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Evaluation of self-collected oral swab sample for early detection of *Mycobacterium tuberculosis* by Xpert MTB assay in Karu, Nasarawa State, Nigeria

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Abstract:

Background: Tuberculosis (TB) is one of the leading causes of death worldwide, with an estimated 1.25 million people dying from TB in 2023. Most current diagnostic tests for TB rely on sputum sampling from symptomatic individuals. Sputum collection procedure involves expectoration of potentially infectious aerosols, which pose safety risks to health care workers; hence, an easier, safer, non-invasive, non-aerosol, and more effective alternative approach is warranted. This study evaluated the effectiveness and diagnostic yield of self-collected oral swab (SC-OS) against sputum in detecting *Mycobacterium tuberculosis* (MTB) by Xpert MTB/RIF assay.

Methodology: A cross-sectional comparative design was used in evaluating SC-OS against sputum for early diagnosis of TB in adolescents and adults with presumed TB in Karu Local Government Area, Nasarawa State, Nigeria. Two samples, comprising early morning SC-OS, and one sputum sample were collected from each consented participant. SC-OS and sputum were transported immediately to the laboratory at room temperature and cold chain, respectively. The Xpert MTB/RIF Ultra assay was performed on both specimens, and the graph of the cycle threshold values was plotted for both samples. The sensitivity, specificity, and predictive values of SC-OS were calculated, with sputum as the 'gold standard' sample.

Results: Of the 419 participants, 266 (63.5%) were males, and 12 (2.8%) were ≤ 14 years. Thirty-six (8.6%) were positive, with 2 (5.6%) rifampicin resistant. When compared to sputum Xpert MTB as the 'gold standard', the sensitivity and specificity of the SC-OS Xpert MTB were 97.2% and 99.7%, respectively.

Conclusion: The self-collected oral swab showed high sensitivity and specificity with the sputum sample, and is potentially easier, safer, non-invasive, non-aerosol, and effective in detecting TB by Xpert/MTB. Although further research is warranted, our findings show that SC-OS can serve as an alternative sample for early detection of *M. tuberculosis*.

Keywords: Self-collected oral swab, Sputum, Xpert MTB, Diagnostic performance

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Évaluation d'un prélèvement buccal auto-effectué pour le dépistage précoce de *Mycobacterium tuberculosis* par le test Xpert MTB à Karu, État de Nasarawa, Nigéria

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Résumé:

Contexte: La tuberculose (TB) est l'une des principales causes de mortalité dans le monde, avec environ 1,25 million de décès estimés en 2023. La plupart des tests diagnostiques actuels de la TB reposent sur le prélèvement d'expectorations chez les personnes symptomatiques. La procédure de prélèvement d'expectorations implique l'expectoration d'aérosols potentiellement infectieux, ce qui présente des risques pour la sécurité des professionnels de santé; par conséquent, une approche alternative plus simple, plus sûre, non invasive, sans aérosol et plus efficace est nécessaire. Cette étude a évalué l'efficacité et la performance diagnostique de l'écouvillon buccal auto-prélevé (EBAP) par rapport à l'expectoration pour la détection de *Mycobacterium tuberculosis* (MTB) par le test Xpert MTB/RIF.

Méthodologie: Une étude comparative transversale a été menée pour évaluer l'EBAP par rapport à l'expectoration pour le diagnostic précoce de la tuberculose chez les adolescents et les adultes présentant une suspicion de tuberculose dans la zone de gouvernement local de Karu, État de Nasarawa, au Nigéria. Deux échantillons, un EBAP prélevé tôt le matin et un échantillon d'expectoration, ont été recueillis auprès de chaque participant ayant donné son consentement. L'EBAP et l'expectoration ont été transportés immédiatement au laboratoire, respectivement à température ambiante et sous chaîne du froid. Le test Xpert MTB/RIF Ultra a été réalisé sur les deux types d'échantillons, et la courbe des valeurs de seuil de cycle (Ct) a été établie. La sensibilité, la spécificité et les valeurs prédictives de l'EBAP ont été calculées, l'expectoration servant de référence.

