WHO Strategic and Technical Advisory Group on TB (STAG-TB) meeting, June 2008:

Queries/comments from STAG members following presentation of Task Force work and related background document (draft Policy Paper), and related responses and suggestions

A. Prevalence of TB disease surveys

1. Why is India not in the list of 21 countries to be surveyed?
   The routine recording and reporting of TB data in India is now very good and their new smear-positive case detection rate is currently estimated to be 64%. For this reason, India did not meet the epidemiological criteria used by the Task Force to identify countries that are suitable candidates for implementing a survey of the prevalence of TB disease. The criteria that we used are shown in Table 6 of the Policy Paper on p22.

   Before the Task Force meeting in December 2007 India had already developed a plan for measuring trends in TB incidence and prevalence and this plan has been approved by a Government of India expert committee. They intend to carry out sub-national surveys of the prevalence of TB disease in 7 districts. ARI surveys have recently been carried out in four defined regions covering the whole country. They intend to calibrate the ARI data against the measured prevalence of TB disease in the Model DOTS Project in South India in order to make a national estimate of the prevalence of disease (see p.25 of the Policy Paper).

2. Children, HIV+ people and extrapulmonary cases will be missed if surveys rely only on smears

   Children are not included in prevalence of TB disease surveys. It would be ethically unacceptable to examine healthy children with the currently available, highly invasive, diagnostic methods which involve venepuncture, radiation and gastric tubing. The epidemiological burden of TB in children is best measured by improving surveillance, and tracing children who have been in contact with infectious adults.

   Similar arguments apply to the diagnosis of extra-pulmonary TB. This would also require invasive diagnostic methods and would be very difficult to apply in a population survey of around 100 000 people. The WHO guidelines on disease prevalence surveys do not recommend the inclusion of extrapulmonary TB (Assessing TB prevalence through population-based surveys Western Pacific Regional Office, World Health Organization; 2007).

   It is, however, the case that culture and smear are recommended for everyone who is suspected of having TB in a clinical setting (Policy Paper page 23 point 1) where the intention is to diagnose or rule out TB in a particular patient who is likely to have TB.
In the case of people with HIV this is strongly recommended to ensure that HIV-positive TB suspects are not overlooked.

**Proposed revisions to policy paper**

We will provide additional text in section 7 of the Policy Paper to clarify the reasons why children should not be included in prevalence of disease surveys. We will include a discussion of the alternative methods that can be used to determine the epidemiological burden of TB in children (see new Box 5 on p19).

The policy paper already mentions the reasons for not including extrapulmonary TB in prevalence of disease surveys but we will add text to explain this in more detail (see also Box 5, p19).

The text in Box 5, which was added to the Policy Paper post-STAG to addresses these points reads:

"1. **Extrapulmonary cases**. Typically, surveys do not look for or identify extrapulmonary cases. The diagnostic methods needed to diagnose such cases are invasive and it would be difficult to apply them in the context of a population survey. For this reason, investigations to diagnose extrapulmonary TB are not recommended in the WHO guidelines on surveys of the prevalence of TB disease.

2. **Children**. Typically, surveys do not try to identify TB cases among children. This is because the current technology used for screening is too invasive (e.g. venepuncture, radiation and gastric tubing) for use in healthy children. Alternative ways to measure the epidemiological burden of TB in children are to strengthen surveillance and to conduct systematic contact tracing. To measure the number of TB cases in children in population-based surveys, better diagnostic tools are needed.

4. **HIV-positive cases**. The recommended screening strategy includes culture examinations, so culture-positive (but smear-negative) TB among HIV-positive individuals will be diagnosed."

3. **Including DST**

Including DST in prevalence surveys is not explicitly addressed in the current draft of the policy paper but is addressed in Annex 11 of the guidelines on disease prevalence surveys *(Assessing TB prevalence through population-based surveys* Western Pacific Regional Office, World Health Organization; 2008). While it is technically feasible to carry out DST for TB cases identified in prevalence surveys the number of cases of TB that are found in such surveys are typically of the order of 100 to 300 and one would only identify about 20 to 60 cases of drug-resistant TB in the whole country, at best. A much cheaper, more effective, more precise and more useful way of measuring drug resistance is to carry out a survey of drug resistance among TB patients following the standard guidelines. *(Anti-tuberculosis drug resistance in the world: Fourth Global Report.* Geneva: World Health Organization; 2008.) If no data are available at all, countries could consider testing culture-positive TB patients for drug resistance to obtain an initial indication of the scale of the problem and to decide if a proper survey is needed.
Proposal

