National Tuberculosis Prevalence Survey

Guidance document
for development of
standard operating procedures (SOPs)

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version November 8th 2010
Foreword

This document is designed to provide guidance on the development of standard operating procedures (SOPs) for tuberculosis (TB) prevalence surveys. This document was developed by the research unit of KNCV.

A group of 21 countries is advised by the World Health Organisation (WHO) to carry out at least one TB prevalence survey before 2015. Several of these countries are preparing to carry out a TB prevalence survey in their country in 2010-2012. When providing technical assistance (TA) to countries for TB prevalence surveys we received several questions from country staff content and development of SOPs and felt it would be useful to prepare a generic outline that can serve as a base for developing country specific SOPs.

The SOPs assume the survey is conducted using the screening strategy recommended by the World Health Organization (WHO 2010\(^1\)) which consist of:

i) Symptom screening of all eligible individuals aged ≥ 15 years

ii) Chest X rays of all eligible individuals aged ≥ 15 years except those individuals meeting the exclusion criteria for chest X ray

iii) Sputum collections for smear culture and DST of all those with symptoms or an abnormal chest X-ray (as defined in the survey protocol)

The information in this document is compiled from presentations and existing SOPs available at the research unit of KNCV Tuberculosis Foundation. Previous drafts of this guidance document have been used to guide the development of SOPs in the National TB Prevalence Surveys in Pakistan and Rwanda. Furthermore, we are grateful for the examples of SOPs which KNCV Tuberculosis Foundation has received from Dr Anja van het Hoogt and Dr Janet Agaya from the Kenya Medical Research Institute / Centers for Disease Control and Prevention in Kisumu, Kenya who have kindly shared their general prevalence survey SOPs, parts of which have been integrated into this generic training manual.

Countries which are planning a TB prevalence survey may use this document to guide development of SOPs for their national TB prevalence surveys. Updated version of this document will be prepared if needed. For suggestions or more information please contact the Unit Research of KNCV Tuberculosis Foundation (secretary.research@kncvtbc.nl)

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\(^1\) WHO A handbook for tuberculosis prevalence surveys, the new, the updated and the lessons learned. 2010
Acknowledgements

We like to thank the Dr Ejaz Qadeer, Dr Rumina Hasan and Ms Razia Fatima from the National Tuberculosis Program Pakistan and Dr Abdul Ghafoor and Dr Laeeq Ahmad from the KNCV Office Pakistan whose request initiated the development of this document. Their feedback on previous drafts during the preparations for the Pakistan prevalence survey have been very useful in developing this guidance document. We also acknowledge the great input of Dr Emily Bloss of CDC for her useful comments to this document.
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Abbreviations

DST  Drug susceptibility testing
MOTT  Mycobacterium other than TB
NTP  National Tuberculosis Program
PI  Principal Investigator
SOP  Standard Operating Procedure
TB  Tuberculosis
TST  Tuberculin Skin Test
1. Background

1.1 Role of SOPs in a TB prevalence survey

A standard operating procedure describes the steps which are required to complete a process. A process is defined as a set of actions that a person or group of people must perform to complete an objective. The SOP specifies and documents the way of performing an activity and achieving an objective in a standardized way. All aspects that are covered in a prevalence survey should be standardized. SOPs are important to ensure that all team members perform the tasks using standardized methods. During the course of the prevalence survey, several teams are operating at the same time, which makes standardization especially important. The large sample size of a prevalence survey also emphasizes the importance of standardization.

The SOPs can be seen as a general script to carry out the survey. To identify for which areas SOPs are needed in the prevalence survey, the following sources can be used:

- Prevalence survey protocol
- Routine activities also carried out during the prevalence survey, i.e. laboratory procedures for which SOPS are already available that can be used as a base for survey specific SOPs
- Regulatory guidelines (e.g. X-ray protection)

Flow diagrams of site and study activities are useful tools to identify when and where SOPs are needed in a prevalence survey. Each country should therefore review their prevalence survey protocol, existing activities and regulatory guidelines to determine what SOPs are necessary. As much as possible existing SOPs should be used as starting point to develop specific TB prevalence survey SOPs.

The SOPs as outlined in this guidance document include a minimal list of SOPs that we propose to develop during the preparations of the prevalence survey. Depending on the country additional SOPs might need to be added. We propose to use a standardize way of setting up the SOPs. All details of the SOPs need to be filled and reflect the country specific situation.
1.2 General instructions for developing SOPs

In general, there are four main steps in developing SOPs:

**Step 1 Decide which SOPs need to be developed**

Making a flow diagram depicting all steps (i.e. field data collections steps (census, informed consent, interview, sputum collection & examination, X-ray etc), central level (quality assurance, monitoring, etc)) included in the prevalence survey will assist identifying which SOPs need to be developed.

**Step 2 Check to ensure key elements have been included in the flow diagram.**

Before writing the SOPs, brainstorm and discuss with involved partners to make sure all steps in the prevalence survey have been included and correctly depicted and/or if certain steps should be excluded. Once consensus has been reached on the flow diagram, it should be further discussed if all SOPs that need to be developed have been correctly identified.

**Step 3 Write the SOP**

In general, the first SOP that needs to be written is the SOP which specifies the format and process for initiation/revision, review and approval of SOPs. In paragraph 1.3 we propose a general format for the SOPs included in the prevalence survey. If a fixed outline is used it is easier to include all information in a standardize way. The process for initiation/revision/review and approval of the SOPs should be decided by the steering committee.