Résultats: Sur les 419 participants, 266 (63,5%) étaient des hommes et 12 (2,8%) avaient 14 ans ou moins. Trente-six (8,6%) étaient positifs, dont 2 (5,6%) résistants à la rifampicine. Par rapport au test Xpert MTB sur expectorations, considéré comme la méthode de référence, la sensibilité et la spécificité du test SC-OS Xpert MTB étaient respectivement de 97,2% et 99,7%.

Conclusion: L'écouvillon buccal auto-prélevé a démontré une sensibilité et une spécificité élevées par rapport à l'échantillon d'expectorations. Il est potentiellement plus simple, plus sûr, non invasif, sans aérosolisation et efficace pour la détection de la tuberculose par Xpert/MTB. Bien que des recherches supplémentaires soient nécessaires, nos résultats montrent que le SC-OS peut servir de prélèvement alternatif pour le dépistage précoce de *M. tuberculosis*.

Mots-clés: Écouvillon buccal auto-prélevé, Expectorations, Xpert MTB, Performance diagnostique

Introduction:

Tuberculosis (TB) continues to be one of the most pervasive and deadly infectious diseases worldwide, representing a formidable public health burden, particularly in low-and-middle-income countries (LMICs) (1,2). Caused by the *Mycobacterium tuberculosis* complex (MTBC), TB claimed an estimated 1.25 million lives in 2023, according to the World Health Organization (WHO) report (3). Despite significant advances in diagnostics and therapeutic interventions, TB remains entrenched as one of the top ten causes of mortality globally (2,3). The disease primarily affects the lungs, although it can disseminate to other organs, leading to extrapulmonary manifestations that are often harder to detect and manage (4).

In 2020, 86% of new TB cases were reported in 30 high-burden countries, highlighting the uneven distribution of disease burden and the urgent need for targeted interventions. Among these nations, Nigeria stands out, ranking first in Africa and sixth globally in TB burden (2,5). It is also one of the 10 countries contributing to over 70% of the global gap in TB case detection and notification (6). These statistics underscore the substantial challenges Nigeria faces in effectively diagnosing and tre-

ating TB, despite being a focus of global and national TB control efforts.

Early detection and prompt initiation of treatment are pivotal in reducing TB transmission and improving patient outcomes. However, achieving these goals is often hindered by several limitations associated with the conventional diagnostic methods (7). Currently, most TB diagnostic algorithms are centered on the detection of *M. tuberculosis* in sputum samples through microscopy, culture, or molecular techniques such as the GeneXpert MTB/RIF Ultra assay (8). While these methods have transformed TB detection, especially with the advent of molecular assays, they still rely on sputum samples, introducing several practical and biological challenges (8).

Sputum-based diagnostics pose significant limitations, particularly in populations that are either unable or unwilling to produce sputum. These include young children, elderly individuals, and people living with HIV/AIDS, who often present with paucibacillary disease (9,10). The quality of the sputum sample is another limiting factor, as poorly collected specimens can result in false negatives. (11,12). Furthermore, sputum induction procedures are aerosol-generating, raising the risk of transmission in clinical and laboratory settings, and

necessitating stringent infection control measures (13,14). These issues are further compounded in community-based screening programs, where the logistical difficulties of sample collection, storage, and transportation can delay diagnosis and treatment initiation.

Given these challenges, there has been a growing interest in alternative specimen types for TB diagnosis. Among these, oral swabs have emerged as a promising non-invasive option (15,16,17). Oral swab samples can be collected easily, without the need for specialized training or equipment, making them particularly advantageous in resource-constrained and community settings (17). Early morning self-collected oral swabs (SC-OS) are especially appealing due to their potential to empower patients, increase participation in screening programs, and facilitate decentralized TB diagnostic efforts (18,19). The concept of using oral swabs for TB diagnosis builds upon the principle that *M. tuberculosis* DNA may be expelled from the lungs and deposited on the buccal or oropharyngeal surfaces. (20) Molecular diagnostic techniques, such as the GeneXpert MTB/RIF Ultra assay, are sensitive enough to detect this DNA, even when present in low quantities (21).

