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Rapid Diagnosis of HIV Infection and Initiation of Antiretroviral Treatment

Mónica Mantilla[1], Leonardo Arevalo [1], Hector Mueses [2]
[1]VirreysolisIPS, Bogotá, Colombia [2] Corposida, Santiago de Cali, Colombia

BACKGROUND

In Colombia, 39% of people living with HIV are diagnosed at stage 3, and the time between diagnostic confirmation and starting antiretroviral therapy takes an average of 35 days, with an interval range between 20-52 days. It is well known that rapid start of therapy is a key factor in achieving therapeutic objectives at the individual level and reducing transmission from a public health perspective. However, there are still barriers for most people to gain access to the test quickly, such as pre-test counseling, informed consent, requirement of a medical prescription, lines in a clinical laboratory with limited hours of operation, and sometimes fasting requirements. A potential solution to facilitate access to screening tests for HIV infection and reduce antiretroviral treatment initiation times could be the utilization of rapid point-of-care testing (POCT), which currently has been implemented only in pregnant women and occasional screening campaigns that happen in health centers and community-based centers. However, after diagnostic confirmation, further workup (e.g., viral load, CD4 lymphocyte count, and hepatitis B and C screening, etc.) is carried out only in centralized laboratories.

METHODS

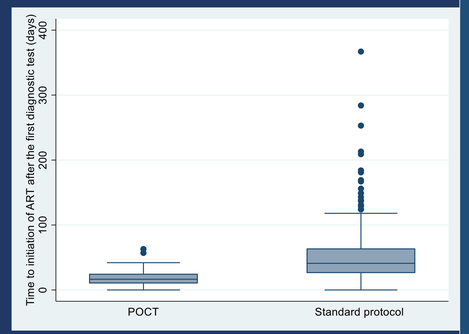
In Medellín (CO), an open-label randomized clinical trial was conducted in a network of ten healthcare-associated institutions with emergency and outpatient services. The study compared two arms. Arm 1 included patients going through the conventional process for HIV screening, confirmation, and complementary tests as part of the established HIV program guideline (Standard of Care). Arm 2 included patients with POCT implemented in one of the ten mentioned facilities. The POCT included HIV screening (3rd and 4th generation) in addition to syphilis, hepatitis B and C tests, viral load, and CD4.

Patients with a prescription for HIV screening by any of the ten healthcare services included in the study would call a dedicated service line where a trained nurse assigned the participant to one of the study arms using a randomized list of numbers.

Recruitment ended once 50 patients enrolled in the POCT arm.

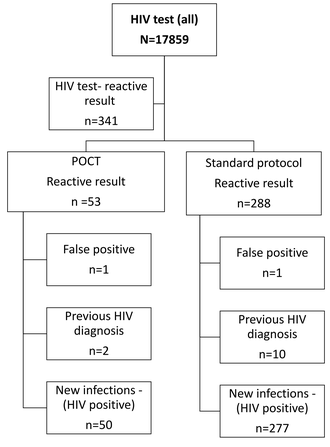
Once a patient was assigned to the POCT group and confirmed consent, the HIV rapid test was performed. If the test was reactive, a second confirmatory test was immediately performed. If the confirmatory test was reactive, the results were disclosed by a trained nurse, in addition to post-test counseling which informed the need of additional laboratories to stratify the HIV infection and identify coinfections.

The mean time to initiation of ART after the first diagnostic test was 20 days in POCT vs. 54 days in standard protocol (p< 0.0001)



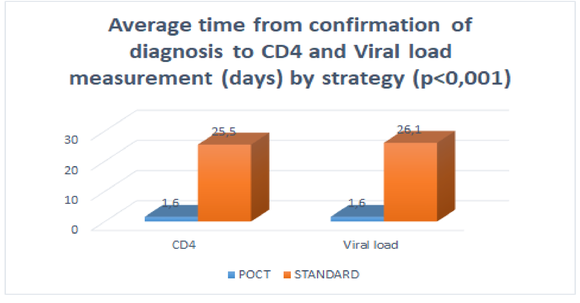
Variable	Obs.	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]		p-value
POCT	50	19	1.8	13.0	15.3	22.7	p<0.001
Standard diagnostic protocol	274	54	2.7	45.4	48.6	59.4	
Combined	324	49	2.4	43.9	43.8	53.4	
Diff		-35.0	6.5		-47.8	-22.3	

RESULTS



	All (n=327) n (%)	Strategy: POCT (n=50) n (%)	Strategy: Standard protocol (n=277) n (%)	p-value
Age (years old) at diagnosis (mean; sd)	31.5;10.4	29.8;8.8	31.9;10.7	0.1962
Biological Sex (Male)	285 (87.2)	39 (78.0)	246 (88.8)	0.036
Keys populations				
MSM	196 (59.9)	23 (46.0)	173 (62.4)	0.216
Transgender women	2 (0.6)	0 (0)	2 (0.7)	
injecting drug users	1 (0.3)	0 (0)	1 (0.4)	
None	128 (39.1)	27 (54.0)	101 (36.5)	
Sexual orientation				
Bisexual	24 (7.3)	4 (8.0)	20 (7.2)	0.589
Heterosexual	99 (30.3)	18 (36.0)	81 (29.2)	
Homosexual	204 (62.4)	28 (56.0)	176 (63.5)	
Ways HIV Transmission				
Sexual	322 (98.5)	49 (98.0)	273 (98.6)	0.768
Unknown	5 (1.5)	1 (2.0)	4 (1.4)	

Analysis: Proportions compared by Chi-2 tests; continuous values compared by t-student and Kruskall-Wallis tests



- The time from test order to sampling was <48h in 95% of POCT vs. 15% in standard protocol (p<0.05).
- 100% of patients with POCT got a viral load measured in <8 days after the first positive test vs. 0% in the standard protocol.
- Average time from day of diagnosis confirmation to CD4 measurement (days) by strategy was, POCT 1,6 days vs Standard 25,5 days (p<0.001).
- Average time from day of diagnosis to viral load measurement (days) by strategy was, POCT 1.6 days vs Standard 26.1 days (p<0.001).
- The mean time to initiation of ART after the first diagnostic test was 20 days in POCT vs. 54 days in standard protocol (p<0.0001).

CONCLUSIONS

- This study demonstrates the benefits of utilizing POCT vs. the standard protocol with a reduction of time between confirmed diagnosis and initiation of ART by more than 60%. There remains opportunities for improvement in the timely manner of starting ART for patients from POCT by identifying hurdles such as administrative, which leads to low opportunities for a timely physician appointment.
- Fingerstick blood testing and shorter turnaround time for results using rapid testing could improve the access and linkage of patients to HIV programs, through timely clinical actions that support the strategies to decrease the late diagnosis and patient lost in healthcare process.

ADDITIONAL KEY INFORMATION

Author Contact Information:
Monica Mantilla Suarez
monicams@virreysolisips.com.co

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