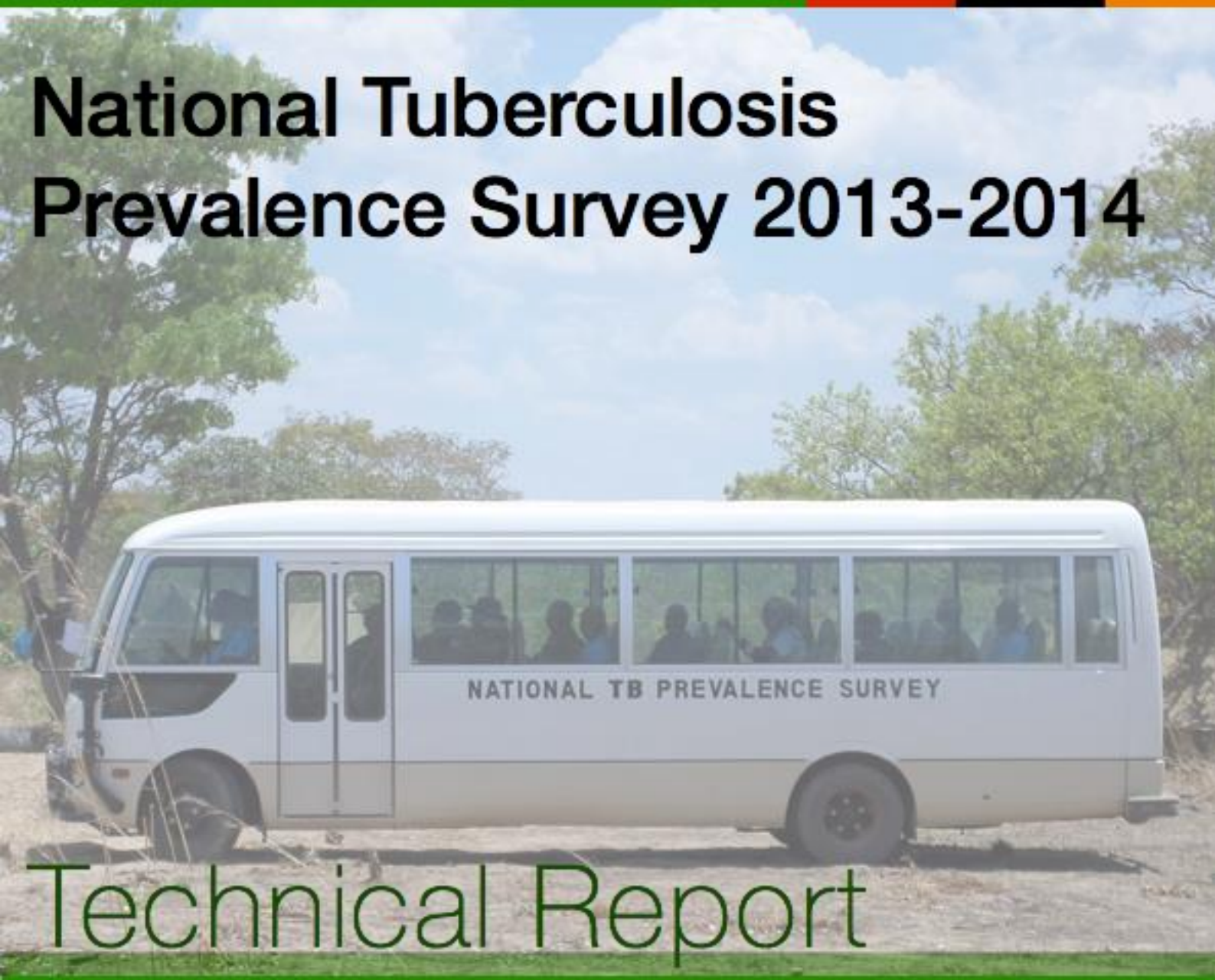
Z a m b i a

National Tuberculosis Prevalence Survey 2013-2014



Technical Report

Government of the
Republic of Zambia
Ministry of Health

Republic of Zambia

Ministry of Health

National Tuberculosis Prevalence Survey 2013-2014

The survey was co-funded by the Government of the Republic of Zambia (GRZ) through the Ministry of Health (MoH) and the United States Government (USG) through USAID/CDC/TBCARE I.

Additional information about the National Tuberculosis Prevalence Survey 2013-2014 may be obtained from the Directorate of Disease Surveillance, Control and Research, Research Unit, Haile Sellaise Avenue, Ndeke House, P.O. Box 30205, Lusaka, Zambia (Tel: +260-1-25306026; Fax: +260-1-253026).

Acknowledgements

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I wish to applaud the Provincial health teams and their respective district and community staff for their unwavering support during survey implementation and case management follow up. My gratitude goes to all the Traditional Leaders for their invaluable leadership and support. Community Volunteers worked tirelessly supporting the field teams in sensitisation, daily cluster operations and participant follow up. I extend a big thank you to all the survey participants who made this survey possible.

I specifically want to congratulate Dr. Nathan Kapata, for leading as Principal Investigator of this landmark study for Zambia. Let me thank the Director Disease Surveillance and Research, Dr Elizabeth Chizema, and Deputy Directors Dr. M Bweupe, Dr. M Kamuliwo, Dr. I Muteba, Mr Mate; Director Policy and Planning Dr. Christopher Simoonga, Director Mobile and Emergency Services Dr. G Siyakantu, and his Deputy Dr. C. Shumba for facilitating the survey. I want to thank all the Advisory and Steering Committee members for their expertise during the whole process.

Finally, I most sincerely applaud the Survey Coordinator and Co-Principal Investigator, Dr. Pascalina Chanda-Kapata for having successfully managed this multidisciplinary team from inception to completion of this very important endeavour.

Dr. Davy M. Chikamata
PERMANENT SECRETARY
MINISTRY OF HEALTH

Foreword

I am delighted to present this report on the findings of the first ever national TB prevalence survey in Zambia and the first fully digital TB survey globally. This report represents a great milestone in the history of TB control and research in Zambia. The TB burden has continued to cause an enormous health challenge to the people of Zambia and is a big public health challenge to the health system in Zambia. Additionally TB presents an economic challenge and impacts negatively on the livelihood of the citizens. The WHO estimates that there are more than 3 million people currently being missed by the TB programs globally. This therefore means that understanding the true burden, is critical to devise policies and strategies to eliminate and eventually eradicate TB.

My government is committed to conducting locally relevant research to respond effectively to the health needs of the citizens. National TB prevalence surveys, such as this one, are one way of improving disease estimates. This survey was conducted throughout the country in both rural and urban areas; without excluding any hard to reach areas or populations. It was scientifically conducted with utmost ethical consideration by a highly competent team and for this I am proud. The survey team was composed of local experts in various disciplines. The survey also followed the laid down international procedures in accordance with the WHO recommendations on conducting national TB surveys.

I also wish to highlight the enormous financial investment by my government to ensure that this high quality research was conducted as prescribed. In addition, the United States Government through USAID/CDC contributed greatly to complement government efforts in conducting this survey.

This report highlights the burden of tuberculosis and identifies gaps for improving TB and TB/HIV comorbidity. It underscores the importance of understanding epidemiological profiles of the disease in Zambia. It is my hope that developed strategies will be meaningfully scaled up so that by the time a follow up survey is conducted; the burden will have reduced significantly. I urge all stakeholders, to work with the government through the National TB Control Program to ensure the findings in this report are used to devise appropriate interventions for impact.

Finally, I congratulate the team of investigators for this landmark achievement in the history of our country, after 50 years of independence.

Dr Joseph M. Kasonde, MP
HON. MINISTER OF HEALTH

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Acronyms

ARTI	Annual Risk of TB Infection
CDL	Chest Diseases Laboratory
CHV	Community Health Volunteers
CXR	Chest X-Ray
DOTS	Direct Observed Treatment Short Course
EPTB	Extra-Pulmonary Tuberculosis
MDGs	Millennium Development Goals
MDR	Multiple Drug Resistance
MGIT	Mycobacteria Growth Indicator Tube
NTM	Non-tuberculous mycobacteria
NTP	National TB Control Program
PI	Primary Investigator
PPS	Probability Proportional to Size
PSU	Primary Sampling Unit
PTB	Pulmonary Tuberculosis
SC	Survey Coordinator
SOP	Standard Operating Procedure
TB	Tuberculosis
TDRC	Tropical Diseases Research Centre
TOR	Terms of Reference
TST	Tuberculin Skin Test
UPIC	Unique Personal Identity Code
WHO	World Health Organization
XDR	Extreme Drug Resistance

Executive Summary

The first ever Zambia national tuberculosis prevalence survey was conducted between August 2013 and September 2014. The main aim was to estimate in a nationwide survey the prevalence of sputum and culture positive pulmonary tuberculosis (PTB) in adults 15 and older. The specific objectives were: i) to estimate/determine the prevalence of PTB, associated symptoms, radiological abnormalities, and HIV-infection in the Zambian adult population; ii) to study the health seeking behaviour of the community for PTB related symptoms; iii) to determine the association between household income and TB disease in Zambia

The cross sectional household survey included a census to identify eligible individuals (15 years and above residents) from 66 clusters across all the 10 provinces of Zambia. This was followed by enrolment of eligible participants who were screened for TB using reported symptoms and chest x-ray (CXR), and offered HIV testing. Participants who were found to have symptoms suggestive of TB and/or abnormal CXR underwent in-depth interview using a structured questionnaire to obtain more detailed information on health seeking behaviour. Thereafter, two sputum samples were collected (one on spot and a second in the morning) and packaged. Within 24 hours of collection samples were transported for smear microscopy and culture to the three central reference laboratories at Tropical Diseases Research Centre (TDRC), Chest Diseases Laboratory (CDL) and University Teaching Hospital (UTH.

From the initial census, 98,458 participants were enumerated. Out of these, 54,830 (55.7%) were eligible to participate. Of those eligible to participate, 46,099 took part in the survey, giving a participation rate of 84.1%. There were more rural participants (65.2%, n=30,042) compared to urban (34.8%, n=16,057). The median age of the enrolled participants was 32 years (IQR; 22 to 47) with more females (56.4%) than males (43.6%).

All the 46,099 participants underwent symptom screening, while 45,633 (99.0%) were screened by CXR at field level. From these, 4,453 (9.7%) had positive symptom screenings while 3,758 (8.2%) had an abnormal CXR.

Based on the results of the symptom screening and the CXR, 6,708 (14.6%) of the survey participants qualified to submit sputum samples (presumptive TB patients); 5,520 (90.7%) submitted at least one spot sputum sample; 4,124 (67.8%) submitted at least a morning sample; with 4,057 (66.3%) submitting both spot and morning sample. Smear results were available for 91.3% (n=6,123) of those who submitted sputum samples whereas the remainder (585) had no smears processed.

Among those eligible for sputum, 356 (5.3%, n=6,708) were smear positive. Of the smear positive, 118 (33.1%) were culture positive. From the 231 culture confirmed cases, 118 (51.1%) were smear positive while 113 (48.9%) were smear negative. Contamination rate was 5.4%. Of the cases subjected to Xpert-MTB/RIF, 39 cases were confirmed to be TB. As a result, 265 definite cases were identified during the Zambia survey.

The prevalence of smear positive TB was 319 (232-406)/100,000 in the adult population and that of culture positive TB was 568 (440-697)/100,000 in the adult population. Combining this, the bacteriologically confirmed TB prevalence was 638 (502-774)/100,000 in the adult

population. The prevalence of bacteriologically confirmed TB was higher in males (833/100,000), HIV positive participants (1,726/100,000), those in the age group 35-44 years (947/100,000), and those from urban areas (993/100,000). Using different wealth scores for urban and rural, wealth indicated the TB burden to be similar across the wealth tertiles in the rural areas, but the lowest and middle urban tertiles had nearly double the TB burden than the highest urban tertile.

Based on the WHO recommended extrapolation approach to account for children and extra-pulmonary TB, the prevalence of all forms of TB was estimated to be 455 (366-544)/100,000 population for Zambia in 2014.

A total of 936 MOTT cases were isolated; 58 from the smear positive and 878 from the smear negative individuals respectively. 71 percent of the MOTT cases were symptomatic (i.e. had either cough, chest pain or fever for two weeks or more). MOTT/MTB co-infection was found in 13 (0.2%, n=6,708) individuals.

HIV pre-test counseling was conducted on 44,761 (97.1%) of the 46,099 survey participants. Of these 30,626 (68.4%) consented to be tested out of which 30,605 were tested. Of those tested 2,063 (6.7%) were positive, 28,453 were negative and 90 had an indeterminate result. Using these results, the adult (15 years and above) HIV prevalence for Zambia is estimated to be 6.8% (95% CI, 5.6-7.9). HIV prevalence was higher in females, the married, the urban population and those in the higher wealth quintiles. The HIV prevalence was four times higher among individuals with bacteriologically confirmed TB than those without.

The application of various technologies to implement a fully digital survey resulted into high quality data collection, timely monitoring, efficient data management and timely reporting of survey findings. The time from collection to reporting is the shortest ever in the history of national TB surveys globally.

Funding:

The survey was co-funded by the Government of the Republic of Zambia (GRZ) through the Ministry of Health (MoH) and the United States Government (USG) through USAID/CDC/TBCARE I.

Introduction

Chapter 1

CHAPTER 1. Introduction

1.1. Background and survey justification

Globally, 6.1 million cases of tuberculosis (TB) were notified in 2013; of which 93% (5.7 million) were newly diagnosed and 6.5% (0.4 million cases) were already on treatment (WHO 2014). WHO estimates that at least 3 million cases are "missed cases" that are either not detected or not notified on national TB programmes in the year 2013. This calls for improved case detection and notification in order for all cases to be properly treated and under adequate TB care.

Zambia, with a population of about 14.5 million people is one of the countries experiencing high TB notification rates which in 2010 were reported to be at 365 per 100,000 population for all ages (Kapata et al 2011). There has been an increase in TB notification rates from 216 per 100,000 population in 1990 to 524 per 100,000 population in 2004 and thereafter the notification rates have been declining steadily (Kapata et al 2011). Furthermore, since 1984 with the advent of HIV pandemic, Zambia has experienced a four-fold increase in TB case notification rates. Other factors which are exacerbating the TB burden in Zambia include high poverty levels, poor housing (CSO 2011), limited TB control strategies in congregate settings (O'Grady et al 2011) and challenges with diagnosing TB in paediatric patients (Chintu et al 2004, Mwaba et al 2011).

The disease burden varies among provinces. The highest notification rates are reported from Lusaka, followed by Copperbelt and Southern Provinces. The higher notification rates are consistent with regions along the line of rail while the lowest rates of notifications are from provinces off the line of rail (MOH TB Programme Report 2011). This distribution is similar to that of the HIV prevalence rates in the country. This information is drawn from the fact that HIV is a strong predisposing factor fuelling the TB infection in sub-Sahara Africa (Godfrey-Faussett 2002, WHO 2011). In Zambia, 50-70% of TB patients are co-infected with HIV (MoH 2008, MOH TB Programme Review Report 2011; Kapata et al 2013).

The hallmark of TB control is early case detection and treatment which is promoted by direct observed treatment-short course (DOTS) strategy. Evaluation of the performance of the National TB control program is measured by aligning national targets and indicators with recommended global targets and indicators. The high TB burden in Zambia has moved TB control from hospital to community-based programs (Godfrey-Faussett 2002, MOH TB Programme Review Report 2011), thereby creating the need for an alternative approach to assessment of disease prevalence in the population and impact assessment of interventions.

The estimates of TB burden in Zambia rely on TB notification data and WHO annual estimates derived from passive case finding and epidemiological models. In order to determine population-based estimates for pulmonary TB in the population aged 15 years and above and define a baseline to evaluate the impact of TB control programmes in the future, a national prevalence survey was conducted from 2013-2014.

1.2. Global targets and indicators for TB control

The global targets and indicators for TB control have been developed within the framework of the Millennium Development Goals (MDG) as well as by the Stop TB Partnership and the World Health Assembly (WHA). MDG 6, indicator 6.8, focuses on incidence, prevalence and death rates associated with tuberculosis and indicator 6.9 on proportion of tuberculosis cases detected and cured under DOTS.

The STOP TB Partnership has set the targets that the global burden of TB (per capita prevalence and death rates) will be reduced by 50% compared to 1990 levels (WHO 2006). This means reducing prevalence to approximately 150 cases per 100,000 population or lower and deaths to approximately 15 deaths per 100,000 population per year or lower by 2015 (including TB cases co-infected with HIV). The number of people dying from TB in 2015 should be less than 1 million, including those co-infected with HIV. The WHO post-2015 global TB strategy has a goal to "*end the global TB epidemic, with corresponding 2035 targets of a 95% reduction in TB deaths and a 90% reduction in TB incidence (both compared with 2015). The strategy also includes a target of zero catastrophic costs for TB affected families by 2020*" (WHO 2014). By 2050 the global incidence of active TB is targeted to be less than 1 case per million population per year (the criterion for elimination adopted within the USA).

National Targets for TB Control

The Ministry of Health Zambia set national targets for TB control in line with the global targets aiming to detect 70% of expected pulmonary smear positive TB cases and successfully treat at least 85% of these.

1.3. The 2013-2014 Prevalence Survey

In order to measure progress towards the national targets in control and prevention of tuberculosis, WHO recommends implementation of population based prevalence surveys to estimate the prevalence of TB for baseline and impact assessment after interventions. In 2007, WHO's Global Task Force on TB Impact Measurement identified 53 countries that met epidemiological and other criteria for implementing a survey. Out of this Zambia was amongst 22 high priority countries selected to undertake a prevalence survey (WHO 2013).

Historically Zambia has never conducted a national TB prevalence survey and therefore lacks baseline data. Currently the only notification data on the TB situation is limited to routine surveillance records from health facilities in the MoH. This data has limitations such as under reporting problems and in addition it does not give information on the number of undetected cases in the community, the number seeking care outside of the public sector, care seeking behaviour and diagnostic delay. Furthermore, the routine surveillance data may have gaps due to recording bias. A national TB prevalence survey will not only estimate the burden of disease to inform policy makers but also provide baseline data for measurement of program achievements and challenges. A second survey five to ten years after intensive implementation of the National TB control program will indicate the disease trends to help assess whether or not the global and national target to reduce prevalence has been a success in Zambia.

It is acknowledged that national prevalence surveys have inherent limitations as information on TB among children less than 15 years old, extra pulmonary TB and, smear and culture negative cases is not collected. Those screened negative, meaning no symptoms and normal CXR are assumed not to have TB.

Aim & Objectives

Chapter 2

CHAPTER 2. Aim and Objectives

Aim

The aim of the survey was to estimate in a nationwide representative sample the adult (15yrs and older) prevalence of bacteriologically confirmed pulmonary TB (PTB), the risk factors for prevalent tuberculosis and the health care seeking behaviour of participants with symptoms suggestive of TB in Zambia in 2013-2014.

Primary objectives

1) To estimate the prevalence of sputum smear positive pulmonary TB

2) To estimate the prevalence of sputum culture positive pulmonary TB

Secondary objectives

1) To estimate the prevalence of the symptoms associated with bacteriologically confirmed pulmonary TB in presumptive TB patients

2) To estimate the sensitivity and positive predictive values of specific symptoms for TB among presumptive TB patients

3) To estimate the prevalence of radiological abnormalities suggestive of bacteriologically confirmed pulmonary TB among presumptive TB patients identified in the survey

4) To study the health care seeking behaviour of presumptive TB patients

5) To determine the prevalence of HIV among TB prevalence survey participants and the association of HIV with prevalent TB

6) To investigate the association of household asset score (as a proxy for socio-economic status) and prevalence of bacteriologically confirmed pulmonary TB

Survey Design & Methods

Chapter 3

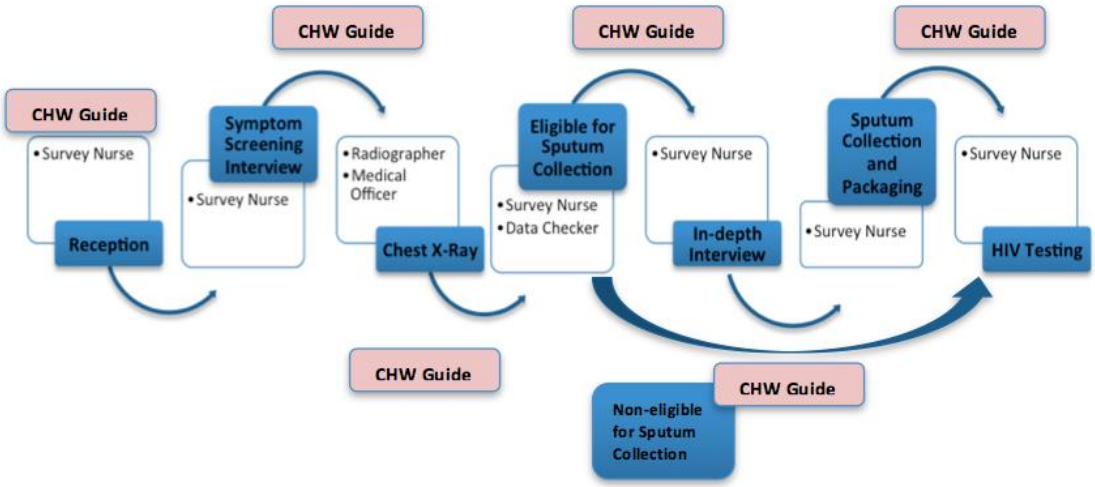
CHAPTER 3. Survey design and methods

3.1. Survey design

The study was designed as a nationally, representative cross-sectional community-based survey among households in selected clusters. The survey was conducted between September 2013 and July 2014.

Case detection method

Eligible household members aged 15 years and above living in the selected clusters were enumerated and approached to participate in the survey. All enrolled participants were screened for TB symptoms using a structured questionnaire and CXR. Household members reporting to have any of the following symptoms: cough for ≥ 2 weeks, or fever for ≥ 2 weeks, or chest pains for ≥ 2 weeks, or abnormal shadows on chest X-ray or chest X-ray indeterminate were requested to submit two sputum samples, one on the spot and one morning sample. The samples were examined for AFB smear and culture in the three central reference laboratories at Tropical Diseases Research Centre (TDRC), University Teaching Hospital (UTH) and Chest Disease Laboratory (CDL). History of the other symptoms associated with TB was also collected. Additionally, all consenting survey participants were



offered HIV testing using the nationally approved testing algorithm. Figure 1 outlines the flow of participants during data collection.

Figure 1: Flow chart of field data collection

3.2. Sampling frame and survey population

Administrative divisions

A household survey was conducted in 66 selected clusters (CSAs) in 49 districts in all the 10 provinces of Zambia. Zambia is divided into ten provinces namely Central, Copperbelt, Eastern, Luapula, Lusaka, Muchinga, Northern, Northwestern, Southern and Western provinces. Each province is in turn subdivided into districts and by 2014 Zambia had 90 districts (CSO 2014). Each district is further subdivided into constituencies and wards. For statistical purposes each ward is subdivided into Census Supervisory Areas (CSAs), which in turn, are subdivided into Standard Enumeration Areas (SEAs). The SEAs are geographical areas, classified as either rural or urban, with information on the number of households and the population size. This demarcation is done through a mapping exercise. Zambia has 150 constituencies, 1,421 wards, 6,583 census supervisory areas (CSA's) and 25,631 Standard Enumeration Areas (SEAs). In urban CSAs the number of households ranges from 360 to 480; while in rural CSAs the number of households ranges from 180 to 300.

Sampling frame

The sampling frame consisted of the list of CSAs as primary sampling units (PSUs). All administrative areas were included in the sampling frame because there were no administrative areas in Zambia in which there were serious safety or feasibility concerns.

Study population

The eligible study population were individuals (whether nationals or not) who met the inclusion criteria and did not meet the exclusion criteria. Individuals who were physically incapacitated but were eligible to participate were provided with transport to the screening site. Military base, diplomatic compounds, refugee camps, hotel, and institutional facilities such as prisons and hospital in a selected CSA were excluded from the survey census. However, households within such compounds were surveyed (i.e. Military barrack with family, prison's staff quarters or hospital staff quarters.) Lodging for seasonal workers in urban areas were also excluded.

Inclusion criteria

1. Age 15 years or older and able to give informed consent and/or assent
2. Individuals living in households within the selected clusters who had slept in the household in the previous 24 hours prior to the survey team visit

Exclusion criteria

1. Individuals who were unable to understand the information given to them because they;
    - Were deaf or hard of hearing and a sign language interpreter was not at hand at the time of recruitment
    - Had speech impediments and thus could not communicate

- Were incapacitated by disease such that they could not understand the information given to them

2. Individuals who were resident in the following institutional settings prisons, boarding schools, military camps, hotels and lodges, refugee camps and other institutional facilities with restricted access
3. Individuals unable to provide consent or assent

Sample size and sampling strategy

Sample size

A targeted sample size of 54,400 adults (aged 15 years or more) was required to estimate the prevalence of smear-positive pulmonary TB based on the following assumptions:

Prevalence of smear-positive pulmonary TB = 199/100,000 population (MOH 2011).

Precision = 25%

Design effect = 1.5

Expected response rate of 85%

Average number of 15 years and above per cluster = 825

Number of clusters = 66

Total population 15 years and above = 7,149,497 (CSO 2011)

The assumptions on the populations shown in table 1 below are based on the Census figures for 2010.

Table 1: Sample Assumptions based on 2010 Census

Sample Assumptions	
Total population	**13,092,666**
Number of households	2,817,219
Population 15 years and above	**7,149,497 (54.6%)**
Average number of people 15 years and above /Household	2.5
Sample size required	54,400
Households required	21,760
Average number of households/cluster (CSA)	326
Required number of clusters	66
Number of provinces	10
Number of districts	74*
Number of constituencies	150
Number of wards	1,421
Number of clusters on frame	6583

*At the time of the survey, there were 74 districts. However, these have since increased to 90.

A cluster sampling strategy was performed and 66 clusters consisting of at least 825 eligible adults were selected. The 66 clusters were distributed to Urban and Rural strata according to recent population statistics (40% to Urban and 60% to Rural) for Zambia (CSO 2010). There were presumed differences in the TB incidence between rural and urban areas, however the reason for stratification was not to provide a different estimate for rural and urban areas as this would increase the sample size which was not considered feasible; but was performed to obtain a population in the sample which was representative of the Zambian population. This stratification would improve sampling efficiency and the precision of the national point-estimate of TB prevalence.

Selecting primary sampling units

Random selection of census supervision areas

Systematic (multistage) probability proportional to size (PPS) was applied to select CSAs in urban and rural strata independently. The order of CSAs was randomized only within a district, and the order of districts was randomized only within a province. Therefore, provinces were allocated clusters according to urban and rural population size. This would ensure that smaller provinces, in terms of population, were also allocated a good number of CSAs.

1. Based on the number of the urban and rural CSAs, the Kish Optimal allocation method was used to determine the number of CSAs to be covered in a province.

2. Proportional allocation method was used to determine the rural/urban distribution of the sample within each province. Probability proportional to size method was used to select clusters within province-rural and province-urban strata with the number of households in the Census 2010 as the measure of size.

3. In each CSA, all eligible individuals were to be approached/targeted. The average population size of those aged > 15years in each CSA was 1,100. However the target sample for a cluster was 825. This meant that there were differences between the actual size of the CSA and the target sample for the survey. If a selected CSA had eligible subjects less than 750, a part of the adjacent CSA was added to fill the sample size. However, when a selected CSA had greater or equal to 1,100 eligible subjects, the CSA was divided by blocks, and blocks were randomly selected to fill the sample size.

Where a pre-survey assessment identified non-feasibility of the survey operation in a selected CSA, the PI re-selected an alternative CSA in a same district randomly. If the survey operation in a particular district was totally not feasible, an alternative CSA was selected randomly within the same province. When such a situation seemed to be temporal, the field activities were postponed to the end stage of the survey so as not to change the schedule for other clusters.

3.3. Case definitions

Presumptive TB patients: Individuals were eligible for sputum examination if they had any of the following findings:

1. cough for ≥ 2 weeks, *or*

2. fever for ≥ 2 weeks, *or*
3. chest pains for ≥ 2 weeks, or
4. abnormal shadows on chest X ray
5. Chest X-ray indeterminate

**All those refusing CXR were asked for sputum if they had a positive symptom screening*.

Acid fast bacilli positive smear: Fluorochrome-stained smear with at least one acid fast bacilli by 40X magnification in 100 fields.

Smear positive pulmonary TB patient: A patient with at least one specimen positive for AFB by smear microscopy and confirmed by culture and/or *Xpert MTB/RIF*.

Culture positive pulmonary TB patient: A patient with MGIT positive tube showing presence of AFB and coding by ZN and identified with TAUNS (capillia) test as *Mycobacterium tuberculosis complex* within the maximum incubation period of 42 days.

Bacteriologically confirmed pulmonary TB patient: A patient with smear-positive and/or culture-positive pulmonary TB.

New smear-positive pulmonary tuberculosis patient: A smear-positive pulmonary TB patient having no history of treatment for tuberculosis or has taken anti-tuberculosis drug for less than a month.

Individual with normal chest X-ray: Clear lung fields and no abnormality detected

Individual with abnormal chest X-ray: Any lung abnormality detected on interpretation by a medical officer (e.g. opacities, cavitation, fibrosis, pleural effusion, calcification, any unexplained or suspicious shadow) and excluding heart and bony abnormalities.

Household: ***A*** group of people who usually eat together and sleep in the same dwelling. A household may include more than one housing unit (this may apply to rural areas) as long as the individuals comprising these housing units meet the definition of a household. Any person who spent the last 24 hours with a household as defined above will be eligible for recruitment.

Adult definition for survey purposes: Any person aged 15 years and above.

HIV positive definition: A participant whose test result is positive on both HIV antibody tests, Alere Determine™ HIV-1/2 and UniGold.

HIV indeterminate: A participant whose test result is positive on the first test (Alere Determine™ HIV-1/2) and negative on the second test (UniGold)

Study participants: those who consent and are at least screened by interview and/or CXR

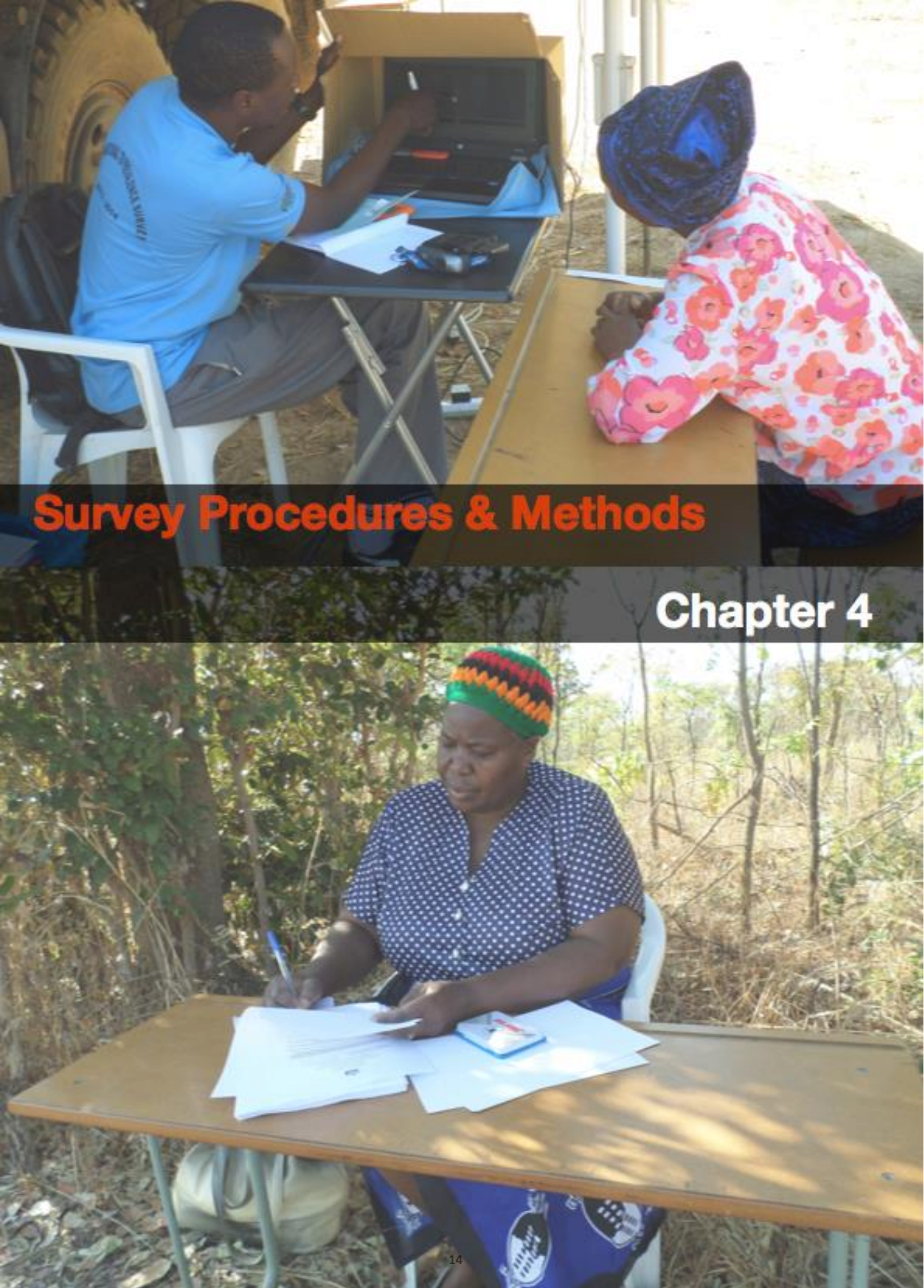
Participation rate: number of participants in the survey/total number of eligible participants

Ethical considerations

The study protocol was submitted to University of Zambia Biomedical Research Ethics Committee (UNZABREC) for ethical clearance (Annex 23). Authority to conduct the survey

was sought in line with the existing national policies and guidelines at national, provincial and district levels. District authorities and local leadership were informed about the aim and procedures of the survey. Written informed consent forms (Annex 2) providing for verbal and written consent were available in English and the seven major languages of Zambia namely Bemba, Lozi, Lunda, Luvale, Kaonde, Nyanja, and Tonga. During the census part of the survey, the population was informed of the survey aims and public information materials on the study were developed.

For minors, both parent legal guardian consent and minors' assent were required to be administered before participation in the survey procedures.



