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Operations research study to implement HIV and syphilis point-of-care tests and assess client perceptions in a marginalised area of Lima, Peru

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Rosabel Lino⁵ and Angela M Bayer^{4,6}

Summary

In Peru, a significant proportion of people tested for HIV and syphilis do not receive timely results. Our objective was to assess the institutional feasibility of implementing simultaneous HIV/syphilis point-of-care tests and client perceptions regarding these point-of-care tests. Point-of-care tests were implemented in a hospital consultation room in a marginalised zone of Lima. A time-series design was used to compare the proportion of tested clients who received timely results, with and without the point-of-care test intervention. Experience and satisfaction with point-of-care tests was evaluated with 149 people. In the 6 months without intervention, 69% and 61% of clients tested for HIV and syphilis, respectively, received their results within the required 45-minute window. During the 2-month point-of-care test intervention, all clients tested for HIV ($n = 387$) and syphilis ($n = 398$) received their results within 45 minutes. All clients surveyed were completely satisfied (52%) or satisfied (48%) with the simultaneous HIV/syphilis point-of-care test screening process. Additionally, 73% strongly agreed with the statement 'I feel satisfied with the rapid testing process.' Screening using point-of-care tests represents an important opportunity to reduce the time, resource and cost burden for users and institutions and increase the proportion of users receiving their test results in a timely manner.

Keywords

HIV, syphilis, point-of-care tests, implementation feasibility, client satisfaction, Peru

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Introduction

HIV and syphilis impact the health of diverse populations worldwide, including Latin America and the Caribbean (LAC). An estimated 1.5 million adults and children in LAC live with HIV,¹ with HIV concentrated among men who have sex with men (MSM) and transwomen (TW) in most LAC countries.^{2–4} A recent systematic review of syphilis in key populations in LAC found high prevalences among MSM (0.3–28.9%), TW (6.5–43.3%) and women sex workers (0.0–45.7%).⁵ Mother-to-child transmission (MTCT) of HIV/syphilis continues to represent a challenge in LAC, although there have been improvements. The HIV MTCT rate for LAC decreased from 18.6% in 2010 to 14.2% in 2011, with significant variations across countries.⁶

The critical first step for key populations to access HIV/syphilis support, care and treatment, and to

prevent transmission from infected individuals to their sexual partners and newborns, is screening. Simultaneous screening for HIV/syphilis and other relevant sexually transmitted infections (STIs) should

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be offered.⁷ However, patients and health establishments face obstacles to achieving opportune screening, including extensive time, steps and costs. A recent study in Lima, Peru, documented the time and steps required for pregnant women to complete their first antenatal care (ANC) visit, which includes HIV/syphilis screening. Women had to visit the health establishment six times over 27 days and received their results on day 27 or later. Treatment, if needed, was initiated following further delays.⁸ The study also demonstrated how multiple health personnel were involved in the screening process, with each personnel contributing time and resource costs.⁸

HIV/syphilis point-of-care tests (POCTs) can address the delays and costs associated with opportune screening and other challenges such as lack of access to a laboratory with the technical capacity and equipment to carry out confirmatory testing.⁹ Ideal POCTs should meet the ASSURED criteria: Affordable; Sensitive; Specific; User-friendly (simple to use with minimal training); Robust (can be stored at room temperature) and rapid (provide results in under 30 minutes); Equipment-free or requiring minimal equipment; and Deliverable to those who need them.^{9,10}

The use of HIV/syphilis POCTs at the point of care was not standard of care in Peru when this study was implemented. Although HIV POCTs in Peru have been mandated since 2005,¹¹ for many years, most health establishments incorrectly implemented HIV POCTs using venous blood at central laboratories.⁸ Syphilis POCTs were piloted in certain areas of Lima in 2010 through the CISNE Immediate Cure for Neonatal Syphilis project, the Peru arm of a multi-country operations research study. The CISNE team worked with policymakers to integrate syphilis POCTs into the updated Peruvian 'Guidelines for the Prevention of Mother-to-Child Transmission of HIV/Syphilis,' making them standard of care in ANC since late 2011.⁸

This study was conducted in a marginalised area of Lima, Peru to (1) determine the impact of the use of simultaneous HIV/syphilis POCTs in the consultation room on the proportion of key populations who receive timely screening test results and (2) measure clients' perceptions of HIV/syphilis testing using POCTs.

