Second edition of the "Red Book"; rationale, objectives, proposed content, timelines, and major new/updated recommendations

Task Force on TB Impact Measurement
17-18 March 2010

Babis Sismanidis
(overall coordination)
Questions to the Task Force

1. Does the Task Force agree with the need for revision of the Red Book?

2. Does the Task Force agree with the proposed outline for the second edition to the Red Book?
Overview of presentation

• Rationale for revision

• Objectives of second edition

• Proposed outline & authors

• Timelines

• Major new and updated recommendations
  (after March 16th meeting)
What is the Red Book?

"A publication providing practical guidelines to countries planning population-based surveys to estimate the prevalence of TB disease at a national level"
Rationale for revision

• Countries seeking stronger/clearer recommendations including more practical advice in several topics

• Some chapters need improvement, others need update

• A few NEW topics need to be included

• Platform for sharing valuable lessons learned during recent survey implementation
Objectives of second edition

• Add NEW recommendations, such as on:
  – Collect data to understand how cases are missed
  – Repeat surveys
  – Other types of surveys (sub-national or 'special' populations)

• UPDATE existing recommendations and add practical advice, such as on:
  – Screening
  – Laboratory methods
  – X-ray technologies
  – Analysis

• Showcase recent nationwide prevalence surveys
  – Include examples to illustrate recommendations in practice in every chapter
36 authors from 12 institutions

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Overall structure & content

The book will be structured in four parts:

- Part I. Introduction and rationale
- Part II. Design & methods
- Part III. Management, organization, logistics & field work
- Part IV. Analysis, reporting & dissemination of results
Part I. Introduction and rationale

• Chapter 1. Introduction
• Chapter 2. Why are surveys important?
• Chapter 3. Learning from the past
Part II. Design and methods

- Chapter 4. Survey objectives & indicators
- Chapter 5. Screening strategies
- Chapter 6. Sampling design
- Chapter 7. Interviews
- Chapter 8. Chest X-rays
- Chapter 9. Bacteriology
- Chapter 10. Repeat surveys
- Chapter 11. Ethical considerations
- Chapter 12. Medical services to be offered in the context of a survey
- Chapter 13. Protocol development
- Chapter 14. Budgeting and funding
Part III. Management, organization, logistics & field work

• Chapter 15. Survey organization and preparation
• Chapter 16. Field operations
• Chapter 17. Quality assurance of overall survey
• Chapter 18. Data management
Part IV. Analysis, reporting & dissemination

• Chapter 19. Analysis, reporting and dissemination of results

Appendix I. Suggested supplementary data to be collected:
  – Socio-economic status
  – Risk factors and co-morbidity
Timelines (2010)

- Invitation of authors and start-up meeting
- Preparation of outline
- Version 1 production cycle
- All to revise and 2nd author meeting
- Version 2 production cycle
- Peer review
- Editing and production
- Publishing cycle; launch 11 November
New recommendations
Survey objective; data on why cases are missed

• Collect data (typically referred to as "health seeking behaviour") from all suspects at the time of screening in order to understand why cases are missed by the NTPs

• Add a recommended list of minimum questions on this (indicators to be defined)

• These data will not necessarily inform health systems failure discussion
Repeat surveys

• Include clear guidance on when a repeat survey is appropriate

• Include guidance for countries who would like to do repeat surveys

• Include a caution that impact of TB control is slow (allow at least 5 years between surveys) and its magnitude moderate (large sample size required)

• Both new and old technologies should be used to allow for comparisons, where possible

• The task force will consider meta-analysis or pooled data analysis to estimate the regional or global trend from quality country surveys
Other than national surveys

- In settings where nationwide prevalence surveys are not appropriate/possible, consider other types of surveys (such as sub-national or 'special' populations).

- Include guidance on when sub-national surveys could be useful (security concerns, e.g. Pakistan).

