Tongue swab user acceptance for tuberculosis diagnosis: Characterizing the facilitators and barriers of tongue swab use during the era of COVID-19

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A thesis

submitted in partial fulfillment of the

requirements for the degree of

Master of Public Health, One Health

University of Washington

2021

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Program Authorized to Offer Degree:

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Abstract

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Workers who come into contact with tuberculosis (TB) patients are at elevated risk of TB infection and disease.[1] Tongue swabbing is an alternative diagnostic sample collection approach that was designed to mitigate this risk.[2] This study assessed risk perceptions among healthcare workers (HCWs) using tongue swabs for TB diagnosis in South Africa during a respiratory virus pandemic.

We characterized the facilitators and barriers of tongue swab use for TB diagnosis during the era of COVID-19. Our study site location was with one of the world's premier TB research facilities, the South African Vaccine Initiative (SATVI) in the Western Cape, South Africa, where TB is endemic. HCWs making home visits have a complex array of factors influencing their willingness to use the tongue swab method in comparison to the gold standard of sputum sample collection. Findings will guide the development of training materials and/or policies and procedures that enhance worker safety and comfort when using tongue swabs in different contexts such as at home visits or in clinical settings.

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Key words: Tuberculosis, user acceptance, occupational health and safety, COVID-19, non-sputum sampling, tongue swab, Zoom interviews, perceived bio security, pandemic response, formative research.

LITERATURE REVIEW

Background and Significance

Tuberculosis (TB) remains a leading cause of infectious disease morbidity and mortality around the world, with an estimated 1.4 million deaths in 2019.[3] Unfortunately, we continue to fall behind on global TB control goals in terms of incidence and number of deaths.[3] TB control depends on preventing latent TB infection from becoming established or developing into active disease, and on diagnosing and treating active disease as soon as it has developed.[4] The United Nations Declaration on TB states the urgency to increase the diagnosis reach in low-middle income countries and to increase research in diagnosis technologies to reach those most vulnerable.[5]

South Africa is one of the 30 highest TB burden countries in the world and one of six countries accounting for 60% of the global tuberculosis burden.[6] The country's TB epidemic is driven by a number of factors including low socio-economic status and a high HIV coinfection burden.[7] Additionally, delayed health-seeking behavior among individuals with TB, as well as a high burden of undiagnosed disease in communities, also drive the TB epidemic.[7]

Healthcare workers (HCWs), particularly those working in high TB prevalence settings, are at increased risk of TB compared with the general population despite efforts to scale up infection control and reduce nosocomial TB transmission.[8] HCWs were found to have an approximately three times greater risk of active TB compared with the general population.[8]

The impact of COVID-19 has set back a lot of the progress that has been made against tuberculosis in recent years with estimates of a 12-year setback on TB control efforts.[3,9] While it is still unclear how lockdown and social distancing measures impact TB, it is clear that COVID-19 has limited access to healthcare services or deterred patients from seeking healthcare.[3,9] In addition, many financial and technical resources were diverted from TB as well as other infectious disease programs in order to address the immediate impacts of COVID-19.[3]

New Sampling for TB Diagnosis

Currently the gold standard sample collection method used for diagnosing pulmonary *Mycobacterium tuberculosis* (MTB) is through sputum sample collection and processing.[10] Sputum is a viscous material derived from patient airways.[11] Sputum is the best place to detect MTB DNA which confirms diagnosis TB as well as the MTB strain specificity. Cepheid Gene Xpert is the preferred molecular diagnostic test for TB as per WHO guidance.[3]

Sputum is difficult for some patients to produce (especially children and patients living with HIV.[12,13] For microbiological confirmation of diagnosis of pulmonary tuberculosis (PTB) in young children, sequential gastric lavage (GL) is recommended. However, GL is invasive, stressful, and usually requires the admission of children to hospital and overnight fasting.[13] Sputum sampling requires the patient to cough which can aerosolize MTB particles.[14]

Sputum collection also presents safety risks to HCWs while collecting samples. Sputum collection via expectoration or induced sputum sampling aerosolizes bacteria and other respiratory pathogens (e.g., SARS-CoV-2) creating a transmission risk.[15] All specimen collection procedures that produce aerosols that potentially contain MTB (e.g., sputum, bronchoalveolar lavage, etc.) should be performed in properly ventilated or isolated areas by personnel using adequate respiratory protection.[16,17] In low resource settings where aerosol containment procedures or PPE are limited, sick patients providing sputum samples are often in crowded clinics or hospital wards providing samples, exposing other patients, their families and clinic staff to the infectious aerosolized particles.[2] These limitations make HCWs in such settings at an elevated risk of TB exposure. The availability of alternative, noninvasive samples, which can easily be collected outside of the clinic, would increase the efficiency of testing and reduce the exposure risk to health care professionals.[18,19]

Tongue swabs have the promise to be a safer and easier way for HCWs to collect samples from patients for TB testing as opposed to the gold standard collection method of sputum.[2] MTB DNA is deposited on the oral epithelium during active TB disease and can be detected by oral swab analysis

(OSA).[2,20–24] In OSA, the dorsum of the tongue is gently brushed with a sterile disposable swab. The swab head with collected material, consisting of bacterial biofilm and host cells, is ejected into a tube for nucleic acid amplification testing (NAAT) targeting MTB DNA.[11]

Tongue swabs do not require individuals to cough, which can aerosolize particles of MTB.[14] Tongue swabbing is painless, noninvasive, and relatively nonaerosol producing. In contrast to many alternative TB sample types swabbing takes only seconds to complete and does not require privacy or isolation.[25–28] Self-sampling at home is routine in direct-to-consumer genetic testing and has the potential to be applied with tongue swabbing for TB diagnosis as well.[29] Sputum-scarce patients such as children and HIV-positive adults are easily swabbed in any setting, and self-sampling is straightforward.[30] Tongue swab sensitivity ranges from 88%-93% with specificities ranging from 79%-92%, relative to sputum testing.[2,11,20]

Occupational Risks of TB Exposure Among Healthcare Workers

HCWs are at an increased risk of occupationally acquired TB than people of their community[1]. They are three times more likely to have drug susceptible TB than those in their community.[8] A meta-analysis of 21 studies from 18 countries looked into the prevalence of HCWs with drug susceptible TB. Compared with the general population, the risk of latent TB infection (LTBI) was greater for HCWs (odds ratio [OR], 2.27; 95% confidence interval [CI], 1.61–3.20), and the incidence risk ratio for active TB was 2.94 (95% CI, 1.67–5.19).[8]

A South African study looking at HCWs in KwaZulu Natal, found that HCWs were more likely to be hospitalized for multi drug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB) as compared to non-HCWs across KwaZulu Natal. The estimated incidence of MDR-TB hospitalization was 64.8 per 100,000 for HCWs versus 11.9 per 100,000 for non-HCWs (I.R.R.: 5.56, 95% C.I. 4.87–6.35). Estimated incidence of XDR-TB hospitalizations was 7.2 per 100,000 among HCWs versus 1.1/per

100,000 in non-HCWs (I.R.R. 6.69 95% C.I. 4.38–10.20).[1] While it is unclear the extent to which sample collection contributes to this, it highlights the increased risks that HCWs face.

