Title

Exploration of Pregnant and Breastfeeding Women's Acceptability of Rapid Point-of-Care Urine Testing Within Antenatal and Postnatal Care, and Its Perceived Impact on PrEP Adherence When Paired with PrEP Biofeedback Adherence Counselling in Cape Town,...

Journal

AIDS and Behavior, 30(6)

ISSN

1090-7165

Authors

Court, Lara
Mvududu, Rufaro
Schoetz Dean, Sarah
et al.

Publication Date

2026-06-01

DOI

10.1007/s10461-025-04961-y

AIDS and Behavior
https://doi.org/10.1007/s10461-025-04961-y

ORIGINAL PAPER

Exploration of Pregnant and Breastfeeding Women's Acceptability of Rapid Point-of-Care Urine Testing Within Antenatal and Postnatal Care, and Its Perceived Impact on PrEP Adherence When Paired with PrEP Biofeedback Adherence Counselling in Cape Town, South Africa

Lara Court[1] · Rufaro Mvududu[2,3] · Sarah Schoetz Dean[4] · Lucia Knight[1,5] · Kathryn Dovel[4] · Monica Gandhi[6] · Landon Myer[2] · Thomas Coates[4] · Dvora L. Joseph Davey[2,4]

Accepted: 25 October 2025

Abstract

Pregnant and breastfeeding women (PBFW) on oral pre-exposure prophylaxis (PrEP) face barriers to adherence and persistence which may be improved by point-of-care adherence monitoring using urine tenofovir testing. We explored the acceptability of urine tenofovir testing for PrEP adherence monitoring among PBFW on oral PrEP, and how this, together with PrEP biofeedback adherence counselling, may have shaped PBFW's PrEP adherence and persistence. Between September 2022 and May 2024, we conducted a study among PBFW without HIV on oral PrEP in Cape Town, South Africa. Participants were randomized to intervention (urine tenofovir testing at each study visit with biofeedback adherence counselling) or standard-of-care arms (urine collected but not analyzed with participant, with standard PrEP adherence counselling). Participants, with consistent and inconsistent PrEP use, were purposively sampled from both study arms between October and December 2023 for qualitative interviews. Analysis was guided by the Theoretical Framework of Acceptability and Consolidated Framework for Implementation Research 2.0 using codebook thematic analysis. Among n = 39 women, who were pregnant (n = 16) or postpartum (n = 13); mean age was 29 years (SD = 7), and median time on PrEP was 11.9 weeks (IQR = 4.0,12.1). Acceptability of urine tenofovir testing was high, as it was perceived as familiar, appropriate and easy to use. Most felt that the limited perceived burden and opportunity costs were outweighed by the benefits, which included receiving feedback on their PrEP-taking behavior and if PrEP was present for HIV protection. Urine tenofovir testing with biofeedback counselling was seen as motivational to daily PrEP use. It positively reinforced PrEP-taking behaviors among those consistently using PrEP and allowed others the opportunity to reconsider their risk for HIV acquisition. Urine tenofovir testing facilitated more accurate self-reporting of PrEP adherence, although some reported restarting taking PrEP prior to visits. Participants' PrEP-taking was supported by non-judgmental and encouraging biofeedback counselling which included co-development of strategies to overcome pregnancy and postpartum related barriers to PrEP persistence. Confusion of urine tenofovir testing with other antenatal urine tests and perceptions of blood-based testing being more effective hindered application to motivating PrEP use. Addressing perceived efficacy and coherence related to urine tenofovir testing within counselling is key. Urine tenofovir testing with biofeedback counselling was perceived as acceptable and motivational to PrEP adherence among PBFW. Integration is further recommended, given that other urine tests are routinely utilized in antenatal care.

Keywords Pregnancy · Postpartum · PrEP adherence · Urine tenofovir testing · Biofeedback · Pre-exposure prophylaxis · South Africa

Extended author information available on the last page of the article

Published online: 12 January 2026

Abbreviations

PBFW:	Pregnant and breastfeeding women
PrEP:	Pre-exposure prophylaxis
SCOPE-PP:	Stepped care to optimize PrEP effectiveness in pregnant and postpartum women

Background

Women accounted for nearly two thirds of all newly HIV infected persons in 2023. [1] The risk for HIV acquisition more than doubles during pregnancy and the postpartum period compared to non-pregnancy [2–4], leading to increased risk of vertical HIV transmission. [5] Acute maternal HIV infection, estimated at 3.3 per 100 woman-years, significantly increases the risk of vertical transmission, contributing to one-third of infant HIV infections in South Africa [6]. Although the total annual number of new infections has declined in Eastern and Southern Africa, down 57% since 2010 [5], substantial work remains in promoting acceptable, effective HIV prevention methods for pregnant and breastfeeding women (PBFW).

Daily oral pre-exposure prophylaxis (PrEP) is recommended for those at risk of HIV infection by the World Health Organization [7, 8], which, in South Africa, now includes PBFW living without HIV. [9] Evidence has demonstrated the safety and efficacy of PrEP use during pregnancy and breastfeeding. [10, 11] However, while PBFW's interest and initiation of PrEP has shown promise to date [12], challenges to PrEP adherence persist, especially among postpartum women, impacting its efficacy. [13, 14] Barriers to oral PrEP adherence in PBFW include reduced perceived risk for HIV acquisition and challenges in accessing PrEP through clinics postpartum, side-effects with physical symptoms of pregnancy, and fear of inter-personal violence and stigma following disclosure of PrEP use. [15, 16] Further, standard counselling at follow-up visits currently evaluates recent PrEP use via self-reported measures, which is subject to social desirability bias. [17] Self-reported adherence may not reflect actual use and thereby restrict opportunities to discern individual-level barriers and provide tailored adherence support. [18]

Biofeedback counselling, which provides individuals with their point-of-care or laboratory-based test results as related to their recent use of a prescribed medication, is an emerging tool to promote adherence. [19] Tenofovir drug-taking for treatment or PrEP can be evaluated by measuring tenofovir (or metabolite) concentrations in hair, blood or urine. Traditional pharmacologic measures to evaluate tenofovir-diphosphate levels in dried blood spots, while reliable and quantifiable, are expensive and lengthy to conduct and have yielded mixed results when used as counseling tools to improve adherence. [20, 21] Qualitative research has found that the delay between providing a specimen for laboratory testing and receiving feedback is a barrier to adherence support, suggesting that a gauge for monitoring PrEP use which allows for simultaneous feedback may be more effective in improving both objective and self-reported PrEP adherence. [22]

Newly developed point-of-care urine tenofovir rapid assays provide real-time, accurate results of recent PrEP use. [23–26] They have been used to support PrEP adherence with women in Kenya and Uganda, where they were perceived as acceptable and feasible, and the immediate feedback being appreciated. [27, 28] Integrating urine tenofovir testing into PrEP counselling motivated PrEP use and improved both short-term and long-term adherence metrics, [27–29] parallel to counselling approaches incorporating point-of-care viral load results among people living with HIV in South Africa. [30] Test use also facilitated open conversations between clients and providers, leading to more accurate self-reporting of PrEP adherence and sexual behaviors. [27, 28] Evidence remains scant for use of urine tenofovir testing to support PrEP adherence amongst PBFW in the African context, who present with unique challenges to PrEP persistence and in whom the risk of HIV acquisition is amplified. [12, 31, 32]

To fill this gap, our study, Stepped Care to Optimize PrEP Effectiveness in Pregnant and Postpartum Women (SCOPE-PP), sought to optimize PBFW's PrEP use through a stepped package of evidence-based interventions, including using the newly developed urine tenofovir test [25] coupled with PrEP biofeedback adherence counselling. Given that this is the first study using the urine tenofovir test paired with enhanced PrEP biofeedback adherence counselling among PBFW within an antenatal setting in South Africa, participant perspectives of the intervention are of primary importance – especially those pertaining to its acceptability and perceived impact. Interventions perceived as acceptable are more likely to engage users (uptake), leading to better adherence and desired outcomes. [33] Qualitative methods were used to explore the acceptability of urine tenofovir testing for PrEP adherence monitoring among PBFW and how use of the urine tenofovir test, together with PrEP biofeedback adherence counseling, impacted on their perceived motivation, need, capability and opportunity to use PrEP.

