Assessment of Repeat HIV Testing and Utilization of HIV Self-Testing to Increase Repeat Testing Amongst Pregnant and Postpartum Women in Kisumu County, Kenya

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Abstract

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Repeat HIV testing of pregnant and postpartum women is key to prevention of mother-to-child transmission (PMTCT) of HIV, treatment for pregnant and postpartum women who are living with HIV, identification of untested positive partners and timely care for HIV infected children. Incident maternal HIV infection during pregnancy or in the postpartum period may lead to infant HIV acquisition; early diagnosis of such incident HIV infection provides opportunity for additional interventions. This thesis describes the results of two studies on the frequency and improvement of repeat HIV testing amongst pregnant and postpartum women.

First, we conducted a cross-sectional study among 300 HIV seronegative women who were attending during the third trimester, at delivery, or at six weeks or six months postpartum. The objective of the study was to determine the frequency of repeat HIV testing. Overall, at 57.3% (95% CI: 51.5, 63.0) of visits, repeat HIV testing was done. The frequency of testing was higher within the antenatal period (54/72, 75.0%) compared to during delivery (43/64, 67.2%), and during the six-week (56/121, 46.3%) and-six month postpartum visit (19/43, 44.2%); in multivariate analysis, the postpartum period was associated with reduced likelihood of repeat HIV testing.

In the second study, we assessed utilization of HIV self-testing to improve repeat testing amongst pregnant and postpartum women in programmatic settings in Kisumu, Kenya. Facility based HIV testing is conventionally offered through provider-initiated testing and counselling (PITC) but with the introduction of

HIV self-testing (HIVST), that alternative approach could provide a user-friendly, time-saving alternative. We conducted a pilot evaluation of HIVST amongst 400 HIV seronegative women attending the third trimester, or at six weeks or six months postpartum within three health facilities. We offered them the opportunity to choose between clinic-based oral HIVST and standard finger prick based PITC for repeat HIV testing. We estimated the frequency of the choice between HIVST and PITC, and described the participants' reasons for and experiences with the choices, as well as preferences for future testing. We found that just over half 53.8% (95% CI: 48.7, 58.7) chose oral HIVST. Unmarried women were more likely to use HIVST (PR: 1.26, 95% CI 1.01 – 1.57). The most frequent reason for choice of oral HIVST was fear of needle prick (101/215, 47%). More HIVST than PITC users (95.3% vs 48.1%, $p<0.001$) would use the same testing approach in future and most HIVST users (94.9% vs 41.6%, $p<0.001$) would recommend their test of choice to other women.

Our results show that repeat HIV testing amongst pregnant and postpartum women fell short of the guideline goals. These results highlight the need to evaluate barriers to HIV testing within PMTCT settings and opportunities for improving testing for maximal benefit for pregnant and postpartum women, their partners and their children. The use of clinic based oral HIVST in Kenyan antenatal and postpartum settings appears to be feasible and acceptable for repeat HIV testing and could improve repeat testing rates. Future work should explore the practical mechanisms for implementing such a strategy and evaluating its cost effectiveness.

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DEDICATION

To my wife Carolyne Oyaro and our daughters, Shammah Mor, Shekinah Hera and Hadassah Gweth for releasing me to be away from home. Thank you for the love and encouragement.

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To the core and lay health workers working towards elimination of mother to child transmission of HIV.

CHAPTER 1: **Assessment of Repeat HIV Testing Amongst Pregnant and Postpartum Women in Kisumu**

Summary

Introduction: HIV testing of pregnant and postpartum women is key to prevention of mother-to-child transmission (PMTCT) of HIV, treatment for pregnant and postpartum women who are living with HIV, identification of untested positive partners and timely care for HIV infected children. An important fraction of infant HIV acquisition occurs from mothers who tested HIV seronegative earlier in pregnancy – i.e., because of incident maternal HIV infection during pregnancy or in the postpartum period. Early diagnosis of such incident HIV infection during pregnancy, delivery or breastfeeding provides opportunity for additional interventions, including immediate maternal initiation on treatment and infant prophylaxis. Little data are available on the frequency of repeat HIV testing across the antenatal-postpartum continuum, despite global and national recommendations to conduct such testing. Our objective was to determine the frequency of repeat HIV testing amongst pregnant and postpartum women in programmatic settings in Kisumu, Kenya.

Methods: We conducted a cross-sectional evaluation to determine the uptake of repeat HIV testing amongst HIV seronegative pregnant and postpartum women in three health facilities. A convenience sample of 300 HIV seronegative women who were attending during the third trimester, at delivery, or at six weeks or six months postpartum were targeted. Log binomial regression was used to assess the predictors of repeat HIV testing.

Results: The median age was 23 (interquartile range, 20-27) years. Three quarters (76%) of the women were married and 92% had at least one child. Overall, at 57.3% (95% CI: 51.5, 63.0) of visits, repeat HIV testing was done; none of the women tested positive for HIV. The frequency of testing was higher within the antenatal period (54/72, 75.0%) compared to during delivery (43/64, 67.2%), and during the six weeks (56/121, 46.3%) and six months postpartum periods (19/43, 44.2%); in multivariate analysis, the postpartum period was associated with reduced likelihood of repeat HIV testing.

Conclusions: Repeat HIV testing amongst pregnant and postpartum women fell short of the guideline goals. These results highlight the need to evaluate barriers to HIV testing within PMTCT settings and

opportunities for improving testing for maximal benefit of pregnant and postpartum women, their partners and their children.

