Federal Democratic Republic of Ethiopia
Ministry of Health

Ethiopian Health and Nutrition
Research Institute

First Ethiopian National Population Based Tuberculosis Prevalence Survey

July 2011
Addis Ababa

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ACRONYMS

ACSM	Advocacy Communication and Social Mobilization
AFB	Acid Fast Bacilli
CXR	Chest X-ray
CSA	Central Statistics Authority
DOTS	Directly Observed Therapy, Short-course
EHNRI	Ethiopian Health and Nutrition Research Institute
FMOH	Federal Ministry of Health
HIV	Human immunodeficiency virus
IPT	Isoniazid Preventive Therapy
ISN	Individual Survey Number
IUATLD	International Union Against TB and Lung Disease
LJ	Lowenstein-Jensen
MDG	Millennium Development Goals
MDR TB	Multi Drug Resistant Tuberculosis
MTB	Mycobacterium Tuberculosis
NTP	National TB Programme
PI	Principal Investigator
PPS	Population Proportion to Size
SC	Steering Committee
SCT	Survey Coordinating Team
TAG	Technical Advisory Group
TB	Tuberculosis
WHO	World Health Organization
ZN	Ziehl Neelsen
SOPs	Standard Operating Procedures

ACKNOWLEDGMENTS

This study was implemented by the Ethiopian Health and Nutrition Research Institute in collaboration with The Federal Ministry of Health of Ethiopia and with the technical support from the World Health Organization. In addition, the following organizations have supported the study in various ways: Global Fund, TBCARE Ethiopia, USAID Ethiopia, GLRA Ethiopia, and Italian Cooperation.

MESSAGE FROM H.E, Dr Kesetebirhan Admasu
State Minister, FMOH

As Ethiopia is one of the 22 Highest TB burden countries in the world, Federal Ministry of Health of Ethiopia is implementing TB Prevention and control program at all level of the health facility. The implementation of TB prevention and control interventions is guided by the five year TB Strategic plan, prepared in line with the HSDP IV and the STOP TB Strategies. In the last 10 years much effort had been made to control and prevent TB throughout the country. The recent scale up of community TB Care by health extension workers ensured access of DOTS at grass root level in the community. However compared to the previous estimation of TB burden for the country, the program achieved TB case detection rate less than 36% which is much lower than the minimum target (70%). The steady progress in case detection rate raised a question whether the previous estimate was reliable or not.

As a result Federal ministry of Health in collaboration with the Ethiopian Health and Nutrition Research Institute conducted the first Ethiopian National TB prevalence survey, which is the first in its kind in the country and also in Africa.

Since reliable baseline information is essential for TB control program, the findings of this survey will be of great importance for the overall management of the National TB control Program particularly for planning, policy and decision making. In addition the findings will assist the national TB control program in guiding the efforts of the government and partners towards reaching the millennium Development goal not only national but also regionally and globally. Therefore it is my great pleasure to recommend using this survey finding for planning and decision making of TB prevention and control activity in Ethiopia.

MESSAGE FROM Dr Amha Kebede, Director General, EHNRI

As TB prevalence is one of the indicators of MDGs and the Global Stop TB Plan, the Ethiopian Ministry of Health and the Ethiopian Health and Nutrition Research Institute, EHNRI have conducted this population based National TB Prevalence Survey.

The Ethiopian Ministry of Health, which stresses the importance of research for health development, delegated its health research arm, EHNRI to undertake this survey as it has long years of fruitful research experience on the national priority health research agendas including on infectious and non infectious diseases, nutritional problems as well as on modern and traditional drugs.

This survey is conducted with international standard methods that address the WHO recommendation. It is the first of its kind ever conducted in Africa. It is the result of excellent collaborative effort of Ethiopian Health and Nutrition Research Institute, Federal Ministry of Health and various partners working on TB.

This survey, which mainly helped to know the true epidemiology of TB, monitor the ongoing program impact and collect relevant data on incidence and prevalence, is believed to strengthen the national TB prevention and control program.

EXECUTIVE SUMMARY

The aim of this study was to conduct a nationwide TB prevalence survey to directly measure TB disease prevalence, estimate the proportion of cases detected and treated by the National Tuberculosis Programme, and identify factors associated with the relatively low case notification rate in Ethiopia. The study was conducted between October 2010 and June 2011 by a research team from the Ethiopian Health and Nutrition Research Institute (EHNRI), the Federal Ministry of Health (FMOH), in collaboration with local partners and technical assistance from the World Health Organization (WHO) head quarters and funding from the Global Fund to fight AIDS, TB, and Malaria, TB CARE, USAID, GLRA, and WHO.

The survey was conducted on a representative sample of 46,697 (the minimum sample size was 46,514) adults age > 15 years old in 85 clusters throughout the country, stratified in rural, urban, and pastoralist areas. It was estimated in the design stage that each sampled cluster would have 548 eligible individuals. All participants were screened for TB symptoms by individual interviews and a chest X-ray (CXR). Those who had TB symptoms, specifically cough for at least 14 days, and/or abnormal CXR findings, submitted two sputum specimens (spot and morning). These were both examined microscopically for acid-fast bacilli and the morning specimen was cultured for Mycobacterium tuberculosis at the National TB Reference Laboratory at EHNRI.

> *"Prevalence of Smear Positive TB among adult and all age group was 108 and 63/ 100,00 respectively."*

Among 51,667 eligible individuals, 46,697 (90%) participated in the survey and completed at least the screening interview. A very high turnout was documented for CXR screening) with a total of 46,548 (99.7%) respondents participating. Based on the CXR results and/or symptoms screening, a total of 6,080 (13%) participants were eligible for sputum examination. A total of 110 bacteriologically positive TB patients including 47 smear positive were detected. The prevalence of smear positive TB among people aged 15 and above was found to be 108/100,000 (95% C.I. 73-143), whereas prevalence of bacteriologically confirmed TB within the same age group was 277/100,000 (95% C.I. 208-347). With extrapolation to the total population, including children (using data from routine reporting of case notifications), prevalence of smear positive TB was estimated to be 63/100,000 population.

The key findings from the survey include:

(i) A three times lower prevalence of smear positive TB in 2010/11 compared with the prevalence from indirect estimation (284/100,000, in 2008)
(ii) Routine data from surveillance of smear positive TB are consistent with data obtained from the TB prevalence survey,
(iii) 55% of TB cases in this survey are younger than 35 years old
(iv) 90% are newly diagnosed cases,
(v) 43% of survey TB cases were identified by smear microscopy, the remaining 57% were smear negative and culture positive.

Therefore, the national TB control program should exert concerted effort to identify undetected TB cases in the community. The use of smear microscopy as the only means of TB diagnosis is limited and it is time to consider other diagnostic options. Although the prevalence of TB was lower than previous estimates, it is concerning that most TB patients in community are young adults, which indicates TB is circulating in the community.

1 INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease caused by *Mycobacterium tuberculosis* (MTB). It typically affects the lungs (pulmonary TB) but can affect other parts of the body as well (extra pulmonary TB). The disease is spread via droplet infection when people with pulmonary TB expel the bacilli while coughing, sneezing, talking, etc. Without treatment, mortality rates are high. Treatment using combinations of anti-TB drugs, developed in the 1940s and 1950s, can dramatically reduce mortality rates (1).

Despite the availability of highly efficacious treatment for decades, TB remains a major global public health problem. Almost one-third of the world population (about 2 billion people) is infected with M. tuberculosis (1). TB is the second leading cause of death from an infectious disease worldwide, after HIV. In 1993, the World Health Organization (WHO) declared TB a global public health emergency, at a time when an estimated 7–8 million cases and 1.3–1.6 million deaths occurred each year (1).

At that time, two targets for TB control at global level were established: 70% case detection rate and 85% cure rate by the year 2000. These two targets were embedded within the DOTS strategy launched by WHO in 1994, and subsequently endorsed by the WHO Stop TB Strategy in 2006.

A recent publication (WHO Global TB Report 2011) showed that in 2010, there were 8.8 million (range, 8.5–9.2 million) new cases of TB worldwide, 1.1 million (range, 0.9–1.2 million) deaths from TB among HIV-negative

people, and an additional 0.35 million (range, 0.32–0.39 million) deaths from HIV-associated TB (1).

The 2015 global targets include a decrease in TB incidence (MDG Target 6.c) and a reduction of 50% of TB prevalence and death rates from the 1990 levels (2).

Two of these three indicators are quite difficult to measure. TB incidence has never been directly measured at the national level, since it requires long-term studies among large cohorts of people (hundreds of thousands) which can be costly and logistically challenging. TB mortality among HIV-negative people can be directly measured if causes of death are accurately coded according to the latest revision of the international classification of diseases (ICD-10) by national vital registration (VR) systems of high coverage. Mortality surveys could also be used to directly measure deaths caused by TB.

"No National TB Prevalence Survey Conducted in the last 50 years in Africa using the international standard method."

On the other hand, TB prevalence (defined as the number of cases of TB in a population at a given point in time) can be directly measured in nationwide surveys in countries with a high burden of TB, using sample sizes of around 50, 000 people and costs in the range of US$ 1–4 million per survey(3). Relatively few countries with a high burden of TB have conducted prevalence surveys in recent years; most have been conducted in Asia. Few countries have conducted more than one survey to measure the trend of TB over time. No African country has conducted a nationwide TB prevalence survey according to international recommendations in the last 50 years.

In Ethiopia, a tuberculin survey was carried out during 1953-1955 showing an annual risk of infection of 3.0% (4). A second tuberculin survey was conducted between December 1987 and April 1990 and the results indicated a risk of infection of 1.4% revealing a reduction of 2.2% when compared to the first study (5, 6). A limitation of both surveys is that bacteriological parameters were not used to differentiate infection from disease prevalence. So far no such national TB prevalence survey has ever been conducted in Ethiopia using both microscopy and culture.

1.1 TB situation in Ethiopia

Ethiopia is located in the Horn of Africa and is bordered by Kenya, Somalia, Sudan, South Sudan, Eritrea, and Djibouti. Based on the 2007 national housing and population census, the total population of Ethiopia was estimated to be 74 million (7). Administratively, the country is divided into nine regional states and two city administrative councils (Addis Ababa and Dire Dawa). Each regional state is further divided into zones, woredas, and kebeles. The woredas are the decentralized administrative level and kebeles, within woredas, are the lowest administrative unit in Ethiopia. The average population size of a kebele is 5,000 in rural areas and 25,000 in urban area. They consist of blocks or household groups known as Mengistawi Buden or Gote in Amhara Region and Geere in Oromia Region (number and size of blocks vary) but on average are composed of 50 geographically adjacent households in most parts of the country. The administrative structure is different in urban centres since City Councils don't have zones and woredas. Addis Ababa consists of 10 sub-cities, and each one is further divided in to kebeles. Dire Dawa is directly divided into Kebeles. During the study period, there were a total of 94 zones, 810 woredas, and 15,022 kebeles in Ethiopia.

> *"There are different community structure in Ethiopia: Region, Zone, Woreda, Kebele, Gote or Geere"*

1.1.1 History of national TB programme in Ethiopia

Tuberculosis has been recognized as major public health problem in Ethiopia more than half a century ago. The effort to control tuberculosis began in the early 1960s with the establishment of TB centres and sanatoria in three major urban areas in the country namely Addis Ababa, Asmara, and Harar. The Central Office of the National Tuberculosis Control Programme (NTCP) was established in 1976. In 1992, a standardized TB prevention and control programme, incorporating Directly Observed Treatment, Short Course (DOTS), was started as a pilot in Arsi and Bale zones of Oromia Region. The DOTS strategy has been subsequently scaled up in the country and implemented at the national level.

In 1994, it was decided to combine the National TB Control Programme and the Leprosy Control Programmes into one National Tuberculosis & Leprosy Control programme (NTLCP), under the coordination and technical leadership of the MoH. In the same year, the MoH and WHO conducted a review of the TB component of the NTLCP with the objective to revise the NTLCP throughout the country.

In June 2000, the Epidemiology/AIDS Department of the MoH was restructured and named the Disease Prevention and Control Department (DPCD). The TB and Leprosy Control Programme was subsequently accommodated within this department and the former coordinating office was renamed Tuberculosis and Leprosy Control Team (TLCT). Following the 2009 reform at the Federal Ministry of Health (FMoH), the TLCT was integrated with other communicable disease control activities and restructured under the newly formed Health Promotion and Diseases Prevention General Directorate.

At the national level, there is one TB program manager who oversees a team of 11 TB programme officers who are assigned to each region. These officers work closely with the Regional Health Bureaus to ensure appropriate implementation of national policies. Each region has a TB and Leprosy Unit that is led by a Regional TB Coordinator who oversees the harmonization of program design and implementation across the respective woredas. These coordinators work closely with the district-level full-time TB/HIV officers who lead the implementation of the TB program across their respective communities including primary health care units (PHCUs). Within each woreda, there are on average one health centre and five satellite health posts. Each health centre has a designated TB clinic, which is managed by a full-time and trained nurse. Each health post is staffed by two health extension workers.

Currently, major partners actively collaborating with the FMoH in the TB-Leprosy control activities include: WHO, German Leprosy and TB Relief Association (GLRA), USAID, CDC, Italian Development Cooperation, TB CARE, Heal TB etc.

1.1.2 TB burden in Ethiopia

According to the WHO Global TB Report 2009 (used as background document for the development of this study protocol), Ethiopia ranked seventh in the world for TB burden and third in Africa in 2008, with an estimated TB incidence (all forms) of 378 new cases per 100,000 persons, 163 new smear positive cases per 100,000 persons, and a prevalence (all forms) of 579 per 100,000 population (8).

Following an update to estimates for TB cases and deaths in the African Region, the most recent WHO estimates for Ethiopia are: annual

TB incidence (including HIV positive) of 261 per 100,000; prevalence (including HIV positive) of 394 per 100,000 and mortality (excluding HIV) of 35 per 100,000 people (1).

In the year 2009/10 Ethiopia registered 146,172 cases of TB. Among these, 139,261 were new cases; 46,132 new smear-positive (33.1%); 49,037 new smear-negative (35.2%); 44,092 new extra-pulmonary TB (31.6%) (9).

TB is affecting all sexes and age groups. Poverty is a risk factor for developing TB, which places Ethiopia as a high-risk environment. The country is one of the least developed in the world.

Among the total smear positive TB cases reported in 2009/10, 55.5% were males, 7.5% were children <14 years old, and 2% were above the age of 65. The 15 to 34 age group was found to be the one most affected with TB, accounting for 62% of notified new smear positive TB cases (9). The disproportionately large burden of TB in this age group, which comprises a large part of the total workforce in the country, could be contributing to poverty. The same age group, being parents of young children, could also be heavily contributing to transmission of TB in the household and to the overall burden of childhood TB in the country.

Age disaggregation is available from routine data only for new TB cases (smear positive, smear negative and EPTB). Due to this reason the total number of paediatric TB cases is not known, but the number of new TB cases among children (< 14 years old) accounted for 10.5% of the total new cases, as shown in the table below.

Table 1: Total New TB Cases notified in 2010, 14 years old and younger

	New smear Positive PTB cases	New Smear Negative PTB Cases	New EPTB cases	Total new cases
Total cases notified	46132	49037	44092	139261
0-4	350	1404	1104	2858
5-14	3115	3997	4740	11852
Total pediatric TB cases	3465	5401	5844	14710
% of total pediatric cases	7.5%	11%	13.2%	10.5%

1.1.3 TB/HIV collaborative activities

In Ethiopia the proportion of TB patients with known HIV status is 43% and 15% of those with known HIV status are positive. Sixty-nine percent of TB and HIV co-infected patients have started cotrimoxazole prophylaxis, while 39% are on ART (1).

1.1.4 Multi-Drug Resistant TB

The first Drug Resistance Survey, conducted between 2003 and 2006 showed that multi-drug resistance to TB drugs (MDR-TB) is present in 11.8% of previously treated cases and 1.6% of newly diagnosed TB cases, with an estimated 5,200 cases annually (10). The programme's capacity to treat MDR-TB patients is limited to two referral hospitals in Addis Ababa (St Peter & ALERT) and one in Gondar (Gondar University Hospital). At the end of February 2012, a total of 424 cases of MDR-TB patients were enrolled on treatment. The routine MDR-TB surveillance system to detect MDR-TB suspects for early diagnosis and treatment is not yet fully formed. The second National Drug Resistance Survey is currently ongoing and results will be available in 2014.

> *"Prevalence of MDR TB among newly diagnosed TB is 1.6%."*

1.1.5 TB control strategies in Ethiopia

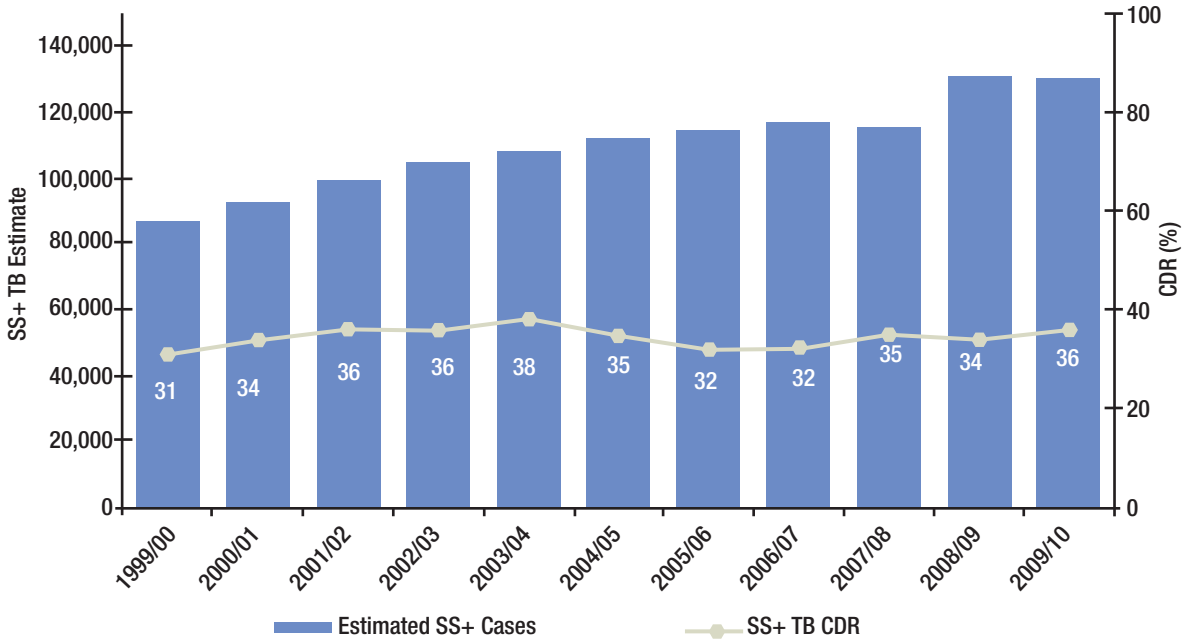
Ethiopia has adopted the WHO Stop TB strategy, which is reflected in Ethiopia's various policy documents and many implementation guidelines, for example: HSDP IV, the National TB and Leprosy Strategic Plan 2011-2015 and the TB/Leprosy, MDR TB, TB/HIV, PPM-DOTS, Community-based TB Care implementation, and TB infection control guidelines. The national TB control program has currently achieved 100 percent geographical coverage and 92% of public hospitals and health centres offer DOTS(11).

The TB programme emphasizes the need to increase the access of quality DOTS by expanding TB diagnostic and treatment services in line with the increasing number of public and private health facilities. The programme is scaling up the access to drug sensitivity testing (DST) and MDR treatment with quality-assured drugs supplied through the Green Light Committee. TB/HIV collaborative activities are being scaled-up in health centres and hospitals to provide TB patients access to HIV testing and HIV care including ART, and reducing TB burden in people living

with HIV (PLHIV) through TB screening and scale-up of IPT. To maximize case detection and treatment, the TB program engages all health care providers in the country (e.g. private health facilities, factories, boarding schools, and prisons) through the massive expansion of diagnosis and treatment services. Tuberculosis Prevention and Control is one of the 16 package programmes of the health service extension programme at the community level. The Health Extension Workers (HEWs) are engaged in awareness creation, promotion of TB prevention (e.g. cough hygiene, better ventilation), better TB diagnosis, and treatment through early suspect referral and patient treatment support. Through the use of ACSM, the TB program aims to promote awareness of key prevention and control strategies throughout the general population.

