REPUBLIC OF KENYA

MINISTRY OF HEALTH

KENYA TUBERCULOSIS PREVALENCE SURVEY 2016

Survey Report


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REPUBLIC OF KENYA

MINISTRY OF HEALTH

KENYA TUBERCULOSIS PREVALENCE SURVEY

Final Edition
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FOREWORD

Tuberculosis (TB) is a disease of major public health concern in Kenya. It is the fourth leading cause of death, presenting an enormous economic burden to the nation and negatively impacting the lives of its citizens. In the last two decades, Kenya has made significant investments aimed at achieving a satisfactory level of TB control. However, the true burden of the disease upon which to measure these efforts has remained unknown.

In July 2015, we commenced the first national TB prevalence survey in post-independence Kenya; a survey that used Xpert MTB/RIF technology and culture for diagnosis.

Kenya's national TB Prevalence Survey provides a precise estimate of the burden of TB and assesses the associated health seeking behaviour of TB patients and those reporting TB symptoms. The findings will be used to inform country planning and policy for TB control.

A highly competent multi-disciplinary team conducted the survey across 45 counties in Kenya with the support of international experts, and in line with World Health Organisation (WHO) procedures for conducting a national TB Prevalence Survey.

The results show a much higher prevalence of TB than previously estimated and calls for the need to institute measures to arrest the situation. Through the findings, discussions and recommendations presented in this report, we have a rare opportunity to critically re-engineer TB control strategies. Furthermore, these strategies will provide a robust response that will ensure that no TB cases go undetected, untreated and will place Kenya on the road towards ending TB.

Sicily Kariuki

Cabinet Secretary,

Ministry of Health

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Survey Taskforce

Dr Joseph Sitienei – PI; Dr Enos Masini (NTLD-Program)**;** Dr Hillary Kipruto (WHO); Dr Jane Ong'ang'o - Study Coordinator (KEMRI); Dr Bernard Langat (National Treasury); Dr Brenda Mungai (CHS - TB ARC); Dr Joel Kangangi (WHO); Dr Veronica Manduku (KEMRI); Josephine Wahogo Mburu (NTRL); Benson Ulo (AMREF); Peter Kagiri (RPB); Drusilla Nyaboke (NTLD-Program); Faith Ngari (NTLD-Program); Jesse Wambugu (FIND); Wendy Nkirote Mwirigi (NTRL); Geoffrey Okallo (NTLD-Program); Janice Njoroge (CHS); Juliet Mutheu (PATH); Martin Githiomi (NTLD-Program); Mike Mwangi (NPHLS); Samuel Misoi (NTLD-Program); Dickson Kirathe (NTLD-Program); Richard Kiplimo (NTLD-Program); Amos Ndombi (NTLD-Program); Lazarus Odeny (KEMRI/CDC); Timothy Kandie (CHS); Dr Maurice Maina (USAID); Dr Herman Weyenga (CDC Kenya); Dr Martinus Willem Borgdorff (CDC/CGH/OD –KSM); James Nganga (KNBS); Abdulkadir Amin Awes (KNBS); Dr Beatrice Mulama (KNH); Dr Beatrice Mugi (KNH).

Advisory Board Committee

Dr Nicholas Muraguri – DMS - Chair (October 2014-December 2015); Dr Jackson Kioko- DMS - Chair (December 2015- March 2016); Dr Evans Amukoye (KEMRI); Dr Maurice Maina (USAID); Dr Kevin Decock (CDC); Dr Custodia Mandlhate (WHO Representative to Kenya); Mr Zachary Mwangi (Director General KNBS); Josephine Wahogo Mburu (NTRL); Dr Enos Masini (NTLD-Program).

External Experts

Colleen Scott (CDC); Emily Bloss (CDC/OID/NCHHSTP); Eveline Klinkenberg (KNCV); Hazim Timimi (WHO); Ikushi Onozaki (WHO); Irwin Law (WHO); Julia Ershova (CDC); Marina Tadolini (WHO); Satha Peou (WHO); Sayori Kobayashi (WHO); Sushil Pandey (Brisbane Supranational TB Reference Laboratories); Samuel Kamiru (CDC); Ken Omondi (CDC); Nicky Okeyo(CDC)

Contributors to Survey Report Writing

Dr Joseph Sitienei (PI); Dr Enos Masini (Head, NTLD-Program); Dr Hillary Kipruto (WHO); Dr Jane Ong'ang'o (KEMRI); Dr Brenda Mungai (CHS - TB ARC); Dr Martinus Willem Borgdorff (CDC); Christy Hanson (USAID); Josephine Wahogo Mburu (NTRL); Drusilla Nyaboke (NTLD-Program); Faith Ngari (NTLD-Program); Geoffrey Okallo (NTLD-Program); Juliet Mutheu (PATH); Mike Mwangi (NPHLS); Wendy Nkirote Mwirigi (NTRL); Samuel Misoi (NTLD-Program); Benson Ulo (AMREF); Dickson Kirathe (NTLD-Program); Richard Kiplimo (NTLD-Program); Amos Ndombi (NTLD-Program); Lazarus Odeny (KEMRI/CDC); Timothy Kandie (CHS); Dr Stephen Macharia (NTLD-Program); Dr Maurice Maina (USAID); Dr Herman Weyenga (CDC Kenya); Eunice Mailu (NTLD-Program); Joyce Kiarie (NTLD-Program); Rose Wanjiru (NTLD-Program); Aiban Rono (NTLD-Program); Dorothy Mibei (NTLD-Program); Elias Kirimi (NTLD-Program); Dr Newton Omale (NTLD-Program); Dr Immaculate Kathure (NTLD-Program); Dr Richard Muthoka (NTLD-Program); Dr Eunice Omesa (NTLD-Program); Dr Maureen Kamene (NTLD-Program);Dr Jeremiah Chakaya (KAPTLD); Dr Joseph Aluoch (KAPTLD); James Nganga (KNBS); Abdulkadir Amin Awes (KNBS); Janice Njoroge (CHS)

Peter Tum
Principal Secretary of Health

Ministry of Health

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ABBREVIATIONS

AB	Advisory Board
AFB	Acid-Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retroviral Treatment
CDC	Centers For Disease Control and Prevention
CDR	Case Detection Rate
CHMTs	County Health Management Teams
CHVs	Community Health Volunteers
CHWs	Community Health Workers
CI	Confidence Interval
CPT	Co-Trimoxazole Preventive Therapy
CSOs	Civil Society Organisations
CTLC	County Tuberculosis and Leprosy Coordinator
CXR	Chest X-Ray
Deff	Estimated Design Effect
DLTLD	Division of Leprosy, Tuberculosis and Lung Disease
DMU	Data Management Unit
DR TB	Drug Resistant Tuberculosis
DRS	Drug Resistance Survey
DSC	Deputy Survey Coordinator
EA	Enumeration Areas
FAQs	Frequently Asked Questions
HIV	Human Immunodeficiency Virus
HSB	Health Seeking Behaviour Questionnaire
ID	Study Identification Number
IEC	Information Education and Communication Materials
IPT	Isoniazid Preventive Therapy
IT	Information Technology
KEMRI	Kenya Medical Research Institute

KNBS	Kenya National Bureau of Statistics
KPHC	Kenya Population and Housing Census
LIMS	Laboratory Information Management System
LJ	Löwenstein Jensen Medium
MFS	Mobile Field Site
MOH	Ministry of Health
MOTT	Mycobacteria Other Than Tuberculosis
MOS	Measure of Size
MTB	Mycobacterium Tuberculosis
NTLD-P	National Tuberculosis, Leprosy and Lung Disease Program
NLTP	National Leprosy and Tuberculosis Control Program
NTM	Non-tuberculous mycobacteria
NTRL	National Tuberculosis Reference Laboratory
PA	Posterior-Anterior
PACS	Picture Archiving and Communication System
PDA	Personal Digital Assistant
PI	Principal Investigator
PPS	Probability Proportional to Size
PTB	Bacteriologically-confirmed Pulmonary Tuberculosis
QA	Quality Assurance
RIF	Rifampicin Resistance
SARAM	Kenya Service Availability and Readiness Assessment Mapping
SAS	Statistical Application Software
SC	Survey Coordinator
sCHMTs	Sub-County Health Management Teams
sCTLC	**S**ub-County TB Leprosy Coordinator
SIRE-MGIT	Mycobacterial Growth Indicator Tube
SOP	Standard Operating Procedure
SRL	Supranational Reference Laboratory
STATA	Data Analysis and Statistical Software

TB	Tuberculosis
TB ARC	Tuberculosis Accelerated Response and Care
TF	Prevalence Survey Taskforce
TIBU	Electronic Case-Based Surveillance
USAIDS	United States AIDS Program
VE	Village Elders
WHO	World Health Organisation
XDR-TB	Extensively Drug Resistant Tuberculosis

EXECUTIVE SUMMARY

Kenya conducted its first tuberculosis (TB) prevalence survey approximately 60 years ago in 1958-59. Since then, Kenya has relied on WHO estimates to extrapolate incidence and case detection rates. In 2015-16, the National Tuberculosis, Leprosy and Lung Disease Program (NTLD-Program) and her partners successfully conducted the first post-independence TB prevalence survey. The survey was fully digital and was conducted in accordance with World Health Organisation (WHO) guidelines for national TB prevalence surveys. The objective of this survey was to determine the prevalence of bacteriologically confirmed pulmonary TB and to assess the health seeking behaviour of TB patients and those reporting TB symptoms.

This was a population based cross sectional survey with a sample size of 72,000 individuals designed to provide national level estimates. One hundred clusters were randomly selected using the probability proportional to size (PPS) method from a Kenya National Bureau of Statistics (KNBS) sampling frame with 32 clusters in urban stratum and 68 in rural stratum. All persons 15 years and above in the selected clusters who had lived in the household for a minimum of 30 consecutive days prior to the survey and who consented to the survey were included. Congregate settings like prisons, schools were excluded. Screening for eligible participants was through the WHO recommended screening strategies: symptom questionnaire and chest radiograph. Bacteriological confirmation for the sputum eligible was by Xpert MTB/RIF positive and/or culture positive.

A census to identify eligible participants enumerated 126,389 individuals. Of these, 76,291 (60%) were eligible and 63,050 were enrolled into the survey hence a participation rate of 83% Participation of females was higher than that of males at 87% and 77% respectively. The highest participation rate was among the older age groups of 65 years and above at 93% and lowest among males 15-34 years at 70%. Rural clusters had a higher participation rate at 87% compared to urban clusters at 74%.

All 63,050 survey participants underwent symptom screening while 99% were screened using chest X-ray. There were 9,715 participants (15%) eligible for sputum examination with a higher number eligible by chest X-ray findings (53%) only and 30% eligible by symptoms only. Out of those eligible for sputum examination, 9,120 (94%) had at least one smear done, 9,121 (94%) had at least one culture done and 8,954 (92%) had Xpert MTB/RIF done.

The key findings were as summarised below:

1. The survey identified a total of 305 prevalent TB cases translating to a weighted prevalence of 558 [95%CI 455-662] per 100,000 adult population. Compared to the 2016 reported notification rate for Kenya, the prevalence to notification ratio was 2.5:1
2. The highest burden of disease was in the 25-34 age group, with a prevalence of 716 per 100,000. Males had a high prevalence rate of 809 per 100, 000 compared to

female prevalence of 359 per 100,000. There was a higher burden of TB in the urban (760 per 100,000 population) compared to rural settings (453 per 100,000 population) and among the elderly over the age of 65 years.

3. The gap between prevalence and notification rates is higher among males, age groups 25-34, and the older age group of 65 years and above.
4. Screening for TB using cough of more than two weeks would have missed 52% of the cases. The combination of cardinal symptoms of cough of more than two weeks, fever, night sweats and weight loss would miss 41% of the prevalent cases. Testing all people with any symptom consistent with TB - cough of any duration, hemoptysis, night sweats, weight loss, fatigue, fever, and shortness of breath - would have substantially increased the case yield to 74%.
5. Twenty six percent of prevalent cases diagnosed during the survey were asymptomatic. They did not have any current cough, fever, weight loss, night sweats, fatigue, breath shortness nor chest pains.
6. The use of Xpert MTB/RIF identified 77.7% of the bacteriological confirmed cases hence increasing the diagnostic yield compared to smear microscopy which had a lower sensitivity of 46%.
7. Chest x-ray emerged to be a good TB screening tool with a sensitivity of 88%. Over 50% of the confirmed TB cases had no classical TB symptoms but had an abnormal chest x-ray.
8. Twenty one percent of the survey participants with respiratory symptoms reported to have sought prior care at private clinics and retail chemists.
9. Sixty seven percent of the prevalent cases with at least one TB related symptom had not sought any health care prior to the survey; majority of them were men.
10. Among the prevalent cases who had sought prior care for their respiratory symptoms, 80% of them had not been diagnosed with TB before the survey.
11. A lower prevalence of HIV among survey cases (16.7%) compared to notified cases (31% in 2015).

Extrapolation of survey prevalence to all forms of TB and all ages presents the following results:

1. An overall national prevalence of 426 (347-504) per 100,000 in 2016.
2. An upward revision of the TB incidence rate to 348 (213-516) in 2016, compared to the pre-survey WHO estimate of 233 per 100 000 (95% CI 188–266) in 2016.
3. By actual numbers, there were about 169,000 (103,000-250,000) people who fell ill with TB disease in 2016.

In response to the high undetected burden of TB, we recommend:

1. Replacement of smear microscopy with a rapid point-of-care diagnostic test, such as Xpert MTB/RIF across all health facilities while enhancing sputum delivery mechanisms at all levels.
2. Implementation of chest X-ray screening for TB.
3. Increasing engagement of private providers including retail pharmacies in TB screening, diagnosis and care.
4. Using integrated and innovative communication strategies to influence community health-care seeking behaviour with a special focus to men.
5. Use of broader TB symptom screening criteria that considers any TB related symptom: cough of any duration, hemoptysis, night sweats, weight loss, fatigue, fever, and shortness of breath.
6. Screening all persons seeking care in all health facilities for TB.
7. An enhanced focus on urban TB care and prevention to address the skewed burden.

1. INTRODUCTION, SURVEY ORGANISATION, METHODS AND PROCEDURES

1.1 Introduction

1.1.1 TB Epidemiology

Tuberculosis is a major public health problem in Kenya. Listed among the 30 high burden countries, Kenya is estimated to detect 72% of bacteriologically confirmed TB and 80% of all cases (WHO, 2016). In 2015, the estimated prevalence of all forms of TB was 233 per 100,000 population while the mortality from all forms of TB was 20 per 100,000 population (WHO, 2016).

Case Notification

Kenya's TB case notification increased from 11,000 (50 per 100,000) in 1990 to a peak of 116,723 (359 per 100,000) cases in 2007 (Ministry of Health, DLTLD, 2008, Kipruto, et al., 2015, WHO, 2016). This increase has been largely attributed to the HIV epidemic and in addition, improved case detection due to the improved diagnostic capacity in the health system with better access to care by decentralization of health facilities.

As shown in Figure 1.1 after 2008, TB cases notified showed a steady decline to an estimated incidence of 268/100,000 population in 2013 (Ministry of Health, NTLD-Program, 2014). The continuous decline of notified TB cases may be due to the scale up of antiretroviral therapy (ART) coverage among people living with HIV and the possibility of already diagnosed TB cases remaining un-notified as demonstrated in the TB inventory study which indicated that 21% of identified cases remain un-notified (Tollefson, et al., 2016).

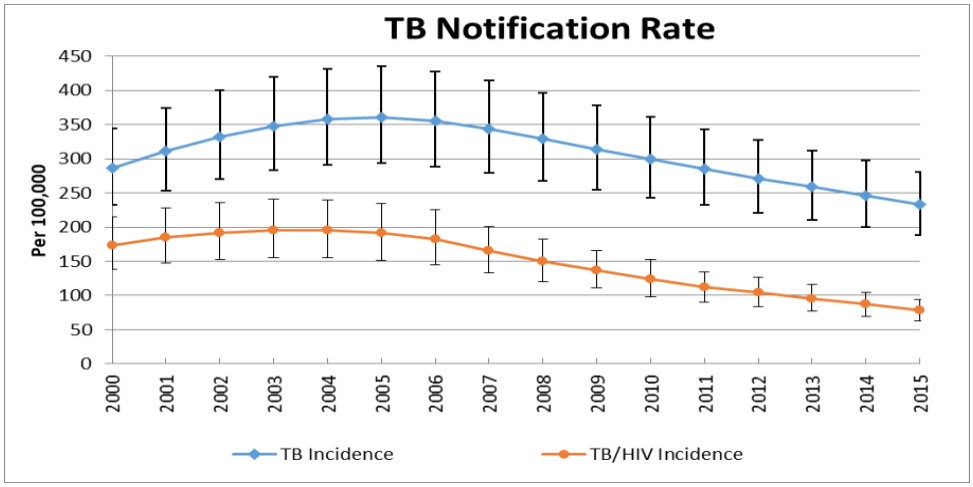


Figure** 1.**1**: **Trend** in **TB** Case Notification 2000-2015, **Kenya

In 2015, a total of 81,518 caes were notified with 83% being pulmonary TB cases of which 45% (36,817) were bacteriologically confirmed TB and previously treated TB cases were 8% (6,776). Half of the cases were among people between the ages of 25 and 44 years while

children from zero to 14 years of age comprised 8.5% of all TB notified cases (Ministry of Health, NTLD-Program, 2015).

Among the notified TB cases, males are disproportionately affected in the ratio 1.4:1 with the highest number in the 24 to 34 years age group. People in urban areas, and particularly those living in informal settlements, bear the biggest brunt of TB in Kenya. In 2015, three regions had the highest reported cases of TB, namely: Nairobi, Nyanza and Coast (Ministry of Health, NTLD-Program, 2015). Ten out of 47 counties accounted for 76% of the notified cases with Nairobi County contributing 15% of all cases.

TB/HIV Co-infection

The TB/HIV co-infection rate has been declining from 60% in 2004 to 31% in 2015 (Ministry of Health, NTLD-Program, 2015) as summarized in Figure 1.2. In line with this, uptake of antiretroviral therapy among HIV co-infected TB patients has been on the increase over time with an uptake of 94% in 2015.

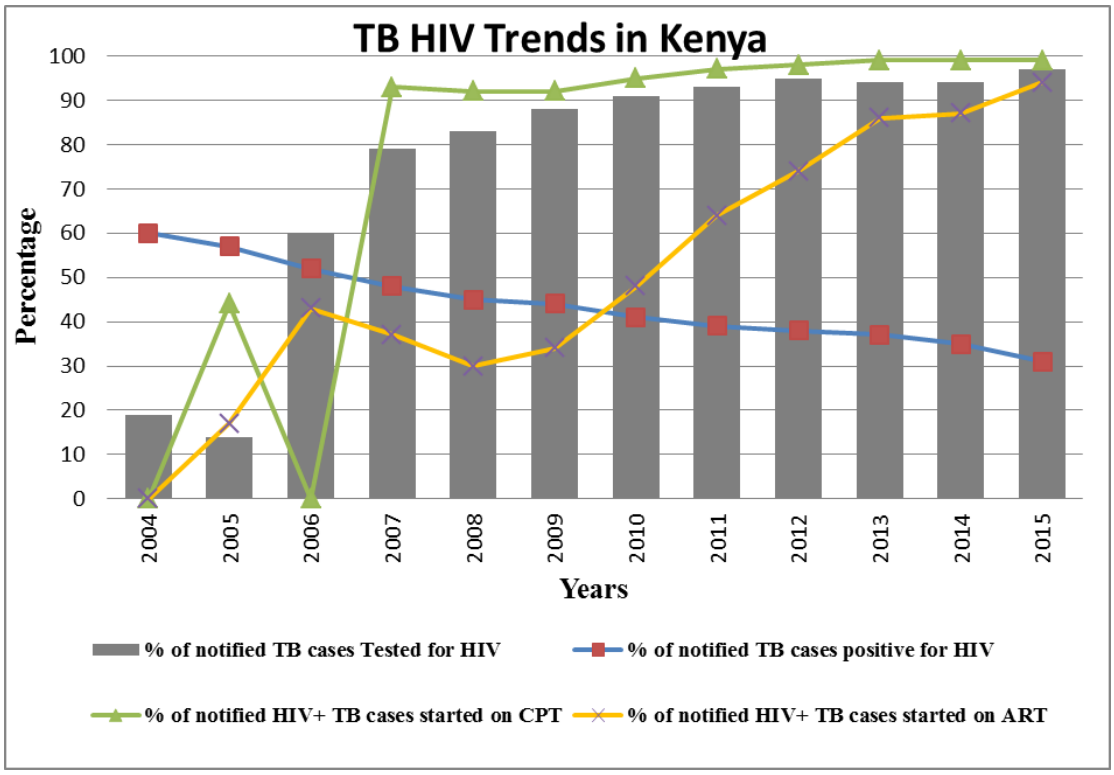


Figure 1.2: TB HIV trends in Kenya, 2004-2015

Drug Resistant TB

According to the drug resistance survey (DRS) of 2015, the prevalence of MDR TB among the previously treated and new cases is 2.1 % and 0.7 % respectively (Ministry of Health, NTLD-Program, 2016). In 2015, 433 DR TB cases were notified with 368 being rifampicin resistant. Twice as many males had MDR TB whilst 2.3 % were children below 15 years of age (Ministry of Health, NTLD-Program, 2015).

1.1.2 Policies, Priorities and Strategies for Tuberculosis Control

Kenya's Vision 2030 aims to achieve **'a globally competitive and prosperous Kenya with a high quality of life by 2030'** (Ministry of Planning and Development, 2008)**.** Health has been identified as one of the key components of the vision's social pillar since it plays a key role in maintaining the healthy and skilled workforce needed to drive the economy. Chapter IV Article 43 I (a) of the Kenyan Constitution envisages access to the highest attainable standard of health to the people of Kenya. Further to this, the Kenya Health Policy 2012 – 2030 aims at attaining the highest possible health standards in a manner responsive to the population needs.

Kenya largely depends on passive case finding for TB case detection. In addition, targeted active case finding strategies are implemented to screen for TB among patients seeking services within the health facilities, contact tracing for TB cases and routine screening of high risk populations (people living with HIV and prisoners). Kenya has also adopted the use of innovative new diagnostics like Xpert MTB/RIF, the expansion of which is expected to increase the number of bacteriologically confirmed and drug resistant TB cases detected.

1.2 Justification for the Survey

Kenya conducted its last national TB prevalence in 1958. At that time, the prevalence of TB was 3,142 per 100,000 population (110,000 cases in a population of 3.5 million aged 10 years or more) (Roelsgaard & Nyboe, 1961). The drivers of TB have certainly changed over the past 60 years.

Recent subnational TB prevalence surveys were conducted in HIV prevalent areas and had limited geographic scope making it difficult to generalize their findings to the whole country. Nonetheless, their results suggest that TB incidence in Kenya may be underestimated (van't Hoog, et al., 2011).

Kenya has thus relied on estimates from WHO to extrapolate incidence and case detection rate of TB. These estimates are based on modelling that uses routine notification data and a number of assumptions including known or estimated annual risk of TB infection, HIV prevalence and socio-economic factors. Considering the known limitations of routine TB data, these estimates are unreliable and are of limited use for country specific planning.

This survey provides more accurate TB prevalence estimates as well as insights on the associated health seeking behaviour of TB patients and those reporting symptoms. The survey further characterizes persons identified with TB that are not yet detected by the NTLD-Program while providing a platform for measuring the impact of TB control activities and progress towards meeting TB control targets.

The findings provide a rare opportunity to critically re-engineer TB control strategies that provide a robust response towards the detection and treatment of all TB cases placing Kenya on the road towards ending TB.

1.3 Objectives

The general objective of the survey was to estimate the burden of Tuberculosis in Kenya.

The specific objectives were:

1. To determine the prevalence of bacteriologically confirmed pulmonary TB (PTB) in the adult population of Kenya.
2. To assess the health care seeking behaviour of symptomatic TB patients and those reporting TB symptoms.

1. 4 Survey Organization

1. 4.1 The Survey Task Force

The Survey Management Committee was referred as the Prevalence Survey Task Force (TF). The TF had representative membership from various stakeholders – Ministry of Health (MoH), the Kenya National Bureau of Statistics (KNBS) and health partner organisations including Civil Society Organisations (CSOs). The TF advised the Principal Investigator (PI) and the Survey Coordinator (SC) on technical issues regarding preparation, implementation, management and reporting of data and its analysis.

Terms of reference of the TF included:

- Finalising the survey protocol and the field manual/standard operating procedures (SOPs)
- Advising on purchase of equipment and supplies
- Advising on pre-testing of materials, training and conducting pilots
- Monitoring data collection and quality control
- Supervision of data collection teams to assure consistency with the SOPs
- Advising on data management and analysis
- Advising on reporting of results

1.4.2 Survey Secretariat

The technical committee was referred to as the secretariat. It comprised of the Principal Investigator (PI), Survey Coordinator (SC), Deputy Survey Coordinator, Laboratory Coordinator, Head of the NTLD-Program, Survey Logistician and selected members of the TF.

The terms of reference for the secretariat included:

- Planning and budgeting for the survey
- Regular meetings to review the progress of survey implementation
- Following up on action points from the TF and Advisory Board

1.4.3. Advisory Board

The Advisory Board (AB) consisted of the Director of Medical Services, representatives from KNBS, World Health Organisation (WHO), United States Agency for International Development (USAID), US Centers for Disease Control and Prevention (CDC) and the Kenya Medical Research Institute (KEMRI).

The primary objective of the board was to guarantee commitment and secure resources for the survey from all stakeholders. The board also provided overall oversight on implementation of the survey.

1.4.4 Principal Investigator

The Principal Investigator (PI) had the overall responsibility for all the survey processes including: funding, data collection, data management and dissemination of the results. The PI was advised by the Task Force (TF) and Advisory Board (AB) and would delegate tasks and responsibilities to the Survey Coordinator (SC).

1.4.5 Survey Coordinator

The Survey Coordinator (SC) had the day-to-day responsibility to execute the survey including:

- Preparing field manual/SOPs
- Planning field work
- Editing and producing study materials
- Arranging training and pilot study
- Supervising field work
- Supervising the data management team
- Preparing monitoring reports
- Relaying results for survey participants whose samples turned positive for TB to the County TB and Leprosy Coordinators for initiation on treatment

The SC was answerable to the PI and received technical support from the TF members.

1.4.6 National Tuberculosis, Leprosy and Lung Disease Program

The National Tuberculosis, Leprosy and Lung Disease Program (NTLD-Program) hosted the secretariat and availed the resources required for the survey implementation.

1.4.7 National Tuberculosis Reference Laboratory

Sputum samples collected from the Mobile Field Sites (MFS) were sent to National Tuberculosis Reference Laboratory (NTRL) in Nairobi through a contracted courier service. The NTRL was responsible for processing and performing TB microscopy, Xpert MTB/RIF and culture examinations on all specimens. The NTRL maintained internal quality controls while the Supranational Reference Laboratory (SRL) in Brisbane Australia provided external quality assurance. Results were captured in both the electronic laboratory information management system (LIMS) as well as the laboratory register then automatically transmitted to the SC upon completion. The CDC-KEMRI laboratory in Western Kenya was identified as the backup laboratory for the NTRL. Routine supervision and monitoring visits were conducted to the MFS to support quality sputum collection processes and transport.

