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AHD Supply Chain Management Systems | Supply Updates and Learning From Early Adoption Countries

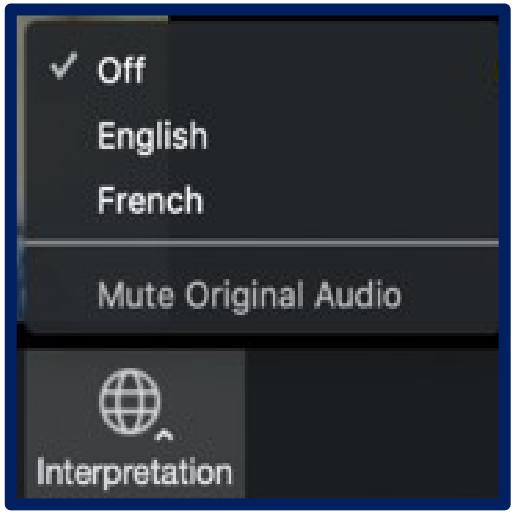
Tuesday, September 5, 2023

HIV Coverage, Quality, and Impact Network

Welcome/ Bienvenue

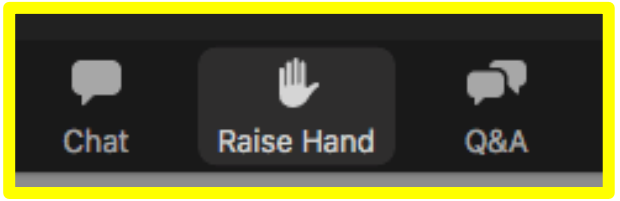
Peter Preko
CQUIN Project Director
ICAP at Columbia University

- Be sure you have selected the language of your choice using the “Interpretation” menu on the bottom of your screen.
- Assurez-vous d’avoir sélectionné la langue de votre choix à l’aide du menu <<Interprétation>> en bas de votre écran Zoom.



Housekeeping

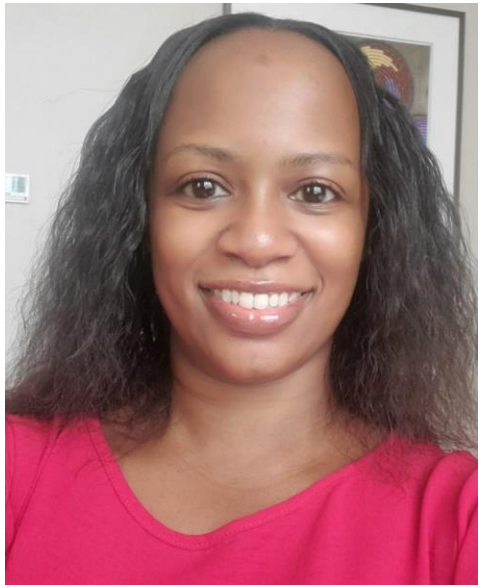
- 90-minute webinar with framing presentations followed by a panel discussion with Q&A
- Slides and recording will be available on the CQUIN website (www.cquin.icap.columbia.edu)
- Please type questions in the Q&A box located on the toolbar at the bottom of your screen
- If you would prefer to speak, please use the “raise hand” function on the toolbar and we will unmute you so that you have control of your microphone
- If you are a French or English speaker, please ask your question in your language of choice and the interpreters will translate as needed



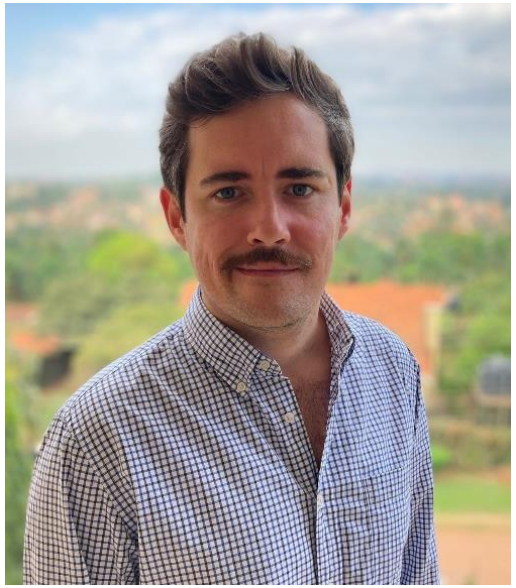
Agenda

Time	Title	Facilitator
5 mins	Introduction	Moderator – Peter Preko (ICAP/CQUIN)
50 mins	Presentations	
10 mins	ICAP presentation – The CQUIN AHD CMM 2023 Findings on the AHD Diagnostic Capability and Client Coverage Domains	Maureen Syowai (ICAP-CQUIN)
10 mins	CHAI presentation – State of the Advanced HIV Disease Commodity Landscape	James Conroy (CHAI)
15 mins	Lesotho presentation	Tapiwa Tarumbiswa
15 mins	Nigeria presentation	Professor Akanmu
30 mins	Q&A and Plenary Discussions	Moderator - Williams Eigege (CHAI)
	ICAP presenter	Maureen Syowai
	CHAI Presenter	James Conroy
	MOH Nigeria	Professor Akanmu
	MOH Lesotho	Tapiwa Tarumbiswa
	CSO / Network of PLHIV	Mr. Peter Odenyo
5 mins	Closing remarks	Moderator – Peter Preko (ICAP/CQUIN)

Presenters

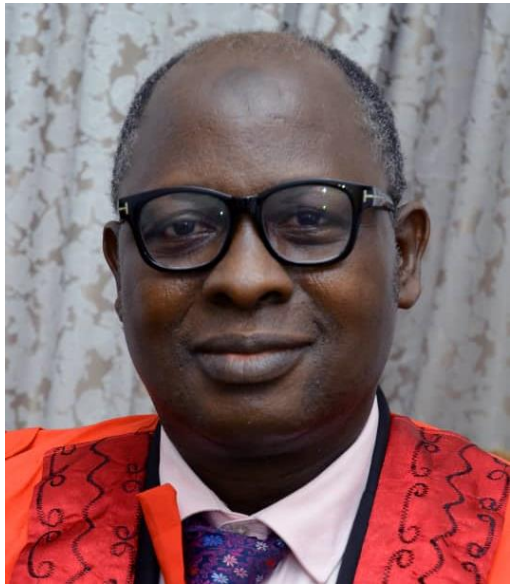


Maureen Syowai
CQUIN Deputy Director (Technical)
ICAP in Kenya



James Conroy
Associate Director
AHD Program Lead
CHAI, Uganda

Tapiwa Tarumbiswa
HIV/AIDS Manager
Ministry of Health, Lesotho



Akanmu Alani Sulaimon
Chairman, AHD Technical Working Group
Nigeria Ministry of Health

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The CQUIN AHD CMM 2023 Preliminary Findings from the AHD Diagnostic Capability and Client Coverage Domains

Dr. Maureen Syowai
CQUIN Deputy Director / Technical
5 September 2023

Outline

- Defining the CQUIN Capability Maturity Model
- Review of the Diagnostic Capability, Client Coverage and Supply Chain domains on the CQUIN AHD Capability Maturity Model
- Update on the AHD Capability Maturity Model self-staging across CQUIN-member countries
- Findings from the AHD Capability Maturity Model from Nigeria and Lesotho