INTRODUCTION

HIV testing amongst pregnant and postpartum women is an essential strategy to help in identification of incident HIV infections among women, initiation of antiretroviral therapy (ART) for the health of the woman and of prophylaxis interventions for prevention of mother-to-child transmission (PMTCT) and prevention of HIV transmission to partners (1). Through the option B plus and treatment for all initiatives, the majority of women with chronic HIV have been initiated on ART and in many countries that includes most HIV-positive pregnant women (1). However, failure to detect incident infections among initially HIV negative pregnant and postpartum women carries high risk for transmission to infants (1), as a result of high transmission probability during acute infection and missed opportunity to receive ART and infant prophylaxis. Children who are exposed to acute HIV during or after delivery and become HIV positive may miss opportunities to initiate ART early, risking infant morbidity and mortality (2).

One meta-analysis found a pooled incidence rate of 4.7 per 100 person-years during pregnancy and 2.9 per 100 person-years during the postpartum period among African women, an incidence comparable to that found in high-risk populations globally (3). This elevated risk for HIV incident infection during pregnancy and the postpartum period is due to several biological and behavioral factors (3-9). It has been estimated that 34% of infant HIV infections are because of incident infections amongst pregnant mothers who previously had tested HIV seronegative at their first antenatal visit (10). The MTCT rate is double to triple amongst these women compared to those who acquired HIV prior to pregnancy (3, 11-13).

As part of PMTCT programs to help in identification of incident infections, the World Health Organization (WHO) recommends repeat HIV testing in the third trimester, during labor or shortly after delivery (1). In settings where breastfeeding is the norm, guidelines also recommend repeat HIV testing during the breastfeeding period (1). Kenya is amongst the 23 high priority countries for improved PMTCT services (14), so repeat HIV testing is recommended in the third trimester, during labor/delivery, and at six weeks and six months postpartum for women who test negative prior to these points. In many African settings,

including Kenya, there is high uptake of HIV testing (>90%) amongst women attending the first antenatal clinic (ANC) visit (15). However, there are limited data globally on the uptake of repeat HIV testing amongst pregnant and postpartum women and no known study has estimated repeat HIV testing frequencies across all required testing periods (antenatal, delivery, and postpartum).

METHODS

Study design and population

We conducted a cross-sectional study to assess the uptake of repeat HIV testing amongst pregnant and postpartum women within three large health facilities in Kisumu County, Kenya. Kisumu County has the third highest HIV prevalence (16.3%) in Kenya. The three government health facilities (Rabuor Sub-County Hospital, Nyahera Sub-County Hospital and Railways Health Centre serve both urban and rural populations. They are supported by the Family AIDS Care and Education Services (FACES) program, which is funded by the United States President Emergency Plan for AIDS Relief (PEPFAR) via the United States Centers for Disease Control and Prevention (CDC) and in collaboration between the University of California San Francisco (UCSF) and the Kenya Medical Research Institute (KEMRI). The study took place at the antenatal, maternity and postnatal departments and targeted HIV seronegative women aged between 16 and 49 years who presented to the antenatal clinic in the third trimester (≥27 weeks and had been tested ≥3 months ago) or at delivery, six weeks or six months postpartum. The cross-sectional sampling thus allowed for measuring repeat HIV testing across the antenatal-maternity-postpartum spectrum.

Study procedures

Research staff approached antenatal and postnatal women once they completed their normal clinic visit, and women who had delivered in the preceding 12 hours once they had been discharged. Research assistants administered the survey at the three study sites on randomly chosen days to avoid influencing testing behaviors of health care staff. Few women declined to participate citing time constraints however, for all consenting women, the survey collected demographic information (age and marital status), maternal characteristics (gestation, parity and type of clinic visit) and HIV testing data (whether HIV testing was done on the material day, on previous clinic visits, and the results). The women's mother baby booklets and the

clinics' departmental registers were used to cross-reference the information on testing. The data from the questionnaires were entered into an electronic database in preparation for analysis.

All women reporting not tested in the health facility were provided with an oral based HIV self-testing (HIVST) kit (Oraquick) and instructions on its use, to test themselves at home. The Kenya National AIDS and STI Control Programme (NASCOP) approved the OraQuick test (*Orasure Technologies*) for use within community settings. Contact information for the investigator and research assistants was provided in case they had challenges with testing or had questions. No data were collected on HIVST use.

Sample size

The sample size was calculated guided by the historical number of women who attended antenatal, delivery and postnatal clinic/services and went through HIV testing process in the three health facilities. Assuming 40% uptake of repeat HIV testing and using Stata 15.0 calculations for confidence intervals for proportions, over a period of 3 months, we picked a sample of 300 women with an expected estimation of a true proportion within +/- approximately 6%.

Data analysis

Using descriptive statistics, we summarized the distribution of maternal age, parity and marital status per testing period among the study participants. The primary study outcome was repeat HIV testing defined as testing during each of the Kenyan recommended time points (third trimester (≥27 weeks), at delivery or six weeks and six months postpartum. Other variables used in the analysis included maternal age, parity, marital status, period of testing and site. We estimated overall prevalence of repeat HIV testing with 95% confidence intervals and prevalence by testing period (antenatal, delivery, six weeks and six months postpartum).

We conducted bivariate and multivariate analyses to test an association between repeat HIV testing and maternal age described as 16 to 24 years, 25 to 30 years and 31 to 40 years old, parity described as nulliparous versus multiparous, marital status described as married versus not married and testing period described as antenatal, delivery, six weeks, and six months postpartum. The analyses were conducted using log-link binomial generalized linear model to allow for prevalence ratio estimates.

Ethical review

Ethical approval to conduct this study was obtained from the University of Washington Human Subjects Division and the Kenya Medical Research Institute Scientific and Ethics Review Unit. Informed verbal consent was obtained from all those who participated in the study. The study procedure was short, non-invasive and collected short responses on routine HIV testing services. The only identifier collected in the questionnaire was the clinic ID to enable us cross-reference the HIV testing information in the clinic register. We therefore obtained a waiver of the written consent, which did not affect the rights of the women receiving routine health services.

