Subgroup Report
Prevalence Survey

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WHO/HQ/HTM/STB/TBS
Role of sub-group

- Facilitate planning, implementation and reporting of National TB surveys in the 21 priority countries designated by the TF (Impact measurement & Re-estimation)
- Standardize the survey methods and reporting (at least to enable inter-survey comparison)
- Mobilize funding for the survey and TA
- Providing Technical advise/guidance to other countries (Survey for re-estimation)
21 priority countries

- **AFRO(12):** Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, Rwanda, Sierra Leone, South Africa, Tanzania, Uganda, Zambia
- **EMRO(1):** Pakistan
- **SEARO(4):** Bangladesh, Indonesia, Myanmar, Thailand
- **WPRO(4):** Cambodia, China, Philippines, Viet Nam
- Information collection from country and regional STB staff, TA partners and different units of WHO
- Preparatory Workshops
- Other meetings (Viet Nam Workshop, TSRU, GF WS ---)
- E-mail communication
- TA visits
Group 1-1
Experienced national survey after 1990

- China(1990, 2000): Planned in 2010
- Indonesia(2004): 2014?
- Philippines(1997, 2007): Finalization of data analysis
- Viet Nam(2007): Preliminary result discussion in March 2008. will report soon

(Note: Though Thailand carried out the national survey in early 1990s, it was moved to the group 2)
Group 1-2
about to start as of the end of 2007

• Bangladesh (2008-09): Sputum from all; A little behind the schedule; will complete in 1\textsuperscript{st} semester of 2009

• Tanzania: Delay due to the \textit{procurement} problem
Group 2-1
already planned or intending to plan

• Mali: Protocol drafted (Mission in Dec ’07), Requesting TA for Lab
1st WS in March 2008
• Malawi: GF-R7 not signed yet
• Nigeria: SOP drafted, Procurement begun
• Pakistan: TBCAP (KNCV, RIT/JATA, Union & WHO) support confirmed
• Uganda: Requesting TA for finalization of the protocol, GF-R6 not yet mobilized
Group 2-2
already planned or intending to plan

2nd WS in August 2008

- Kenya: Experience of sub-national survey. GF-R8 Applied
- South Africa: Financial constraints due to demands for stratification. Need in-country coordination
- Thailand(2011): Re-designing with lessons from uncompleted survey in 2006. GF-R8 applied
- Zambia: Apply to R9
Group 3
Not yet planned

- Mozambique
- Sierra Leone

Assessment mission
Collaboration/Contract with 3rd party
Objectives

Primary objective of the TB disease prevalence survey is:
To determine the prevalence of pulmonary TB at a defined point in time in a specified country:
   (symptoms suggestive of TB)
   smear positive pulmonary TB
   culture positive pulmonary TB
   (radiological abnormalities suggestive of pulmonary TB)

And that of a series of surveys is:
To assess trends in TB prevalence
However, a carefully designed survey can tell you lots more

- Health seeking behaviour of TB patients and individuals reporting chest symptoms
- Utility of private sector such as proportion TB patients under treatment in private sector
- Where missing cases are, and who they are
- TB Risk factors
- Drug resistance in prevalent cases in community
- Relation between ARI and Disease Prevalence
However

- TB survey needs time and labour intensive works
- It needs numbers of clinical staff such as a physician to screen CXR, radiographers and a lab technician
- Most decisive factor to limit number of survey participants per day is often a clinical examination capacity including interviews and CXR
- Adding other components may require not only additional staff but also additional days to stay in a cluster village, and it may affect a whole survey schedule and human resource management.
Challenges from STAG

- Why not piggybacked on other survey
- Why not survey in children
- Why not HIV counseling and testing to every participant

- Why not DST
  - We will discuss them later
Preparatory Workshop

10-14 March & 25-29 August

• To develop a proposal and/or a draft protocol of National TB prevalence survey

• To understand the nature of the survey from country experiences
  – Objectives, Screening methods, Sampling, Ethics, Organization, Operation, Data management, Budgeting and Financing ----
  – Cycle of “Lecture-Discussion-Group Work-Presentation-Peer and Expert review”

• (To develop consensus among TA partners)
Preparatory Workshops

- Countries could develop outlines of the survey protocol
- Countries could identify possible in-country and international partners
- Countries could make a draft budget and consulted with GF staff
- Countries could learn other country's experiences to indentify possible constraints
Budgeting

