ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Assessment of Reasons for Service Interruption and Unsuccessful Test Results Related to GeneXpert Diagnostic Service in Addis Ababa Public Health Facilities.

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A Thesis Submitted to the Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University, in Partial Fulfillment of Master of Science Degree in Clinical Laboratory Sciences (Clinical Laboratory Management & Quality Assurance Specialty Track)

January, 2021

Addis Ababa, Ethiopia.

Addis Ababa University

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

This is to certify that the thesis prepared by Mesafint Merkebu, entitled: *Assessment Of Reasons For Service Interruption And Unsuccessful Test Results Related to GeneXpert Diagnostic Service In Addis Ababa Public Health Facilities* submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Laboratory management and quality assurance track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Full Title of the Project	Assessment of Reasons for Service Interruption and Unsuccessful Test Results Related to GeneXpert Diagnostic Service in Addis Ababa Public Health Facilities.
Type of protocol	Medical
Duration of the project	8 Months
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Acknowledgement

I am grateful to express my thanks and appreciation to my advisors Ato Abay Sisay and W/ro Fatuma Hassen for their constructive comment and unreserved advices and made continuous follow up to complete this thesis.

My special thanks goes to Department of Medical Laboratory Sciences College of Health Sciences, Addis Ababa University

I also thank my Instructors and staffs in the department for their valuable comments in the preparation of this thesis.

My appreciation extends to health facilities and health professionals participated in this study.

Last but not least appreciation goes to my friends for their support to finalize this thesis.

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Abbreviations

AAPHREMD Addis Ababa Public Health Research and Emergency Management Directorate.

APHI Amhara Public Health Institute

AFB Acid fast bacilli

EPHI Ethiopian Public Health Institute

EPSA Ethiopian Pharmaceutical Supply Agency

FMoH Federal Ministry of Health

HFs Health facilities

HIV Human Immunodeficiency Virus

IPLS Integrated Pharmaceutical Logistics System

MDR Multi drug resistance

MTB Mycobacterium Tuberculosis

NTP National TB Control program

PCR Polymerase Chain Reaction

PI Principal Investigator

RIF Rifampicin

RR Rifampicin resistance

UPS Uninterrupted power supplies

TB Tuberculosis

XDR Extensively drug resistance

WRD WHO recommended rapid diagnosis

Abstract

Background: *Tuberculosis (TB) was one of the top 10 causes of death worldwide in 2018. It is also the leading killer of people with HIV and a major cause of deaths related to antimicrobial resistance. Ethiopia is among the 30 high burden tuberculosis countries, with annual estimated TB incidence of 151/100,000 population and HIV negative TB mortality of 22/100,000 population as of 2018 global TB report. At present, the major problem in managing TB is lack of an accurate and rapid diagnostic test. Accordingly, rapid diagnostic test for detection of TB and rifampicin resistance currently available is the GeneXpert assay as WHO recommended. However health facilities which having GeneXpert diagnostic device encountered different challenges during implementation.*

Objective: *This study was aim to assess the reasons for service interruption and Unsuccessful test results related to GeneXpert diagnostic service in Addis Ababa public health facilities.*

Methods: *Cross sectional study design was conducted in public health facilities which provided GeneXpert diagnostic service in Addis Ababa, Ethiopia. Quantitative and qualitative questionnaires based data was collected from January to March 2020. The data was cleaned, entered and analyzed using SPSS version 20 at a statistical significance of P value ≤ 0.05 using logistic regression. While the qualitative data obtained was summarized in thematic narrative form.*

Results: *Reasons of GeneXpert diagnostic services resulted to service interruptions and unsuccessful test results identified in this study. At least once or more than one times of service interruption of GeneXpert were occurred in 82% of the health facilities in the study period. Service interruption were dependent on the stock out of cartridge (X^2 =10.6, p value <0.01). While, a total of 4% (1078/26998) unsuccessful test result were occurred, of which 2.3% (618/26998) was due to 'Error' followed by 'No result' 1.2% (334/26998) and 'Invalid' 0.5% (126/26998).*

Conclusion: *The main reasons of GeneXpert diagnostic service which resulted to service interruptions were stock out of cartridge, machine down, system failure, module failure and cartridge malfunction. In the other hand, insufficient sample volume, power interruption, poor sample quality, food contaminant and technical errors were reasons for unsuccessful test result. Thus, sustainable power supply, responsive maintenance support, sustainable supply chain system and refresher training are at most important.*

Key Words: *Reasons, Error, GeneXpert*

1. Introduction

1.1 Background

Tuberculosis (TB) is contagious and airborne disease caused by Mycobacterium tuberculosis (1). TB was one of the top 10 causes of death worldwide in 2018. It is also the leading killer of people with HIV and a major cause of deaths related to antimicrobial resistance (2).In 2018, 1.5 (1.4-1.6) million people died from TB, including 251 000 (223, 000-281, 000) people with HIV. Globally, the TB mortality rate fell by 42% between 2000 and 2018. The severity of national epidemics varies widely among countries. In 2018, there were fewer than 10 new cases per 100 000 population in most high-income countries, 150 - 400 in most of the 30 high TB burden countries, and above 500 in a few countries including Mozambique, the Philippines and South Africa(1 -3).

Seven million new TB cases were notified to national authorities and reported to WHO in 2018, moreover, between 2000 and 2018 TB treatment saved 58(53-64) million lives globally. This 3 million gaps reflects between incident and notified cases (2, 3).

Globally in 2018, 484 000 (417 000—556 000) people developed TB that was resistant to rifampicin-resistant (RR-TB), the most effective first-line drug, and of these, 78% had multidrug-resistant TB (MDR-TB)(1). 187 000 cases of MDR/RR-TB were detected and notified in 2018. Of these, a total of 156 000 were enrolled and started treatment with a second-line regimen. Treatment success rate at 56%, remains low globally. Among cases of MDR-TB in 2018, 6.2% were estimated to have extensively drug-resistant TB (XDR-TB)(1,2).

Ethiopia is among the 30 high tuberculosis, human immunodeficiency virus and multidrug resistance tuberculosis burden countries that accounted for 87% of all estimated TB cases worldwide with annual estimated TB incidence of 151/100,000 population and death rate of 22/100,000 population for 2017(4).

At present, the major problem in managing TB is lack of an accurate and rapid diagnostic test for M. tuberculosis. Rapid detection of M. tuberculosis in infected patients is essential for diagnosis and treatment of TB because of the high risk of transmission from person to person (4). In China, peripheral anti tuberculosis clinics usually rely on acid-fast staining and the conventional

Lowenstein-Jensen culture method in conjunction with assessment of clinical symptoms and radiographic evidence to diagnose TB (5). Culture is considered the gold standard technique for diagnosing TB, but it is slow and may take 2 to 8 weeks. Although sputum smear microscopy for acid-fast bacilli (AFB) is rapid and inexpensive, it has poor sensitivity. Therefore, rapid detection of M. tuberculosis, which is essential for early diagnosis and treatment, improving patients' outcomes, and taking effective public health measures, relies on nucleic acid amplification techniques (6).

