ASSESSMENT OF TUBERCULOSIS DIAGNOSTIC CAPACITY IN HEALTHCARE FACILITIES IN NAIROBI CITY COUNTY, KENYA

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DEDICATION

This research project is dedicated to my beloved husband Stanley and my daughters Zara, Zena and Zaria, as well as my entire family. Your support and encouragement were truly an inspiration.

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This work was made possible through the contribution of my supervisor Dr. Richard Ayah, who tirelessly devoted his time, energy and effort during this process. I extend my gratitude for the support, advise, guidance and invaluable input.

I wish to acknowledge the administration of the National Tuberculosis, Leprosy and Lung Disease program as well as various health facilities in Nairobi County for granting me permission to undertake this project. Thank you to the various laboratory staff for offering their support where possible.

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LIST OF ABBREVIATIONS AND ACRONYMS

AFB	Acid Fast Bacilli
EQA	External Quality Assurance
ERC	Ethics Review Committee
FBO	Faith Based Organization
FCDRR	Facility Consumption and Data Report and Request Form
GOK	Government of Kenya
IPC	Infection Prevention and Control
KNH	Kenyatta National Hospital
Lab	Laboratory
NTLDP	National Tuberculosis, Leprosy and Lund Disease Program
SCTLC	Sub county TB and Leprosy Coordinator
SOPs	Standard Operating Procedures
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
TB	Tuberculosis
UON	University of Nairobi
WHO	World Health Organization

DEFINITION OF KEY TERMS

Adequate Guidelines and SOPs: Presence of technical guidelines, job aids and SOPs on Laboratory TB diagnosis.

Adequate Staffing: Laboratory staff with a diploma or higher in laboratory sciences, dedicated to processing sputum, having received AFB microscopy refresher training, with someone of a similar capacity for replacement during their absence.

External Quality Assurance: Slides labeled, stored, collected for external review by independent laboratory staff with written feedback and evidence of discussion of major errors.

Adequate Recording and reporting: Request forms, registers and reporting forms all correctly filled and referred specimens entered in a logbook.

Adequate Specimen processing: Specimen processing done within 2 days, smear positivity <12% for new cases, sputum sample ratio to staff number <20:1 and results of molecular tests are available within two weeks.

Adequate Equipment: Microscope/Genexpert in good working condition with good quality reagents used. Genexpert is the trademark name for reagents and kits comprised primarily of reagents for medical, clinical, medical laboratory or medical diagnostic use in connection with the amplification, analysis, labeling and detection of nucleic acids owned by Cephid corporation.

Adequate Supplies: Ordering of supplies is timely, and they are received as per order with no expiries or stock outs.

Adequate Infection prevention and control: Sputum collection is done outside the lab. There is good natural/mechanical ventilation, good disinfection and safe disposal of smearing tools.

Health Facility: Places that provide healthcare within a permanent structure. They include hospitals, clinics, dispensaries and health centers.

ABSTRACT

Assessment of tuberculosis diagnostic capacity in healthcare facilities in Nairobi City County, Kenya

Background: Early diagnosis of Tuberculosis (TB) is an essential component of the World Health Organization's (WHO's) end TB strategy. The Kenya Tuberculosis Prevalence Survey established that TB prevalence in Kenya is higher than had been estimated and that about half of those who fall ill with the disease each year are missed. This calls for early diagnosis of TB that can only be facilitated by a TB laboratory that meets all the necessary requirements. The aim of the study was to determine the tuberculosis diagnostic capacity of healthcare facility laboratories in Nairobi City County.

Methodology: A cross sectional study was done in Nairobi City County in 2016. The sample size was 73 randomly selected TB laboratories. The dependent variable was the TB lab sampled. The independent variables evaluated were: presence and use of TB lab guidelines and Standard Operating Procedures (SOPs), TB lab staffing, TB lab External Quality Assurance (EQA), TB lab recording and reporting, TB specimen processing, TB diagnostic equipment, TB diagnostic supplies and TB infection prevention and control (IPC). The evaluation was done using a modified WHO lab accreditation assessment tool. Analysis was based on the 95% threshold proposed in the WHO's Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) for 5-star accreditation.

Results: The TB labs did not meet the criteria for 5 star accreditation in the following variables: presence and use of TB lab guidelines and SOPs (83.3%), TB lab EQA (60.7%), TB lab recording

and reporting (87.1%), TB specimen processing (71.9%), TB diagnostic equipment (72.9%), TB diagnostic supplies (73%). The labs met the threshold in TB infection prevention and control (IPC) 96.2% and TB lab staffing (94.9%).

Conclusions: The TB diagnostic capacity of laboratories in Nairobi County did not meet SLIPTA 5-star accreditation in six out of eight areas assessed. Building the capacity on leadership and governance and provision of adequate financing have a role in improving TB diagnostic capacity in a bid to address the highlighted areas of weakness.

Recommendations: Building the capacity on leadership and governance and provision of adequate financing have a role in improving TB diagnostic capacity in a bid to address the highlighted areas of weakness. Assessment of the TB laboratory diagnostic capacity using WHO GLI laboratory assessment tool is a useful way of assisting TB laboratories achieve SLIPTA accreditation, ultimately improving TB diagnosis and treatment outcomes.

Key words: TB diagnostic capacity, TB Laboratory, Health Systems

CHAPTER ONE: INTRODUCTION

1.1 Introduction

The End TB strategy proposed by the World Health Organization's (WHO's) calls for early diagnosis of TB that can only be facilitated by a healthcare laboratory that meets all the requirements TB diagnosis readiness (WHO, 2015). This includes adequate supplies and equipment, staffing, external quality assurance, specimen processing, recording and reporting, guidelines and standard operating procedures (SOP's) and infection prevention and control measures (Global Laboratory Initiative, 2013).

Evaluation of a healthcare facilities laboratory's TB diagnostic capacity can be done using the Global Laboratory Initiatives' TB microscopy networks' accreditation assessment tool (Global Laboratory Initiative, 2013). This can evaluation can be used to inform the WHO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) which gives the minimum standards required for laboratory accreditation (WHO, 2011).

1.2 Background

The Global TB report 2015 recommends strengthening TB laboratory diagnostic capacity to facilitate early diagnosis and initiation onto TB treatment in a bid to reduce TB mortality (WHO, 2015). In 2014, WHO estimated that there were 9.6 Million persons with TB disease (133 cases per 100,000 population), of whom 1.5 million died in the same year while Sub Saharan Africa had 28% (281 cases per 100,000 population) of the world's TB cases (WHO, 2015). In 2014, Kenya notified approximately 89,000 TB cases (210 cases per 100,000 population) that were diagnosed

in 1,920 TB labs in healthcare facilities. In the same year, the country reported 6% TB mortality. Nairobi City County reported the highest number (13,917) of TB cases in the same year (387 cases per 100,000 population) diagnosed in 153 TB labs in its healthcare facilities The Kenya Tuberculosis Prevalence Survey established that TB prevalence in Kenya is higher (558 cases per 100,000 population) than had been estimated and that about half of those who fall ill with the disease each year are missed (Enos et al., 2018).

This study evaluated the TB diagnostic capacity in order to identify gaps to be addressed to ensure all TB diagnostic facilities are adequately equipped for timely TB diagnosis. Laboratory health system factors are based on the WHO building blocks of health; leadership and governance (TB laboratory guidelines and SOPS), human resources for health (TB laboratory staffing), health service delivery (specimen processing, external quality assurance, infection prevention and control), Health Information Management Systems (recording and reporting), Medicines and medical products (TB laboratory supplies and equipment) (WHO, 2015). Laboratory health system factors were evaluated using the Global Laboratory Initiatives' TB microscopy networks' accreditation assessment tool (Global Laboratory Initiative, 2013) and the WHO Stepwise Laboratory Improvement Process towards Accreditation standards (WHO, 2011).

1.3 Problem statement

Early diagnosis of TB is an essential component of the WHO's end TB strategy. The Kenya Tuberculosis Prevalence Survey established that TB prevalence in Kenya is higher than had been estimated and that about half of those who fall ill with the disease each year are missed. This calls for early diagnosis of TB that can only be facilitated by a TB laboratory that meets all the necessary requirements for quality TB diagnosis.

1.4 Justification

The Global TB report 2015 recommends strengthening TB laboratory diagnostic capacity to facilitate early diagnosis and initiation onto TB treatment in a bid to reduce TB mortality. (WHO, 2015). Evaluation of a healthcare facilities laboratory's readiness for TB diagnosis will enable facility managers to ensure that TB laboratories provide timely TB diagnosis and prompt TB treatment in order to improve TB patient outcomes.

1.5 Study objectives

1.5.1 Main Objective

To determine the tuberculosis diagnostic capacity of selected TB laboratories in Nairobi City County.

1.5.2 Specific Objectives

i. To determine the characteristics of TB laboratories in Nairobi City County.
ii. To evaluate the diagnostic capacity of TB laboratories in Nairobi City County.

1.6 Conceptual framework for TB lab diagnostic capacity

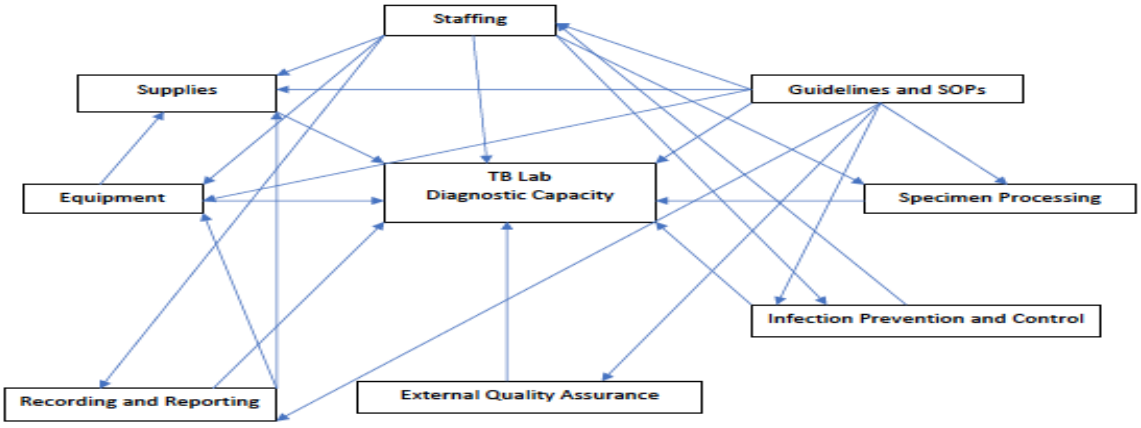


Figure 1: Conceptual framework for TB lab diagnostic capacity. Adapted from the WHO GLI laboratory assessment framework (WHO, 2012).