Survey Procedures & Methods

Chapter 4

CHAPTER 4. Survey Procedures and Organization

4.1. Preparatory Activities

4.1.1. Pre-survey visit, cluster sensitization and community mobilization

Before starting the fieldwork all provinces were informed of the survey through a memorandum by the Permanent Secretary, followed by a visit by steering committee members to conduct provincial briefings, inform all relevant authorities about the objectives and overall timeline of the survey. These preparation visits to the provinces took place in **December 2012**. Pre-survey visits were conducted between January and March of 2013 among the communities in the 66 clusters included in the sampling frame and involved the sensitisation of the local authorities, provincial and district health departments and district commissioners about the survey activities. As part of this visit, the team leader sought co-operation for support in fieldwork activities. In consultation with district officials, a nearby health facility was identified for referral of individuals in need of further medical assistance during the survey. District officials were also requested to ensure the availability of necessary supplies including drugs in these health centres. The pre-survey visits were used to:

- Explain the purpose and procedures of the survey and obtain community consent
- Discuss the planning and practical implications of the survey with the District Health Officer, local political and traditional leadership. Special attention was given to the role of the various authorities and health care staff, information to the population, and to the requirements for utilities such as water and main power supply during survey days;
- Make a situational assessment with regard to accessibility, availability of power, areas to set up screening unit.
- Inform community health staff about their tasks
- Hold the community sensitization activities

The details of the pre-survey activities and findings are contained in the ***Pre-Survey Report***

4.1.2. Preparatory visits and training for provinces

Before the start of the field work all provincial, district and local authorities concerned were informed about the objectives and outline of the survey. Each province included in the survey was then requested to set up members of the flexible part of the field teams. The TOR of the preparation visit to the provinces included planning and carrying out community sensitization and information campaigns to explain the objectives and methods of the survey to the population in the selected communities. Trainings were also held for all provincial medical officers, selected district medical officers, TB officers and the media in the survey sites from ***7th to 11th October 2012***. The training was conducted by a central level team and included theory and practical sessions during the cluster operations. The provincial teams provided further recommendations on how to improve participation rates and community sensitization. The provincial teams were then given the cluster operations programme to enable them to anticipate the dates of cluster operations in their respective areas. The details of the training and recommendations are outlined in the ***Provincial Training Report 2013.***

4.2. Community sensitization activities

The community sensitization sub-working group developed messages for the various forms of media for community sensitisation. The materials included a national media launch by

the Hon. Minister of Health to signal the commencement of survey activities. Other activities included messages on t-shirts, cluster banners and a documentary aired on national television. Further sensitisation was done using news alerts on local radio stations and television spots for cluster operations, visits to district leaders and traditional leaders before commencement of survey operations in each cluster. Some clusters which were known to have difficult religious or cultural sub-groups based on pre-survey findings were targeted for tailored information using chiefs and their community leaders to further address misconceptions on the survey.

4.3. Main Training for Research Assistants

The main training for all survey research assistants was held from **21st to 26th January 2013**. The training sessions focused on survey organization, procedures and technical aspects for each of the working groups: census, radiology, laboratory, HIV and data management. The details of the trainings are contained in the ***National TB Prevalence Survey Main Training Report 2013***.

4.4. Field Simulation

Before the commencement of pilot activities, field simulations were held to test the equipment and data flow procedures in Lusaka from **19th to 23rd August 2013**. These were conducted by respective working groups for all three field and central level teams.

4.5. Pilot Survey

The pilot survey was conducted using one rural and urban cluster from **25th August to 3rd September 2013**. A post pilot review meeting was held on **12th September 2013** to review procedures and fine tune SOPs based on the pilot exercise.

4.5.1. Field team composition

Each field team was composed of a survey medical officer who also served as a team leader, a medical equipment technician, seven survey nurses, two radiographers, three census listing team members, five local community health volunteers (CHVs), two security personnel, one data checker and five drivers—for a total of 27.

4.5.2. Enumeration procedures

At the start of the field work the census team conducted household visits to list all eligible household members *(4.8. Survey Census)*. The census team registered the eligible household members on the electronic census register (Annex 5) which was pre-loaded on the Personal Digital Assistants (PDAs). At each household, the team listed all the eligible individuals, informed them about survey procedures and obtained consent. Appointment cards were given to eligible participants who consented to participate and who were present at the time of the interview. For eligible participants who were not at home at the time of the census appointment cards were issued, but consent to participate was obtained at the central survey site.

4.6. Field Activities

Field activities commenced after completion of the census listing procedures in a cluster. The field activities of the survey were conducted by the three **survey teams each** supervised by a

team leader, the survey medical officer. Each field team spent 7 **days per cluster** (Table 2)**.** Fieldwork was done in sets of **2 clusters at a time,** separated by **1 week** of rest for logistics, maintenance of equipment, and retraining if necessary. However, in areas where the clusters were in one geographical region, the field team would do three clusters continuously and thereafter rest for two weeks.

Fieldwork was usually more difficult in the rural areas due to the wide expanse of some of the clusters; in this case, the survey bus was used to ferry eligible people to the main survey site. In some urban and rural clusters, the field team adjusted work hours to include working late in the evenings. The CHVs also used megaphones to encourage people to turn up at the cluster site. In the event that census operations were not completed before the main survey operations, the census team would continue listing until the target cluster was completed; this was later dubbed the "***hybrid operation***." The hybrid operation was very useful in the bigger, sparsely populated rural clusters.

The field operations cycle was synchronised with the laboratory capacity requirements. The three central reference laboratory (CRL) teams worked throughout the survey using a shift system to ensure quality systematic analysis of sputa, documentation and reporting of results. The fieldwork operations commenced on 15th September 2013 and were completed on 30th July 2014.

4.7. Central survey site procedures

At a central site, all eligible participants underwent a short screening interview to check for TB symptoms followed by chest X-ray examination *(see 4.9. Symptom Screening Interview)*. The PDAs were programmed to automatically identify presumptive TB patients based on the outcome of either the symptom-screening interview or chest X-ray examination. All identified TB suspects would then undergo a presumptive TB patient in-depth interview *(see 4.5. Presumptive TB patient in-depth interview)* and were eligible for sputum examination *(see 4.6. Sputum Collection)*. **Two sputum samples, one on the spot and one morning** sample were collected from each participant. The specimens were then transported at the end of each day by courier to the respective three culture laboratories namely, the Tropical Diseases Research Center (TDRC), University Teaching Hospital (UTH) and Chest Disease Laboratory (CDL) for smear microscopy, culture and *Xpert MTB/RIF* examination. *Xpert MTB/RIF* testing was performed for all smear positive or if the only sample collected yielded inconclusive results after a case definition meeting (see Chapter 6. *Case definition meetings*). All cases found to have TB according to the national TB treatment guidelines were referred to the nearest health facility for further evaluation and treatment. The survey coordinator was responsible for communicating to the provincial and TB focal points in the clusters any TB cases for further case management.

HIV counselling and testing was performed by trained nurse counsellors after the TB-related survey procedures were completed *(see 4.14. HIV Testing)*. All consenting eligible participants were offered HIV testing with an option to know or not to know the results of their HIV status. Participants who tested positive for HIV and wanted to know their test results were informed and referred for further management at the nearest health facility.

Follow-up of non-attendees was undertaken to minimise dropouts *(see 4.15. Follow up Procedures)*. Eligible adults who failed to show up at the survey site for symptom screening, CXR or sputum submission was followed up at household level by CHVs. During the follow up visit, individuals found to be either very old, sick or physically incapable going to the survey site were ferried by the survey vehicle.

The survey medical officer referred any medical conditions identified during the survey to the local health facility for further follow up using referral form.

Table 2: Outline of field activities at cluster level

Friday	**day -2**	**census**	
Saturday	day -1	census	
Sunday	day 0	census	arrival and site build up
Monday	day 1		interview, X-ray & sputum collection, data downloading
Tuesday	day 2		interview, X-ray & sputum collection, data downloading
Wednesday	day 3		interview, X-ray & sputum collection, data downloading
Thursday	day 4		interview, X-ray & sputum collection, data downloading
Friday	day 5		interview, X-ray & sputum collection, data downloading, report writing
Saturday	day 6		finalize cluster, await last morning samples, leave cluster site in afternoon

4.8. Survey census

The census survey teams visited all households in the cluster. The team was composed of three listers, who were staff from the central statistical office (CSO) with experience in conducting mapping and household surveys. The listing teams were supported by 5 CHVs per team. The census team interviewed the head of the household or any adult present to provide the required information. This was meant to:

- Give information about survey;
- List all individuals who slept in the house the night before the team visited the household
- Check and indicate on the register their presence during the household visit and register their details in the census register (Annex 5);
- Collect information on age, gender, occupation, marital status, tribe, level of education and asset ownership;
- Check which individuals will be excluded from the survey;
- Ask for written informed consent of those persons present (Annex 2);
- For the members of the household who were not present during census, the consent process was deferred to before starting the symptom screening questionnaire at the survey site;

- Give each participant an *Individual Survey Card* (Annex 6) on which will be filled in name; unique personal identification code (UPIC) (see Chapter 5 data management) and time and place for symptom screening and X-ray;
- Take household asset characteristics (Annex 5);
- Mark each selected house with the household survey number and date of census

4.9. Symptom screening interview

All participants eligible for the survey were requested to present themselves with their survey ID card which was given to them during the census. A short symptom screening questionnaire (Annex 8) was administered to them at the survey site. All individuals were assessed for presence of cough, fever and chest pain. Individuals with cough, fever or chest pain for 2 weeks or more were automatically identified as presumptive TB patients in the PDA.

4.10. Chest X ray screening

All consenting eligible individuals were invited for CXR. Participants who did not consent to undergo X-ray were excluded from X-ray examinations. Attendance for chest X-ray was entered directly onto the PDA by a survey radiographer.

4.10.1. Radiography Screening: On spot reading category

Digital x-ray images were taken by field radiographers (there were two radiographers per team) after verification of participant details as recorded on both the PDA and the *Individual Survey Card*. The UPIC was captured by scanning the barcode onto the radiographers' screen.

Field interpretation was done by the Group Leader who was a Medical Officer. The medical officers had received intensified training on chest x-ray interpretation at the beginning of the survey. However their reporting format was limited to identifying a normal chest x-ray or record abnormal shadows as follows;

- Normal chest X ray: Clear lung fields and no abnormality detected
- Abnormal eligible for sputum (presumptive TB patient): Any lung abnormality excluding bone and heart abnormalities.
- Un-diagnostic chest X-ray: Not interpretable (poor quality, under/over exposed, rotated)
- Chest X ray not done

All participants with abnormal CXR suspected to be TB or undetermined were eligible for sputum collection. Any images which were not interpretable due to poor quality were retaken immediately. All the field CXR results were recorded in the PDA using the electronic chest X-ray screening form (Annex 12).

If there was a shadow suggesting TB or other active diseases, for which medical officers of the survey team thought further clinical care was urgently required, the patient was referred to the nearest appropriate medical facility.

4.10.2. Chest X-ray reading at central level

The purpose of central reading was for diagnosis of abnormalities and quality assurance of CXRs taken in the field and to identify radiological abnormalities consistent with TB among the participants.

Field x-ray images where received at central radiology (either via network or using a hard-drive where network failed), each image included a comment from the field MO. All the x-rays were reported at central radiology by the Radiologist(s), and a report was attached to each x-ray. The report included the date the x-ray was taken, date of the report, the diagnosis (findings) and the name of the reporting Radiologist. The reports were then saved in PDF format; the data required from the reports by DMU was then extracted and presented in a suitable format which would then allow DMU to merge central radiology data to the final data set.

Central Radiology CXR reporting was conducted by four radiologists. The normal images where reported individually but where an abnormality was evident, suspected or equivocal, at least two radiologists reviewed such images before recording the consensus report.

All abnormal Chest X rays were read, to identify radiological abnormalities consistent with TB following standard methods as:

- Normal
- Abnormality detected, not significant
- Abnormality detected, significant-no active disease
- Abnormality detected, significant-not tuberculosis
- Abnormality detected, significant-tuberculosis
- Abnormality detected, significant-unclassified

The results were recorded directly onto the PACS using the criteria in Annex 12. All participants with a major false negative result were informed through the local health system for further case management follow up. The radiologists also provided feedback to the field medical officer and radiographer on the quality of images.

4.11. Presumptive TB patient in depth interview

All eligible individuals having either cough, fever or chest pain for 2 weeks or more (irrespective of abnormal CXR shadows) and/or having abnormal CXR shadows (irrespective of symptoms) or having non interpretable CXR results underwent an in-depth presumptive TB patient interview. This was a structured questionnaire (Annex 10) which was preloaded on the PDA.

4.12. Sputum collection

Two sputum specimens, a spot and morning sample were collected from each presumptive TB patient.

The reason for sputum examination and instruction on how to collect sputum sample was given to individual participants by survey nurses and/or CHVs. The participant was

provided with a sputum container (screw cap, transparent and leak proof) affixed with the participant bar coded ID for spot specimen and instructed to fill the container with sputum in open air. The morning sample was submitted the following day. Salivary specimens were accepted in the survey. If the participant failed to report with morning specimen the next day, the TB treatment supporter would follow-up the participant for collection of morning specimen. If the participant had not submitted a spot specimen, a morning specimen was still collected the next day.

4.12.1. Sputum safe packaging

After the collection in the field, the sputum specimen containers were sealed by tightening the screw cap and cleaning with bleach any contamination on exterior of the container. Each container was packed in a zip-locked leak-proof plastic bag with biohazard label. The sputum specimens were kept cool and stored in a cool box packed with gel packs. The specimens were then transported in a cool box to the respective central reference laboratories at the end of each day's cluster operation by courier.

4.12.2. Sputum transportation and reception

All sputum specimens were transported by the Zambia Postal Services courier system at the end e of each field work day. This was done to ensure that specimens were transported to the central reference laboratory within 24 hours of collection. Dates of sputum collection and transportation were recorded in the PDA at the field site. Dispatch logs were kept by the field team leader and recipient laboratories in order to keep track of sputum sample transportation times and reception. On arrival at the laboratory, specimens together with their respective dispatch forms and all participant details were registered into manual and electronic TB laboratory registries. Specimen registration included scanning of barcodes into the Epicentre®, a customised laboratory information system. If the barcode scanning malfunctioned, the barcode was manually entered into the laboratory information systems, taking care to avoid transcription errors by double checking the entries.

4.12.3. Sputum processing at the central reference laboratories

Sputum microscopy

Laboratory biomedical personnel received and processed sputum specimens through decontamination and used the innoculum concentrate to prepare smears for acid fast bacilli (AFB) smear microscopy. Both spot and morning specimen were examined by concentrated smear microscopy using fluorescent microscopy (Auramine Phenol method). A second reader confirmed any AFB smear positive slides. All examined slides were stored serially in a slide box

The results of the smear examination were recorded in the laboratory data management system (manual registers, EpiCentre® and Excel). XpertMTB/Rif was performed on some of the smear positives; some smear negative with the only culture sample yielding a contaminated result or smear negative but chest x-ray abnormality significant consistent with TB (by radiologist) with culture indeterminate.

Handling of specimens was done in class II biological safety cabinets.

4.13. Sputum TB culture

Each sample was digested and decontaminated using the Sodium Hydroxide N-acetyl-L-Cysteine (4%NaOH-NALC) method and inoculated into one MGIT media and incubated in automated MGIT machines.

Part of the deposits were used for concentrated AFB smear microscopy using Fluorescent Microscopy technique (see sputum examination). The remaining inoculum was stored at 4°C. Culture reading was done daily and identification/confirmation of positive Mycobacteria tuberculosis growth was by Acid fastness on ZN stain and Capillia Test.

All isolates, both *M. tuberculosis* and Non-Tuberculous Mycobacteria, were stored at -70°C.

Results of cultures, AFB smears and indicators of culture quality (contamination rate) were discussed in weekly laboratory meetings. All results were recorded on the laboratory form and in the laboratory registers.

In case of a positive MTB culture and/or positive X-pert MTB/RIF result the district TB officer was informed immediately. All case management follow ups were communicated by the survey coordinator.

4.14. HIV testing

Rapid HIV testing was performed among study participants on site on an opt out basis. All survey participants were offered HIV testing after they were counseled and consented. Survey nurses with counseling skills conducted a pre-and post-test HIV counseling. The nurses are certified to conduct pre-and post-test HIV counseling. The signed certificate of consent for HIV testing (Annex 3) form was separate from the general consent form. This was to ensure that participants not willing to have an HIV-test performed could still participate in the TB survey. The consent form indicated whether patient wished to be informed about the results of the test or not. Participants who chose not to know the results still provided a blood sample for HIV testing for the purpose of the survey only.

4.14.1. HIV Testing Approach

After completing TB survey related procedures, HIV testing and counselling was conducted in accordance with national algorithm. Pre-test and post-test counselling was provided to all participants who choose to know their results. Participants who consented to HIV testing had their blood collected through a finger prick and placed directly onto the screening test strip (Determine™). The unique identification number (bar code) was affixed to the filter paper card, no other identifiers were attached to the DBS samples. Participants, who did not wish to know their HIV test result, were thanked for participating in the survey.

The process was different for participants who wanted to know their HIV results. Pre-test counselling was done prior to testing. Participants were then led outside for sputum collection; this allowed time for test result to be available (10-20 minutes). Post-test counselling was done and if the test was non-reactive, a negative result was communicated to the participant. However, if the test was reactive, the participant was asked to give a second blood sample from another finger prick for a confirmatory test (Uni-Gold™

Recombigen®). If the second test was reactive, the participant was informed of his/her positive status, appropriately counselled and referred for further management to the nearest health facility. If the second test was non-reactive, the result was considered indeterminate and the participant was advised to visit the nearest health facility for a further testing after six weeks.

The HIV test results for all HIV survey participants were documented directly on the PDA.

4.15. Follow up procedures for eligible individuals who do not show up

Eligible adults who failed to attend the screening interview and/or CXR on the date they are due, were traced at the household by community volunteers in the evening. Any presumptive TB patients who missed either an in-depth interview or spot sputum submission were also identified and followed up.

During follow up of non-attendees, those found to be either very old, sick or physically incapable of going to the survey site were ferried by the survey vehicle.

Presumptive TB patients who failed to submit both the spot and morning specimen were traced the next day by community volunteers. A maximum of 3 follow-up visits were conducted.

4.16. Monitoring

At the end of each day's cluster operations, the field team leader sent a daily cluster report by email to the survey coordinator summarising the days' activities. A daily cluster reporting form (Annex 18) was developed for this purpose. Any incidents in the cluster were also reported and remedial actions taken where necessary. Upon completion of the cluster operations, a cluster summary report, which contained the cumulative information of the daily report was compiled by the field team leader and this too was emailed to the survey coordinator before the team moved to the next cluster.

During cluster operations, the central coordination team conducted monitoring visits to assess the performance of the field teams, for timely detection of problems regarding completeness, data quality of data and to ensure the SOPs were being adhered to. The central coordination team also conducted oversight visits to the central reference laboratories and central radiology units. The central coordination unit held weekly meetings to discuss the progress of the survey operations including reviewing ongoing procurements and logistics management. The survey coordinator also kept a log of cluster summary reports to monitor the performance of all the working groups (field, laboratory, radiology and data management unit).

An epidemiologist and data management consultant from KNCV Tuberculosis Foundation conducted field operations and data management external monitoring visits. The monitoring reports provided insight on the progress of the survey and any matters that needed remedial action were communicated to the Survey Coordinator.

The Steering and Advisory committee meetings were held every quarter to provide updates and review progress of survey operations.

An external mid-term review was conducted in March 2014 by a team from CDC Atlanta commissioned by the WHO Taskforce. A multi-country data management workshop was convened by the WHO Taskforce in June 2014 to prepare for the final analysis of the survey data set.

4.17. Pilot study

A pilot study was held from **25th August to 3rd Sept 2013**, before the start of the survey fieldwork, and included one urban and one rural cluster. The pilot test was very important for the teams to master various skills in cluster logistics, use of technology, interviewing, procedures of CXR, sputum collection and transportation.

The objectives were:

- To pre-test the procedures of the field work and survey materials, including the questionnaires, under 'real-life' conditions;
- To assess whether time and manpower were adequate;
- To provide practical training in field work for the field team staff;
- To assess how the data generated by the different working groups including PDA information would be merged for each participant

The time frame was such that adjustments in the field manuals could be made and communicated before the start of the survey. The pilots covered all procedures of the field work, i.e. preparation of population lists by local authorities; census; interviewing; CXR and reading; sputum sample collection, examination and transport for culturing; completing lists and record forms; and preparation of a field report for monitoring. The duration of the pilot in each cluster was the same as that of the full survey:

The pilot area was selected to have a suitable population size (e.g. area of approximately 825 adults). After the survey pilot, experiences were discussed in a small workshop with the technical committee in order to decide on final protocol adjustments. The details are contained in the *Post- pilot review meeting r*eport.

4.18. Quality Assurance

4.18.1. Interview data

Interview data that was electronically collected was also collected in hard copy for every tenth participant for QA purposes. On a daily basis in each cluster every tenth census, symptom screening interview and participant in-depth interview were entered on hard copy. Quality control checks were performed on a random number of a set of census, symptom screening interview and participant in-depth-interview forms labelled 0 to 9. A duplicate interview was conducted blindly and data entered in new forms with correct PINS (Personal Identification Number). The original and re-interview results were then compared and documented in the monitoring report.

4.18.2. Chest X-rays

Before implementing the survey, all the doctors and technicians of the 3 field groups underwent training in the radiology technical aspects including standardization of x-ray reading. During survey implementation, all X-ray images were digitally sent via PACS to one central X-ray reading unit at the UTH. All the images were re-read at central level by the survey radiologists. In case of discrepant results between field and central units, the radiologist decision overrode the field reading.

4.18.3. AFB Smear microscopy

All slides were examined by trained biomedical technical personnel who meet the national AFB smear microscopy proficiency testing standards. Slides were stored serially after examination to prepare for blinded re-checking of a random sample at the end of each cluster.

4.18.4. Culture

Results of cultures, smear re-reading and indicators of culture quality were summarized in a quarterly laboratory report.

4.18.5. HIV testing

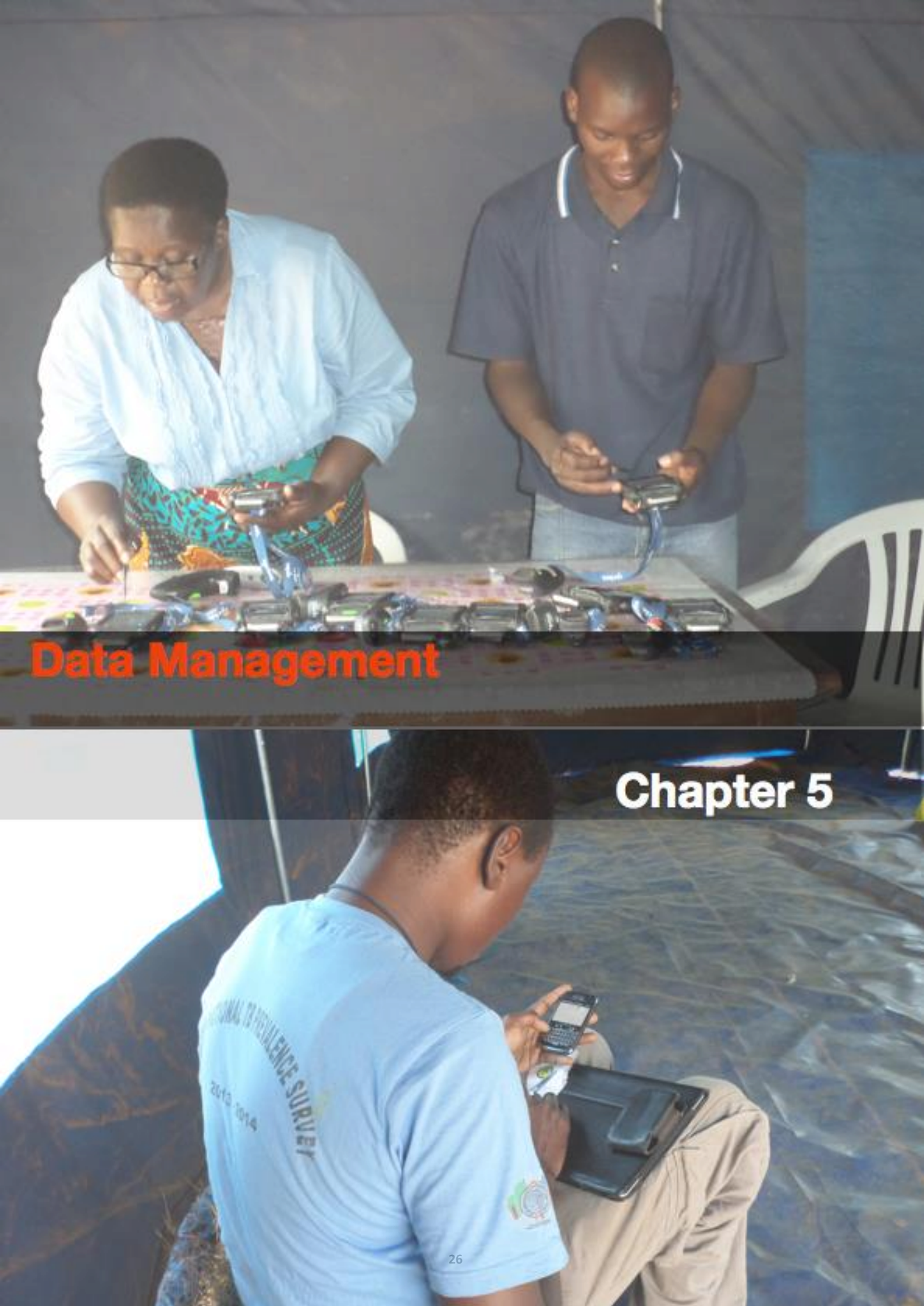
For quality control (QC) purposes, an extra sample was collected from every tenth participant collected on a filter paper and stored as dried blood spots and labelled with a unique identification number for re-testing.

4.18.6. Training

As part of quality assurance, trainings were undertaken before the beginning of pre-survey and survey activities. The trainings included:

- *Pre-survey visit workshop:* Short provincial workshops to prepare field team leaders and selected field team staff for pre-survey visits.
- *National workshop:* -A central workshop was held for all staff involved in the survey at national level, including the complete field teams. Here the survey's objectives and procedures were explained, and the SOPs were discussed in detail.
- *Technical training sessions:* -Technical training workshops were held at national level for the field team staff on X-ray operating and reading, census, interviewing, radiology and laboratory aspects. This included technical aspects and discussion of the draft field manual to allow final adjustment. The training courses were held during the same period in order to allow agreement on the final field procedures.
- *Community level training sessions:* -Local orientations for community volunteers was conducted by provincial or district TB staff and the team leader.

The details of the trainings have already been described in section 4.1 (see 4.1 Preparatory Activities).



Data Management

Chapter 5

CHAPTER 5. Data management

The Zambia TB prevalence survey generated mostly digital data with the exception of participant invitation cards, consent forms and hard copy QA questionnaires. A unique identification number called the Personal Identification Number (PIN) was used in all the stages of data collection and data management. It consisted of three variables as shown below.

	Cluster number	Household number	Individual number
PIN:	# #	# # #	# #

The PIN was converted into a barcode and barcodes were used on all forms/registers and in digital data files to identify each survey participant.

5.1. Organizational aspects of data management

The data management was performed by the Data Management Unit (DMU), which functioned as a central unit for data collection and processing at various levels (field level, CRL level, central X-ray re-reading level). The DMU was in charge of data management, planning, operation and security of the data and the associated information systems.

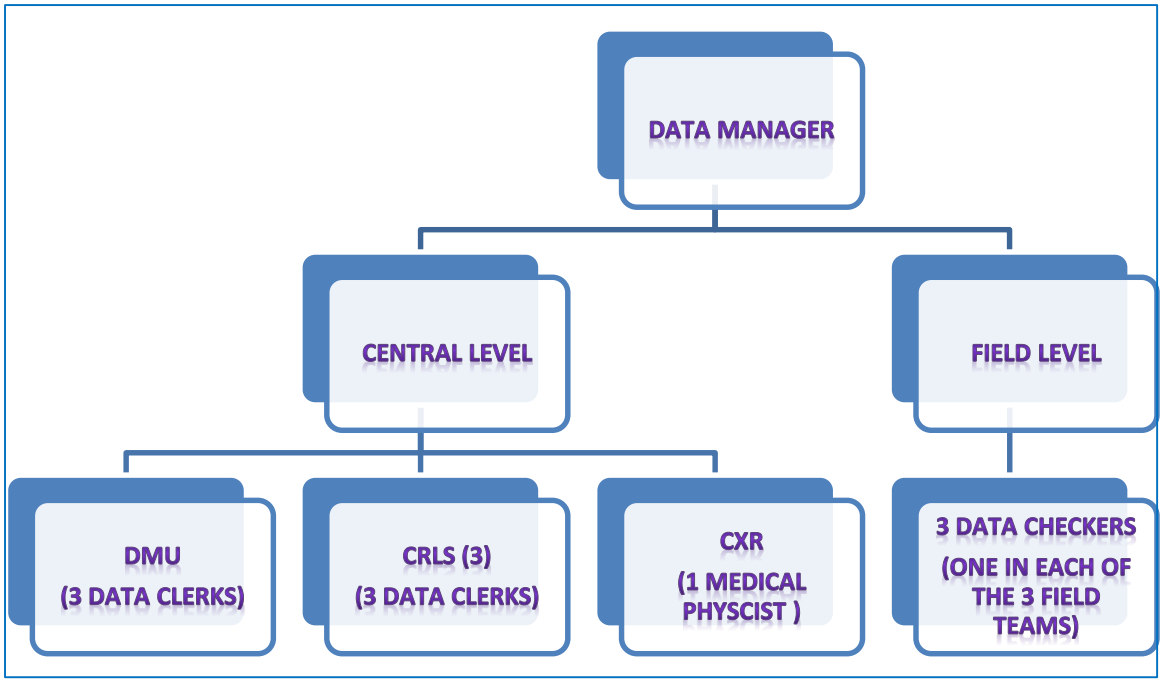


Figure 2. DMU structure

Data collection and data management activities took place at field and central level. The DMU staff members at all levels supported these activities.

5.2. Field level

The census team leader and the survey medical officer initially performed the data management support at the field level. However, after early review of the survey, a data

checker was added to each of the three teams specifically for data management. The data checker provided support in the use of the PDAs and bar coding for data collection and data transfer. The data checkers were responsible for merging the collected data cluster wise at field level and transfer the data file from field level to the central level DMU by email.

5.3. Central X-Ray

The digital images from the field were transmitted to CXR via satellite. During the period when there was no internet connection, digital images were transported to CXR using hard drives (transporters). The Radiologist reviewed the received participants' images and formulated the diagnosis. The reports were exported to PDF by the Data Manager at CXR and converted into digital excel data files and transmitted electronically to DMU.

5.4. Central Reference Laboratories

At the CRL a data clerk was responsible for data collection and data transfer. The data collection was processed in the routine and digital CRL data processing system (Epicentre ™). The barcodes on the samples provided by the field were processed and included in the digital CRL system.

5.5. Data Management Unit

The data clerks at the DMU received the emailed data from the field, CRL or CXR at central level. The data clerks monitored the received data and performed data quality aspects before the data were forwarded to the data manager for inclusion in the final merged database. The data manager performed further data quality and validation checks. The monitored data quality results were reported back to the data checker in the field or CXR or CRL respectively.

5.6. PDA and IT Support

The DMU received IT assistance from the Ministry of Health. Local PDA experts provided on-going support for software upgrades, troubleshooting and retrieval of data from malfunctioning PDAs and computers. Any further programming required, based on feedback from the field, was performed and the updated versions were 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.

5.7. Operational aspects of data management

5.7.1. Pre-Survey Data Collection

The pre-survey data collection focused on the preparation of the survey by collecting data in the field. The census team enumerated members of each household and eligible participants were issued an ID card with the name, PIN and barcode at household level. The field team enumerated the household members by entering the data in the census register loaded on the PDA. Based on the PIN, a barcode was generated by the system and stored in the PDA. The barcodes were printed at different stages (at pre-survey data collection, at survey data collection in the field, at CRL and CXR level). The Socio-Economic-Status questionnaire was also taken at household level based on the interview with the head of the household.

5.7.2. Survey Data Collection

Based on the census register verification, the eligible participants were asked to sign a consent form upon arrival at the survey site. All invited participants who were 15 years and above and gave assent/consent proceeded to participate in the symptom screening interview followed by X-ray at the survey site. The census register on the PDA provided the identifying information of each participant based on the barcode (PIN). The answers were directly entered by the survey nurse onto the digital questionnaires loaded on the PDA.

Figure 3. PDA and barcode equipment and barcode examples for sputum smears (S and M*)*

All participants were invited to participate in the X-ray screening. The pictures were stored digitally including PIN and barcode. Once the results were read, they were entered in the PDA and stored by a Survey Medical Doctor. The chest X-ray images were taken from each participant at the Survey Site and a barcode based on the PIN was attached to the image. The image was then sent to the central chest X-ray (CXR) via satellite for second reading using Picture Archiving Communication System (PACS).

Eligible participants were asked for sputum smear examination. The sputum smear containers with barcodes (PIN plus an 'S'=spot or an 'M'=morning) were transferred to one of the 3 CRLs for smear examination, culture and *GeneXpert* results.

Eligible participants were interviewed for the second time (In-depth Questionnaire). The data was entered directly in the PDA and stored. In addition, participants who gave consent to HIV testing underwent the test and the results were entered in the PDA and stored.

5.8. Data flow

At field level, the data collected by PDA was downloaded onto a laptop by the data checker for merging, data checking and cleansing using all the data cleaning operations i.e. validity checks, accuracy, completeness and consistency and checks for duplicates. After the data was cleaned, it was transmitted to the DMU via email by a data checker and imported into the central database for storage by the data management team at DMU.

The survey medical doctor transmitted digital images from the field via satellite to central chest x-ray using the Picture Archiving Communication System (PACS). The chest physician or radiologist at CXR interpreted the digital x-ray images for the second time. After the radiologist read the x-ray images, the results were obtained on the form loaded on the PACS work stations at CXR. The data manager at CXR exported the results to digital excel data files and emailed them to DMU after checking for accuracy and consistency.

At the central reference laboratories, the sputum specimen, on the spot (Sample S) and morning (Sample M) collected from the field were transported to the three CRLs. The sputum specimens were transported in containers with barcode labels e.g. 1200202S and 1200202M. As soon as the results of the smear examinations, as well as the culture results and *GeneXpert* results at one of the CRLs became available, they were obtained in digital excel data files and digitally transferred to the DMU via email.

5.9. Data monitoring, cleaning and validation

The field team leader and the data checker in the field ensured that questionnaires on the PDA were checked at the end of each day during the field operation. The data checker merged the data from different PDAs once the data was downloaded onto the laptop. The data checker ensured that the data was correctly and accurately completed. Data verification and consistency checks were also carried out.