Methods

Overview of SCOPE-PP

This qualitative study is nested within a larger parent study, SCOPE-PP, a two-stepped randomized control trial aiming

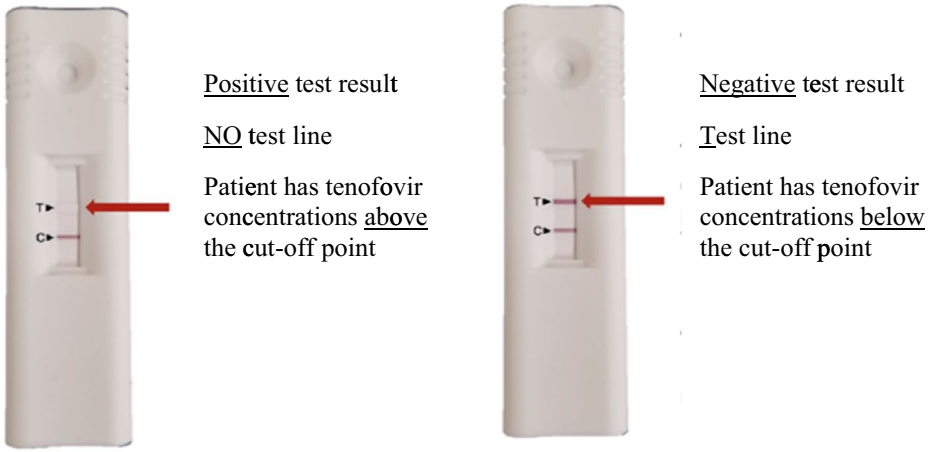

Fig. 1 Image of SCOPE-PP[a] urine tenofovir immunoassay used, depicting visual difference between negative and positive results. [a]Stepped Care to Optimize PrEP Effectiveness in Pregnant and Postpartum Women

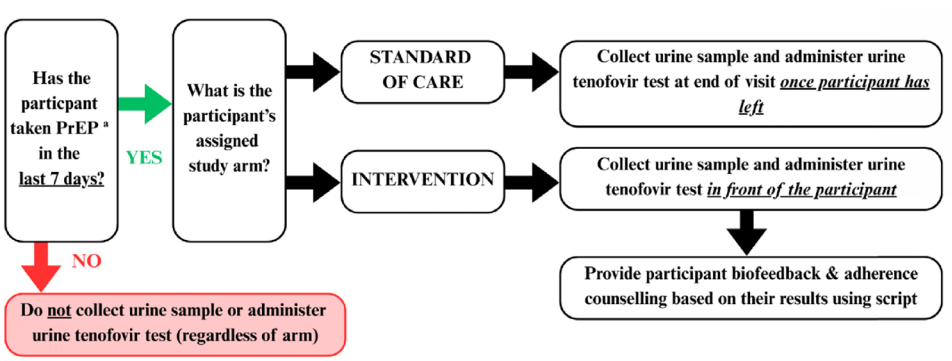

Fig. 2 Diagram depicting the SCOPE-PP[b] protocol for study visits for both standard of care and intervention arm participants, describing when and how the urine tenofovir test is to be used, and type of counselling provided. [a]Pre-exposure prophylaxis. [b]Stepped Care to Optimize PrEP Effectiveness in Pregnant and Postpartum Women

to evaluate the effectiveness of oral PrEP adherence interventions among PBFW. Step 1 of SCOPE-PP was designed to compare the current subdistrict clinic PrEP services (standard of care) to the intervention—the use of a urine tenofovir test, followed by PrEP biofeedback adherence counselling. [34] A real-time, recently validated urine immunoassay [24, 25, 27] was used (100% specific; 96% sensitive), measuring tenofovir levels in the participant's urine as an objective measure of PrEP adherence (verified post hoc via dry bloodspot analysis of tenofovir diphosphate). [35, 36] The urine tenofovir test kit contained a single use device with a disposable pipette and, operating similarly to traditional pregnancy tests, allowed for rapid depiction of any PrEP use in the past 72 h. [25] Tenofovir presence was depicted by a single visible line (control) indicating recent PrEP use, with two visible lines (test and control) indicating the absence of tenofovir or inconsistent or lack of recent PrEP use (Fig. 1). Participants collected urine and study counsellors placed three to four drops of the received participant's sample onto the window of the test device with the provided pipette, either with the participant (intervention arm) or following the study visit (standard of care arm). Results were displayed and discussed 10 min later with intervention arm participants. Participants were informed that the test was used to monitor their day-to-day adherence to talking PrEP, not longer-term adherence, and evaluated if they had taken any PrEP in the past 72 h (or 3 days), with a negative urine tenofovir result being possible if they had taken it more than 3 days ago (Supplementary Material 1). The study counselor assessed self-reported adherence in terms of pills taken over the past 30 days, but no other assessments (e.g., pill counts) were collected.

Between September 2022 and May 2024, 750 participants were recruited and enrolled into Step 1 of SCOPE-PP. Enrolment criteria included: age 16 years and older, gestational age of≥21 weeks, living without HIV, and currently using or initiating oral PrEP at time of enrolment, with follow-up through 12-months postpartum. [34] At enrolment, participants were randomized 1:1 into intervention or standard of care study arms, after which they attended study visits every 3 months, which included a counselling session with study staff. The protocol for every following visit (Fig. 2) included a rapid HIV test, with counselling, and evaluation of participants' PrEP adherence, with the urine tenofovir test being used if PrEP use in the past 7 days was self-reported. Following this, standard of care

arm participants did not receive their results and were given standard adherence counselling, This included HIV counselling and testing, HIV risk assessment, emphasis on HIV prevention measures (such as consistent condom use, PrEP use and STI screening), along with discussion of the benefits of PrEP (Supplementary material 1). Intervention participants, however, received their results after 10 min and enhanced PrEP biofeedback adherence counselling. This included all standard of care adherence counselling and procedures, along with motivation and encouragement for PrEP adherence through an in-depth discussion on PrEP-taking strategies based upon their urine tenofovir results (Supplementary material 1).

SCOPE-PP enrolment took place in the Mitchells Plain-Klipfontein subdistricts of Cape Town, South Africa—a population that is predominantly of low socioeconomic status, with a high HIV prevalence. [34] The public clinics provide antenatal care and PrEP services as per the National Department of Health guidelines. [34] Ethical approval was received from UCT HREC (Ref: 117/2022), the Western Cape Health Research Committee (Ref: WC_202206_003) and City of Cape Town Health Research Committee (Ref: 8148).

Participant Sampling and Recruitment for Qualitative Study from SCOPE-PP

We enrolled n = 39 participants, half from each study arm in Step 1, who had attended at least one follow-up study visit. Participants did not have a history of blood-based adherence monitoring, though study staff drew dried blood spots for confirmation of results that were never reported to participants nor staff. Standard of care arm participants were included to explore the acceptability of urine tenofovir test use for PrEP adherence monitoring, how its use impacted on PrEP adherence without receipt of biofeedback counselling, and to investigate the potential self-report bias may occur from knowing PrEP use was being objectively monitored. [37–39] Participants were purposively sampled based upon consistent (received a positive PrEP result via urine testing at their last study visit) versus inconsistent PrEP use (negative tenofovir test result or did not receive a urine tenofovir test due to self-reported non-adherence) to ensure that a variety of experiences were captured [40–42] Participants were identified for eligibility and stratified into the relevant PrEP use groups by the study data team, who then invited participants to an in-depth interview on the day of their next study appointment.

Table 1 Consolidated Framework for Implementation Research 2.0, Characteristics Subdomain adapted to the context of the study [47, 48]

Characteristics subdomain	
Project characteristics: Characteristics applicable to role of intervention recipients defined below based on the COM-B system [48]	
Construct name	Construct definition (in the context of this study)
A. Need	The degree to which participants have deficits relating to their survival, well-being, or personal fulfilment, which can be addressed by using PrEP[a]
B. Capability	The degree to which participants have interpersonal competence, knowledge, and skills to use and adhere to PrEP
C. Opportunity	The degree to which participants have the availability, scope, and power to use PrEP
D. Motivation	The degree to which participants are committed to using PrEP over time

[a] Pre-exposure prophylaxis

Qualitative Data Collection

An exploratory qualitative study design was used, and semi-structured individual interviews were conducted to explore SCOPE-PP participants' acceptability of urine tenofovir testing to monitor PrEP adherence, and how this, combined with PrEP biofeedback adherence counselling, impacted on their PrEP use. [43–45] Interviews were conducted between October and December 2023 in participant's chosen language (IsiXhosa or English) by two trained interviewers, taking 30 min on average. Interviewers were not part of the study team, nor were they counselors. They were unaware of the participant urine results but did know if they were classified as "consistent" or "inconsistent" users. Participants provided written informed consent prior to participation, and remuneration included grocery and transport vouchers (South African ZAR150, equivalent to ~ USD8). Translation and transcription of audiotapes occurred concurrently to data collection, which included excerpts from interviewers' reflexivity journals. [46] Transcripts were reviewed weekly, after which interview style and questions were adapted where necessary. Topic guides explored experiences with urine tenofovir testing, PrEP biofeedback adherence counselling, and PrEP use, together with HIV self-testing (results reported elsewhere). Topic guide development was informed by the Consolidated Framework for Implementation Research 2.0, specifically the Recipients Characteristics subdomain (Table 1). [47, 48]

Qualitative Data Analysis

Given the importance of acceptability in supporting intervention feasibility, constructs within the Theoretical Framework of Acceptability (Fig. 3) were used to understand participants' acceptability of urine tenofovir testing. [49] The Recipients Characteristics subdomain of the updated Consolidated Framework for Implementation Research (Table 1) was further used to guide analysis of participants'