Defining the CQUIN Capability Maturity Model

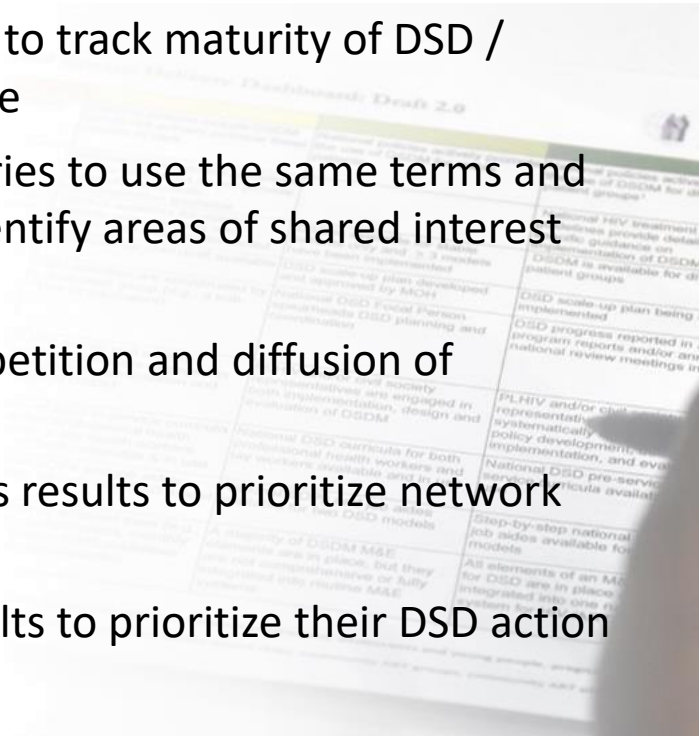
The Capability Maturity Model (CMM) is a systems strengthening approach that:

- Identifies **core functions/domains** in which capability is required to achieve organizational goals
- Describes **sequential stages of maturity** within each domain
- Sets a clear path towards achieving maturational goals
- Is **used repeatedly over time** to track change

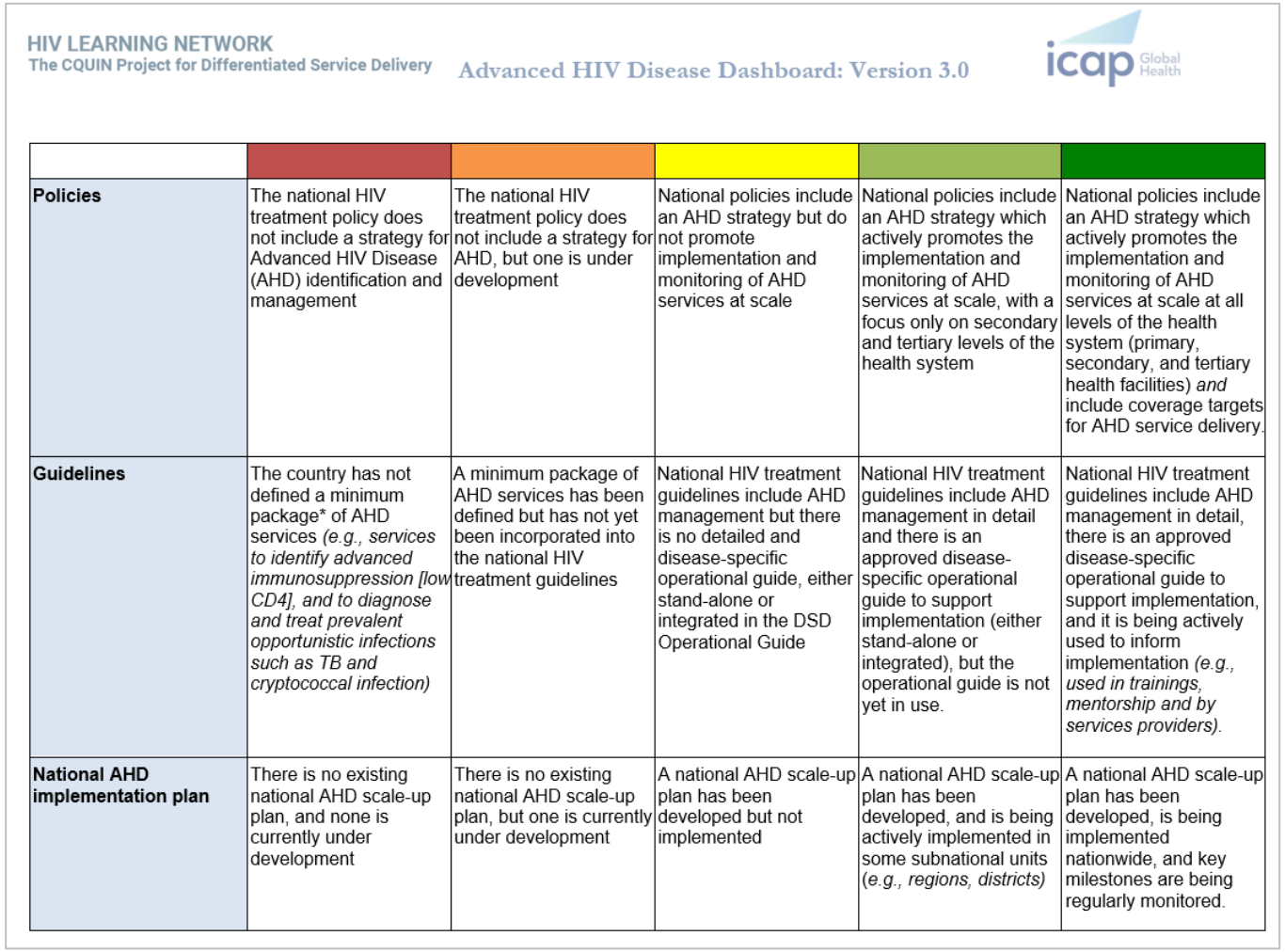
RED	ORANGE	YELLOW	LIGHT GREEN	DARK GREEN
Early or preliminary stages of planning and development; Useful in identifying next steps to take in the scale-up process	Work has begun and the initial efforts are ongoing; Highlights areas that can prioritized for improvement	Efforts have resulted in measurable progress, such as a draft for review or achievement of more than 25% progress to a target	Considerable progress has been made, resulting in over 50% progress to a target or working systems only in need of finalization	Achievement of a highly-evolved implementation of the domain; Further improvements and refinements can be made as needed

Annual systematic self-assessment of the national DSD programs' maturity by multidisciplinary country teams, including recipients of care

- Compared year-to-year to track maturity of DSD / AHD programs over time
- Enables network countries to use the same terms and indicators – helps to identify areas of shared interest and challenges
- Promotes friendly competition and diffusion of innovation
- ICAP's CQUIN team uses results to prioritize network activities
- Country teams use results to prioritize their DSD action plan activities



AHD Capability Maturity Model



HIV LEARNING NETWORK
The CQUIN Project for Differentiated Service Delivery

Advanced HIV Disease Dashboard: Version 3.0

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Policies	The national HIV treatment policy does not include a strategy for Advanced HIV Disease (AHD) identification and management	The national HIV treatment policy does not include a strategy for AHD, but one is under development	National policies include an AHD strategy but do not promote implementation and monitoring of AHD services at scale	National policies include an AHD strategy which actively promotes the implementation and monitoring of AHD services at scale, with a focus only on secondary and tertiary levels of the health system	National policies include an AHD strategy which actively promotes the implementation and monitoring of AHD services at scale at all levels of the health system (primary, secondary, and tertiary health facilities) *and* include coverage targets for AHD service delivery.
Guidelines	The country has not defined a minimum package* of AHD services *(e.g., services to identify advanced immunosuppression [low CD4], and to diagnose and treat prevalent opportunistic infections such as TB and cryptococcal infection)*	A minimum package of AHD services has been defined but has not yet been incorporated into the national HIV treatment guidelines	National HIV treatment guidelines include AHD management but there is no detailed and disease-specific operational guide, either stand-alone or integrated in the DSD Operational Guide	National HIV treatment guidelines include AHD management in detail and there is an approved disease-specific operational guide to support implementation (either stand-alone or integrated), but the operational guide is not yet in use.	National HIV treatment guidelines include AHD management in detail, there is an approved disease-specific operational guide to support implementation, and it is being actively used to inform implementation *(e.g., used in trainings, mentorship and by services providers).*
National AHD implementation plan	There is no existing national AHD scale-up plan, and none is currently under development	There is no existing national AHD scale-up plan, but one is currently under development	A national AHD scale-up plan has been developed but not implemented	A national AHD scale-up plan has been developed, and is being actively implemented in some subnational units *(e.g., regions, districts)*	A national AHD scale-up plan has been developed, is being implemented nationwide, and key milestones are being regularly monitored.