Despite there is improvements towards the 2020 milestones of END TB strategy, the number of people enrolled in treatment in 2018 was equivalent to only one in three of the approximately half a million people who developed MDR/RR-TB (1). Closing this wide gap requires one or more of the following to be increased: detection of TB cases, the proportion of TB cases bacteriologically confirmed, coverage of testing for drug resistance among bacteriologically confirmed cases and coverage of treatment for those diagnosed with MDR/RR-TB (1, 2).

As countries intensify efforts to improve TB diagnosis and treatment and close gaps between incidence and notification, the proportion of notified cases that are bacteriologically confirmed needs to be monitored, to ensure that people are correctly diagnosed and started treatment as early as possible (7). The aim should be to increase the percentage of cases confirmed bacteriologically by scaling up the use of recommended rapid molecular tests diagnostics that are more sensitive than smear microscopy (8).

Currently available diagnostic test recommended by WHO for detection of TB and rifampicin resistance is the GeneXpert assay (5). Of the 48 countries in at least one of the lists of high burden countries, 37 had adopted national algorithms positioning the GeneXpert as the initial diagnostic test for all people suspected of having pulmonary TB by the end of 2018 (6).

GeneXpert mycobacterium tuberculosis (MTB)/rifampicin (RIF) is a cartridge based, automated and rapid molecular diagnostic device that performs sample processing and hemi-nested real-time PCR analysis in a single, hands-free step for identifying M. tuberculosis and rapid detection of rifampicin (RIF) resistance in sputum samples(6,7).The GeneXpert challenges resulted to service interruption and unsuccessful diagnostic test results have no any documented evidence related to the magnitude of the challenges in Addis Ababa, Ethiopia.

Therefore, this study aims to conduct assessment reasons of service interruption and unsuccessful test results of GeneXpert diagnostic service encountered among Addis Ababa health-facilities, Ethiopia.

1.2 Statement of the problem

TB cases which were tested for drug resistance which is often diagnosed after prolonged diagnostic delays. The long delay (up to several weeks) required to obtain results has devastating consequences for patients who go undiagnosed (and therefore untreated or inappropriately treated), or are diagnosed too late (7). Detecting more cases, detecting them early and rapidly identifying drug resistance are essential for improving individual patient health and avoiding transmission in the community. This requires universal access and early detection using contemporary tools and innovative strategies (8, 9).

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 (1). Furthermore, the WHO guidance updated in recommending that GeneXpert MTB/RIF be used as the initial diagnostic test for all patients with presumptive TB in 2013 (23). This was considered a breakthrough for TB control by bringing a near point-of-care test for TB. After years of implementation, it was observed that many countries using GeneXpert as the first diagnostic tool recorded a decrease in microscopy/GeneXpert ratio, signifying an increased use of GeneXpert (8).The massive deployment of GeneXpert to some resource limited high burden settings is however matched with few reports so far on the program outcomes and challenges (11).

The available evidence confirmed the robustness of the GeneXpert assay under varying temperature and humidity conditions, the need for minimal staff training, basic bio-safety requirements (as for sputum smear microscopy) and high levels of user satisfaction. Operational challenges included the requirement for an ambient temperature $<30^0$C, and uninterrupted and stable electrical power supply. Furthermore, supply chain management, service and maintenance, referral linkage, no of specimens collected and turnaround time of results as well as storage space

and conditions, waste generated (considerably more than for microscopy), the 12-month shelf-life of cartridges were listed as main operational challenges (9 -11).

The total of 314 GeneXpert machines had been distributed and installed in 283 health facilities (HFs) since June 2019. Among this HFs, five sites have three machines whilst 21 sites have two machines (13).Despite of this rapid diagnostic service implemented in Ethiopia public health facilities, reports from evaluation of the diagnostic service indicated that repeated service interruption happened in most of the health facilities due to different reasons. Of these, trained staff turnover, shortage of cartridge, poor preventive maintenance, power fluctuations and less motivation of referral site staffs for referring health facilities are some of the common challenges observed in the health facilities (13).However, there is limited documented information in Addis Ababa, Ethiopia.

1.3 Significance of the study

As it is known GeneXpert diagnostic service detect more cases, detecting them early and rapidly identifying drug resistance are essential for improving individual patient health and avoiding transmission in the community. Since this study was employed participated health facilities professionals particularly Regional Laboratory, TB focal person at all levels, Lab heads and logistician who are actively engage in GeneXpert analysis; the main gaps for service interruption and unsuccessful test results was identified.

So that a systematic proactive response proposed based on the challenges encountered so far for the improvement of quality GeneXpert diagnostic service. Also, the findings of the study in Addis Ababa health facilities which was under the administration of Addis Ababa City Administration gave baseline information for other study in the country. Therefore, this study identified the challenges of GeneXpert diagnostic service resulted to service interruption and Unsuccessful test results in Addis Ababa public health facilities and recommend the best solution for improving the quality of service in the Country. Moreover, researchers and program managers working on this program can have used this evidence data for planning and coordinating their proactive activity as a baseline information.

2. Literature review:

The WHO End TB Strategy calls for the early diagnosis of TB including universal DST, currently defined as DST for at least rifampicin, among all patients with bacteriologically confirmed TB. A prerequisite for any NTP to reach this goal is a quality-assured laboratory network equipped with rapid diagnostics. The WHO *Framework of indicators and targets for laboratory strengthening under the End TB Strategy* serves as a guide for all countries in the development of plans for laboratory strengthening in 2016–2025. The indicators measure the programme's capacity to detect patients accurately and rapidly using new diagnostics (i.e., WRDs), provide universal DST, and ensure quality of testing (24).

Study conducted in Nepal indicated that the sensitivity of GeneXpert was 95.50% (91.87, 97.82) and significantly higher than smear microscopy performed on the same fluid, which had a sensitivity of 61.97% (14). In addition, study conducted in Madagascar showed that whether as a first-line assay or as follow-on testing for smear-negative TB suspects, GeneXpert was highly sensitive and specific for the diagnosis of pulmonary TB and proved to significantly increase case detection (15).

In a study done at Mongolian on operational and technical challenges of GeneXpert diagnostic service implementation were training, quality assurance, planning processes and equipment servicing and maintenance, issues with continuous power supply which considered as similar problems as health facilities which implemented GeneXpert during analysis (8-10).

Similar study conducted in Bangladesh revealed that the most common challenges faced in operating machines was module failure, delay in maintenance support, inadequate cartridge supply and load shading (11). In addition, problems faced by health workers was sample referral system not well established , false negative result of Rif Resistance due to low bacterial load, lack of appropriate centrifuge machine for processing of samples and inadequate manpower (12).