One potential solution to the risks associated with provider swabbing is the option to have an individual self-swab while being supervised by their HCW. Moreover, tongue swabbing opens the door to case finding efforts where sputum is hard to produce in populations such as children and people who live with HIV.[2]

Theoretical Framework

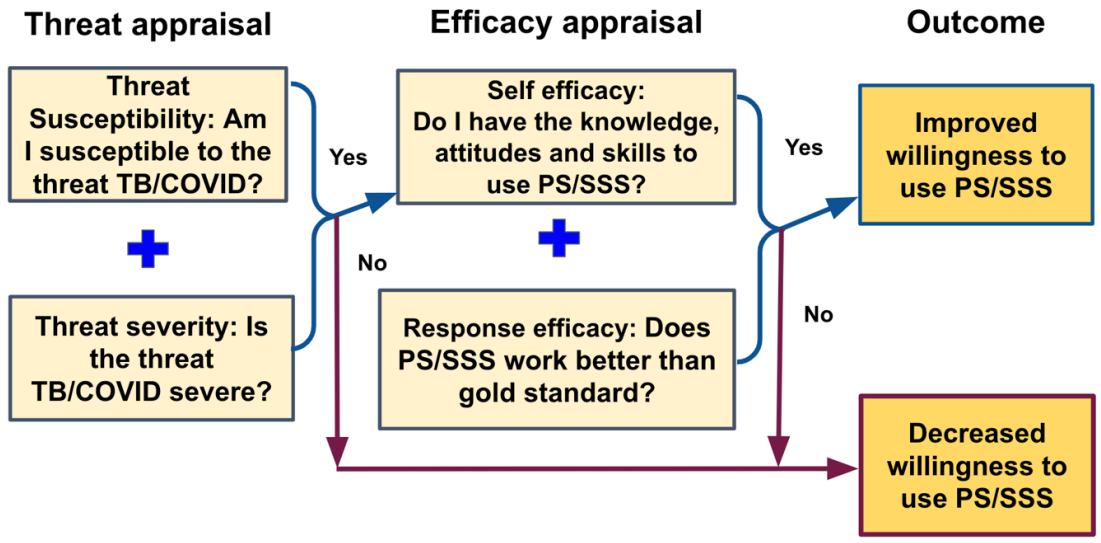
Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services.[31] A fundamental challenge of implementation science is identifying contextual determinants (e.g., barriers and facilitators) and determining which implementation strategies will address them.[32] In the implementation science literature, risk perception is a factor that modifies implementation of public health interventions which have unknown risks.[33]

This study draws on the Extended Parallel Process Model (EPPM) (**Figure 1**), a risk communication model that posits that individuals take action to control danger when they perceive that the severity and susceptibility are high and also perceive that they are competent to take mitigating action.[34] Specifically, it describes how people, when faced with a potential hazard, will sequentially appraise the threat and efficacy content of related health and safety protection messages, and will respond accordingly.[35] The EPPM theorizes that behavior change will result from risk communication messages that concurrently convey components of threat and efficacy.[34]

A potential application of the EPPM is to guide assessments of whether the willingness to use a novel tool is impacted by perception of risk.[33] We have adapted this model for our purposes of assessing risk perceptions using tongue swab either provider swabbing (PS) or supervised self-swabbing (SSS) for TB diagnostics in endemic settings during the era of COVID-19 (**Figure 1**). According to our adaptation

when the HCW personally perceives the hazard (exposure to TB, COVID-19 or any other self-identified threat) to be of negligible (low severity) or improbable (low susceptibility) consequence, the willingness to use PS/SSS standard operating procedures (SOP) decreases **(Appendices C & D)**. If, however, they determine the consequences to be significant and likely, the HCW will assess their efficacy to mitigate the hazard (efficacy appraisal). The efficacy appraisal contains two components: self-efficacy and response efficacy. If the HCW does not find the PS/SSS SOP method to be achievable (low self- efficacy) or efficacious (low response efficacy), the HCW will not be willing to use PS/SSS SOP methods (described as ‘‘fear control’’ in the EPPM); this will be accompanied by decreased willingness to use PS/SSS. If, however, their appraisal determines high self-efficacy and high response efficacy, they will have increased willingness to use tongue swabs, leading to adoption of tongue swabs intended protective behavior change outcomes by taking desirable steps to minimize personal risk against the actual hazard TB, COVID or any other risks (described as ‘‘danger control’’ in the EPPM).[34]

Figure 1: Adaption of Extended Parallel Process Model



INTRODUCTION

Tongue swabs were developed to reduce the occupational health risks associated with sputum sampling collection as well as the difficulties many patients have in producing sputum[2]. However, there may be new risks associated with tongue swab sampling in the field that are unknown. In addition, the new method was developed before the COVID-19 pandemic. The emergence of the SARS-CoV-2 virus created new occupational threats to HCWs working with oral patient samples.[36] It may also have changed healthcare worker attitudes toward such procedures. A formal HCW acceptance study has not been performed in locations where tongue swabs are being investigated. In order to understand if a proposed method for TB diagnosis is safer, an explorative qualitative study needed to be conducted. Qualitative research methods allow the researcher to develop deep understanding of what is being studied by considering context and dealing with the complexity of multiple, overlapping, and sometimes conflicting themes.[37] Gathering rich, in-depth data through qualitative research methods such as interviews brings personal, social and cultural knowledge into the research domain.[37]

Therefore, we investigated the context-specific scenarios influencing HCW willingness to perform provider swabbing (PS) and supervised patient self-swabbing (SSS) as compared to the gold standard sputum sample collection. This study is the first formal characterization of the facilitators and barriers of tongue swab use for TB diagnosis during the era of COVID-19. We are doing formative research in parallel to the investigative stage of the PS/SSS sampling method. Our formative research can guide best practices for PS/SSS implementation with the intended users. This study addresses the scientific gap in literature regarding HCW willingness to use novel tools during a pandemic. Findings from this research may help guide the global community's implementation of tongue swabs as well as other novel diagnosis tools in low-resource settings.

Purpose of the Study

The purpose of this study was to understand facilitators and barriers among HCWs who work in the clinic and those who make home visits to patients through the lens of risk perception. These workers in the Western Cape of South Africa exemplify intended end-users of tongue swabs for TB diagnosis. We explored how local context and current events (including COVID-19) influence participants' perceptions of risk. Findings can guide the development of training materials and/or policies and procedures that enhance worker safety and comfort when using tongue swabs in different contexts.

Study Aim

Our aim was to conduct the first formal characterization of the facilitators and barriers of tongue swab use for TB diagnosis during the era of COVID-19. We described HCWs willingness to use PS and SSS for TB diagnosis among HCWs who make home visits and those who work strictly in the clinical setting in the Western Cape, South Africa in the era of COVID-19. This study describes HCWs willingness to use tongue swabs, especially with regard to perceptions of risk of occupational exposure to TB and COVID-19. The results help us to 1) understand perceived facilitators and barriers toward HCWs willingness to use the new method; 2) understand and anticipate perceived occupational safety risks, if any, associated with tongue swabs; and 3) collect user ideas for improving the method, such as SSS.

METHODS

Study Site Location

The South African Tuberculosis Vaccine initiative (SATVI) field site is located in the Boland region, 110km outside Cape Town, South Africa where the prevalence of TB is amongst the highest in the world. This rural area of about 12,000 square kilometers has a population of about 350,000, of whom more than 20,000 have participated in SATVI studies to date. SATVI has been a key partner in the Cangelosi lab's evaluation of tongue swabs for TB diagnosis. SATVI staff include HCWs who are experienced in both traditional sputum sampling and tongue swabs, making them an ideal fit for the study.

Participant Selection

Participants (n=18) were selected through purposive sampling of HCWs from our partner study sites in South Africa. Purposive sampling is a technique widely used in qualitative research for the identification and selection of information-rich cases for the most effective use of limited resources.[38] This involves identifying and selecting individuals or groups of individuals that are especially knowledgeable about or experienced with a phenomenon of interest.[39]

Participants included in the sample were referred to us by their site manager as having sufficient experience with traditional methods for sputum collection and with the new tongue swab sampling methods. All staff who met this inclusion criterion were approached. This was done in order to obtain a varied population sample of the key informants experienced in using the tongue swab sampling method for TB. Participants ranged from 5-20 years of experience collecting TB samples for diagnosis. A sample size of 18 was projected to be sufficient for theoretical saturation.[40] Theoretical saturation refers to the point at which no new themes are likely to be found in data collection and only variations of known themes appear.[40] After 18 interviews, we discontinued recruitment of participants as no new meta themes were expected to emerge and to minimize participant burden.