Lack of prompt access to TB diagnostic facilities has been shown to contribute to increased morbidity and mortality from late initiation onto treatment (Moolphate et al., 2011) (A. Harries et al., 2001) (A. D. Harries et al., 2001) (Alavi et al., 2011). Inadequate supplies and equipment, staffing, external quality assurance, recording and reporting, guidelines and standard operating procedures (SOP's) and infection prevention and control measures are contributing factors to lack of TB diagnostic treatment capacity (Global Laboratory Initiative, 2013).

CHAPTER TWO: LITERATURE REVIEW

2.1 Characteristics of TB laboratories

Though there have been some studies done to identify diagnostic delay as a contributing factor towards TB mortality, there have been, however, few studies done to identify which health systems failures could possibly contribute to TB mortality and consequently give recommendations on how to ensure efficient and effective health systems are in place to reduce TB diagnostic delays.

The World Health Organization (WHO) acknowledges that delayed TB diagnosis leads to suffering, economic strain and sustained transmission. It therefore developed a protocol for active diagnosis of TB though systematic screening (WHO, 2013).

Systematic screening for active TB is defined as the systematic identification of people with suspected active TB, in a predetermined target group, using tests, examinations or other procedures that can be applied rapidly. The screening tests, examinations or other procedures should efficiently distinguish people with a high probability of having active TB from those who are unlikely to have active TB. Among those whose screening is positive, the diagnosis needs to be established by one or several diagnostic tests and additional clinical assessments, which together have high accuracy. The primary objective of screening for active TB is to ensure that active TB is detected early and treatment is initiated promptly, with the ultimate aim of reducing the risk of poor treatment outcomes, health sequelae and the adverse social and economic consequences of TB, as well as helping to reduce TB transmission (WHO, 2013).

The National TB, Leprosy and Lung Disease Program recommends genexpert to be used as the first test and sputum smear microscopy as an adjunct test for TB diagnosis in Kenya (Ministry of Health, Kenya, 2014a).

In Kenya, health facilities are categorized as Level 1: Community, Level 2: Dispensaries, Level 3: Health Centers, Level 4: Primary referral facilities, Level 5: Secondary referral facilities, Level 6: Tertiary referral facilities. TB diagnostic labs are decentralized to all levels of healthcare service provision (with the exception of the community/level 1) in order to facilitate timely TB diagnosis. Nairobi has one national public level 6 facility, 54 level 4-6 facilities and 599 level 2-3 facilities of which 216 facilities provide TB treatment (Ministry of Health, Kenya, 2014b).

The Kenya service Provision Assessment Survey 2010 shows that 74% of healthcare facilities provide any form of TB services that includes any or all of the following: diagnosis, treatment, and follow up (Ministry of Medical Services, Kenya et al., 2010).

2.2 Diagnostic capacity of TB laboratories

The global laboratory initiative in advancing TB diagnosis developed a guideline on TB microscopy network accreditation which provides for a checklist of key indicators on TB diagnostic capacity that includes Guidelines and SOPs, Staffing, Specimen processing, Supplies, Equipment, External Quality Assurance, Recording and reporting and Infection Prevention and Control (Global Laboratory Initiative, 2013) .

Guidelines and SOPs on laboratory diagnosis of TB

Guidelines and SOPs are critical to ensuring TB diagnosis is performed as per the required

standards to give consistent and accurate results (Ridderhof et al., 2007). They inform on staffing and supplies requirements, equipment specification, specimen processing procedures, recording and reporting as well as infection prevention and control procedures. Guidelines and SOPs on TB laboratory diagnosis is critical in providing standards that should be adhered to for optimal TB diagnostic services. (Ridderhof et al., 2007)

Staffing in TB laboratories

Inadequate staffing affects the quality of specimen processing as overworked staff are more likely to make errors when processing specimen, performing infection prevention and control procedures, recording and reporting, ordering supplies or maintaining equipment. Minimal training of a 2-3 year diploma to a university degree has been recommended as the requirements to man a TB lab with additional refresher training in new technologies and management skills. (Ridderhof et al., 2007). It has also been documented that shortage of trained laboratory technicians' hampers TB lab services. The recommended ratio of number of samples assessed per month to number of lab staff is <20:1(Global Laboratory Initiative, 2013).

External Quality Assurance of TB laboratory specimen processing

External Quality Assurance (EQA) improves the quality of TB diagnostic services and is influenced by the diligence of the TB lab staff in adherence to outlined guidelines and SOPs. EQA has been shown to strengthen TB laboratory services and improving diagnostic quality (Ridderhof et al., 2007).

Specimen processing of TB laboratory samples

Specimen processing directly affects the quality of TB diagnostic services. Poor specimen processing techniques by staff often results in erroneous results, whereas adherence to guidelines and SOPs while processing specimen contributed to good quality TB diagnostic services. Delay in specimen processing results in delayed diagnosis and consequently delay in initiation onto TB treatment. WHO recommends that sputum samples arrive are processed within two days of arrival at the TB diagnostic facility. (World Health Organization, 2013)

Supplies and equipment for TB laboratories

Inadequate supplies and equipment directly affect the laboratory's capacity to diagnose TB as there will be no equipment or reagents to perform the TB diagnostic tests. Equipment available in the TB Lab directly influences the type of supplies that are ordered which should be compatible for the specified equipment. Well-functioning equipment is critical in provision of TB diagnostic services. Equipment management policies and maintenance strategies involving the health facility staff , equipment manufacturers as well as leaders and administrators need to come together to ensure TB diagnostic equipment is procured and maintained according to the needs of the population. (Fonjungo et al., 2012) Adequate supplies are critical in the provision of TB lab diagnostics as even the best equipment would be rendered useless without suitable supplies and reagents. Timeliness in supply provision and avoidance of stock outs is critical in preventing TB diagnostic delays. (Ridderhof et al., 2007)

Recording and reporting in the TB laboratory

Poor recording and reporting could indicate that the patients test results may not be accurate or get to them on time. It may also result on supplies and equipment not ordered in time leading to stock outs that negatively affect its TB diagnostic capacity. A study in Malawi showed that there was complete documentation of lab specimen in 95% of the cases which contributed to timely TB diagnosis. (Mundy et al., 2002)

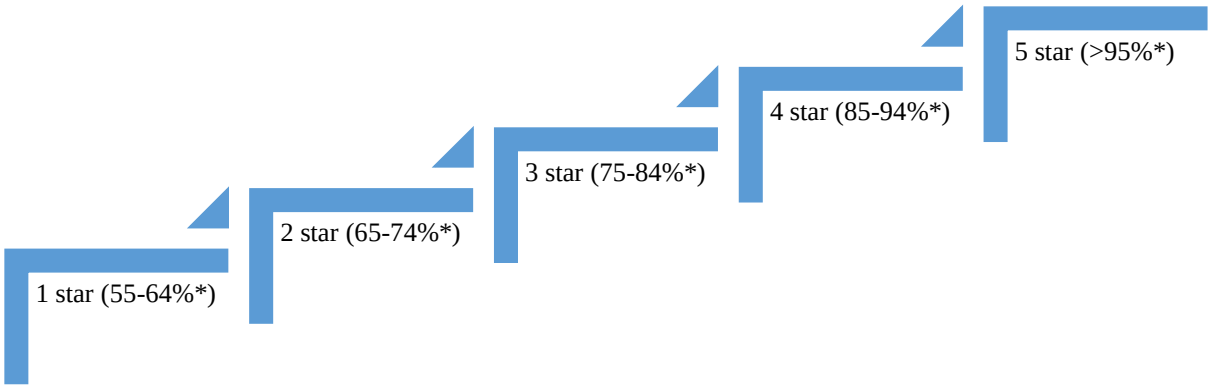
Infection prevention and control in TB laboratories

Poor infection prevention and control practices and could contribute to inaccurate results of TB diagnostic tests due to contamination of the patient's specimen. Lack of a bio chamber / hood

required to maintain s safe working environment for the staff could contribute to their reluctance to perform the TB tests. Lab IPC is critical in preventing laboratory acquired infections as well as preventing errors in specimen processing and should be considered when assessing TB laboratory services. (Ridderhof et al., 2007)

In 2011, The WHO Africa Regional Office reached a consensus on minimum standards for laboratory accreditation an launched the WHO Stepwise Laboratory Improvement Process towards Accreditation (SPILTA) (WHO, 2011). It recommends that following the prescribed WHO checklist, the laboratories must meet the minimum threshold of at least 95% in order to qualify for 5-star accreditation, 85% for four star, 75% for 3 star, 65% for 2 star and 55% for one star as per the figure below.

The SLIPTA stepwise process towards accreditation



*% score on on-site audit.

≥ 95% score on on-site audit leads to national/regional/international accreditation body.

Figure 2: SLIPTA tiers of recognition of laboratory quality management (WHO, 2011)

CHAPTER THREE: METHODOLOGY

This chapter outlines the study design, study area, study population, sampling, data collection instruments and procedures, including the data processing and analysis plans and ethical considerations.

3.1 Study design

A cross sectional survey of 73 selected TB laboratories in Nairobi County was conducted in 2016.

3.2 Study area

This study was carried out in Nairobi City County, which is the smallest of the 47 counties, but with the largest population in Kenya. It has a total area of 696 square kilometers with a general population of 3,375, 000 and a population density of 4,8000 per square kilometers (Kenya National Bureau of Statistics, 2015). Nairobi City County had the highest number (13,917) of TB patients reported in 2014 out of 89,294 total TB cases reported that year, accounting for nearly 16% of all TB cases in the country.