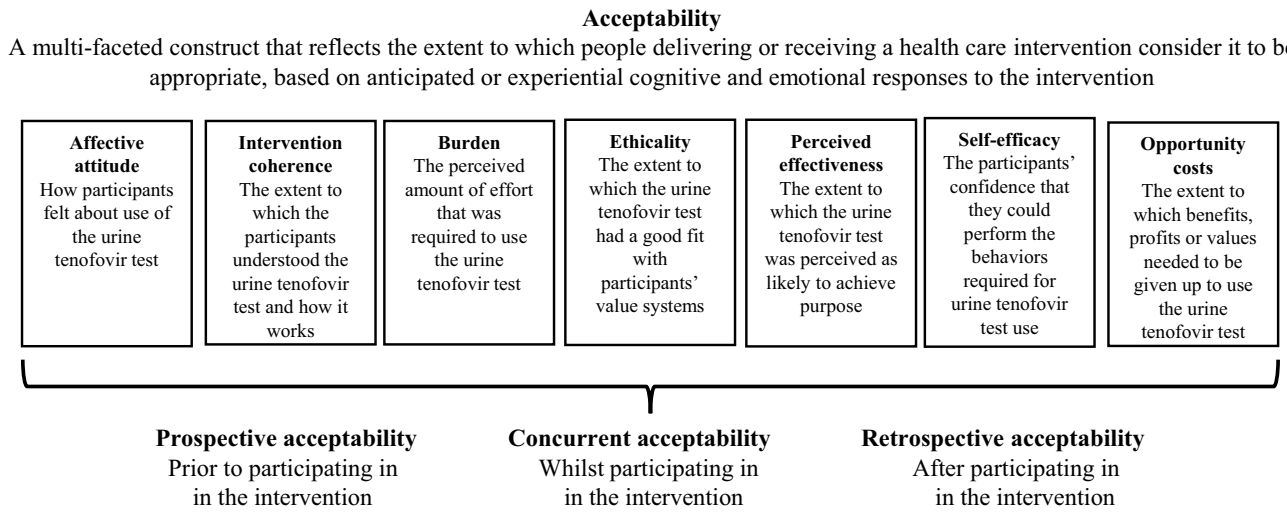

Fig. 3 Theoretical Framework of Acceptability [49], with its seven constructs adapted to the context of the study (i.e. retrospective acceptability of urine tenofovir test use)

perspectives on the perceived impact that the intervention had on their PrEP use. [47, 48] Specifically, COM-B constructs supported the analysis of how participants' need, capability, motivation and opportunity to take PrEP was perceived to change through urine tenofovir testing, together with biofeedback counselling.

Codebook thematic analysis was used, with the initial codebook developed deductively following familiarization, using broad categories based on Consolidated Framework for Implementation Research, interview guides and a literature review. [50] Data was co-coded by three researchers using Dedoose Version 9.0, a computer-assisted qualitative data analysis software. [51] Researchers coded two transcripts together, adding codes to the codebook inductively, followed by a review of an independently coded transcript (by all coders). Discrepancies in individual coding were then discussed and resolved, after which a final codebook was developed. [52] This was applied independently by each coder to analyze a subset of remaining transcripts, alongside regular peer debriefing meetings and use of note-taking, reflexive journals and an audit trail to ensure rigor and reflexivity. [53–55] Sub-themes and themes were refined and categorized using the Theoretical Framework of Acceptability. [48]

Results

Following a description of participant characteristics, we present results about a) PBFW's retrospective acceptability of urine tenofovir testing for PrEP adherence monitoring according to the Theoretical Framework of Acceptability [48]. This is followed by findings exploring the b) Perceived impact of urine tenofovir test use and biofeedback counselling on PBFW's PrEP adherence (receiving standard or enhanced biofeedback counselling). Informed by the Consolidated Framework for Implementation Research 2.0 [50], we specifically describe perceived changes to their need, motivation, capability and opportunity to take PrEP. These interrelated concepts are presented under themes of how 1) *Seeing PrEP-taking is motivating* and 2) *Biofeedback counselling helped intervention arm participants identify need, support motivation and build capability to use PrEP*. (Fig. 4) Perspectives of participants from both the standard of care and intervention arm were included the first theme, as we found that urine collection for testing impacted standard of care arm participants' PrEP adherence, despite them not receiving their urine tenofovir test results.

Participant Characteristics

We enrolled 39 participants in total, from both standard of care (n = 19) and intervention (n = 20) arms, where approximately 50% of each group was taking PrEP consistently on their last study visit[1] (Table 2). At the time of the interview, median gestational age was 24.5 weeks (IQR = 20.5,28.5) among those pregnant (n = 16). Median weeks postpartum was 8.5 weeks (IQR = 4.0,12.0) among those postpartum (n = 18). Participant's mean age was 29 years (SD = 7), and median time on PrEP was 11.9 weeks (IQR = 4.0,12.1) from baseline study visit until date of interview. Three participants described themselves as being in sero-discordant relationships, with a further three not having partners at the time of the interview. One third of participants were young adults under the age of 24 (n = 11) and approximately two-thirds of participants were unemployed (n = 25).

[1] according to their prior study visit's urine tenofovir test results.

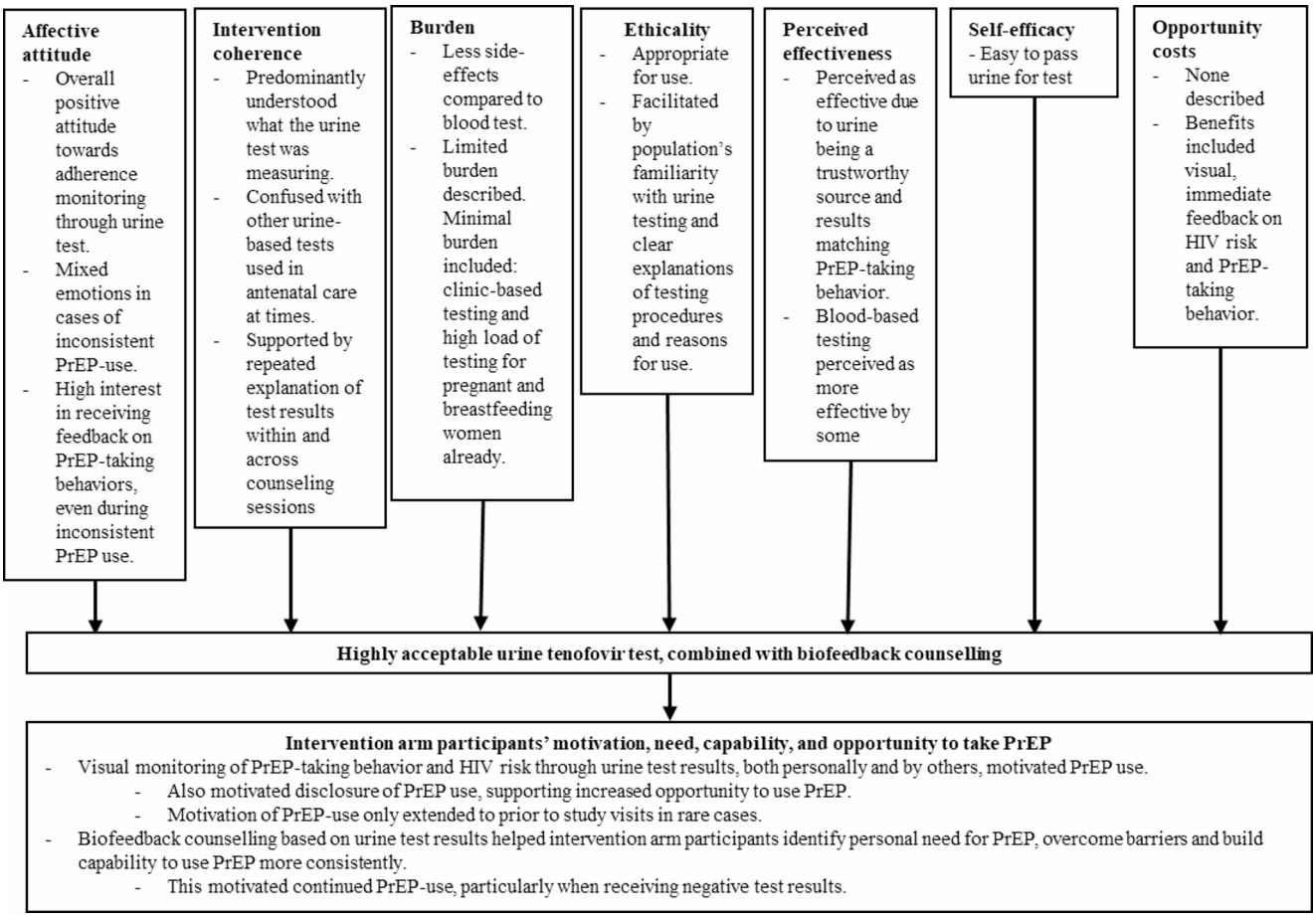

Fig. 4 Pregnant and breastfeeding women's retrospective acceptability of urine tenofovir test use, and how test use paired with biofeedback counselling supported their motivation, need, capability and opportunity to use PrEP informed by the Theoretical Framework of Acceptability and Consolidated Framework for Implementation Research 2.0 (Recipients characteristics subdomain) respectively

PBFW's Retrospective Acceptability of Urine Tenofovir Testing for PrEP Adherence Monitoring

