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Uptake and feasibility of task-shifting of Xpert MTB/RIF Ultra testing from laboratory technicians to nurses to increase access and reduce time to results: a multicountry mixed method research

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ABSTRACT

Introduction Task-shifting tuberculosis (TB) rapid molecular testing from laboratory technicians to nurses could help decentralise TB diagnosis at primary health centres (PHCs) and allow in-ward testing to shorten treatment decision for very sick patients. We assessed the feasibility of Xpert MTB/RIF Ultra (Ultra) testing on nasopharyngeal aspirate (NPA) by nurses in children with presumptive TB at PHCs and in hospitalised children with severe pneumonia within the TB-Speed project in seven countries.

Methods Of 23 PHCs and 15 paediatric wards, 9 and 4 respectively had nurses trained to perform Ultra using the battery-operated GeneXpert Edge. Laboratory technicians performed testing in the other sites. We compared the proportion of samples tested, invalid or error results, TB detection yield, turnaround time (TAT) between sample reception and result at PHC and time to clinician between sample collection and result delivery to clinicians in paediatric wards between nurses and laboratory technicians. External quality assessment (EQA) and site support supervision assessed performance. Self-administered questionnaire and semistructured individual interviews assessed nurses' perceptions.

Results Ultra was done in 253/254 (99.6%) and 258/258 (100%) samples for PHC and hospital nurses versus 895/897 (99.8%) and 874/874 (100%) for laboratory technicians, respectively. At PHC, TAT was below 1 hour 30 min for 158/252 (62.7%) samples tested by nurses versus 677/893 (75.8%) by laboratory technicians, p<0.001. Ultra results were available to clinicians within 3 hours in 201/258 (77.9%) samples for nurses versus 464/874 (53.1%) for laboratory technicians in hospitals, p<0.001. EQA results <87.5% was more common for PHC nurses than PHC laboratory technicians or hospital nurses. Technical difficulties, lack of practice and workload were the main challenges, and training and supervision the main facilitators reported by nurses.

Conclusion Task shifting of Ultra testing from laboratory technicians to nurses under close supervision could support decentralisation of TB diagnosis and shorten time to treatment decision for very sick patients.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Centralisation of management of tuberculosis (TB) in children contributes to the important gap in paediatric TB notifications observed in many high burden and low middle income countries, and in 2022, WHO recommended the decentralisation of childhood TB diagnosis to increase access.

⇒ The rapid TB molecular Xpert MTB/RIF Ultra test recommended by WHO can be deployed at primary healthcare level but there is still limited data on its use at this level of care and no data for settings without a laboratory.

⇒ Another diagnostic challenge is the diagnostic delay, which can be fatal in very sick children.

⇒ There is no data on in-ward Xpert Ultra testing to shorten diagnostic delays in very sick children.

WHAT THIS STUDY ADDS

⇒ As part of the TB-Speed operational research in 6 countries, we trained nurses from primary health centres without laboratory to perform Xpert Ultra tests on nasopharyngeal aspirate (NPA) sample, using the GeneXpert Edge equipment and with close supervision and sufficient training, task-shifting of NPA Xpert Ultra testing from laboratory technicians to nurses was feasible and well accepted.

⇒ Similarly, in order to reduce diagnostic delays in very sick children, we trained hospital nurses to perform in-ward Xpert Ultra tests on NPA in six countries, nurses were able to achieve similar performance as laboratory technicians and the time to treatment decision was shorter when Xpert Ultra testing was done by nurses as compared with laboratory technician.

⇒ To our knowledge this is the first study assessing Xpert Ultra testing by nurses in high TB burden and low- and middle-income countries (LMICs).

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ It is our hope that results from this study will foster the development of content and context specific approach of task-shifting to increase access and quality of healthcare services for TB diagnosis within the same labour force especially in LMICs.

INTRODUCTION

In 2024, of 10.7 million people estimated to have developed tuberculosis (TB) according to the WHO, 11% (1.2 million) were children. Only 49% of children with TB were notified to WHO by National TB programmes (NTPs) mainly due to under diagnosis.[1] Challenges in diagnosing childhood TB include the paucibacilliary nature of pulmonary TB in children resulting in low sensitivity of existing microbiological diagnostic tests and the difficulty of obtaining respiratory samples in young children.[2 3] In addition, the centralisation of childhood TB diagnostic services in several high TB incidence and low- and middle-income countries (LMICs) reduces access to TB care, and thereby contributes to the gap of childhood TB diagnosis.[4]

