†]	Level of facility			<i>P</i> [‡]
	Public, <i>n</i> (%)	Private, <i>n</i> (%)		Primary, <i>n</i> (%)	Secondary, <i>n</i> (%)	Tertiary, <i>n</i> (%)	
Total machine	318 (86.9)	48 (13.1)		23 (6.3)	287 (78.4)	56 (15.3)	
Utilization and test outcome							
Successful	279,100 (91.6)	45,148 (91.3)	0.02	23,740 (89.3)	242,809 (91.6)	57,699 (92.2)	<0.01
Unsuccessful	25,744 (8.4)	4329 (8.7)		2844 (10.7)	22,374 (8.4)	4855 (7.8)	
Total	304,844	49,477		26,584	265,183	62,554	
Bacteriology and drug resistance profile							
MTB negative	232,256 (83.0)	37,969 (83.9)	<0.01	19,998 (84.1)	201,509 (82.8)	48,718 (84.2)	<0.01
MTB positive	47,440 (17.0)	7273 (16.1)		3789 (15.9)	41,808 (17.2)	9116 (15.8)	
MTB positive, RIF negative	43,672 (92.1)	6620 (91.0)	<0.01	3478 (91.8)	38,510 (92.1)	8304 (91.1)	<0.01
MTB positive RIF positive	3172 (6.7)	559 (7.7)	0.11	264 (7.0)	2790 (6.7)	677 (7.4)	0.93
MTB positive RIF indeterminate	596 (1.2)	94 (1.3)	0.75	47 (1.2)	508 (1.2)	135 (1.5)	0.32
Unsuccessful test outcome category							
Invalid	4486 (1.5)	721 (1.5)	0.20	379 (1.4)	3884 (1.5)	944 (1.5)	<0.01
Error	20,662 (6.8)	3514 (7.1)		2418 (9.1)	17,982 (6.8)	3776 (6.0)	
Indeterminate	596 (0.2)	94 (0.2)	0.54	47 (0.2)	508 (0.2)	135 (0.2)	<0.02
Patients demographic, clinical characteristics							
Age, years, median (IQR)	35 (24-48)	35 (24-47)	<0.01	33 (21-45)	35 (24-49)	34 (22-47)	0.93
Gender (<i>n</i> =90,783)							
Male	38,698 (51.1)	7532 (50.1)	0.02	4868 (54.0)	33,953 (50.6)	7409 (50.6)	0.97
Female	37,036 (48.9)	7517 (49.9)		4153 (46.0)	33,160 (49.4)	7240 (49.4)	
Known HIV status							
Positive	12,080 (22.4)	2821 (27.1)	<0.01	583 (13.5)	12,095 (24.3)	2223 (21.8)	<0.01
Negative	41,895 (77.6)	7593 (72.9)		3736 (86.5)	37,777 (75.7)	7975 (78.2)	

[†]Pearson's Chi-square for type of facility (public; private); [‡]Pearson's Chi-square test for level of facility (primary; secondary; and tertiary); *P*<0.05. MTB – *Mycobacterium tuberculosis*; RIF – Rifampicin resistance; HIV – Human immunodeficiency virus; IQR – Interquartile range

Table 3: GeneXpert *Mycobacterium tuberculosis*/rifampicin machines' utilization rate stratified by the type and level of health-care facilities

Category	GeneXpert machine, <i>n</i> (%)	Current utilization, <i>n</i> (%)	Expected utilization [†] , <i>n</i> (%)	Utilization rate [‡]	<i>P</i>
Total	366	354,321	1,054,080	33.6	
Type of health facility					
Public	318 (86.9)	304,844 (86.0)	915,840 (86.9)	33.3	<0.01
Private	48 (13.1)	49,477 (14.0)	138,240 (13.1)	35.8	
Type of health facility					
Primary	23 (6.3)	26,584 (7.5)	66,240 (6.3)	40.1	<0.01
Secondary	287 (78.4)	265,183 (74.8)	826,560 (78.4)	32.1	
Tertiary	56 (15.3)	62,554 (17.7)	161,280 (15.3)	38.8	<0.01

[†]Expected utilization – 4 test × 3 rounds × 5 days a week × 48 weeks; [‡]Utilization rate – Total test performed/expected number of test × 100; *P*<0.05

was no statistically significant difference in the number of successful test outcomes between the primary- and tertiary-level health facility-based machines (*P* = 0.83).