Nairobi City County borders Kiambu County to the North, Kajiado County to the south and Machakos County to the east. The County has 17 parliamentary constituencies; Westlands. Dagoretti North and South, Langata, Kibra, Roysambu, Kasarani, Ruaka, Embakasi North, South, Central, East and West, Makadara, Kamukunji, Starehe and Mathare. The Kenya Health Policy 2014 – 2030 categorizes health facilities as Level 1: Community, Level 2: Dispensaries, Level 3: Health Centers, Level 4: Primary referral facilities, Level 5: Secondary referral facilities, Level 6: Tertiary referral facilities. Nairobi has one national public level 6 facility, 54 level 4-6 facilities

and 599 level 2-3 facilities of which 216 facilities provide TB treatment. (Ministry of Health, Kenya, 2014b). According to the Kenya Service Provision Assessment survey, 43% of facilities in Nairobi provide TB diagnostic services (Ministry of Health, Kenya, 2014b).

3.3 Study population

The study population was all health facilities in Nairobi city county providing TB laboratory diagnostic services.

The Kenya Service Provision Assessment Survey 2010 indicates that 74% of healthcare facilities provide any form of TB services that includes any or all of the following: diagnosis, treatment, and follow up. Approximately only 84 (38%) provided TB diagnostic services (Ministry of Medical Services, Kenya et al., 2010). In Nairobi, 43% of facilities offer any TB diagnostic services (Ministry of Medical Services, Kenya et al., 2010).

3.4 Inclusion and exclusion criteria

3.4.1 Inclusion criteria

- Health facilities providing TB diagnostic services

3.4.2 Exclusion criteria

- Health facilities in Nairobi whose administrators declined to participate

3.5 Sampling

3.5.1 Sample size calculation

Sample size calculation was done using Yamane simplified formula to calculate sample size for proportions (Yamane, 1967).

$$n = \frac{N}{1 + N (e)^2}$$

Where
n is the sample size
N is the population
e is the confidence interval 95% and P =0.5

$$n = \frac{84}{1+ 84 (0.05)^2}$$

$$n = 69$$

3.5.2 Sampling procedure

The sampling approach was simple random sampling where all 216 facilities with TB diagnostic capacity were listed as per the sampling frame in appendix 3. Every TB lab within a healthcare facility was selected without replacement to obtain the 73 sampled facilities.

3.6 Data collection procedure

Data were collected using an excel sheet based modified version of the GLI Lab assessment tool (Global Laboratory Initiative, 2013) (Appendix 2).

The data abstraction form (see appendix 2) was pretested for use in facilities that were not selected for the study in Nairobi City County. It was then administered at the sampled facilities with the help of two trained research assistants. The facility manager was given information concerning the

study and requested to sign the consent form (appendix 1). The research assistants then proceeded to the health facility TB laboratory and administered the questionnaire to the laboratory personnel therein on sputum processing techniques and infection prevention and control practices, as they made observations on the availability of guidelines and SOPs, supplies and equipment.

The recording and reporting tools; AFB Register, Genexpert register, Facility consumption and data report and request (FCDRR) form (appendix 4 and 5 respectively) were reviewed for completeness of the last months entry and submissions, including date of receipt of supplies and equipment compared to when the request was placed. External quality assurance reports were reviewed by reviewing the EQA files stored in the laboratory and scrutinized for evidence of the report having been discussed with the relevant laboratory staff by verifying the staff signature as acknowledgement of receipt of results.

3.7 Variables

The dependent variable was the TB lab diagnostic capacity with 5-star SLIPTA ranking. The independent variables evaluated were presence and use of TB lab guidelines and Standard Operating Procedures (SOPs), TB lab staffing, TB lab External Quality Assurance (EQA), TB lab recording and reporting, TB specimen processing, TB diagnostic equipment, TB diagnostic supplies and TB infection prevention and control (IPC).

3.8 Data processing and analysis

Data abstraction forms were checked for completeness, and verification done before the research assistant exited the healthcare facility. Thereafter, the data was double entered into an electronic database to ensure quality. At data entry, completeness was verified, and the data entry form was

formatted not to allow any value other than 1 or 2. Data cleaning was performed to check for accuracies and consistencies using MS Excel and data analysis was performed using SPSS version 23 and Epi info version 7.2.

Descriptive analysis was done to describe the frequencies and proportions of the data. The average of all questions was computed as the average score for each independent variable described in the variables section (3.6). The data collected was stored in a secure password protected personal computer, with restricted access to the principle investigator on the premises of the University of Nairobi School of Public Health as were the signed consent forms. The laboratories were assessed, and their evaluation was based on 8 key factors of the WHO's GLC criteria for assessing TB laboratories. These key factors include the policy documents, guidelines and SOPs on AFB microscopy and Genexpert, staffing, external quality assurance, standardized recording and reporting formats, standardized specimen processing, Equipment, Supplies, and finally the infection prevention and control aspect. Each response was scored with one (1) for availability of the item under each independent variable in question and zero (0) for unavailability. An average score was computed, and the results tabled. The health facility laboratory services were reviewed against the threshold of at least 95% according to the SLIPTA recommendations (WHO, 2011) and P values were calculated to determine deviation from the 5 star SLIPTA ranking.

3.9 Ethical considerations

Ethical approval from KNH-ERC/A/469 was obtained on 13th December 2016 (see appendix 4).Ethical considerations included confidentiality of all the healthcare facility details as provided in the TB 4 register. Confidentiality of the score of the evaluation facility TB lab diagnostic capacity was also observed. This was done by coding for the facility names. Additional permission

was sought and obtained from the head of the National TB Leprosy and Lung Disease Program (see appendix 5) and the health facility managers to go ahead with abstraction of data at the health facility.

CHAPTER FOUR: RESULTS

This chapter presents findings of the study which has been organized based on the study objectives.

4.1 Characteristics of selected TB laboratories in Nairobi City County

Of the 73 facilities sampled, 31 were government owned while 42 were owned by private individuals or Faith Based Organizations (FBOs). There were 55 facilities sampled that were classified as level 2 or 3 i.e. were at the level of dispensaries and Health Centers (26 government owned and 29 private or FBO owned). There were 13 facilities sampled at level 4 or 5 i.e. were primary or secondary referral facilities (5 government owned and 8 private or FBO owned). There were only 5 level 6 (tertiary referral facilities) sampled and all were private or FBO owned as shown on figure 3 below.

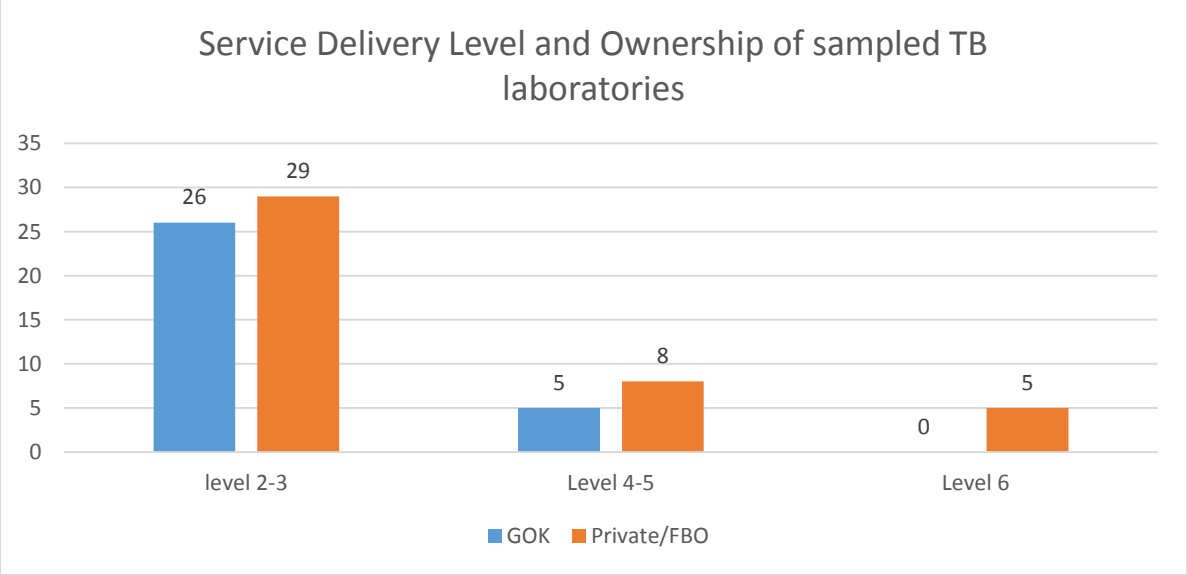


Figure 3: Service delivery level and ownership of sampled TB laboratories

4.2 Assessment of TB diagnostic capacity independent variables

4.2.1 Assessment of availability and use of TB laboratory guidelines and SOPs

Technical guidelines on AFB microscopy, Internal Quality Control, External Quality Assessment and biosafety were available in only 66% of the facilities (P<0.05), while SOPs were available in only 31% of the facilities (P<0.05). Standard forms for ordering supplies and referral of specimen were only available in 85% (P<0.05) and 80% (P<0.05) of facilities respectively. All facilities had SOPs and job aids (P>0.05) and all were implementing the policy of processing two samples for follow up sputum (P>0.05). The table 1 below presents a summary of the presence or absence of policy documents, guidelines and SOPs on AFB Microscopy and Genexpert of the 73 facilities.

Table 1: Assessment of presence and use of guidelines and SOPs in TB labs (n=73)

Guidelines and SOPs parameters	**Frequency n (%)**		**P Value**
	Yes	**No**	
Technical guides on Acid Fast Bacilli microscopy, Internal Quality Control, External Quality Assessment and biosafety	48 (65.8)	25 (34.2)	< 0.05
SOPs	23 (31.5)	50 (68.5)	< 0.05
Job aids	73 (100.0)	0 (0.0)	0.95
Sputum request and report form	73 (100.0)	0 (0.0)	0.95
Quarterly/annual performance report form	71 (97.3)	2 (2.7)	0.82
Standard form for ordering supplies (Facility Commodity and Drugs Recording and Reporting tool)	62 (84.9)	11 (15.1)	< 0.05
Inventory of supplies/stock cards	66 (90.4)	7 (9.6)	0.04
Policy on specimen referral	60 (82.2)	13 (17.8)	< 0.05
Request form for referral of specimen	59 (80.8)	14 (19.2)	< 0.05
2 samples processes for follow up sputum >75% of follow up cases	73 (100.0)	0 (0.0)	0.95
Average Score	60.8 (83.3)	12.2 (16.7)	< 0.05

4.2.2 Assessment of TB laboratory staffing

All facilities had at least one person dedicated to AFB microscopy and all were qualified with a minimum qualification of a diploma (P> 0.05). However only 94.5% of labs had a trained replacement (P> 0.05), and only 11 labs (84.9%) had personnel that had undergone refresher training 11 (P<0.05). The table 2 below shows the level of staffing within the facilities assessed.