Methods

Context and study population

This study was conducted at the 'Carlos Lanfranco La Hoz' Hospital in Puente Piedra, a marginalised, peri-urban area located 31 km north of Lima. This is a level II-2 Ministry of Health (MOH) establishment, serving

an estimated 500,000 low-resource inhabitants of four districts of Lima, and is the reference hospital for 15 primary care health centers.¹²

Study design and procedures

This study used a quasi-experimental time-series design in two phases between June 2011 and January 2012. The two phases were (1) three months of retrospective collection of study indicators prior to the intervention and three months of prospective collection of the same indicators, when HIV/syphilis testing was carried out following Hospital guidelines, with samples collected and analysed in the laboratory following referral from the consultation room; and (2) two months of collection of study indicators when HIV/syphilis POCTs were provided as the alternative Hospital standard of care. Indicators were collected from the monthly archives of the Hospital HIV/STI program, compiled from daily consultation room and laboratory records. Data were collected about all populations who sought HIV and/or syphilis testing either as part of the National HIV/STI Strategy or ANC for pregnant women.

During phase 2, all populations seeking HIV/syphilis testing were provided POCT testing. Bioline HIV 1/2 3.0 and Bioline Syphilis 3.0 tests were used (Standard Diagnostics, Korea). A sub-group of clients who received both HIV/syphilis POCTs were surveyed about their experience. Participants completed an interviewer-administered, paper-and-pencil survey with: (1) socio-demographic and sexual health information and (2) a 14-item scale assessing client experience and satisfaction with HIV/syphilis POCTs. This scale had high internal consistency (Cronbach's alpha of 0.89) in this study.

Data analysis

For the quasi-experimental time-series data, we consolidated the information into a Microsoft Excel database. We calculated the proportion of clients who received their results in a timely manner, defined as within 45 minutes after the samples were obtained, per the Peruvian MOH norm. For the POCT survey evaluation data, statistical analysis was performed using STATA 12.0 for Windows (StataCorp; College Station, TX). For the socio-demographic and sexual health variables, we calculated measures of central tendency and dispersion. For the client perception scale data, participants answered questions on a four-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). Univariate analyses were conducted to determine simple frequencies. Two items were

reverse-scored. The total score was calculated as a simple sum of these ratings and categorised as: 43–56, completely satisfied; 29–42, satisfied; 15–28, dissatisfied; and 14 or lower, completely dissatisfied.

Research ethics

This study was approved by the Institutional Review Board of Universidad Peruana Cayetano Heredia. Clients who participated in the POCT evaluation

Table 1. Percentage of clients screened for HIV/syphilis who received their test results within 45 minutes.^a

	HIV			Syphilis		
	Without intervention % (n/N)	Intervention period % (n/N)	p Value	Without intervention % (n/N)	Intervention period % (n/N)	p Value
Pregnant women	59.8 (216/361)	100 (162/162)	<0.001	61.0 (216/354)	100 (162/162)	<0.001
General population women	80.5 (165/205)	100 (136/136)	<0.001	N/A	100 (142/142)	N/A
General population men	81.1 (137/169)	100 (56/56)	<0.001	N/A	100 (53/53)	N/A
Men/women sex workers	55.7 (34/61)	100 (17/17)	0.001	N/A	100 (22/22)	N/A
MSM	65.2 (15/23)	100 (16/16)	0.008	N/A	100 (19/19)	N/A

Not available: N/A.
^aPeruvian MOH norm.