In 2022, to improve diagnosis and access to treatment for childhood TB, WHO recommended (1) decentralising childhood diagnosis services to low-level peripheral health facilities and (2) improving the quality of the diagnosis approach and specifically the microbiological testing component by using low-complexity automated nucleic acid amplification tests (LC-aNAAT) like the Xpert MTB/RIF Ultra (Ultra; Cepheid, Sunnyvale, California, USA) on stool samples and nasopharyngeal aspirates (NPAs).[5] This automated GeneXpert platform reduces sample manipulation time and biosafety risks and thereby increases the possibility of using the Xpert assay at low levels of healthcare.[6] The single module GeneXpert Edge (G1), a cheaper, heat and dust resistant, more user-friendly and battery-operated platform could be introduced at primary health centre (PHC) levels where there is a lower number of tests to perform daily.[7] Literature is limited on its use and placement at PHCs or at bedside. Two proof of concept studies reported good feasibility of using G1 at community level by study staff to provide on-site testing too difficult to reach people and at home by means of mobile transportation (boats) and in-home testing of household TB contacts where it eliminated dependence on clinic and referral based testing systems.[8 9] In PHCs without laboratory and thus laboratory technicians, nurses could be trained on how to operate the G1 platform and to perform the Ultra assay. Another use for G1 and reason justifying training of nurses to perform Ultra would be to make the Xpert testing available in paediatric wards to shorten time to diagnosis for highly vulnerable children outside laboratory opening hours.

Apart from simple point-of-care testing such as urine-lipoarabinomannan test, there is no literature on task-shifting of microbiological TB diagnostic tests from laboratory technicians to nurses.[10 11] However, previous experiences in other fields of TB-related healthcare have shown that task-shifting/sharing from workers in specialised or higher cadres to healthcare workers (HCWs) from a different background could address human resource challenges, address unmet health needs, improve healthcare quality in terms of service delivery and accessibility after short trainings with support supervisions in health services.[12–15]

To address the unmet need to improve access to childhood TB microbiological diagnosis, the TB-Speed Decentralisation study implemented Ultra testing on NPA by either nurses or laboratory technicians in children with presumptive TB at PHC level.[16] Similarly, the TB-Speed Pneumonia study that evaluated systematic TB detection in children admitted for severe pneumonia implemented in-wards Ultra testing on NPA by nurses to reduce time to treatment decision.[2]

In this study, we compared the feasibility of Ultra testing on NPA in terms of uptake, performance and turnaround times (TATs) between nurses and laboratory technicians, and we assessed the nurses' perception and experience of Ultra testing on NPA within the TB-Speed Decentralisation and Pneumonia studies.

MATERIALS AND METHODS

Study design, setting and population

We conducted secondary analyses of multicountry, mixed-methods, research data from the TB-Speed Decentralisation and TB-Speed Pneumonia studies. The TB-Speed Decentralisation was an operational research study implemented in Cameroon, Cambodia, Uganda, Mozambique, Côte d'Ivoire and Sierra Leone to assess the impact on paediatric TB case detection of the decentralisation of a comprehensive paediatric TB diagnostic package at district hospitals and PHCs in children <15 years with presumptive TB. Ultra testing of NPA was performed by nurses and laboratory technicians in 9 and 14 PHCs respectively.[16] The TB-Speed Pneumonia study was a pragmatic stepped-wedge, cluster-randomised trial evaluating the effect of adding systematic TB detection

using Ultra on NPA and stools to the WHO standard of care on mortality of children aged 2–59 months admitted for severe pneumonia in 15 tertiary hospitals in Cameroon, Côte d'Ivoire, Cambodia, Uganda, Mozambique and Zambia. 11 hospitals had Ultra testing performed on NPA by laboratory technicians when rapid testing was possible in a laboratory, and 4 hospitals by in-ward nurses[2] (online supplemental material,table S1). In both studies, stool testing by Ultra was performed in a laboratory due to specimen processing requirements prior to testing. G1 was introduced in PHCs and in paediatric wards at bed-side in addition to the GeneXpert devices existing in the laboratory of the same hospital when there was no 24 hours access to the laboratory. In hospital laboratories Ultra testing was done on four module GeneXpert platform. NPA was collected by trained nurses in a separate room in PHC and in a separate room or paediatric ward in hospital. In paediatric wards, Ultra testing was done in small ward laboratory or procedure room. Wastes were discarded according to country policy in some sites and facility's procedure of biohazardous waste disposal in others which included autoclaving and incineration or buried in pits.

The site selection was jointly agreed on based on baseline capacity assessment information by the NTPs and the TB-Speed investigators.

The analyses were conducted among three different populations: children <15 years old with presumptive TB enrolled at PHC level in the TB-Speed Decentralisation study; children 2–59 months old admitted for severe pneumonia enrolled in the intervention arm of the TB-Speed Pneumonia; and all nurses performing Xpert Ultra on NPA in both studies. For this study, the Standards for Quality Improvement Reporting Excellence (SQUIRE) reporting guidelines were used.[17]

Patient and public involvement

The study had community advisory boards at country levels that included former patients with TB to review the proposed intervention, study protocol and the information notice to participants prior to informed consent. The study was overseen by a scientific advisory board at international level that included one patients' representative.