**Step 4 Validate the SOPs in a pilot study**

The SOPs need to be tested in the pilot study. It is essential to assess if all key steps are indeed covered by SOPs and if the persons responsible for following the specific SOPs are able to work according to the SOPs.
1.3 General format SOPs

A standard format for all SOPs included in the prevalence survey is desired. While several different formats can be used for writing SOPs, we propose to use the following standard format when developing the SOPs for the prevalence survey.

1. Purpose: Describe the purpose of the specific SOP
2. Definitions: Explain the terminology used in the specific SOP where needed
3. Abbreviations: List the abbreviations used in the specific SOP
4. Scope: Describe for which persons/teams the specific SOP is relevant. Doing this will also facilitate the identification of training needs of the prevalence survey staff
5. Responsibilities: Identify those responsible for each of the activities outlined in the specific SOP
6. Materials: Describe which materials are needed for each procedure outlined in the specific SOP
7. Procedures: Briefly describe the relevant steps and procedures in the specific SOP
8. Forms and registers: List all forms/registers used to document the procedures in the specific SOP
9. Other SOPs: If applicable, list other SOPs which are associated with the specific SOP. Note of course all SOPs are linked to the prevalence survey but within a SOP reference might be made to another SOP, for example before conducting the interview informed consent needs to be obtained so these SOPs are directly linked
10. Signature page: Once agreed and approved the page is signed to make it final and will also be signed and dated if any amendments are made. It should be decided per country who will be this signatory, this could be the principle investigator for example.
2. SOP General

2.1. Purpose
The purpose of this SOP is to provide a general overview of the authority liaison procedures, the detailed flow of persons involved in the prevalence survey, their terms of reference, forms to be filled out and the template for the field report procedures. This SOP outlines the overall procedures of the survey.

2.2 Definitions
Explain the terminology used in this SOP where needed, for advisory board= team of technical partners and stakeholders overseeing the survey.

2.3 Abbreviations
List abbreviations used, for example ToR (terms of reference).

2.4 Scope
This SOP is relevant for all survey staff members for a general overview of the fieldwork organization involved, authority liaison procedure and flow of person and forms.

2.5 Responsibilities
Describe the roles & responsibilities (terms of references) of all key survey personnel with regards to the overall survey activities.

2.6 Materials
List materials needed for the procedures outlined in this SOP, i.e. field reporting.

2.7 Procedures
• Provide a flow chart TB prevalence survey
• Describe briefly the field work organization (e.g. the number of teams, constitution of teams, involvement and sensitization of local authorities, presurvey visits, census, when and where and from whom interviews, chest X ray and sputum will be collected, number of clusters etc...)
• Provide detailed calendar of day to day activities per cluster
• Describe authority liaison procedure (e.g. describe how the national and local authorities will be involved in the survey and what the responsibilities are)
• Describe flow of persons and forms (Describe which teams will collect which specific data and are responsible for filling out the correct form and the flow of field reporting procedures )

2.8. Forms and registers
List all registers/forms relevant for this SOP, i.e. field report.

2.9 Other SOPs
The general SOP is related to all other SOPs.
3. SOP Pre-survey visit

3.1. Purpose
This SOP provides an overview of the procedures that take place during the pre-survey visit to a selected cluster.

3.2 Definitions
Provide definitions for terminology used in this SOP where applicable, i.e. cluster

3.3 Abbreviations
List abbreviations used in this SOP, i.e. DMO=district medical officer

3.4 Scope
This SOP is relevant for the field team leaders, the survey coordinator, the district TB coordinator and other persons directly involved in the pre-survey visits.

3.5 Responsibilities
Describe the roles and responsibilities (terms of references) of the field team members who will be involved in the pre-survey visit.

3.6 Materials
List all materials needed to carry out the pre-survey visits, i.e. population listing, sketch maps, pencils, GPS (if applicable).

3.7 Procedures
• Describe the purpose of the pre-survey visit
• Describe the timing of the pre-survey visit and by whom the visits will be conducted, i.e. number of weeks (preferably 2 to 3 weeks) before the start of the survey the clusters will be visited
• Describe all the activities that will be conducted during the pre-survey visit
  Minimal activities include:
  o Explain purpose and procedures of survey to relevant authorities
  o Obtain commitment of local authorities
  o Perform situation assessment for field team using pre-survey checklist
  o Instructions for preparation/use of population listing (if applicable)
  o Identification and training of flexible team members in census taking, where applicable
• Describe what to do if certain clusters turn out not to be accessible (if so whether this is seasonal or permanently, if seasonal during which period can the cluster be visited); include trouble shooting (what to do if the community is not receptive to the survey (whom to consult), what if the selected cluster can not be reached due to flooding, broken bridge etc).
• Describe ‘what if’ scenarios\(^2\) (e.g. what if the field team members have insufficient time to complete the required tasks; or what if no accommodation for field team can be identified etc.)

3.8. Forms and registers
List all registers/forms relevant for the specific SOP. Include checklist for situation assessment of the cluster (e.g. regarding accessibility, availability of power, areas to set up screening unit, laboratory and X-ray unit, accommodation for field team, cooking arrangements).

3.9 Other SOPs
If applicable, list other SOPs which are associated with this SOP. For example the authority liaison procedures, how are the authorities informed of the pre-survey visits.

