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Original Article

GENE XPERT OUTCOMES OF ADULT PRESUMPTIVE PULMONARY TUBERCULOSIS PATIENTS IN NNAMDI AZIKIWE UNIVERSITY TEACHING HOSPITAL (NAUTH) NNEWI, ANAMBRA STATE, NIGERIA.

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ABSTRACT
Background: Tuberculosis (TB) and drug-resistant TB are public health issues in Nigeria. Gene Xpert assay is currently used to detect TB and Multidrug-resistant/Rifampicin-resistant tuberculosis (MDR/RR-TB). This study assessed the Gene Xpert outcomes of adult presumptive pulmonary tuberculosis patients in NAUTH Nnewi, Anambra State, Nigeria.
Methodology: A descriptive cross-sectional study was carried out among 180 adult presumptive pulmonary tuberculosis patients aged ≥ 18 years who presented to the TB centre, NAUTH Nnewi between June and September 2024. A semi-structured, interviewer-administered questionnaire was used to obtain data, while sputum samples were examined using Gene Xpert assay. Data were analyzed using SPSS version 25.
Results: Ninety-five (52.8%) of the respondents were males. Their mean age was 40.46 ± 15.72 years. Out of the 180 sputum samples, 63(35.0%) had Mycobacterium tuberculosis (MTB) detected using Gene Xpert assay; out of the 63 MTB-positive sputum samples, 6(9.5%) were resistant to rifampicin, 60.3% were not resistant to rifampicin, while 30.2% were indeterminate.
Conclusion: TB and MDR/RR-TB are public health issues in the study area. The use of improved diagnostic tests like the Gene Xpert MTB/RIF assay should be scaled up at each point of care in the State to improve case detection.
Keywords: Gene Xpert assay, Presumptive TB, Pulmonary TB, Adult.

INTRODUCTION
Tuberculosis is a communicable disease caused mainly by bacterium, Mycobacterium tuberculosis, and rarely by Mycobacterium bovis or Mycobacterium africanum.(Alao, 2023; WHO, 2024) The TB bacilli primarily affects the lungs (> 80% of the cases), giving rise to pulmonary TB. However, other sites in the body could be affected (about 20% of the cases), giving rise to extrapulmonary TB (EPTB). TB constitutes a global public health problem, but the disease burden is more in the low and middle-income countries

(LMICs).(Alao , 2023; Fenta *et al.*, 2023). In 2023, about 10.8 million people fell ill with TB globally, with an estimated 1.25 million deaths (including 16100 people living with HIV). (WHO, 2024) In the same year, there were more than 360,000 reported cases of TB in Nigeria. (WHO-AFRO, 2024) TB death rate (per 100,000 people) in Nigeria was reported at 28 % in 2023. (World Bank, 2025) Incidentally, Anambra state, in southeast Nigeria, has been found to be one of the high TB burden states. (Ugwu *et al.*, 2021) In addition to the increasing morbidity and mortality caused by TB, the disease burden in Nigeria impacts negatively on the country's growth and development.(Adebayo *et al.,* 2020)**.** The problem of TB in Nigeria is made worse by the emergence of drug-resistant TB (DR-TB) and the impact of Human immunodeficiency virus (HIV) on the disease. (NTBLCP, NASCP, DPH, FMOH, 2021; Ugwu *et al.,* 2021) Nigeria is among the 14 countries with the highest burden of TB/HIV co-infection and MDR/RR-TB. (Ajide *et al.,* 2020). Drug-resistant TB which occurs when there is resistance of MTB to any of the anti-TB drugs is an emerging public health issue that is currently posing an obstacle to effective TB control.(NTBLCP, DPH, 2021) Drug-resistant TB could manifest as Isoniazid-resistant TB, multi-drug-resistant TB (MDR/RR-TB), and extensive drug resistance (XDR-TB), among others.(Alao , 2023; NTBLCP, DPH, 2021)