Ethics

Human studies ethics approvals were provided by the University of Cape Town and the University of Washington. Participants provided verbal informed consent to be interviewed. Information collected about participants was confidential. Interview transcripts were de-identified, and their names are not used in any published documents. Participants received an honorarium of 300 ZAR in compensation for their time. Participants could withdraw from the study at any time by notifying the study researcher (verbally, electronically, or in writing) of their desire to withdraw. There was no penalty or loss of benefits to participants if they chose to withdraw from the study. Transcripts and contact information collected by study participants have been maintained for further use by the researcher.

Data Collection Method

Through semi-structured individual interviews, participants were invited to share their experiences and perceptions of the barriers and facilitators to working with tongue swabs and with the traditional sputum sampling collection method for TB diagnosis. We collected information on participant occupation (works in the clinic vs makes home visits), spoken maternal language and working languages (Xhosa, English or Afrikaans) and other demographic and descriptive information such as sex, if they lived and worked in the same community, if they lived in a multigenerational household and if they had TB or COVID-19 (active disease diagnosis and treatment) before the study.

Interview Setting

We conducted interviews using a semi-structured interview guide developed based on the study aim and conceptual framework. The interview guide contained a series of structured, demographic questions in addition to open ended questions. This guide allowed the interviewer to adapt the order of interview questions to gain depth and insight on the topics determined to be of significance *a priori*.

Remote interviews using Zoom, where the interviewee could take the interview from a private space, lasted for 45-60 minutes and allowed for a brief but in-depth discussion. When requested, the questions were given to the interviewee prior to the interview to aid in their preparation. Interviewee consent was sought and provided before the interview. An interview summary was returned to participants to check for accuracy and resonance with their experiences.[41] We also conducted a manual data check where we took the interview summary and went back to confirm with the data that everything in the summary was reflected in the data.

Collected data included detailed notes and audio recordings of the interviews. Interviews were professionally transcribed through Transcribeme, an online secure platform for professional interview transcriptions. Within two weeks of the interview, participants received a summary of their interview to confirm that we interpreted what was said accurately. Participants had four weeks to confirm the accuracy of the summary.

Data Analysis Method

Thematic analysis is a search for themes that emerge as being important to the description of the phenomenon.[42] The process involves the identification of themes through "careful reading and re-reading of the data.[43] It is a form of pattern recognition within the data, where emerging themes become the categories for analysis.[44] Our hybrid approach incorporated both the data-driven inductive approach and the deductive a priori template of codes approach.[45,46]

We employed a hybrid approach of deductive and inductive coding for thematic analysis. Prior to the analysis, a preliminary codebook that includes definitions and examples was developed based on the study aim and the EPPM. For the deductive coding process, we used the EPP constructs (e.g., threat susceptibility, threat severity) and dimensions of the study aim (e.g., opportunities and challenges) to develop codes that were given definition, which were based on their native constructs where relevant. For the inductive phase, we re-read interview transcripts and member checking summaries to identify

emergent themes. These were formalized into codes and given a definition based on our evolving understanding of the theme. Codes, their definitions, and examples of when to apply were formalized into a codebook.

The first four transcripts were co-coded to ensure code book reliability. This process sought to ensure the code book is very clear, can be used by someone else and clearly conveys the analytic framework. We did this by having the main researcher and an additional public health professional apply the codebook using NVivo a qualitative data analysis software. Researchers meet to discuss discrepancies, make appropriate adjustments to code definitions, and add additional examples of when to apply code.

The preliminary data analysis reported herein explored high-level facilitators and barriers to PS/SSS use, and specifically focused on constructs related to threat and efficacy perceptions among the two occupational groups and settings, among HCWs in the clinic and HCWs that also make home visits in informal communities. We developed memos to summarize key themes within and across coded text (**Appendix: Table A**). Through the process of thematic analysis, we detailed the experiences the data represents through key themes (or the patterned responses) researchers discerned from the topics raised.[47] The preliminary results presented include quotes, provided to represent exemplary statements related to the key themes. Additional analyses on codes related to threat and efficacy appraisals will expand on the factors contributing to the willingness to use the PS/SSS methods.

RESULTS

Study Population

The study analyzed data from 18 semi-structured key informant interviews (KII) conducted from January 2021-April 2021 via the remote Zoom platform. The demographic information for participants is outlined in **(Table 1)**. Of the 18 participants, 14 (78%) identified as female and 4 (22%) identified as male. A majority of the participants, 15 (83%), make both home visits and work in a clinic, whereas 3 (17%) participants work strictly in the clinic setting. Six (33%) participants work in the same community that they live in. Most of the participants 16 (89%) work with patients that are between the ages of 18 and 65 years. Only one participant sees patients that are between 5 and 18 years old, and 2 (11%) of the participants see patients that are less than five years old. Participants were also asked about their health history related to TB and COVID-19. Two of the participants (11%), have had a previous TB diagnosis and treatment. Both cases were reported as due to occupational exposure. Three of the participants (17%), had a previous COVID-19 diagnosis, with all three cases reported as community exposure.

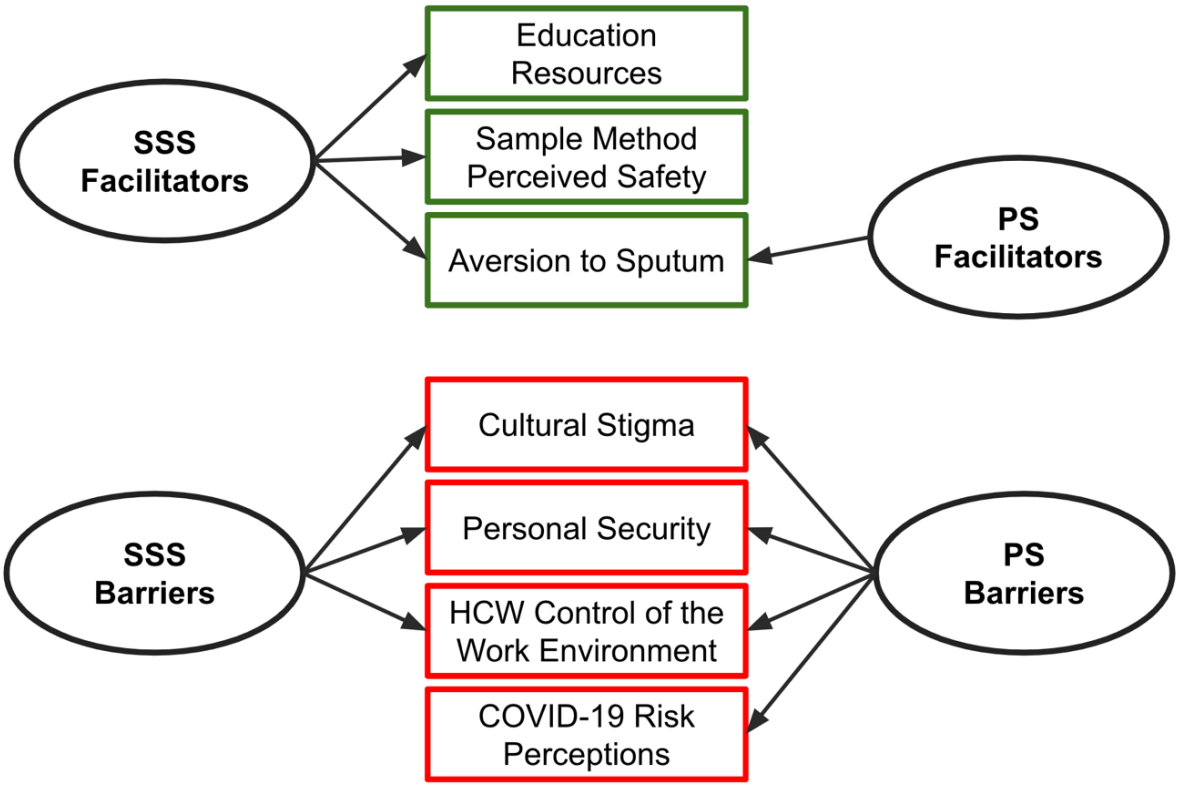
Table 1: Demographic data of key informants

Participant Demographics	**(n=18)**	**%**
Female Identifying	14	78
Male Identifying	4	22
Works with Patient Age 0-5 (years)	2	11
Works with Patients Age 5-18 (years)	1	6
Works with Patients Age 18-65 (years)	16	89
Works Strictly in Clinics	3	17
Makes Home Visits	15	83
Lives and Works in the Same Community	6	33
Previous TB Disease Diagnosis; reported as occupationally acquired	2	11
Previous COVID-19 Diagnosis; reported as community acquired	3	17

Thematic Analysis

Our preliminary analysis generated seven major themes that influence use of tongue swabs, acting as either facilitators or barriers (**Figure 2**).

