Training workshop for consultants of TB prevalence surveys

Protocol Development

Chapter 3 Protocol development & standard operating procedures

25 February 2011
Phnom Penh, Cambodia

Norio Yamada, RIT/JATA
Protocol and SOPs

• The protocol provides a general overview of the survey procedures
• The SOPs provide full details of all procedures to ensure operation be implemented in a standardized way.
Protocol Development Process

• Iterative process (parallel to process of deciding survey design/methods)
• Involvement of Multiple partners
• Define roles & responsibilities early
• Protocol development workshop
• Peer-review by Task Force Members
• Ethical approval
Technical skills required

- Epidemiologist
- Statistician
- Radiologist
- Laboratorian
- M&E officer
- Procurement/Logistics expert
- Local HCW & community members
- Data management expert
When survey planning is initiated

• Formulate committee (with core-partners)
  – Strong commitment and leadership from the NTP, the Ministry of Health and a core group of professionals (1.4.1)

• Consult WHO Task Force
  – Recommendation based on theories and experiences of previous surveys.
  – The Task Force help to identify TA agencies.
Essential Contents (1)

1. Synopsis (summary)
2. Background and survey justification
3. Objectives
4. Survey design and methods
   ▪ Survey design and screening strategy
   ▪ Sampling frame and survey population
   ▪ Case definitions
   ▪ Sample size and sampling strategy
Essential Contents (2)

5. Survey procedures and organization
   – Survey outline
   – Informing authorities
   – Pre-survey visit, cluster sensitization and community mobilization
   – Survey census
   – Symptom screening interview
   – Chest X ray screening
   – In depth interview
   – Sputum examination
   – Data Collection Tools
   – Mop-up procedures for non-attendees
   – Tuberculosis treatment of identified TB patients
   – HIV-testing
   – Optional sections
6. Pilot study
7. Monitoring and Quality Assurance
8. Training
9. Data management, analysis & reporting
10. Survey management
11. Ethical considerations
12. Timeline of the survey
13. Technical assistance
14. Dissemination plan
15. Budget
16. References
Kick-off

• Major objectives are discussed.
• Sample size (no. cluster x cluster size under several assumptions) for major objectives is estimated to see scale of the survey and budget.
Survey Organization

• One of critical issues in the planning is to identify organizations implementing a survey.
  – Planning/ Design
  – Central unit
  – Field team
  – Laboratory
Cambodia

- Central units: National TB centre with one provincial laboratory
- Basically survey is carried out by existing central NTP staff with support from province/district level

China

- Implementation is decentralised and carried out by local medical staff.
  - National training to province staff
Philippines

- Steering committee was organized by the DOH to set the policies and guidelines and to oversee the implementation of the survey.
- Implementation is outsourced to Tropical Disease Foundation.
  - Implementation staff at field level is employed for the survey.
Objectives of surveys
Major Objectives

• To estimate prevalence of bacteriologically confirmed pulmonary TB cases (not only smear-positive cases)

• To obtain data on why cases are missed from NTP

• To compare prevalence with past surveys

• To provide baseline for future comparison.
Other objectives

- Other investigation such as social determinants and risk factors (see appendix-5) may be included.
- Additional studies should not affect quality of the results for major objectives.
Study Population
Denominator
Eligibility of study population inclusion/exclusion criteria

• Clear description of eligibility criteria.
• The reasons for exclusion.

Common criteria example:
• Geographical areas if some part of a country is excluded (due to security problems)
• Age group (Recommendation: >= 15yrs)
• Types of dwelling places if some special institution (barracks/prisons/hospitals/…. ) is excluded (usually excluded due to feasibility).
• Length of stay at a current dwelling place
Issues in determining eligible population

• The less excluded from the target population aged $\geq 15$ yrs, the better representative sample.
  – If the eligible is limited to registered residents, many might be excluded in urban areas.

• However *de facto* population at a time of a survey may not be suitable for the survey.
  – Some moves in survey sites just before survey because sick.
  – Individual in institutions (hospital, prison, military barracks): may not be accessible and proportion is small but much different in prevalence
Eligible individuals and Participants

• Clear description of definitions of eligible individuals and participants.
  – Eligible individuals is individuals who meet eligibility criteria in each selected survey sites regardless of participation in TB screening.
  – Participants are individuals who attend the TB screening (interview and/or CXR).

• The number of the eligible individuals is required to assess participation rate.
Definition of individuals eligible for sputum examination

• The eligibility of sputum examination is determined by symptom and/or CXR.
• Definition of symptom eligible for sputum collection
• Definition of CXR shadows eligible for sputum collection
Description of Methods if comparison is one of objectives

• If the results are compared with the past survey or with future survey, issues of comparability of the results should be described.
5.2 Informing authorities

• Activities to be undertaken after ethical approval to inform all respective authorities about the survey

• Information and sensitization activities to take place at central, regional or local levels
Field Operation
Description of Field Team

• Leader
• Census
• Interview
• CXR examination
  – Technician
  – CXR readers
• Laboratory
• Driver, administrative staff
5.3 Pre-survey visit, cluster sensitization and community mobilization

• Processes for explaining the purpose and procedures of the survey to community members and for obtaining community consent if applicable.

• Situation assessment
  – Accessibility, Availability of electrical power,
  – Identification of areas to set up screening unit and field laboratory (if needed)
  – Availability of accommodation and cooking facilities for the field team

• Identification of the survey population within the selected cluster and need for sub sampling, if required
Outline of Field operation

• Schedule of activities in each cluster
  – Arrival day
  – Census
  – Screening
  – Mop-up
• Procedures for each of activities
5.4 Survey census (see Chapter 14)

– When, how and by whom the survey census will be performed
– Explanation to household members
– Procedures for identifying and recording categories of individuals (eligible/non-eligible Adult/Children)
  • The number of non-eligible individuals is required to assess population coverage of the survey.
– Invitation of the eligible to TB screening
– Procedures for collection of household data (e.g. assets) if applicable.
5.11 Tuberculosis treatment of identified TB patients (see Chapter 11)

• Describe how feedback of examination results for treatment of identified TB patients will be made.
  – by whom, within which timeframe.

• Procedures for collection of additional information from TB cases identified in the survey, where applicable (that is, HIV test result, treatment outcome)
Documents to be attached

• Data collection forms/register
  – Census Register (Household register)
  – Symptom Screening questionnaire
  – Chest X-Ray screening form
  – Chest X-ray register
  – Individual eligible for sputum exam register
  – Sputum examination request/results form
  – Laboratory register

• Informed consent and participant information sheet (see Chapter 6)
The end