Least mature — Most mature

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HIV Learning Network
The CQUIN Project for Differentiated Service Delivery

18 Domains consisting of:

- Polices
- Guidelines
- AHD Scale-up Plan
- SOPs
- Coordination
- ROC Engagement
- Training
- Diagnostic Capability 1
- Diagnostic Capability 2
- Facility Coverage
- Client Coverage 1
- Client Coverage 2
- Client Coverage 3
- Client Coverage 4
- Supply Chain
- M&E System
- Quality
- Impact

Our focus for today will be on these seven domains

https://cquin.icap.columbia.edu/resources/cquin-capability-maturity-model-for-advanced-hiv-disease/

Diagnostic Capability Domains in the AHD CMM

Diagnostic capability 1: **Capacity to identify AHD (advanced immunosuppression)**	PLHIV are not routinely assessed for advanced immunosuppression using CD4 testing *AND/OR* Insufficient information is available to estimate	PLHIV are routinely assessed for advanced immunosuppression using CD4 testing in < 25% of health facilities	PLHIV are routinely assessed for advanced immunosuppression using CD4 testing in 25% to 50% of health facilities	PLHIV are routinely assessed for advanced immunosuppression using CD4 testing in 50% to 75% of health facilities	PLHIV are routinely assessed for AHD using CD4 testing in > 75% of health facilities
Diagnostic capability 2: **Capacity to identify opportunistic infections and comorbidities:** Xpert MTB/Rif assay, TB LAM, and CrAg	Access to the diagnostic tests and procedures needed to identify key OIs (Xpert MTB/Rif assay, TB LAM, CrAg) is rarely or never available *AND/OR* Insufficient information is available to estimate	Access to at least one of the three "minimum package" diagnostic tests is available *on site* at > 75% of referral health facilities	Access to one of the three "minimum package" diagnostic tests is available at > 75% of all health facilities (on site or by referral) *AND* has a national sample & client referral system to ensure access to AHD diagnostics by lower-level HF	Access to two of the three "minimum package" diagnostic tests are available at > 75% of all health facilities (on site or by referral) *AND* has a national sample & client referral system to ensure access to AHD diagnostics by lower-level HF	Access to all three of the "minimum package" diagnostic tests are available at > 75% of all health facilities (on site or by referral) *AND* has a national sample & client referral system to ensure access to AHD diagnostics by lower-level HF

Client Coverage Domains in the AHD CMM

Client Coverage 1: Assessing for AHD among people at risk of AHD	In this domain, "AHD screening coverage" means the proportion of people at risk of AHD for whom CD4 testing and/or WHO clinical stage is documented during the reporting period People at risk of AHD for whom screening is recommended include: 1. PLHIV newly enrolled on ART. 2. PLHIV returning after treatment interruption. 3. PLHIV with virologic failure. 4. PLHIV who are seriously ill. Note: All children under five diagnosed with HIV should be considered to have AHD.				
	None of the four groups of people at risk of AHD listed above are routinely assessed for advanced immunosuppression using CD4 testing or WHO clinical staging *AND/OR* There is **insufficient** information to determine the AHD screening coverage for all the four groups of people at risk of AHD listed above.	**At least one** of the four groups of people at risk of AHD listed above are routinely assessed for advanced immunosuppression using CD4 testing or WHO clinical staging *AND/OR* There is sufficient information to determine the AHD screening coverage for **one** of the four groups of people at risk of AHD listed above *AND* The AHD screening coverage data for the group is < 50%.	**At least two** of the four groups of people at risk of AHD listed above are routinely assessed for advanced immunosuppression using CD4 testing or WHO clinical staging *AND/OR* There is sufficient information to determine the AHD screening coverage for **two** of the four groups of people at risk of AHD listed above *AND* The AHD screening coverage data in at least **one** group is >50%.	**At least three** of the four groups of people at risk of AHD listed above are routinely assessed for advanced immunosuppression using CD4 testing or WHO clinical staging *AND/OR* There is sufficient information to determine the AHD screening coverage for **three** of the four groups of people at risk of AHD listed above *AND* The AHD screening coverage data in at least **two** groups is >50%.	**Four** of the four groups of people at risk of AHD listed above are routinely assessed for advanced immunosuppression using CD4 testing or WHO clinical staging *AND/OR* There is sufficient information to determine the AHD screening coverage for **all four** groups of people at risk of AHD listed above *AND* The AHD screening coverage data in **all four** groups is >75%.

Client Coverage Domains in the AHD CMM

Client Coverage 2: Screening of people with advanced immunosuppression for prevalent opportunistic infections/ comorbidities CrAg, TB LAM, cervical cancer screening, screening for psychosocial risk factors, etc.	National implementation of AHD screening has not begun *AND/OR* Insufficient information is available to estimate the proportion of PLHIV screened for prevalent OI/comorbidities	Fewer than 25% of clients with advanced immunosuppression receive screening services for TB and CM as per the national AHD package *(e.g., TB LAM, CrAg)*	25-49% of clients with advanced immunosuppression receive the screening services for TB and CM as per the national AHD package *(e.g., TB LAM, CrAg)*	50-75% of clients with advanced immunosuppression receive the screening services for TB and CM as per the national AHD package *(e.g., TB LAM, CrAg)*	Over 75% of clients with advanced immunosuppression receive the screening services for TB and CM as per the national AHD package *(e.g., TB LAM, CrAg)*
Client Coverage 3: Prevention of opportunistic infections/ comorbidities amongst people with advanced immunosuppression OI prophylaxis (e.g., TPT, CTX, cryptococcal prophylaxis)	National implementation of the OI prevention services in the AHD minimum package has not begun *AND/OR* Insufficient information is available to estimate the proportion of eligible PLHIV receiving OI prevention services	Fewer than 25% of eligible clients receive the OI prevention services in the national AHD package *(TPT and CTX prophylaxis as well as cryptococcal pre-emptive treatment)*	25-49% of eligible clients receive the OI prevention services in the national AHD package *(TPT and CTX prophylaxis as well as cryptococcal pre-emptive treatment)*	50-75% of eligible clients receive the OI prevention services in the national AHD package *(TPT and CTX prophylaxis as well as cryptococcal pre-emptive treatment)*	More than 75% of eligible clients receive the OI prevention services in the national AHD package *(TPT and CTX prophylaxis as well as cryptococcal pre-emptive treatment)*
Client Coverage 4: Management of opportunistic infections/ comorbidities	National implementation of AHD prevention and management has not begun *AND/OR* Insufficient information is available to estimate the proportion of eligible PLHIV receiving OI management services	Fewer than 25% of eligible clients receive the OI management services in the national AHD package *(e.g., treatment of TB, cryptococcus and other OIs)*	25-49% of eligible clients receive the OI management services in the national AHD package *(e.g., treatment of TB, cryptococcus and other OIs)*	50-75% of eligible clients receive the OI management services in the national AHD package *(e.g., treatment of TB, cryptococcus and other OIs)*	More than 75% of eligible clients receive the OI management services in the national AHD package *(e.g., treatment of TB, cryptococcus and other OIs)*

