Healthcare-worker versus self-collected tongue swabs for *Mycobacterium tuberculosis* detection

963

Anura David[1], Gregory P. Bisson[2], Salome Charalambous[3], Lesley Scott[1], Griffiths Kubeka[3], Lyndel Singh[1], Pedro da Silva[4], Wendy Stevens[1, 4], Yeonsoo Baik[2]

[1]Wits Diagnostics Innovation Hub, Health Sciences Research Office, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa; [2]Perelman School of Medicine, University of Pennsylvania, Philadelphia, USA; [3]The Aurum Institute for Health Research, Parktown, Johannesburg, South Africa; [4]National Priority Programmes, National Health Laboratory Services, Johannesburg, South Africa

BACKGROUND

Tongue swabs (TS) are emerging as a promising non-invasive tool for detecting *Mycobacterium tuberculosis* complex (MTBC) using molecular diagnostics. Analytical performance varies, depending on the TS processing protocol as well as the molecular test used[1]. Most studies have focused on either healthcare worker collected (HCWC) or self-collected (SC) TS for detecting MTBC, but rarely on both. We assessed the clinical performance of HCWC and SC TS for MTBC detection, on specimens collected from the same participant, using the Xpert MTB/RIF Ultra (Xpert Ultra) (Cepheid, Sunnyvale, CA, USA). In addition, we assessed participant acceptability of both collection procedures.

METHODS

- In this cross-sectional, prospective study, 669 participants who met eligibility were consented and enrolled at eight healthcare facilities in the Ekurhuleni District of Johannesburg, South Africa.
- Two sputum and two TS were collected from each participant (Figure 1).
- A total of 314 participants used a short-shaft (4 cm) spun polyester XpressCollect™ swab (Steripack, USA), while 355 participants used a longer-shaft (15 cm) Copan FLOQ swab (Copan Italia S.p.A.) (Figure 2).
- Sputum and TS (dry) were transported at 2-8°C to the laboratory where Xpert Ultra was processed with either phosphate buffer (PB) or 66% Sample Reagent (SR) buffer.
- For diagnostic performance, Ultra Xpert TS results were compared to a liquid culture (MGIT) reference standard.
- Participant observations on TS feasibility and usability were noted.

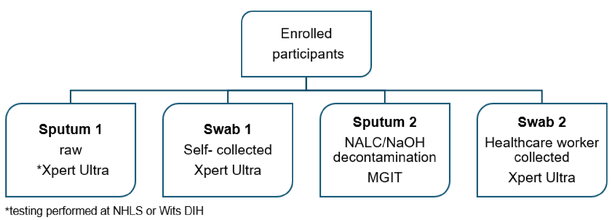


Figure 1: Description of study design indicating specimen laboratory pathways

Self-collected and healthcare worker-collected tongue swabs demonstrated comparable clinical performance for MTBC detection, with high participant acceptability for both collection methods.

RESULTS

- Of the 669 enrolled participants, 149 participants were excluded due to missing specimens or invalid laboratory results (on MGIT, TS Ultra or sputum Ultra). Valid results on all assays were therefore available from 520 participants for statistical analysis with TS performance shown in Table 1.
- The median age was 41 years (54% male), 47% were HIV-positive and 7% bacteriologically confirmed using MGIT.
- A total of 462/520 (89%) participants were comfortable with TS collection and confident with self-collection, however participants using XpressCollect™ reported difficulty with collection due to the short swab shaft.
- TS processed with 66% SR buffer[2] showed a reduced error rate (3%) compared to TS processed with PB (4%)
- Preferences among participants for TS collection are shown in Figure 3.

Table 1: Clinical performance of self-collected and healthcare worker collected TS using Xpert Ultra compared to a liquid culture (MGIT) reference standard

	Sensitivity (95% CI)	Specificity (95% CI)	Error rate
SC TS	68.3% (95% CI: 51.9%-81.9%)	99.8% (95% CI: 98.8%-100%)	23/669 (3.4%)
HCWC TS	68.3% (95% CI: 51.9%-81.9%)	99.4% (95% CI: 98.2%-99.9%)	21/666 (3.2%)

SC, self-collected; HCWC, healthcare worker collected; TS, tongue swabs

2a) 2b)



Figure 2: Different swab types used for TS collection, 2a) XpressCollect™ swab spun polyester swab; 2b) Copan FLOQswab® with 30 mm breakpoint

CONCLUSIONS

- In this clinical performance evaluation, both HCWC and SC TS showed comparable sensitivity and high specificity compared to MGIT, demonstrating that TS is a viable specimen type for TB detection in clinical settings.
- Protocol modification using a diluted SR buffer reduced assay error rates.
- Majority participants expressed comfort with TS collection and confidence in self-collection, highlighting the acceptability of this method, although swab design was shown to affect usability.
- The preference data suggests that both self-collection and HCW-collection are suitable options, offering flexibility for patient-centered care.

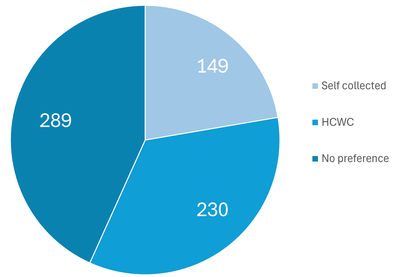


Figure 3: Pie chart showing participant preference for TS collection

REFERENCES

1. Church ECC, *et al*. Oral swabs with a rapid molecular diagnostic test for pulmonary tuberculosis in adults and children: a systematic review. Lancet Glob Health. 2024;12(1):e45-e54.
2. Ahls. C *et al.* (2024). Xpert MTB/RIF Ultra testing from tongue swabs – Diluted SR method v1. 10.17504/protocols.io.14egn69nyl5d/v1.

ACKNOWLEDGEMENTS

The authors would like to thank the study participants and their families, the Johannesburg Health District, South African Department of Health, TB R&D staff, study clinic staff, Penn Center for AIDS Research (P30 AI 045008) and Bill and Melinda Gates Foundation (grant # OPP1171455).

AUTHOR CONTACT INFORMATION

Anura David, anura.david@witsdih.ac.za