1.4.8 Central Data Management Unit

The Central Data Management Unit (DMU) consisted of a Data Manager and two Assistant Data Managers supported by the NTLD-Program IT Department. The data was electronically transmitted from the MFS to the central unit. The DMU also received data electronically from the NTRL and the central chest X-ray unit. The central data management team monitored the survey database to ensure routine and timely data collection and backup. The team also participated in field supervision and liaised with field data managers to ensure a seamless data collection process.

1.4.9 Central Chest X-Ray Unit

After chest x-ray (CXR) reading in the field, digital chest radiographs were electronically transmitted to the central chest x-ray unit. Chest x-ray image management was done through the use of a picture archival and communications system (PACs) integrated into the chest x-ray equipment. Images captured from the x-ray equipment were stored on a local PACs laptop within the MFS and submitted to the central imaging system whenever the laptop sensed reliable internet connectivity.

Participant identification was verified using the barcode reader and study ID entered into PACs. The digital field images from PACs were transmitted and uploaded into the MFS system for further transmission to the server at the central DMU. All abnormal chest x-rays, 10% of normal (sampled by the digital system) and all images with discordant findings between the two field Clinicians were read by two qualified Radiologists for quality assurance (QA) using a standardized assessment form. In situations where the two radiologists did not agree, a third radiologist gave the final reading. The radiologists participated in MFS support supervision on monthly basis or when required. They also reviewed the digital chest radiographs of confirmed TB cases during the clinical management meetings.

1.4.10 Field Teams

The survey had five data collection teams each comprising of a Cluster Team Lead, an MFS Supervisor, two Clinical Officers, two Radiographers, one Laboratory Technologist, a Field Data Manager, five Field Interviewers and an MFS Nurse. They were supported by the respective County and sub-County TB Leprosy Coordinators (CTLCs and sCTLC), Chiefs, Assistant Chiefs, Community Health Extension Workers (CHEWs)/Public Health Officers, Community Health Volunteers (CHVs), Village Elders, County Commissioners, Deputy County Commissioners and Assistant County Commissioners. Field teams were responsible for: community mobilization, household listing, administration of survey/socio-economic questionnaires, symptom screening, enrolling participants, taking digital chest radiographs and sputum collection from eligible participants. The flow chart (Figure 1.3) shows the survey management structure.

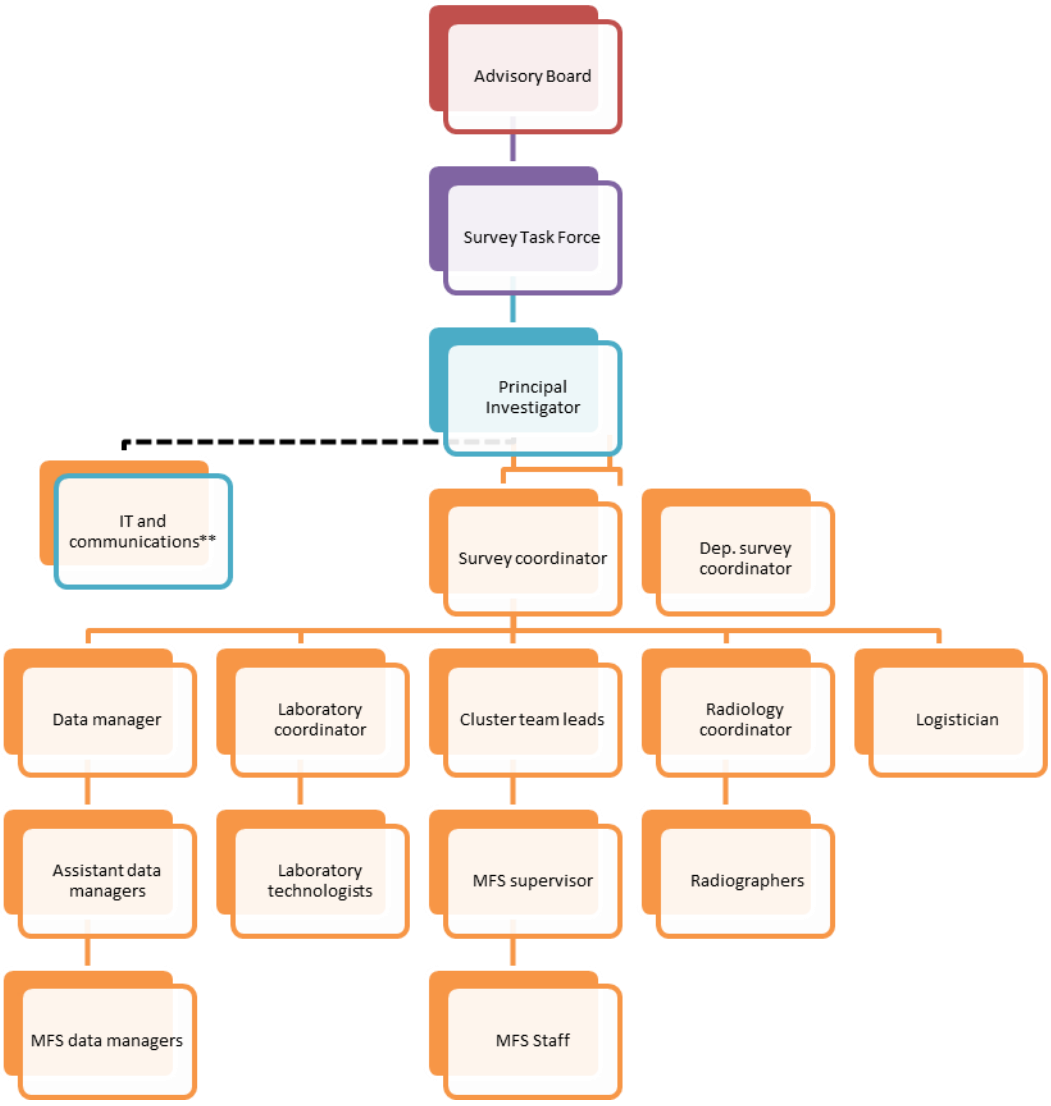


Figure 1.3: Survey management structure

**** IT and communications teams supported the survey teams at all levels**

1.5 Survey Methods

1.5.1 Survey Design

The Kenya TB prevalence survey was a nationwide, cluster-based, cross-sectional survey carried out between July 2015 and July 2016.

1.5.1.1 Sample Size

The required sample size was estimated as 72,000 individuals aged 15 years and above. To calculate the sample size, the key indicator used was the estimated adult TB prevalence. The following formula was used to estimate the required sample size:

$$N = 1.96^2 \frac{(1-\pi_g)}{d^2 \pi_g}$$

Where:

- *n* is the required sample size, expressed as number of adults aged 15 years and above
- π_g is the estimated adult TB prevalence
- *d* is the desired relative precision

For the calculation, the estimated adult prevalence (πg) was assumed to be 268.7 per 100,000 according to the (Ministry of Health, DLTLD, 2009). The relative precision (*d)* to be tolerated at 95 per cent level of confidence was fixed at 20%. The resulting sample size, using the formula above and the stated assumptions, was 35,646 persons. To cater for use of clusters in the survey design, this sample size was adjusted using an estimated design effect (deff) of 1.7. It was also adjusted to cater for an expected 85% participation rate. Based on this, the ultimate sample size was 71,266 adults. Ultimately, the targeted sample size was 72,000 adults.

1.5.1.2 Sampling Frame and Selection of Clusters

For purposes of this survey, the Kenya National Bureau of Statistics (KNBS) created a sampling frame comprising of clusters which were based on the 2009 Kenya Population and Housing Census (KPHC) Enumeration Areas (EAs). During the 2009 KPHC, each sub-location was subdivided into census enumeration areas (EAs), i.e. small geographic units with clearly defined boundaries. To create the clusters for the survey sampling frame, smaller EAs in the 2009 census database were merged together so that each cluster could have one measure of size (MoS) defined as having an average of 500 households (ranging between 400 and 600 households).

The clusters were selected using the probability proportional to size (PPS) method with the households in each cluster being the measure of size. Sampling of the clusters was done independently in the urban and rural strata. Ultimately, 100 clusters were randomly selected

with the urban stratum contributing 32 clusters while the rural stratum contributed 68 clusters, reflecting the general population share living in urban and rural settings.

In the selected clusters, all individuals in the households were listed and household structures numbered in order to get a complete list of all the households and individuals in each of the selected clusters.

The acceptable cluster size for eligible individuals was 650 to 790 (+/- 10% of 720). There were different scenarios of total number of eligible individuals identified within each cluster: either lower or higher than the target cluster size. In situations of lower than the target size (650), a neighbouring cluster was randomly selected and combined with the initially selected cluster in order to reach the target size. The decision on which direction (north, east, south, west) to take in extending the cluster was made by one of the community members by randomly selecting one of four folded papers each labelled with each of the directions. The four directions were identified using the area map provided. If the cluster size was much higher than the target size, then a sub-set of cluster individuals equal to the target size was randomly selected. Random selection of the sub-set of clusters entailed the following: the villages in the cluster were numbered sequentially before the local population listing began; after the listing, small pieces of paper each with one of the village numbers was placed in a box and shuffled. The community leaders identified one of them to pick a paper whose number would reveal where the listing to contribute to the eligible cluster number of 650 – 790 would begin. The community leaders also agreed on the direction in which the listing would proceed; either clockwise or anticlockwise on completing the first selected village so as to achieve the eligible numbers for the cluster.

1.5.1.3 Target Population

The target population comprised of all persons (male and female) aged 15 years and above residing in Kenya and drawn from 100 clusters across the country selected by PPS. Usual members of households in the selected clusters who had lived in the household for a minimum of 30 consecutive days prior to the date of the survey and who consented were recruited into the survey. Participants in special institutions (non-conventional households) requiring special clearance (prisons, police/military/NYS camps, health facilities, diplomatic compounds, schools excluding staff residents, refugee camps, hotels and lodgings) were excluded. The target population of eligible people invited to participate per cluster was 720 (range: 650-790).

1.5.2 Questionnaires

Three types of questionnaires were used in the survey: listing (census) questionnaires, socio-economic and symptom screening. The symptom questionnaire was used to screen eligible participants for TB symptoms while the socio-economic one was used to collect household information that would assist during the calculation of wealth quintiles. The listing questionnaire was used to capture details of all household members in the selected clusters including characteristics of each person listed such as age and sex. The main purpose of the

household questionnaire was to identify participants who would be eligible for the survey and describe the entire population listed.

1.5.3 Screening Methods

Individuals eligible to participate in the survey were screened using the WHO recommended screening strategies for TB prevalence surveys: symptom questionnaire and chest x-ray. Those who were symptomatic (i.e. cough of two weeks or more), and/or had abnormal chest x-rays suggestive of TB, and those who declined or could not undergo chest x-ray were requested to submit sputum specimens for examination. Those with no cough for a period of two weeks or more, nor a chest x-ray with abnormalities not suggestive of TB were not considered for sputum submission. This is demonstrated in Figure 1.4 below.

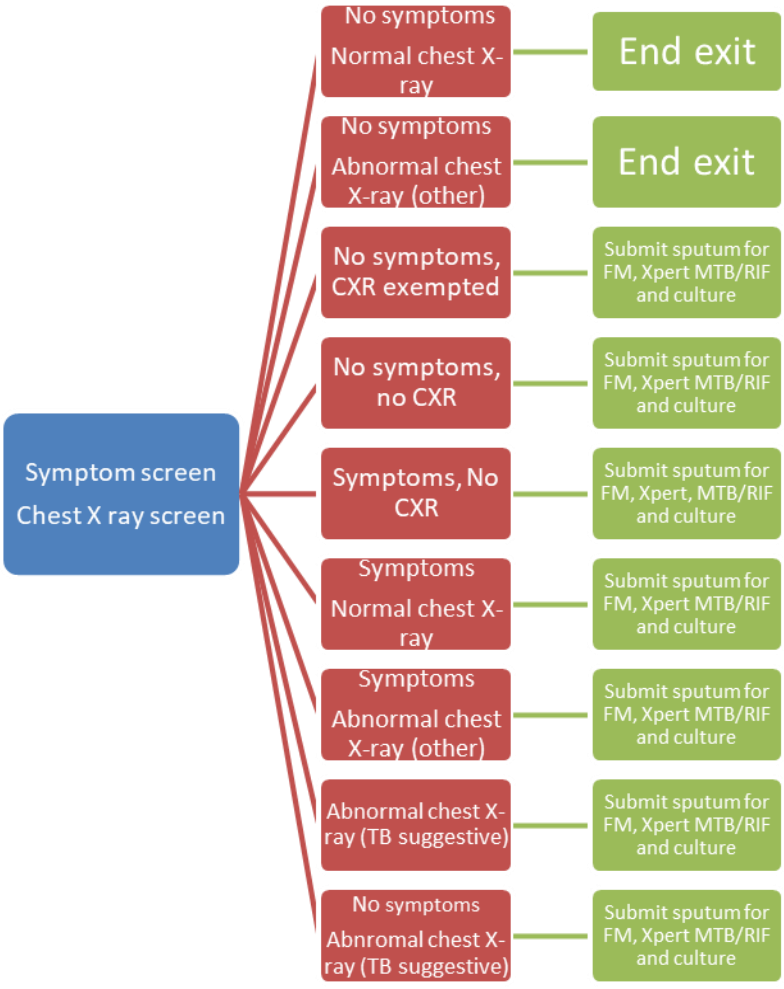


Figure 1.4: Flow chart describing screening methods and steps

1.5.4 Case Definition

For the purpose of the survey, a person was defined as a pulmonary TB case if he or she was:

- In the census population
- Eligible to participate in the survey
- Enrolled into the survey and assigned a study identification number (ID)

- Identified as having a cough of two weeks and/or abnormal chest x-ray suggestive of TB as per field reading
- Eligible for sputum submission
- Bacteriologically confirmed (Xpert MTB/RIF positive and/or culture positive for *Mycobacterium tuberculosis* (MTB))

1.5.5 Training

The TF developed a training curriculum and training materials during a one-week workshop prior to training of teams. The following materials were developed:

- SOPs
- Training slides
- Survey manual
- Data collection tools

A five-day training by the TF oriented teams on the survey protocol, survey procedures and use of the electronic data collection and transmission system. This was to ensure that data collected in the field by teams were standardised and met the expected quality. Standardised field tools were used during training to ensure a common understanding of the survey procedures. Laboratory Technologists at NTRL were taken through a day's training on survey procedures and laboratory techniques while Radiographers went through a four-day hospital-based training on image acquisition and quality.

Role plays were used to simulate field settings during the training to delve into focus areas as detailed below:

- Field Interviewers: community entry, how to conduct household interviews, use of net books, timely and accurate recording of household information
- Radiographers: operation of the mobile digital x-ray, picture archiving and communication system (PACS) and radiation safety
- Clinicians: image interpretation, classification and symptom screening, referral of participants with severe conditions
- Laboratory Technologists: sample collection and labelling, storage, packaging, transportation and safety
- Field Data Managers: downloading of data, accuracy, checking of errors, data backup and transmission to the central data base

1.5.6 Pilot Testing

A pilot survey was conducted in July 2015 to pre-test tools and procedures and to have better understanding of survey preparations including the feasibility of time allocated for data collection. This took place in two clusters excluded from the survey; one urban cluster in

Nairobi and a rural cluster in Kajiado. The pilot findings informed amendments to the protocol, revision of survey procedures and tools, logistical plans and time allocated for data collection.

1.6 Field Work Procedures

1.6.1 Sensitization

Given the magnitude and delicate requirements of the survey including the use of x-ray equipment, an elaborate sensitization was undertaken. This entailed passing of information to various stakeholders through various mediums. County health committees were the first to be notified about the survey, followed by a national launch of the Kenya Tuberculosis Prevalence survey on July 9, 2015 where various stakeholders participated.

To enlist county support, national sensitization teams visited the counties to sensitize County Health Management Teams (CHMTs) and County Commissioners and explain survey procedures. This was followed by visits to the Sub County Health Management Teams (sCHMTs), Deputy County Commissioners and cluster gatekeepers (Chiefs, Assistant Chiefs, Village Elders (VEs) and Community Health Volunteers (CHVs)). In consultation with the local leadership, the national teams identified potential sites for setting up the MFS and liaised with the nearest health facility for sputum sample storage before transportation to the NTRL. Thereafter, the census teams visited households within the clusters to enlist and administer the socio-economic questionnaire. Eligible participants at household level were invited to the MFS for enrolment into the survey.

1.6.2 Pre-Census

The KNBS Cartographer and Cluster Team Lead met the identified local leaders and mapped out the cluster boundaries. The Cluster Team Lead and County and Sub County TB Coordinators trained the VEs and CHVs on how to conduct manual household listing. To aid in community mobilization, information, education and communication (IEC) materials (posters, stickers, brochures) and identification tags were issued. Household listing was done to generate the population list that helped determine the number of eligible (≥15 years) individuals in a cluster against a target of 650 – 790 per cluster. Security arrangements for the survey sites were agreed on with local Police Departments.

1.6.3 Digital Listing/Survey Census

The cluster population list was used to identify households for digital listing, done by the Field Interviewers accompanied by the VEs and CHVs. Verbal consent to administer the socio-economic questionnaire to the household head was obtained. Every eligible consenting household member was issued with an invitation card containing a unique survey identification number (ID) and invited to the MFS. The unique survey ID was labelled to include identity of the survey as PS followed by identity of cluster e.g. C0102, this was

followed by the household number identity e.g. H0003 and finally household member number e.g. 001 to make the unique survey ID PS/C0102/H0003/001. The Listing Supervisor coordinated the listing process and assigned household numbers to avoid duplication. All the Field Interviewers assigned and marked each household with a unique survey number e.g. (PS/C0102/H0003).

1.6.4 MFS Procedures

Reception: The MFS Nurse received the invitation cards from eligible individuals and verified their identity by asking random questions like age and middle name. Written and informed consent was obtained from the participant (18 years and above) after a detailed explanation of the survey procedures. For minors 15-17 years old, consent from a parent or guardian and individual assent was obtained, unless they were mature minors (married, pregnant, parent, head of a household), who provided individual consent.

A movement tracking form was printed and used as a checklist for when participants passed through the various stations at the MFS. A barcode study ID was printed and attached to the consent form signed by the participant. At every service delivery point, the movement card was signed as a proof of service rendered and the identity of the participant was verified and confirmed by scanning the barcode on the movement tracking form.

Enrolment: This was done by the Field Interviewer (Enroller) who verified the identity of the survey participant, scanned the barcode study ID and administered the symptom screening and health seeking behaviour (HSB) questionnaire. This questionnaire was administered to all survey participants.

Taking Chest X-rays: Participant identification was verified using the barcode reader and study ID entered into the PACS. The radiographers enquired the date of the last menstrual period to determine pregnancy status for women of reproductive age. An opt-out approach for the pregnant women was used. Radiation procedures were explained, and the participants provided with a lead gown to wear for protection against radiation. A posterior-anterior (PA) chest radiograph was taken and saved in the system for review by the Clinicians.

Clinicians' Desk: Each Clinician individually checked the quality of the radiographs and made an interpretation as either normal, abnormal suggestive of TB or abnormal other. The second Clinician assessed the symptom screening results and image interpretations to make an informed decision on:

- Participants with cough ≥ two weeks and/or abnormal x-ray suggestive of TB or both were referred to the laboratory for sputum collection
- Participants not eligible for sputum collection (cough < two weeks, normal x-ray or abnormal other x-ray) were not eligible for sputum collection, thus ending their survey processes at the MFS after visiting the 2nd Clinician's desk
- Participants who declined x-ray were requested to submit two sputum samples irrespective of whether they had symptoms or not

- Participants with other medical complaints were referred to the nearest health facility for further management

MFS Laboratory: The sputum collection process was explained to the participant after printing the spot sputum request form. The participant was then issued with a labelled spot sputum container and directed to the sputum booth with signage on how to produce sputum. Once the sample was received, quality and quantity were checked, and the specimen stored under cold chain for transportation to the NTRL. The participant was issued with a second labelled sputum container to collect and submit a morning sample. On receiving the morning sputum sample, a request form was printed and packaged with the sample stored under cold chain and transported to the NTRL. The participant was thanked and exited from the survey. Samples were accompanied by a shipment log and temperatures were monitored to ensure cold chain was maintained.

1.7 Central Level Procedures

1.7.1 Laboratory Procedures

On receiving specimens at the NTRL, temperatures were re-checked, and the specimens were checked for quality, quantity, leakages and labelling. A direct smear was done on all samples and stained with Auramine O followed by microscopic examination at (20x and 40x magnification) using a fluorescent microscope. Xpert MTB/RIF was done on all morning samples and on spot samples lacking a matching morning sample. Each specimen was decontaminated with 4% sodium hydroxide and inoculated onto two slopes of solid Loweinstein Jensen medium. Inoculated media were monitored for growth for up to eight weeks before being discarded as culture negative. Except for samples that were contaminated, all visible colonies grown on culture media were confirmed by acid-fast bacilli (AFB) microscopy and Mycobacterium protein 64 (MPT64) speciation to confirm presence of MTB complex. Subsequent susceptibility testing using SIRE-MGIT medium was done to rule out resistance to first line drugs. Non-Tuberculous Mycobacterium (NTM) and preliminary resistance to Rifampicin and Isoniazid were identified using GenoType Mycobacterium AS and GenoType MTBDRplus (Hain Lifescience) test kits. Aliquots of all decontaminated samples and isolates of positive cultures were archived at -80^{o}C.

1.7.2 Radiology Procedures

1.7.2.1 MFS Radiology Procedures

All consenting study participants had a digital x-ray taken. The two Clinicians independently read the x-ray images and entered their reports into the database. Participants with x-rays suggestive of TB irrespective of symptoms were referred to the MFS laboratory to produce a sputum specimen.

1.7.2.2 Central Radiology Procedures

All abnormal chest x-rays, 10% of normal (sampled by the digital system) and all images with discordant findings between the two field Clinicians were read by two qualified Radiologists for quality assurance (QA) using a standardized assessment form. In situations of disagreement between the two Radiologists, a third Radiologist provided the final reading. All the images of bacteriologically confirmed TB cases were re-read, and their clinical information discussed by the case management team.

1.7.3 Data Management Procedures

The Kenya TB prevalence survey generated mostly digital data with the exception of participant invitation cards, consent forms and hard copy QA questionnaire. A unique identification number - Study Identification Number (Study ID) was used at all stages of data collection and management. It consisted of three variables as shown below:

	Cluster number	Household number	Individual number
ID:	C####	H#####	###

The individual number was a sequential number starting with 001 for the household head to the number of members in a household. The ID was converted into a barcode and barcodes were used on all forms/registers and in digital data files to uniquely identify each survey participant.

1.7.3.1. Organizational Structure of Data Management

Data management was handled by the DMU, which functioned as the central unit for data collection and processing at various levels (field level, CXR level, central CXR reading and central laboratory level). The DMU was in charge of planning, operation and security of the data and the associated information systems.

Data collection and management activities took place at field and central level, with the support of the DMU (Figure 1.5).

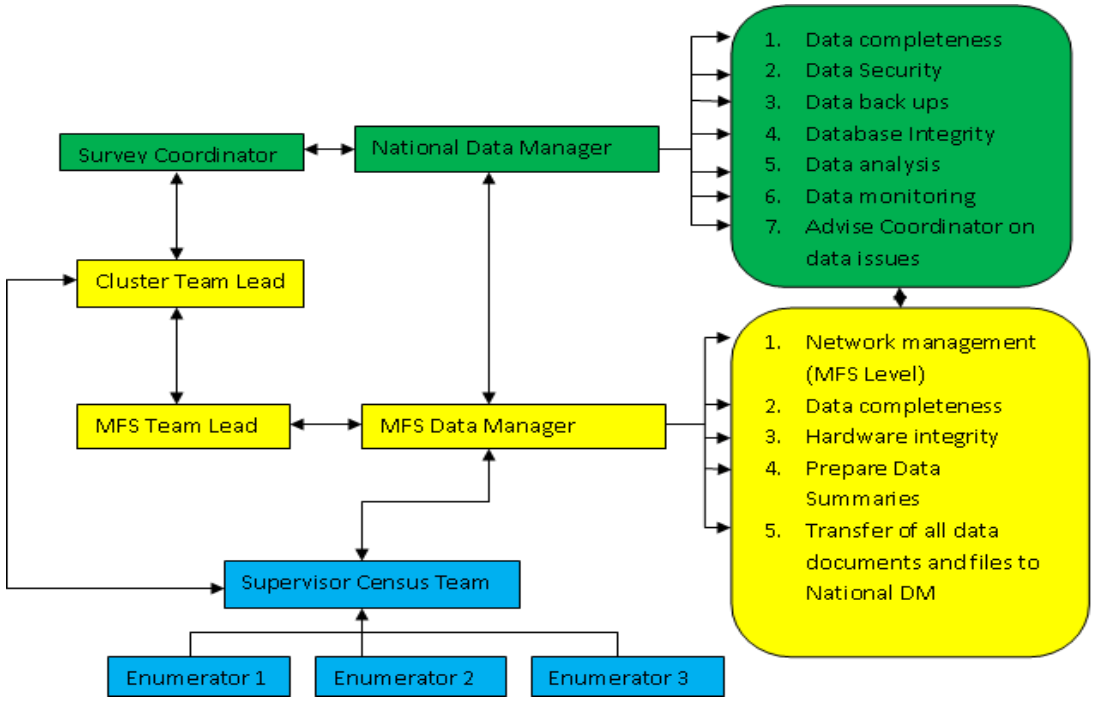


Figure 1.5 Functions of the Data Management Unit

1.7.3.2 PDA and IT Support

The DMU received IT support from the NTLD-Program IT team. Local PDA experts provided on-going support for software upgrades, troubleshooting and retrieval of data from malfunctioning PDAs and laptops. Any further programming required based on feedback from the field was performed and the updated versions of the software communicated to all field teams. Remote IT support was provided by the vendors of the medical equipment who were on standby to provide technical support throughout the survey.

1.7.3.3 Medical Engineers

Medical engineers ensured the efficient operation of the x-ray equipment and related electrical accessories.

1.8 Security During Field Operations

Sensitization teams made prior security assessment in each cluster and made necessary arrangements to protect the field teams particularly in clusters with insecurity. Two security officers were hired to provide security at the MFS in all the clusters.

1.9 Communications and Media Engagement

A team led by a communications and media specialist supported all communications and media engagement functions of the survey. This team developed a survey communications and media strategy whose objectives included:

- Creating awareness of TB, building an understanding of the survey, its process and findings
- Development of survey branded IEC materials such as brochures, infographics, banners, t-shirts, reflector jackets, bags, stickers, frequently asked questions (FAQs), invitation cards, identification cards, MFS signage, flow charts, job aids, sputum collection posters, and certificates of participation and merit
- Sensitization of the public through the use of the media i.e. radio and TV spots, scheduled interviews, journalist field site visits to produce newspaper articles and the use of digital media such as social media and blogs
- Documentation of survey activities through video, photography and news articles
- Supporting community sensitization and mobilization for increased participation in the survey

1.10 Ethical Considerations

Human Subjects

Benefits of the study: Members of the community presumed to have TB were offered screening tests. TB cases identified during the survey were linked to local health facilities for treatment initiation and follow up as per national guidelines. Individuals who did not know their HIV status were encouraged to visit HIV counselling and testing centres for appropriate care. The survey did not address tuberculosis prevalence in children. However, children in survey clusters who exhibited symptoms of TB were referred to nearby health facilities for appropriate care. In households where an adult with active tuberculosis was identified, the sub-county TB coordinator for the cluster ensured that children were investigated and provided with isoniazid preventive therapy (IPT) as per the guidelines (Ministry of Health, NTLD-Program, 2013). Any sick child identified in the compound during survey home visits was referred and assisted where necessary in getting to a nearby health facility.