Application of the Theoretical Framework of Acceptability [48] and its constructs showed that participants in both study arms perceived the urine tenofovir test as **appropriate** for use for PrEP monitoring with PBFW, noting that they had "no problem" with it or "saw nothing funny" about it. Important in **ethicality** were clear explanations by study staff on the testing procedure and reasons for urine tenofovir test use, as well as participants' familiarity with providing urine for testing within routine antenatal care visits. As such, **self-efficacy** was felt to be high and participants described being able and willing to provide urine for tenofovir testing:

> *They said they are going to check if you are taking PrEP from the urine…Because we are used to giving urine as pregnant women, so it was no big deal. (34 years, standard of care arm, inconsistent PrEP use)*

Intervention participants voiced how a urine test was the "easiest" way to check for sufficient presence of PrEP for HIV protection. Overall limited **burden** and **opportunity costs** were perceived by standard of care and intervention arm participants, as urine tenofovir testing did not require one to be "pricked", as a blood test does, and did not have aftereffects (i.e., swelling or pain). Described burden included coming to the clinic to have the urine tenofovir test done, which was "boring" and extended the length of their clinic appointment, with one mentioning that she would prefer to do it at home herself. Two others mentioned that providing urine for the test was "cumbersome", especially in the context of pregnancy, where other urine and blood tests are being done. One participant recommended that testing for PrEP use be integrated with other testing:

> *It's better checking PrEP maybe on the blood, because basically when we're here for your [antenatal] appointment they do take the test to check if you're still um [HIV] negative, they can summa take the results, can summa take their blood as well to check PrEP…*

Table 2 Baseline characteristics of SCOPE-PP[a] participants included in qualitative interviews (N = 39)

	Total	Standard of care (Counseling) Arm	Intervention (Biofeedback) Arm
	N = 39 (100%)	n = 19 (49%)	n = 20 (51%)
Demographics			
Age, years			
Mean (SD)	29 (7)	29 (6)	29 (7)
years	11 (28%)	5 (26%)	6 (30%)
≥24 years	28 (72%)	14 (74%)	14 (70%)
Pregnancy status at time of interview			
Pregnant	16 (47%)	6 (38%)	10 (56%)
Postpartum	18 (53%)	10 (63%)	8 (44%)
Gestational age at time of interview, weeks (among pregnant participants n = 16)			
Median (IQR)	24.5 (20.5, 28.5)	28.5 (25.0, 29.0)	22.5 (20.0, 26.0)
Postpartum age at time of interview, weeks (among postpartum participants, n = 18)			
Median (IQR)	8.5 (4.0, 12.0)	11.5 (7.0, 14.0)	5.5 (3.5, 8.5)
Educational attainment			
Did not complete secondary	24 (62%)	10 (53%)	14 (70%)
Completed secondary	15 (38%)	9 (47%)	6 (30%)
Socio-behavioral Factors			
Relationship status (*missing n = 3*)			
Cohabitating	19 (53%)	10 (56%)	9 (50%)
Not cohabitating	17 (47%)	8 (44%)	9 (50%)
Condom use, past 3 months			
Never	29 (74%)	13 (68%)	16 (80%)
Rarely/sometimes	1 (3%)	1 (5%)	0 (0%)
Almost always / always	0 (0%)	0 (0%)	0 (%)
No sexual activity	9 (23%)	5 (26%)	4 (20%)
Primary partners HIV status[b]			
Living with HIV	3 (8%)	0 (0%)	3 (15%)
Living without HIV	19 (49%)	9 (47%)	10 (50%)
Unknown	14 (35%)	9 (47%)	5 (25%)
No recent partner	3 (8%)	1 (5%)	2 (10%)
PrEP[c] Use			
Self-reported time on PrEP, weeks[d]			
Median (IQR)	11.9 (4.0, 12.1)	12.0 (4.0, 12.4)	4.6 (4.0, 12.0)
PrEP Use Classification[e]			
Consistent (urine tenofovir + at last visit)	20 (51%)	10 (53%)	10 (50%)
Inconsistent (urine tenofovir- or no PrEP use at last visit)	19 (49%)	9 (47%)	10 (50%)

[a] Stepped Care to Optimize PrEP Effectiveness in Pregnant and Postpartum Women

[b] Missingness included as unknown partner HIV serostatus

[c] Pre-exposure prophylaxis

[d] Includes time (weeks) from participant baseline study visit until follow-up study visit date prior to in-depth interview

[e] Classification determined by urine tenofovir test result at previous study visit (present vs. absent) prior to interview invitation

The last time I didn't have the urine, so I had to drink a lot of water so that [was hard]. (29 years, intervention, inconsistent PrEP use)

Intervention participants described that, despite this perceived challenge, they still wanted the urine tenofovir test to be used due to the immediacy of the feedback and the visual observation of their urine tenofovir results, or the presence of PrEP in their system, at their study visit. The test was recognized as an objective measure of their PrEP taking efforts, which they liked:

I liked the fact that when you take your urine, I also get the opportunity to see whether the pills [PrEP] work well or not. Because for example, I can be taking pills every day and not know how they work…So

the sampling of urine gives me an opportunity to see that, these are the results of this thing that I am doing, which means I am doing it well. (34 years, intervention, consistent PrEP use)

The urine tenofovir test was **perceived as effective** by participants in both arms, seen as a trustworthy way to demonstrate their "protection" from HIV, with two participants emphasizing that it was as reliable as the alternative, blood-based testing. Intervention participants receiving both positive and negative test results described how seeing the urine tenofovir test results mirror their current PrEP-taking behavior reinforced trust in the test. Using urine was also perceived to be effective because urine is used for other tests during pregnancy and urine comes from the urethra, near the vagina, where protection is desired to be achieved:

I trust them [urine tests], I don't trust it [blood tests] more than the urine test. There are slim chances of something getting passed in urine and not getting detected if you have it, I don't know how I can put it (laughing)… one of the reasons why I say the urine test results are the best, we have sex using the same organs, so to me nothing gets past urine. (38 years, intervention, inconsistent PrEP use)

In contrast, some intervention participants felt that blood-based testing was more trustworthy, explaining that results are processed in a lab and provide greater certainty of HIV protection as compared to urine tests, which impacted on their acceptability:

I wouldn't say it's fine [to check PrEP in urine], but it's the way they do it. Since HIV is tested in the blood, I think it would be better if it was tested the same way… I would like to see the test done in the blood, that's all. (28 years, intervention, consistent PrEP use)

Overall **intervention coherence** was high. Participants in both study arms understood that the urine tenofovir test evaluated whether PrEP was present in their urine for HIV protection. Some described how it was being used to evaluate whether they were using PrEP "correctly" and were protected from HIV, with some participants feeling it was being used to determine if they were "lying" about taking PrEP. Others specified that it was an indicator of presence of PrEP in their "system", "blood" or "body":

It is to see whether you had PrEP in your body in the past seven days… I didn't feel bad, because we were told we were going to give a urine sample, … But it motivated me, I would say, yes, I had to know that I need to drink my PrEP, because I know that when I get here, my urine is going to be tested. (29 years, standard of care, inconsistent PrEP use)

Participants in the intervention arm, receiving biofeedback counselling, described how they understood the results of the urine tenofovir test at each study visit. Repeated counselling across study visits, specifically having the reasons for the test and meaning of the results explained throughout the appointment (i.e., prior to urine tenofovir test use, while the test was done in front of them and again when being given their results), was described as integral to their intervention coherence. Although some participants could not recall the mechanics of the test (Fig. 1), counselling helped them understand and process their results:

She told me what it means when it shows that line... So, you tend to understand it, what your situation is like… when that line is there, it means that there is PrEP in your body. When there is no line at all, it means there is no PrEP in your body…. I understood that I took my pills, so I am protected, because my line was visible. (34 years, intervention, inconsistent PrEP use)

Some examples of low intervention coherence in the intervention arm were observed, particularly in those who received negative test results. Two intervention participants confused the urine tenofovir test with another antenatal care urine test, two others were confused about what the urine tenofovir test tested for—thinking it tested for PrEP presence alongside other "diseases" or for pregnancy:

I didn't know what they were doing when they were testing the urine… So, she first asked me questions… I lied and said, "No, no I take PrEP, and I take it every day." So, they tested the urine... There were two lines, and she said, "you see it?" In my head I am saying, "you can obviously see that I am pregnant". She said, "do you know what this [urine test] is for?" I'm thinking, "who doesn't know what it's for, man" … She says, "it's for testing whether you take PrEP" and then I start coming back to my senses… (23 years, intervention, inconsistent PrEP use)

Affective attitudes towards urine tenofovir test use were explored, specifically prior to its use in a study visit and when receiving the results. Women in both arms described feeling worried prior to urine tenofovir testing when their PrEP-taking was inconsistent, with those taking PrEP consistently describing how they were confident and not stressed. Despite this apprehension, many women in the intervention arm noted how they were interested in receiving

feedback on "how their PrEP is working", often regardless of whether they had been taking their PrEP consistently or not. Intervention arm participants described feeling happy and excited when results showed the presence of PrEP. They were pleased that the study staff could see that they were making good choices and looking after themselves and their baby by taking PrEP consistently. They liked being able to observe their "protection" from acquiring HIV, as they could see for themselves that they were taking PrEP appropriately and that PrEP was working as intended:

> *I was happy because I could see also that I am protected…it changed how I looked at PrEP, let me rather say [before] I was just using PrEP, not sure if it will really protect me. (30 years, intervention, consistent PrEP use)*

For intervention participants, feelings after receiving feedback that insufficient PrEP was present often depended on whether this was expected. Those who did not use PrEP prior to the study visit noted how they were not surprised, whereas others who had been taking PrEP inconsistently were unsure of what their result would be and described feeling concerned after receiving negative urine tenofovir test results. Inconsistent use was reported due to work-related issues (i.e., changes in shift times) or pregnancy and postpartum-related challenges (i.e., vomiting up their medication, nausea, having a new baby, brain fog) or generally finding it challenging to remember to take a pill daily.