Despite the extensive expansion of DOTS services in the country and the massive involvement of HEWs in TB prevention and control activities at the grass-root level, the programme performance indicators, in particular the case detection rate for smear positive TB, was estimated to be low and almost constant in the last 10 years (Figure 1).

Figure 1: Trend of WHO SS+ TB Estimate versus Case Detection Rate (CDR) in Ethiopia-FMoH 1999/00-2009/10 (1992-2002EC)



1.1.6 Diagnostic capacity in the country

TB diagnosis relies on smear microscopy, as it is the most accessible test for TB in the country. TB microscopy services are available at the health centre and hospital levels. Currently all health centres provide AFB (sputum smear) diagnosis, while culture is provided only by six laboratories in the country (two in Addis Ababa and four at the regional level). Overall, TB laboratory services are coordinated by the national reference laboratory at EHNRI. At the region level, the provision of lab reagents, supplies, and external quality assurance is managed by the regional reference laboratories.

The availability of diagnostic and investigative technologies such as LED microscopy, X-rays, fine needle, and other diagnostic tools to support smear negative, childhood TB, and extra-pulmonary TB diagnosis is limited and diagnostic expansion plans are currently ongoing.

1.1.7 Drugs and supplies procurement

TB drugs and supplies are provided to districts and health facilities by Pharmaceutical Fund and Supply Agency (PFSA) of the Ministry via its regional and sub-regional hubs.

2

TB PREVALENCE SURVEY: RATIONALE AND OBJECTIVES

2.1 Rationale for the survey

"Annual Incidence of smear positive TB estimate for Ethiopia increased from 152 to 168/100,000."

Between 2007 and 2008, the WHO annual estimate of smear positive TB incidence in Ethiopia increased from 152 to 168 per 100,000 people (12,13). The WHO TB estimates for Ethiopia used at the time of survey protocol development were extrapolated from an exercise undertaken in 1997, using the assumptions of a 50% case detection rate, 48% DOTS coverage, and trends based on high HIV prevalence countries in the region. This outdated exercise did not take into consideration crucial factors driving TB burden, such as the extensive DOTS service expansion and the recent establishment and expansion of HEW network for TB prevention and control activities delivered in the community. Furthermore, the current adult HIV point prevalence in Ethiopia is 2.3%, which is much lower than the prevalence of HIV infection in other sub-Saharan Africa countries (14). Therefore, these factors were not fully employed to inform TB burden estimation in Ethiopia. In addition, the quality of existing programmatic and surveillance data was considered insufficient to overhaul the TB burden estimates for the country.

Therefore, in order to clarify the TB epidemiological situation in Ethiopia using an evidence-based approach and to strengthen the TB programme, the Ministry of Health decided to conduct a population-based national TB prevalence survey in 2010/11, with financial support from the Global Fund TB Round 6 grant, in collaboration within country partners working on TB, and technical support from WHO headquarters.

2.2 Aims and objectives

2.2.1 Primary aim

The primary aim of the National Prevalence Survey was to estimate the prevalence of pulmonary TB in Ethiopia in 2010-2011, as a basis for evaluation of current performance in case detection and as a baseline measurement for subsequent surveys in the future. To estimate the prevalence in the general population, the prevalence among adults aged 15 year or more has been measured.

2.2.2 Primary objectives

1. To determine the prevalence of smear positive TB
2. To determine the prevalence of culture positive TB
3. To determine the prevalence of symptoms suggestive of TB
4. To determine the prevalence of radiological abnormalities suggestive of TB

2.2.3 Secondary objectives

1. To measure the prevalence of cervical lymphadenitis among study participants;
2. To assess knowledge, attitudes, and practices of the population concerning TB
3. To assess health seeking behavior among participants with TB symptoms

2.2.4 Additional study components

- Individuals with positive symptom screening were interviewed in-depth about their health seeking behavior, in order to clarify factors which may affect health service utilization, to better understand the utilization of the government and private health system, and the possible reasons for not seeking treatment.
- Survey participants with TB history in the last two years were interviewed to explore in detail the classification of TB, the previous/current TB treatment, outcome, and responsible health facility.
- Furthermore, a KAP survey was conducted among ten percent of the study participants, randomly selected, in order to capture information on general knowledge, attitudes and practices about TB.

3 SURVEY ORGANIZATION

3.1 Steering committee

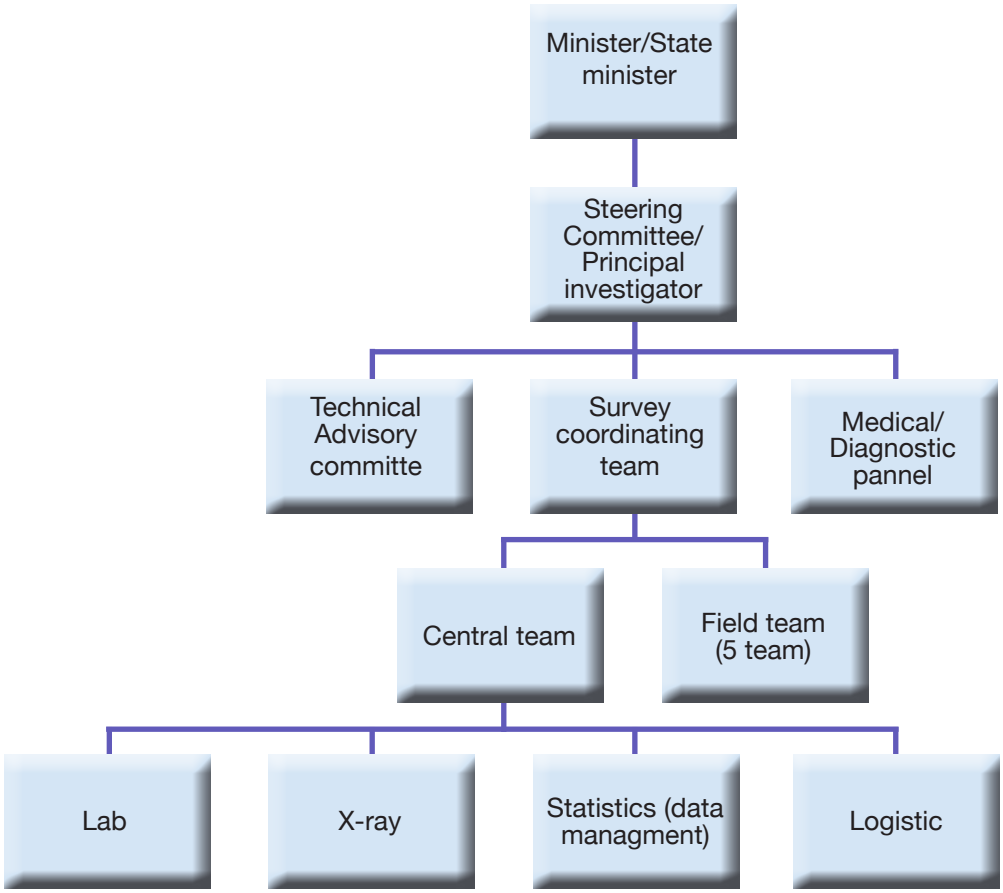
A steering committee composed of the FMoH State minister, NTP manager, Ethiopian Health and Nutrition Director, survey coordinator, representatives of national and international institutions (Addis Ababa University medical faculty, Ethiopian Radiation control Authority, Ethiopian Central statistics Authority, Armauer Hansen Research Institute and international organizations: WHO, TBCARE, USAID, GLRA, Italian Cooperation, and CDC) was formed. The steering committee had the primary responsibility for selecting the survey implementing organization and the principal investigator, designing the study, eliciting funding, and ensuring the quality of survey implementation. One senior staff of EHNRI has been nominated as the Principal Investigator (PI), and chair of the Steering Committee (SC). Specific terms of reference for the PI have been developed and approved by the SC. The SC met on a regular basis as well as when it was necessary to monitor progress and to provide support to the survey teams. Members of the SC participated in monitoring and supervisory activities directly both in the field and at the central level.

3.2 Survey Coordinating Team / National Survey Coordinator

The Survey Coordinating Team (SCT) composed of chiefs for the Lab, Radiography, Statistics and Logistic teams as well as the leaders of field teams was established (Figure 2). The SCT was responsible for carrying out the survey and reporting to the SC. A Survey Coordinator was nominated December of 2008. The Survey Coordinator chaired the SCT and also served as secretary of SC. The Survey Coordinator was an NTP staff member engaged full-time for the whole duration of the survey. He had responsibility for day-to-day survey preparation and management, organization and coordination of training, piloting, field work, survey implementation, data management, monitoring of progress, and data quality. He reported to the Steering Committee on progress and general monitoring issues.

> *Members of the SC participated in monitoring and supervisory activities directly both in the field and at the central level.*

Figure 2: Organizational structure of survey team



3.3 Technical Advisory Group

The Technical Advisory Group (TAG) consisted of national TB experts as well as international experts in survey, lab, radiology, and epidemiology. The aim of TAG was to timely provide technical advice to the Survey Coordinator and central units. The TAG also assisted the SC and PI in training and quality assurance activities.

3.4 Medical/diagnostic Panel

A medical/diagnostic panel was established, in order to make medical decisions during the survey. The panel could be called upon by field teams, and could overrule the team's decisions on case management. The panel reviewed documents, X-rays, and lab results for all suspected TB cases and reached consensus on definite, probable, and possible study cases according to the study case definitions

3.5 Field teams

Survey operations were carried out by five teams, specifically recruited for the prevalence survey. Each team consisted of fixed and flexible components. The fixed part consisted of one team leader (physician or senior health professional), one receptionist, three census takers/ interviewers, two X-ray technicians, one radiologist or physician as CXR reader, one lab assistant, and three drivers. The flexible part of the team included local staff from the region, zone, woreda, kebele, local health workers including HEWs and community assistants/volunteers.

Training workshops were held for regional and woreda staff. Health centre staff and health workers received a brief training during the preparation visit by the central team approximately one month before the start of field data collection. Community volunteers received instructions during the preparation visit and on the arrival of the survey team.

Survey teams worked in rotation; every week three teams went on duty to the field to implement the survey and collect data, while two teams stayed at the centre to summarize and submit field data, get maintenance, prepare logistics, and rest.

Each field team had a field team leader and a deputy field team leader. The field team leaders had direct responsibility for the implementation of the field work. In particular, they were responsible for logistics and organization of the field work, coordination of the day-to-day field work, communication with local, woreda and zonal/provincial authorities on issues regarding the field work, report to local authorities and Survey Coordinating Team.

Standard operating procedures (SOPs) were prepared and laid out in the field manual for each field activity (team leadership, census, interviews, X-ray, lab). They described in detail the tasks and responsibilities of each field team members.

4 TRAINING

In order to prepare the survey activities, extensive training of staff was conducted. The training was organized in different steps and included in-house training as well as field visit experience. Training events included:

- One week capacity building workshop at WHO-HQ, Geneva for the core survey team members (PI, survey coordinator, data manager, lab managers and researchers) on the development of the TB prevalence survey protocol.
- Two weeks workshop to develop SOPs and to develop one field team to test survey instruments. Participants of the workshop became trainers for other field team members.
- In-house 1.5-2 days workshop to give general guidance to all staff members.
- 1-2 week specialized capacity building training for lab technicians, X-ray technicians, census taker/ interviewers and data management. After the in-house staff training, an integrated field test was arranged, in order to reproduce and gain experience in all field activities, including checking of the equipment (chest X-ray), collecting, storing and transporting lab samples, completing forms, etc. The field test took place near Addis Ababa.
- One pilot cluster in rural area was conducted before the launch of the survey. One team was engaged in the pilot, as well as all team leaders and some observers. The pilot survey has not been included in the study sample.

- Instructional sessions were organized for local health workers and volunteers during the preparation visit approximately one month before the field operations and on arrival day of the survey team.

All SOPs have been developed before starting the training and finalized after the pilot cluster.

5 METHODOLOGY

5.1 Study design

A nationwide, cross-sectional, stratified, multi-stage clustered sample survey was carried out between October 2010 and June 2011 to estimate TB prevalence in Ethiopia.

5.1.1 Sample size

Data from the Central Statistics Agency (CSA) derived from the last national census conducted in 2007 were used for the sampling frame. According to census data, the projected population size during the proposed study period (2010) was estimated to be 79,731,054.

The prevalence of smear-positive pulmonary TB during study period was estimated to be 200 per 100,000 in the total population (including children). This was a "conservative" estimate compared with the one made by WHO for 2008 (284/100,000) (15), taking into consideration that TB prevalence might have fallen in recent years as a result of DOTS expansion and other health service interventions.

The target population for the prevalence survey was composed of individuals aged ≥15 years, and it was estimated that 55% of the total population was in this age group (in line with last census data). The

prevalence estimate of 200 per 100, 000 was made using the assumption that the prevalence of smear-positive pulmonary TB is 0 in children aged <15 years. This means that the prevalence of smear-positive pulmonary TB in the target population of individuals aged ≥15 years was estimated to be 200/0.55 per 100,000 = 364 per 100,000 (rounded up to the nearest whole number). The relative precision required was 20%.

Minimum desired sample size was 46,514.

To calculate the required sample size for a simple random sample survey the following formula is recommended:

$$N = z^2 \frac{1-p}{d^2 p}$$

Where N- required sample size of 15+ individuals
p- prior estimate of the prevalence of smear positive TB
z- standard normal value for type I error rate of 5% (95% confidence) =1.96
d- relative precision

$$N = 1.96^2 \frac{1-0.00364}{0.2^2 \times 0.00364} = 26{,}289$$

Since the survey was cluster sampled and in order to account for the clustering, we needed to inflate the sample size of the simple random sampling calculation by the design effect. The design effect (DEFF), dependent on the cluster size m which was chosen to be 550 and the coefficient of between-cluster variation k which was assumed to be 0.5, was calculated by the formula:

$$DEFF = 1 + (m-1) \times \frac{k^2 p}{1-p} = 1 + (550-1) \times \frac{0.5^2 \times 0.00364}{1-0.00364} = 1.5$$

Finally, the participation rate was assumed to be 85%. Therefore, the total required sample size for the survey was calculated as:

$$N = \frac{26{,}289 \times 1.5}{0.85} = 46{,}514$$

Sampling was stratified by rural, urban and pastoralist.

5.1.2 Stratification

In order to increase the efficiency of sampling and precision of the overall national estimate of prevalence, stratification in the sampling of clusters has been applied as follows. The general population of Ethiopia is divided into three sub-groups, according to their living area and living conditions:

1. Population living in urban area
2. Population living in rural area
3. Pastoralist or nomadic population

In this survey, the **urban** population is defined as people who live in town with a minimum population size of 2,000 and is registered by the Ethiopian Central Statistics Authority (CSA) as urban. The urban population represents the 16% of the total population.

The **rural** population is defined as people whose main source of livelihood is agriculture (other than pastoralist); the population living in this area represents the majority (76%) of the total population.

The **pastoralist** population is defined as people whose main source of livelihood is livestock, with which they move seasonally in search of fresh grazing land and water; pastoralists represent the 8 % of the total population.

5.1.3 Sampling procedures

Following the experience of some Asian countries who have conducted TB prevalence surveys, the size of a cluster unit has been set to approximately 550 eligible persons (>15 years old), with accepted ranges of 520-600 persons, in order to complete one cluster activities within one week. To select 46,514 people, a total of **85 clusters/kebeles** were needed.

The number of clusters selected from each stratum was proportional to the population size living in each area:

1. Urban population: 14 clusters
2. Rural population: 63 clusters
3. Pastoralist population: 8 clusters

Multistage cluster sampling was performed. From each stratum a number of woredas corresponding to the number of clusters allocated to that stratum were sampled first, utilizing Probability Proportion to Size (PPS). For each selected woreda, the complete list of kebeles with the corresponding population was provided by the woreda authorities. Then kebeles were selected by PPS as a basic sampling unit.
The complete list of selected woredas and kebeles is attached in the annex J.

In most cases, the selected kebele was bigger than the maximum cluster size (600), thus it was necessary to conduct the survey in only a limited part of the kebele. In this case, each gotes/gares (roughly equally sized household blocks) of the kebele was assigned a serial number and one household block was randomly selected as the starting point of the survey. Household blocks to the north and in clockwise direction to the starting block were included until the required cluster size was reached.

5.2 Inclusion and exclusion criteria

5.2.1 Exclusion criteria for sampling frame

Of the 810 woredas within the country, 37 were excluded from the sampling frame from the beginning due to security and logistical reasons. The population living in these 37 woredas accounted for only 3 percent of the total population of Ethiopia.

Ultimately, the sampling frame included 773 woredas, which accounted for 97 percent (77,174,699 individuals) of the total population of the country. The population living in each woreda has been derived during the last national census (2007).

5.2.2 Exclusion criteria during woreda/kebele sampling

In case an entire selected woreda was determined not to be accessible or if the survey was unexpectedly found to be unfeasible in that woreda (e.g due to natural disasters, epidemics, inaccessibility problems, etc.) another woreda from the same zone was selected to replace the problematic one. For example, after selecting 85 woredas, it was determined that it would take more than one full day to reach one woreda in North Gondar Zone and that it would not be possible to carry all of the equipment. As a result another woreda in the same zone was selected.

Similarly, if the selected kebele was not accessible or if the survey was not feasible for major unexpected reasons, another kebele from the same woreda was selected to replace the first one. After the initial selection of kebeles, two kebeles (one from rural and one from Pastoralist) were replaced.

5.2.3 Exclusion criteria in the selected kebele

To increase the feasibility of data collection and to avoid bias due to inclusion of high risk groups that are not representative of the overall population, the following settings were excluded from the study: military compound, diplomatic compounds, jail/prisons, refugee camps, hospitals, schools, universities and dormitories, orphanages, monasteries, and homeless populations.

5.2.4 Individual eligibility criteria for participation in the study

- Age > 15 years
- Residents who stayed at least one night in a household during the 14 days prior to the census day
- Visitors who stayed in a household for at least the past 14 days prior to the census day

5.2.5 Individual exclusion eligibility criteria:

- Age < 15 years
- Residents who have been away during the entire past 14 days from a household
- Visitors who arrived and stayed in the household less than 14 days prior to the census

The prevalence survey did not include children under the age of 15 because bacteriological positivity is rare and collection of sputum samples is difficult in this age group (particularly among the very young children).

5.2.6 Inclusion/exclusion criteria for study participation

Individuals were included in the survey screening only if they provided informed consent after receiving clear information about the objectives and procedures of the study (Annex I). Individuals below 18 years or disabled persons unable to provide written consent by themselves needed the informed consent to be signed by a family member or a guardian of 18 years or older. Individuals who were eligible for the study but refused to provide consent were counted as absentees.

5.3 Survey operations

After the training, a pilot test was conducted in a rural cluster before the launch of the survey in order to familiarize the trained staff to survey operations, field test the forms and registers, and finalize the SOPs. Results from pilot cluster have not been included in final study results.

5.3.1 Survey period

The field data collection of the first Ethiopian National TB Prevalence Survey 2010-2011 was carried out from October 2, 2010 to June 25, 2011. One week per cluster was required (520-600 persons per cluster). The census took one day and field operations another 5-6 days. Hard-to-reach clusters required up to 10 days of field operations, including travel to the survey area.

