



# BMJ Open Experiences and perceptions of urine sampling for tuberculosis testing among HIV patients: a multisite qualitative descriptive study

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**To cite:** Lissouba P, Rücker SCM, Otieno LA, *et al.* Experiences and perceptions of urine sampling for tuberculosis testing among HIV patients: a multisite qualitative descriptive study. *BMJ Open* 2023;**13**:e058805. doi:10.1136/bmjopen-2021-058805

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-058805>).

Received 18 March 2022  
Accepted 27 October 2023



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## ABSTRACT

**Objectives** Evidence on the acceptability of urine-based assays for tuberculosis (TB) diagnosis among patients remains limited. We sought to describe patients' experiences and perceptions of urine sampling for TB testing at point of care.

**Setting** Study sites in Kenya, Uganda, Mozambique and South Africa.

**Participants** Adult ambulatory HIV patients enrolled in a TB diagnostic study were selected purposively.

**Intervention** For this qualitative descriptive study, audiorecorded individual interviews conducted with consenting participants were translated, transcribed and analysed using content analysis. Ethical agreement was obtained from relevant ethical review committees.

**Results** Fifty-eight participants were interviewed. Three domains were identified. Overall, participants described urine sampling as easy, rapid and painless, with the main challenge being lacking the urge. Urine was preferred to sputum sampling in terms of simplicity, comfort, stigma reduction, convenience and practicality. While perceptions regarding its trustworthiness for TB diagnosis differed, urine sampling was viewed as an additional mean to detect TB and beneficial for early diagnosis. Participants were willing to wait for several hours for same-day results to allay the emotional, physical and financial burden of having to return to collect results, and would rather not pay for the test. Facilitators of urine sampling included cleanliness and perceived privacy of sampling environments, comprehensive sampling instructions and test information, as well as supplies such as toilet paper and envelopes ensuring comfort and privacy when producing and returning samples. Participants' motivation for accepting urine-based TB testing stemmed from their perceived susceptibility to TB, the value they attributed to their health, especially when experiencing symptoms, and their positive interactions with the medical team.

**Conclusions** This study suggests that urine sampling is well accepted as a TB diagnostic method and provides insights on how to promote patients' uptake of urine-based testing and improve their sampling experiences. These results encourage the future broad use of urine-based assays at point of care.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ As per its naturalistic methodology, this qualitative descriptive study provides a literal and comprehensive summary of HIV patients' perceptions and experiences of urine-based assays for tuberculosis (TB) diagnosis at point of care.
- ⇒ Conducted in four sub-Saharan African settings, in both primary care health facilities and HIV clinics, this study assesses urine-based TB testing acceptability in a variety of settings and contexts.
- ⇒ However, because the study was embedded in a diagnostic study, it does not provide any insights on patients who refused participation or not willing to be investigated for TB.
- ⇒ Furthermore, this study was conducted in a context that afforded participants several advantages, including an informed consent process that may have influenced their general attitudes towards urine-based TB testing.

## INTRODUCTION

Tuberculosis (TB), 1 of the top 10 causes of mortality worldwide,<sup>1</sup> is curable and preventable. However, its suboptimal case detection rate is a major obstacle for global TB control efforts. Current TB diagnostic standards involve the sampling of body fluids that may be challenging for patients to produce, such as sputum, and procedures that can be time-consuming and carry a risk of infection. Generally, they require specific equipment and specialist workforce that is not always available in low-resource settings and which can be costly.<sup>2</sup>

In response to calls for inexpensive, rapid, easy-to-perform, point-of-care (POC) tests for TB diagnosis,<sup>3</sup> urine-based assays are promising,<sup>2</sup> as they can be performed by health workers during routine care.<sup>4</sup> Currently,

the WHO-endorsed urine-based test, Alere Determine TB LAM Ag assay (AlereLAM; Abbott, Chicago, Illinois, USA) is commercially available<sup>5–8</sup> and third-generation TB-LAM tests are in development.

While a test's diagnostic accuracy is a key consideration, it does not guarantee its successful introduction, uptake and sustainability in its intended settings. Notably, patients' acceptability of TB testing is a key aspect that is often overlooked.<sup>9</sup> However, the acceptance of body fluids sampling for clinical purposes may go against social norms or cultural values, causing reluctance among patients.<sup>10</sup> Therefore, it is important, when advancing urine-based diagnostic methods, to explore perceptions of urine sampling for TB testing.

Research on the acceptability of urine-based TB testing remains limited, probably due to the newness of the technology. Studies assessing the feasibility of AlereLAM have reported potential challenges to patients' acceptability: one indicated that menstruating female patients may be less likely to accept urine-based testing<sup>4</sup> while another suggested that a diagnostic algorithm including urine-based testing would be too complex to explain and thus not acceptable to patients.<sup>11</sup> However, these issues were identified by health personnel performing the test, not patients.