While there was no significant difference between the mean number of unsuccessful test outcomes in public and private health facility-based machines [Table 5], primary-level health facility-based machines had the highest proportion of unsuccessful test outcomes (*F* (1,2) = 29.04, *P* < 0.01) compared to those in secondary- and tertiary-level health

facility-based machines. Further analysis using the Tukey's *post hoc* test indicated that the mean difference in some unsuccessful tests between the three groups (primary, secondary, and tertiary) was statistically significant (*P* < 0.01). One-way between-groups ANOVA was conducted to explore the association of type and level of health facilities implementing GeneXpert MTB/RIF machine and performance outcomes [Tables 4 and 5]. There was a statistically significant difference in the number of successful test outcomes between

Table 4: Association of type and level of health-care facility implementing GeneXpert *Mycobacterium tuberculosis*/rifampicin machines and successful test outcome

Category	Utilization (n=366), n (%)	Successful test, n (%)	F (df _{1,2})	P	Mean±SD	P ^a
Total	354,321	324,248				
Facility type						
Public	304,844 (86.0)	279,100 (91.5)	21.81 (1, 324246)	0.02	1.08±0.27	
Private	49,477 (14.0)	45,148 (91.3)			1.09±0.28	
Facility level						
Primary	26,584 (7.5)	23,740 (89.3)	41.24 (2,324245)	<0.01	1.84±0.36	<0.01
Secondary	265,183 (74.8)	242,809 (91.6)			1.83±0.37	
Tertiary	62,554 (17.7)	57,699 (92.2)			1.84±0.36	0.83

F – Measure of difference in variance between and within groups; SD – Standard deviation; ^aP – Post hoc test; P<0.05

Table 5: Association of type and level of health-care facility implementing GeneXpert *Mycobacterium tuberculosis*/rifampicin machines and unsuccessful test outcome

Category	Utilization (n=366), n (%)	Unsuccessful test, n (%)	F (df _{1,2})	P	Mean±SD	P
Total	354,321	30,073				
Facility type						
Public	304,844 (86.0)	25,744 (8.4)	1.911 (1, 30071)	0.16	1.92±0.27	
Private	49,477 (14.0)	4329 (8.7)			1.91±0.28	
Facility level						
Primary	26,584 (7.5)	2844 (10.7)	29.035 (2, 30070)	<0.01	4.83±0.41	<0.01
Secondary	265,183 (74.8)	22,374 (8.4)			4.78±0.47	
Tertiary	62,554 (17.7)	4855 (7.8)			4.75±0.49	<0.01

F – Measure of difference in variance between and within groups; SD – Standard deviation; P – Post hoc test; P<0.05

public- and private-level health facility-based machines as determined by one-way ANOVA ($F(1,2) = 21.81, P = 0.02$) and between primary-, secondary-, and tertiary-level health facility-based machines ($F(1,2) = 41.24, P < 0.01$) [Table 4]. *Post hoc* comparisons using the Tukey's HSD test revealed that the mean difference in the number of successful test outcomes in secondary health facility-based machines ($1.83 \pm 0.37, P < 0.01$) was statistically significantly different from those in primary ($1.84 \pm 0.36, P < 0.01$)- and tertiary ($1.84 \pm 0.36, P < 0.01$)-level health-care facilities. There was no statistically significant difference in the number of successful test outcomes between the primary- and tertiary-level health facility-based machines ($P = 0.83$).

DISCUSSION

One major challenge of TB response in Nigeria is low case finding both in adults and children. The country was recently ranked 7th among the 30 high TB burden countries and 2nd in Africa and contributes 8% of the missing TB cases globally.¹ Despite the increasing burden of TB, high unmet needs, and the giant stride of adopting GeneXpert machine as the primary diagnostic tool, in 2016, Nigeria had one of the lowest case detection rates among the high TB burden countries with suboptimal GeneXpert machine utilization rate. The purpose of this study was to determine whether type and level of health-care facilities influence the utilization and quality of GeneXpert services. This would provide useful information and guide to stakeholders on

effective policies for improved detection and treatment of TB.