The field team leader also observed the administration of questionnaires on the PDA to ensure that the field staff were using the formal translation of the questions and not paraphrasing questions as this could alter the meaning. The data checker collected all forms and registers (such as the individual survey card and consent forms) in the field cluster wise and ensured that they were sent to the DMU for storage.

Data monitoring at CXR level was conducted by the radiologist for X-ray images received from the field. The radiology staff provided feedback in real time to the medical officer in the field on poor quality images received from the field. The data management staff at CXR ensured that the digital data file consisted of all X-ray results from the CXR.

Data monitoring at the CRLs was conducted by laboratory biomedical staff and the data manager. When samples from the field were received at the laboratory, they were scanned into the Epicenter system by reading the barcodes on the sputum tubes. The Laboratory staff provided feedback to the field members in a pre-defined report on samples that had leaked out immediately after acknowledging receipt of the samples. The data management staff ensured that after completion of every laboratory test for smears or culture, the test result forms were checked for accuracy, completion and consistency and the supervisors checked for inconsistencies which occurred when obtaining the results.

Data monitoring by data management staff at DMU level was conducted using MS Access and SPSS and continuous authorization to the server on which the database was running. The DMU staff checked the data file for consistency, completeness and validity and saved the data file in the database at the DMU server. The DMU prepared standardized feedback

to the data checker in the field of the results of the transfer of the data file directly after the data had been checked and stored.

Before data cleaning, a backup was made and stored in a separate folder to ensure that original data from the field was always available when needed. Data cleaning was performed on the data before it was imported on the database. This included checking for duplicate information, missing data or redundant data on data files from the field, CXR and CRLs. This was performed by the data clerks as well as the data manager. A standard query was designed and it was run automatically to detect duplicate records with the same PIN in the database. Before removal of any duplicates, the data manager contacted the data checker in the field to learn the reason for duplicates in the data file and to decide with the data checker and/or the field team leader which record needed to be removed. The results of this process were documented by the DMU.

Data cleaning included checking for correctness and completeness of the data. A standard cross tabulation query was designed in a Microsoft Access database. This process involved checking for all known measures or values recorded and when incomplete records were detected, predefined reports were prepared for such records and were sent to the originating cluster for correction.

Data cleaning also included checking for inconsistencies. A standard cross-tabulation query was designed in Microsoft Access database and run automatically to detect inconsistencies and errors between two variables. The data was evaluated by way of checking if there was different information of the same person in different data files (different tables/queries in Access) which contradicted each other; for example, records of the same participant but with different age or sex. Predefined reports for such errors detected was prepared and sent to the originating cluster for correction.

Data cleaning further involved checking, for each record, if they were any test results that were missing such as HIV test results, chest x-ray results and bacteriological examination results. Predefined reports of the missing results were sent to the field, CXR and the CRLs.

The DMU also monitored the number of paper-based forms and registers from the field and stored the information in such a way that confidentiality was secured. The storage was done in an organized manner which made it easy to retrieve the paper forms and registers as and when needed.

5.10. Merging files

Data files from the field and the CRLs and the CXR were stored separately before all data files were merged into the final database. This was a day to day task performed by the data clerks at the DMU and monitored by the data manager at the central level using an MS Access database on desktop computers. The merge key was the PIN which had been entered in the separate data files from the field, the CRLs and the CXR by reading the barcode of the participant. The data collected from the field using PDAs had tables (of all different forms and registers loaded on the PDA) containing information with different variables per individual. The records from the different tables were merged by linking the information per

individual using a variable that uniquely identified the individual (PIN). A standard query was designed which was run automatically. The purpose was to combine all the different variables of one participant into one record. A relational Access database was used which was made up of tables of data from the field, CRLs and CXR linked by the PIN.

5.11. Validating Database

Data validation included all processes and procedures to check, detect and correct inconsistencies to assure high data quality. The following processes were used in both MS Access and in SPSS using a merged export data file.

5.11.1. Data checking for empty records/empty fields missing results and/or missing forms

This involved checking for missing variables and/or missing forms and all the findings were documented by the DMU staff using the data management register.

5.11.2. Data checking for system missing within variables in the database

This process involved running frequencies for all variables and checking for system missing variables. The staff at DMU corrected the system missing variables by liaising with the field staff, CRL staff and CXR staff.

5.11.3. Data checking for duplicates

The process involved tracing duplicates using the PIN which consisted of the cluster number, the household number and the participant number. Other variables such age, names of participant, place name together with the PIN were used to identify the duplicates. Duplicates identified by the DMU staff were documented and corrected by contacting the source of information (field, CRL and CXR).

5.11.4. Data checking for completeness of reported number of records

The process involved checking for consistency of the number of survey participants with the number of completed screening results and all the other results were checked cluster wise. The cluster summary report and the tables of monitoring the indicators were updated and used to monitor completeness and consistency of the data flow from field and central levels to the DMU.

5.11.5. Cross-tabulation of two variables

This process involved looking at two variables at the same time and check for unlikely association in the variables using cross-tabulation (for example, a daughter whose relationship to the head of household is son). This process was performed in both MS Access and SPSS by the DMU staff and all inconsistencies identified were reported and corrected.

5.12. Data storage

5.12.1. Data storage at the field

The data manager in the field stored the merged data files on the laptop in the field before the data files was transferred to the DMU. Laptops were accessible with a personal password given by the data manager at the DMU. Data files were stored in a zipped format and transferred to the DMU with a password given by the data manager at the DMU. The

data storage was done on the laptop in a separate folder for each cluster. At the end of the survey the laptops were returned to the DMU and all folders containing data of the survey were checked for completeness with the central database before the contents of the laptops were deleted.

5.12.2. Data storage at CRLs

The data manager at the CRLs stored the data on the desktop on which the Epicenter software was running as well as on hard drives provided by the data manager at the DMU. The digital data files were backed up on hard drives and CDs.

5.12.3. Data storage at CXR

The data manager at the CXR stored all the digital images received from the field on the server which had enough capacity to store more than 54,000 images. The digital data files obtained from the PACS were stored on the laptops which were accessible with a personal password by the data manager only at CXR. The data was backed up on hard drives and DVDs.

5.13. Data storage at the DMU

All zipped and raw data received from the field, CRL and CXR were stored cluster wise at the DMU on password protected desktops and backups were made daily on the server. After data cleaning and merging, the data was stored again in separate folders. The data stored on the server was securely held. This was sensitive data, therefore it was encrypted and protected with a password and no unauthorized access to the database was allowed to ensure confidentiality and integrity of the personal data. The Data Manager was responsible for ensuring the data files were securely held. The Data Manager ensured that computers used had effective and up-to-date anti-virus programs and firewalls and were protected physically from risks such as theft, power breaks or power surges.

The Data Manager ensured that data files stored on the database were backed up regularly. Data backups were done on a daily basis and version wise (everyday a new version was stored) using external sources such as external hard disk drive. This was done during the late evenings and also in the early morning hours. A monthly version wise backup was also done. The backup storage media was stored in a safe secured place, one within DMU and a second one in another building to avoid losing the data in event of fire occurring.

5.13.1. Storage of paper based documents

All paper-based documents (consent forms, individual survey card) were stored under the responsibility of the DMU in folders in a secured and safe storage room. The paper-based documents were transferred to the DMU cluster wise.

Case Definition Meetings

Chapter 6

CHAPTER 6. Case Definition Meetings

After the data management unit received and merged the census data, field surveys data, central chest x-ray results and laboratory results for each cluster, case definition meetings were convened by the survey coordinator. The participants included members of the laboratory, radiology, data management and central coordination unit. This was done to ensure all areas of expertise were available to undertake a case-by-case review of the results so as to classify the survey participants as per case definition framework (Annex 4). Any cases that required further follow up were referred to the respective working group for verification and final incorporation into the database. Case definition meetings were held every last week of the month to consider all cases with a complete set of results.

Survey Management

Chapter 7

CHAPTER 7. Survey management

The management structure of the survey was composed of the central level and field level as outlined in Figure 4.

7.1. Survey management at central level

The survey was organized through the steering committee and three field teams.

Steering committee (St C)

The PI was the chair of the steering committee. The steering committee had the final responsibility for the protocol, data collection, data management and analysis and dissemination of the results.

Principal investigator (PI)

The PI had final responsibility for protocol, funding, data collection, data management and analysis, and dissemination of the results. The PI was advised by the Technical Advisory. He also delegated tasks and responsibilities to the SC.

Survey Coordinator (SC)

The survey coordinator assisted the PI in overall supervision of the survey. The SC had responsibility to timely secure all necessary resources and technical assistance to carry out the prevalence survey in line with the protocol. The SC was accountable to the Principal Investigator for all technical and administrative matters. The Central Coordination Unit, chaired by the SC, was formed to assist with survey coordination. The members of the CCU included a Logistics Manager, Data Manager and Central Data Clerks and two assistants to the SC (one for field operations and another laboratory operations).

Technical advisory group (TAG)

The TAG advised the steering committee and the SC on technical issues regarding preparations, conduct of the survey, management, analysis and reporting of the data. Its terms of reference included:

1. To advise on finalizing the survey protocol and the field manual/SOPs
2. To advise on purchase of equipment and supplies
3. To advise on pre-testing materials, training and pilots
4. To monitor data collection and quality control
5. To advise on data management and analysis
6. To advise on reporting of results

Members of the TAG included experts in the following areas: survey methods (interviewing and census), X-ray (technical and reading), laboratory (including HIV), data management, data analysis, sensitization and community awareness.

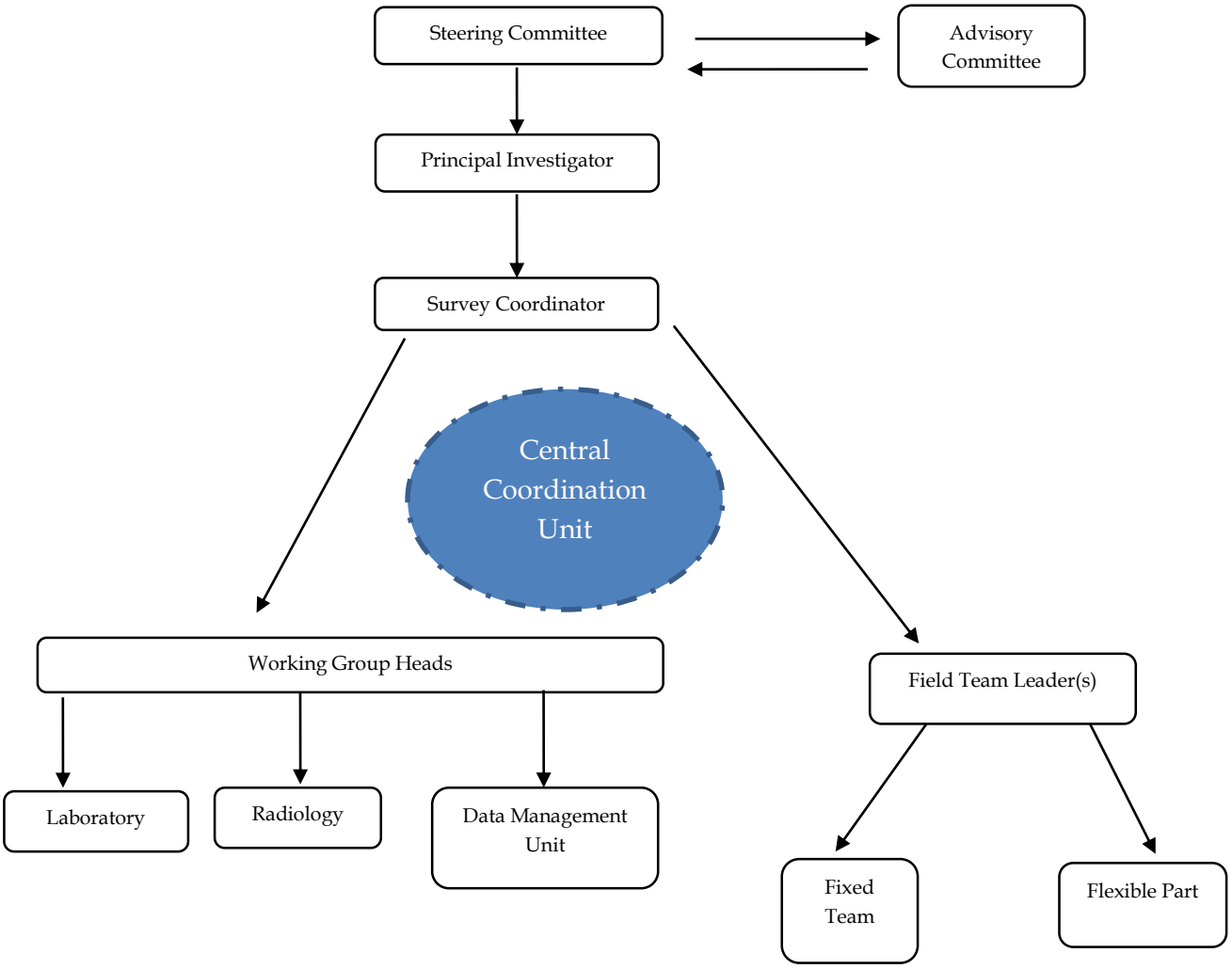


Figure 4. Organization of Survey Personnel and Staff

7.2. Survey management and Organization at Field Level

There were three field teams; each field team consisted of a management group, interviewing group, radiology group, and laboratory group. Each group contains a fixed and a flexible part (Table 3).

Table 3. Composition of the field team (cluster level)

Title	N	Tasks
Fixed team		
Team leader (medical doctor)	1	• Participate and facilitate in trainings • Communicate and coordinate with local, district, and provincial authorities on issues regarding the field work; • Coordinate with community leaders and secure community support • Organize and supervise team at cluster site • Conduct the pre-survey visit • Coordinate and supervise the day to day field operations • Ensure completion of the field data collection forms and field report • Perform quality checks of radiographs • Check whether data collection is done according to the protocol • Blind rechecking of census, symptom screening interview, Presumptive TB patient in depth interview
Medical equipment engineers	1	• Ensure all necessary arrangements for lodging and transportation • Manage supplies, and ensure the maintenance of equipment
Census clerks	3	• Participate in pre-survey visit (community sensitization) • Carry out the census
Interviewing group (Nurses)	6	• Set up area for sputum collection • Supervise and ensure the quality of sputum collected • Interview all survey Participants for symptom screening • Identify presumptive TB patients • Conduct presumptive TB patient in-depth questionnaire • Specimen packaging and dispatching • Conduct HIV counselling and testing
Radiographer	2	• Set up the chest X ray unit • Conduct the Chest X ray • Read the X ray
Drivers	6	• Drive • Other tasks at field level
Flexible part		
District TB coordinator	1	• Facilitate logistics and supervise the field operations. • Follow up on smear positive TB patients
TB treatment supporter (community volunteers)	5	• Sensitize community • Provide instruction for sputum collection • Collect on the spot samples • Assist with labelling and packing sputum • Follow-up on non- attendees and • Ensure the submission of the morning samples

7.3. Technical assistance

Local technical expertise was available to conduct a national TB prevalence survey. These included TAG as well as the steering committee. The WHO Taskforce provided technical assistance from proposal development, monitoring, data analysis plans and facilitated inter-country exchange meetings.

KNCV Tuberculosis Foundation was the technical lead agency and provided support during all steps of the survey. Further technical support during protocol development was received from WHO, CDC, KNCV and RIT/ JATA in 2012.

Technical assistance on programming, training and the use of PDAs was obtained locally.

7.4. Dissemination plan

It is the responsibility of the Principal Investigator to ensure that the findings from the prevalence survey are widely disseminated to all stakeholders at community, district, provincial, national and international levels.

The preliminary report was disseminated in country after the initial survey analysis was completed. Preliminary findings were also disseminated at the 45th Union Congress of Lung Diseases in Barcelona.

This final full report will be disseminated at national and provincial levels once all quality assurance aspects have been concluded. The dissemination meetings will include all relevant stakeholders in Tuberculosis and HIV/AIDS programmes.

The Principal Investigator shall ensure that all data generated from this survey remains secure in line with the established guidelines. The manuscripts for peer-reviewed journals will be developed and published. The contributing authors will be in line with international recommendations on co-authorship.

Data Analysis

Chapter 8

CHAPTER 8. Data analysis

Data were analyzed using the STATA software package version 11 and 12. The first stage in the analysis focused on describing eligibility, enrollment and participants by age, sex, province and wealth quintile. Subsequently outcome of screening (interview and x-ray film) and sputum testing was described, disaggregating by key characteristics namely sex, age, type of symptoms or x-ray abnormality, setting and education level.

Using a two-step approach and three different models, a robust estimate of the TB prevalence was made. As a first step, a simple cluster level analysis was done whereby the prevalence rates are calculated at cluster level and then combined to one single point estimate with confidence boundaries. The second step was an individual level model analysis whereby three different logistic regression models were applied.

Model 1 was restricted to participants with complete outcomes only, so called complete case analysis. Individuals with missing data on outcome were excluded. Model 2 included all eligible individuals irrespective of participation and through multiple missing value imputation, outcomes were imputed for all eligible. In Model 3, multiple missing value imputation was done only for those eligible for sputum examination that missed data on outcome. All participants screened out where considered not having TB. In a second step, using inverse probability weighting, extrapolation was done to represent all eligible individuals. For more details see Appendix 20.

8.1. Extrapolation to national WHO TB prevalence methods

The following formula as used by WHO was applied to extrapolate the prevalence estimated for adults to the whole population in Zambia.

pr = (c*pr.c + (100-c)*pr.ad) / (100-ep)

Whereby :
c = Percentage of children over total country population
pr.c = TB prevalence among children
ep = Percentage of extra-pulmonary over total notifications
pr = Updated estimate of prevalence, all ages
pr.ad = TB prevalence among adults from survey

Step I. Calculate pulmonary TB (all ages) as a weighted average of TB in adults (from the prevalence survey) and TB in children. TB in children is either calculated from notification or an assumed uniform distribution of 5%-10% childhood over adult TB.

Step II. Inflate upwards pulmonary TB by the same percentage as extra-pulmonary over total (all forms) TB notifications.

8.2. Geospatial analysis plan

The geospatial data collected during the survey was mapped using ArcGIS 10.2 software. GPS coordinate data collected at each household during census listing was aggregated to the district level in order to protect participant privacy and confidentiality and maintain ethical research guidelines.

The clinical data was mapped along with 2010 census population density distributions obtained from the Central Statistical Office. District areas that were non-existent during the 2010 census data collection process were excluded from the mapped population density distribution and these areas were indicated in the maps. All of the cluster areas included in the TB survey were within areas that were included in the 2010 census. There were 66 survey cluster areas that were located in 49 out of 103 district areas existing in the 2010 census within 10 provinces.

For each district, the numbers of persons identified during clinical diagnosis were aggregated into totals for MTB, MOTT, and HIV in each district area. These cases were mapped to visualize the spatial distribution of these cases within districts for each provincial area of the survey. In addition to the clinical disease cases, qualifying screening symptoms were mapped, which included Cough, Fever, Chest Pain, and Abnormal Chest X-ray both consistent and inconsistent for TB for each survey district area.

Results

Chapter 9

CHAPTER 9. Results

9.1. Survey duration

The data collection phase was conducted by three survey teams from 25th August 2013 to 30th July 2014, amounting to 294 days or 42 weeks (inclusive of rest and travel days between clusters). All the targeted clusters were covered in order of cluster operation timeline, with only two clusters namely Chiengi in Luapula province and Namwala in Southern Province rescheduled to the end of the period due to a cholera outbreak and flooding respectively.

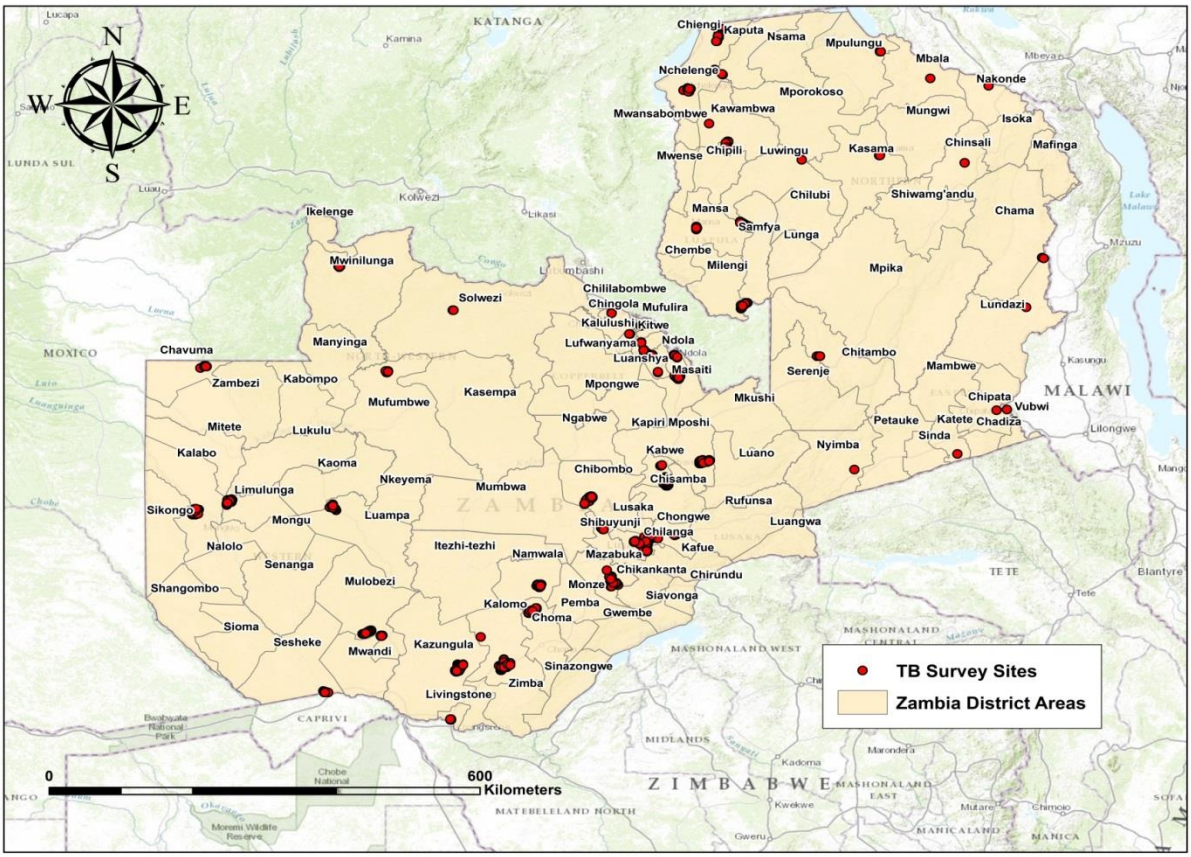


Figure 5. Map of Zambia

9.2. Enumeration

During the listing exercise, 98,458 individuals were enumerated in all the 66 clusters from the 10 provinces of Zambia. Children under the age of 15 were 43,424 (44.1%) and these were not eligible for further screening using the symptom questionnaire and chest x-ray. There were notably more females (53.5%) than males (46.5%), with mean age for females being 23.8 (SD 19.4) and 21.5 (SD 19.1) for males.

Table 4: Background characteristics of enumerated population

Characteristic	Male 45,756 (46.5%)	Female 52,702 (53.5%)	Total 98,458 (%)
Age group			
0-4	8,066(17.6%)	7,976(15.1%)	16,042(16.3%)
5-14	13,652(29.8%)	13,730(26.1%)	27,382(27.8%)
15-24	8,472(18.5%0	9,707(18.4%)	18,179(18.5%)
25-34	5,348(11.7%)	7,414(14.1%)	12,762(13%)

Characteristic	Male 45,756 (46.5%)	Female 52,702 (53.5%)	Total 98,458 (%)
35-44	4,133(9%)	5,419(10.3%)	9,552(9.7%)
45-54	2,547(5.6%)	3,618(6.9%)	6,165(6.3%)
55-64	1,635(3.6%)	2,555(4.9%)	4,190(4.3%)
65+	1,903(4.2%)	2,283(4.3%)	4,186(4.3%)
Tribe			
Bemba	8,450(18.5%)	11,140(21.1%)	19,590(20%)
Lozi	2,031(4.4%)	2,505(4.8%)	4,536(4.6%)
Lunda	891(2%)	924(1.8%)	1,815(1.8%)
Luvale	1,027(2.2%)	1,252(2.4%)	2,279(2.3%)
Kaonde	592(1.3%)	759(1.4%)	1,351(1.37%)
Nyanja	5,241(11.5%)	7,236(13.7%)	12,477(12.7%)
Tonga	3,768(8.2%)	4,313(8.2%)	8,081(8.2%)
Other	2,038(4.5%)	2,867(5.4%)	4,905(5%)
Unknown for <15	21,718(47.5%)	43,424(44.1%)	43,424(44.1%)
Marital Status			
Never married	9,144(20%)	6,968(13.2%)	16,112(16.4%)
Currently living as married	13,427(29.3%)	17,604(33.4%)	31,031(31.5%)
Divorced or separated	957(2.1%)	2,577(4.9%)	3,534(3.6%)
Widowed	510(1.1%)	3,847(7.3%)	4,357(4.4%)
Unknown for <15	21,718(47.5%)	21,706(41.2%)	43,424(44.1%)
Occupation			
Unemployed	4,699(19.6)	7,505(24.2)	12,204(12.2)
Economically Active Population			
Occasional/seasonal	980(4.1)	614(2.0)	1,594(3.0)
Employed by Government	744(3.1)	517(2.0)	1,261(2.3)
Employed in private sector	2,771(11.5)	1,059(3.4)	3,830(7.0)
Self-employed	2,457(10.2)	3,18710.3)	5,644(10.3)
Working on own land	7,654(31.8)	10,194(33.0)	17,848(32.4)
Economically Inactive Population			
Pupil/student	4,469(18.6)	3,601(11.6)	8,070(14.7)
Housewife/homemaker	35(0.2)	4,003(12.9)	4,038(7.3)
Other	229(1.0)	316(1.0)	545(1.0)
Total	24,038	30,996	55,034
Education			
Never attended	1,175(4.9)	3,746(12.1)	4,921(8.9)
Primary	9,652(40.2)	15,193(49.0)	24,845(45.1)
Secondary	11,870(49.4)	11,035(35.6)	22,905(41.6)
Above Secondary	1,325(5.5)	1,003(3.2)	2,328(4.2)
Missing	16(0.1)	19(0.1)	35(0.1)
Total	24,038	30,996	55,034
Setting			
Rural	32,169(70.3%)	36,056(68.4%)	68,225(69.3%)
Urban	13,587(29.7%)	16,646(31.6%)	30,233(30.7%)
Province			
Central	4,122(9%)	4,286(8.1%)	8,408(8.5%)
Copperbelt	6,098(13.3%)	7,473(14.2%)	13,571(13.8%)
Eastern	6,466(14.1%)	7,610(14.4%)	14,076(14.3%)
Luapula	4,007(8.8%)	4,662(8.9%)	8,669(8.8%)
Lusaka	7,501(16.4%)	9,554(18.%)	17,055(17.3%)
Muchinga	2,466(5.4%)	2,614(5.0%)	5,080(5.2%)
Northern	3,897(8.5%)	4,361(8.3%)	8,258(8.4%)
North-Western	2,606(5.7%)	2,699(5.1%)	5,305(5.39%)

Characteristic	Male 45,756 (46.5%)	Female 52,702 (53.5%)	Total 98,458 (%)
Southern	5,458(11.9%)	5,703(10.8%)	11,161(11.3%)
Western	3,135(6.9%)	3,740(7.1%)	6,875(7%)
Total	**45,756(100%)**	**52,702(100%)**	**98,458(100%)**
Wealth Quintile			
Lowest	7,979(20.1%)	9,130(20%)	17,109(20%)
Second lowest	8,278(21%)	8,815(19.3%)	17,093(20%)
Middle	8,163(20.5%)	8,924(19.5%)	17,087(20%)
Fourth	7,835(19.7%)	9,280(20.3%)	17,115(20%)
Highest	7,501(18.9%)	9,574(20.9%)	17,075(20%)
Missing	6,000 (13.11%)	6,979 (13.2%)	12, 979(13.2%)
Total	**45,756(100%)**	**52,702(100%)**	**98,458(100%)**

9.2.1. Enumeration by Province

Majority of the enumerated individuals were from Lusaka province representing 17.3% of the total survey sample followed by Eastern with 14,076 participants (14.3%). In third and fourth place were Copperbelt with 13,571 (13.8%) and Southern with 11,161 (11.3%). Luapula, Central and Northern had 8,669 (8.8%), 8,408 (8.5%) and 8, 258 (8.4%) in fifth, sixth and seventh places respectively. The last three were Western, North Western and Muchinga provinces with 6, 875 (7%); 5, 305 (5.4%); and 5,080 (5.2%) respectively.

9.2.2. Enumeration by age and sex

Age and sex are important demographic variables and are the primary basis of any analysis. They are particularly important variables in the study of health outcomes, and are illustrated by a population pyramid below which indicates whether the population is "young" or "old". The broad base of the pyramid for the survey population indicates that the population is young. The pyramid also shows that there are slightly more females than males, depicted by slightly longer bars for females than males especially in the younger age groups. The population pyramid for the survey participant was comparable to that of 2010 Zambia census of population and housing as shown in Figures 6 and 7.

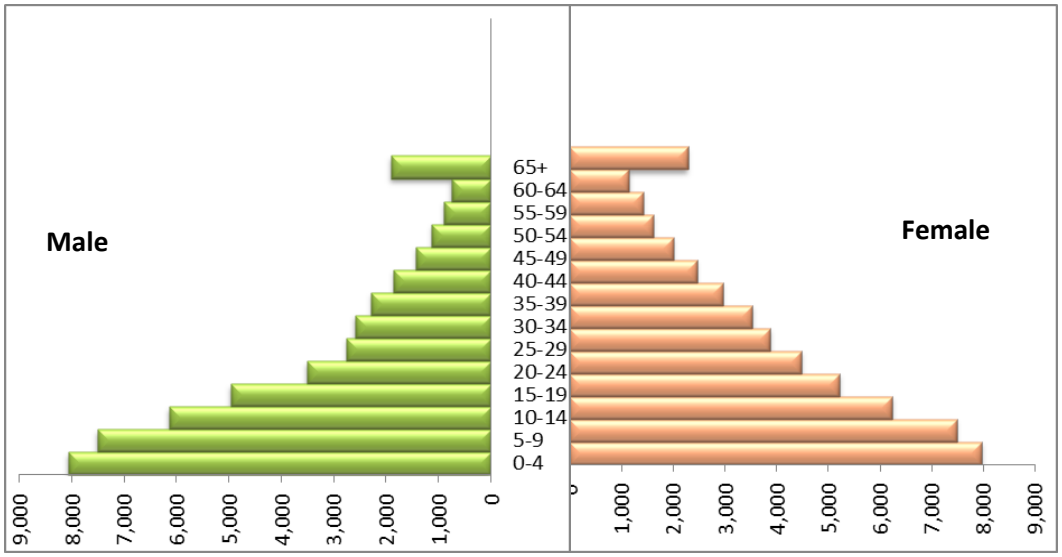


Figure 6. Population pyramid of enumerated individuals

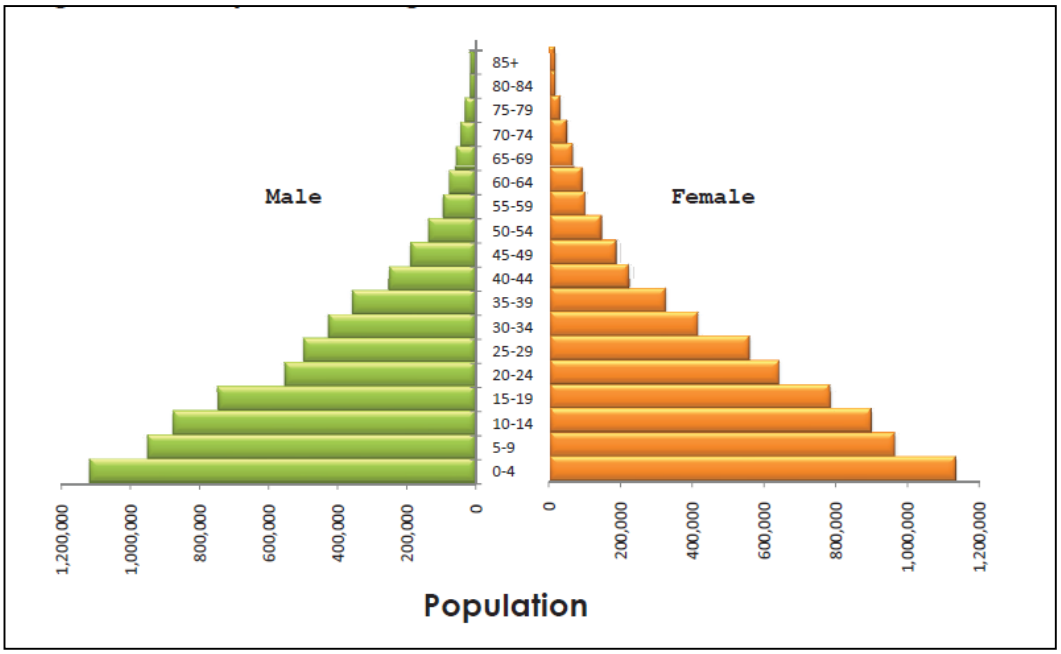


Figure 7. Population pyramid of Zambia according to the 2010 census of population and housing

9.2.3. Enumeration by Residence

Majority of the individuals enumerated were rural residents accounting for 69% versus 31% of the urban counterparts. The proportion of rural and urban residents were fairly similar for males and females respectively; males at 70.3% and 29.7% respectively and females at 68.4% and 31.6% respectively.

9.3. Socio- economic characteristics

The distribution of the survey population by selected socioeconomic variables is shown in Table 4. Primary education was reported as the highest level of education attained by 45% (n=24,845) of the participants, while only 4% (n=2,328) had more than secondary education. There were differences in educational attainment by sex, with females reporting primary as

the highest education level attained (49%, 15,193), while males reported secondary as the highest educational attainment (49%, 11,870). About one in five participants were unemployed. More females (24.2%, 7,505) than males (19.6%, 4,699) were unemployed. Of the participants who were economically active, a high proportion reported working on their own land (32.4%, 17,848), these are also referred to as unpaid family worker. Similar proportions were observed by sex.