Several studies (18,19,20,) have demonstrated that oral swab samples could detect MTB DNA with high specificity using molecular tools. Similarly, studies (19,20) showed that oral swabs offered a viable alternative to sputum samples, especially in patients unable to produce sputum. Another study (22) further reported that the diagnostic performance of oral swabs, when analyzed using sensitive molecular assays, was comparable to that of conventional sputum-based tests. These findings are particularly relevant for TB screening initiatives targeting populations that are difficult to reach or engage using traditional diagnostic methods. The non-invasive nature of oral swabs reduces stigma, increases compliance, and opens opportunities for large-scale community-based TB screening campaigns (23).

However, despite these promising findings, oral swab diagnostics for TB are still in the early stages of validation and implementation (16). Several operational and technical challenges need to be addressed before widespread adoption can occur. One major concern is the variability in sample quality when collected by patients themselves. While self-collection is logistically advantageous to allow for early morning (before brushing or eating) sampling, it raises concerns about the consistency and adequacy of the specimens. The use of standardized collection kits and comprehensive

patient education materials is essential to mitigate this risk (24).

Another consideration is the optimization of pre-analytical and analytical protocols, including sample storage, transport, and processing. Unlike sputum, which may contain high concentrations of MTB bacilli, oral swabs may yield lower DNA quantities, necessitating highly sensitive detection methods (25). This makes the GeneXpert MTB/RIF Ultra assay an attractive option, as it offers enhanced sensitivity compared to earlier versions of the Xpert system. Yet, studies assessing the real-world performance of early morning SC-OS samples processed with GeneXpert MTB/RIF Ultra, especially in diverse populations and settings, remain limited (26).

Social stigma surrounding TB in Nigeria further complicates case detection efforts (27). Many individuals delay seeking care due to fear of discrimination or ostracization. The ability to privately self-collect oral swabs can help circumvent this barrier and encourage greater community participation in TB screening programs (28). Moreover, self-collected oral swabs are lightweight, compact, and pose a lower biohazard risk than sputum, simplifying sample transport and reducing costs associated with cold chain requirements and infection control (29). From a cost-effectiveness perspective, integrating oral swab diagnostics into existing TB programs could provide significant benefits. While the upfront cost of molecular testing platforms like GeneXpert is relatively high, the potential reduction in diagnostic delays and associated transmission can result in long-term savings (30). Furthermore, the adoption of self-collection methods could reduce reliance on trained personnel, thereby alleviating some of the human resource constraints faced by health systems in LMICs.

Importantly, while various studies have shown the potential utility of oral swabs in detecting MTB DNA, most have been conducted in clinical or laboratory-based settings. There is a paucity of data evaluating the performance of SC-OS in real-world, community-based environments, particularly in semi-urban and rural contexts where TB diagnostic gaps are most pronounced (31). As such, further research is urgently needed to assess the feasibility, diagnostic accuracy, and operational implications of this approach under field conditions. By assessing the diagnostic performance, feasibility, and operational practicality of SC-OS in this context, this research contributes valuable evidence to support the potential integration of oral swab-based testing into Nigeria's national TB control strategy. The outcomes may also

inform the development of standard operating procedures for SC-OS sample collection, transport, and processing. Ultimately, the findings from this research may have broader implications beyond Nigeria. They could inform TB diagnostic strategies in other high-burden countries facing similar challenges related to sputum-based testing and limited healthcare infrastructure. The scalability of SC-OS, coupled with the sensitivity of the GeneXpert MTB/RIF Ultra platform, presents a promising avenue for improving TB case detection, especially in marginalized and underserved populations (30).

