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Use of stool swabs in molecular transport media increases access to Xpert Ultra testing for TB in children

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SUMMARY

SETTING: Tertiary level hospital in Lusaka, Zambia.

OBJECTIVE: To measure concordance between Xpert® MTB/RIF Ultra (Ultra) results of stool with and without transport media, and compare Ultra results from the two stool processing methods to Ultra and culture results using gastric aspirates (GA).

DESIGN: This was a cross-sectional study collecting stool and GA from children 0–5 years presenting with signs and symptoms of TB. Stool was processed for Ultra testing by two methods: the Simple-One-Step (SOS) on an aliquot of stool and PrimeStore® MTM Molecular Transport Medium (PS-MTM) using a stool swab.

RESULTS: A total of 114 children (median age: 17 months, IQR 7–30) provided both a stool and a GA sample. Stool Ultra results processed using the PS-MTM method showed high concordance with stool Ultra results processed by the SOS method, with only 1/114 discordant results. Concordance with GA Ultra was high as well, as 9/13 *Mycobacterium tuberculosis* (MTB) cases detected were identified by all three methods.

CONCLUSION: Ultra results from stool swabs collected using PS-MTM were equivalent to results from stool using the SOS method and GA. Given that PS-MTM inactivates MTB and stabilises DNA without cold chain, using it for stool has the potential to increase access to a TB diagnosis for children in underserved areas.

KEY WORDS: Zambia; children; stool testing; Xpert Ultra; tuberculosis; Primestore MTM

The burden of TB in children is increasingly recognised as an important component of the global TB burden. An estimated 1 million children develop TB annually, mostly in low-income countries. Children contributed 16% of all global TB deaths among HIV-negative people and 9.8% among HIV-positive people.[1] Bacteriological confirmation of TB in young children is hampered by their inability to produce sputum, necessitating an invasive procedure like the collection of gastric aspirates (GA) for mycobacterial testing. Stool is a non-invasive alternative sample for bacteriological confirmation of TB using the Xpert® MTB/RIF (Xpert) or Xpert® MTB/RIF Ultra (Ultra) (Cepheid, Sunnyvale, CA, USA) test and is now recommended by the WHO.[2–4] Stool requires only minimal processing for testing using the recent WHO/Global Laboratory Initiative (GLI) recommended Simple-One-Step (SOS) stool Ultra method.[5,6] The SOS stool processing method does not require any additional tools or equipment compared to sputum Xpert testing and is easy to implement.[6,7] Use of stool Ultra testing close to point-of-care is shown to be cost-effective and is expected to increase access to bacteriologically confirmed diagnoses for children with TB and reduce mortality.[8–10] However, as not all health facilities have a GeneXpert instrument on site, sample transportation would be required to further expand access. PrimeStore® MTM Molecular Transport Medium (PS-MTM) (Longhorn Vaccines and Diagnostics, Bethesda, MD, USA) inactivates pathogens and stabilises DNA/RNA at ambient temperature for storage, transport, and later molecular testing.[11,12] PS-MTM has been shown to be compatible with molecular tests, including Xpert and Ultra to detect *Mycobacterium tuberculosis* (MTB) in sputum swabs and tissue samples from human and animals.[12–14]

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More recently, PS-MTM has been used on a large scale for collecting and transporting samples for SARS-Cov-2 Xpert testing.[15] However, PS-MTM has never been used on stool samples for detection of MTB.

Our aim was to conduct a proof-of-concept study to determine whether PS-MTM works using a stool swab. We compared two stool processing methods—stool swabs in PS-MTM and stool processed using the SOS stool processing method, both tested using Ultra. In addition, we compared the results of both stool processing methods against Ultra and culture test results on GA. This innovative approach using PS-MTM with a swab could potentially increase access to a bacteriological confirmation of a TB diagnosis beyond sites with GeneXpert instruments.