> *First time, I was happy, because… it showed that I take PrEP in the appropriate way…and then the second time it wasn't alright, because it showed that there is PrEP in my body, but it is not enough. So, I was disappointed…But then, it is good…you are able to see where you stand. Even though, perhaps I would've thought that I am still taking it the right way, only to find out, that no, I am not taking it the right way…I think it is the right way to have this option where you check whether you take PrEP or not through your urine. (17 years, intervention, inconsistent PrEP use)*

Despite not feeling good after the result, participants continued to describe that they preferred to receive the results and be informed of their PrEP taking.

Perceived Impact of Urine Tenofovir Test Use and Biofeedback Counselling on PBFW's PrEP Adherence

Using a lens informed by the Consolidated Framework for Implementation Research 2.0. participants described how 1) the urine tenofovir test motivated PrEP use, and 2) how it, used in combination with PrEP biofeedback adherence counselling, helped them identify their need for PrEP, build capability to use PrEP and encouraged further PrEP use in the case of negative test results.

Seeing PrEP-Taking is Motivating

Overall, urine tenofovir test use was found to support motivation to take PrEP for participants in both study arms, although via different mechanisms. Intervention participants described how being able to personally monitor their PrEP taking behavior through biofeedback and results motivated them to attend their appointments, increased their "interest" in taking PrEP and "encouraged" them to continue taking PrEP. Seeing that sufficient PrEP was present for HIV protection positively reinforced their current behavior and increased their opportunity to take PrEP at times, through facilitating disclosure of PrEP use to partners, friends or family after seeing that their PrEP-taking behaviors were effectively preventing HIV:

> *I saw that PrEP is really working and there's no turning back, I will keep using PrEP… and I told them at home, my mom had doubts about PrEP… As old as she is she is [now] also using PrEP… I was very happy I even called my man before I got home… You know at first if there was someone in the house, I couldn't take my PrEP. But now I don't care who is in the house, I take my PrEP… in front of them. I'm so motivated to the point I don't need to hide anymore, because it protects me. (29 years, intervention, consistent PrEP use)*

The visual observation of PrEP drug detection by study staff motivated ongoing PrEP use for intervention participants and some standard of care participants. Those in the intervention found being accountable to study staff motivated consistent PrEP use, particularly at times when PrEP taking was challenging, such as in the early months following initiation. Standard of care participants also described how study staff being able to see their PrEP taking behavior motivated them to take their PrEP, despite not seeing the results themselves. Standard of care arm participants described further how being asked questions about their recent PrEP use at study visits motivated them to take PrEP more consistently and self-report their PrEP use more accurately. This was due to knowing that urine tenofovir test results were dependent on their self-report of recent PrEP use (Fig. 1) and that PrEP use would be visible to the study staff through test results. It encouraged them to "pay attention" to how they take their PrEP and gave some "strength" to not forget to take their pills daily:

It can happen that I say, "No, I'm drinking my PrEP well" … All the while knowing that, no, I am not drinking it in the appropriate way. But, if I know that they will be looking for it in the urine, I know that I have to drink it, because they are going to see. If I lie when I am talking to them, it is going to be visible in the urine. So, it encouraged that I use it, yes. (22 years, standard of care, consistent PrEP use)

A small number of participants in both standard of care and intervention arm reported that the urine tenofovir testing motivated PrEP-taking in the period just before their study visit. Some described how they were not taking their PrEP consistently, but made sure that they would take their PrEP on the days before their study visit so that sufficient PrEP would be present on the day of their study visit:

I took it (laughs) thinking that it will show… I thought let me take it, thinking that it will show, because I came [for my appointment] during the week. Then that lady explained that you don't take it today then it shows in your urine, it takes six days inside you [to show]…Being lazy doesn't work, you must take, and you are fooling yourself. (34 years, standard of care, inconsistent PrEP use)

Specific instances were described where testing for PrEP presence had no or limited impact on their motivation to use PrEP, such as when participants were not aware that the urine tenofovir test was measuring PrEP presence; they were already used to taking PrEP consistently; or were internally motivated by other factors, such as their children or their need for HIV protection:

It didn't change anything, how I am going to put this? It's because I was drinking PrEP before…I started taking it because I got pregnant. So, and then everything I was doing, I was doing so that I would be alright and for the baby and I to be safe, and then in terms of urine…I don't think it is going to make it difference. (41 years, standard of care, inconsistent PrEP use)

Biofeedback Counselling Helped Intervention Arm Participants Identify Need, Support Motivation and Build Capability to Use PrEP

Rather than demotivating PrEP use, receipt of negative urine tenofovir test results by intervention participants was described by some as reinforcing their perceived need for daily PrEP use to protect them against HIV. This was found specifically in the context of knowing or questioning if their partner had other sexual partners or wanting to protect their baby and themselves from acquiring HIV during pregnancy and breastfeeding, amongst others (i.e., risk of sexual assault, HIV positive partner, unaware of partner's serostatus). Biofeedback counselling following negative results facilitated this by encouraging participants to take PrEP more consistently (i.e., if they were not taking it daily), or restart PrEP:

I was also interested in knowing and seeing it [how much PrEP was present], because sometimes when you haven't taken it [PrEP], you get the opportunity to know that "no, now you no longer have PrEP in your body." So, it gives you, a thing that says, "drink [take PrEP]." So, it does motivate you…because you can see that, "okay now… I am not protected." So, if we didn't have the test, you wouldn't see where you stand. (34 years, Intervention, inconsistent PrEP use)

Discussing the risks of contracting HIV in pregnancy and postpartum, and the benefits of remaining on PrEP in counselling sessions were also useful in helping participants understand their unique, specific need for PrEP. One intervention arm participant in a sero-discordant relationship detailed how she "didn't mind personally" if she got HIV, however she improved the way she took her PrEP daily following biofeedback counselling, wherein the importance of PrEP to protect her unborn child was emphasized by the counsellor:

The study assistant asked why I don't take them. And then she spoke about her story with her boyfriend, it's the same as mine. And then she said that there is no need for me to skip them, I must take them because, I must also consider the child…And then I never stopped again after that. (18 years, Intervention, consistent PrEP use)

Biofeedback counselling was key in maintaining motivation to use PrEP when experiencing negative emotions in response to urine tenofovir test use, which could demotivate PrEP use or study visit attendance. Negative emotions could occur when receiving a negative urine tenofovir test result despite trying to take PrEP consistently, or when participants self-reported stopping PrEP or inconsistent use, which they felt to be socially undesirable:

Like if I don't take PrEP well…I know that I am going to get my urine tested. So, if I am lying and say that "no, I am taking it well, I am taking it well." then I'm going to become discouraged, because I keep getting the told the truth, I get told, "no sister, you are not eating it." Then I get discouraged because, even when they see me, they are going to say, "no, here's that

one." …We know her". So that is the one that this will cause demotivation. (23 years, Intervention, inconsistent PrEP use)

In these instances, counselling around contextual circumstances impacting test results or participants expressing interest in accurately self-reported PrEP use seemed to increase participants' capability to take PrEP. Biofeedback counselling was described as helping them learn different tactics to adapt their PrEP taking behaviors and persist with PrEP, supporting their motivation when receiving negative test results. Vital to this was that the counselling was provided in a motivational, "kind", non-judgmental manner. Helpful advice included strategies to overcome interpersonal barriers, where women were finding it challenging to take their PrEP in front of someone, they had not disclosed their use to, as well as individual level barriers. Advice in overcoming side effects, the pill burden related to pregnancy (i.e., taking of prenatal vitamins and PrEP) or forgetting to take the oral pill daily (i.e., due to having a new baby, not being used to taking pills, finding it challenging to take an oral pill daily), especially in the initial stages of taking PrEP, were specifically helpful:

I didn't feel good man, because I wasn't taking it the right way… She spoke well with me... She said that that can happen sometimes. So, I came back a second time. And then another lady gave me advice, she said that what I should do is, take in the morning, because I had said that I sometimes forget. So, I changed and took it in the morning... I would get discouraged when I drink PrEP, but my urine shows that it is not yet in my body, but [getting my results] encouraged me, because you get advice when you get here, right. So, they also encourage a person, here at the clinic. (34 years, Intervention, inconsistent PrEP use)

Further education on PrEP, reassurance of the safety of PrEP use in pregnancy and debunking any myths they had heard about PrEP also supported participants' knowledge of PrEP and their motivation to persist with PrEP. One participant, who only decided to start taking PrEP after her first negative urine tenofovir result and corresponding biofeedback counselling described the following educational benefits:

