

PRACTICAL EXERCISE: REVIEW OF A PROTOCOL FOR A TB PREVALENCE SURVEY

**Checklist for review of protocols compared with Task Force recommendations,
based on the WHO handbook on TB prevalence surveys (The Lime Book)**

Chapter 3 of the handbook provides an overview of the structure/content of a protocol

Country name:

Topic/issue	TF recommendations for a national survey	Protocol consistent?
SURVEY GOAL AND OBJECTIVES (Chapters 1 and 2)		
1. Goal	The goal is to gain a much better understanding of the burden of disease caused by TB and to identify ways in which TB control can be improved.	
2. Objectives	<p>The six major objectives that could be defined are:</p> <ul style="list-style-type: none"> i) To measure the prevalence of bacteriologically confirmed TB among the adult population ii) To identify the extent to which people with TB or those with symptoms suggestive of pulmonary TB have already sought care from health-care providers and, if so, with which types of care provider iii) To identify reasons for lack of contact with services provided by or in collaboration with the NTP, among people with TB or those with symptoms suggestive of pulmonary TB iv) To update all population-based estimates of the burden of disease (measured as TB incidence, prevalence and mortality) using results from the prevalence survey combined with in-depth assessment of surveillance and programmatic data and other survey data v) To assess whether the burden of disease caused by TB has fallen since the last survey vi) To provide a baseline for future measurement of trends in the burden of disease caused by TB 	

SCREENING STRATEGY AND CASE DEFINITIONS (Chapter 4)		
3. Screening strategy	Chest X-ray and screening interview for all, then sputum smear and culture for all TB suspects, with 2 sputum samples per TB suspect.	
4. Case definitions	Case definitions must be clearly stated in the protocol: i) Eligible for sputum examination ii) Smear-positive pulmonary TB patient iii) Culture-positive pulmonary TB patient iv) Bacteriologically confirmed pulmonary TB patient v) Individual with normal/abnormal chest X ray	
SAMPLING DESIGN (chapter 5)		
5. Exclusion criteria	Reasons why parts of the population will be excluded should be explicitly commented on in the protocol. Excluded population should not be more than 5% of the total population Exclusion criteria must be clearly identified for the different stages of the survey: i) Sampling frame: Need to have a good estimate of the population living in excluded areas. ii) Within selected areas: Description of mobile and institutionalized populations iii) Household and Individual level: Description of enrolment procedures for inclusion of seriously sick people, or others who are unable or unwilling to attend the field site or the X-ray examination. Imperative to enumerate all eligible individuals, and classify them as: i) survey participant, ii) absent or iii) no consent	
6. Participation rate in survey in sampled areas	At least 85% of eligible population must be sampled, and the expected % should be identified in the protocol.	
7. Sample size calculation	Use standard formula in Lime Book, justifying choices of values for cluster size, k , the prior guess of the true population prevalence, relative precision.	
8. Relative precision	Should be 20% or maximum 25%.	

9. Stratification in sampling	Stratification should be used to increase sampling representativeness of the overall country and precision of final results (e.g. urban/rural, north/central/south).	
10. Sampling strategy for cluster selection	Should use PPS (probability proportional to size). Need to identify beforehand the reasons why clusters could be excluded after initial selection (e.g. inaccessibility as verified during assessment visit) and how they would be replaced.	
11. Number of clusters	At least 30, but preferably over 50.	
12. Cluster size	Preferably at least 400, maximum 1000.	
13. Age groups to be included in survey	≥15 years old only.	
14. Information on children <u>and</u> those who do not comply with residency definition	Protocol must include identification of the proportion of children and individuals in the population of each cluster who do not comply with the residency criteria.	
INTERVIEWS, RADIOGRAPHY AND BACTERIOLOGY (Chapters 6, 7 and 8)		
15. Interviews on health-seeking behaviour	Must be part of survey.	
16. X-ray equipment and safety	X-ray equipment must comply with the regulations of the national radiation authority and approval from this authority must be obtained. Lead abdominal shield must be provided for women who are or may be pregnant. A restricted area should be set up in every cluster to prevent people other than concerned staff and an examinee from radiation exposure.	
17. Conventional or digital X-ray technologies	Choice should be justified in terms of cost, opportunity to use the equipment after the survey is completed (it is a waste of resources to purchase X-ray equipment that is not suitable for use in routine services once the survey is over), workload (digital is more efficient when the workload is consistently high), field conditions (digital radiography requires good transportation, more power and a more powerful electric generator) and the availability of staff (digital requires less staff).	