9.4. Wealth Index

Household wealth was constructed from data on household assets, housing characteristics and access to utilities such as type of toilet (Annex 7 SES Questionnaire). There were marked differences in wealth status by residence. More than half (53.2%) of urban residents were in the highest wealth quintile, while only 6.9% of rural residents were in the same wealth quintile. In contrast, in rural areas the highest proportion of the population was in the lowest wealth quintile. Distribution of wealth by province shows that Copperbelt and Lusaka had the highest proportion of the population in the highest wealth quintile. Luapula province had the highest proportion of poor people (Table 5).

Table 5: Wealth index of enumerated participants

	Wealth Index						
Residence & Province	**Lowest**	**Second**	**Middle**	**Fourth**	**Highest**	**Total**	**Number**
Rural	28.3	27.9	24.9	13.1	5.9	100	60,005
Urban	0.5	1.4	8.5	36.5	53.2	100	25,474
Province							
Central	17.3	29.9	32.6	17.8	2.6	100	8,252
Copperbelt	5.0	8.3	19.0	28.1	39.7	100	11,753
Eastern	32.3	28.9	19.9	13.6	5.4	100	10,363
Luapula	53.0	24.7	11.1	5.8	5.5	100	6,683
Lusaka	0.3	0.9	8.3	36.6	53.9	100	14,930
Muchinga	39.8	39.0	16.3	4.8	0.1	100	5,065
Northern	35.2	30.1	16.9	10.4	7.5	100	7,774
North Western	18.4	26.3	31.9	15.1	8.3	100	4,784
Southern	7.7	16.8	27.8	28.0	19.7	100	9,359
Western	27.8	26.6	28.6	10.8	6.2	100	6,516
Total	**20.0**	**20.0**	**20.0**	**20.0**	**20.0**	**100**	**85,479**

9.5. Survey Eligibility

Among the 98,458 enumerated individuals, 54, 830 (55.7%) were eligible to participate in the survey; the remainder 43,424 (43.1%) and 204 (0.2%) were ineligible (44.3%) to participate based on age and residence respectively. The characteristics of the eligible population were similar to the enumerated population as shown in the Figure 8. The age range of the eligible population was from 15 to 110 years with a mean of 35 years and the majority (74%) were aged between 15 and 45 years. More females (56.4%) than males (43.6%) were eligible to

participate (p=0.000). By setting, there were more eligible from rural (66.6%) than urban (33.4%) as expected (p=0.000).

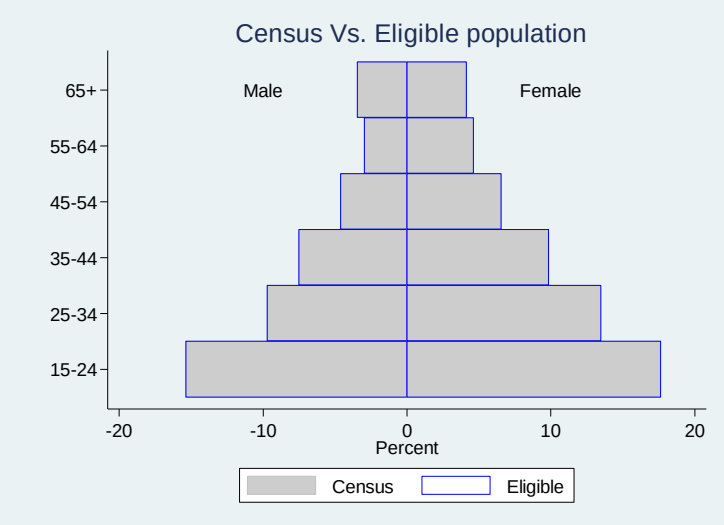


Figure 8. Comparison of the census versus eligible population

9.6. Survey Participation

Among the 54,830 individuals who were eligible to participate, 46,099 (84.1%) actually participated in the screening. The participation rate ranged from 45.5% at the beginning of cluster operations and increased gradually to more than 80% in most clusters as shown in Figure 9.

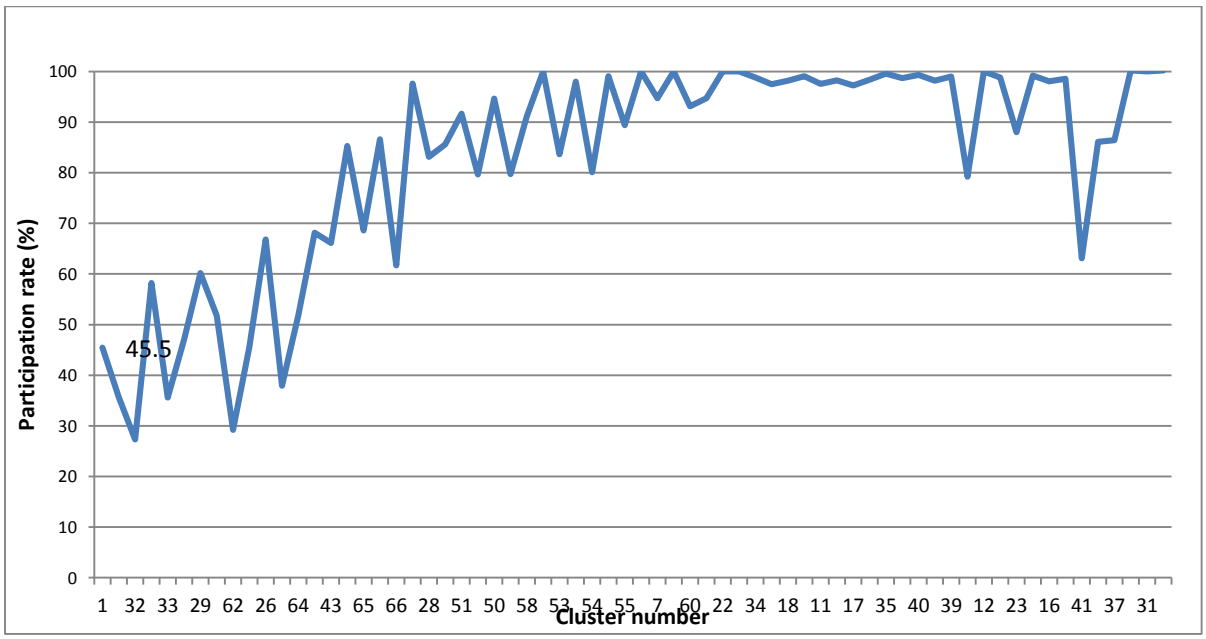


Figure 9. Participation rate by cluster (chronological order)

A total of 46,099 were considered eligible to undergo procedures with median age of 32 years (IQR; 22 to 47). The population characteristics of the eligible and participating

population were similar with slightly more females participating between 35 and 54 years while males found 15-34 years were slightly underrepresented (Figure 10).

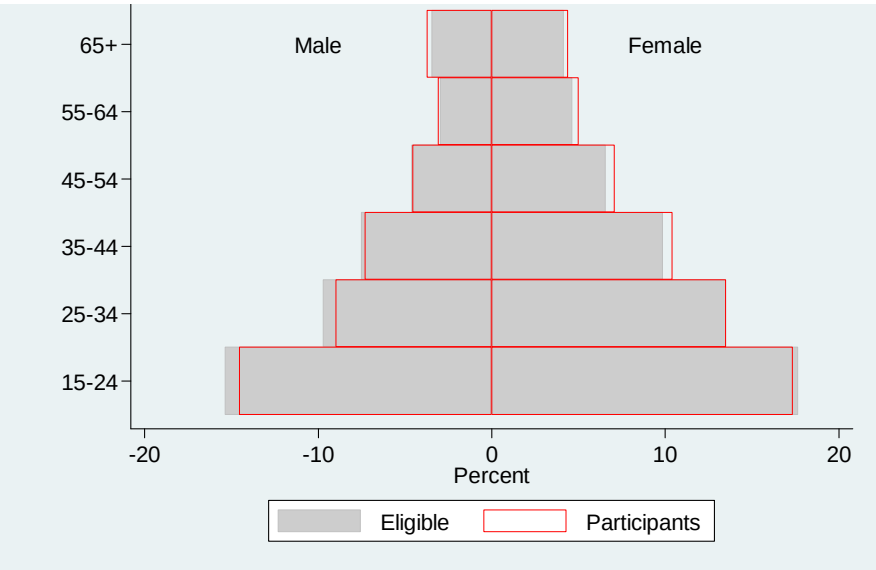


Figure 10. Population pyramid of the eligible and participant population by age and sex

Participation was higher among female (56.4%) than male (43.6%) [p < 0.01] survey participants for all age groups except for those aged more than 65 years old shown in Figure 11. Overall, participation rate increased with increasing age of survey participants.

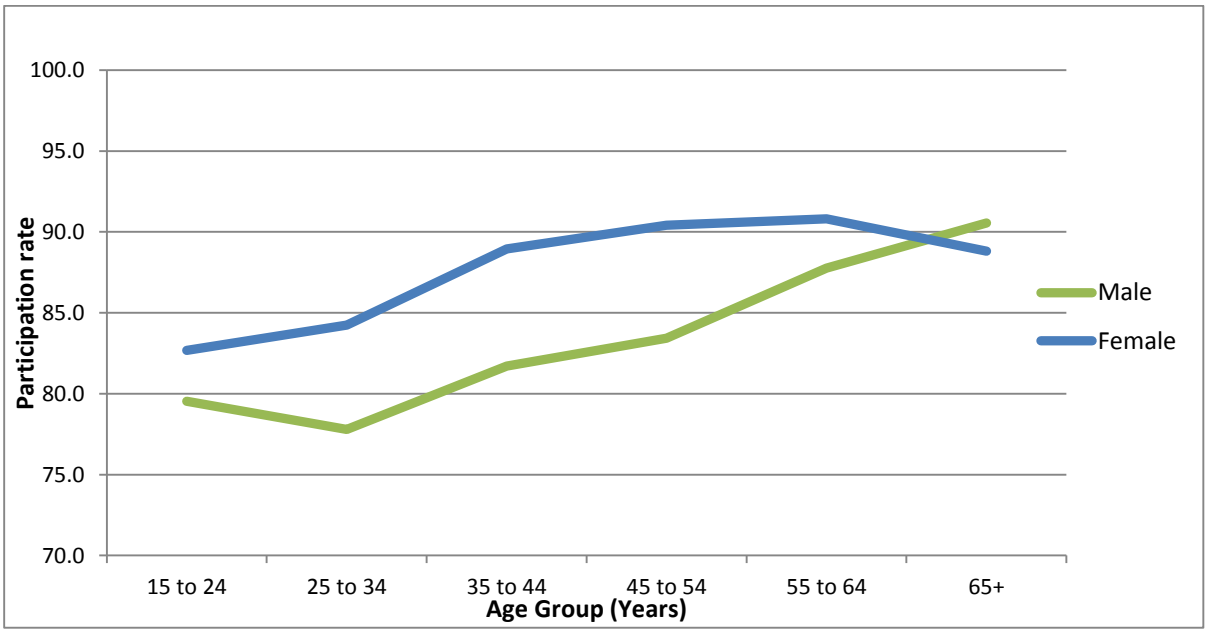


Figure 11. Participation by age group and gender

Table 6 outlines the background characteristics of 46,099 survey participants. Majority of the survey participants were married (56.5%), working on own land (32%) and unemployed (23.6%). Majority of individuals had a least primary or secondary education (42-45%) There

were more rural (65.2%) than urban participants (34.8%). By province, Lusaka and Copperbelt accounted for the majority of the participants (18.5%, 17.9% respectively) while Muchinga and Western accounted for the lowest proportion (2.7%, 4.2% respectively). Nearly a quarter of the participants were from the highest wealth quintile (24%).

Table 6. Background characteristics of survey participants

Characteristic	Male n(%)	Female n (%)	Total n (%)
Age group			
15-24	6,701(34.4%)	8,001(30.0%)	14,702(31.9%)
25-34	4,144(21.3%)	6,232(23.4%)	10,376(22.5%)
35-44	3,362(17.3%)	4, 806(18%)	8,168(17.7%)
45-54	2,105(10.8%)	3,264(12.3%)	5,369(11.6%)
55-64	1,428(7.3%)	2,313(8.7%)	3,741(8.1%)
65+	1,717(8.8%)	2,026(7.6%)	3,743(8.1%)
Marital Status			
Never married	7,306(37.6%)	5,749(21.6%)	13,055(28.3%)
Currently living as married	10,881(55.9%)	15,178(57%)	26,059(56.5%)
Divorced or separated	823(4.2%)	2,250(8.5%)	3,073(6.7%)
Widowed	477(2.3%)	3,465(13.0%)	3,942(8.5%)
Occupation			
Unemployed	4,063(20.9%)	6,798(25.5%)	10,861(23.6%)
Occasional/seasonal	795(4.1%)	510(1.9%)	1,305(2.8%)
Employed by Government	577(3%)	428(1.6%)	1,005(2.2%)
Employed private sector	2,239(11.5%)	859(3.2%)	3,098(6.7%)
Self employed	1,931(10%)	2,797(10.5%)	4,728(10.3%)
Pupil/Student	3,584(18.4%)	2,914(10.9%)	6,498(14.1%)
Housewife/homemaker	30(0.2%)	3,339(12.5%)	3,369(7.3%)
Working in own land	6,041(31.1%)	8,720(32.7%)	14,761(32.0%)
Other	197(1.0%)	277(1.0%)	474(1.0%)
Education			
No schooling	973(5%)	3,305(12.4%)	4,278(9.3%)
Primary school	7,626(39.2%)	13,049(49.0%)	20,675(44.8%)
Secondary school	9,847(51%)	9,474(35.6%)	19,321(41.9%)
Tertiary education	999(5.1%)	795(3%)	1,794(3.9%)
Unknown	12(0.1%)	19(0.1%)	31(0.07%)
Setting			
Rural	12,807(65.8%)	17,235(64.7%)	30,042(65.2%)
Urban	6,650(34.2%)	9,407(35.3%)	16,057(34.8%)
Province			
Central	1,277(6.6%)	1,629(6.1%)	2,906(6.3%)
Copperbelt	3,451(17.7%)	4,785(18%)	8,236(17.9%)
Eastern	2,985(15.3%)	4,172(15.7%)	7,157(15.5%)
Luapula	1,491(7.7%)	2,166(8.1%)	3,657(7.9%)
Lusaka	3,336(17.2%)	5,206(19.5%)	8,542(18.5%)
Muchinga	545(2.8%)	706(2.7%)	1,251(2.7%)
Northern	1,706(8.8%)	2,184(8.2%)	3,890(8.4%)
North-Western	1,288(6.6%)	1,552(5.8%)	2,840(6.2%)
Southern	2,682(13.8%)	2,999(11.3%)	5,681(12.3%)
Western	696(3.6%)	1,243(4.7%)	1,939(4.2%)

Characteristic	Male n(%)	Female n (%)	Total n (%)
Total	**19,457(100%)**	**26,642(100%)**	**46,099(100%)**
Wealth quintile* (missing excluded)			
Lowest	2,768(16.3%)	4,136(17.8%)	6,904(17.2%)
Second lowest	3,014(17.8%)	3,787(16.3%)	6,801(16.9%)
Middle	3,599(21.2%)	4,462(19.2%)	8,061(20.1%)
Fourth	3,696(21.8%)	5,095(22.0%)	8,791(21.9%)
Highest	3,896(23%)	5,736(24.7%)	9,632(24.0%)
Total	**16,973(100%)**	**23,216(100%)**	**40,189(100%)**

There were 225 individuals who initially consented to participate during census but later withdrew consent at the survey site. These were excluded from further survey operations and analysis.

The consort diagram below outlines the flow of participants in the survey.

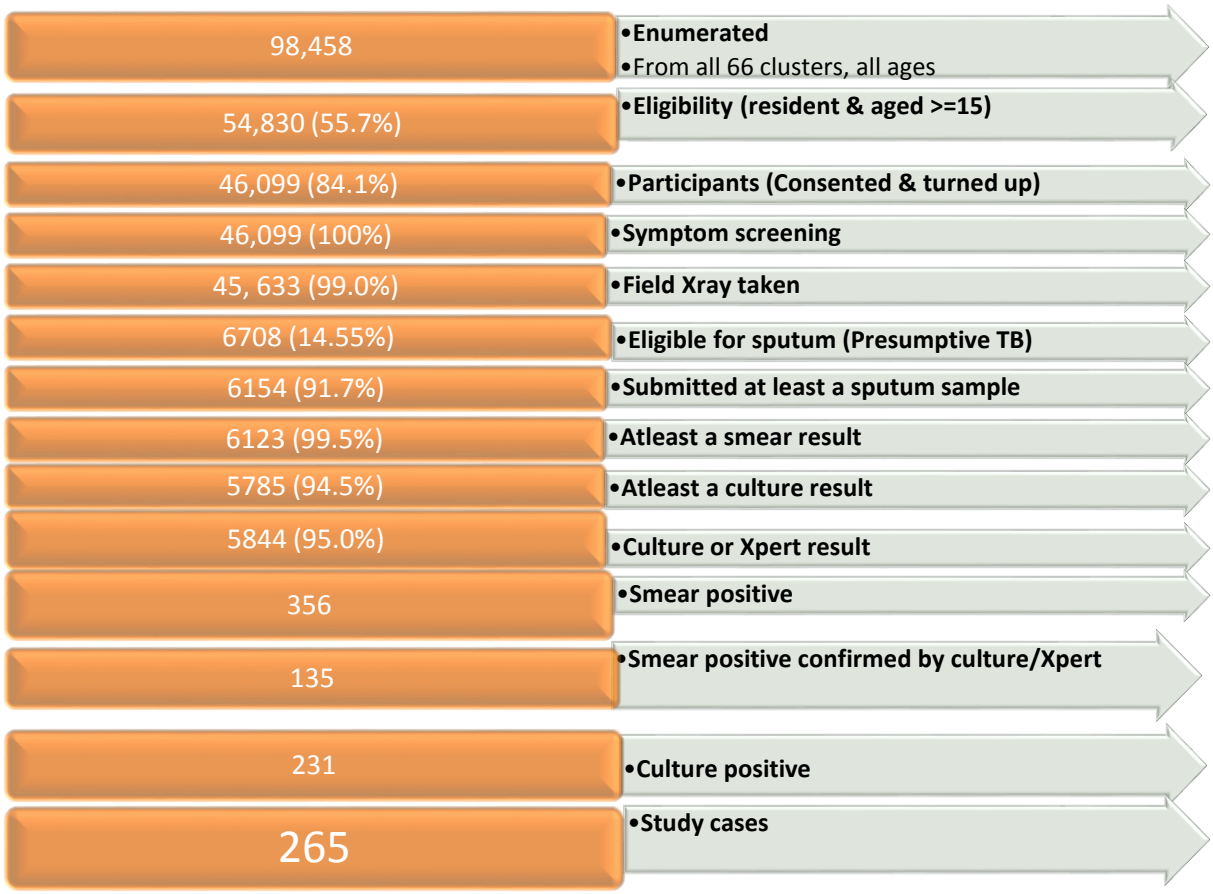


Figure 12. Survey data flow

9.7. TB Symptom Screening

A total of 46,099 participants took part in the TB symptom screening questionnaire. Based on the symptoms screening criteria, 9.7% (4,453) were found to be eligible for sputum

collection; participants with a history of cough and/or fever or chest pain for two weeks or more. The outcome of the symptom screening is summarised in Table 7.

History of cough

A history of any cough was reported by 11,466 (24.9%) of the participants; with 34, 633 (75%) reporting no history of cough. Of those with any cough, 2,405 (5.2%), reported a cough lasting for two weeks or more.

History of fever

A history of fever of any duration was reported by 7,195 (15.6%); with 2.2% (1,030) of the participants reporting fever duration of two weeks or more.

Chest pain

A total of 13,760 (29.9%) participants reported having chest pains of any duration; with 7.4% (3,426) reporting having had chest pains for two weeks or more.

Table 7. Symptom Screening at Field Level

Participant Variable	N (%)
History of cough (any duration)	11,467 (24.9)
Cough duration 1 week	*9,061 (19.7)*
Cough duration 2 weeks or more	*2,405 (5.2)*
No cough	34,633 (75.1)
History of fever (any duration)	7,195 (15.6)
Fever duration 1 week	*6,165 (13.4)*
Fever duration 2 weeks or more	*1,030 (2.2)*
No fever	38,904 (84.4)
History of chest pain (any duration)	13,760 (29.9)
Chest pain duration 1 week	10,334 (22.4)
Chest pain duration 2 weeks	3,426 (7.4)
No Chest Pain	32,339 (70.1)
Overall Symptom Screening Result	
Eligible for sputum collection	4,453 (9.7)
Not eligible for sputum collection	41,646 (90.3)
Total participants in symptom screening	**46,099 (84.1)**

Figure 13 shows that there were more participants who reported chest pain than cough or fever respectively regardless of symptom duration.

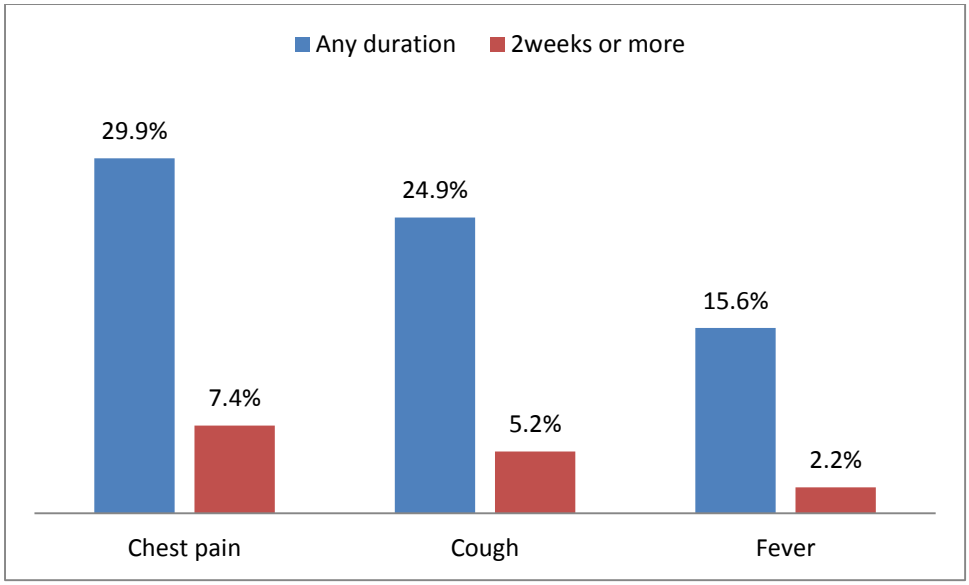


Figure 13. Symptoms screening result by duration

Table 8 shows the symptom screening and X-ray results by the participants' background characteristics. More females were eligible to submit sputum than males. The participants who were aged 65 years and above, currently married, with lower wealth quintiles, residents of Lusaka province, rural setting and working on own land were also likely to be eligible to submit sputum than their counter parts.

The highest proportion of participants with abnormal CXR result were males, aged 65 years and above, unemployed, residents of rural areas, from the Copperbelt region and with at least primary school level of education. The higher wealth quintiles were associated with higher proportions of abnormal CXR results.

Table 8. Symptom screening and X-Ray results by demographic

	Symptom screening result		Field X-ray		
Variable	Positive, N (%)	Negative, N (%)	Positive, N (%)	Negative, N (%)	Not applicable
Overall	**4,453 (9.7)**	**41,646 (90.3)**	**3,760 (8.2)**	**41,737(90.5)**	**602 (1.3)**
Gender					
Male	2,088 (46.9)	17,369 (41.7)	2,129 (56.6)	17,090 (41)	238 (39.5)
Female	2,365 (53.1)	24,277 (58.3)	1,631 (43.4)	24,637 (59.1)	364 (60.5)
Age					
15-24	561 (12.6)	14,141 (34.0)	232 (6.2)	14,234 (34.1)	236 (39.2)
25-34	750 (16.8)	9,626 (23.1)	481 (12.8)	9,765 (23.4)	130 (21.6)
35-44	859 (19.3)	7,309 (17.6)	644 (17.1)	7,415 (17.8)	109 (18.1)
45-54	718 (16.1)	4,651 (11.2)	612 (16.3)	4,705 (11.3)	52 (8.6)
55-64	627 (14.1)	3,114 (7.5)	644 (17.1)	3,059 (7.3)	38 (6.3)
65+	938 (21.1)	2,805 (6.7)	1,147 (30.5)	2,559 (6.1)	37 (6.2)
Marital status					
Never married	565 (12.7)	12,490 (30.0)	345 (9.18)	12,493 (29.9)	217 (36.1)
Currently or living as married	2,742 (61.6)	23,317 (56.0)	2,278 (60.6)	23,471 (56.2)	310 (51.5)
Divorced or separated	429 (9.6)	2,644 (6.4)	371 (9.9)	2,667 (6.4)	35 (5.8)

Variable	Symptom screening result		Field X-ray		
	Positive, N (%)	Negative, N (%)	Positive, N (%)	Negative, N (%)	Not applicable
Widowed	717 (16.1)	3,195 (7.7)	766 (20.4)	3,106 (7.4)	40 (6.6)
Occupation					
Unemployed	955 (21.5)	9,906 (23.8)	1,242 (33.0)	9,499 (22.8)	120 (19.9)
Occasional/seasonal	157 (3.5)	1,148 (2.8)	148 (3.9)	1,145 (2.7)	12 (2.0)
Employed by government	44 (1.0)	961 (2.3)	57 (1.5)	937 (2.3)	11 (1.8)
Employed in private sector	237 (5.3)	2,861 (6.9)	326 (8.7)	2,733(6.6)	39 (6.5)
Self-employed	482 (10.8)	4,246 (10.2)	497 (13.2)	4,169 (10)	62 (10.3)
Pupil/student	189 (4.2)	6,309 (15.2)	87 (2.3)	6,296 (15.1)	115 (19.1)
Housewife/homemaker	256 (5.8)	3,113 (7.5)	165 (4.4)	3,136 (7.5)	68 (11.3)
Working on own land	2,054 (46.1)	12,707 (30.5)	1,160 (30.9)	13,437 (32.2)	164 (27.2)
Other	79 (1.8)	395 (1.0)	78 (2.1)	385 (0.9)	11 (1.8)
Education					
No schooling	789 (17.7)	3,489 (8.4)	679 (18.1)	3,531 (8.5)	68 (11.3)
Primary School	2,422 (54.4)	18,253 (43.8)	1,827 (48.6)	18,608 (44.6)	240 (39.9)
Secondary School	1,151 (25.9)	18,170 (43.6)	1,123 (29.9)	17,927 (43)	271 (45.0)
Tertiary Education	90 (2.0)	1,704 (4.1)	131 (3.5)	1,641 (3.9)	22 (3.7)
Unknown	1 (0.0)	30 (0.1)	679 (18.1)	30 (0.1)	1 (0.2)
Setting					
Urban	1,057 (23.7)	15,000 (36.0)	2,017 (53.6)	14,023 (33.6)	291 (48.3)
Rural	3,396 (76.3)	26,646 (64.0)	1,743 (46.4)	27,714 (66.4)	311 (51.7)
Province					
Central	569 (12.8)	2,337 (5.6)	239 (6.4)	2,659 (6.4)	8 (1.3)
Copperbelt	310 (7.0)	7,926 (19.0)	961 (25.6)	7,257 (17.3)	18 (3.0)
Eastern	559 (12.6)	6,598 (15.8)	220 (5.9)	6,765 (16.2)	172 (28.6)
Luapula	404 (9.1)	3,253 (7.8)	258 (6.9)	3,359 (8.1)	40 (6.6)
Lusaka	661 (14.8)	7,881 (18.9)	828 (22.0)	7,443 (17.8)	271 (45.0)
Muchinga	274 (6.2)	977 (2.4)	54 (1.4)	1,192 (2.9)	5 (0.8)
Northern	541 (12.2)	3,349 (8.0)	347 (9.2)	3,505 (8.4)	38 (6.3)
North Western	429 (9.6)	2,411 (5.8)	239 (6.4)	2,596 (6.22)	5 (0.8)
Southern	321 (7.2)	5, 360 (12.9)	374 (10.0)	5,275 (12.6)	32 (5.3)
Western	385 (8.7)	1,554 (3.7)	240 (6.4)	1,686 (4.0)	13 (2.2)
Wealth quintiles					
Lowest	1,004 (25.7)	5,900 (16.3)	636 (18.8)	6,213 (17.1)	55 (11.3)
Second	880 (22.5)	5,921 (16.3)	469 (13.9)	6,274 (17.3)	58 (11.9)
Middle	869 (22.3)	7,192 (19.8)	670 (19.8)	7,338 (20.2)	53 (10.9)
Fourth	664 (17.0)	8,127 (22.4)	801 (23.7)	7,857 (21.6)	133 (27.3)
Highest	488 (12.5)	9,144 (25.2)	806 (23.8)	8,638 (23.8)	188 (38.6)

9.8. Field Chest X-ray

Field x-ray screening was performed among 45,633 (99%) of the participants. 460 did not consent to field x-ray screening; 4 could not attend the central site for X-ray and 2 consented but had no X-ray taken.

Of the 45,633 who had an X-ray taken, 3,760 (8.2%) had an abnormal chest x-ray; 19 (0.04) were not interpretable and 136 (0.3) had no field x-ray result available. All the participants

who had an abnormal chest- x-ray result or result not interpretable were eligible for sputum collection as shown in Table 9.

Table 9. Field x-ray screening outcome

Variable	N (%)
Field X-ray taken	**45,633 (99.0)**
No Field X-ray taken	466 (1.0%)
Field X-ray result:	
Normal	41,662 (91.3)
Abnormal	3,741 (8.1)
Not interpretable	19 (0.04)
No field x-ray result	136 (0.3)
Other specify	75 (0.2)
Eligible for sputum collection by x-ray	**3760 (8.2)**

9.9. In-depth Interview among Presumptive TB Cases

After symptom screening or chest x-ray examinations, 6,708 participants were found to be eligible to submit sputum. The presumptive TB cases underwent an additional detailed in-depth questionnaire on symptoms, health seeking behavior, treatment history and health care access issues.

Older participants were more likely to be eligible for sputum examination than the younger ones. The mean age of presumptive TB cases was 48.6 years (with a range of 15-105) and 50.1% were males. By setting, two thirds of the presumptive TB cases were resident in rural (66.7%, 4,471) compared to urban (33.3%, 2,442) areas). Lusaka and the Copperbelt provinces accounted for majority 17.5% (1,177) and 15.6% (1,045) while fewer cases were observed in Western (7.2%, 486) and Muchinga (4.5%, 301) respectively. The majority of presumptive TB cases belonged to the two lowest wealth quintiles (41.2%, 2,479), more than two thirds (68.9%) had no formal education or attained primary level education. Other characteristics of the presumptive TB cases are summarised in Table 10.

Table 10. Background characteristics of presumptive TB cases

	Male		Female		Total	
Characteristic	n	%	n	%	N	%
Age group						
15-24	375	11.2	341	10.2	716	10.7
25-34	532	15.8	519	15.5	1,051	15.7
35-44	656	19.5	593	17.7	1,249	18.6
45-54	552	16.4	548	16.4	1,100	16.4
55-64	448	13.3	571	17.1	1,019	15.2
65+	800	23.8	773	23.1	1,573	23.4
SUB-TOTAL	**3,363**	**100**	**3,345**	**100**	**6,708**	**100**
Marital Status						
Never married	528	15.7	256	7.7	784	11.7
Currently living as married	2,387	71.0	1,750	52.3	4,137	61.7
Divorced or separated	253	7.5	388	11.6	641	9.6
Widowed	195	5.8	951	28.4	1,146	17.1

Characteristic	Male		Female		Total	
	n	%	n	%	N	%
SUB-TOTAL	**3,363**	**100**	**3,345**	**100**	**6,708**	**100**
Occupation						
Unemployed	796	23.7	956	28.6	1,752	26.1
Occasional/seasonal	177	5.3	67	2.0	244	3.6
Employed by Government	68	2.0	22	0.7	90	1.3
Employed private sector	385	11.4	67	2.0	452	6.7
Self employed	436	13.0	356	10.6	792	11.8
Pupil/Student	163	4.8	88	2.6	251	3.7
Housewife/homemaker	1	0.0	357	10.7	358	5.3
Working in own land	1,294	38.5	1,358	40.6	2,652	39.5
Other	43	1.3	74	2.2	117	1.7
SUB-TOTAL	**3,363**	**100**	**3,345**	**100**	**6,708**	**100**
Education						
No schooling	296	8.8	863	25.8	1,159	17.3
Primary school	1,622	48.2	1,841	55.0	3,463	51.6
Secondary school	1,311	39.0	592	17.7	1,903	28.4
Tertiary education	133	4.0	49	1.5	182	2.7
SUB-TOTAL	**3,362**	**100**	**3,345**	**100**	**6,707**	**100**
Setting						
Rural	2,143	63.7	2,328	69.6	4,471	66.7
Urban	1,220	36.3	1,017	30.4	2,237	33.3
SUB-TOTAL	**3,363**	**100**	**3,345**	**100**	**6,708**	**100**
Province						
Central	320	9.5	354	10.6	674	10.0
Copperbelt	606	18.0	439	13.1	1,045	15.6
Eastern	332	9.9	337	10.1	669	10.0
Luapula	234	7.0	322	9.6	556	8.3
Lusaka	640	19.0	537	16.1	1,177	17.5
Muchinga	145	4.3	156	4.7	301	4.5
Northern	326	9.7	348	10.4	674	10.0
North-Western	237	7.0	323	9.7	560	8.3
Southern	316	9.4	250	7.5	566	8.4
Western	207	6.2	279	8.3	486	7.2
SUB-TOTAL	**3,363**	**100**	**3,345**	**100**	**6,708**	**100**
Wealth Quintile						
Lowest	589	19.7	734	25.0	1,323	22.3
Second lowest	529	17.7	590	20.1	1,119	18.9
Middle	644	21.5	614	20.9	1,258	21.2
Fourth	630	21.0	549	18.7	1,179	19.9
Highest	601	20.1	450	15.3	1,051	17.7
SUB-TOTAL	**2,993**	**100**	**2,937**	**100**	**5,930**	**100**

The majority of the presumptive TB cases reported at least a history of chest pains (4,653, 69.4%) followed by cough (3,708, 55.3%), night sweats (2,418, 36.0%), fever (2,375, 35.4%), sputum production (2,369, 35.3%), and weight lost (2,306, 34.4%) in that order as shown in the Figure 14.