Study conducted in 18 countries indicated that the main limitation of the test was the high rate of inconclusive results, which correlated with factors such as defective modules, cartridge version (G3 vs. G4) and staff experience (8). While, operational and logistical hurdles included

infrastructure renovation, basic computer training, regular instrument troubleshooting and maintenance, all of which required substantial and continuous support (8,9).

Moreover, the study carried out in Nigeria depicted, the key challenges in the roll out and scale up of GeneXpert were no standardized sample referral system, frequent power fluctuation, long turnaround time due to lack of internet which can sends instant results, inefficient GeneXpert cartridge supply management system (10).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 (12).

Similar study findings which was conducted in Uganda found that, machine down time due to cartridge stock out, module down time due to module malfunction which resulted in reduction the total GeneXpert module capacity among all facilities during the study period and consistently high invalid/error rates were common problems (17).

The Implementation Guideline for GeneXpert assay in Ethiopia which is endorsed in 2014, describe and facilitate processes for the smooth introduction of the GeneXpert assay system into the National TB diagnostic network within the framework of the National TB Control Program (NTP) (18). In so doing, it will improve TB and MDR-TB case detection in presumptive MDR-TB patients and in difficult to diagnose groups of patients such as children and HIV infected presumptive TB cases (18).

Since the ultimate goal of the introduction and expansion of GeneXpert for the diagnosis of TB, bring a rapid diagnostic technology to diagnose TB and drug-resistant TB (DR-TB), improve the quality of TB diagnosis, and help to find more TB cases overall (16). The placement of the instruments was based on the HF workload of TB/HIV cases, accessibility by other HFs via a diagnostic laboratory referral network, and the availability of the necessary infrastructure at the respective HF (19).

In Ethiopia as of June 2019, a total of 314 functional GeneXpert machines had been distributed and installed in 283 health facilities (HFs). Among these health facilities, five sites have three machines whilst 21 sites have two machines. Almost all the machines installed in the country were four-module systems, except two two-module machines, and one sixteen-module machine (13).

In August 2018, the Ethiopian National TB Control Program recommended that the GeneXpert assay be used for testing on specimens from all presumptive TB patients irrespective of risk for DR-TB, HIV status, and age of the patient if GeneXpert is accessible (19). Although a lower index of suspicion for TB patients tested declined the percentage of positives, the trend of utilization rate has improved from 28 percent in 2014 to 78 percent in 2018 (14).

In a Challenge TB Annual report year 4 showed that insufficient cartridge, budget gaps for module procurement and technical support, inadequate availability of power backup, lack of clear and easy reporting mechanism, budget gap for technical support and delays in postal sample transportation and turnaround time were challenges observed in GeneXpert implemented health facilities after the implementation technical support close out (14).

Furthermore, there are variety of challenges despite the GeneXpert test decrease a diagnostic delays and increase the impact of TB transmission and the detection of drug resistance. These are inadequate training and mentoring, lack of, or poor adherence to, standard operating procedures (SOPs), stock-outs and use of expired reagents, absent or inadequate maintenance of equipment and poor quality of samples being tested (20).

Therefore, this study tried to identify whether the above mentioned problems observed regarding to GeneXpert diagnostic service in different studies are repeated or not in Addis Ababa City Administration GeneXpert diagnostic service deployed health facilities.

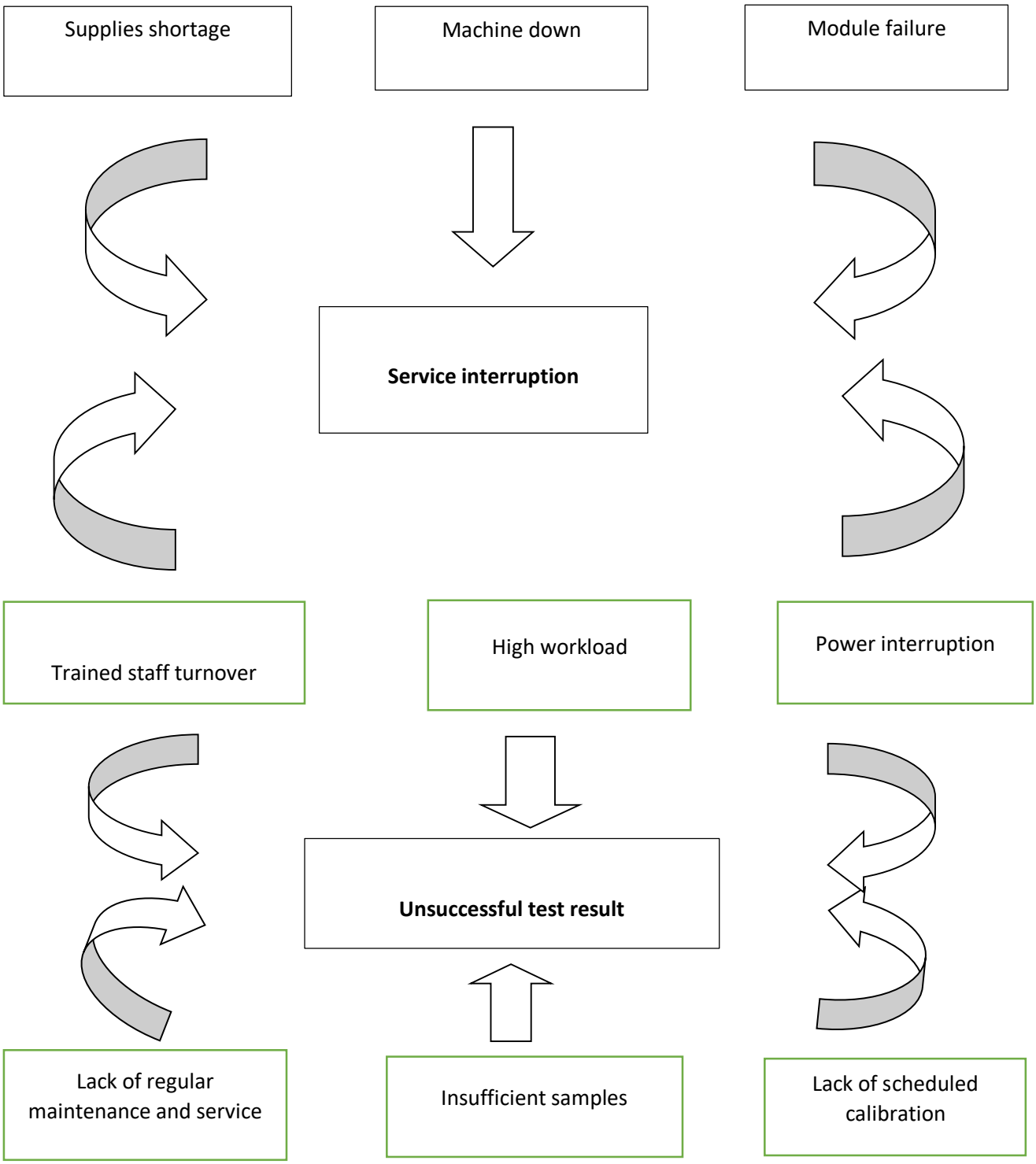

Figure 1. Conceptual framework of reasons for GeneXpert diagnostic service resulted to Service interruption and Unsuccessful test results, Addis Ababa, Ethiopia 2019/2020 (adopted from reference # 21).

