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 **Unitaid**



Welcome!
November
17, 2020

Topic

AHD screening in the out-patient setting

CDC/CHAI/Unitaid Advanced HIV Disease

Global ECHO Webinar Series:

Advanced HIV Disease in the context
of the COVID-19 pandemic in Africa

Hosted by the [CDC Mycotic Diseases Branch](#)

Advanced HIV Disease Global Webinar Series

Session 1 Agenda: AHD Screening in the out-patient setting

EST	CET	SAST	Topic	Presenter
9:30 – 9:33	3.30 – 3.33	4:30 – 4:33	Housekeeping	Jutta Lehmer (ECHO Insititute)
9:33 – 9:38	3.33 – 3.38	4:33 – 4:38	Welcome and overview of webinar series	Tom Chiller (CDC) and Carolyn Amole (CHAI)
9:38 – 9:40	3.38 – 3.40	4:38 – 4:40	Introduction of today's session and speakers	Ike Amamilo (CHAI)
9:40 – 9:55	3.40 – 3.55	4:40 – 4:55	CD4 testing as a critical component of the AHD screening package	Ana Moore (CHAI)
9:55 – 10:10	3.55 – 4.10	4:55 – 5:10	Expanding CD4 Access: progress and challenges	Dr Cordelia Katureebe (National AIDS Control Program, MOH, Uganda)
10:10 – 10:25	4.10 – 4.25	5:10 – 5:25	Advanced HIV disease care at Lighthouse clinics in Malawi - How far have we come?	Dr. Tom Heller (Lighthouse Clinic Trust)
10:25 – 10:55	4.25 – 4.55	5:25 – 5:55	Live Q&A	Ike Amamilo (CHAI) and Amir Shroufi (CDC)
10:55 – 11:00	4.55 – 5.00	5:55 – 6:00	Closing Remarks	Tom Chiller (CDC)

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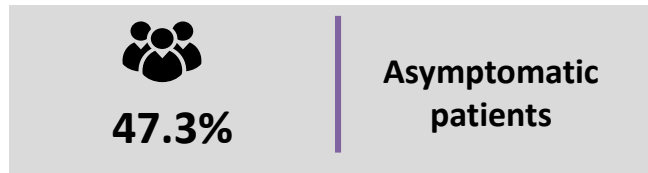
CD4 testing as a critical component of the AHD screening package

November 17, 2020



CD4 is a gateway to diagnosing and managing advanced HIV disease (AHD)

REALITY Trial Patient Demographics



Clinical staging alone cannot
be used to diagnose AHD
CD4 is needed!

