Implementation of the CD4 Advanced Disease Rapid Test: Lessons Learned from the Pilot Test in Uganda

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Background

- In 2018, WHO recommended several interventions to prevent mortality among individuals with advanced HIV disease (AHD), most of which have since been adopted by Uganda.
- Identifying people with AHD begins with performing a CD4 cell count (CD4+), since most individuals remain asymptomatic for some time even when their CD4+ is less than 200.
- Since only about 50% of ART treatment centers have CD4+ machines, the introduction of VISITECT CD4 Advanced Disease rapid test (VISITECT), a semi-quantitative instrument-free test, could improve CD4 coverage at lower-level treatment centers that have limited laboratory capacity.

Description

- Between January and August 2021, the Ministry of Health with support from Clinton Health Access Initiative, Inc. (CHAI), through funding from Unitaid, field tested VISITECT at 11 health facilities across Uganda with the aim of understanding its performance in an uncontrolled setting for consideration of potential scale-up.
- The healthcare workers (HCWs) at these 11 facilities were trained in January 2021 and given a tool to collect the comparative data from VISITECT and point-of-care (POC) CD4+ machines at the facilities. Periodic supportive supervisions were conducted to assess the feasibility of VISITECT.



Region	Facility	No. of tests done
North Central	Kassandra HC IV	114
North Central	Kayunga RRH	63
North Central	Kiboga Hospital	16
South Central	Masaka RRH	66
Busoga	Mayuge HC III	112
Bugisu	Mbale RRH	68
North Central	Mubende RRH	64
Bugisu	Nakaloke HC III	37
Teso	Soroti RRH	93
Teso	Tiriri HC IV	15
South Central	Villa Maria Hospital	33

Lessons Learned

- Data from 681 comparative tests were collected from February to August 2021, highlighting 177 CD4 ≤200 and 504 CD4 >200 test results for the POC CD4+ machines while VISITECT had 195 CD4 ≤200 and 486 CD4 >200 test results. From this data, VISITECT's sensitivity and specificity was determined to be 97% and 95%, respectively.
- Although HCWs highlighted the long turnaround time with VISITECT (45 minutes) as a challenge, they reported that access to such a test would facilitate quick clinical action in lower-level facilities without CD4+ machines as opposed to referring samples to other health facilities. It was also noted that VISITECT was portable, easy to use, and fit for facilities with limited technical expertise.

		POC CD4+ result		
		≤200	>200	
VISITECT result	≤200	172	23	195
	>200	5	481	486
		177	504	

Conclusions

Implementation of VISITECT testing is feasible, in addition to yielding good results, and could significantly increase access to CD4+ testing and the AHD package of care.







