LabCoP EXTENDED ECHO SESSION

Near Point of Care (nPOC) TB Diagnostics: from demand forecast to diagnostic system design

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nPOC Use Cases and Zim Experience

1. **What are you referring to when you talk about nPOC?**
   - ⇒ Near point of care (nPOC) nucleic acid amplification tests (NAAT) are a new class of rapid molecular technologies that were recommended by WHO in early 2026 to strengthen detection of tuberculosis.
   - ⇒ Compared with conventional molecular platforms, nPOC devices are more portable, require less sophisticated laboratory infrastructure, and are available at a lower device and test cost, making them well suited for deployment at peripheral and primary health care facilities that currently lack on site molecular testing capacity. The molecular technology for first recommended nPOC (Pluslife) also gives you a result in less 30 minutes.
   - ⇒ There are now three main classes of molecular WHO recommended rapid diagnostics (mWRD): nPOC (with Pluslife as first in class), LC-NAAT (Xpert, Truenat, TB-LAMP) and MC-NAAT (BD, Roche). WHO also recommended the use of tongue swabs on nPOC and LC-automated NAATs for detection of TB and rifampicin resistance in adults and adolescents that are unable to produce sputum.

2. **What is the performance of the test**
   - ⇒ Evidence on test accuracy that supported the WHO recommendation included five studies (9 countries, 3921 participants) that evaluated sputum samples and six studies (10 countries, 3335 participants) that evaluated tongue swabs against a microbiological reference standard. Use of NPOC-NAAT on sputum had a sensitivity of 85.4% (95% CI 82.2-88.1) and specificity of 97.6% (95% CI 96.9-98.1). In tongue swabs, the sensitivity was 76.4% (95% CI 71.2-80.9) with specificity of 99.2% (95% CI 98.7-99.5). In Zimbabwe, compared to Xpert MTB/RIF Ultra on sputum samples the positive percentage agreement was 86.7% (95% CI 82.5 - 90.1) and a negative percentage agreement of 97.9% (95% CI 97.0 - 98.1).

3. **Is the intention to replace GeneXperts with nPOC? How would this impact on current Rif testing capabilities at country levels? Wouldn't replacement be counterproductive? can roll out of nPOC be done side by side to GXP**
    - ⇒ The intention is not to replace GeneXpert, but to complement it by using nPOC to move initial TB testing closer to patients. The strongest case for nPOC is at lower-level sites/PHCs that currently host microscopy or refer TB samples to GeneXpert/TrueNAT sites and where patients first seek care. At these sites, nPOC can expand access to molecular testing, shorten turnaround time, and reduce loss to follow up. Where GeneXpert is already available on-site, shifting initial testing to nPOC may provide limited additional access benefit while using an assay with lower per-test sensitivity than Xpert Ultra. We would therefore prioritize nPOC placement at sites where it expands access to molecular testing.
    - ⇒ However, GeneXpert will still be critical part of TB diagnostic network. Current generation nPOC platforms do not provide rifampicin resistance testing. Patients with a positive nPOC result would therefore still need reflex testing on GeneXpert or another appropriate platform for RIF resistance. GeneXpert would consequently remain an important part of the diagnostic network, but its role could increasingly shift from initial diagnosis toward reflex drug-resistance testing.

4. **Thanks for Zimbabwe experience presentation, for microscopy sties with 100 % treatment initiation, could it please be possible to clarify where reflex testing took place and estimated time to Tx initiation?**
    - ⇒ At these sites, treatment was initiated on the same day following positive nPOC result. The same sample was subsequently referred to GeneXpert site for reflex rifampicin-resistance testing. Treatment was initiated without waiting for the rifampicin resistance result.

5. **This topic is very interesting and regard this I want to know how to mix or combined nPOC and alternative sample to improve the performance in terms of diagnostic and increase the notification of TB case in our countries?**
    - ⇒ MiniDock MTB can test either sputum or tongue swabs, with sputum remaining the preferred sample. WHO emphasized that tongue swabs can be used with nPOC among adults and adolescents who are unable to produce sputum.
    - ⇒ Despite lower per test sensitivity, tongue swabs could help improve diagnostic yield at the program level because they are easier to collect and can be obtained from nearly all patients. There is early modelling evidence (Bezuidenhout et al., CID January 2026) that a strategy combining both

sputum and tongue swab testing could substantially increase case detection, particularly in community and household contact screening. However, no published clinical trial has yet evaluated the incremental yield of testing both samples on nPOC.