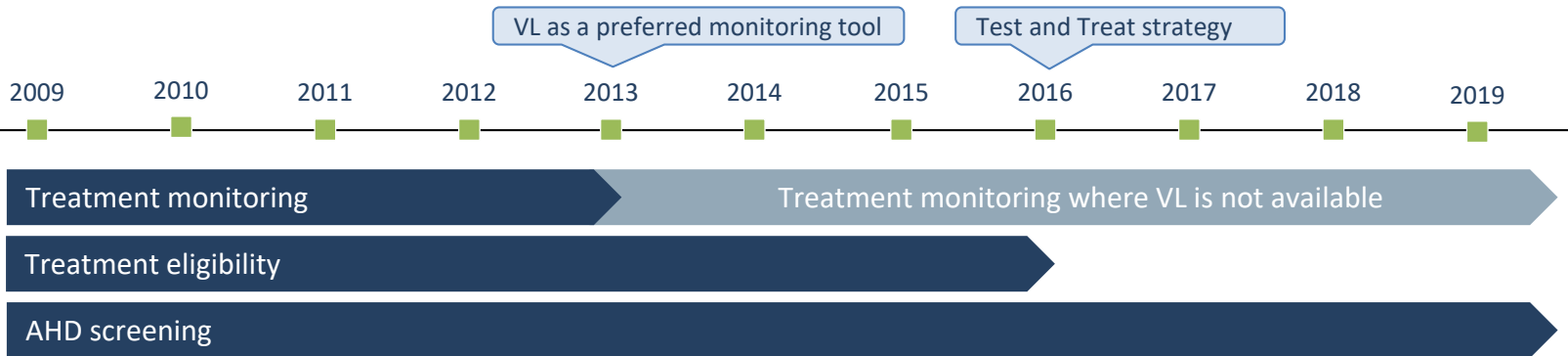


Current WHO Guidelines on CD4

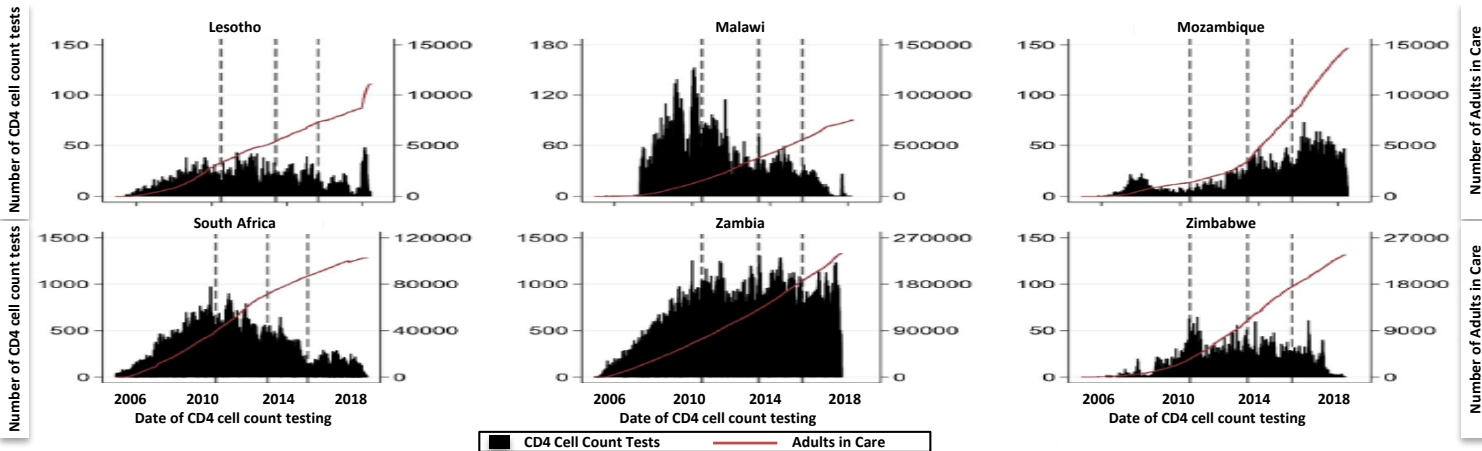
- CD4 count is the best predictor for disease status and immediate risk of death and thus should be **used to identify those who have advanced HIV disease**
- **All patients entering or re-entering care** should receive a CD4 test at treatment baseline and as clinically indicated for **patients who are unstable or with advanced HIV disease**
- It is strongly recommended that **patients with advanced HIV disease (CD4 count below 200 cells/mm³)** receive a **package of care** as defined in the 2017 WHO Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy

As WHO recommendations for the use of CD4 have evolved, use of and funding for CD4 testing has declined or plateaued