Compensation: Transport was provided for participants from distant villages, the disabled and the elderly. There was no monetary compensation. Milk and/or soap were provided to all participants who visited the MFS as a token of appreciation.

Infection control: All survey workers were trained on standard operating procedures aimed at minimizing contamination to the environment when collecting sputum samples, reducing

possible exposure of study participants and staff to M. *tuberculosis* and other airborne diseases. Some of the measures taken included having participant sputum production done outdoors or in direct sunlight away from other individuals. Radiology equipment and accessories were regularly sanitized, and gowns cleaned to avoid cross contamination.

Radiation protection: All field staff were trained on radiation safety procedures. An area of 25 square metres was isolated, identified, marked and cordoned off. A spot was identified for positioning of the digital x-ray equipment ensuring that the x-ray beam was directed away from the study personnel and sitting areas. All equipment was assessed and certified by the Kenya Radiation Protection Board. Women with known pregnancy were informed about the potential risks, offered double protective shielding and given the opportunity to opt out of the x-ray and instead provide sputum samples. All other women and men of reproductive age (between 15-49 years) wore lead aprons to protect the pelvis and abdomen. The radiographers used thyroid shields and lead gowns/shields for protection. Radiation exposure was measured and analysed monthly and staff had quarterly haematological monitoring.

Confidentiality: No survey participant was or will be identified by name in any report or publication derived from information collected for the survey. All digital information was protected using restricted passwords and data collection forms kept in secure locked cabinets. Names and locations were only used to trace participants for case identification and follow up procedures. Privacy and confidentiality of medical records collected during the survey were maintained using the MoH guidelines for patient records.

Informed consent: Informed consent was obtained from each household head before administration of the socioeconomic questionnaire. Written informed consent was obtained from each eligible participant before enrolment into the study and after thorough explanation of the risks and benefits of participating in the study. Any questions raised by the potential participants were answered before participation in the study. The voluntary nature of participation in the survey and the option to withdraw from the study at any time without affecting participant rights and benefits was explained. Consent for eligible participants with low or no literacy was obtained in the presence of a witness and signatures obtained using their thumb print. Consent for minors aged 15 to 17 years was sought from a parent or guardian and individual assent obtained, with the exception of mature minors (married, pregnant, parent, head of a household), who provided individual consent.

Ethical approval: The study protocol and amendments were approved by the Kenya Medical Research Institute (KEMRI) scientific and ethical review committees. The approval reference was SSC 2094.

1.11 Statistical Analysis for the Estimation of TB Prevalence Rates (Analytical Methods)

To obtain TB prevalence rates, all analysis was conducted separately for the binary survey outcomes which were coded as either ("yes" or "no") as described in the survey protocol for smear-positive pulmonary TB and bacteriologically-confirmed pulmonary TB.

The average of the cluster-level prevalence estimates is the point estimate of survey prevalence among all survey participants, and the standard error was obtained by dividing the standard deviation of the cluster-level prevalence estimates by the square root of 99, which was the total number of clusters reached in the survey.

Individual Level Analysis

The individual level analysis of pulmonary TB prevalence was obtained by implementing logistic regression in which the log odds, i.e. $\log(\frac{P_{ij}}{1-P_{ij}})$ was modelled. Here P_{ij} is the probability of individual ***i*** in cluster ***j*** being a prevalent TB case as defined by TB prevalence survey protocol.

The simplest model that was fitted had the following type of relationship. $\beta = \log(\frac{P_{ij}}{1-P_{ij}})$ where the overall prevalence of pulmonary TB was then estimated as: $p = \frac{\exp(\beta)}{1+\exp(\beta)}$, where ***p*** is the observed overall proportion of survey participants with pulmonary TB.

The main purpose why logistic regression was used was because of the binary outcome: for each individual there is a probability of having pulmonary TB at the time of the cross-sectional survey (in the generalized linear models' framework, the logistic link function is the 'natural link function').

The most crucial characteristic of such analyses is that they take into account the clustering of individuals. If this is not done, the calculated 95% confidence interval (CI) for true pulmonary TB prevalence would have less than the nominal 95% coverage due to underestimation of the standard error of the prevalence estimate.

This study utilized individual analysis, cluster, model 1, model 2 and model 3 to explore the data. Model 3 results were used to describe the weighted TB prevalence rate.

Model one: robust standard errors on complete case dataset

This model does not account for variation in the number of individuals per cluster or correlation among individuals in the same cluster when estimating the point prevalence of pulmonary TB (logit command with the robust option in Stata).

Equal weight is given to each individual in the sample. However, the model corrects for clustering (by using the observed between-cluster variation) when estimating the 95%

confidence interval and can control for the strata that were part of the survey design.

This model corresponds to the classical analysis of surveys (svy commands with Stata) when one does not need to adjust for sampling weights. This is the case in the self-weighting survey design for nationwide TB prevalence surveys. This model is restricted to survey participants.

Model two: robust standard errors with multiple imputations for missing value

This model uses multiple missing value imputation for individuals: a) without a field CXR result and/or symptom screening, and b) for individuals with a positive CXR result or TB symptoms but without smear and/or culture results. This approach was taken in order to include all individuals who were eligible for the survey in the analysis.

This model (logit command with the robust option in Stata) allows for both the clustering in the survey design and the uncertainty introduced by imputation of missing values when estimating the 95% confidence interval for the prevalence of pulmonary TB.

Model three: random-effects logistic regression

This model takes account of both clustering and variation in the number of individuals per cluster, when estimating both the point prevalence of pulmonary TB and its 95% confidence interval. As with model one, this model is restricted to survey participants.

Handling of Missing Data

In this survey, there was utility of electronic systems during data collection and the system was designed to minimize missing values. Describing missing data can apply to data missing from the outcome or the exposure variables:

Missing data in the outcome variables:

- Participants categorized as eligible for sputum examination by symptom (including cough with unknown duration) but having no or only one bacteriological result of sputum examination
- Participants eligible for sputum examination by field CXR reading regardless of types of shadows, but having no or only one bacteriological result of sputum examination
- Participants having abnormal shadow detected by central CXR reading but having no or only one bacteriological result of sputum examination.

Missing data in the exposure variables:

- The results of field and/or CXR reading are not available (CXR not taken, quality un-

readable)

- Cough with unknown duration.

Imputation Models

All imputation models were run in STATA 14 using the mi group of commands for the imputation of data and calculation of pooled estimates combining all imputed datasets.

Outcome of bacteriologically confirmed TB codes as TB cases: All variables associated with a bacteriologically-confirmed case and missing data were investigated for inclusion in the imputation model. These were strata, age group, sex, field CXR result, central CXR result, cough of two or more weeks, weight loss, chest pain, fever, shortness of breath, night sweats, fatigue and history of or current TB treatment. The final imputation model included: age group, sex, stratum, cough for more than two weeks, treatment history and central CXR results. Twenty datasets were imputed after 20 cycles for each saved and combined for final estimates. The same imputation model was used for imputation of values among survey participants (model 3).

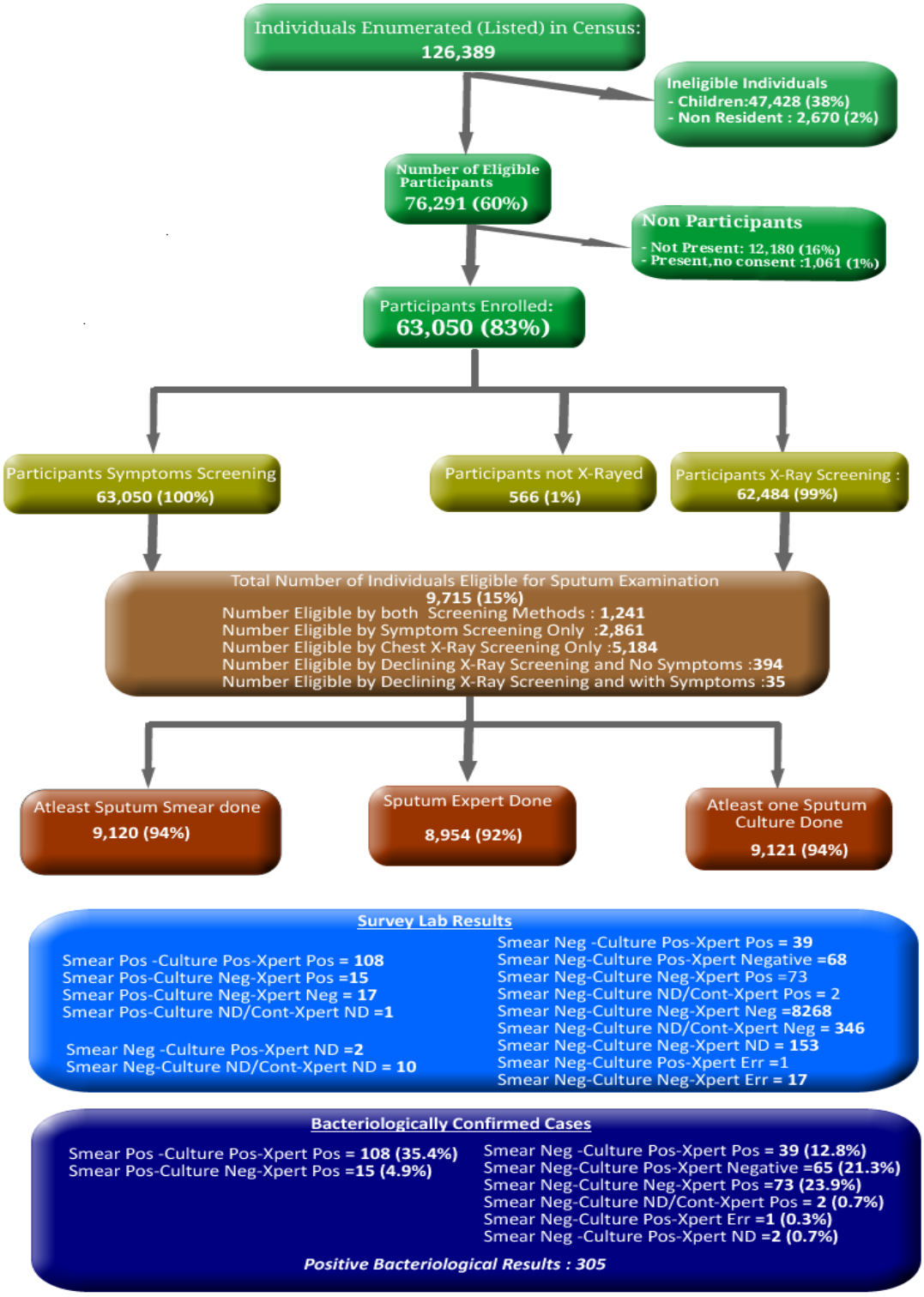
2. DESCRIPTION OF THE SURVEY DATA

2.1 Survey Background

Data collection was done within a period of 11 months (August 2015 - July 2016) by five mobile field teams, with four in operation at any one time. This was preceded by a two week pilot in two clusters, one urban (Nairobi) and one rural (Kajiado). A total number of 99 clusters out of the 100 clusters sampled were visited. One rural cluster (Mandera) was not visited due to security concerns. Rural clusters made up 70% (67) of the survey clusters, while urban clusters made up 30% (32).

2.2 Summary of Data Flow

Figure 2.1: Schematic diagram of number of participants screened for TB in the survey



2.2.1 Household Listing Information

A total of 126,389 individuals were enlisted at their households. Females accounted for 67,056 (53%) of the respondents. Majority of the individuals 88,108 (70%) were rural residents, and 38% (47,428) were children under the age of 15 years. Table 2.1 below describes the age, sex and residence of the listed individuals.

Table 2.1: Household listing characteristics

Characteristic	Female	Male	Total
	N (%)	N (%)	N (%)
Age Groups (years)			
< 15	23,666 (35)	23,762 (40)	47,428 (38)
15 - 24	12,822 (19)	10,497 (18)	23,319 (18)
25 - 34	11,486 (17)	8,905 (15)	20,391 (16)
35 - 44	7,441 (11)	6,680 (11)	14,121 (11)
45 - 54	4,955 (7)	3,987 (7)	8,942 (7)
55 - 64	3,161 (5)	2,682 (5)	5,843 (5)
65+	3,525 (5)	2,820 (5)	6,345 (5)
Overall	**67,056 (53)**	**59,333 (47)**	**126,389 (100)**
Setting			
Rural	46,474 (69)	41,634 (70)	88,108 (70)
Urban	20,582 (31)	17,699 (30)	38,281 (30)
Overall	**67,056 (53)**	**59,333 (47)**	**126,389 (100)**

The survey census pyramid was comparable to the projected Kenya national population 2015 (based on the 2009 population census) as shown in Figure 2.2 below. The TB survey listed more elderly persons (65 years and above) compared to the projected population.

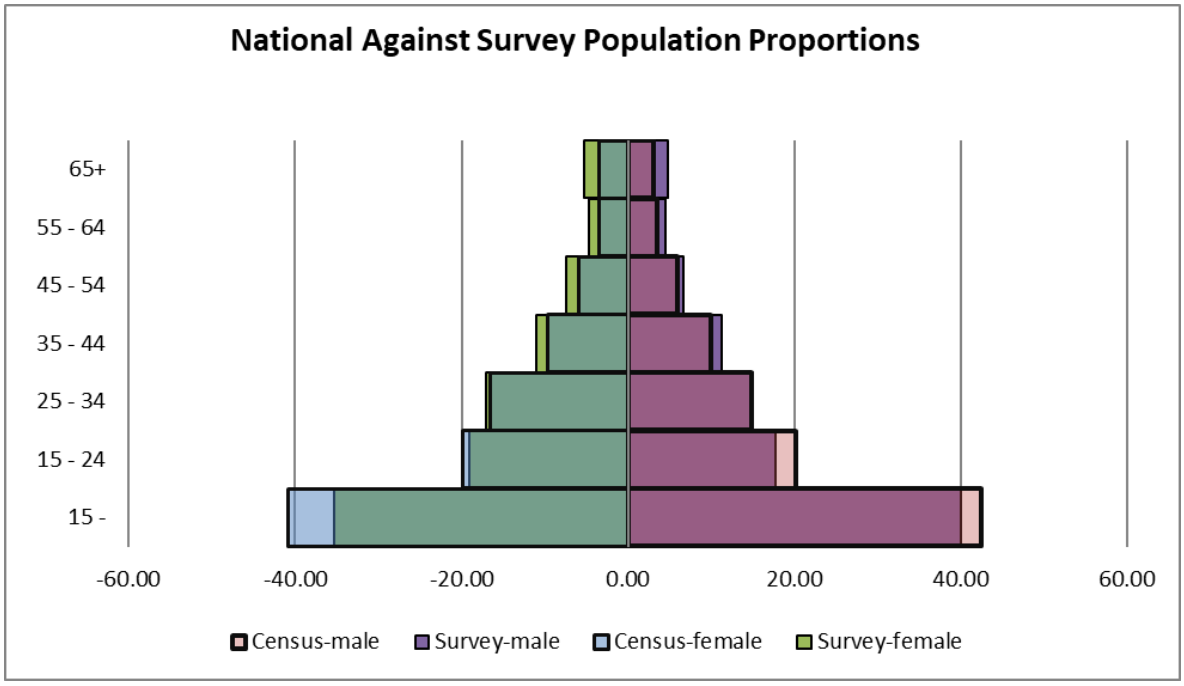


Figure 2.2: TB survey census population against projected national population census

2.2.2 Survey Eligibility

Out of the listed population, 76,291 (60%) were eligible to participate. Females comprised 56% of the survey participants. Those not eligible were 47,428 (38%) children under the age of 15 years and 2,670 (2%) non-resident adults. Majority of non-residents were male at 1,809 (68%) (Table 2.2).

Table 2.2: A table of survey eligible and enrolled participants

	Ineligible			**Eligible**	**Enrolled**	**Total Individuals Enumerated**
	Child Non-Resident	**Child Resident**	**Adult Non-Resident**	**Adults Residents**	**Adults Residents**	
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**N (%)**
SEX						
Male	154 (54)	23,608 (50)	1,809 (68)	33,762 (44)	26,044 (41)	59,333 (47)
Female	131 (46)	23,535 (50)	861 (32)	42,529 (56)	37,006 (59)	67,056 (53)
Setting						

	Ineligible			Eligible	Enrolled	Total Individuals Enumerated
	Child Non-Resident	Child Resident	Adult Non-Resident	Adults Residents	Adults Residents	
	n (%)	n (%)	n (%)	n (%)	n (%)	N (%)
Rural	176 (62)	35,696 (76)	2,061 (77)	50,175 (66)	43,606 (69)	88,108 (70)
Urban	109 (38)	11,447 (24)	609 (23)	26,116 (34)	19,444 (31)	38,281 (30)
Overall	**285 (0)**	**47,143 (37)**	**2,670 (2)**	**76,291 (60)**	**63,050 (50)**	**126,389 (100)**

2.3 Survey Participation

A total of 76,291 eligible people were invited to participate in the survey. Out of this, 63,050 (83%) were enrolled into the survey. Table 2.3 describes the age-sex distribution of the survey participants. Females comprised 37,006 (59%) of the participants with a participation rate of 87% while the males had a lower participation at 77%.

Table 2.3: Survey participation rate

	Adults Residents		Total Participation Rate
	Eligible	Enrolled	
	N (%)	N (%)	%
SEX			
Male	33,762 (44)	26,044 (41)	77
Female	42,529 (56)	37,006 (59)	87
Setting			
Rural	50,175 (66)	43,606 (69)	87
Urban	26,116 (34)	19,444 (31)	74
Overall	**76,291 (60)**	**63,050 (50)**	**83**

There was a higher participation rate among the older age groups of 55 years and above with the highest participation (93%) among the ≥ 65 years as shown in Figure 2.3 below. The lowest participation rate (70%) was among males of age group 15-34 years (Figure 2.4).

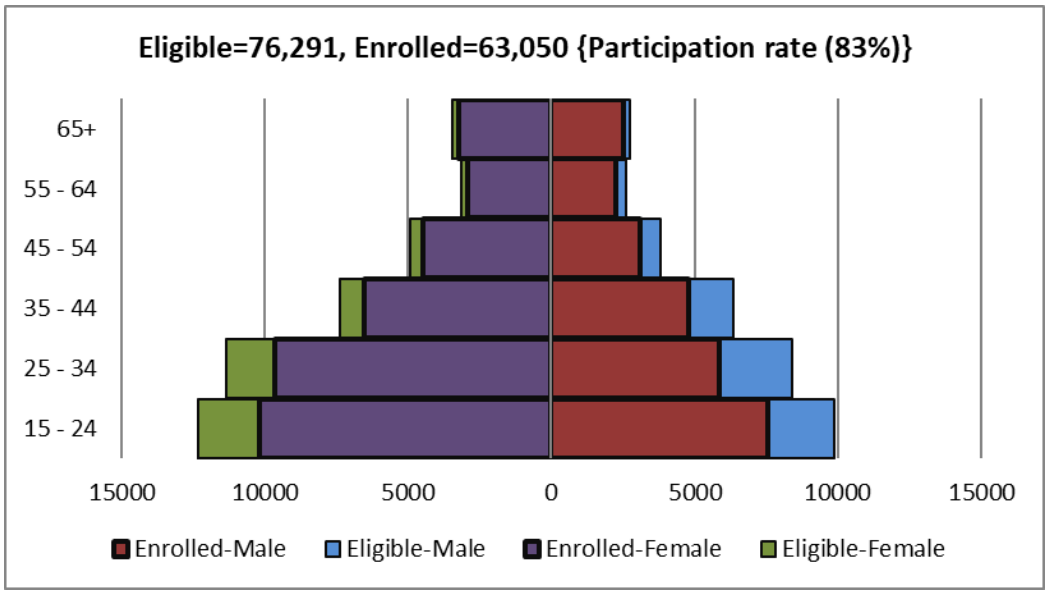


Figure 2.3: Population pyramid of the eligible and participant population by age and sex

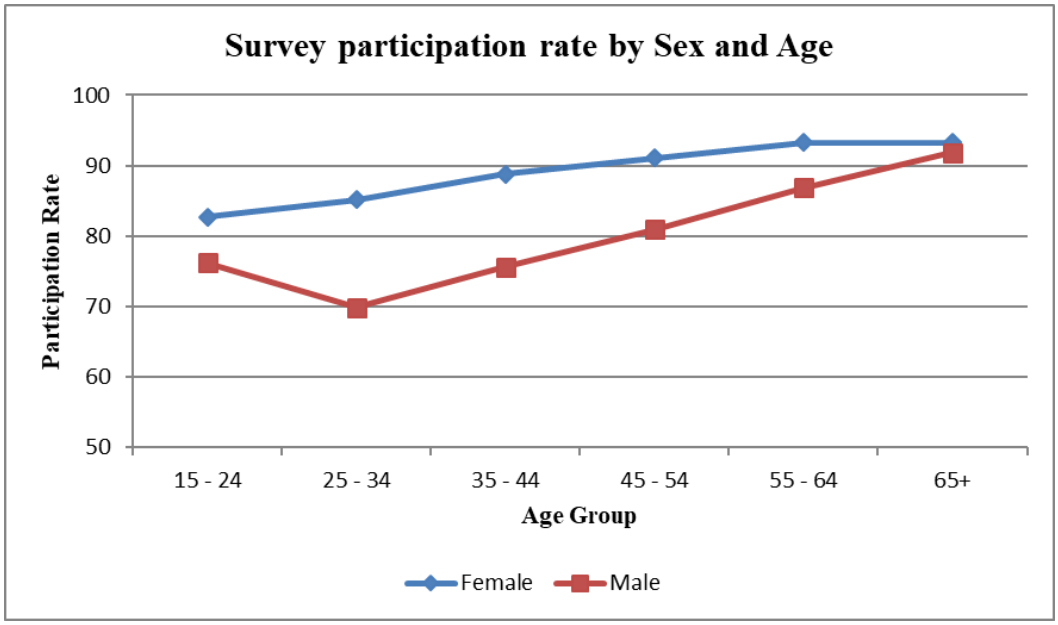


Figure 2.4: Participation rates by sex and age group

The participation rate varied in the course of the survey with lower rates in the initial phases of implementation (Figure 2.5). The average number of survey participants per cluster was 770 with a range of 503-1573. Wide variation occurred in the initial survey stages.

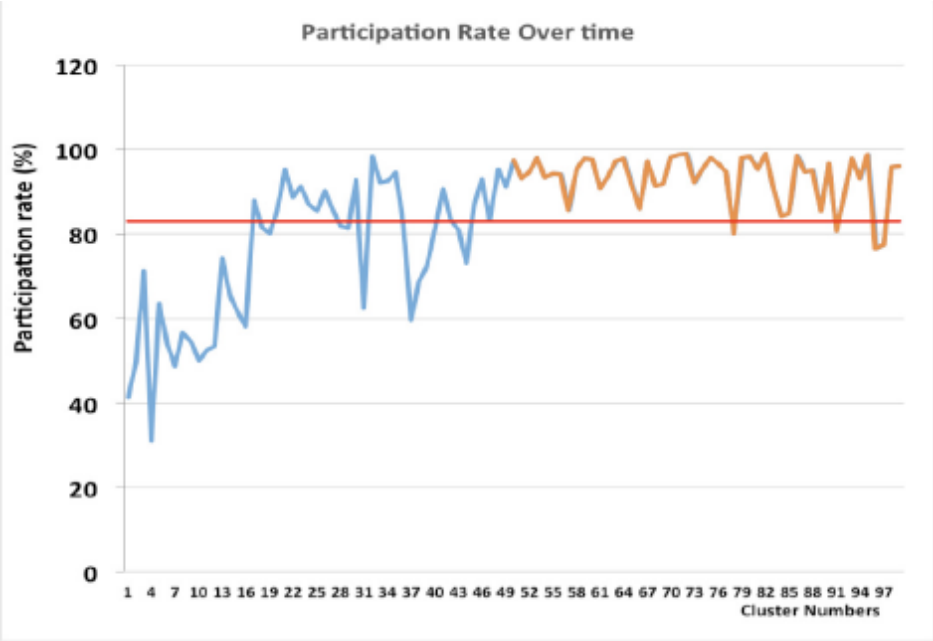


Figure 2.5: Survey participation rate by chronological order of cluster implementation

2.4 Characteristics of Survey Participants

In terms of level of education, 85% of the participants had at least attended school and 50% only had primary level education (with or without completing). The main occupations of the participants were farming (36%), business (18%) and students (14%), while 9% were unemployed. Seventy percent of the participants were from rural settings. Majority of the participants (67%) were in the three lower socio-economic quantiles. The high socio-economic quantile had the least (14%) of the study participants as indicated in Table 2.4.

Table 2.4: Background characteristics of survey participants

	Female	Male	Total
Characteristic	**n (%)**	**n (%)**	**N (%)**
Age Groups (yrs)			
15 – 24	10,199 (28)	7,536 (29)	17,735 (28)
25 – 34	9,641 (26)	5,863 (23)	15,504 (25)
35 – 44	6,531 (18)	4,787 (18)	11,318 (18)
45 – 54	4,470 (12)	3,079 (12)	7,549 (12)
55 - 64	2,930 (8)	2,253 (9)	5,183 (8)
65+	3,235 (9)	2,526 (10)	5,761 (9)
Setting			
Rural	25,335 (68)	18,271 (70)	43,606 (69)
Urban	11,671 (32)	7,773 (30)	19,444 (31)
Marital Status			

		Female	Male	Total
Characteristic		**n (%)**	**n (%)**	**N (%)**
Single (Never married)		8,089 (22)	8,549 (33)	16,638 (26)
Married		25,197 (68)	16,846 (65)	42,043 (67)
Divorced/Separated		1,146 (3)	436 (2)	1,582 (3)
Widowed		2,574 (7)	213 (1)	2,787 (4)
Schooling				
No schooling		6,753 (18)	2,485 (10)	9,238 (15)
Primary school not completed		10,968 (30)	7,726 (30)	18,694 (30)
Completed primary school		7,370 (20)	5,090 (20)	12,460 (20)
Secondary school not completed		5,349 (14)	4,051 (16)	9,400 (15)
Completed Secondary school		4,440 (12)	4,375 (17)	8,815 (14)
Further education after secondary		2,126 (6)	2,317 (9)	4,443 (7)
Occupation				
SELF-EMPLOYED	**Farming**	13,849 (37)	8,895 (34)	22,744 (36)
	Fishing	98 (0)	260 (1)	358 (1)
	Business	6,378 (17)	5,365 (21)	11,743 (19)
	Other	45 (0)	108 (0)	153 (0)
Employed by government		766 (2)	1,016 (4)	1,782 (3)
employed in private sector		1,589 (4)	2,442 (9)	4,031 (6)
pupil/Student		4,409 (12)	4,659 (18)	9,068 (14)
Housewife		6,067 (16)	73 (0)	6,140 (10)
Unemployed		3,550 (10)	2,465 (9)	6,015 (10)
Others		255 (1)	761 (3)	1,016 (2)
Socio-economic				
1 (low)		8,016 (22)	6,015 (23)	14,031 (22)
2 (second low)		8,114 (22)	5,845 (22)	13,959 (22)
3 (middle)		8,411 (23)	5,836 (22)	14,247 (23)
4 (second middle)		6,965 (19)	4,898 (19)	11,863 (19)
5 (high)		5,500 (15)	3,450 (13)	8,950 (14)
Total		**37,006 (59)**	**26,044 (41)**	**63,050 (100)**

2.5 Field Screening

All 63,050 participants enrolled into the survey were taken through symptom screening, 62,484 (99%) had chest x-rays done while 566 (1%) were not x-rayed. Among those not x-rayed, 429 declined and the rest were not x-rayed in situations when the x-ray machines malfunctioned. From the screening, 9,715 (15%) participants were eligible for sputum submission.