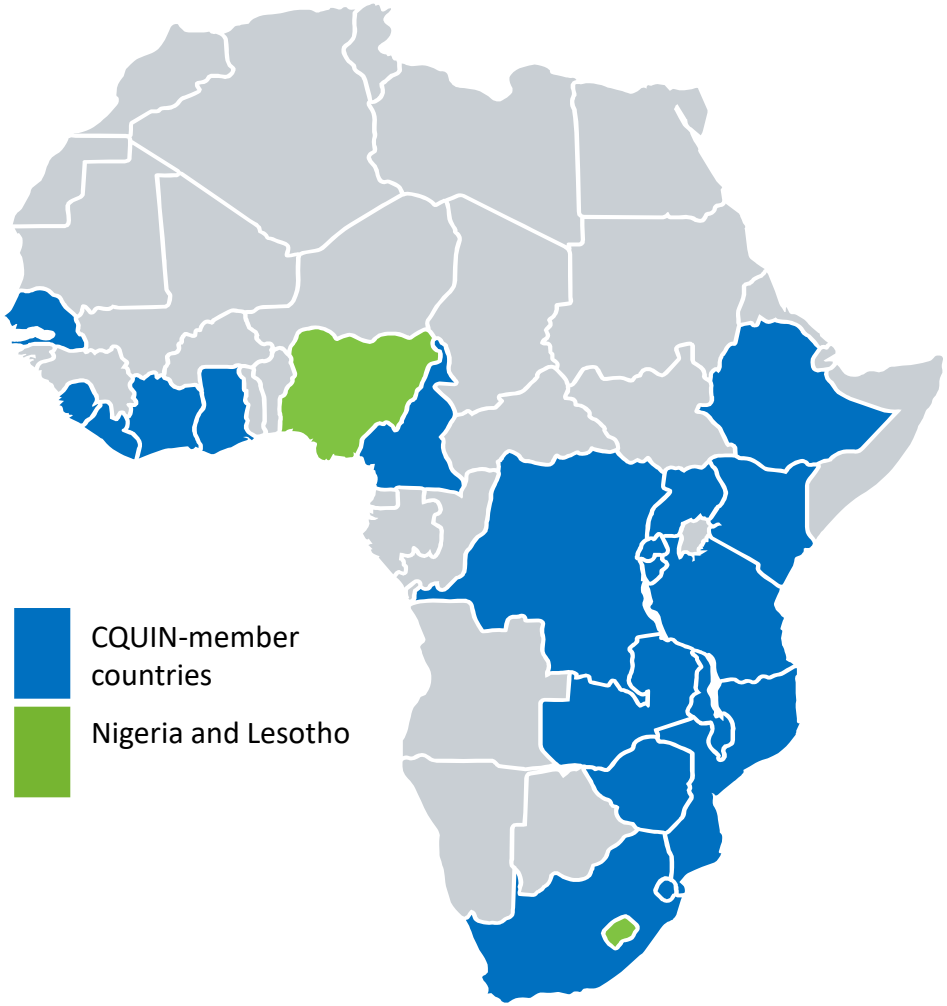
Supply Chain Domain in the AHD CMM

Supply Chain Management for AHD Commodities	Supply chain planning for AHD related commodities has not been done and no discussions are ongoing	AHD related commodities forecasting, quantification and funding request discussions are ongoing	AHD related commodities forecasting, quantification and procurement plans finalized but operationalization of the supply plan for diagnostic supplies and OI drugs has been delayed OR stock-outs of commodities reported in the past 3 months	AHD related commodities forecasting, quantification and procurement completed for AHD minimum package of care, with effective procurement planning, warehousing and last mile distribution in place and no stock-outs reported in the past 3 months.	An **integrated** AHD related commodities forecasting, quantification and procurement implemented for **all relevant opportunistic infections** with effective procurement plan, warehousing and distribution and consumption in place and no stock-outs reported in the past 3 months.

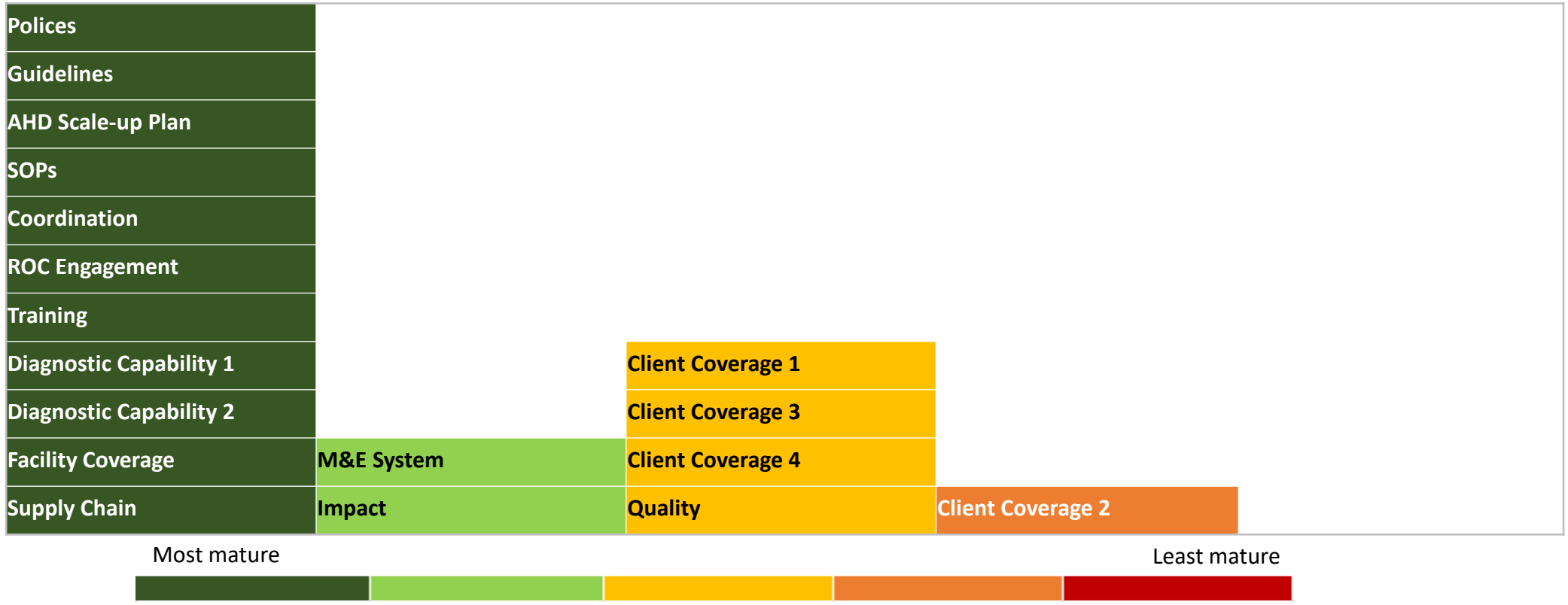
AHD Capability Maturity Model – Current Progress

- Completed in 21 CQUIN member countries
- Countries using the AHD CMM for the first time:
  - Burundi, Cameroon, Ghana, Lesotho, Liberia, Rwanda, Senegal
- Preliminary findings from two countries:
  - Nigeria
  - Lesotho