> *Data was collected October 2, 2010 to June 25, 2011.*

5.3.2 Field survey procedures

The following schedule was used to guide the fieldwork:

Basic schedule for field survey

Saturday	➢ Travelling day ➢ Arrival at cluster ➢ Meeting with local authorities and HEWs
Day (1) Sunday	➢ Taking census through household visits and inviting the participants
Day (2) Monday	➢ Survey Field Operation (Interview, Spot CXR, Sputum collection) carried out with an average of 150 persons/day ➢ Forms reviewed and rechecked by team leader
Day (3) Tuesday	➢ Survey Field Operation - 150 persons/day ➢ Absentees from the previous day called ➢ Forms reviewed and rechecked by team leader
Day (4) Wednesday	➢ Survey Field Operation -150 persons/day ➢ Collected sputum specimens sent to central reference lab with cold chain ➢ Absentees from the previous days called
Day (5) Thursday	➢ Survey Field Operation - 150 persons/day ➢ Absentees from the previous days called ➢ Forms reviewed and rechecked by team leader
Day (6) Friday	➢ Final collection of sputum specimens ➢ Second batch of sputum specimens sent to central lab with cold chain ➢ Departure from survey site to next cluster or to base

Day 1: Census taking

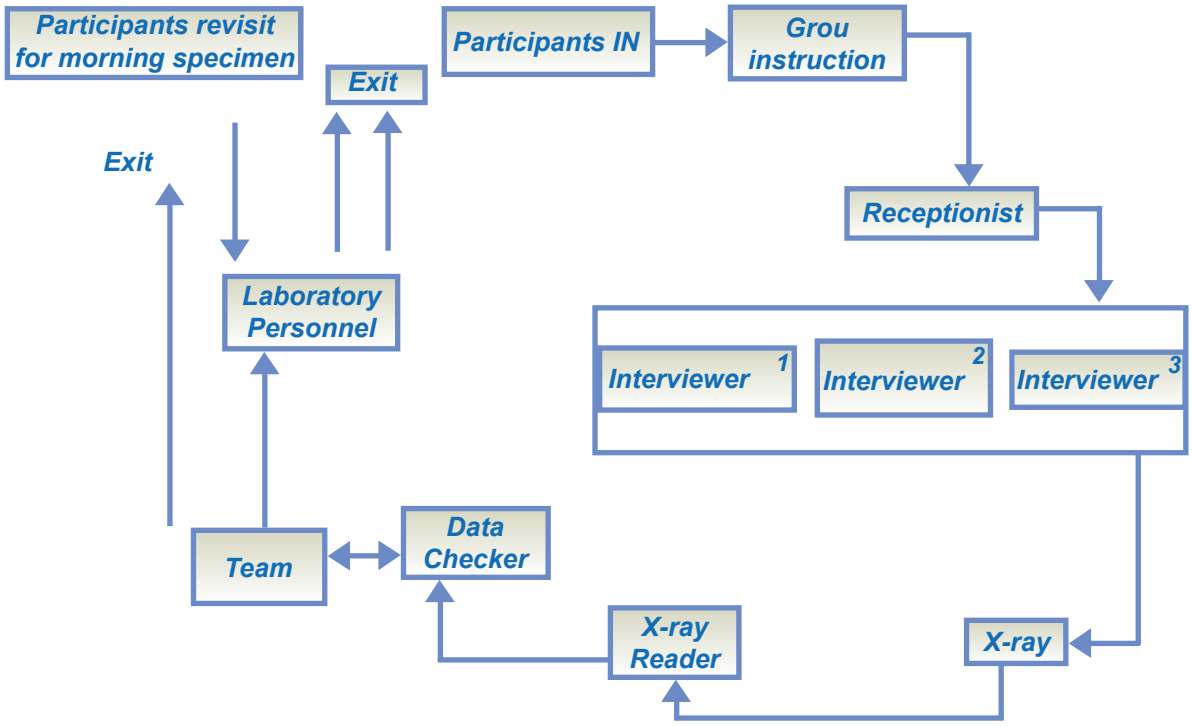
The first step was to conduct a census of households in the selected household blocks on the first day of cluster activities. This included enumerating all the individuals living in the households, including children < 15 years old and temporary visitors. All individuals per household who met the inclusion criteria were considered eligible and were provided with a survey invitation card. (Annex H).

Day 2-5: Interview, CXR and sputum specimen

All eligible and consenting participants underwent screening interview and chest X-ray. The arrangement of screening at the survey camp site is indicated in Figure 3. All participants of each cluster were screened in a total of 4 days (days 2-5). The number of participants screened daily varied from 140 to 200 depending upon the local situation.

If the participant reported cough, current or past TB treatment history, or presented cervical lymph nodes enlargement during their initial interview, he/she received a second short interview about the health seeking behavior after completing the chest x-ray(Annex H). Furthermore, a KAP interview was carried out in a randomly selected 10% of the participants.

Figure 3: Screening Arrangement at Survey Camp Site



Day 6: Debriefing to local authorities and the community

At the final date of data collection field team leader conduct a meeting with the local authority including: Head of the Woreda, Head of Woreda Health Bureau, Woreda TB focal person, Kebele Principal and Health extension workers. The team leader present a brief summary of survey activities conducted and discus a plan for the feedback mechanism of the laboratory results of participants to facilitate case management at the local health facility.

5.3.3 Symptoms screening

> *Cough of two weeks or more was considered to identify survey TB suspects*

All study participants were requested to answer study questions from a pre-tested questionnaire explained to them in their local language by a qualified health worker. The questionnaire included:

1. Personal data, including individual survey number (ID), name, age, sex
2. Questions concerning the presence of TB suggestive symptoms at the time of the survey (according to the National TB Manual) (16):
   a) Cough and duration
   b) Presence of: fever, night sweats, body weight loss
   c) Enlargement of neck lymph nodes. Each study participant was examined by a health care worker to assess the absence or presence of swollen cervical lymph nodes
   d) Past or present anti-TB treatment. In the case of history for TB or ongoing anti-TB treatment, the participant was asked to answer a second set of questions at the end of the survey to explore in detail past TB history, previous treatment, outcomes, health care facilities, etc.

Persons reporting cough for 14 days or more were considered eligible for sputum examinations (regardless of CXR findings). The presence of any TB suggestive symptoms were used to assess eligibility for sputum examinations for persons who did not receive a CXR (either because they refused or because of mechanical error).

5.3.4 CXR screening

All survey participants underwent upright posteroanterior CXR on the spot, using a portable X-ray machine with an automatic processor. The x-ray films were classified on site by a trained physician as one of the following:

1. *Normal:* No abnormal finding on the lungor mediastinum.
2. *Abnormal:* any abnormality in lung field or mediastinum, including cavities, infiltrates, pleural effusion, hilar or mediastinal lymphadenopathy, pulmonary nodules, interstitial abnormalities, and healed TB.
3. Other abnormalities (cardio vascular diseases, goiter, injury, etc)

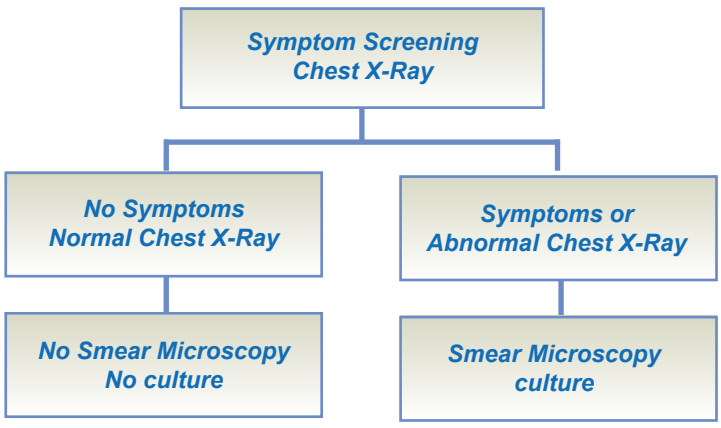
If any abnormality was found in the lung field or mediastinum, participants were requested to submit two sputum samples, regardless of the presence of TB symptoms.

Survey participants with an illness and/or CXR abnormalities requiring medical care were referred to a nearby health facility (health centre or district hospital) as appropriate.

5.3.5 Bacteriological screening

All persons with TB suggestive symptoms and/or CXR abnormalities were instructed on how to produce good quality sputum and requested to provide two sputum specimens (one spot, one early morning). Collected specimens were stored in ice boxes at four degrees and then transported to the National Reference Laboratory(EHNRI) in Addis Ababa within three days (at most five days) for bacteriological examination.

Figure 4: Method of Screening



5.4 Laboratory methods

5.4.1 Sputum smear microscopy

All sputum samples received at the national reference laboratory, both spot and morning, were examined with fluorescence microscopy: one slide from each sample was air dried, fixed and stained with auramine. If one or more acid fast bacilli (AFB) per equivalent or 100 immersion fields were observed, the slide was considered positive. All positive slides and 10% of negative slides were double checked by a second reader/ supervisor for quality control purpose.

5.4.2 Culture

All morning sputum samples have been processed for culture. If morning sample was not available for a particular participant, his/her spot sample was inoculated instead. Samples were processed according to standard procedures using modified Petroff's method for decontamination, inoculated on to a slant of Lowenstein-Jensen (LJ) with glycerol and a second slant of LJ medium supplemented with pyruvate and incubated at 37 degrees with weekly examination for growth. Specimens that did not have colonies growing at eight weeks were defined as negative. Specimens with any growth were examined by Ziehl-Neelsen (ZN) microscopy and positive isolates were characterized by the Capilia test, an immunochromatographic assay.

5.4.3 Laboratory results feedback

All the positive results of sputum microscopy and culture were reported back by the Survey Coordinating Team to the local health centre for further follow-up, medical management, and HIV testing, according to National TB/HIV guidelines (FMOH, 2008).

5.5 Central X-ray reading

At the central level, all abnormal CXR films and approximately 15% of normal films have been reviewed by senior radiologists in Addis Ababa (St Paul Hospital, Radiology Department) for internal quality control and further classification.

6

CASE DEFINITIONS

Prevalent TB cases were defined according to the survey case definitions recommended by WHO Global Task Force on TB Impact Measurement.

6.1 Laboratory definitions of positive result

AFB smear positive – any positive with FM smear microscopy
MTB Culture positive –any positive growth of mycobacterium Tuberculosis Isolate using capla.

6.2 Study case definition

The following definitions were used to classify cases in this study:

Bacteriologically definite TB case – CTB positive: Study participant with one culture positive specimen with Mycobacterium tuberculosis and at least one of following conditions:

- AFB-smear positive
- Culture positive in another specimen
- CXR consistent with TB by audited central reading

Sputum smear-positive TB case: AFB-smear positive confirmed case can be definite or probable study TB cases. Study participants with one AFB-S positive specimen AND at least one of following conditions:

- Culture positive TB ---*definite case*
- AFB-smear positive in another specimen and no culture (TB) positive AND no isolation of MOTT --*probable case*
- CXR (audited reading) TB consistent and no CTB positive AND no isolation of MOTT - *probable case*

Isolation of mycobacterium other than tuberculosis is not rare in survey specimens. Two positive smear slides with MOTT isolates have not been considered as TB case in the study analysis.

Study participants can be either a definite or probable case. The table below shows summary of the definition of prevalent TB cases in the survey.

Table 2: Overview of classifications according to culture and AFB-smear positive results

Study TB case	Definite			Probable
Classification of definite (CTB positive) TB cases according to AFB-S	AFB-S negative, CTB positive	AFB-S unknown, CTB positive	AFB-S positive, CTB positive	
Classification of AFB-S positives			AFB-S positive TB confirmed case	
Laboratory results	CTB positive AND AFB-S negative	CTB positive AND AFB-S unknown	CTB positive AND AFB-S positive	CTB indecisive* AND AFB-S positive

CTB: Mycobacterium TB Complex culture positive

*Culture results missing, unknown or contaminated

Possible TB cases were not counted as TB cases in this study and did not contribute to the estimates of TB in Ethiopia. However, they will be followed up according to the recommendations of the central medical panel. The panel reviewed collected data and examination results of participants with any positive results (chest X-ray, smear, culture) to classify final study results and to provide advice for treatment or further medical interventions.

7

DATA MANAGEMENT AND ANALYSIS

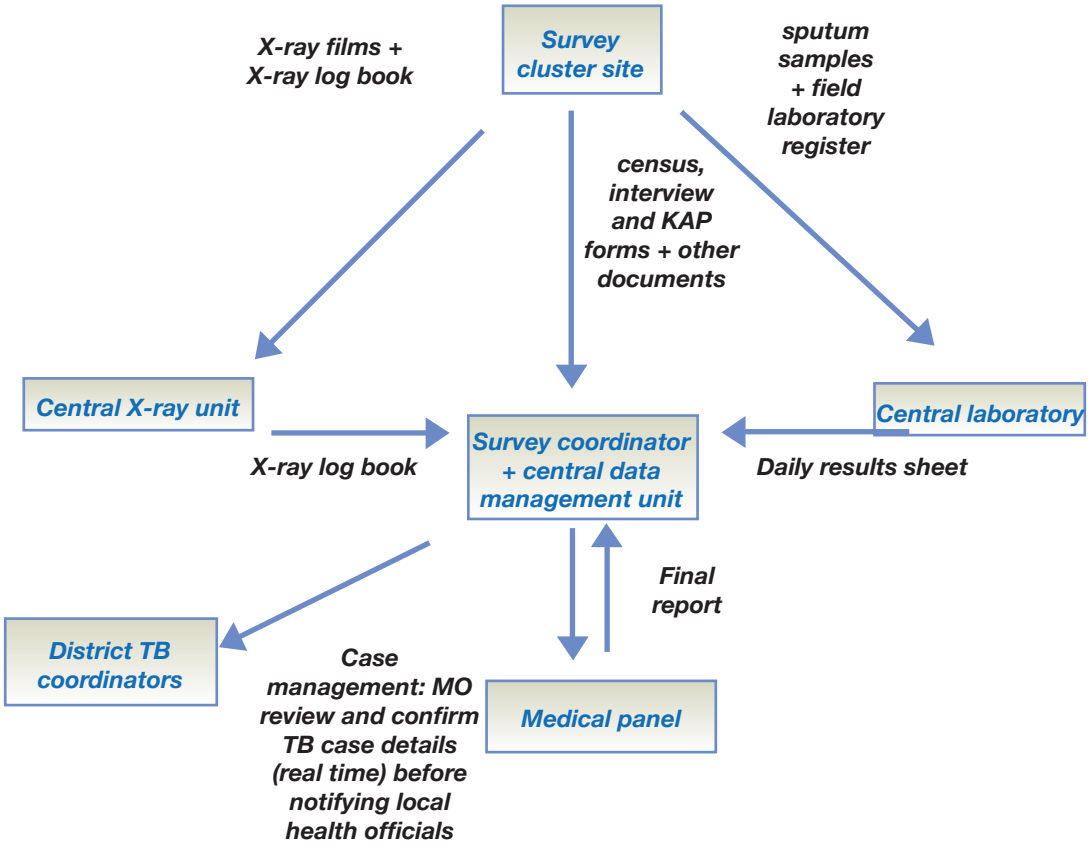
The survey coordinating unit appointed a central data management unit, composed of a qualified data manager and two data entry clerks. The central data management unit was responsible for entry of field and central data entry using (CSPro) as database. Data entry was done concurrently and continuously as data were collected.

The central data management unit paid attention to the confidentiality of survey participants. WHO provided technical assistance on data management.

Quality controllers and team leaders followed data safeguarding procedures during data collection. These included the transfer of data from completed questionnaires into computers, maintaining a data collection monitoring sheet, and back-up of data in case of any computer failures.

Data from the household register and individual survey form, lab report/ register and X-ray central reading form were entered into the CSPro by the senior data manager and data entry clerk. Single data entry was done, and data were verified with original documents when there were any discrepancies in data entry. Key variables of the Individual Survey Card were used to verify double-entry data files. The data entry screens had a number of validation checks that could trap errors. In addition, the data manager ran a data validation script at the end of each week that identified logical inconsistencies. Data flow is summarized by the diagram below:

Figure 5: Data flow



7.1 Statistical analysis

All data were entered and cleaned using CSPro database. After validation, data were exported into SPSS and Stata for statistical analysis.

Statistical analysis was done in collaboration with WHO. Analysis consisted of the estimation of prevalence and situation analysis of health-seeking behaviour of TB suspects.

A detailed explanation of the methods used to obtain prevalence is provided in Annex B.

8

MONITORING AND EVALUATION

Monitoring of the survey activities was conducted internally and externally.

8.1. Internal monitoring

The team leader had the responsibility to monitor and supervise the team members throughout the duration of field activities, checking the quality of activities performed, as well as attitudes of team members, consistency and accuracy of data collection, quality of chest X-rays, sputum collection, etc. Each field team has been periodically supervised by a member of the central team (survey coordinator, central lab staff, chest X-ray, data manager, etc) to ensure quality of field operations and data collection.

8.2 External monitoring

External monitoring has been conducted by international experts from WHO Global Task Force through periodic missions to the field and to the central level.

A mid-term review was organized in February 2011 with the participation of SC members and international experts from WHO. Field and central level findings were discussed with Survey Coordinating Team and survey staff in order to identify the strengths and pitfalls of the survey and take appropriate corrective actions to ensure the quality of the survey.

8.3 Quality assurance, technical assistance

Survey quality control involved specific tasks and procedures to ensure the highest quality, including standardization of procedures and definitions, training and periodic supervision. Supervisory visits to survey sites were made by the Steering Committee and technical committees, together with international and in-country technical organization (WHO), other countries experts (NTP Cambodia) and partner organizations, for quality assurance at the field and central level.

CXR quality assurance was secured through standardization of X-ray taking and reading in the field. The system was developed to describe and record the appearance of films in the field, double reading of all abnormal films and around 10% of normal films at central level, and finally reviewing them again with the expert panel for final decision on identified TB cases. Specific training and supervision on CXR taking and reading was provided from WHO and NTP Cambodia.

Central laboratory quality control was monitored both through internal and external evaluation: internal quality control for smear microscopy was provided by double reading of all positive slides and 10% of negative slides by a lab supervisor. In addition, lab activities were supervised by external monitoring, provided by WHO through periodic lab visits, samples management supervision, monitoring of lab registers, lab reports and lab performance indicators (contamination rate, recovery yield, etc). In addition, EQA was carried out with a team of lab experts from CDC, AHRI and TB-CARE.

WHO collaborated fully with Survey Coordinating Team in data analysis and in formulating the program implications of the findings.

9 RESULTS

9.1 Census: eligible survey populations

The census team screened 95,092 individuals including 41,125 children under the age of 15 (43.2%) in 85 clusters. Among 53,967 individuals aged 15 years and above, 51,667 (95.7%) were registered as eligible survey individuals (Table 3). Slightly more females (97%) than males (94.5%) were eligible for the study. The main reason for ineligibility for adults was that they did not meet the residency criteria discussed above.

The proportion of children among the population was slightly (43.2%) lower than the national (45%). However, the proportion of children (44.3%) is almost the same as the national figure if those not eligible are excluded.