Figure 2. Key theme interactions acting as facilitators and barriers to PS/SS sampling methods



Facilitators

The following facilitators influencing HCWs willingness to use tongue swabs were identified from key informant interviews: Education resources, sample method perceived safety, and aversion to sputum. All of these facilitators relate to the SSS method, but "aversion to sputum" is also a facilitator for the PS method **(Figure 2).**

Education Resources

All of the participants shared their enthusiasm regarding the opportunity for the creation of culturally appropriate training modules as an opportunity for their patients to learn how to effectively collect the samples using the SSS method. The majority of the HCWs shared that they doubted their patient's ability to safely and effectively collect samples using the SSS method while they made home visits especially in situations where participants did not have control of their working environment. Many participants shared concerns that they would have to resort to the PS method and it made them hesitant especially with the dual threat of TB and COVID-19 exposure when so close to the patient. The potential educational materials are a key facilitator increasing their willingness to use the SSS sampling method. Participants shared the need for these education materials to include illustrations and videos that can be understood regardless of literacy levels and maternal language.

In addition, opportunities for HCWs and community members who had a TB diagnosis and treatment to share their stories was perceived as a facilitator to connect with the patients and community members, sharing the personal human side of the consequences of TB. While not in existence, these educational resources are hypothesized to increase HCW willingness to use SSS by addressing and/or providing guidance on issues related to social distancing, aversion to sputum, cultural stigmas associated with TB and HIV coinfection, patient ability to follow directions, and fear associated with COVID-19.

Sample Method Perceived Safety

HCWs discussed that they were encouraged to use SSS because of their perceptions of enhanced safety compared to both PS and sputum sample collection methods. The majority of the HCWs shared that being close to the patient in front of their mouth while using the PS method made them hesitant, especially with the dual threat of TB and COVID-19 exposure. HCW's making home visits shared that the lack of control about their environment impacted their perceptions on the safety of the sampling methods. SSS was the preferred method for the majority of the HCWs interviewed as they shared it keeps

them at a safe distance from the patient and they can observe the patient to make sure they are doing it correctly. While in the home, the majority reported preferences for the SSS method.

However, not all HCWs expressed confidence that their patients could follow directions to collect the sample safely and effectively themselves. Participants who make home visits expressed concerns regarding their patients who present the greatest challenges. These include patients who are intoxicated, children, elderly, and patients who are too sick to follow directions. The majority of the HCWs shared that with improved educational materials and resources for themselves and their patients that they can envision the SSS being implemented with their patients who can follow directions.

Aversion to Sputum

Facilitators to PS and SSS include the aversion to sputum and the perceived safety of the sampling methods in comparison to sputum collection for patients to produce. HCWs shared that aversion to sputum can serve as a challenge to using the gold standard method. Many shared that they do not like looking at and collecting sputum samples which increases their willingness to use any alternative method. HCWs shared that it is not only the challenge of collecting sputum, but also that they then must confirm the color of the sample and the volume and that they do not enjoy this process. They also shared that it can be messy if the sample is not collected properly and if the jar is not closed properly.

HCWs who work with infants and children expressed population-specific challenges with obtaining sputum. The gold standard for children is not coughing to collect sputum samples, but rather gastric lavage. HCWs shared that there needs to be another sampling method and that they were interested in trying PS method with infants and children. However, one HCW working with babies was concerned that the babies don't sit still and it can provide a challenge to collect an adequate sample using PS.

Table 2. Illustrative Quotes for Each Identified Facilitator

Facilitators	**Illustrative Quotes**
Education resources	*"I need to have videos. Nowadays, people are very lazy to read. So many people...are now very digitized to their phones. So maybe a free website that will give some free education pertaining to certain signs and symptoms and diseases."* - HCW working in the community and in the clinic *"Videos would be helpful to put into the waiting rooms for parents and participants to see. Videos should be in English, Afrikaans and Xhosa."* - HCW working in the clinic *"Drawings are needed to explain to everyone, especially to the kids.*" - HCW working with children in the clinic *"We need videos with testimonials from families talking about how their child got TB from an adult and the impact TB has on their child and the family. Sharing this will help parents understand the importance of adhering to meds and treatments even when the child doesn't have symptoms. It will also help keep the community educated and informed. They are fearful of COVID but not for TB."* - HCW working with children in the clinic

	"I think to lower your risk (of exposure to TB and COVID-19), you can train your participant to do it." - HCW who makes home visits and works in the clinic
Sample method perceived safety	*"SSS is safer for the family members in the house and if it is done at the clinic then it is safer for the other staff members"* - HCW who makes home visits and works in the clinic *"...if the participant has swab and they hand it over, you can contaminate it any time when they give it to you like this. So much better just to slide it into the container. You lift it up, yeah, and break the rest unused part because you will have gloves on."* - HCW who makes home visits and works in the clinic
Aversion to Sputum	*"I actually prefer the swab more than the sputum because seeing the participant cough up sputum, that is actually not nice."* - HCW who makes home visits and works in the clinic *"The challenge is that we give them stuff to collect the (sputum) samples at home. So, in the morning we go fetch. Sometimes the participants don't close the lid of the stuff on the sputum jars and then when you get there, everything is out of the sputum jar. The swab is less messy than sputum and you know that you get a sample that's not going to leak or something like that."* - HCW sharing testimony of home visit scenarios

	"Tongue swab is nicer because it's less gross, I feel, than the sputum." - HCW who makes home visits and works in the clinic *"Tongue swabs may be challenging for babies as they (babies) are unpredictable."* HCW working with children under 5 years of age *"Tongue swabs would be a feasible alternative to gastral lavage."* - HCW working with children under 5 years of age *"Inducing sputum production in kids is difficult for parents to see their child go through and there is loss to follow up because parents don't want to put their kids through that. It would be interesting to see if we can start to use swabs on children."* - HCW working with children in the clinic

Barriers

Four key themes related to barriers to tongue swab use were identified from our interviews: cultural stigma related to the health of the patient, threats to personal security while collecting samples, HCW control of their work environment, and fear of COVID-19 exposure. As described by Figure 2**,** three barriers are related to both the PS and SSS methods: cultural stigma related to the health of the patient, threats to personal security, and HCW control of their work environment. PS had one additional barrier, fear of COVID-19.

Cultural Stigma

Cultural Stigma: TB association with HIV

The majority of the participants who make home visits shared how they are striving to protect their patients from experience the cultural stigma associated with being identified as having TB. The HIV-TB co-epidemic alters TB stigma and its management among HCWs.[48] Due to the stigmas associated with TB, the HCWs shared they do not have the authority to ensure that social distancing occurs in the house when they show up for home visits. Moreover, HCWs reported not wanting to do anything to identify patients as having TB such as disclose to household members or insist on infection control measures when they enter the home. Participants shared that they are reluctant to use tongue swabs because to do so, while maintaining participant privacy around TB status, they have to place themselves at risk of infection which is a barrier to collecting PS/SSS samples safely.

This is a barrier to all sample collection methods, including sputum, PS and SSS, and is compounded by other factors that influence HCW Authority in and Control of the Work Environment, as discussed below. Participants described how their patients are hesitant to share with their family that they have TB for fear of being rejected by their family or community. The repercussions of this stigma impact the HCWs ability to control their working environment. The majority of HCWs making home visits shared that when they go into the house for sample collection or consenting visits the rest of the family doesn't know why they are there. They have to do their work incognito. As a result, there are no prevention measures in the household to reduce TB transmission and the HCW is forced to enter an environment void of those protections.