CQUIN Member Countries



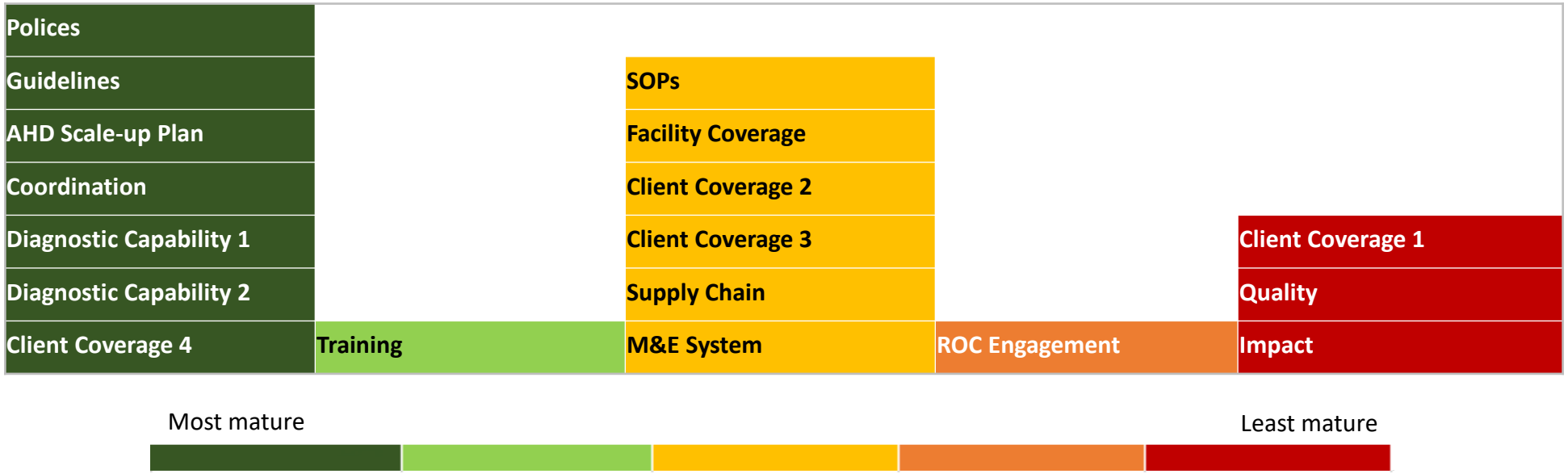
Nigeria



- **Predominantly mature AHD program** with 13 out of 18 **(72%)** domains in dark or light green
- **M&E system:** Most of the necessary AHD-related data elements are being systematically collected, reported, analyzed, and reviewed regularly and refinements to the data elements are needed to fully integrate into national M&E tools or the national HMIS for HIV/ART services.
- **Impact:** At least one evaluation of implementation of the national AHD package of care has been conducted, with evidence indicating impact in both process and outcome indicators

Nine enabling domains on the AHD CMM:
Policies, Guidelines, Implementation Plan, SOPs, Coordination, Engagement of recipients of care, Training, Supply chain management, and M&E

Lesotho



- **Heterogenous findings** with 8 out of 18 **(44%)** domains in dark or light green; 6 out of 18 **(33%)** in yellow; and 4 out of 18 **(22%)** in orange or red
- Majority of the **'enabling domains'**: 5 out of 9 **(56%)** are in dark or light green

Nine enabling domains on the AHD CMM:
Policies, Guidelines, Implementation Plan, SOPs, Coordination, Engagement of recipients of care, Training, Supply chain management, and M&E

Next Steps

- The country case studies from Nigeria and Lesotho in today's webinar will enable us to understand how these two countries set about achieving their successes in the diagnostic capability domains and explore how they plan to strengthen monitoring the client coverage domains
- In addition, join us at the CQUIN Annual Meeting in November 2023 for a deeper dive into the AHD CMM findings. For those will not be able to make it, the resources from the AHD session will be shared on the CQUIN website as well

  https://cquin.icap.columbia.edu/event/cquin-7th-annual-meeting/

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Thank you!

The State of the Global Advanced HIV Disease Commodity Landscape

James Conroy
Associate Director, Advanced HIV Disease – Clinton Health Access Initiative

CQUIN Webinar - September 2023

Agenda

- Current Status of Diagnostic and Treatment Commodities
- Snapshot of Global Adoption
- Looking Ahead: Commodities in the Pipeline

Current Supply Landscape | Key Advanced HIV Disease Diagnostics

	Product	Price/Test	Result	Sample	Turnaround Time	Capacity
CD4	 **Beckman Coulter Aquios CL Flow Cytometer**	**$7.00**[2]	Quantitative Absolute CD3, CD4, CD8, CD45 # & % Lymphocyte # & %	Venous WB	20 min/test	>600 tests/day *Assumes 40 samples[1] per batch * 20 mins per batch[1] * batches per hour*
	 **Sysmex Partec Cyflow**	**$3.45**[3]	Quantitative Absolute CD4 & CD4%	Venous WB	20 min/test	100 - 160 tests/day *Up to 20 samples per hour*
	 **BD FACSPresto**	**In the process of being phased out, last orders accepted through March '24 and support for final orders available through mid '26**				
	 **Abbott Pima**	**Production of analyzers ceased May '22; mapping and servicing of existing fleet underway; supply of cartridges will continue for foreseeable future**				
	 **Omega VISITECT® Advanced Disease** *(200 CD4 cutoff)*	**$3.98** Unitaid-CHAI Pricing Agreement[5]	Semi-Quantitative Absolute CD4	Finger prick/ venous blood	40 min/test	10 - 100 tests/day *>10 possible with batching*
TB	 **Determine TB LAM**	**$3.70**[7]	Qualitative	Urine	25 min/test	48 tests/day
CrAg	 **IMMY CrAg LFA**	**$2.34**	Qualitative	Whole blood, serum, plasma, or CSF	10 min/test	~48 tests/day *with no batch/pool testing*
	 **Biosynex CryptoPS**	**$2.17- $2.71**[8]	Semi-Quantitative	Whole blood, serum, plasma, or CSF	10 min/test	~48 tests/day *with no batch/pool testing*

[1] Beckman Coulter Aquios CL Brochure; [2] Placement deal offered to CHAI; [3] UNICEF Supply Division, 09/05/23; [4] Botswana Harvard AIDS Institute - 2014; [5] Global Access Price; [6] UNICEF Supply Division April 2023; [7] Global Access Price (March, 2021); [7] USD equivalent of €2.00-2.50/test as of 8/24/23

Current Supply Landscape | Key Advanced HIV Disease Treatment & Prevention Products