Multidrug-resistant/Rifampicin-resistant tuberculosis (MDR/RR-TB) is a type of TB that is resistant to at least Isoniazid and Rifampicin, which are the two most powerful anti-TB drugs.(NTBLCP, DPH, 2021) Rifampicin resistance is a proxy (surrogate marker) for MDR/RR- TB, and a reliable predictor of multidrug resistance in settings where there is a high prevalence of rifampicin-resistant MTB. (Akwaowo *et al.,* 2021; Mchaki *et al.,* 2023; Ulasi *et al.,* 2022) The ability to prevent the emergence of DR-TB strains through early detection and prompt treatment with quality-assured drug measures is one of the ways to measure the success of TB programs.(NTBLCP, DPH, 2021; NTBLCP, NASCP, DPH, FMOH, 2021). Diagnosis of TB begins with the identification of a presumptive TB (a person with signs or symptoms of TB), with a high suspicion of TB based on sound clinical judgment.(NTBLCP, DPH, 2021) The commonest symptoms of PTB include a persistent cough lasting for ≥ 2 weeks, sputum that may be blood stained, chest pain, shortness of breath, other constitutional symptoms like body weakness, fever, weight loss, drenching night sweats, and loss of appetite, among others.(NTBLCP, DPH, 2021).

The laboratory diagnosis of TB depends on the identification of the tubercle bacilli in a clinical specimen (sputum, cerebrospinal fluid, stool, peritoneal fluid, urine, gastric and joint aspirates, etc) or its marker in a biological specimen using any of these methods: Gene Xpert Mycobacterium tuberculosis/Rifampicin (Gene Xpert MTB/RIF), sputum microscopy for acid fast bacilli (AFB), culture and line probe assay (LPA).(NTBLCP, DPH, 2021). A major component in effective TB control and management is rapid and accurate diagnosis of the disease.(NTBLCP, DPH, 2021) In fact, the use of rapid and accurate diagnostic tools are important in achieving the global targets for ending TB epidemic by 2035.(WHO,2021) In recent times, molecular diagnostic techniques like the Gene Xpert MTB/RIF assay, LPA, and culture have been introduced to rapidly detect TB and drug resistant TB.(Edem *et al.,* 2021; Hosle and Dotmi , 2023; Ilesanmi *et al.,* 2021) Gene Xpert MTB/RIF assay is a novel rapid molecular test that allows for the detection of MTB, and the genetic mutations associated with rifampicin resistance in less than 2 hours.(Edem and, Olaniyan , 2021; Olatunji *et al.,* 2023) It is a fully automated nested real-time, catridge based, user-friendly, Polymerase Chain Reaction (PCR), molecular system that has changed TB diagnosis, treatment and infection control, especially in the LMICs.(Mulengwa and Monyama 2022; Ramachandra *et al.,* 2024). The outcome/result of the Gene Xpert MTB/RIF assay could be "MTB detected" (positive result for MTB) or "MTB not detected" (negative result for MTB). However, if MTB was detected, the results will also state whether rifampicin resistance was "Detected" (positive result for TB with resistance to rifampicin, "Not detected" **(**positive result for TB with no resistance to rifampicin) or "Indeterminate" (positive result for TB with inconclusive result

on rifampicin**)**. In some instances, the result is "invalid,"(no result), whereby the test should be repeated. (NTBLCP, DPH, 2021). The conventional diagnostic tests for TB have some drawbacks. For instance, the use of sputum culture for TB diagnosis is slow, complex, and requires skilled workers.(Alao , 2023) LPA has higher turnaround times when there is need to process high volumes of specimens.(Maningi *et al.,* 2017) Sputum smear microscopy for AFB is easier to perform, cheap, and relatively common in resource poor settings like Nigeria.(Ilesanmi *et al.,* 2021) However, its sensitivity is low, especially in the HIV-positive persons.(Ilesanmi *et al.,* 2021)