Our findings showed that, though the majority of GeneXpert machines are in the public sector, the utilization rate was higher among the few in the private sector. There was no significant difference between the rates of unsuccessful tests emanating from both public and private health-care facilities. However, the error rate from private health-care facilities was slightly higher than the rate in the public health-care facilities. The high utilization rate of GeneXpert machines in private health-care facilities demonstrates the health-seeking behavior of TB patients. Studies have shown that TB patients tend to seek medical care in an accessible, less expensive, responsive, and patient-friendly health facilities.¹⁴⁻¹⁶ Patients can equally access private health-care facilities far from home for fear of stigmatization and confidentiality protection.^{17,18}

Geographic location was also an important determinant of an individual's choice of health-care provider. People residing in urban locations where there are increase number and variety of private providers tend to use private facilities more.¹⁹ In line with the above, adequate number and proper distribution of TB diagnostic and treatment centers would improve access to TB services. This is not the case in Nigeria, as reports have demonstrated the skewed distribution of GeneXpert machines in a limited number of health facilities.²⁰ Ukwaja *et al.*, 2013, in Ekiti State, Nigeria, reported that more than nine-tenths of the patients walked for over 1 h to access the nearest public health-care facility from their homes, reflecting the

inadequate number of public health-care facilities in a rural setting where it is preferred.¹⁸ National TB program and other stakeholders need to adopt the patient-centeredness approach when developing strategies and policies for increasing access to health services which include GeneXpert machine placement.

Another important reason for high machine utilization in the private sector is the business-oriented nature of this sector. Although TB diagnostic and treatment services are provided free of charge in private facilities, all patients irrespective of their health problem pay administrative fees.¹⁸ In addition, the facility needs to be in business always as such infrastructures are often maintained to ensure continuous services with limited interruptions arising from strikes, holidays, staff attrition, and incessant power outage, as constantly observed in public health facilities. This is in line with a previous report that the private sector was more efficient, accountable, or medically effective than the public sector.²¹

Some authors claimed that diagnostic accuracy and adherence to medical management standards are worse among private than public sector care providers,²² as such private sector care providers had greater risks of low-quality care. This is at variance with our study which showed no significant difference between rates of unsuccessful tests conducted in both sectors. The slightly higher rate in error test outcome was greatly associated with the increased internal temperature of the machine which arose from frequent and prolonged usage. Consequently, machines with high utilization rates recorded a higher proportion of temperature-related errors.

The study also recorded more machine placement and low utilization in secondary-level facilities than other levels with a greater proportion of error rate and unsuccessful test outcome occurring within the primary health facility level. This result is in agreement with a previous research conducted in Nigeria by Gidado *et al.*, 2018, which indicated that more machines were installed in secondary- and tertiary-level health facilities on the assumption that they have a relatively stable power supply to sustain the operation of GeneXpert machine.²⁰ In the Nigerian health system, services are provided at three levels, namely, primary, secondary, and tertiary. The local government areas (LGAs) provide the primary level of care, state governments provide the secondary level of care and provision of technical guidance to the LGAs, and the federal government is responsible for the tertiary level of care as well as policy formulation and technical guidance to the states.²³ Majority of the secondary-level health facilities under the state governments are fully integrated into the TB program,¹⁸ as such, it was very easy to get their commitment and buy-in during the initial rollout of GeneXpert technology.

The usefulness of Genexpert test in intensified case finding has been demonstrated;^{24,25} however, in agreement with Agizew, 2017, its usefulness depends largely on the proportion of valid test outcomes.²⁶ Error rate beyond the acceptable limit is an indication of poor performance. In contrast with a recent study conducted in Botswana where no difference

was recorded in the proportion of error rates emanating from the peripheral and centralized-based laboratories,²⁶ our study demonstrated a significantly higher error rate among the primary health-care facilities. This may be attributed to the low-skilled staff in primary health-care facilities. Such staff require consistent mentoring for skill advancement and better insight on GeneXpert technology. Furthermore, there has been poor counterpart funding and commitment on the side of government for infrastructural maintenance, as such basic infrastructural and other requirements for optimal performance of the GeneXpert machine are not readily available in most primary health-care facilities.

CONCLUSION

The involvement of more private health facilities, both faith based and private for profit in the diagnosis and early referral of patients with pulmonary symptoms, could increase case detection. Furthermore, continuous mentoring of GeneXpert operators particularly in primary-level health facilities, infrastructural maintenance, and scaling up of TB diagnostic services to densely populated areas for increased access are some of the factors that would improve GeneXpert utilization and quality of the test.

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Conflicts of interest

There are no conflicts of interest.

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