Detection of *Mycobacterium tuberculosis* complex in the stool of pediatric patients using the Xpert MTB/Rif Ultra assay

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Introduction

- Tajikistan has a **high MDR/RR-TB** burden
- Children represent **8.2%** of all TB cases
- Most children treated for DR-TB in Tajikistan are diagnosed **clinically and radiologically**
- **Study Aim**: to describe performance of the Xpert MTB/RIF *Ultra* assay for MTB detection in fresh stool from children <15y

Methods

- A prospective, observational Lab study
- Induced sputum and stool samples from children tested by Xpert Ultra MTB/RIF
- Used the modified "**Banada**" method of sample preparation: stool was treated using a digestion buffer followed filtration before loading to the cartridge"**
- Confirmed TB disease = ≥1 TB sign or symptom plus microbiologic confirmation

Results

- **17/688** = confirmed TB disease (**2.5%**)
- Xpert Ultra implementation was **feasible**
- Xpert Ultra stool = *sensitivity 64.7%*
- Xpert Ultra stool = *specificity 98.6%*
- MTB Trace stool = 10, MTB trace sputum = 4
- 3/9 patients with **only a positive Xpert Ultra stool** assay later treated for TB
- 16/17 with confirmed TB disease were **on treatment** within 6 weeks

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- The Xpert MTB/RIF Ultra assay on stool in children <15y from Tajikistan had a *sensitivity of 64.7% compared to **induced sputum sensitivity of 80%***

- The Xpert MTB/RIF Ultra assay on stool in children <15y from Tajikistan had a *specificity of 98.6% compared to **induced sputum specificity 97.7%***

- Performing the Xpert MTB/Rif Ultra assay using the modified "Banada" method with a standard laboratory protocol was *feasible compared to centrifuge-used method*

- "*Trace calls*" were more frequent with stool.

- 16/17 cases with confirmed TB disease were known to be *on treatment within 6 weeks*

- Patients whose only positive test was an Ultra stool are at *high risk* of developing TB disease

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Discussion

We demonstrated the feasibility of implementing the Xpert MTB/Rif Ultra assay for stool in children <15y in Tajikistan using the modified Banada method. The sensitivity rate (64.7%) and specificity rate (98.6%) in our study were equal to or higher than published studies. Trace calls were more frequent for stool than sputum. Of 17 confirmed TB disease cases, 16 were known to be on treatment within 6 weeks of diagnosis. Children whose only positive test on Xpert Ultra stool were at high risk of developing TB disease.

Conclusions

1. Xpert MTB/Rif Ultra for stool should be an option as a baseline test to diagnose TB in children, especially those <15y

2. Xpert MTB/Rif Ultra using the Banada method is feasible in comparison with centrifuged-used method for low-income countries. Although our method shows a promising result, recent publication showed a simpler method with similar performance (e.g. SOS method)

3. If not in the country's treatment guideline, we recommend children whose only positive test is the Xpert Ultra stool should be monitored