Training and quality assurance of Ultra testing

Hospital nurses had between 1 month and 2 years of experience working in the paediatric ward where the study was conducted. PHC nurses were all involved in outpatient consultations and sample collection. Nurses were trained on NPA sample collection and were trained with laboratory technicians to perform Ultra on NPA. For children with severe pneumonia, the time from sample collection to Ultra result delivery to clinician (time to clinician (TTC)) was set at 3 hours. At PHC level taken into consideration that children were less sick and the implementation aspect, results were expected to be delivered within 24 hours. A 3–5 days theoretical and practical training by each country's project national laboratory coordinators included Ultra testing of at least 1 mL NPA sample according to the manufacturers' instructions using the G1 platform, sample documentation in laboratory registers, issuing of results and basic equipment maintenance and troubleshooting.

For external quality assesment (EQA) of Ultra testing, dried culture spots (DCSs) with inactivated biomimetic controls and negative control test samples manufactured by the accredited SmartSpot Xpert MTB/RIF Ultra EQA Programme (SmartSpot Quality, Johannesburg, South Africa) were dispatched yearly to the respective countries with 12 and 8 DCSs per site (4 DCSs per panel) to be analysed systematically by HCWs biannually for TB-Speed Decentralisation and quarterly for TB-Speed Pneumonia.

In the TB-Speed Decentralisation sites only, site support supervision visits were planned to supervise the decentralisation of the diagnostic package once every month for the first quarter and then quarterly. During each visit, laboratory specialists from the national referral hospitals assessed PHCs' laboratory technicians' and nurses' performance on Ultra testing (through a specific scoring system) and provided technical guidance. In the TB Speed Pneumonia study, Ultra results per site were reviewed monthly from the GeneXpert equipment platforms by the national laboratory coordinator where, error rates (>5%), invalid and no results rates (>2%) called for actions such as re-training or technical intervention.

Study endpoints

We assessed the feasibility of Ultra testing according to four specific outcomes. First, the uptake and yield of Ultra testing on NPA samples was assessed based on the following indicators: (1) proportion of Xpert Ultra tests performed on successfully collected NPA samples; (2) proportion of invalid or error Ultra results; (3) MTB detection yield among Ultra valid tests. Second, TAT of Ultra testing defined by the measure of time from sample reception to test result (when the test is complete) in the TB-Speed Decentralisation with a cut-off set at 1 hour 30 min based on the manufacturer test brochure and time from sample collection to test result communication to clinician (TTC) in the TB-Speed Pneumonia with a cut-off set at 3 hours to ensure prompt treatment decision. Third, the performance of Ultra testing was assessed by the EQA results in both studies and the performance scores from site support supervision reports in the TB-Speed decentralisation study. We classified EQA panel result of 87.5% or above as acceptable as per the EQA sample manufacturer Smartspot (SmartSpot Quality). The performance indicators for Ultra-testing included: (1) availability of laboratory procedure for Ultra testing; (2) testing of NPA samples at PHC as planned; (3) delivery of Ultra results to clinical team within 24 hours; (4) proper reporting of results in the sample register; (5) proper entry of sample identification number into the GeneXpert software; and (6) punctual testing of TB samples (on G1). Each indicator was scored using the

Likert scale (1—Never, 2—Rarely, 3—Sometimes, 4—Often, 5—Always). The indicators were assessed through real-time observation. In cases where no sample was available for testing, the NPA Ultra testing procedure was simulated, and any indicators that could not be observed were marked as 'NA' (non-applicable). Lastly, the experience and perceptions of nurses towards performing Ultra test on NPA samples, using the G1 platform, were assessed using self-administered questionnaires in the TB-Speed pneumonia study and by semistructured interviews with nurses in both studies. Barriers, facilitators and possibilities for scaling-up and sustaining Ultra testing on NPA performed by nurses were specifically assessed. Nine nurses (3 males and 6 females), median age 32 (31–36) years from seven sites in Cambodia, Cameroon and Côte d'Ivoire in the Decentralisation study and 16 nurses (3 males and 13 females), median age 39 (36–44) years, from four sites in Côte d'Ivoire, Mozambique and Zambia in the Pneumonia study, were interviewed.

Data collection

To assess the uptake, yield indicators and times, data were retrieved from the clinical database of both studies using Research Electronic Data Capture (REDCap) and imported into an excel database. EQA panel sample testing results exported by sites from the GeneXpert platform were uploaded to the SmartSpot platform as .CSV files by country's laboratory coordinator and frame scores were sent back to laboratory coordinators by the SmartSpot team after analysis. All sites' results were recorded in an excel database (online supplemental material table S2). Performance indicators were collected in paper-based site support supervision forms completed by supervisors on site. Score results were entered into a REDCap database by research assistants.