3. Objectives:

3.1. General Objective

The general objective of this study was to assess the reasons for service interruption and unsuccessful test results related to GeneXpert diagnostic service from January to December 2019 among Addis Ababa City Administration Health Bureau Public Health facilities.

3.2. Specific Objectives:

- To identify reasons of service interruption of GeneXpert diagnostic service in Addis Ababa City Administration Health Bureau public health facilities.
- To describe Unsuccessful test results related to GeneXpert diagnostic service in Addis Ababa City Administration Health Bureau public health facilities.
- To propose a proactive recommendations on the identified gaps
- To compare the detection rate of tuberculosis by GeneXpert diagnostic technique and Zeihl Nelson staining methods

4. Materials and Methods

4.1 Study area:

This study was conducted in Addis Ababa, Ethiopia. Addis Ababa is the capital and largest city in the country of Ethiopia. Located in the center of Ethiopia, Addis Ababa currently has a population of more than 4.8 million people in its area. It is a chartered city having three layers of government namely, city government at the top, 10 sub cities in the middle and 116 woreda, (22).Currently there are six regional hospitals and 104 health centers under the administration of Addis Ababa City Administration Health Bureau. There are 24 health facilities with GeneXpert diagnostic service, however only 22 health facilities have functional machines.

4.2 Study Design and period:

We employed a cross sectional study design in order to assess reasons related to GeneXpert diagnostic service interruption and unsuccessful test results in Addis Ababa public health facilities , using qualitative and quantitative research data from January to December 2019. In addition, registration book were reviewed for Zeihl Nelson staining technique which was analyzed before the implementation of GeneXpert diagnostic service in the health facilities.

4.3. Population:

4.3.1 Source population: Addis Ababa public health facilities and health professionals working in the health facilities which were managed under Addis Ababa City Administration Health Bureau and TB and Leprosy program advisor at FMoH.

4.3.2 Study Population: Public health facilities in Addis Ababa which started provision of GeneXpert diagnostic service and health professionals working on TB diagnosis and treatment selected by sampling method and willing to participate from selected health facilities.

4.4 Inclusion and Exclusion criteria

4.4.1Inclusion Criteria: Health facilities provided GeneXpert service within 1 Jan 2019 to 31 December, 2019 was included in the study. And health professionals working on TB diagnosis and treatment and willing to participate from selected health facilities also included in the study.

4.5 Study variables:

4.5.1 Dependent Variables:

- Unsuccessful test results
- Service interruption

4.5.2 Independent variables:

- Power interruption
- Shortage of supplies
- No of trained Lab professionals
- Insufficient samples
- Test performance (Total test conducted)
- Supportive supervision
- Referral linkage
- Regular Maintenance and service

4.6 Sample size calculation and sampling method

4.6.1 Sample size calculation: We did not applied specific sample size calculation, rather we included 24 public health facilities managed under Addis Ababa City Administration Health Bureau which have been providing GeneXpert service (Annex-3).

4.6.2 Sampling method:

Among the total of 24 health facilities (5 regional hospitals, 16 health centers, 1regional lab) using exclusion/Inclusion criteria two health facilities were not included in the study since GeneXpert machine was nonfunctional and not installed respectively. In addition a TB focal personnel which involved and led GeneXpert service at FMoH directorate was also included in the study. Since the number of health facilities implemented GeneXpert were limited, convenient sampling technique was applied in order to select these health facilities.

In addition key informants (TB focal personnel's) were included using purposive sampling in the study from GeneXpert service providing health facilities and at FMoH in relation to GeneXpert diagnostic service according to their responsibility in the Organization.

Since, TB focal personnel's in the health facilities and at FMoH were responsible in GeneXpert product forecasting, quantification, distribution, and usage. Besides, design a sample referral linkage and performance evaluation of the GeneXpert diagnostic service.

4.7 Measurement and Data collection:

4.7.1 Data collection procedure:

Data were collected by oriented two data collectors using semi structured questionnaire to identify challenges encountered in the GeneXpert diagnostic service in the health facilities. Data on power interruption, supplies, training status, regular supervision, maintenance was obtained from documents and interviewed laboratory professionals/ or quality officer/ laboratory head. GeneXpert register and machine was reviewed to obtain the test performance and the rate of unsuccessful test result. In addition, Zeihl Nelson staining technique methods results were collected from registration book before the implementation of GeneXpert in the health facilities. While structured questionnaire was used to interview the key informants (TB focal) involved in the GeneXpert diagnostic service in the health facilities.

Addis Ababa City Administration Health Bureau have 24 public and 1 private health facilities deployed of GeneXpert diagnostic service however, this study was conducted in public health facilities which provided GeneXpert diagnostic service from Jan – Dec 2019.The data were collected from a total of 22 health facilities (sixteen health centers, five hospitals and one public health laboratory). Two health facilities Teklehaimanot and Arada health centers) were not included as their GeneXpert analyzer were nonfunctional and not installed respectively. Therefore, health facilities included in the study have participated professionals working on GeneXpert machine operation 22 laboratory professionals and coordinated the TB program (22 TB focal personnel).

4.8 Data quality assurance:

The data collection instrument was pretested in ALERT hospital (similar level of GeneXpert service with other health facilities), which were not be included in the study so as to ensure its validity. The tool was modified based on the feedback obtained during the pretest. Data collectors were oriented on how to collect the necessary data using the tool and additional written guide was provide to them on interpreting each of the study variables. The principal investigator was closely supervised the data collection process to ensure the completeness and consistency of the data collection. In addition, data was double entered to prevent error during data entry via cross-checking.

4.9 Data analysis and Interpretation:

Data was entered and analyzed using SPSS version 20. Descriptive data was summarized by table and figures. The effect of reasons on service interruption and unsuccessful test result were tested at statistical significance of P value < 0.05 using logistic regression. However, it was difficult to calculate as the sample size were small. While the qualitative data obtain from key informant interviewed was summarized in thematic narrative form.