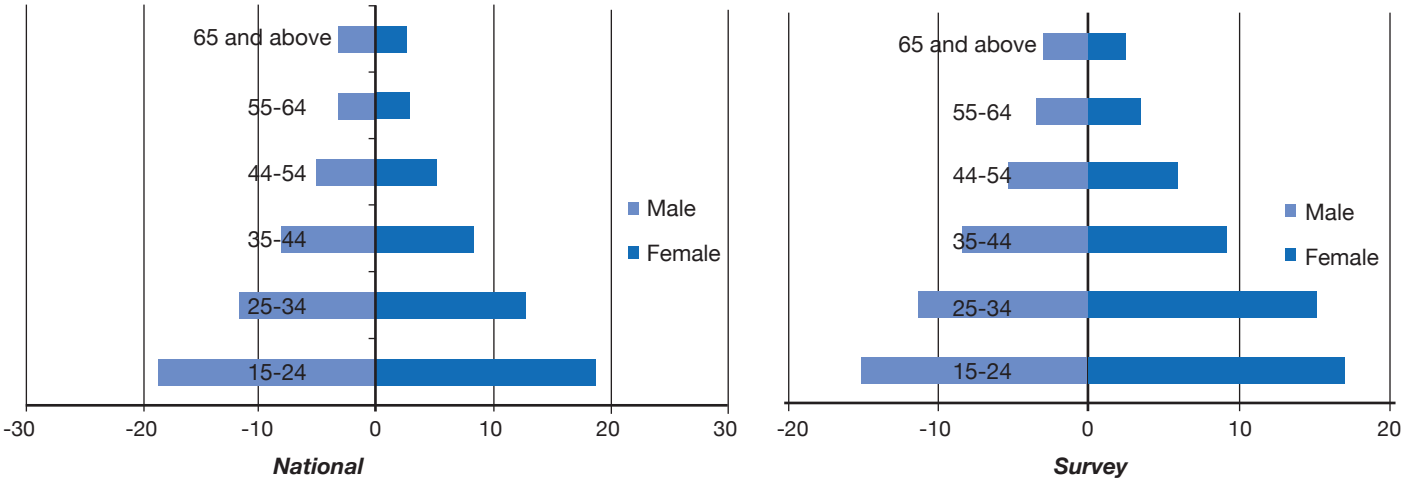
Table 3: Survey census population by sex, age group, place of residence, and eligibility for study

	Eligible		Not Eligible aged>=15yrs		Not Eligible aged < 15yrs		Total enumerated
	number	Percentage[1]	num	%[1]	num	%[1]	
Total	51667	54.3	2300	2.4	41125	43.2	95092
Sex							
Male	24623	52.2	1438	3.0	21125	44.8	47186
Female	27044	56.5	862	1.8	20000	41.7	47906
Age							
0 - 4	0	0.0	0	0.0	12414	100.0	12414
5 - 14	0	0.0	0	0.0	28711	100.0	28711
15 - 24	17291	94.2	1072	5.8	0	0.0	18363
25 - 34	13589	95.8	589	4.2	0	0.0	14178
35 - 44	8841	96.8	290	3.2	0	0.0	9131
45 - 54	5623	97.1	167	2.9	0	0.0	5790
55 - 64	3470	97.2	100	2.8	0	0.0	3570
65 and above	2853	97.2	82	2.8	0	0.0	2935
Strata (Resident Type)							
Urban	8654	59.5	1074	7.4	4805	33.1	14533
Rural	38181	53.5	1075	1.5	32093	45.0	71349
Pastoral	4832	52.5	151	1.6	4227	45.9	9210

[1]Percentage calculated over total number enumerated

Population pyramids of survey participants and national population of the same age group are shown in Figure 3. The age and sex distributions between the study participants, and the population statistics of the national data of population census of 2007 look similar.

Figure 6: Comparison of national population with survey population



According to the survey design a cluster size of 520-600 eligible adult subjects was expected per cluster. However, in this survey, on average, 608 subjects per cluster were recruited as eligible subjects. Major possible reasons for over sampling were:

- Uncertainties of the proportion of children which resulted in a higher recruitment of individuals. The proportion of adults increased in the study participants by 2% from the expected in the design stage.
- Field teams tend to recruit more eligible subjects to secure enough participants in the event of a lower participation.
- Difficulty for the survey team to stop the recruitment in the middle of a household group/block, once the survey team began census, resulting in recruiting all households in the same block.

9.2 Participants

9.2.1 Study Participation

Among 51,667 eligible adults invited, 46,697 (90.4%) participated in the study, and received the symptom screening interview (Table 4). The participation was greater than 90% which is more than the expected during study design (85%). The average number of study participants per cluster was 549, with a range 490-592. The participation rate was higher in females (92%) than in males (88.6%). Rural clusters had a slightly higher participation rate (91.5%) than pastoral clusters (88.1%) and urban clusters (86.5%). No cluster recorded participation rate less than 85%. There was no significant difference in participation rate between age groups.

Table 4: Participation rates

		Participants		Non-Participants		Interviewed		Field X-ray Performed	
	Eligible	Number	%[1]	Number	%[1]	Number	%[1]	Number	%[1]
Total	51667	46697	90.4	4970	9.6	46697	90.4	46548	90.1
Sex									
Male	24623	21819	88.6	2804	11.4	21819	88.6	21750	88.3
Female	27044	24878	92.0	2166	8.0	24878	92.0	24798	91.7
Age group									
15 - 24	17291	15030	86.9	2261	13.1	15030	86.9	14978	86.6
25 - 34	13589	12397	91.2	1192	8.8	12397	91.2	12363	91.0
35 - 44	8841	8214	92.9	627	7.1	8214	92.9	8196	92.7
45 - 54	5623	5286	94.0	337	6.0	5286	94.0	5271	93.7
55 - 64	3470	3222	92.9	248	7.1	3222	92.9	3216	92.7
65+	2853	2548	89.3	305	10.7	2548	89.3	2524	88.5
Stratum									
Urban	8654	7490	86.5	1164	13.5	7490	86.5	7463	86.2
Rural	38181	34952	91.5	3229	8.5	34952	91.5	34841	91.2
Pastoral	4832	4255	88.1	577	11.9	4255	88.1	4244	87.8

9.2.2 Occupational Status of participants

The most common occupation (see Table 5) among the participants was agriculture/ farming (49.6% total; 59.2% of male; 41.1% of female) followed by student (17.6% total; 20.1% male; 15.4% female).

Table 5: Occupational status of participants

	Sex					
	Male		Female		Total	
Occupation	Num	%	Num	%	Num	%
Farmer	12926	59.2%	10234	41.1%	23160	49.6%
Merchant	504	2.3%	564	2.3%	1068	2.3%
Student	4381	20.1%	3835	15.4%	8216	17.6%
Employed	682	3.1%	462	1.9%	1144	2.4%
House Wife	0	0.0%	6453	25.9%	6453	13.8%
Pastoral	1337	6.1%	1415	5.7%	2752	5.9%
Others	1536	7.0%	1261	5.1%	2797	6.0%
NA	453	2.1%	654	2.6%	1107	2.4%
Total	21819	100.0%	24878	100.0%	46697	100.0%

[1]Percentage over total number of individuals interviewed

9.2.3 TB contact history of participants

A close contact history to a TB patient was reported in 2,109 (4.5%) of the participants. The proportion of TB patient contact history was almost the same between male (4.7%) and female (4.3%) (Table 6).

Table 6: TB contact history by sex

	Yes	%	Total
Male	1034	4.7%	21819
Female	1075	4.3%	24878
Total	2109	4.5%	46697

[1]Percentage calculated among total participants

> *Close contact history to a TB patient was reported in 2,109 (4.5%) of the participants*

9.2.4. TB history

A total of 75 participants (161/100,000 population) reported that they were receiving TB treatment at the time of the survey: 42 males (193/100,000) and 33 females (133/100,000). A higher proportion of urban respondents reported currently being on treatment (240/100,000) than rural (146/100,000) and pastoralists respondents (141/100,000).

Table 7: Current anti-TB treatment history by sex and residence

	Yes	/100,000	Total
Sex			
Male	42	192	21819
Female	33	133	24878
Total	75	161	46697
Residence			
Urban	18	240	7490
Rural	51	146	34952
Pastoral	6	141	4255
Total	75	161	46697

Out of the 75 people on anti-TB treatment, information on where treatment was received was collected from 64 participants. Out of them, 54 (84.4%) report that they were receiving treatment at a government or public health facility: at government hospital (7.8%), at health centre (68.8 %) and at health post (7.8%). Of the 10 not receiving treatment at a government or public health facility, 7 received treatment at a private clinic, while the remaining respondents report receiving treatment at a private pharmacy, NGO. One respondent said they were getting drugs to treat their TB from outside the country (Table 8).

The proportion of those on anti-TB treatment during the survey who were receiving their treatment at non public or non government facilities (15.6%) is particularly high, if compared with the ratio of PPM DOTS sites registered by FMOH over the total number of DOTS clinics in the country (<10%). This high proportion may suggest that some private health facilities are treating TB without any agreement with FMOH, which may highly affect monitoring of TB Control program in the country.

In the remaining 11 cases, the information on where the anti-TB treatment was provided was missing, mainly because the team leader who was supposed to conduct the re-interview of individuals on anti-TB treatment was busy with other survey activities and the individuals left the study site without being re-interviewed. In the future this issue may be solved by attaching the re interview form for eligible individuals right after they completed the first interview form (Form 4) in order to easily track the incomplete forms.

Table 8: Place of treatment for participants currently on anti-TB treatment

Treatment place	Sex				Resident Type						Total	%
	Male	%	Female	%	Urban	%	Rural	%	Pastoral	%		
Government Hospital	4	9.52	1	3.03	4	22.22	0	0.00	1	16.67	5	6.67
Health Center	27	64.29	17	51.52	7	38.89	33	64.71	4	66.67	44	58.67
Health Post	2	4.76	3	9.09	0	0.00	5	9.80	0	0.00	5	6.67
Private Clinic	3	7.14	4	12.12	1	5.56	5	9.80	1	16.67	7	9.33
Pharmacy	1	2.38	0	0.00	1	5.56	0	0.00	0	0.00	1	1.33
NGOs	1	2.38	0	0.00	0	0.00	1	1.96	0	0.00	1	1.33
Other	1	2.38	0	0.00	1	5.56	0	0.00	0	0.00	1	1.33
NA	3	7.14	8	24.24	4	22.22	7	13.73	0	0.00	11	14.67
Total	42	100.00	33	100.00	18	100.00	51	100.00	6	100.00	75	100.00

9.2.5 Previous anti TB treatment history

Anti-TB treatment history in the last 5 years (excluding those currently on treatment) was reported among 733 (1.6%) participants. Out of this number there was missing information on place of treatment for 141 participants (19.2%). From the 592 participants whose treatment facility information was recorded, 498 (84.1%) individuals reported that they had received treatment at public or government health facilities: 51 (8.6%) at government hospital, 416 (70.2%) at a health centre and 31 (5.2%) at health post. The remaining 94 (15.9%) individuals had received treatment at non-public or non-government health facilities: 22 (3.7%) at private hospital, 48 (8.1%) at private clinic, 2 (0.3%) at private pharmacy, 13 (2.2%) at NGO and 9 (1.5%) reported receiving treatment through other means, like getting drugs outside of the country. The majority of respondents who were previously treated and are currently on treatment report receiving treatment at a health centre but a slight increase was observed in the proportion of respondents who currently receive treatment who report receiving treatment at a health post compared with those who were previously treated. This difference may suggest the current expansion of DOTS at health post level.

Table 9: Place where previously received TB treatment

Treatment place	Sex				Resident Type						Total	
	Male	%	Female	%	Urban	%	Rural	%	Pastoral	%		%
Government Hospital	27	7.54	24	6.40	17	9.39	25	5.52	9	9.09	51	6.96
Health Center	209	58.38	207	55.20	118	65.19	255	56.29	43	43.43	416	56.75
Health Post	13	3.63	18	4.80	2	1.10	27	5.96	2	2.02	31	4.23
Private Hospital	7	1.96	15	4.00	3	1.66	4	0.88	15	15.15	22	3.00
Private Clinic	18	5.03	30	8.00	6	3.31	35	7.73	7	7.07	48	6.55
Pharmacy	0	0.00	2	0.53	1	0.55	1	0.22	0	0.00	2	0.27
NGOs	7	1.96	6	1.60	0	0.00	11	2.43	2	2.02	13	1.77
Other	2	0.56	7	1.87	3	1.66	2	0.44	4	4.04	9	1.23
NA	75	20.95	66	17.60	31	17.13	93	20.53	17	17.17	141	19.24
Total	358	100.00	375	100.00	181	100.00	453	100.00	99	100.00	733	100.00

9.3 Screening

9.3.1 TB related symptoms

A total of 46,697 participants were interviewed for symptom screening. From those interviewed, 5,930(12.7%) reported they had a cough but only 3,025 (6.5%) reported that they were coughing for 2 weeks or more; these respondents were identified as possible TB suspects according to the NTP definition.

A total of 17,729 (37.8%) participants reported at least one out of the four TB related symptoms mentioned during screening (chronic cough, fever, night sweat, weight loss) during the survey period (Table 10).

Table 10: TB symptom screening outcome

	Number	%
Symptom		
Cough : 1-13 days	2,905	6.22
Cough: 14-20 days	905	1.94
Cough: 21+days	2,120	4.54
Cough: Total	5,930	12.66
Night sweat>=2wks	8,177	17.51
Fever>=2wks	5,920	12.68
Wt loss>=3kg in the last 1 month	10,014	21.44
Any Symptoms	17,729	37.97
Eligible for Sputum by interview(Cough≥2 weeks)	3,025	6.48

Prevalence of chronic cough was almost the same among males 1,486(6.2%) and females 1,539(6.8%). Prevalence of chronic cough increased with age. Chronic cough was more prevalent among pastoralists, 390(9.2%) compared with 2,333(6.6%) 312(4.2%) for rural and urban areas, respectively (Table 11).

Table 11: Characteristics of respondents with cough for more than 14 days

	Cough>=14 days	%	Total
Sex			
Male	1486	6.80	21819
Female	1539	6.20	24878
Age			
15-24	631	4.20	15030
25-34	647	5.20	12397
35-44	544	6.60	8214
45-54	470	8.90	5286
55-64	350	10.90	3222
65 and above	383	15.00	2548
Residence			
Urban	312	4.20	7490
Rural	2323	6.60	34952
Pastoral	390	9.20	4255
Total	3025	6.50	46,697

9.3.2 Chest X-Ray

Out of the total 46,697 participants, 46,548 (99.7%) received a CXR (Table 12). The proportion of CXR examination among male and female was exactly the same: Male 21,749 (99.7%) and Female 24,798 (99.7%). Seventy (0.3%) males and 80 (0.3%) females were exempted from CXR examinations for various reasons such as being too ill to come to the X-ray site or not wanting to get the X-ray. The proportion of CXR completed was similar across the strata (Rural 99.7 %, Urban, 97.6% and Pastoralist, 99.7%). Participants unable to stand on the X-ray stationary stand received interviews at home and were also exempted from chest X -ray. Pregnancy was not a criterion for exemption from X-ray examination. All female participants in the reproductive age group wore a gonadal shield and were screened by X-ray regardless of their pregnancy status after consent was requested. Those who were exempted from CXR screening were advised to submit sputum specimens if they had at least one screening symptom or risk factor: Chronic cough>2weeks,

Fever >2weeks, night sweat >2weeks, weight loss in the last month or previous contact history with a TB patient. Among 149 participants who were exempted for chest X-ray, 42 were eligible for sputum examination.

From the total field X-ray reading done, 3,818 (8.2%) were categorized as eligible for sputum examination due to having any abnormality in the lungs (Table 12). A higher proportion of lung abnormality was observed among male participants, 2,212 (10.2%) than female participants, 1,606 (6.5%).

Table 12: CXR field screening results

Variable	Field CXR performance				Field X-ray result						
	Total	Taken		not taken	Total	Normal		Other abnormal		Abnormal	
						Not eligible for sputum		not eligible for sputum		eligible for Sputum	
		num	%	num		num	%	num	%	num	%
Sex											
Male	21819	21750	99.7	70	21750	19452	89.4	86	0.4	2212	10.2
Female	24878	24798	99.7	80	24798	23039	92.9	153	0.6	1606	6.5
Age											
15 - 24	15030	14978	99.7	52	14978	14431	96.3	46	0.3	501	3.3
25 - 34	12397	12363	99.7	34	12363	11608	93.9	35	0.3	720	5.8
35 - 44	8214	8195	99.8	19	8196	7421	90.5	44	0.5	731	8.9
45 - 54	5286	5271	99.7	15	5271	4544	86.2	33	0.6	694	13.2
55 - 64	3222	3216	99.8	6	3216	2619	81.4	44	1.4	553	17.2
65+	2548	2524	99.1	24	2524	1868	74.0	37	1.5	619	24.5
Residence											
Urban	7490	7463	99.6	27	7463	6834	91.6	80	1.1	549	7.4
Rural	34952	34840	99.7	112	34841	31835	91.4	148	0.4	2858	8.2
Pastoral	4255	4244	99.7	11	4244	3822	90.1	11	0.3	411	9.7
Total	46697	46548	99.7	150	46548	42491	91.3	239	0.5	3818	8.2

Central CXR reading by specialists (St. Paul's Hospital Radiology department) was carried out for all field readings of five clusters, all abnormal X-ray films and 10 % of the normal films of field reading of 80 clusters. From all the 5 field teams, all films of one cluster were reread with the central X-ray team in order to give feedback and re train the X-ray readers if necessary.

From the total X-ray field screenings conducted, a total of 10,556 films (6,738 not eligible for sputum or no abnormality on the lung and 3,818 eligible for sputum examination by field CXR screening) were sent for central X-ray reading (Table 13). The central X-ray reading suggested that 224 images (205 from eligible and 19 non eligible by field reading screening) the presence of active TB and 143 images (134 from eligible and 9 non eligibly by field screening) suggested possible TB suspects. The central reading team also classified 203 (1.92%) images: 190 from eligible and 9 not eligible for sputum by field screening as healed TB. A total of 2,439(64%) out of 3,818 of films classified as abnormal and eligible for sputum examination in the field were classified as normal by the central reading. A possible reason for the high rate of false TB suspect rate could be that field readers were encouraged to over read the field screening in order to avoid missing possible cases. Although over-reading was practiced in the field reading, the central expert reading detected 19(0.28%) TB suggestive chest X-rays and 9(0.13%) chest X-rays with TB suspected findings that were judged as non-eligible for sputum examinations by the field reader. Overall, the field reading missed 0.41% images suggesting active TB or TB suspect.

Table 13: Comparison of field and central CXR readings

Central Reading	Field Reading					
	(A)		(B)		(C)	%
	Total Number	%	Eligible for exam	B/10556 (%)	Non-eligible	C/6738
Normal	8,653	81.97	2,439	63.88	6214	92.22
Active TB Suggestive	224	2.12	205	5.37	19	0.28
TB suspect	143	1.35	134	3.51	9	0.13
Healed TB	203	1.92	190	4.98	13	0.19
Other lung disease	221	2.09	198	5.19	23	0.34
Cardio vascular abnormality	119	1.13	72	1.89	47	0.7
Other findings in lung	392	3.71	243	6.36	149	2.21
Not interpretable	465	4.41	189	4.95	276	4.1
Not available for reading	287	2.72	287	7.52	0	0
Total Film (excluding double count in case of multiple abnormality)	10556	100	3,818	100	6,738	100

Note: Those images with false negative results by field readers were re-assessed. There was no major error such as cavitary or moderate/far advanced findings observed. False negatives were those with non-cavitary, minimum or lower lobe findings.

9.3.3 Result of symptom and CXR screening and eligible participants for sputum examination

A total of 6,080(13.0%) participants who were screened positive with at least one of the screening methods (symptoms or CXR) were eligible for sputum examination. Among them, 806 were eligible both by symptoms and CXR abnormality, 2210 were eligible only by symptom, and 3012 were eligible only by CXR abnormality (Table 14). Fifty individuals who did not receive a CXR were eligible by the presence of symptoms: 9 had chronic cough and 41 had other TB symptoms without chronic cough (Table 14).

Table 14: Summary results of the screening: Reasons of eligible for sputum examinations

With and Without CXR		Interview		
		Eligible	Not Eligible	Total
With CXR(N=46548)	Eligible	806	3013	3019
	Not Eligible	2211	40518	42729
CXR not taken(N=149)	with chronic cough	9	0	9
	without chronic cough but with other symptoms	41	99	140
Total		3077	43620	46697

Note: Total eligible=806+3013+2211+9+41=6080

9.4. Laboratory Examinations

9.4.1 Sputum collections

A total 6,080(13.1%) out of the 46,697 study participants were considered eligible for sputum examinations and were requested to submit two sputum specimens. Out of these eligible for sputum examination, 5,864 (96.6%) participants submitted at least one specimen and 5,606(92%) participants submitted two sputum specimens. A total of 11,470 specimens were collected from 85 clusters with an average of 135 specimens per cluster. From the total eligible individuals for sputum examination: 5,863(96%) individual had at least one smear result, 5,596(92%) individuals had both smear results and 5,770(95%) individuals had one culture result (table 15). Ninety-one percent of those eligible by symptoms and 94% of those with CXR results that were suggestive of TB were examined with two specimens smear and one specimen culture.

