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TB
Conference
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Impact of stool-based TB testing on TPT initiation among child contacts of TB patients: a nested cross- sectional study in Ekurhuleni, South Africa.

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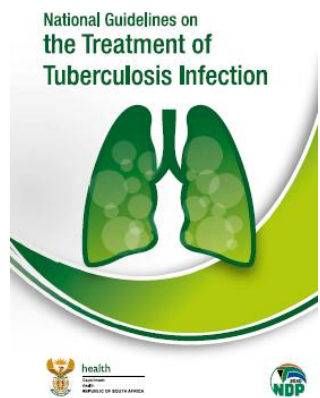
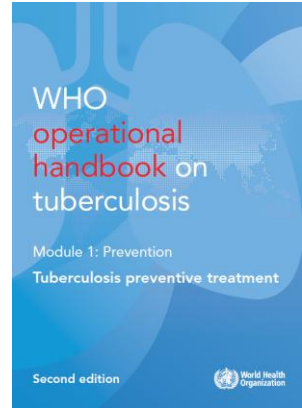
EDCTP

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Rationale: What we do know

- 1) Household and significant contacts are at high risk of TB infection (up to 50%) and disease¹
- 2) Children <5 are at significantly higher risk of progressing to disease¹
- 3) TB prevention therapy (TPT) is effective in preventing TB infection-> disease (91% in children, adolescents)¹
- 4) **WHO recommends: systematic evaluation of contacts** according to national guidelines of household contacts to identify TB disease and eligibility for TPT¹. This often relies on symptom screening as a 'gatekeeper'.¹
- 5) **SA guidelines recommend :**
 - Symptom screening and chest X-ray (where possible) for all contacts and
 - NAAT testing for ALL contacts > 25kg ,regardless of symptoms (TUTT: Targeted Universal test-and-treat)
 - NAAT testing for only SYMPTOMATIC contacts < 25kg (presuming poor yield and difficulty obtaining samples) prior to initiating TPT²



References:

- 1- WHO operational handbook on tuberculosis. Module 1: prevention - tuberculosis preventive treatment, second edition. Geneva: World Health Organization; 2024
- 2- National Guidelines on the treatment of Tuberculosis infection, South Africa, 2023

....but what we also know:



- 1) **TPT uptake remains suboptimal** (25%, target: 90%), especially in contacts < 5 years (SA 62% of target) ^{1,5}
- 2) Up to 50% of bacteriologically confirmed TB clients are asymptomatic -> **symptom screening may miss active disease** ^{2,3}
- 3) **Sample collection for TB is a barrier for children** to access TPT and treatment
- 4) Children have paucibacillary disease and microbiological **confirmation of disease is less likely in children** ⁴

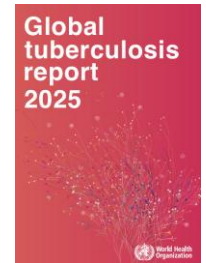
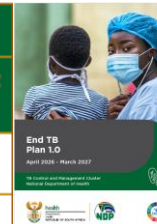


Table 2: UNHLM TB Targets and Performance for South Africa

Indicators	2023			2024		
	Target	Achievement (N)	Achievement (%)	Target	Achievement (N)	Achievement (%)
Notifications – All TB	220,000	222,119	101	239,476	202,511	85
Notifications – Children (<15 years)	21,129	15,066	71	23,948	14,849	62
Notifications – DR-TB	8,718	7,626	87	12,309	6,538	53
TPT – Contacts ≥ 5 years	128,810	24,979	19	120,003	58,439	49
TPT – Contacts < 5 years	30,934	15,814	51	29,710	18,524	62
TPT – Contacts ≥ 5 years	465,806	246,756	53	618,841	271,128	44



So, what we need:

Better approaches to household contacts to:

- a) Find and treat active TB
- b) Exclude active TB and initiate TPT
- c) Include children in both of those

References:

- 1- Global tuberculosis report 2025. Geneva: World Health Organization; 2025.
- 2- Implementing the end TB strategy: the essentials, 2022 update. Geneva: World Health Organization; 2022.
- 3- Baloyi DP et al. Reasons for poor uptake of TB preventive therapy in South Africa. Public Health Action. 2022;12(4):159-164.
- 4- WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022
- 5- End TB Plan 1.0, April 2026 – March 2027

Rationale: New possibilities

The **WHO** now endorse stool and nasopharyngeal aspirates as an alternative sample in children¹, as it is easy to collect, especially in very young children

Table 4.2. Diagnostic accuracy of Xpert MTB/RIF and Ultra In paediatric specimen types against a microbiological reference standard^a