A few of the participants who make home visits and are female-identifying shared that they take the patient outside of the home to do their consenting and collect samples in privacy to maintain the patient's confidentiality that they have TB. If it is raining, then they have to find another place. A few of the participants shared that they will take the patient into their car to do their work. While they are well trained and know the risks, they described making a choice to risk exposure with the patient in their car in

order to ensure that that sample is taken correctly, the patient's confidentiality is maintained and cultural stigma is not inflicted.

Cultural Stigma: SOP's requiring samples taken in the morning before eating/brushing teeth

In some experimental oral swab protocols, patients are asked not to brush their teeth before sample collection. Participants also expressed concerns with the logistical challenges with early morning sample collection before the patient eats, brushes their teeth or goes to work on the farm. Participants also shared their perceptions of patient comfort when taking early morning tongue swab samples stating that the patient is shy and concerned with their early morning breath. HCWs shared that collecting samples during the daytime and not before brushing their teeth in the morning may reduce the barrier that the patients feel when opening their mouth before they get a chance to brush their teeth so early in the morning.

Threats to Personal Security

HCWs described threats to their personal security as a prohibitive barrier to performing all of the sampling methods discussed, including the gold standard of sputum collection, PS, and SSS. Both male and female-identifying HCWs who make home visits expressed concerns and challenges with personal safety in doing their work. HCWs shared examples of logistical and socioeconomic factors that influence personal security while doing their work. Eight key informants shared testimonies that highlight the impact of these factors on their personal security risk while making home visits. For example, HCWs whose patient community are seasonally employed in agriculture shared that their patients working on the farm leave at 06:00 in the morning. In order to abide by the SOP for TS sample collection the HCW needs to collect the sample in the morning before the patient brushes their teeth or eats, these patients necessarily need to have samples collected before sunrise. This was described as dangerous for the HCW because they need to collect samples on their own, during hours where it is dark and witnesses are not likely to be awake.

HCW Authority in and Control of the Work Environment

Participants in the clinic reported that they had control of their environment to implement their training to mitigate risk while collecting samples. However, participants who make home visits shared they did not have the same control of their environment and often did not have the authority to control their patients' actions specifically when related to others in the household. HCWs expressed greatest concern with being able to keep their distance and abide by safety standards when in the home. The majority of the participants who make home visits shared examples of situations when they did not have the authority or agency to protect themselves. Their inability to control the environment in the home setting impacts their agency to respond to perceived threats. Female identifying participants expressed concern with being treated more like an "auntie" (a family friend who doesn't challenge the norms of the household) than as a professional. While they were in the clinic, these same participants did not experience that challenge. In the home, participants shared that they struggled with the boundary between collecting the samples safely and being culturally respectful when entering someone else's home who does not have the safety protocols in place to prevent TB or COVID-19 transmission.

Many female identifying participants shared examples of when children will hop on their laps, play with their hair, cough in their face and do not honor their pleas to socially distance. They also discussed that the residents in the home do not abide by social distancing measures due to the limited space, multi-generational households, the stigma of TB and living conditions in the informal setting.

The majority of the HCWs shared their concerns related to patients who cannot follow directions such as infants, children and those who are intoxicated or too ill to follow directions. HCWs shared that they have a lack of authority, and lack of control of the patient environment when making home visits is exacerbated by cultural stigmas associated with TB and HIV coinfection, comfort with obtaining the sample before the patient brushes their teeth, and the context of the COVID-19 pandemic.

Many HCWs shared that they preferred the PS method for patients who are unable to follow directions even though they are hesitant to be close for fear of TB and/or COVID-19 transmission. For instance, two key informants shared their lack of willingness to use the tongue swabs because of the threat

of COVID-19. They shared that they would rather have the patients produce the sputum at the clinic or if they have to make a home visit then the patient produce the sputum before the HCW arrives to pick it up.

Many HCWs making home visits shared that it is a common to find that their patient under the influence of drugs or alcohol and they struggle producing sputum and don't have faith in their ability to follow directions in this state so they prefer the PS method.

COVID-19 Risk Perceptions

Although all of the participants stated that sputum sampling collection was a challenge and that tongue swabs would be a preferred alternative, they expressed a variety of barriers to tongue swabs related to their perceived risk of COVID-19 while collecting samples. More than half of the individuals expressed that the threat of COVID-19 exposure impacted their willingness to stand in front of the patient to collect the samples (PS). They described that they were fearful of being close to the patient because they do not know if the patients have COVID-19 or not.

In addition, many participants shared that the novelty of the hazard of COVID-19 influenced their risk perceptions. All participants shared that they are more afraid of COVID-19 than TB when doing their work or out in the community. Many shared that TB is a known disease and there is a treatment whereas COVID-19 does not have a treatment and they still did not know how you get it. Three participants who had positive COVID-19 diagnosis said they have no idea how they got COVID since they were on lock down at home. They all knew it was not occupationally acquired since it was during the lockdown but neither of them had an idea of a possible transmission route. Notably, interviews were conducted before the scientific community confirmed that fomite transmission was not the dominant exposure route to SARS-CoV-2.

An unexpected finding related to COVID-19 was that a few participants shared their perception of reduced spread of TB in their community, and associated threat susceptibility, during the era of COVID-19. Participants shared perceptions based on their observations of reduction in TB threat susceptibility in their community now that COVID-19 has taken the forefront. Participants shared a

variety of justifications for this, including: reduction in health care seeking behaviors; testing resources for TB being reallocated to COVID-19 pandemic response, which may be contributing to reduced case findings; South Africa's government-controlled lock down and enforcement of mitigation strategies such as social distancing and PPE use, which could be contributing to the reduction in spread of TB.

In addition, many HCWs shared that they were not previously using all the PPE and precautions for TB as they currently are to prevent COVID-19. Participants shared how COVID-19 influenced implementation of safety practices that are also helpful in reducing spread of TB and other respiratory diseases.

Table 3. Illustrative Quotes for Each Identified Barrier Decreasing Willingness to use PS/SSS

Barriers	**Illustrative Quotes**
Cultural Stigma: TB and association with HIV	*"(the patient) He is sitting with the whole family and he did not start with the TB treatment...but we are always trying to convince them."* – HCW discussing a patient's hesitancy to discuss the reason for their visit in front of their family
Cultural Stigma: SOP's requiring samples taken in the morning before eating/brushing teeth	*"They don't feel comfortable not brushing their teeth."* - HCW who makes home visits
Threats to Personal Security	*"As I was looking, this other guy was carrying a knife. I did not feel safe going out of the car to walk up the stairs to the participant's home."* - HCW making home visits *"You don't know who's there. And there's always youngsters and people walking up and down, so your personal security's always at risk. They (are) looking for something to steal or somebody to rob"* - HCW making home visits *"In the community there is a danger of getting raped or killed. We deal with it because we stay in the community. But to prevent this always must be in pairs...That was always our mission that we mustn't go alone. But nowadays, if there's so much work, then*

	there's not enough people, so then you go out alone. But I really prefer not to, because you actually put yourself at risk. And there's other dangers too, like for instance, you get in an accident-- there's nobody else to report. You know what I mean?" - HCW who is a member of the community she serves
HCW Control of the Work Environment	"*If you're at a patient's home, their kids, they will come and touch you. So we are in high risk at the home of the participant*." - HCW who makes home visits and works in the clinic *"I cannot say to the person whose house, open the window more… In the morning windows are closed, participant's got TB, and I must get the sample and there's also COVID risk."* - HCW who makes home visits *"But with the swab, you must be close to the person even though you've got protective gear, but you're still at-risk and... you don't know if the person's got COVID."* - HCW who makes home visits
COVID-19 Risk Perceptions	*"For now, because of the pandemic, I prefer the sputum over the (provider) swab. I don't want to be so close. But before the pandemic, the (provider) swab was a good alternative to sputum."* - HCW working in the community and in the clinic