WHO Guidelines on use of CD4 Cell Count Testing

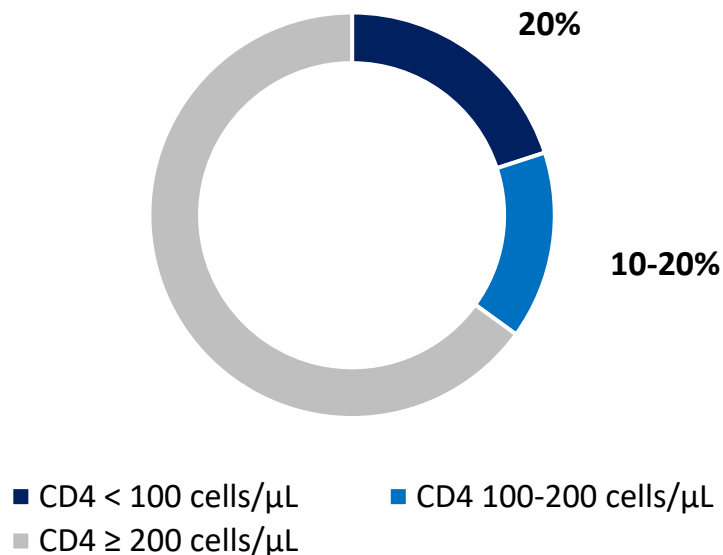


Frequency of CD4 testing (per day and cumulative) of adult patients in care



Early identification of AHD and linkage to care is critical due to high risk of disease progression, morbidity, and mortality among patients with AHD

Percent of (re-)initiating PLHIV starting ART with various CD4 counts



Importance of immediate linkage to care for AHD patients



In sub-Saharan Africa **1 in 3 PLHIV present to care with AHD**; of these patients **10% will die within 3 months**



High rates of LTFU from diagnosis to treatment: 4-38% pre-treatment LTFU for patients diagnosed with TB¹



Rapid disease progression: CrAg+ patients progress to CM within 3 weeks²



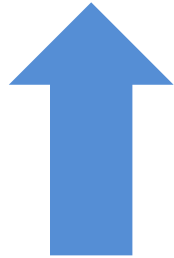
High mortality rates from OIs: 50% of deaths among PLHIV are due to TB and CM



Limited time from admission to mortality for hospitalized patients: 25% of mortality occurs within 48 hours; 80-90% within 2 weeks³

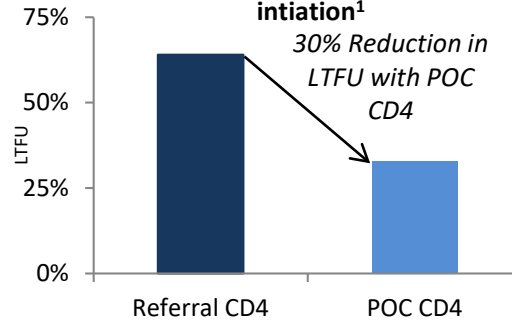
POC testing has been shown to accelerate clinical action and reduce loss to follow-up

POC CD4 increases ART initiation rates¹

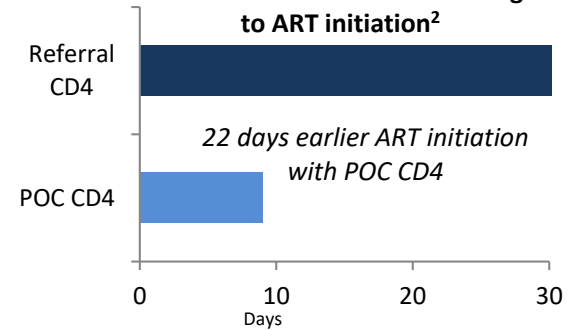


10% Increase in patients initiating ART

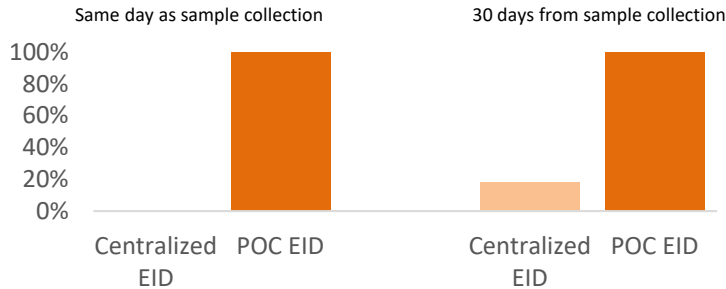
POC CD4 reduces LTFU before ART initiation¹