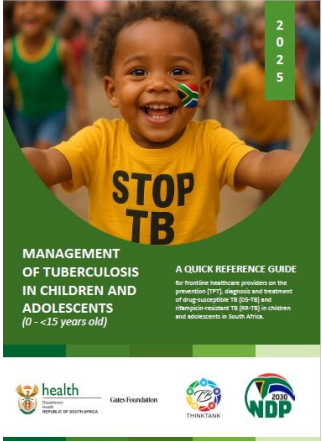
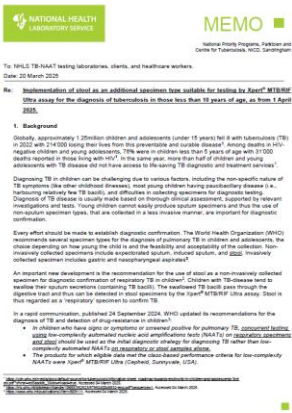
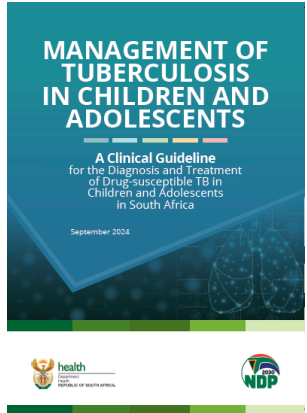
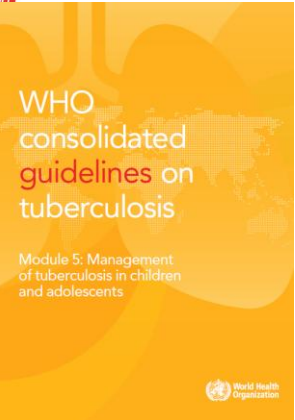
Specimen type (population)	Sensitivity	Specificity	Certainty of evidence
Xpert MTB/RIF			
Sputum	0.65	0.99	Moderate
Gastric aspirate	0.73	0.98	Very low (se) to low (sp)
NPA	0.46	1.00	Moderate (se) to high (sp)
Stool	0.61	0.98	Low (se) to moderate (sp)
Stool (HIV-positive)	0.70	0.98	Low (se) to high (sp)
Xpert Ultra			
Sputum	0.73	0.97	Low (se) to high (sp)
Gastric aspirate	0.64	0.95	Moderate
NPA	0.46	0.98	Very low (se) to low (sp)
Stool	0.53	0.98	Moderate

se: sensitivity; sp: specificity.

^a Microbiological reference standard: TB culture on respiratory samples.

Stool:

- Low sensitivity compared to gold standard (culture)
- Studies on presumptive TB
- High caregiver acceptability



References:
1- WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022

Context: **CUT-TB** (**C**ommunity and **U**niversal **T**esting for **TB** among contacts)



Main Study: Not for detailed discussion here

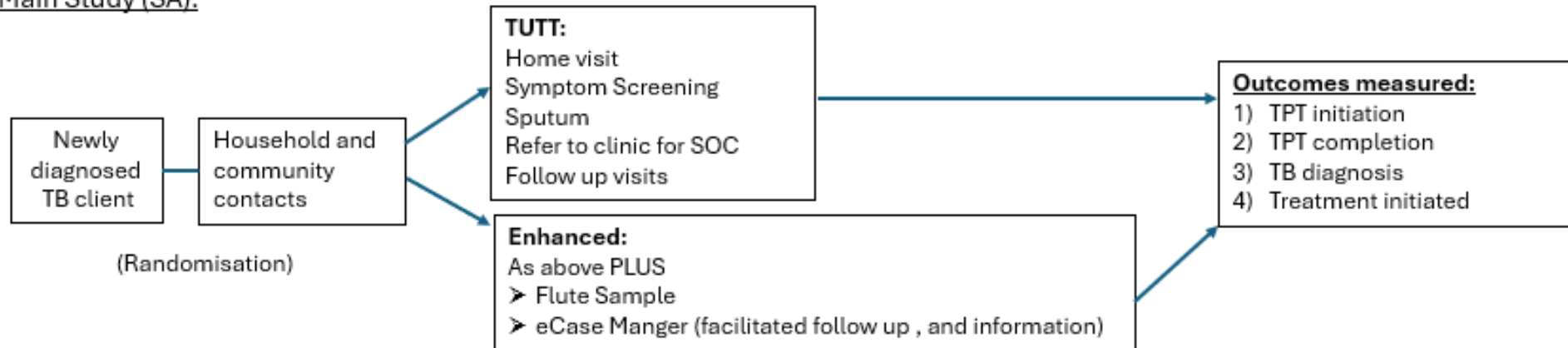
Pragmatic cluster randomized trial (CRT) in Lesotho, South Africa and Tanzania (only SA discussed here)

Primary objective in SA: **Comparing Enhanced Universal TB Testing vs TUTT**

Recruitment: Primary Health Facilities in Ekurhuleni

Eligibility: Diagnosed with TB in last 6 weeks, not living alone, > 18 years -> household/community contacts recruited

Main Study (SA):