Estimated budget: 0.6M in Myanmar to 2M+ in AFRO countries

Increasing compared with previous studies

Expensive Human Resources Salary

Larger sample size for more accurate estimation for future comparison

Screening and Diagnostic equipment
digital X-ray, culture

Other study components
Financing

• Very close communication with the GF
  – Consultation session in the WS
  – Prevalence survey in ME toolkit
  – Follow up activities/ Briefing to TP members

• Mobilization of other funds and bi-lateral
  – B&M Gates, TBCAP, USAID, JICA

• Partnership/Cost sharing
Constraints (1)

• Financing and Budgeting: GF: Influenced by other factors. Not independent budget (cf. fund for research and study)

• Procurement
  – Timeline
  – Specification

• Country rules and regulations
  – Transportation of Medical samples
  – X-ray outside hospital compound
  – Automobiles
Constraints(2)

• Lab
  – Culture
  – Transportation (cf. direct inoculation)

• Human Resources

• Data management
  – Pressure to have more study items
  – Often assisted by voluntary contributions of KNCV and RIT

• Technical assistance
Informal meeting during the 2\textsuperscript{nd} WS

- STAG Report and Responses to its questions
- Situations of 21 priority countries
- Review of WPRO’s handbook/Technical issues
- Future support from TA partners (CDC, KNCV, RIT, UNION and WHO) to countries
- Shall we develop a generic protocol?
- Role of academic institutes and their involvement
- Advocacy
Field operations: Basic steps

• Census to confirm eligible study subjects
• Individual interviews to get consent, to get basic demographic information and to screen for further examinations (Must: health conditions including TB related symptoms, TB treatment past history and current medical interventions if any, pregnancy and its term; Optional: behaviour to symptoms, risks)
• CXR (take any abnormality except some defined condition as positive, not only active TB suspects or TB suggestive)
• Sputum collection from those "positively" screened by interview and/or X ray (for smear and culture)
• Further interview to TB suspects (optional)
• Post survey structured interview to identified TB cases when treatment is arranged (optional, but strongly recommended) and program based HIV counselling and testing
Technical issues

• Sample size
• Sampling design
  – Purpose of Stratification
• Screening strategy
• Data management
  – Standard Format
  – Detected case file
• Case definition
  – New case, known case, on treatment
Sample size

- Design a single survey with a certain accuracy rather than design two surveys with 5 year interval at once
  - Uncertainty of real prevalence
  - Limitation by Funding cycle (max 5y)

Relative Precision: 20% (max. 25%)
Design effect: consider theoretical figures (1.25-1.5)
Participation rate: >85%

- Design the 2\textsuperscript{nd} survey with the 1\textsuperscript{st} survey result
Should be one national survey?

• Seek only a nationwide prevalence principally

• However, it might be possible to have a few geographical strata in a large country (small countries may have more budget constraints)

• Feasible if less precise stratum-wise prevalence is acceptable (nationwide with a relative precision of 20%, two or three strata with 30%)

• Funding?: GF may not allow increase of budget due to stratification
Eligibility

• Inclusion/Exclusion criteria
  – Age: 10y old or more
  – Concern with migrated population (cf. registered residents)
  – Known patients on treatment (should be included in the survey to evaluate current status)
  – Overnight stay in a previous night of the survey
  • Intentional migration/invitation of sick relatives
Definition of TB case

- Stricter than new international definition
- Allow country's program based specific definitions with a breakdown report

May omit from the cases

- Single positive slide without any other supportive evidence such as mycobacterium tuberculosis isolates by culture or CXR finding consistent with TB disease
- Significant growth of MOTT by culture
- Smear negative/ Culture less than 20 (5) colonies without any other supportive evidence
Among TB cases

Confusion by “New” (Sum of never treated, currently on treatment for less than a month and previously treated for less than a month)

- Never treated (possibly include known cases who were detected previously but never treated previously)
- On 1st treatment
- Previously treated, not treated currently
- On Retreatment (very difficult to have breakdown)
Screening and diagnostic methods

• Screening: Take sputum specimens from those either positive in Interview or X ray