2.5.1 TB Symptom Screening

Of all the enrolled participants, 24,256 (38%) reported at least one symptom; 9,305 (15%) reported coughing and 7% had a cough for more than two weeks. Sputum eligibility based on symptoms was for those with a cough of two weeks or more. The most frequently reported symptoms were: chest pain (19%), cough (15%), drenching night sweats (12%), fatigue (11%), fever (8%), cough with sputum (5%) as shown in Table 2.5.

Table 2.5: Frequency of TB related symptoms among survey participants

Symptoms	Number	% Symptomatic	% Enrolled
Cough > 2 weeks	4,137	17	7
Chest pain	12,290	51	19
Coughing	9,305	38	15
Drenching night sweats	7,357	30	12
Fatigue	7,228	30	11
Cough < 2weeks	5,168	21	8
Fever	4,937	20	8
Cough with sputum	3,256	13	5
Shortness of Breath	3,417	14	5
Weight loss	1,609	7	3
Other symptoms	1,114	5	2
Hemoptysis (Blood Cough)	393	2	1
Total symptomatic	**24,256**		38
Total enrolled	**63,050**		

The symptoms of cough, chest pains and fatigue were reported more frequently with an increase in age (Table 2.6).

Cough of any duration was the second most common symptom, reported in 15% of the participants. Night sweats and fatigue had a frequency of 11%, followed by fever, shortness of breath and hemoptysis at 8%, 5% and 1% respectively. Only 7% of the participants reported a cough of more than two weeks. The older age group of 65 years and above had the highest frequency of any cough at 26%. The frequency of cough among females and males was comparable at 14% and 15% respectively. The frequency of cough was higher among participants in urban settings.

Table 2.6: Reported symptoms by sex, age and setting among survey participants

Reported Symptoms		Enrolled	Cough	Chest Pain	Weight Loss	Fever	Fatigue	Drenching night sweats	Shortness of breath	Any symptoms
		N (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
SEX	Female	37,006 (59)	5,335 (14)	7,708 (21)	891 (2)	3,122 (8)	4,596 (12)	4,572 (12)	2,145 (63)	14,821 (40)
	Male	26,044 (41)	3,970 (15)	4,582 (18)	718 (3)	1,815 (7)	2,632 (10)	2,785 (11)	1,262 (37)	9,435 (36)
Age-group (years)	15 - 24	17,735 (28)	2,073 (12)	2,407 (14)	307 (2)	820 (5)	1,152 (6)	1,090 (6)	696 (20)	4,977 (28)
	25 - 34	15,504 (25)	2,029 (13)	2,795 (18)	420 (3)	1,060 (7)	1,555 (10)	1,435 (9)	789 (23)	5,488 (35)
	35 – 44	11,318 (18)	1,585 (14)	2,332 (21)	330 (3)	921 (8)	1,384 (12)	1,344 (12)	611 (18)	4,474 (40)
	45 – 54	7,549 (12)	1,204 (16)	1,785 (24)	237 (3)	805 (11)	1,060 (14)	1,234 (16)	472 (14)	3,469 (46)
	55 – 64	5,183 (8)	937 (18)	1,300 (25)	145 (3)	585 (11)	849 (16)	961 (19)	359 (11)	2,537 (49)
	65+	5,761 (9)	1,477 (26)	1,671 (29)	170 (3)	746 (13)	1,228 (21)	1,293 (22)	490 (14)	3,311 (57)
Setting	Rural	43,606 (69)	5,939 (14)	8,381 (19)	971 (2)	3,500 (8)	5,024 (12)	5,302 (12)	2,287 (67)	16,634 (38)
	Urban	19,444 (31)	3,366 (17)	3,909 (20)	638 (3)	1,437 (7)	2,204 (11)	2,055 (11)	1,130 (33)	7,622 (39)
Total		**63,050**	**9,305 (15)**	**12,290 (19)**	**1,609 (3)**	**4,937 (8)**	**7,228 (11)**	**7,357 (12)**	**3,417 (5)**	**24,256 (38)**

Among the sputum eligible survey participants (9,715), 74% (7,185) had at least one symptom. The most common symptom was cough of two weeks or more (43%), followed by chest pain (41%), cough with sputum (32%), drenching night sweats (27%), fatigue (27%), fever (19%), shortness of breath (11%), weight loss (8%) and hemoptysis (4%) (Table 2.7).

Table 2.7: Frequency of TB related symptoms among sputum eligible participants

Symptoms	Number	% symptomatic	% Eligible to give sputum
Cough > 2 weeks	4,137	58	43
Coughing	4,873	68	50
Chest pain	3,982	55	41
Cough with sputum	3,128	44	32
Drenching night sweats	2,653	37	27
Fatigue	2,612	36	27
Fever	1,833	26	19
Shortness of Breath	1,060	15	11
Cough < 2weeks	736	10	8
Weight loss	779	11	8
Other symptoms	473	7	5
Hemoptysis (blood cough)	384	5	4
Total symptomatic	**7,185**	**100**	**74**

Total (Eligible to give sputum)	**9,715**		**100**

2.5.2 Chest X-Ray Examinations

Cumulatively, 62,484 individuals (99% of the survey participants) were screened using chest x-ray while 429 participants declined. Among those eligible for sputum submission, 5,184 (53%) were eligible based on chest x-ray alone while 1,241 (13%) were eligible based on both symptoms and x-ray. Abnormal chest x-ray findings suggestive of TB were higher among male participants and those 65 years and above.

Table 2. 8: Field chest X-ray reading by sex, age and geographical setting among participants

Characteristics	Field Chest X-ray Reading					
	Enrolled	Normal	Abnormal Suggestive Of TB	Other Abnormalities	Not X-Rayed	X-Rayed
	N (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Sex						
Female	**37,006 (59)**	30,063 (81)	3,172 (9)	3,434 (9)	337 (1)	36,669 (99)
Male	**26,044 (41)**	20,872 (80)	3,253 (12)	1,690 (6)	229 (1)	25,815 (99)
Age Group (years)						
15 – 24	**17,735 (28)**	16,482 (93)	702 (4)	399 (2)	152 (1)	17,583 (99)
25 – 34	**15,504 (25)**	13,599 (88)	1,120 (7)	614 (4)	171 (1)	15,333 (99)
35 – 44	**11,318 (18)**	9,252 (82)	1,211 (11)	767 (7)	88 (1)	11,230 (99)
45 – 54	**7,549 (12)**	5,691 (75)	977 (13)	839 (11)	42 (1)	7,507 (99)
55 – 64	**5,183 (8)**	3,310 (64)	913 (18)	919 (18)	41 (1)	5,142 (99)
65+	**5,761 (9)**	2,601 (45)	1,502 (26)	1,586 (28)	72 (1)	5,689 (99)
Setting						
Rural	**43,606 (69)**	35,076 (80)	4,321 (10)	3,856 (9)	353 (1)	43,253 (99)
Urban	**19,444 (31)**	15,859 (82)	2,104 (11)	1,268 (7)	213 (1)	19,31 (99)
Total	**63,050**	**50,935 (81)**	**6,425 (10)**	**5,124 (8)**	**566 (1)**	**62,484 (99)**

Concordance between MFS and national chest x-ray readings

For quality assurance, 17% of all x-ray images were sampled for central re-reading by the national radiologists. Overall concordance levels between national radiologists and MFS clinicians was 92% on normal, 28% on abnormal suggestive of TB and 24% on abnormal other. Concordance improved in the second phase of implementation (clusters 49 - 100) on abnormal TB suggestive readings from 21% to 74%, and for abnormal other readings from 19% to 64% (Table 2.9). This was due to enhanced MFS mentorship for the clinicians by the

national radiologists and daily discussion of discordant readings by the MFS clinicians to understand differences and get to a consensus.

Table 2.9: Concordance between MFS clinicians and national radiologists' chest x-ray readings

Central Reader	Field Reader			
	Normal	Abnormal TB	Other Abnormalities	Total
	N (%)	N (%)	N (%)	N (%)
Overall				
Normal	5,121 (92)	1,616 (60)	1,388 (66)	8,125 (78)
Abnormal TB	220 (4)	771 (29)	209 (10)	1,200 (12)
Other Abnormalities	242 (4)	314 (12)	500 (24)	1,056 (10)
Total	**5,583 (54)**	**2,701 (26)**	**2,097 (20)**	**10,381**
Phase 1				
Normal	2,304 (94)	1,553 (67)	1,332 (71)	5,189 (78)
Abnormal TB	73 (3)	501 (21)	186 (10)	760 (11)
Other Abnormalities	77 (3)	280 (12)	362 (19)	719 (11)
Total	**2,454 (37)**	**2,334 (35)**	**1,880 (28)**	**6,668**
Phase 2				
Normal	2,817 (90)	63 (17)	56 (26)	2,936 (79)
Abnormal TB	147 (5)	270 (74)	23 (11)	440 (12)
Other Abnormalities	165 (5)	34 (9)	138 (64)	337 (9)
Total	**3,129 (84)**	**367 (10)**	**217 (6)**	**3,713**

2.6 Eligibility to Submit Sputum

A total of 9,715 (15%) participants were eligible for sputum submission. Of these, 5,184 (53%) were eligible through chest x-ray findings only, 2,896 (30%) through symptoms only, 1,241 (13%) through both x-ray and symptoms, while 394 (4%) were eligible because they declined x-ray screening though asymptomatic (Table 2.10).

Table 2.10: Sputum eligible participants by x-ray and symptoms

Sputum eligibility criteria	N (%)
Eligible by chest x-ray screening only	5,184 (53)
Eligible by symptoms only	2,896 (30)
Eligible by both (x-ray and symptoms screening)	1,241 (13)
Eligible by declining chest x-ray screening and are asymptomatic	394 (4)
Total	**9,715 (100)**

2.7 Laboratory Examinations

A total of 9,120 (94%) sputum eligible participants submitted at least one sputum specimen, while 7,763 (80%) submitted both. Among these participants, 9,120 (94%) had smear microscopy and culture done, whilst 8,954 (92%) had Xpert MTB/RIF test as shown in Table 2.11. Of the specimens tested, Xpert MTB/RIF had the highest number of positives (2.7%) followed by culture with 2.4%, while microscopy yielded only 1.6% (Table 2.11). The contamination rate was 3.9%.

A total of six multi-drug resistant TB (MDR-TB) study participants were diagnosed (two from both culture and Xpert, and from Xpert alone). A total of 225 participants had DST done.

Table 2.11: Laboratory examination results

Laboratory Method	Results	Freq. (%)	Spot (%)	Morning (%)
Smear	POS	141 (1.6)	140 (1.6)	131 (1.7)
	NEG	8,979 (98.5)	8,834 (98.4)	7,777 (98.3)
	Total	**9,120**	**8,974**	**7,908**
Xpert MTB/RIF	MTB	237 (2.7)	235 (3.0)	218 (2.5)
	MTB Not Detected	8,699 (97.2)	7,623 (96.8)	8,557 (97.3)
	Error	9 (0.1)	16 (0.2)	17 (0.2)
	Invalid	8 (0.1)	0	0
	Not Done	1 (0.1)	0	0
	Total	**8,954**	**7,874**	**8,792**
Culture	MTB	218 (2.4)	216 (2.4)	197 (2.5)
	NTM	236 (2.6)	0	0
	No Growth reported	8,307 (91.1)	8,427 (93.9)	7,462 (94.4)
	Contaminated	359 (3.9)	331 (3.7)	249 (3.1)
	Total	**9,120**	**8,974**	**7,908**

2.7.1 Comparison of screening methods and laboratory test results

Eighty nine percent (188/211) of the participants who were culture positive and 94% (221/223) of those with Xpert MTB/RIF positive results had x-rays suggestive of TB. Fifty-five percent (102/186) of the participants with culture positive results and 49% (117/237) of participants with Xpert MTB/RIF positive results had a cough of more than two weeks (Table 2.12).

Table 2.12: A comparison of screening methods with laboratory test results

	Culture					Xpert MTB/RIF					
	Pos	Neg	NTM	Cont	Total	MTB	Neg	Error	Invalid	No result	Total
	n (%)	n (%)	n (%)	n (%)	N (%)	n (%)	n (%)	n (%)	n (%)	n (%)	N (%)
X-ray											
Normal	19 (0.2)	2,035 (23)	39 (0.4)	77 (1)	**2170 (25)**	10 (0.1)	2,100 (24)	2 (0)	6 (0)	0 (0)	**2,118 (24)**
Abnormal TB	188 (2)	5,492 (62)	175 (2)	239 (3)	**6,094 (69)**	221 (3)	5,766 (67)	6 (0)	2 (0)	1 (0)	**5,996 (69)**
Abnormal Other	4 (0)	516 (6)	17 (0.2)	28 (0.3)	**565 (7)**	2 (0)	550 (6)	1 (0)	0 (0)	0 (0)	**553 (6)**
Total	**211 (2)**	**8,043 (91)**	**231 (3)**	**344 (4)**	**8,829 (100)**	**233 (3)**	**8,416 (97)**	**9 (0.1)**	**8 (0)**	**1 (0)**	**8,667 (100)**
Cough											
Cough<2weeks	84 (1)	4,743 (52)	111 (1)	211 (2)	**5,149 (56)**	120 (1)	4,932 (55)	5 (0.1)	2 (0)	1 (0)	**5,060 (57)**
Cough>=2weeks	102 (1)	3,662 (40)	59 (1)	148 (2)	**3,971 (44)**	117 (1)	3,767 (42)	4 (0)	6 (0)	0 (0)	**3,894 (43)**
Total	**186 (2)**	**8,405 (92)**	**170 (2)**	**359 (4)**	**9,120 (100)**	**237 (3)**	**8,699 (97)**	**9 (0.1)**	**8 (0)**	**1 (0)**	**8,954 (100)**

2.8 Health Seeking Behaviour of Survey Participants

A total of 24,256 (39%) study participants reported at least one symptom. Among them, 3,948 (16%) reported that they had sought health care for the symptoms and 19,463 (80%) reported not seeking for care at all, while 845 (3.5%) gave no response. Of those that did not seek health care, 43.7% of them gave no reason while 10,957 (56.3%) had varying reasons. A majority (82%) of these respondents did not seek care for the symptoms because they felt the symptoms were not serious as indicated in Table 2.13.

Table 2.13: Reasons for not seeking health care by sex, age and setting among survey participants

Why did you not seek for care?			Symptoms not serious	No money	Health care too far	Already on treatment	Other reason	Overall
Sex	**Male**	**n (%)**	3,734 (84)	223 (5)	39 (1)	151 (3)	322 (7)	**4,469 (41)**
	Female	**n (%)**	5,283 (81)	304 (5)	86 (1)	301 (5)	514 (8)	**6,488 (59)**
Settings	**Urban**	**n (%)**	2,868 (81)	172 (5)	24 (1)	166 (5)	308 (9)	**3,538 (32)**
	Rural	**n (%)**	6,149 (83)	355 (5)	101 (1)	286 (4)	528 (7)	**7,419 (68)**
Age Group (years)	**15-24**	**n (%)**	1,880 (85)	93 (4)	23 (1)	68 (3)	164 (7)	**2,228 (20)**
	25-34	**n (%)**	2,129 (84)	122 (5)	25 (1)	93 (4)	172 (7)	**2,541 (23)**
	35-44	**n (%)**	1,746 (83)	79 (4)	15 (1)	71 (3)	183 (9)	**2,094 (19)**
	45-54	**n (%)**	1,306 (82)	73 (5)	17 (1)	76 (5)	118 (7)	**1,590 (15)**
	55-64	**n (%)**	909 (81)	51 (5)	22 (2)	65 (6)	77 (7)	**1,124 (10)**
	65+	**n (%)**	1,047 (76)	109 (8)	23 (2)	79 (6)	122 (9)	**1,380 (13)**
Total		**N (%)**	**9,017 (82)**	**527 (5)**	**125 (1)**	**452 (4)**	**836 (8)**	**10,957 (100)**

Most of the participants who sought care for the symptoms went to county public hospitals (78%) whilst 16% visited private practitioners as shown in Table 2.14. Females had a slightly higher percentage (79%) visiting county hospitals compared to the males (75%), while visits to private practitioners were comparable between males and females. The age groups of 55 years and above had the highest percentage (83%) visiting the county hospitals compared to the lower age groups. The age group 25 – 44 years had the highest percentage (20%) visiting private practitioners (Table 2.14).

Table 2.14: Facilities where health care was sought by sex and urban/rural setting among survey participants

Where did you seek for care?			County Hospital	Peripheral Health Facility	Pharmacy	Private Practitioner	Traditional Healer	Other	Overall
Sex	**Male**	**n (%)**	959 (75)	13 (1)	79 (6)	223 (17)	6 (0)	2 (0)	**1,282 (32)**
	Female	**n (%)**	2,111 (79)	6 (0)	107 (4)	424 (16)	10 (0)	5 (0)	**2,663 (68)**
Settings	**Urban**	**n (%)**	793 (63)	7 (1)	110 (9)	348 (27)	4 (0)	4 (0)	**1,266 (32)**
	Rural	**n (%)**	2,277 (85)	12 (0)	76 (3)	299 (11)	12 (0)	3 (0)	**2,679 (68)**
Age Group (years)	**15-24**	**n (%)**	495 (81)	1 (0)	29 (5)	84 (14)	1 (0)	0 (0)	**610 (15)**
	25-34	**n (%)**	547 (72)	2 (0)	55 (7)	154 (20)	3 (0)	1 (0)	**762 (19)**
	35-44	**n (%)**	557 (73)	6 (1)	42 (6)	154 (20)	4 (1)	1 (0)	**764 (19)**
	45-54	**n (%)**	473 (78)	4 (1)	26 (4)	100 (17)	2 (0)	1 (0)	**606 (15)**
	55-64	**n (%)**	374 (83)	2 (0)	14 (3)	62 (14)	0 (0)	1 (0)	**453 (11)**
	65+	**n (%)**	624 (83)	4 (1)	20 (3)	93 (12)	6 (1)	3 (0)	**750 (19)**
Total		**N (%)**	**3,070 (78)**	**19 (0)**	**186 (5)**	**647 (16)**	**16 (0)**	**7 (0)**	**3,945 (100)**

3. TB PREVALENCE: KEY RESULTS

3.1 TB Prevalence Rate

The case definition of pulmonary TB among survey participants was that an enrolled participant had to be sputum eligible with bacteriologically confirmed (Xpert MTB/RIF positive and/or culture positive for *Mycobacterium tuberculosis* (MTB) in sputum. A total of 320 survey participants were bacteriologically confirmed positive for MTB, nine of them were excluded as survey prevalent cases because they were not eligible for sputum submission; they had no cough of ≥ two weeks and their field chest x-rays were interpreted as abnormal other. A further six bacteriologically confirmed individuals were excluded as prevalent cases because of the following reasons: one individual was not in the survey census population, another did not meet the survey residential criteria thus should not have participated in the survey, there was an individual without screening data, another had no cough of ≥ two weeks with no field CXR data, there was a sputum eligible participant with three laboratory specimens and another with a specimen number not matching their survey ID. With the exclusion of these 15 bacteriologically confirmed participants, the survey reported 305 bacteriologically confirmed positive results.

Of 76,291 eligible participants, 63,050 (83%) were enrolled into the study yielding 305 bacteriologically confirmed cases.

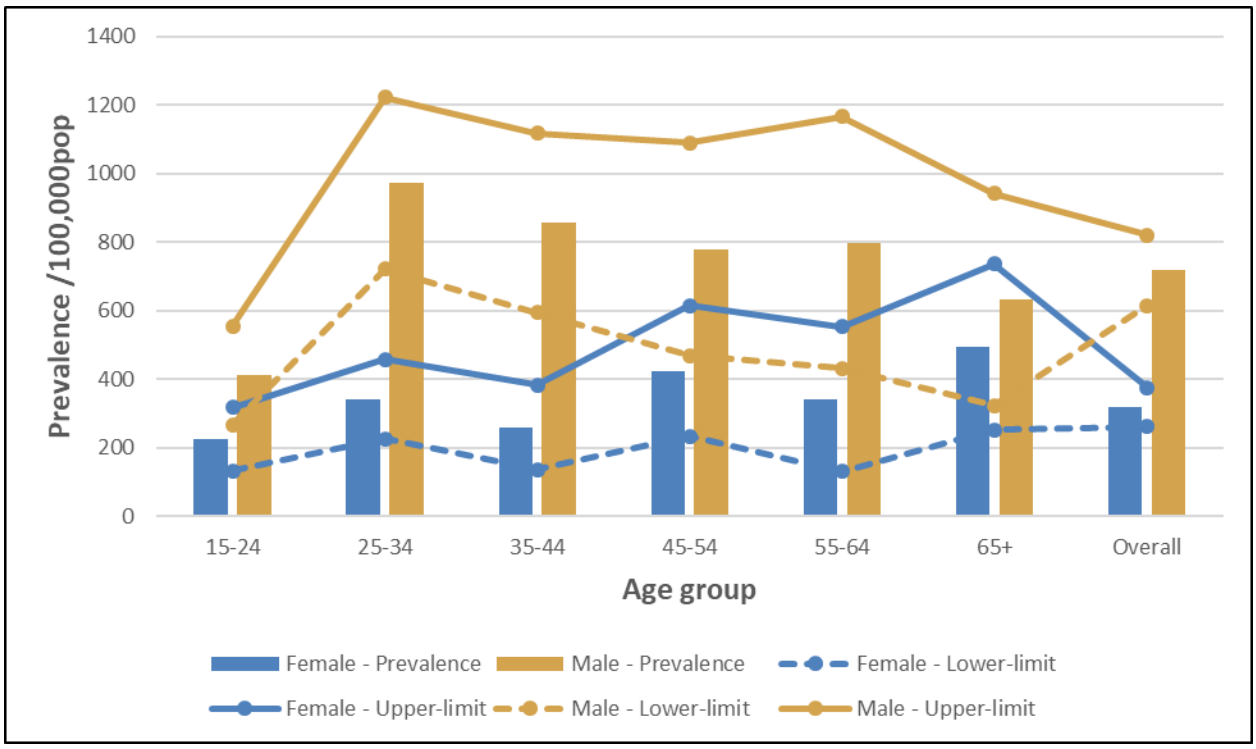
3.1.1: Crude Prevalence Rates of TB by Sex, Age Group and Setting in 15 Years and above Population

The crude prevalence of bacteriologically confirmed TB was highest in males at 530 (442-618) per 100,000 population compared to females at 208 (162-255) per 100,000. The disease burden was highest in the age groups 25-34 and 55-64 (419 and 386 per 100,000 respectively) and lowest in the age group of 15-24 (237 per 100,000) (Table 3.1).

Table 3.1: Crude Prevalence rates of TB in 15 years and above population

			Smear-positive (95%CI)	Bact Confirmed (95%CI)	Xpert-only (95%CI)
1	**Sex**	**Male**	311 (243, 379)	530 (442, 618)	557 (466, 647)
		Female	113 (79, 148)	208 (162, 255)	249 (198, 299)
2	**Age Group**	**15-24**	180 (118, 243)	237 (165, 308)	259 (185, 334)
		25-34	219 (146, 293)	419 (318, 521)	445 (340, 550)
		35-44	256 (163, 349)	353 (244, 463)	424 (304, 544)
		45-54	199 (98, 299)	371 (234, 508)	450 (299, 601)
		55-64	116 (23, 208)	386 (217, 555)	289 (143, 436)
		65+	122 (32, 211)	347 (195, 499)	434 (264, 604)
3	**Setting**	**Urban**	627 (516, 738)	627 (516, 738)	627 (516, 738)
		Rural	420 (359, 480)	420 (359, 480)	420 (359, 480)

Males in the age group 25-34 (972 per 100,000) and females 65 years and above (495 per 100,000) had the highest prevalence as shown in Figure 3.1 below.



*Prevalence per 100,000 population

Figure 3.1: Prevalence of TB by sex and age group among survey cases

3.1.2 Weighted Prevalence Rates of TB by Sex, Age Group and Setting in Population 15 Years and Above

The weighted TB prevalence rate of bacteriologically confirmed cases was 558 (455-662) per 100,000 adult population using model three imputations. The males had more than twice the prevalence rate compared to the females; 809 per 100,000 adult population against 359 per 100,000 adult population (Table 3.2). The age group 25 - 34 still had the highest prevalence rate of 716 (526 -906) per 100,000 adult population compared to the other age groups.

Table 3.2: Overview of weighted (module 3) pulmonary TB prevalence in 15+ year population

Model 3 (m20, 20 cycles)		**Smear Positive (N=123)**	**Bacteriological Confirmed (N=305)**	**Xpert Only (N=237)**
Robust standard errors with multiple imputation and inverse probability weighting		**Smear-Positive (95%CI)**	**Bacteriological Confirmed (95%CI)**	**Xpert Only (95%CI)**
1	**National**	230 (174,286)	558 (455,662)	431 (353,509)
2	**Sex**			
	Male	346 (260,431)	809 (656,962)	614 (498,729)
	Female	138 (79,196)	359 (258,460)	286 (202,370)
3	**Age**			
	15-24	218 (133,303)	360 (242,478)	311 (206,416)
	25-34	259 (164,353)	716 (526,906)	530 (381,679)
	35-44	297 (164,430)	602 (422,782)	484 (319,649)
	45-54	234 (101,367)	607 (432,781)	492 (327,656)
	55-64	118 (24,211)	587 (372,803)	313 (159,467)
	65+	125 (24,226)	576 (368,783)	449 (264,634)
4	**Setting**			
	Urban	335 (213,456)	760 (539,981)	603 (439,767)
	Rural	175 (126,224)	453 (357,549)	341 (268,414)
Variables used for this model included: age group, sex, strata, cough 2wks, history of treatment and central CXR reading				

3.1.3 TB Prevalence Rate for All Forms of TB and All Ages

Extrapolation of the burden to all forms of TB and all ages resulted in a national prevalence of 426 (347-504) per 100,000 population.

3.1.4 Comparison with TB Notification Data from Routine TB Surveillance

Figure 3.2 below describes the distribution of TB prevalence from the survey findings and case notification rate from the routine surveillance system. Generally, the notification rate is lower than the prevalence rate by age groups. The gap between prevalence and notification rates is higher, mainly affecting age groups 25-34 and the older age group of 65+ years.