\(^2\) what if scenario’s are description of hypothetical situations that potentially occur during the survey (the what) and what should be done if they occur (the if)
4 SOP Field data collection

This part of the SOPs consists of five different parts listed below:

4.1 Survey census
4.2 Enrolment participants and informed consent
4.3 Symptom screening interview
4.4 Chest X ray at field level
4.5 Laboratory field procedures
4.6 In depth interview for those eligible for sputum examination

4.1 SOP Survey Census

4.1.1 Purpose
This SOP provides an overview of the procedures that take place during the survey census. Depending on the survey design the census might take place during a separate visit few weeks before the main survey team arrives in the cluster or the survey is done in the first days after the main survey team arrives in the cluster. This differs per country.

4.1.2 Definitions
Explain terminology used in this SOP where needed, for example: households; eligible persons for census

4.1.3 Abbreviations
List abbreviations used in the SOP, ID number= identification number

4.1.4 Scope
This SOP is relevant for the field team leaders, all team members, the census & interviewing team and if applicable members of the flexible team who will be involved like community health care workers or other community volunteers

4.1.5 Responsibilities
Describe the responsibilities of the field team members related to the activities that will be involved in the survey census;

4.1.6 Materials
Include detailed list of materials which field team members should bring when visiting the household, i.e. register, pencils etc. This list should be used by the field team members as a checklist before they set out into the field.

4.1.7 Procedures
• Describe the purpose of survey census.
• Describe how the different households are divided over the different census takers. Census is taken by a group of people and it should be described what the
procedure for dividing the households among them is and how it will be ensured there are no duplicate households in the census, i.e. how are household marked to have been enumerated.

- Describe the procedures for listing eligible household members (including description of in- and exclusion criteria).
- If applicable describe how to use the population list (how to deal with the situation if the list is not up to date, describe when to add individuals who are not on the population list to the census, and describe when to exclude an individual who is on the population list from the census).
- Describe the specific information that needs to be recorded on each form and register (e.g. separate register for adults and children). Describe for each field to be filled what information needs to be recorded.
- Describe procedures for additional information collected during the census, if any. In some countries socio-economic or risk factor data is collected from all participants. Note that if additional data is collected informed consent for the survey needs to be obtained at the census stage before the additional information can be collected.

4.1.8. Forms and registers
Include list of all study forms and registers that are needed during the census.

4.1.9. Other SOPs
SOP 4.2 Enrolment participants and informed consent
4.2: SOP Enrolling participants and informed consent

4.2.1. Purpose
This SOP provides an overview of the procedures for enrolling participants and informed consent.

4.2.2 Definitions
Explain terminology used in this SOP where needed, for example: household, eligible person for census, eligible person for survey, adult, guardian etc.

4.2.3 Abbreviations
List abbreviations used in this SOP

4.2.4. Scope
This SOP is relevant for the field team leaders and the census and interviewing team.

4.2.5 Responsibilities
Describe the responsibilities of the field team members related to the activities involved in enrolling participants and taking informed consent.

4.2.6 Materials
Include detailed list of materials needed for enrolling of participants and taking informed consent.

4.2.7 Procedures
• Describe which persons are eligible for enrollment in the survey using the inclusion and exclusion criteria as defined in the protocol and describe how to use the census list to identify them. Discuss different what if scenarios (i.e. a child at boarding school, a relative visiting etc)
• Describe from which persons informed consent will be asked directly and for which persons informed consent need to be asked from parents or guardians.
• Describe the stepwise instructions for asking informed consent (including e.g. shortly explaining the study, providing the participant with a copy of the consent form, procedure of reading the informed consent form and giving the potential participant the time to ask questions)
• Include ‘what if’ scenarios in the procedures (e.g. what to do with eligible persons who are not at home during the time of the census/enrollment; what to do if the participant is unable to sign; what to do if you are not sure about the eligibility of a person)
• Describe how to record the consent/refusal
• Describe the procedures following informed consent (e.g. including instructions for handing out information (verbal or by distributing leaflets) on who is expected where, when for which procedure; marking the households for prevalence survey)
• Describe the provision of survey identification cards
4.2.8. Forms and registers
• Include list of all study forms and registers that are needed during enrollment, e.g.
  o Participant informed consent form
  o Parent/Guardian informed consent form
  o Survey identification card
  o etc.

4.2.9. Other SOPs
Depending on when informed consent is obtained during census, before the screening interview the following SOPs are connected to this SOP:
• SOP 4.1 Survey census
• SOP 4.3 Symptom screening interview
4.3: SOP Symptom screening interview

4.3.1. Purpose
This SOP provides an overview of the procedures that take place during the screening interview.

4.3.2 Definitions
Explain terminology used in this SOP where applicable, e.g. person eligible for providing sputum

4.3.3 Abbreviations
List abbreviations used in this SOP

4.3.4 Scope
This SOP is relevant for the field team leaders and the interviewing team members

4.3.5 Responsibilities
Describe the responsibilities of the field team members related to the activities that will be involved in symptom screening interview

4.3.6. Materials
Include detailed list of materials, other than the forms described in 5.3.8 which are needed for the screening interviews

