Treatment decision algorithms

Developing generic study materials

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Background

• March 2022: new WHO guidelines published
• Included a recommendation to use an integrated treatment decision algorithm
• Aimed to increase TB detection in children with presumptive pulmonary TB attending health facilities
• Classified as *interim, conditional, very low certainty of evidence*
• Validity period of 24 months – aim to generate evidence during this time to review ongoing recommendation
Algorithms

- Two algorithms developed for children < 10 years
- Internal validation using an IPD of paediatric diagnostic studies
- Algorithms with and without x-ray
- Focus on:
  - Specimen collection & diagnostic testing
  - Contact history
  - X-ray (when available)
  - Scoring symptoms and signs
- Available in WHO Operational Handbook
Generating evidence

- To assist external validation, WHO GTB with TDR proposed to develop generic materials
  - Research protocol
  - E-data collection tool
- Harmonization of research efforts from NTPs and research groups
- Call for EOI from researchers in June 2022 yielded 4 interested groups
- TDR experience from ShORRT for TB protocol (2019)
ShORRT timeline

- **Benin workshop**: March 2019
- **Protocol development**: Summer 2019
- **First in-country mission**
  - Cambodia: Nov 2019
- **Launch of the CAM-ShORRT study**: Apr 2020
- **Workshop with LAC**: July 2020

**Creation of the ShORRT initiative**
First meeting of the protocol writing committee: May 2019

**Launch at the Union conference in Hyderabad**: Nov 2019

**Mission to work with Benin, DRC & Nigeria**: Dec 2019

**Launch of the study in Nigeria & Vietnam**: June/July 2020

37 countries: November 2022
Objectives

• Performance of the treatment decision algorithms compared to a consensus definition of intra-thoracic TB in children

• Describe various process indicators to measure the feasibility of using the algorithm

• Semi-structured questionnaire to capture HCW acceptability

• Indirect effects on the detection of TB in adults – before/after comparison of notifications rates
Data collection

- **Generic paper-based** data collection forms
  - Available upon request

- **Electronic** data capture using the REDCap platform
  - Data dictionary and codebook
  - User manual
  - Training material
Implementation considerations

• Aim to complete inclusion within 6 to 12 months

• Gold standard evaluation requires re-assessment 2 months after assessment

• Desirable to gather diverse data:
  • Geographical
  • Study population – e.g. children living with HIV, malnutrition, age structure
  • Health care level
  • Access to diagnostic and x-ray evaluation
Progress

• African Regional Child and Adolescent TB meeting – Lusaka, Zambia - September 2022
• Researchers, NTPs – key questions for discussion
• Protocol drafted – WHO GTB feedback incorporated
• Soon ready for online feedback from interested researchers
• Generally available early January 2023
Thanks for listening!

Any questions?

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