Self-administered questionnaires were filled anonymously by referral hospital nurses only on tablets directly into a dedicated REDCap database after each sample testing by Ultra in TB-Speed pneumonia study. Semistructured interviews, following a predefined interview guide, were conducted with nurses either face to face or on phone (during the COVID-19 pandemic) by trained social science research assistants (SSRAs) in each country, from June to August 2021, for TB Speed Decentralisation and from November 2020 to March 2021, for TB Speed Pneumonia. The interviews were recorded with the nurse's permission, transcribed and translated to English when required and uploaded on a secure server from where it was retrieved for the purpose of this study.

Data analysis

Quantitative data were presented using percentages, median and IQR values by study and by site for EQA and performance scores between nurses and laboratory technicians by study. χ^2 tests were used to compare proportion. Median of TAT and TTC was compared using the Wilcoxon rank test where TAT and TTC were ranked order in both groups (nurses vs laboratory technicians) and the distribution between the two groups was compared with the null hypothesis that the distribution in group one is equivalent to the distribution in group 2. Density distribution overlaid on box plot of Log10 transformed TAT and TTC were presented. This was performed using R studio software (V.4.3.2, R Foundation for Statistical Computing).

For qualitative data, codebooks were developed by the implementation research team, based on deductive and data-led approach. Interviews were coded by country SSRAs and analysed by country in NVivo Release qualitative data management software, QSR International Private, V.1.5, 2021. Multicountry intercoder reliability was maximised by SSRAs coding the same three transcripts and reviewing together the coded data. Thematic summaries were prepared by SSRAs, with support from the study investigators; themes were defined based on the Sekhon theoretical framework of acceptability where we categorised themes under relevant domains of the framework as follows: Knowledge; Burden (workload, technical issues, long and difficult sample process, lack of samples); and Self-efficacy (training, supervision visits, support from research team, specific delegation of task).[18]

RESULTS

In terms of uptake, at PHC level, 253/254 (99.6%) and 895/897 (99.8%) samples were tested by nurses and laboratory technicians respectively, and at referral hospitals, all samples were tested independently of operators being a nurse (258/258, 100%) or a laboratory technician (874/874, 100%). The average number of NPA Ultra tests per month ranged between 0.5 and 5.0 across PHC sites with Ultra testing done by nurses and 0.3 and 16.4 for testing done by laboratory technicians. For paediatric wards it ranged between 5.0 and 9.5 in settings with Ultra testing done by nurses and 2.2 and 19.3 for sites with Ultra testing done by laboratory technicians (online supplemental material, table S3).

There was no significant difference of detection yield between nurses and laboratory technicians. Although the proportion of invalid and error results was overall very low (<5%) it was significantly higher when testing was done by nurses versus laboratory technicians at both PHC and referral hospitals (table 1).

All PHCs participated in both EQA panels but one due to a missing EQA panel. There were 2/9 (33.3%) PHCs with nurses that had results >87.5% in all EQA panels versus 9/14 (64.3%) for PHCs with laboratory technicians, p=0.487. At referral hospitals, 1/4 sites with Ultra testing done by nurses and 3/11 sites with testing done by laboratory technicians did not participate in any EQA panel because panels had expired when the sites were randomised to the intervention. Since the TB-Speed pneumonia study had a stepped wedge design, the number of EQA panels per site depended on the time of randomisation to the intervention of each site. There were 2/3 (66.7%) sites that had all EQA panel results

Table 1 Uptake of Xpert Ultra testing on nasopharyngeal aspirate by nurses and laboratory technicians

	Primary health centres			Reference hospitals		
	Nurses	Laboratory technicians	P value	Nurses	Laboratory technicians	P value
Samples received, N	254	897		258	874	
Samples tested, n (%)	253 (99.6)*	895 (99.8)*	0.637	258 (100)	874 (100)	NA
MTB detected, n (%)	2 (0.8)	3 (0.3)	0.348	1 (0.4)	20 (2.3)	0.047
MTB not detected, n (%)	242 (95.7)	877 (98.0)	0.037	249 (96.5)	847 (96.9)	0.748
Invalid or error, n (%)	9 (3.6)	11 (1.2)	0.012	8 (3.1)	7 (0.8)	0.005
GeneXpert Platform, n (%)						
G1	253 (100)	895 (100)	NA	258 (100)	0	NA
G4	0	0	NA	0	874 (100)	NA

*One missing sample by nurses and two missing samples by laboratory technicians due to technical issues and sample not received by the laboratory.
G1, EDGE; G4, GeneXpert IV; MTB, *Mycobacterium tuberculosis*; NA, non-applicable.

>87.5% vs 6/8 (75.0%) in sites with nurses or laboratory technicians (p=0.640), respectively (figure 1).