4.3.7. Procedures
• Describe the purpose of the screening interview.
• Describe where symptom screening will take place. Depending on the survey set up this is either at the central location in the cluster or at the household level.
• If at the central location in the cluster describe organization of the testing day including procedures for:
  o Preparation of clients who present with survey personal identification card (include reception of client, explanation of procedures)
  o Instructions for filling out the symptom screening questionnaire
  o Instructions for checking the symptom screening questionnaire for completeness and consistency
  o Instructions for referring the client to chest X ray screening
  o Instructions for filling out sputum request register based on results symptom screening
  o Include flow chart of field work including the registers and forms
• If at household level describe procedures and organization of the screening interview
  o Information provided to clients after informed consent is obtained (explanation of procedures)
  o Instructions for filling out the symptom screening questionnaire
  o Instructions for checking the symptom screening questionnaire for completeness and consistency
Instructions for referring the client to the central areas for chest X ray screening
Instructions for documentation of results symptom screening
Include flow chart of field work including the registers and forms

- Describe procedures for quality assurance and monitoring:
  - Instructions for checking if all eligible participants have been approached and interviewed
  - Instructions for crosschecking of procedures by field team leader

- Describe ‘what if’ scenario’s (what if person selected for interview refused to take part, or refuses to answer certain questions, what if person it too ill to answer questions, what if person showing up does not seem to be the person listed in the census, etc)

4.3.8 Forms and registers
- Include list of all study forms and registers that are needed during the screening interview. For example:
  - Symptom screening questionnaire
  - Sputum request register

4.3.9 Other SOPs
- 4.1 Survey Census
- 4.2 Enrolling participants and informed consent
- 4.4 Chest X ray at field level
- 4.5 Laboratory field procedures
- 4.6 In depth interview for those eligible for sputum examination
4.4 SOP Chest X ray at field level

4.4.1 Purpose
This SOP provides an overview of the procedures that take place during the preparations, examination and interpretation and quality assurance of chest X-rays at field level.

4.4.2 Definitions
Explain terminology used in this SOP where needed, for example definitions for chest X ray outcomes that will be used to distinguish a person eligible for sputum examination (e.g. criteria used for normal and abnormal chest X-ray).

4.4.3 Abbreviations
List abbreviations used in this SOP

4.4.4 Scope
Describe for which persons/teams the specific SOP is relevant, e.g. field team leaders, chest X-ray team etc.

4.4.5 Responsibilities
Describe the composition of the chest X-ray team and responsibilities of the team members involved in setting up the field site, chest X-ray reading and storage of images.

4.4.6 Materials
Include list of materials need to conduct the procedures outlined in this SOP.

4.4.7 Procedures
- Describe aim and objectives of the chest X-ray taking
- Describe methods:
  - Describe people eligible to undergo chest X-ray, how are they identified
  - Describe exclusion criteria for participation in chest X-ray and what happens to these persons (will they submit a sputum sample for example)
  - Describe when and where chest X-ray will be performed
- Field activities
  - Describe organization of the testing day including procedures for:
    - Preparation of work site and set up of the unit (including checks if all equipment is functioning, calibration of equipment where needed, power up of generator, X-ray unit, digital unit, preparation of plates and other accessories)
    - Preparation of clients (include reception of client, explanation of procedures, physical preparation, breathing exercises)
    - The examination (taking of X-ray, processing the image, digital storage, checking image for quality)
    - Reading X-rays (describe normal/abnormal interpretation) and criteria for interpreting the chest X-ray


- Client aftercare (post examination instructions, referral to sputum collection if needed)

- Describe handling of images (on daily basis, after completion of the cluster, visit, after the survey)

- Describe quality assurance and monitoring
  - Describe periodic quality checks for equipment
  - Describe random selection of images for quality control in the field
  - Describe supervisory visits, frequency, what will be monitored

- Safety procedures
  - Radiation safety procedures
    - How to ensure regulation are adhered to
    - Liaison with relevant authorities (refer to general SOP)
  - Hygiene and safety procedures
    - Cleanliness of working area
    - Cleanliness of the x-ray equipment and accessories
    - Disposal of waste

- Maintenance and repair: Describe for each part of equipment used (i.e. X-ray equipment, generator, truck) who will, at which time period/frequency, provide maintenance. This will be members of the team but depending on the service contract also the company who delivered the machines.

- Problem solving at field level, what to do in certain anticipated situations (what if scenario’s, what if the X-ray breaks down and cannot be fixed in the field, what if the X-ray truck cannot reach the cluster, what if the generator breaks down etc.)

- Data management of x-ray data at field level
  - Specify in which register the date are entered
  - List the information that will be recorded by the chest X-ray team
  - Describe how data are summarized (daily, after cluster completion) and with whom this report is shared
  - Describe how data is stored and shared (daily, after cluster completion) to hand over the data every day

- Describe procedure for communication with chest X-ray readers at central level (see SOP 5.1)

4.4.8 Forms and registers
- List all registers/forms relevant for the specific SOP.

4.4.9 Other SOPs
- 4.3 Symptom screening interview
- 4.5 Laboratory field procedures
- 5.1 Chest X-ray at central level
- For some items that need to be included in the chest X-ray SOPs, SOPs might already be available, these can be incorporated in the specific prevalence survey SOPs and adjusted where needed to specific survey conditions.
4.5 SOP Laboratory field procedures

4.5.1. Purpose
This SOP provides an overview of the procedures that take place during the field data collection including organization of the field site; preparations for collection of sputum, the collection of sputum, specimen transport and bio safety. Depending on the survey set up, reading of smear is either done at field level or at regional/central level.

4.5.2 Definitions
Explain terminology used in this SOP where applicable e.g. person eligible for sputum examination, positive smear

4.5.3 Abbreviations
List abbreviations used in this SOP

4.5.4 Scope
The SOP is relevant for the field team laboratory members and members of the central level lab team and team leaders.

