Information Session
for civil society representatives:
Update on the WHO TB guidelines development
Guidelines development at WHO
Principles behind guideline development

• Sound scientific and ethical principles and practices

• Evidence is:
  – relevant (applicable to the key question at hand),
  – obtained ethically and in accordance with human rights standards and ethics;
  – of the highest quality ("best") available (based on assessment of risk of bias);
  – publicly-available at the time of publication of the recommendation or guideline.

• Transparent in the methods used for searching, retrieving, summarizing and assessing the evidence, and the rationale for decisions on selected approaches and methods, and for each recommendation must be clear.
Formulating evidence-based recommendations

Djulbegovic & Guyatt, Lancet 2017
Why systematic reviews are important

- Millions of healthy women were prescribed hormone replacement therapy for cardiovascular risk reduction
- More Americans died from unnecessary use of antiarrhythmic drugs than from Vietnam war
- Millions of HIV positive pregnant women denied superior HIV treatments because of concerns about safety
Contributors to WHO guidelines

• WHO Steering Group
  – Support development of recommendations by the GDG
  – Draft the guideline document
  – Are subject to WHO Staff Regulations for COI and confidentiality

• Guideline Development Group
  – Formulate recommendations; approve the final guideline
  – Complete DOI; COI assessed and managed by WHO staff
  – Participate as individuals; do not represent institutions

• Meeting Observers
  – Technical consultants: provide information, opinions, guidance
  – Do not participate in deliberations on recommendations
  – Provide comments on request
  – No DOI needed; may represent an institution or group
Contributors to WHO guidelines (cont.)

- Guideline methodologists
  - Helps the GDG to develop recommendations informed by evidence using a transparent and explicit process
  - Technical expertise on systematic review and guideline development methods
  - Completes DOI; generally has no COI

- Other technical experts: Systematic review team
  - Presents the SR; provides technical expertise on review methods
  - Completes DOI; generally has no COI

- External Review Group
  - Peer review
Community voices

WHO GTB systematically engages with affected communities & civil society in advancing TB agenda at all levels

- Policy setting and Guidelines development
- Monitoring and Evaluation
- Implementation of End TB Strategy in SDG era
- Research
- Capacity Building and technical assistance
- Technical Events and Conferences
Update of guidelines on treatment of latent TB infection
Update of guidelines on LTBI treatment: New data

An update to the 2018 guidelines is motivated by user demands for more operational guidance and clarity on the implementation of the recommendations, as well as the release of new evidence since its publication:

• Phase 3 trials of 4 months rifampicin in adults and children
• A trial of 1 month rifapentine-isoniazid in PLHIV
• A trial on the safety of isoniazid in pregnancy in women with HIV
• More results on the combined use of rifapentine and dolutegravir in PLHIV
## Update of guidelines on LTBI treatment: Timeline

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial preparation, first meeting of the Steering group</td>
<td>April 2019</td>
</tr>
<tr>
<td>Systematic review</td>
<td>April - June 2019</td>
</tr>
<tr>
<td>Public comment process</td>
<td>July 2019</td>
</tr>
<tr>
<td>Guidelines Development Group (GDG) meeting (virtual)</td>
<td>July 2019</td>
</tr>
<tr>
<td>Draft guidelines with comments from GDG</td>
<td>August - September 2019</td>
</tr>
<tr>
<td>Peer review of the guidelines by the External Review Group and public comments</td>
<td>October 2019</td>
</tr>
<tr>
<td>Finalization of guidelines; finalization of operational guide</td>
<td>November - December 2019</td>
</tr>
<tr>
<td>Launch of updated consolidated guidelines</td>
<td>February 2020</td>
</tr>
</tbody>
</table>
Update of guidelines on treatment of drug-resistant tuberculosis
Update of guidelines on drug-resistant tuberculosis treatment: New data

Since the 2019 edition, new evidence in critical areas became available prompting WHO to initiate a guideline development process, to complement earlier recommendations.

New evidence is available on:

- Use of bedaquiline longer than six months duration for MDR/RR-TB
- Concurrent use of bedaquiline and delamanid for MDR/RR-TB
- Use of bedaquiline, pretomanid and linezolid in combination for patients with XDR-TB
- All-oral shorter regimens for MDR/RR-TB
### Update of guidelines on drug-resistant tuberculosis treatment: **Timeline**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial preparation, first meeting of the Steering group</td>
<td>April 2019</td>
</tr>
<tr>
<td>Public call for data</td>
<td>July 2019</td>
</tr>
<tr>
<td>Public comment process</td>
<td>August 2019</td>
</tr>
<tr>
<td>Data analysis</td>
<td>August - November 2019</td>
</tr>
<tr>
<td>Guidelines Development Group (GDG) meeting</td>
<td>12-14 November 2019</td>
</tr>
<tr>
<td>Rapid Communication</td>
<td>December 2019</td>
</tr>
<tr>
<td>Finalization of guidelines; finalization of Companion Handbook</td>
<td>February - March 2020</td>
</tr>
<tr>
<td>Launch of updated consolidated guidelines</td>
<td>April 2020</td>
</tr>
</tbody>
</table>
Rapid Communication: Key changes to the treatment of drug-resistant tuberculosis

Authors:
WHO

Publication details
Number of pages: 6
Publication date: 2019
Languages: English
WHO reference number: WHO/CDS/TB/2019.26

Downloads
Download the Rapid Communication

Significant improvements in treatment outcomes and quality of life for patients with drug-resistant tuberculosis are expected, following key updates to treatment approaches, announced by the World Health Organization (WHO) in a Rapid Communication.

Treatment success for multidrug-resistant (MDR) and rifampicin-resistant (RR)-TB is currently low in many countries. This could be increased by improving access to new regimens that are more effective, less toxic and easier to implement for eligible patients. In November 2019, WHO convened a meeting of its Guideline Development Group to update WHO's standard treatment recommendations for drug-resistant tuberculosis.
Update of guidelines on tuberculosis diagnostics
Update of molecular assays intended as initial tests for the diagnosis of pulmonary and extrapulmonary TB in adults and children: New data

New evidence has become available on the following molecular assays for the diagnosis of active TB (pulmonary and extra-pulmonary) and rifampicin-resistance in adults and children:

- Xpert® MTB/RIF
- Xpert® MTB/RIF Ultra
- Molbio TrueNat MTB/Rif ➔ prospective, multicentre trial to assess the diagnostic accuracy of the Truenat Assays in four countries: India, Peru, Papua New Guinea and Ethiopia.
Update of molecular assays intended as initial tests for the diagnosis of pulmonary and extrapulmonary TB in adults and children: **Timeline**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial preparation, first meeting of the Steering group</td>
<td>July 2019</td>
</tr>
<tr>
<td>Systematic review</td>
<td>August - November 2019</td>
</tr>
<tr>
<td>Public comment process</td>
<td>September 2019</td>
</tr>
<tr>
<td>WHO Guideline Review Committee approval</td>
<td>September 2019</td>
</tr>
<tr>
<td>Guidelines Development Group meeting</td>
<td>3-6 December 2019</td>
</tr>
<tr>
<td>Rapid Communication</td>
<td>January 2019</td>
</tr>
<tr>
<td>Revision of guidelines and peer-review process</td>
<td>December 2019 - March 2020</td>
</tr>
<tr>
<td>Launch of updated consolidated guidelines</td>
<td>April 2020</td>
</tr>
</tbody>
</table>
Thank you for listening