## Objectives

The present inquiry aims to describe the experiences and perceptions of urine sampling for TB testing among ambulatory HIV positive patients in four sub-Saharan countries in order to provide insights into the acceptability of this method and inform the implementation and future use of urine-based assays for TB testing at point of care.

## METHODS

### Design

The study was drawn methodologically from qualitative description (QD), a naturalistic approach which allows the exploration of a phenomenon without making theoretical assumptions.<sup>12</sup> It aims to yield rich, straight description of experiences from those undergoing the phenomenon under investigation.

This paper follows the Standards for Reporting Qualitative Research guidelines.<sup>13</sup>

### Patient and public involvement

Patients were not involved in the planning of the study nor were they consulted regarding the findings of the study. However, in sharing their lived experiences and perspectives, they informed our reporting. As per the QD approach,<sup>12 14 15</sup> the coding process remained close to the data, and was minimally interpretative to provide a literal and comprehensive summary of participants' experiences. Participants' recommendations are reported in the findings.

### Settings

The inquiry was conducted in the context of a TB diagnostic prospective study<sup>16</sup> carried out in Uganda, Kenya,

Mozambique and South Africa. Study sites included two outpatient HIV clinics attached to referral hospitals (The HIV clinic of the Mbarara Regional Reference Hospital in Uganda and the HIV and TB clinics of the Homabay County Teaching and Referral Hospital in Kenya), the outpatient department of Eshowe Hospital in South Africa and two primary healthcare centres (the Alto Maé Reference Centre in Mozambique and the Eshowe Gateway Clinic in South Africa). The diagnostic study included HIV-positive patients aged 15 and older, either with signs and symptoms of TB, or with advanced HIV disease and no signs or symptoms of TB. As part of the study procedures, all patients underwent sputum sampling collected spontaneously or by induction, as well as urine sampling for POC AlereLAM and Fujifilm SILVAMP TB LAM (FujiLAM; Fujifilm, Tokyo, Japan) testing. FujiLAM test results were not disclosed nor used for the diagnosis and clinical management of patients.

### Participants

In collaboration with the diagnostic study medical team, purposive sampling<sup>17</sup> was used to identify, among patients enrolled in the TB diagnostic study, potential participants with characteristics relevant to the inquiry. As it was hypothesised that key patient characteristics could affect urine sampling acceptability, those invited to participate were selected in terms of presence or absence of TB symptoms, gender (male or female), and age group (three categories, 18–24, 25–44 and 45 and older). This allowed to ensure a diverse sample and capture a range of perspectives about urine sampling for TB testing. Sample size per site was determined by 'saturation', that is, the point in the research process where the research team considered that collecting additional data would produce similar results and not add further information.<sup>18</sup>

### Data collection

In each site, data were collected through face-to-face individual interviews by one experienced qualitative field researcher recruited at national level and fluent in the consenting participants' preferred language (Runyan-kore and Rutooro in Uganda, Luo in Kenya, Portuguese and other dialects in Mozambique and isiZulu in South Africa).

The interview guide (see online supplemental file) was developed collaboratively by the qualitative inquiry investigators to address the study questions, then reviewed and translated in the relevant languages by the four field researchers. The topics explored through open-ended questions addressed both practical and attitudinal aspects of urine sampling, including: (1) interactions with the study medical team, content, context and quality of their communication about urine sampling, list of supplies provided and participants' thoughts and opinions of these interactions; (2) experience and perceptions of urine sampling, consisting of participants' detailed description of their experience from the moment they were given the sampling supplies to their sample submission to the

medical team; (3) participants' perceptions of urine-based testing, notably compared with other methods of TB testing, and their expectations on waiting time to obtain results and (4) participants recommendations, suggestions, concerns or comments regarding urine sampling and urine-based TB diagnosis.

Data collection took place 15 December 2020–23 December 2020 for the Homa Bay (Kenya) site, 18 January 2021–15 March 2021, for the Mbarara (Uganda) site, 24 March 2021–10 May 2021, for the Maputo (Mozambique) site, and 15 February 2021–6 June 2021, for the Eshowe (South Africa) site. Interviews lasted between 30 and 60 min and were audiorecorded. The recordings were subsequently translated and transcribed verbatim by the field researchers. To ascertain data quality, prior to the start of the study, field researchers were provided with a comprehensive overview of the objectives and methods of the study and a refresher training on qualitative interviewing techniques. Furthermore, during the data collection period, regular one on one online debriefings were held between the field researchers and the qualitative inquiry investigators to reflect and discuss issues faced during interviews, review findings and adapt the interview guide as needed.