Also, it does not detect drug resistant TB. The use of rapid molecular diagnostic techniques such as Gene Xpert MTB/RIF assay, have been developed in recent times to address these issues**.** Being faster and more sensitive than smear microscopy, the World Health Organization (WHO) adopted the use of Gene Xpert MTB/RIF in 2010, and has recommended that this should replace sputum smear microscopy as this will lead to greater improvements in early detection of TB and DR-TB.(Ilesanmi *et al.,* 2021). By 2016 Gene Xpert MTB/RIF was adopted as the first diagnostic tool for TB in Nigeria (Ilesanmi *et al.,* 2021); and currently in Nigeria, it is a molecular test used as the initial diagnostic test for TB in presumptive TB patients, while sputum smear microscopy is used for monitoring the progress of TB treatment.(NTBLCP, DPH, 2021; Oluwasanu *et al.,* 2020) However, the National Tuberculosis and Leprosy Control Program (NTBLCP) currently recommended the use of sputum smear microscopy for diagnosing TB only in places where Gene Xpert MTB/RIF is not available.(NTBLCP, DPH, 2021). There are limited studies on the outcomes of Gene Xpert MTB/RIF assays of adult presumptive PTB patients in Anambra State, Nigeria .The findings of this study will provide valuable insights for policymakers, healthcare professionals, researchers and other relevant stakeholders involved in TB control to improve Nigeria's TB control program, thereby improving patient outcomes. This study aimed to assess the Gene Xpert outcomes of adult presumptive PTB patients in NAUTH Nnewi Anambra State, Nigeria.

MATERIALS AND METHODS

Study area

This study was carried out at NAUTH, Nnewi Anambra State, Nigeria. The hospital is located at old Oba Onitsha road in Nnewi–Ichi, in Nnewi North Local Government Area (LGA). It is a tertiary healthcare institution that serves as a site for diagnosing and treating TB in Anambra State. The hospital serves as a referral centre for all presumptive TB cases seen in the hospital, or other private clinics in the state and its environs. As of 4th July 2024, most of the clinical activities of the hospital have been moved to the permanent site, but the TB/Directly Observed Therapy Short-course (DOTS) activities of the hospital still take place at the temporary site. NAUTH Nnewi has a separate Gene Xpert MTB/RIF assay section with one Gene Xpert MTB/RIF assay machine that has 4 sample analysis potentials at a time. The facility is currently the only TB/ DOTS facility in Nnewi North LGA that has a Gene Xpert machine for the detection of TB and rifampicin-resistant TB among presumptive TB cases.

The use of Gene Xpert MTB/RIF as a primary diagnostic tool for TB diagnosis and detection of rifampicin resistance was introduced at NAUTH Nnewi in 2019. The facility is integrated with the National Tuberculosis and Leprosy Control Program (NTLBCP) and provides free anti-TB treatment and services to the public. The activities in the unit include screening of patients with suspected TB, as well as diagnosis of TB and DR-TB by using sputum and other biological samples for Gene Xpert MTB/RIF assay. The hospital has six annexes/outstations which are involved in TB management in their various capacities, with NAUTH Nnewi as the hub.

Study Design
The study was a facility-based descriptive cross-sectional study of adult presumptive PTB patients presenting to or referred to NAUTH Nnewi within the study period.

Study Population
Adult (≥18 years) presumptive PTB patients presenting to the TB/DOTS clinic of the selected health institution or referred from peripheral hospitals were randomly selected and enrolled at the time of the study.

Included in the study were
1) All presumptive PTB patients≥18 years (adults) who consented to participate in the study.
2) All adult presumptive PTB patients presenting to TB/DOTS clinic or referred from peripheral hospitals within the study period.
3) All adult presumptive PTB patients presenting to the TB/DOTS clinic who were bacteriologically confirmed to have PTB but are yet to start anti-TB drugs within the study period.

Excluded from the study were
1) All presumptive PTB patients below 18 years of age.
2) Adult presumptive PTB patients suspected to have extra-pulmonary TB.
3) Adult presumptive PTB patients who were too ill to participate in the study.

Sample Size Determination
The minimum sample size was calculated using Fisher's formula for cross-sectional studies,(Onwuasigwe, 2010) as shown below:

$$n = \frac{z^2pq}{d^2}$$

Where:

n = the minimum sample size
z = the standard normal deviate at 95% confidence interval =1.96
p = the proportion of adult presumptive TB patients who had cough =86% (Ndubisi *et al.*, 2016) = 0.86
q=1.0-p =1.0-0.86= 0.14
d=degree of accuracy set at 0.05
Calculating n,

$$n = \frac{(1.96)^2 \times 0.86 \times 0.14}{(0.05)^2}$$

$$= \frac{3.8416 \times 0.86 \times 0.14}{0.0025}$$

=185.01 =185(approx)