4.10 Operational definitions

- **Adequate volume specimen:** A minimum of 1ml of sputum is required for the GeneXpert MTB/RIF test.
- **Good quality specimen:** A sputum specimen must be from the lungs, not from the nose and mouth.
- **Poor quality specimen:** A sputum with too bloody or contains too much pus, or food particles.
- **Referral health facilities:** health facilities which receive specimens from other health facilities to analyze the test.
- **Referring health facilities:** health facilities collect specimens from patient and send through referral linkage to health facilities which provide GeneXpert analysis.
- **Service interruption:** GeneXpert diagnostic service stop test analysis in the health facilities due to different reasons but refer the collected specimen to other functional site.
- **Unsuccessful test results:** GeneXpert analysis test resulted to either invalid, No result or error results.

4.11 Ethical consideration

To conduct this research a dual ethical approval was obtained from Medical Laboratory Sciences departmental Research and Ethical Review Committee (DRERC) and Addis Ababa Public Health Research and Emergency Management Directorate ethics research committee. Support letter was obtained from Addis Ababa Health City Administration Health Bureau to the health facilities.

During data collection process, the data collectors was informed each study participant about the purpose and anticipate benefits of the research project and the study participants which were informed on their full right to refuse, withdraw or completely reject part or all of their part in the study. Finally, they were asked for their informed written consent to participate or not to participate in the study and for their willingness on use of their files and records for the study. Interviews was conducted in a quiet, ventilated, lighted room to respect the study participants' anonymity and boost their confidence on the study.

4.12 Dissemination of the result

The final research findings will be submitted to Department of Medical Laboratory Sciences, Addis Ababa University, after defense. Summary reports also given to the study health facilities and Addis Ababa City Administration Health Bureau. In addition, the finding will be presented on annual conferences of professional societies. Also the manuscript will be submitted to peer reviewed journal for publication.

5. Results

5.1. Background information of Health Facilities.

This study was conducted in public health facilities which actively provided GeneXpert diagnostic service during data collection period. Accordingly, the data were collected from a total of 22 health facilities (sixteen health centers, five hospitals and one public health laboratory (table 1).

Table 1: Type of health facilities included in the study in Addis Ababa, Ethiopia 2019/2020.

S.No	Health facilities	Number
1	Health Centers	16
2	Hospitals	5
3	Public health Laboratory	1
	Total	22

Among the participated health facilities, 77% (17/22) of the health facilities have separate room which is in agreement with the guidelines (closed room) while 32% (5/22) were without standby generator as a power source. In addition 50% of them are without Biosafety cabinet (hood), which were not disagree as the guideline required biosafety level equivalent to smear microscopy (cross ventilated room). Except AAPHREMD which was deployed of GeneXpert in 2012 the remaining health facilities were installed from 2015-2018 (two in 2015, seven in 2016, three in 2017 and nine in 2018). GeneXpert analyzers implemented in the health facilities have four modules except AAPHREMD machine has six modules. Despite the health facilities were implemented a four module machine 45% of them either one or two or three or four of their modules were nonfunctional.

Although 100% of the health facilities have updated SOP, conducted daily preventive maintenance and annual calibration, scheduled service maintenance were not conducted in 28% of the health facilities.

5.2 Reasons of service interruption

Atleast once or more than one times of service interruption of GeneXpert were occurred in 18/22 (82%) of the health facilities due to different causes in the study period. The most common reasons were cartridge stock out next by machine failure, system failure and UPS (uninterrupted power supplies) failure (Figure 2). Even though the curative maintenance team were responded from immediate to 30 days of interval for system failure, module failure not yet replaced in the health facilities. As a result of this, most of the health facilities run the samples using the remaining functional modules. To implement GeneXpert machines in all health facilities is not feasible due to its highest cost and load of the specimen, a referral linkage was designed for non GeneXpert facilities. So that 19 of the health facilities received specimens from other health facilities via a referral linkage mapping.

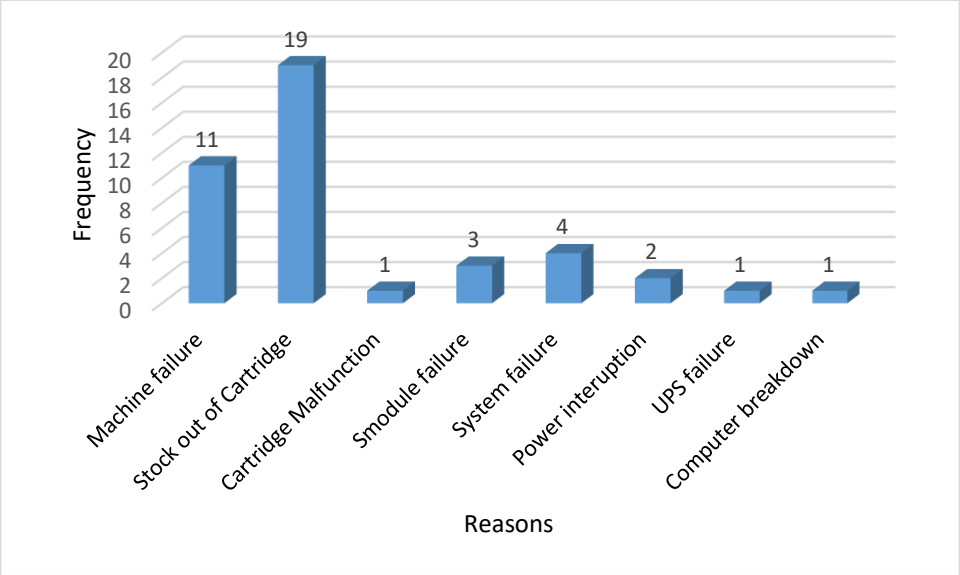

Figure 2: Reasons of service interruption of GeneXpert analyzer in Addis Ababa, Ethiopia, 2019/2020.

As it depicted in Figure 2, the main repeated reasons of service interruption found in most of the health facilities were stock out of cartridge (19) which is next by machine failure (11), however other causes mentioned above were also the reasons for service interruption. The frequency and reasons of service interruption among the health facilities were different.

The tuberculosis diagnostic service in Addis Ababa were done through the tier networking referral system ,especially the MDR TB diagnostic service implemented and used a postal referral system ,in order to get timely quality result. Accordingly, a total of 11344 sputum specimens were managed via referred from the 88 health facilities and also 15719 were collected onsite for the diagnostic of drug resistance tuberculosis from the presumptive. However 2.6% (296/11344) specimen were rejected due to either insufficient or poor quality. In eight health facilities 23.3% of the total specimens with daily average of 1-4 samples are tested per day/year and in another eight sites (42.2%) of the total specimens with average 5-8 samples run /day/year while daily average of 9-20 samples are tested in six (34.5%) centers (Table 2). The daily average test performed were 7 in these health facilities which were analyzed 5 days in a week. Whereas the total test analyzed were 67% of the expected performance of the total health facilities (26998 /40040) per year.

Table 2: Average number of samples run per day/year in Addis Ababa public health facilities having GeneXpert analyzer, 2019/2020.