METHODS

Study setting and population

We conducted a cross-sectional study at the national public referral Children's Hospital of the University Teaching Hospitals (UTH-CH) in Lusaka, Zambia, between August 2020 and April 2021. Children aged 0–5 years with signs and symptoms suggestive of TB, history of TB contact or referred for confirmation of TB diagnosis from the peripheral level but not on anti-TB treatment for more than 7 days were enrolled after obtaining informed consent from caregivers. At enrolment, demographic and clinical characteristics of the child were collected. The child received a full physical examination and nutritional status was determined using the WHO reference standard.[16] HIV testing was performed for children with undocumented HIV status. An early-morning GA was collected into two sample tubes after an overnight fast. If a GA sample could not be retrieved, 10–20 mL of saline was injected through the nasogastric tube to retrieve the sample. The GA sample for TB culture was neutralised using an equal amount of sodium bicarbonate (unknown brand procured from local pharmacy; 8.4% diluted 1:1 prior to adding to the specimen). The first GA was used for culture and the second for Ultra testing. Both GA samples were delivered in a cooler box the same day to the nearby Zambart Laboratory, Lusaka, Zambia, for TB culture and Ultra testing. One stool sample was collected either at the hospital or at home as soon the child opened bowels but within 24 hours of GA collection and tested at the UTH laboratory. All laboratory results were returned to the physicians to guide the treatment decision. Standard TB treatment was provided in accordance with the Zambia National Tuberculosis Programme guidelines.

Laboratory procedures

The procedure for the swab-PS-MTM method is shown in Figure 1. Using a floc swab, approximately 150 mg of the stool was collected and transferred into a tube containing 1.5 mL of PS-MTM and shaken vigorously before transport to the laboratory at UTH-CH Upon receipt, the sample was vigorously shaken again and left standing upright for 10 min at room temperature to allow larger stool particles to settle to the bottom, whereafter 0.7 mL of the supernatant was transferred to a clean tube and mixed with 1.4 mL of sample reagent (SR). Two mL of this mixture was transferred into the Ultra cartridge for testing as per manufacturer's guidelines.[17] In parallel from the same stool specimen, an aliquot (±0.8 g) was processed using the SOS processing method.[5]