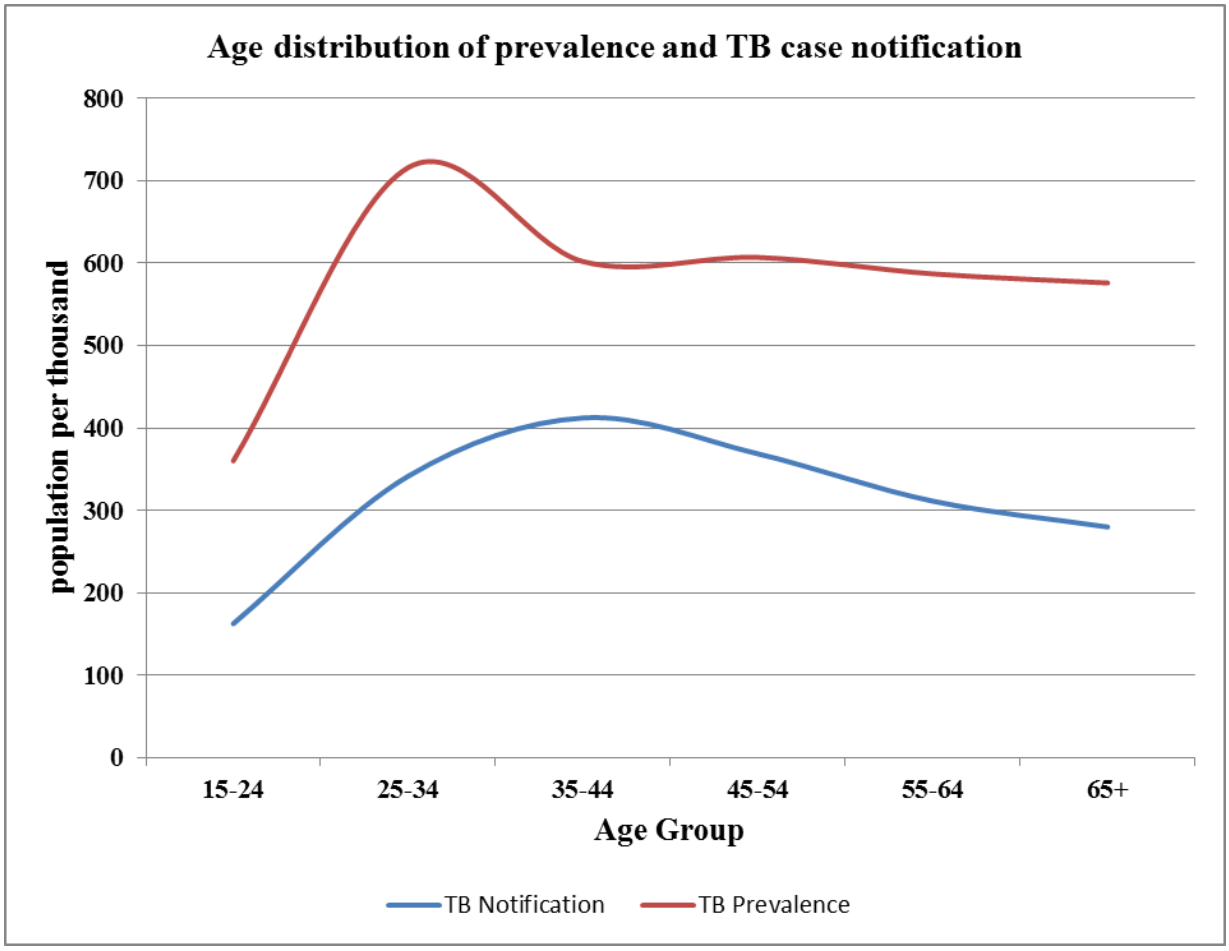


Figure 3.2: Age distribution of prevalence and TB case notification

3.1.5: Proportion of Prevalent TB Cases Screened by Cough and Chest X-Ray

By using the different screening symptoms, 175 (57%) of the prevalent cases reported a cough of any duration. Among the prevalent cases, 147 (48%) reported cough of greater than two weeks while 28 (9%) reported a cough of less than two weeks. Forty-three percent of the prevalent cases reported no history of cough (Table 3.4).

Digital chest x-ray was able to detect 269 (88.2%) and missed 29 (9.5%) of the prevalent cases while 7 (2.3%) had no chest x-ray done.

New cases contributed the highest number of prevalent cases at 219 (72%) while previously treated cases accounted for 71 (24%) and those current on treatment represented 15 (5%) (Table 3.3).

Table 3.3: Proportion of prevalent cases by screening methods

	Bacteriologically Confirmed Cases	Percentage of Prevalent Cases
Symptoms Present		
Cough >=2 Weeks	147	**48.2**
Cough < 2 Weeks	28	**9.2**
No Cough	130	**42.6**
Overall	**305**	**100**
Field X-ray Results		
Abnormal TB	269	**88.2**
Normal	24	**7.9**
Abnormal others	5	**1.6**
Declined/Missing	7	**2.3**
Overall	**305**	**100**

Table 3.4 below demonstrates that if cough of ≥ two weeks was used as the only screening method, 158 (52%) of the prevalent cases would have been missed. When a combination of the four cardinal symptoms (cough ≥ two weeks, fever, night sweat and weight loss) were used for screening, 124 (41%) of the cases would have been missed. Use of any TB related symptom for screening would have missed only 80 (26%) of the prevalent cases.

Table 3.4: Symptoms profile of the prevalent TB cases

Symptom	Cases	%
Cough > two weeks only	147	48
Night sweats only	85	28
Fever only	62	20
Weight loss only	41	13
Weight loss or fever or night sweats or cough more than two weeks	181	59
Any coughing or fever or weight loss or night sweats or fatigue or other symptoms or shortness of breath or chest pains (At least one symptom)	225	74
Total	**305**	**100**

3.1.6: Comparison of Yield by Diagnostic Methods

Table 3.5 below describes the concordance level of results between Xpert MTB/RIF and culture methods. Of the 305 TB cases, 48.2% were detected by both methods. A total of 90 cases (29.5%) were diagnosed by Xpert MTB/RIF but were missed by culture, while 65 (21.3%) were diagnosed by culture but missed by Xpert MTB/RIF.

Table 3.5: Comparison of TB yield by diagnostic methods among the 305 prevalent cases

			Culture results			
			Culture MTB Positive	Culture Negative	Contaminated	Grand Total
Prevalent cases	**Xpert MTB/RIF results**	**MTB Positive**	147 (48.2%)	88 (28.9%)	2 (0.8%)	**237 (77.7%)**
		MTB Negative	65 (21.3%)	-	-	**65 (21.3%)**
		Error	1 (0.3%)	-	-	**1 (0.3%)**
		Not Done	2 (0.7%)	-	-	**2 (0.7%)**
		Grand Total	**215 (70.5%)**	**88 (28.9%)**	**2 (0.7%)**	**305 (100%)**
			Culture results			
			Culture MTB Positive	**Culture Negative**	**Contaminated**	**Grand Total**
Smear +ve cases	**Xpert MTB/RIF results**	**MTB Positive**	111 (76.0%)	15 (10.3%)	-	**126 (86.3%)**
		MTB Negative	-	18 (12.3%)	-	**18 (12.3%)**
		Error	-	-	-	-
		Not Done	-	1 (0.7%)	1 (0.7%)	**2 (1.4%)**
		Grand Total	**111 (76.0%)**	**34 (11.1%)**	**1 (0.7%)**	**146 (100%)**
			Culture results			
			Culture MTB Positive	**Culture Negative**	**Contaminated**	**Grand Total**
Smear -ve cases	**Xpert MTB/RIF results**	**MTB Positive**	39 (0.4%)	73 (0.8%)	2 (0.0%)	**114 (1.3%)**
		MTB Negative	68 (0.8%)	8,268 (96.7%)	346 (3.9%)	**8,682 (96.7%)**
		Error	1 (0.0%)	17 (0.2%)	0	**18 (0.2%)**
		Not Done	2 (0.0%)	153 (1.7%)	10 (0.1%)	**165 (1.8%)**
		Grand Total	**110 (0.1)**	**8,511 (94.8%)**	**358 (4.0%)**	**8,979 (100%)**

3.1.7 Combined Culture and Xpert MTB/RIF Examinations Vs Screening Methods Among Survey Cases

Among the prevalent cases, 269 (88%) had abnormal chest x-ray findings suggestive of TB at field level, 147 (48%) had cough of two weeks or more and 115 (38%) had both (Table 3.6).

Table 3.6: Combined results (culture and/or Xpert MTB/RIF) tabulated by chest X-ray reading at MFS and eligibility for sputum examination to a) X-ray, b) symptoms and c) symptoms and X-ray

	Combined result (culture and/or Xpert MTB/RIF)				**Total**
	Positive	**Negative**	**Invalid**	**Not available**	
	n (%)	**n (%)**	**n (%)**	**n (%)**	**N (%)**
Field X-ray reading					
Normal	24 (0)	2,146 (22)	0 (0)	105 (1)	2,275 (23)
Abnormal (suggestive of TB)	269 (3)	5,825 (60)	1 (0)	330 (3)	6,425 (66)
Abnormal other	5 (0)	560 (6)	0 (0)	12 (0)	577 (6)
Not x-rayed	7 (0)	284 (3)	0 (0)	147 (2)	438 (5)
Eligible for sputum examination according to symptoms (i.e. cough ≥2 weeks)					

	Combined result (culture and/or Xpert MTB/RIF)				Total
	Positive	Negative	Invalid	Not available	
	n (%)	n (%)	n (%)	n (%)	N (%)
No	158 (3)	4,991 (51)	1 (0)	428 (4)	5,578 (57)
Yes	147 (4)	3,824 (39)	0 (0)	166 (2)	4,137 (43)
Eligible for sputum examination according to both X-ray and symptoms					
No	190 (2)	7,722 (79)	1 (0)	561 (6)	8,474 (87)
Yes	115 (1)	1,093 (11)	0 (0)	33 (0)	1,241 (13)
Overall	**305 (3)**	**8,815 (91)**	**1 (0)**	**594 (6)**	**9,715 (100)**

3.2: HIV Status of the Prevalent Cases

Survey participants with confirmed TB were linked to routine care and treatment which included HIV counselling and testing. The cases were included into the TB electronic reporting system -TIBU. This made it possible to retrieve HIV status results of the prevalent cases. The HIV prevalence rate among the documented 245 cases was 16.7% (n=41) (Table 3.7).

Table 3.7: HIV status of the prevalent cases by age group and sex

Age group (years)	HIV-Negative	HIV-Positive	Died before start of RX	Declined	Not traced	Grand Total
15-24	39	4	0	1	10	**54**
25-34	53	13	0	3	21	**90**
35-44	34	14	0	2	9	**59**
45-54	35	5	0	0	3	**43**
55-64	16	4	0	0	7	**27**
65+	27	1	1	0	3	**32**
Total	**204 (66.9%)**	**41 (13.4%)**	**1 (0.3%)**	**6 (2.0%)**	**53 (17.4%)**	**305**

Sex	HIV Status					
	Negative	Positive	Died before start of RX	Declined	Not Traced	Total
Female	73	22	0	1	23	**119**
Male	131	19	1	5	30	**186**
Total	**204**	**41**	**1**	**6**	**53**	**305**

The survey sought to verbally establish the study participants' HIV status. About 32,386 (51%) of the participants knew their HIV status and of these, 1,627 (5%) reported to be HIV positive

(Table 3.8). Among the prevalent survey cases, 200 (23%) reported to be HIV positive, a percentage much higher than that obtained from HIV screening (16.7%).

Table 3.8: Survey participants HIV status from self-reporting

	HIV	Enrolled (%)	TB Cases (%)
1	Know HIV status	32,386 (51)	200 (66)
2	Positive	1,627 (5)	46 (23)
3	Negative	30,759 (95)	154 (77)
4	No knowledge	30 (0)	0 (0)
5	No answer	30,634 (49)	105 (34)
	Total	**63,050 (100)**	**305 (100)**

3.3 History of TB Treatment Among the Bacteriologically Confirmed Cases

Only 15 (5%) of the prevalent cases were currently on treatment.

Table 3.9: History of TB treatment among the bacteriologically confirmed cases

History of TB Treatment	Bacteriologically Confirmed Cases n (%)
Past history	73 (24)
Current TB treatment	15 (5)
No history of TB treatment	217 (71)
Overall	**305 (100)**

3.4 Health Seeking Behaviour of Prevalent TB Cases

Among the prevalent cases (n=305), 225 (74%) presented with TB related symptoms. Among those who presented with any symptoms, 146 (64.9%) had not sought treatment prior to the survey, 75 (33.3%) had sought treatment and 4 (1.8%) did not respond to the question.

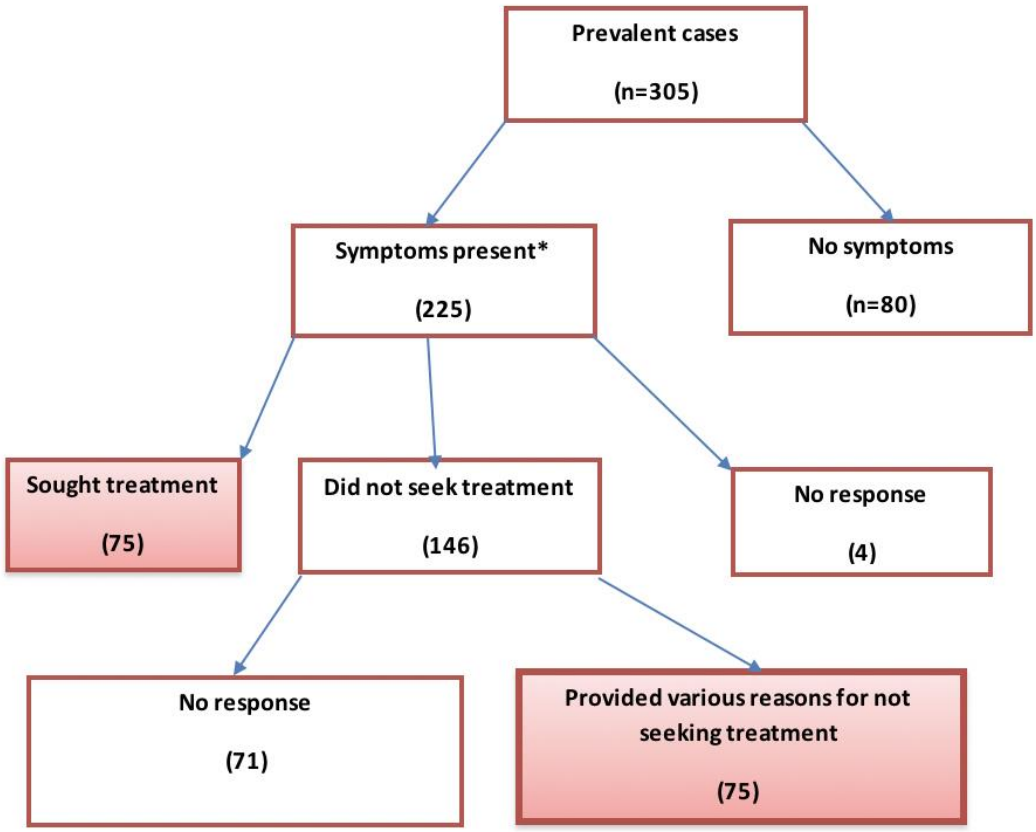


Figure 3.3: Flow chart on health seeking behaviour among prevalent cases

Table 3.10 shows the facilities where the 75 symptomatic participants sought treatment. County hospitals were the most visited facilities at 58 (77.3%), while the private sector (pharmacies and private practitioners) were 16 (21%).

Table 3.10: Summary of health seeking behaviour of symptomatic prevalent cases (n=75) by sex, residence, marital status, education and occupation

Characteristics		County Hospital N (%)	Peripheral Health Facility N (%)	Pharmacy N (%)	Private Practitioner N (%)	Traditional Healer N (%)	Other N (%)	Overall N (%)
Sex	Males	34(82)	1(2)	2(4)	4(9)	0(0)	0(0)	**41(54)**
	Females	24(70)	0(0)	1(2)	9(26)	0(0)	0(0)	**34(45)**
Residential status	Urban	22(64)	1(2)	1(2)	10(29)	0(0)	0(0)	**34(45)**
	Rural	36(87)	0(0)	2(4)	3(7)	0(0)	0(0)	**41(54)**
Marital Status	Single	13(72)	0(0)	0(0)	5(27)	0(0)	0(0)	**18(24)**
	Married	39(81)	1(2)	2(4)	6(12)	0(0)	0(0)	**48(64)**
	Divorced	4(80)	0(0)	1(20)	0(0)	0(0)	0(0)	**5(6)**
	Widowed	2(50)	0(0)	0(0)	2(50)	0(0)	0(0)	**4(5)**
	No schooling	8(72)	0(0)	1(9)	2(18)	0(0)	0(0)	**11(14)**

Characteristics		County Hospital N (%)	Peripheral Health Facility N (%)	Pharmacy N (%)	Private Practitioner N (%)	Traditional Healer N (%)	Other N (%)	Overall N (%)
Education status	Primary school, not completed	19(79)	1(4)	2(8)	2(8)	0(0)	0(0)	**24(32)**
	Completed primary school	13(86)	0(0)	0(0)	2(13)	0(0)	0(0)	**15(20)**
	Secondary school Not completed	6(66)	0(0)	0(0)	3(33)	0(0)	0(0)	**9(12)**
	Completed secondary school	10(90)	0(0)	0(0)	1(9)	0(0)	0(0)	**11(14)**
	Further education after secondary school	2(40)	0(0)	0(0)	3(60)	0(0)	0(0)	**5(6)**
Occupation status	Farming	17(94)	1(5)	0(0)	0(0)	0(0)	0(0)	**18(24)**
	Fishing	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	**0(0)**
	Business	13(72)	0(0)	1(5)	4(22)	0(0)	0(0)	**18(24)**
	Employed by Government	2(100)	0(0)	0(0)	0(0)	0(0)	0(0)	**2(2)**
	Employed by private sector	1(33)	0(0)	0(0)	2(66)	0(0)	0(0)	**3(4)**
	Pupil/ Student	2(66)	0(0)	0(0)	1(33)	0(0)	0(0)	**3(4)**
	Housewife	7(70)	0(0)	2(20)	1(10)	0(0)	0(0)	**10(13)**
	Unemployed	14(77)	0(0)	0(0)	4(22)	0(0)	0(0)	**18(24)**
	Other	2(66)	0(0)	0(0)	1(33)	0(0)	0(0)	**3(4)**
TOTAL	**N (%)**	**58(77.3)**	**1(1.3)**	**3(4.0)**	**13(17.3)**	**0**(0)	**0**(0)	**75(100)**

For those who presented with symptoms, 146 (64.9%) did not seek treatment and only 75 (51.4%) provided reasons for not seeking treatment. The Table 3.11 shows the reasons why the cases did not seek treatment and their social economic characteristics. About 56 (75%) did not seek treatment because they thought the symptoms were not serious.

Table 3.11: Summary of reasons for not seeking health care among the prevalent cases by sex, residence, marital status, education and occupation

Characteristics		Symptoms Not Serious N (%)	No Money N (%)	Already on Treatment N (%)	Other Reason N (%)	Overall (With Reason) N (%)	No Response N (%)
Gender	**Males**	37(75)	4(8)	2(4)	6(12)	**49(65)**	41(58)
	Females	19(73)	1(3)	3(11)	3(11)	**26(34)**	30(42)
Residential status	**Urban**	20(68)	1(3)	5(17)	3(10)	**29(38)**	28(39)
	Rural	36(78)	4(8)	0(0)	6(13)	**46(61)**	43(61)
Marital status	**Single**	15(71)	2(9)	1(4)	3(14)	**21(28)**	20(28)
	Married	38(76)	2(4)	4(8)	6(12)	**50(66)**	37(52)
	Divorced	2(66)	1(33)	0(0)	0(0)	**3(4)**	8(11)
	Widowed	1(100)	0(0)	0(0)	0(0)	**1(1)**	6(8)
Education status	**No schooling**	9(90)	1(10)	0(0)	0(0)	**10(13)**	10(14)
	Primary school, not completed	17(73)	2(8)	1(4)	3(13)	**23(30)**	21(30)
	Completed primary school	13(72)	1(5)	1(5)	3(16)	**18(24)**	19(27)
	Secondary school Not completed	8(66)	1(8)	2(16)	1(8)	**12(16)**	10(14)
	Completed secondary school	6(66)	0(0)	1(11)	2(22)	**9(12)**	7(10)
	Further education after secondary school	3(100)	0(0)	0(0)	0(0)	**3(4)**	4(6)
Occupation status	**Farming**	23(82)	2(7)	1(3)	2(7)	**28(37)**	25(25)
	Fishing	0(0)	0(0)	0(0)	0(0)	**0(0)**	1(1)
	Business	16(72)	2(9)	1(4)	3(13)	**22(29)**	14(20)
	Employed by Government	3(75)	0(0)	0(0)	1(25)	**4(5)**	0(0)
	Employed by private sector	3(75)	0(0)	0(0)	1(25)	**4(5)**	4(6)
	Pupil/ Student	4(80)	0(0)	0(0)	1(20)	**5(6)**	6(8)
	Housewife	3(75)	0(0)	1(25)	0(0)	**4(5)**	8(11)
	Unemployed	4(57)	1(14)	1(14)	1(14)	**7(9)**	10(14)
	Other	0(0)	0(0)	1(100)	0(0)	**1(1)**	3(4)
TOTAL	**N (%)**	**56 (75)**	**5 (6.5)**	**5(6.5)**	**9(12)**	**75(100)**	**71**

4. DISCUSSION

The prevalence of bacteriologically confirmed pulmonary TB in those ≥15 years in Kenya was found to be 558 (455-662) per 100,000 adult population. The TB adult prevalence was comparable with findings in Nigeria 524 (378-670) per 100,000 population and Zambia 638 (502-774) per 100,000 population but higher than that reported in Ethiopia 277 (208 -347) per 100,000 population (Ministry of Health, Zambia, 2013 - 2014) (Federal Republic of Nigeria, 2012) (Federal Democratic Republic of Ethiopia, Ministry of Health, 2011).

Extrapolation of the survey prevalence to all forms of TB and all ages results in an overall prevalence of 426 (347-504) per 100,000 population (refer to Annex 10). Compared to the 2016 reported notification rate for Kenya, the prevalence to notification ratio is 2.5:1 (WHO, 2017). It also results in an upward revision of the TB incidence rate to 348 (213-516) in 2016, compared to the WHO pre-survey estimate (which had assumed a decline from 2005) of 233 per 100,000 (95% CI 188–266) (WHO, 2016, WHO, 2016c,). Kenya is thus facing one of the highest burdens of TB in the world and by actual numbers, there were about 169,000 (103,000-250,000) people who fell ill with TB disease in 2016, yet only 46% (77,376) were diagnosed and put on treatment (WHO,2016c, WHO,2017).

This survey data helps to point at some of the causes of the high burden of TB and the case detection gap. First, 67% of TB patients with symptoms are in the community but do not seek health care for various reasons. Second, 80% of those who seek care with symptoms, do not get diagnosed at initial contact with the health facility for various reasons like the widespread use of smear microscopy - 60% of the survey cases had smear-negative TB. Third, 23% of people with TB disease are undiagnosed while being considered 'asymptomatic' and would not qualify for evaluation on account of the lack of cardinal TB symptoms (weight loss, fever, night sweats and cough of more than two weeks) unless a broader 'symptomatic criteria' is used (Wells, 2017). Fourth, triangulation of data from this survey and the patient pathway analysis shows a gap in actual notification and treatment of TB in the private health sector. The percentage of TB patients seeking care in the private sector varies from 21% to 41% against 18% of the notifications (Masini, 2017) (Ministry of Health, NTLD-Program, 2017). In addition, as reported in Philippines, broader social and economic influences could be driving the Kenyan TB epidemic. These broader influences include level of undernourishment, with a prevalence of 19% in 2015; level of poverty, with 46% of people living below the national poverty line in 2016; and low coverage of health insurance, with coverage of only 13.6%, leading to financial barriers to accessing health services.

As reported by other surveys, there were wide variations in the burden of TB by location and age category (Federal Republic of Nigeria, 2012) (Ministry of Health, Zambia, 2013 - 2014) (Ministry of Health, Cambodia, 2011) (WHO, 2016). The TB prevalence was twice as high in males compared to females; consistent with notification data from routine surveillance (Ministry of Health, NTLD-Program, 2015, Horton et al.,2016). However, the prevalence survey showed a

higher male to female ratio of 2.3:1 compared to 1.6:1 as reported in 2015 showing that notification data understates the share of TB burden accounted for by men (WHO, 2016). This high burden of TB among men could be due to biological susceptibility and other common social factors such as alcohol use and cigarette smoking (Ministry of Health, Division of Non-Communicable Diseases, 2015). In addition, routine notification data has demonstrated that malnutrition, a known risk factor for development of TB disease, is more prevalent in men (Ministry of Health, NTLD-Program, 2016).

WHO estimates that people with TB experience a 30% decline in productivity during the course of the disease (WHO, 2017). The highest burden of disease was in the economically productive age groups of 25-34, 35-44 and 45-54, with a prevalence of 716 per 100,000, 602 per 100,000 and 607 per 100,000 respectively. This underscores the negative economic effects of TB disease on households. In addition, these age groups are considered reproductive age groups and therefore the high burden of TB among them poses a potential risk of fuelling further transmission to children.

Cumulatively, 66% of the prevalent TB cases were 44 years old and younger, suggesting that TB disease in Kenya is marked by active transmission. This is unlike Tanzania's findings where majority of the cases were 45 years and older, indicative of progression from earlier latent infection (Ministry of Health and Social Affairs, Tanzania, 2013). About 95% of the prevalent cases had not been identified as TB cases prior to the time of the survey; the reasons for this need to be *further* investigated.

This survey shows the need to address underlying determinants and barriers to TB control. It demonstrates a higher burden of TB in urban (760 per 100,000 population) compared to rural settings (453 per 100,000 population) consistent with routine TB data which shows higher notification in the big cities of Nairobi and Mombasa (Ministry of Health, NTLD-Program, 2015). Overcrowding, poor housing and sanitation, conditions commonly found in the informal settlements, are known predisposing factors for TB disease. In Kenya, close to 60% of the urban population lives in these informal settlements (World Bank Group, 2013) highlighting the fact that effective TB prevention and treatment will require actions resulting in improved nutrition, better living and working conditions, as well as strategies to address health care access barriers (Global Fund, 2016).

The TB/HIV co-infection rate among the prevalent TB cases (16.7%) was lower than that reported among notified TB cases (31%) in Kenya (Ministry of Health, NTLD-Program, 2015). It is however, similar to Uganda's findings that reported 27% co-infection rate among survey cases compared to 48% in routine TB surveillance data (WHO Africa Region Office, 2015). This low co-infection rate could be attributed to the effective implementation of HIV interventions in Kenya (WHO, 2016) such as increased antiretroviral therapy coverage, a situation that is likely to improve with the new test and treat strategy (National AIDS & STI Control Program, 2016). Majority (83%) of the prevalent TB cases were HIV-negative, suggesting that a large burden of TB exists in the HIV un-infected population and highlighting the need to re-define case finding strategies among this

group. However, the lower prevalence of HIV among the survey cases compared to notified cases may also be explained by the high mortality associated with undiagnosed TB among people living with HIV. This conceals the actual burden of people with HIV associated TB in the community. Among the survey participants, 51% knew their HIV status and of these, 5% reported to be HIV positive, an almost similar proportion to the national HIV prevalence of 5.6% (KAIS 2012).