Average number of samples run per day/year	No of health facilities	Test performed
1- 4 Samples	8	23.3%(6267/26998)
5- 8 Samples	8	42.2%(11414/26998)
9- 20 Samples	6	34.5%(9317/26998)
Total	**22**	**100 %**

As it indicated in the table 3 below, the predominant challenges of service interruption in the health facilities is dependent on stock out of cartridge at X^2 =10.6, at p value <0.01.

Table 3: Analysis of stock out with service interruption of GeneXpert diagnostic service in Addis Ababa, Ethiopia 2019/2020.

		Stock out		
		Yes	No	total
Service interruption	Yes	17(78%)	1(4%)	18 (82%)
	No	1(4%)	3 (14%)	4(18%)
Total		18(82%)	4(18%)	22(100%)

X^2= 10.6, P-value =0.01

5.3 Reasons for unsuccessful test results

Among the total specimens successful and unsuccessful test results accounted 25920 and 1078 respectively. From the total successful test result (25920), MTB not detected accounted 91.3% (23683/25920) of the specimen, MTB detected were 8.6 % (2237/25920).In general, MTB detected RIF not detected (susceptible) were 95.4 % (2136/2237), MTB detected RIF indeterminate were 1.1 % (25/2237), MTB detected RIF resistance detected were 3.3% (76/2237).

Furthermore, a total of 4% (1078/26998) unsuccessful test result were occurred which was due to 'Error' 2.3 % (618/26998), this error rate was within the targets (<3%), followed by 'No result' 1.2% (334/26998) which was higher than the targets (<1%) and 'Invalid' 0.5% (126/26998) result rate was within the targets (<1%) (Table 4).

Table 4: GeneXpert MTB/RIF results at Addis Ababa Public health facilities Addis Ababa, Ethiopia, January –December 2019,N = 26998**.**

GeneXpert MTB/RIF test outcomes		**Frequency%**
Successful results, N=25920	MTB not detected	23683 (91.4)
	MTB positive	2237 (8.6)
	Rifampicin resistant	76 (3.3%)
	Rifampicin indeterminate	25 (1.1%)
	Rifampicin susceptible	2136(95.4%)
Unsuccessful test result , N=1078	Error	618 (2.3 %)
	Invalid	126 (0.5 %)
	No result	334 (1.2 %)

Therefore, reasons for unsuccessful test result were 18/22 (82%) poor sample quality, 17/22 (77%) power fluctuation and 9/22 (41%) insufficient sample volume. In addition improper sample preparation, technical error and UPS failure were also other causes next to the above reasons.

However, factors for unsuccessful test result were not affected by preventive maintenance, annual calibration and stand by generator by linear regression (Table 5).

Table 5: Factors for unsuccessful test results of GeneXpert diagnostic service in Addis Ababa, Ethiopia 2019/2020.

Factors	t	P-value	Confidence interval	
			Lower	upper
Preventive maintenance	-1.457	0.162	-93.305	16.880
Annual calibration	0.553	0.587	-46.560	79.842
Stand by Generator	0.153	0.880	-43.041	49.800

5.3.1 Turnaround Time

We also try to look at and summarize the turnaround practices of the study facilities. The turnaround times (TAT) for samples from outside of the testing site (referral specimen) results delivered were 2-48 hours which is agreed with the guideline five working days from the day of receipt. While delivery of test results for patients from the same facility should be within same day of sample collection. Panic results were managed within 2 to 6 hours except two health facilities needs 24 hours. However there is no difference between hospitals and health centers. Zeihl Nelson staining method registration book was reviewed which has been done in the past one year before the implementation of GeneXpert in 17 health facilities respectively. The total specimen examined with this technique were 24780 which reported 8% (2016/24780) Acid fast bacilli positive , though this technique has a drawback to identify Rif resistance bacteria. This result 8% acid fact positive and 8.6% MTB positive in GeneXpert indicated that Zeihl nelson staining technique is a choice of method for diagnosis of M. tuberculosis in the absence of GeneXpert in the health facilities.

5.3.2 Supply Chain Management System

The supply chain system for GeneXpert commodities were integrated with other health commodities. Since stock status monitored using bin cards, health facilities reported, requested, and received from Ethiopian Pharmaceutical Supply Agency (EPSA). Despite of enough earmarked budget for purchasing GeneXpert Cartridge by FMoH, shortage of these commodities are common. As a result of this, sometimes due to shortage of GeneXpert commodities health facilities borrowed horizontally from other health facilities otherwise service interuptted. Besides, Stock on hand (SOH) of Cartridge at the day of visit showed that only four health facilities were stocked out for cartridge. Although, the yearly trends of cartridge stock status indicated that stocked out were happened in 86% (19/22) of health facilities at different times. These health facilities were analyzed the test either using Ziehl Nelson Method, refer the specimen to assigned back up site based on referral linkage mapping or borrowed cartridge from other health facilities. The total annual consumption of cartridge in the health facilities were 27,340 which had a 342 pieces of discrepancy from the total analyzed tests.

The overall operation of GeneXpert service were supervised by Regional Laboratory experts every four months, hence support like refresher training was given based on identified gaps in the health facilities.

5.4: Challenges of GeneXpert diagnostic Service Interview findings with TB focal personnel:
In depth interview were conducted with key contact persons in GeneXpert diagnostic service at all levels from MOH to the health facilities based on below three questions.

- Reasons of GeneXpert diagnostic services causing service interruption and unsuccessful test results
- Lesson learnt
- Suggestions for diagnostic service improvement

This interview were conducted with key contact personnel's (TB focal at MOH, RHB and health facilities). As the common problems faced in operating of GeneXpert in the health facilities were captured in the first part of the questionnaire with lab personnel's and reviewed the document, most of the key contact personnel's had also informed similar information like cartridge stock out, machine failure, system failure, module failure and power interruption were the main challenges encountered in the health facilities. Therefore, understanding of these challenges helps them to support the diagnostic service improvement accordingly since they led the TB program. These key contact personnel's suggested that health facilities support supervision should not be integrated with other programs for better management.

In line with this, memorandum of understanding signed with partners working on TB to procure additional cartridge besides the government supply chain system when there is shortage of cartridge. Operation of GeneXpert refresher training curriculum include the day to day preventive maintenance for laboratory personnel's so that, gap filling training helps for sustainable device functionality. As well as recommendation to establish regional maintenance team at Regional Health Bureau level better to respond timely in case of machine failure for health facilities.

In general, this study identified that challenges for GeneXpert diagnostic service interruption were stock out, machine failure, system failure and module failure. Furthermore, challenges affecting the GeneXpert diagnostic service resulted to unsuccessful test result predominantly were sample quality and power fluctuation.

6. Discussion

This study was tried to analyze data collected from the health facilities throughout the year, though the dominate month of challenges happened not able identified. Findings summarized as GeneXpert diagnostic service challenges causes either service interruptions or unsuccessful test results as follows.