A total 6,080(13.1%) out of the 46,697 study participants were considered eligible for sputum examinations

Table 15: Screening and CXR results and sputum examinations

	Eligible	2S1C	%	2S0C	%	1S1C	%	1S0C	%	0S1C	%	no exam	%
Eligible by Symptom only	2211	2012	90.67	0	0.00	107	4.82	1	0.03	0	0.00	99	4.46
Eligible by CXR Abnormality only	3012	2804	93.09	4	0.13	132	4.38	0	0	1	0.03	71	2.36
Eligible by both symptom and CXR	806	777	96.40	0	0.00	24	2.98	0	0	0	0.00	5	0.62
CXR exempted or Refused without symptom	41	2	4.88	0	0.00	0	0.00	0	0	0	0.00	39	95.12
CXR exempted or refused with chronic cough	9	9	100	0	0	0	0	0	0	0	0	0	0
Total	6080	5595	92.0533	4	0.07	263	4.33	1	0.012	0	0.00	214	3.52
CXR central reading													
Normal	2785	2602	93.43	3	0.11	119	4.27	1	0.04	0	0.00	60	2.15
Active TB Suggestive	208	196	94.23	0	0	9	4.33	0	0.00	0	0.00	3	1.44
TB suspect	135	127	94.07	0	0	4	2.96	0	0.00	0	0.00	4	2.96
Healed TB	192	185	96.35	0	0	4	2.08	0	0.00	0	0.00	3	1.56
Other lung disease	201	189	94.03	0	0	7	3.48	0	0.00	0	0.00	5	2.49
Cardio vascular abnormality	72	67	93.06	0	0	4	5.56	0	0.00	0	0.00	1	1.39
Findings other than lung	256	243	94.92	0	0	8	3.13	0	0.00	0	0.00	5	1.95
Not interpretable	203	190	93.60	1	0.49	8	3.94	0	0.00	0	0.00	262	129.06
NA	287	266	92.68	0	0	10	3.48	0	0.00	1	0.35	0	0.00
Total	4339	4065	93.69	4	0.09	173	3.99	1	0.02	1	0.02	343	7.91

[1]2s1c- two smear and one culture, 2s0c- two smear and no culture, 1s1c- one smear and one culture, 1s0c- one smear and no culture,0s0c- no smear and no culture.

9.4.2 Smear and culture examination results

In total, 61 participants showed at least one positive slide by LED fluorescent microscope.

The spot specimens showed 50 positive slides and the morning specimens showed 47 positive slides (Table 16). Scanty positive slides occupied 50% of positives in spot (25/50) and 17% of positives in morning specimens (8/47). From all positive slides 36 subjects (59%) had smear grade1+ and above.

Among 61 AFB smear-positive, 34 subjects, (57.7%) had culture-positive result (Tables 17 and 18). Mycobacterium tuberculosis was identified from 96 participants; 33 from smear-positive and 63 from smear-negative. Mycobacterium Other Than TB (MOTT) was isolated from 91 participants (1 from smear-positive and 90 from smear-negative, without co-isolate of Mycobacterium tuberculosis).

Table 16 Smear examination results

	Spot Smear				Morning smear			Combined					
	Total	Positive	Negative	NA	Positive	Negative	NA	2Ps	1P1N	1P1NA	2Ns	1N only	2NAs
Eligible by Symptom only	2122	5	2109	8	4	2018	100	1	7	0	2006	108	0
Eligible by CXR Abnormality only	2943	21	2916	6	17	2798	128	12	14	0	2784	132	1
Eligible by both symptom and CXR	801	24	777	0	26	751	24	23	3	1	751	23	0
CXR exempted with symptom	2	0	2	0	0	2	0	0	0	0	2	0	0
Total	5868	50	5804	14	47	5569	252	36	24	1	5543	263	1
Resident Type													
Urban	759	5	752	2	5	706	48	4	6	0	703	50	0
Rural	4425	35	4379	11	35	4210	180	27	21	0	4192	189	1
Pastoral	684	10	673	1	7	653	24	5	9	1	648	24	0
Age category													
15 - 24	997	15	977	5	15	904	78	13	5	1	899	80	1
25 - 34	1206	11	1193	2	10	1135	61	6	11	0	1128	63	0
35 - 44	1101	9	1089	3	10	1055	36	9	4	0	1052	39	0
45 - 54	1004	8	994	2	7	971	26	4	11	0	965	28	0
55 - 64	746	6	739	1	5	721	20	4	4	0	718	21	0
65+	814	1	812	1	0	783	31	0	1	0	781	32	0
Male by age													
Total	3176	29	3137	10	27	3005	144	24	13	1	2992	151	1
15 - 24	499	11	484	4	9	441	49	9	2	1	437	50	1
25 - 34	609	3	605	1	5	565	39	3	2	0	564	40	0
35 - 44	614	6	606	2	6	589	19	6	2	0	587	21	0
45 - 54	554	4	548	2	4	534	16	3	4	0	531	18	0
55 - 64	419	4	415	0	3	407	9	3	2	0	406	9	0
65+	481	1	479	1	0	469	12	0	1	0	467	13	0
Female by age													
Total	2692	21	2667	4	20	2564	108	12	23	0	2551	112	0
15 - 24	498	4	493	1	6	463	29	4	3	0	462	30	0
25 - 34	597	8	588	1	5	570	22	3	9	0	564	23	0
35 - 44	487	3	483	1	4	466	17	3	2	0	465	18	0
45 - 54	450	4	446	0	3	437	10	1	7	0	434	10	0
55 - 64	327	2	324	1	2	314	11	1	2	0	312	12	0
65+	333	0	333	0	0	314	19	0	0	0	314	19	0

Table 17 Relationship between morning and spot smear

Spot grade	Total	Morning grade			
		Negative	Scanty	3+	NA
Negative	5804	5543	7	1	250
Scanty	25	11	7	1	1
1+	14	2	1	1	0
2+	9	0	0	4	0
3+	2	0	0	2	0
NA	14	13	0	0	1
Total	5868	5569	15	9	252

Table 18 Relationship between smear and culture Result

	Culture Result					
	Total	Positive MTBC	Positive NTM	Negative	Contaminated	NA
Spot grade						
Total	5868	96	91	5319	357	5
Negative	5804	69	90	5289	351	5
Scanty	25	8	1	15	1	0
1+	14	9	0	1	4	0
2+	9	8	0	0	1	0
3+	2	2	0	0	0	0
NA	14	0	0	14	0	0
Morning grade						
Total	5868	96	89	5321	357	5
Negative	5569	63	86	5075	341	4
Scanty	15	7	0	8	0	0
1+	10	6	0	1	3	0
2+	13	11	1	0	1	0
3+	9	9	0	0	0	0
NA	252	0	2	237	12	1

9.5 Case review by Central Medical Panel

The central medical panel reviewed all available information for the individuals with positive results from the laboratory. The panel provided medical advice to survey participants with positive results and certified individual study results according to the case definition of the study protocol. As indicated in table 19, among 61subjects with AFB smear positive result, 33 with Mycobacterium tuberculosis isolates were categorized as definite smear positive TB cases. Fourteen subjects were categorized as probable smear positive TB cases without culture confirmation. Among them, 8 subjects had two smear positive slides and 6 subjects had one smear positive slide with a CXR consistent with TB by a panel reading.

However, 13 subjects with one smear positive result without any CXR finding consistent with TB disease were excluded from the study case list as possible TB cases. One subject with isolates MOTT was also excluded from the case list as non-TB.

Among 63 smear negative culture positive subjects with mycobacterium TB isolates, 59 were categorized as definite culture positive TB cases with CXR results consistent with TB disease. Whereas 4 subjects without CXR finding consistent with TB disease were categorized as probable smear negative culture positive cases.

> *Fourteen subjects were categorized as probable smear positive TB cases without culture confirmation*

Table 19. Medical Panel review of study cases

Sputum			Panel CXR result					Treatment history		Symptom	final decision			total
sp1	sp2	c	TB			BE	Normal				TB			
			sug.	consist	Healed			on	ex		Definite	Probable	Possible	
+	+	+	27					1	5	19	27			27
	+	+	6							1	6			6
+		+												0
		+	41	17	1		4	1(ex/on)	3	29	59	4		63
+	+		5	1	1	1		1(ex/on)	1	4		8		8
+			2	2	3	5	2		3	6		4	10	14
	+		1	1		2	1			4		2	3	5
			82	21	5	8	7	3	12	63	92	18	13	123

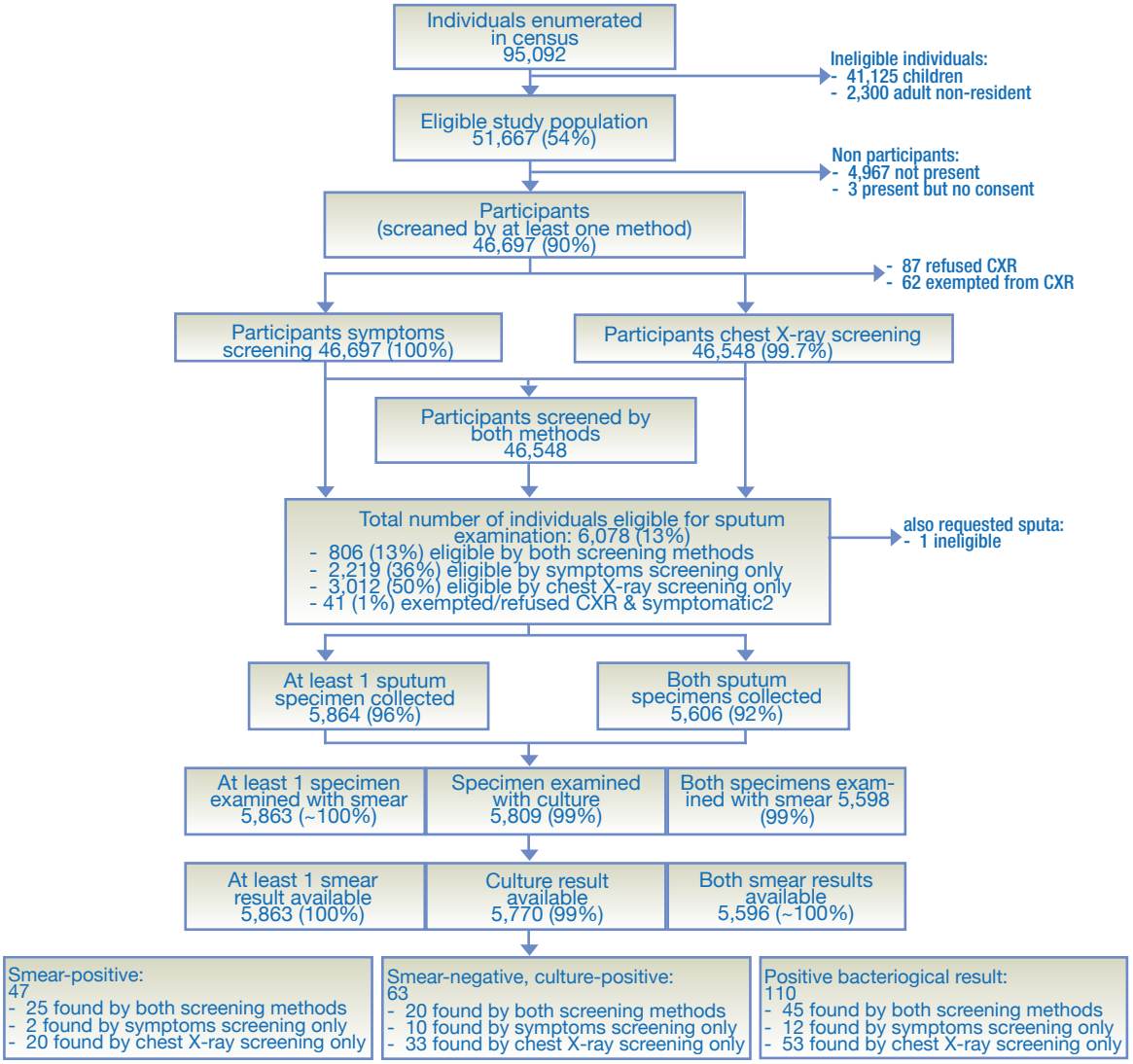
BE: Bronchial Echtasis, ex: previously treated, on: currently on treatment, ex/on: previously treated and currently on treatment.

Table 20. Number of prevalent cases (study cases) by interview and CXR results

	S+C+	S+C-	S-C+	Smear positive	Bacteriologically confirmed	Non study cases / (probable/Motto)		All Total
	TB case	TB case	TB case	study case	study case	S+C-	S+MOTT	
Total	33	14	63	47	110	13	1	124
Symptoms only								
Eligible	0	2	10	2	12	5	1	18
Non-eligible	0	0	0			0	0	0
CXR only								
Eligible	12	8	33	20	53	6	0	59
Non-eligible	0	0	0	0		0	0	0
Both Symptoms & CXR		0		0				0
Eligible	21	4	20	25	45	2	0	47
Non-eligible	0	0	0	0	0	0	0	0
No-CXR	0	0	0	0	0	0	0	0
Central CXR Result :								
Normal	4	2	17	6	23	8	0	31
Active TB	15	5	9	20	29	0	0	29
TB Suspect	7	0	5	7	12	0	0	12
Healed TB	2	1	3	3	6	1	0	7
Other lung disease	7	1	10	8	18	0	0	18
Cardio vascular disorder	0	0	0	0	0	1	0	1
Other findings	2	0	5	2	7	0	0	7
Not interpretable	2	1	2	3	5	0	0	5
Sex Total	33	14	63	47	110	13	1	124
Male	21	5	30	26	56	6	0	62
Female	12	9	33	21	54	7	1	62
Age								
Total	33	14	63	47	110	13	1	124
15 - 24	11	4	21	15	36	2	0	38
25 - 34	7	3	14	10	24	4	1	29
35 - 44	8	1	9	9	18	1	0	19
45 - 54	3	4	9	7	16	4	0	20
55 - 64	4	1	6	5	11	2	0	13
65+	0	1	4	1	5	0	0	5
Resident Type								
Total	33	14	63	47	110	13	1	124
Urban	2	3	12	5	17	1	0	18
Rural	26	9	46	35	81	8	0	89
Pastoral	5	2	5	7	12	4	1	17

Figure 7 below summarizes the results of the recruitment of participants and TB outcomes.

Figure 7: Summary of census and screening result



[1] Pregnant, too sick/old, CXR not working; [2] At least one of fever, weight loss, night sweats or contact of a TB case

9.6. Prevalence of TB

Point estimates of the prevalence of bacteriologically confirmed TB of different groups/strata are shown in Table 21. Different analytical methods were used to estimate the prevalence of TB and the result of design-based analysis of participants with imputation was applied.

9.6.1 Smear positive TB (S+)

Forty seven subjects (26 male and 21 female) met the survey definition of S+TB cases, with a prevalence of 108/100,000 (72-138). From smear positive TB cases, 37(78.7%) were new cases, 2(4.3%) were on treatment, and 8(17%) were previously treated in the last five years.

One smear positive and culture positive, one smear positive and culture negative, and one smear negative and culture positive cases were on treatment during the survey period, and two of them also had previous treatment history in the last five years.

Thirty cases (63.8%) reported symptoms suggesting TB (chronic cough). Though the number of cases was highest in the 54-64 age group and lowest in the 65+ age group, prevalence increased with age (Table 21). Higher prevalence of smear positive TB was observed in males 123(75-171) than in females 88(44-122)/100,000.

The highest prevalence was observed among pastoralists 170(60-280)/100,000 while the lowest was observed in urban areas, 77(6-135)/100,000. The rural prevalence, 109(67-1151)/100,000, was close to the national prevalence.

9.6.2 Smear-negative/culture-positive TB (S-/C+)

The survey detected 63 S-/C+ TB cases, 145(98–187) /100,000 among the population aged 15 or more.

9.6.3 Bacteriologically confirmed TB (S+ and/or C+)

A total of 110 bacteriologically confirmed TB patients (47 smear positive and 63 smear negative culture positive) were detected by the survey, corresponding to a prevalence of 277 (208–347)/100 ,000 with a design effect of 1.26. The prevalence in males was 287 (201-374)/100,000 which was higher than in females, was 232(163-301)/100,000. Similar to the prevalence of smear positive TB, the highest prevalence was observed in pastoral clusters and the lowest in urban clusters (Table 21).

Table 21 Different methods of calculation of Prevalence of TB among age >15 Years

Prevalence of bacteriologically confirmed pulmonary TB (per 100 000 population)						
% (95% CI)	Cluster-level	Model 1[1]	Model 2[2]	Model 3[3]	Model 4[4]	Model 5[5]
Overall point prevalence	240 (190–290)	240 (190–290)	257 (204–311)	221 (167–275), P^0=0.09	247 (192–303)	277 (208–347)
Point prevalence by stratum						
Urban	232 (107–357)	230 (121–339)	251 (125–376)	213 (98–327)	237 (113–362)	273 (130–416)
Rural	236 (177–295)	236 (176–297)	252 (189–315)	217 (157–277), P^0= 0.09	238 (175–300)	273 (189–356)
Pastoral	291 (126–456)	287 (173–402)	310 (163–457)	270 (96–444)	294 (106–482)	316 (163–468)
Design effect	1.26					
	n/ N(%, 95% CI)					
Overall crude [6] prevalence	110/45874 (239, 197–289)					
Stratum crude [6] prevalence						
Urban	17/7384 (230, 134–368)					
Rural	81/34316 (235, 187–292)					
Pastoral	12/4174 (290, 150–506)					

[1] Robust standard errors; [2] Robust standard errors with missing value imputation; [3] Random-effects logistic regression; [4] Random-effects logistic regression with missing value imputation; [5] Robust standard errors with missing value imputation and inverse probability weighting; [6] Crude prevalence is calculated as the total number of individuals with a positive combined smear and/or culture result divided by the total number of individuals who have been screened for TB by chest X-ray and/or interview with smear and culture results available. Confidence interval for this estimate is calculated with exact binomial probability theory; 0P-value calculated as a result of likelihood ratio test of rho=0 in the random-effects model, equivalent to testing a null hypothesis of no between-cluster variation (which is the same thing as no within-cluster correlation)

Prevalence of smear positive pulmonary TB (per 100 000 population)						
% (95% CI)	Cluster-level	Model 1[1]	Model 2[2]	Model 3[3]	Model 4[4]	Model 5[5]
Overall point prevalence	103 (69–136)	102 (68–135)	103 (70–136)	83 (47–119), P^0=0.06	89 (54–123)	108 (73–143)
Point prevalence by stratum						
Urban	68 (0–151)	68 (7–128)	75 (6–143)	56 (1–111)	66 (0–132)	70 (6–135)
Rural	102 (63–142)	101 (61–141)	102 (59–144)	84 (44–123), P^0= 0.07	89 (47–131)	109 (67–151)
Pastoral	168 (58–279)	166 (65–267)	156 (53–260)	141 (15–267)	138 (16–261)	170 (60–280)
Design effect	1.31					
	n/ N(%, 95% CI)					
Overall crude [6] prevalence	47/46221 (102, 75–135)					
Stratum crude [6] prevalence						
Urban	5/7406 (68, 22–157)					
Rural	35/34600 (101, 70–141)					
Pastoral	7/4215 (166, 67–342)					

[1] Robust standard errors; [2] Robust standard errors with missing value imputation; [3] Random-effects logistic regression; [4] Random-effects logistic regression with missing value imputation; [5] Robust standard errors with missing value imputation and inverse probability weighting; [6] Crude prevalence is calculated as the total number of individuals with a combined smear positive result divided by the total number of individuals who have been screened for TB by chest X-ray and/or interview with smear results available. Confidence interval for this estimate is calculated with exact binomial probability theory; 0P-value calculated as a result of likelihood ratio test of rho=0 in the random-effects model, equivalent to testing a null hypothesis of no between-cluster variation (which is the same thing as no within-cluster correlation)

10 DISCUSSION

The survey results indicate that TB prevalence in Ethiopia is nearly three times lower than what had been previously estimated. This section will discuss issues of eligibility criteria, survey participation, and implications of the survey findings.

10.1 Eligibility criteria

The eligibility criteria of the survey subjects took into account mobile populations as much as possible, especially those who migrated to urban areas to work, even if only seasonally. Those who stayed in a survey area for 14 days or more were included in the survey regardless of their residential status. However, it was difficult to catch the population temporarily away from home for work or study. Those who were registered as residents but basically stayed in another place during weekdays to work or study were categorized as eligible regardless of their actual availability on the survey day.