This approach aligns with global efforts to enhance early diagnosis, decentralize care, and eliminate TB as a public health threat (32). Through rigorous scientific evaluation in a real-world setting, this study seeks to provide the evidence base needed to support the broader adoption of self-collected oral swab testing in TB-endemic regions. This study aims to address these critical knowledge gaps by evaluating the use of early morning self-collected oral swabs for the detection of *Mycobacterium tuberculosis* using the GeneXpert MTB/RIF Ultra assay in a community setting in Karu, Nasarawa State, Nigeria. Karu is a semi-urban locality comprising diverse populations with varying levels of access to healthcare services.

Materials and method:

Study design and setting:

This study utilizes an observational cross-sectional approach in evaluating early morning self-collected oral swabs for early diagnosis of TB in adolescents and adults with presumed TB in hard-to-reach communities in Karu. Routine TB testing (sputum Xpert MTB/RIF Ultra) was used for comparison with the novel tests (SC-OS). Participants were enrolled from August 2024 to February 2025 in different hard-to-reach villages in Karu Local Government Area (LGA) in Nasarawa State, Nigeria.

Karu Local Government Area sits along the busy border corridor between Nasarawa State and the Federal Capital Territory, yet beyond its urban edges lies a landscape that quickly turns rural and uneven. The area is home to a mix of ethnic groups, small farming communities, and expanding peri-urban settlements (33). Villages are surrounded by rolling hills, scattered farmland, and pockets of dense vegetation. Most households depend on small-scale farming, petty trade, and daily-wage labor to sustain their livelihoods. Markets are lively but seasonal, roads become difficult during the rains, and many communities rely on

boreholes, streams, and long walks to access basic services.

Most remote communities are accessible only by motorcycle or long footpaths, and transport is often unreliable, especially during the wet season when roads become impassable. Health facilities are few, and the nearest primary health centre may require hours of travel, leaving many residents dependent on traditional healers, local chemists, and community beliefs. These hard-to-reach areas face gaps in routine healthcare, diagnostic services, and health information (34). The combination of geographic isolation, limited infrastructure, and socioeconomic constraints not only affects disease detection and treatment but also makes community engagement essential for any public health study conducted in this setting.

Study population and sample size:

The study population comprised individuals of all genders, adolescents, and adults (aged 15 years) in hard-to-reach areas of Karu LGA with either cough ≥ 2 weeks' duration, night sweat, weight loss, fever, and other commonly accepted criteria for identifying people with presumed pulmonary TB risk factors for which TB screening is always recommended. A total of 419 consented participants were enrolled from August 2024 to February 2025 in different communities in hard-to-reach areas of Karu LGA, Nasarawa State, Nigeria. Participants were enrolled during community outreach activities in the areas within the enrollment period.

Participant eligibility criteria:

We included adolescents and adults (aged 15 years) with either cough ≥ 2 weeks' duration, night sweat, weight loss, fever, and other commonly accepted criteria for identifying people with presumed pulmonary TB risk factors for which TB screening is always recommended. We excluded people who were hospitalized, and or are unwilling to provide informed consent

Data and sample collection:

Demographic and clinical data were obtained using a structured data collection form. Two samples were collected from each participant; (i) one sputum sample on the spot during outreach, and (ii) one early morning self-collected oral swab (collected the following day by the participants). Samples were transported to Zankli Research Center TB Reference Laboratory for testing. Sputum samples were transported in a cold-chain system, while the SC-OS were transported at room temperature.

Method of sputum sample collection:

Participants were asked to refrain from eating, drinking, brushing their teeth, and/or using mouthwash for at least 30 minutes before sputum sample collection. Also, the participants were asked to make a deep cough and produce good-quality sputum in a sputum cup. The demographic and clinical data of participants were collected before the sample was collected

Method of swab collection:

Participants were educated on how to collect the oral swab, which was collected early in the morning before brushing the mouth, eating, or drinking. Participants stuck out their tongue and, using a sterile, individually wrapped swab, ran the swab over the length and breadth of the front 2/3 of their tongue, and between the teeth and the tongue. Pressure was sufficient to slightly bend the swab shafts.