### Data analyses

Translated transcripts were uploaded in Atlas TIV.9 for Windows (Scientific Software Development, Berlin, Germany). Content data analysis,<sup>19–21</sup> focusing on the manifest content, was conducted by one of the study investigators, who, after reading transcripts several times to gain familiarity with the data, reduced textual material to codes representing manageable units of data. The coding frame was developed in an iterative manner, coding data abductively, with predefined codes related to the research question, codes generated from memos, debriefings and discussions notes

compiled during data collection and analysis, as well as inductively from the data. Codes were then organised into categories and subcategories in a way best suited to the data, and fitted into three domains which connected to the research question collaboratively by all study investigators and the researchers in charge of data collection.<sup>21</sup> Several techniques were used to ensure rigour and results' validity and quotes were selected to substantiate the findings.

### Researchers characteristics

In addition to the four field researchers, the qualitative assessment team included three international investigators who were epidemiologists: one with a nursing background and field experience in TB and HIV programme management and research including urine-based TB testing, one medical doctor with extensive TB and HIV practice and research experience who is also the coordinating principal investigator of the diagnostic study, and one field epidemiologist with experience in qualitative research, HIV and TB prevention and management and a degree in sociology.

## RESULTS

### Participants' characteristics

Across all sites, a total of 58 participants were recruited and interviewed, including 32 women and 26 men. Gender was self-reported. Participants' data are summarised in [table 1](#). No difference in terms of gender was found in the analyses.

### Domains and categories

Patients' data on urine sampling and urine-based TB testing were organised in categories and subcategories

Participant characteristics	Homa Bay, Kenya	Mbarara, Uganda	Eshowe, South Africa	Maputo, Mozambique	Total
Gender					
Female	9	8	9	6	32
Male	7	8	3	8	26
Age group					
18–24	5	4	0	2	11
25–44	7	8	7	5	27
45 and older	4	4	5	7	20
Symptoms					
Patients with signs and symptoms of TB	7	8	12	5	32
Patients with advanced HIV disease and no signs or symptoms of TB	9	8	0	9	26
Total	16	16	12	14	58
TB, tuberculosis.					

**Table 2** Domains and categories of TB diagnostic study patients' acceptance of urine sampling and urine-based TB testing

Domains	Categories
Experience and perceptions of urine sampling and urine-based TB testing	▶ Positive attitudes towards urine sampling
	▶ Preference of urine versus sputum sampling
	▶ Trustworthiness and plausibility of urine sampling for TB testing
	▶ Expectations on waiting time for urine-based TB testing and diagnosis
	▶ Perspectives about bearing the cost of the test
Facilitators of urine sampling	▶ Urine sampling environment
	▶ Urine sampling instructions
	▶ Urine sampling supplies and support
Motivational factors of acceptance of urine-based TB testing	▶ Perceived susceptibility to TB infection
	▶ Collaborative interactions with the medical team
	▶ Advantages of being enrolled in a study
TB, tuberculosis.	

and classified within the following three identified domains (see [table 2](#)):

- ▶ Experience and perceptions of urine sampling and urine-based TB testing: This domain encompasses how participants experienced and viewed urine sampling for TB testing, how they compared it to sputum sampling, their beliefs on the plausibility and pertinence of urine-based TB testing, their expectations on waiting time for results and their opinions on bearing the cost of the test.
- ▶ Facilitators of urine-sampling: This domain includes contextual aspects which may influence patients' urine sampling experiences based on their level or degree of availability. They include characteristics of the physical sampling environment, the sampling instructions received, and the supplies and/or support participants were provided.
- ▶ Motivational factors of acceptance of urine-based TB testing: This domain consists of the factors that motivated or influenced participants to accept providing urine for TB testing. They include heightened perceived susceptibility to TB, especially when experiencing symptoms, the collaborative relationship they had with the medical team, and the advantages of taking part in a research study.

## Experience and perceptions of urine sampling and urine-based TB testing

### Positive attitudes towards urine sampling

Participants considered urinating a common body function, requiring little effort, that they could accomplish competently. They viewed urine as a natural body fluid with no intrinsic value that is readily available and quick to produce, and described their urine sampling experience as having been easy, painless and rapid, especially when they were feeling the urge to urinate:

[Urine] is something I got easily. It was not a problem collecting the urine. With urine, there is no pain (...) it is also good because it does not consume a lot of time. Another thing is also that it does not consume a lot of energy. (Participant 5, Kenya)

The main reported challenge was lacking the urge to urinate, but it was reportedly managed within a reasonable time frame (about 15–20 min), by drinking water and/or waiting for a while.

### Preference of urine vs. sputum sampling

Participants, equally represented among symptomatic and asymptomatic individuals, often compared the relative simplicity of urine sampling to the struggles they faced for the expectoration of sputum, including discomfort, repulsion, disgust, nausea, pain in the chest and dry cough. Sputum sampling seemed particularly difficult and lengthy for participants who did not have coughing symptoms, whereas for urine, the urge eventually came. All participants expressed a marked preference for urine sampling, citing as its advantages the following:

(a) It was easier and simpler to produce than sputum.