	"Self-swabbing with me there guiding at a distance would be better now with COVID." - HCW working in the clinic *"TB is an old disease and we know how to protect ourselves at work unlike COVID-19"* - HCW working in the clinic *"No one is getting TB anymore; we don't see it. I don't know why but we don't see it anymore."* - HCW working in the community and in the clinic *"Now with COVID you hear "No, you can't have my cigarette." It's only one person smoking that cigarette. It can be also because...you have to be very sick for the clinic to see you because they also have their COVID rules at the clinics now. So it could be also because... either they're not getting diagnosed or they're staying safer because they're not sharing their exposure."* - HCW working in the clinic *"Before COVID I got TB because a patient coughed in my face in the clinic. I was not wearing a mask because I did not know he had TB. That would not have happened now because I am afraid of COVID and wear PPE all the time at work."* - HCW working in the clinic

DISCUSSION AND RECOMMENDATIONS

Our research identified several barriers and facilitators that influence HCW willingness to use PS/SSS, that these influencing factors differed across HCW work environments (in the clinic versus in the patient's home), and solutions for improving HCW willingness must be customized to their work settings. Our interviews revealed a key factor, aversion to sputum, that positively influenced HCW willingness to use both PS and SSS. For SSS specifically, perceived safety of the sampling approach was also described to positively influence HCW willingness to use. While not yet in existence, our participants indicated that the development of culturally appropriate educational resources for patients and providers would also positively influence willingness to use SSS. We also identified three factors that negatively influenced HCW willingness to use PS/SSS. These barriers include: cultural stigma, personal security and HCW control of the work environment. One additional factor was identified to negatively influence HCW willingness to use PS: the fear of COVID-19 exposure while collecting samples given provider proximity to the patient's open mouth.

Although participants did not explicitly suggest solutions to overcome most of these barriers, particularly those related to cultural stigma, educational resources were identified as a potential facilitator of provider willingness to use both PS and SSS. Several different forms, including videos and storytelling, were suggested. These resources could integrate information about several of the barriers identified herein. For example, resources might suggest strategies for workers to establish safe and professional boundaries while in the home. In addition, visualizations targeted to the patient community could be created to educate patients on what to expect and how to effectively swab themselves while in the home. We hypothesize that information about how to train patients to use the SSS method will amplify the SSS sample method perceived safety and reduce restore HCW's trust in their patient's ability to follow the SOP and safely and effectively produce a SSS sample.

COVID-19 was described to influence perception of risk while collecting samples for TB diagnosis. The fear of the unknowns associated with asymptomatic transmission and the patients' current

COVID-19 status increased participants use of PPE and increased willingness to use SSS because it was felt to lower risk of COVID-19 transmission. This is interesting because TB (including MDR TB and XDR TB) is a serious threat to HCWs and the risks are mitigated using the same precautionary practices as for COVID-19. We suggest that future trainings address the risks of occupationally acquired COVID-19 and include periodic refresher trainings with updates as the science of TB and SARS-CoV-2 transmission reductions strategies progress. Future research should explore how precautionary behaviors and practices implemented for COVID-19 impacted precautionary behaviors and practice for TB during swabbing and other activities.

In addition, this study was conducted before the widespread rollout of SARS-CoV-2 vaccines and before we understood the impacts of the Delta variant in South Africa. While Delta variant is the current focus at the time of this writing, other variants will undoubtedly emerge as long as uncontrolled transmission is occurring globally.[49] Further research is needed to see how risk perception around tongue swabbing changes with the COVID-19 vaccine roll out and as new variants emerge.

The results of our study have already influenced protocols for SSS, which is becoming the preferred method and "norm" among our global partners. For instance, the SSS SOP was amended by our partners at SATVI to reduce threat to HCW personal safety by ensuring that home visits are made with a colleague during the daytime. Additional amendments were made so that HCWs can go to the farms and test participants on site in the afternoon when they are on their lunch break instead of testing before participants leave for work on the farm. Furthermore, midway through this study HCWs making home visits shared serious threats to personal safety. This alerted our team to stop and reflect on how we can amend the SOP to mitigate these personal safety threats. As SSS is being used in research studies not only at SATVI but all of our global partners in South Africa, Uganda, Vietnam and India, these protocol modifications have the potential to have far-reaching impacts on worker health and safety.

Our study's ability to improve HCW safety in the field and willingness to use SSS in real time demonstrates the importance of parallel and integrated qualitative implementation science studies for novel medical diagnostics, particularly when there are potential impacts for worker health and safety.

When threats to safe practice are identified through studies, there should be plans and procedures in place to halt practice, consider the risk, and co-create solutions with those at risk. Our study materials, including our interview guide and codebook **(Appendices A & B)**, can be used as a reference for designing such studies.

Limitations

This study had a few limitations. The primary researcher's positionality as a foreigner, a public health graduate student, and conducting the interviews remotely via Zoom in the participant's second language likely influenced both the responses given and, to some degree, their interpretation. The potential for these factors to influence the validity of the results was mitigated by the inclusion of South African collaborators in the study design, implementation, and during the member checking portion of the analysis. In addition, the member checking process asked participants to confirm that the primary researchers' interpretations of their interview in relation to the study questions was indeed in alignment with HCWs perspective. Interview recording and professional transcription also reduced these risks.

Notably, the results presented herein reflect findings from a preliminary analysis. Additional codes need to be analyzed to move beyond the barriers and facilitators but also the threat and efficacy appraisals leading to HCWs willingness to use PS/SSS. In addition, this exploratory study was confined to a single site in South Africa. This limits our ability to generalize these findings to other sites in South Africa and in other countries.

CONCLUSION

Collecting samples for TB diagnosis poses a serious risk to HCWs, particularly in areas where resources for aerosol containment from sputum sampling methods are scarce. Through key informant interviews with 18 South African HCWs who are experienced users of PS/SSS, facilitators and barriers to HCW willingness to use the TS were characterized. The facilitator for both PS/SSS was aversion to sputum. For SSS specifically, perceived safety of the sampling approach and the education resources to train patients how to collects SSS samples were also described to positively influence HCW willingness to use TS. The barriers for both PS/SSS included cultural stigmas associated with TB infection, personal security when HCWs collect samples in the community, and HCW control of their work environment when making home visits. For PS specifically, COVID-19 risk perception was identified as an additional barrier.

Traditional approaches to risk reduction for HCWs in limited resource settings during the era of COVID-19 need refinement. Motivating reasons behind HCW willingness to use TS differ substantially by HCW environment and if the HCW has the authority and agency to implement safety precautions in the home, and may require contextually specific solutions. We suggest the development of educational resources using visualizations and videos in patients' primary language to enhance patients' understanding and adherence to the SOP and HCW's willingness to use the SSS collection method.

Funding

The first author was supported by the University of Washington Department of Environmental and Occupational Health Sciences Top Scholar Award and The Bill and Melinda Gates Foundation.