Samples were collected for 15-20 secs while rotating the swab throughout. The swabs were transferred into an empty disposable 15 ml Falcon tube. Each sample container was appropriately labeled with the participants information details. Informed consent/assent was obtained from each participant before sample collection

Sputum for MTB detection by Xpert MTB/RIF:

The Xpert MTB/RIF Ultra test was performed by trained laboratory technicians at the Zankli TB Reference laboratory according to the manufacturer's instructions. A 2:1 sample reagent was added to the sputum and incubated for 15 minutes at room temperature after shaking for 30 seconds. About 2 ml was transferred into the Xpert cartridge using a sterile transfer pipette and loaded onto the Xpert machine. Results were documented at the end of the test.

Oral swab for MTB detection by Xpert MTB/RIF:

Trained personnel performed the SC-OS TB testing using the Xpert MTB/RIF Ultra according to the manufacturer's instructions and the formulated swab sample preparation. About 3 ml of the sample reagent was added to each 15 ml Falcon tube containing the SC-OS. The content was then vortexed for 20 secs and incubated for 15 minutes at room temperature. The entire liquid content was transferred into the Xpert cartridge using a sterile transfer pipette and was loaded onto the Gene-Xpert platform according to the manufacturer's instructions. Results were documented at the end of the test.

Ethical consideration:

Ethical approval (NHREC/21/05/2005/01309) was obtained from Bingham University Karu Ethical Committee before the commencement of this study. Eligible participants were informed of the study objectives, procedures, potential benefits, and risks in a language they understood. Written informed consent was obtained from all participants before enrolment. For participants under 18 years of age, assent was obtained along with parental or guardian consent. Each participant was assigned a unique identification code to ensure anonymity and no personal identifiers (names, addresses, or phone numbers) appeared in any database or publication.

Participants were made aware of their rights to withdraw from the study without stating any reason. Potential risks were minimal and related mainly to the collection of sputum samples, which is standard for TB diagnosis and may cause mild discomfort. The potential benefits included improved understanding of the self-collected oral swab for TB diagnosis, which could inform national TB diagnostic guidelines, improve laboratory efficiency, and enhance patient outcomes. All sputum samples were collected as part of routine TB diagnostic services, with no additional invasive procedures performed for research purposes. Results were disseminated in aggregate form only, with no possibility of linking findings to individual participants or facilities.

Data analysis:

Data were initially captured using Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA) and subjected to double-entry verification to minimize transcription errors. Cleaning procedures included screening for missing or inconsistent values, verifying dates of sample collection and receipt, and ensuring correct coding of categorical variables. The dataset was then exported to IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA) for statistical analysis.

Descriptive statistics were used to summarize demographic, clinical, and laboratory characteristics. Categorical variables (e.g., sex, age, HIV status) were presented as frequencies and percentages. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratio (LR) of the SC-OS were calculated against the sputum sample Xpert MTB results as the 'gold standard'. The graph of the cycle threshold (Ct) values against positive outcomes was plotted for both sputum and SC-OS.

Results:

This study enrolled 419 participants with presumptive pulmonary TB, of whom 266 (63.5%) were male, and 12 (2.8%) were less than or equal to 14 years. Of the 419 participants, 36 (8.6%) were confirmed TB positive, with 2 (5.7%) rifampicin-resistant and 32 (91.4%) rifampicin-sensitive on both sputum and SC-OS Xpert MTB/RIF ultra, while 1 (2.9%) was rifampicin indeterminate on Xpert MTB/RIF Ultra.

dium, 6 (16.7%) were low, 5 (13.9%) very-low, and 2 (5.6%) were trace on both sputum and SC-OS Xpert MTB/RIF ultra (Table 1). The sensitivity and specificity of the SC-OS compared to sputum for *M. tuberculosis* detection by Xpert MTB/RIF Ultra were 97.2% and 99.7%, respectively, while the PPV, NPV and LR were 97.2%, 99.7% and 372.4 respectively (Table 2).