Applying the formula for sample size when population <10,000,(Onwuasigwe, 2010) $nf = \frac{n}{1+ (n)/(N)}$

Where:
nf = the desired sample size when the population is less than 10,000
n = the desired sample size when the population is more than 10,000
N=the estimate of the population size
nf = 185/1+185/1000

= 185/1.185 =156

The calculated sample size was 156, but to compensate for non-response and errors due to sample collection, an additional 10% of the minimum sample size was considered. Anticipating a non-response rate (f) of 10%, therefore the adjusted sample size (n_s) selected was $n_s = n/1-f$
Given, f = 10% = 0.1,
Then $n_s = \frac{156}{0.9} = 173.33 = 173$ approximately

This implied a minimum sample size of 173 participants for this study. However, 180 participants were recruited in this study.

Sampling technique
A simple random sampling technique was used to select the study participants who were recruited prospectively in a consecutive manner until the required sample size of 180 was obtained.

Demographic and clinical data collection
Firstly, the questionnaires were used to collect socio-demographic and clinical data from the respondents after prior informed consent. The principal researcher maintained a site register where all the recruited participants were recorded after allocating them a unique study number.

Laboratory sample collection, processing, and analysis
Before the actual specimen collection, the respondents were instructed about the procedure on how to collect the sputum specimen. With the assistance of two TB/DOTS clinic nurses, a single sputum specimen (about 3-5mls) was collected from each of the eligible patient into appropriately labeled, wide-mouthed, unbreakable, leak-proof, sterile containers in a well-ventilated area. With the container lids tightly closed and the containers place in a carton, the sputum samples were taken to the Gene Xpert laboratory in less than 24 hours for processing and analysis. The processing and analysis were done in collaboration with the trained medical laboratory personnel working at the Gene Xpert laboratory section of the hospital, using the Gene Xpert MTB/RIF assay, to detect MTB and identify rifampicin resistant TB following the manufacturer's instructions.
All the collected samples were processed in the laboratory using standard procedures for the Gene Xpert technique (Cepheid Inc., Sunnyvale, CA, USA). At least 1 ml of sputum was required from each sample. Sodium hydroxide (NaOH) and Isopropanol-containing sample reagent was added to each sputum sample in the ratio of 2:1 using a sterile pipette. The sputum samples were mixed with sample reagent and shaken manually for about 10 minutes to unclog the sputum, then allowed to stay for about 15 minutes at room temperature. Thereafter, 2mls of each of the reagent treated samples were pipetted into the sample chamber of the Xpert catridge while the barcodes on the catridges were scanned and the catridges were loaded into

the Gene Xpert instrument (Cepheid, Dx system Version 4.8), following the manufacturer's instructions. The software was allowed to run. After about 2 hours (120 minutes) of sample loading, the results were interpreted by the Gene Xpert assay system computerization diagnosis system which were automatically generated indicating if MTB was detected or not detected, or invalid/error for MTB. However, all the results in the present study were valid. Where MTB was detected, the Gene Xpert automatically generated result indicating if the MTB was rifampicin resistant or not resistant (susceptible), or indeterminate. The results were visualized and printable in the view results window. The recommended procedure for specimen collection, proper labeling, and storage was followed strictly.

Also, all the study participants were screened for HIV sero-positivity by standard protocols according to the national algorithm, using their blood samples. A serial testing algorithm comprising of Determine HIV-1/2 as test 1(T1), Unigold HIV-1/2 as test 2(T2) and StatPak HIV-1/2 as the tie-breaker test (T3) was done. The HIV testing was done in collaboration with the medical laboratory personnel working at the TB/DOTS laboratory section of the hospital. Individuals reactive with T1 and either T2 or T3 were considered HIV-positive.

Measurement of Variables

The main dependent/outcome variables for this study were MTB detection and DR-TB identification using Gene Xpert MTB/RIF. For the MTB test results, the outcome variable was categorized as either "MTB detected" or "MTB not detected"; while for the DR-TB test results, the outcome variable was categorized as "RIF resistance detected" or "RIF resistance not detected" or "RIF resistance indeterminate".