RESULTS

A total of 300 women were enrolled, with a median age of 23 (interquartile range 20-27) years. Three quarters (76%) of the women were married and 92% had at least one child (Table 1). Overall, at 57.3% (95% CI: 51.5, 63.0) of visits, repeat HIV testing was done and none of them tested positive. The frequency of testing was higher within the antenatal period (54/72, 75.0%) compared to during delivery (43/64, 67.2%), and during the 6-week (56/121, 46.3%) and 6-month postpartum visit (19/43, 44.2%) (Figure 1). Amongst those tested, (168/172,97.7%), had their results documented in both register and mother baby booklet, three in register only and one in neither register nor booklet.

From the bivariate analysis, nulliparous women (PR: 1.51, 95%CI 1.23-1.86) had an increased likelihood of getting a repeat HIV test, while those in the six-week (PR: 0.62, 95% CI: 0.49-0.78) and 6-month postpartum visit (PR: 0.59, 95%CI 0.41-0.85), had a reduced likelihood of getting a repeat HIV test. In the multivariate analysis, the association was sustained for testing during the six-week (PR: 0.63, 95%CI 0.49-0.81) and six-month postpartum visit (PR: 0.63, 95% CI: 0.44-0.92) but not for nulliparous women (Table 2).

DISCUSSION

In this study, we documented that the frequency of repeat HIV testing was only just over half the visits by pregnant and postpartum women. The frequency of testing was higher in the antenatal period and lowest in the six months postpartum period. Both six-week and six-month postpartum visits were associated with lower likelihood of repeat HIV testing.

Few studies have evaluated repeat HIV testing in the context of PMTCT, and to the best of our knowledge this is the first study measuring repeat HIV testing across the antenatal-maternity-postpartum spectrum in Kenya. In comparison to three prior studies in Zambia (24.5%), the United States of America (28.4%) and Kenya (26.8%) that assessed repeat HIV testing within the antenatal period only (16-18), our study recorded a higher frequency of repeat HIV testing. This may reflect evolving systems to better conduct repeat HIV testing or could be because of their use of a cohort study designs, which depended on data abstraction from health facility registers that might be prone to missing data and data transcription errors. One prospective study from London that assessed the feasibility and acceptability of third trimester antenatal HIV testing found higher frequency (71%) of repeat HIV testing (19); however, the high resource setting for that work is not comparable with the Kenyan study setting here.

The untested 43% in our study represent missed opportunities for the elimination of mother to child transmission (eMTCT) agenda. The missed opportunities can be due to several health systems factors that need to be further investigated. The health workers and PMTCT program officers need to review adherence to the WHO and Kenyan set points for repeat HIV testing. Whereas lack of HIV test kits is known to be an impediment to HIV testing (19), there were no reports of HIV test kits stock-outs during the study period. Notably, postpartum women were less likely to be tested and this could be due to less prioritization of HIV testing and less perception of risk of HIV infection in them by clinic staff. Nevertheless, testing during the breastfeeding period is important because of the high risk of transmission to the child because of high viremia if maternal acute infection occurs (1, 20, 21). The testing negative at this time point gives opportunity for introduction of more HIV preventive strategies like pre-exposure prophylaxis (PrEP) for HIV negative pregnant and postpartum women after risk assessment (22, 23).

The strength of the study is that ascertainment of HIV testing directly from women did not face the challenge of missing information in clinic registers, which has been cited in one of the studies on HIV testing (24). The work was independent of the clinics, allowing a more unbiased assessment. Unlike previous studies, this study included data from the different points within the ante and postpartum continuum. The study sites involved represent rural and urban populations of pregnant and post-partum women. The use of antibody-based methods of HIV testing is cost effective in resource-limited settings but we are limited from diagnosis of acute HIV infections. A clear limitation of the cross sectional design is that we could not account for the

women who failed to return to the clinic. No women were identified as newly HIV-infected in this study, although the sample size was small for detecting incident HIV.

CONCLUSION

Repeat HIV testing amongst pregnant and post-partum women in three large health facilities in Kisumu County, Kenya fell short of the national guideline goals. These findings may well be applicable to other counties, countries and regions implementing the WHO PMTCT guidelines and supported by the PEPFAR. Understanding why almost half of the women who come to the health facility were not being tested at the PMTCT appointed timelines is a priority – whether it is due to high workload, time constraints, knowledge gap, or other reasons. Our study targeted those who came to the facility; however, due to loss to follow-up of women within the antenatal-postpartum continuum, more women remain at risk of not being tested. Our results call for implementation work to bridge the gaps associated with missed opportunities for repeat HIV testing.

Table 1: Participant characteristics

	All women N=300 n (%)	Antenatal N=72 n (%)	Delivery N= 64 n (%)	6 weeks PNC N=121 n (%)	6 months PNC N=43 n (%)
Maternal age (years) Median(IQR)	**23 (20-27.3)**				
≤20	96 (32.0)	30 (41.7)	23 (36.0)	24 (19.8)	19 (44.2)
21-25	108 (36.0)	16 (22.2)	27 (42.2)	52 (43.0)	13 (30.2)
26-30	55 (18.3)	15 (20.8)	6 (9.4)	26 (21.5)	8 (18.6)
31-35	29 (9.7)	8 (11.1)	6 (9.4)	12 (9.9)	3 (7.0)
36-40	12 (4.0)	3 (4.2)	2 (3.1)	7 (5.8)	0
Marital status					
Married	228 (76.0)	56 (77.8)	48 (75.0)	96 (79.3)	28 (65.1)
Single	68 (22.7)	13 (18.1)	16 (25.0)	24 (19.8)	15
Separated	3 (1.0)	3 (4.2)	0 (0)	0 (0)	0
Widow	1 (0.3)	0 (0)	0 (0)	1 (0.8)	0 (34.9)
Parity					
Primigravida	24 (8.0)	22 (30.6)	0 (0)	1 (0.8)	1 (2.3)
1	103 (34.3)	28 (38.9)	18 (28.1)	37 (30.6)	20 (46.5)
2	74 (24.7)	7 (9.7)	24 (37.5)	28 (23.1)	15 (34.9)
3	58 (19.3)	7 (9.7)	12 (18.8)	36 (29.8)	3 (7.0)
≥4	41 (13.7)	8 (11.1)	10 (15.6)	19 (15.7)	4 (9.3)