4.5.5 Roles and responsibilities
Describe the roles and responsibilities of the field laboratory team members

4.5.6 Materials
List materials required for conducting the procedures outlined in this SOP (set up of sputum collection site (e.g. microscopes, slides, etc), collection of smear, reading of smears (where applicable)

4.5.7 Procedures
- Methods
  - Describe people who will undergo sputum examination
  - Describe exclusion criteria to identify people who will not undergo sputum examination
  - Describe when and where sputum examination will be performed
- Describe procedures for arrangement of the sputum collection field site
- Describe sputum collection in the field:
  - Sputum collection (i.e preparation of clients, sensitization procedures for sputum collection, number of samples collected, location of sputum collection, type of containers, specimen reception at survey site
  - Procedure for requesting a new sample if the morning specimen has insufficient quality or quantity of sputum
  - Procedures for storage of sputum samples during field work

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3 In this guidance document it is assumed that smear staining will be conducted at district or central level. If smear staining and reading will be done in the field laboratory the SOPs should be adapted accordingly.
• If applicable describe procedures for sputum examination in the field. If reading is done at regional/central level describe them in the relevant SOP (5.2)
• Describe transportation of sputum cups/smears to regional/central laboratory (specimen preparation, transportation means, timing, forms, communication)
• Describe filling of laboratory registers and forms and reporting of results
• Describe bio safety issues, in field lab, during transport to regional/central lab
• Describe how problems will be solved, e.g. what if scenario’s (what to do if sputum cups leaked, what if ID number is not readable, what if person refuses to submit sputum etc)
• Describe quality assurance procedures (at field level, by regional/central level)
• Describe mop up operations for those who were requested to submit sputum sample but have not submitted the required number of samples

4.5.8. Forms and registers

• List all registers/forms relevant for the specific SOP, e.g. laboratory registers, transportation forms etc.

4.5.9 Other SOPs

• 4.5 Chest X ray at field level
• 4.6 In depth interview those eligible for sputum examination
• For some items that need to be included in the laboratory field SOPs, SOPs might already be available, e.g. the SOPs used by the laboratory. These SOPs can be incorporated by adapting them where needed to be survey specific.
4.6: SOP In-depth interview of those eligible for sputum examination

4.6.1. Purpose
This SOP provides an overview of the procedures that take place during the in-depth interview of those eligible for sputum examination.

4.6.2 Definitions
Explain terminology used in this SOP where needed, e.g. person eligible for sputum examination etc.

4.6.3 Abbreviations
List abbreviations used in this SOP

4.6.4 Scope
This SOP is relevant for the field team leaders, the census and interviewing team including the interviewing team for those eligible for sputum examination and the sputum collection group.

4.6.5 Roles and responsibilities
Describe the roles and responsibilities of the field team members related to the activities that will be involved in persons eligible for sputum sampling interviewing

4.6.7. Materials
Include detailed list of materials, other than the forms described in 4.6.9 which are needed for the in depth interview of those eligible for sputum examination

4.6.8. Procedures
- Describe the purpose of the in depth interview of those eligible for sputum examination
- Describe organization of the testing day including procedures for:
  - Preparation of survey participants who have been referred for n-depth interview (greeting of client, explanation of procedures)
  - Filling out the in depth questionnaire those eligible for sputum examination, explain in details how each question should be filled
  - Checking the in depth questionnaire for completeness and consistency
  - Referring the person eligible for sputum examination to sputum collection site
  - Filling out the sputum collection register
- Include flow chart of field work including the registers and forms
- Describe procedures for quality assurance and monitoring
  - Instructions for checking if all eligible participants have been approached and interviewed
  - Instructions for crosschecking of data quality by field team leader
• Describe ‘what if’ scenario’s and problem solving in the field, e.g. what if a person refuses to be interviewed or answer part of the questions, what if a person is too sick to answer questions etc.

4.6.9 Forms and registers
Include list of all study forms and registers that are needed during the in-depth interview for those eligible for sputum examination, e.g. registers, questionnaires, quality assurance forms etc.

4.6.10 Other SOPs
• 4.1 Survey census
• 4.2 Enrolment participants and informed consent
• 4.3 Symptom screening interview
5. SOP Central Level
These SOPs consist of two different parts listed below:

5.1 SOP Chest X ray at central level

5.2 SOP laboratory procedures for regional/central level

5.1 SOP Chest X ray at central level

5.1.1. Purpose
This SOP provides an overview of the procedures that take place at central level related to the Chest X-ray taking:
• assembling/approval of X-ray station/truck by national radiation authority
• quality assurance of field X-ray taking
• full reading of chest X-rays at central level if applicable

5.1.2 Definitions
Explain terminology used in this SOP where needed.

5.1.3 Abbreviations
List abbreviations used in this SOP.

5.1.4 Scope
This SOP is relevant to the central level radiologists involved in chest X-ray reading and persons conducting quality assurance of chest X rays collected in the field as well as for the field X-ray team so they know what to expect from central level.

5.1.5 Roles and responsibilities
Describe the roles and responsibilities of all prevalence survey staff involved with chest X-rays at central level

5.1.6 Materials
Include list of materials used to carry out the procedures outlined in this SOP, e.g. storage facilities for films, X-ray viewer etc.