The median TAT of Ultra testing from sample reception to Ultra results at PHC levels, was 1.13 hours (IQR 1.08–1.79) for nurses and 1.10 hours (1.07–1.45) for laboratory technicians, p<0.001. The TAT was below 1 hour 30 min for 158/252 (62.7%) samples tested by nurses versus 677/893 (75.8%) for samples tested by laboratory technicians, p<0.001. At referral hospitals, the TTC was 1.95 hours (1.5–2.87) for nurses and 2.87 hours (1.97–4.81) for laboratory technicians, p<0.001. The TTC was within 3 hours for 201/258 (77.9%) samples for nurses versus 464/874 (53.1%) for laboratory technicians, p<0.001 (online supplemental material figure S1).

The median performance score results ranged between 4 and 5 out of 5 points for all performance indicators at PHC levels for sites with nurses and laboratory technicians (figure 2).

At referral hospital sites, self-administered questionnaires were available for 16 nurses. Nurses reported the Ultra testing procedure easy for 72/156 (46.2%) tests performed and facing technical difficulties for 18/156 (11.5%) tests (table 2).

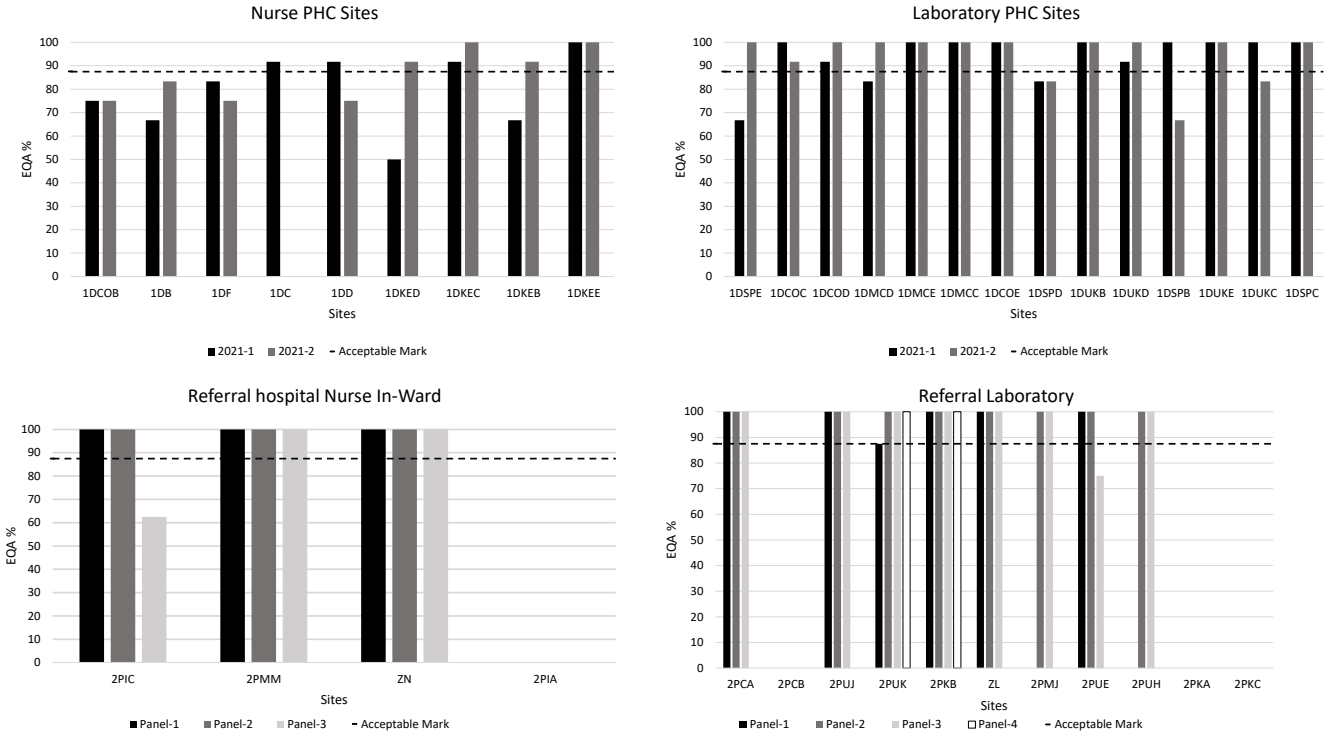

Figure 1 EQA panel results. (a) For nurses at PHC sites. (b) For laboratory technicians at PHC sites. (c) For nurses at referral hospitals. (d) For laboratory technicians at referral hospitals. EQA, external quality assurance; PHC, primary health centre.