Previous history of TB treatment among the prevalent cases was higher (23%) compared to routine notification data (8%). This may imply that routine TB control activities under detect TB among previously treated persons and efforts should be intensified to find TB cases among this category of patients. The other possible explanation for this is that the use of Xpert MTB/RIF as a diagnostic test could have led to over-diagnosis of TB among previously treated patients due to detection of deoxyribonucleic acid (DNA) of non-viable bacilli (WHO, 2014). A further analysis may therefore be required to further explore this relationship.

About 95% of the prevalent cases had not been identified prior to the time of the survey; the reasons for this need to be investigated. However, as established in the Zambia survey, most of the cases identified may have been in the early stages of the disease and hence may not have yet felt the need to visit health facilities for investigation (Ministry of Health, Zambia, 2013 - 2014). On the other hand, 80% of the prevalent cases with symptoms (n=60) who had sought care had not been diagnosed with TB and only 15 reported taking anti-TB treatment at the time of the survey. This suggests that many TB patients with respiratory symptoms presenting at health facilities are currently being missed. This could be due to poor sensitivity of the current screening algorithm and diagnostic tools like smear microscopy, as well as inadequate knowledge on the part of health care providers. This underscores the need for rapid roll-out of more sensitive tools like Xpert MTB/RIF and adequate training of health care providers in order to have a high index of suspicion for TB. In addition, there is a need to optimize the TB care cascade to eliminate leakages for persons who have accessed care at all levels of the health care system and develop and implement approaches to screen all persons seeking care in all health care facilities for TB.

Surveys in other countries have reported varying findings related to participants with TB related symptoms. Nigeria (Federal Republic of Nigeria, 2012) reported similar findings with this survey while Cambodia (Ministry of Health, Cambodia, 2011) reported higher numbers. This survey reported chest pain, (19%), drenching night sweats (12%) and fatigue (11%) as the most common symptoms reported by participants. While the frequency of chest pain varied in relation to other surveys (Cambodia, Zambia and Nigeria), it remained the most commonly reported symptom. However, it was less frequently reported among confirmed TB cases in this survey suggesting that it is non-specific and may have limited value in TB screening.

As observed in other prevalence surveys (Nigeria, Zambia, and Cambodia), cough of two weeks or more was reported in 7% of the participants. Among the confirmed cases, the survey results indicated that screening using cough of more than two weeks would have missed 52% of the cases. The combination of cardinal symptoms as per Kenya's current TB guidelines of cough of more than two weeks, fever, night sweats and weight loss would miss 41% of the prevalent cases

(Ministry of Health, Division of Leprosy Tuberculosis and Lung Disease, 2013). Testing all people with any symptom consistent with TB - cough of any duration, hemoptysis, night sweats, weight loss, fatigue, fever, and shortness of breath - substantially increased the case yield to 74%. These findings suggest missed opportunities for TB diagnosis in current TB control practices and highlight the urgent need to redefine the TB screening triage and expand the scope of testing beyond persons with the cardinal symptoms.

In this survey, sputum submission was based on symptom screening and chest x-ray findings accounting for 15% (9,715) of participants. Chest x-ray identified most of those eligible for sputum submission, while symptom screening and a combination of both methods identified 29% and 13% respectively. Prevalence surveys in other countries reported varying proportions of eligible participants with some reporting lower (Nigeria) while others reported similar (Zambia).

Chest x-ray screening alone helped to identify an additional 42% of the prevalent cases; similar to the findings in Zambia (39%). Considering that Kenya uses symptom screening for identification of those with presumptive TB, this survey shows that an approach that excludes chest x-ray screening misses a large proportion of TB cases and reinforces the urgent need for the local adaptation of recent recommendation by WHO for routine chest x-ray use as a sensitive TB screening tool (WHO, 2016b). While x-ray may be very useful in diagnosing symptomatic paucibacillary PTB in a clinic setting, the added value in asymptomatic individuals in the population may be relatively minor. In this survey, the prevalence of TB in asymptomatic individuals was approximately two per 1,000, suggesting that screening asymptomatic individuals for TB with chest x-ray would be a relatively low yield activity.

Perceived severity of illness and the number of symptoms has been noted to be a predictor of health seeking behaviour (Taffa & Chengeno, 2005). In this survey, majority of the symptomatic participants (80%) and confirmed TB cases (67%) who had at least one TB related symptom did not seek health care because they did not perceive the symptom as being serious. This could be due to low awareness of TB symptoms among the general public or there may be stigma related issues resulting in fear of being diagnosed with TB. Although the Kenya Demographic Health Survey (KDHS) found that 80% of Kenyans know about TB, these findings suggest that the population may be unaware of the actual disease symptoms and consequently delay seeking care leading to increased disease transmission. Among the prevalent TB cases, those who were more likely not to seek care were farmers (41%), married (68%) and had up to primary level education (54%). According to the KDHS (2014), the knowledge of TB transmission is lower with decreasing levels of education. For this reason, emphasis on seeking health services early should be part of TB health education.

Gender disparity in health seeking behaviour has been observed in HIV care showing a greater reluctance among men to seek health care when sick (UNAIDS, 2016). In the confirmed cases, majority (65%) of those with symptoms who did not seek treatment were men. This, together with the finding that men had a higher burden of the disease, shows that Kenya needs to develop innovative approaches to remove any access barriers, reduce delays in diagnosis and improve

management of TB among men. To support this, further studies will be required to gain an understanding of the barriers associated with poor health seeking behaviour among men (Galdas, Cheater, & Marshall, 2005).

The findings that 21% of the respondents first sought health services from private practitioners and private pharmacists highlight the need to develop partnerships with such private providers to further increase access to TB screening. In addition, knowledge on availability of free TB services at public health facilities may explain why a majority of the survey participants (78%) sought care from public county hospitals. Distance to health facilities was not cited as a main reason for not seeking care probably due to the extensive decentralization of health services as indicated in the SARAM 2013 report with 2.04 facilities per 10,000 population (Ministry of Health, SARAM Report, 2013).

One key feature of this survey is that it employed smear microscopy, culture and Xpert MTB/RIF for diagnosis. Of the survey cases identified, 60% were smear negative, meaning that these cases could have been missed by routine case detection that relies on microscopy only. The use of Xpert MTB/RIF identified an additional 90 (29.5%) prevalent cases, while culture alone identified an extra 68 (22.3%) cases. This low performance of culture compared to Xpert MTB/RIF could be attributed to reduced viability of the bacilli during sputum sample transport to the National TB Reference Laboratory or contamination and underscores the advantage of using Xpert MTB/RIF in TB prevalence surveys as a possible replacement for culture. In addition, culture could have missed non-viable bacilli in the prevalent cases who had previous history of TB. The additional prevalent cases identified by culture can be explained by the higher sensitivity of this method over Xpert MTB/RIF (68%) in detecting TB in smear negative individuals (WHO, 2014). These results confirm the low sensitivity of smear microscopy as a diagnostic tool and underline the important role of Xpert MTB/RIF in the identification of TB cases. It is therefore important to scale up Xpert MTB/RIF as the initial diagnostic test to minimize the chances of missing cases.

The overall survey participation rate was 83%, two percent lower than WHO's 85% target, and this was due to lower participation in the initial phase of the survey. Intensive community mobilization brought about increased participation in the later stages of the survey. Other countries that have conducted prevalence surveys reported varying participation rates with Zambia, Ethiopia, Myanmar, Cambodia reporting higher rates while Nigeria reported rates lower than those of the Kenyan survey.

The female participation rate was higher (87%) compared to that of males (77%), similar to findings from Nigeria, Zambia, Cambodia and Myanmar (Federal Republic of Nigeria, 2012, Ministry of Health, Myanmar, 2009 – 2010, Ministry of Health, Cambodia, 2011, Ministry of Health, Zambia, 2013 - 2014). The high participation rate (93%) observed among those aged 65 years and above could be explained by the proactive measures put in place to provide them with vehicle transport to the mobile field sites.

The eligibility criteria to participate in this survey was persons of 15 years and above who were resident in the households visited for at least 30 days. This was similar to the criteria used by

other countries except for differences in definition of duration of residence as shown in Zambia (24 hours), Nigeria (14 days) and Cambodia (14 days). The Kenyan survey excluded households found in congregate settings because they required special access and clearance that would have complicated the execution of the survey. Moreover, the residents in these institutions are not permanent and keep moving. This is unlike Zambia's survey (2014), which included households in military barracks, prisons and hospital staff quarters.

Limitations

Similar to other surveys, data on children under the age of 15 years and extra-pulmonary TB was not collected. Furthermore, screening of participants for HIV was not done. This survey only provides estimates of the national TB burden and not subnational estimates.

There may be potential underestimation of the prevalence due to chest x-ray under-reading in the field resulting in lost opportunities for possible sputum eligible. In the imputation of the estimated prevalence survey, field x-ray interpretation was not factored in.

There could have been a limitation of culture recovery indicated from Xpert positive specimens failing to culture positive, especially the S+ ones.

The survey missed to implement the survey in one cluster.

5. PROGRAMMATIC IMPLICATIONS AND RECOMMENDATIONS

In reference to the findings of the survey that show that slightly above half of the TB cases that occur in Kenya every year go undetected and untreated; the following recommendations are proposed:

1. The NTLD-Program should redefine the TB screening triage to include any TB related symptom as follows: cough of any duration, haemoptysis, night sweats, weight loss, fatigue, fever, and shortness of breath.
2. The NTLD-Program should review the TB diagnostic algorithm and elevate chest x-ray to a TB screening tool for all people suspected to have TB, while the Ministry of Health, county governments and partners, should ensure increased access to this test across the country.
3. The Ministry of Health and county governments should ensure universal availability of Xpert MTB/RIF as the first test for TB diagnosis.
4. The Ministry of Health, county governments and partners should optimize the TB care cascade to eliminate leakages for persons who have accessed care at all levels of the health care system and develop and implement approaches to screen all persons seeking care at all health facilities for TB.
5. The Ministry of Health should enhance the involvement of all private practitioners including pharmacies in TB screening, diagnosis and care.
6. The Ministry of Health and partners should develop and implement targeted approaches for TB care and prevention among young males and elderly persons.
7. The Ministries of Health and Education should expand school health programs to include TB and target children as change agents to reach their families. In addition, investment should be made in TB health communication to increase awareness and encourage people to seek early intervention for symptoms.
8. The Ministry of Health, county governments and partners should enhance focus on urban TB care and prevention to address the skewed burden of TB in cities and towns around Kenya.

6. CONCLUSION

The survey found that the prevalence of bacteriologically confirmed pulmonary TB in the adult population of Kenya was 558 (95% CI: 455–662) per 100,000 population.

The prevalence rate among men (809 per 100,000) was twice that of females (359 per 100,000), higher in urban settings (760 per 100,000 population) than in rural settings (453 per 100,000 population) and highest in the 25 - 34 age group (716 per 100,000).

The extrapolated prevalence rate of 426 per 100,000 population for all forms of TB and for all ages was significantly higher than the 2016 pre-survey WHO estimate of 233 per 100,000.

Smear microscopy as a diagnostic test was re-confirmed to be a test with limited capacity. Digital chest X-ray emerged to be a good screening tool for TB compared to symptom screening alone. Over 50% of the confirmed TB cases had no cough of 2 weeks or more, however had abnormal chest X-ray.

As relates to health-seeking behaviour, the majority of people suspected to have TB in the community do not seek health care for their symptoms.

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ANNEXES

Annex 1: Survey Funding and Cost Breakdown

Funding Sources

OVERALL KENYA PREVALENCE SURVEY BUDGET			
Funding Source	**Contribution (USD)**	**% of Total (USD)**	**Description**
Global Fund/USAID TB ARC	30,627.03	0.6	
Global Fund	4,530,712.09	87.6	
USAID	491,891.89	9.5	
WHO/USAID	121,611.89	2.4	
Grand Total	**5,174,842.90**		

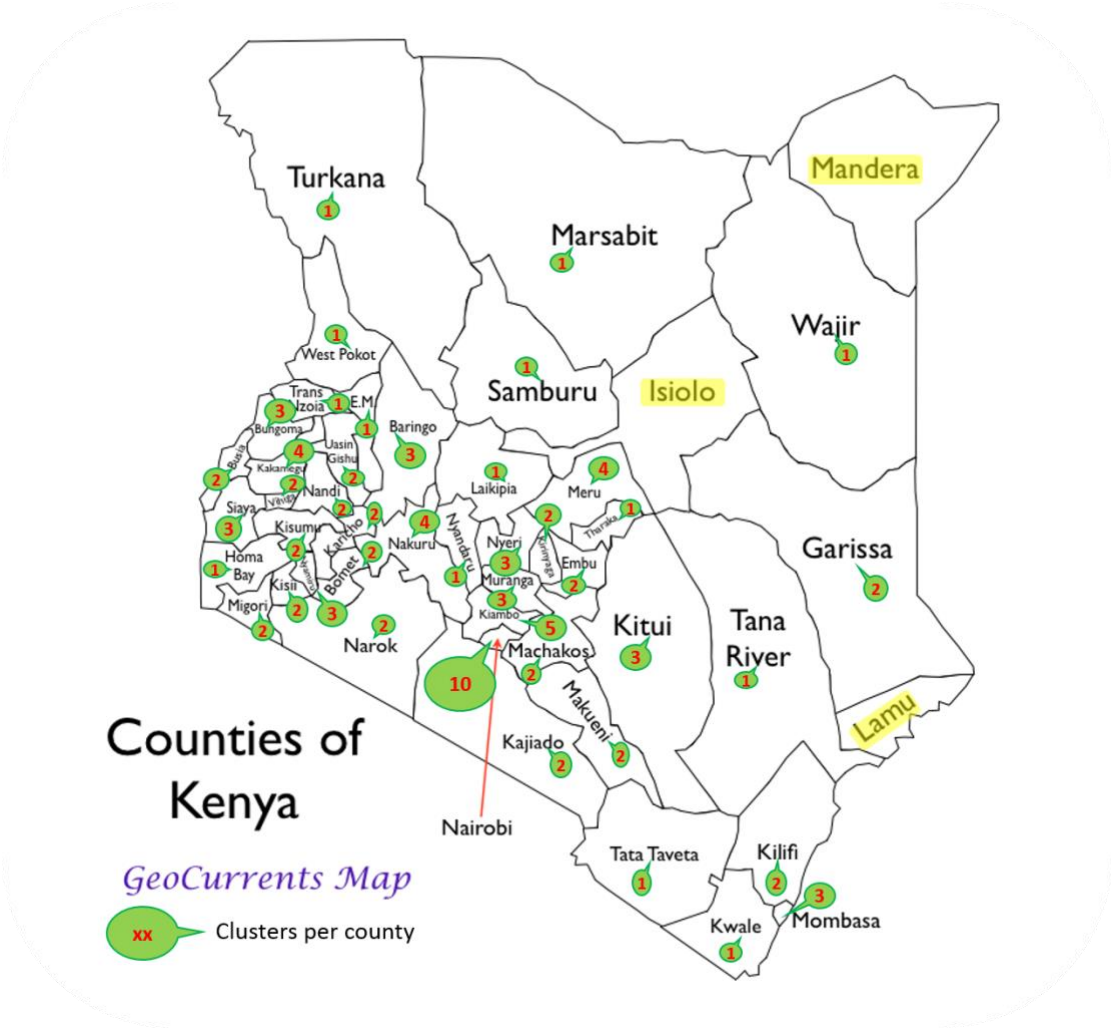
Breakdown of Costs

OVERALL KENYA PREVALENCE SURVEY BUDGET			
Item	**Cost (USD)**	**% of Total (USD)**	**Supporting Donor**
Procurement capital	1,249,978.38	24.2	Global Fund
Laboratory consumables	267,156.15	5.2	Global Fund
Human resource	144,237.84	2.8	Global Fund
Training	89,940.54	1.7	Global Fund
Launch	30,627.03	0.6	Global Fund/USAID TB ARC
Development of maps	11,705.95	0.2	Global Fund
Coordination team	11,762.16	0.2	Global Fund
Pre-shipment inspection	7,567.57	0.1	Global Fund
CTLC/CMLT orientation	43,654.05	0.8	Global Fund
Retreat to finalise training materials	24,864.86	0.5	USAID
Pilot	149,664.86	2.9	Global Fund
Cluster budget	1,987,259.46	38.4	Global Fund
Central Reference Lab	108,108.11	2.1	Global Fund
Technical assistance	121,611.89	2.4	WHO/USAID
Transport	467,027.03	9.0	USAID
Honoraria	37,837.84	0.7	Global Fund
X-ray	80,138.38	1.5	Global Fund
Communication	216,216.22	4.2	Global Fund
Lab field expenses	23,414.31	0.5	Global Fund
Data management	102,070.27	2.0	Global Fund
Grand Total	**5,174,842.90**		

Annex 2: Survey Field Team Members

No.	ROLE / TEAM NAME		1 ELEPHANT	2 LEOPARD	3 RHINO	4 BUFALLO	5 LION
1	**Cluster Team Leader**	1	Moses Nyinge	Eunice Mailu	Hellen Gitau	Roseline Nyanchama	Damiana Syonuu
2	**MFS Supervisor**	1	Magoba Ronald	Enock Nzomo	Florence Lokuru	Martha Muthoni	Joy Makena
3	**MFS Reception**	1	Irene Etiang	Dennis Audi	Angeline Wairimu	Priscah Jepkoech	Carolyne Njoroge/Stephen Kinyati
4	**MFS Enrollers**	1	Wincliffe Wangechi	Fridah Limo	Davies Mwebi	Naomi Wangui	Carolyne Mwei
5		2	Nancy Cherop	Elias Kirimi	Elizabeth Njeri	Doreen Wanjiku	Evelyne Njeri Kagia
6	**Radiographers**	1	Fred Owino	Nicholus Ogallo	Andrew Muya	Eric Gikundi	Dan Wasike
7		2	Gladys Biwott	Zipporah Chelangat	Eric Kiloi	Geoffrey Koech	Millicent Mugo
8	**MFS Clinical Officer**	1	Jenifer Nyambura	Jackline Wambui	Gilbert Mutua	Kennedy Bwire	Moses Nderitu
9		2	Kelvin Koome	CO of Rest Team	Lydia Nthenya	Beatrice Bartai	Janet Ntabo
10	**Laboratory Technologists**	1	Antony Oyugi	Keneth Gitau Kung'u	Kipngetich Kemei	Faith Nkirote	Alex Mukosi
11	**Listing Supervisor**	1	Peter Muema Muoki	Ken Musau	Jamah Muhammed	Nathan Cheboi	Stella Buluma
12	**Listers**	2	Charity Chebet	Vayoda Makambo	Mary Wanjiru	Cindy Nyawera	Nelly Jepkorir
13		3	Olive Mchawia	Martin Mwangi	Caren Mbayaki	Kennedy Ngumbau Mutava	Raphael Mutembei
14	**MFS Data Managers**	1	James Muisyo	Edwin Momanyi	Ken Njuguna	Samuel Obure	Alex Maina
15	**Medical Engineers**	1	Victoria C. Ouma	Gordon K. Wanyoike			

Annex 3: Distribution of clusters in the country



Footnote:

Clusters not selected or visited

Annex 4: List of Sampled Clusters

S/No	Cluster No	COUNTY NAME	DISTNAME	EANAME	EA Type (1=Rural; 2=Urban; 3=Sub-Urban)	Phase	Eligible	Enrolled	Participation rate per cluster	TB Cases
1	1	NAIROBI	NAIROBI WEST	KARAMA	2	23	732	625	85%	2
2	2	NAIROBI	NAIROBI WEST	SATELITE 'B'	2	23	674	544	81%	2
3	3	NAIROBI	NAIROBI WEST	SOWETO EAST	2	23	679	605	89%	3
4	4	NAIROBI	NAIROBI EAST	JUA KALI	2	25	732	702	96%	2
5	5	NAIROBI	NAIROBI EAST	LUCKY SUMMER 'B'	2	25	730	702	96%	9
6	6	NAIROBI	NAIROBI EAST	WHITE HOUSE/MANYATTA	2	25	767	595	78%	3
7	7	NAIROBI	NAIROBI NORTH	NDURURUNO 'A'	2	24	865	855	99%	13
8	8	NAIROBI	NAIROBI NORTH	SOWETO 1	2	24	864	845	98%	5
9	9	NAIROBI	NAIROBI NORTH	CLAY WORKS	2	24	713	546	77%	0
10	10	NAIROBI	NAIROBI NORTH	MUTHURWA ESTATE 'B'	2	24	875	815	93%	3
11	11	NYANDARUA	NYANDARUA SOUTH	KIBURUTI/MWIRERI	1	9	720	668	93%	2
12	12	NYERI	NYERI NORTH	BURGURET CENTRAL 'B'	1	10	673	485	72%	3
13	13	NYERI	NYERI SOUTH	KIANDUMBA	1	9	731	674	92%	1
14	14	NYERI	NYERI SOUTH	TOWN CENTRE	2	10	616	368	60%	0
15	15	KIRINYAGA	KIRINYAGA	MBAHATI B	1	8	738	726	98%	2
16	16	KIRINYAGA	KIRINYAGA	NGUGU-INI	1	8	771	716	93%	2
17	17	MURANG'A	MURANGA NORTH	GITITU	1	9	655	620	95%	2
18	18	MURANG'A	MURANGA SOUTH	KIHA "B"	1	9	747	615	82%	5
19	19	MURANG'A	GATANGA	GATUIKU 'A'	1	8	683	428	63%	2
20	20	KIAMBU	GITHUNGURI	GATHIONGOI 'A''	1	1	826	410	50%	0
21	21	KIAMBU	GATUNDU	LAINI	1	1	918	655	71%	2
22	22	KIAMBU	KIAMBU	MATOPENI	2	1	899	379	42%	4
23	23	KIAMBU	KIKUYU	CHURA A	2	2	1217	593	49%	9
24	24	KIAMBU	RUIRU	LANGATA PHASE 1'B'	2	1	800	249	31%	1
25	25	MOMBASA	MOMBASA	JUAKALI 'B'	2	3	1169	624	53%	9
26	26	MOMBASA	MOMBASA	MAKUMBA	2	3	1017	544	53%	3
27	27	MOMBASA	KILINDINI	KWA BN KOMBO MDFUNI	2	4	822	477	58%	10
28	28	KWALE	MSAMBWENI	MWABOVU "B"	1	4	932	610	65%	2
29	29	KILIFI	KILIFI	KALONGONI	1	4	796	590	74%	1
30	30	KILIFI	KILIFI	MTAANI	2	4	852	525	62%	1
31	31	TANA RIVER	TANA RIVER	BURA DIMA	1	3	601	315	52%	1
32	32	TAITA TAVETA	TAITA	KISALAGHALA	1	5	800	686	86%	0
33	33	MARSABIT	MOYALE	GABABOSTACHO/GURACHA/DAMBALA/SORA	1	21	503	498	99%	4

S/No	Cluster No	COUNTY NAME	DISTNAME	EANAME	EA Type (1=Rural; 2=Urban; 3=Sub-Urban)	Phase	Eligible	Enrolled	Participation rate per cluster	TB Cases
34	34	MERU	IMENTI NORTH	KINYENJERE/MBARIA MARKET	1	6	714	683	96%	3
35	35	MERU	IGEMBE	KIBUENE 'A'	1	7	762	654	86%	7
36	36	MERU	IGEMBE	THEUKA	1	7	744	634	85%	9
37	37	MERU	IMENTI NORTH	NGUSISHI "A"	2	6	746	662	89%	3
38	38	THARAKA NTHI	MERU SOUTH	KARABANI	1	7	719	649	90%	10
39	39	EMBU	EMBU	GITUARA "A"	1	7	722	592	82%	0
40	40	EMBU	MBEERE	MARURU "B" NORTH	1	8	741	605	82%	3
41	41	KITUI	KITUI	MALALANI	1	5	763	622	82%	5
42	42	KITUI	MWINGI	KALALANI	1	5	757	607	80%	6
43	43	KITUI	KITUI	THUSI	3	5	740	651	88%	1
44	44	MACHAKOS	MWALA	KIKELENZU	1	2	1311	745	57%	1
45	45	MACHAKOS	YATTA	MAIYUNI 'A'	3	2	1574	855	54%	2
46	46	MAKUENI	MAKUENI	THOMA 'B'	1	6	776	676	87%	2
47	47	MAKUENI	KIBWEZI	NZWII 'B'	1	6	729	665	91%	3
48	48	GARISSA	GARISSA	DOLOLOWYN	1	21	679	617	91%	1
49	49	GARISSA	GARISSA	IQRA	3	21	695	586	84%	2
50	50	WAJIR	WAJIR NORTH	MOGORE	1	22	719	681	95%	0
52	52	SIAYA	SIAYA	IMBAYA 'B'	1	17	707	646	91%	4
51	53	SIAYA	SIAYA	SILULA	1	17	718	661	92%	1
53	54	SIAYA	RARIEDA	KABUONG' 'B'	1	18	760	698	92%	1
54	55	KISUMU	NYANDO	ONENO NAM UPPER	1	17	728	708	97%	1
55	56	KISUMU	KISUMU EAST	BANDANI 'A'	2	17	738	635	86%	1
56	57	MIGORI	MIGORI	OGANGA 'A'/ANGEGA 'B'	1	16	663	602	91%	3
57	58	MIGORI	RONGO	MARAM	2	16	717	671	94%	8
58	59	HOMA BAY	SUBA	KISUI WEST "B"	1	16	721	701	97%	4
59	60	KISII	KISII CENTRAL	RIOMA II	1	15	707	691	98%	4
60	61	KISII	GUCHA	NYAMARUMA / NYAMAGATIRA	1	16	716	700	98%	1
61	62	NYAMIRA	MASABA	MATUNWA A	1	15	729	697	96%	5
62	63	NYAMIRA	MANGA	KENYORO	1	15	760	744	98%	2
63	64	NYAMIRA	BORABU	KIJEURI ROCHE	2	15	712	610	86%	4
64	65	TURKANA	TURKANA NORTH	ABUNE 'A'	1	22	658	558	85%	2
65	66	WEST POKOT	WEST POKOT	KAPCHEMOGEN	1	22	759	722	95%	9
66	67	SAMBURU	SAMBURU CENTRAL	LORIENY/LCHINGEI	1	21	769	733	95%	1
67	68	TRANS NZOIA	TRANS NZOIA EAST	CHEPTIL	1	22	762	751	99%	6
68	69	BARINGO	BARINGO	CHEMOMUL	1	12	678	577	85%	1
69	70	BARINGO	KOIBATEK	KAPKECHIR	1	12	731	637	86%	0