6.1. GeneXpert Service interruption:

Generally, a robust inventory system is required to monitor GeneXpert MTB/RIF cartridge consumption. Accurately forecasting GeneXpert MTB/RIF test supply needs reduces the risk of an interruption in service due to shortage of reagents. This study showed that despite there is strong integrated logistic system in the country, cartridge stock out were the main reasons for service interruption. In fact there was allocated budget to purchase these supplies as the MOH contact person explained, the system failed to do so. This study identified retrospective inventory records (Bin Card) and at the day of visit reviewed in the health facilities. Failure to maintain an adequate, uninterrupted supply of quality-assured reagents can affect quality because stock-outs result in delayed testing and delayed reporting of results and use of poor quality or expired reagents can result in high error rates and inaccurate test results.

In this study cartridge stock out (86.3%) was the top reasons next by machine failure (50 %) faced which is comparable with study conducted in Bangladesh shown that machine operation problems happened due to module failure (67.4 %) followed by machine failure or delay in maintenance support (46.5 %) (11). The finding of this study also in agreement with this study *Colleen F. Hanrahan,et al*.(cartridge stock outs, module malfunction, and consistently high invalid/error rates were common problems (17).

Furthermore, this study indicated that repeated service interruption were happened, which is not comparable with a study conducted at Amhara public health Institute (APHI)by *M. Shiferaw and A. Misganaw*(25) revealed GeneXpert did not experience service interruption. In this study the main cause of service interruption might be due to improper supply chain management at health facilities in comparison to APHI.

6.2. GeneXpert unsuccessful test results

This study revealed that underutilization of GeneXpert machines 67% (26998/40040) in Addis Ababa though referral linkage were implemented for non GeneXpert sites. The distribution of workload among the study health facilities indicated that eight health facilities which run 1-4 samples/day was 23.3% and other eight health facilities which run 5-8 samples/day accounts 42.2% as well as the remaining six health facilities which run 9-20 samples/day cover 34.5% (table 1)Similarly, underutilization shown in study conducted in Nigeria (10). However, annual total test done has no difference between hospitals and health centers (P=0.217). Analysis indicated that total test uptake affected by suboptimal scheduled service maintenance ($p<0.03$), module failure ($p<0.019$) and no of days working in a week ($p<0.04$).

Total unsuccessful test result is no difference between hospitals and health centers ($p=0.07$). Nevertheless, this study indicated that a total of 4% (1078/26998) unsuccessful test result were occurred. The result was due to 'Error' 2.3 % (618/26998), this error rate was within the targets (<3%), followed by 'No result' 1.2% (334/26998) which was higher than the targets (<1%) and 'Invalid' 0.5% (126/26998) result rate it was within the targets (<1%). In the study conducted at Ethiopian Public Health Institute, the error rate of (8.9%) was reported which was higher than the targets and with this study. In agreement to study conducted at Amhara Public Health Institute (26), the error rate was within the targets (1.4%), while this study reported (2.3%) which was within the targets (3%).

In this study, the most common error depicted were technical problems, electrical fluctuation and machine failure, which is concordance agreement with study reported by *Gidado M et al*(12) that facility-documented error codes were identified and categorized into five groups based on causes of error (temperature-related, technical problems, cartridge malfunction, electrical connection and machine malfunction errors).

In the other hand the most common reason for unsuccessful test result were power fluctuation, insufficient specimen and poor sample quality. The level of unsuccessful performance of GeneXpert of the health facilities in this study revealed 4% which was not compromised the tests since according to manufacturer of GeneXpert a cumulative error rate of > 5% is unacceptable. Moreover, Ethiopia *GeneXpert Technical Brief* of the unsuccessful test result accounted 6.2% in

2018 GeneXpert machines available throughout the country. The decline in this study might be small sample size, strong site-level mentoring by regional laboratory advisors with non-government partners, staff training, and UPS distribution (2). Whereas, the total unsuccessful test result findings in health centers and hospitals did not have statistically significant difference (1).

In addition, the key contact persons (TB focal) in most of the health facilities were in the same page with laboratory personnel's on challenges faced on service interruption and unsuccessful test results. Generally, their findings directed to similar proposal of recommendation for the common challenges happened in the health facilities.

We did not perform a logistic regression because of small sample size in order to triangulate the factors and identifying the most contributing factors, thus reader should consider this limitation while inferring this finding.

7. Conclusion and Recommendation

7.1. Conclusion:

As the strategy to END TB has a prerequisite for National Tuberculosis Program (NTP) to reach this goal a quality-assured laboratory network equipped with rapid diagnostics were at most very important. Identifying challenges which affects service interruption and unsuccessful test results were the key area for the improvement their challenges. As a result, this study shown stock out of cartridge, machine down, system failure, module failure and cartridge malfunction were the common and main challenges for service interruption, while, reasons for unsuccessful test results were power interruption, incorrect sample volume, poor sample quality, food contaminant and technical errors.

7.2. Recommendations

In order to curb the global tuberculosis burden and in queue of end TB strategy, based on the evidence generated from the current study, we come up with the following recommendations. Sustainable power supply, responsive maintenance support, sustainable supply chain system should implement at regional health Bureau and provide refresher training for laboratory professionals working on it for diagnostic service improvement.

Moreover, further large scale study should be conducted since we did not perform it because of limited available budget.

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8. ANNEX

8.1. Annex 1: INFORMATION SHEET

Good morning/good afternoon. My name is _____. We came from Addis Ababa University Medical Faculty. We are working for an investigator doing his thesis for the partial fulfillment of Master's degree in Clinical Laboratory Science. We would like to ask you few questions about challenges of service interruption and unsuccessful test result related to GeneXpert diagnostic service faced in your health facility.

You have full right to refuse, withdraw or completely reject part or all of your participation in the study. But we encourage your full participation as the answers you give on this form are very important to this study and will help to develop recommendations for the improvement of quality of service. We need also to take some information from your files and records of Pharmacy and Laboratory in the health facility.

We would like to assure you that all of your responses to our questions will be kept confidential throughout the study process. Any of your information you provide will be used only by the research team and will, by no means, be revealed to a third party. We will ask you questions in a place where other people or conditions couldn't interfere. We would like to assure you that your participation on this research will not affect any of your service.

We would be thankful if you spend some time with us answering questions related to the issues described above. The interview will take 30-45 minutes.

May I get your permission to continue my interview?

Yes 1

No 2_ Stop

8.2. Annex 2: CONSENT FORM

I have read the information sheet above and clearly understood the purpose and anticipated benefit of the research. I hereby need to assure with my signature below that, I without any coercion or forceful act by the research team, have decided to voluntarily participate in the study to contribute my part in the effort being made for the improvement of GeneXpert diagnostic service.

