



KNCV SIMPLE ONE-STEP STOOL (SOS) PROCESSING METHOD

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EVIDENCE

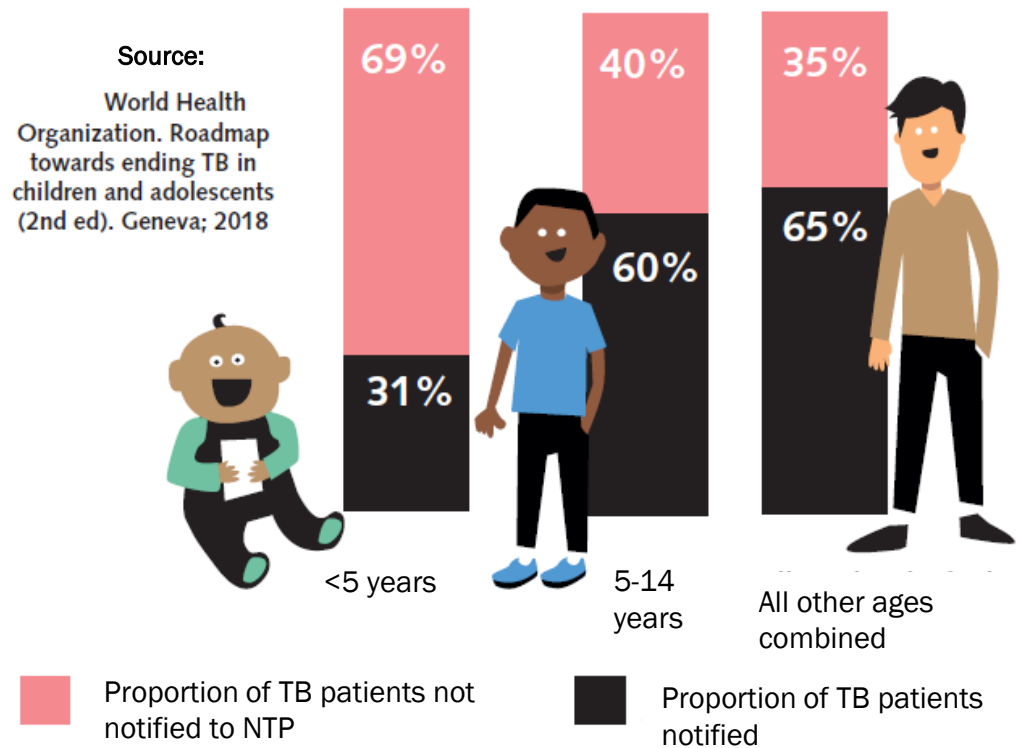
TB in children is hard to diagnose

69% of children <5y missed in notification



EVIDENCE

Source:
World Health
Organization. Roadmap
towards ending TB in
children and adolescents
(2nd ed). Geneva; 2018



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*



EPIDEMIOLOGY



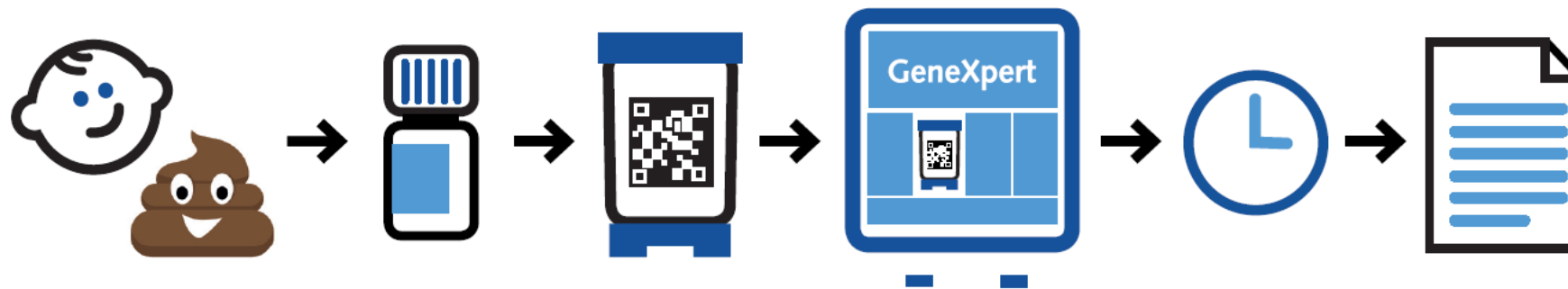
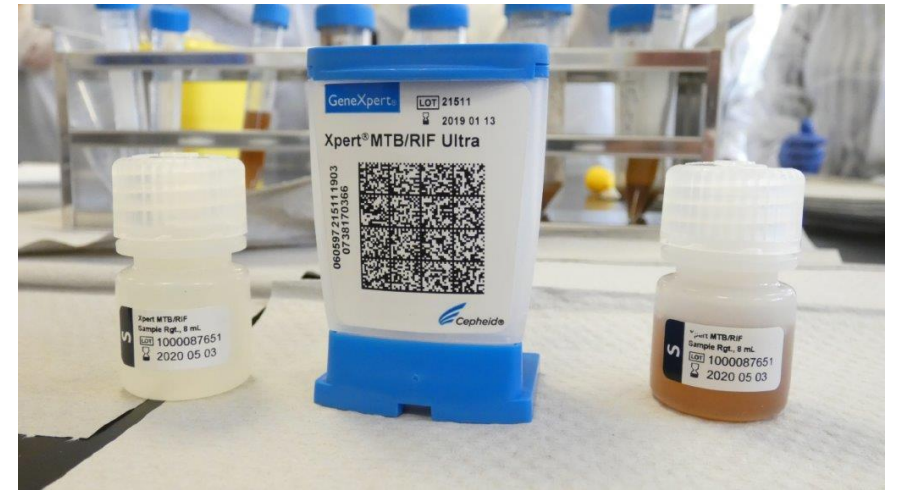
Diagnostic Accuracy of Stool Xpert MTB/RIF for Detection of Pulmonary Tuberculosis in Children: a Systematic Review and Meta-analysis