5.1.7 Procedures
• Describe process of approval by national radiation authority of the X-ray equipment used in the survey
• Describe aim and objectives of the chest X-ray reading at central level
  o quality assurance
  o full reading of X-ray images
  o provision of support the field X-ray team
• Describe procedures for receipt of chest X-rays arriving from field level
  o registration of images
- checking of images
- Describe procedures for central re-reading and reporting results (make distinction between quality assurance and full reading of images)
  - process of selection of images
  - blinded reading
  - format for results reporting
  - decision of final result, what happens in case of discordance
  - format for reporting final X-ray results to survey coordinator
- Describe procedures for storage X-ray images including issues of access and confidentiality

5.1.8. Forms and registers
List all registers and forms relevant for central X-ray team, e.g. results forms, X-ray image register

5.1.9 Other SOPs
Some items that need to be included in the chest X-ray SOPs might already be available. These can be adapted for the specific prevalence survey SOPs. This SOP is linked to the field X-ray reading SOPs
5.2 SOP Laboratory procedures for regional/central level

5.2.1. Purpose

This SOP provides an overview of the procedures that take place during the laboratory tests including smear microscopy, sputum culture and drug susceptibility testing which take place at regional or central level. Depending on the country, smear reading might take place in the field (see 4.5)

5.2.2 Definitions

Provide definitions, for example, for acid fast bacilli positive smear, culture positive pulmonary TB, smear positive pulmonary TB, bacteriological confirmed pulmonary TB, multidrug resistance TB, extensively drug resistance TB.

5.2.3 Abbreviations

List all abbreviations used in this SOP, e.g. DST = Drug susceptibility testing

5.2.4 Scope

This SOP is relevant for the central laboratory team, the survey coordinator and

5.2.5 Roles and responsibilities

• Describe the roles and responsibilities of the laboratory team members at regional/central laboratory level.
• Describe the responsibilities of other staff involved in aspects related to laboratory issues, i.e. sputum transportation

5.2.6 Materials

List equipment and materials required for the procedures outlined in this SOP, e.g. reagent preparation, microscopy, sputum culture, and drug susceptibility testing

5.2.7 Procedures

• Describe aim and objectives of sputum microscopy, sputum culture, culture identification and drug susceptibility testing
• Describe sputum specimen receipt at the district/central laboratory:
  o Registration of sputum samples received at the laboratory from the field site
  o Procedure for requesting a new sample if the morning specimen has insufficient quality or quantity of sputum
• Describe sputum microscopy:
  o Staining preparation
  o Smearing/ staining techniques
  o Recording and reporting of results, including how to fill out the required forms and registers
  o Quality control of smear microscopy
• Describe sputum culture:
  o Specimen decontamination and culture inoculation
  o Reading of culture results
  o Culture reporting
  o Procedures for identification of TB and mycobacterium other than TB (MOTT)
  o Quality control of sputum culture
• Drug susceptibility testing (DST)
  o Steps and procedures for conducting DST
  o Reporting of DST results
  o Quality control of DST
• Quality control
  o Describe quality assurance and monitoring both of the field site as well as the procedures performed at the regional/central laboratory including EQA by supra national reference laboratory
• Describe how positive results will be reported, e.g. format, who is responsible for reporting, to whom will results be reported and what is the time frame
• Data management
  o Specify in which register the data are entered
  o List the information that will be recorded by the laboratory team
  o Describe how the data flow from the laboratory to the data management unit will be and where the data will be entered and by whom
• Describe how problems related to laboratory procedures will be solved using “What if scenario’s?”, e.g. what if the culture is contaminated, what if the sample is lost, what if not all samples are received.

5.2.8 Forms and registers
List all registers/forms relevant for this SOP. e.g. form for sputum examination, laboratory results reporting forms, transport forms etc.

5.2.9 Other SOPs
For some steps for which SOPS need to be developed, SOPs might already be present in the laboratory SOPs, e.g. culture, DST etc. These SOPs can be adapted for the specific prevalence survey SOPs.
6. SOP Case notification and management

6.1. Purpose
This SOP provides an overview of the procedures related to case notification and management throughout the survey, depending on where smear and culture is being done results come from different places and at different times.

6.2 Definitions
Explain terminology used in this SOP, for example, TB case, MDR TB case etc

6.3 Abbreviations
List all abbreviations used in this SOP, e.g. MDR= multi drug resistance

6.4 Scope
This SOP is relevant for the central laboratory team, the survey coordinator and

6.5 Roles and responsibilities
• Describe the roles and responsibilities of the laboratory team members at regional/central laboratory level.
• Describe the responsibilities of other staff involved in aspects related to laboratory issues, i.e. sputum transportation

6.6 Materials
List equipment and materials required for the procedures outlined in this SOP, e.g. reagent preparation, microscopy, sputum culture, and drug susceptibility testing

6.7 Procedures
• Describe aim and objectives of case notification and management
• Outline procedures for case notification from smear results:
  o What are considered cases that require action
  o Describe which action is required for which type of cases
  o When are results notified, to whom and by whom
  o How are cases traced and ensured to receive treatment
• Outline procedures for case notification from culture and DST:
  o What are considered cases that require action
  o Describe which action is required for which type of cases
  o When are results notified, to whom and by whom
  o How are cases traced and ensured to receive adequate treatment
  o How is dealt with MDR cases that have started regular treatment before DST results became available.
• Describe how access to adequate treatment for cases detected during the survey is guaranteed
• Describe procedures for documentation of all cases and their related information, e.g. keeping of a separate case register and ensuring all information is complete for cases

6.8 Forms and registers
List all registers/forms relevant for this SOP. e.g. case register, results form

6.9 Other SOPs
For some steps for which SOPS need to be developed, SOPs might already be present, these SOPs can be adapted for the specific prevalence survey SOPs.
7. SOP Monitoring & Supervision

7.1 Purpose
This SOP provides an overview of the procedures that take place during the preparations and performance of monitoring visits.

