

Segundo R Leon^{1,5}, Lourdes B Ramos¹, Kelika A Konda^{1,2}, Juan A Flores¹, Lottie Romero¹, Hector J Salvatierra³, Brandon J Brown⁴, Jeffrey D Klausner² and Carlos F Caceres¹

1. Universidad Peruana Cayetano Heredia, 2. University of California Los Angeles, 3. Alberto Barton Health Center, 4. University of California Irvine, 5. University of Washington

BACKGROUND

- Rapid point of care testing (R-POC) has been widely implemented and accepted by healthcare workers and populations at high-risk for HIV infection
- R-POC are affordable and easy-to-perform tests with reported high sensitivity and specificity
- Most screening programs are based on 3rd generation R-POC technology, with an unknown amount of false negatives
- High-risk populations in Lima are requested to be regularly tested using rapid tests but these are not always available.
- 4th generation EIA assays available could diminish the HIV infection window period

METHODS

- We are conducting an observational cohort study to understand the syphilis and HIV epidemic among men who have sex with men (MSM) in Lima, Peru
- Recruited participants (N=400) included MSM and TW who are 18 years old or older, live in Lima or Callao and have at least three of the following inclusion criteria;
 - have had syphilis in the past 2 years, are HIV positive, have been sexually active for 5 or more years, have had 5 or more sex partners in the past 3 months, have been had an STI diagnosis in the past 6 months, have current STI symptoms, or have had 5 unprotected sex acts in the past 6 months.
- Blood samples were collected and tested for HIV infection using the following algorithm:
 - Initial 3rd generation HIV R-POC (Determine, Alere Medical Co, Japan)
 - All samples were re-screened using a 4th generation Ag/Ab HIV EIA serum test (Genscreen ULTRA HIV Ag-Ab, Bio Rad, Redmond, WA)
 - Any R-POC or EIA positive results were confirmed using Western Blot (WB) (Genetic Systems HIV-1 Western Blot, Bio Rad, Redmond, WA)
- Participants are returning every 3 months for 2-years follow-up testing
- R-POC results were provided to participants along with post-test counseling and referral the same day of testing, and EIA screening and WB confirmatory results were delivered after two weeks.

RESULTS

- Of 400 participants tested for HIV, 124 (31%) were positive using the 3rd generation R-POC HIV test and 129 (32%) were positive using the 4th generation EIA test.
- There were five discordant results between the R-POC and the HIV-EIA during the baseline assessment. All 5 were EIA positive and R-POC negative.
 - 1 indeterminate for WB, the remaining four were WB negative.
- HIV EIA testing increases HIV case detection by 3.9 % when used as a

Table 1. Sensitivity and Specificity for rapid point care test*

	EIA +	EIA -
R-POC +	119	0
R-POC -	5	259
	Point Estimate(%)	95% CI
Sensitivity	96%	(90.4 - 98.5)
Specificity	100%	(98.1 - 100.0)

*Gold standard: 4th generation HIV ELISA

- In longitudinal follow-up: Among the 11 individuals who were EIA positive and WB negative or indeterminate at baseline:
 - 4 retested EIA positive and WB positive
 - 2 were EIA negative at subsequent testing
 - 5 have not yet returned for follow-up (not shown in tables)

There were fewer discrepancies between the R-POC and the EIA (n=5) compared to the EIA and WB (n=11).

Table 2: Test Results Among R-POC, EIA, and WB at follow-up visits

HIV positive at follow-up visit

Participant	R-POC1	EIA1	WB1	R-POC2	EIA2	WB2
1	-	+	-	+	+	+
2	+	+	-		+	+
3	-	+	indet	+	+	+
4	+	+	indet	+	+	+

Revert to EIA negative at follow-up visit

Participant	R-POC1	EIA1	WB1	R-POC2	EIA2	WB2
5	-	+	-	-	-	NA
6	-	+	-	-	-	NA

- In subsequent study visits, there were an additional 4 discordances between R-POC and EIA.
 - Among these:
 - 1 reverted to EIA negative,
 - 3 have not returned for additional follow-up, 1 of whom was WB indeterminate
 - The majority of WB discrepancies with EIA from the baseline go on to be HIV positive in later visits

DISCUSSION

- Among High-risk populations, samples tested for HIV antibodies based on 3rd generation R-POC assays should be also screened using a 4th generation HIV EIA assay to avoid false negatives
- R-POC and EIA discordant results are explained by the differences in the target markers detected by each test. While the R-POC detects only antibodies, the HIV-EIA used also detects antigen, this increases the detection of recent infections
- New confirmatory algorithms are needed when R-POCs are used
- Number and prevalence of false positive EIA for HIV is within known limits (0.4 – 1%)
- We will continue to monitor discordances between the R-POC and EIA tests too see if discordant participants become HIV positive

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Contact:

Segundo Leon: srleons@gmail.com