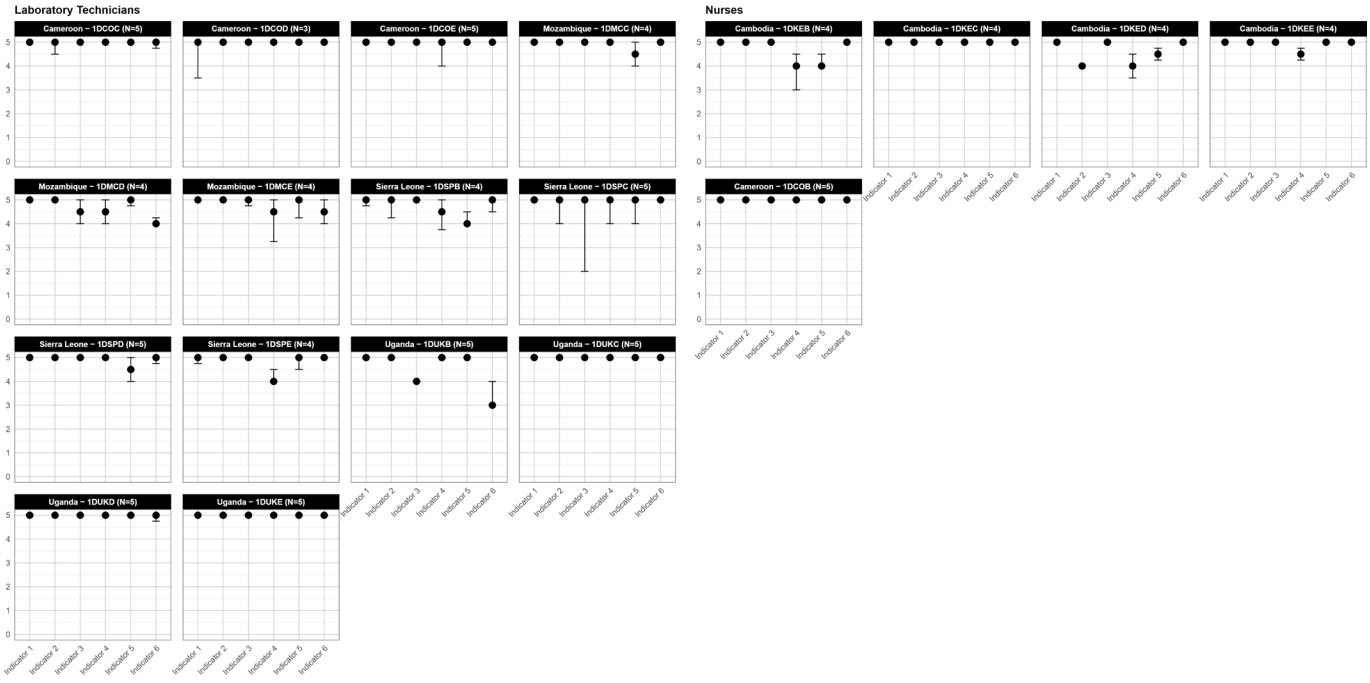

Figure 2 Performance score results of site support supervision at primary healthcare levels. (a) Laboratory technicians. (b) Nurses. IQR Likert scale; 1—Never, 2—Rarely, 3—Sometimes, 4—Often, 5—Always and NA. *Indicator 1*=Availability of laboratory standard operating procedure (SOPs) for TB testing. *Indicator 2*=Testing of NPA samples for TB on site. *Indicator 3*=NPA results sent to clinical team within 24 hours. *Indicator 4*=Proper reporting of results in the specimen register. *Indicator 5*=Proper entry of sample IDs into the GeneXpert software. *Indicator 6*=Timely testing of TB samples (on GeneXpert). NA, non-applicable; NPA, nasopharyngeal aspirate; TB, tuberculosis.

Table 2 Self-administered questionnaires on Xpert Ultra testing from nasopharyngeal aspirate reported by nurses at referral hospital level

	NPA samples tested (N=156)
How would you qualify the Ultra test you performed for this child?	
Easy	72 (46.2)
Neither easy nor difficult	73 (46.8)
Difficult	6 (3.8)
Impossible	4 (2.6)
Missing	1 (0.6)
Did you face any technical difficulties during this Ultra testing?	
No	137 (87.8)
Yes	18 (11.5)
Missing	1 (0.6)
Technical difficulties reported by study nurse running Ultra on G1	Nurses (n=18)
Spilling of sample occurred	0 (0)
Issue while pipetting the sample or the reagent	3 (16.7)
Difficulties in manipulating the G1 edge	0 (0)
Technical error occurred when running the test	14 (77.8)
Ran out of battery	1 (5.6)
Unidentified reason for the technical difficulty	0 (0)
Other	2 (11.1)

NPA, nasopharyngeal aspirate.