*PNC: Postpartum
IQR: Interquartile range

Figure 1: Bar graph on uptake of repeat HIV testing

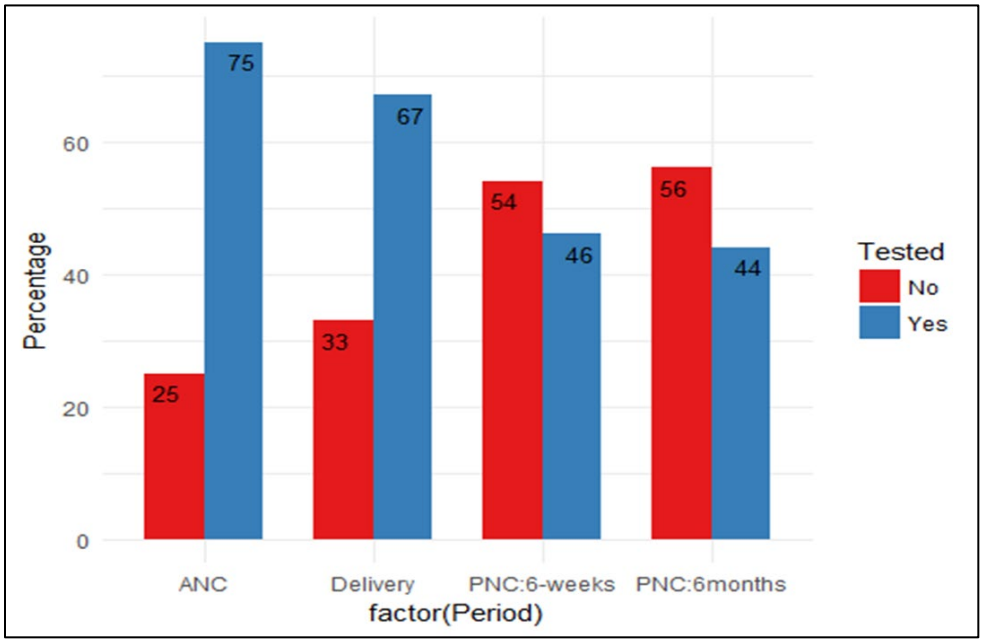

Table 2: Correlates of repeat HIV testing among antenatal, delivering and postpartum women

Variables	Bivariate analysis PR (95% CI)	Multivariate analysis* PR (95% CI)
Maternal Age		
16-24 years	Ref	Ref
25-30 years	0.96 (0.76-1.21)	0.93 (0.72-1.19)
31-40 years	1.06 (0.80-1.40)	1.14 (0.89-1.45)
Marital Status		
Married	Ref	Ref
Unmarried	0.87 (0.68-1.11)	0.86 (0.68-1.08)
Parity		
Multiparous	Ref	Ref
Nulliparous	**1.51 (1.23-1.86)**	1.21 (0.93-1.57)
Testing period		
Antenatal	Ref	Ref
Delivery	0.90 (0.72-1.11)	0.91 (0.72-1.16)
Post-partum 6 weeks	**0.62 (0.49-0.78)**	**0.63 (0.49-0.81**)
Postpartum 6 months	**0.59 (0.41-0.85)**	**0.63 (0.44-0.92)**

*Multivariate model adjusted for all the four variables
PR: Prevalence Rate
CI: Confidence Interval
Ref: Referent variable

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CHAPTER 2: **HIV Self-Testing as a Strategy to Increase Repeat Testing amongst Pregnant and Postpartum Women: A Pilot Evaluation in Kenya**

Summary

Introduction: Repeat HIV testing amongst pregnant and postpartum women is important for identification of incident HIV infections and subsequent HIV treatment and prevention interventions. Facility based HIV testing is conventionally offered through provider-initiated testing and counselling (PITC) but with the introduction of HIV self-testing (HIVST), that alternative approach could provide a user-friendly, time-saving alternative.

Methods: We conducted a pilot evaluation of HIVST for pregnant and postpartum women within three health facilities in Kisumu, Kenya. We offered 400 pregnant and postpartum women who had previously tested HIV seronegative the opportunity to choose between clinic-based oral HIVST and standard finger prick based PITC for repeat HIV testing. We estimated the frequency of each choice, and described the participants' reasons for and experiences with the choices, as well as preferences for future testing. We conducted a log binomial regression to identify predictors of choice for repeat HIV testing approach and a 2-sample test for equality of proportions of experiences and decisions between the HIVST and PITC groups.

Results: The median age was 23 (interquartile range 20-28) years. More than three quarters (313/400, 78.3%) were married and few (17/400, 4.3%) had their first pregnancy. Just over half 53.8% (95% CI: 48.7, 58.7) chose oral HIVST. Unmarried women were more likely to use HIVST (PR: 1.26, 95% CI: 1.01 – 1.57). The most frequent reason for choice of oral HIVST was fear of needle prick (101/215, 47%) while the largest group of PITC users (79/185, 42.7%) had no reason for making their choice. More HIVST than PITC users indicated lack of pain (99.1% vs 34.6%, p <0.001) and having to ask for help (18.1% vs 1.1%, p<0.001) as reflective of their HIV testing experiences. Fewer HIVST than PITC users (82.8% vs 90.8%, p=0.03) indicated that their test of choice was quick to conduct. More HIVST than PITC users (95.3% vs 48.1%, p<0.001) would use the same testing approach in future and most HIVST users (94.9% vs 41.6%, p<0.001) would recommend their test of choice to other women.