It [biofeedback counselling] also helped clarify some of the things people say, because the only thing that makes it scary is what the people are saying outside… They say it [PrEP] causes dizziness, there is a lot that people say. Because with that first visit, I was supposed to have taken it then, but then I listened to people (30 years, Intervention, inconsistent PrEP use)

Discussion

In this qualitative study of PBFW who reported both consistent and inconsistent PrEP use, most found urine tenofovir testing as a part of antenatal and postnatal care to be acceptable and motivational to their PrEP adherence and continuation during the pregnancy and postpartum period. The urine tenofovir test was viewed as a trustworthy and effective method for detecting recent PrEP use and ensuring protection from acquiring HIV—and preferable to blood-based testing. Biofeedback was also seen as acceptable and improved PrEP adherence among intervention participants. However, a subset of women were initially skeptical of the test's efficacy and expressed a preference for PrEP adherence to be evaluated using blood specimens, consistent with previous studies. [56, 57] The non-invasive nature of urine-based testing facilitated acceptability among PBFW, as well as the ease of visually interpreting real-time results. A unique facilitator among our PBFW was their familiarity with providing urine samples in routine antenatal care, which reinforced their confidence in the test's effectiveness and perceived self-efficacy. Concerns about extended clinic appointments due to additional urine testing were raised, particularly when participants found it difficult to provide urine samples "on demand." Additionally, our study demonstrated how the use of multiple, different urine tests within routine antenatal care could lead to confusion or mis-recollection regarding urine tenofovir testing, where it was occasionally mistaken for other urine-based tests, such as pregnancy tests. Recent literature has also reported how urine tenofovir test users found results counter-intuitive to interpret at times, as most familiar rapid tests use two lines to indicate a 'positive' or 'present' result, whereas in the urine tenofovir test, two lines indicate 'absence' of PrEP. [56] Integrating different urine tests into a single sample collection, while ensuring counselling and education on urine tenofovir test use (i.e. on test's purpose and the meaning of results) at multiple points, will be essential in improving users' acceptability, aligning with findings from other African studies involving healthcare workers, and women. [56–59]

Recent research in Kenya on biofeedback counselling, informed by urine tenofovir test use among women living without HIV, demonstrated both high acceptability of the test and an increased odds of both short- and long-term PrEP adherence with the urine assay use compared to standard counselling. [27] In our recent preliminary analysis of the impact of urine tenofovir testing in our SCOPE-PP study, biofeedback using urine tenofovir testing was associated with significant increases in PrEP adherence (32% of intervention participants had urine tenofovir+vs. 25% in control; RR=1.29; 95% CI=1.03–1.63). [60] Our qualitative data further highlights how urine tenofovir test use supported adherence through motivating participants to take PrEP. Participants in both arms noted how accountability

to study staff, partners and babies through the urine tenofovir test use encouraged them to pay closer attention to their PrEP-taking habits, particularly in the early stages of use or during adherence challenges. Knowing that their adherence was visible to others motivated them to take PrEP consistently, as receiving a negative result after reporting good adherence was seen as socially undesirable. [56] Urine tenofovir testing paired with biofeedback counselling facilitated PrEP adherence by providing PBFW with the opportunity to personally monitor PrEP levels and protection from HIV acquisition and increased motivation to attend study visits, even amongst those with inconsistent PrEP use. Receipt of positive urine tenofovir results allowed study staff to see how participants were making positive health choices for themselves and their babies, supporting adherence. [56, 58] Positive test results affirmed to participants that PrEP was working and providing HIV protection, therefore reinforcing consistent PrEP-taking behavior, as well as increasing opportunities for disclosure to family members.

Concerns have been raised that receiving negative urine tenofovir test results with biofeedback could demotivate PrEP use or lead to missed appointments to avoid urine testing which will detect non-adherence out of fear that negative results could impact on their study participation, access to benefits, or altering healthcare providers' attitudes toward them. [58, 59, 61] The possibility of this was endorsed by a few of our study participants who reported restarting PrEP only shortly before study appointments—behavior consistent with self-report bias, as observed in another study. [56] Intervention arm participants in our study noted how the combination of urine tenofovir test with kind, non-judgmental and motivational adherence counselling motivated them to continue PrEP despite experiencing stress, worry, or apprehension prior to urine tenofovir testing in study visits during periods of inconsistent PrEP use. This echoes findings from other studies emphasizing the value of empathetic and supportive counselling when using real-time adherence feedback in reinforcing PrEP commitment and adherence. [56, 58] Therefore, reinforcing use of non-judgmental, supportive sexual healthcare at routine clinic visits, regardless of past PrEP use, may help improve accurate reporting of recent adherence, mitigate the potential stress associated with objective adherence testing and promote more consistent engagement with PrEP services. [56, 58] Finally, destigmatizing negative results, echoed in studies from Kenya and Uganda, is key in using a supportive, non-punitive approach to adherence monitoring. [27, 56, 58]

Although these concerns were noted, SCOPE-PP intervention arm participants also described how seeing a negative result reinforced their awareness that they were not protected from HIV increased their perceived need for PrEP, motivating them to restart or use PrEP more consistently, especially during pregnancy and postpartum, periods of heightened HIV risk. Enhanced biofeedback adherence counselling was key in supporting this perceived need for PrEP by 1) emphasizing the benefits of PrEP during pregnancy and postpartum, 2) reassuring participants about PrEP's safety, and 3) addressing common myths that could discourage use (i.e. negative impacts on the fetus or infant, confusion of PrEP with anti-retroviral treatment for HIV). Similarly, a recent study among non-pregnant women found that biofeedback adherence counselling combined with urine tenofovir testing enabled participants to gain a clearer understanding of their protection status which significantly improved PrEP adherence. [27] Additionally, both intervention and standard of care participants described how urine tenofovir test's objective assessment of PrEP adherence encouraged more accurate self-reporting to healthcare providers. Knowing that study staff could verify adherence helped facilitate open discussions about real-life barriers to PrEP use, which participants valued. These conversations addressed pregnancy-related challenges (e.g., pill burden, pregnancy symptoms) and postpartum difficulties (e.g., caring for a newborn), helping participants build their capability to use PrEP consistently. Similar findings on the role of adherence counselling in overcoming individual and interpersonal barriers have been reported in other studies on point-of-care urine tenofovir testing, [27, 56, 58] as has the increased veracity of self-reported adherence when urine testing is being performed [28]. Recommendations for PrEP adherence counselling in the context of urine tenofovir test use are outlined in Box 1.

Some participants reported that urine tenofovir testing with biofeedback counselling had little impact on their PrEP use in certain situations, such as when pre-existing internal motivation was sufficient to ensure adherence, when they were driven by external factors (e.g., infant health and safety), when participants misunderstood its purpose (low intervention coherence) or in cases of low perceived effectiveness in comparison to blood-based testing, aligning with other findings. [58] Negative affective attitudes toward results indicating insufficient PrEP levels were described as potentially demotivating, whereas experiencing gratification or reassurance from positive results had the opposite effect, reinforcing adherence. These findings highlight the importance of considering the acceptability of the urine tenofovir test within the broader context of its impact on adherence.

Box 1

Recommendations for optimal PrEP[2] adherence counselling for pregnant and breastfeeding women in the context of objective measures of PrEP adherence:

- Non-judgemental and motivational approach to reviewing recent PrEP use (including non-use or intermittent use) by lay counsellors from the same community
- PrEP education in the context of pregnancy and breastfeeding is key including, benefits and safety of PrEP for mother and infant, and improving disclosure of PrEP use to family and partners.
- Co-development of strategies to address individual and interpersonal barriers to PrEP adherence, including those specific to pregnancy and postpartum.
- Address aspects related to acceptability of the test, by describing reasons for test use, the process of using the test and meaning of results before and after testing every time the test is used

[2] Pre-exposure prophylaxis.

Limitations

Our study focused on PBFW in a clinical trial during their first six months of follow-up, which presented certain limitations. At the time of data collection, acceptability of test use and counselling was assessed only after one to three times of participant use. Further research among PBFW with longer exposure to the intervention would be needed to capture perspectives pertaining to long-term (e.g., further into postpartum period) PrEP adherence. Additionally, because participants were aware of the test's purpose and timeframe, our data may be subject to the reporting bias where adherence is overestimated due to participants modifying their behavior in response to monitoring. Further, there may be social desirability bias on urine test appropriateness and acceptability, which we sought to limit by having separate interview staff. Finally, our results may not be generalizable outside of urban, ante and postnatal care services in South Africa. However, given that this analysis is one of the first to examine the acceptability of urine tenofovir testing, and its perceived impact on PrEP adherence among the PBFW population when used together with counselling, these findings offer valuable insights that can inform the implementation of future PrEP adherence interventions among PBFW and other populations who may struggle with oral PrEP use over time. With acceptability in PBFW being demonstrated and point of care tenofovir testing being shown as feasible in HIV clinics in South Africa (i.e. administered at reasonable costs, estimated at USD $13 per client, and requiring less than 10 min of healthcare provider time) [62], investigation into feasibility of urine tenofovir testing for PrEP monitoring in the antenatal setting would be beneficial.