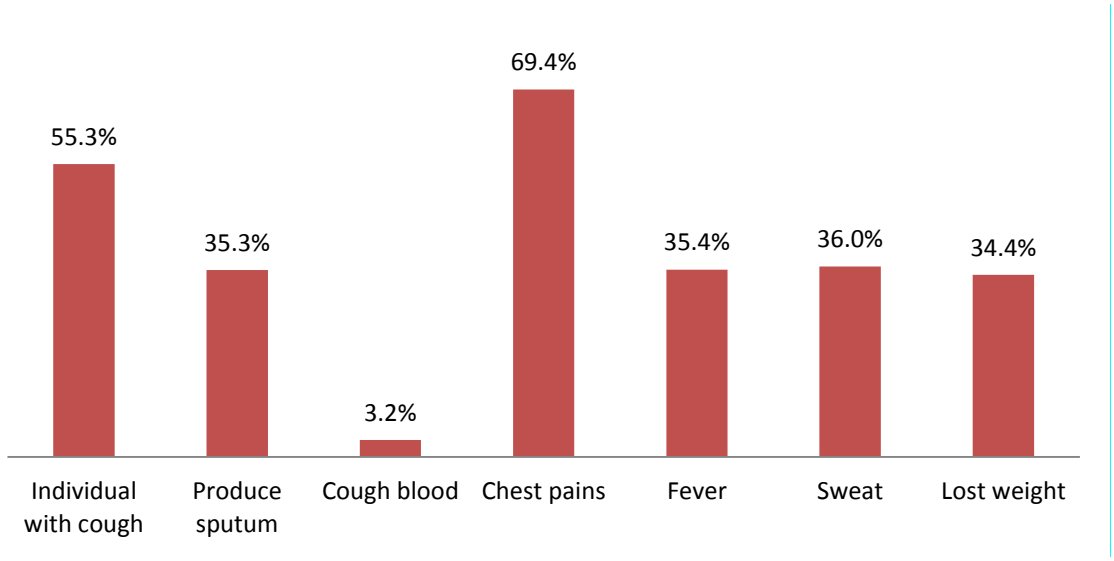


Figure 14. Symptomology of presumptive TB cases

Table 11 outlines the symptoms and background characteristics among presumptive TB cases. Female presumptive TB cases more often reported chest pains, fever, sweats, weight loss and other respiratory complaints than the male counterparts. By age, presumptive TB cases aged 65 years and above reported more symptoms (regardless of the symptom) than the younger age groups. Presumptive TB cases who were married, unemployed, with at least primary education, living in a rural area and belonging to lower wealth quintile reported higher frequencies of any of the symptoms. By province, TB suspects from Lusaka and Copperbelt provinces generally had higher occurrence of symptoms than other provinces as shown in Table 11.

Table 11. Symptoms and background characteristics of presumptive TB cases

Demographic characteristics	Have Cough		Chestpain		Fever		Sweat		Lost weight		Respiratory complaints	
	N	%	N	%	N	%	N	%	N	%	N	%
Sex												
Male	1,910	51.5	2,142	46.0	1,141	48.0	1,110	45.9	1,105	47.9	119	41.5
Female	1,798	48.5	2,511	54.0	1,234	52.0	1,308	54.1	1,201	52.1	168	58.5
Age												
15 - 24	476	12.8	518	11.1	298	12.6	217	9.0	195	8.5	23	8.0
25 - 34	607	16.4	755	16.2	375	15.8	359	14.9	349	15.1	41	14.3
35 - 44	671	18.1	891	19.2	432	18.2	381	16.0	406	18.0	44	15.0
45 - 54	563	15.2	744	16.0	364	15.3	432	17.9	386	16.7	45	15.7
55 - 64	527	14.2	693	14.9	318	13.4	410	17.0	374	16.2	52	18.1
65+	864	23.3	1052	22.6	588	24.8	619	26.0	596	26.0	82	29.0
Marital Status												
Never married	507	13.7	537	11.5	307	12.9	234	9.7	247	10.7	25	8.7
Currently or living a	2,232	60.2	2,860	61.5	1,421	59.8	1,476	61.0	1,364	59.2	165	57.5
Divorced or separated	387	10.4	454	9.8	233	9.8	235	9.7	253	11.0	39	13.6
Widowed	582	15.7	802	17.2	414	17.4	473	19.6	442	19.2	58	20.2
Employment												
Unemployed	984	26.5	1,158	24.9	615	25.9	609	25.2	657	28.5	73	25.4
Occasional/seasonal	140	3.8	160	3.4	103	4.3	83	3.4	76	3.3	7	2.4
Employed by Government	33	0.9	57	1.2	14	0.6	15	0.6	17	0.7	3	1.1
Employed in private s	223	6.0	246	5.3	108	4.6	97	4.0	113	4.9	6	2.1
Self-employed	416	11.2	490	10.5	221	9.3	242	10.0	248	10.8	25	8.7
Pupil/student	159	4.3	162	3.5	98	4.1	68	2.8	64	2.8	7	2.4
Housewife/homemaker	173	4.7	258	5.5	125	5.3	118	4.9	109	4.7	15	5.2
Working on own land	1,513	40.8	2,041	43.9	1,059	44.6	1,146	47.4	979	42.5	148	51.6
Other	67	1.8	81	1.7	32	1.4	40	1.6	43	1.9	3	1.1
Education												
No Schooling	641	17.3	860	18.5	462	19.5	518	21.4	468	20.3	56	19.5
Primary School	1,959	52.8	2,533	53.4	1,310	55.2	1,320	54.6	1,217	52.8	145	50.5
Secondary School	1,038	28.0	1,163	25.0	573	24.1	556	23.0	580	25.2	75	26.1
Tertiary Education	70	1.9	96	2.1	30	1.3	556	23.0	41	1.8	11	3.8
Setting												
Rural	2,523	68.0	3,390	72.9	1,742	73.4	1,841	76.1	1,713	74.3	226	78.8
Urban	1,185	32.0	1,263	27.1	633	26.7	577	23.9	593	25.7	61	21.3
Province												
Central	382	10.3	512	11	259	10.9	257	10.6	274	11.9	61	21.3
Copperbelt	572	15.4	636	13.7	305	12.8	349	14.4	403	17.5	42	14.6
Eastern	433	11.7	568	12.2	253	10.7	265	11.0	219	9.5	16	5.6

Demographic characteristics	Have Cough		Chestpain		Fever		Sweat		Lost weight		Respiratory complaints	
Luapula	298	8.0	419	9	230	9.7	222	9.2	187	8.1	33	11.5
Lusaka	620	16.7	622	13.4	322	13.6	188	7.8	222	9.6	16	5.6
Muchinga	167	4.5	234	5.0	139	5.9	160	6.6	93	4.0	16	5.6
Northern	384	10.4	541	11.6	321	13.5	330	13.7	223	9.7	20	7.0
North-Western	268	7.2	412	8.9	164	6.9	269	11.1	316	13.7	55	19.2
Southern	311	8.4	328	7.1	153	6.4	165	6.8	147	6.4	10	3.5
Western	273	7.4	381	8.2	229	9.6	213	8.8	222	9.6	18	6.3
Wealth Quintile												
Lowest	777	23.8	1,017	25.0	576	27.9	605	28.4	554	26.8	74	28.4
Second Lowest	635	19.5	869	21.4	425	20.6	484	22.7	432	20.9	65	24.9
Middle	702	21.5	911	22.4	477	23.1	471	22.1	472	22.9	65	24.9
Fourth	645	19.8	731	18.0	344	16.7	350	16.4	350	17.0	38	14.6
Highest	503	15.4	543	13.3	241	11.7	224	10.5	256	12.4	19	7.3

9.9.1. Treatment seeking for symptoms and history of treatment among presumptive TB cases

The presumptive TB cases were also asked if they had sought treatment for any of the symptoms. About a third (35%) of those who reported having symptoms said they sought treatment for their symptoms. Almost 5% of those who sought treatment had a CXR investigation while 4% (283) reported having had a sputum exam performed.

Of the presumptive TB cases, 644 (9.6%) reported previous history of TB treatment while 114 (1.7%) were on TB treatment at the time of the survey. A total of 663 (9.5%) said a member of their household was previously treated for TB prior to the survey.

9.9.2. Provider choice for first visit among symptomatic presumptive TB cases who sought care

Majority of the symptomatic presumptive TB cases, who sought care, chose a government facility for their first visit (Table 12). The remainder sought care from a private clinic or pharmacy (1.03%), from a faith-based (2.35%) and only one individual indicated to have sought care from a traditional healer.

Table 12. Health care seeking behavior among presumptive TB cases by provider

Provider type	N	%
Government/community clinic	1915	81.8
Private Clinic	85	3.6
Government Provincial Hospital	228	9.7
Pharmacy	24	1.0
Private doctor	3	0.1
Traditional Healer	1	0.02
Faith based organization	55	2.4
Other	29	1.2
Total	**2340**	**100**

The detailed background characteristics of the presumptive TB cases who sought care from a given provider type is shown in Table 13. Men more often use pharmacies and women faith-based facilities when seeking care. Older patients (65+) use government, faith-based, and other facilities for seeking care at greater rates than other age groups.

Table 13. First visit-Health seeking by background characteristics and provider type

Demographic	Government		Private		Pharmacy		Traditional		Faith-based		Other	
	N	%	N	%	N	%	N	%	N	%	N	%
Sex												
Male	970	45.3	39	44.3	15	62.5	1	100	18	32.7	12	41.4
Female	1,173	54.7	49	55.7	9	37.5	0	0	37	67.3	17	58.6
Age (Years)												
15 - 24	173	8.1	9	10.2	3	12.5	0	0	5	9.1	2	6.9
25 - 34	352	16.4	16	18.2	4	16.7	0	0	6	10.9	5	17.2
35 - 44	370	17.3	20	22.7	5	20.8	0	0	9	16	6	21
45 - 54	366	17.1	19	21.6	5	20.8	1	100	11	20	5	17.2
55 - 64	339	15.8	12	13.6	5	20.8	0	0	11	20	3	10.3
65+	543	25.3	12	13.6	2	8.3	0	0	13	24	8	28
Marital Status												
Never married	193	9.0	9	10.2	4	16.7	0	0	9	16.4	6	20.7
Currently or living a	1,304	60.9	57	64.8	19	79.2	0	0	28	50.9	16	55.2
Divorced or separated	232	10.8	9	10.2	1	4.2	0	0	6	10.9	2	6.9
Widowed	414	19.3	13	14.8	0	0	1	100	12	21.8	5	17.2
Occupation												
Unemployed	592	27.6	18	20.5	4	16.7	0	0	14	25.5	3	10.3
Occasional/seasonal	54	2.5	7	8.0	0	0	0	0	3	5.5	1	3.5
Employed by Government	24	1.1	2	2.8	1	4.2	0	0	1	1.8	0	0
Employed in privates	95	4.4	10	11.4	6	25	0	0	1	1.8	3	10.3
Self-employed	214	10.0	10	11.4	5	20.8	1	100	3	5.5	3	10.3
Pupil/student	59	2.8	1	1.14	1	4.2	0	0	3	5.5	1	3.5
Housewife/homemaker	88	4.1	12	13.6	0	0	0	0	3	5.5	1	3.5
Working on own land	972	45.36	27	30.7	7	29.2	0	0	25	45.5	17	58.6
Other	45	2.1	1	1.1	0	0	0	0	2	3.6	0	0
Education												
No Schooling	448	20.9	10	11.4	0	0	0	0	19	34.6	4	13.8
Primary School	1,136	53.0	41	46.6	7	29.2	1	100	25	45.5	19	65.5
Secondary School	517	24.1	34	38.64	14	58.3	0	0	11	20.0	6	20.7
Tertiary Education	41	1.9	3	3.41	3	12.5	0	0	0	0	0	0
Setting												
Rural	1,595	74.4	55	62.5	12	50	0	0	50	90.9	28	96.6
Urban	548	25.6	33	37.5	12	50	1	100	5	9.1	1	3.5
Province												

Demographic	Government		Private		Pharmacy		Traditional		Faith-based		Other	
	N	%	N	%	N	%	N	%	N	%	N	%
Central	222	10.4	8	9.1	1	4.2	0	0	0	0	2	6.9
Copperbelt	412	19.2	9	10.2	6	25	1	100	2	3.6	0	0
Eastern	360	16.8	9	10.2	0	0	0	0	0	0	2	6.9
Luapula	83	3.9	1	1.1	1	4.2	0	0	0	0	1	3.5
Lusaka	160	7.5	15	17.1	9	37.5	0	0	0	0	2	6.9
Muchinga	84	3.9	6	6.8	2	8.3	0	0	0	0	6	20.7
Northern	296	13.8	2	2.3	1	4.2	0	0	0	0	3	10.3
North-Western	320	14.9	8	9.1	3	12.5	0	0	2	3.6	3	10.3
Southern	108	5.0	9	10.2	0	0	0	0	17	30.9	1	3.5
Western	98	4.6	21	23.9	1	4.2	0	0	34	61.8	9	31.0
Wealth Quintile												
Lowest	473	25.1	12	15.2	1	4.6	0	0	13	24.5	13	48.1
Second Lowest	401	21.3	14	17.7	5	22.7	0	0	20	37.7	5	18.5
Middle	469	25.0	26	32.9	2	9.1	0	0	13	24.5	6	22.2
Fourth	316	16.8	11	13.9	5	22.7	1	100	4	7.6	2	7.4
Highest	223	11.9	16	20.3	9	40.9	0	0	3	5.7	1	3.7

9.10. Central Chest X-ray

The results of the central reading showed that more than 90% of the participants had a normal chest x-ray, 1.2% were abnormal consistent with TB while seven percent were considered to be abnormal inconsistent with TB (3,371). About 214 images were missing from the central radiology centre and were thus were not classified as shown in Table 14.

Table 14. Results of central Chest X-ray reporting

Central CXR Reporting	Frequency	Percent
Normal	41,509	91.0
Abnormal consistent with TB	539	1.2
Abnormal inconsistent with TB	3,371	7.4
Central results not available	214	0.5
Total	**45,633**	**100**

9.10.1 Field versus central x-ray results

Comparing field and central reading of CXRs, there was a 96% agreement between the field and central reading among x-rays scored as normal. However, 1,684 images (4.1%) classified as normal in the field were classified as abnormal centrally, out of which 69 were abnormal consistent with TB as shown Table 15. A total of 1,527 (3.7%) images which were classified as abnormal in the field were considered normal at central level. Majority of the images which had a result missing at field level were found to be normal at central and vice versa.

Among the 6,708 (14.5%) eligible for sputum submission; 2,948 (44%) were based on symptoms alone, 2,255 on chest x-ray alone (34%) and 1,505 (22%) on both symptoms and chest x-ray.

Table 15. Comparison between field and central chest x-ray reports

	Central X-ray result				
Field x-ray result	**Normal N (%)**	**Abnormal TB N (%)**	**Abnormal, Not TB N (%)**	**Not available**	**Total**
Normal	39,863 (96.0)	69 (12.6)	1,615 (47.9)	194 (90.6)	41,741 (91.4)
Abnormal	1,527 (3.7)	466 (87.2)	1,742 (51.7)	20 (9.4)	3,760 (8.2)
Not available	151 (0.4)	1 (0.2)	14 (0.4)	0 (0.0)	166 (0.4)
Total	**41,541**	**539**	**3,373**	**214**	**45,667**

9.11. Laboratory examinations

9.11.1. Eligibility to submit sputum sample

Of the 6,708 eligible for sputum examination, 6,154 (91.7%) submitted at least one sputum specimen. Six Thousand eighty-seven (90.7%) submitted at least a spot sample; 4,057 (66.7%) participants submitted both spot and morning sputa; 2,030 (30.3%) submitted only a spot sample and 67 (0.01%) participants submitted only a morning specimen. Despite submission, samples from 135 participants were not received or analysed by the lab because the containers were either empty, leaking or had the wrong specimen (i.e. Sample other than sputum).

There were 554 (8.3%) participants who did not submit any sample despite being eligible. Participants unable to submit sputum were more likely to be from a rural setting ($p<0.01$), male ($p<0.01$), with a history of cough ($p<0.01$), had chest pain ($p<0.01$) without other respiratory complaints ($p=0.03$) and HIV negative ($p=0.02$).

9.12. Laboratory results

Out of the 6,708 individuals who were eligible for sputum collection, 356 (5.31%) individuals had a positive smear result and for 231 positive cultures were isolated (Table 16). Of the 470 participants whose samples were analysed by *Xpert* MTB/RIF, 39 MTBs were isolated. The overall contamination rate for the liquid culture method in this survey was found to be 5.04%.

Table 16. Laboratory results by test

Smear Result	**Number**	**Percentage**
Positive	356	5.31
Negative	5767	85.97
Not available	585	8.72
Total Eligible for Sputum	**6708**	**100**
Culture Result		
Positive	231	3.44
Negative	5,554	82.80
Contaminated	338	5.04
Not available	585	8.72

Smear Result	Number	Percentage
Total Eligible for Sputum	6708	100
Xpert MTB/RIF Result*		
Positive	39	8.30
Negative	396	84.26
Not applicable	35	7.45
Total eligible for Xpert MTB/RIF	**470**	**100**

***For details on the cases subjected to Xpert MTB/RIF refer to Annex 25**

Out the 130 cases that were found negative by smear, 113 were actually culture positive MTB. That is at 86.9% false negative by smear. Of the 135 positive on smear, 15 were in fact culture negative at 11% false positive (Table 17).

Table 17. Final smear versus culture MTB detection

Final Smear result	Negative	Positive	Contaminated	Total
	n	n	n	n
Negative	12	113	5	130
Positive	15	118	2	135
Total	**27**	**231**	**7**	**265**

9.13. Mycobacterium other than Tuberculosis (MOTT)

A total of 936 (14%) individuals were found to have Mycobacterium other than Tuberculosis (MOTT) with 13 cases being MOTT/MTB co-infection (0.2%). About half of the MOTT cases had an abnormal chest x-ray and 71% were symptomatic (i.e. had either cough, chest pain or fever).

Table 18. MOTT Result

Result	Number	Percent
Negative	4849	72.3
Positive	923	13.8
MOTT-MTB	13	0.2
CTD	338	5.0
Not available	585	8.7
Total	**6708**	**100**

For clinical cases identified as MOTT, there were high numbers of MOTT cases in a number of districts as compared to MTB. There were three provinces and seven districts with MOTT cases that ranged from approximately 40-80 cases per district.

These districts were Kalabo, Sesheke, Kaoma, Mumbwa, Katete, Lusaka, and Kafue within Central, Eastern, Western, and Lusaka provinces. The district with the greatest number of MOTT cases was Lusaka district in Lusaka province with cases ranging from 54-83.

9.14. Final Case definition results

A total of 265 survey cases were identified by the expert panel as shown in the Table 19. About 45% (118) of the cases were culture and smear positive; 43% (113) were culture positive and smear negative; 12 (4.5%) cases were negative on both smear and culture but positive on GeneXpert; 15 (5.7%) were smear positive culture negative but GeneXpert positive.

9.15. Prevalence of smear, culture and bacteriologically confirmed Tuberculosis

Based on model 3 estimates, the prevalence of smear positive TB was found to be 319 (232-406)/100,000 population; the culture positive pulmonary TB prevalence was 568 (440-697)/100,000 population and bacteriologically confirmed TB was 638 (502-774)/100,000 population as shown in Table 19. By setting, the prevalence of smear positive TB was three times higher in the urban than in the rural while the prevalence of culture and bacteriologically confirmed TB was two times in the urban than in the rural areas respectively. The prevalence of smear, culture and bacteriologically confirmed TB was two-times higher in the males than in the females respectively. Generally, the prevalence of TB increased with increasing age but the peak was around the age band 35-54 years. By HIV status, the prevalence of smear, culture and bacteriologically confirmed TB was five times higher in the HIV positive than in the HIV negative.

Table 19. Smear, Culture and Bacteriological confirmed TB Prevalence

	Smear		Culture		Bacteriological	
Model	***Estimate***	**95% CI**	***Estimate***	**95% CI**	***Estimate***	**95% CI**
Overall	**319**	**232-406**	**568**	**440-697**	**638**	**502-774**
Setting						
Rural	**187**	**130-243**	**404**	**295-513**	**460**	**344-577**
Urban	**583**	**391-775**	**897**	**632-1163**	**993**	**714-1273**
Gender						
Male	**445**	**309-580**	**726**	**548-904**	**833**	**641-1024**
Female	**221**	**139-303**	**446**	**316-576**	**487**	**353-621**
HIV						
Overall	**319**	**232-406**	**568**	**440-697**	**638**	**502-774**
Negative	**182**	**129-236**	**336**	**249-422**	**387**	**294-480**
Positive	**887**	**424-1350**	**1675**	**978-2371**	**1726**	**1029-2423**
Unknown	**499**	**324-675**	**857**	**615-1099**	**964**	**704-1225**

The TB prevalence was higher among rural participants with higher than those with lower socioeconomic status whereas in the urban areas, the higher TB prevalence was found among participants with lower socio-economic status (Table 20).

Table 20. TB prevalence by socioeconomic status for rural and urban

Variable						
Wealth status	**Smear**		**Culture**		**Bacteriological**	
	Estimate	**95% CI**	***Estimate***	**95% CI**	***Estimate***	**95% CI**
Overall	**319**	**232-406**	**568**	**440-697**	**638**	**502-774**
Rural Wealth						
Lowest	**205**	**99-310**	**422**	**240-603**	**483**	**294-672**
Middle	**138**	**67-209**	**320**	**196-445**	**364**	**224-505**
Highest	**248**	**151-345**	**528**	**358-698**	**610**	**423-797**
Urban Wealth						
Lowest	**729**	**412-1046**	**1141**	**685-1597**	**1208**	**750-1666**
Middle	**763**	**468-1057**	**1098**	**785-1410**	**1251**	**911-1592**
Highest	**359**	**183-535**	**521**	**319-723**	**603**	**386-820**

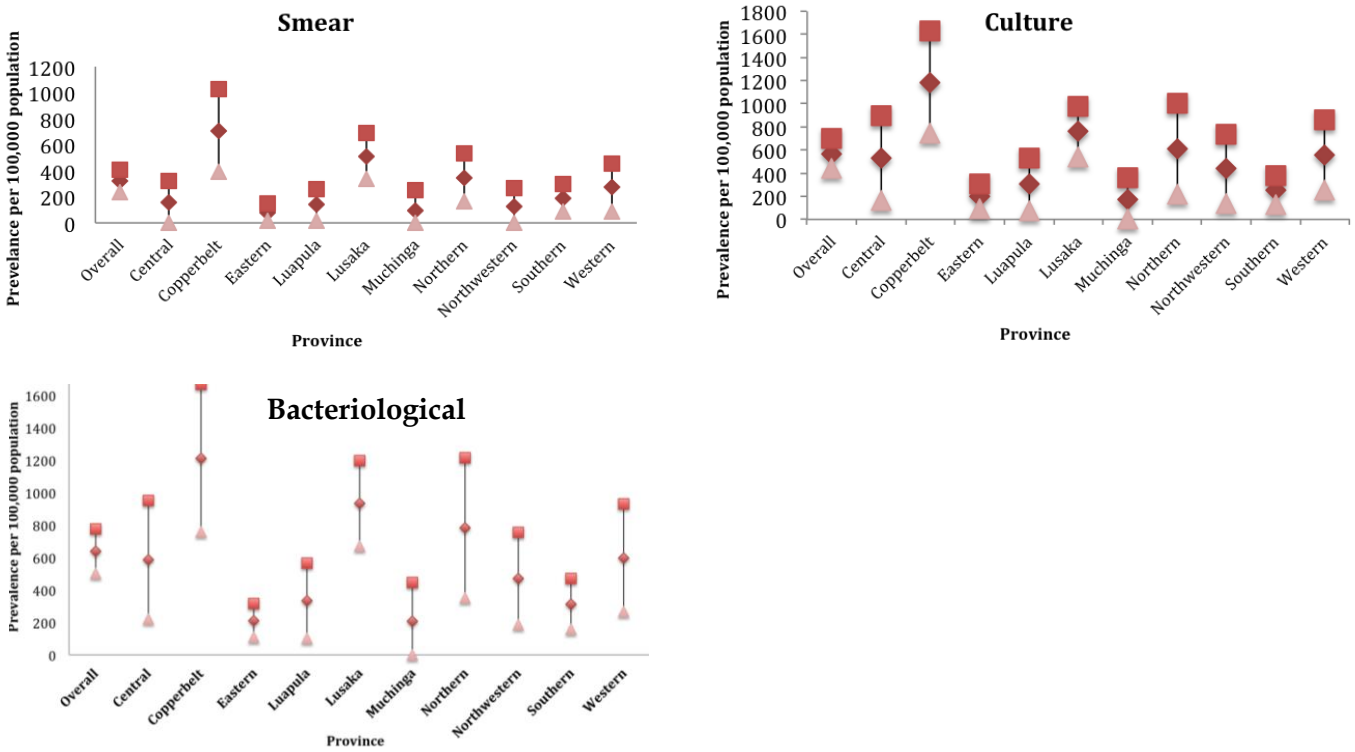


Figure 15. Estimated TB Prevalence by province for adults in Zambia with 95% confidence intervals

By province, Copperbelt recorded the highest prevalence of bacteriologically confirmed TB (1,211/100,000) followed by Lusaka (932/100,000) and the least was Muchinga (208/100,000). Figure 15 outlines the prevalence ranges of smear, culture and bacteriologically confirmed TB by province.

There was no difference found in the prevalence of TB by either number of persons sleeping per room or the type of fuel used for cooking. The results are presented in Table 21.

Table 21. Impact of living conditions on TB prevalence

	Smear		Culture		Bacteriological	
Crowding	*Estimate*	95% CI	*Estimate*	95% CI	*Estimate*	95% CI
Overall	**319**	**232-406**	**568**	**440-697**	**638**	**502-774**
Crowding (persons per room)						
0-≤2	**346**	**230-463**	**655**	**485-825**	**716**	**543-888**
>2-≤5	**296**	**196-396**	**525**	**390-660**	**598**	**452-745**
>5	**431**	**89-773**	**723**	**232-1214**	**890**	**351-1448**
Cooking method						
Charcoal/wood open fire	**256**	**149-362**	**432**	**315-548**	**530**	**395-666**
Charcoal/wood surrounded fire	**385**	**229-542**	**710**	**484-935**	**747**	**518-976**
Charcoal/wood stove w combustion chamber	**380**	**177-582**	**727**	**385-1069**	**846**	**474-1219**
Electricity/gas/	**301**	**151-451**	**620**	**359-882**	**681**	**420-942**

Bacteriological

9.15.1. Distribution of the TB burden by clusters

There was a variation in the TB burden by clusters. Majority of the clusters had a smear prevalence ranging from 0 to 500/100,000 population. However, four (4) clusters were found to have very high smear positive prevalence of over 1,000/100,000 population as show in Figure 16.

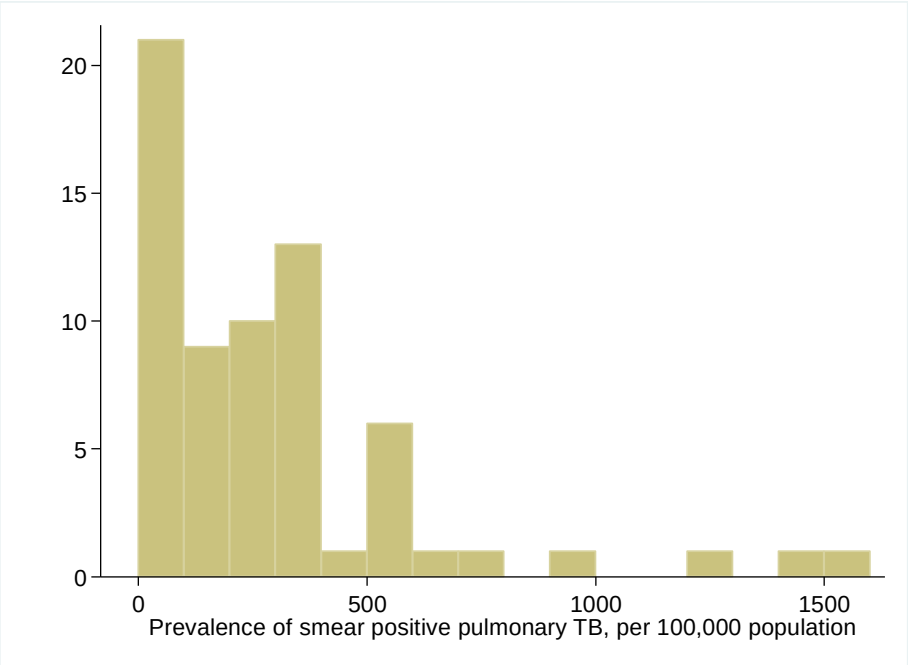


Figure 16. Distribution of smear positive among clusters

Similarly, the distribution of culture positive TB among the clusters was varied. The prevalence of culture positive TB ranged from 0 to 2400/100,000. Nine (9) clusters reported culture positive TB of over 2000/100,000 as shown in Figure 17.

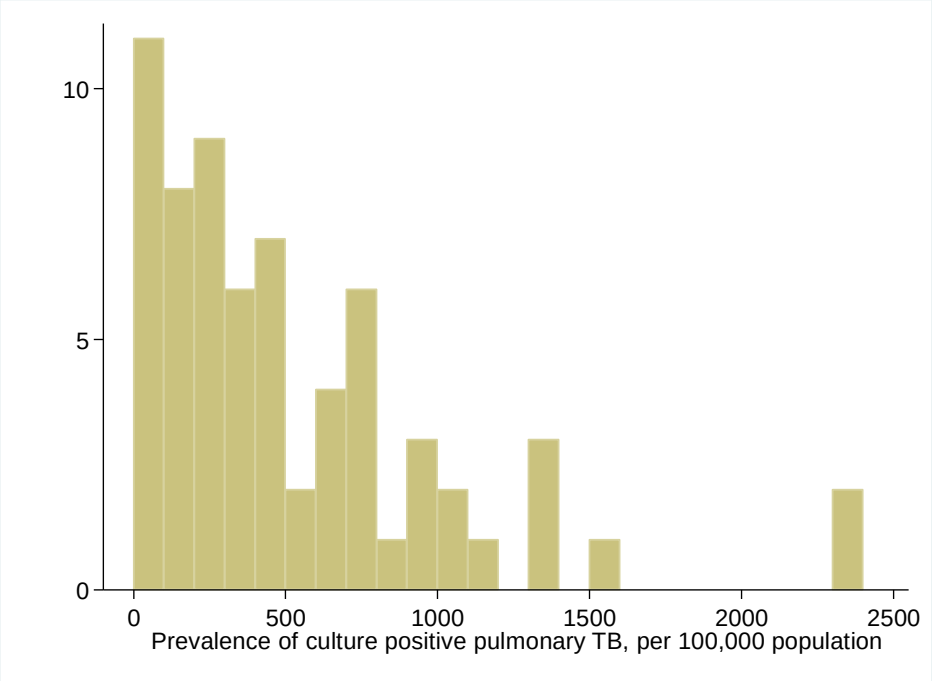


Figure 17. Distribution of culture positive TB among clusters

Consequently, the bacteriologically confirmed TB burden was very varied with majority of clusters recording 0 to 1,000/100,000 population, with 10 clusters reporting over 1,000/100,000 bacteriologically confirmed TB as shown in Figure 18.

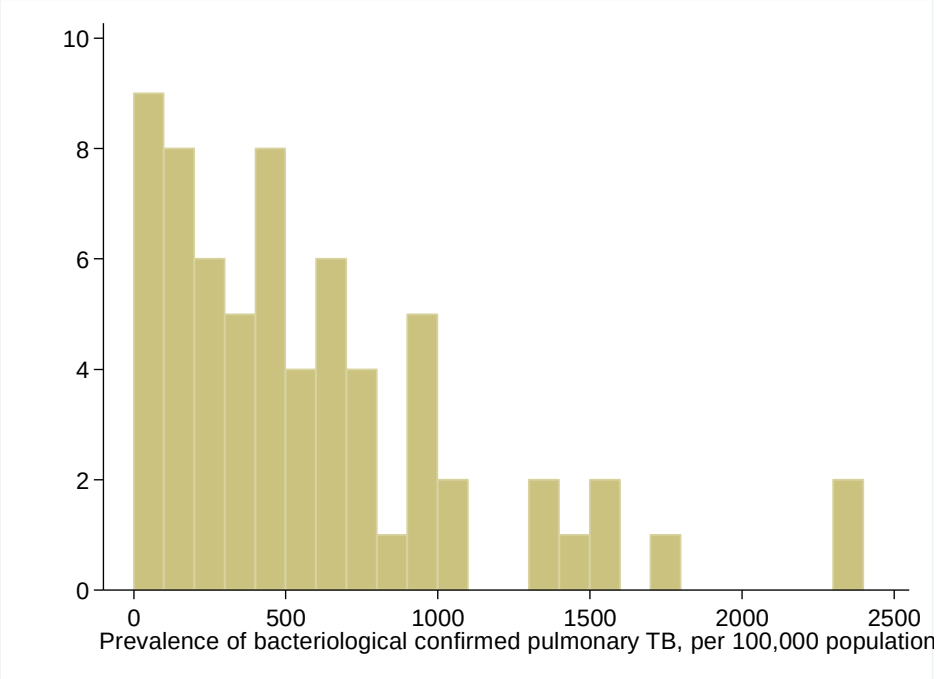


Figure 18. Distribution of bacteriological TB among clusters

9.16. Health seeking behavior among survey cases

The majority of the symptomatic survey cases (97%) were not on anti-TB treatment at the time of the survey. Nearly half (49.7%) of the cases that were not on treatment had sought care for their symptoms. Of the 156 symptomatic TB cases not on treatment but who sought care; 93% (74) had sought care from a public health facility, 4% (3) from a private facility and another 4% (3) from either a traditional healer of faith-based organization. Of the TB cases (7) who were already on treatment, five were treated at a public facility, none from a private clinic and two from other facility.

Table 22. Health seeking and treatment status of survey cases

Variable	N	%
Total number of TB survey cases	265	100
Number of TB survey cases who were not on treatment at the time of the interview	258	97.4
Number of TB cases detected by the survey who were already on treatment	7	0.3
Number of TB survey cases who were symptomatic	161	60.6
Number of ***symptomatic*** TB survey cases not on treatment at the time of the interview	156	96.9
Number of ***symptomatic*** TB cases not on treatment but who sought care	80	49.7
Number of ***symptomatic*** TB survey cases not on treatment who sought care at a public facility	74	94
Number of ***symptomatic*** TB survey cases not on treatment who sought care at a private facility	3	4
Number of ***symptomatic*** TB survey cases not on treatment who sought care at other facility	3	4

9.17. Extrapolation to all population and all forms

The extrapolated estimated TB prevalence of all forms of TB for all age groups for Zambia is 455 (366-544) per 100,000 population in 2013-2014. This is higher than what is estimated by the WHO for 2013, which is 338 (193-524) per 100,000 population (WHO 2014), yet still within range.