- 'Special' (e.g. prisons, nomads, refugee camps) populations are often excluded from national surveys. Clarify such surveys are a programmatic activity and beyond the scope of the Red Book.
Updated recommendations
Survey objectives & indicators

• Recommend prevalence of bacteriologically confirmed (either S+ or C+) as the primary outcome
  – Also maintain S+ as a co-primary outcome, since sample size calculations so far were done based on this
  – Sample size calculations based on S+ are sufficient for the revised primary outcome because $S+ < (S+ \text{ or } C+)$

• Leave the decision to countries for using as secondary outcomes:
  – Prevalence of healed TB (based on chest X-ray)
  – Prevalence of X-ray suggestive of TB
Screening strategies

• Current recommendation for definition of a TB suspect is based on chest X-ray and symptoms screening (strategy 3)

• Is the current symptom screening algorithm adequate in settings where HIV burden is high?
  – Need to review literature, and existing prevalence survey data, on sensitivity and specificity of symptom screening algorithms, stratified by HIV status
  – Pilot test different algorithms in the first African countries to implement a survey

• Current strategy 4, sputum microscopy (without culture) for all, to be dropped

• Adopt the new screening policy with two smears (instead of three) from everyone identified as a TB suspect (one morning)
Laboratory methods

• 2 spot without morning?
  – No, keep the morning sputum (add incentive pending ethical approval)

• Microscopy at local or referral (established culture) laboratory?
  – At least one specimen (morning) per suspect both for microscopy and culture at referral lab

• Is one culture enough for culture positive definition?
  – At least one

• Can liquid-based culture method be used instead of solid media?
  – Not instead, if used then it must be combined with solid

• How many days recommendable from collection to inoculation?
  – Ideally $\leq 3$, no more than 5 (when in cold chain)

• Do not use CPC, unless exceptionally for very remote areas.
Eligibility criteria for survey participants (1)

• Eligible=15+ years and all 'resident' in the house (2-4 weeks)

• Recommend a full census of the household members by the survey team

• Prepared enumeration lists (e.g. by village chiefs) are possible only in countries with vital registration system or regular update of population by local authorities
  – Although most countries in Asia have local population/household registration that can be utilized for pre-survey census to define survey sampling area in a cluster village/ward, it may not be applicable in most African settings
Eligibility criteria for survey participants (2)

- Define clearly and list in the protocol, by item, the inclusion/exclusion criteria (**eligibility** and **consent** are not such criteria and must be distinguished)

- Include mobile populations as much as possible
Chest X-ray; screening definitions

- **Normal CXR** - A normal chest X-ray means clear lung fields and no abnormality detected

- **Abnormal CXR** - An abnormal chest X-ray means any lung abnormality detected on interpretation by the medical officer (e.g. opacities, cavitation, fibrosis, pleural effusion, calcification, any unexplained or suspicious shadow, etc.). Bony abnormalities like fractures are excluded by definition as are findings like increased heart size
Chest X-ray; digital or not?

• Base your decision according to these parameters:
  – funding
  – average workload
  – manpower availability and cost
  – accessibility (portable or mountable)
  – infrastructure in the country (e.g. electricity, water)
  – long term use
  – compatibility with existing imaging infrastructure (what happens to these after the survey?) &
  – availability of maintenance service

• Standardised training protocol, training material

• QA protocol for X-ray quality and interpretation
Definitions of TB case & suspect

• TB case (*no consensus reached)*:
  – Definition to be based on bacteriology
  – List the various scenarios, revise current evidence and make recommendation. Other authors will have a chance to review at a later stage

• TB suspects:
  – Definition to be based **only** on CXR and symptoms (not TB on current treatment, with treatment history, or TB contact)
  – Those with abnormal CXR
  – Those with chronic cough (according to national policy)
  – Test symptoms algorithm in HIV high burden settings
Add-on studies

- Consider add-on studies in relation to specific data needs in the country, and highlight that other data sources may be more suitable to fill data gaps

- Do not promote add-on studies if the primary objective of the survey is threatened

- Indicate the usefulness of these studies, but also place them into context

- Country experience shows these are feasible when adequate manpower and time/budget are provided

- Include guidance on add-on studies as an appendix or supplement documents in web site

- Add case-control study design/discussion
How does this revision affect soon-to-start surveys?

• Revision should not be contradicting with existing recommendations, unless absolutely necessary

• The revision is a response to country requests

• Practical advice and stronger recommendations will make guidelines more user-friendly

• Clear guidance to be given on adapted issues for countries currently preparing for surveys

• Revisions should be incorporated by technical agencies wherever feasible?
Surprise question to the Task Force!

Should the second edition of the Red Book remain red?

...or should it become blue, green or yellow?