



XPRT ULTRA IN STOOLS AND URINE FOR THE DIAGNOSIS OF TUBERCULOSIS IN CHILDREN LIVING WITH HIV: MÉDECINS SANS FRONTIÈRES EXPERIENCE IN GUINEA- BISSAU AND SOUTH SUDAN



L. Fidelle¹, R. Mahajan², J. Gallo³, E. Biague³, R. Gonçalves³, M. Rocaspana⁴, M. Camará⁵, L. Flevaut⁴, B. Tut⁶, E. Osman⁶, M. Sangma⁷, G. Ohisa⁸, M. José Sagrado⁴, L. Moretó Planas⁴

¹Médecins sans Frontières, OCBA, Malakal, South Sudan, ²Médecins sans Frontières, OCBA, New Delhi, India, ³Médecins sans Frontières, Bissau, Guinea-Bissau, ⁴Médecins sans Frontières, Barcelona, Spain, ⁵National TB Program, National TB, Leprosy and Buruli Ulcer Control Programme, Bissau, Guinea-Bissau, ⁶Médecins sans Frontières, Juba, South Sudan, ⁷Médecins sans Frontières, Nairobi, Kenya, ⁸ministry of health, Juba, South Sudan



Background and objectives

- Over half of childhood tuberculosis (TB) remains undiagnosed yearly.
- TB culture is often unavailable.
- In December 2010, the WHO recommended Xpert-Ultra as first test for diagnosis of paediatric TB, but microbiological confirmation remains low and often requires invasive procedures.





Background and objectives

AIM :

We aimed to determine the utility of Xpert-Ultra on stools and urine samples to diagnose TB in children living with HIV (CLWH) in two high-TB burden settings.





Methods

- **Sites:** Simão Mendes Hospital, Guinea-Bissau (July 2019 - April 2020) & Malakal Hospitals, South Sudan (November 2019 - June 2023)
- **Participants:** Children aged 6 months to 15 years with suspected TB.
- **Sample Collection:**
 - One respiratory or extrapulmonary sample (considered the gold standard)
 - One stool specimen
 - One urine specimen
 - All specimens were analysed using Xpert-Ultra





Methods

Patients were categorised :

- **Confirmed TB** (Xpert-Ultra positive on at least one sample)
- **Unconfirmed TB** (clinical diagnosis using a clinical-decision based algorithm)
- **Unlikely TB** (alternative diagnosis and good response to other treatment)





Results

Table 1: Baseline demographic and clinical characteristics

Characteristic	Overall, N = 93	Confirmed, N = 20	Unconfirmed, N = 51	TB, N = 71	TB Unlikely, N = 22	p-value
Study site						0.024
Bissau	57 (61%)	9 (45%)	30 (59%)	39 (55%)	18 (82%)	
Malakal	36 (39%)	11 (55%)	21 (41%)	32 (45%)	4 (18%)	
Age < 5years	53 (57%)	9 (45%)	32 (63%)	41 (58%)	12 (55%)	0.9
Females	49 (53%)	14 (70%)	23 (45%)	37 (52%)	12 (55%)	0.8
Past TB history	9 (9.7%)	2 (10%)	6 (12%)	8 (11%)	1 (4.5%)	0.7
TB contact	37 (40%)	8 (40%)	23 (45%)	31 (44%)	6 (27%)	0.2
SAM	70 (75%)	16 (80%)	39 (76%)	55 (77%)	15 (68%)	0.2
CD4 < 200 cells/mm³	26 (34%)	5 (29%)	14 (33%)	19 (32%)	7 (41%)	0.5
Missing CD4 data	16	3	8	11	5	
On ART	72 (77%)	13 (65%)	39 (76%)	52 (73%)	20 (91%)	0.14
Lung involvement	NA	17 (85%)	43 (84%)	60 (85%)	NA	



Results

- A total of 93 CLWH were enrolled from Bissau (n=57) and Malakal (n=36).
- 49 (53%) females and median (IQR) age of 3.3 (1.5-10) years.
- Three-quarters of children had severe acute malnutrition (SAM).
- A total of 72 (77%) children were on ART at baseline and 26/72 (36%) had CD4 count $<200\text{cells/mm}^3$.
- Confirmation of TB was achieved in 20 (22%); 51 (55%) had unconfirmed TB, and 22 (24%) had unlikely TB.
- The overall yield of positive TB results was 22% (20/93): 10% (9/90) in pulmonary samples and 20% (1/5) in extrapulmonary samples.
- A total of 86 and 91 samples were used to evaluate Xpert-Ultra on stools and urine, respectively



Results

Parameter	Xpert-ultra Stool Estimate (95% CI)	Xpert-ultra urine Estimate (95% CI)
Total samples	86	91
True positives	7	3
False Positives	0	0
False negatives	1	7
True negatives	78	81
Sensitivity	87.5% (52.9, 97.8)	30% (10.8, 60.3)
Specificity	100% (95.3, 100)	100% (95.5, 100)
Positive Predictive Value	100% (64.6, 100)	100% (43.9, 100)
Negative Predictive Value	98.7% (93.2, 99.8)	92.1 (84.5, 96.1)

No patients were positive in stools or urine and negative with gold standard



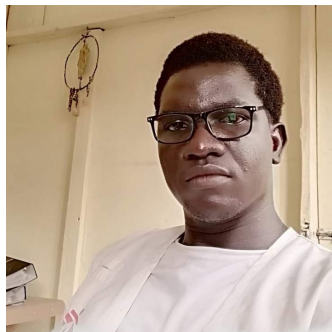
Conclusions

- ✓ Xpert-Ultra in stools showed high sensitivity and specificity in HIV-infected children when compared to gold standard, which may support its use as a screening test.
- ✓ Sensitivity of urine was low, but more research is needed to determine its clinical indication.



Acknowledgements

- THANKS TO...
- The patients and families that made this study possible
- The field teams that believed in the project
- The Ministry of Health who supported the study



This study has been reviewed and approved by the Institutional Review Board (IRB) or Ethics Review Board (ERB) of my institution, and has local ethics approval or permission in the study country, in accordance with local requirements