Signature _____

Date_____

Name of Health facility_____

Data collector

Name _____ Signature _____

Supervisor

Name____ _____ Signature _____

8.3 Annex 3

Questionnaires used to collect data from health facilities which implemented GeneXpert MTB/RIF device.

Date of visit: _____

Key contact person and Data collectors

Name	**Position**	**Telephone**	

Part I. General Information	
Health Facility Name	Facility Type
Telephone: -_____	□ **Health Center** □ **Regional Lab** □ **Hospital**
Part II. Human Resource and Training related information	
1. Number of lab professionals _____ 1.1 Number of Diploma lab professional _____ 1.2 Number of Degree lab professionals _____ 1.3 Number with MSc. Degree _____	
2 How many lab professionals trained GeneXpert testing? _____	
3 How many of them currently working on GeneXpert in the health facilities? _____	

Part III Infrastructure of Gene Xpert device			
No	Description	Choices	**Remark**
1	Does it have separate room?	1. Yes 2. No	
2	Does it have standby functional (automatic) Generator?	1. Yes 2. No	
3	Does it have functional UPS?	1. Yes 2. No	
4	Does it have Biosafety (safety hood)?	1. Yes 2. No	
5	Does it have functional air conditioner?	1. Yes 2. No	
Part IV Equipment			
1	When does the GeneXpert machine installed?		
2	How many modules your health facility machine have?		
3	How many of these modules are functional?		
4	Do you have an updated SOP for GeneXpert in the lab?	1. Yes 2. No	
5	Is preventive maintenance regularly conducted? (See the record)	1.Daily.Yes/No _____ 2.Weekly Yes/No _____ 3.Monthly Yes/No _____ 4.Annual GeneXpert Check/ Calibration done? Yes/No_____	
6	Does scheduled service maintenance done?	1. Yes 2. No	
7	Have you come across machine break down?	1. Yes 2. No	
8	For how many days the service interrupted?		
9	How fast the curative maintenance responded?		

10	Have you come across with module failure?		
11	How fast to replace the failed Module?		
12	What are the reasons of service interruption?		
Part V Referral linkage			
1	Number of health facilities linked to your health facility for GeneXpert test?	1. Directly 2. Backup	
2	Means of specimen transportation	1. Through Postal service 2. Patients goes to referring HF	
3	Means of result delivery	1. Through postal service 2. Patient collects	
4	How many specimens averagely collected from referring Health facilities?	1. Daily _____ 2. Monthly_____ 3. Total per year_____	**Remark:** Add all from register
5	Number of specimens rejected from referring Health facilities?	1. Monthly _____ 2. Yearly_____	
6	How many days do you perform the test per week		
7	Average test run per day? (Min and Max)		
8	Number of specimens tested on referred samples?	1. Weekly_____ 2. Monthly_____ 3. Total per year_____	**Remark:** Add all from register
9	Number of specimens tested on onsite (from OPD of the GeneXpert site)	1. Weekly_____ 2. Monthly_____ 3. Total per year_____	**Remark:** Add all from register

10	Total number of tests performed (onsite and referred samples)?	1. Weekly_____ 2. Monthly_____ 3. Total per year_____	**Remark:** Add Q8 and Q9
11	Test result (GeneXpert)	1. MTB not detected ___ 2. MTB detected RIF resistance not detected_____ 3. MTB detected RIF indeterminate_____ 4. MTB detected RIF resistance detected_ 5. Error_____ 6. No result _____ 7. Invalid_____ 8. Total unsuccessful test (5+6+7) ____	**Remark:** Add from the record or machine
12	What are the reasons for Unsuccessful test result?	1._____ 2._____ 3._____	
13	Turnaround time		
14	Turnaround time for panic result		
Part VI – Ziehl Nelson Stain			
1	How many patient do you examine in the last two years before the implementation of GeneXpert?		
2	How many patient detected as TB positive?		
Part VII Supply Chain Management			
1	Are supplies of GeneXpert integrated with IPLS?	1. Yes 2. No	

2	If the response for the question is No 1 is no, from where do you get supplies?	1. EPSA 2. Sub city 3. RHB 4. Regional Lab 5. Donor	
3	Did you monitor the stock status using Bin Card? (cartridge, Falcon tube)	1. Yes 2. No	
4	How do you request the supplies from the next level?	1. RRF 2. Letter 3. Telephone.	
5	Stock on Hand of Cartridge at the day of visit?		
6	Have you come across stock out of cartridge?	1. Yes 2. No	
7	How many days the service interrupted due to stock out of cartridge? (See occurrence form)		
8	How do you manage the testing service during cartridge stock out?		
9	Have you come across stock out of Falcon tube?	1. Yes 2. No	
10	Does the service interrupted due to Falcon tube stock out?	1. Yes 2. No	
11	How many days?		
12	How do you manage the testing service during Falcon tube stock out?	…… …… …… ……	
13	Is there any additional supplies you come across stock out? List out		

8.4. Annex 4

Questionnaire for TB Focal persons/Lab Head at MOH, Addis Ababa City Administration Health Bureau, Regional Lab and health facilities. (*Please respond the questions which is applicable for your responsibility in the Organization*)

1. What are the reasons of GeneXpert diagnostic service resulted to service interruption and unsuccessful test result?
2. What are the lesson learnt from the challenges?
3. What are your suggestions/recommendation for GeneXpert diagnostic service improvement?

8.5. Annex 5: List of health facilities implemented GeneXpert diagnostic service

SN	Sub city	Facility name
1	Arada	Yekatit 12 Medical College Hospital
2		Ras desta Damtew Hospital
3		Arada Health Center
4	Kirkos	Zewditu Memorial Hospital
5		Meshualekia Health Center
6	Yeka	Minillik II Hospital
7		Kotebe Health Center
8		Yeka Health Center
9		Yeka W-13 Health Center
10	Bole	Amoraw Health Center
11		Bole 17 Health Center
12	AkakiKality	TiruneshBejing Hospital
13		Kality Health Center
14	KolfeKeranio	Kolfe Health Center
15		KolfeKeranio W-3 Health Center
16		KolfeKeranio W-9 Health Center
17		Alembank Health Center
18	N/S/L	N/S/L W-2 Health Center
19		N/S/L W-3 Health Center
20		N/S/L W-9 Health Center
21		N/S/L W-11 Health Center
22	Addis ketema	Addis Ketema Health Center
23	Lideta	T/Haimanot Health Center
24	Health Bureau	Addis Ababa Public Health Laboratory

9. Declaration

The undersigned declares that this thesis complies with the regulations of the University and meets the accepted standards with respect to originality and quality. PI also agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports.

M.Sc. candidate: Mesafint Merkebu (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: Abay Sisay (MSc, PhD fellow)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Fatuma Hassen (BA, BSC, MPH, PhD candidate)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.