'There is that particular sputum sample that is needed. Even if you have it in the throat, it is hard to produce. They may ask you for sputum and you instead provide saliva. But for urine, it is easy to provide the sample'. (Participant 14, Uganda)

(b) It was easier to manage urine sampling failure (not urinating spontaneously), by drinking fluids and waiting, than failing to expectorate sputum, which often entailed undergoing induction (involving the inhalation of a nebulised mist) to provoke sputum production.

'I'd rather collect urine (.) because as I said, you may not be coughing, and it is not easy to have to take the test, first you have to induce it, whereas with urine that procedure is not necessary' (Participant 7, Mozambique)

(c) It was less stigmatising than sputum sampling because it could be performed autonomously, privately and near silently, without 'shameful' coughing noises.

'If you do not like people to see what you are doing, you go to the toilet, take urine, and hide it. While with sputum (...) a person can hear you coughing,

and you find that the other person feels disgusted (...) The urine is better' (Participant 7, South Africa)

(d) It was in support of a more advanced, newer technology of TB testing.

'A urine sample is far better; the technology is evolving. It's true that in the past they used sputum, until they got that test. If now it's possible to diagnose TB via blood, via urine, it means that there's been an evolution.' (Participant 4, Mozambique)

(e) Urine samples were cleaner and easier to handle and transport.

'I collected urine well...that urine did not scare me because it was just clean [that's why] I can take this kind of urine sample' (Participant 3, Kenya)

(f) It was easier to ensure urine samples' quality, as it did not have specific standards, unlike sputum which could be rejected due to poor quality if it was only saliva.

'Urine can be produced better than these other samples. Because I can go and collect a lot of saliva and the doctor will say that I have not produced quality sample (...) but for urine you collect it once and you are done. And it is something which is clear and will not lie or deceive you' (Participant 10, Kenya)

#### Trustworthiness and plausibility of urine sampling for TB testing

Trustworthiness of urine sampling was associated with how participants conceptualised the association between the urinary tract and the aetiology of TB, and how they perceived it was plausible that TB could be detected in urine. Some participants could conceive that urine was a plausible medium for TB diagnosis because as water circulating all over the body, it could 'collect' TB germs when present, especially because TB could affect other organs beyond the lungs and be 'silent' and 'hide'. Other participants held the conviction that TB was primarily affecting the chest and the lungs and questioned the connection between the urinary tract and the pulmonary system. For these participants, testing for TB in sputum was something 'they had always known', while they considered urine-based TB testing as experimental. Mistrust about urine-based TB results could be upheld even if there was a stated preference for urine sampling. Trust in urine-based TB results was further influenced by previous experiences with urine-based TB testing. Participants who had received a positive TB diagnosis while obtaining discordant urine and sputum results were more likely to admit their trust in the one test that had turned positive. Nevertheless, several participants asserted that testing both samples was justified and necessary to optimise the detection of TB, and that both results were equally trustworthy due to the various clinical presentations of TB:

'TB manifests in many different ways. There is TB that affects the bones and that which affects the chest as well as that which affects the blood. So, I believe

that is the reason why those many samples are taken to test for TB. You know they may take only the sputum sample and they may not detect the TB, but the TB is already eating you up and by the time they detect the TB, it is already too late. So TB affects people in different ways.' (Participant 1, Uganda)

Urine-based TB testing was also incorrectly perceived as useful for early diagnosis, based on the notion that coughing and producing sputum was a symptom of advanced sickness while urinating was a common, 'normal' function that was not associated with being ill:

'The urine test is good because tuberculosis can be detected earlier before it destroys many things and you develop a cough (...) before you start coughing, you cannot just run to the hospital (...) sometimes [TB] has no symptoms. (...) [With the sputum] you are like someone who is sick. But (with) the urine test, you are just normal.' (Participant 3, Kenya)

#### Expectations on waiting time for urine-based TB testing and diagnosis

Expectations regarding waiting times for urine-based TB results were primarily to have them on the same day, as participants emphasised the emotional, physical and financial burdens associated with having to return a day or more later to the health facility to collect their results, which included the anxiety of not knowing one's status, the efforts required to travel back and forth to the health facility and importantly the costs associated with multiple transport fares:

'Yes, [rather] than to come back the next day because of money for transport and time. As we are sick, we need not to overwork ourselves by keeping on coming here. It is better to just go to the hospital and be prepared to wait. Same day can be better and easy because you want to know what is happening and be free, it must not take long. [If] I must wait [longer than a day], maybe I would get even more sick because of the wait' (Participant 2, South Africa)

Finding ways to procure enough money for transport could delay participant's return to the health facility. There were also issues associated with missed periods of work and having to organise for childcare, which could also incur financial losses or expenses. Furthermore, same-day results, if positive, allowed for same-day treatment initiation and would benefit patients clinically. Several participants stated that they would prefer to obtain test results on the same day within 3 hours at most, but many also stressed that they were ready to wait for as long as it took for the sake of their health, as they felt that it was not up to them but up to the medical team to decide how long the testing process had to take to ensure they received an accurate diagnosis and appropriate care.