Conclusion

This study found that urine tenofovir test use was acceptable among PBFW in our study, and that urine tenofovir test use and biofeedback counselling motivated PrEP continuation and adherence in pregnancy and postpartum. Non-judgmental and motivational biofeedback counselling together with urine tenofovir testing played a crucial role in improving motivation, need and capability to take PrEP despite barriers to PrEP use (including work-related issues, pregnancy and postpartum-related challenges, and pill fatigue). However, certain factors could reduce its effectiveness or could even demotivate use, such as the receipt of negative test results and low intervention coherence (i.e. lack of understanding of what the urine tenofovir test is testing) or could only motivate PrEP use before a study visit. Additionally, the use of the urine tenofovir test as an objective adherence measure provided opportunities for more tailored counselling strategies, showing potential for improving long-term PrEP use. Given the high acceptability of the urine tenofovir test and its ability to enhance adherence when paired with biofeedback counselling, integrating this intervention into ante- and postnatal care services should be prioritized for this population where feasible. Future research should explore long-term implementation to assess its sustained impact on PrEP adherence beyond the early postpartum period.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10461-025-04961-y.

Acknowledgments We extend our sincere gratitude to the SCOPE-PP study participants who took time out of their lives to provide such meaningful perspectives for this analysis. We also appreciate the contributions of our research team, including those who coordinated recruitment, conducted interviews, and analyzed our findings. Their dedication was essential to this work.

Author Contributions Rufaro Mvududu was the study coordinator, oversaw arrangement for participant interviews, and contributed to data analysis and manuscript development. Lara Court led conceptual development for data collection, analysis and development of this article, with support by Sarah Schoetz Dean, who also contributed to data analysis. Dvora L. Joseph Davey, the study principal investigator, developed the SCOPE-PP study protocol and design, provided overall study oversight, and supported manuscript development. Kathryn Dovell contributed to IDI guide development and study design. In addition to these authors, Monica Gandhi, Landon Myer, and Thomas Coates reviewed, revised and approved this article.

Funding This study was made possible through NIH funding under award numbers R01HD106862 and 2R01AI143340. The study sponsor had no role in study design, data collection, data analysis, nor preparation of the manuscript.

Data Availability Our codebook is able to be supplied upon request. A supplementary article has been included which contains our script for both intervention and standard of care arms.

Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethical Approval Our study received ethical approval from UCT HREC (Ref: 117/2022), the Western Cape Health Research Committee (Ref: WC_202206_003) and City of Cape Town Health Research Committee (Ref: 8148).

Consent to Participants Participants provided written informed consent prior to participation.

References

1. UNAIDS. Country factsheets; South Africa 2023. Available at https://www.unaids.org/en/regionscountries/countries/southafrica. Accessed 22 July 2024.
2. Graybill LA, Kasaro M, Freeborn K, Walker JS, Poole C, Powers KA, et al. Incident HIV among pregnant and breast-feeding women in sub-Saharan Africa: a systematic review and meta-analysis. AIDS. 2020;34(5):761–76.
3. Drake AL, Wagner A, Richardson B, John-Stewart G. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. PLoS Med. 2014;11(2):e1001608.
4. Thomson KA, Hughes J, Baeten JM, John-Stewart G, Celum C, Cohen CR, et al. Increased risk of HIV acquisition among women throughout pregnancy and during the postpartum period: a prospective per-coital-act analysis among women with HIV-infected partners. J Infect Dis. 2018;218(1):16–25.
5. The path that ends AIDS: UNAIDS global AIDS update 2023. Geneva: Joint United Nations Programme on HIV/AIDS; 2023. https://www.unaids.org/en/resources/documents/2023/global-aids-update-2023
6. Johnson LF, Meyer-Rath G, Dorrington RE, Puren A, Seathlodi T, Zuma K, et al. The effect of HIV programmes in South Africa on national HIV incidence trends, 2000–2019. J Acquir Immune Defic Syndr. 2022;10(2):115–23.
7. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Geneva: World Health Organization; 2016.
8. World Health Organisation. WHO Technical brief: Preventing HIV during pregnancy and breastfeeding in the context of pre-exposure prophylaxis (PrEP). Geneva: World Health Organization; 2017. Available from https://apps.who.int/iris/bitstream/handle/10665/255866/WHO-HIV-2017.09-eng.pdf.
9. South African guidelines for the provision of pre-exposure prophylaxis (PrEP) to persons at substantial risk of HIV infection (2020). Available at https://www.prepwatch.org/wp-content/uploads/2020/07/South-Africa-PrEP-Guidelines_Jan2020.pdf. Accessed 30 July 2024.
10. Joseph Davey D, Nyemba DC, Mvududu R, Mashele N, Johnson L, Bekker LG, et al. Pregnancy outcomes following self-reported and objective-measured exposure to oral preexposure prophylaxis in South Africa. AIDS. 2024;38(1):75–83.
11. Van de Perre P, Goga A, Ngandu N, Nagot N, Moodley D, King R, et al. Eliminating postnatal HIV transmission in high incidence areas: need for complementary biomedical interventions. Lancet. 2021;397(10281):1316–24.
12. Joseph Davey DL, Mvududu R, Mashele N, Bheemraj K, Khadka N, Johnson LF, et al. Initiation and continued use of oral pre-exposure prophylaxis among pregnant and postpartum women in South Africa (PrEP-PP): a demonstration cohort study. Lancet HIV. 2024;11(11):e746–55.
13. Joseph Davey D, Nyemba DC, Castillo-Mancilla J, Wiesner L, Norman J, Mvududu R, et al. Adherence challenges with daily oral pre-exposure prophylaxis during pregnancy and the postpartum period in South African women: a cohort study. J Int AIDS Soc. 2022;25(12):e26044.
14. Marrazzo J, Tao L, Becker M, Leech AA, Taylor A, Ussery F, et al. HIV preexposure prophylaxis with emtricitabine and tenofovir disoproxil fumarate among cisgender women. JAMA. 2024;331(11):930–7.
15. Joseph Davey D, Knight L, Markt-Maloney J, Tsawe N, Gomba Y, Mashele N, et al. I had made the decision, and no one was going to stop me" - facilitators of PrEP adherence during pregnancy and postpartum in Cape Town, South Africa. AIDS Behav. 2021;25(12):3978–86.
16. Pintye J, Joeseph Davey D, Wagner AD, John-Stewart G, Baggaley R, Bekker LG, et al. Defining gaps in pre-exposure prophylaxis delivery for pregnant and post-partum women in high-burden settings using an implementation science framework. Lancet HIV. 2020;7(8):e582–92.
17. Simoni JM, Kurth AE, Pearson CR, Pantalone DW, Merrill JO, Frick PA. Self-report measures of antiretroviral therapy adherence: a review with recommendations for HIV research and clinical management. AIDS Behav. 2006;10(3):227–45. https://doi.org/10.1007/s10461-006-9078-6.
18. Hebel S, Kahn-Woods E, Malone-Thomas S, McNeese M, Thornton L, Sukhija-Cohen A, et al. Brief report: discrepancies between self-reported adherence and a biomarker of adherence in real-world settings. J Acquir Immune Defic Syndr. 2020;85(4):454–7.
19. Van der Straten A, Montgomery ET, Musara P, Etima J, Naidoo S, Laborde N, et al. Disclosure of pharmacokinetic drug results to understand nonadherence. AIDS. 2015;29(16):2161–71.
20. Celum C, Hosek S, Tsholwana M, Kassim S, Mukaka S, Dye BJ, et al. PrEP uptake, persistence, adherence, and effect of retrospective drug level feedback on PrEP adherence among young women in southern Africa: results from HPTN 082, a randomized controlled trial. PLoS Med. 2021;18(6):e1003670.
21. Landovitz RJ, Beymer M, Kofron R, Amico KR, Psaros C, Bushman L, et al. Plasma tenofovir levels to support adherence to TDF/FTC preexposure prophylaxis for HIV prevention in MSM in Los Angeles, California. J Acquir Immune Defic Syndr. 2017;76(5):501–11.
22. Montgomery ET, Mensch B, Musara P, Hartmann M, Woeber K, Etima J, et al. Misreporting of product adherence in the MTN-003/VOICE trial for HIV prevention in Africa: participants' explanations for dishonesty. AIDS Behav. 2017;21(2):481–91.
23. Gandhi M, Bacchetti P, Rodrigues WC, Spinelli M, Koss CA, Drain PK, et al. Development and validation of an immunoassay for tenofovir in urine as a real-time metric of antiretroviral adherence. EClinicalMedicine. 2018;2(3):22–8.
24. Gandhi M, Bacchetti P, Spinelli MA, Okochi H, Baeten JM, Siriprakaisil O, et al. Brief report: validation of a urine tenofovir immunoassay for adherence monitoring to PrEP and ART and