7.2 Definitions
Explain terminology used in this SOP where applicable.

7.3 Abbreviations
List all abbreviations used in this SOP.

7.4 Scope
This SOP is relevant for the monitoring team.

7.5 Roles and responsibilities
Describe the roles and responsibilities of the different members of the monitoring team.

7.6 Materials
Describe which materials are needed for the monitoring of the different elements of the survey.

7.7 Procedures
- Describe aim and objectives monitoring.
- Describe frequency and organizing of monitoring missions, different types of monitoring mission as applicable.
  - Describe checklist to be used for monitoring visits and how to fill this list.
  - Describe crosschecks to be performed during monitoring visits.
- Discuss persons involved in and processes for problem solving during and after monitoring visits.
- Describe reporting format for monitoring visit and to whom a report should be made within which time frame.

7.8 Forms and registers:
List all forms/registers relevant for this SOP, e.g. monitoring checklist, monitoring reporting format etc.

7.9 Other SOPs
This SOP is related to all other SOPs as that is what is being monitored.
8. SOP Data management (data management plan)

8.1 Purpose
This SOP provides an overview of the data management procedures during the survey.

8.2 Definitions
Explain terminology used in this SOP for example systematic errors, non-systematic errors, inconsistency error.

8.3 Abbreviations
List abbreviations used in this SOP

8.4 Scope
This SOP is relevant for the central data monitoring coordinator, the field monitoring coordinator and the prevalence survey coordinator.

8.5 Roles and responsibilities
Describe the roles and responsibilities of the data management team.

8.6 Materials
Describe which materials are needed to carry out the activities outlined in this SOP.

8.7 Procedures
• Describe field work procedures for:
  o Sending and receiving data forms and registers (specify which registers and forms, expected number of forms)
  o Checking data for completeness
  o Data transfer from field to data management unit
  o Storage raw data in the field
  o Quality assurance and monitoring
• Describe procedures at central level/data management unit for:
  o Data sorting and filing
  o Data entry (optional (partly) double entry)
  o Data validation/cleaning/duplicate tracing/merge optional  double entries
  o Data cleaning
  o Data merging
  o Data storage and backup
  o Progress analyses
  o Checklist for data validation for statistical analyses
• Describe procedures at central level/data management unit for:
  o Data reporting to the survey coordinator and steering committee, i.e. format and frequency of data reporting
8.8 Forms and registers:
List all forms/registers needed for this SOPs, i.e. needed specifically for data management. All forms are related as those are the ones to be entered.

8.9 Other SOPs
All SOPs related to data collection as well as 9.1 SOP for data analysis
9. SOP data analysis (data analysis plan) and reporting (dissemination plan)

This SOP consists of two main parts
9.1. data analysis plan
9.2. dissemination plan

9.1 SOP data analysis
9.1.1 Purpose
This SOP provides an outline of the anticipated data analysis, also called the data analysis plan

9.1.2 Definitions
Explain terminology used in this SOP for example missing value, model validation etc.

9. 1.3 Abbreviations
List all abbreviations used in this SOP

9. 1.4 Scope
This SOP is relevant for the persons responsible for data analysis

9. 1.5 Roles and responsibilities
Describe the roles and responsibilities of the persons involved in data analysis

9. 1.6 Materials
Describe which materials are needed to carry out the activities outlined in this SOP.

9. 1.7 Procedures
Outline the different steps in the analysis and the procedure to be followed:
• Description and assessment of the completeness and internal consistency of the core data
  o Participation rate, potential bias by gender, age and other characteristics
  o Coverage by chest X-ray and symptom screening
  o Correspondence between field and central reading of chest X-ray
  o Screening results (interview and X-ray)
  o Smear and culture results
  o Estimation of pulmonary TB prevalence including procedures for accounting for clustering/stratification, accounting for missing data, sensitivity analysis
  o Description of analysis of supplementary data and procedures (risk factor studies, socio-economic data, HIV data etc)
  o Comparisons with previous surveys (within country if applicable)

9. 1.8 Forms and registers:
List all forms/registers needed for this SOPs, i.e. table formats.
9.1.9 Other SOPs
8.1 SOP for data management

9.2 SOP dissemination of results

9.2.1 Purpose
This SOP provides an outline of the procedures for writing of the final report and dissemination of the results to the relevant authorities and at all levels.