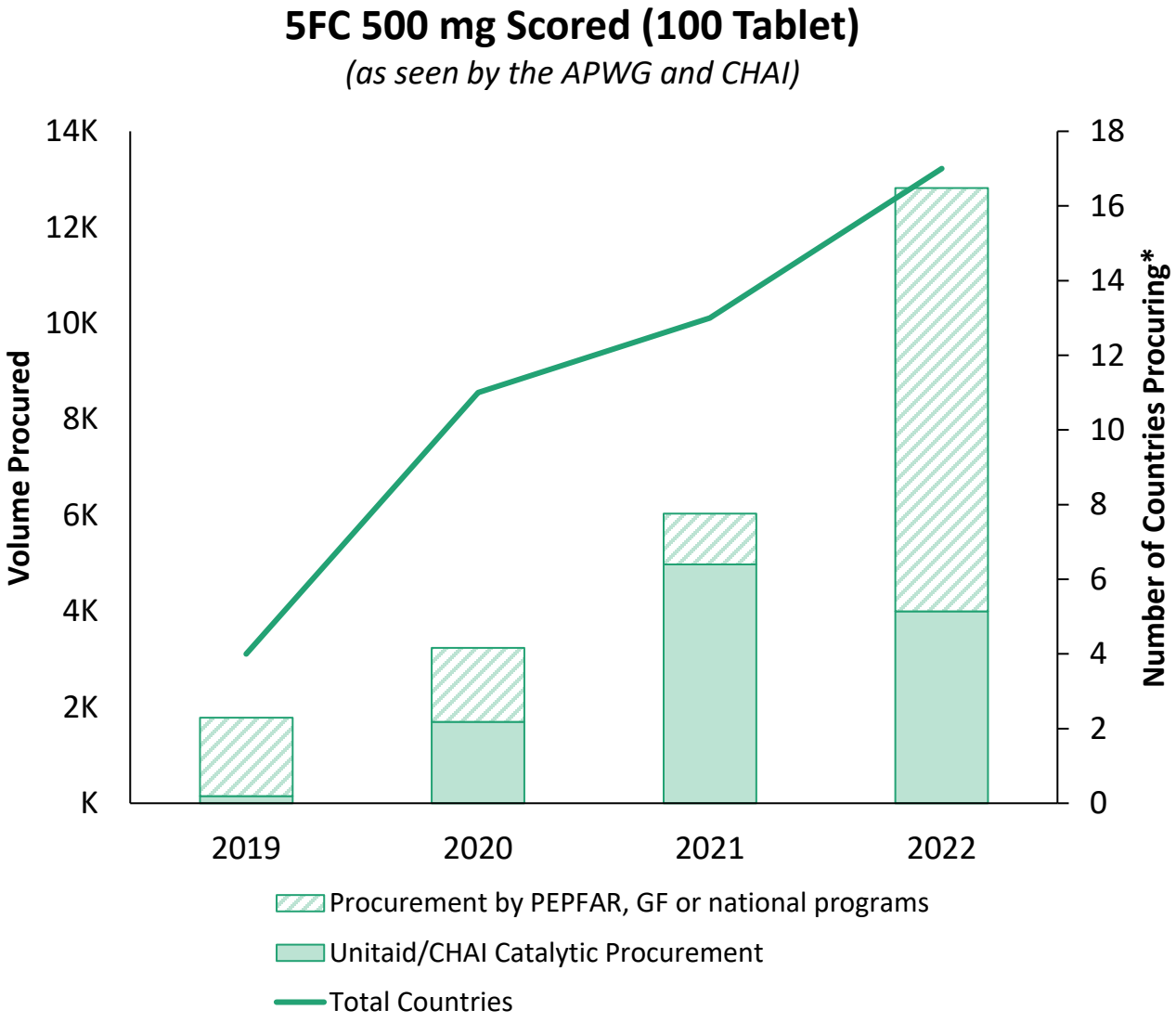
Product	Overview	Price/Test	Suppliers
 **L-AmB**	Antifungal medication used as backbone in treatment of CM	$23 / Vial	Gilead
 **5FC**	Antifungal used in combination with amphotericin B or fluconazole for treatment of CM	$65/pack[2]	Mylan, Strides
 **Fluconazole**	Antifungal medication used for both prophylaxis and treatment of OIs	$16.50/patient[3] Full course CM regimen	Generic Manufacturers
 **3HP**	Prophylaxis for preventing TB	$14.25/pack[4]	Lupin, Macleods

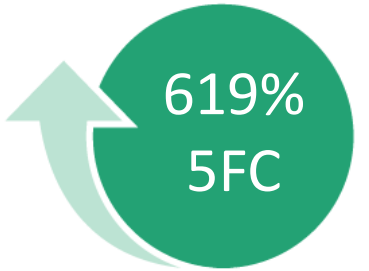
[1] Unitaid, July 2022. Link; [2] Shiri et al., 2020. Link; [3] Global Fund Pooled Procurement Mechanism; [4] Unitaid, Aug 2022

Agenda

- Current Status of Diagnostic and Treatment Commodities
- Snapshot of Global Adoption
- Looking Ahead: Commodities in the Pipeline

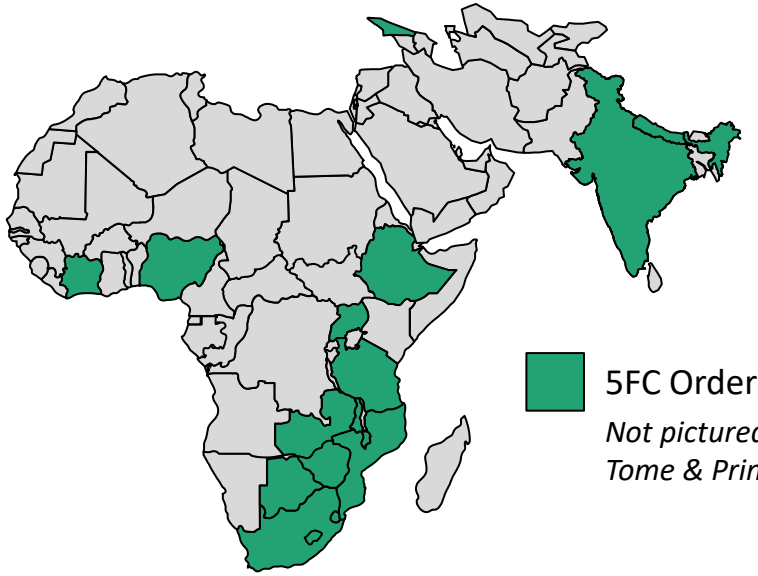
Snapshot of Global Adoption | 5FC





increase in 5FC order volumes seen by the APWG between 2019 - 2022

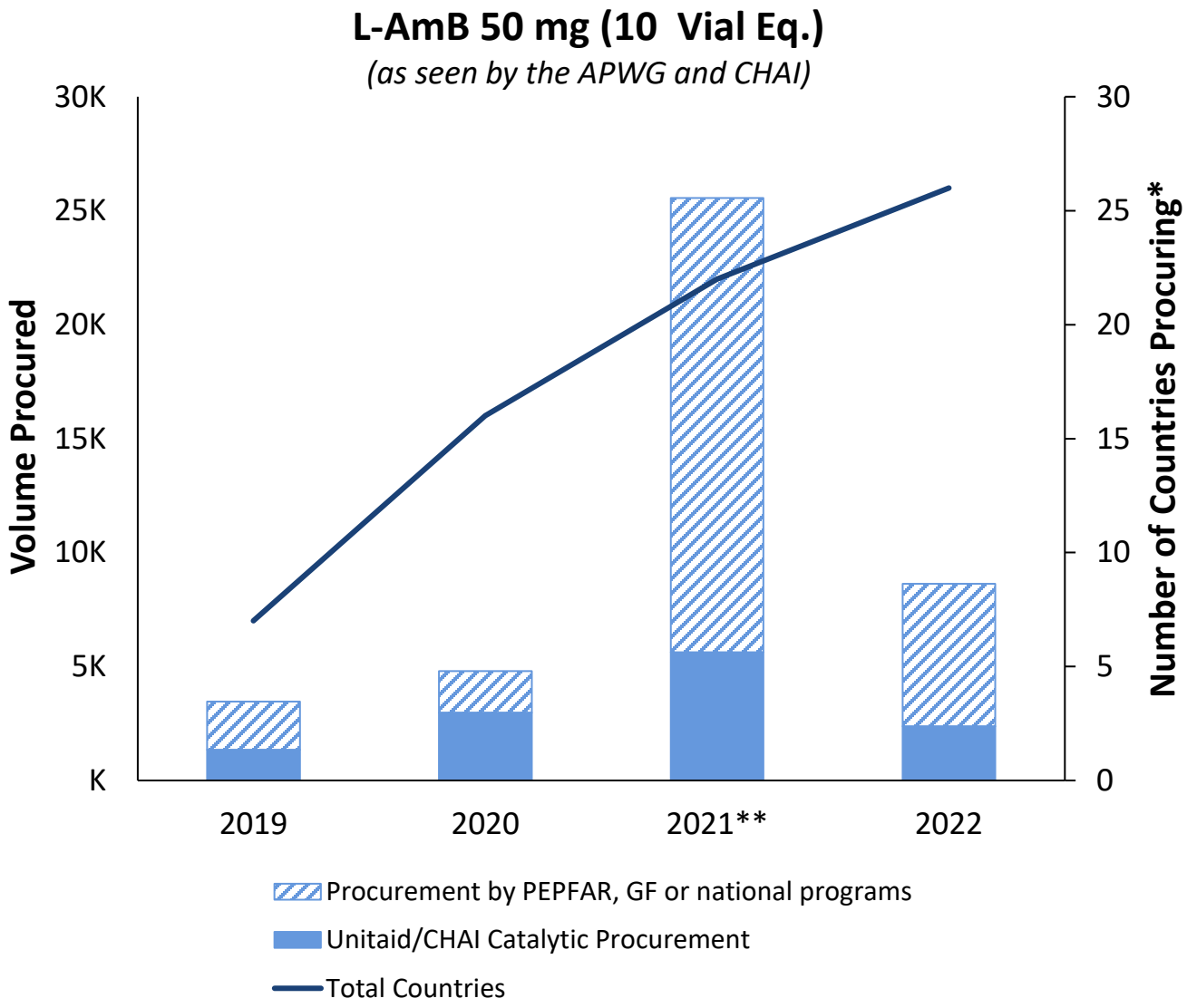
5FC Adoption Map (2019-2022)