Table 2: Assessment of staffing of TB labs (n=73)

Staffing parameters	**Frequency n (%)**		**P Value**
	Yes	**No**	**(0.05)**
1 dedicated person to process sputum for TB microscopy	73 (100.0)	0 (0.0)	0.95
Lab staff have a minimum qualification of diploma	73 (100.0)	0 (0.0)	0.95
Lab staff have had refresher training on sputum microscopy in the last year	62 (84.9)	11 (15.1)	< 0.05
Provision of a trained replacement during absence of trained staff	69 (94.5)	4 (5.5)	0.42
Average Score	69.3 (94.9)	30.8 (5.1)	0.48

4.2.3 Assessment of TB laboratory external quality assurance

Facilities performed well in all areas of external quality assurance with almost all (96%) performing poorly in 3 major areas (P<0.05) facilities had slides collected by someone other than the Sub county TB and Leprosy Coordinator (SCTLC), EQA feedback was not received from last quarter and therefore did not have the opportunity to discuss major errors with the lab staff for investigation and possible solutions in 98.6% of the facilities (P<0.05) of the facilities. The table below shows the evaluation of External Quality Assurance.

Table 3: Assessment of TB labs external quality assurance (n=73)

External Quality Assurance parameters	Frequency n (%)		P Value (0.05)
	Yes	No	
Slides are identified with lab registration number	73 (100.0)	0 (0.0)	0.95
Slides are stored according to serial number	71 (97.3)	2 (2.7)	0.82
Slides collection corresponds to work done in the last month	71 (97.3)	2 (2.7)	0.82
Slides are collected quarterly	71 (97.3)	2 (2.7)	0.82
Slides are collected by SCTLC	3 (4.1)	70 (95.9)	< 0.05
Written EQA feedback	31 (42.5)	42 (57.5)	< 0.05
EQA feedback for the last quarter has been received	1 (1.4)	72 (98.6)	< 0.05
Evidence of Major errors discussed with the Lab staff, investigated and solved	1 (1.4)	72 (98.6)	< 0.05
Evidence of supervision by lab staff and non-lab staff in the last quarter	61 (83.6)	12 (16.4)	< 0.05
Evidence of supervision reports and follow up actions taken	60 (82.2)	13 (17.8)	< 0.05
Average score	44.3 (60.7)	55.7 (39.1)	< 0.05

4.2.4 Assessment of use of TB standard recording and reporting tools

Of the laboratories assessed, all had standard recording and reporting formats (P>0.05). Quarterly reports, Facility Commodity and Drugs Recording and Reporting tool (FCDRR) and referred specimens' logs were done in 93%, 95% and 92% of labs respectively (P>0.05). Of the facilities assessed, 43.8 % (P<0.05) did not correctly and completely fill the sputum request forms. The standardized recording and reporting formats and the findings are as shown below.

Table 4: Assessment of recording and reporting in TB labs (n=73)

Recording and Reporting parameters	Frequency n (%)		P Value
	Yes	No	
The Lab registers are correctly filled	73 (100.0)	0 (0.0)	0.95
Sputum request forms are correctly and completely filled	41 (56.2)	32 (43.8)	< 0.05
Quarterly reports are accurate for the last quarter	68 (93.2)	5 (6.8)	0.24
FCDRR is correctly filled	69 (94.5)	4 (5.5)	0.42
Referred specimens are entered in a logbook	67 (91.8)	6 (8.2)	0.11
Average Score	63.6 (87.1)	36.4 (12.9)	<0.05

4.2.5 Assessment of TB specimen processing procedures

Almost all specimen was processed within 2 days in 97%, (P>0.05) with most facilities 93% having a smear positivity rate of less than 12% (P>0.05). Most labs (96%, P>0.05) had number of samples assessed per month to number of lab staff ratio as less than 20:1 as per the recommended guidelines and 99%, (P<0) did not receive molecular test results within a minimum of 2 weeks. The Table 6 below shows the facilities standardized specimen processing capabilities and efficiency

Table 5: Assessment of TB specimen processing in TB labs (n=73)

TB Specimen Processing parameters	**Frequency n (%)**		**P Value**
	Yes	**No**	
Specimen is processed within 2 days	71 (97.3)	2 (2.7)	0.82
Smear positivity rate is <12% for new patients	68 (93.2)	5 (6.8)	0.24
Ratio of number of samples assessed per month to number of lab staff is <20:1	70 (95.9)	3 (41.1)	0.64
Results of referred molecular tests arrive within a minimum of 2 weeks	1 (1.4)	72 (98.6)	< 0.05
Average score	52.5 (71.9)	47.5 (28.1)	< 0.05

4.2.6 Assessment of TB diagnostic equipment

Of the laboratories assessed, all had adequate equipment that was in good condition (P>0.05) There were only 6 out of 73 facilities that had a genexpert machine. Some facilities 83.6% (P<0.05) did not have good smear staining as per the guidelines. The results below show the findings on the evaluation of the equipment available at the facilities.

Table 6: Assessment of TB lab diagnostic equipment (n=73)

TB diagnostic equipment parameters	Frequency n (%)		P Value
	Yes	No	
Microscope in good working order present	73 (100.0)	0 (0.0)	0.95
Good quality immersion oil is used (not cedar or xylene)	73 (100.0)	0 (0.0)	0.95
Genexpert in good working order present	6 (8.2)	N/A	< 0.05
Quality of smear staining is good	61 (83.6)	12 (16.4)	< 0.05
Average score	53.3 (72.9)	46.7 (27.1)	< 0.05

4.2.7 Assessment of TB lab diagnostic supplies

Of the laboratories assessed, 78.1% did not have supplies delivered on time during the last quarter (P<0.05). Laboratories that did not receive supplies according to their order in the last quarter were 30% (P<0.05). All facilities reported that there were however no stock outs or expiries in the last year (P>0.05). The results in Table 8 shows the findings on supplies received and maintained by the facilities.

Table 7: Assessment of TB lab diagnostic supplies (n=73)

TB diagnostic supplies parameters	Frequency n (%)		P Value
	Yes	No	
Supplies ordered on time in the last quarter	16 (21.9)	57 (78.1)	< 0.05
Supplies received were according to the order in the last quarter	51 (69.9)	22 (30.1)	< 0.05
There were no stock outs in the last year	73 (100.0)	0 (0.0)	0.95
There were no expiries in the last year	73 (100.0)	0 (0.0)	0.95
Average score	53.2 (72.9)	46.8 (27.1)	< 0.05

4.2.8 Assessment of infection prevention and control measures at the TB laboratory

All facilities had good natural or mechanical ventilation, a sputum collection area outside the laboratory and were practicing disinfection or safe disposal of smearing tools (P>0.05). However only 85% (P<0.05) of facilities had protected work surface for smearing e.g. disposable paper/ or disinfectable surfaces. The table below shows findings on the laboratory's infection prevention and control status of the facilities

Table 8: Assessment of TB infection and control in TB labs (n=73)

TB Infection Prevention and Control parameters	**Frequency n (%)**		**P Value**
	Yes	**No**	
There is good natural or mechanical ventilation	73 (100.0)	0 (0.0)	0.95
Sputum collection area is done outside the laboratory	73 (100.0)	0 (0.0)	0.95
Work surface for smearing is protected e.g. disposable paper/can be disinfected	62 (84.9)	11 (15.1)	< 0.05
There is disinfection or safe disposal of smearing tools	73 (100.0)	0 (0.0)	0.95
Average score	70.2 (96.2)	29.8 (3.8)	0.68

4.3 Evaluation of the Diagnostic capacity of selected TB laboratories in Nairobi City County

Analysis was done as per the accreditation thresholds provided by the SLIPTA criteria of 95% for 5-star ranking. 5-star ranking was achieved by 94.9% of all the labs on average in staffing (P>0.05), and 96.2%, if the labs in infection prevention and control P>0.05). The most poorly performing was external quality assurance (60.7%), followed by specimen processing (71.9%), supplies and equipment (72.9%), guidelines and SOP availability and use (83.3%) all having P values of less than 0.05 as shown in table 9 below.

Table 9: Nairobi City County TB lab diagnostic capacity at per the 5-star SLIPTA ranking

TB diagnostic capacity independent variables – SLIPTA 5-star ranking	**Frequency n (%)**		**P Value**
	Yes	**No**	**95%**
Guidelines and SOPs availability and use checklist of TB labs	60.8 (83.3)	12.2 (16.7)	< 0.05
Staffing checklist of TB labs	69.3 (94.9)	30.8 (5.1)	0.48
External Quality Assurance checklist of TB labs	44.3 (60.7)	55.7 (39.1)	< 0.05
Recording and Reporting checklist of TB labs	63.6 (87.1)	36.4 (12.9)	< 0.05
Specimen Processing checklist of TB labs	52.5 (71.9)	47.5 (28.1)	< 0.05
Equipment checklist of TB labs	53.3 (72.9)	46.7 (27.1)	< 0.05
Supplies checklist of TB labs	53.2 (72.9)	46.8 (27.1)	< 0.05
Infection Prevention and Control of TB labs	70.2 (96.2)	29.8 (3.8)	0.68

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

The aim of the study was to determine the tuberculosis diagnostic capacity of selected TB laboratories in Nairobi City County.

5.1.1 Characteristics of selected TB laboratories in Nairobi City County

The characteristics of sampled health facilities shows that all levels of healthcare facilities are able to provide TB diagnostic facilities indicating that TB diagnosis has been decentralized to the lowest health facility level. The characteristics of sampled health facilities shows that the private or FBO sector provides more than half 42 (58%) of facilities sampled indicating that they are key stakeholders where TB diagnostic capacity is concerned. This is similar to data derived from the Kenya Service Provision Assessment survey that showed, that 43% of sampled facilities in Nairobi providing any TB diagnostic services, are in the private or FBO sector (Ministry of Medical Services, Kenya et al., 2010).