### Perspectives about bearing the cost of the test

Receiving the test free of charge appeared to be an important aspect influencing urine-based TB testing acceptance, as many participants, expecting the cost to be high, acknowledged that they would not be able to pay for it without diverting money destined to their basic needs such as food, delaying getting the test while trying to procure money, or forgoing the test all together. Having to pay for the test was viewed as inequitable, because only those who could afford it would be able to get it:

‘Some people are poor, others don’t work, others are old (...) if they pay for this test, it will be a little complicated, only the person who has money, the person who works will survive, but the elderly, the unemployed, those who live in the countryside, will not have life. I think that it’s not necessary to pay for it’ (Participant 11, Mozambique)

The few participants who stated that they would be willing to pay for the test would only be able to afford a small amount, primarily for the sake of their health, but added that they would only do it if they perceived it was really needed, that is, if they felt ill and were experiencing TB symptoms.

### Facilitators of urine sampling

#### Urine sampling environment

Environmental and contextual aspects which influenced the provision of the urine sample included toilet cleanliness, privacy and distance. In Kenya, Uganda and Mozambique, the diagnostic study participants used the general health facilities’ toilets, which were shared by large numbers of patients, and were at some distance from the study site. In South Africa, the toilet was located near the diagnostic study site. When both cleanliness and privacy aspects were present, the experience of urine sampling was described as having been comfortable. However, lack of cleanliness was reported by some participants as an actual barrier to urine sampling, who stated fearing that they would catch diseases or infections, or that the urine sample would be contaminated. Participants reported that it made them feel bad, and that it discouraged them from sampling urine. ‘When you go to the toilet and you find that it is dirty, it does not give you the morale to do what you have to do there. But if it is clean, then you do what you have to do without any worries’ (Participant 13, Uganda). In a few instances, the conditions were reported to be so bad that participants only managed to collect the sample by urinating outside the toilet. Fear of infection was further exacerbated if there were no functioning handwashing points on sites. Similarly, lack of privacy, in particular, having other people present such as in a urinal, or running the risk of being seen such as in an unlockable space, was perceived as unsafe and embarrassing and could delay the production of the urine sample. ‘Sometimes someone is close to you, and you cannot start urinating when people are observing you’ (Participant 1, Kenya). Lack of cleanliness and lack of privacy were often experienced at the same

time. Some participants admonished that such environments were ‘typically for patients’ and was indicative of a lack of consideration for them, as if they were ‘not meriting attention’.

Overall, participants expressed their preference for toilets dedicated for urine sampling that ensured their safety from infections, discomfort and exposure as TB presumptive patients. Interestingly, home sampling was not considered a convenient alternative option.

#### Urine sampling instructions

In addition, instructions and information received about urine sampling appeared to encourage participants to engage in urine sampling. While nearly all participants reported having been satisfied with their communication with the medical team, few reported being told about the amount to provide in the urine containers or whether a mid-stream urine sample was needed. Many felt that it was necessary to provide more in-depth information about the urine sample, how to collect it, and its purpose and function for TB testing, notably in contrast to the sputum sample:

‘When they tell you to do something that you have never done before, of course I was wondering, why are they asking me for urine, what do they want it for? You know for most of us, someone can explain to you something and you believe in them, but if they tell you to take action [provide the sample] that is when you start to question.’ (Participant 2, Uganda)

#### Urine sampling supplies and support

Lastly, while it did not seem to be common practice, the provision of supplies and support, including fluids to stimulate the urge to urinate, a sampling space organised for comfort and ease of access for patients with disabilities for example, as well as wipes for the actual urine sampling process, and importantly, envelopes to conceal the urine samples and return them confidentially to the medical team was appreciated and acknowledged as important by several participants. Indeed, those who were not given such supplies reported having had to wrap the samples in cloth or conceal them in their pockets or handbags.

### Motivational factors of acceptance of urine-based TB testing

#### Perceived susceptibility to TB

Participants’ acceptance of urine-based TB testing appears to be motivated by their high perceived susceptibility to TB, how severe they considered the disease to be and the value they attributed to their health. When they were experiencing symptoms at the time of the study, their main concern was to obtain a diagnosis to receive treatment and restore their health. Being sick, especially with presumptive TB symptoms, was also stigmatising, so participants reported being compelled to seek care. As a participant asserted: ‘The important thing for me is to restore my health. I am tired of going to sit among people, because when

**Table 3** Recommendations for improvement of patients' experience and acceptability of urine sampling and urine-based TB testing

1	Providing a standard 'package' for urine sampling, including comprehensive instructions on how to sample urine, and set of necessary supplies (eg, envelopes to keep the urine sample, wipes or toilet paper)
2	Ensuring the availability, relative proximity, cleanliness, maintenance and privacy of urine sampling spaces as well as the availability of functional handwashing points. Whenever possible, assess the relevance and possibility of having an acceptable, dedicated space for TB presumptive patients.
3	Providing the test free of charge to patients
4	Ensuring that TB results, diagnosis and when applicable, on-site anti-TB treatment are obtained on the same day, preferably within 3 hours, and that they are communicated and provided confidentially to patients.
5	Ensuring patient/provider collaborative relationship and confidential, clear, honest communication on urine-based TB testing and instructions on urine sampling to support patients' needs for information and assistance
TB, tuberculosis.	