According to the survey design, a cluster size of 520-600 eligible adult subjects was expected. However, 608 subjects per cluster were recruited on average as eligible subjects. The possible reasons for oversampling were:

- Uncertainty of the size of the population in each household block of the kebele, field teams tend to recruit more blocks to secure the minimum cluster size.

- Uncertainties about the proportion of children, resulting in a higher overall recruitment of individuals.
- Field teams were able to examine more than 180 participants a day.
- Securing enough participants in clusters where they anticipated a lower participation rate, such as in urban or remote areas where there were many absentees.
- Difficulty for the survey team to stop the recruitment in the middle of a household group/block, so once the team began the census, it tended to recruit all households in the same block.

10.2 Survey participation

The involvement of health extension workers, other local health staff, different local administrative staff (Sub-village leaders, kebele Manager, kebele Principal, District Head, Head of woreda Health office) and the community, including religious leaders, contributed to the high participation rate in the survey.

The recruitment of participants in urban areas was rather challenging due to the difficulty of finding eligible respondents on the survey days. The working hours for the survey were extended from 17:00 to 21:00 to allow for the participation of workers occupied during the daytime. Health extension workers in Addis Ababa faced difficulty in guiding the field team to the selected households. As a result, the census in Addis took more than two days to complete while in most other areas, the census was completed in one day. A recommendation for future surveys in urban areas is to conduct sketch map of each house with a household number to facilitate access for census, mop-up, and revisiting the family. Although a participation rate of 86% was achieved in urban clusters, recruitment of participants in communities with a more urbanized lifestyle will be a big challenge for future surveys. Transportation by a survey team car also facilitated the participation of disabled and elderly people. Despite all of these efforts, a slightly lower participation rate was observed among urban clusters.

10.3 Participants

TB history

The NTP's notification rate of all forms of TB was 175/100,000 in 2010/11. Given that the average duration of treatment is 8 months, it is estimated that 242/100,000 adults in this survey populations received TB treatment in a year. The observations of the survey were 1.4 times higher than notification data of the NTP report.

The difference in the proportion of TB patients currently receiving treatment at a health centre/post (65%) and those previously treated who went to a health centre/post (61%) may suggest a successful expansion of DOTS to peripheral facilities in recent years. Particularly, the proportion of patients currently receiving treatment at health post is 2 times higher (7%) than the proportion in previously treated in the past five years (4%).

10.4 Smear examination results

There were 96 Mycobacterium tuberculosis isolates from the total suspects who submitted sputum. There were 91 (48%) MOTT from the total suspects and one of them was also smear positive with LED microscope. The observed proportion of NTM in this survey is high compared with that of survey findings in Asia countries: for example the recent survey (2009) in Myanmar observed 7% MOTT among the total culture positive specimens. This needs further investigation on the source of MOTT and why the rate is so high in Ethiopia.

10.5 Prevalence of TB

Point estimates of the prevalence of bacteriologically positive TB of different groups/strata are shown in Table 21. Among the different analytical methods applied to determine the prevalence, the method that estimated the robust standard errors with missing value imputation and inverse probability weighting is the officially accepted prevalence.

Even though the analytical method that was selected yields a higher prevalence, the prevalence in this survey was still significantly lower than what had been anticipated.

10.6 Prevalence in population (all ages)

10.6.1 .1 Prevalence of smear positive TB (S+) in Ethiopia

In order to estimate the prevalence of S+ TB for all age groups, the following assumptions are taken into consideration:

- Children (less than 15 years of age) occupied 45% of the population according to the 2007 Ethiopian census report.
- Prevalence of smear positive TB among age <15 is assumed to be the same as the notification rate of the NTP data.
- S+ notification rate per 100,000 of children from 2000 to 2010 has: mean=7.5 SD=1.1
- Assuming notification is a correct estimate of prevalence rate
- Prevalence of S+ TB among age > 15 is 108/100,000 population.

Therefore prevalence in S+ TB in the population is calculated P=((P>15x0.55) +(P<15 X0.45))

Hence, the observed prevalence of smear positive TB in Ethiopia was found to be 63(44-82)/100,000. This is 3 to 6 times lower than the 2008 estimate which was (284/100000). In 2010/11 NTP data indicated that there was 61/100,000 S+ TB cases in the population which make the case detection rate of S+, 96.8%. This shows prevalence of smear positive TB is consistent with the NTP notification rate and DOTS is working properly in Ethiopia.

10.6.1.2. Prevalence of Bacteriologically confirmed TB in Ethiopia

Assumptions:

Smear negative, culture positive TB in children is estimated to be zero. Hence, only the S+ notification rate of 7.5/100,000 discussed above was used to estimate the number of bacteriologically confirmed TB cases among children. We made this assumption in the absence of any nationally

representative data and this is a limitation that may lead to underestimate of the prevalence. Therefore prevalence in bacteriologically confirmed TB in the population is calculated P=((P>15x0.55) +(P<15 X0.45))
With this assumption the observed prevalence of bacteriologically confirmed TB in Ethiopia was found to be 156(118-194)/100,000.

10.6.1.3. Prevalence of All forms of TB in Ethiopia

The prevalence of all forms of TB in Ethiopia includes the estimates from this survey adjusting for extra-pulmonary TB. The following assumptions are taken into consideration when adjusting for extra-pulmonary TB:

- Assuming the extra pulmonary TB prevalence rate is constant across all ages
- Percentage of extra pulmonary TB over total notifications from 2000 to 2010 has: mean=34.8% SD=1.2%
- Prevalence pulmonary TB(smear negative and smear positive TB) is equivalent to prevalence of bacteriologically confirmed TB: 156/100, 000 population
- Proportion of pulmonary TB is 65%.

Therefore prevalence of all forms of TB is calculated as: P=(P PTBX100/65): where P PTB is prevalence of Pulmonary TB.

Therefore the prevalence of all forms of TB in Ethiopia is estimated to be 240 (182-298)/100,000. This means Ethiopia with a population of 80 million has around 192,000 cases. In a year at the time of the survey (2010/11), NTP notified 175/100,000 all forms of TB cases which make the total case detection rate of 73% which is also consistent with the WHO 2011 report (72%). This extrapolated prevalence of all forms of TB is much lower than the best estimate in the WHO 2011 report (394/100000), but within the 95% confidence interval of 173-623.

10.6.2 Cluster variation and geographical differences

Although the National TB Prevalence survey aimed to estimate the TB prevalence at the national level, the high participation rate and high TB prevalence made comparison between strata feasible. The observed variation between clusters (design effect of S+ TB: 1.24) was lower than assumed by the survey design (design effect of S+ TB: 1.5).

There were 110 bacteriologically confirmed cases from all 85 clusters, but 25 clusters did not have any bacteriologically confirmed cases. In a few clusters, the prevalence of bacteriologically confirmed TB exceeds 1,000/100,000. This showed the distribution of TB across region and nationally. A higher prevalence rate of both smear positive and bacteriologically confirmed TB was observed in pastoral clusters. This might be due to problem in treatment adherence during mobility and access to health service facilities.

10.6 Comparison with other surveys in Asian countries

Prevalence of smear positive TB (63/100,000) is much lower than other recent survey findings in Asian countries. Cambodia conducted the first national TB prevalence survey in 2002 and found smear positive prevalence of 269/100,000. The Philippine national TB survey in 2007 found the rate to be 260/100,000, while the rate was found to be 171/100,000 in Myanmar in 2009. Unfortunately, there is no national data in Africa to compare the Ethiopian results.

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PROGRAMME IMPLICATIONS

The result of this first national TB prevalence survey has shown the magnitude of smear positive TB to be three times lower than the previous estimate. According to the 2009 WHO global TB report, the incidence rate of smear positive pulmonary TB in Ethiopia was 163 per 100,000 (11). With this estimate the case detection rate of new smear positive TB for Ethiopia in 2010 was 36% (12). Since the prevalence of smear positive TB is three times lower than the previous estimate, it is estimated that the incidence of TB in Ethiopia will be at least two times lower than the previous estimate (less than 80/100,000). Therefore, the current case detection rate is adjusted with the new incidence estimate and it increases from 36% to 72%. This indicates that Ethiopia has achieved the MDG target of case detection rate of smear positive TB (70%) which was previously diluted with an overestimated denominator. However, this lower prevalence estimate should not be considered as an indicator to reduce efforts or resources allocated to the TB control program. Rather there is a need to further strengthen the program until TB ceases to be a public health threat in Ethiopia. The main reasons for the previous over estimation of TB in Ethiopia were the many assumptions for modeling the magnitude of TB in Ethiopia, the lack baseline data, and the lower HIV prevalence in Ethiopia compared to other sub-Saharan countries.

By generating baseline data, the recently completed TB prevalence survey provides useful information for planning and decision making for the TB control program in the country and serves as a reference for similar surveys in the future or for conducting pocket studies in specific

parts of the country. Although the survey provided a lower prevalence of TB compared to the previous estimate, many cases identified by the survey were new cases not captured by the TB control program. Of concern is the fact that 55% of these previously undetected cases in the community were among the younger age groups (15-34 years), pointing to a segment of the population where intervention is likely to be most needed. Therefore there is a need to strengthen community screening for early detection and treatment of cases to limit circulation of TB in the community.

More than 50% of the survey cases were smear-negative and identified only by culture. This highlights the need to have significant expansion of culture diagnosis services. Among all confirmed TB cases more than 50% were without chronic cough and were identified by CXR screening. This suggests that CXR screening should be widely available to screen and diagnose TB. Finally, the experience of conducting such a survey successfully in the country could be very useful when implementing future surveys. The survey was accomplished within the specified time boundary adhering to international standards. It can also serve as a good model to provide many useful lessons to countries who are contemplating on initiating similar TB prevalence survey.

LIMITATION OF THE STUDY

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This study did not include age less than 15 years and prevalence among this age group was determined by extrapolating from the routine surveillance data.

Relatively high contamination rate at the beginning of the survey and the use only a single culture (usually morning) may underestimate prevalence of culture positive TB.

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ANNEXES

Annex A. Survey Budget and Source of Fund

Table 22 Survey Budget

S.No	Budget Description	Budget in USD	Remark
1	Salary	844550	
2	Procurement	922,270	
3	Field operation	702,800	
4	Workshop and training	227,922.50	
	Total	2,697,542.50	
	5% contingency	134,877.10	
	Grand total	2,832,419.60	

Table 23 Source of Funding

Source of funding	Allocated for	Funds in USD	% from total
Global FUND/ FMOH	Procurement , training, salary and field operation	2,625,520	92.7%
WHO	TA	106,900	3.8%
TB CARE/USAID	Salary	100,000	3.5%
Grand total		2,832,420	

Annex B. Statistical analysis

1.1 Participant flow

Table 24: Participant flow, code and number of individuals in each step

Category	Code	Number of individuals
Enumerated at census	N	95092
Eligible survey population	N1	51667
Participants	N2	46697
Received symptoms screening	N3	46548
Received CXR	N4	46697
Received both	N5	46697
Eligible for sputum exam either based on symptoms or CXR	N6	6080
At least two smears examined	N7	5606
At least one culture done	N8	5807

1.2 Methods for the estimation of survey prevalence

1.2.1 Cluster-level analysis

As a simple summary figure, the cluster-level average prevalence was calculated (see Tables 2, 3, 4). The unit of analysis was the cluster. The average cluster-level prevalence was a point estimate of prevalence in the survey participants. Standard error was calculated by dividing the standard deviation of the cluster-level prevalence by the square root of the number of clusters.

1.2.2 Individual-level analyses

For results from all the individual-level analyses and all outcomes see Tables 25, 26, 27.

1.1.2.1 Robust standard errors

This model does not account for variation in the number of individuals per cluster, or correlation among individuals in the same cluster, when estimating the point prevalence of pulmonary TB (logit command with the robust option in Stata). Equal weight is given to each individual in the sample. However, the model does correct for clustering (by using the observed between-cluster variation) when estimating the 95% confidence interval, and can control for the strata that were part of the survey design. This model exactly corresponds to the classical analysis of surveys (svy commands with Stata) when one does not need to adjust for sampling weights. This is indeed the case in the self-weighting survey design for nationwide TB prevalence surveys. This model is restricted to survey participants (=N2 in Table 1).

1.1.2.2 Robust standard errors with multiple imputation for missing values

This model uses multiple missing value imputation for individuals: a) without a field CXR result and/or symptom screening, and b) for individuals with a positive CXR result or TB symptoms but without smear and/or culture results, in order to include all individuals who were eligible for the survey in the analysis (=N2 in Table 1). This model (logit command with the robust option in Stata) allows for both the clustering in the survey design and the uncertainty introduced by imputation of missing values when estimating the 95% confidence interval for the prevalence of pulmonary TB.

1.1.2.3 Random effects logistic regression

This model (xtlogit command in Stata) takes account of both clustering and variation in the number of individuals per cluster when estimating both the point prevalence of pulmonary TB and its 95% confidence interval. As with Model 1, this model is restricted to survey participants (=N2 in Table 1).

1.1.2.4 Random effects logistic regression with multiple imputation for missing values

This model (xtlogit command in Stata) takes account of both clustering and variation in the number of individuals per cluster when estimating

both the point prevalence of pulmonary TB and its 95% confidence interval, and also incorporates imputation of the missing data. It includes all individuals who were eligible for the survey in the analysis (=N2 in Table 1).

1.1.2.5 Robust standard errors with missing value imputation and inverse probability weighting

Missing value imputation is used for individuals eligible for sputum examination (defined as having a field CXR reading that was abnormal and/or TB symptoms) for whom data from one or more of the central CXR reading, symptom questions, and smear and/or culture results were not available. Survey participants were defined for this analysis as individuals who had a CXR that was technically adequate and also participated in the symptom screening survey. Inverse probability weighting (IPW) was then used to correct for differentials in the participation of individuals by age, sex, and cluster. Through the combination of imputation of missing data and the use of weights, the analysis (using the logit command with the robust option in Stata) aims to represent the whole of the survey eligible population (=N1 in Table 1), but the weights are applied only to individuals who were screened by both CXR and symptoms (=N5 in Table 1).

1.2.3 Handling missing data

1.2.3.1 Describing missing data

Missing data in the outcome variables:

- Participants categorized as eligible for sputum examination by symptom (including cough with unknown duration) but having no or only one decisive result of sputum examination
- Participants eligible for sputum examination by field CXR reading regardless of types of shadows, but having no or only one decisive result of sputum examination
- Participants having abnormal shadow detected by central CXR reading but having no or only one decisive result of sputum examination
- Missing data in the exposure variables:
- The results of field and/or CXR reading are not available (CXR not taken, quality unreadable)
- Cough with unknown duration
- All interviews not done

1.2.3.2 Imputation models

All imputation models have been run in STATA 11 using the ICE command for the imputation of data and the MICOMBINE command for the calculation of pooled estimates combined all imputed datasets.

Outcome of bacteriologically-confirmed TB: All variables which are associated with being a bacteriologically confirmed case have been included in the model. These are stratum, age group, sex, field CXR result, cough for more than 2 weeks, weight loss, having history of TB treatment and being a contact of a TB case. The same model has been used for imputation of values among the N2 survey participants (Models 2 and 4) and the N5 eligible for sputum examination (Model 5).

Outcomes of smear positive TB and having a smear positive result: All variables which are associated with being a smear positive case have been included in the model. These are stratum, age group, sex, field CXR result, cough for more than 2 weeks and having history of TB treatment. The same model has been used for imputation of values among the N2 survey participants (Models 2 and 4) and the N6 eligible for sputum examination (Model 5).

1.3 Results of survey prevalence (for all outcomes)

TABLE 25: Prevalence of bacteriologically confirmed pulmonary TB (per 100 000 population)

% (95% CI)	Cluster-level	Model 1[1]	Model 2[2]	Model 3[3]	Model 4[4]	Model 5[5]
Overall point prevalence	240 (190–290)	240 (190–290)	257 (204–311)	221 (167–275), P0=0.09	247 (192–303)	277 (208–347)
Point prevalence by stratum						
Urban	232 (107–357)	230 (121–339)	251 (125–376)	213 (98–327)	237 (113–362)	273 (130–416)
Rural	236 (177–295)	236 (176–297)	252 (189–315)	217 (157–277), P^0= 0.09	238 (175–300)	273 (189–356)
Pastoral	291 (126–456)	287 (173–402)	310 (163–457)	270 (96–444)	294 (106–482)	316 (163–468)
Design effect	1.26					
	n / N (%, 95% CI)					
Overall crude 6 prevalence	110/45874 (239, 197–289)					
Stratum crude [6] prevalence						
Urban	17/7384 (230, 134–368)					
Rural	81/34316 (235, 187–292)					
Pastoral	12/4174 (290, 150–506)					

[1] Robust standard errors; [2] Robust standard errors with missing value imputation; [3] Random-effects logistic regression; [4] Random-effects logistic regression with missing value imputation; [5] Robust standard errors with missing value imputation and inverse probability weighting; [6] Crude prevalence is calculated as the total number of individuals with a positive combined smear and/or culture result divided by the total number of individuals who have been screened for TB by chest X-ray and/or interview with smear and culture results available. Confidence interval for this estimate is calculated with exact binomial probability theory; 0 P-value calculated as a result of likelihood ratio test of rho=0 in the random-effects model, equivalent to testing a null hypothesis of no between-cluster variation (which is the same thing as no within-cluster correlation)

TABLE 26: Prevalence of smear positive pulmonary TB (per 100 000 population)						
% (95% CI)	Cluster-level	Model 1[1]	Model 2[2]	Model 3[3]	Model 4[4]	Model 5[5]
Overall point prevalence	103 (69–136)	102 (68–135)	103 (70–136)	83 (47–119), P0=0.06	89 (54–123)	108 (73–143)
Point prevalence by stratum						
Urban	68 (0–151)	68 (7–128)	75 (6–143)	56 (1–111)	66 (0–132)	70 (6–135)
Rural	102 (63–142)	101 (61–141)	102 (59–144)	84 (44–123), P^0= 0.09	89 (47–131)	109 (67–151)
Pastoral	168 (58–279)	166 (65–267)	156 (53–260)	141 (15–267)	138 (16–261)	170 (60–280)
Design effect	1.31					
	n / N (%, 95% CI)					
Overall crude [6] prevalence	47/46221 (102, 75–135)					
Stratum crude [6] prevalence						
Urban	5/7406 (68, 22–157)					
Rural	35/34600 (101, 70–141)					
Pastoral	7/4215 (166, 67–342)					

[1] Robust standard errors; [2] Robust standard errors with missing value imputation; [3] Random-effects logistic regression; [4] Random-effects logistic regression with missing value imputation; [5] Robust standard errors with missing value imputation and inverse probability weighting; [6] Crude prevalence is calculated as the total number of individuals with a combined smear positive result divided by the total number of individuals who have been screened for TB by chest X-ray and/or interview with smear results available. Confidence interval for this estimate is calculated with exact binomial probability theory; 0 P-value calculated as a result of likelihood ratio test of rho=0 in the random-effects model, equivalent to testing a null hypothesis of no between-cluster variation (which is the same thing as no within-cluster correlation)

TABLE 27: Prevalence of smear positive results (per 100 000 population)						
% (95% CI)	Cluster-level	Model 1[1]	Model 2[2]	Model 3[3]	Model 4[4]	Model 5[5]
Overall point prevalence	131 (91–172)	132 (92–172)	133 (92–174)	101 (61–142), P0=0.07	105 (64–147), P0=0.07	142 (98–187)
Point prevalence by stratum						
Urban	81 (0–180)	81 (19–143)	87 (18–155)	67 (1–127)	73 (5–142)	90 (20–161)
Rural	126 (80–173)	124 (79–170)	125 (75–176)	101 (58–144), P^0= 0.07	104 (57–151)	135 (84–185)
Pastoral	259 (128-389)	285 (114–456)	269 (109–429)	237 (56–418)	229 (56–402)	295 (106–485)
Design effect	1.42					
	n / N (%, 95% CI)					
Overall crude [6] prevalence	61/46221 (132, 101–170)					
Stratum crude [6] prevalence						
Urban	6/7406 (81, 30–176)					
Rural	43/34600 (124, 90–167)					
Pastoral	12/4215 (285, 147–497)					

[1] Robust standard errors; [2] Robust standard errors with missing value imputation; [3] Random-effects logistic regression; [4] Random-effects logistic regression with missing value imputation; [5] Robust standard errors with missing value imputation and inverse probability weighting; [6] Crude prevalence is calculated as the total number of individuals with a combined smear positive result divided by the total number of individuals who have been screened for TB by chest X-ray and/or interview with smear results available. Confidence interval for this estimate is calculated with exact binomial probability theory; 0 P-value calculated as a result of likelihood ratio test of rho=0 in the random-effects model, equivalent to testing a null hypothesis of no between-cluster variation (which is the same thing as no within-cluster correlation)

1.4 Extrapolating nationwide TB prevalence from the survey

The prevalence estimates drawn from the survey population are among adults and based on bacteriological confirmation of TB. Since we are interested in prevalence estimates for all ages, all forms we need to make some adjustments in the survey estimate of prevalence.