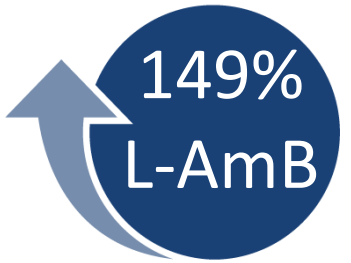


Source: APWG Data 2019-2022, data displayed by order year

*Includes all countries who have ever procured

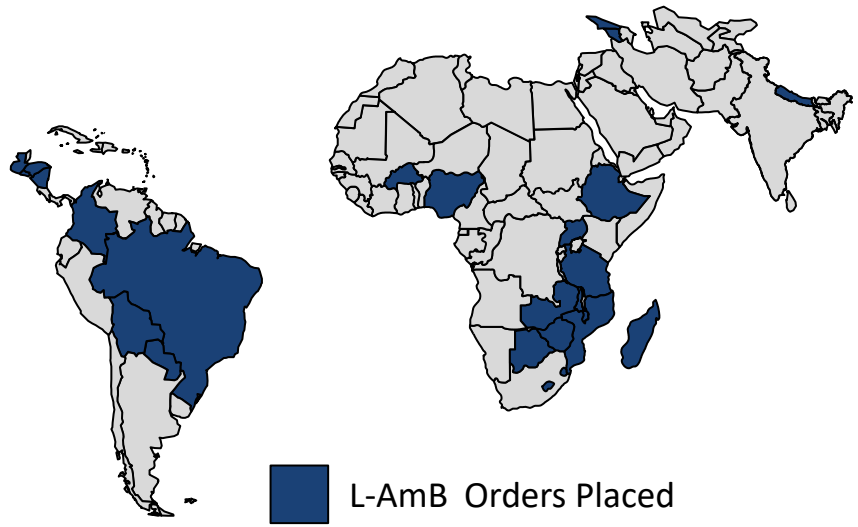
Snapshot of Global Adoption | L-AmB





increase in L-AmB order volumes seen by the APWG 2019 - 2022

L-AmB Adoption Map (2019-2022)



L-AmB Orders Placed

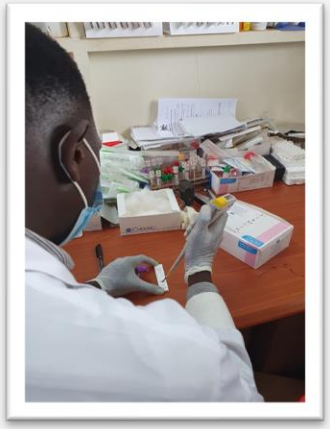
Not pictured: Sao Tome & Principe, Trinidad & Tobago

Source: APWG Data 2019-2022, data displayed by order year

*Includes all countries who have ever procured; ** 2021 volumes include a large order from Brazil

Snapshot of Global Adoption | VISITECT CD4 Test

Adoption of VISITECT CD4 Test



- **CD4 testing for all PLHIV remains an important tool** for identifying AHD and providing access to the recommended package of care.
- VISITECT **has the potential to significantly expand access to same-day CD4** result through its simple service provision capabilities and low cost.
- **45+ countries have placed orders** for VISITECT. Countries are at a mix of the national adoption, scale-up, or research / implementation phase.

VISITECT CD4 Orders Placed

As of June 2023

*Includes orders placed for national adoption and research and feasibility assessments

Source: Accubio Data, July 2023

Agenda

- Current Status of Diagnostic and Treatment Commodities
- Snapshot of Global Adoption
- Looking Ahead: Commodities in the Pipeline

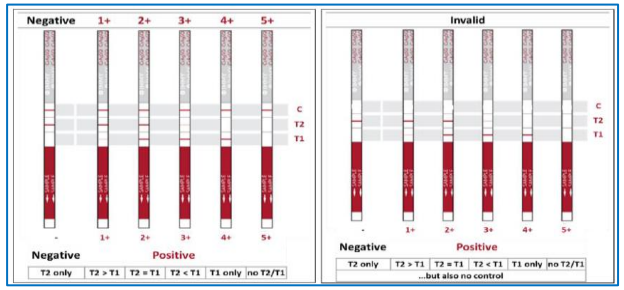
A number of promising products are in the pipeline that can better meet the needs of AHD programs and PLHIV

Cryptococcal Antigen Semi Quantitative Test

Product Overview

IMMY has developed a semi-quantitative CrAg test for detection of CrAg in serum, plasma, whole blood, and CSF with slightly improved performance for high titers and reduced rate of false positives.

- Performance - Sensitivity: 98%; Specificity: 98%[1]
- Time to Process & Daily Throughput - 10 min/test; Up to ~48 tests/day
- Price Per Test - TBC[2]
- Regulatory Status – CE for serum, plasma, and CSF; FDA submission expected by EOY for procurement in 2024



CrAg SQ
Visual Interpretation Guide

Key Benefits

- Exceptionally high sensitivity and specificity
- Measures very high titers, which the CrAg LFA can record as false positives
- Provides information on the severity of disease and probability of positive culture in a single rapid diagnostic, potentially negating the need for confirmatory lumbar puncture and improve linkage to care

Key Considerations

- Interpretation is challenging and will require a shift in thinking and additional training
- Countries may consider national requirements that need to be addressed to consider adopting
- If successful, linkage to treatment and thus need for therapies will increase

[1] Skipper et. al., 2020, link
[2] Pre-market entry discussions with supplier indicate suggest price may be ~$1 higher than the LFA; Unitaid is targeting price parity

A number of promising products are in the pipeline that can better meet the needs of AHD programs and PLHIV

Histoplasmosis Lateral Flow Assay

Product Overview[1]

IMMY has developed an LFA test for detection of Histo in urine and serum. A number of other histoplasmosis diagnostic options are on the market but are not yet FDA-approved, cost-accessible, or require skilled technicians (i.e., EIA devices).