9.18. HIV among the Survey Participants

Of the 46,099 survey participants 44,761 (97.1%) underwent HIV counselling out of which 30,584 (68.3%) were tested (Figure 19); 9,719 (31.8%) were aged 15-24 years and 17,641 (57.7%) were females. The majority who participated in the HIV component of the survey were from rural (21,052, 68.8%) compared with urban areas 9,532 (31.1%). Over half of them (17,800, 58.2%) were married or living with a partner, 14,128 (46.2%) had completed primary education; the males, 816 (56.4%), tended to achieve higher level of education than females, 631 (43.6%). Thirty-five percent (10,721) of the participants reported 'working on their own land' as their main occupation.

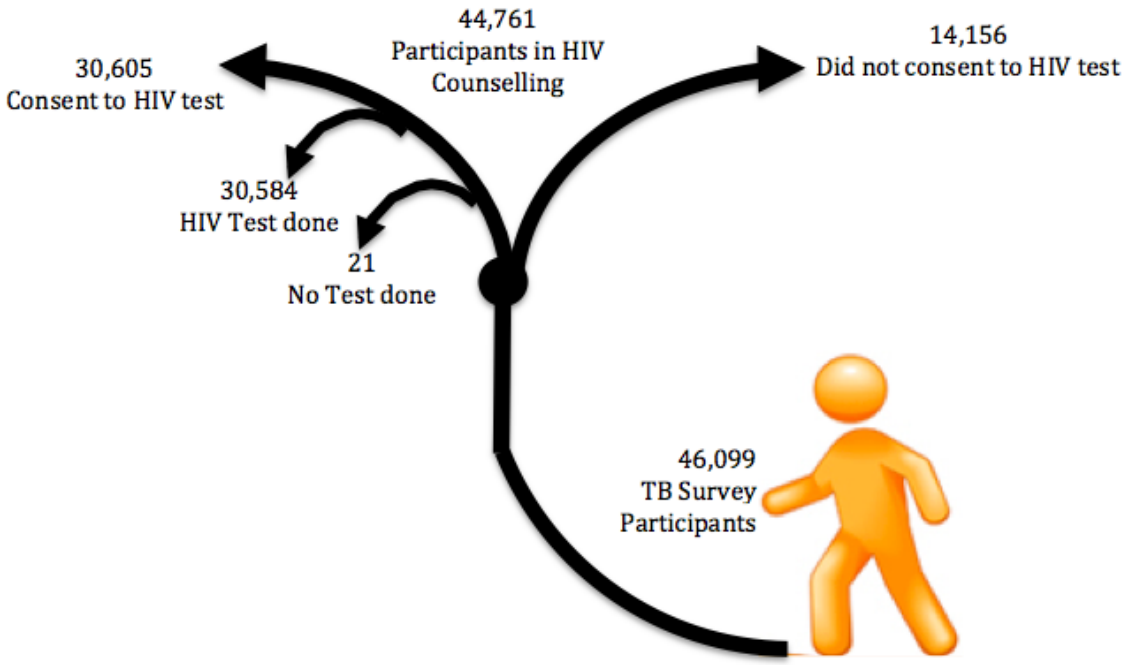


Figure 19. HIV testing participation

Of the 44,761 (97.1%) that underwent HIV counselling, 30,584 (68.3%) tested for HIV, with 30,353 (99.2%) wishing to have the results of the HIV testing disclosed to them. Table 23 outlines the HIV testing outcome by participant characteristics.

Table 23. HIV counseling participation and HIV Positivity rate by background characteristics

Characteristic	Negative		Positive		Indeterminate		Total	
	N	%	N	%	N	%	N	%
Sex								
Male	12,223	43.0	680	33.0	40	44.4	12,943	42.3
Female	16,208	57.0	1,383	67.0	50	55.6	17,641	57.7
Age group								
15 - 24	9,418	33.1	273	13.2	28	31.1	9,719	31.8
25 - 34	6,624	23.3	573	27.8	22	24.4	7,219	23.6

35 - 44	4,791	16.9	656	31.8	19	21.1	5,466	17.9
45 - 54	3,204	11.3	377	18.3	10	11.1	3,591	11.7
55 - 64	2,308	8.1	141	6.8	6	6.7	2,455	8.0
65+	2,086	7.3	43	2.1	5	5.6	2,134	7.0
Marital status								
Never married	8,052	28.3	290	14.1	30	33.3	8,372	27.4
Currently or living as married	16,552	58.2	1,203	58.3	45	50	17,800	58.2
Divorced or separated	1,785	6.3	287	13.9	8	8.9	2,080	6.8
Widowed	2,042	7.2	283	13.7	7	7.8	2,332	7.6
Occupation								
Unemployed	6,203	21.8	566	27.4	15	16.7	6,784	22.2
Occasional/seasonal	783	2.8	85	4.1	3	3.3	871	2.9
Employed by Government	542	2.0	59	2.9	1	1.1	602	2.0
Employed in private s	1,879	7.0	198	9.6	6	6.7	2,083	6.8
Self-employed	2,737	9.6	386	18.7	11	12.2	3,134	10.3
Pupil/student	3,763	13.2	49	2.4	8	8.9	3,820	12.5
Housewife/homemaker	2,023	7.1	203	9.8	11	12.2	2,237	7.3
Working on own land	10,181	35.8	506	24.5	34	37.8	10,721	35.1
Other	320	1.1	11	0.5	1	1.1	332	1.1
Education								
No Schooling	2,495	9	156	7.6	4	4.4	2,655	8.7
Primary School	13,088	46	987	47.8	53	58.9	14,128	46.2
Secondary School	11,796	41.5	848	41.1	31	34.4	12,675	41.4
Tertiary Education	1,040	3.7	72	3.5	2	2.2	1,114	3.6
Unknown	12	0.04	0	0	0	0	12	0.04
Setting								
Rural	19,889	70.0	1,103	53.5	60	66.7	21,052	68.8
Urban	8,542	30.0	960	46.5	30	33.3	9,532	31.2
Province								
Central	2,030	7.1	111	5.4	25	27.8	2,166	7.1
Copperbelt	4,385	15.4	395	19.2	10	11.1	4,790	15.7
Eastern	5,224	18.4	182	8.8	8	8.9	5,414	17.7
Luapula	1,911	6.7	104	5.0	9	10.0	2,024	6.3
Lusaka	4,826	17.0	618	30.0	9	10.0	5,453	17.8
Muchinga	969	3.4	15	0.7	8	8.9	992	3.2
Northern	3,185	11.2	98	4.75	9	10	3,292	10.8
North-Western	1,621	5.7	102	4.9	2	2.2	1,725	5.6
Southern	2,964	10.4	260	12.6	6	6.7	3,230	10.6
Western	1,316	4.6	178	8.6	4	4.4	1,498	4.9
Wealth Index								
Lowest	4,620	19.0	190	10.3	20	24.0	4,830	18.1
Second Lowest	4,596	19.0	235	12.7	13	16.0	4,844	18.2
Middle	5,102	21.0	424	22.9	13	16.0	5,539	20.8

Fourth	5,080	20.5	506	27.3	24	29.3	5,610	21.0
Highest	5,339	22.0	496	26.8	12	14.6	5,847	21.9
TB								
Definite	98	3	35	8.5	0	0	133	3.2
No case	3,314	89.1	358	86.7	20	95.2	3,692	88.9
Undefined	308	8	20	4.8	1	4.8	329	7.9

HIV Prevalence

The crude prevalence of HIV among survey participants was 6.8% (2062/30,584). Using an individual level statistical model; the prevalence was 6.8% (95% CI 5.6-7.9). The prevalence of HIV was two times more in the urban than in the rural (10% versus 5%). The HIV prevalence was 1.5 times more in the females than the males.

Table 24. HIV Prevalence by Setting and Sex

	Estimate	95% CI
Overall	6.8%	5.6-7.9
By setting		
Rural	5.2%	4.1-6.4
Urban	10.1%	8.6-11.6
By Sex		
Male	5.3%	4.3-6.2
Female	7.9%	6.5-9.2

By province, Western recorded the highest HIV prevalence (11.9%), followed by Lusaka (11.3%) and the least HIV prevalence was found in Muchinga (1.5%). However, there was variation in the testing acceptance rates. The testing refusal rates ranged from 12.4% in Northern province to 42% in Luapula province.

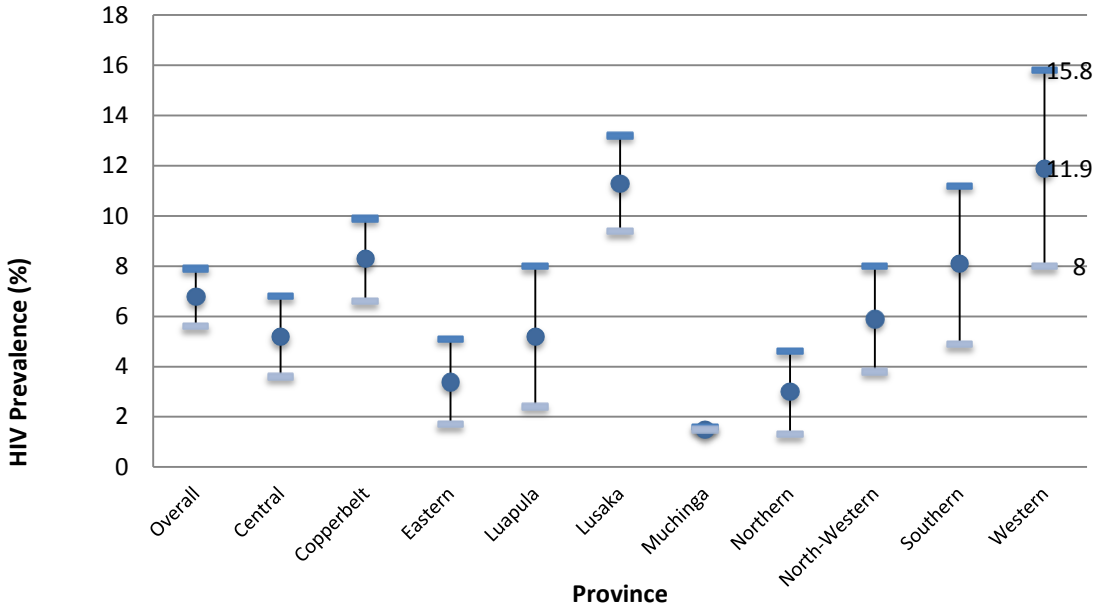


Figure 20. HIV Prevalence for adults in Zambia by province with 95% confidence interval

Overall, the HIV prevalence was highest among the 35-44 years in both males and female participants as shown in Figure 20. The younger (15-24 years) and older age bands (65 years and above) were found to have lower HIV Prevalence.

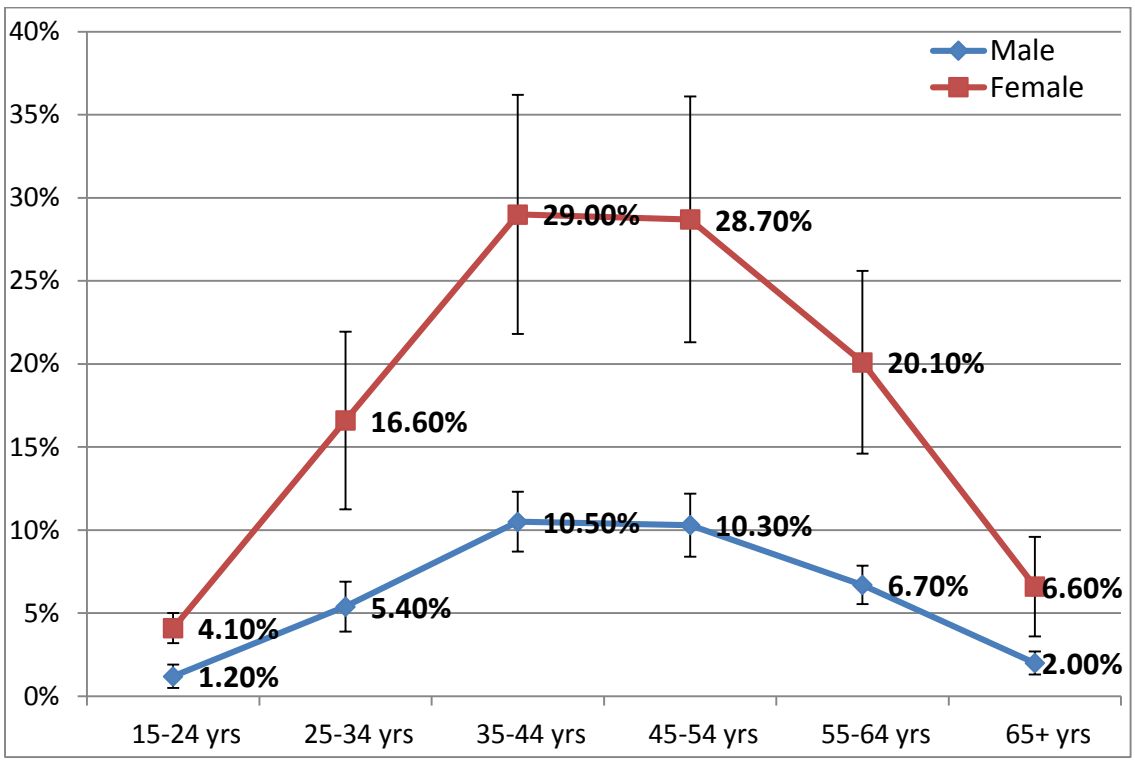


Figure 21. HIV prevalence by age and sex with uncertainty bounds (Model 1 results)

The HIV prevalence was generally higher with increasing wealth quintiles, this was however more clearly so among the urban than the rural survey participants as shown in Table 25.

Table 25. HIV Prevalence by socioeconomic characteristics and TB status

Model	Estimate	95% CI
Overall	**6.8%**	
By Wealth quintile		
Lowest	4.0%	2.8-5.1
Second lowest	4.8%	3.7-6.1
Middle	7.7%	6.0-9.4
Fourth	9.1%	7.6-10.5
Highest	8.5%	6.8-10.2
By Marital Status		
Never married	3.6%	3.0-4.3
Currently/living as married	6.9%	5.9-8.0
Divorced/separated	15.1%	12.9-17.3
Widowed	11.7%	10.0-13.4
By Education level		
no schooling	5.9%	4.8-7.0
primary school	7.1%	6.0-8.3
secondary school	7.0%	6.0-7.9
tertiary education	7.3%	5.7-9.0
By MOTT status		
No Symptomatic MOTT	6.7%	5.6-7.8
Symptomatic MOTT	9.3%	6.8-11.7
By TB status (bacteria)		
no bact confirmed TB	6.5%	5.4-7.5
Bact confirmed TB	26.8%	17.3-36.3
By TB status (smear)		
Not smear + TB	6.7%	5.64-7.8
Smear + TB	26.8%	14.4-39.3

The HIV prevalence was four times higher among individuals with bacteriologically confirmed TB than those without TB (26.8% versus 6.5%) for both smear and bacteriologically confirmed. By marital status, the HIV prevalence was highest among the divorced or widowed.

9.19. Geospatial Analysis for Symptoms, TB and HIV

9.19.1. Symptoms

History of Cough

The distributions of cough cases based on symptom screening results were greatest in 6 districts located within Lusaka, Eastern, Copperbelt, and Luapula (Figure 22). The districts with the greatest number of participants with cough symptoms occurring for 2 weeks or more were Lusaka, Chipata, Kitwe, Lundazi, Chiengi and Ndola. Within these provinces, the number of participants surveyed within the districts ranged between approximately 350 to over 1200 people. The district with the greatest number of participants with cough symptoms was Lusaka district with the number of respondents ranging between 740-1214 people.

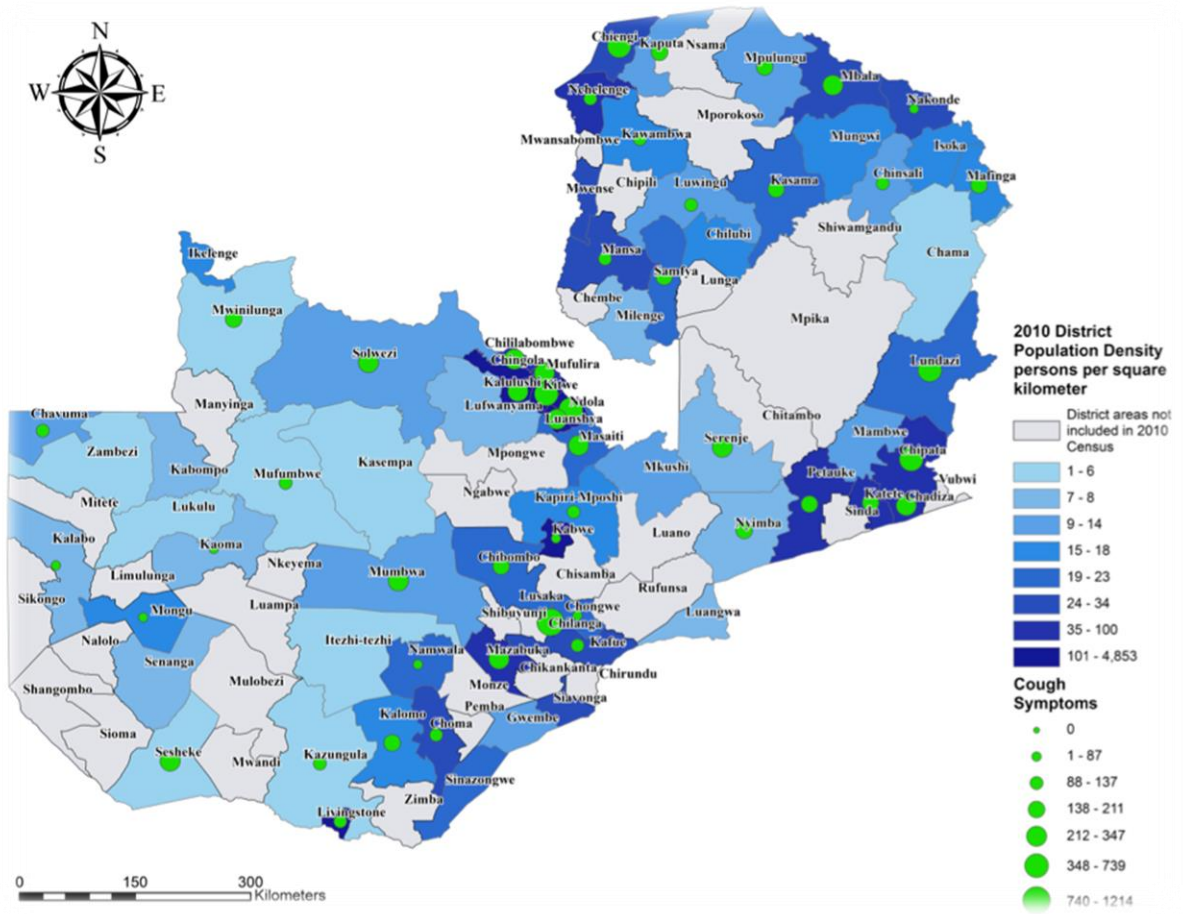


Figure 22. Geographical distribution for cough symptoms

History of Fever

Those stating to have had a fever for more than 2 weeks ranged approximately between 350 –480 people in 5 districts (Figure 23). The districts were Lusaka, Chipata, Kitwe, Lundazi, and Chiengi located in four provinces. It should be noted that the locations where fever symptoms were greatest, coincided with the same locations as cough symptoms.

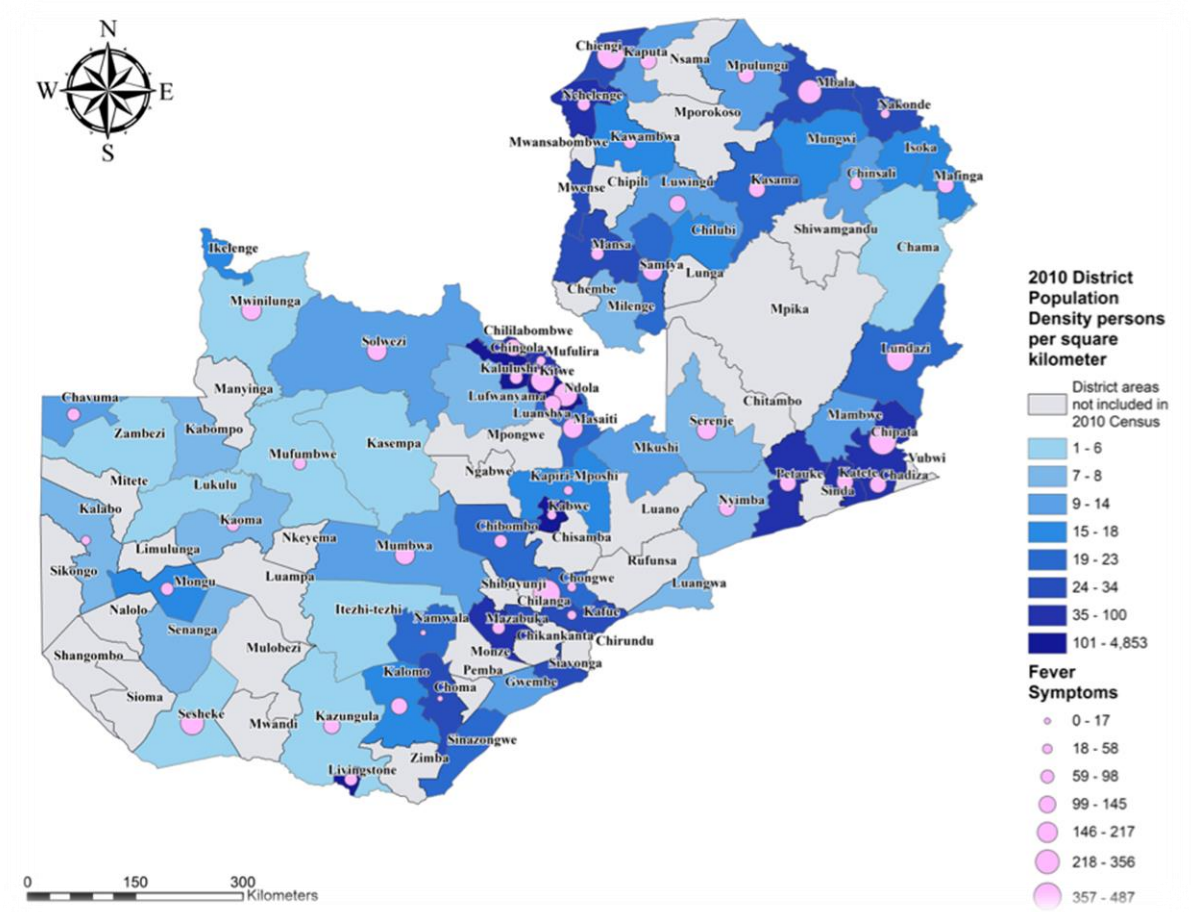


Figure 23. Geographical distribution for fever symptoms

History of Chest Pain

The distributions of chest pain cases based on symptom screening results were greatest in the same regions as both fever and cough symptoms (Figure 24). Within these provinces, the number of participants surveyed within the districts ranged from approximately 350 to 1000 people.

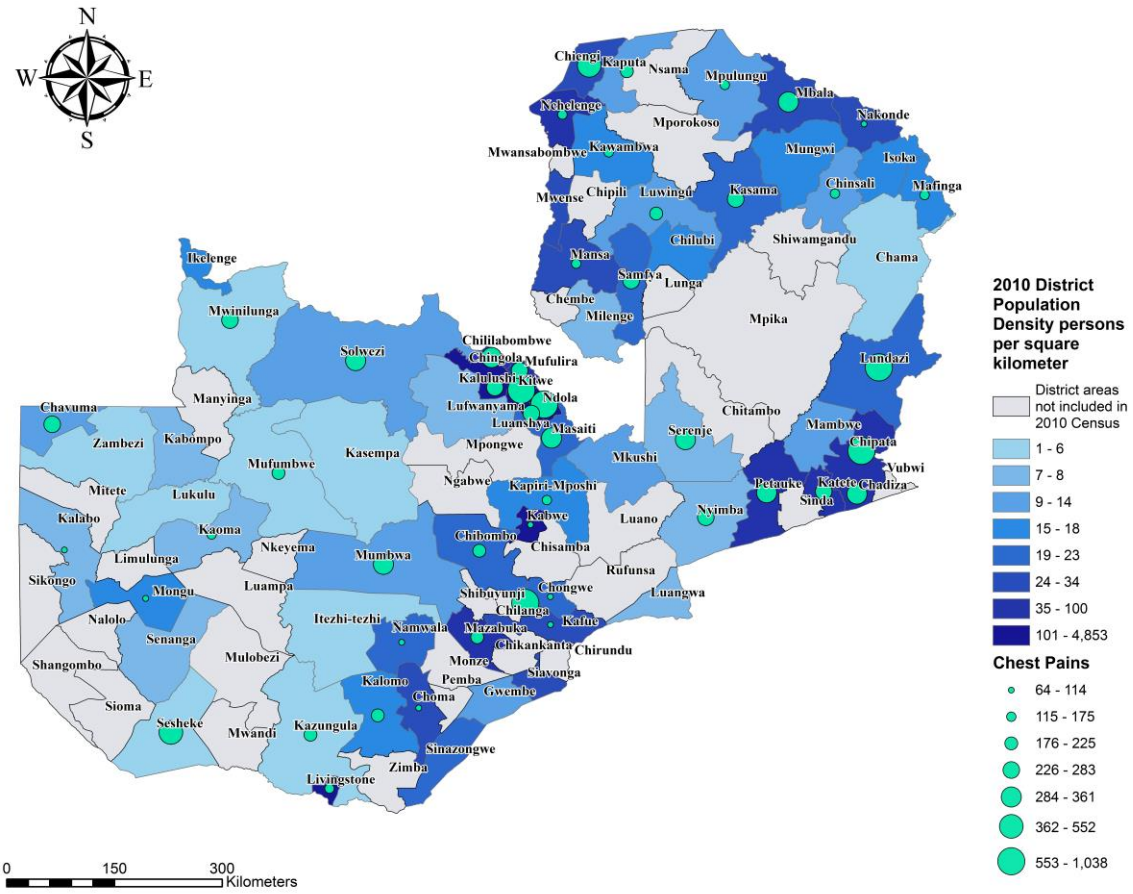


Figure 24. Geographical distribution for chest pains

Abnormal Chest X-ray

The distributions of abnormal X-ray cases were greatest in 8 districts located within Lusaka, Eastern, Northwestern, Copperbelt, and Western (Figure 25). These included abnormalities both consistent and inconsistent for TB. The districts with the greatest number of participants with abnormalities consistent with TB were Lusaka and Nyimba. The districts had cases that ranged from 30 to 167 in number. The areas with the greatest number of participants with chest X-rays with abnormalities inconsistent with TB were Lusaka, Chavuma, Kitwe, Chililabombwe, Lundazi, Ndola, and Sesheke. Within these districts, the number of participants surveyed within the districts with X-rays inconsistent with TB ranged from 100 to 526 people. The district with the greatest number of participants with all abnormal chest X-rays was Lusaka district in Lusaka province with the number of respondents ranging between 55-167 and 211-526 people for X-rays consistent and inconsistent for TB respectively.

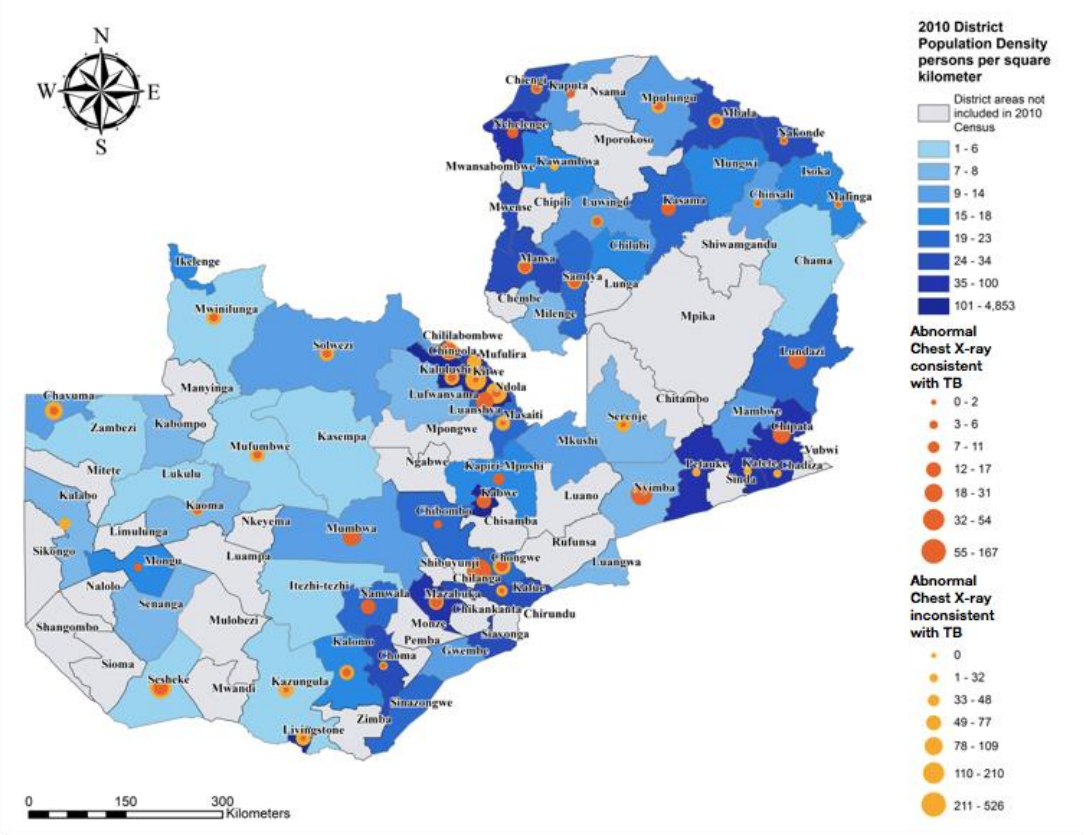


Figure 25. Geographical distribution for abnormal chest X-ray

9.19.2. TB

MTB

The greatest numbers of MTB cases were in the Copperbelt and Lusaka Provinces (Figure 26). The districts with more than 25 MTB cases were Kitwe and Ndola districts in the Copperbelt Province and Lusaka district in the Lusaka Province. Lusaka district had the most cases ranging between 31-62 cases within the district.

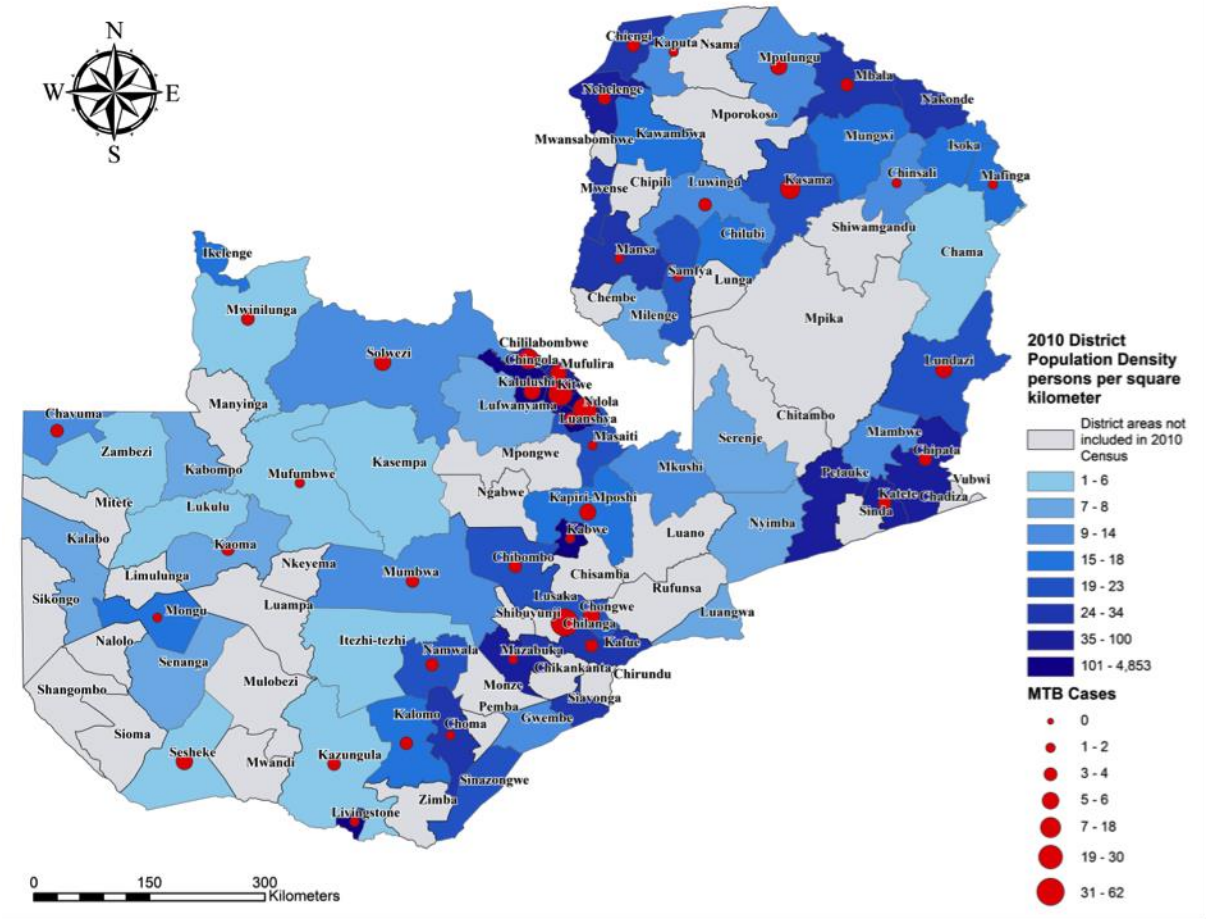


Figure 26. Geographical distribution for MTB

MOTT

For clinical cases identified as MOTT, there were high numbers of MOTT cases in a number of districts as compared to MTB (Figure 27). There were three provinces and seven districts with MOTT cases that ranged from approximately 40-80 cases per district.

These districts were Kalabo, Sesheke, Kaoma, Mumbwa, Katete, Lusaka, and Kafue within Central, Eastern, Western, and Lusaka provinces. The district with the greatest number of MOTT cases was Lusaka district in Lusaka province with cases ranging between 54-83.