Difficulties were mostly related to the occurrence of technical errors when running the tests. During interviews, nurses reported that, during the first few weeks, performing Ultra testing was not so easy, but that they had felt more confident with time and practice*:* "First, the process is difficult, long process for it. For other work process, if we do more and more, we get faster, but for this process, it is related to a lot technical, like computer and typing. It takes time it is difficult" *(Cambodia-PHC Nurse*).

Among the challenges, nurses reported experiencing technical issues with scanning barcode of the cartridge: "Sometimes, scanning barcode doesn't match with cartridge. So, the cartridge will be broken, and we need to change new one. When scanning doesn't match, we disconnect the cable from computer and then connect and scan again. Sometime, we put it in machine but computer also errors. It ran for a while then it can run backward. I had met this challenge. Then, I tried to put it again and call to Mr. XXXX and he suggested to put it again" *(Cambodia- PHC Nurse);* inserting the cartridge in the GeneXpert module: "With the machine, what we often have difficulty with is the last stage where the machine has to open, the part where you put the cassette in, and it often refuses, so you have to start again several times. (…) So that's the difficulty. Otherwise, when it works, there are no problems" *(Cote d'Ivoire PHC Nurse);* and using the computer for documentation and navigating the platform: "My dear, we don't know how to handle computers, that's our problem (laughs). We don't know how to handle computers. I myself had to… it's because I had to force it…force it a little bit, that's my little worry, technology is not my forte. But as I wanted. I was curious, so I forced it" *(Cote d'Ivoire, ward nurse*).

Another challenge more specific to PHC nurses was the lack of practice, due to few samples to test each week, "If I did not do it long time, I will forget it again. … I get confused. If I do it more often I will remember it. …" *(Cambodia-PHC nurse*). On the other hand, some nurses reported the issue of increase in workload, especially when they have to rerun a test due to error result: "….it's an extra activity yeah, …. it's the lab to run except the RDT, now in this case it me to wait for probably 87 minutes for it to run, if it gives me error then I need to retrieve the bio-banked sample I start preparing, I has given me a work overload" *(Zambia, Ward Nurse*).

Nurses highlighted several experiences of facilitators that included the training and training materials that they could consult after training and the support during supervision visits: "When I take the NPA sample, I mark everything because you have to mark the time of sampling. I go to my laboratory because it's a small lab there, I go to the lab, the procedure for doing the technique is there, I look at the procedure, I technique the NPA and then I put it into the Xpert and I wait 87 minutes and then the result comes out." (*Cote d'Ivoire PHC Nurse*).

Nurse explained that the technical challenges could be overcome by contacting laboratory technicians: "Sometimes when we have such errors we usually call for a meeting with the lab so that we help and understand why we are having such errors, so they usually attend." *(Zambia, ward nurse*). They appreciated the battery operated equipment: "(…) the machine itself runs on an autonomous battery, and we have up to two batteries. So even if there's a power cut, we can work". (*Cote d'Ivoire PHC Nurse*). Additional results can be found in online supplemental material table S4.

DISCUSSION

In these two studies, task-shifting of Ultra testing on NPA samples with G1 from laboratory technicians to nurses was feasible and well appreciated irrespective of the level of facility with the support of training, supervision and quality assurance. These findings support the decentralisation of childhood TB diagnosis at PHC level to increase access to care.[19] Using Ultra testing by nurses in-ward significantly reduced the time to result communication to clinicians as compared with sites where testing was done in laboratory by laboratory technician.

The uptake of Ultra testing was very high in all facilities with either nurse or laboratory technician with only few invalid or error results. However, the proportion of invalid or error results was higher when testing was done by nurses, which is consistent with the lower EQA results in sites where the testing was done by nurses, especially at PHC level. This highlights the importance of training and supervision, as raised by the nurses during the interviews. The PHC nurses mentioned their challenge with the lack of experience due to the few samples to be tested per week, which can explain the trend of lower performance by PHC nurses than by referral hospital nurses. The number of tests per week might be a criterion to consider before decentralising Ultra testing at PHC level to secure good performance.

Among challenges, nurses mostly reported technical challenges in relation to laboratory practices such as pipetting or to data entry. Increased workload, fear of getting infected from positive samples, and lack of reliable power supply were additional challenges reported by nurses, which are similar to previous experiences regarding implementation of on-site molecular TB testing in Uganda and Mongolia.[20 21]

Training and close supervision were highlighted as key facilitators by nurses. This is consistent with previous experience on task shifting of TB–HIV coinfection management in Uganda.[22]

In as much as task-shifting was possible in our study, we need to be wary of the workload of the nurses and to recommend that a content and context-specific approach should be considered for task shifting where applicable to support nurses to effectively adapt to performing new tasks.