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APPENDICES

Appendix A: Codebook and definitions

Table A: Codebook

Code	Short- hand	Examples of when to apply	Description
Attributes			
Participants Demographics	Demog	"Years in the field" or "makes home visits."	Apply to key background information about the key informant relevant to the research, e.g., professional or personal demographics to help keep the inductive codes linked to the individual participants
Interesting fact	Fun Fact	How COVID-19 is impacting precautionary behaviors for TB.	Apply to key points that are interesting facts that may guide creation of codes for the inductive process.
Great quote	Quote	For phrases or sentences that might be particularly great to include in a final document “I think sputum is gross and messy and I like	Apply to particularly great or well-phrased quotes from the interview which can be used when reporting findings.

		tongue swab because it is cleaner and easier to use." ie) comparing the two methods Sputum vs tongue swab. Any context specific reasoning supporting their sample collection method of preference. Any ideas on improving safety.	
Provider Swab	HCW Swab	I preferer to take the smaples myself becoasue I don't think the patients can do it right.	Apply to discussion about provider swabbing co-coded with relevant parent/child codes.
Supervised Self Swab	SS Swab	I don't want to be so close to the patient with their mouth open so I prefer to have them do it themselves and I can guide them from a safe distance.	Apply to discussion about supervised self-swabbing co-coded with relevant parent/child codes.
Comparison of Tongue Swab with Gold Standard	tongue swab vs gold	Sputum is hard for many of my patients to produce so tongue swab would help ensure that those	Apply to discussion comparing tongue swab to traditional sputum sampling which is the "Gold Standard" for TB

Sputum Sampling		patients can still get a TB diagnosis test.	diagnostics co-coded with relevant parent/child codes.
Patient Communities	Patient Com	"The community is very open and eager to join our studies." or "Now with COVID, community members are not as eager to join our studies because they think we are giving them a vaccine that they are afraid of."	Apply to text that discusses key informants' beliefs or perceptions about the patient community's beliefs, perceptions or actions that may be related to facilitators or barriers to use or willingness to use tongue swab.
Parent Codes			
Exposure Pathway	ExpPathway	Being exposed to a patient with TB not using proper PPE	Apply to text that discusses the ways in which the key informant may be exposed to hazards that affect their safety or health in their workplace or in their community.
Perceived Threat	Threat	If I come into contact with TB there is a likelihood that I will have a severe outcome.	Apply to text that describes the likelihood that a threat (TB or COVID) will affect the key informant and/or how bad it will be if it does.
Training	Training	SOP's and training to	Apply to text that discusses

		protect myself from exposure to TB while using the tongue swabs.	skills or knowledge acquired through formal training prior to collecting samples using the tongue swab method. Formal training may include, but is not limited to, field training, live simulation, power points, reference guides and/or illustrations.
Self-Efficacy	S-Efficacy	I cannot control the patients who are intoxicated and cannot follow directions when collecting samples. The HCW does not find the SOP to be achievable (low self- efficacy). The HCW is able to prevent getting exposed to TB by following the SOP. (e.g., HCW is able to effectively and easily prevent occupational	Apply to text that discusses perceptions related to the Skills and Knowledge necessary to implement the relevant diagnostic effectively to diagnose TB, including the perception the key informant has of being competent to perform associated tasks to control the risk of getting (TB/COVID/other).

		acquired tuberculosis by using tongue swabs). the HCW does not find the SOP to be achievable.	
Response Efficacy	R-Efficacy	I think that the tongue swab will be a great way to test patients who are challenged with producing sputum for the "gold standard" TB diagnostics.	Apply to text that describes perceptions of effectiveness of relevant diagnosis test (PS, SSS, Gold Standard) for **detecting TB**. Can I successfully collect a sample for diagnosis?
Mitigation Strategies	Mitigation	I have all the PPE I need when collecting tongue swab samples.	Apply to text that describes strategies that were used to control/ mitigate occupational health hazards from spreading at work or in the community. (TB/COVID/other)
Challenges	Challenge	Going into the home early in the morning to collect samples and all the family is in the house. Kids jump on my lap and it is hard to	Apply to text that describes challenges faced in the workplace that are perceived to impact the ability to implement tongue swab or Gold Standard safely or effectively.

		maintain a safe physical distance.	
Opportunities	Opportunity	training videos or an illustration to use to help explain how the patient can swab themselves while being supervised.	Apply to text that describes resources or systems that the key informant does not currently have access to, but perceive would facilitate the safe or effective tongue swab sample collection process.
Pre COVID-19	Pre-COVID	"Before COVID we did not wear masks with the babies but now with COVID we wear masks all the time".	Apply to text that describes behaviors, beliefs or perceptions before COVID vs during the COVID pandemic.
Social Support	Support	I have social support from my colleagues when one of them volunteers to accompany me to make home visits.	Discusses how team dynamics and/or support systems can be used to reduce occupational health risk while collecting tongue swab samples.
Child Codes			
Exposure Pathway/Workplace	Work Exp	When a patient coughs in your face while collecting the sample	Apply to text that discusses the ways in which the key informant may be exposed to hazards that

Exposure Pathway			affect their safety or health in their workplace.
Exposure Pathway/Community Exposure Pathway	Community Exp	When a neighbor has active TB	Apply to text that discusses the ways in which the key informant may be exposed to hazards that affect their safety or health in their community.
Training/ Provider Training	Training Provider	I received an SOP on how to safely using the PS use the tongue swab	Apply to text that describes types of provider training, and/or issues related to provider training, on how to use the diagnostic (PS, SSS, or gold standard)
Training/ Patient Training	Training Patient	I received training on how to demonstrate to my patients how to safely swab themselves while I am watching them.	Apply to a text that describes types of patient training, and/or issues related to patient training, on how to use diagnostic (PS, SSS, or gold standard).
Perceived Threat /Susceptibility COVID-19	COVID Susceptibility	I got COVID-19 when we were in lockdown and I was not going to work so I know it was not occupationally acquired.	Discusses perceptions of the likelihood that a threat (COVID) will affect the key informant and/or cause them harm.

		If I can get TB in my community, I can also get it at work if I am not careful. Or: They don't think that they could get COVID-19 by using the traditional sputum sampling method and would rather not change to tongue swabs.	
Perceived Threat/ Susceptibility TB	TB Susceptibility	I have been working with TB for 15 years now and have not been infected. I eat healthy and take care of myself so I won't get TB.	Discusses perceptions of the likelihood that a threat (TB) will affect the key informant and/or cause them harm.
Perceived Threat/ Severity COVID-19	COVID Consequences	There isn't a cure or treatment for COVID-19 so I am concerned with getting COVID-19 and maybe being seriously ill.	Describes the perception of the severity of consequences that exposure to a threat (COVID-19) will result.

Perceived Threat/ Severity TB	TB Consequences	There is a cure and treatment for TB so if I get it at work that is a part of the risk, I accept to do my job. I can easily do the treatment and I will be OK.	Describes the perception of the severity of consequences that exposure to a threat (TB) will result.
PS Swab/ Willingness to use Provider Swabbing	Use HCW	I don't trust my patient who is intoxicated to swab themselves so I would prefer to swab them myself.	Describes contexts where the provider is willing to use the tongue swabs to collect samples for diagnosis of TB.
SS Swab/ Willingness to use Supervised Self Swabbing	Use SS Swab	With the proper training tools, I can guide my patients to swab themselves in their presence.	Describes issues related to where the provider is willing to supervise their patients to collect their own sample for TB diagnosis.

Appendix B: Interview guide

User Acceptance and Risk Perceptions of Healthcare Workers Using Tongue Swabs for TB Diagnosis

Thank you so much for taking time out of your day to hop on this call.
Hello my name is xxxx. I am a graduate student at the xxxx of Public Health. I work in the xxxx lab developing diagnostics from TB and COVID-19.

I work on improving diagnostic technologies and educational materials protecting workers in the healthcare setting. I will review the research statement and study procedures now and then we can have a discussion about your experiences.

Researchers' Statement

Welcome and Study Procedures

Thank you for agreeing to participate in our study. We've asked you to participate because you are experienced in collecting samples for TB diagnostics using both the traditional sputum and tongue swab method. As participants in tongue swab sample collection activities in endemic settings during the era of COVID-19 we are interested in understanding what risks you are being exposed to and if you have the tools to mitigate these risks in your work. Each interview will last 45-60 minutes.

The purpose of this interview is to describe you and your experiences during sample collection from patients that are suspected to have TB during the era of COVID-19. We'd also like to hear your thoughts on potential recommendations that could minimize any threats and risks if any during future tongue swab sampling, including training and resource provision.

Benefits and Risks to the Study

There are no known personal benefits to participating in this study. There are minimal risks to your participation. It may benefit society and your occupation by providing more knowledge about perceived risks of using tongue swab in clinical practice. This understanding could lead to improving training and education materials for tongue swab and to inform protocols and procedures for tongue swab use.