Conclusions: In this pilot evaluation, the use of HIVST in Kenyan antenatal and postpartum settings appears to be feasible and acceptable for repeat HIV testing. Future work should explore the practical mechanisms for implementing such a strategy and evaluating its cost effectiveness.

INTRODUCTION

Identification of incident HIV infections amongst pregnant and postpartum women is essential for their treatment and for the prevention of HIV transmission to their infants and sexual partners (1, 2). Specifically, a woman newly diagnosed with HIV would be initiated on antiretroviral therapy (ART) immediately (1), reducing infectiousness to sexual partners and infants (3-5), and an infant born to an HIV infected mother would be initiated on antiretroviral prophylaxis until confirmed to be HIV negative and if infected would be initiated on antiretroviral therapy (6).

A pregnant woman who tests HIV negative in the first antenatal visit is still at risk of incident HIV infection (1), and so repeat HIV testing helps in identification of incident HIV infections (1, 2). Incident HIV infections during pregnancy or postpartum period increase the risk of mother to child transmission of HIV due to high infectiousness and it is estimated that 34% of infant HIV infections are because of incident infections amongst pregnant women after the first antenatal visit (7). Therefore, prevention of mother to child transmission (PMTCT) of HIV programs have recently emphasized enhancing efforts to conduct repeat HIV testing. An HIV negative woman at risk of infection could benefit from effective HIV prevention interventions like pre-exposure prophylaxis (8-10), which can be initiated at any time during pregnancy or the postpartum period.

Health provider-initiated HIV testing and counselling (PITC) has been the mainstay of HIV testing in public health facilities in high HIV burden settings including in Kenya. This approach is dependent on the existing health workers introducing and conducting the test. However, with advancement in HIV prevention research, HIV self-testing (HIVST) has been introduced (11). In May 2017, Kenya launched HIV self-testing (HIVST) as an alternative HIV testing approach and the test kits were availed in selected public health facilities by mid-2018. Pregnant women who attend these health facilities are issued with these kits for their partners of unknown HIV status to test at home.

Several studies on PITC have documented challenges to full coverage of HIV testing using PITC including infrastructural, resource and ethical challenges (12). In addition, most of the studies evaluating the prevalence of repeat HIV testing within health facilities in different countries have documented incomplete uptake, ranging from 25% to 71% (13-16). One study on repeat HIV testing which identified barriers like inconsistent patient volumes, space limitations, high patient workload and other reasons, suggested that to

successfully implement Kenya's national repeat HIV testing guidelines during pregnancy and postpartum period, it is essential that the barriers be addressed and enablers capitalized on through a multi-faceted intervention program (17). Though several studies have evaluated HIVST amongst different populations, none has assessed clinic-based oral HIVST for repeat HIV testing of pregnant and postpartum women. As one of the ways of exploring solutions to the barriers identified with PITC and repeat HIV testing, we conducted a pilot evaluation of choice between PITC (HIV testing by finger prick blood sample - the standard of practice) and oral based HIVST for repeat HIV testing amongst pregnant and postpartum women in public health facilities in Kenya, assessing feasibility and experiences.

METHODS

Study design and population

This pilot evaluation study was conducted within three large health facilities in Kisumu, a county with the third highest HIV prevalence (16.3%) in Kenya. The three government health facilities (Rabuor sub-County Hospital, Nyahera sub-County Hospital and Railways Health Centre) serve both urban and rural populations. They are supported by the Family AIDS Care and Education Services (FACES) program, which is funded by the President Emergency Plan for AIDS Relief (PEPFAR) via the United States Centers for Disease Control and Prevention (CDC) and in collaboration between the University of California San Francisco (UCSF) and the Kenya Medical Research Institute (KEMRI). The study took place at the antenatal and postnatal departments and targeted HIV seronegative women aged between 16 and 49 years who presented to the antenatal clinic in the third trimester (≥27 weeks and had been tested ≥ 3 months ago) or at six weeks or six months postpartum.

Study procedures

Research staff conducted health talks, or one-on-one discussions later in the day, within the antenatal and integrated maternal child health clinics about the study on HIV testing. Women were then screened for eligibility by the research staff. After confirmation of eligibility, each woman provided written informed consent. Based on their choice of testing approach, the research team referred the participants who chose PITC to the routine counsellor/nurse for HIV counselling and testing services. Those who chose oral HIVST were offered brief counselling, similar in content to the PITC one, and given the oral HIVST kit to test themselves within a testing booth built for the pilot. The booths were of simple wooden design, with a

tabletop for testing and an umbrella ceiling; four connected booths were built, able to accommodate four clients at any given time, each in a private space. The booths were placed a few meters from the maternal and child health clinics. Prior to testing, research assistants administered standardized questionnaires about demographics, obstetric history and reasons for choice of HIV test; they completed the remaining section of questionnaire (experience with the process) after testing.

The PITC kits used were part of the laboratory supplies provided by the Kenya Ministry of Health (MOH) and the oral HIVST kits were OraQuick (*Orasure Technologies*), procured by the Kenya National AIDS and STI Control Programme (NASCOP) for use in the HIV testing services. Apart from Oraquick insert with instructions on how to test, a laminated poster with instructions in English, Kiswahili and Dholuo (the dominant local language) was placed on each testing booths' wall. Research assistants were accessible around the HIV testing booths for consultations from the participants if needed.

Women who tested positive were referred to the routine HIV counsellor for further counselling and confirmatory tests and immediate ART as per the national guidelines. Those who tested HIV negative were briefly counselled on HIV prevention by the research assistant (HIVST users) or the PITC counsellor (PITC users). The summary flow chart of the study process is as shown in Figure 1.