Fig 1 shows the comparison of cycle threshold (Ct) values of sputum sample and that of self-collected oral swab of the positive samples on Xpert MTB/RIF assay, which showed a very high yield of *M. tuberculosis* by the SC-OS when compared to the sputum.

For the semi-quantitative readout of the 36 positive samples, 21 (58.3%) were me-

Table 1: Distribution of sputum Xpert MTB/RIF ultra results across gender and age of the participants and comparison with self-collected oral swab

Variable	Sputum Xpert MTB/RIF Ultra result, RIF status, and semi-quantitative read-out									
	Negative (%)	Positive (%)								
		Total	RIF R	RIF S	RIF IND	High	Medium	Low	Very low	Trace
Gender										
Male (n=266)	241 (90.6)	25 (9.3)	2 (8.0)	22 (88.0)	1 (4.0)	2 (8.0)	14 (56.0)	3 (12.0)	5 (20.0)	1 (4.0)
Female (n=153)	142 (92.8)	11 (7.1)	0	11 (100.0)	0	0	7 (63.6)	3 (27.3)	0	1 (9.1)
Age group (years)										
<14 (n=12)	6 (50.0)	6 (50.0)	1 (16.7)	5 (83.3)	0	1 (16.7)	2 (33.3)	1 (16.7)	1 (16.7)	1 (16.7)
>15 (n=407)	377 (92.6)	30 (7.3)	1 (3.3)	28 (93.3)	1 (3.3)	1 (3.3)	19 (63.3)	5 (16.7)	4 (13.3)	1 (3.3)
Oral swab Xpert MTB/RIF Ultra result, RIF status, and semi-quantitative read-out										
Positive (n=36)	1 (2.7)	35 (97.2)	2 (5.7)	32 (91.4)	1 (2.9)	1 (2.9)	21 (60.0)	6 (17.1)	5 (14.3)	2 (5.7)
Negative (n=383)	382 (99.7)	1 (0.02)	0	1 (100.0)	0	1 (100.0)	0	0	0	0
Total (n=419)	383 (91.4)	36 (8.6)	2 (5.6)	33 (91.7)	1 (2.8)	2 (5.6)	21 (58.3)	6 (16.7)	5 (13.9)	2 (5.6)

RIF R = Rifampicin resistant; RIF S = Rifampicin sensitive; RIF IND = Rifampicin indeterminate

Table 2: Diagnostic performance of self-collected oral swab compared to sputum in detecting *Mycobacterium tuberculosis* by Xpert MTB/RIF ultra

Diagnostic parameter	Xpert MTB/RIF result	
	Self-collected oral swab	Sputum (gold standard)
True Positive	35	36
False Positive	1	0
True Negative	382	383
False Negative	1	0
Sensitivity (%)	97.2 (95% CI: 85.5 - 99.9)	100
Specificity (%)	99.7 (95% CI: 98.6 - 99.9)	100
Positive Predictive Value (%)	97.2 (95% CI: 85.5 - 99.9)	100
Negative Predictive Value (%)	99.7 (95% CI: 98.6 - 99.9)	100
Likelihood Ratio	372.4	

