National TB Prevalence Survey Protocol, Ethiopia, 2010/11

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Outline of presentation

- Introduction
- Objective
- Study method/design
- Screening and diagnosis
- Survey operation
- Survey organization
- Budget plan
1. Introduction

- Projected Population for 2010 = 79,731,054

  (76% - rural, 16% - Urban and 8% - Pastoralist)

  ≥15 years = 55%

- Administratively divided into: 9 Regions and 2 City Administrations, 810 Districts and 15,022 Kebeles
Epidemiologic indices of TB in Ethiopia

- Prevalence of TB all forms 579/100000 (WHO estimate)
- Incidence Rate SS+ =163/100000 (WHO estimate)
- 7th high TB burden country in the world
- 3rd high TB burden country in Africa

Program achievement
- Current SS+ CDR=36%
- TSR =84%

Global target
- 70%
- 85%
Between 2007 & 2008, WHO estimate of SS+ TB increased from 152 to 168/100,000. No sufficient justification for this increment by that time since TB control program become more decentralized to the community more than before.

The case detection rate remain steady between 32-34 % against the expected 70% global target.

Evidence based approach is essential for plan and decision making to provide quality service in prevention and control of TB.
As TB prevalence is one of indicators of MDGs and the Global STB Plan, TB prevalence survey is one of the most effective tools to monitor the impact of the program.
2. Objectives

General objective:

To understand the epidemiological characteristics of TB and strengthening the national TB control program
primary aim is to estimate the prevalence of pulmonary TB in Ethiopia in 2010/11, as a basis for evaluation of current performance in case detection and as a baseline measurement for subsequent surveys in the future.
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
Secondary objectives

1. To measure the prevalence of cervical lymphadenitis among study participants
2. To assess the knowledge, attitude, and practice of the population concerning TB
3. To assess health seeking behavior among participants with TB symptoms
3. Method/Survey Design

- Cross-sectional survey
- Multistage cluster sampling
- Stratified: Urban, rural & pastoral populations
- Sample size: 46,514 (aged ≥ 15)
- Clusters: 85 (Urban: 14; Rural: 63; Pastoral: 8)
  - Cluster size: 550 subjects
Sample size

\[ n = \frac{Z^2 p (1-p)}{d^2} \]

Where

- \( n \) - sample size
- \( p \) - estimated prevalence of smear positive TB.
- \( Z \) - SNV at 95% confidence = 1.96
- \( d \) - relative precession

We consider: \( p = 0.002 \), Design effect = 1.5

Participation rate = 85%, \( d = 20\% \)

P of TB in age <15 assumed to be zero
Portion of adult \( \geq 15 = 55\% \)
The desired sample size at 95% CI

\[ n = (1.96 \times 1.96) \times 0.002 \times (1 - 0.002) \times 1.5 \times 0.55 \times (0.002 \times 0.2) \times 0.85 \]

\[ = 46,514 \]
Sampling Stage

District

Kebele

Household blocks

PPS

85 (63 R, 14 U & 8 P)

PPS

1 in each district, total 85

Random selection

n blocks, 550 individuals
Sample sites
Exclusion criteria

Exclusion criteria for sampling frame

- 38 Woredas (3 of the total population) has been excluded because of logistic difficulty
Exclusion criteria during Woreda/Kebele sampling

Once sampling is completed and if an entire selected Woreda is not accessible/ feasible (e.g. due to natural disasters, epidemics, etc) another Woreda from the same Zone will be selected to replace the first one.

- Similarly, if the selected Kebele is not accessible or if the survey is not feasible for major unexpected reasons another Kebele from the same Woreda will be selected to replace the first one.
Exclusion criteria in the selected Kebele

In the selected Kebele the following settings will be excluded

- Military compound
- Diplomatic compounds
- Confined setting: Jail/prison, refugee camps
- Hospitals
- Schools and universities
- Orphanages
- Monasteries
- Homeless persons
Individual exclusion eligibility criteria

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

- Age ≥ 15 years
- Residents who have stayed at least one night in a household during the 14 days prior to the census day
- Visitors who have stayed in a household for at least the past 14 days prior to the census day
The individual inclusion criteria for study participation

- Eligible individuals, based on study criteria
- Consent provided: (adult consent, guardian consent and assent for age 15-17, consent for 15-17 live independently in the house).
Additional study components

- KAP will be conducted on 10% of survey participants
- Health seeking behavior of study participants who have chronic cough
- HIV co infection for TB cases identified by the survey
4. Screening and Diagnosis
Screening...