Statistical Analysis

All completed data collection forms were examined for completeness, uniformity of responses, and clarity and then coded. Data generated from lab results were coded as well.

Data generated from questionnaires and laboratory results were analyzed using International Business Machines-Statistical Package for Social Sciences (IBM-SPSS) version 25. Frequencies and proportions were computed as descriptive measures for the variables. The results of the study were presented by using tables and charts to depict the socio-demographic and other variables.

Duration of Study

This study took place from June 1, 2024 to September 30, 2024.

Ethical Considerations

Ethical approval was obtained from the Nnamdi Azikiwe University Teaching Hospital Ethics Committee (NAUTHEC). Permission was obtained from the Head of TB/DOTS unit, NAUTH Nnewi. Patients' privacy and confidentiality were preserved as all personal information that could link a patient to the study were removed from the study. Informed consent was obtained from the study participants prior to the study. Participation was completely voluntary and at no cost to the consenting clients.

RESULTS

A total of 180 adult presumptive PTB patients were examined using questionnaires between 1st June, 2024 and 30th September 2024. A total of 180 sputum samples were collected from the respondents and were analyzed in the laboratory using Gene Xpert/MTB-RIF assay. All the questionnaires and samples were retrieved, giving a response rate of 100%. All the participants that were tested had valid results.

Table 1a: Socio-demographic characteristics of the respondents

Variable	Frequency (n=180)	Percentage (%)
Age category(in years)		
18-24	38	21.1
25-34	35	19.4
35-44	32	17.8
45-54	41	22.8
55-64	20	11.1
≥ 65	14	7.8
Mean age ± SD	40.46 ± 15.72	
Minimum 18	Maximum 82	
Gender		
Male	95	52.8
Female	85	47.2
Tribe		
Ibo	167	92.8
Hausa	5	2.8
Yoruba	4	2.2
*[1]Others	4	2.2
Religion		
Christianity	168	93.3
Islam	3	1.7
Traditional	8	4.4
*[2]Others	1	0.6
Marital status		
Single	59	32.8
Married	86	47.8
Divorced	8	4.4
Separated	16	8.9
Widowed	11	6.1

Table 1b: Socio-demographic characteristics of the respondents

Variable	Frequency (n=180)	Percentage (%)
Occupation		
Unemployed	34	18.9
Trading	64	35.6
Health Care Worker	12	6.7
Artisan	19	10.6
Teaching	8	4.4
*[3]Others	43	23.9
Highest level of education		
No formal education	3	1.7
Primary	39	21.7
Secondary	78	43.3
Tertiary	60	33.3
Average monthly income		
< 10,000	56	31.1
10,000-19,000	44	24.4
20,000-29,000	34	18.9
≥ 30,000	46	25.6
Type of residence		
Rural	53	29.4
Urban	127	70.6
HIV status		
Positive	57	31.7
Negative	123	68.3

*[1]Others = Ibibio, Tiv.
*[2]Others = Buddhism, Hinduism.
*[3]Others = Pastors, Drivers, Students

Table 1 summarizes the socio-demographic characteristics of the respondents. Their ages ranged from 18 to 82 years. The mean age of the respondents was 40.46 ± 15.72 years. The majority of the respondents (22.8%) were in the 45-54 years age group. More than half of the respondents (52%) were males. A greater proportion

of the respondents (43.3%) attained a secondary level of education. The majority of the respondents were Ibos (92.8%) and Christians (93.3%). A greater proportion of the respondents were married (47.8%), traders (35.6%), and were earning <10,000 per month on average (31.1%). The majority of the respondents (70.6%) were urban residents, while 31.7% of them had positive HIV status.