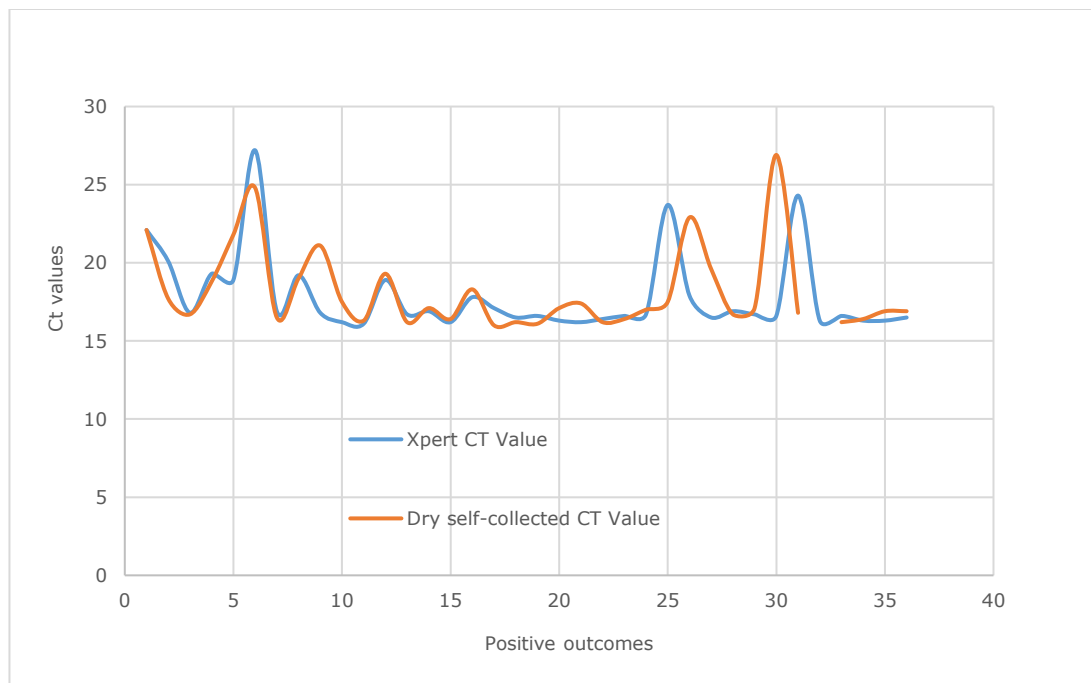


Fig 1: Comparison of the Cycle threshold (Ct) values of sputum sample and self-collected oral swab Xpert MTB assay

Discussion:

This study was performed among 419 participants in Karu, Nigeria, and focused on determining the effectiveness of early diagnosis of TB by Xpert MTB/RIF with Self-collected Oral Swabs. The results provide important data on how self-collection strategies may improve TB diagnosis, particularly in low-resource environments and hard-to-reach communities. Consistent with existing literature, which supports that men have higher TB prevalence, due to transient occupational and social behaviors (35), males made up most of the participants in this study (63.5%), and only 2.8% were aged ≤ 14 years. The cohort had an average of 8.6% prevalence for TB, with MTB positives in 36 participants. This result is similar to a study (36) that reported a prevalence of 5.8% per 100 participants.

The sensitivity and specificity of the SC-OS compared with sputum samples were 97.2% and 99.7%, respectively. A study by Church et al., (15) reported a sensitivity of 81.5% for oral swab in adults and 26% in children. These sound metrics suggest the method SC-OS is a robust approach to detect TB, capturing correctly most true positive cases without generating false positives. A study by Zhang et al., (16) reported a sensitivity and specificity of oral swabs at 73% and 93%, respectively. Another study by LaCourse et al., (37) reported an overall buccal swab sensitivity

was 65.0% and a specificity of 81.3%. The high positive and negative predictive values (PPVs and NPVs) of 97.2% and 99.7%, which the SC-OS showed in this study, further support the potential of the sample type and technique as an important clinical tool, especially in settings where conventional sputum collection may be challenging.

Of the TB positives, 58.3% were of medium bacterial load semi-quantitative read-out, which is important in providing a near real-time estimate for infectiousness as well as maximum detection yield from symptomatic PCR-positive cases. The presence of a medium load could mean that many participants may be infectious, and note the importance of early diagnosis followed by commencement of treatment. With a lower number of 'very low' and 'trace' results (13.9% and 5.6%, respectively), the distribution suggests that SC-OS samples can capture biologically relevant numbers of TB bacteria, rendering this method feasible for TB screening, which is in agreement with the study by Luabeya et al., (23) that reported a similar finding.

