Background document 3.B

National TB prevalence surveys:

Progress on recommendations from the April 2016 Task Force meeting

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Background

In the April 2016 Task Force meeting, there was strong agreement about the value of national TB prevalence surveys and the substantial achievements in implementing such surveys 2009–2015 were applauded. It was agreed that surveys would continue to be needed between 2016 and 2020.

Recommendations were made for three specific topics:
1. Replacement of sputum smear microscopy and culture with Xpert MTB/RIF (or equivalent or better molecular test).
2. Overall governance/oversight mechanisms for surveys.
3. Funding for report production and associated efforts to communicate and disseminate results.

This document explains the recommendations that were made, and progress made in the past two years.

1. Replacement of sputum smear microscopy and culture with Xpert MTB/RIF (or equivalent or better molecular test)

Recommendations

At the April 2016 Task Force meeting, there was agreement in principle with the idea that future surveys should use Xpert MTB/RIF (or an equivalent or better molecular test) instead of sputum smear microscopy and culture. The main reason for such replacement was the challenges in ensuring quality culture specimens and testing evident in several surveys implemented since 2009.

However, it was also recommended that such a transition should await results from ongoing surveys in Bangladesh, Kenya and the Philippines, which were using Xpert MTB/RIF and culture in parallel. It was further recommended that any other surveys implemented in 2016 or 2017 should use both culture and Xpert MTB/RIF, pending results from evaluation of the new Xpert Ultra cartridge.

It was noted that research might be needed to assess the specificity and sensitivity of Xpert (MTB/RIF or Ultra) in the general population, since this may be different compared with clinical settings given the on-average earlier stage of disease. If Xpert Ultra were found to have equivalent performance to culture, it was further noted that such research may not be necessary.

Progress since April 2016

WHO organized an expert consultation in January 2017 to compare the performance of Xpert Ultra with Xpert MTB/RIF. It was agreed that Ultra was non-inferior to the Xpert MTB/RIF assay for the detection of *Mycobacterium tuberculosis* and for the detection of rifampicin resistance.¹ Culture remains the gold standard for bacteriological confirmation of TB. However, Ultra’s sensitivity may also be superior to the current reference standard (liquid culture) depending on specimen quality and methods used for specimen handling and processing i.e. when culture is not performed optimally.

Since April 2016, results have become available from three national surveys that systematically used Xpert MTB/RIF in parallel with culture: Bangladesh (2015–2016), Kenya (2015–2016) and the Philippines (2016). Results will shortly be available from two other surveys that also used Xpert MTB/RIF: Namibia (2017–2018) and Viet Nam (2017–2018). Xpert is also being used in parallel with culture in three ongoing surveys: Mozambique, Myanmar and South Africa (the latter two are using Xpert Ultra).

A meeting of the TB prevalence survey subgroup of the Task Force will be held on 30 April 2018 to discuss issues related to the interpretation of results from these surveys. The main outcomes of this meeting will be presented during the Task Force meeting on Wednesday 2 May 2018.

2. Overall governance/oversight mechanisms for surveys

Recommendations

There was agreement that ways to strengthen the overall governance/oversight mechanisms for surveys should be explored. In particular, more formal arrangements for survey monitoring and related actions by implementers and sponsors, based on Good Clinical Practices (GCP), were suggested. This includes establishment of a body to provide independent oversight, for example using an entity such as a Data Safety and Monitoring Board (DSMB).

Progress since April 2016

GTB/TME has initiated a collaboration with WHO’s Special Programme for Research and Training in Tropical Diseases (TDR), which has extensive experience with GCP methods and associated training. TDR has produced a concept note to define and establish methods that would be appropriate in the context of national TB prevalence surveys. This will be the basis for further work in 2018. The concept note will be discussed with the prevalence survey subgroup of the Task Force during the Task Force meeting, on Thursday 3 May 2018.

3. Funding for report production and associated communication and dissemination of results

Recommendations

There was agreement that funding for report production and associated efforts to communicate and disseminate results should be included in survey budgets from the outset. It was also suggested that a standard template could help with report writing and that a standard database that would generate standard sets of figures and tables could help as well.

Progress since April 2016

Those providing technical assistance to countries are regularly reminding countries to include funding for survey reports and associated publication and dissemination of results (including an effective communication plan) from the outset.

All available published reports and papers are currently housed in an online repository maintained by WHO. This is shared with all survey principal investigators and those providing technical assistance, to help facilitate report writing.

The time between completion of field operations and official public release of results from the surveys of Bangladesh, Kenya and the Philippines ranged from 4 to 8 months. The time between completion of field operations and production of a draft (or final) report ranged from 8 to 16 months. The implementing partners of these three surveys were research agencies who were familiar with report writing and publications, but the length of time taken to disseminate results and publish a report was influenced by the time taken to clean the dataset and the number of people available to write the reports. Of note, one implementing agency was only paid once a final report was satisfactorily completed.

2 https://drive.google.com/drive/folders/0BxHfvd7XsxxqBUE5yenl4bU40Snc?usp=sharing