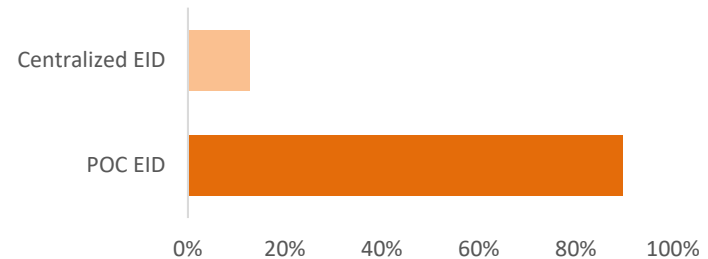
POC CD4 reduces time from HIV diagnosis to ART initiation²





POC EID increases timely result return to clients³



POC EID Increases ART initiation rates within 60 days from sample collection⁴



Two WHO pre-qualified device-based POC CD4 products have been widely deployed across low-, middle-income countries to decentralize CD4 testing

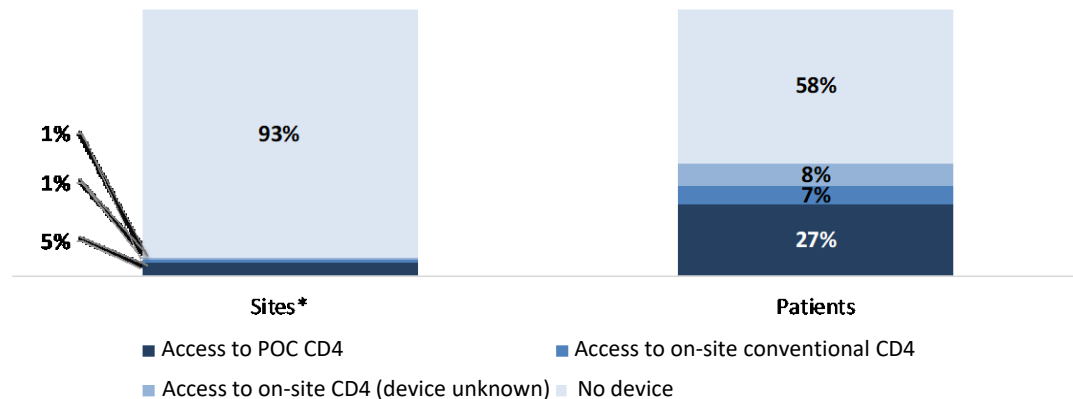
Product Name	Test Type	Time to Process	Throughput
 Abbott Pima	<ul style="list-style-type: none"> Quantitative Absolute CD4 count Finger prick or venous blood 	20 min per test	15-20 tests per day
 BD FACSPresto	<ul style="list-style-type: none"> Quantitative Absolute CD4 count, CD4 %, Hb Finger prick or venous blood 	22 min per test (18 min incubation; 4 min in instrument)	60-80 tests per day

Because of patient distribution patterns, a large proportion of patients in need of CD4 testing receive care at sites without a POC CD4 device

450 facilities have a CD4 device

58% of patients in need of CD4 testing receive care at facilities without a device