S/No	Cluster No	COUNTY NAME	DISTNAME	EANAME	EA Type (1=Rural; 2=Urban; 3=Sub-Urban)	Phase	Eligible	Enrolled	Participation rate per cluster	TB Cases
70	71	BARINGO	KOIBATEK	KAPTEMBWO/S.M	2	11	688	574	83%	2
71	72	UASIN GISHU	ELDORET EAST	MUIYENGWET	1	13	699	651	93%	7
72	73	UASIN GISHU	WARENG	KAPTINGA QUARRY	3	13	693	632	91%	4
73	74	ELGEYO-MARAKWET	KEIYO	SOY	1	23	738	714	97%	1
74	75	NANDI	NANDI CENTRAL	CHEIROT	1	13	724	684	94%	2
75	76	NANDI	TINDERET	KABUNYERIA	1	13	667	650	97%	10
76	77	LAIKIPIA	LAIKIPIA WEST	MIFUGO	1	10	622	427	69%	5
77	78	NAKURU	NAIVASHA	KIMUNYU	1	11	736	539	73%	3
78	79	NAKURU	MOLO	KAPKESSEK	1	11	735	667	91%	3
79	80	NAKURU	NAKURU	ELISA	2	11	718	581	81%	6
80	81	NAKURU	NAIVASHA	SITE 'B'	2	10	657	536	82%	2
81	82	NAROK	NAROK NORTH	NDERO	1	14	711	671	94%	1
82	83	NAROK	NAROK SOUTH	CHEMALUTANY/KIPTENDEN	1	14	727	684	94%	4
83	84	KAJIADO	LOITOKITOK	ESAMAI	1	3	1449	725	50%	3
84	85	KAJIADO	KAJIADO NORTH	ADMINISTRATION	2	2	1090	694	64%	4
85	86	KERICHO	KERICHO	KABONDO	1	12	636	591	93%	2
87	87	KERICHO	KIPKELION	TEGUNOT	3	12	663	633	95%	5
88	88	BOMET	BURET	CHEBORGE	1	14	738	689	93%	2
86	89	BOMET	SOTIK	SUGUTEK	1	14	723	709	98%	2
89	90	KAKAMEGA	KAKAMEGA CENTRAL	ESHIEMBELA	1	19	723	690	95%	0
90	91	KAKAMEGA	KAKAMEGA NORTH	LUYESHE 'A'	1	19	742	727	98%	0
91	92	KAKAMEGA	LUGARI	LUKUSI 'B'	1	19	742	718	97%	1
92	93	KAKAMEGA	BUTERE	EMUSABA	1	19	723	667	92%	2
93	94	VIHIGA	EMUHAYA	MUSILILO	1	20	725	714	98%	3
94	95	VIHIGA	VIHIGA	MAJENGO	2	20	662	531	80%	0
95	96	BUNGOMA	BUNGOMA SOUTH	MWIBALE	1	18	792	785	99%	0
96	97	BUNGOMA	BUNGOMA NORTH	SAWA	1	18	779	770	99%	5
97	98	BUNGOMA	BUNGOMA WEST	CHEKULO "B" A	1	18	829	814	98%	0
98	99	BUSIA	BUSIA	KAMUYOGA	1	20	738	723	98%	0
99	100	BUSIA	BUNYALA	IYANGA	1	20	681	645	95%	2
100	51	MANDERA	MANDERA CENTRAL	DADACHAQOLOY	1		0	0	0%	
		TOTAL					**76,291**	**63,050**	**83%**	**305**

Note: Phase - visit stage at which cluster(s) was done by team(s)

Annex 5: Survey Instruments

1 TB Prevalence Survey - Manual Listing

TUBERCULOSIS PREVALANCE SURVEY, KENYA **Cluster Name:_____**

Register Form for Prevalence Survey **Village Name:_____**

Village Elder CHV's Name:_____

Household Number:_____ **Household Number:_____**

	Name	Sex (M/F)	Age (Years)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

	Name	Sex (M/F)	Age (Years)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

2 Census Register Form

Census Forms for Prevalence Survey

Cluster Name: **Cluster Number:**

Census Team Leader's Name:

Census Form Adults (>15 years)

Household ID	Household location/address	Subject ID	name	sex	age	Have you lived in this household for more than 30 days	Eligible*	SE Score taken	remarks
#		#		M/F	years	Y/N	Y/N	Y/N	

*If not eligible note why not. Note any other remarks of importance to the field teams

Census Form Children (<15 years)

Household ID	Household location/address	Subject ID	name	sex	Age*	Remarks
#		#		M/F	years	

* If below one year, indicate the age as 0 and indicate the age in months under remarks

3 Socio-Economic Questionnaire

Socio-Economic Score

(DHS 2008/2009)

HOUSEHOLD ID NUMBER: _____/_____/_____

Verbal Consent Given Yes ____ No _____

101	What is the main source of drinking water for members of your household?	PIPED WATER PIPED INTO DWELLING . . . . . 11 PIPED TO COMPOUND/PLOT . . . . . 12 → 106 PUBLIC TAP/STANDPIPE . . . . . 13 TUBE WELL OR BOREHOLE . . . . . 21 DUG WELL PROTECTED WELL . . . . . 31 → 103 UNPROTECTED WELL . . . . . 32 WATER FROM SPRING PROTECTED SPRING . . . . . 41 UNPROTECTED SPRING . . . . . 42 RAINWATER . . . . . 51 → 106 TANKER TRUCK . . . . . 61 CART WITH SMALL TANK . . . . . 71 SURFACE WATER (RIVER/DAM/ LAKE/POND/STREAM/CANAL/ IRRIGATION CHANNEL) . . . . . 81 → 103 BOTTLED WATER . . . . . 91 OTHER _____ 96 → 103 (SPECIFY)	
102	What is the main source of water used by your household for other purposes such as cooking and handwashing?	PIPED WATER PIPED INTO DWELLING . . . . . 11 PIPED TO COMPOUND/PLOT . . . . . 12 → 106 PUBLIC TAP/STANDPIPE . . . . . 13 TUBE WELL OR BOREHOLE . . . . . 21 DUG WELL PROTECTED WELL . . . . . 31 UNPROTECTED WELL . . . . . 32 WATER FROM SPRING PROTECTED SPRING . . . . . 41 UNPROTECTED SPRING . . . . . 42 RAINWATER . . . . . 51 → 106 TANKER TRUCK . . . . . 61 CART WITH SMALL TANK . . . . . 71 SURFACE WATER (RIVER/DAM/ LAKE/POND/STREAM/CANAL/ IRRIGATION CHANNEL) . . . . . 81 OTHER _____ 96 (SPECIFY)	
103	Where is that water source located?	IN OWN DWELLING . . . . . 1 IN OWN YARD/PLOT . . . . . 2 → 106 ELSEWHERE 3	
104	How long does it take to go there, get water, and come back?	MINUTES . . . . . ☐☐☐ DON'T KNOW 998	
105	Who usually goes to this source to fetch the water for your household?	ADULT WOMAN . . . . . 1 ADULT MAN . . . . . 2 FEMALE CHILD UNDER 15 YEARS OLD . . . . . 3 MALE CHILD UNDER 15 YEARS OLD . . . . . 4 OTHER _____ 6 (SPECIFY)	

106	Do you do anything to the water to make it safer to drink?	YES . . . . . 1 NO . . . . . 2 DON'T KNOW 8	→ 108
107	What do you usually do to make the water safer to drink? Anything else? RECORD ALL MENTIONED.	BOIL . . . . . A ADD BLEACH/CHLORINE . . . . . B STRAIN THROUGH A CLOTH . . . . . C USE WATER FILTER (CERAMIC/ SAND/COMPOSITE/ETC.) . . . . . D SOLAR DISINFECTION . . . . . E LET IT STAND AND SETTLE . . . . . F OTHER _____ X (SPECIFY) DON'T KNOW . . . . . Z	
108	What kind of toilet facility do members of your household usually use?	FLUSH OR POUR FLUSH TOILET FLUSH TO PIPED SEWER SYSTEM . . . 11 FLUSH TO SEPTIC TANK . . . . . 12 FLUSH TO PIT LATRINE . . . . . 13 FLUSH TO SOMEWHERE ELSE . . . 14 FLUSH, DON'T KNOW WHERE . . . 15 PIT LATRINE VENTILATED IMPROVED PIT LATRINE . . . . . 21 PIT LATRINE WITH SLAB . . . . . 22 PIT LATRINE WITHOUT SLAB/ OPEN PIT . . . . . 23 COMPOSTING TOILET . . . . . 31 BUCKET TOILET . . . . . 41 HANGING TOILET/HANGING LATRINE . 51 NO FACILITY/BUSH/FIELD . . . . . 61 OTHER _____ 96 (SPECIFY)	→ 111
109	Do you share this toilet facility with other households?	YES . . . . . 1 NO 2	→ 111
110	How many households use this toilet facility?	NO. OF HOUSEHOLDS IF LESS THAN 10 . . . . . 0 ☐ 10 OR MORE HOUSEHOLDS . . . . . 95 DON'T KNOW 98	

111	Does your household have:	YES	NO
	A clock or watch?	CLOCK/WATCH 1	2
	Electricity?	ELECTRICITY 1	2
	A radio?	RADIO 1	2
	A television?	TELEVISION 1	2
	A mobile telephone?	MOBILE TELEPHONE 1	2
	A non-mobile telephone?	NON-MOBILE TELEPHONE . 1	2
	A refrigerator?	REFRIGERATOR 1	2
	A solar panel?	SOLAR PANEL 1	2

112	What type of fuel does your household mainly use for cooking?	ELECTRICITY . . . . . 01 LPG/NATURAL GAS . . . . . 02 BIOGAS . . . . . 03 KEROSENE . . . . . 04 COAL, LIGNITE . . . . . 05 CHARCOAL . . . . . 06 WOOD . . . . . 07 STRAW/SHRUBS/GRASS . . . . . 08 AGRICULTURAL CROP . . . . . 09 ANIMAL DUNG . . . . . 10 NO FOOD COOKED IN HOUSEHOLD . . . . . 95 OTHER _____ 96 (SPECIFY)	→ 117

115	Is the cooking usually done in the house, in a separate building, or outdoors?	IN THE HOUSE . . . . . 1 IN A SEPARATE BUILDING . . . . . 2 OUTDOORS . . . . . 3 OTHER _____ 6 (SPECIFY)	→ 117
116	Do you have a separate room which is used as a kitchen?	YES . . . . . 1 NO 2	
117	MAIN MATERIAL OF THE FLOOR. RECORD OBSERVATION.	NATURAL FLOOR EARTH/SAND . . . . . 11 DUNG . . . . . 12 RUDIMENTARY FLOOR WOOD PLANKS . . . . . 21 PALM/BAMBOO . . . . . 22 FINISHED FLOOR PARQUET OR POLISHED WOOD . . . 31 VINYL OR ASPHALT STRIPS . . . . . 32 CERAMIC TILES . . . . . 33 CEMENT . . . . . 34 CARPET . . . . . 35 OTHER _____ 96 (SPECIFY)	
118	MAIN MATERIAL OF THE ROOF. RECORD OBSERVATION.	**NATURAL ROOFING** GRASS / THATCH / MAKUTI . . . . . 11 DUNG / MUD . . . . . 12 **RUDIMENTARY ROOFING** CORRUGATED IRON (MABATI) . . . . . 21 TIN CANS . . . . . 22 **FINISHED ROOFING** ASBESTOS SHEET . . . . . 31 CONCRETE . . . . . 32 TILES . . . . . 33 OTHER _____ 96 (SPECIFY)	
119	MAIN MATERIAL OF THE WALLS. RECORD OBSERVATION.	NATURAL WALLS NO WALLS . . . . . 11 CANE/PALM/TRUNKS . . . . . 12 DIRT . . . . . 13 RUDIMENTARY WALLS BAMBOO WITH MUD . . . . . 21 STONE WITH MUD . . . . . 22 UNCOVERED ADOBE . . . . . 23 PLYWOOD . . . . . 24 CARDBOARD . . . . . 25 REUSED WOOD . . . . . 26 FINISHED WALLS CEMENT . . . . . 31 STONE WITH LIME/CEMENT . . . . . 32 BRICKS . . . . . 33 CEMENT BLOCKS . . . . . 34 COVERED ADOBE . . . . . 35 WOOD PLANKS/SHINGLES . . . . . 36 OTHER _____ 96 (SPECIFY)	

120	How many rooms in this household are used for sleeping?	ROOMS	
121	Does any member of this household own:	**YES** **NO**	
	A bicycle?	BICYCLE 1 2	
	A motorcycle or motor scooter?	MOTORCYCLE/SCOOTER . . . 1 2	
	An animal-drawn cart?	ANIMAL-DRAWN CART 1 2	
	A car or truck?	CAR/TRUCK 1 2	
	A boat with a motor?	BOAT WITH MOTOR 1 2	
121A	Does your household own this structure (house, flat, shack), do you rent it, or do you live here without pay?	OWNS . . . . . 1 PAYS RENT/LEASE . . . . . 2 NO RENT,W. CONSENT OF OWNER . . . . . 3 NO RENT, SQUATTING 4	
121B	Does your household own the land on which the structure (house, flat, shack) sits?	OWNS . . . . . 1 PAYS RENT/LEASE . . . . . 2 NO RENT,W. CONSENT OF OWNER . . . . . 3 NO RENT, SQUATTING 4	
122	Does any member of this household own any agricultural land?	YES . . . . . 1 NO 2	→ 124
123	How many hectares of land (altogether) are owned by the members of this family. IF MORE THAN 95, WRITE '995'. IF UNKNOWN, WRITE 998'.	NUMBER OF HECTARES	
124	Does this household own any livestock, herds, other farm animals, or poultry?	YES . . . . . 1 NO 2	→ 125A
125	How many of the following animals does this household own? IF NONE, WRITE '00'. IF MORE THAN 95, WRITE '95'. IF UNKNOWN, WRITE '98'.		
	Local cattle (indegeneous)?	CATTLE (INDIGENEOUS)	
	Milk cows or bulls?	COWS/BULLS	
	Horses, donkeys, or mules?	HORSES/DONKEYS/MULES . . .	
	Goats?	GOATS	
	Sheep?	SHEEP	
	Chicken?	CHICKEN	

4 TB Prevalence Survey - Consent Form - English-Kiswahili

INFORMED CONSENT EXPLANATION FOR ELIGIBLE STUDY PARTICIPANTS.

Title of Study:

The Tuberculosis Prevalence Survey, Kenya.

Introduction:

My name is _____ from Ministry of Health. I am here to gather information from you, which will help us assess whether you have symptoms related to Tuberculosis. I will also take an X-ray of your chest to check for any signs of tuberculosis.

Purpose of Study:

This study is being conducted by the Ministry of Health and its main purpose is to determine the magnitude of tuberculosis in the country by screening all TB suspects that will participate in the study. In addition, the study will describe the characteristics of the TB suspects, including their health seeking behaviour. This information will be very useful for the management of TB in the country.

Procedure to be followed:

The screening will be based on two tools

1. A Symptom questionnaire will be administered to you. Questions related to tuberculosis disease will be asked and you will give responses.
2. A plain chest X-ray will also be done on you to look for signs of TB in the chest.

If you will have symptoms related to tuberculosis or an abnormal chest X-ray, you will be requested to provide a sputum sample for examination in the laboratory. If you will have no abnormalities or symptoms during screening, you will be not to be a TB suspect and you will not require to submit a sputum sample.

Risks:

Efforts will be taken to maintain confidentiality so that risks of disclosing the information you have given us will be fully minimized. All data collected will be handled confidentially and no names will be included in the report. The data will be stored in computers with passwords and hard copies will be kept in lockable cabinets that have authorised access to the investigators only.

Benefits:

There will be no direct benefit to you for your participation. But your contribution will help us to better understand the magnitude and risk factors related to tuberculosis in this country. This will go a long way in improving the management of TB. Anybody diagnosed with TB will be referred appropriately to receive standard TB treatment in our Public Health facilities.

Assurance of confidentiality:

All the answers you have provided us will be handled confidentially. Your identity will not be disclosed in any public reports or publications or to any other parties.

Storage of data:

Records relating to your participation in the study will be stored at the Central Survey Office for analysis. Access to these records will only be to the investigators.

Right to refuse or withdraw:

Your participation is voluntary. You may wish to withdraw from this study at any time without any penalty.

Subject: If during the course of this study you have any questions concerning the nature of this research you should contact Dr Joseph Sitienei, P.O. Box 20781-00100, Nairobi.

Telephone Number: 0202713198/721890 or 0722 740130

If in case you have a question concerning your rights of participation, you should contact; The Secretary, KEMRI/National Ethical Review Committee, P.O. Box 54840-00200, Nairobi.

Telephone Number: 0202722541

I _____ have read/been read to the information shown above and had the opportunity to ask questions and all were answered satisfactorily. I hereby give consent for my participation as explained to me.

Study participant's name: _____Sign: _____

Date _____

Name of Investigator/enumerator: _____

Sign: _____

Date _____

MAELEZO JUU YA IDHINI YA KUSHIRIKI KWA WATAKAOSHIRIKI KWENYE UCHUNGUZI

Anwani ya uchunguzi

Uchunguzi wa kuwepo kwa Kifua Kikuu nchini Kenya

Utangulizi

Jina langu ni _____ kutoka kwa Wizara ya Afya ya Umma na Usafi. Nipo hapa kuchukuwa taarifa kutoka kwako ambayo itatusaidia kutafuta iwapo una dalili zinazoambatana na Kifua Kikuu. Pia nitakupiga picha ya X-ray ya kifua chako kuchunguza iwapo zipo ishara za kifua kikuu.

Kusudi la Uchunguzi

Uchunguzi huu unatekelezwa na Wizara ya Afya ya Umma na Usafi na kusudi lake kuu ni kupeleleza kiwango cha kifua kikuu nchini kwa kuwachunguza kwa undani wote wanaoshukiwa kuwa na kifua kikuu watakaoshiriki kwenye uchunguzi huu. Taarifa hii itakuwa ya muhimu kwa usimamizi wa kifua kikuu nchini.

Hatua za Kufuatwa

Uchunguzi wa kindani utakuwa kulingana na vyombo viwili;

1. Utaulizwa masuala kwenye jewdwali lenye masuala ya dalili. Utaulizwa maswali yanayohusiana na ugonjwa wa Kifua Kikuu na utatoa majibu.
2. Picha ya X-ray itachukuliwa kwa kifua chako kutazama kuwepa kwa ishara za Kifua Kikuu. Iwapo una dalili zinazoambatana na Kifua Kikuu ama picha ya X-ray isiyo ya kawaida, utaombwa kutoa mate kidogo ya uchunguzi kwenye maabara. Iwapo hutakuwa na vitu visivyo vya kawaida ama dalili wakati wa uchunguzi hutakuwa mshukiwa wa Kifua Kikuu na hutahitajika kutoa mate.

Hatari

Hatua itachukuliwa kuhifadhi siri ili hatari ya kutambulika kwa taarifa uliyotupatia itapunguzwa kabisa. Taarifa zote zilizochukuliwa zitawekwa kwa siri na hakuna majina yatakayotumika kwa ripoti. Taarifa zitahifadhiwa kwenye tarakilishi zikiwa na hifadhi maalum na nakala ya karatasi zitahifadhiwa kwenye kabati za kufungwa ambazo zitafikiwa tu na wachunguzi.

Manufaa

Hakutakuwa na manufaa za moja kwa moja kwa kushiriki kwako. Lakini mchango wako utatusaidia kuelewa zaidi kiwango na masuala hatari zinazoambatana na Kifua Kikuu nchini.

Hii itapelekea kuboresha usimamizi wa Kifua Kikuu. Ye yote atakayepatikana na kifua kikuu ataelekezwa ipasavyo kupokea matibabu ya Kifua Kikuu kwenye zahanati zetu za afya ya umma.

Hakikisho la Kuhifadhi Siri

Majibu uliyotupatia yatachukuliwa kwa siri. Hutatambulika kwa taarifa yo yote ama nakala ama kwa makundi yo yote.

Kuhifadhiwa kwa taarifa

Hifadhi zako zinazohusiana na kushiriki kwako kwenye uchunguzi huu zitahifadhiwa kwenye Afisi Kuu inayohusiana na uchunguzi huu kwa uchunguzi zaidi. Kufikiwa kwa hifadhi hizo zitakuwa tu kwa wachunguzi wakuu.

Haki yako ya kukataa au kujiondosha

Kushiriki kwako ni kwa hiari. Unaweza kujiondoa kwa uchunguzi huu kwa wakati wo wote bila adhabu yo yote.

Mada

Iwapo kwenye wakati wa uchunguzi huu uko na maswali yo yote kuhusiana na hali ya utafiti huu wapaswa kuwasiliana na Daktari Joseph Sitienei, S.L.P. 20781-00100, Nairobi.

Nambari ya simu: 0202724264 au 0722 733829

Iwapo kwa sababu Fulani uko na swali kuhusiana na haki ya kushiriki, wasiliana na: Katibu Mkuu, KEMRI/Kamati Kuu ya Kitaifa ya Uchunguzi wa Masuala ya Siri, S.L.P. 54840-00200, Nairobi.

Mimi _____ nimesoma/kusomewa taarifa iliyo hapo juu na kupata fursa ya kuuliza maswali na yote yakajibiwa yapasayo. Ninatoa idhini ya kushiriki kwangu nilivyoelezwa hapo.

Jina la mshiriki wa uchunguzi _____ Sahihi _____

Tarehe _____

Jina la mchunguzi/anayehesabu: _____

Sahihi _____

Tarehe _____

5 Questionnaire for The TB Prevalence Survey of Kenya - MFS

Questionnaire for the TB prevalence survey of Kenya (For manual use)

This is programmed into the netbooks for the interviewers at the MFS

Cluster Number |__||__||__|

Household Identification Number |__||__||__|

Individual Identification Number |__||__||__|

Initials of interviewing research assistant |__||__||__|

Date *(dd/mm/yyyy)* |__||__|/|__||__|/|__||__||__||__|

Nationality _____

1. What is your age? |__||__||__|years

2. When is your date of birth? *(dd/mmm/yyyy)* |__||__|/|__||__|/|__||__||__||__|

3. Sex ○ Male ○ Female

4. Please state your main occupation: |__||__|

Self-employed: Farming=1

Fishing=2

Business=3

Other=4 Specify _____

Employed by government=5

Employed in private sector=6

Pupil/student=7

Housewife=8

Unemployed=9

Other=10 (Specify) _____

5. What is the highest level of schooling you have achieved? |__|

no schooling=1

primary school, not completed=2

completed primary school=3

secondary school, not completed=4

completed secondary school=5

further education after secondary school=6

6. Marital Status |__|

Single (Never been married)

Married

Divorced/Separated

Widowed

7. Do you currently have a cough? |__|

0=no (skip to question 11)

1=yes

8. How many weeks have you been coughing? |__||__|

(If the cough is for 2 weeks or more, then the person should be invited to submit two sputum samples)

9. Are you currently bringing up sputum when you cough? |__|

0=no

1=yes

10. Is there blood or blood-stained sputum when you cough? |__|

0=no

1=yes

11.Do you currently have chest pain? |__|

0=no

1=yes

12. Do you currently have fever? |__|

0=no

1=yes

13. Do you currently have drenching night sweats? |__|

0=no

1=yes

14. Are you feeling fatigued? |__|

0=no

1=yes

15. Do you currently have difficulty breathing or shortness of breath? |__|

0=no

1=yes

16. Over the last month, did you experience unexpected weight loss? |__|

0=no

1=yes

17. Other symptoms?

_____

_____

18. Did you seek treatment for *any* of these symptoms? |__|

0=no

1=yes (skip to Q20)

19. Why did you *not* seek healthcare? |__|

1. Symptoms not serious
2. No money
3. Health care too far from home
4. Already on TB treatment
5. Other, please specify …….

(Skip to Q30)

20. Where did you first seek care for your symptoms? |__|

1. County hospital
2. TB Centre
3. Dispensary
4. Pharmacy
5. Private practitioner
6. Traditional healer
7. Other health service provider, please specify ……
8. If you did not use Public Health System, Why? ……

	Visit 1	Visit 2	Visit 3
21. How much money did you spend on treatment/ services received? 1. Registration/ Card 2. Drugs/vaccines (including outside purchase) 3. Consultation 4. Diagnosis tests (X-ray, lab etc.) 5. Medical Check up 6. Other (specify) 7. Overall Spent 8. Don't know (enter 9999)	Kshs		

22. How did you pay for these services? 1. Cash 2. NHIF/HISP 3. Given opportunity to pay later (credit) 4. Waived / exempted 5. Paid in kind 6. Private insurance 7. Don't know			
23. How much did you spend on transport to get to the health provider and back (return)?	Kshs	Kshs	Kshs
24. How long did it take to get to the health provider and back, including the time of service delivery?	Hr/Min	Hr/Min	Hr/Min
25. How much did you spend on accommodation (if needed) related to your visit to the health facility?	Kshs	Kshs	Kshs
27. Where did you get the funds to pay for the services and how much was paid from each source (record all that apply)	**Visit 1**	**Visit 2**	**Visit 3**
Source of funds: 1. Had own cash available 2. Was given money by friends, family members & relatives- No repayment was expected 3. Borrowed money 4. Community health insurance (paid directly to provider or reimbursed to patient after service was rendered) 5. NHIF/HISP 6. Sold household assets 7. Waived/exempted 8. Given opportunity to pay later (Credit) 9. Others (specify) 10. Don't Know (Enter 00)	KSh	KSh	KSh

28. Have you had X-ray Examinations for these Symptoms? |__|

0=no

1=yes

29. Have you had Sputum Examination for these Symptoms? |__|

0=no

1=yes (skip to Q32)

30. Have you ever been treated for Tuberculosis? |__|

0=no

1=yes

31. If you have never received TB treatment:

i) **Have you had the same Symptoms in the past?** |__|

0=no

1=yes

ii) **Have you had other symptoms of Lung Disease in the past (Hemoptysis, Chest Pain, Cough)?** |__|

0=no

1=yes

iii) **Have you had X-ray Examinations in the Past** |__|

0=no

1=yes

iv) **Have you had Sputum Examinations in the Past** |__|

0=no

1=yes

v) **Have you taken TB Drugs for more than one Month** |__|

0=no

1=yes

vi) **Have you had Injections for more than one month** |__|

0=no

1=yes

32. Are you currently taking treatment for TB? |__|

0=no (skip to Q40)

1=yes

33. Have you had X-ray Examinations for these Symptoms |__|

0=no

1=yes

34. Have you had Sputum Examination for these Symptoms |__|

0=no

1=yes

35. When did you start anti-TB treatment? (Check date from TB clinic treatment card, if available)

Date *(dd/mm/yyyy)* |__||__|/|__||__|/|__||__||__||__|

if the start date is unavailable,

36. How many months have you taken anti-TB treatment? |__||__|months

(If duration not known, then write "UN")

37. At which health facility do you collect your anti-TB drugs? |__|

1. District hospital
2. TB Centre
3. Provincial hospital
4. Pharmacy
5. Private practitioner
6. Traditional healer
7. Other, please specify ……..

38. If available, what is the registration number on the NLTP TB treatment card?

|__||__||__||__||__||__||__||__||__|

(If not available, enter "not available")

39. If available, what is the registration year of the NLTP TB treatment card?

|__||__||__||__|

(If not available, enter "not available")

40. Have you ever been on anti-TB treatment before? |__|

0=no

1=yes

9=unknown

41. How many times have you been on anti-TB treatment before? |__||__|

42. Do you know your HIV status? |__|

0=no (Thank the participant and finish the interview)

1=yes

2= Decline to answer

43. Are you willing to disclose your HIV status? |__|

0=no (Thank the participant and finish the interview)

1=yes

44. What is your HIV status? |__|

0= HIV negative

1=HIV positive

Please thank the participant for their cooperation and lead the participant to the chest X-ray station.