© Emily MacLean,^{a,b} Giorgia Sulis,^{a,b} Claudia M. Denkinger,^{b,c,d} James C. Johnston,^{b,e,f} Madhukar Pai,^{a,b} Faiz Ahmad Khan^{a,b,g}

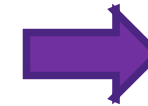
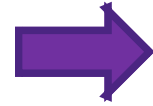
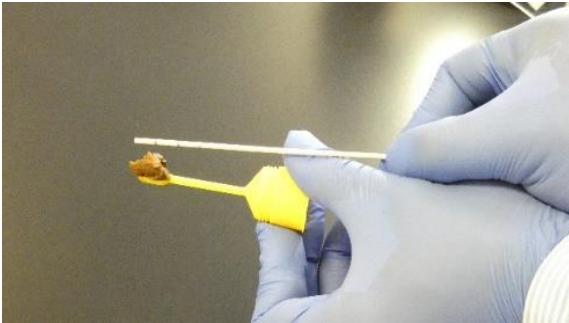
- N=1681 children from 9 studies
- Pooled sensitivity against reference standard: 67% (95%CI: 52-79)
- Pooled specificity: 99% (98-99)
- Sensitivity higher in children with HIV: 79%

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



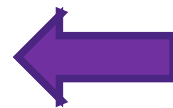
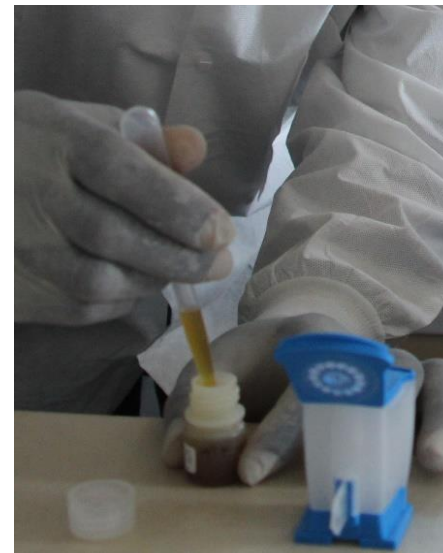
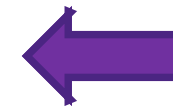
How does it work?



As simple as sputum processing



2x 10 min



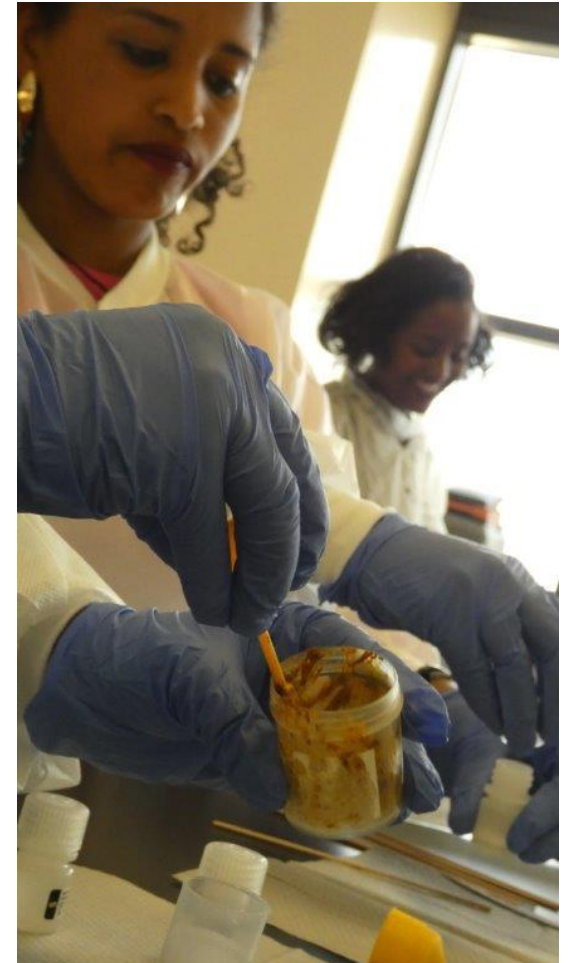
EVIDENCE

Ongoing and planned work to generate evidence

Project	Purpose	Results expected	Healthcare level	Laboratory level
ASTTIE	<ul style="list-style-type: none"> Continue data collection in parallel with routine testing on respiratory samples 	Q4 2020	Primary, secondary and tertiary	Xpert labs
Cap-TB	<ul style="list-style-type: none"> Pilot implementation in 3 selected sites 	Q2 2020	Primary	Xpert labs
PODTEC	<ul style="list-style-type: none"> Gain insight into robustness of SOS method 	Q2 2020	NA	NRL
	<ul style="list-style-type: none"> Develop routine implementation and scale-up package 	Q2 2020	NA	NRL
	<ul style="list-style-type: none"> Test in routine in remote area 	Q4 2021	Primary and up	Xpert labs
H2H	<ul style="list-style-type: none"> Compare KN CV SOS with TB Speed 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