INTERVIEWS, RADIOGRAPHY AND BACTERIOLOGY (Chapters 6, 7 and 8)		
18. Laboratory capacity	<p>Protocol must demonstrate that laboratory capacity of sufficient quality (especially for culture) will be available, and that the laboratories used in the survey have at least 6 months experience in using the methods to be used in the survey.</p> <p>Laboratory workload should be estimated in advance of the survey: when the recommended strategy is used, it can be assumed that 10-20% of the survey participants will need to have sputum smears and cultures done.</p>	
19. Number of samples to be collected	At least 2 sputum samples should be collected from every participant: spot and early morning, or two specimens one hour apart on the same day, according to operational considerations.	
20. Sample transportation system	<p>It is often necessary to establish the survey's own transportation system of survey specimens, since most countries do not have a reliable and regular courier system with reverse cold chain (from periphery to central level).</p> <p>The sample transportation system should ideally be piloted from all distant and hard to reach areas</p>	
21. Time from collection of sputum to reaching laboratory for culture	<p>Preferably within 3 days, at most 5 days.</p> <p>Essential to record time and day of sputum collection and start of laboratory processing for all samples.</p>	
22. Methods for culture examinations	Concentrated culture using solid or liquid media; liquid preferred if laboratory staff are familiar with it and it is already common practice.	
23. Informing participants about laboratory results	<p>How to deliver the individual result particularly to those who need further medical intervention such as TB treatment should be defined clearly in the survey protocol and manuals.</p> <p>Protocol must plan which results are to be informed to participants and how to handle situations where the results of smear examinations carried out by the survey team on spot are discrepant with smear or culture results carried out by central laboratories.</p>	
24. DST for confirmed TB cases (see also Appendix on testing for drug resistance)	Optional, not encouraged. Can be done for all confirmed TB cases, especially if DRS data not yet available (to give indication of drug resistance levels), but only if second-line drugs are available for cases identified as being resistant to first-line drugs.	

ETHICS, HIV TESTING AND OTHER INTERVENTIONS, BUDGETING (chapters 10, 11 and 12)		
25. Ethical issues	<p>Must be addressed in protocol with ethical approval then obtained from national bodies and international agencies providing technical assistance Informed consent must be obtained from all participants prior to them taking part in the prevalence survey and answering any questions. <i>See separate Ethical issues checklist</i></p>	
26. HIV testing	<p>Must be offered according to national policy to all confirmed TB cases, with testing provided in routine care services.</p>	
27. Budget	<p>Must be as detailed as possible. Must allow for contingency situations. Must allow for variations in currency exchange rates.</p>	
SURVEY MANAGEMENT, ORGANIZATION, LOGISTICS AND FIELDWORK (chapters 13 and 14)		
28. Piloting of survey	<p>Recommended that pilot survey be performed in both rural and urban areas.</p>	
29. Accuracy of sampling frame	<p>Must be checked during mini-census.</p>	
30. Number of teams	<p>Number of teams that often defined by capacity of culture laboratories. A smaller number of teams increase survey duration and costs, but allows closer supervision and standardization.</p>	
31. Involvement of local government and community	<p>This is essential. Support needed from MoH should be communicated to all relevant authorities at the administrative levels that are involved in the implementation of the survey, such as states, provinces, districts, and local communities. Three occasions should usually be utilized to facilitate cluster-community involvement: Assessment visit, Pre-visit and Cluster operation</p>	
32. Mop-up operations	<p>Mop-up operations should be done to increase participation rate, particularly in urban areas where participation is expected to be low. Essential to allocate enough time to these activities, as well as human and financial resources.</p>	
33. Tuberculin survey	<p>Only when prior data are already available - if so must note this in protocol.</p>	

MONITORING AND QUALITY ASSURANCE (chapters 2, 13, and 14)

34. Monitoring and quality assurance	Essential at every step (e.g. participation rate, completion of field forms, % of individuals eligible for sputum collection, X-ray quality, average time from sputum collection to processing, culture contamination rate). Data monitoring and the completion of monitoring checklists should take place as quickly as possible after data collection and processing in the field.	
35. Indicators and benchmarks	Indicators and benchmarks should be clearly defined in the survey manuals and team leaders and supervisors should be well trained to take action whenever benchmarks are not being met. Examples: i) Data clerks should check the individual form to confirm all necessary areas are completed. If not, the form should be immediately sent to the appropriate section to be completed ii) Survey registry should be daily reviewed by a the team leader to monitor the participation of survey eligible persons. If below 85-90%, mop-up operations have to take place	
36. Supervision	Strong lines of supervision needed throughout the study to ensure a proper implementation of the survey activities. Supervision activities must be properly planned and budgeted.	

DATA MANAGEMENT, ANALYSIS AND REPORTING (chapters 15 and 16)		
37. Staff for data management and analysis	Data manager and statistician should be involved from the beginning, and plan for data management and analysis described in the protocol.	
38. Data entry	Data entry should be a continuous process to prevent large numbers of forms and registers from piling up.	
39. Confidentiality	All survey staff handling data (both on paper and electronically) should respect the confidentiality of the information collected.	
40. Analysis strategy	In analysis, should use missing value imputation to address bias introduced by non-participation, and sensitivity analysis to assess possible impact of non-participation on estimate of TB prevalence. Recommend a cluster-level analysis (simple, and valid) followed by an individual-level analysis. Individual-level analysis should use either or both of robust standard errors to allow for clustering in the study design, and a random-effects logistic model to allow for clustering in both the calculation of confidence intervals and the point estimate of TB prevalence. Individual-level analysis should be conducted with and without multiple imputation of missing data, and both results presented and compared.	
41. Feedback of results to local authorities	Survey results should be reported to local authorities as soon as they become available.	