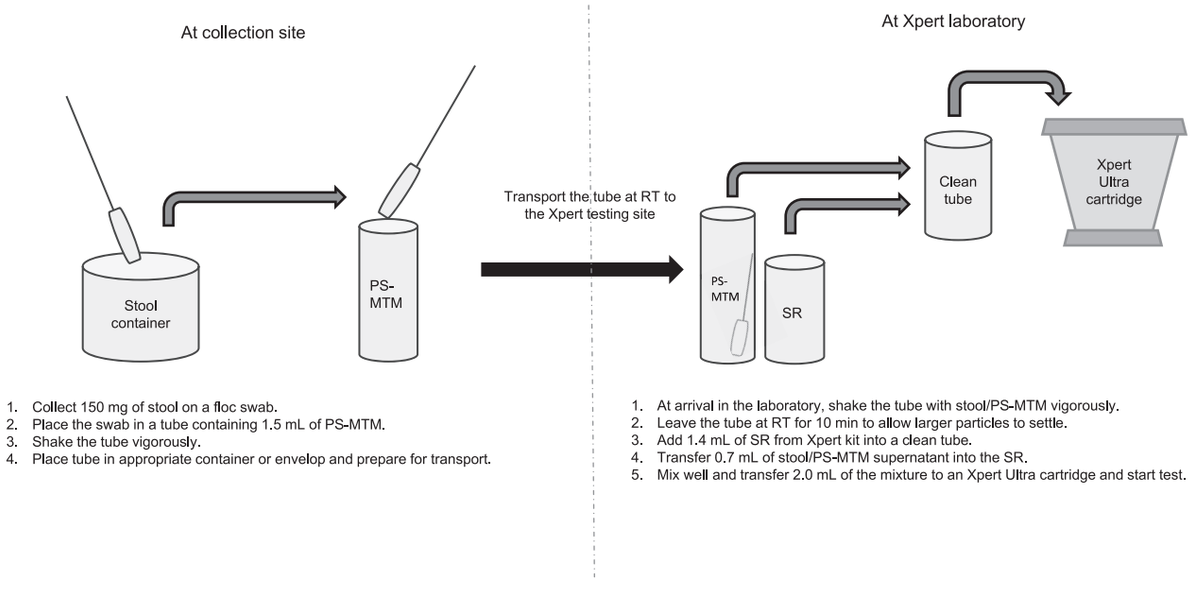

Figure 1 Schematic overview of the stool swab PS-MTM processing method. PS-MTM = PrimeStore® MTM molecular transport medium; RT = room temperature; SR = sample reagent.

Table 1 Listing of the 13 children identified in this study, with bacteriologically confirmed TB and their diagnostic test results

Study ID	Age months	Sex	GA Ultra	GA culture	Stool SOS	Stool PS-MTM	On anti-TB treatment
SM02	2	Male	MTB detected (medium) RR-negative	Negative	MTB detected – (medium), RR-negative	MTB detected – (medium), RR-negative	No
CM13	35	Female	MTB detected (very low), RR-negative	MTB	MTB detected (very low), RR-negative	MTB detected (very low), RR-negative	No
BP14	11	Female	MTB detected (very low), RR-negative	MTB	MTB detected (very low), RR-negative	MTB not detected	Yes
FS38	36	Male	Negative	Negative	MTB detected (low), RR-negative	MTB detected (low), RR-negative	No
LA42	22	Male	MTB detected (very low), RR-negative	Negative	MTB detected (very low), RR-negative	MTB detected (very low), RR-negative	No
VM47	6	Female	MTB detected (low), RR-negative	MTB	MTB detected (low), RR-negative	MTB detected (low), RR-negative	No
MM59	30	Female	MTB detected (very low), RR-negative	Negative	MTB detected (very low), RR-negative	MTB detected (very low), RR-negative	No
CC66	22	Male	Negative	MTB	MTB not detected	MTB not detected	No
RM84	55	Female	MTB detected (low), RR-negative	MTB	MTB detected (low), RR-negative	MTB detected (medium), RR-negative	No
PN86	28	Female	MTB detected (low), RR-negative	MTB	MTB detected (low), RR-neg	MTB detected (low), RR-negative	No
RS94	48	Female	MTB detected (very low), RR-negative	MTB	MTB detected (very low), RR-negative	MTB detected (very low), RR-negative	No
LM106	4	Female	MTB detected (low), RR-negative	Negative	MTB detected (low), RR-negative	MTB detected (very low), RR-negative	Yes
JZ110	24	Female	MTB detected (very low), RR-indeterminate	Negative	MTB not detected	MTB not detected	No

GA = gastric aspirate; SOS = simple-one-step; PS-MTM = PrimeStore molecular transport medium; ATT = anti-TB treatment; RR = rifampicin-resistant, MTB = *Mycobacterium tuberculosis*.

One GA sample was decontaminated using the sodium hydroxide/*N*-acetyl-l-cysteine (NaOH/NALC) procedure and inoculated into two Mycobacteria Growth Indicator Tubes (MGIT™; BD, Franklin Lakes, NJ, USA) for TB culture.[18] The other GA sample was subjected to Ultra testing following the standard procedure for sputum Ultra testing.[19]

Data collection and analysis

Standardised forms were used to collect each child's clinical details and laboratory results. Data were analysed using STATA v15 (Stata, College Station, TX, USA). Descriptive statistics were used to characterise the study population and outcomes. Bacteriologically confirmed TB was defined as MTB-positive on either the GA sample using culture and/or Ultra or using Ultra on either stool method. In the absence of bacteriological confirmation, the physician could make a clinical TB diagnosis based on symptoms, chest X-ray findings or history of TB contact.

Ethical consideration

Ethical clearance and approval were obtained from both institutional and national research ethics bodies (University of Zambia, Lusaka, Zambia; BREC IRB 00001131).

