KNCV SIMPLE ONE-STEP STOOL
(SOS) PROCESSING METHOD

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TB in children is hard to diagnose

69% of children <5y missed in notification

Source:
A bacteriological diagnosis?

- Children often have paucibacillary disease
  - *Sensitive methods needed (culture, Xpert (Ultra))*

- Sputum is hard to obtain:
  - *Invasive methods*
  - *Not available at lowest level health facilities*

→ **Delayed diagnosis**
  
  *Simple test needed with quick results and access at lower levels of healthcare where children report*

- Stool is easy to obtain
  - *Has been shown to contain MTB in adults with pulmonary TB*
  - *MTB can be detected using Xpert MTB/Rif*
Recommendation: stool as rule-in test

■ Xpert stool can be used as a **rule-in** test for the diagnosis of TB in children:
  - *If it is positive, TB disease can be confidently diagnosed*

- **N=1681 children from 9 studies**
- Pooled sensitivity against reference standard: 67% (95%CI: 52-79)
- Pooled specificity: 99% (98-99)
- Sensitivity higher in children with HIV: 79%
The KNCV SOS - Simple One-step stool method

- As simple as sputum testing with Xpert
- Feasible to perform in lower level health centers
- Can be performed at every GeneXpert site without need for additional materials
- Only short training required for Xpert staff
How does it work?

As simple as sputum processing
## Ongoing and planned work to generate evidence

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<th>Project</th>
<th>Purpose</th>
<th>Results expected</th>
<th>Healthcare level</th>
<th>Laboratory level</th>
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<tr>
<td>ASTTIE</td>
<td>• Continue data collection in parallel with routine testing on respiratory samples</td>
<td>Q4 2020</td>
<td>Primary, secondary and tertiary</td>
<td>Xpert labs</td>
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<tr>
<td>Cap-TB</td>
<td>• Pilot implementation in 3 selected sites</td>
<td>Q2 2020</td>
<td>Primary</td>
<td>Xpert labs</td>
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| PODTEC  | • Gain insight into robustness of SOS method  
• Develop routine implementation and scale-up package  
• Test in routine in remote area | Q2 2020 | NA | NRL |
|         |                                                 | Q2 2020 | NA | NRL |
|         |                                                 | Q4 2021 | Primary and up | Xpert labs |
| H2H     | • Compare KNCV SOS with TBSPEED sucrose flotation and FIND stool processing kit | Q4 2020 | Secondary and tertiary | NRL |
KNCV SOS stool test: lessons learned

- It works – MTB and rifampicin resistance detected in pilot studies
- Children can produce stool for testing
- Laboratory staff can perform the test
- Low error rates (similar to sputum)
In conclusion

**KNCV SOS processing for Xpert will offer:**

- Quick accurate diagnostic test that includes RIF resistance
- Simple processing (as simple as sputum)
- Access to diagnosis at decentralized level

**What we aim for:**

- Stool to be included as possible sample for TB diagnosis in new Xpert guidelines
- Xpert stool test to be accepted as rule in test
- Recommendations on stool testing in the new childhood TB guidelines based on evidence obtained