*I start to cough, they begin to shun me, I do not deserve that.* (Participant 12, Uganda).

Nonetheless, even when not experiencing symptoms, several participants stated that they would accept urine based-TB testing as they believed TB infection could be silent.

#### Collaborative interactions with the medical team

The reportedly positive collaborative interactions participants had with the medical personnel was an important motivational factor. Most participants reported having had satisfactory communication with the medical team, whom they viewed as knowledgeable, skilled and acting in their patients' best interests. This perception in turn encouraged their trust in the clinicians' recommendations regarding their care, and their full compliance with their advice and directives on health-related procedures, notably urine-based TB testing. As explained by a participant: *[I did the test] for my health, because they were going to check up for diseases that I can live for years without knowing that I have such diseases. When [the health workers] ordered the urine sample, I didn't say no, I accepted'* (Participant 9, Mozambique). Indeed, several participants stated that they felt they could not doubt, question, or refuse what was proposed to them at the health facility to receive good care:

If they can tell me that I have [TB] I will get help and live again if I take treatment as I am also taking my other pills [HIV treatment]. I will be happy there is nothing that will make me feel bad, I will accept everything. (Participant 11, South Africa)

#### Advantages of being enrolled in a study

Lastly, several participants cited the many advantages of being included in a research study as having motivated them to accept study procedures including urine-based TB testing. These advantages included the personalised, sustained medical care and monitoring with personalised reminder phone calls and screening tests, and other supportive care practices, including receiving lunch during health facility visits, reimbursement for transport,

being escorted throughout the health facility to undergo procedures, and more generally being assisted and supported at every step, which made participants feel valued and cared for.

#### DISCUSSION

Our patient-focused inquiry of the acceptability of urine-based TB testing indicates that it is well accepted as a diagnostic method among participating HIV-positive patients investigated for TB. Acceptability is shaped by internal perceptions about the ease, convenience and practicality of urine sampling, the perceived plausibility of urine-based TB diagnosis, motivational factors such as perceived susceptibility to TB, concerns about one's health and trust in health workers, as well as external, supportive factors, such as the appropriateness of the sampling environment to ensure comfort and privacy. These are encouraging results for the implementation of urine-based assays, supplementing evidence showing that the use of urine-based TB-LAM tests at POC is feasible and acceptable among healthcare workers and managers.<sup>4 22</sup>

The acceptance and preference of urine sampling among study participants concurs with research conducted on the acceptability of urine sampling for the testing of TB,<sup>23</sup> as well as other infectious conditions, such as sexually transmitted infections and pneumonia.<sup>24-27</sup> As in previous research,<sup>24 26-28</sup> this study found that urine sampling was also a favoured, often preferred sampling method. Among study participants, urine was viewed as a 'waste' with no intrinsic meaning except that it could be useful for the detection of disease and health conditions. However, it may be different in certain settings where urine is not considered 'neutral' due to social norms or cultural values, as it can be the case for the sampling other body fluids such as blood and semen.<sup>10 29 30</sup> In addition, while the general view was that urine could be obtained effortlessly and painlessly, it is worth noting that this study was conducted among mostly able-bodied ambulatory patients. However, urine may be difficult to produce by severely ill patients.<sup>31</sup> Nonetheless, even if at times



challenging, a noteworthy perceived advantage of urine sampling was that it was less stigmatising than sputum sampling, which is an important aspect of its acceptability, since TB stigma has been associated with diagnosis delay and treatment non-adherence.<sup>32</sup> If patients want to keep the fact that they are being investigated for TB confidential, a urine sample will not automatically be associated with TB testing.

Other notable findings were that patients' conceptualisation of the plausibility of urine-based TB testing directly influenced their trust in the results. Urine-based TB testing was not necessarily considered as a standalone test but one that could be combined with other diagnostic methods such as sputum (or other body fluids) testing and X-ray to increase the likelihood of detecting TB, a view also shared by healthcare providers in a qualitative study on the perceptions of AlereLAM.<sup>31</sup> The idea that urine based-testing should be associated with other diagnostic methods contradicts the argument that a diagnostic algorithm including multiple tests and procedures would be too complex to explain to patients.<sup>11</sup> However, it would be important, when scaling up and advocating for urine-based TB diagnosis, to provide clear and comprehensive information on the use of such tests to dispel misconceptions on urine testing.