RESULTS

A total of 130 children were assessed for eligibility and 116 (89%) were enrolled after caregivers provided informed consent (Figure 2). GA samples were collected from all 116 children enrolled, and 114 (98.3%) also provided a stool sample. Of the two children without a stool sample, one tested Ultra MTB detected medium (rifampicin resistance not detected) on GA but died before stool collection, while the other tested Ultra MTB-negative on GA and was discharged before a stool sample was collected. A diagnosis of TB was made in 79/114 (69.3%) of children: 13/79 (16.4%) were bacteriologically confirmed using either stool or GA Ultra or culture, while 66/79 (83.5%) were diagnosed on clinical grounds only. Table 1 shows detailed results of the 13 children who were bacteriologically confirmed. In total, 12 children were bacteriologically confirmed on GA and 11 using stool, with a high concordance (10/11) between both stool processing methods (Figure 2). Of the 13 bacteriologically confirmed children, 10 (77%) were MTB-confirmed using GA and stool (9 on both methods, 1 on SOS only), 2 (15%) only using GA (1 on Ultra only and 1 by culture only) and 1 (8%) only using stool (both processing methods) (Figure 2). Six (55%) of the 11 Ultra MTB detected GA samples were MTB-positive on culture (Table 1). None of the Ultra results showed mutations associated with rifampicin resistance.

Characteristics study population

Table 2 shows the characteristics of the 114 children included in the analysis, overall and by TB status. Their median age was 17.5 months (interquartile