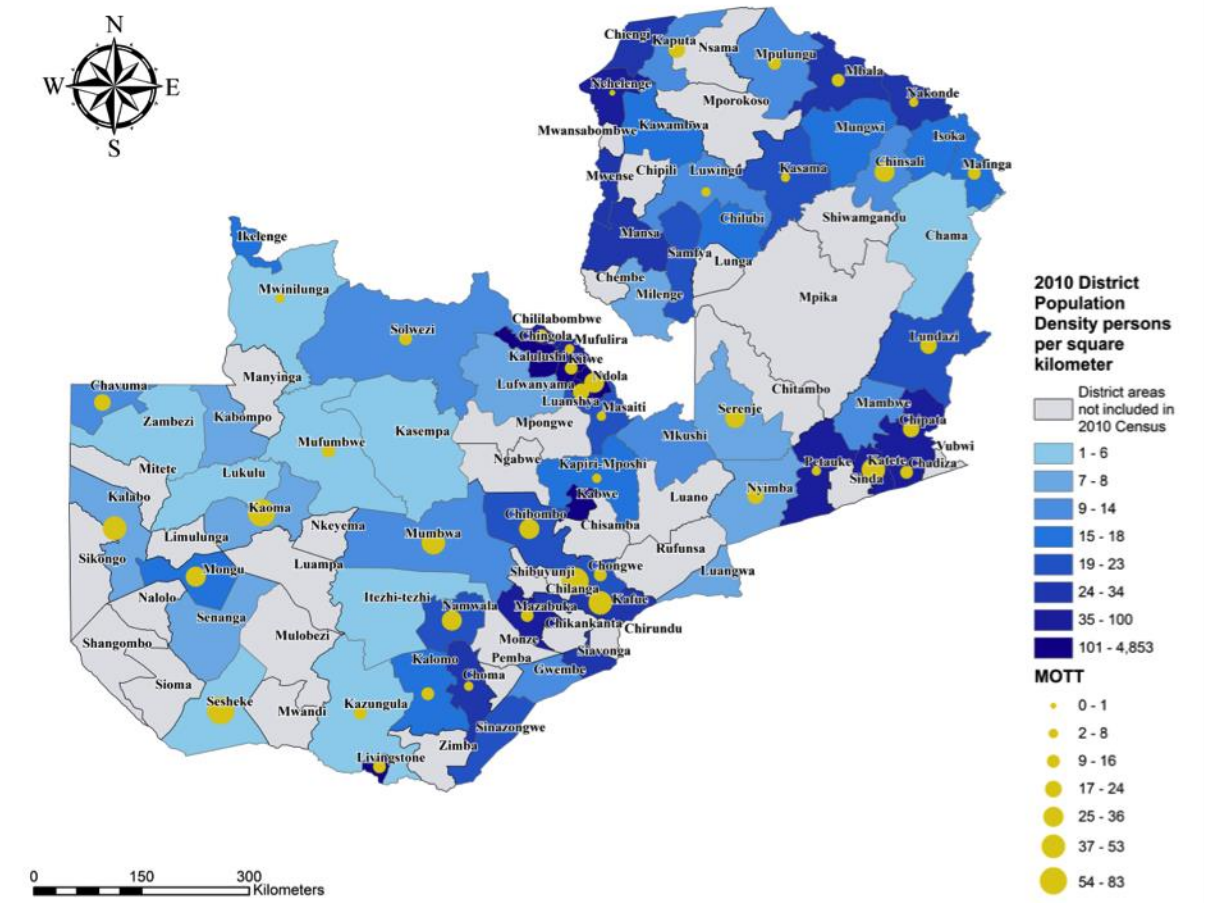


Figure 27. Geographical distribution for MOTT

9.19.2. HIV

HIV cases were greatest in 5 districts located within four provinces. The greatest number of HIV cases were within Lusaka district in Lusaka province with over 500 cases. Namwala, Kitwe, Ndola, and Sesheke within Southern, Copperbelt, and Western provinces had case number ranging between 67-113 (Figure 28).

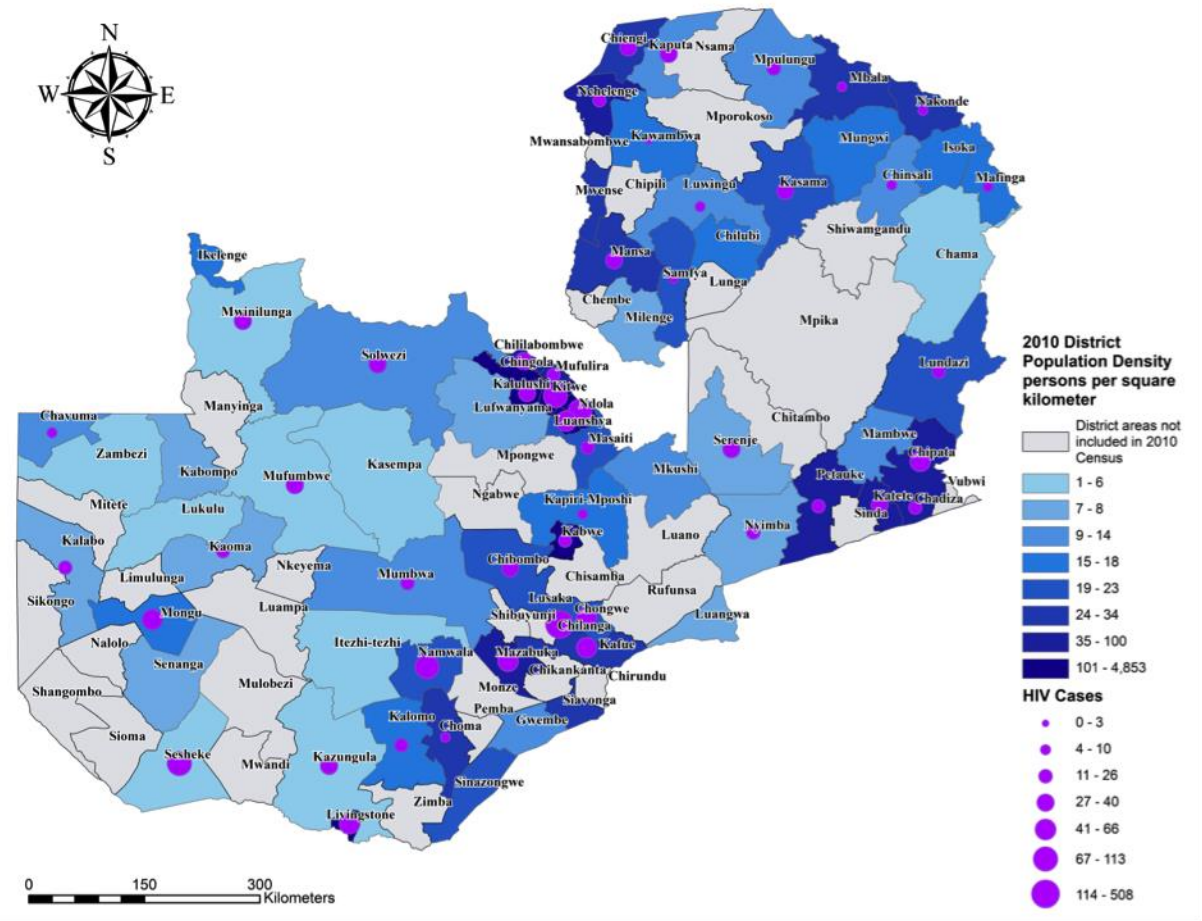


Figure 28. Geographical distribution for HIV

Discussion and Conclusion

Chapter 10

CHAPTER 10. Discussion and Conclusion

Tuberculosis

The results of the first ever national TB prevalence survey in Zambia have shown that the prevalence of bacteriologically confirmed MTB was 638 (502-774) per 100,000 adult population in 2013 -2014. This is higher than the estimated prevalence bacteriologically confirmed MTB based on routine surveillance data. However, in routine data collection, microscopy is what is mainly used for diagnosis. The survey has also shown that there are wide variations in the burden of TB by location, gender, social economic status and age category. The prevalence of MTB was two to three times higher in the urban than in the rural areas; this was true for smear, culture and bacteriologically confirmed TB. The burden of TB was higher in the male than females in the ratio of 2:1 for all forms. The survey has also demonstrated the importance of the TB/HIV co –morbidity, with the HIV positive having 5 times more TB than their HIV negative counter parts. In terms of socio-economic status using wealth tertiles; the burden of MTB was generally two times higher among the lowest wealth quintiles in the urban areas. However, in the rural areas, the burden of TB was similar across different socioeconomic groups. By province, Copperbelt, Lusaka and Northern recorded higher prevalence of TB, above 600 per 100,000 population; Central, North-Western and Western provinces had a prevalence ranging from 400-600 per 100,000 population; the least prevalence was from Eastern, Luapula, Muchinga and Southern which recorded prevalence below 400 per 100,000 population.

This survey has also highlighted that the cases of TB are likely being missed by routine passive case finding as 97 percent of the symptomatic cases found in the survey were not currently on treatment. Half of the symptomatic cases not on treatment had actually sought care for their symptoms. The symptomatic cases not captured by the NTP presents a pool for perpetuation of TB burden if left unchecked. There is need to sensitize health workers on ensuring that they provide quality health care services so as to avoid missing cases which could have otherwise been picked.

The cases of TB were largely occurring between the ages 25-44 years (51%) with the peak being around the 35-44 age band. This is a group which is also economically viable and hence points to the TB burden having potential economic consequences on the micro and macroeconomic level. This is an important area for future research to estimate the economic consequences of TB especially among the workforce. The survey detected more cases in the age group similar to what is pertaining under routine surveillance.

Of the survey cases identified, 49 percent were smear negative, meaning that these cases could have been missed by routine case detection without culture identification. It is therefore important to scale up TB culture laboratory facilities so that the chances of missing MTB cases is minimized. Additionally, 62 percent of the smear positive cases were actually found not to be MTB with some of them being NTM. It is therefore recommended that smear positivity alone may not be useful in the detection of TB patients at the health facility. More specific point of care test are required so that only true MTB positive cases are put on anti-

TB treatment. Other studies have shown that smear positivity is not a good indicator of MTB disease (Kebede et al 2014, Mineab et al 2007). There is need to improve the specificity of MTB case detection.

If only one of the symptoms was used to screen potential cases; 84 percent, 57 percent and 53 percent of the survey cases would have missed by fever, cough and chest pain respectively. Fortunately, in the Zambia survey, all the three symptoms were used in combination or alone to come up with potential survey participants to submit sputum for laboratory investigation. Nonetheless; using symptoms alone; 39 percent of the survey cases could have gone undetected in the survey. The additional 104/265 were detected using chest x-ray screening. On the other hand, if only chest-x-ray screening alone was used to identify cases eligible for sputum submission; 17% of the survey cases would have been missed. It is therefore cardinal to use both symptom screening in combination with chest x-ray screening so as to optimize the case detection in TB prevalence surveys. Missing of cases would lead to an underestimation of the prevalent cases in a given country. Another important feature of the Zambian survey was the use of XpertMTB/RIF for all cases that were either smear positive or the culture results were inconclusive. This way, 12 additional cases were detected which could have otherwise gone undetected. The role of XpertMTB/RIF in national TB surveys needs to be further evaluated in other settings especially when the only available culture sample is contaminated and chest x-ray is consistent with TB.

An important incidental finding was the high prevalence of symptomatic non-tuberculous mycobacteria (NTM) with wide geographical variations. This calls for further characterization of the NTM in Zambia so that the clinically relevant NTM cases can be appropriately managed. To date; this is the first large-scale study to document the prevalence of symptomatic NTM across all the 10 provinces of Zambia.

The application of the screening strategies (both symptoms and chest x-ray) as recommended by the WHO Task force on Impact Measurement and the available technology not only made data collection efficient but also improved the chances of detecting TB cases. Through the use of digital systems, the usually anticipated data transcription errors were minimized through the use or pre-programmed electronic questionnaires, barcoding and scanning thereby leading to efficient and quality data collection.

This is the first fully digital national TB prevalence survey to be conducted globally. The application of technology and digital collection systems reduced the time from data collection to reporting of results. Also, the designed data collection systems made it possible for the survey teams to receive immediate feedback on data quality and make necessary improvements to the functioning of the pre-programmed data entry screens and updated versions provided to the teams with no or minimal disruptions of field operations. The use of digital data collection systems also facilitated an efficient system to monitor survey operations of all the three teams on a daily basis. This resulted into high quality data being collected.

Comparison of the prevalence of bacteriologically confirmed TB with other countries

The survey finding of bacteriologically confirmed TB of 638/100,000 (range 502-774/100,000) in Zambia in 2014 is higher than what has been found for Pakistan (296.6/100,000 range 248.1-345.2/100,000) in 2011, Myanmar (612.8/100,000 range 502.2-747.6/100,000 in 2010 and Nigeria (524/100,000 range 378-670/100,000) in 2012 but lower than that of Cambodia (831/100,000 range 707-977/100,000) in 2011. This therefore implies that Zambia has very high burden of TB and may compare with some of the high burden countries.

Survey Operations

The field phase of the survey was conducted within the expected time frame with minimal interruptions. The team only took a longer break over the Christmas and New Year period and immediately resumed cluster operations after the festive period. The field phase was planned in such a manner that the hard to reach rural areas were covered first early on in the survey, during the drier parts of the year. Stand-in officers were also trained to fill in for any officer who was unable to make it for cluster operations.

Even though the 7-day cluster operational period was manageable, this required field staff to work long hours depending on the flow of participants; for example in the rural areas participants tended to report to the cluster site later in the day which meant that the teams had to work late into the night to clear the people and then transport was provided for those coming from locations distant to the main survey camp site. This is a valuable lesson to note because, sending away people has the potential to reduce the participation rates.

The use of a courier system to transport samples to the central reference laboratories (CRLs) provided an efficient way to deliver samples timely to the laboratories. The samples were processed in laboratories with good laboratory practice (GLP) and this minimized problems associated with specimen handling. The use of a courier system in a nation- wide survey has provided an example for potential application in routine surveillance. However, all the staff involved requires adequate training in handling and transportation of biohazards.

Participation Rate

The participation rate found in this survey (84%) was similar to the expected 85%, although at the beginning, the rates were lower (about 49%), due to long distances in the larger, sparsely populated areas. Additionally, the survey teams encountered some myths and misconceptions among community members, which impacted negatively on the participation rates. The remedial measures to improve participation rates included use of in-cluster community sensitizations, involvement of the local political and traditional leadership and ongoing community education using mainstream television and community radio stations to disseminate the objectives and procedures of the survey.

The participation rate found in this survey was higher than that found in the National Prevalence survey conducted in Nigeria (56.8%) in 2012 (First National TB Prevalence Survey Report 2012, Nigeria), but slightly lower than what was found in Cambodia 92.6% in 2010-2011 (Mao et al 2014) , Myanmar 89.2% in 2009-2010 (Report on National TB Prevalence Survey 2009-2010, Myanmar), Ethiopia 90% (Kebede 2014). However, the finding that there

were more female than male participants is similar to all the findings of the surveys in Nigeria, Cambodia and Myanmar. The differences in the participation rate may be explained by differences in cluster size, population density and prevailing cultural and political contexts.

Human Immunodeficiency Virus (HIV)

This survey provides the largest data capture for HIV prevalence estimate in Zambia. The national level estimate for HIV was found to be 6.8% with regional, gender and socio-economic variations. The gender disparities were such that more female had HIV than males. The provinces with the highest HIV burden were also those along the line of rail, that is from Copperbelt to Southern Province. This is a stretch which also has high TB burden and is also considered the economic hub of Zambia. Additionally, the burden of HIV was noticed to increase with increase in wealth quintile and years of schooling. It appears that the HIV burden is then affecting the affluent in the Zambian society. By age group and gender, the prevalence of HIV was more than three-fold higher in the female aged 25-34 signaling a need to target interventions for women of this age band.

Of note is the quadruple burden among the participants with TB compared to those without. The importance of tackling TB/HIV co-infection cannot be underestimated.

Strengths and limitations

The use of the recommended method for conducting the TB survey has provided a basis for more reliable estimates of the TB burden in Zambia. The application of digital data collection and management systems reduced the occurrence of systematic errors and subsequently facilitated the collection of high quality data. This is the largest population based estimate of both TB and HIV for Zambia.

The main limitation of the survey was that paediatric TB and extra-pulmonary TB was not estimated. Future surveys should be designed to estimate the burden of these important parameters in a bid to improve estimates of all forms of TB among all age groups in Zambia.

Implications of the survey findings

The first ever national TB prevalence survey in Zambia has provided a baseline for future surveys for the evaluation of impact of TB control interventions. The findings have also highlighted the extent of the burden of TB in Zambia in 2013-2014. Apart from just demonstrating the burden, areas for program improvement have been highlighted.

Previously undetected cases have been found, with the majority of cases being on the Copperbelt province. There is need therefore to expand coverage of diagnosis and treatment interventions in the hot spots so as to facilitate the much-needed reduction in TB burden.

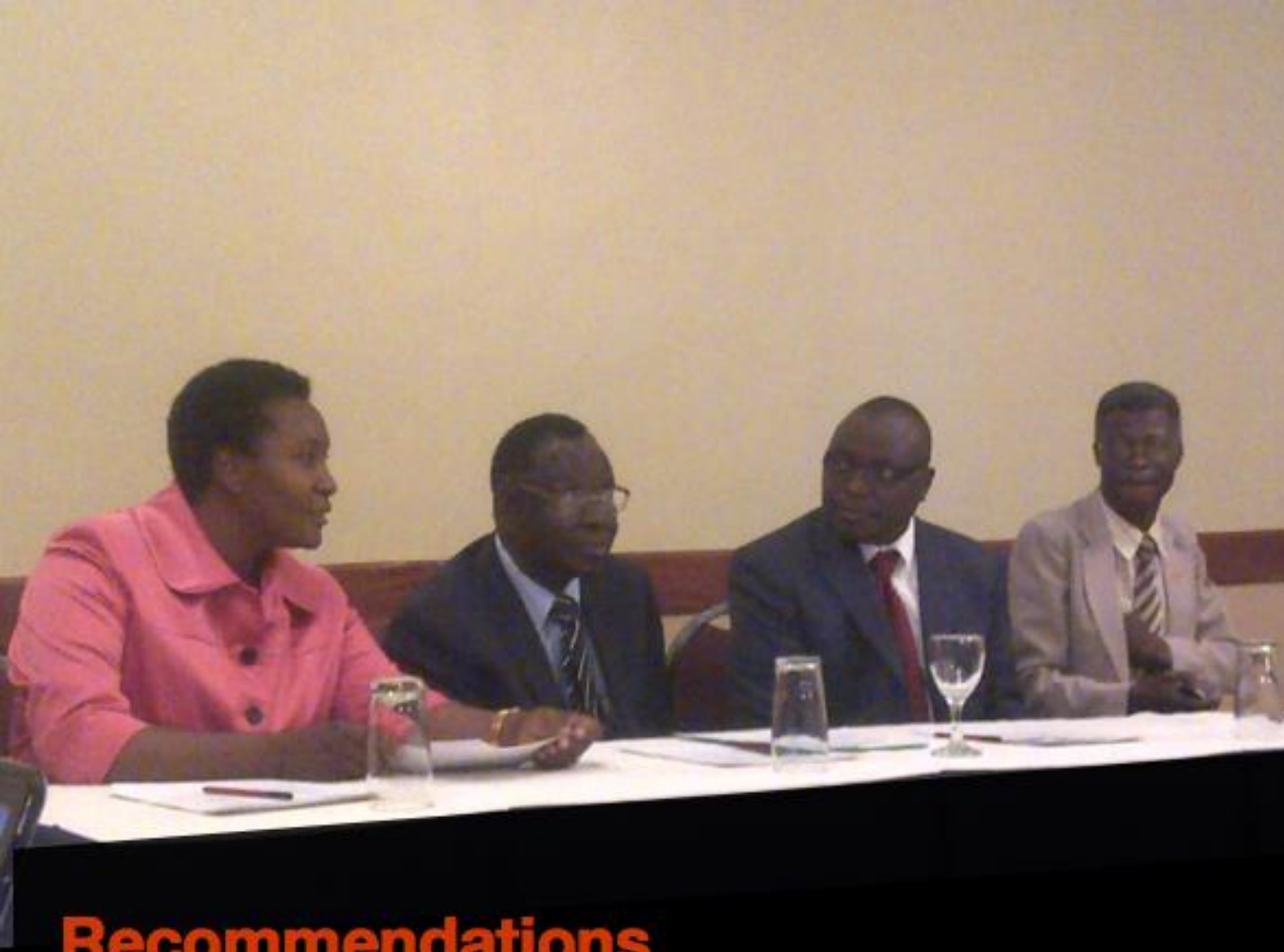
The survey has also shown the socio-demographic disparities of the TB burden. This implies that targeted efforts to male, urban poor and congested populations in farming areas need intensified case finding and treatment.

The TB burden is not evenly distributed with some areas having more TB than others even when the other variables are similar. The areas with lower burden also have high program activity coverage, which seems to point to the need for improved coverage across the country especially in the underserved areas.

The finding that chest pain was the most prevalent symptom has implication for screening of potential TB patients.

The occurrence of symptomatic NTM in Zambia needs to be investigated so that appropriate case management strategies are put in place.

The survey has also provided further evidence to support integration of TB/HIV interventions.



Recommendations

Chapter 11

CHAPTER 11. Recommendations

In view of the findings of the National TB Prevalence Survey 2013-2014, key recommendations are:

Organizational and structural

- There is need to strengthen the National TB Control Program (NTP) and ensure there are appropriate structures at all levels, i.e. central or provincial, district and community, in order to mitigate the high burden of TB that has been evidently established.
- In order to adequately address the high burden of TB in the Country, matching resources should be mobilized accordingly through the government and cooperating partners.
- The NTP and the Laboratory network through the National Reference Laboratory should be harmonized so that diagnostic services can be strengthened alongside the TB control strategies and activities.

Programmatic

- There is need to expand the coverage of TB program interventions especially among the urban poor, the HIV positive and the aged to target the ''hot spots'' as highlighted by the survey.
- It is cardinal that efforts are made to strengthen the routine surveillance so that new cases of TB can be immediately picked up by the NTP to avoid uninterrupted transmission in communities.
- There is need to invest in ICT systems and digitize the x-ray systems on mobile hospitals so that satellite areas can have access to high quality specialized radiology service.
- Given the time it takes from planning to actual execution of the survey, the NTP should start planning activities for the follow up national TB prevalence survey. The future surveys should take cognizance of the importance of investigating EPTB, paediatric populations and DST.
- The occurrence of symptomatic NTM in Zambia needs to be further investigated so that patient management can be optimized.
- In view of chest radiological findings other than TB, further investigations are needed to ensure the epidemiology of the other findings that were of clinical significance are fully understood in order to improve the quality of life for the public.
- Digital data management systems in large scale national surveys should be the norm, rather than the exception.

This survey was conducted at a time when the TB control strategy is evolving into new approaches and therefore the findings will form a good basis and platform to inform the End TB Strategy.

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Annexes

Annex 1. Sample Size considerations

The TB prevalence survey is designed to calculate the sample size based on the idea that only one survey with a good precision will be performed, as recommended by the WHO Task Force in March 2009. If another survey will be conducted in the upcoming 5 years, this survey will be designed after the results of the first survey become available.

The sample size is based on the formula to calculate the required number of people for obtaining a prevalence rate with a certain precision. Because prevalence studies from Philippines and Vietnam showed design effects varying from 1.82 to 2.69, we have calculated the sample size for a design effect of 1.5, 2.0 and 2.5.

The sample size that will be able to estimate the prevalence rate with 25% precision is as follows:

$N= (Z\alpha^2 * (1-P) / d^2*P$ **[formula 1]**

$N = [1.96^2*(1-0.00199)/0.25^2*0.00199]*1.5 =46,239$

Accounting for 15% non response =54,398

$Z\alpha^2 =1.96$

P= prevalence of pulmonary TB in adult population

d=precision 25%

Design effect = 1.5

Assumptions

- NTP estimate for SS+ prevalence among adults for 2011: 199 per 100,000 population (MOH 2011).
- Proportion adult population 2011: 0.546 (CSO 2011)
- Adult population: 7149,497 (CSO 2011)
- Absolute number of adult SS+ cases notified in 2011: 14,200 (MOH 2011)
- Note: Zambia does not have previous prevalence survey results. The ZAMBART study was only done "along the line of rail", an area whose TB prevalence is not considered to be representative for the whole Zambia. The current estimates are based on the NTP national notification rates for SS+ for adults (15years and above).

Annex 2. Informed consent (General)

FOR NEVER MARRIED PARTICIPANT AGED 15-17 YEARS, SEEK CONSENT FROM THE PARENT OR OTHER ADULT IDENTIFIED AS RESPONSIBLE FOR THE ADOLESCENT BEFORE ASKING THE ADOLESCENT FOR HIS/HER CONSENT. ENROL ONTO STUDY ONLY IF BOTH THE PARENT (OTHER ADULT) AND THE ADOLESCENT CONSENT.

Information for Tuberculosis Disease Prevalence Survey Zambia

Principal Investigator
Dr N Kapata
Ministry of Health
National Tuberculosis and Leprosy Program
Ndeke House PO Box 30205, Lusaka

Dear participant:

My name is _____ and I am from Ministry of Health.

You are invited to take part in a survey which is planned to find out how many persons in Zambia have tuberculosis (TB). We have selected you in the survey because you are living in the area which we have selected to include in the survey. If you decide to participate in the survey, the following procedure will be taken:

We will ask you to come to a central study site where a person from our staff will ask you few questions regarding symptoms for TB.

You will be asked to have a chest X-Ray. The purpose of this chest X-Ray is to see if you have any lung disorder. If you do not have any symptoms and there are no abnormalities visible on the X-Ray, then you no further steps will be taken.

But, if you have specific symptoms and/or abnormalities on the chest X-Ray which may indicate any lung disorder, we will ask you few more questions in detail. We will ask you to provide two sputum samples. These sputum samples will only be used for the diagnosis of TB. These sputum samples will be examined in the laboratory for the presence of the particular germ that may indicate TB. If these germs are found in the sputum, you will be given free treatment.

We will also then offer HIV testing to you at this central site by means of a finger prick. For the HIV, test, we will need a few drops of blood from a finger. The equipment used in taking the blood is clean and completely safe. It has never been used before and will be thrown away after each test. If you do not wish to know your HIV results you can still contribute by allowing your test results to be used for this survey.

In this case, no name will be attached to your blood sample and so we will not be able to tell you the test results and no one else will be able to know the test results either. If you wish to know your HIV status, the survey team has trained counselors onsite who can test you for HIV and provide you with your test results immediately. If you are found to be HIV positive, you will be referred for appropriate free care within the government health system. You do not have to agree to the HIV testing to participate in the survey, you can still participate in the tuberculosis survey without testing for HIV.

The benefit for you of participating is that when any disease is discovered during the screening, you will receive care on the central site or referred to appropriate facility. Your participation will provide information that will help the Ministry of Health to improve health services in Zambia. This may benefit you in the long term.

The risks of participation are minimal. The finger prick for HIV testing may present slight discomfort from the needle/lancet prick. The chest X-Ray procedure may harm very small amounts of cells in your body. Also, you might feel some discomfort when providing sputum samples because you will be asked to breathe very deeply.

The samples you provide may be sent abroad for external quality assurance (EQA) purposes only.

All results will be kept confidential. Participation in this survey is voluntary. If you choose not to participate, it will not affect in any way the provision of health services to you. You can withdraw yourself from the survey at any moment.

We will highly appreciate your participation in the survey.

If you have any question please contact the Principal Investigator: Dr Nathan Kapata, Ministry of Health, Cell: 0977427584.

OR

The Chairperson, University of Zambia Biomedical Research Ethics Committee, Telephone, 211 256067, Lusaka.

Certificate of Consent for TB Survey (GENERAL)

9-Digit PIN Code: ☐☐-☐☐☐-☐☐☐☐

(Cluster Code + Household ID + ParticipantID)

FOR NEVER-MARRIED PARTICIPANT AGE 15-17 YEARS ASK CONSENT FROM THE PARENT OR OTHER ADULT IDENTIFIED AS RESPONSIBLE FOR THE ADOLESCENT BEFORE ASKING THE ADOLESCENT FOR HIS/HER CONSENT. ENROL ONTO STUDY ONLY IF BOTH THE PARENT (OTHER ADULT) AND THE ADOLESCENT CONSENT.

I have read/understood the Information Sheet concerning the Tuberculosis Prevalence Survey in Zambia.

I have had the opportunity to ask questions about the survey and the questions that I have asked have been answered to my satisfaction.

I now understand what will be required of me and what procedures I will have to go through during this survey.

I understand that I may withdraw from this survey at any time without giving a reason and withdrawal will not affect my usual care and treatment.

I consent voluntarily to participate in this survey.

Signature / thumb impression: _____ Date: _____

Name: _____

Witness Signature / thumb impression: _____ Date: _____

Name: _____

Annex 3. Certificate of Consent for HIV Testing

9-Digit PIN Code: ☐☐-☐☐☐-☐☐☐☐

(Cluster Code + Household ID + ParticipantParticipant ID)

FOR NEVER-MARRIED PARTICIPANT AGE 15-17 YEARS ASK CONSENT FROM THE PARENT OR OTHER ADULT IDENTIFIED AS RESPONSIBLE FOR THE ADOLESCENT BEFORE ASKING THE ADOLESCENT FOR HIS/HER CONSENT. CONDUCT THE TEST ONLY IF BOTH THE PARENT (OTHER ADULT) AND THE ADOLESCENT CONSENT.

I have read/understood the Information Sheet concerning the Tuberculosis Prevalence Survey in Zambia.

I have had the opportunity to ask questions about the HIV testing procedure and the questions that I have asked have been answered to my satisfaction.

I now understand what will be required of me and what procedures I will have to go through for HIV testing.

I understand that I may refuse to give blood for HIV testing, without giving a reason, and still participate in the survey. My refusal to HIV testing will not affect my care and treatment in the survey.

I consent voluntarily to give blood for HIV testing in this survey.

AGREE ☐ REFUSE ☐

I wish to know my results:

AGREE ☐ REFUSE ☐

Signature / thumb impression: _____ Date: _____

Name: _____

Witness Signature / thumb impression: _____ Date: _____

Name: _____

Annex 4. Case Definition Framework

Symptoms	Central X-ray	Central Reference Lab Smear		Mgit Culture	Gene Xpert	Study Case	Clinical Case	Type
Either Result		Spot (S)	Morning (M)	S or M				
+	+	+	+	+	+	Definite	Definite	C+/S+
+	+	+	+	+	-	Probable	Definite	C+/S+
-	+	+	+	+	+	Definite	Definite	C+/S+
+	-	+	+	+	+	Definite	Definite	C+/S+
-	+	+	+	+	-	Probable	Probable	C+/S+
+	-	+	+	+	-	Probable	Probable	C+/S+
+	+	+	-	+	+	Definite	Definite	C+/S+
-	+	+	-	+	-	Probable	Probable	C+/S+
+	-	+	-	+	+	Definite	Definite	C+/S+
+	+	+	-	+	-	Probable	Probable	C+/S+
-	+	+	-	+	-	Probable	Probable	C+/S+
+	-	+	-	+	-	Probable	Probable	C+/S+
+	+	-	-	+	N/A	Definite	Definite	C+/S-
-	+	-	-	+	N/A	Definite	Definite	C+/S-
+	-	-	-	+	N/A	Definite	Definite	C+/S-
+	+	+	+	-	+	Definite	Definite	C-/S+
-	+	+	+	-	+	Definite	Definite	C-/S+
+	-	+	+	-	+	Definite	Definite	C-/S+
+	+	+	+	-	-	Probable	Probable	C-/S+
-	+	+	+	-	-	Probable	Probable	C-/S+
+	-	+	+	-	-	Probable	Probable	C-/S+
+	+	+	-	-	+	Definite	Definite	C-/S+
-	+	+	-	-	+	Definite	Definite	C-/S+
+	-	+	-	-	+	Definite	Definite	C-/S+
+	+	+	-	-	-	Negative	Negative	C-/S+
-	+	+	-	-	-	Negative	Negative	C-/S+
+	-	+	-	-	-	Negative	Negative	C-/S+
+	+	-	-	-	N/A	Negative	Negative	C-/S-
-	+	-	-	-	N/A	Negative	Negative	C-/S-
+	-	-	-	-	N/A	Negative	Negative	C-/S-
-	+	-	-	-	N/A	Potential (examine further)	Potential (further invest)	C-/S-
+	-	-	-	-	N/A	No case	No case	C-/S-
-	-	+	-	-	+	Negative	Negative	C-/S-
-	-	-	-	-	N/A	No case	No case	C-/S-

Note:

A. For all probable and definite cases put on ATT;
B. For potential cases: further clinical investigation and a second set of sputum sample

Annex 5. Household census register

Registration of all individuals who slept in this household last night.

PIN ☐☐-☐☐☐
(Cluster no + HH no)

Date: __ / __ / ____ (dd/mm/yyyy)

Wards: _____ **Zones: Plot / House No. _____**

Township: _____

Village/City: _____

Verified by (Team Leader):

Name:
_____

DATA COLLECTED DURING CENSUS											**Actions done to identify TB suspect**		**Outcome**
Subject ID	**Barcode**	**First name/Surname**	**Age**	**Sex**	**Head of Household**	**Tribe**	**Marital statues**	**Occupation**	**Education**	**Present at visit.**	**Symptom Screening**	**Chest X-Ray**	**Suspect**
			(In Years)	M/F	Y/N	(Category code) Select 1-7 See reverse of form	(Category code) Select 1-4 See reverse of form	(Category code) Select 1-10 See reverse of form	(Category code) Select 1-6 See reverse of form	Y/N	Y/N	Y/N	Y/N

Backside of TB Prevalence Survey Census Register for One Household

Tribe

☐ 1. Bemba
☐ 2. Lozi
☐ 3. Lunda
☐ 4. Luvale
☐ 5. Kaonde
☐ 6. Nyanja
☐ 7. Tonga

Marital status

☐ 1. Never married
☐ 2. Currently married or living as married
☐ 3. Divorced or separated
☐ 4. Widowed

Main Occupation

☐ 1. Unemployed
☐ 2. Occasional/seasonal employment
☐ 3. Employed by government
☐ 4. Employed in private sector
☐ 5. Self-employed
☐ 6. Pupil / student
☐ 7. Housewife / homemaker
☐ 8. Working on own land
☐ 9. Other (Specify – Max. 25 characters) _____

Highest Schooling Level

☐ 1. No schooling
☐ 2. Primary school (grade 1 to 7), not completed
☐ 3. Primary school (grade 1 to 7), completed
☐ 4. Secondary school (grade 8 to 12 / form 1 to 5), not completed
☐ 5. Secondary school (grade 8 to 12 / form 1 to 5), completed
☐ 6. Further education after secondary school

Annex 6: Individual patient card

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Locality Name: _____

Participant Name: _____

Age: _____ Sex: _____

Appointment Date: _____ Time: _____ Place: _____

Census Register	YES: ☐	NO: ☐	Date: _____
Consent Done (Gen)	YES: ☐	NO: ☐	Date: _____
Consent HIV Done	YES: ☐	NO: ☐	Date: _____
Screening interview	YES: ☐	NO: ☐	Date: _____
X-ray done	YES: ☐	NO: ☐	Date: _____
Eligible for Sputum Collection	YES: ☐	NO: ☐	Date: _____
Sputum Spot	YES: ☐	NO: ☐	Date: _____
Sputum Morning	YES: ☐	NO: ☐	Date: _____
In-Depth interview	YES: ☐	NO: ☐	Date: _____
HIV Test	YES: ☐	NO: ☐	Date: _____

PIN ☐☐-☐☐☐
(Cluster no + HH no)

Please stick BARCODE here

(of the head of the household)

ALL QUESTIONS IN THIS SECTION MUST BE ANSWERED
Administer questionnaire to head of household or any responsible adult who is available

Q01_INC	**Interviewer's code**	
Q02_DAT	**Date today**	D D M M Y Y Y Y

Q03_HOH Are you the Head of Household?