5.1.2 Diagnostic capacity of selected TB laboratories in Nairobi City County

5.1.2.1 Guidelines and SOPs of TB laboratories

Lack of technical guidance in a third of the facilities and lack of SOPs in about three quarters of the facilities is a point of concern as it could compromise the quality of TB laboratory services. On average, none of the laboratories sampled met the SLIPTA (WHO, 2011) threshold for five star accreditation on the average score on guidelines and SOP availability and use (83.3%), $P<0.05$. Technical guidance on TB laboratory diagnosis is critical in providing standards that

should be adhered to for optimal TB diagnostic services. (Ridderhof et al., 2007)

5.1.2.2 Staffing of TB laboratories

It has been documented that shortage of trained laboratory technicians hampers TB lab services and recommends minimal training of a 2-3 year diploma to a university degree as the requirements to man a TB lab with additional refresher training in new technologies and management skills. (Ridderhof et al., 2007). On average, most labs met the SLIPTA (WHO, 2011) threshold for five star accreditation on the average score on staffing.

5.1.2.3 External Quality Assurance of TB laboratories

Facilities performed well in laboratory preparation for external quality assurance; Slides were identified with lab registration number and were stored according to serial number, collected quarterly with slide collection corresponding to work done in the last month. External factors influencing the external quality assurance performed poorly, where almost all (96%) of facilities had slides collected by someone other than the Sub county TB and Leprosy Coordinator (SCTLC) ($P<0.05$). EQA feedback had not received from the preceding quarter and therefore the external lab personnel did not have the opportunity to discuss major errors with the lab staff for investigation and possible solutions in 98.6% of the facilities ($P<0.05$).

On average, most labs did not meet the minimum SLIPTA threshold for 5-star accreditation in terms of external quality assurance. This is a major gap in the provision of TB diagnostic services as EQA has been shown to strengthen TB laboratory services and improving diagnostic quality. (Ridderhof et al., 2007)

5.1.2.4 Recording and reporting of TB laboratories

Of the laboratories assessed, all had correctly filled lab registers, though about half did not correctly and completely fill the sputum request forms ($P<0.05$). Quarterly reports, Facility Consumption and Data Reporting and Requesting tool (FCDRR) and referred specimens' logs were well done in almost all facilities. On average, most labs did not meet the minimum SLIPTA threshold for 5-star accreditation with regards to recording and reporting mainly due to incomplete filling of sputum request forms.

There have been almost similar results shown in Kenya indicating that laboratory staff are well trained in recording and reporting and ensure that it is done. However, the main challenge lies in the completion of sputum request forms that needs improvement.

5.1.2.5 Specimen Processing of TB laboratories

Almost all specimens were processed within 2 days in 71 labs which is in line with the WHO recommendation (World Health Organization, 2013). Most labs had number of samples assessed per month to number of lab staff ratio as less than 20:1 as per the recommended guidelines. However almost all labs (99%), did not receive molecular test results within a minimum of 2 weeks ($P<0.05$).

With the exception of the turnaround time for molecular testing, most labs were able to achieve a SLIPTA 5-star rating. However poor performance on turnaround time for molecular texting (Genexpert testing) reduced this average to 72% ($P<0.05$). This could be due to the fact that there were few Genexpert testing facilities as per the equipment assessment in table 7 where only 6 of the 73 facilities assessed had Genexpert equipment.

5.1.2.6 Equipment of TB laboratories

Of the laboratories assessed, all had adequate equipment that was in good condition. There were only 6 facilities that had a Genexpert machine. This would indicate that there is a need to increase the number of Genexpert testing laboratories or improve the transportation of specimen and results. On average, the laboratories were not able to achieve a SLIPTA 5-star rating based on the average score for equipment.

Well-functioning equipment is critical in provision of TB diagnostic services. Equipment management policies and maintenance strategies involving the health facility staff , equipment manufacturers as well as leaders and administrators need to come together to ensure TB diagnostic equipment is procured and maintained according to the needs of the population. (Fonjungo et al., 2012)

5.1.2.7 Supplies of TB laboratories

Of the laboratories assessed, about a quarter did not have supplies delivered on time during the last quarter, with about a third of them not receiving supplies according to their order in the last quarter. All facilities reported that there were, however, no stock outs or expiries in the last year. Adequate supplies are critical in the provision of TB lab diagnostics as even the best equipment would be rendered useless without suitable supplies and reagents. Timeliness in supply provision and avoidance of stock outs is critical in preventing TB diagnostic delays. (Ridderhof et al., 2007)

5.1.2.8 Infection Prevention and Control of TB laboratories

All facilities had good natural or mechanical ventilation, a sputum collection area outside the

laboratory and were practicing disinfection or safe disposal of smearing tools. However only 85%, of facilities had protected work surface for smearing e.g. disposable paper/ or disinfectable surfaces. With the exception a disinfectable work surface, most labs were able to achieve a SLIPTA 5-star rating.

Lab IPC is critical in preventing laboratory acquired infections as well as preventing errors in specimen processing. This is an important factor and should be considered when assessing TB laboratory services. (Ridderhof et al., 2007)

5.1.2.9 Overall characteristics of the diagnostic capacity of selected health facilities in Nairobi County

5-star ranking was achieved by all the labs on average in staffing and infection prevention and control ($P>0.05$). The most poorly performing was external quality assurance 60.7%, followed by specimen processing (71.9%), supplies and equipment (72.9%), guidelines and SOP availability and use (83.3%) all with significant P values.

Improvements are required in technical guidelines and SOP use, refresher training for lab staff, external quality assurance, filling of sputum request forms, Genexpert availability and transport of specimen and results to and from Genexpert sites, timely ordering and dispatching of lab supplies and provision of disinfectable work surfaces are the most critical improvements needed in order for labs in Nairobi county to achieve SLIPTA 5 star accreditation.

A Study in Uganda concluded that the systematic use of a standardized laboratory checklist can be a tool to improve performance of peripheral TB labs through correction of identified shortcomings proactively to reduce errors and delays in diagnosis. (Aziz and Bretzel, 2002).A study in Malawi reached a similar conclusion that incorporating quality control procedures in routine TB diagnosis

results in reliable TB diagnostic services and is useful for implementing national quality assurance programs. (Mundy et al., 2002) This approach could be used in Kenya to ensure that assessment of TB laboratory capacity is useful to improve quality and reduce TB diagnostic delays.

5.2 Study Limitations

The main limitation of this study was its inability to assess additional factors that influenced TB diagnostic service provision, for example budgetary allocation towards TB supplies and equipment, salaries and wages and training of staff. Other factors could include leadership and governance of the health facility management.

5.3 Conclusions

The TB diagnostic capacity of laboratories in Nairobi County did not meet SLIPTA 5-star accreditation in six out of eight areas on assessment using the GLI assessment tool. The WHO GLI laboratory assessment tool is a useful tool that can assist laboratories achieve stepwise WHO lab accreditation towards improved TB diagnosis consequently contributing to reduction of morbidity and mortality related to tuberculosis.

5.4 Recommendations

Building the capacity on leadership and governance and provision of adequate financing have a role in improving TB diagnostic capacity in a bid to address the highlighted areas of weakness. Assessment of the TB laboratory diagnostic capacity using WHO GLI laboratory assessment tool is a useful way of assisting TB laboratories achieve SLIPTA accreditation, ultimately improving TB diagnosis and treatment outcomes.

Additional factors that influence TB diagnostic service provision, for example, leadership and governance of the health facility management, budgetary allocation towards TB supplies and equipment, salaries and wages and training of staff should be studied as possible factors that affect the diagnostic capacity of TB laboratories,

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APPENDICES

Appendix 1 Informed consent form

Modified WHO informed consent form for qualitative studies

University of Nairobi	REPULBLIC OF KENYA MINISTRY OF HEALTH National Tuberculosis, Leprosy & Lung Disease Program

Informed Consent Form for Healthcare facilities in Nairobi County

This informed consent form is for in charges of healthcare facilities in Nairobi and who we are inviting to participate in this research titled "Relationship between healthcare facility tuberculosis diagnostic capacity and tuberculosis mortality in Nairobi County, Kenya".

Principle Investigator: Dr. Christine Wambugu

Organizations: University of Nairobi and National Tuberculosis, Leprosy and Lung Disease Program

Part I: Information Sheet

Introduction

I am a student studying MSc. Health Systems Management at the University of Nairobi and working as the tuberculosis and HIV program coordinator at the National Tuberculosis, Leprosy and Lung Disease Program. I am doing a research on the diagnostic capacity of the healthcare

facilities. Please find below some background information on this study. Any questions regarding information not provided for will be answered by the principle investigator whose contacts are provided for at the end of this form.

Purpose of the research

The purpose of this study is to look at the capacity of health facilities to offer TB diagnostic services.

Type of Research Intervention

This study will involve the filling in of a data abstraction form administered to the staff working in the laboratory.

Participant Selection

Your Healthcare Facility has been chosen to participate in this study because it provides tuberculosis treatment and tuberculosis diagnostic services in Nairobi.

Voluntary Participation

Your participation in this study is entirely voluntary. All tuberculosis related governmental assistance will still be provided to your facility whether or not you participate in this study. You may change your mind later even after agreeing to participate in the study with no consequence.

Procedures

We are asking you to help us learn more about the tuberculosis diagnostic capacity of the healthcare facilities. We are inviting your facility to take part in this study. If you accept, you will be some questions.

The questionnaire will be read out to you by the principle investigator who will record your responses. There will not be any recording of any facility or individual patient's names.

If you do not wish to answer any of the questions included in the study, you may skip them and move on to the next question. The information recorded is confidential and the name of the healthcare facility will not be included in the forms. The healthcare facility will only be identified by a unique number known only to the principle investigator.

Duration

This study is expected to take approximately three hours, of which will be in the healthcare facilities laboratory.

Risks

The facility name will not be revealed in the study. All tuberculosis related governmental assistance will still be provided to your facility whether or not you participate in this study. You may change your mind later even after agreeing to participate in the study with no consequence.