RADIOGRAPHY

REVIEW OF CHEST X-RAYS

Name: _____

Study ID No. _____

CXR image acquisition Date and time: _____

Comments: _____

_____

_____

Name of Radiographer: _____

CLINICAL OFFICER 2

Classification of quality of chest X-rays (mark the box as appropriate)

Quality X-rays Parameter	**Classification of Quality of X-rays**
☐ **ID** on the right side ☐ **Position:** clavicles and ribs symmetric on each side of the spine ☐ **Boundaries**: rib cage and costophrenic angles ☐ **Inspiration**: dome of the diaphragm is below the anterior tip of the 6th right rib. ☐ **Movement:** heart, diaphragm, central vessels and ribs sharply defined, without blurring. ☐ **Exposure:** vascular shadows can be seen in lung periphery, thoracic vertebrae lower lobe vessels visible through cardiac silhouette. ☐ **Contrast:** Background outside patient's silhouette is black, bones and airway easily distinguished from soft tissues	☐ **Uninterpretable**: if the features of the image are not interpretable without additional images. No further reading should be made for such images. ☐ **Suboptimal:** if the features allow interpretation of primary endpoint but not of other infiltrates for such images. ☐ **Adequate:** if the features allow confident interpretation of endpoint as well as other abnormalities.

CLASSIFICATION OF FINDINGS OF CHEST X-RAYS (mark the box as appropriate)

☐ **Abnormal: to provide sputum**

where abnormal can be infiltrate or consolidation, nodules, cavitary lesion, pleural effusion, hilar or mediastinal lymphadenopathy, linear or interstitial disease (in children only).

☐ **Abnormal other**: **Not eligible for sputum**

Musculoskeletal abnormality, cardiac abnormality, pulmonary abnormality, pleural, diaphragmatic, costophrenic angle blunting, solitary calcified nodules or node

☐ **Normal findings:**

These films are completely normal, with no identifiable cardiothoracic or musculoskeletal abnormality.

Notes:

Name: ---------- **Reader ID: ----------**

Date: _____

Sputum Eligible: Yes: _____ No: _____

If Yes, by 1. Symptoms

2. X-ray

3. By both X-ray and Symptoms

4. Decline of X-ray and no symptoms

LABORATORY SPUTUM COLLECTION REQUEST FORM (To be sent with specimen to NTRL)

Name: _____

Study ID: _____

SPOT SPECIMEN

Date of Collection: ……/……/……

Day Month Year

Quantity: _____ mls

Quality: (Indicate if blood stained)

Salivary: _____

Mucoid: _____

Purulent: _____

Date of Transportation: ……/……/……/…….

Time Day Month Year

Remarks: _____

_____

_____

Laboratory Technologist: _____

Date: _____

LABORATORY SPUTUM COLLECTION REQUEST FORM (To be sent with specimen to NTRL)

Name: _____

Study ID: _____

MORNING SPECIMEN

Date of Collection: ……/……/……

Day Month Year

Quantity: _____ mls

Quality: (Indicate if blood stained)

Salivary: _____

Mucoid: _____

Purulent: _____

Date of Transportation: ……/……/……/…….

Time Day Month Year

Remarks: _____

_____

_____

Laboratory Technologist: _____

Date: _____

CLINICAL OFFICER 1

Name: _____

Study ID: _____

CLASSIFICATION OF FINDINGS OF CHEST X-RAYS (mark the box as appropriate)

☐ **Abnormal: to provide sputum**

where abnormal can be infiltrate or consolidation, nodules, cavitary lesion, pleural effusion, hilar or mediastinal lymphadenopathy, linear or interstitial disease (in children only) .

☐ **Abnormal other: Not eligible for sputum**

Musculoskeletal abnormality, cardiac abnormality, pulmonary abnormality, pleural, diaphragmatic, costophrenic angle blunting, solitary calcified nodules or node

☐ **Normal findings:**

These films are completely normal, with no identifiable cardiothoracic or musculoskeletal abnormality.

Notes:

Name: ---------- **Reader ID:** ----------

Date: _____

6 Shipment Log for MFS Filing

KENYA TUBERCULOSIS PREVALENCE SURVEY SPECIMEN SHIPMENT LOG

	Sample ID	Type (Spot/Morning)	Date of collection	Date of Shipment	Comment
No					

LAB TECH …… SIGN……

SUPERVISOR…… SIGN…….

7 MFS Job Aids

8 NTRL Worksheet

LAB NUMBER:

Patient Name: _____

Specimen Receive Date: _____ Received by (Tech Initial):_____

Specimen Type: _____ Processing Date: _____Tech: _____

Type of Patient _____

SMEAR RESULT	
SPOT	**MORNING**
FM (Direct)_____ Date_____ Tech _____	FM (Direct)_____ Date_____ Tech _____
Report released on (date): _____Tech _____	Report released on (date): _____Tech _____

Reviewed by _____Date_____

DRplus RESULT					
MTBC	RpoB	KatG	inhA	Date Performed:	Tech:
				Report released on (date):	Tech:

Reviewed by_____ Date_____

Gene Xpert			
MTB	**Result**	**Tech Initial**	**Date Performed**
Not Detected			
Detected			
RIF Resistant			
Rif Sensitive			
In determinant			
Error			

Reviewed by _____Date _____

LOWENSTEIN-JENSEN (LJ) RESULTS									
Slopes	**W0**	**W1**	**W2**	**W3**	**W4**	**W5**	**W6**	**W7**	**W8**
LJ 1									
LJ 2									
Date/Tech									

Document LJ work-up here (Date and initial each observation/work-up):

Reviewed by _____ Date _____

Summary of Positive LJ Work-up:

Work Up	Date Performed	Result	Tech Initial
ZN			
ICA (Capilia, etc.)			
LPA /PNB/Room Temp			

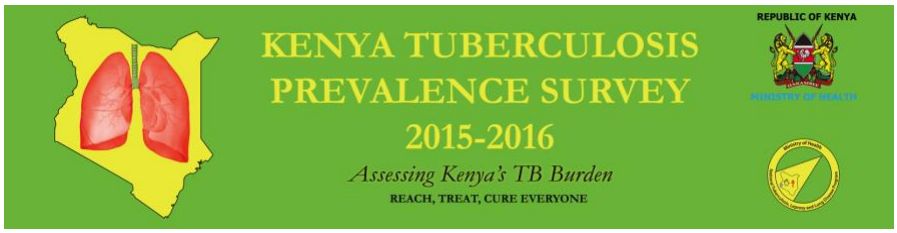
Reviewed by _____ Date_____

DST RESULTS						
STR	INH	RIF	EMB	PZA	Date set-up:	Tech:
					Date unloaded:	Tech:

Reviewed by _____ Date_____

Final Report released on (date): _____ Tech initial _____

Annex 6: Survey Processes



SENSITIZATION & COMMUNITY MOBILIZATION

First visit to the community to assess cluster location and plan survey logistics

1. County authorities informed of survey through government channels.
2. Public sensitized through print and electronic media.
3. Involvement of County and Sub-County Tuberculosis, Leprosy Coordinators (CTLCs/sCTLCs), Community Health Workers (CHWs), village elders, chiefs and assistant chiefs in the respective clusters. This group will be engaged through Chief or community *barazas*.

PRE-SURVEY VISIT & SURVEY ENROLMENT

Household visit and listing

1. Households in identified clusters will be visited two weeks prior to the survey.
2. All household members will be listed. Verbal consent will be obtained from household heads and a Social Economic Status questionnaire administered.
3. The list created by the initial pre-survey household visit serves as the basis for enrolment of eligible persons (15years and above) for the prevalence survey.
4. **SURVEY ENROLMENT:** A second household visit will be done where eligible persons for the survey will provide written informed consent, enrolled into the survey, given a survey ID and a Symptom questionnaire administered. Participants will be invited to the Mobile Field Site (MFS).

MOBILE FIELD SITE & DATA COLLECTION

Chest X-ray, Sputum Samples and Health Seeking Behavior

1. **SURVEY ID:** Enrolled participants will visit the MFS after the household visit and will present their study ID to be logged into the MFS system. Participants will be issued with an MFS movement card and directed to the chest X-ray room.
2. **CHEST X-RAY:** Eligible participants will have their X-rays taken, uploaded into a computer and reviewed for any anomalies to determine if participants should provide sputum samples. ***Eligibility for sputum collection will be based on presence of TB symptoms, abnormal X-ray or both.*** The MFS movement card will be signed and participants moved to the next step. Participants not eligible for sputum submission will be logged off the system.
3. **SPUTUM SUBMISSION:** Participants eligible for sputum are referred to the laboratory technologist who explains the procedure of sputum production and sends them for spot sample. S/He then administers the health seeking behavior questionnaire and gives participants a separate sputum mug for the morning sputum sample. On delivery of the morning sample, the laboratory technologist logs off the participants from the system.
4. At the end of each day, all samples are packed and shipped to the National Tuberculosis Reference Laboratories (NTRL) via a courier service for testing and analysis.

Annex 7: MFS Procedures

TB Survey Mobile Field Site (MFS) Flowchart

1. HOME SCREENING INTERVIEW

Participants listed by community members at home and later invited to the MFS by the survey field team

2. RECEPTION

Invitation card will be received and checked and MFS flow will be explained and written consent signed

3. ENROLMENT

Participants will be asked questions related to TB

4. CHEST X-RAY

Participant will be directed to the X-ray area

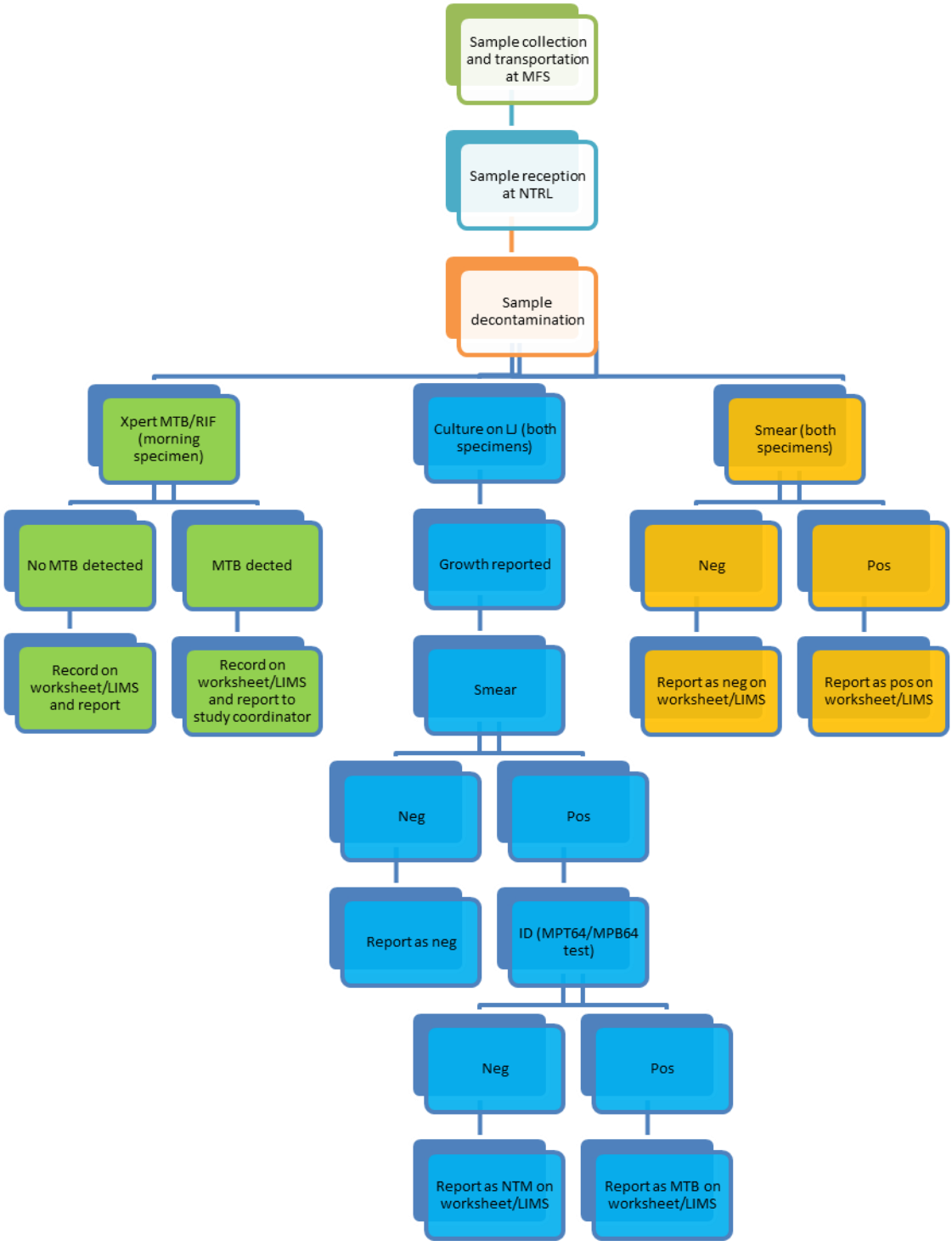
5. DOCTOR

The doctor will assess the x-ray images and decide whether to exit the participant or send him to laboratory to produce sputum

6. LABORATORY

Participant will be instructed on how to produce sputum and given two containers to produce a first sputum sample and a second morning sputum sample

Annex 8: NTRL Workflow

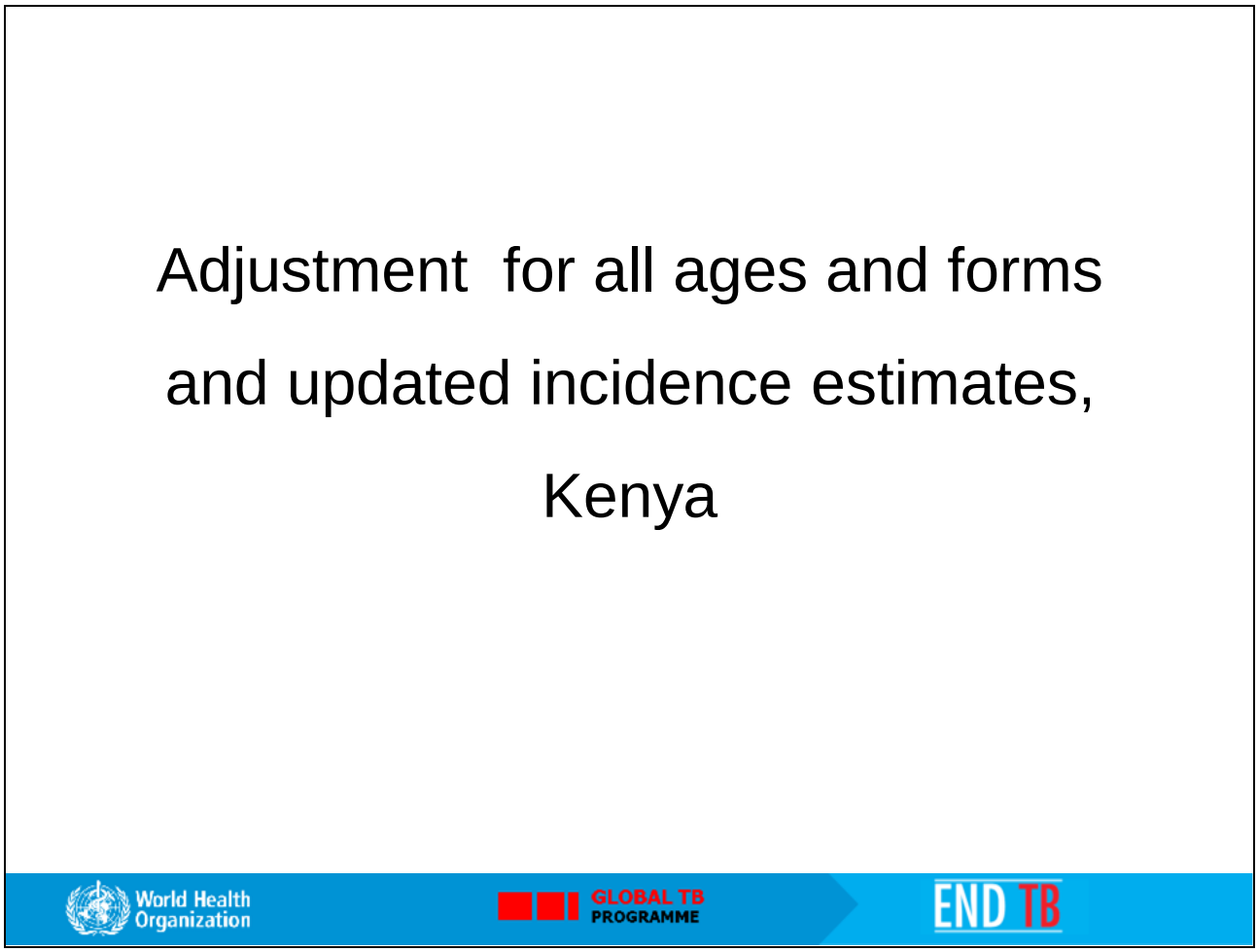


Annex 9: Prevalence rates of TB by different imputation models

			Smear-positive (95%CI)	Bact confirmed (95%CI)	Xpert-only (95%CI)	Details
1	**National**	**Model 1**	197 (150, 244)	489 (403, 576)	381 (312, 449)	Robust standard errors without multiple imputation
		Model 2	217 (168, 266)	524 (441, 608)	409 (339,478)	Robust standard errors with multiple imputation
		Model 3	230 (174, 286)	558 (455, 662)	431 (353, 509)	Robust standard errors with multiple imputation & inverse probability weighting

			Model 1 (95% CI)			**Model 2 (95% CI)**			**Model 3 (95% CI)**		
			Smear-positive	**Bact confirmed**	**Xpert-only**	**Smear-positive**	**Bact confirmed**	**Xpert-only**	**Smear-positive**	**Bact confirmed**	**Xpert-only**
1	**Sex**	**Male**	315 (237, 393)	727 (596, 858)	564 (456, 673)	341 (260, 422)	759 (328, 889)	595 (486, 704)	346 (260, 431)	809 (656, 962)	614 (498, 729)
		Female	115 (66, 164)	322 (235, 409)	252 (181, 322)	118 (70, 167)	338 (254, 422)	261 (190, 332)	138 (79, 196)	359 (258, 460)	286 (202, 370)
2	**Age Group**	**15-24**	182 (113, 251)	307 (214, 401)	262 (181, 343)	198 (129, 267)	329 (231, 427)	275 (194, 356)	218 (133, 303)	360 (242, 478)	311 (206, 416)
		25-34	222 (139, 305)	587 (430, 744)	451 (323, 578)	249 (162, 336)	642 (487, 796)	500 (359, 640)	259 (164, 353)	716 (526, 906)	530 (381, 679)
		35-44	259 (153, 366)	518 (371, 665)	424 (290, 569)	277 (170, 385)	558 (408, 709)	459 (322, 595)	297 (164, 430)	602 (422, 782)	484 (319, 649)
		45-54	200 (94, 307)	575 (419, 731)	455 (312, 597)	217 (109, 325)	618 (439, 796)	490 (335, 646)	234 (101, 367)	607 (432, 781)	492 (327, 656)
		55-64	117 (25, 209)	546 (344, 749)	293 (152, 434)	131 (31, 230)	591 (378, 804)	313 (165, 461)	118 (24, 211)	587 (372, 803)	313 (159, 467)
		65+	124 (22, 226)	566 (360, 773)	443 (261, 626)	123 (23, 226)	575 (363, 787)	455 (268, 641)	125 (24, 226)	576 (368, 783)	449 (264, 634)
3	**Setting**	**Urban**	294 (188, 399)	639 (463, 816)	520 (379, 660)	323 (219, 427)	694 (532, 856)	567 (427, 708)	335 (213, 456)	760 (539, 981)	603 (439, 767)
		Rural	155 (110, 200)	423 (330, 516)	319 (249, 390)	161 (117, 206)	436 (349, 523)	326 (259, 393)	175 (126, 224)	453 (357, 549)	341 (268, 414)

Annex 10: Adjustment for all ages and forms and updated incidence estimates, Kenya



Prevalence survey 2017

Prevalence of bacteriologically confirmed TB in adults:

P_a = 5.58 (4.55 – 6.62)/1000

Adjust for all ages and extra-pulmonary

c = children / total population

r = rate ratio children / adults

$$P = \frac{1 - c + cr}{1 - e} P_a$$

e = extrapulmonary / total cases

Propagate errors about *r*, *e* and P_a

Adjustment for all forms all ages

c = 41.3% children in the population*

r = 12% (SD = 2%) – from notifications

e = 17% (SD = 0.4%) – from notifications

Correction factor *f*

$$f = \frac{1 - c + cr}{1 - e}$$

mean(*f*) = 0.76, SD(f) = 0.01

Overall prevalence

***P* = 4.26 (3.47-5.04)/1000**

**UN Population Division, July 2017*

Errors propagated using 2nd order Taylor expansion about moments

Approximation using first-order Taylor expansion,
$y = h(x_i)$, h is a function of x_i random variates

$$E[y] = h(\bar{x}_i)$$

Gradient *Covariance matrix*

$$\sigma_y^2 = \begin{pmatrix} \frac{\partial}{\partial a} & \frac{\partial}{\partial b} \end{pmatrix} \begin{pmatrix} \sigma_a^2 & \sigma_{ab} \\ \sigma_{ab} & \sigma_b^2 \end{pmatrix} \begin{pmatrix} \frac{\partial}{\partial a} \\ \frac{\partial}{\partial b} \end{pmatrix}$$

$$\sigma_y^2 = \nabla_x \Sigma_x \nabla_x^T$$

Approximation using second-order Taylor expansion

H_x = Hessian matrix

$$E[y] = h(\bar{x}_i) + \frac{1}{2} tr\left(H_x \ \Sigma_x\right)$$

$$\sigma_y^2 = \nabla_x \Sigma_x \nabla_x^T + \frac{1}{2} tr\left(H_x \Sigma_x \ \right)$$

From prevalence to incidence

- Assume stable state equilibrium
- Make assumptions about disease duration based on literature reviews*
- Assume disease duration distributed exponential. Cases are removed independently from the prevalence pool at a constant average rate that varies with HIV and detection status.

** http://www.who.int/tb/publications/global_report/gtbr2016_online_technical_appendix_global_disease_burden_estimation.pdf?ua=1*

Case types: HIV status

- prevalence of HIV in incident cases is derived from routine HIV testing if coverage of testing >50%. Otherwise derived from expected TB incidence rate ratio (HIV+/HIV-)*.
- prevalence of HIV among prevalent TB cases was found equal to 45% of that in notified cases (SD 8.8%) using pooling with mixed effects.

** http://www.who.int/tb/publications/global_report/gtbr2016_online_technical_appendix_global_disease_burden_estimation.pdf?ua=1*

Case types: detection status

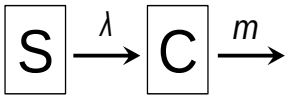
- The ratio of known cases (on treatment at the time of the survey k = 62/305 = 0.2) is used to disaggregate overall prevalence into prevalence detected P_k and non detected:

  $$P_k = kP$$

- Incidence is estimated for 4 case types: HIV+, HIV-, ever detected, never detected

Prevalence to incidence

Susceptible Cases



assumptions about disease duration *d*

TB treatment	*HIV status*	*d* distribution *(year)*
on	-	U (0.2 - 2)
on	+	U (0.01 – 1)
off	-	U (1 - 4)
off	+	U (0.01 – 0.2)

$$P = \frac{C}{S + C}$$

$$d = m^{-1}$$

at equilibrium,

$$\lambda S \Delta t = mC\Delta t$$

$$\lambda = \frac{mC}{S} = \frac{P}{d(1-P)}$$

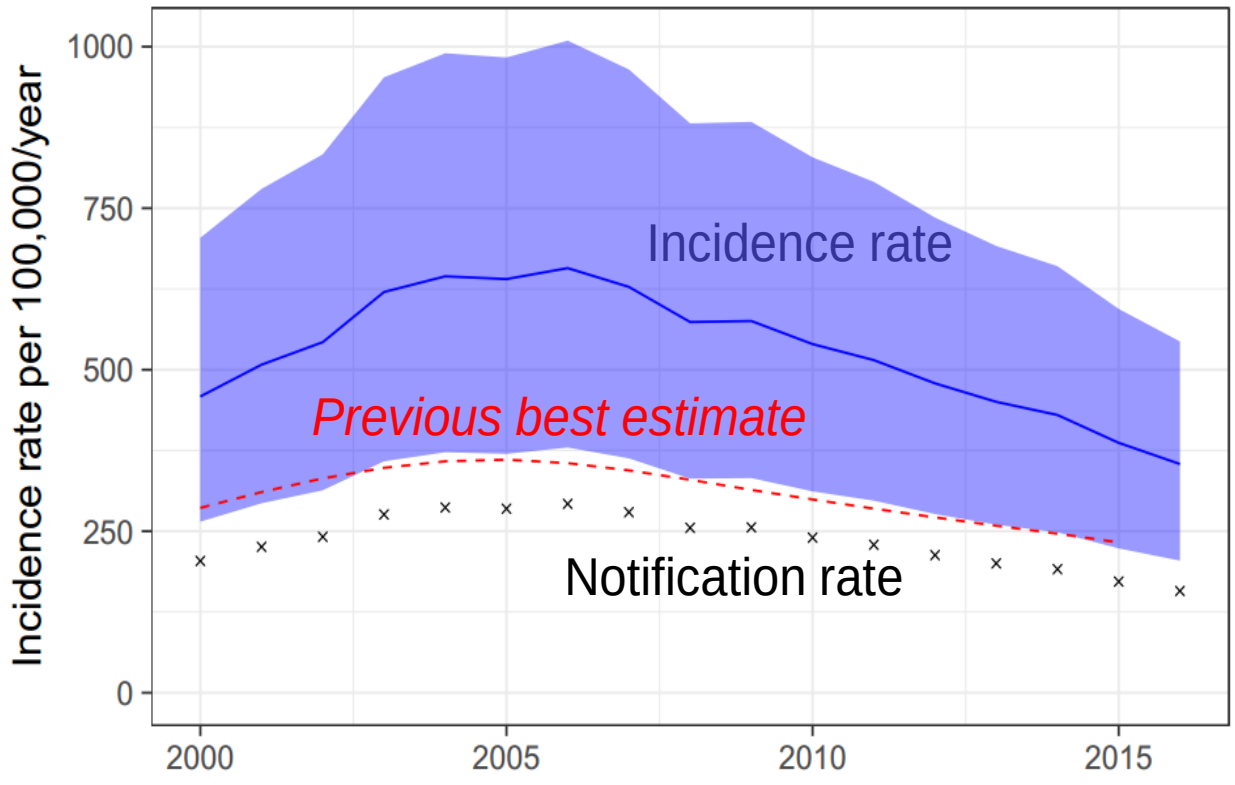
Incidence 2015

I = 380 (233 - 564) per 100,000/yr

Incidence trends

2000-2016 series rescaled based on updated 2015 estimate (trajectory // to notifications)

Incidence series



For more information, contact:

The National Tuberculosis Leprosy and Lung Disease - Program
P.O. Box 20781 - 00202 Nairobi, Kenya
Email: info@nltp.co.ke

www.nltp.co.ke