6. **Can other tests, apart from TB, be conducted on nPOC**
   ⇒ nPOC platforms are designed to run assays for multiple diseases, not only TB. These include assays for respiratory infections (influenza and RSV), sexually transmitted infections (STIs), HPV, and HIV viral load, which are currently being considered. However, the Pluslife TB assay is currently the only one that has received WHO policy recommendation and Global Fund ERPD listing. The Pluslife TB assay is yet to receive WHO Prequalification (WHO PQ). HPV assays on these platforms are undergoing validation, while other disease assays are at varying stages of development, design lock, clinical trials, and regulatory review across manufacturers.

Training & Quality Control

7. **What material is being used for operator training?**
   ⇒ Zimbabwe adapted training materials developed through the RADxAR TB trainer-of-trainers program to the local context. The NTP and CHAI developed operator training manuals, SOPs, and MiniDock operation and troubleshooting guides, which remain available at trained sites for ongoing reference.
   ⇒ Zimbabwe focused on integrating the HPV arm into single training package alongside TB, distinguishing the two workflows at the bench level, and incorporating the referral linkage for further drug susceptibility testing.

8. **Was the assay operated by trained lab personnel only, or also by health care workers?**
   ⇒ In Zimbabwe, only trained lab personnels are currently operating the platform and running the tests. At present, the program does not have any plans to extend this to health care workers

9. **What EQA/QC processes do you have in place for nPOC in Zimbabwe**
   ⇒ In December 2025, CHAI established and supported in-country proficiency testing (PT) panel production capacity at NMRL for HIV, syphilis, hepatitis B, and TB LAM. This model is now being replicated at Zimbabwe's National TB Reference Laboratory (NTBRL) for Pluslife nPOC panels. NTBRL, which leads the country's TB reference laboratory functions, is

developing Pluslife specific panels using the same hands-on approach, with distribution to testing sites planned for Q4 2026.

10. **In your context how you handle the issue of samples quality in the implementation of nPOC?**
    ⇒ Our guidance is to test all samples rather than reject them based on their appearance or perceived quality. This helps keep the process simple and avoids excluding patients unnecessarily. If a test produces an invalid or unsuccessful result, it should be repeated or managed according to the testing algorithm.

11. **Also, now we are talking about molecular testing on nPOC mainly for diagnostic, how about the follow-up knowing that for that we still using microscopy?**
    ⇒ nPOC tests are being recommended for initial TB diagnosis, not for treatment follow-up. Smear microscopy would continue to play a role for treatment monitoring and follow-up. WHO recommends molecular WHO-recommended rapid diagnostics (mWRDs) as the initial test for all people being evaluated for TB, yet only 54% of people with TB received an mWRD as their initial diagnostic test in 2024. Aim is for nPOC to help close this diagnostic access gap.

Cost & Sustainability

12. **According to sensitivity and specificity, smear microscopy is very poor to diagnosis TB, but GeneXpert is the preferred. In the low resource settings like Africa, is it affordable to achieve nPOCT?**
    ⇒ Yes, nPOC is expected to be more affordable than existing NAAT platforms in resource-limited settings, given its substantially lower device and test costs. In countries where GeneXpert is already widely used, placing nPOC at peripheral facilities could also reduce sample transport costs by limiting referrals to GeneXpert sites. While patients with a positive nPOC result may still require GeneXpert or a similar test for rifampicin-resistance testing, this would involve a much smaller proportion of samples than if GeneXpert were used for initial diagnosis.

13. **Looks like great results to increase the number of cases detected with Pluslife vs Microscopy. That means more specimens to be reflexed to the higher level for resistance testing. The challenge I am not sure l understand is the financial one: replacing Microscopy with Pluslife means more $. It means more positive cases funds to be reflexed to GX, so again more $. One earlier**

slide was talking about utilization of cost savings… which cost savings? Again, costs is one aspect but finding more cases is just fantastic!