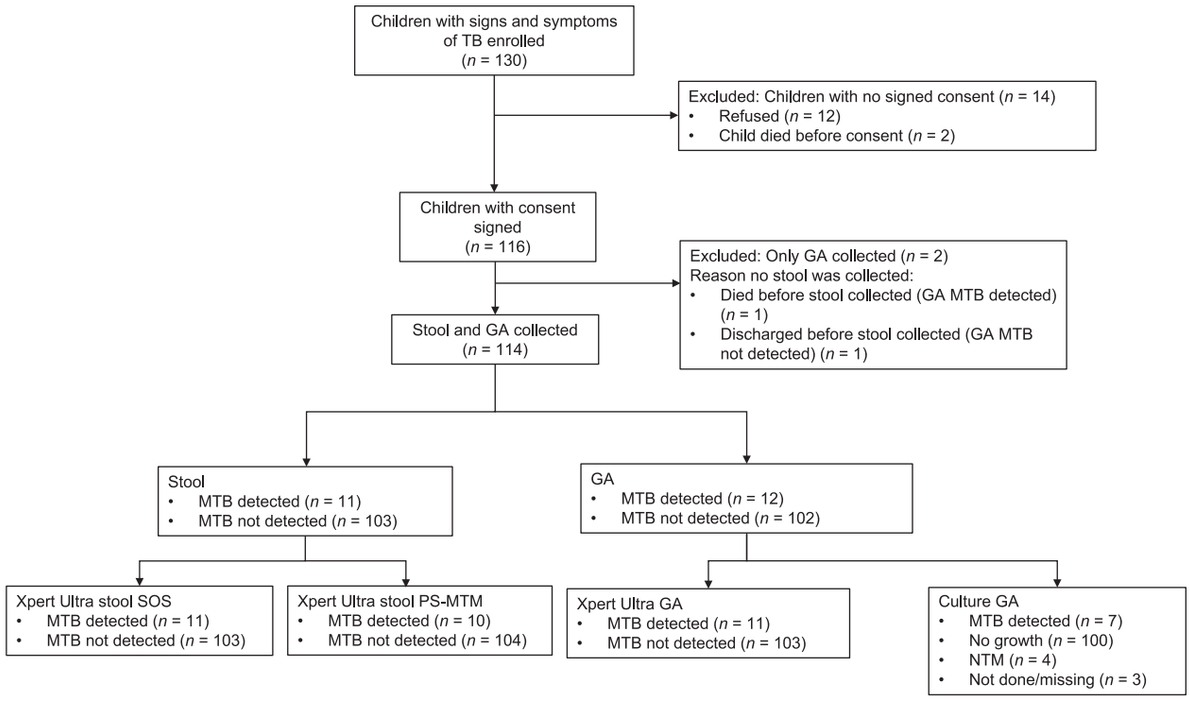

Figure 2 Flow diagram showing the number of children enrolled and their outcome on GA and stool. GA = gastric aspirate; SOS = Simple One Step; MTB = *Mycobacterium tuberculosis*; PS-MTM = PrimeStore® MTM molecular transport medium.

range [IQR] 7–30); 65 (57%) children were male and 27 (23%) HIV-infected, while 18 (15.8%) were HIV-exposed but uninfected. In terms of nutritional status, 54/114 (47.4%) had normal nutritional status while 40/114 (35.1%) had severe acute malnutrition (SAM). Cough, fever and weight loss were the main TB suggestive symptoms reported for respectively 112 (98.3%), 111 (97.4%) and 89 (78.1%) children. A fifth (25/114, 21.6%) of the children reported a history of TB household contact. Seven (6.1%) children were already diagnosed with TB at the time of enrolment and were receiving anti-TB treatment for less than 7 days. All 7 were female, 5 less than 1-year-old and 2 over 1-year-old (42 and 48 months). Excluding these seven children did not result in obvious differences in the results given in Table 2.

Table 2 shows characteristics of the 79 (out of 114 children) diagnosed with TB: the majority (59%) were aged 12–60 months, one-fifth had a history of TB contact, all had symptoms suggestive of TB cough (99%), weight loss (87%), fever (99%) and night sweats (25%), while one-third had enlarged lymph nodes. Also, children diagnosed with TB had poorer nutritional status, with 41.8% of children diagnosed with TB having SAM vs. 20.0% for children not diagnosed with TB ($P = 0.025$).

Among the children with bacteriologically confirmed TB, in comparison to those clinically diagnosed, a larger proportion were female (69% vs. 41%, $P = 0.06$) and 11/13 (84.6%) had signs of moderate to severe respiratory distress compared to 23/66 (34.8%) among the clinically diagnosed ($P < 0.001$). Overall, 10 children included in the study died during hospitalisation; 4 with bacteriologically confirmed TB, 3 with clinically diagnosed TB and 3 children who were not diagnosed with TB.

Comparison between stool processing methods

Table 3 shows the comparison of the semi-quantitative Ultra results of the MTB-positive stool samples for both stool methods. In total, 8 out of 11 results were identical, while one was 'MTB Detected Low' using the SOS stool method and 'MTB Detected Very Low' using the swab-PS-MTM method; one was 'MTB Detected Low' using the SOS method and 'MTB Detected Medium' using the swab-PS-MTM method. There was one discordant result comparing both stool processing methods, one child had MTB not detected by the swab-PS-MTM method, while the SOS method was 'MTB Detected Very Low', the GA Xpert result was 'MTB Detected Very Low' and the GA culture was MTB-positive.

DISCUSSION

On comparing the performance of Ultra using two stool processing methods, the SOS and swab-PS-MTM methods demonstrated very high concordance (113/114, 99.1%) between both methods. There was also very high concordance of stool Ultra results with Ultra results for GA (111/114, 97.4%); this is comparable to other studies[20] and supports the use of stool

Table 2 Clinical characteristics of children diagnosed with and without TB and bacteriologically confirmed and clinically diagnosed TB in the study ($n = 114$)