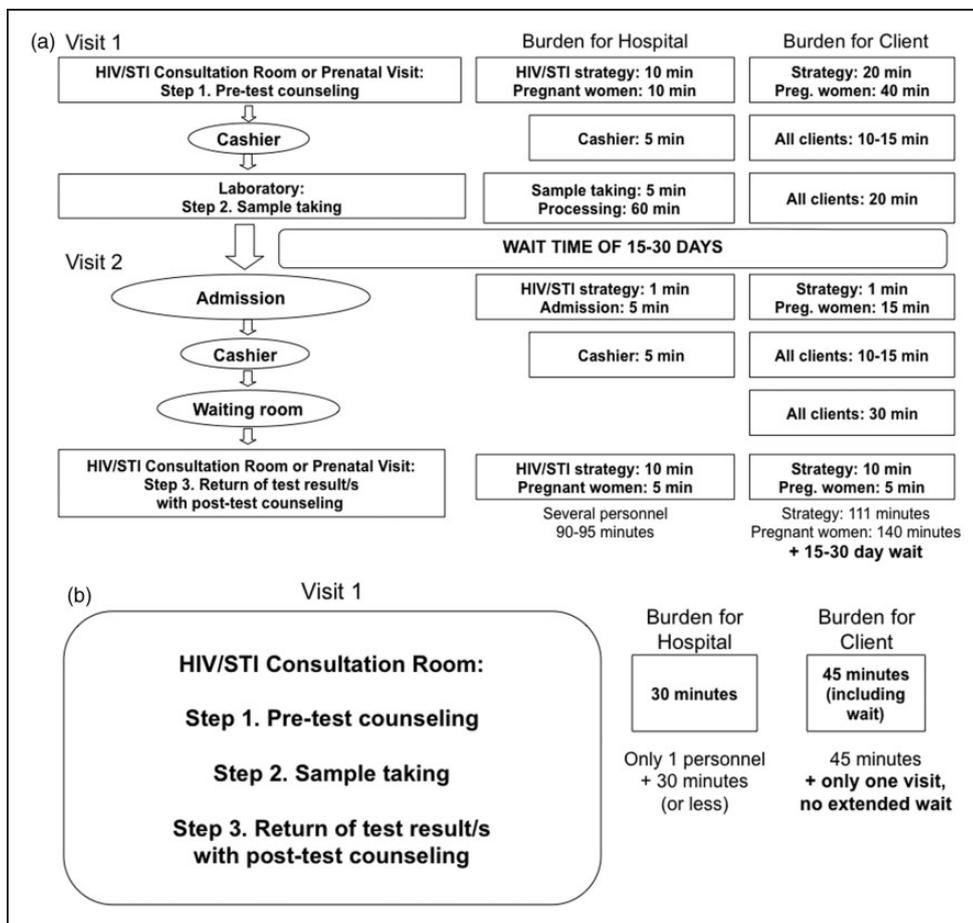


Figure 1. (a) Flowchart of HIV/syphilis testing process without intervention (standard of care). (b) Flowchart of HIV/syphilis testing process with intervention (POCTs).

survey provided verbal informed consent prior to completing the survey.

Results

Impact of HIV/ syphilis POCTs on timely screening test results

During the 6 months without intervention, HIV/syphilis testing was carried out in the laboratory post-referral from the consultation room. During the 2-month intervention phase, 387 HIV POCTs and 398 syphilis POCTs – which include sample collection and analysis – were implemented in the consultation room. During the non-intervention period, 69.2% of those tested for HIV received their results within 45 minutes, compared to 100% during the POCT intervention period. This corresponds to a 30.8% increase between the two periods ($p < 0.0001$). Similarly, 61.0% of pregnant women tested for syphilis received timely results during the non-intervention period, compared to 100% of pregnant women and 100% of other key populations screened using syphilis POCTs. This corresponds to a 35.7% increase for pregnant women ($p < 0.0001$). During the non-intervention period, clients that did not receive their results within the 45-minute norm obtained their results after a minimum of 24 hours, and often following days and weeks (Table 1).