A distinct advantage of urine-based testing is that it is a POC test that can yield same-day results. POC tests have been shown to increase the likelihood of receiving a diagnosis and facilitate rapid treatment initiation among diagnosed patients, thus reducing lost to follow-up and improving retention into care.<sup>11</sup> Same-day results allow patients to wait at the health facility to obtain results as opposed to having to return at a later date, reducing waiting anxiety, physical efforts and importantly, travel costs. Most patients reported preferring waiting times of less than 3 hours, so the current turnaround time of 25 min for AlereLAM and the estimated 1 hour for FujiLAM could be readily accepted. However, it is important to ensure that health facilities implementing the test can practically deliver same-day results. Compared with tests performed at centralised testing facilities, POC tests, even with fast turnaround times, could be challenging in low-resources settings, mostly due a workforce who may be tasked to perform the tests while busy taking care of patients. As indicated in a study on AlereLam, same-day results were not always available due to organisational issues.<sup>31</sup> Moreover, same-day results do not ensure same-day treatment initiation if Anti TB-drugs are not available on-site.

The idea of paying for the test was contested by a majority of participants who expected the cost to be high and asserted that they would not be able to afford it, suggesting that a paid-for test would be a barrier to urine-based TB testing acceptability and uptake.

In our study, sampling environment as well as instructions and supplies were identified as facilitators of urine-based testing, affecting recipients' engagement in the intervention<sup>33</sup> and their ability or willingness to produce a sample. Indeed, participants' concern with hygiene,

comfort, safety and privacy should be addressed as they could have programmatic implications for the future implementation of the test. Lack of cleanliness and privacy have been suggested as barriers to urine-based TB testing in a qualitative study on AlereLAM,<sup>31</sup> and in other studies on urine sampling.<sup>24</sup> While study participants who experienced them all managed to produce urine, this may not be the case for patients who are unconcerned, unmotivated, suspicious or afraid to undergo TB testing.

Lastly, participants' motivation and their reasons for accepting the test were recurrent topics during interviews. Motivation is considered an important determinant of behaviour.<sup>34</sup> Nearly, all participants expressed high perceived susceptibility to TB, which is associated with higher rates of testing,<sup>26</sup> and asserted that they valued the opportunity to know their TB status to obtain an accurate diagnosis and an effective treatment if positive. They also reported positive interactions with and high trust towards health providers, which have been associated with better patient health outcomes due to enhanced engagement, compliance with medical advice and improved adherence to treatment.<sup>35</sup> Our findings suggest that when participants trust the medical team, they trust the tests they endorse and are more likely to adhere to their directives. This is illustrated by the facts that participants provided urine samples, despite at times reporting dire toilet conditions, and their admission that they are willing to wait for 'however long it takes' for their results and do 'whatever they are told' if their TB results are positive. Indeed, studies have found that good patients–providers relationships are crucial for successful POC testing, even with infrastructure challenges.<sup>36 37</sup> Nonetheless, while high trust and quality rapport with the medical team is desirable, it can influence how patients perceive that they have a choice in accepting urine-based TB testing. For some participants, the data suggest that acceptability of the test arises from a sense of obligation or resigned agreement to do and accept whatever it takes to get better. Others, however, value the opportunity to get tested with a new technology and feel that by accepting the test voluntarily, they are taking responsibility for their health.

Lastly, we reassessed our data through the lens of the Theoretical Framework of Acceptability (TFA) developed by Sekhon *et al.*,<sup>38</sup> a seven-component theoretical construct designed to systematically assess the acceptability of healthcare interventions from the perspective of intervention deliverers and recipients. We found that our first and third domains were aligned with the TFA and corroborated the acceptability of urine-based TB testing. However, our second domain, facilitators of urine sampling, went beyond the TFA construct. However, it is the domain where several practical and actionable recommendations can be issued to improve patient's experience of urine provision for TB testing.

### Limitations

There are several limitations to this study. First, only patients enrolled in the diagnostic study were included in



the evaluation, so our findings do not provide any insights on patients who refused participation or not willing to be investigated for TB. Second, participants displayed a fairly good knowledge of TB and of the availability of an effective treatment, which could have been partially acquired during the informed consent process and may have influenced their general attitudes towards urine-based TB testing. Lastly, several participants mentioned that they had been motivated to enrol to benefit from many advantages of being part of a study. Such conditions are not likely to be met once the test is implemented as part of routine care.

## CONCLUSION AND RECOMMENDATIONS

This study indicates that overall, and despite some challenges, urine-based TB testing is viewed positively and accepted as a diagnostic method among HIV positive patients. As a patients-focused exploration, it offers concrete insights into participants' attitudes, perspectives, preferences and motivations for this diagnostic method and provides an understanding of their subjective experiences. From our findings, we have formulated several patient-centred recommendations that can be used to improve urine sampling experiences and inform policy and practice for the future use of urine-based assays. They are described in [table 3](#).