Variables	All children in analysis ($n = 114$) n (%)	Children not diagnosed with TB ($n = 35$) n (%)	Children diagnosed with TB* ($n = 79$) n (%)	Children with clinically diagnosed TB† ($n = 66$) n (%)	Children with bacteriologically confirmed TB (any sample type) ($n = 13$) n (%)
Sex					
Female	49 (43)	13 (37.1)	36 (45.6)	27 (40.9)	9 (69.2)
Male	65 (57)	22 (62.9)	43 (54.4)	39 (59.1)	4 (30.8)
Age, months					
<12	47 (41.2)	21 (60)	26 (32.9)	22 (33.3)	4 (30.8)
12–60	67 (58.8)	14 (40)	53 (67.1)	44 (66.7)	9 (69.2)
HIV status					
HIV-infected	27 (23.7)	5 (14.3)	22 (27.8)	18 (27.3)	4 (30.8)
HIV-exposed	18 (15.8)	7 (20)	11 (13.9)	10 (15.2)	1 (7.7)
HIV-uninfected	69 (60.5)	23 (65.7)	46 (5.82)	38 (57.6)	8 (61.5)
Reason for presumptive TB					
TB exposure	25 (21.9)	5 (12.5)	20 (20.2)	16 (19.5)	4 (23.5)
TB symptoms	114 (100)	35 (100)	79 (100)	66 (100)	13 (100)
Cough	112 (98.3)	34 (97.1)	78 (98.7)	65 (98.5)	13 (100)
Weight loss	89 (78.1)	19 (54.3)	70 (88.6)	58 (87.9)	12 (92.3)
Fever	111 (97.4)	33 (94.3)	78 (98.7)	65 (98.5)	13 (100)
Night sweats	23 (20.2)	3 (8.6)	20 (25.3)	14 (21.2)	6 (46.2)
Enlarged lymph nodes	31 (27.2)	5 (14.3)	26 (32.9)	23 (34.8)	3 (23.1)
CXR findings abnormal	96 (84.2)	26 (74)	70 (89)	57 (86)	13 (100)
Nutritional status					
Normal	54 (47.4)	23 (65.7)	31 (39.2)	26 (39.4)	5 (38.5)
MAM	20 (17.5)	5 (14.3)	15 (19)	13 (19.7)	2 (15.4)
SAM	40 (35.1)	7 (20)	33 (41.8)	27 (40.9)	6 (46.2)
TB status at enrolment, on ATT <7 days	7 (6.1)	0 (0)	7 (8.9)	5 (7.6)	2 (15.4)
Respiratory findings					
Normal–mild RD	66 (57.9)	21 (0.6)	45 (57)	43 (65.2)	2 (0.2)
Moderate–severe RD	48 (42.1)	14 (0.4)	34 (43)	23 (34.8)	11 (0.9)
Outcome					
Died	10 (8.8)	3 (0.1)	7 (8.9)	3 (4.5)	4 (0.3)
Discharged	104 (91.2)	32 (0.9)	72 (91.1)	63 (95.5)	9 (0.7)

* Clinically or bacteriological confirmed.
† Without bacteriological confirmation.
CXR = chest X-ray; MAM = moderate–acute malnutrition; SAM = severe—acute malnutrition; ATT = anti-TB treatment; RD = respiratory distress.

as an alternative sample for bacteriological confirmation of TB in children as recommended by the WHO.[2]

The high concordance between stool samples processed using the SOS and swab-PS-MTM methods supports our hypothesis that the swab-PS-MTM method does not compromise the Ultra test results. Use of the swab-PS-MTM when implemented could provide several benefits: 1) the PS-MTM stool method requires only 150 mg of stool compared to 0.8 g thus far recommended for the SOS stool method. This can facilitate immediate sample collection by rectal swab, for example, if a child is severely unwell or unable to open bowels at the time of collection. This would avoid a second hospital visit, possible loss to follow-up and reduce patient costs; 2) stool storage conditions are critical, high storage temperatures seem to compromise the quality of the stool resulting in a higher proportion of non-determinate Ultra results.[21,22] Collecting stool in PS-MTM inactivates the TB bacilli and other pathogens and stabilises DNA and RNA at ambient temperature, eliminating the need for cold chain transport and storage; this could facilitate transport of stool from remote sites without degrading the sample quality; 3) the leftover

Table 3 Correlation between the semi-quantitative Ultra results of the MTB-positive stools from both the SOS stool and swab PS-MTM methods