Text will be added to the Policy Paper to cover the role of DST in surveys of the prevalence of disease (now point 7, p24-25). Since this matter was not discussed at the December 2007 Task Force meeting, the Task Force will discuss this topic at the next meeting in September. The additional text drafted post-STAG currently reads:

"Positive cultures from a survey of the prevalence of TB disease should be tested for drug susceptibility, provided that patients who are found to have drug resistance will be able to access appropriate treatment. Including DST in a survey of the prevalence of TB disease is especially relevant for countries that have not yet implemented a representative drug resistance survey. However, it should not be a substitute for conducting such a survey. The overall number of drug-resistant cases found in a disease prevalence survey (which typically identifies a total of around 100–300 TB cases) is likely to be too small to provide precise estimates of the prevalence of drug-resistant TB (although the data will help to calculate the sample size needed for a drug resistance survey and may provide an initial estimate of the prevalence of drug resistance). Further discussion of DST in the context of surveys of the prevalence of TB disease is provided in Annex 11 of the WHO guidelines."

4. Socio-economic status (poverty)

The question of whether or not to collect data on the socio-economic status of survey participants was explicitly considered by the Task Force in its December 2007 meeting. The recommendation was that such data could be collected, provided that it would not compromise the main purpose of the survey which is to estimate the prevalence of TB disease in the community. The concern with collection of such data is that it makes interviews with sampled individuals more time-consuming. Recommendations about collection of additional data (e.g. on risk factors, health seeking behaviour) are provided in the Policy Paper. The analysis of the data from the recent prevalence survey conducted in the Philippines will be of particular interest since they collected data on socio-economic status and a range of possible risk factors for TB. The experience gained in that survey will help to inform the TB community of any problems and addition burden that arises from collecting such data as part of a prevalence survey as well as giving an indication of the usefulness of the analysis and the conclusions that are obtained from the additional information.

Proposal

We will revise the text on page 24 of the Policy Paper to explain the recommendation made by the Task Force about the collection of socio-economic and other data in more detail. When the analysis of the Philippines prevalence survey has been completed, including the analysis of the additional data that were collected on risk factors, the Task Force will consider the implications of this for other surveys.

The revised text now reads (points 5 and 6 page 24):

"Collection of data on health-seeking behaviour. Questions about health-seeking behaviour and the extent to which identified cases had already had contact with health services are strongly recommended. Results can be used to assess how many cases have not had contact with health services, the number that had not been diagnosed despite visiting health services, and the number of cases that had not been notified due to health-care providers not being linked to the NTP. Such findings will help to identify the fraction of cases likely to be included in notification data, reasons for lack of
access to TB care and the absence of notification, and to develop interventions that will accelerate progress in TB control (see also section 6.3.3). Recent examples of surveys that have included the collection of such data are those undertaken in the Philippines and Myanmar.

AND

"Collection of data on socio-economic status and risk factors for TB. The collection of data on socio-economic status and risk factors for TB should be carefully considered. It is essential that the time and effort required to collect such data do not compromise the quality of the basic survey data. Recent experience from a survey of the prevalence of TB disease in the Philippines will help to inform decisions about whether or not similar information should be collected in future surveys."

5. HIV testing

This issue is discussed in the Policy Paper (page 23-24) which advises against testing all participants but advises that all those diagnosed with TB should be offered HIV testing according to national policy and practice. The text reads:

"HIV testing. All TB cases identified in a survey should be offered HIV testing according to national policy and standard practice. In general, however, HIV testing should not be undertaken for all of the sampled population. Reasons include: (i) providing HIV screening for all of the sampled population is logistically difficult; (ii) obtaining informed consent from all participants may reduce the percentage of people willing to participate in the survey; and (iii) it may be difficult to ensure that results are provided to all those who are tested."

This recommendation was based on an in-depth discussion of this issue at the December 2007 meeting of the Task Force.

Proposal

Given the importance of this issue and changes in national policy guidelines for HIV testing, the Task Force will be asked to reconsider this issue during the September 2008 meeting.

6. Piggy-backing/synergies with other on-going surveys and/or surveying other diseases during a TB prevalence survey

The issue of using existing population-based surveys and survey platforms for TB prevalence surveys is discussed in the Policy Paper.