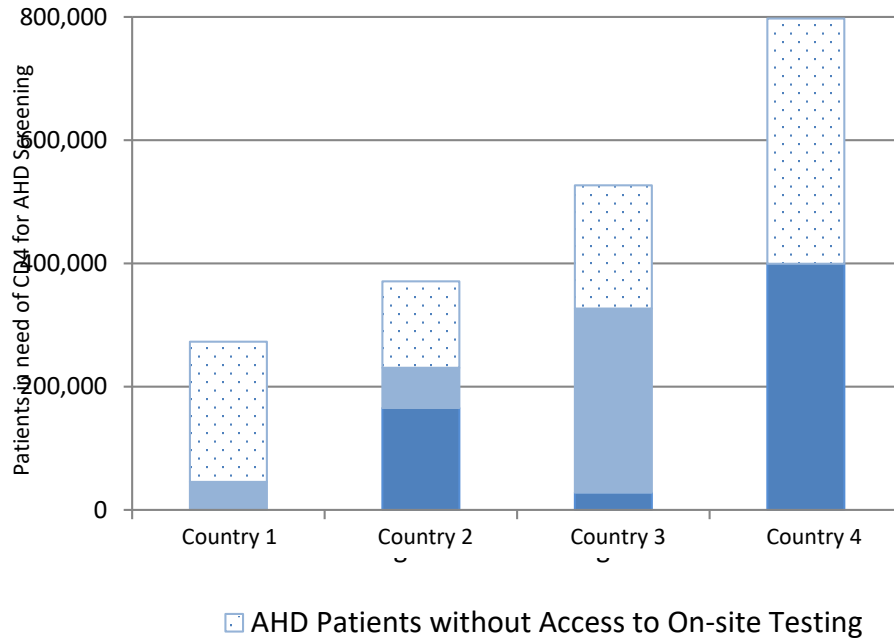
CD4 Coverage across 2 Countries: 2019



*CHAI analysis across two sub-Saharan Africa countries; 7,484 sites assessed.

Other analyses have found similar results with < 50% of patients in need of AHD screening having access on-site CD4 screening

Patients in need of AHD screening with access to on-site CD4 testing (2018 data)



Why is POC CD4 so important for AHD patients?

POC CD4 reduces loss-to-follow up

Same day testing and result return allows AHD patients to be identified and receive the complete AHD package of care in a single visit, including CrAg screening and TB LAM testing.

Timely CrAg screening can prevent disease progression

Asymptomatic CrAg+ patients become symptomatic within 22 days, rapid initiation of preemptive fluconazole can prevent progression to CM¹

Source: CD4 Market Segmentation. 4 CHAI focal countries included in CD4 market segmentation




1) Rajasingham (2012); 2) WHO AHD Guidelines (2017)

The first device-free CD4 LFA product, VISITECT® CD4 Advanced Disease from Omega Diagnostics, has the potential to further decentralize access to CD4 testing at a lower cost than device-based tests






VISITECT® CD4 Advanced Disease test is a rapid, semi-quantitative LFA that indicates if the patient's CD4 count is above or below 200 cells/ μ L

It has the potential to significantly expand access to same-day CD4 result, transforming how AHD package of care can be provided in low- and middle-income countries



Product Name	Test Type	Time to Process Daily Throughput*	Upfront investment	Price per test
Abbott Pima 	<ul style="list-style-type: none"> Quantitative Absolute CD4 count Finger prick or venous blood 	20 min/test 15 - 20 tests/day	\$5,000 + service and maintenance	\$6.94¹
BD FACSPresto 	<ul style="list-style-type: none"> Quantitative Absolute CD4 count, CD4 %, Hb Finger prick or venous blood 	22 min/test 60 - 80 tests/day	\$5,000 + service and maintenance	\$8.20¹
Omega VISITECT Advanced Disease <i>(200 cutoff)</i> 	<ul style="list-style-type: none"> Semi-Quantitative Absolute CD4 Finger prick or venous blood 	40 min/test 10 - 100 tests/day; >10 possible with batching	None	\$3.98²