	Ultra results swab PS-MTM method				
Ultra results SOS stool method	MTB detected: medium	MTB detected: low	MTB detected: very low	MTB not detected	Total
MTB detected: medium	1				1
MTB detected: low	1	3	1		5
MTB detected: very low			4	1	5
Total	2	3	5	1	11

Ultra = Xpert MTB/RIF Ultra; PS-MTM = PrimeStore® MTM molecular transport medium; SOS = Simple-One-Step; MTB = *Mycobacterium tuberculosis*.

mixture with stabilised DNA and RNA can be used to perform additional molecular testing (e.g., line-probe assay, Xpert® MTB/XDR testing [Cepheid] and DNA sequencing), and transported easily and safely to a more advanced laboratory in the network, if needed. As this was only a proof-of-concept study we did not test these anticipated benefits for stool samples in practice and further research would be needed to confirm this.

We anticipate that the benefits of the swab-PS-MTM method, as outlined above, could increase access to a bacteriologically confirmed diagnosis, contributing to finding the missing TB cases in children and resulting in more timely treatment for children with TB even more than the current recommended stool processing methods. Further field evaluation is required to measure the feasibility and acceptability of using swab-PS-MTM to transport stool samples. However, transport media such as PS-MTM would need to be sourced separately as it is not provided in the Ultra kit, unlike the SR buffer. This would incur additional costs and would possibly need to be added to the routine supply management system to ensure availability. On the other hand, when using PS-MTM some cost will not be incurred like for cold chain transportation. Also, there might be possible cost savings for the healthcare system from earlier diagnosis. Lessons could be learned from experiences during the SARS-Cov-2 pandemic where PS-MTM was used to safely transport specimens from collection sites to testing sites in several countries.[15,23]

In addition, the use of a swab to collect stool directly from the rectum could be explored, as in the current study we swabbed from a stool sample. We also did not investigate whether conducting the SOS stool method with approximately 150 mg of stool instead of the current recommended 0.8 g would affect Ultra test results. Within the PODTEC (Painless Optimized Diagnosis of TB in Ethiopian Children) Study, experiments were done using different quantities of stool to determine the optimal volume for the SOS stool method. The study protocol outlines details of all experiments designed,[22] the first results indicate that using 300 mg instead of the recommended 800 mg for the SOS stool method did not affect the proportion of MTB detected using Ultra.[22] Based on our experiences and results to date, we expect that lower quantities, like that used for a stool swab, will not significantly affect the proportion of MTB detected. However, such low quantities were not yet tested in practice.

GA culture only detected 54% (7/13) of the bacteriologically confirmed cases included in the analysis. Our findings are similar to other studies where culture performed poorly using GA samples compared to the Ultra test.[24,25] We used recommended methods for collecting GA into two tubes, which were collected during the same procedure. Unfortunately, it was not documented for which child saline was added to enable the GA collection. However, it only occurred occasionally, therefore we do not expect that this is the reason for the poor culture outcome. A more logical reason for the poor culture outcome might be the use of bicarbonate. Conventionally, bicarbonate is used to neutralise the acid in the gastric aspirate to improve culture yield, though research suggests that the use of bicarbonate with MGIT decreases the culture yield.[26,27]

In our analysis, seven children were included that had commenced anti-TB treatment, although all less than seven days. Two children had bacteriological confirmation. One child was MTB culture-positive and had MTB detected in two Ultra tests (GA and SOS stool). The second child was MTB-negative on culture and had MTB detected in all three Ultra tests (GA, SOS stool and PS-MTM stool). We adopted a period of 7 days as in drug resistance surveys (DRS) where samples undergo culture and drug susceptibility testing to determine drug resistance status. A threshold of 7 days is recommended in global DRS guidelines to determine eligibility for enrolment,[28] with patients being treated for less than 7 days being excluded. We also performed the analysis done excluding those seven children and did not observe significant differences.