No	Yes
0	1

ALL QUESTIONS IN THIS SECTION MUST BE ANSWERED
Household questions to be asked

Q04_HHH In your Household is there

(Check every option)

	No	**Yes**
Electricity	**0**	**1**
A radio/radio cassette	**0**	**1**
A television	**0**	**1**
A refrigerator/freezer	**0**	**1**
A bicycle	**0**	**1**
A motorcycle	**0**	**1**
A car	**0**	**1**
A domestic worker not related to household head	**0**	**1**
A mobile phone	**0**	**1**
A landline (non mobile telephone)	**0**	**1**

Q05_WOL **Do members of your household work on their or the family's agriculture land?**

No	Yes
0	1

Q06_WAT **What is the main source of DRINKING WATER for this household (check only one option)**

Piped water inside the residence	**1**
Piped water in the yard	**2**
Piped water from a public tap	**3**
Protected well	**4**
Unprotected shallow well	**5**
Traditional well	**6**
Bore hole	**7**
River, stream, lake etc	**8**
Other	**9**

Q07_TOI **What is the main type of TOILET facility for this household?**

(Check only one option)

Private flush toilet	**1**
Shared flush toilet	**2**
Pit Latrine without ventilation	**3**
VIP Latrine	**4**
None- use bush/field	**5**
Bucket system	**6**
Chemical	**7**
Other	**9**

Q08_DWE **Which of the following type's best describes the main dwelling unit that this household occupies?**

House/brick structure on own stand(single unit)	**11**
Cluster/Multi-Unit (Z))	**12**
Traditional dwelling/hut/structure made from traditional material	**21**
Flat in block of flats	**22**
Servant quarter for Z	**31**
Caravan/Tent	**32**
Worker's hostel	**34**
Other	**99**

Q09_1_HMP **How many people – including children - live in your household (-1 if unknown)** ☐

Q09_2_HMR **How many sleeping rooms does your household have? (-1 if unknown)** ☐

Q10_FLO **What is the main type of flooring for this household?**

(Check only one option)

Dirt/earth	**11**
Wood, plank	**12**
Parquet, lino	**21**
Cement	**22**
Tile flooring	**31**
Other	**95**

Q11_HEA **What type of fuel does your household mainly use to keep warm inside the house during winter?**

(Check only one option)

Nothing	**1**
Electricity	**2**
Liquefied Petroleum Gas	**3**
Kerosene/Paraffin	**4**
Charcoal	**5**
Wood	**6**
Other	**7**

Q12_FFC **What type of fuel does your household mainly use for cooking?**

(Check only one option)

No cooking is done	**1**
Electricity	**2**
Gas	**3**
Paraffin	**4**
Charcoal	**5**
Wood	**6**
Other	**7**

If charcoal or wood continue, else go to Q14

Q13_ TOS **What type of stove is usually used for cooking?**

Open fire	**1**
Surrounded fire	**2**
Stove with combustion chamber	**3**

Q14_WCH **Where does cooking mainly happen?**

(Check only one option)

Indoors in main house	**1**
Indoors separate building	**2**
Outdoors	**3**

Q15_RON **Did your household have to rely on any of the following in the last 18 months?**

(Each item must be answered)

	No	Yes
Relief food, free food from government and other bodies	**0**	**1**
Reducing number of meals or food in-take	**0**	**1**
Borrowing cash (e.g. kaloba (=borrowing with interest), borrowing from friends etc)	**0**	**1**
Sale of assets	**0**	**1**
Sending household members away	**0**	**1**

Q16_HUN **During the past three months, did it happen even once that you or any member of your family experienced hunger because you did not have any food to eat?**

No	**0**
Yes	**1**
Unk	**-5**

	Interviewer's Code	Date								Signature
		d	d	m	m	y	y	Y	y	
Interviewer										
Field Manager										

Annex 8. Symptom Screening

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

Age: _____ Sex: _____
Wards: _____
Zones: Plot / House No. _____
Township: _____
Village/City: _____
Date: _____ / _____ / _____ (dd/mm/yyyy)

1. Do you have cough?

1. ☐ Yes (Go to Q2)
2. ☐ No (Go to Q3)

2. For how many weeks did you have this cough?

1. ☐ < 2 week
2. ☐ ≥ 2 weeks

3. Do you have fever ?

1. ☐ Yes
2. ☐ No

4. For how many weeks did you have this fever?

1. ☐ < 2 week
2. ☐ ≥ 2 weeks

5. Do you have chest pain?

1. ☐ Yes
2. ☐ No

6. For how many weeks did you have this chest pain?

1. ☐ < 2 week
2. ☐ ≥ 2 weeks

Annex 9. Chest X-ray Field Screening and Interpretation Form

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

1. X ray taken?

☐ 1. Yes
☐ 2. No, no consent for chest X ray
☐ 3. No, excluded because pregnant
☐ 4. No, not able to come to field/study site

2. X ray Reading/Result

☐ 1. Normal
☐ 2. Abnormal
☐ 3. Other specify …….
☐ 4. Not interpretable

Step 1: Identify person eligible for sputum collection (TB suspects)

Person is eligible for sputum collection if any of the following applies (circle which applies)

1. Person has cough for ≥ 2 weeks (answer Q2 is ≥ 2 weeks) *or*
2. Person has fever for ≥ 2 weeks (answer Q4 is ≥ 2 weeks) *or*
3. Person has chest pains for ≥ 2 weeks (answer Q6 is ≥ 2 weeks)

4. Person has abnormal chest X ray *or*
5. Persons with not interpretable chest X rays

Annex 10. Presumptive TB Patient In-Depth Questionnaire

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Interviewer: First I am going to ask you a few demographic questions.

Q2. **How old are you? _____(fill in age in years)**

Q3. **What is your marital status?**

☐ Never married (1)
☐ Currently married or living as married (2)
☐ Divorced or separated (3)
☐ Widowed (4)

Interviewer: Now, I am going to ask you a few questions about respiratory symptoms.
I am going to say out loud several complaints and ask you to tell me if you had these complaints during the last month.

Q3.1 Do you currently have a cough?

☐ Yes (1)
☐ No (2), go to Q3.4

If yes, for how many weeks have you been coughing
_____(weeks)

Q3.2 Do you currently produce sputum while coughing?

☐ Yes (1)
☐ No (2), go to Q3.3

If yes, for how many weeks have you been producing sputum? _____(weeks)

Q3.3 Do you currently cough up blood?

☐Yes (1)
☐ No (2), go to Q3.4

If yes, for how many weeks have you been coughing up blood? _____(weeks)

Q3.4 Do you currently have chest pains?

☐ Yes (1)
☐ No (2), go to Q3.5

If yes, for how many weeks did you have chest pains? _____(weeks)

Q3.5 Do you currently have fever at night?

☐Yes (1)
☐ No (2), go to Q3.6

If yes, for how many weeks did you have fever at night? _____(weeks)

Q3.6 Do you currently have night sweats?

☐Yes (1)

☐ No (2), go to Q3.7

If yes, for how many weeks did you have night sweats? _____(weeks)

Q3.7 In the last month have you lost weight unintentionally?

☐ Yes (1)
☐ No (2), go to Q3.8

If yes, how many weeks ago did you start to loose weight? _____(weeks)

Q3.8 Do you currently have other respiratory complaints?

☐ Yes (1)
☐ No (2), go to 4

If yes, which other complaints did you have? _____

Q4. Did you seek treatment for any of these complaints?

☐ Yes (1), go to Q5.1A
☐ No (2), go to Q8
☐ Not applicable, no complaints (8)

Interviewer: In the next questions I am going to ask you which type of health care you have visited because of these complaints and in which order you have visited this health care provider. If you have visited one health care provider more than once, please remember the first visit to this specific health care provider.

Q5.1A Which health care provider have you visited first to seek treatment or advice for your complaints? (Tick only one)

☐ Government/Community Clinic (1)
☐ Private clinic/hospital (2)
☐ Government Provincial District Hospital (3)
☐ Pharmacy (4)
☐ Private doctor (5)
☐ Traditional healer (6)
☐ Faith Based Organization (7)
☐ Other (8), first I visited the following provider: _____

Q5.1.B How long ago did you have your first visit to this health care provider?
_____(weeks)

Q5.2A Which health care provider have you visited secondly to seek treatment or advice for your complaints? (Tick only one)

☐ Government/Community Clinic
☐ Private clinic/hospital (1)
☐ Government Provincial District Hospital (2)
☐ Pharmacy (3)
☐ Private doctor (4)
☐ Traditional healer (5)
☐ Faith Based Organization (6)
☐ Other (7), secondly I visited the following provider:
☐ Not applicable (8) because person had not visited 2 health care providers, go to Q6.1

Q5.2.B How long ago did you have your first visit to this health care provider?
_____(weeks)

Q5.3A Which health care provider have you visited thirdly to seek treatment or advice for your complaints? (Tick only one)

☐ Government/Community Clinic
☐ Private clinic/hospital (1)
☐ Government Provincial District Hospital (2)
☐ Pharmacy (3)
☐ Private doctor (4)
☐ Traditional healer (5)
☐ Faith Based Organization (6)
☐ Other (7), secondly I visited the following provider:
☐ Not applicable (8) because person had not visited 3 health care providers, go to Q6.1

Q5.3.B How long ago did you have your first visit to this health care provider?
_____(weeks)

Q5.4A Which health care provider have you visited fourthly to seek treatment or advice for your complaints? (Tick only one)

☐ Government/Community Clinic
☐ Private clinic/hospital (1)
☐ Government Provincial District Hospital (2)
☐ Pharmacy (3)
☐ Private doctor (4)
☐ Traditional healer (5)
☐ Faith Based Organization (6)
☐ Other (7), secondly I visited the following provider:
☐ Not applicable (8) because person had not visited 3 health care providers, go to Q6.1

Q5.4B How long ago did you have your first visit to this health care provider?
_____(weeks)

5.5A Which health care provider have you visited fifth to seek treatment or advice for your complaints? (Tick only one)

☐ Government/Community Clinic
☐ Private clinic/hospital (1)
☐ Government Provincial District Hospital (2)
☐ Pharmacy (3)
☐ Private doctor (4)
☐ Traditional healer (5)
☐ Faith Based Organization (6)
☐ Other (7), secondly I visited the following provider:
☐ Not applicable (8) because person had not visited 3 health care providers, go to Q6.1

Q5.5.B How many weeks ago did you have your first visit to this health care provider?
_____(weeks)

Q6.1 Did you have X-ray examinations for these complaints?

☐ Yes (1)
☐ No (2), go to Q7.1

Q6.2 Did you have chest X ray examinations taken at a public health facility or at a private facility?

☐ Public health care facility (1)
☐ Private facility (2)

Q7.1 Did you have sputum examination for these symptoms?

☐ Yes (1)
☐ No (2), go to Q8.1

Q7.2 Did you have sputum examinations taken at a public health facility or at a private facility?

☐ Public health care facility (1)
☐ Private practitioner (2)

Q8.1 Have you ever been treated for TB? (Probe and be sure only convential treatment)

☐ Yes (1)
☐ No (2)
☐ Don't know (3) go to Q9

Q8.2 In which health care facility have you been treated for TB?

_____

Q8.3 From which date to which date have you received TB treatment?

Date start treatment: _____ (day/month/year)

End date treatment:_____ (day/month/year)

Q9.1 Has anybody in your household been treated for TB in the past?

☐ Yes (1)
☐ No (2), go to Q10
☐ Do not know (3), go to Q10

Q9.2 How long ago has the most recent TB patient in your household been treated?
_____(months)

Q10 What type of transport do you mainly use to visit the nearest health facility?

☐ walk (1)
☐ bicycle (2)
☐ motorbike (3)
☐ private car/taxi (4)
☐ tractor / truck (5)
☐ cattle cart (6)
☐ bus (7)
☐ other, specify_____ (8)

Q11 How long would it take to reach the nearest health facility using this means?

☐ Less than 1 hour (1)
☐ 1 to 3 hours (2)
☐ 6 hours / half day (3)
☐ 12 hours / full day (4)
☐ More than 1 day (5)

Annex 11. HIV Testing Results Form

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

1. Agreed to HIV testing?
   1. Yes
   2. No, no consent for HIV test
   3. No, excluded because pregnant
   4. No, not able to come to study site

2. Wants to know result:
   1. Yes
   2. No (Only Determine)

3. HIV result

Determine Positive ☐ Negative ☐

(if positive)
Uni Gold Positive ☐ Negative ☐

Interviewer:
Name: _____
Designation: _____
Signature: _____
Date: _____ / _____ / _____ (dd/mm/yyyy)

Annex 12. Chest X-ray interpretation at Central Level

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

Mark X in the appropriate box:

☐ 1. N = Normal
☐ 2. AD – NS = abnormality detected - not significant
☐ 3. ADS – NA = abnormality detected, significant – no active disease
☐ 4. ADS – NTB = abnormality detected, significant – not tuberculosis
☐ 5. ADS – TB =abnormality detected, significant – tuberculosis
☐ 6. ADS – U = abnormality detected, significant - unclassified

Name of Radiologist: ……
Date: __/__/____ (dd/mm/yyyy)

Annex 13. TB Survey Sputum Dispatch Form

Cluster Number:_____

Total Number of Specimens Sent:_____

Date Specimens Sent:__/__/____ (dd/mm/yyyy)

Name of Sender:_____ Signature:_____

Name of Receiver:_____ Signature:_____

Date Specimens Received:_____

No.	Participants PIN/Barcode	Date sample collected	Tick Received Specimen	Comment
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Delivered by:

Name_____

Date:

Time:

Signature:

Note: Use red pen if there are any problems with the sample

Annex 14. Smear/GeneXpert Form for Sample "S"

Processed by (Tick applicable CRL):

☐ CDL (1)
☐ TDRC (2)
☐ UTH (3)

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

Date Received: __/__/____ (dd/mm/yyyy)

Date Processed: __/__/____ (dd/mm/yyyy)

Smear Microscopy (Test Results S smear)

1) First Spot Sputum (S)

☐ Positive(1)
☐ Negative(2)
☐ Unknown(9)

GenXpert (Test Results)

2) GenXpert Sputum (S)

☐ Positive(1)
☐ Negative(2)
☐ Indeterminant(9)

Counter Checked By .....

Date __/__/____ (dd/mm/yyyy)

Annex 15. Smear/GeneXpert Form for Sample "M"

Processed by (Tick applicable CRL):

☐ CDL (1)
☐ TDRC (2)
☐ UTH (3)

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

Date Received: __/__/____ (dd/mm/yyyy)

Date Processed: __/__/____ (dd/mm/yyyy)

Smear Microscopy (Test Results M smear)

1) First Spot Sputum (M)

☐ Positive(1)
☐ Negative(2)
☐ Unknown(9)

GenXpert (Test Results)

2) GenXpert Sputum (M)

☐ Positive(1)
☐ Negative(2)
☐ Indeterminant(9)

Counter Checked By .....

Date __/__/____ (dd/mm/yyyy)

Annex 16. Culture Form for Sample 'S'

Processed by (Tick applicable CRL):

☐ CDL (1)
☐ TDRC (2)
☐ UTH (3)

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

Date Received: __/__/____ (dd/mm/yyyy)

Date Processed: __/__/____ (dd/mm/yyyy)

Culture (Test Results smear S)

☐ Positive MTB(1)
☐ Negative MTB(2)
☐ MOTT(3)
☐ CTD(4
☐ Unknown(9)

Counter Checked By .....

Date __/__/____ (dd/mm/yyyy)

Annex 17. Culture Form for Sample 'M'

Processed by(Tick applicable CRL):

☐ CDL (1)
☐ TDRC (2)
☐ UTH (3)

PIN ☐☐-☐☐☐-☐☐
(Cluster no + HH no + Subject ID)

Please stick BARCODE here

Date Received: __/__/____ (dd/mm/yyyy)

Date Processed: __/__/____ (dd/mm/yyyy)

Culture (Test Results smear M)

☐ Positive MTB(1)
☐ Negative MTB(2)
☐ MOTT(3)
☐ CTD(4
☐ Unknown(9)

Counter Checked By .....

Date __/__/____ (dd/mm/yyyy)

Annex 18. Monitoring Report Forms

Monitoring Report

Cluster Code:…….. **Cluster Name:……..**

Cluster Start Date…… **Cluster End Date……..**

No.	Questions	Yes	No	Comment
1.	Are all the Forms/Registers loaded on the PDA as well as the paper based Forms/Register being used for all the Data Collection in the field and are the barcodes printed during enumeration of participants at household level and stuck on the Individual Survey Card (Annex 6)?			
2.	Is Data Monitoring being carried out during data collection by the Field Team Leader every evening and also before the end of all field work activities?			
3.	Are the Census data for all individuals correctly stored on the PDA (That is, PIN, first name, surname, age, sex, tribe, marital status, occupation, education, etc.			
4.	Are all the Forms/Registers on the PDA being checked for Inconsistent Data Errors? (That is, there is different / conflicting data of the same Participant on different forms on the PDA?)			
5.	Are all the data stored on the PDA for Symptom Screening Form (Annex 8), TB Suspect In-Depth Questionnaire (Annex 14), Social Economic Status (Annex 7) being checked for accuracy, completeness and consistency?			
6.	Are barcodes printed for Chest X-ray images taken and for sputum specimen collected from eligible participants and stuck on the images as well as the side of the sputum container?			
7.	Are the Chest X-Ray Field Screening and Interpretation Forms (Annex 10) loaded on the PDA checked for accuracy, completeness and consistency?			
8.	Are all the Data files being checked for accuracy, completeness and consistency by field Team Leader before they are emailed to the Central DMU?			
9.	Are the edits or changes made on Forms/Registers loaded on the PDA for missing, incomplete and incorrect data being done under supervision by the Team Leader?			
10.	Are all Forms/Registers completely secured from theft, unauthorized, access, fire and harsh weather conditions?			
11.	Are the PDAs charged regularly and secured from theft, fire and harsh weather conditions?			
12.	Is the Privacy of all Forms/Registers strictly followed during field work?			
13.	Are all the paper based Forms/Registers securely packed and dated before transporting to the Central DMU level?			
14.	Are the collection, monitoring, management and transfer of data being carried out under the supervision by the Field Team Leader?			

NAME OF FIELD TEAM LEADER…… SIGNATURE AND DATE …….

Annex 19. Data Management Register

Data Management Register

Cluster Code:…… **Cluster Name:……**

Cluster Start Date__/__/____ (dd/mm/yyyy) Cluster End Date__/__/____ (dd/mm/yyyy)

Annex Number	Forms & Registers Received From Cluster/Field To DMU (Electronic & Paper Based)	Date Received	Name Of Receiver	Number Of Paper Based Forms/Number of Electronic Records
Annex xx	Informed Consent (General)			
Annex xx	Certificate of Consent for HIV Testing			
Annex xx	Household Census Register			
Annex xx	Individual Survey Card			
Annex xx	Social Economic Status			
Annex xx	6 Symptom Screening Form (1st Interview)			
Annex xx	Chest X Ray Field Screening & Interpretation			
Annex xx	TB In-depth Questionnaire			
Annex xx	HIV Testing Results			
Annex xx	TB Suspect Register (not used during pilot)			
Annex xx	Chest X-ray Interpretation Form at Central Level			
Annex xx	Sputum Dispatch Form			
Annex xx	CRL Results Smears/GenXpert Form Sample 'S'			
Annex xx	CRL Results Smears/GenXpert Form Sample 'M'			
Annex xx	CRL Culture Results Form Sample 'S'			
Annex xx	CRL Culture Results Form Sample 'M'			
Annex xx	Monitoring Report Forms			

Annex 20. Description of the 3 different models of analysis

*Adapted from Floyd et al 2013 (*Floyd, S. *et al.* Analysis of tuberculosis prevalence surveys : new guidance on best-practice methods. *Emerg. Themes Epidemiol.***10,** 1 (2013)*)*

Method 1 (complete-case or CC/CC)

This method uses a logistic regression model with robust standard errors, no missing value imputation, and analysis is restricted to survey participants (=N2 in Figure 4), and also excludes individuals who were eligible for sputum examination but smear and/or culture results are missing. Individuals who were not eligible for sputum examination are assumed not to have pulmonary TB, unless their chest X-ray was later found to be suggestive of TB based on a reading at "central level" by an experienced radiologist –in which case they are also excluded from the analysis. The 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. Equal weight is given to each participating individual in the sample. However, the model does correct for clustering (by using the observed between cluster variation) when estimating the 95% CI, and can control for stratification in the sampling design. This method corresponds to a classical individual-level analysis of a survey, in the case that one does not need to adjust for sampling weights. TB prevalence surveys are designed to be "self-weighted", with each individual in the population having the same probability of selection into the sample [4] and thus the same "weight" in the analysis. Among participants, this method always underestimates true TB prevalence – because data on pulmonary TB are missing only among individuals who were eligible for sputum examination, who have a relatively higher probability of being a TB case compared with those not eligible. Differential participation in the survey by cluster, age group, and sex may either exacerbate or reduce this bias.

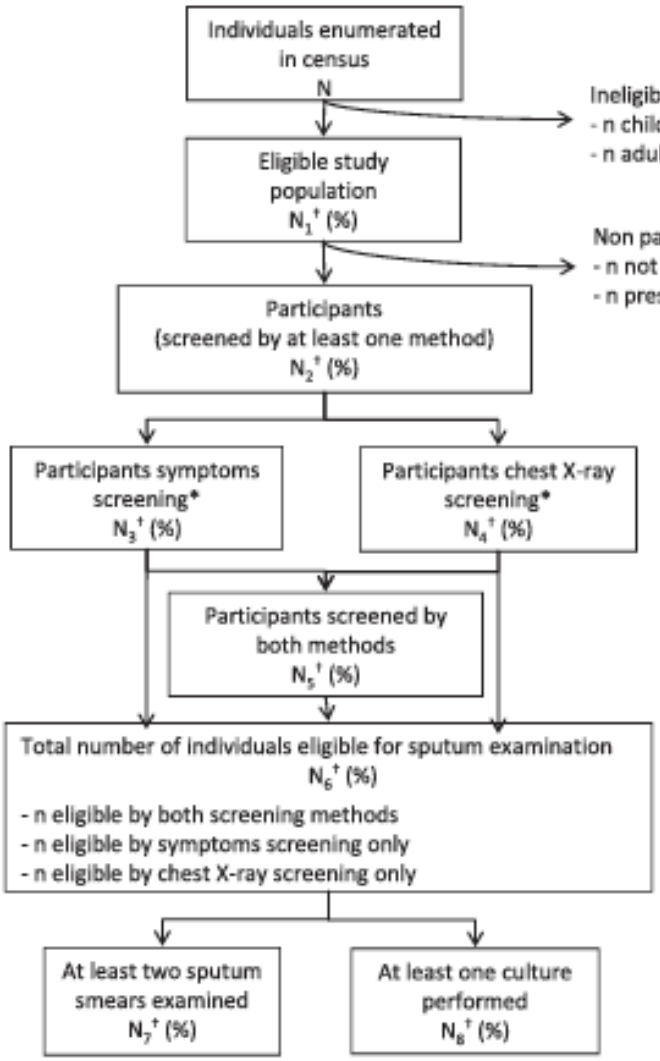
Method 2 (MI/MI)

This method uses a logistic regression model with robust standard errors, with missing value imputation for survey non-participants as well as participants, and includes all individuals who were eligible for the survey in the analysis (=N1 in Figure 4). Multiple missing value imputation is used for all individuals: a) without a field chest X-ray result and/or symptom screening – which includes all individuals who did not participate in the survey, b) with a field chest X-ray reading that the survey protocol stated should also be read at central level, but missing the central reading, c) eligible for sputum examination but whose status as a pulmonary TB case is unknown due to missing smear and/or culture results and d) ineligible for sputum examination, but with a central X-ray reading that was suggestive of TB, whose status as a pulmonary TB case is thus unknown. This method allows for both the clustering in the sampling design and the uncertainty introduced by imputation of missing values when estimating the 95% CI for the prevalence of pulmonary TB.

Method 3 (IPW/MI)

The third method is also a logistic regression model with robust standard errors, with missing value imputation done among the subset of survey participants who were eligible for sputum examination but for whom smear and/or culture results were missing, and inverse probability weighting applied to all survey participants. This method aims to represent the whole of the survey eligible population (=N1 in Figure 4), but the weights are applied only to individuals who participated in the survey. An individual is considered to have participated in the survey if they were screened by both chest X-ray and symptoms, or they refused or were exempted from X-ray screening but provided sputum samples for TB diagnosis (=N5 in Figure 4). Missing value imputation is used for individuals eligible for sputum examination (=N6 in Figure 4), plus individuals who were not eligible for sputum examination but whose chest X-ray was read as suggestive of TB at central level, for whom data on one or more of the central chest X-ray reading, symptom questions, and smear and/or culture results were not available. Inverse probability weighting is then used to correct for differentials in participation in the survey by age, sex, and cluster. This is considered the "safer" method compared with Method 2 because a smaller amount

of missing data is imputed. This means that if the imputation model is miss-specified, the bias in the resulting estimates will be smaller.



Smear-positive, culture-positive**:	n	(% of S+ cases)
Smear-positive, culture-negative**:	n	(% of S+ cases)
Smear-positive, culture not done/contaminated**:	n	(% of S+ cases)
Smear-negative, culture-positive**:	n	(% of C+ cases)
Smear not done, culture-positive**:	n	(% of C+ cases)
Positive bacteriological result**:	n	

† *Subscripts are used to allow reference of different numbers throughout the paper;*
* *Assuming that, according to WHO's recommendations, at least symptoms screening and chest X-ray examination will be applied;*
** *For definitions of a positive smear and culture, see the WHO handbook section 17.3.1 [4]*

Figure 4 Survey participant flow. Schematic of numbers of participants screened for TB in the prevalence survey according to survey protocol.

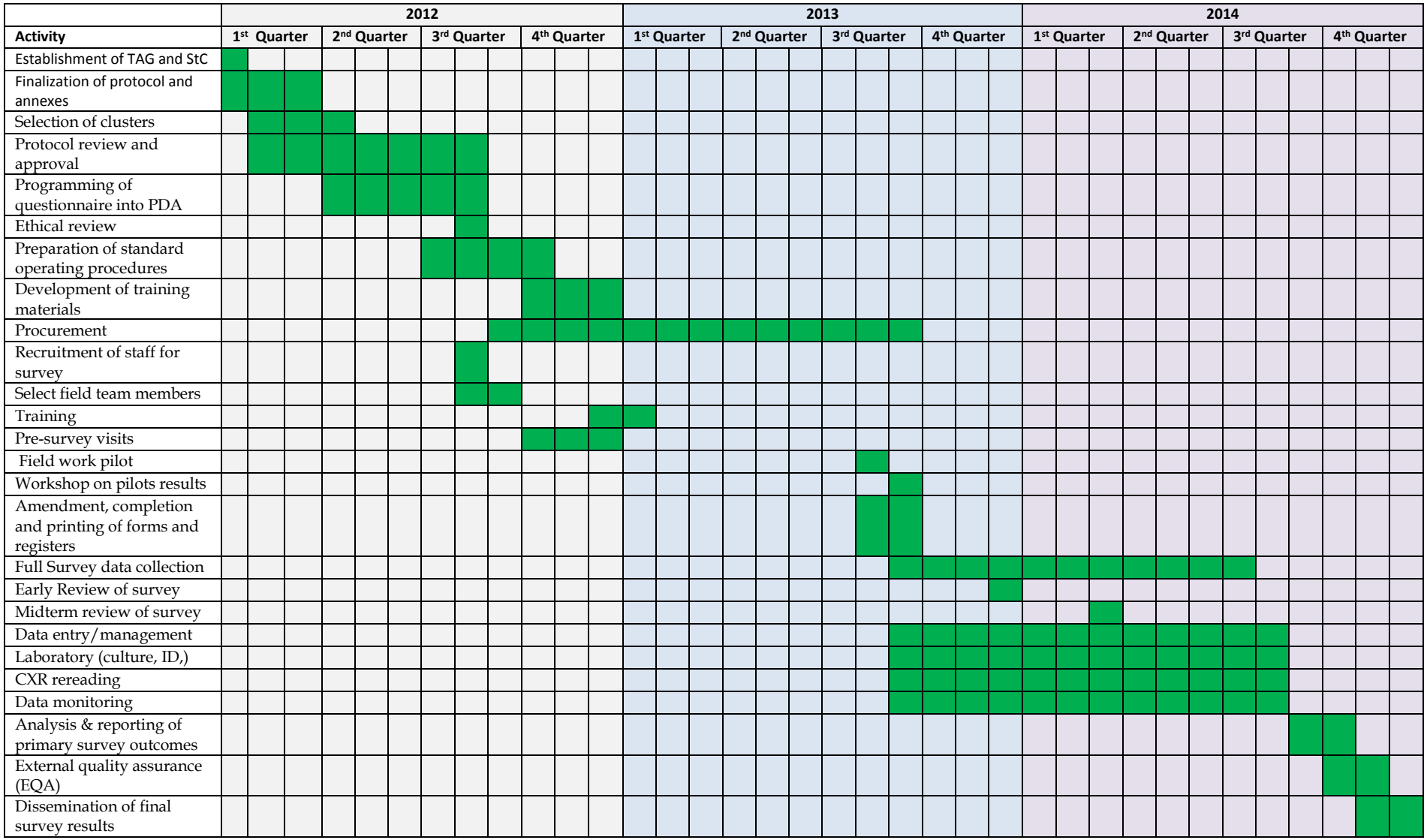
Annex 21. Budget

The budget estimates are made for different categories as shown in table 26. The total expenditure was USD 5,144,844.28.

Table 26. Survey budget

Item	Amount (ZMK)	Amount (USD)	Funding source
Vehicles (fuel and servicing)	645,024.00	129,004.80	GRZ/CDC
Field monitoring activities	2,936,193	587,238.6	GRZ/CDC
Communication: Airtime and internet bundles	500,000	100,000	GRZ
ICT Equipment (BGANs, Server and Software)	591,382.00	118,276.40	GRZ
Trainings, review meetings and data analysis meetings	1,401,500.00	280,300.00	GRZ
Printing: bags, SOPs, T-shirts	546,900.00	109,380.00	GRZ
Refreshments for survey participants	276,452.00	55,290.40	CDC
Courier of Sputum samples	1,119,870.39	223,974.08	CDC
Personnel	7,666,900	1,533,380	GRZ/CDC
Purchase of Xpert MTB/RIF Cartridges	40,000.00	8,000.00	CDC
Digitisation of mobile units, Laboratory supplies, Data checkers	10,000,000	2,000,000	USAID/TBCARE I
Grand Total	**25,724,221.39**	**5,144,844.28**	

Annex 22. Work Plan



Annex 23. Ethical Clearance

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

4th September , 2013.

Your Ref.: 020-08-12

Dr. Nathan Kapata
Ministry of Health
P.O. Box 30205
Lusaka.

Dear Dr. Kapata,

RE: APPLICATION FOR EXTENSION: **"NATIONAL TUBERCULOSIS PREVALENCE SURVEY" (REF. NO. 020-08-12)**

We acknowledge receipt of your letter dated 28th August 2013 requesting for approval of annual renewal for this protocol

We also acknowledge the progress report.

The study is renewed for a further one year. The new approved period is from 4th September 2013 to 3rd September, 2014.

Yours sincerely,

Dr. J.C Munthali
CHAIRPERSON

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

4th September, 2012.

Your Ref: 020-08-12.

Dr. Nathan Kapata,
Ministry of Health,
PO Box 30205,
Lusaka.

Dear Dr. Kapata,

RE: RE-SUBMITTED RESEARCH PROPOSAL: **"NATIONAL TUBERCULOSIS PREVALENCE SURVEY"**

The above mentioned research proposal was re-submitted to the Biomedical Research Ethics Committee with recommended changes on 24th August, 2012. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr. J.C Munthali
CHAIRPERSON

Date of approval: 04 September, 2012 **Date of expiry:** 03 September, 2013

Annex 24: Smear, Culture and XpertMTB/Rif results

		XpertMTB/Rif				
Smear	**Culture**	MTB	Negative	Not tested	Not applicable	**TOTAL**
Positive	MTB	4	2	112	0	**118**
	MOTT	8	39	0	4	**51**
	Negative	7	142	0	16	**165**
	Contaminated	2	20	0	0	**22**
	Total	**21**	**203**	**112**	**20**	**356**
Negative	MTB	1	0	0	0	**1**
	MOTT	3	95	n/a	4	**102**
	Negative	9	66	n/a	5547	**5622**
	Contaminated	5	32	n/a	5	**42**
	Total	**18**	**193**	n/a	**5556**	**5767**
	TOTAL	**39**	**396**	**112**	**5576**	**6123**

Annex 25. Survey Staff and Contributors

Principal Investigator:
Dr. Nathan Kapata, National TB Leprosy Programme Manager, Zambia

Survey Coordinator and Co-Principal Investigator:
Dr. Pascalina Chanda-Kapata, Principal Surveillance and Research Officer, Ministry of Health HQ, Zambia

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Dr. Mwendaweli Maboshe	WHO
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Mr. Joseph Mwanza

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Mr. Tindo Liboma

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Mr. Kabuswe Kayula
Mr. Nelson Mbewe
Mr. Shadreck Kanyaka
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Dr. Eugene McCray

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Zambia Postal Services

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