Within TB-Speed, Ultra testing was a new experience for nurses and was met with enthusiasm about the positive impact it would have on the quality of childhood TB

diagnosis services. The experience of learning something technical and independently executing it after a few days of training and periodic support gave the nurses a sense of confidence, increased their knowledge and autonomy in their capacity to provide reliable and quality healthcare services in shorter time to the community. This tends to increase job satisfaction of the HCW.[18 23] Nurses at PHC levels perceived that being able to provide such a high level of service which is normally not at their level to provide will boost their career, increase confidence of the community in them and the visibility of their health facilities and roll-out patient referral, as mentioned in the interviews, thus increasing population access and coverage.[22 24 25]

The main study limitation was the potential site selection bias. Sites with Ultra testing done by nurses or laboratory technicians were selected for convenience based on implementation requirements following site assessment. Therefore, sites implementing Ultra by nurses or laboratory technicians were not randomly selected and the study did not perform direct comparison within different cadres in the same context. We did not control for the heterogeneity between sites including factors related to the healthcare system and its cadres. Although it was an operational research done with existing facility staff, the study conditions in terms of support may not reflect what would be available in real life. In addition, since the completion of the study, the G1 has been discontinued by the manufacturer, further assessment with nurses using other platforms for NAAT might be necessary. Truenat MTB Plus assay (Molbio diagnostics, Goa, India) is another WHO recommended LC-aNAAT suitable to PHC level and a large cluster randomised trial in Mozambique and Tanzania have shown its effectiveness and feasibility when used by microscopists.[26 27] Although this test has been rolled out in many high TB burden and resource limited countries—including some of the countries that participated in the study since its conclusion, such as Cameroon and Mozambique, there is however no data on stool analysis for TB diagnosis using Truenat, thus limiting its application for diagnosing TB in children. Furthermore, no data has been published regarding its use by nursing staff. While among near point of care-NAAT, the MiniDock MTB test (Pluslife, Guangzou, China) is the only one recommended by the WHO using sputum or tongue swab in adults but not for childhood TB diagnosis.[28 29] Finally, we were not able to assess the potential negative externality because we did not document the impact of adding a new task on the performance of the other nurses' tasks.

In conclusion, the study findings suggest that task-shifting from laboratory technicians to nurses for on-site TB molecular diagnostic testing could contribute to improve access to microbiological TB diagnosis at PHCs and could reduce time to treatment decision. If the testing capacity of the GeneXpert device allows for, other tests could be used on the same platform offering the possibility to increase access to different point of care tests in settings without laboratories. Also, considering the simplification of the stool specimen processing using the Simple One-Step method prior to Ultra testing, stool Ultra testing by nurses could be considered pending adequate training and support.[30] The cost-effectiveness of this task-shifting would be also interesting to evaluate in a healthcare services perspective.

Regardless of the technological advancements and development of molecular testing platforms geared towards increasing accessibility to tests and overcoming infrastructural and environmental limitations, close support supervision and support after training is key in identifying and addressing underlying challenges. This can aid to redesign or develop context and content-specific training programmes followed by periodic refresher trainings to build the capacity of the HCW in adopting and performing new tasks.[23 26 27] Human resource shortage and high mobility are a huge challenge in LMICs and task-shifting could contribute to fill-in this gap.

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Contributors OM, MB and EW conceived and designed the TB-Speed Decentralisation and Pneumonia studies. JO-G coordinated the qualitative component of both studies. OM, MB and EW led the study at international level. J-VT, RM, GB, JM-A, LBB, CC, CK and EW coordinated the implementation of these studies in the different countries. RMK, MSNG, KMK, EMAM, SY, EMN, TDO and JRM coordinated laboratory activities at country level in the different countries. BB and JB coordinated on site qualitative data collection. ML and EMN coordinated laboratory activities at the international level. EMN as part of her PHD project collected data, performed analyses and wrote the first draft of the manuscript with support from JO-G, MB, BB and JB. All authors reviewed and approved the final version of the manuscript. MB is the guarantor.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Ethics approval The study was approved by National Ethics Committees of all the participating countries, the WHO Ethical Review Board and the Institutional Review Board of Inserm (Institut National de la Santé et de la Recherche Médicale, Paris, France). Individual consent was obtained from the parent/guardian of each child before enrolment in the studies and an assent was obtained if the child was old enough. Written informed consent was taken prior to administration of questionnaires and interviews from all the nurses who participated. The study was globally approved by the WHO Ethical Review Committee (ERC). For the TB-Speed Pneumonia, the dates of national approvals are: Côte d'Ivoire, 24 June 2021; Uganda, 3 December 2020; Zambia, 12 January 2021; Cambodia, 1 September 2020; Cameroon, 19 May 2021; Mozambique, 17 June 2021; Inserm, 12 November 2020. TB-Speed Decentralisation was approved by the WHO Ethical Review Committee (ERC). ERC approval: Protocol ID: ERC.0003166.

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