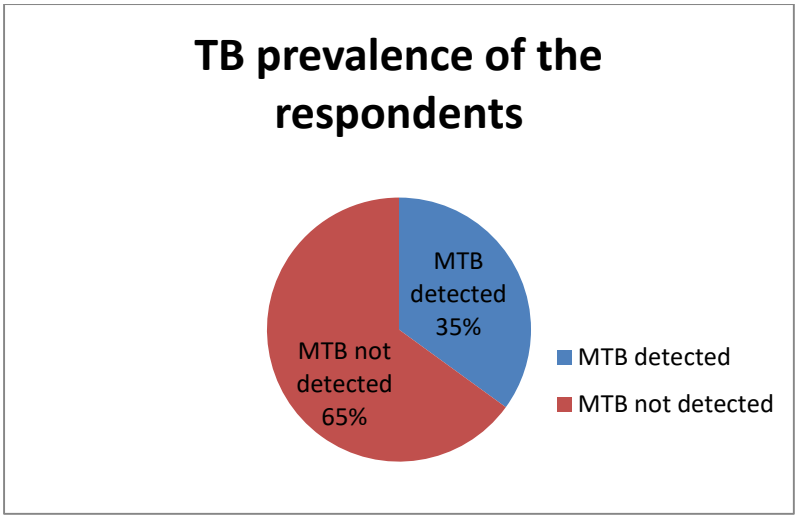

Figure 1: Prevalence of TB among the respondents

Figure 1 shows that the overall TB prevalence among the respondents. The overall TB prevalence among the respondents is 35%.

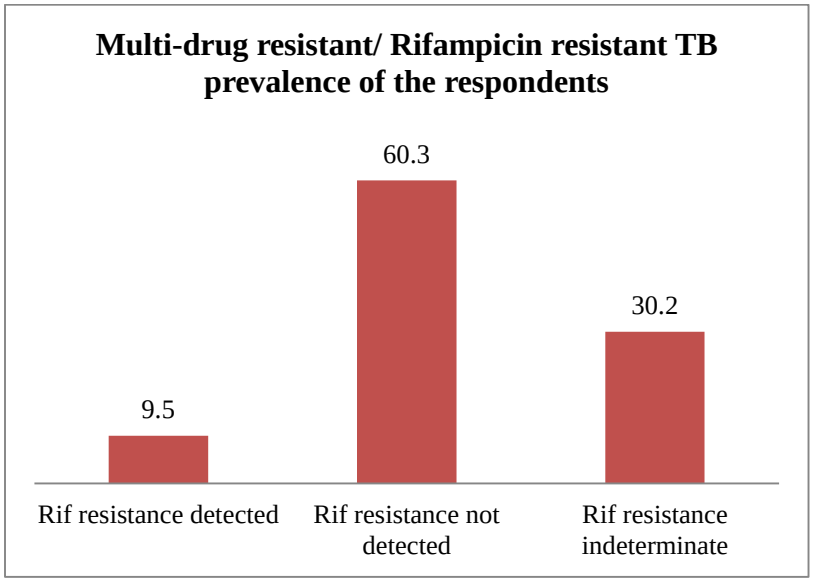

Figure 2: Multi-drug resistant/Rifampicin resistant TB prevalence of the respondents

Figure 2 shows the MDR/RR-TB prevalence among the repondents.The overall MDR/RR-TB prevalence is 9.5% (1.6 % among new cases and 7.9% among previously treated cases).

Table 2: Gene Xpert outcomes of the respondents

Variable	Frequency	Percentage (%)
MTB	(n=180)	
Detected	63	35.0
Not detected	117	65.0
RIF Resistance	(n=63)	
Detected	6	9.5
Not detected	38	60.3
Indeterminate	19	30.2

Table 2 shows the outcome of the Gene Xpert MTB/RIF assays of the respondents. Out of the 180 sputum samples, 63(35.0%) had MTB detected using Gene Xpert MTB/RIF assays. Out of the 63 Gene Xpert positive sputum samples, 6(9.5%) were resistant to rifampicin, 38(60.3%) were not resistant (susceptible) to rifampicin, while 19(30.2%) were indeterminate to rifampicin.