- ⇒ Most TB programs have been increasing molecular testing on low complexity NAAT tests (LCNAAT) such as GeneXpert or TrueNAT given smear is not recommended for initial TB diagnosis by WHO given its low sensitivity. The cost savings from nPOC would come from replacing LCNAAT for initial diagnostic testing. Every initial diagnostic test that shifts from LCNAAT GeneXpert to nPOC would yield savings in the budget. While replacing microscopy with nPOC would increase cost, it offers a different value proposition of improved sensitivity and expanded molecular access. In practice, most countries would need to concurrently substitute for both the existing tests. Savings generated from LCNAAT substitution by replacing referral volumes can offset the cost increase from replacing microscopy.
- ⇒ On the point about reflex testing: reflex volumes are a fraction of total initial diagnostic volumes because TB positivity rates are typically lower than 10%. In our model, the savings generated from shifting a portion of initial LC-NAAT testing to nPOC exceed the incremental cost of additional reflex testing.
- ⇒ The reinvestment scenario presented in the session illustrates what happens when programs hold their diagnostic commodity budget constant and recycle these savings into additional testing.

14. **At the microscopy sites, do you test NPOC using only tongue swabs, or do you also test sputum samples? And a second question, did you encounter any significant issues with power outages or interruptions during NPOC runs at those sites?**
    - ⇒ Sputum remains the preferred sample type. Where a patient is unable to produce sputum, a tongue swab can be collected as an alternative. In Zimbabwe specifically, however, the current implementation is using sputum samples only.
    - ⇒ On power supply, we have not seen major disruptions to nPOC testing so far. The MiniDock itself is battery-operated, so continuous mains power is not required during the test run. UPS power is primarily needed during the sample processing step for the ThermoLyse. In Zimbabwe, sites do experience power outages, and these contribute to some of the testing errors reported, but to date they have not been a major constraint on implementation.

15. **Could you please also indicate what are the plans if any to shift procurement of NPOC reagents to domestic funding (i.e.: does the NSP include transition of the associated costs) as this would be key to longer term sustainability of the pilot?**
    ⇒ For the period 2027 to 2029 there are no plans to shift procurement of nPOC reagents to domestic funding as these will be procured through Global Fund.

16. **Can Dr. Kelvin please share an example of one of the reflex pathways utilized in Zim? Thank you.**
    ⇒ The reflex pathway utilised in Zimbabwe is such that only samples from patients with the positive results on nPOC are referred from the microscopy sites upstream to a site with a GeneXpert machine and usually the district level Lab.

17. **Why did the NTP not plan to cover a % of health facilities that don't have TB diagnosis available or at community level to improve access to TB diagnosis.**
    ⇒ The rollout included 57 microscopy sites that previously did not provide initial TB diagnostic testing and were used primarily for treatment follow-up. In Mashonaland West alone, 10 sites that had not previously been providing TB diagnostic testing were trained and are now using nPOC. This allows testing to move closer to patients while building on existing facility infrastructure.

18. **Could you say a few words about maintenance of the hardware, service needs and the support network?**
    ⇒ In Zimbabwe, the local distributor is responsible for equipment maintenance and servicing. If a platform malfunctions and cannot be repaired, the distributor also manages equipment replacement. This provides a local support mechanism for sites and helps minimize downtime.

19. **nPOC will have impact where referral system rate is high, especially at microscopy sites. Let us keep in mind that referral system did not work in all the sites. What are you doing to strengthen both sample referral and result return?**
    ⇒ Zimbabwe already has a relatively well-established sample referral and result dissemination system through the Integrated Specimen Transport (IST) network. Motorbike couriers typically visit microscopy sites once a week to collect samples and support result return.

⇒ There can still be operational disruptions. For example, at one site, sample collection was interrupted due to fuel shortage and then later addressed and services resumed. These experiences reinforce the importance of monitoring the referral network alongside nPOC rollout and addressing site-level bottlenecks quickly.

Demand Generation & Advocacy

20. We would like to know the roles played by the CSOs in the Zimbabwe efforts in terms of messaging and mobilization

⇒ CSOs were not engaged in community mobilization. Subject to available resources, CSOs could support community awareness and linkage of people who may benefit from testing to nPOC-enabled sites.