Diagram:
- Symptom screening, Chest X-ray screening
  - No symptoms
    - Normal chest X-ray
      - No smear microscopy
      - No culture
  - Symptoms or Abnormal chest X-ray
    - Smear microscopy
    - Culture
Symptom Screening

- **Symptom screening**: Cough 14 days or more, weight loss, night sweet, Fever
- Lymph node swelling around the neck
X-ray screening

- any abnormality in the lung or mediastinum
- Portable x-ray with automated processor will be used
X-ray machine
Eligibility for sputum examination

1. Cough 14 days or more
2. x-ray abnormality
3. both symptom & x-ray abnormality
4. Chest x-ray not done but have one screening symptom or risk factor like weight loss, night sweet, fever, previous contact

• All participants eligible for sputum examination shall submit two sputum specimens (Spot and Morning)
Bacteriological screening

- Two sputum specimen (morning & spot) will be taken from each TB suspects
- Morning specimen for culture and AFB, and spot for AFB microscopy.

Smear

Culture
Smear

- Fluorescence Microscope
Culture

- Processing of culture should be started with less than 7 days of sputum collection (transportation plus storage time)
## Case definition

**TABLE.** Overview of classifications according to culture and AFB-smear positive results

<table>
<thead>
<tr>
<th>Study TB case</th>
<th>Definite</th>
<th>Probable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification of definite (CTB positive) TB cases according to AFB-S</td>
<td>AFB-S negative, CTB positive</td>
<td>AFB-S positive, CTB positive</td>
</tr>
<tr>
<td>Classification of AFB-S positives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory results</td>
<td>CTB positive AND AFB-S negative</td>
<td>CTB positive AND AFB-S positive</td>
</tr>
<tr>
<td></td>
<td>CTB positive AND AFB-S unknown</td>
<td></td>
</tr>
</tbody>
</table>

*Indecisive* results refer to inconclusive or uncertain test outcomes.
5. Survey Operation

There are 5 operational field teams: 3 will be in the field at the same time, and 2 will take rest. Each consists of a fixed and a flexible part. The fixed part is established at the center.

The flexible part is established at the zonal and district and kebele level and may vary for each cluster.
For each field activity (team leader, census, interviews, X-ray, lab) standard operating procedures (SOPs) has been prepared in the survey manual
Field team composition

- The fixed part consists of 13 members as follows:
  - one team leader
  - One Assistant team leader
  - census & interviewing group: 3 staff
  - mobile X-ray group: 3 staff (1 doctor, 2 technicians)
  - laboratory: 1 staff
  - 1 clerk/receptionist
  - 3 drivers
Local members include 17-19 members:

- Regional/zonal TB coordinator: 1 staff
- Woreda Health office: 1 staff
- Hospital/Health center: 1 staff
- Health social worker: 1 staff
- Assistants/Volunteers: 3 staff
- Kebele chair person/manager: 1
- Village (Gote, Gare) leaders: 6-8 leaders
- Interpreter: 1 staff
- Clerk/receptionist: 1
- Driver (optional): 1
Field work duration

- One cluster (550 Subjects) will be completed within a week.
- It will take 8-9 months
Field work procedure

- Inform community and necessary administrative level about objective detail activities and ensure clearance.

Pre-visit the selected kebele

- Checking accessibility, select convenient time, draft map, assess infrastructure, inform local authority etc)
Field work procedure....