Proposal

We will revise the text in the Policy Paper to discuss in more detail the issues that arise in combining TB prevalence surveys with other surveys. The text now reads:
"Adding surveys of the prevalence of TB disease to other surveys is difficult if not impossible. This is because surveys for other diseases are usually designed to estimate the prevalence of diseases and conditions for which the prevalence is much higher than the prevalence of TB. This means that the size of the population studied (required sample size) is much smaller than the 100 000 to 200 000 people who need to be included in a survey of the prevalence of TB disease. Adding a TB-prevalence component to an existing Demographic and Health Survey (DHS), for example, would overwhelm the DHS. In addition, TB surveys depend on mobile X-rays, radiographers to read the X-rays, facilities for collecting and transporting sputa, and laboratories to process the samples; in contrast most surveys depend mainly (or only) on the results of questionnaires. It is therefore more likely that surveys of other diseases and health conditions would be added to surveys of the prevalence of TB disease, rather than vice versa."

And point 4 page 24 reads:

"Combining surveys of the prevalence of TB disease with surveys for other diseases. It is difficult if not impossible to add surveys of the prevalence of TB disease to other surveys or survey platforms (see Box 5). It is more feasible to add surveys of other diseases to surveys of the prevalence of TB disease. However, while adding other surveys to surveys of the prevalence of TB disease allows collection of additional data, the disadvantage is that it will increase the time required for interviews as well as the overall complexity of the survey (e.g. training needs, logistics and analysis). The diseases and conditions that it is most suitable to survey in combination with TB have the following characteristics: (i) they occur mostly in the adult population (≥15 years); (ii) the prevalence is higher than the prevalence of TB; (iii) screening methods do not diverge, or diverge only marginally, from those used for TB; and (iv) they help with the differential diagnosis of TB e.g. chronic respiratory diseases. Collection of data beyond that needed for the survey of TB prevalence should only be attempted if it will not compromise the quality of the basic TB survey data."

B. Other issues

1. MDR monitoring and evaluation should be included in the work of the Task Force

This is currently under discussion within the Stop TB Department and can be discussed at the next Task Force meeting in September. A meeting on MDR surveillance is being held the week immediately prior to the next Task Force meeting. The recommendations from the MDR meeting will be reported to the Task Force and this will offer a good opportunity to discuss the integration of work on MDR with that of the Task Force on TB Impact Measurement.

2. No "HIV expert" in the Task Force

We invited the HIV department to send a suitable person to both of the Task Force meetings that have been held to date. We will continue to invite the HIV department to send a representative and we may consider inviting a representative from UNAIDS to future meetings.
3. Can a target be established for the year by which countries should have surveillance systems that meet the standards required for their TB surveillance data to be certified?

This can be discussed during the September Task Force meeting, which will focus on the use/analysis of routine surveillance data including the role of certification.

4. Integration of TB recording/reporting with general health information systems

This will depend on the current status of the general health information system, which will vary by country.

Proposal

We will expand the text in the Policy Paper (section 6.3.1 on routine surveillance), to discuss this issue in more detail. The additional text now reads:

"Case-based national TB information systems allow much more precise analysis of TB data than is possible with aggregated data that are compiled on a quarterly basis. For this reason, countries should develop case-based recording and reporting systems using flexible computer solutions. Ideally, these systems should be web-based to allow remote data entry and real-time data management and reporting. They should also be designed with flexibility and safety in mind, so that systems can be readily adapted when information needs change. If general health information systems provide an adequate platform for case-based reporting of TB cases (reports are timely, reliable and complete), then for improved efficiency countries are encouraged to integrate case-based TB reporting into general health information systems."

5. How can TB programmes contribute to the development of vital registration?

The policy paper states that measuring TB mortality will be improved if vital registration systems are strengthened. TB programmes cannot develop vital registration systems, the Policy Paper contains the following policy and recommendation (page 28):

"Policy 1. WHO will promote the strengthening of vital registration (VR) systems in all countries, as part of more general efforts to improve health information systems. Where reliable VR systems are not yet in place, the use of sample vital registration will be encouraged.

Recommendation 1. The best way to measure deaths from TB is through a national vital registration system in which causes of death are coded using the ICD-10 system. All countries should strengthen their vital registration systems so that TB deaths, as well as other causes of death, can be reliably measured."

6. It is important to use and analyse sub-national data as well as national data

The importance of using and analysing sub-national data is discussed the Policy Paper (Section 6).

7. Case detection rates estimated nationally should not be applied sub-nationally

We will add text to the Policy Paper to make this clear.