Sample size

We assumed that half of women would choose HIVST for the sample size calculations. Using Stata 15.0 calculations for confidence intervals for proportions, we calculated a sample of 400 women to be able to estimate the true proportion within +/- approximately 5%. With reference to the historical data on the number of women who previously attended antenatal and postnatal services in the three health facilities and went through HIV testing process, the three facilities were adequate.

Data analysis

Using descriptive statistic, we summarized the distribution of maternal age, parity, marital status, and testing period among the study participants. The primary study outcome was the proportion of HIV testing approach chosen by the participants (HIVST or PITC). The predictor variables included maternal age, marital status, parity and testing period.

We estimated the overall prevalence of HIV self-testing with 95% confidence intervals. We conducted bivariate and multivariate analyses using log-binomial regression to allow a prevalence ratio estimation to

test for associations between maternal age, parity, marital status or testing period with preference of HIV testing approach. We also calculated the frequencies of the different reasons for choice of HIV testing approach, experiences with HIV testing approach and decisions following HIV testing approach. Using a 2-sample test for equality of proportions with continuity correction, we tested for statistical significance in difference in frequency of experiences and decisions between the HIVST and PITC groups.

The reasons for choice of HIV testing approach included: speed (being a quick process), need of assistance by health worker, causes less anxiety, having privacy, fear of testing self, need to know status first/confidentiality, no reason, fear of needle prick and other. The list of experiences with HIV testing approach included easy or difficult, not painful or painful, private or not private, fast or slow, asked for help or not, felt supported or not, test being accurate or not and others. The decisions made by the participants following the HIV testing approach used included: Whether they would use the same test in future and whether they would recommend it to other women.

Ethical review

Ethical approval to conduct this study was obtained from the University of Washington Human Subjects Division and the KEMRI Scientific Ethics Review Unit. Informed written consent was obtained from all women who participated in the study.

RESULTS

A total of 400 women were enrolled, and offered the choice between oral HIVST and PITC. The median age was 23 (interquartile range 20-28) years. More than three-quarters (313/400, 78.3%) were married, the median parity was two (interquartile range 1-3) children, and few (17/400, 4.3%) had the first pregnancy (Table 1). Overall, just over half (53.8%, 95% CI 48.7, 58.7) chose oral HIVST, with similar proportions in the antenatal clinic (36/69, 52.3%) and in the post-partum clinic (179/331, 54.1%). Based on multivariate analysis unmarried women status (PR: 1.26, 95% CI: 1.01 – 1.57, $p<0.05$), was associated with high likelihood of choosing HIV self-testing (Table 2).

Reasons for choice of oral HIVST or PITC

Most, 379 (94.8%) participants picked a reason for their choice while 21 (5.2%) picked more than one reason for choice of HIV testing approach; for the 21 who picked more than one choice we only included the first choice in the analysis. The most frequent reason for choice of oral HIVST was the fear of needle

prick at (101/215, 47%) followed by “no reason” (73/215, 34%). The largest group of PITC users had no reason for picking it (79/185, 42.7%) followed by those feeling that it was a quick procedure at (59/185, 31.9%) (Figure 2).

Experiences with oral HIVST or PITC

More HIVST than PITC users indicated lack of pain, (99.1% vs 34.6%, p<0.001) and asked for help, (18.1% vs 1.1%, p<0.001) during or after the HIV testing. Fewer HIVST than PITC users (82.8% vs 90.8%, p=0.03) indicated that their test of choice was quick (Table 3). One woman tested positive for HIV using PITC (prevalence 0.25%) and was referred for a confirmatory retest and enrolled for HIV treatment.

Future use and recommendations

More HIVST than PITC users would use the same HIV testing approach in future (95.3% vs 48.1%, p<0.001) and recommend the same HIV testing approach to other women (94.9% vs 41.6%, p<0.001) (Table 3). Two (0.9%) HIVST users would not use it again while eight (3.8%) would use either of the tests in future. None of the HIVST users would not recommend it, while a small number (11/215, 5.1%) would recommend either of the testing approaches. One-third (60/185, 32.4%) of the PITC users would not use it again while (36/185, 19.5%) would use any testing approach. In addition, about a quarter, (42/185, 22.7%) of the PITC users would not recommend it, while (66/185, 35.7%) would recommend either of the testing approaches.

DISCUSSION

In this pilot evaluation of repeat HIV testing in pregnancy and the postpartum period in Kenya, we documented that slightly more than half of antenatal and postpartum women offered HIVST as an alternative to PITC chose HIVST. We found that most HIVST users would use the same test in future and recommend it to other women.

The findings on HIVST uptake show the acceptability of clinic-based oral HIVST as an alternative testing approach in health facilities. A review of 11 previous HIVST studies showed variable acceptability (22-94%) of HIVST within the community, with acceptability of HIVST higher among men than women in sub-Saharan Africa (18). To our knowledge, no study has provided women in antenatal and postpartum settings HIVST as an option to facilitate repeat HIV testing.

Most oral HIVST users' reason for choosing HIVST was the fear of needle prick. The inclusion of clinic based oral HIVST as an alternative approach may serve such women to prevent them from declining HIV testing or missing clinic altogether. Most PITC users preferred it because it was a quick procedure, reflecting that the test execution (not including counselling sessions) is slightly shorter for blood samples (15 minutes) compared to oral HIVST (20 minutes). Time therefore is an important factor to consider in the design or implementation of health strategies; one factor not considered in this pilot is that HIVST can bypass waiting time for a staff member to conduct PITC.

Privacy and confidentiality was either a minor reason for the choice of either of the HIV testing approaches; however, after conducting the test, the participants highly scored their respective testing approaches as private. Previous studies have reported privacy and confidentiality to be determinants for uptake of HIV testing (19), therefore well-implemented clinic based oral HIVST may offer women privacy and confidentiality outside of their homes and improve HIV testing uptake.

