Diagnostic performance and feasibility of two new treatment decision algorithms for pulmonary tuberculosis in children

Nigeria, Niger, Guinea, Uganda, South Sudan

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Objectives

• Médecins Sans Frontières (MSF) provides medical care for children in a wide variety of contexts, levels of care and populations.

• **Primary objective:**
  • To assess the performance of the Treatment decision algorithms (TDAs) against a reference standard *(WHO protocol definition)*

• **Secondary objectives:**
  • To document the diagnostic cascade using the TDAs (children undergoing each step of the algorithms, started on TB treatment etc).
  • To assess clinical evolution and mortality at 2 months of follow-up.
  • To assess health workers and caregivers’ perspectives on the TDAs (challenges and enablers to the introduction of the recommended algorithms).
  • To report changes on case notification rates 12 months prior to, and 12 months following the implementation of the TDAs.
Methodology

• **Study design:**
  - Observational prospective multi-country study to assess the TDAs performance.
  - Mixed-methods study to assess TDAs feasibility and acceptability.
  - Analysis of routine program data to assess case notification rates before and after TDAs implementation.

• **Population:**
  - Children under 10 years with symptoms of TB
  - Health workers, program managers, key informants, and parents.

• **Settings and study Sites:**

<table>
<thead>
<tr>
<th>Population</th>
<th>Type of care</th>
<th>Level of care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malakal, South Sudan</td>
<td>General</td>
<td>Ambulatory &amp; Hospitalized</td>
</tr>
<tr>
<td>Mbarara, Uganda</td>
<td>General</td>
<td>Ambulatory &amp; Hospitalized</td>
</tr>
<tr>
<td>Madarounfa, Niger</td>
<td>Malnourished</td>
<td>Ambulatory &amp; Hospitalized</td>
</tr>
<tr>
<td>Maiduguri, Nigeria</td>
<td>Malnourished</td>
<td>Hospitalized</td>
</tr>
<tr>
<td>Conakry, Guinea</td>
<td>Living with HIV</td>
<td>Ambulatory</td>
</tr>
</tbody>
</table>

• **Target sample size:** 2020 children over 12 months enrolment period
Progress

• Launch of the study:
  • 2 sites opened out of 5 sites => Nigeria in August 2023 & Niger in November 2023
  • 2 sites to be opened in Nov 2023 => Guinea & Uganda
  • 1 site to be opened in Jan 2024 => South Sudan

• Enrolment to date (if applicable)
  • N=200

• Estimated end of enrolment period:
  • January 2025

• Estimated date when results (for the primary endpoint) will be available
  • Final results by March 2025
  • Interim results on part of the population by June 2024
• Médecins Sans Frontières, France
• Médecins Sans Frontières, Belgium
• Médecins Sans Frontières, Spain
• Epicentre, France
• Ministry of Health, Nigeria
• Ministry of Health, Niger
• Ministry of Health, Guinea
• Ministry of Health, Uganda
• Ministry of Health, South Sudan
• University of Tübingen, Germany
• ANRS, France