CUT-TB (SA): Stool Sub-Study



Design: Nested cross-sectional sub study

Objectives: Assessing stool samples obtained at household level from children < 10 years with significant TB exposure with regards to:

- Feasibility and acceptability of household stool samples
- Diagnostic yield
- Impact on TPT initiation

Eligibility: All participants <10 years already recruited for the SA main study (any arm) from July - November 2024 were considered for additional recruitment onto the sub-study

Inclusion: < 10 years old at time of recruitment, who met consent (and assent) requirements

Exclusion: On TPT/ TB Treatment, too unwell

Sample aim: 80



CUT-TB (SA): Stool Sub-Study



Method: (In addition to main study activities)

Stool sample collection kits and instructions provided to caregivers on collection

Once samples available-> study team notified-> couriered to NICD

Once results available-> shared with caregivers, referred (as per min study) for SOC

Outcomes:

- Suitable stool (and pulmonary samples) collected at household level.
- TB yield using Xpert Ultra
- TB diagnosis made by any means
- TPT initiation



CUT-TB (SA): Main Study Participants < 10 years:

Age and Sputum production and yield

Significant Contacts n = 932

< 10 years
195 (20,1%)

< 5 years
76 (8,2%)

Produced sputum
128 (65,6%)

21
(27,6%)

107
(89,9%)

TB detected
2 (1,6%)

TPT eligibility and initiation

< 10 years
195

Eligible for TPT
160 (82,1%)

Initiated TPT
51 (31,9%)

CUT-TB (SA): Stool sub-study Results



CUT-TB (SA):	Stool Sub- Study
Participants *	80/80 (100%) < 5: 60 (75,0%) 5-9: 19 (23,8%) 10*: 1 (1,25%)
Samples	<u>Sputum</u> 4/80 (5,0%)# <u>Stool</u> 80/80 (100%)
TB Yield (Xpert/Ultra positive)	0/80 (0%)
TPT eligible TPT initiated	80/80 19/80 (23,8%)
* Included 1 child > 10 erroneously included	# included in main study total



Interpretation



No Surprises:

- High Proportion of household contacts < 10 years old

Surprises:

- High Proportion of household sputum collected in children (?)
- Lower sputum yield using flute (10/41)



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- Despite formal referral, with negative results and study team support -> very low TPT uptake

- Contacts don't like going to facilities

- Caregivers don't like giving medication to 'well' children with negative results

Conclusions



- **Home- based stool samples are a feasible, convenient option for TB testing in children**
 - Reduced visits
 - Reduced referrals
 - Especially very young children (most challenging to get other samples)

- **Home-based stool samples did not contribute to TB yield in (mostly) asymptomatic TB contacts**
 - May be better for presumptive TB

- **Negative results from stool samples did not significantly improve TPT uptake**
 - Suggesting that factors other than sample collection are barriers to TPT uptake

- **Children of all ages can be included in community based contact tracing and investigation activities**

Programmatic / Policy Implications

1) Stool sampling is now part of SA guidelines (in children with presumptive TB)

- The NHLS has confirmed national laboratory availability
- Uptake has been poor – likely due to low healthcare worker awareness

➤ Awareness Campaigns

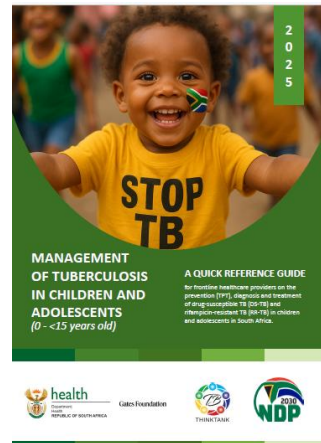
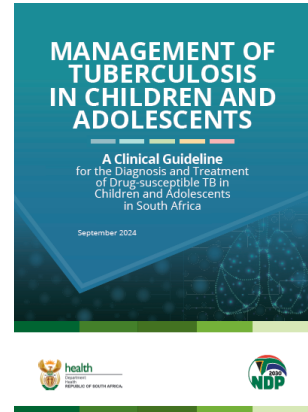
2) Even in study conditions , TPT uptake was poor

Despite shorter regimens, more tolerable medications and negative results on referral

- HCW training and awareness of TPT guidelines, interpretation of negative results in children
- Fully decentralised, community level, integrated options for TPT access
- Community sensitisation on TPT in ‘well’ children

3) Microbiological confirmation is uncommon in children, and should be viewed as only part of a more holistic approach to diagnosis (including contact, symptoms, weight trend, clinical examination, radiology and other investigations)

- HCW training and support on TB guidelines and decision algorithms



Thank You



Acknowledgements:

Participants and families for their time and willingness to provide 'not so fun' samples

Index patients for their willingness to provide contact lists to protect others

CUT-TB Study Team

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Co-Investigators and Co-Authors



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