DISCUSSION

This study was carried out to assess the Gene Xpert outcomes of adult presumptive PTB patients in NAUTH Nnewi Anambra State, Nigeria. The age range of the respondents was 18 to 82 years, which is almost similar to what was found in studies that were conducted in Ethiopia (Awulachew and Diriba, 2022; Churiso and Diriba, 2022), where the ages of the respondents ranged from 18 to 91 years and 18 to 88 years respectively. The mean age of the respondents is 40.46 ± 15.72 years, which is higher than what was found in a similar study that was done in Ethiopia (Andarge *et al.,* 2021), where the mean age of the respondents was found to be 38.5±14.5 years. The disparity in the mean age could be likely due to the variations in the sample size and age composition in the different studies. The majority of the respondents in the present study are in the age range of 45-54 years, showing that they are adults in their most productive years. A similar study that was carried out in Nigeria also showed that majority of the respondents were in their economically productive years (Olatunji *et al.,* 2023) However, other studies that were done in Ethiopia (Andarge *et al.,* 2021; Awulachew and Diriba, 2022; Gebretsadik *et al.,* 2020) and Nigeria (Ajide *et al.,* 2020) showed that majority of the respondents were relatively younger adult working population in the 30-44 years, 18-24 years, 29-39 years, and 30-39 years age ranges respectively. The respondents in the present study are predominantly males which is similar to the findings in other studies.(Abayneh and Teressa, 2022; Ajide *et al.,* 2020; Andarge *et al.,* 2021; Ashefo, 2023; Churisco and Diriba , 2022; Gebretsadik *et al.,* 2020; Kabir *et al.,* 2021; Olatunji *et al.,* 2023) On the contrary, a greater proportion of female respondents were found in another study that was carried out in Enugu, southeast, Nigeria.(Ugwu and Agbo 2021) The majority of the respondents in the present study are low-income earners (less than 10 thousand naira per month), similar to what was found in studies that were done in Ethiopia (Andarge *et al.,* 2021) and Nigeria.(Olatunji *et al.,* 2023) This buttresses the fact that TB is commoner among people of low socio-economic status (Jayasooriya *et al.,* 2023; Olarewaju *et al.,* 2023; Olatunji *et al.,* 2023) Majority of the respondents (43.3%) attained a secondary level of education, and are mainly traders (35.6%). Only 6.7% of the respondents are healthcare workers, while 18.9% are unemployed. Lesser proportion of the respondents (31.7%) in the present study tested positive for HIV, similar to what was reported in cross-sectional studies that were done in Ethiopia (Gebretsadik *et al.,* 2022) Higher rates of TB/HIV co-infection were found among the respondents in certain studies (Ajide *et al.,* 2020; Olatunji *et al.,* 2023; Selfegna, 2022) compared to the finding in the index study where lesser proportion of the respondents(23.8%) had TB/HIV co-infection. The TB/HIV co-infection rate in the index study is higher than what was found in studies that was carried out in Ethiopia and North central Nigeria,

where the TB/HIV co-infection rates among the respondents were 7.89% and 20.6% respectively (Ajide *et al.,* 2020; Gebretsadik *et al.,* 2020) The discrepancy in the TB/HIV co-infection rates in these studies could be likely due to variations in sample sizes of the different studies. Urban dwellers accounted for 70.6% of the respondents in the present study, contrary to what was found in cross-sectional studies that were conducted in Sudan (Alfaham *et al.,* 2022), and Ethiopia(Abayneh and Teressa , 2022; Gebretsadik *et al.,* 2020; Selfegna , 2022), where greater proportion of the respondents were rural residents. In this study, MTB was detected in 35.0% of the sputum samples while MTB was not detected in 65.0% of the samples, using Gene Xpert MTB/RIF assay. Out of the sputum samples with confirmed MTB, rifampicin resistance was identified in 9.5% of the samples, 60.3% were not resistant (susceptible) to rifampicin, while 30.2% were indeterminate to rifampicin. This shows that both TB and MDR/RR-TB are public health issues in the study area.