Explanation of the process

We are using an interview format to help understand the context behind the answers you will provide to our questions, as we believe they will provide a more in-depth understanding than a written survey can provide. There are no wrong answers.

We will be taking notes and recording the interviews. Interviews will be professionally transcribed for data analysis. Interview data that has been de-identified may be placed in a data repository to answer alternative research questions. Your name or contact information will not be associated with any data that is shared in such a repository or with other researchers.

The findings may be written into a report or manuscript for publication in a peer-reviewed journal. We will not refer to you by name in any report or publication without your explicit written consent.

Your participation in this interview is completely voluntary and you may opt to stop at any point in the interview process and leave the study at any time. You will not be penalized for not answering questions or leaving the study. We will provide you with a complete copy of our results at the conclusion of the study.

In the next few weeks, I will send you a summary of the key points gleaned from your interview. I will ask that you review them and let me know if I accurately captured the perspectives you shared within two weeks of receiving that email.

Questions and consent

Do you have any questions before we begin?

Do you consent to be a participant in our study? (Ask participants to provide a verbal "yes".)

Do you consent to the recording of this interview?

Discussion (threat susceptibility, threat severity, self-efficacy, response-efficacy)

Intro

We would like to hear about your background and experience with collecting samples for diagnosis.

1. Before we continue, how would you like me to refer to you as? Can you please pronounce your name?
2. What is your job title?
3. Can you tell me a little bit about your experience collecting samples for TB, including through sputum samples and tongue swab?
4. How long have you been working on this?
5. What language/es do you use in your work?
6. How would you describe your patient community?
7. How would you describe your community where you live?
8. How do you think your risk of getting TB at work compares to getting TB in your community?
9. How does your risk of getting TB compare to other risks of getting other diseases at work (e.g., COVID-19)?
10. What would be the consequences of getting TB at work?

a. What are the consequences to you?

b. What about your family?

Background

Now, we'd like to hear a little bit more about how the risks that traditional sputum sample collection pose to your health and safety.

1. How does collecting sputum to assess TB impact your risk of getting TB?
2. Do you feel like you have the knowledge, skills and ability to safely collect sputum samples?
    a. Posed: How do you reduce your risk of TB while taking samples?

3. Under what circumstances do you prefer to use the traditional sputum sampling collection method for TB diagnostics? Why?
    a. Prompt: Can you provide an example of a situation where you would prefer to use the traditional sputum sample as opposed to the oral swab?
4. Do you think your prior experience with sputum samples has helped you to mitigate risks of disease exposure? How? Why?
    a. To TB?
    b. To COVID-19? Other diseases?
        i. Prompt example: Because of a patient coughing while taking the sample, e.g., TB patient sick in hospital bed and not able to get outside to self-collect a sputum sample.

Now, we'd like to hear a little bit more about how the risks that tongue swab poses to your health and safety.

5. How does collecting samples to assess TB via tongue swab impact your risk of getting TB?
6. Do you feel like you have the knowledge, skills and ability to safely collect samples via tongue swab?
    a. Posed: How do you reduce your risk of TB while taking samples?

7. Under what circumstances do you prefer to use the tongue swab method for TB diagnostics? Why?
    a. Prompt: Can you provide an example of a situation where you would prefer to use tongue swab?
8. Do you think your prior experience with tongue swab has helped you mitigate risks of disease exposure? How? Why?
    a. To TB?
    b. To COVID-19? Other diseases?
        i. Prompt example: Because of a patient coughing while taking the sample, e.g., TB patient sick in hospital bed and not able to get outside to self-collect a sputum sample.

Now, we'd like to hear a little bit more about how the risks that supervised patient self-swabbing poses to your health and safety. Reference link to supervised self-swab for flu test which I will extrapolate on for tongue swab for TB.

9. How does collecting samples to assess TB via supervised patient self-swabbing impact your risk of getting TB?
10. Do you feel like you have the knowledge, skills and ability to implement self-swabbing?
    a. Prompt: Do you feel like your patients can safely and effectively collect their self-swab samples?
    b. Prompt: How do you reduce your risk of TB while taking samples?

11. How do you think collecting samples via patient self-swabbing affects your risk of getting TB?
12. Under what circumstances do you prefer to use the supervised tongue swab method for TB diagnostics? Why?
    a. Prompt: Can you provide an example of a situation where you would prefer to use tongue swab?
13. Do you think your prior experience with supervised self-swabbing has helped you mitigate risks of disease exposure? How? Why?
    a. To TB?
    b. To COVID-19? Other diseases?
        i. Prompt example: Because of a patient coughing while taking the sample, e.g., TB patient sick in hospital bed and not able to get outside to self-collect a self-swabbing sample.

Prompt for flow of conversation:

I know that you mentioned this….

Do you have any additional comments…

Training

14. Can you describe any training that you've received to protect yourself from TB exposure at work?
    - Prompt: Was any of this training specific to traditional sputum samples? To tongue swab? To self-swabbing?
15. Do you feel like your workplace conditions allow you to implement the training you received to protect your health and safety?
        i. What barriers exist in your workplace?
16. What additional training do you think you need to do your job safely?
17. What additional resources do you think you need to do your job safely?

18. How do you think your use of any of these methods influences the health and safety of other workers at your facility?
19. What training might they need to protect their health and safety if any?

Closing

- Thank you so much for sharing your expertise and experiences. Is there anything else you would like to share before we go?
- Would you mind if we contact you if we have additional questions in the future?
- Thank you very much for your participation. Wishing you and your team well during these uncertain times.

Appendix C: SOP for supervised self-swabbing

*Note: All sample collection outside the clinical setting needs to be conducted in pairs and during the daytime while abiding by personnel security protocols of the partnering agency.

Swab Collection

1. The swabs are single-use, sterile, and packaged individually.
2. The health care worker (HCW) and patient should wear appropriate PPE.
3. Conditions for ideal sample collection (will vary for Aim 1):
    a. The patient should not eat, drink, brush their teeth or use mouthwash for at least 30 minutes before giving the sample.
    b. The sample should be collected in the morning, if possible.

Copan FLOQ tongue swab: Supervised self-Swabbing

4. Prior to swabbing, explain proper tongue swab collection to the patient.
    a. Open the packaging and have the patient pull the swab out by the shaft. They should not touch the swab head.
    b. The tongue swab will be collected by the patient following these directions:
        i. Firmly swab the length and breadth of the tongue dorsum, from the front to as far back as is comfortable.
        ii. Press hard enough to slightly bend the shaft of the swab.
        iii. Rotate the swab head during sampling.
        iv. Swab for 15 seconds.
        v. Swabbing may leave the tongue feeling dry but should not cause any pain or discomfort.
    b. After sampling, the patient should put their mask back on with one hand and place the swab into the 2 mL tube held by the study staff member.
    c. The HCW will break off the head of the swab into the tube.
    d. Discard the shaft of the swab.

Appendix D: SOP for Provider Swab

*Note: All sample collection outside the clinical setting needs to be conducted in pairs and during the daytime while abiding by personnel security protocols of the partnering agency.

Swab Collection

1. The swabs are single-use, sterile, and packaged individually.
2. The health care worker (HCW) and patient should wear appropriate PPE.
3. Conditions for ideal sample collection (will vary for Aim 1):
    a. The patient should not eat, drink, brush their teeth or use mouthwash for at least 30 minutes before giving the sample.
    b. The sample should be collected in the morning, if possible.
    c. Open packaging and pull the swab out of the wrapper by holding the shaft.
    d. They should not touch the swab head.
    e. Collect sample:
        i. Firmly swab the length and breadth of the tongue dorsum, from the front to as far back as is comfortable.
        ii. Press hard enough to slightly bend the shaft of the swab.
        iii. Rotate the swab head during sampling.
        iv. Swab for 15 seconds.
        v. Swabbing may leave the tongue feeling dry but should not cause any pain or discomfort.
    f. After sampling, place the swab into the 2 mL tube
    g. Break off the head of the swab into the tube.
    h. Discard the shaft of the swab.