• Bacteriological examinations
  – Smear on spot for immediate case management is an understandable option in some settings
  – Fluorescence MS result is acceptable without confirming by ZN
  – Recapping of sputum container after smearing to transport to central lab for culture should be avoided (at least one untouched specimen for central exam)
  – There should be 3 layers (sputum container, individual package to stop further leaking and box) for transportation
  – Consider to use Direct Inoculation Method with Kudoh media

• Diagnosis: culture and identification are essential
Sputum from all

• Sputum from all for smear
  – Not recommended, however, it is an acceptable option, the last resort, in resource poor settings (or constraint with CXR) at least with culture confirmation of S+

• Sputum from all for culture
  – Possible only in research settings?
  – Transportation of high volume samples
  – Confirmation of S-C+ cases (can we diagnose only by culture?)

Common constraints:

• Low positive predictive value
• Quality of sputum specimen (collection without knowing who are real suspects)
• Workload
CXR

– Portable unit:
  • CXR in open space requires to check country's regulation

– Digital technology
  • Manufacturers show interests, but they are reluctant to guarantee its field use with bumpy road

– Radiological safety:
  • X ray in open space
  • Pregnant

– Screening reading: sample films, training

– Quality assurance: New handbook is available (TBCAP)

Need to develop some instruction documents/materials on CXR (for procurement, training)

delay of the recruitment of a radiologist in WHO → APW?
Studies beyond TB disease prevalence

Tuberculin survey
   – Not recommended to do with a disease prevalence survey

Additional Studies (discuss separately)
• Combination with other basic health surveys
   – Nutrition, COPD, Malaria ----
• Risk factors
   – Tobacco
   – Malnutrition: BME from BW & height?
   – HIV
• Socio-economic factors

How can we simplify?: “Proposed questionnaires are longer than TB questionnaires”

Ethical issues: “Don’t examine what we can’t intervene.”
Surveys other than 21 priority countries

• Provide technical guidance to design a single survey to know TB epidemiological situation more precisely

• Discuss necessity and feasibility
  – Survey in lower prevalence countries (EMRO)
Advocacy

• Funding for survey
• Funding for TA
Next step

• Draft answers to FAQs (will be circulated to the members)
• Develop mailing list (and hopefully web-site)
• Technical assistance plan and coordination: the sub-task force as a platform Sub-group meeting early next year: review draft protocols from countries; and consensus on some technical issues
• Develop procurement guide and training material
• Short training courses (CXR –portable and Lab – Kudoh media) if needed
• Workshop with Asian countries: Survey results and future plan (not yet funded)
Procurement

• Some innovative approach seems to be essential to secure procurement of proper items in time.

For example:
X-ray cars with WHO logo for multi-country use
Thank you
Adding other surveys to TB survey

• As TB is "rare" disease, a large sample size is necessary. It is theoretically possible to add other (disease) surveys to TB survey if additional resource is provided appropriately.

• However, additional components must not risk TB survey's quality especially in participation rate. (When HIV testing or blood collection is required, taking independent consent may be recommended)

• TB program must not be very ambitious to carry out additional components without sharing work with other program and academic institutes to support the survey.

• While adding TB survey to other survey is usually extremely difficult not only because TB survey requires a larger sample size but also because the technical and logistic requirements of TB survey is much more complicated.
HIV test for all study participants

- This needs a huge resources to provide pre and post test counseling (and follow up including treatment). They are beyond the capacity of the NTP.
- It is not necessary to have a large sample as TB survey to determine HIV prevalence in a country.
- It risks TB survey itself to have lower participation rates especially from higher risk groups.
- A study should be followed by a service. However, differences between a study, a prevalence survey, and a service, a mobile clinic, should be recognized.
- Detected TB cases should be involved in routine TB/HIV collaborative activities including HIV counseling and testing.
Why children are excluded from a disease prevalence survey

• Screening procedure is not established in Children: individual interpretation of tuberculin test is also difficult
• Interpretation of Chest X ray is difficult and radiological exposure to healthy children also requires ethical consensus
• Similar concern with IGRA that needs veno-puncture
• Even when TB is suspected, as bacteriological positive cases by sputum is very rare in children, invasive examinations such as gastric juice collection and aspiration biopsy are often required to confirm cases (that cannot be done within survey activities)
• Sick children in survey cluster should be properly advised to take further medical interventions
• Availability of new diagnostic tool such as urine screening may make survey in children feasible in future