(Bitet *et al.,* 2020) MTB was detected in 34% of the sputum samples of presumptive PTB patients attending a TB centre in Sudan, while rifampicin resistance was identified in 9.7% of the MTB positive sputum samples, using Gene Xpert MTB/RIF assay (Alfaham *et al.,* 2022) ; and these proportions are comparable to what was found in the present study. Andarge et al.(Andarge *et al.,* 2021), reported that MTB was detected in 32.8% of sputum samples, while 14.1% of the TB confirmed samples showed resistance to rifampicin by Gene Xpert MTB/RIF assay, in a retrospective cross-sectional study that was done in Indonesia. In a cross-sectional study that was carried out in a Primary Health Centre in Malaysia by Kabir S et al.(Kabir *et al.,* 2021), 11.4% of the AFB smear negative samples were positive for MTB using Gene Xpert MTB/RIF assay; however, only 0.54% case of drug resistance was detected from the smear-negative samples. In another study that was carried out in Nepal among smear negative presumptive PTB patients, 19.1% of their sputum samples were confirmed to have MTB by Gene Xpert MTB/RIF assay. Of the Gene Xpert positive samples, only 12.9% showed resistance to rifampicin, 80.6% were susceptible to rifampicin, and 6.45% were indeterminate to rifampicin.(Rimal *et al.,* 2022) The result of a cross-sectional study that was done in Kaduna State, Nigeria shows that using Gene Xpert MTB/RIF assay, 40.4% of the sputum samples had MTB detected, while rifampicin resistance was identified in 1.25% of the MTB positive samples.(Olatunji *et al.,* 2023) Using the Gene Xpert technique, MTB was detected in 22.9% of the sputum samples in a health facility in Uyo, Akwa Ibom State, Nigeria. However, only 3.1% of the MTB-positive samples showed resistance to rifampicin. (Edem *et al.,* 2021) There are variations in the proportions of the Gene Xpert MTB/RIF outcomes in the present study and the other studies, which might likely be due to the variations in sample sizes of the different studies.

In recent times, the use of Gene Xpert MTB/RIF assay has made possible the rapid detection of MTB as well as the resistance to first-line anti-TB drugs such as rifampicin and isoniazid. The introduction of the Gene Xpert MTB/RIF method in TB diagnosis is an important milestone which enhances TB control efforts even in resource-poor settings. (Selfegna, 2022) Initially, the use of Gene Xpert MTB/RIF assay was limited to certain groups which include TB/HIV co-infected patients, known symptomatic contacts of DR-TB for adults and all child contacts of DR-TB patients, and all previously treated drug-susceptible TB cases.(Adejumo *et al.,* 2018; NTBLCP, DPH, 2021) Currently, the National TB program (NTP) has recommended Gene Xpert MTB/RIF assay for all presumptive TB patients in centres where it is available.(Adejumo et al, 2018). This study has assessed the Gene Xpert outcomes of adult presumptive PTB patients in NAUTH Nnewi, Anambra State, Nigeria. However, the presumptive TB patients below 18 years of age, and the presumptive patients with extrapulmonary TB were not assessed. Further research in these areas needs to be done. Also, carrying out a community-based study is a potential area for future studies.

CONCLUSION

In the present study, 63(35.0%) out of the 180 sputum samples, had MTB detected using Gene Xpert MTB/RIF assays. Out of the 63 Gene Xpert positive sputum samples, 6(9.5%) were resistant to rifampicin, 38(60.3%) were not resistant (susceptible) to rifampicin, while 19(30.2%) were indeterminate to rifampicin. This shows that both TB and MDR/RR-TB are public health issues in the study area.

RECOMMENDATION

1. To achieve the 'End TB' target, there is a need to strengthen the laboratory networks for fast and accurate diagnosis of TB cases. With the current rise in TB and MDR-TB burden in the country, there is a need for improved TB case detection which requires rapid molecular diagnostic techniques like the Gene Xpert MTB/RIF assay with better sensitivity and timeliness than the conventional diagnostic tests such as smear microscopy and culture.
2. The State Government under the aegis of the State Tuberculosis Buruli Ulcer and Leprosy Control Program (STBLCP), should provide adequate funds for the procurement of better instruments like the Gene Xpert MTB/RIF machines for rapid diagnosis of TB and MDR/RR-TB. Also, Gene Xpert MTB/RIF should be established at all points of care in Anambra State, which can be used as the initial diagnostic test for PTB and MDR/RR-TB. This will help to minimize disease transmission rates, and transmission of resistant strains of the disease, as well as improve patients' outcomes.

LIMITATION The research was carried out in only one health institution which can affect the extent of generalizing the study. It would have been better if several health institutions were incorporated for a better representation of the study subjects.

CONFLICT OF INTEREST: The authors declared no conflict of interest in this study.

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