In our study, 6/11 (55%) children had a MTB Detected Low or Medium Ultra result, whereas the other five were 'MTB Detected Very Low'. We did not observe any MTB trace results. These higher Ultra detection grades possibly reflect more severe TB disease in these children. The large number of clinically diagnosed children (85%) in our study could indicate that despite new options, such as using stool as an alternative sample, important challenges remain to prompt and accurate diagnosis of TB in young children. UTH-CH is a tertiary level referral hospital where children are sent from lower-level facilities. Most of the children included were very sick when seen and the large proportion of study participants eventually diagnosed with TB may reflect missed diagnoses at lower-level facilities.

Having the correct diagnosis early could contribute to reduced mortality. In our study, 10/114 (9%) children died; among those with bacteriologically confirmed TB, 4/13 (31%) died. Although the study was not designed to investigate risk factors for mortality, the children with TB more often had a very poor nutritional status (especially SAM) and respiratory distress. Cost-effectiveness modelling indicated that using stool Xpert or Ultra SOS stool testing close to point of care can be cost-effective and impacts on mortality with a 14–20% relative reduction in mortality observed.[8] The authors indicated that it is crucial that clinical assessment be undertaken alongside negative bacteriological test results because bacteriological testing has a low negative predictive value, especially in young children.[8] It is therefore

imperative that diagnosis of TB in young children is enhanced and access to a bacteriological diagnosis is expanded at lower levels of care to prevent TB-associated mortality among young children.[9,10]

Enhancing the availability of a rapid and straightforward method for testing TB in children is crucial, particularly when a child is critically ill or unable to provide stool or other samples immediately. This innovative approach of utilising a stool swab at the point of care could revolutionise the process of confirming TB through rapid bacteriological testing. This study demonstrates the use of stool swabs in molecular transport media as a potential method for increasing access to Ultra testing on stool for children. Further research is required to confirm whether it could contribute to further decentralising access to a bacteriological confirmation of TB in children.

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None of the authors reported a conflict of interest, except that BK joined Longhorn Vaccines and Diagnostics in November 2021 after completion of all study procedures and main analysis of results.

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RÉSUMÉ

CADRE : Hôpital de niveau tertiaire à Lusaka, en Zambie.
OBJECTIF : Mesurer la concordance entre les résultats du test Xpert® MTB/RIF Ultra (Ultra) sur des échantillons de selles avec et sans milieu de transport, et comparer les résultats Ultra obtenus par les deux méthodes de traitement des selles aux résultats Ultra et aux résultats de culture obtenus à partir d'aspirats gastriques (GA).
MÉTHODE : Cette étude transversale a recueilli des échantillons de selles et de GA auprès d'enfants de 0 à 5 ans présentant des signes et symptômes de TB. Les selles ont été traitées pour le test Ultra selon deux méthodes : la méthode Simple-One-Step (SOS) sur un échantillon de selles et le milieu de transport moléculaire PrimeStore® MTM (PS-MTM) à l'aide d'un écouvillon de selles.
RÉSULTATS : Au total, 114 enfants (âge médian : 17 mois, IQR 7–30) ont fourni à la fois un échantillon de selles et un échantillon de GA. Les résultats Ultra des selles traitées avec la méthode PS-MTM ont montré une grande concordance avec les résultats Ultra des selles traitées par la méthode SOS, avec seulement 1/114 résultats discordants. La concordance avec l'Ultra GA était également élevée, puisque les 9/13 cas de *Mycobacterium tuberculosis* (MTB) détectés ont été identifiés par les trois méthodes.
CONCLUSION : Les résultats Ultra obtenus à partir d'écouvillons de selles prélevées avec le PS-MTM étaient équivalents aux résultats obtenus à partir des selles avec la méthode SOS et du GA. Étant donné que le PS-MTM inactive le MTB et stabilise l'ADN sans chaîne du froid, son utilisation pour les selles a le potentiel d'améliorer l'accès au diagnostic de la TB pour les enfants des régions mal desservies.