Second visit
- Communicate local authority and leader, Map the area, Designate survey area, identify local people who can assist, make linkage to near by health facility etc.
Conduct Survey

- Day 0 arrival
- Day 1 Census
- Day 2-5 data collection
- Day 6 Debriefing
- Field report
- Follow up
Day 1 census
Day 2-5 data collection
Day6: Debriefing and packing
6. Central work

- The data collected in the field (laboratory, x-ray finding, interview) will be sent to central team.
- Central team composed of Principal Investigator, Survey coordinator, Team leaders, Data manager, Lab responsible, radiologist, medical panel for final decision
7. Data management

- Data will be collected in predesigned forms, log books or survey records according to standard operating procedures (data management SOPs).
Survey participants with sickness and chest x-ray abnormalities that need medical intervention will be referred to the nearby health facility (health centre or district hospital) with chest x-ray reports and will be managed as per the standard of care in the country’s guideline.

Local health authority is responsible to manage cases.
9. Ethical consideration

- Ethically reviewed by national review committee and EHNRI ERC
- Consent
- Suspects or cases will be referred or linked to the local health authority for detail diagnosis and medication
10. Training

- In-house training  CXR, lab, interview
- Integrated training
- Field test/ pilot testing
- Revise protocol
## 11. Time line

- Protocol development October 2009
- Procurement May 2010
- Staff recruitment June-August 2010
- Selection of survey sites & 1\textsuperscript{st} Pre visit and Protocol revision August 2010
- Staff training, finalization of survey schedule July –August 2010
- Sensitization workshop for regional and district people September 2010
Start of Field Operation (October, 2010)
Completion of Field Operation, May, 2011
Confirmation of Lab results, August, 2011
Preliminary Results, October, 2011
Final Results December, 2011
Field Team Operation Schedule

Field operation schedule
Survey Organization

- Steering Committee/Principal investigator
  - Technical Advisory committee
  - Survey coordinating team
    - Central team
      - Lab
      - X-Ray
      - Statistics (data management)
    - Field team (5 team)
      - Logistic
  - Medical/Diagnostic panel
## Budget plan

<table>
<thead>
<tr>
<th>S. No</th>
<th>Budget description</th>
<th>Budget in USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Salary</td>
<td>844,550</td>
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<tr>
<td>2.</td>
<td>Procurement</td>
<td>922,270</td>
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<tr>
<td>3.</td>
<td>Field operation</td>
<td>702,800</td>
</tr>
<tr>
<td>4.</td>
<td>Workshop and training</td>
<td>227,922.50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>2,697,542.50</strong></td>
</tr>
<tr>
<td>5% Contengency</td>
<td></td>
<td>134,877.10</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td><strong>2,832,419.60</strong></td>
</tr>
</tbody>
</table>
## Source of Fund

<table>
<thead>
<tr>
<th>Source of fund</th>
<th>Mainly Budgeted for</th>
<th>Fund In USD</th>
<th>% from total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Global Fund</td>
<td>Procurement, training, salary and field operation</td>
<td>2,625,519.60</td>
<td>92.7%</td>
</tr>
<tr>
<td>2 WHO</td>
<td>TA</td>
<td>106,900.00</td>
<td>3.8%</td>
</tr>
<tr>
<td>3 USAID/TBCAP</td>
<td>Salary</td>
<td>100,000</td>
<td>3.5%</td>
</tr>
</tbody>
</table>
Lesson learned from Pilot study

1. Census taking with the initial design procedure took long time more than two days.

Corrective action: prepare invitation cards and household number at survey camp site for each individual based on the pre population list recorded by health extension workers.
2. x-ray film taking took long time at the start, undressing and dressing took long time.
Corrective action taken: x-ray room partitioned for dressing and undressing so that time required for dressing before the next participant called is reduced.

3. Low participation rate 371/600
Corrective action taken: involve sub village leaders to guide the census teams and involve mobilizing the community and mop-up activity.
4. More suspect flow (24%) than expected (10%) as a result respondent bias in seeking bacteriological examination by responding have cough while it is not. Those who have symptom have high participation rate compared to those without symptom.

Corrective action taken: Proper orientation of HEWS and local assistants during mobilizing the community, not to give detail information on the procedure of the survey.
5. Missing some of last day morning specimen because of market day.

Corrective action taken: consider data collection date to be completed on Friday.

Proper counseling of last day participants to get their morning specimen since there is no time to mop up for the last day participants.
Thank you