The graph of the cycle threshold values of sputum samples and the SC-OS captured a high MTB yield of the SC-OS compared to sputum. This implies that SC-OS samples may be adequate and a suitable alternative sample for TB diagnosis. This is an important finding given the difficulty in obtaining sputum from some patient populations, such as children and

adults of advanced age or those with physical impairments and people living with HIV. Self-collection is convenient and may increase participation in TB screening programs because it provides patients with privacy and minimizes stigma, as well as providing patients with the opportunity to participate in their healthcare delivery.

The findings from this study support inclusion of SC-OS as part of routine TB diagnostics, especially in hard-to-reach communities where collection and transportation of sputum in a cold chain is difficult. SC-OS has an advantage over sputum samples since it can be self-collected by patients and transported at room temperature to the testing laboratory, thereby eliminating the cold-chain transport system, which is hard to maintain in most cases, especially in hard-to-reach communities. This implementation could improve early diagnosis, reduce the spread of TB, and may lead to better TB control in Nigeria as well as other countries at comparable levels. Public health interventions are needed to educate communities on the advantages of SC-OS, reverse TB-related stigma, and impart knowledge regarding the appropriate ways individuals can collect samples.

The limitation of this study is that it was a cross-sectional study and therefore did not impact on the long-term outcome of TB patients in other centers. Furthermore, the low representation of younger people in this demographic composition may fail to reflect entirely on the TB burden among these age groups and thus underscores a case for tailored research. Future research should aim to understand the scalability of SC-OS methods among diverse populations and settings, as well as the durability of their effects on TB diagnostics and treatment compliance.

Conclusion:

This study demonstrates that early morning self-collected oral swabs offer a highly effective and practical alternative to sputum for the early diagnosis of pulmonary TB by Xpert MTB, especially in hard-to-reach settings such as the remote communities in Karu. With sensitivity and specificity of 97.2% and 99.7%, the method performed remarkably well when compared with sputum Xpert MTB/RIF Ultra, capturing nearly all true positive cases and showing a strong capacity to detect *M. tuberculosis* even at lower bacterial loads. The strong concordance between sputum and oral swab results, alongside the high MTB yield reflected in the Ct values, highlights the diag-

nostic potential of this approach.

Beyond laboratory performance, the study also underscores the operational value of oral swabs in communities where sputum collection is difficult, cold-chain transport is challenging, and stigma affects care-seeking behaviors. By eliminating the need for invasive procedures, specialized personnel, and cold-chain logistics, self-collection can improve access to testing, increase community participation, and support earlier diagnosis and treatment initiation. Although further field validation and larger studies across different populations are needed, these findings provide promising evidence that self-collected oral swabs can strengthen TB case detection in Nigeria and similar high-burden regions. This approach can contribute meaningfully to national and global goals aimed at closing diagnostic gaps and improving the timeliness of care for individuals affected by tuberculosis.

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Contributions of authors:

TTE conceptualized the study, developed the study protocol, and made the first draft of the manuscript; PJ and AAA finalized and proofread the manuscript; TTE and SA performed the laboratory analysis; CU and TTE performed data analysis; JB reviewed the manuscript and provided overall guidance.

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Conflict of interest:

The authors declare that they have no financial or personal relationships that may

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AI use disclosure:

ChatGPT 3.5 and Grammarly were used during the early drafting of this manuscript. All intellectual contributions and final content are the result of the authors' work. The content was reviewed and edited by the authors, who take full responsibility for its accuracy

Data availability

The authors will make the data supporting the findings of this study available through the corresponding author upon reasonable request following our data sharing policy.

Disclaimer:

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of all the authors' affiliating institutions, nor the National Tuberculosis, Leprosy and Buruli Ulcer Control Programme (NTBLCP).

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