9.2.2 Definitions
Explain the terminology used in this SOP where needed

9.2.3 Abbreviations
List all abbreviations used in this SOP

9.2.4 Scope
This SOP is relevant for the persons responsible for writing the final survey report and dissemination of the survey results

9.2.5 Roles and responsibilities
Describe the roles and responsibilities of the persons involved in writing of the final survey report and dissemination of the survey results

9.2.6 Materials
Describe which materials are needed to carry out the activities outlined in this SOP.

9.2.7 Procedures
• Outline the procedures for reparation of the final survey report
• Outline the different levels of result dissemination
  o Approval and dissemination of results to the national authorities
  o Dissemination of result to the regional and district level
  o Dissemination of result to the communities that participated in the cluster
  o Dissemination of result to international audience (presentation of result at international fora, publications)

9.2.8 Forms and registers:
List all forms/registers needed for this SOPs, i.e. outline of table of content of final report

9.2.9 Other SOPs
9.1 SOP for data analysis
10. Optional SOPs

Countries may have decided to include HIV testing; tuberculin survey or to conduct interviews with TB patients registered in the TB program or comparison between cases detected in the survey and the TB program. In this chapter we have included a guidance for the following SOPs: HIV testing (9.1); tuberculin survey (9.2) and Program TB patient interview (9.3). However countries may also include SOPs on e.g. security during the course of the survey.

10.1 SOP HIV Testing

10.1.1 Purpose
This SOP provides an overview of the procedures that take place during HIV testing

10.1.2 Definitions
Explain terminology used in this SOP where appropriate, i.e. counseling

10.1.3 Abbreviations
List abbreviations used in this SOP, e.g. VCT= voluntary counseling and testing etc.

10.1.4 Scope
This SOP is relevant for the field team leaders; the HIV counselors performing the HIV testing.

10.1.5 Roles and responsibilities
Describe the roles and responsibilities of those individuals involved with the procedures of the HIV testing.

10.1.6 Materials
Include list of materials required for set up of HIV site and conduct the HIV testing

10.1.7 Procedures
• Describe the purpose of the HIV testing;
• Describe organization of the testing day including procedures for:
  o Preparation of clients who have provided a sputum sample (include greeting of clients and processes for explanation of procedures);
  o Instructions for counseling of clients
  o Instructions for performing the HIV test
  o Instructions for informing the client of the result notification
  o Instructions for post test counseling for HIV positive clients;
  o Instructions for recording of results
  o Include flow chart of field work including the registers and forms.
  o Include discussion of confidentiality issues.
• Describe procedures for quality assurance and monitoring
  o Instructions for checking if all eligible participants have been approached and tested;
  o Instructions for crosschecking by field team leader;
  o Discussion of ethics related to HIV testing
• Describe ‘what if’ scenario’s
• Report
  o List of contents for final report of HIV testing results

10.1.8 Forms and registers
Include list of all study forms and registers that are needed during the HIV testing.

10.1.9 Other SOPs
If applicable list other SOPs that are associated with current SOP.
10.2 SOP Risk factor study

10.2.1 Purpose
This SOP provides an overview of the procedures for collecting data on risk factors within the prevalence survey. This SOP would be needed if within the general survey a risk factor study is embedded and data collection is not integrated in the standard questionnaires being administered.

10.2.2 Definitions
Describe which individuals are eligible for the risk factor study and how they will be selected.

10.2.3 Abbreviations
List abbreviations if any relevant.

10.2.4 Scope
This SOP is relevant for the team leaders and the interview team and any others involved in the risk factor study.

10.2.5 Responsibilities
Describe the responsibilities of the persons listed above in collecting the risk factor data.

10.2.6 Materials
Describe which materials are needed to collect the risk factor data.

10.2.7 Procedures
• Describe aim and objectives of the risk factor study
• Describe how and when in the survey participants will be selected for the risk factor study
• Describe organization of the interview including procedures for:
  o Selection of client to be interviewed
  o Instructions for filling out the questionnaire
  o Instructions for checking the questionnaire for completeness and consistency
  o Include flow chart of field work including the registers and forms
• Describe procedures for quality assurance and monitoring
  o Instructions for checking if all eligible participants have been approached and interviewed;
  o instructions for checking completeness of the filled questionnaire
  o Instructions for crosschecking of questionnaires by field team leader
• Describe ‘what if’ scenario’s (if selected person refuses, is not available, stops halfway the interview etc)
• Describe data flow of forms for this SOP
10.2.8 Forms and registers:
List all forms/registers relevant for the specific SOP.

10.2.9 Other SOPs
Describe to which other SOPs this SOP is linked, i.e. the SOPs of the process wherein the risk factor data collection is integrated.
10.3 SOP Program TB patient interview

10.3.1 Purpose
This SOP provides an overview of the procedures for interviewing cases detected in the TB program, a side study to the prevalence survey.

10.3.2 Definitions
Include definitions if any relevant e.g. definition TB patient according the program.

10.3.3 Abbreviations
List abbreviations

10.3.4 Scope
This SOP is relevant for the survey coordinator, the field team leaders and the interviewers conducting the survey who may not be part of the fixed prevalence survey team.

10.3.5 Roles and responsibilities
Describe the roles and responsibilities of the interviewer related to the activities that will be involved in interviewing the program TB patients.

10.3.6 Materials
Include detailed list of materials, others than the forms described in 11.3.8 which are needed for the program TB patient interview.

10.3.7 Procedures
- Describe the purpose of the TB patient interview;
- Describe organization of the interview day including procedures for:
  - Selection of client to be interviewed, how to list all eligible persons from the TB register
  - Instructions for filling out the questionnaire
  - Instructions for checking the questionnaire for completeness and consistency
  - Include flow chart of field work including the registers and forms
- Describe procedures for quality assurance and monitoring
  - Instructions for checking if all eligible participants have been approached and interviewed;
  - Instructions for crosschecking by field team leader
- Describe ‘what if’ scenario’s

10.3.8 Forms and registers
Include list of all study forms and registers that are needed during the Program TB patient interview.