establishing the cutoff for a point-of-care test. J Acquir Immune Defic Syndr. 2019;81(1):72–7.
25. Gandhi M, Wang G, King R, Rodrigues WC, Vincent M, Glidden DV, et al. Development and validation of the first point-of-care assay to objectively monitor adherence to HIV treatment and prevention in real-time in routine settings. AIDS. 2020;34(2):255–60.
26. Spinelli MA, Rodrigues WC, Wang G, Vincent M, Glidden DV, Okochi H, et al. Brief report: high accuracy of a real-time urine antibody-based tenofovir point-of-care test compared with laboratory-based ELISA in diverse populations. J Acquir Immune Defic Syndr. 2020;84(2):149–52.
27. Gandhi M, Glidden DV, Chakravarty D, Wang G, Biwott C, Mogere P, et al. Impact of a point-of-care urine tenofovir assay on adherence to HIV pre-exposure prophylaxis among women in Kenya: a randomised pilot trial. The Lancet HIV. 2024;11(8):e522–30.
28. Zewdie K, Muwonge T, Ssebuliba T, Bambia F, Nampewo O, Stein G, et al. A point-of-care tenofovir urine test improves accuracy of self-reported preexposure prophylaxis adherence and increases condomless sex reporting among young women. AIDS. 2024;38(14):1965–71.
29. Gati Mirembe B, Donnell D, Krows M, Zwane Z, Bukusi E, Panchia R, et al. High recent PrEP adherence with point-of-care urine tenofovir testing and adherence counselling among young African women: results from the INSIGHT cohort. J Int AIDS Soc. 2024;27(12):e26389.
30. Drain PK, Dorward J, Violette LR, Quame-Amaglo J, Thomas KK, Samsunder N, et al. Point-of-care HIV viral load testing combined with task shifting to improve treatment outcomes (STREAM): findings from an open-label, non-inferiority, randomised controlled trial. Lancet HIV. 2020;7(4):e229–37.
31. Beesham I, Dovel K, Mashele N, Bekker LG, Gorbach P, Coates TJ, et al. Barriers to oral HIV pre-exposure prophylaxis (PrEP) adherence among pregnant and post-partum women from Cape Town, South Africa. AIDS Behav. 2022;26(9):3079–87.
32. Joseph Davey D, Mvududu R, Mashele N, Lesosky M, Khadka N, Bekker LG, et al. Early pre-exposure prophylaxis (PrEP) initiation and continuation among pregnant and postpartum women in antenatal care in Cape Town, South Africa. J Int AIDS Soc. 2022;25(2):e25866.
33. Perski O, Short CE. Acceptability of digital health interventions: embracing the complexity. Transl Behav Med. 2021;11(7):1473–80.
34. Joseph Davey D, Dovel K, Cleary S, Khadka N, Mashele N, Silliman M, et al. Stepped care to optimize pre-exposure prophylaxis (PrEP) effectiveness in pregnant and postpartum women (SCOPE-PP) in South Africa: a randomized control trial. BMC Public Health. 2022;22(1):1306.
35. Castillo-Mancilla JR, Zheng JH, Rower JE, Meditz A, Gardner EM, Predhomme J, et al. Tenofovir, emtricitabine, and tenofovir diphosphate in dried blood spots for determining recent and cumulative drug exposure. AIDS Res Hum Retroviruses. 2013;29(2):384–90.
36. Castillo-Mancilla JR, Searls K, Caraway P, Zheng JH, Gardner EM, Predhomme J, et al. Short communication: tenofovir diphosphate in dried blood spots as an objective measure of adherence in HIV-infected women. AIDS Res Hum Retroviruses. 2015;31(4):428–32.
37. Mansoor LE, Lewis L, Naicker CL, Harkoo I, Dawood H, Naidoo K, et al. Prospective study of oral pre-exposure prophylaxis initiation and adherence among young women in KwaZulu-Natal, South Africa. J Int AIDS Soc. 2022;25(7):e25957.
38. Musinguzi N, Muwonge T, Thomas K, Baeten JM, Bangsberg DR, Haberer JE. Does adherence change when no one is looking? Comparing announced and unannounced tenofovir levels in a PrEP trial. AIDS Behav. 2016;20(11):2639–43.
39. Hannaford A, Arens Y, Koenig H. Real-time monitoring and point-of-care testing: a review of the current landscape of PrEP adherence monitoring. Patient Prefer Adherence. 2021;15:259–69.
40. Robinson RS. Purposive sampling. In: Maggino F, editor. Encyclopedia of quality of life and well-being research. Cham: Springer; 2023. p. 5645–7.
41. Campbell S, Greenwood M, Prior S, Shearer T, Walkem K, Young S, et al. Purposive sampling: complex or simple? Research case examples. J Res Nurs. 2020;25(8):652–61.
42. Tongco M. Purposive sampling as a tool for informant selection. Ethnobotany Res Appl. 2006. https://doi.org/10.17348/era.5.0.147-158.
43. Hunter DJ, McCallum J, Howes D. Defining exploratory-descriptive qualitative (EDQ) research and considering its application to healthcare. GSTF Journal of Nursing and Health Care. 2019; 4 (1).
44. Sandelowski M, Barroso J. Classifying the findings in qualitative studies. Qual Health Res. 2003;13(7):905–23.
45. Hamilton AB, Finley EP. Qualitative methods in implementation research: an introduction. Psychiatry Res. 2019;280:112516.
46. Braun V, Clarke V. Toward good practice in thematic analysis: avoiding common problems and be(com)ing a knowing researcher. Int J Transgender Health. 2023;24(1):1–6.
47. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated consolidated framework for implementation research based on user feedback. Implement Sci. 2022;17(1):75.
48. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42.
49. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017;17(1):88.
50. Braun V, Clarke V. Conceptual and design thinking for thematic analysis. Qual Psychol. 2022;9(1):3–26.
51. Dedoose Version 9.0.107, cloud application for managing, analyzing, and presenting qualitative and mixed method research data (2025). Los Angeles, CA: SocioCultural Research Consultants, LLC www.dedoose.com.
52. King N, Brooks JM. Template Analysis for Business and Management Students. 55 City Road, London: SAGE Publications Ltd; 2017: https://methods.sagepub.com/book/mono/template-analysis-for-business-and-management-students/toc. Accessed 2025/02/09.
53. Ulin P, Robinson E, Tolley E. Qualitative methods in public health: a field guide for applied research. Med Sci Sports Exerc. 2005;37:1249.
54. Finlay L. Thematic analysis: the 'good', the 'bad' and the 'ugly.' EJQRP. 2021;11:103–16.
55. Chen YY, Shek DT, Bu FF. Applications of interpretive and constructionist research methods in adolescent research: philosophy, principles and examples. Int J Adolesc Med Health. 2011;23(2):129–39.
56. Mujugira A, Karungi B, Mugisha J, Nakyanzi A, Nampewo O, Naddunga F, et al. Urine tenofovir testing for real-time PrEP adherence feedback: a qualitative study involving transgender women in Uganda. J Int AIDS Soc. 2024. https://doi.org/10.1002/jia2.26255.
57. Hunt T, Lalley-Chareczko L, Daughtridge G, Swyryn M, Koenig H. Challenges to PrEP use and perceptions of urine tenofovir adherence monitoring reported by individuals on PrEP. AIDS Care. 2019;31(10):1203–6.
58. Thuo N, Polay M, Leddy AM, Ngure K, Chatterhee P, Gandhi M, et al. Point-of-care test for assessing tenofovir adherence: feasibility and recommendations from women in an oral PrEP program in Kenya and their healthcare providers. AIDS Behav. 2021;25(11):3617–29.

59. McInziba A, Wademan D, Viljoen L, Myburgh H, Jennings L, Decloedt E, et al. Perspectives of people living with HIV and health workers about a point-of-care adherence assay: a qualitative study on acceptability. AIDS Care. 2023;35(10):1628–34.
60. Joseph Davey D, Bhreemraj K, Mvududu R, Dadan S, Dovel K, Cleary S, et al. Impact of urine TFV testing on PrEP adherence in South African pregnant & postpartum women: an RCT. Paper presented at: CROI, March 2025; San Francisco, California.
61. Bardon AR, Simoni JM, Layman LM, Stekler JD, Drain PK. Perspectives on the utility and interest in a point-of-care urine tenofovir test for adherence to HIV pre-exposure prophylaxis and antiretroviral therapy: an exploratory qualitative assessment among U.S. clients and providers. AIDS Res Ther. 2020;17(1):50.
62. Wang M, Moodley P, Khanyile M, Bulo E, Zondi M, et al. Cost and clinical flow of point-of-care urine tenofovir testing for treatment monitoring among people living with HIV initiating ART in South Africa. J Int AIDS Soc. 2025;28(7):e70004.

Authors and Affiliations

Lara Court[1] · Rufaro Mvududu[2,3] · Sarah Schoetz Dean[4] · Lucia Knight[1,5] · Kathryn Dovel[4] · Monica Gandhi[6] · Landon Myer[2] · Thomas Coates[4] · Dvora L. Joseph Davey[2,4]

✉ Lara Court
lara.court@uct.ac.za

[1] Division of Social and Behavioural Sciences, School of Public Health, University of Cape Town, Cape Town, South Africa

[2] Division of Epidemiology and Biostatistics, School of Public Health, University of Cape Town, Cape Town, South Africa

[3] Desmond Tutu Health Foundation, University of Cape Town, Cape Town, South Africa

[4] Division of Infectious Diseases, Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA, USA

[5] School of Public Health, University of the Western Cape, Bellville, South Africa

[6] Division of HIV, Infectious Diseases, and Global Medicine, Department of Medicine, University of California San Francisco, San Francisco, CA, USA