Benefits

There are no direct benefits in participating in this study, but your participation will help us find out more about how to enhance tuberculosis diagnosis.

Reimbursements

There will not be any incentives or reimbursements provided to take part in this study.

Confidentiality

Results from this study will not include the name of the healthcare facility for confidentiality. No other individual aside from the principle investigator will have access to this data. Any information concerning this facility will be listed under a random number and not the facility name and this will be stored under lock and key at the University of Nairobi School of Public Health. It shall not be shared with or given to anyone except those with prior access such as officials from the Ministry of Health's' National Tuberculosis, Leprosy and Lung Disease Program, and the University of Nairobi School of Public Health.

Sharing the Results

Knowledge that we get from this study will be shared with you before it is made available to the public. Each participant will receive a summary of the results. The results will also be published so that other interested people may learn from this study.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your facility or facility-related evaluations in any way. You may stop participating in the study at any time that you wish without your facility being affected. You will be given an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with the responses or if you were not understood correctly.

Who to Contact

This proposal has been reviewed and approved by National Ethics Review Committee, which is a committee whose task it is to make sure that research participants are protected from harm. If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Dr. Christine Wambugu, NTLD-P, Afya House annex building, First floor room 125, 0722676696, cwambugu@nltp.co.ke. Dr. Richard Ayah, University of Nairobi, School of Public Health, Kenyatta National Hospital Grounds, 0720940526, richardayah@gmail.com. The secretariat KNH- UON ERC, University of Nairobi, College of Health Sciences P. O. Box 19676 Code 00202, Nairobi. Tel. (254-020) 2726300-9 Ext 44355, E-mail: uonknh_erc@uonbi.ac.ke Kenyatta National Hospital, P. O. Box 20723, Code 00202, Nairobi, Tel. (254-020) 2726300-9 Ext 44355, E-mail: uonknh_erc@uonbi.ac.ke

Part II: Certificate of Consent

I have been invited to participate in the research on the tuberculosis diagnostic capacity of healthcare facilities.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked to have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant: _____

Signature of Participant: _____

Date: _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability, made sure that the participant understands that the following will be done:

1. Interviews to the laboratory staff

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this form has been provided to the participant.

Date: _____ _____ (Day/month/year)

Signature: _____

Appendix 2 Data collection tools

GLI data collection tool (WHO, 2012)

B3. Peripheral level

For accreditation mandatory policies and procedures are highlighted in white on grey background

1. Checklist of documentation on AFB microscopy

Copies of following national documents and forms should be available:

	Document	Available Y/N	Comment
1	Technical guides on AFB-microscopy, internal quality control , EQA and bio-safety		
2	SOPs or Job Aides		
3	AFB-microscopy register		
4	Sputum request and report form		
5	Quarterly/annual report form on AFB laboratory performance		
6	Standard form for ordering supplies (if existing separately)		
7	Inventory of supplies/stock cards (if required by guidelines)		
8	Policy on referral of specimens for reference testing		
9	Request form for referral of specimens (reflecting eligibility criteria)		

The column for comments can be used for information such as: included in document…., not applicable

2. Checklist for validation of implementation of policies and procedures at the peripheral level

For accreditation mandatory policies and procedures are highlighted in white on grey background

Annual period of assessment (Note: must include four consecutive quarters): _____

Standard 2. A national AFB-microscopy manual with standard operating procedures exists, and is accessible in some format at all microscopy laboratories.	
The national AFB microscopy manual or at minimum SOPs and job aides are available	Y/N
For at least 75% of TB suspect / follow-up examinations, the appropriate number of smears has been tested according to the national policy (last quarter of the period of assessment only)	Y/N
Standard 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.	
The laboratory position(s) for microscopy has/have been filled with qualified staff according to the national policy If not elaborate:	
All staff responsible for AFB-microscopy, including support staff preparing smears, has been trained	Y/N
- The training included substantial time on practical exercises	
- New laboratory staff responsible for AFB-microscopy has been trained within 3 months, either formally or on-the-spot	
Staff responsible for AFB-microscopy has attended refresher training (including introduction of new AFB microscopy techniques). Year since last training:	
There is provision for qualified staff taking over during absence of trained staff assigned to AFB-microscopy	
Standard 5. External quality assessment targets all laboratories and includes regular supervision visits.	
Rechecking of smears is implemented according to national policy (if this is the EQA method)	Y/N
- Slides are identified with Lab. Registration number	
- Slides are stored according to serial number	
- Results are not written on the slides	
- The collection of slides corresponds to the work done since last sample was taken (total number, first and last lab. registration number)	
- Frequency of collection of slides is according to the national policy	
- The person who collects the slides is according to the national policy	
- There is evidence of written and timely feedback on rechecking results	
- The frequency of feedback is according to the national policy	
- Smears with serious errors are returned to the laboratory staff and discussed	
- If excessive serious errors are found the problem is investigated and solved	

Panel testing is implemented accordingly to national policy (if this is the EQA method)	Y/N
- The frequency of testing is according to the national policy	
- The method of testing (taken on-site or unsupervised) is according to the national policy	
- There is evidence of written feedback of the results	
- There is evidence of remedial action in case of serious problems	
Frequency of supervision during the year assessed has been according to the national policy	Y/N
- By laboratory staff	
- By non-laboratory staff	
Non-routine visits by laboratory staff for serious problems during the year assessed have been conducted	
Supervision reports are available at the microscopy laboratory	
There is evidence of follow-up actions in case of identified challenges	
Standard 6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance are used at all levels of the network.	
The recording and reporting formats are correctly used	Y/N
- The laboratory register is correctly used	
- The sputum request and report form is correctly used	
- The quarterly/annual reports on sputum tests volume gives the correct data during the last quarter	
- The standard for ordering supplies is correctly used	
There is prompt registration and processing of newly arriving specimen (within 2 days)	
The smear positivity rate among TB suspects during the last quarter (or four quarters in case of small numbers) is:	
The smear positivity rate among follow-up smears from smear-positive cases on treatment during the last year is:	Y/N
The total number of smears examined during the year assessed is:	
The total number of smears examined during the year assessed per full time AFB microscopy staff is:	
Type of available microscope (bright field mono/binocular, classical FM, LED FM):	
The condition of the microscope(s) is good	Y/N
Good quality immersion oil is used (ZN) (no cedar oil nor xylene)	
Small tools for smearing and staining are available	
The quality of staining of the smears is adequate: macroscopically (background ZN) and microscopically (AFB in recently stained smears)	Y/N
The average quality of smears kept for rechecking is adequate	
Standard 7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.	

The frequency of ordering supplies is according to the national policy	
The supplies received during the year assessed were according to the requests. If not, elaborate:	
There is an inventory of supplies/stock cards (if required by national guidelines)	
There have been no stock-outs during the period of assessment	Y/N
There are no expired supplies	
Standard 8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.	
The laboratory collaborates with the private sector in examination of sputum smears (referral of patients or sputum specimens)	
Standard 10. AFB-microscopy laboratories are safe for the staff and the community.	
The AFB-smear laboratory environment is adequate and safe	Y/N
- There is good natural or mechanical ventilation	
- The sputum collection area is outside or inside with adequate infection control	
- The work surface for smearing is protected, e.g. disposable paper, disinfection	
- There is disinfection or safe disposal of smearing tools	
- Used sputum pots and other waste is correctly disposed of	
Standard 11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional diagnostic testing.	
- There is evidence that specimens are referred (e.g. logbook)	Y/N
- Results of molecular tests on referred specimens arrive within a maximum of 2 weeks	Y/N

NTLDP modified data collection tool

Assessment of the tuberculosis diagnostic capacity of selected facilities in Nairobi County, Kenya.

Questionnaire Number …… Date …….

Interviewers name……. Consent given? (Y/N)…..

Facility Name ……... Facility MFL Code……

	Description	Response	Coding
Checklist of documentation on AFB microscopy& / genexpert			
	Technical guides on AFB microscopy, IQC, EQA and biosafety	Y/N	Y=2, N=1
	SOPs	Y/N	Y=2, N=1
	Job aids	Y/N	Y=2, N=1
	Sputum request and report form	Y/N	Y=2, N=1
	Quarterly/annual performance report form	Y/N	Y=2, N=1
	Standard form for ordering supplies (FCDRR)	Y/N	Y=2, N=1
	Inventory of supplies/stock cards	Y/N	Y=2, N=1
	Policy on specimen referral	Y/N	Y=2, N=1
	Request form for referral of specimen	Y/N	Y=2, N=1
	2 samples processes for follow up sputum >75% of follow ups	Y/N	Y=2, N=1
Checklist of staffing			
	1 dedicated person to process sputum for TB microscopy	Y/N	Y=2, N=1
	Lab staff have a minimum qualification of diploma	Y/N	Y=2, N=1
	Lab staff have had refresher training on sputum microscopy	Y/N	Y=2, N=1
	Provision of a trained replacement during absence of staff	Y/N	Y=2, N=1
Externa Quality Assurance			
	Slides are identified with lab registration number	Y/N	Y=2, N=1
	Slides are stored according to serial number	Y/N	Y=2, N=1
	Slides collection corresponds to work done in the last month	Y/N	Y=2, N=1
	Slides are collected quarterly	Y/N	Y=2, N=1
	Slides are collected by SCTLC	Y/N	Y=2, N=1
	Written EQA feedback	Y/N	Y=2, N=1
	EQA feedback for the last quarter has been received	Y/N	Y=2, N=1
	Evidence of Major errors discussed with the Lab staff, investigated and solved	Y/N	Y=2, N=1
	Evidence of supervision by lab staff and non-lab staff in the last quarter	Y/N	Y=2, N=1
	Evidence of supervision reports and follow up actions taken	Y/N	Y=2, N=1