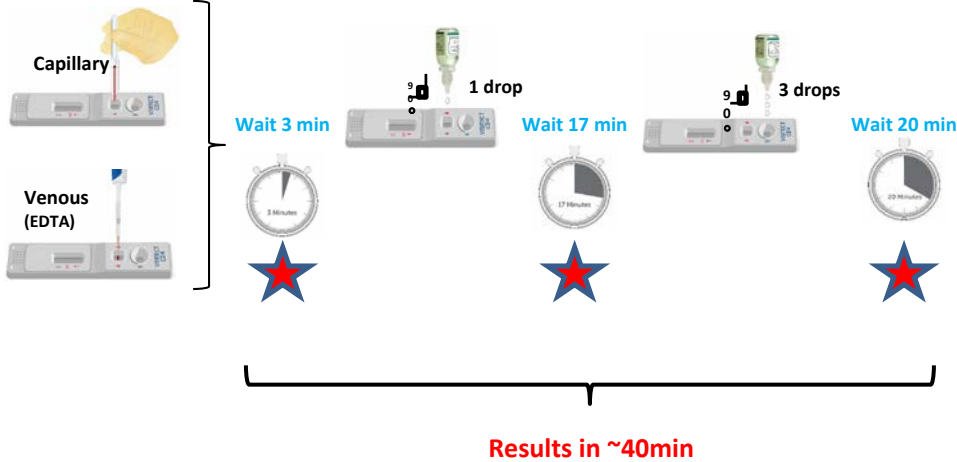
Advantages

- 
Accelerate clinical disease management
 Faster decision-making, reduce burden on health systems
- 
Reduce costs
 No instrument, no sample transport
- 
Reduce patient loss to follow-up
 Improve patient retention
- 
Test anywhere, anytime
 Convenient and decentralizable
- 
Improve patient outcomes
 Accelerate clinical actions

An MSF evaluation of the VISITECT found the test to have accuracy and operational feasibility in resource limited settings

VISITECT Test Procedure

30 μ L of sample



Technical Accuracy

Per Omega, the technical performance compared to BD FACSCalibur is:

- Capillary samples: 89.3% sens / 92.3% spec
- Venous samples: 86.3% sens / 92.8% spec

An MSF evaluation show¹ higher sensitivity and lower specificity, potentially leading to over-diagnosis of AHD:

- Capillary samples: 98.3% sens / 77.2% spec
- Venous samples: 95.0% sens / 81.9% spec

Operational feasibility

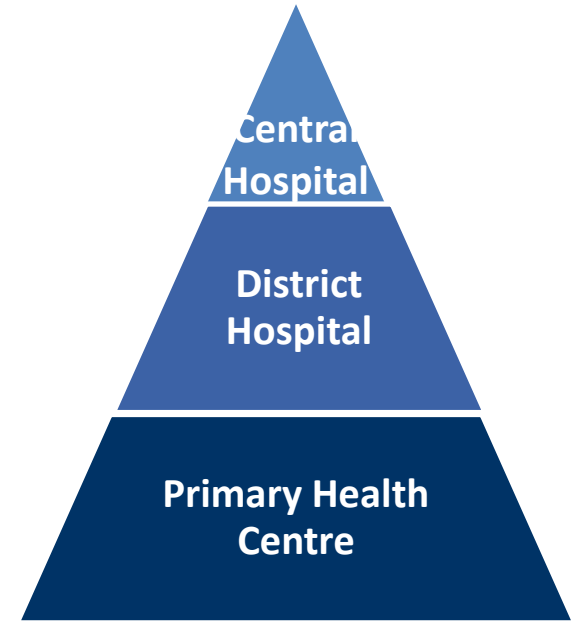
The MSF evaluation¹ shows that VISITECT[®] CD4 Advanced Disease is feasible and usable

- Low invalid rates: 2.8%
- Minimum result deviation when the two incubation times were varied
- No observed result deviation one week after testing
- 97.2% overall testing success rate by different cadres of HCWs unassisted

The introduction of a device-free CD4 LFA product can open up opportunities to implement POC CD4 testing more flexibly and expand access to same day CD4 results and the AHD screening package

Key considerations for implementation include:

- **Facility types:** CD4 LFA can be implemented at any level of health facility, potentially focusing on facilities without a POC CD4 device
- **Patient volume:** Daily testing volume will depend on HR availability and effective patient flow
- **Testing location:** CD4 LFA can be offered at various locations within a facility (clinic, in-facility lab, or inpatient ward, etc...)
- **HR requirements:** Appropriate level of task-shifting should be assessed for each country context
- **Patient / clinic workflow:** Workflow needs to be adjusted to enable same-day AHD/OI screening as much as possible



National programs are advised to evaluate and determine the optimal implementation models for VISITECT® CD4 Advanced Disease in the broader context of national CD4 networks and AHD guidelines

Thank you!

CHAI's work in Advanced HIV Disease
is made possible by the generous support and partnership of Unitaid