Almost all HIVST and PITC users felt that their test of choice was an easy process and this may be a reflection in the strong belief in their choice and supports provision of both testing approaches in the health facility. It was interesting that about two thirds of the PITC users indicated that the procedure was painful but went ahead to use it.

A subset (39/185, 18.1%) of oral HIVST users asked for assistance compared to only two PITC users. Therefore, if clinic based oral HIVST were to be implemented, there may need to be available health care workers to respond to queries or provide additional support during such testing. Very few women (11/400, 2.8%) expressed concerns on the accuracy of the testing approach.

Oral HIVST users overwhelmingly seemed positive about using it again and recommending it to other women. On the contrary, among PITC users, just about half would use it again and less than half would recommend it to other women. More worrying was on the women who indicated that they would not use PITC again. Further qualitative investigation is needed to understand the reasons for women's choices, to evaluate health care worker attitudes and preferences and to conduct time motion studies to determine the cost benefit savings of HIVST as an approach.

This study is amongst the first to assess uptake of clinic based oral HIVST for repeat HIV testing amongst pregnant and postpartum women and highlights some of the patient and health systems related issues. We

did not assess education levels of the women in our study, though literacy challenges underscore the need for clear and simple language in test kit inserts (20-22). Our inclusion of user-friendly charts in three languages may have been beneficial to the participants.

Other studies of repeat HIV testing have reported challenges of heavy workload, time constraints, difficulty checking repeat test eligibility, inconsistent antenatal clinic volume and lack of private space for testing (17), all of which might lower repeat HIV testing completion. Clinic based oral HIVST can solve some of these challenges; in studies from Malawi, Zambia and Zimbabwe, clients performing HIVST within the outpatient department of public facilities was able to decongest clinical testing facilities as health workers focused on other things (19). Our study utilized simple testing booths that enabled a maximum of four women test at a time and this design could be used or modified to other settings.

CONCLUSION

When provided with the option of HIVST within the facility, just over half of women chose this option with over 94% being willing to use it in future and recommend it to others. If deployed strategically to complement PITC then this option has the potential to bridge the gaps that have been identified in the antenatal and postnatal setting for repeat HIV testing.