In addition to improving the receipt of timely test results, HIV/syphilis POCTs also minimised client and hospital time and cost burden. When the standard of care for HIV/syphilis screening was in place, clients had to visit the hospital twice, go through multiple steps each time, wait 111–140 minutes while at the hospital and wait 15–30 days between visits. Also, the hospital relied on multiple personnel who dedicated 90–95 minutes to screening (Figure 1a). By contrast, when HIV/syphilis POCTs were implemented, clients visited the hospital once, receiving their test results within 45 minutes. One staff member of the hospital dedicated 30 minutes or less to the process (Figure 1b).

Clients' perceptions of HIV and syphilis testing using POCTs

We surveyed 149 individuals who received HIV and syphilis screening with POCTs. Most participants were women, 15–39 years old and of low-income. The majority (73%) perceived their HIV risk to be none, very low or low. Regarding previous lifetime screening, 56% reported HIV testing and 37%, syphilis testing. Interestingly, 29% of those HIV-tested and 30% of those syphilis-tested reported never receiving their test results (Table 2). Regarding clients' perceptions of the POCT tests and process, 52% were completely satisfied and 48% satisfied

Table 2. Characteristics of HIV/syphilis POCT clients surveyed (n = 149).

Characteristics	n	%
Gender		
Women	123	82.5
Men	22	14.8
Transwoman	4	2.7
Age (years)		
15–24	47	31.5
25–29	40	26.8
30–39	33	22.3
40–49	19	12.8
50+	10	6.7
Socio-economic status[‡]		
Low	107	71.8
Middle	30	20.1
High	12	8.1
Self-reported HIV risk		
None/very low	56	14.7
Low	53	58.4
Average	15	10.1
High/very high	25	16.8
Ever previous HIV test		
Yes	83	55.7
No	66	44.3
Previous HIV test result (n = 83)		
Negative	59	71.1
Did not receive results	24	28.9
Ever previous syphilis test		
Yes	50	36.6
No	99	66.4
Previous syphilis test result (n = 50)		
Positive	3	6.0
Negative	32	64.0
Did not receive results	15	30.0

POCT: point-of-care test.

[‡]Socio-economic status was calculated using an assets-based index where less valuable items were assigned fewer points and more valuable items, more points.

(Table 3). The scale items with the most positive responses were 'I am satisfied with the rapid testing process,' and 'I liked the process of having the two tests taken at the same time,' with which 73% and 72% strongly agreed, respectively. Other item with which 50% or more strongly agreed was, among others: 'I liked getting my result the same day.' Strong agreement was lowest for 'I understand the result of my HIV (or syphilis) test' and 'I think that my HIV (or syphilis) rapid test result is correct.' Instead, most of those surveyed said that they agreed (versus strongly agreed) that they had understood their results or felt that

Table 3. Clients' experiences with HIV/syphilis POCT testing process (n = 149).

Survey item	% of responding participants			
	Strongly Agree	Agree	Disagree	Strongly Disagree
I would prefer to have my finger stuck than to have blood drawn from my arm.	47.6	47.6	4.6	0
It would have been better to wait 1–2 weeks to get my result.	0	6.0	83.9	10.1
I understand the result of my HIV test.	30.9	69.1	0	0
I liked getting my results the same day.	56.4	42.3	1.3	0
I would recommend the HIV rapid test to a friend.	62.4	35.6	2.0	0
I would trust a result taken from blood drawn from my vein more (than a finger stick).	4.0	6.7	84.6	4.7
I understand the result of my syphilis test.	34.2	65.1	0.7	0
I would recommend the syphilis rapid test to a friend.	63.1	34.9	2.0	0
I thought the rapid testing process was stressful.	0	3.4	42.3	54.4
I would trust a result that comes from a laboratory more (than one from a consultation room).	2.0	6.7	87.3	4.0
I think that my syphilis rapid test result is correct.	42.2	57.1	0.7	0
I am satisfied with the rapid testing process.	72.5	26.8	0.7	0
I think that my HIV rapid test result is correct.	42.2	57.1	0.7	0
I liked the process of having the two tests at the same time.	71.8	27.5	0.7	0

POCT: point-of-care test.

they were correct. Regarding 'positive disagreement,' items that represent participant perception in favour of POCTs was found: Nine in ten participants disagreed or strongly disagreed that 'It would have been better to wait 1–2 weeks to get my result,' 'I would trust a result taken from blood drawn from my vein more' and 'I would trust a result that comes from a laboratory more.'