1.4.1 Adjusting survey estimate for children (0-14)

- Percentage of children over total population is 45%.
- S+ notification rate per 100,000 of children since 2000 has: mean=7.5 SD=1.1.
- Assuming notification is a correct estimate of prevalence rate.
- Prevalence among total population

$$ptotal=pchild * c + padult*(1-c)$$

where pchild is the prevalence among children, padult the prevalence among adults drawn from the survey and c the percentage of children in the country.

1.4.2 Adjusting for extra-pulmonary TB

- Assuming EP prevalence rate constant across all ages.
- Percentage of EP over total notifications since 2000 has: mean=34.8% SD=1.2%.

Annex C: Ethiopian National TB Prevalence Survey Staff List

1. Survey Managers and Coordinators

	Name	Job Title
1	Dr Amha Kebede	Acting Director General and Principal Investigator
2	Zeleke Alebachew	Survey Coordinator
3	Fasil Tsegaye	Deputy Survey Coordinator

2. Survey TB Laboratory staff

	Name	Job Title
1	Dr Almaz Abebe	Infectious and Non Infectious Disease Research Directorate Director
2	Dr Eshetu Lema	Senior Laboratory Advisor
3	Mulualem Agonafer	Lab Manager
4	Abebaw Kebede	Laboratory Technologist
5	Abiot Meaza	Laboratory Technologist

6	Daniel Demissie	Laboratory Technologist
7	Feben Girmachew	Laboratory Technologist
8	Muluwork Getahun	Laboratory Technologist
9	Yetneberish Fiseha	Laboratory Technologist
10	Zelalem Yared	Laboratory Technologist
11	Aster Hailemariam	Lab Assistant
12	Meskerem Seyfu	Lab Aid
13	Fanuse Bedada	Lab Aid
14	Tigist Beyene	Lab Aid

3. Survey Data Management staff

	Name	Job Title
1	Feleke Dana	Data Manager
2	Almaz Mamo	Assistant Data Manager
3	Fasil Teshager	Data Clerk
4	Balemeskel Shewa	Data Clerk
5	Mengistu Kefale	Assistant Data manager

4. Survey Central X-Ray readers

	Name	Job Title
1	Dr Gashawtena Fantu	Central X-Ray Reader
2	Dr Shewalem Negash	Central X-Ray Reader
3	Dr Molla Endale	Central X-Ray Reader

5. Survey Field staff

	Name	Job Title
1	Dr Tibebu Biniam	Field Team Leader
2	Dr Menelik Balcha	Field Team Leader
3	Dr Sale Workneh	Field Team Leader
4	Dr Tedla Fiseha	Field Team Leader
5	Kenene Mekonene	Interviewer
6	Tedros Chekol	Interviewer
7	Selemon Getahun	Interviewer
8	Assefa Mulatu	Interviewer
9	Tamirat Abdela	Interviewer
10	Azmach Begigu	Interviewer
11	Betelihem Tilahun	Interviewer
12	Mekides Kebede	Interviewer
13	Zelalem Fekadu	Interviewer
14	Konjit Mulugeta	Interviewer
15	Nuria Yakob	Interviewer
16	Melaku Tsehay	Interviewer
17	Melaku Mengesha	Interviewer
18	Dagnachew Israiel	Interviewer
19	Ermias Achenef	Laboratory Technician
20	Mulugeta Gebire	Laboratory Technician
21	Yared Belete	Laboratory Technician
22	Tedros Girma	Laboratory Technician
23	Sinishawu Yohanis	Laboratory Technician
24	Aleminesh Asfaw	Receptionist

25	Alemzewud Feleke	Receptionist
26	Hana Wubie	Receptionist
27	Sintayehu Beze	Receptionist
28	Mulu Abebe	Receptionist
29	Dr Girma Diro	X-Ray Reader
30	Dr Temam Ahmed	X-Ray reader
31	Dr Ayelech Taddese	X-Ray reader
32	Dr Girma Ayano	X-Ray reader
33	Tatek Getachew	Radiographer
34	Demisse Debebe	Radiographer
35	Solomon Tsigie	Radiographer
36	Abduletif Yosef	Radiographer
37	Jemal Mohamed	Radiographer
38	Birhane Tewolde	Radiographer
39	Hailu Nigusie	Radiographer
40	Dr Million Kebede	Radiographer
41	Damite Gebreyesus	Radiographer
42	Yonas Yimer	Radiographer

Annex D: International Technical Assistant Mission

1. December ' 2008: Feasibility study and orientation – Dr Ikushi Onozaki, WHO
2. July '2009: Preparatory WS and Basic design (group training in Geneva)- Dr Katerin Folyad, Dr Ikushi Onozaki, Dr Philip, Dr Anne, WHO
3. August '2009: Basic design and preparation (in Ethiopia) – Dr Marina Tadolini, Dr Ikushi Onozaki, WHO
4. March '2010: Coordination and advocacy, Protocol review and clearance –Dr Ikushi Onozaki, WHO
5. July '2010: Data management, TOT and Simulation (Field test) including Radiology – Dr Peou Satha, Cambodian Field Survey Coordinator, Tiem Hazim, Dr Ikushi Onozaki, WHO
6. September '2010 Training and Pilot survey – Dr Peou Satha, Dr Marina Tadolini, WHO
7. October '2010 Review in early stage – Dr Ikushi Onozaki, WHO
8. February '2011: Mid-term review, data management – Dr Ikushi Onozaki, Dr Marina Tadolini, WHO
9. April '2011: Follow up visit by Cambodian coordinator – Dr Marina Tadolini, Dr Peou Satha
10. June '2011: Final Review – Dr Ikushi Onozaki, Dr Marina Tadolini, WHO
11. September '2011: Data cleaning- Sismandis Charalampos, Timimi Hazim
12. Sept-Oct '2011: Analysis – Dr Ikushi Onozaki, Sismandis Charalampos
13. December '2011: Dissemination –Dr Marina Tadolini, Dr Ikushi Onozaki, WHO
14. February '2011: Data management review – Timimi Hazim

Annex E: Ethiopian National TB Prevalence Survey Work Schedule

	ACTIVITIES	2009										2010												2011											
		M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
1	Establish Steering Committee (SC)																																		
2	Steering Committee meetings / oversight																																		
3	Establish Survey Coordination Team (SCT)																																		
4	Study Session in Geneva																																		
5	Organize Technical Advisory Group																																		
6	Develop international TA plan																																		
7	International TA presence																																		
8	Identify in-country implementing partners																																		
9	Draft Study proposal (SC and SCT)																																		
10	Finalize Study Protocol**																																		
11	Ethical clearance																																		
12	Develop survey data recording and reporting tools																																		
13	Develop implementation plan**																																		
14	Conduct Advocacy workshop with regional health bureaus																																		

	ACTIVITIES	2009										2010												2011											
		M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
15	Select CXR equipment and start procurement process																																		
16	Start other Procurement																																		
17	All procurement delivered and in place																																		
18	Select Clusters (Kebeles), and assess the sites																																		
19	Appoint unit and field team leaders																																		
20	Orientation of team leaders																																		
21	Develop survey teams																																		
22	Do pre-visit and designate clusters**																																		
23	Setting the data set**																																		
24	Orientation and training of survey teams**																																		
25	Pilot survey**																																		
26	Field operation**																																		
27	Midterm review**																																		
28	Analysis of data**																																		
29	Preliminary results dissemination and feedback**																																		
30	Final report and publication																																		
31	Presentations in international conference																																		

** Activities that need international technical Assistance

Annex F: Ethiopian National TB Prevalence Survey Cluster Operation Schedule

Cluster work Week	Planed cluster for the week	Total cluster to be Completed during the week	FIELD OPERATION TEAM				
			Team A	Team B	Team C	Team D	Team E
Week 1(Oct 2-9, 2010)	1	1	Woliso (C1)R				
Week (Oct 9-16,2010)	0	1					
Week 3,(Oct 16-23,2010)	0	1					
Week 4 (Octo 23-30,2010)	0	1					
Week 5(Oct 30-Nov6,2010)	2	3		Nejo(C16)	Wolmera(C2)R		
Week 6(Nov 6-13,2010)	2	5				Abuna Gindeberet(C4)R	Midakegn (5)R
Week 7, (Nov 13-20,2010	0	5	Internal Review				
Week 8 (NoV 20-27,2010)	2	7	Bako Tibe(C8)R			Boneya Bushe(C7)R	
Week 9 (Nov 27-Dec4,2010)	3	10	Guduru(C6)U	Ejere(C3)R	Mesekan (C33)R		
Week 10(Dec 4-11,2010)	3	13		Gobu Seyo(C9)R	Siltie(C34)R		Yaya Gulele(C31)R
Week 11(Dec11-18,2010)	3	16	Ankasha(C66)			Sinan(C56)R	Enemay(57)
Week 12(Dec18-25,2010)	3	19	Dabat (C65)	Semen Achefer (C59) R		Dembia (C63)R	
Week 13(Dec25-Jan1,2011)	3	22		Alefa(C62)R	Quara (C64)R		Lay Armachoho(C60)R
Week 14(Jan1-8,2011)	3	25			Merab Armachoho (C61)R	Quarit (C58)R	Humera(C67)R
Week 15(Jan8-15,2011)	3	28	Lasta(C54)R	Kalu(C51)R		Jama (C50)R	
Week 16(Jan15-22,2011)	3	31	Albuko (C52)R	Kobo (C55)R		Legambo (C53)R	
Week 17(Jan22-29)	2	33			Mekele town(C69)U		Ofla(C71)R
Week 18(Jan29-Feb 5,2011)	3	36		Gulo Meheda(C72)R	Tahtay Koraro(C68)R		Laelay Maychew(C70)R
Week 19(Feb5-12,2011)	3	39	Hadele Ele(C73)P	Berahile(C74)P		Sokoru (C10)R	
Week 20(Feb 12-19,2011)	0	39	Mid term Review				
Week 21(Feb19-26,2011)	0	39	Internal Review 2				
Week 22(Feb26-Mar5,2011)	3	42			Seyo Nole(C15)R	Gomma (C11)R	Kersa (C14)R
Week 23(Mar 5-12,2011)	3	45			Gawo Kebe (C17)R	Borecha(C12)R	Dega-Wereda(C13)R
Week 24(Mar 12-19,2011)	3	48	Decha(C46)R	Debub Bench(C48)R			Mengesh(C75)R

Cluster work Week	Planed cluster for the week	Total cluster to be Completed during the week	FIELD OPERATION TEAM				
			Team A	Team B	Team C	Team D	Team E
Week 25(Mar 19-26,2011)	3	51	Gewata	Yeki(C49)R		Mengie(C80)R	
Week 26(March26-Apr2,2011)	3	54	Alaba(C37)R		Kucha(C44)R		Humbo(C44)R
Week 27(April 2-9,2011)	3	57		Merab Badwacho(C40)R	Soro (C35)R		Misha (C36)R
Week 28(April 9-16,2011)	3	60	Debub Ari(C45)P	Sawla /Town/(C42)U		Bonke (C43)R	
Week 29(April 16-23,2011)	3	63			Aleta(C38)R	Shashemene Zuria(C25) R	Gorche (C39)R
Week 30(April23-30,2011)	0	63	Easter break				
Week 31(Apr30-May7,2011)	3	66		Denbel-Wereda(C77)P	Awubere (C76)P		Shinile-Wereda(C78)P
Week 32(May7-14,2011)	3	69	Midga (C30)R	Meta (C27)R	Haro Maya(C28)R		
Week33(May14-21,2011)	3	72	Melka Belo (C29) R			Daro Lebu (C32)R	Shala(C24)R
week34(May21-28,2011)	3	75			Sude (C19)R	Diredawa town(C81)U	Munesa(C22)R
Week35(May28-Jun4,2011)	3	78	Bale Gasegar (C20)R	Hitosa(C18)R	Gololcha(C26)R		
Week36(Jun4-11,2011	3	81	Filtu(C79)P	Digluna Tijo(C21)R		Merti(C23)U	
Week37(Jun11-18,2011)	2	83			Addis K-Sub City(C83)U		Kolfe K-Sub City(C85)U
Week38(Jun18-25,2011)	2	85		Gulele-Sub City(C82)U		Bole-Sub City(C84)u	

Annex G: Ethical Considerations

The TB Prevalence Survey study protocol has been reviewed and approved by one institutional ethical review committee (EHNRI) in Ethiopia and the National Ethical Review Committee, as well as by the WHO ethical review committee. X-ray machines used were certified by the Ethiopian Radiation Control Authority.

Study participants were selected based on an epidemiological procedure that picks survey sites and households at random and in which all eligible members of the household were requested to participate. The objectives of the survey have been illustrated to the participants in a language they understood and clarifications given. All participants (or their family members or guardians) provided written informed consent. Participation was voluntary and withdrawal was possible at any point in time. Refusal to participate in the survey did not compromise the rights of any individual in accessing health care or other community services. There was no inducement to recruit participants.

The interview was conducted by a trained interviewer separately for each participant. All collected information were kept confidential and records will be coded. No personal identifiers were kept in the database or used to report findings. Data were managed according to SOPs which have been developed to protect confidentiality of study participants.

Each participant underwent a CXR and thus wasexposed to radiation. However, the dose was minimal (equivalent to about 7 days of natural radiation exposure) and Chest X-rays are a part of routinemedical practice for clinical examination, thus there was little additional risk in participating. Participants have been informed about any risks of examinations, including Chest X-ray. Pregnant women weren't automatically excluded from the CXR examination, but they could decline the procedure at any time.Protective caution (lead aprons) have been used for all female participants.

The participants identified as eligible for sputum examination were requested to provide two sputum samples: they received specific instructions on how to collect sputum and were asked to return to the survey site the following day, for a total of two visits,to deliver the morning sputum.

Individuals with TB symptoms or CXR findings suggestive of TB received counseling and referral to the nearest health facility for appropriate management. Those with swollen cervical lymph nodes were also referred to the nearby public health facility. In case other concomitant illnesses were detected during survey operations, written/verbal referral to the nearest health facility have been provided.

The participants' benefit was free screening for TB. However, the participants identified as TB suspects due to symptoms, CXR and/or laboratory results have been referred to the routine system not for treatment but for TB diagnosis (with further collection and screening of sputum samples) according to national TB guidelines. Detected TB cases were reported to the local health authority and participant traced for proper management. Because of the use of culture results became available much later, and because of the large number of screened participants, it was not recommended for the health facilities to depend on survey results to treat these participants for TB. Participants with symptoms and/or abnormal chest X-rays that need medical intervention were efficiently referred to an appropriate local medical facility with written CXR reports. HIV testing was not offered among study participants, but TB cases were referred to routine TB and TB/HIV services. Local health care providers and community members were informed about the study objectives and procedures and actively participated in field operations. At the end of the survey, the study team briefed the community leaders, local administrative authorities and the health workers on general findings from the survey.

Annex H: Survey forms

National TB Prevalence Survey

Form 1: Census Form (House Hold Registry)

Cluster Name_____Cluster Number_____ House Hold Number_____

Address:_____ Preparation Date: /…./…/……/ Census Date: /…./…/……/

Individual Survey Number		Age	Sex			Resident Status		Duration of stay for visitors	Eligible	Attendance	Consent	Remarks
	Name		M	F	Occupation	Permanent	Temporary		Y/N/C	DD/MM	Y/N	(reason of absence)
CNoHNoSNo												

The shaded region will be filled by Census team. Total Eligible _____Total age<15_____

Name and Signature of Person who filled the Pre list_____ _____Date_____

Name and signature of Person who checked census_____Date_____

Invitation Card

ቅጽ 2፡ የግብዣና የመታወቂያ ካርድ
Form 2. Invitation and ID card
መስፈርቱን ለሚያሟሉ እድሜያቸው 15 እና ከዚያ በላይ ለሆኑ የቤተሰብ አባላት የሚሰጥ
(For household members 15 years old and above and eligible)

ክፍል ፩ part one

የምንጥ ቁጥር Cluster number	የቤተሰብ መለያ ቁጥር Household Number	የግለሰብ መለያ ቁጥር Individual number

ስም Name	የአባት ስም Father's Name	የአያት ስም Grand Fathers Name	እድሜ Age	ፆታ/Sex ☐ ወንድ Male ☐ ሴት Female

ክፍል ፪ part two

በብሄራዊ የቲቢ ላለ ጥናት ለመሳተፍ በ _____ ቀን _____ በ _____ ሰዓት
Please come to Participate at the National TB Survey on (date) at hr

ጥናቱ በሚከናወንበት _____ ቦታ እንዲገኙ ተጋብዘዋል
at survey camp site located in

ይህን ካርድ ማምጣት እንዳይረሱ ያሳስባሉ!
Please Bring This Card With You!

Symptoms questionnaire

National TB Prevalence Survey

FORM 4: Individual Survey Form

Date: ___ / ___ / _____

Cluster Name_____Cluster Number /- - / S.No.....

Decisions: after completing each section of the form check the following

KAP: ☐ Yes ☐ No

Take sputum: ☐ Symptoms ☐ Abnormal X-ray
☐ Refuse X-ray and have symptom other than cough
☐ Not eligible for sputum

Re-interview: ☐ LN ☐ History Current treatment ☐ No re-interview

Fill by receptionist :

Individual Survey Number (ISN) /_ _/ _ _ _/ _ _ /

Name _____

Sex 1. Male ☐ 2. Female ☐ Age in Year _____ check if estimated

5. Current illness and Duration: (present symptoms at the survey time)

Fill by interviewer

	Symptom	Yes(1)	No(2)	Remark
5.1	Has the individual had cough?			
5.2	if yes duration ofcough in days_____			Duration: days (1W=7days, 1M=30days, 1y=365 days
5.3	Cough 14 days or more			If yes mark yes in Q 6
5.4	Fever≥ 2 weeks			If X-ray examination is not done and one or more of the four conditions exist, individual will be requested to submit sputum. (This will be decided later by the team leader)
5.5	Weight loss > 3kg in last 4 weeks			
5.6	Night sweats ≥ 2 weeks			
5.7	Did you live with or had close contact with known TB patients in the last one year?			
5.8	Do you have cervical lymph node swelling?			
5.9	Check Presence of cervical lymphadenitis regardless of the response in 5.7 (Physical examination)			If yes go to 5.10 by Medical officer

By MO or Team Leader

5. 10 No. of cervical lymph node swelling palpable Rt. /_____/ If no; Record "0"
5.11 No. of cervical lymph node swelling palpable Lt. /_____/
5.12 Maximum Size of lymph nodes /_____/mm

6. Symptoms Eligible For Sputum Examinations 1. Yes ☐ 2 . No ☐

7. History of TB treatment

7.1 Are you currently on anti-TB treatment: 1. Yes ☐ 2. No ☐

7.2 Have you ever been treated for TB in the past 5 years: 1. Yes ☐ 2. No ☐
if yes: go to Q 7.3
7.3 When did you start the anti-TB treatment: MM/YY_____

If answer yes to Q7.1 or Q 7.2: go for separate interview (form 5) after chest X-ray CXR(by MO)

7.4 Re-interview 1. Yes ☐ 2. No ☐
When the participant is not willing to take CXR, refer to the team leader

8. Chest X-ray

8 1 ☐ Performed 2 ☐ Exempted (reason :_____),
3 ☐ Rejected

If the response for 8.1 is 2 or 3 refer the participant to team leader

8.2 CXR result by field screening

1 ☐ No abnormality

2 ☐ Abnormal condition of lungs or mediastinum (including healed TB) eligible for sputum examination

3 ☐ Other abnormalities not eligible for sputum examination __(bone, goiter, heart disease etc)_____

Conditions which require urgent/not urgent referral _____
(Please, consult the list of conditions which require urgent/ referral for medical management)

9. Sputum Requested 1. Yes ☐ 2. No ☐

10. Sputum collection

dd mm yyyy

SP1 spot collection date ___/____/___

SP2 morning collection date ____/____/___

If not collected, reason _____

Remarks: Any advice given to the participant

FORM 5: Re-interview

Individual Survey Number ☐☐☐

Name _____

SIDE A: FOR SYMPTOMATICS

You said you have cough 14 days or more. Could you tell me a bit more about your cough?