Figure 1. Flow chart on study processes

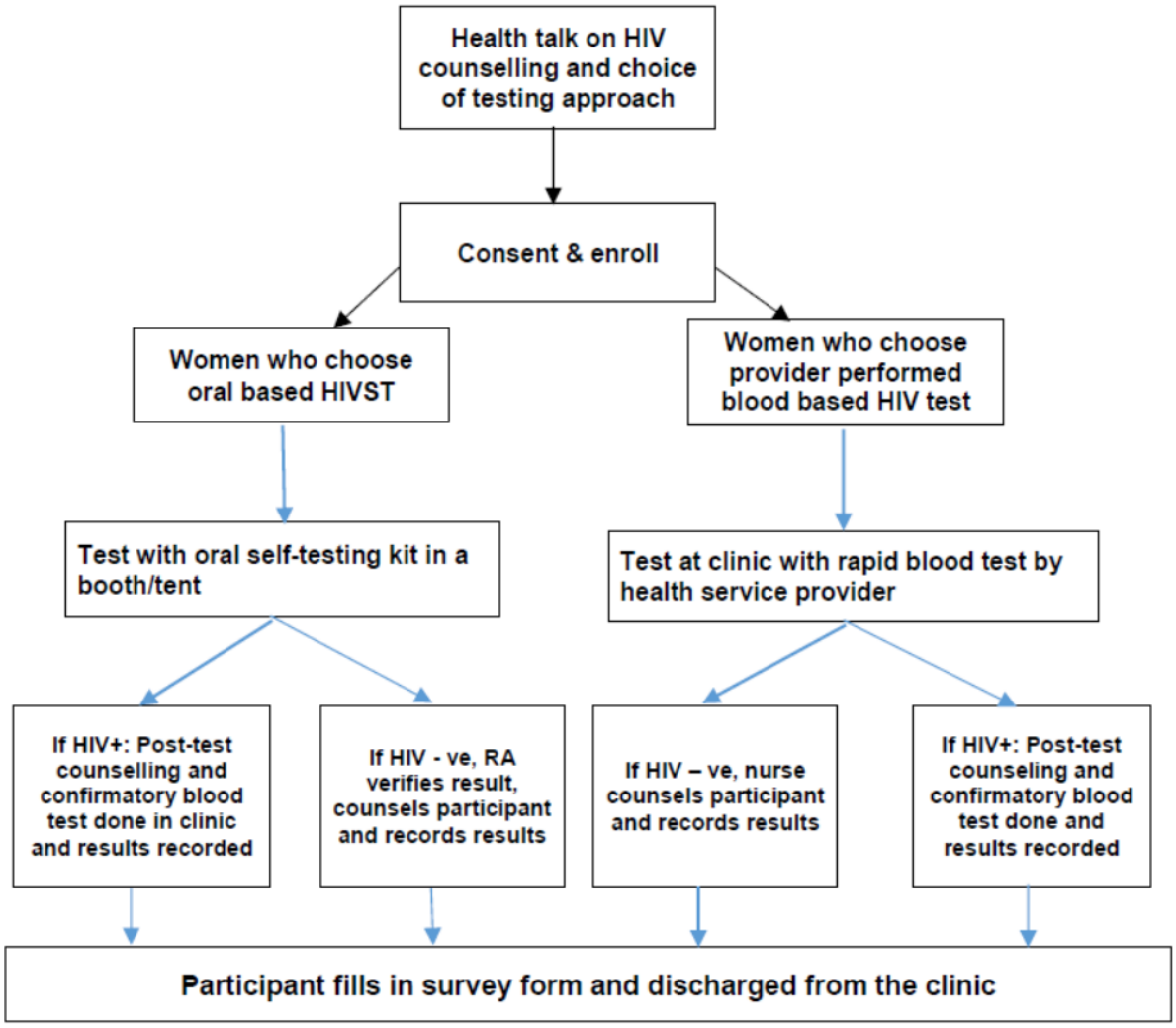

Table 1: Participant characteristics

	All women N=400	Testing Period	
	n (%)	Antenatal N=69 n (%)	Postpartum N=331 n (%)
Maternal age (years) Median (IQR)	23 (20-28)		
≤20	112 (28.0)	16 (23.2)	96 (29.0)
21-25	138 (34.50)	24 (34.8)	114 (34.4)
26-30	98 (24.50)	18 (26.1)	80 (24.2)
31-35	38 (9.50)	9 (13.0)	29 (8.8)
36-40	13 (3.25)	2 (2.9)	11 (3.3)
40+	1 (0.25)	0 (0)	1 (0.3)
Marital status			
Married	313 (78.25)	51 (73.9)	262 (79.2)
Divorced	0	0	0
Separated	1 (0.25)	0	1 (0.3)
Single	86 (21.50)	18 (26.1)	68 (20.5)
Widowed	0	0	0
Parity			
Primigravida	17 (4.25)	15 (21.7)	2 (0.6)
1 child	133 (33.25)	19 (27.5)	114 (34.4)
2 children	127 (31.75)	18 (26.1)	109 (32.9)
3 children	57 (14.25)	6 (8.7)	51 (15.4)
4 children	40 (10.00)	8 (11.6)	32 (9.7)
>4 children	26 (6.50)	3 (4.3)	23 (6.9)

IQR: Interquartile range

Table 2: Correlates of Choice of HIV self-testing method among antenatal and postpartum women		
Variables	**Bivariate analysis PR (95% CI)**	**Multivariate analysis PR (95% CI)**
Maternal Age (years)		
16 - 24	Ref	Ref
25 - 30	0.96 (0.78 - 1.19)	1.07 (0.85 - 1.34)
31 - 42	0.99 (0.75 - 1.31)	1.12 (0.84 – 1.49)
Marital Status		
Married	Ref	Ref
Not married	**1.24 (1.02 – 1.50)**	**1.26 (1.01 – 1.57)**
Parity (no)		
Multigravid	Ref	Ref
Primigravid	1.25 (0.86 - 1.81)	1.27 (0.80 – 2.02)
Testing period		
Antenatal	Ref	Ref
Post-partum	1.04 (0.81 - 1.33)	1.12 (0.84 - 1.50)

*Multivariate analysis includes all the variables
PR: Prevalence Rate
CI: Confidence Interval
Ref: Referent variable

Figure 2: Bar Chart on Reasons for selecting HIVST or PITC

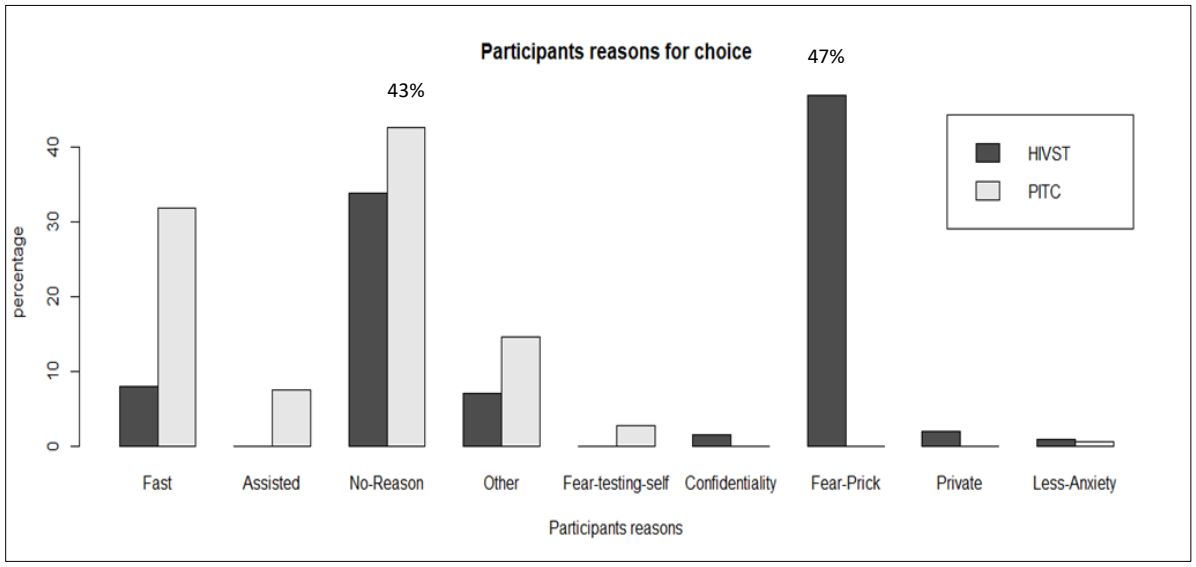

Table 3: Participants Opinions on the HIV testing method after use

	Oral HIVST N=215	PITC N=185	
Experience with choice	**n (%)**	**n (%)**	**P -Value**
Easy process	215(100)	184 (99.5)	0.94
Not painful	213 (99.1)	64 (34.6)	**<0.001**
Private process	210 (97.7)	173 (93.5)	0.07
Fast/quick to conduct	178 (82.8)	168 (90.8)	**0.03**
Asked for help	39 (18.1)	2 (1.1)	**<0.001**
Felt supported	211 (98.1)	182 (98.4)	1
Inaccurate	7 (3.3)	4 (2.2)	0.7
Future Use	205 (95.3)	89 (48.1)	**<0.001**
Recommend test	204 (94.9)	77 (41.6)	**<0.001**

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