Standardized recording and reporting formats			
	The Lab registers are correctly filled	Y/N	Y=2, N=1
	Sputum request forms are correctly and completely filled	Y/N	Y=2, N=1
	Quarterly reports are accurate for the last quarter	Y/N	Y=2, N=1
	FCDRR is correctly filled	Y/N	Y=2, N=1
	Referred specimens are entered in a log book	Y/N	Y=2, N=1
Standardized specimen processing			
	Specimen is processed within 2 days	Y/N	Y=2, N=1
	Smear positivity rate is <12% for new patients	Y/N	Y=2, N=1
	Ratio of number of samples assessed per month to number of lab staff is <20:1	Y/N	Y=2, N=1
	Results of referred molecular tests arrive within a minimum of 2 weeks	Y/N	Y=2, N=1
Equipment			
	Microscope in good working order present	Y/N	Y=2, N=1
	Good quality immersion oil is used (not cedar or xylene)	Y/N	Y=2, N=1
	Genexpert in good working order present	Y/N	Y=2, N=1
	Quality of smear staining is good	Y/N	Y=2, N=1
Supplies			
	Supplies ordered on time in the last quarter	Y/N	Y=2, N=1
	Supplies received were according to the order in the last quarter	Y/N	Y=2, N=1
	There were no stock outs in the last year	Y/N	Y=2, N=1
	There were no expiries in the last year	Y/N	Y=2, N=1
Infection prevention and control			
	There is good natural or mechanical ventilation	Y/N	Y=2, N=1
	Sputum collection area is done outside the laboratory	Y/N	Y=2, N=1
	Work surface for smearing is protected e.g. disposable paper/can be disinfected	Y/N	Y=2, N=1
	There is disinfection or safe disposal of smearing tools	Y/N	Y=2, N=1

Appendix 3 Sampling Frame

*Has a light microscope that can perform AAFB microscopy for TB diagnosis

**Has an FM Microscope that can perform AAFB microscopy for TB diagnosis

***Has a genexpert machine for TB diagnosis

AAR City Centre Clinic*	Afwan Medical Center*
AAR Clinic Sarit Centre(westlands)*	Aga Khan Hospital*
AAR GWH health care Ltd*	Al Amin Nursing Home*
AAR Healthcare Limited (Karen)*	Amurt Health Centre*
Al-Gadhir Clinic*	Andalus Medical Centre
Alice Nursing Home	APTC Health Centre*
Alliance Medical Center	Babadogo (EDARP)*
Avenue Hospital*	Babadogo Health Centre*
Bahati Clinic	Bahati Health Centre**
Central Bank Staff Clinic*	Baraka Dispensary (Nairobi) – Main**
Conerstone Clinic	Baraka medical center (St. Stephen)
CONI Health Centre*	Biafra Lions Clinic
Consolata shrine dispensary*	Bodaki Medical Clinic
Diani Dispensary	Cana Family Life*
Dog Unit Dispensary (O.P. Kenya Police)*	Chandaria Health Centre*
Dorkcare Nursing Home*	Comboni missionary sisters Health Program
Dr. Irimu Medical Clinic	Compassionate Hospital
Dr. J A Alouch	Coptic Hospital (Ngong Road)*
Dr. Kingondu Clinic (Westlands)	Coptic Medical Clinic*
Dr. Mboloi Clinic	Cotolengo Center
Dr. Mureithi Clinic(westlands)	Dandora I Health Centre**
Emmaus Nursing Home*	Dandora II Health Centre**
Family Care Medical Centre & Maternity*	DIWOPA Health Centre*
Garrison Health Centre*	Dr. Muhindi Clinic(Westlands)
Giovanna Dispensary	Dreams Center Dispensary (Langata)**
Githogoro Runda Baptist clinic	Eastleigh Health Centre*
GSU HQ Dispensary (Ruaraka)*	EDARP Dandora Clinic
Huruma Nursing Home & Maternity	Edarp Donholm Clinic
IOM International Organization for migration(gigiri)*	Edarp Komarock Health Centre

Kabete Approved Dispensary(Lower Kabete)*	EDARP Njiru Clinic **
Kabiro Medical Clinic	EDARP Ruai Clinic*
Kahawa Garrison Health Centre	EDARP Soweto Health Centre*
Kamiti Maximum Clinic	Embakasi Health Centre*
KARI Health Clinic*	Gertrude's Hospital*
Kenya Airways Medical Centre	GSU Training School**
Kenyatta University Dispensary	Guru Nanak Hospital*
Kibera Human Development Clinic	Huruma (EDARP)
Kilimanjaro Nursing Home*	Huruma (NCCK) Dispensary
KMTC Dispensary	Huruma Lions Dispensary**
Langata Women Prison dispensary	Imara Health Centre
Lea Toto Clinic (Nairobi West)	Iom Wellness Clinic
Lea Toto Kibera	Jamaa Mission Hospital*
Lea Toto Mukuru	Jericho Health Centre*
Lea Toto Mwiki	Johanna Justin-Jinich Community Clinic (Kibera)
Lithi Clinic*	Kahawa West Health Centre**
Loco Dispensary*	Kaloleni Dispensary
Lower Kabete Dispensary(Kabete)	Kamiti Prison Hospital*
Madina Nursing Home*	Kangemi Health Centre**
Makadara Health Centre	Karen Health Centre
Mary Immaculate Clinic Mukuru*	Kariobangi Edarp
Mary Immaculate Sisters Dispensary*	Kariobangi Health Centre*
Mbagathi District Hospital	Kariobangi South Clinic
Memorial Hospital*	Karura Health Centre(Kiambu Rd)
Metropolitan Hospital Nairobi*	Kasarani Health Centre**
Mji wa Huruma Dispensary	Kayole I Health Centre**
Mkunga Clinic	Kayole II Sub-District Hospital**
Mukuru Crescent Clinic	KEMRI Mimosa*
Nairobi East Hospital*	Kemri VCT
Nairobi Women's Hospital*	Kenyatta National Hospital**
National Spinal Injury Hospital*	Kibera Community Health Centre – AMREF*
National Youth Service HQ dispensary (Ruaraka)*	Kibera D.O. Dispensary*
Ngong Road Health Centre	Kibera South (MSF Belgium) Dispensary**
Nimoli Medical Centre	Kivuli Dispensary*
Nyumbani Diagnostic Laboratory and Medical clinic	Komarock Morden Medical Care

Orthodox Dispensary*	LAD NAN Hospital
Pangani Dispensary	Lagos Road Dispensary
PentaPharm Limited	Langata Health Centre**
Premium Health Services	Lea Toto
Provide International clinic Dandora*	Lea Toto Clinic Kariobangi South
Provide International Korogocho	Lea Toto Kawangware
Radent Hospital	Liverpool VCT
Senye Medical clinic	Lunga Lunga Health Centre**
St Barkita Dispensary Utawala*	Makadara Mercy Sisters Dispensary
St Joseph Nursing Home*	Makkah Nursing Home
St Patrick Health Care Centre*	Mama Lucy Kibaki Hospital – Embakasi**
St Teresa's Parish Dispensary	Mariakani Cottage Hospital Ltd*
St. Angela Merici Health dispensary*	Marura Nursing Home*
Uhuru Camp Dispensary (O.P. Admin Police)*	Marurui Dispensary
University of Nairobi Dispensary*	Mary Mission*
Uzima Dispensary*	Mathare 3A (EDARP)
Wema Medical Clinic*	Mathare North Health Centre
Wentworth Hospital	Mathari Hospital
Westlands Health Centre**	Melchezedek Hospital*
	Menelik Chest Clinic*
	Meridian Equator Hospital*
	Meridian Medical Centre (Town Centre)*
	Moi Air Base Hospital*
	MP Shah Hospital(westlands)*
	Msf-Green House Clinic*
	Mukuru MMM Clinic*
	Muthurwa Clinic
	Mutuini Sub District Hospital*
	Nairobi Hospital*
	Nairobi Remand Prison Health Centre
	Nairobi South Medical Center*
	Nairobi West Hospital
	Nairobi West Men’s Prison Dispensary*
	Nairobi Women’s Hospital Adams*
	Ngara Health center(City Council of Nairobi)*

	Njiru Dispensary
	Pumwani Majengo Dispensary**
	Pumwani Maternity VCT Centre**
	Ray Of Hope Health Centre*
	Reuben Mukuru Health Centre**
	Rhodes Chest Clinic**
	Riruta Health Centre**
	Ruai Health Centre*
	Ruaraka Uhai Neema Hospital
	Shauri Moyo Clinic
	Silanga (MSF Belgium) Dispensary
	SOS Dispensary**
	South B Hospital LTD*
	South B Police Band Dispensary
	Soweto Kayole PHC
	Special Treatment Clinic
	St Alice (EDARP) Dandora*
	St Francis Community Hospital (Kasarani)**
	St John Hospital
	St Joseph Mukasa Dispensary**
	St Joseph W Dispensary (Westlands)*
	St Joseph's Dispensary (Dagoretti)*
	St Mary's Mission Hospital
	St Raphael's Clinic*
	St Vincent Catholic Clinic**
	St. Odilia's Dispensary*
	ST. Veronica EDARP
	Tabitha Medical Clinic
	The Karen Hospital*
	The Mater Hospital Mukuru
	Umoja Health Centre**
	Ushirika Medical Clinic*
	Waithaka Health Centre*
	Wema Nursing Home*

Appendix 4 AFB and Genexpert register

INSTRUCTIONS		
	COLUMN	WHAT TO FILL
1.	Lab Serial No	Enter Serial No. form 001 in 1st January to the last No. on 31st December
2.	Date	Enter the Date when the samples are processed
3.	Time in	Record the time when the sample is received at the Lab
4.	Name	Enter the three Names of the Patient
5.	TB registration number	This is the TB No. given to follow up patients at the chest clinic usually written on the request form
6.	Sex	Enter either M or F
7.	Age	Enter the actual age of the patient
8.	Facility Refferring	Enter the clinic or ward as written on the request form
9.	New	Tick if it is new suspect
10.	Follow up patients	Tick and indicate month of follow up e.g. (2) meaning follow up at 2 months
11.	HIV Status	Indicate either Pos (+ve) or Neg (-ve)
12.	Time Out	Enter time when results are dispatched
13.	Laboratory Officer's Name	Enter the Name of the Examiner

AFB MICROSCOPY SUMMARY													
Enter the monthly summary data	Number of Patients Examined						Number of Smears Examined						
	For Diagnosis			For Follow -Up			For Diagnosis			For Follow -up			
Year ____	Total	Pos.	%	Total	Pos.	%	Total	(+,++, +++)	Exact No.	Total	(+,++, +++)	Exact No.	ZN/FM
January													
February													
March													
April													
May													
June													
July													
August													
September													
October													
November													
December													
Total													

GENEXPERT SUMMARY

Monthly Data	Age		HIV Status		Results						
	Children under 15 years	Adults	Pos +ve	Neg -ve	Total Tests	MTB +ve	MTB +ve RR	MTB +ve Indeter-minate	Invalid	Errors	No Results

Name of Laboratory:_____ Address:_____

Testing laboratory S/ No.	Date	Time in	Name (full)	TB Registra-tion No. for follow ups	Sex M/F	Age (years)	Patients ID No.	Patients Physical Address + phone number	Name of referring facility 1

Type of patient				Microscopy				Serial No.						Time out (Results dispatch)	Laboratory officer's name	Remarks
New	F/up	Others (specify)	HIV Status	Appearance		Results		Date tested	Results (Tick Box)							
				S	M	S	M		MTB-Neg	MTB + RIF	MTB + RiF-	MTB + Rif indeter-minate	Invalid	error			

Appearance: S - saliva B- blood stained M - muco purulent
Results: S- spot M - Morning

Appendix 5 FCDRR

REPUBLIC OF KENYA

MINISTRY OF HEALTH

FACILITY
CONSUMPTION DATA REPORT AND REQUEST (F-CDRR) FOR ANTI-TUBERCULOSIS, LEPROSY MEDICINES & NUTRITION COMMODITIES

Facility Name: .....