Study results were presented to Hospital leaders. Afterwards, the institution implemented HIV/syphilis POCTs as the Hospital standard of care.

Discussion

We found that the proportion of clients that received their results for HIV/syphilis screening within 45 minutes improved significantly with the POCT intervention, by over 30% for HIV and almost 40% for syphilis. Additionally, surveyed clients reported high satisfaction with POCTs and the testing process. The implementation of both POCTs in the consultation room was a feasible, successful intervention with high client satisfaction.

This is one of the few studies we are aware of that evaluates the following for a low-resource setting in a low-resource country: (1) the institutional feasibility of implementing POCTs; (2) simultaneous HIV/syphilis POCT testing; and (3) clients' perceptions about the intervention. Our results are concordant with those of previous studies that employed POCTs. At anonymous HIV testing sites in New York State, all clients received

their rapid test results, compared with 86% of those conventionally tested.¹³ Among the general population in Canada, the proportion who received their results during a rapid test intervention (99%) was higher than in the period with no intervention (93%).¹⁴ Previous studies in the US also found high client satisfaction with HIV rapid tests when tests were implemented in locations other than the laboratory.^{15,16}

Although client satisfaction with POCTs is high in most studies, including this one, further research may be needed to explore clients' understanding of their results. In this study, most clients said that they agreed, versus strongly agreed, that they had understood their results. There have been similar findings in other studies. Among HIV testing clients in Los Angeles, CA, about twice as many users felt that they received their rapid test results too quickly and that it would be better to wait longer.¹⁷ In patients screened for HIV in a US urban emergency department, 28% believed the rapid test was less or much less accurate than the conventional test.¹⁸ In another US study, most preferred HIV rapid testing to conventional testing as it reduced the need for a return visit and the stress of waiting for test results, but they raised concerns about the rapid test's accuracy.¹⁹ Additional research may elucidate why some people prefer to wait for results and perceive that POCTs are less accurate. This will enable policymakers to better design strategies to reach key groups with rapid testing and enable POCT providers to better counsel clients. Improved pre- and

post-test counseling should ensure that clients fully understand that POCTs can provide results that are as accurate as non-POCTs.¹⁹

Our study has limitations. First, since we included only hospital users, findings may not be generalisable to others in Lima or Peru. However, we would argue that participants are typical of low-resource populations who seek HIV/syphilis testing. Second, since our population had significantly more women than men and more pregnant women, we were unable to evaluate a larger subset of higher risk sub-populations such as sex workers, MSM and TW. Third, due to limited resources, it was only possible to assess the perceptions of a subset of – versus all – POCT users and to carry out an introductory analysis of the improvements in the time and resource burden – versus an in-depth cost-benefit analysis – for the hospital and clients. Finally, we did not assess provider perceptions regarding POCT use, given high staff turnover during the intervention period. Despite these limitations, our study is one of the few on both diseases in a marginalised peri-urban setting of Peru.

Conclusion

Moving HIV/syphilis testing from the laboratory to the point of care greatly increases access to timely results and reduces the time, resource and cost burden on the health establishment and the client. Results show that POCTs are highly feasible for institutions and highly satisfactory for clients. Further operations research may explore additional interventions to improve care for HIV/syphilis and other STIs in low-resource settings, such as rapid linkage to treatment and follow-up care.

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Conflict of interest

The authors declare no conflict of interest.

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