5.3.1 How are you? Are you sick? Which condition is nearest to your condition?

1. I am fine. ..... ☐
2. There is something wrong. But I am OK. ..... ☐
3. I am a little sick. ..... ☐
4. I am very sick. ..... ☐
5. I don't know. ..... ☐

5.3.2 If you are sick, for how many days have you been sick?_____Days

5.3.3 Did you seek any treatment for your cough or illness. 1 Yes ☐ 2 No ☐
If yes, go to Q5.3.4 – 5.3.6, If No go to Q5.3.7

5.3.4 Where have you visited for consultation about your cough?

1. Public Hospital
2. Health Centre
3. Health Post/ Extension Health Worker
4. Private hospitals
5. Private Clinic,
6. Pharmacy
7. NGOs
8. Traditional Healers
9. Other _____

5.3.5 Have you had an X-ray examination for these symptoms? 1 Yes ☐ 2 No ☐

5.3.6 Have you had a sputum examination for these symptoms? 1 Yes ☐ 2 No ☐

1. If Q5.3.3 is no, why didn't you seek treatment?
2. Because I don't feel I am sick. ☐
3. Because it is not serious. ☐
4. Because I am busy. ☐
5. Because I don't know where I need to consult ☐
6. Because I don't have enough money ☐
7. Because the medical facility is too far ☐

Current Tobacco Smoking Status

5.3.7 Do you currently smoke tobacco? 1 Yes ☐ 2 No ☐
If no go to 5.3.10

5.3.8 If yes, how often?

2. Daily..... ☐
3. Less than daily ..... ☐

5.3.9 If the answer for Q 5.3.8 is 1 or 2, Do you think your cough is due to smoking?

1. Yes, I believe so..... ☐
2. Yes., but partially ..... ☐
3. Yes, but a little ..... ☐
4. Not at all..... ☐
5. Don't know..... ☐

Past Tobacco Smoking Status

5.3.10 In the past, have you smoked tobacco? 1 Yes ☐ 2 No ☐

5.3.11 If yes how often did you smoke?

1. Daily..... ☐
2. Less than daily..... ☐

5.3.12 If the answer for Q 5.3.11 is 1 or 2, Why did you quit smoking?

1. Because i became sick..... ☐
2. Because smoking is not good for health..... ☐
3. Because it is expensive ..... ☐
4. Because family or friends do not like me smoking ..
5. Don't know..... ☐

SIDE B: FOR THOSE WITH HISTORY OF TB TREATMENT

7.1 Are you currently on anti-TB treatment: No ☐ Yes ☐

7..2 If 7.1 is yes, how many months have you been on anti-TB treatment?
_____ (record 0 if < 1 month)

7.3 Have you ever been treated for TB in the last five years: No ☐ Yes ☐

7.4 Who/where told you that you need TB treatment? (one answer only!)

1. Government Hospital ☐
2. Health Center ☐
3. Health Post ☐
4. Private hospitals ☐
5. Private Clinic ☐
6. Pharmacy ☐
7. NGOs ☐
8. Traditional Healers ☐
9. Other ☐ _____

7.5 Where are/were you getting TB treatment? (most recent episode) (One answer only)

1. Government Hospital ☐
2. Health Center ☐
3. Health Post ☐
4. Private hospitals ☐
5. Private Clinic ☐
6. Pharmacy ☐
7. NGOs ☐
8. Traditional Healers ☐
9. Other ☐ _____

7.6 With which form of TB were you diagnosed?

1. Smear positive TB ☐
2. Smear negative TB ☐
3. Extra-pulmonary TB ☐
4. Don't know

Date_____ Signature_____

13.6.2. Field X-ray Log Book

National TB Prevalence Survey

Cluster NO_____

DATE: / / / /

Form 6: Field X-Ray Log Book

Sr. No	Individual Survey No.	Name	age	Sex		Result			Remarks
				M(1)	F(2)	0	1	2	
1									
2 3									
4 5									
6 7									
8 9									
10 11									
12 13									
14 15									
16									
17									

Results: 0. Normal; 1. abnormal Eligible 2: Other: Write the number to the column

Name and Signature of Reader: _____ Date_____

13.6.3. Field Lab Logbook

								Specimen transport		
Sr. No	Survey No.	Name	age	Sex		Sputum specimen collection date		Specimen stored for transport	Specimen sent for culture	Remarks
				M	F					
1						S				
						M				
2						S				
						M				
3						S				
						M				
4						S				
						M				
5						S				
						M				
6						S				
						M				
7						S				
						M				
8						S				
						M				
9						S				
						M				
10						S				
						M				
11						S				
						M				
12						S				
						M				
13						S				
						M				

FORM 7: Laboratory Register Cluster No:_____ Date_____

Annex I: Survey Consent Forms and Information Sheets

A. Adult Consent form

Your signature below indicates that you have read or listened to and understand the information provided to you about the study. Before you sign, please confirm that you understand the following:

- Purpose of the study
- Study procedures, including
- Interview
- CXR examination
- Sputum sample
- Process for feedback of results, if needed
- Risks and benefits of participating in the study
- Right to refuse or stop participation at any time
- Confidentiality and privacy concerns
- Who to contact if you have questions

By signing, you are making a decision to participate in this study. If you decide that you wish to withdraw or discontinue your participation in the study, you may do so at any time. Do you agree to participate?

I have read and/or listened to the description of the study and I understand what the procedures are and what will happen to me in the study. I agree to participate in it. I know that I can quit the study at any time.

_____
Printed Name

_____ _____
Signature Date

_____ _____
Signature of Investigator representative Date

B. Parental Consent Form for the Participation of Children aged 15-17

Your signature below indicates that you have read or listened to and understand the information provided to you about the study. Before you sign, please confirm that you understand the following:

- Purpose of the study
- Study procedures, including
- Interview
- CXR examination
- Sputum sample
- Process for feedback of results, if needed
- Risks and benefits of participating in the study
- Right to refuse or stop participation at any time
- Confidentiality and privacy concerns
- Who to contact if you have questions

By signing, you are making a decision to allow your child (son/daughter/child/infant/adolescent youth) to participate in this study. If you decide that you wish your child to withdraw or discontinue participation in the study, you may do so at any time. Do you agree for your child to participate?

I have read and/or listened to the description of the study and I understand what the procedures are and what will happen to my child in the study. I agree to allow him/her to participate in it. I know that my child can quit the study at any time.

_____

Printed Name of (son/daughter/child/infant/adolescent youth)

_____ _____

Signature of Parent(s) or Legal Guardian Date

_____ _____

Signature of Investigator representative Date

C. Assent form for child between 15 and 17 years of age

I have read and/or listened to the description of the study and I understand what the procedures are and what will happen to me in the study. I have received permission from my parent(s)/guardian(s) to participate in the study, and I agree to participate in it. I know that I can quit the study at any time.

_____	_____
Signature of Child	Date
_____	_____
Signature Investigator representative	Date

D. Group instruction guidance

To read by TB focal person or other local staff during group instruction

Good morning.
My name is _____ (name and title and organization) and I am part of the tuberculosis prevalence survey research team of the Ethiopian Health and Nutrition Research Institution (EHNRI) and Federal Ministry of Health (FMOH). Tuberculosis (or TB) is an illness that is caused by a germ and mainly affects the lungs, but sometimes can affect other parts of the body. Sometimes you may not even know you have TB disease. TB is usually spread from person-to-person by coughing.

You have already been given a paper that explains the purpose, procedures, risks and benefits of today's activities and of participating in this study (show general information sheet), and now I will explain what is written on the paper briefly.

The reason why you have been asked here today is because you are being invited to participate in a study to learn about TB disease in Ethiopia. The information that your participation will provide will help us to improve the TB prevention and control program in Ethiopia and to provide better service. A total of 46,514 individuals from throughout the country will be participating in this study during a period of one year.

After this talk, we would like to ask you to do the following things:

When your name is called, our receptionist will ask you to sign a document agreeing to your participation in the study. Your participation is entirely voluntary. You can refuse to participate or stop your participation at any time without any penalty. However, by participating, if you are sick with TB, you may be able to get diagnosed and receive appropriate treatment more quickly.

After that, if you agree to participate, we will ask you to have a short interview and a CXR examination with health care professionals to look for signs and symptoms of TB disease. CXR is a safe examination. However if you have any concerns, we can provide more information to you.(show CXR information sheet) We will ask you to wait in a separate waiting area for the results. During this time, some of you will also be asked more questions about your experiences with TB.

Depending on the result of your interview and CXR examination, you may be requested to give a sputum sample two times, one time today and again tomorrow morning. A health care worker will show you today how to do this. One out of 5 to 10 people may be asked for sputum. Being asked for sputum does not necessarily mean you have disease.

If there is a possibility that you might need care based on the exams today, help will be provided to you to ensure you get proper care. After you leave today, the results of your exams will be checked again for TB disease by other health professionals. If there is any evidence of TB disease found, you will be informed by a local health care worker, who will ensure you receive proper treatment. Free treatment for TB is available in Ethiopia.

The total time we estimate for you to participate in this study is approximately one and half hours.

We are very thankful for your involvement today and we are glad you are here. If you have any questions, please come to me so I can answer them one at a time. You may also ask any health care worker during today's activities.

E. General information sheet

Introduction

The reason why you have been asked here today is because you are being invited to participate in a study about tuberculosis disease in Ethiopia. This study is being conducted by a research team from the Ethiopian Health and Nutrition Research Institution (EHNRI), the Federal Ministry of Health (FMOH) and local partners.

This form provides you with information about the study. Please read the information below carefully. Someone will also describe this study to you and can answer your questions before you decide whether or not to take part.

Purpose of the study

By participating today, you will help provide us with information that can be used to improve the tuberculosis prevention and control program and to provide better health care in Ethiopia. A total of 46,514 individuals from throughout the country will be participating in this study during a period of one year.

What is tuberculosis?

Tuberculosis (or TB) is an illness that is caused by a germ and mainly affects the lungs, but sometimes can affect other parts of the body. Sometimes you may not even feel sick or know you have TB disease. TB is usually spread from person-to-person by coughing. TB is curable and free treatment is available in Ethiopia.

Procedures of the study

If you agree to be in this study, we will ask you to do the following things:

- When your name is called, our receptionist will ask you to sign a document agreeing to your participation in the study.
- Participate in a short interview and answer some questions about signs and symptoms related to TB disease.
- Take a CXR examination.
- Wait in a separate waiting area for the results. During this time, you may also be asked more questions about your experiences with TB.
- Depending on the result of your interview and CXR examination, you may be requested to give a sputum sample two times,

one time today and again tomorrow morning. A health care worker will show you today how to do this. Being asked for sputum does not necessarily mean you have disease.

- If there is a possibility that you might need care based on the exams today, help will be provided to you to ensure you get proper care.
- After you leave today, the results of your exams will be checked again for TB disease by other health professionals. If there is any evidence of TB disease found, you will be informed by a local health care worker, who will ensure you receive proper treatment.
- Total estimated time to participate in this study is approximately one and a half hours. However, it is possible that it may be more or even less time.

Benefits of being in the study

By participating, if you are found to have TB, you may be able to get diagnosed and receive appropriate treatment more quickly. We will facilitate diagnosis and medication in the nearby health facility free of charge.

Potential risks of being in the study

There is no anticipated risk in this study.As with other medical procedures, X-rays are safe when used with care. Radiologists and X-ray technologists have been trained to use the minimum amount of radiation necessary to obtain the needed results without any risk on your health. However if you have any concerns, we can provide more information to you.

Voluntary participation

Your participation is entirely voluntary. You can refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You can stop your participation at any time and your refusal will not impact current or future relationships with the people or institutions carrying out this study. If you do not wish to participate, simply tell the researcher you wish to not participate or you can stop participation at any time during the process.

Confidentiality and Privacy Protections:

The records of this study will be stored securely and kept confidential. All publications will exclude any information that will make it possible to identify you. But if you are found to have TB, health workers who are

going to treat or diagnose you will be informed about the findings of the examination for the purpose of your benefit to get treated.

Contacts and Questions:

If you have any questions about the study, you will have an opportunity to ask a health care worker involved in the study immediately after the orientation. You may also ask questions at any point during the survey activities today. If you have questions later, want additional information, or wish to withdraw your participation you can call the researchers conducting the study. If you have questions about the research please contact Dr Amha Kebede, Ethiopian Health and Nutrition Research Institution Deputy Director General, at +251112754645.

F. Chest X-ray information sheet

Definition of a chest X-ray

A CXR is a picture of the chest obtained by using X-rays. A small dose of radiation is used to create this image. It is one of the most common medical tests done.

Reasons for the exam

Chest X-rays are done to look for abnormalities of the heart, lungs, bones, or blood vessels in the chest. In a hospital or clinic your doctor may order a CXR if you have certain symptoms, such as:

- Bad or persistent cough
- Difficulty in breathing
- Coughing up blood
- Chest pain
- Chest injury
- Fever

Chest X-rays are also often taken before surgical or medical procedures. Chest X-rays are widely used for tuberculosis (TB) screening programmes, including for people who live or work in settings where TB is common, contacts of TB patients, new military recruits, and visa applicants.

Chest X-ray and pregnancy

Chest X-rays are done using a very small dose of radiation. Radiation exposure above a certain level is associated with some health problems for pregnant women as well as for the unborn child. However, no significant health risk is recognized by the radiation dose used for taking

a chest X-ray. Radiation exposure of one CXR is equivalent to few days of average natural exposure from the environment (sun light, space, ground, etc).Therefore, the risk to an unborn baby, by performing a CXR of the pregnant mother properly, is negligible.

A CXR is a safe examination. Moreover, attention is paid to restrict the area of exposure to the chest only and avoid direct exposure to the abdomen and reproductive organs. Furthermore, a metal cover over the lower abdomen prevents unnecessary exposure. However, in many places and if possible, X-rays are traditionally avoided during pregnancy.

If you are pregnant or think you may be pregnant, and you are not reassured about safety, please share your concern with the interviewer, doctor or X-ray receptionist. CXR will be waived, particularly when you don't have any health concern (you are healthy and you don't have any symptoms). However, if you have had a TB patient around you in the preceding 2-3 years or if you have any symptoms or health concerns, an X-ray is a helpful tool to identify your health problem earlier.

Anyone can choose not to have a chest X-ray

You can tell your interviewer or the X-ray receptionist that you would not like to undergo the CXR examination. Any person can decline the X-ray, even without disclosing the reason.

What to expect

Prior to exam

The X-ray technician will verify your identity. You will be asked to remove all jewellery and metal accessories from the waist up. You may be asked to wear a gown or t-shirt if your clothes are not appropriate for the examination. A lead apron (cover) may be placed over your hip and waist (to protect abdomen and pelvis). This is done to minimize the risk of radiation.

Description of exam

Undergoing an X-ray is like being photographed. For a chest X-ray, the picture is usually taken from the back. An X-ray technician will position you. You will stand against the X-ray machine with your hands up or placed on your waist. You will then be asked to take a deep breath and hold it while the X-ray is being taken. You will also be asked to stay as still as possible when the X-ray is taken. You may notice that the film cassette feels cool to your skin.

How long will it take?

The X-ray itself will take less than a second. About 3-5 minutes might be needed to prepare and position you, and for you to change your clothes.

Will it hurt?

No. Remember, it is like having your picture taken

Results

A doctor will look at your X-ray a few minutes after the test and decide if you will need a sputum examination. A request to submit sputum does not necessarily mean that you have an illness, but that it is advisable to test further. If the doctor detects some condition that needs further check-up or urgent treatment, he/she will talk to you and explain what further needs to be done, and where.

If your CXR is suggestive of an abnormality, within a few weeks, your X-ray will be looked at by a specialist in Addis Ababa. If the specialist detects any abnormality, your X-ray will be looked at again by some more specialists to arrive at a proper diagnosis. The report and advice by the group of specialists will be given to you through the local health staff in case you need further follow up or treatment. We will make efforts to send feedback as early as possible. However, sometimes it may take a few months especially if we need sputum examination results to corroborate the X-ray findings.

Annex J: List of selected clusters

Region	District	Kebele	Strata
Tigray	Tahtay Koraro	Adikokob	Rural
	Laelay Maychew	Hatsebo	
	Ofla	Hegumberda	
	Gulo Meheda	Sobeya	
	Mekele town	Adehaki	Urban
	Humera /Town/	Kebele 1	
Afar	Hadele Ele	Aftwa	Psturalist
	Berahile	Alla	
Amhara	Jama	Shenkurtima	Rural
	Legambo	Buso	
	Albuko	Tolu Tosegn	
	Kalu	Ancharo	
	Lasta	Genete Mariam	
	Quarit	Zambite Zuguda	
	Semen Achefer	wenberya eysuse	
	Ankasha Guagusa	Hateta Zuriya	
	Enemay	Weyinam	
	Sinan	Tach Chabi	
	Quara	Bermil	
	Dabat	Benker	
	Dembia	Senebet Deber	
	Alefa	Wange Tegena	
	Lay Armachoho	Aykochakir	
	Merab Armachoho	Aberderafi 02	Urban
	Kobo	Kobo town-03	
SNNPR	Decha	Ermo	Rural
	Debub Bench	Faunika	
	Mengie	Obi Megele	
	Gewata	Wediyo	
	Yeki Wored	Adis Birihan	
	Alaba Special	Andegna Tuka	
	Kucha	Gerera	
	Humbo	Buqe Dongola	
	Merab Badwacho	Kacha Bira	
	Misha	Dilbara	
	Soro-Wereda	1st oda	
	Bonke	Geresie Zuria	
	Sawla /Town/	Zirqou	Urban
	Debub Ari	Shepi	Rural
	Gorche	Muracho Gucho	
	Aleta Wendo	Titira	
BG	Menge	Kashaf	
Gam	Mengesh	Gudere Meshin	

Region	District	Kebele	Strata
Oromia	Ejere	Gebiya Jimata	Rural
	Bako Tibe	Gudina welqite	
	Midakegn	Soliekenjo	
	Abuna Ginde/t	Yegot	
	Wolmera	Gebiya Robe	
	Woliso	Fodu Gora	
	Yaya Gulele	Daletina Rimete	
	Gololcha	Buriya	
	Shashemene Zuria	Awasho donku	
	Shala	Danisa Bonge	
	Sude	Merinagerjisa	
	Munesa		
	Bale Gasegar	Jiddagoberbar	
	Hitosa	Seroanketo	
	Digluna Tijo	Lolieabosera	
	Gawo Kebe	Warejiru	
	Gobu Seyo	Ongobo Bekenisa	
	Seyo Nole	Koliba Chana	
	Nejo	Gonde Mikael	
	Borecha	Togogetema	
	Dega	Sotolo Ado	
	Sokoru	Andode	
	Gomma	Aomafantule	
	Kersa	Degoso	
	Daro Lebu		
	Meta	Duydela	
	Haro Maya	Kuro	
	Melka Belo	Dagaya Balo	
	Midga	Uriji	
	Merti	Abomsa 01	Urban
	Guduru	Kombolcha 01	
	Boneya Bushe	Bilo 01	
Somali	Awubere		pastoralist
	Denbel	Harmukale	
	Shinile	Tomy	
	Filtu	Xayadimtu	
Addis Ababa	Gulele SC	Kebele 18	Urban
	Addis Ketema SC	Kebele 16/17	
	Bole SC		
	Kolfe Keraniyo SC	Kebele 04	
DD	Dire Dawa	Kebel 09	

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