Facility Code: .....

County: .....

Sub County: .....

September 2017

COMPLETING THE FACILITY CONSUMPTION DATA REPORT AND REQUEST FOR ANTI-TUBERCULOSIS, ANTI-LEPROSY MEDICINES & NUTRITION COMMODITIES

This data reporting tool is filled by the person in charge of aggregating and reporting on anti-TB and anti-Leprosy medicines for the entire health facility as designated by the facility in-charge.

1) When to perform:

At the end of every reporting period i.e. at the end of every month

The reporting period is the most recent full calendar month (from first day to last day of the month) for which the information is being reported.

2) To be filled on the second page of the F-CDRR book:

Facility name: Write the name of your health facility.

Facility code: Write your Master Facility List (MFL) code.

County: Write the county where the health facility is located.

Sub County: Write the sub county where the health facility is located.

3) To be filled on each report:

Facility name: Write the name of your health facility where the commodities are dispensed.

Facility type: Write the type of facility as dispensary (DISP), health centre (HC), sub County Hospital (SCH), County Referral Hospital (CRH) or National Referral Hospital (NRH)

County: Write the county where the facility is located.

Agency: Indicate by ticking the appropriate box the supporting agency i.e. MOH, Mission, NGO, private or other

Beginning Date (of reporting period): Write the first day of the month and the year (in format dd-mm-yyyy) for the period for which the report is being prepared.

Ending Date (of reporting period): Write the last day, of the month and the year (in format dd-mm-yyyy) for the period for which the report is being prepared.

Commodity/Unit: The commodity and its unit are pre-printed on the report. The commodities are divided into three sections i.e. TB commodities (which include Rifabutin and Cotrimoxazole for Cotrimoxazole preventive therapy amongst TB patients infected with HIV), Leprosy medicines and MDR TB medicines and nutrition commodities.

Beginning Balance at the start of the Quarter (A): Enter the total Quantity (as per the defined unit) of each usable commodity on hand in the facility on the last day of the previous month (reporting period). **The Beginning balance should be equal to the Physical count at the end of the previous month.** If it is not, indicate the loss or adjustment in the respective columns of this F-CDRR and explain in the *Comments* section.

Received this month (B): Enter the Total Quantity (as per the defined unit) of each commodity received by your health facility from an external supplier (e.g. KEMSA) within the month

If no stock was received at the facility during the period, enter a zero ("0") in this column. **The quantities of each commodity received by the facility can be found in the Quantity *Received* column of the Bin card. *Do NOT include quantities issued from the Bulk/ Drug store to the dispensing area.***

Quantity Dispensed (C): Record the total Quantity dispensed to the patients/clients within the month.

If no quantities of a commodity were dispensed to clients / patients during the month, enter "0" in the Quantity dispensed column for that commodity.

Do NOT write the quantities that were issued to the Dispensing area from the Bulk or Drug Store.

The total quantities of each commodity dispensed to clients/patients are recorded in the Total Quantity Dispensed row of the DADR.
If several pages of the DADR have been used over the month, aggregate the figures in this Total Quantity Dispensed row across all the pages used that month for each commodity.

Positive Adjustments (D): Enter the quantity of positive adjustment (in the defined unit) to the stock balance of the commodity. The reason for the positive adjustment should be written in the *"Comments" section.*
A positive **adjustment** refers to stocks of commodities your facility received from other health facilities within the month.

Negative Adjustment (E): A negative adjustment refers to stocks of commodities you issued from your facility to other health facilities within the month.

Adjustments should be recorded in the Bin card when they occur.

Note: Excess quantities counted when stock-taking are also a positive adjustment while quantities of stock found to be missing when stock-taking are indicated as a negative adjustment.

Losses (F): Enter the quantity (in the defined unit) of any loss of stock of the commodity at the facility. Losses include defective, damaged or expired drugs and should be separated from the usable stock. In the Comments section, indicate the actual number of units lost and explain the reason for the loss.

Any missing commodity unaccounted for should be documented and suspected theft investigated according to the government's policy.

Ending Balance (G): This is the stock at the end of the period as reflected on the stock card. It is calculated as indicated in the formula below

G = (A + B + D) – (C + E + F)

Physical Count (H): Enter the total sum (in the defined unit) of usable commodity counted physically in the facility. This should be done at the close of business on the last day of the reporting period and should include quantities from all the dispensing points in the facility.
Note: The Physical count for each commodity should be equal to the expected Ending balance obtained by the calculation above:

Write the Physical count and report any differences between the Physical count and the expected Ending balance from the calculation as Adjustments or Losses. The reason for the adjustments or losses should be written in the "Comments" section.

Earliest Expiry Date (6 months): During the physical count, note and record for each commodity, the Quantity that will expire in less than six months, and write the expiry date (in the format mm/ yyyy). Should there be several short expiry batches, record the dates of each.

Quantity Needed (I): Write the Quantity (in the defined unit) of each commodity required for re-supply for patients. This is determined as follows:

Quantity required for re-supply I = (C x 3) – G i.e. multiply the reporting period's consumption by 3, and then subtract from it the Physical count.

Collection and reporting tools: Indicate the tools required by tool type (DADR, F-CDRR) and page numbers. For a DADR, indicate the size of the book required in number of pages.

Patient Summaries: Indicate the number of patients every month by the following categories: New, Retreatment, Leprosy, MDR, IPT, CPT, NF and RF disaggregated as Adults and Paediatrics.

Supply Box Commodities: Indicate for RHZE and RH tablets, the beginning balances, amount into and out of the supply boxes, amount withdrawn to the district store and ending balances.

Comments: Enter any explanations for the information provided in the report here.
Compiled by: The person responsible for preparing this report should write their full name, designation, contact telephone and date of signing, and then sign

MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

FACILITY LEPROSY, TUBERCULOSIS COMMODITIES CONSUMPTION DATA REPORT & REQUEST FORM

Facility Name: _____ **MFL No.** _____ **County:** _____

Facility Type: ☐ DISP ☐ HC ☐ SCH ☐ CRH ☐ NRH

Agency: ☐ MOH ☐ MISSION ☐ NGO ☐ PRIVATE ☐ OTHER _____

Beginning Date (of Reporting Period): _____ **Ending Date (of Reporting Period):** _____

Commodity	Unit	Beginning Balance (at the start of Month)	Received this Month	Quantity Dispensed	Positive Adjustment	Negative Adjustment	Losses	Ending Balance	Physical Count	Earliest Expiry Date (6 months)		Quantity Needed for Resupply
		A	B	C	D	E	F	G	H	Date	Qty	I
Drug Sensitive TB												
TB Patient Packs	Packs											
R/H/Z/E 150/75/400/275 mg	Tablets											
R/H/Z/E 75/50/150 mg	Tablets											
R/H 75/50 mg	Tablets											
Ethambutol 400 mg	Tablets											
Ethambutol 100 mg	Tablets											
Pyrazinamide 500 mg	Tablets											
Rifampicin 300 mg	Tablets											
Rifampicin 150 mg	Tablets											
Prophylaxis												
Isoniazid 300 mg	Tablets											
Isoniazid 100 mg	Tablets											
Isoniazid syrup 50mg/5ml	Bottle											
Isoniazid 100mg/5ml	Bottle											
Pyridoxine 25 mg	Tablets											
Pyridoxine 50 mg	Tablets											
Leprosy												
MB Adult Blister	Packs											
MB Child Blister Packs	Packs											
PB Adult Blister Packs	Packs											
PB Child Blister Packs	Packs											
Drug Resistant TB												
Capreomycin 1 gm vial	Vial											
Kanamycin 1 gm vial	Vial											
Cycloserine 250mg	Tablets											
Levofloxacin 250mg	Tablets											
Levofloxacin 500mg	Tablets											
Prothionamide 250mg	Tablets											
Para-aminosalicylic acid 4mg	Satchets											
Bedaquiline 100mg	Tablets											
Clofazimine 100mg	Capsule											
Linezolid 600mg	Tablets											
Delaminid 50mg	Tablets											
Nutritional Food Supplements												
RUTF (Ready to use Therapeutic Feed)												
FBF (Fortified Blended Foods)												
Ancillary Medicines (Other)												

Collection or Reporting tool	DAR		CDRR
	50 page	100 page	FCDRR
Quantity Requested			

Patient Summaries

	New	Retreatment	Leprosy	MDR	XDR/BDQ	IPT
Adult						
Children						

Supply Box Commodities

Commodity	Beginning Ballance	Amount into Supply Box	Amount out of Supply Box	Amount withdrawn to county store	Ending Balance
A	B	c	D	E	F
RHZE Tablets					
RH Tablets					

COMMENTS:

Compiled By: _____ **Designation:** _____ **Date:** _____

Appendix 6 KNH-ERC Approval (photocopy)

Appendix 7 NTLDP Approval (photocop