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**Acknowledgements** We extend our gratitude to all the study participants for their time and shared insights. We would like to thank the MSF and EPICENTRE field and coordination teams for all their support and assistance.

**Contributors** PL, SCMR and HH drafted the study proposal and the article. PL conducted the data analyses. SCMR and HH participated in the interpretation of the results. LAO, CA, SX, CM and BO critically reviewed the study proposal, collected data, participated in the interpretation of the results and contributed to the article. MA, AVL, RS, CB, LO, NTA, MM and WM critically reviewed the study proposal, assisted in the organisation and conduct of the study, as well as reviewed and provided input for the article. PL is responsible for the overall content as the guarantor.

**Funding** The author(s) received financial support for the research, authorship and/or publication of this article from the following institutions: Médecins sans Frontières (MSF) (grant number: not applicable) and the Agence Nationale de Recherches sur le Sida et les hépatites virales (ANRS) (grant number: 20314).

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** Ethical agreement to conduct the study was obtained from the Ethics Review Board instituted by Médecins Sans Frontières (approval number:

1985), from the Kenya Medical Research Institute (approval number: 687), the Uganda National Council for Science and Technology (approval number: HS2764), the Comité Nacional de Bioética para Saude (approval number: 172/CNBS/20) and the KwaZulu-Natal University Biomedical Research Ethics Committee (approval number: BREC/1623/2020). All participants provided written informed consent to being interviewed and audio recorded. Interviews were conducted in a private location ensuring confidentiality at the health facility. Transport fees from and to patients' homes were reimbursed, when applicable. Transcripts were anonymised and participants were assigned unique identifiers.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available on reasonable request to the corresponding author's institution.

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## Urine Sampling for TB testing Qualitative study

### Interview guide – Patients

Date : \_\_/\_\_/\_\_

Name of health facility/ Study site : \_\_\_\_\_

Participant ID .....

#### General

1. Gender: \_\_F \_\_M Age : \_\_\_\_

#### Theme 1: Interactions with the medical team, content, context and quality of the communication about urine sampling

2. On the day [give date or time since the visit] when you visited the health facility and agreed to be included in the study, you had several procedures, including a physical examination and a chest x-ray. You provided a sputum sample and had blood drawn. You were also asked to submit a sample of urine. What was said to you about the tests done on the urine sample?

*If not discussed, probe for the following:*

- What general information were you given on the tests performed in urine for the diagnosis of tuberculosis?
- What specific instructions were you given on how to collect the urine sample?
- Who gave you this information and the instructions?
- Where and how were this information and the instructions given to you?

3. How did you feel about having to be given this test? What did you think about the information and the instructions you were given?

*If not discussed, probe for the following:*

- How was the communication with the person who gave you the instructions?
- How satisfied were you with the instructions you were given? Why?
- Did you ask or were you asked if you had any questions? If you did, what did you ask? Were you satisfied with the answers?
- Do you have any suggestions so the communication, or the information given can be improved?

#### Theme 2: Experience of urine sampling

4. Can you explain to me your experience with the urine collection? Please start from the moment you were given the instructions about urine collection to the time when you gave the urine sample to the health worker for testing.

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*If not discussed, probe for the following:*

- Was it easy or hard for you to produce the sample? Were there any delays (queue to toilets, did not feel urgency to urinate etc.)?
- Were you offered something (fluids, cups) to help you urinate or did you ask for anything?
- How was the access to and conditions (i.e., cleanliness, space, lighting) of the toilets? Was there a handwashing facility available? How did those factors affect your experience in providing the urine sample?
- How did you feel about the privacy of the toilets when you collected the urine sample?
- Were there any delays in submitting the collected sample (i.e., waiting in queue again to submit sample, mistake in collecting the sample)?
- Did you hear about or witness any challenges that other patients (apart from yourself) have faced when submitting a urine sample? Can you please describe what you heard or witnessed?

– Theme 3: Perception of urine-based TB diagnosis

5. Can you tell me in a few words what you know about TB and how it is diagnosed?

*If not discussed, probe for the following:*

- Have you or someone you know ever had a TB test done? What type of tests?
- According to what you know, how is TB diagnosed? What does the clinician ask for if they want to test someone for TB?

6. Knowing what you do about TB, how do you feel about submitting a urine sample to be used for TB diagnosis?

*If not discussed, probe for the following:*

- What do you think about a test done on urine to detect TB?
- Do you prefer providing a sputum sample or a urine sample? Why?
- What concerns do you have about providing a urine sample?
- How much do you trust TB results from tests done in urine compared to those done in sputum? Why?
- How long would you be willing to wait at the health facility to get your tuberculosis test results? The test we are interested in takes about one hour to give results; do you think this wait time is acceptable? Why?
- How would you feel about paying for the test? How much would you be willing to pay?

Theme 4: Recommendations and suggestions about urine-based TB testing

7. Do you have any additional comments or recommendations about what we have discussed?

8. Do you have any questions for me?

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