- Performance - TBC
- Time to Process & Daily Throughput - 60 min/test; 8 tests/day
- Price Per Test - TBC
- Regulatory Status - Still undergoing final stability studies ahead of submission to FDA

With growing evidence of rising incidence, awareness of and access to testing for histoplasmosis needs to improve quickly and dramatically.

Key Benefits

- Suitable for decentralized settings with fast results and no device needed
- Expected to improve access to screening and linkage to treatment for an often-undetected OI

Key Considerations

- Product not yet available and FDA timelines to be determined
- Introduction of a Histo test would represent a new diagnostic tool for many countries and may necessitate in-country requirements

[1] IMMY, August 2023

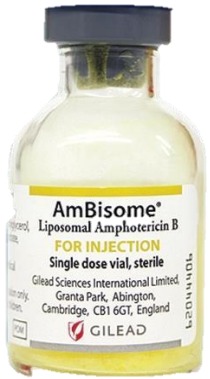
A number of promising products are in the pipeline that can better meet the needs of AHD programs and PLHIV

Generic Liposomal Amphotericin B

Product Overview

CHAI in collaboration with Unitaid and DNDi are working to accelerate access to generic L-AmB to ensure the product is cost-accessible.

- Request for Proposal for generic suppliers closed at the end of last year
- CHAI, Unitaid, and DNDi are now working to down-select suppliers and ensure the product is comparable to the innovator's
- A generic option is key to enabling access to improve uptake and coverage of the product for CM and other indications



Gilead's L-AmB Product

Newly updated WHO guidance following the successful AMBITION trial now **recommends treatment through a single high dose of L-AmB** following by two weeks of fluconazole and flucytosine for cryptococcal meningitis, making treatment simpler and causing fewer toxic side effects for the patient.

While promising, this will only translate into **lives saved if access to the drug is greatly improved**.

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Advanced HIV Disease LESOTHO

Implementation Updates, Learnings, and Challenges

Dr. Tapiwa Tarumbiswa (HIV & AIDS Manager-MOH Lesotho)

Ministry of Health

Presentation Outline

- Country Context
- National AHD Program Overview
- Implementation Updates
- Care Cascade
- Challenges-Lesson Learnt
- Next steps and priorities

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Key take home

- Lesotho is making progress towards 95, 95, 95 targets (**94,91,99**)
- Annual AIDS-related deaths are 4,022 below the set NSP target.
- MOH has taken full stewardship of the AHD program from inception.
- Scale-up of AHD services is a strategic priority with clear visibility in strategic plans (enhances focus and resource mobilization)
- Government financial investments have increased, with AHD commodities being obtained through national and partner financing mechanisms (GOL, Global Fund, PEPFAR).
- Hub and spoke national AHD implementation arrangement, ART facilities-AHD coverage is 31%.
- Strategic focus is now on improving the AHD SI system (data collection, analysis and reporting).

- Lesotho is a mountainous enclave in South Africa
- Highest country in Africa (base altitude).
- Total area of 30,360 km²

- **Lesotho is a constitutional monarchy**, ruled by a king as Head of State and a Prime Minister as Head of Government
- **Population 2.2 million**
- **Low-middle income country:** GDP per capita $ 1,045.9
- **10 administrative districts**
- **70% of population resides within rural regions.**
- **40 % of the people** in Lesotho are aged between 15-35 years
- **Median age:** 22.3 years
- **Fertility rate:** 2.9 live births per woman.
- **Life expectancy:** 54.9 years (males-52.1, females-57.8)

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HIV Epidemiologic Context

HIV Prevalence (Adults aged 15-49): **22.7.%**

Lesotho status on the UNAIDS 95-95-95 targets for 2030:
94% – diagnosed, **91%** – on ART, **99%** - viral load suppressed

Advanced HIV Disease Prevalence: **14.5%**
(excluding clients with unsuppressed Viral Load and those that interrupted treatment)

Annual AIDS-related deaths**: 4,022**

Leading causes of AIDS-related mortality include Tuberculosis and Cryptococcal Meningitis.

Sources: Spectrum 2023 & LePHIA 2020

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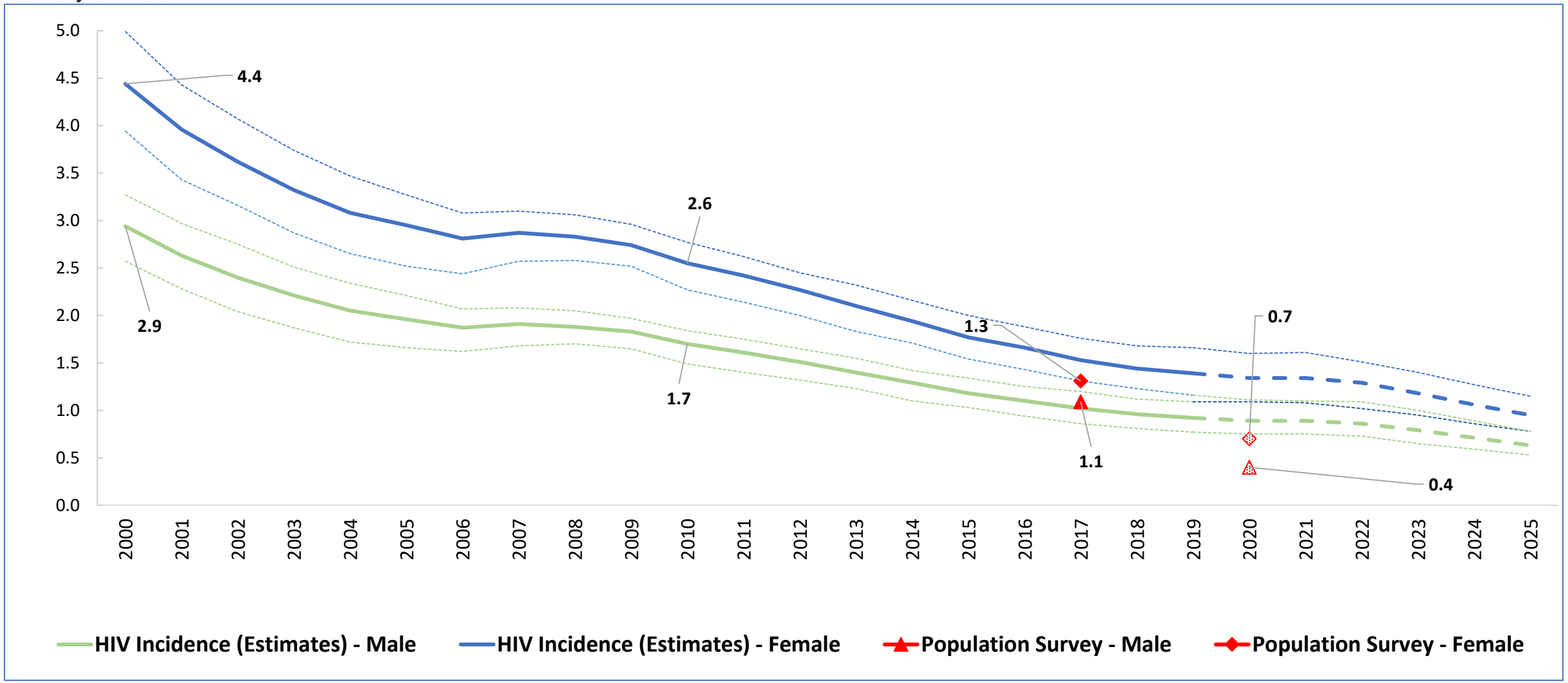
Incidence



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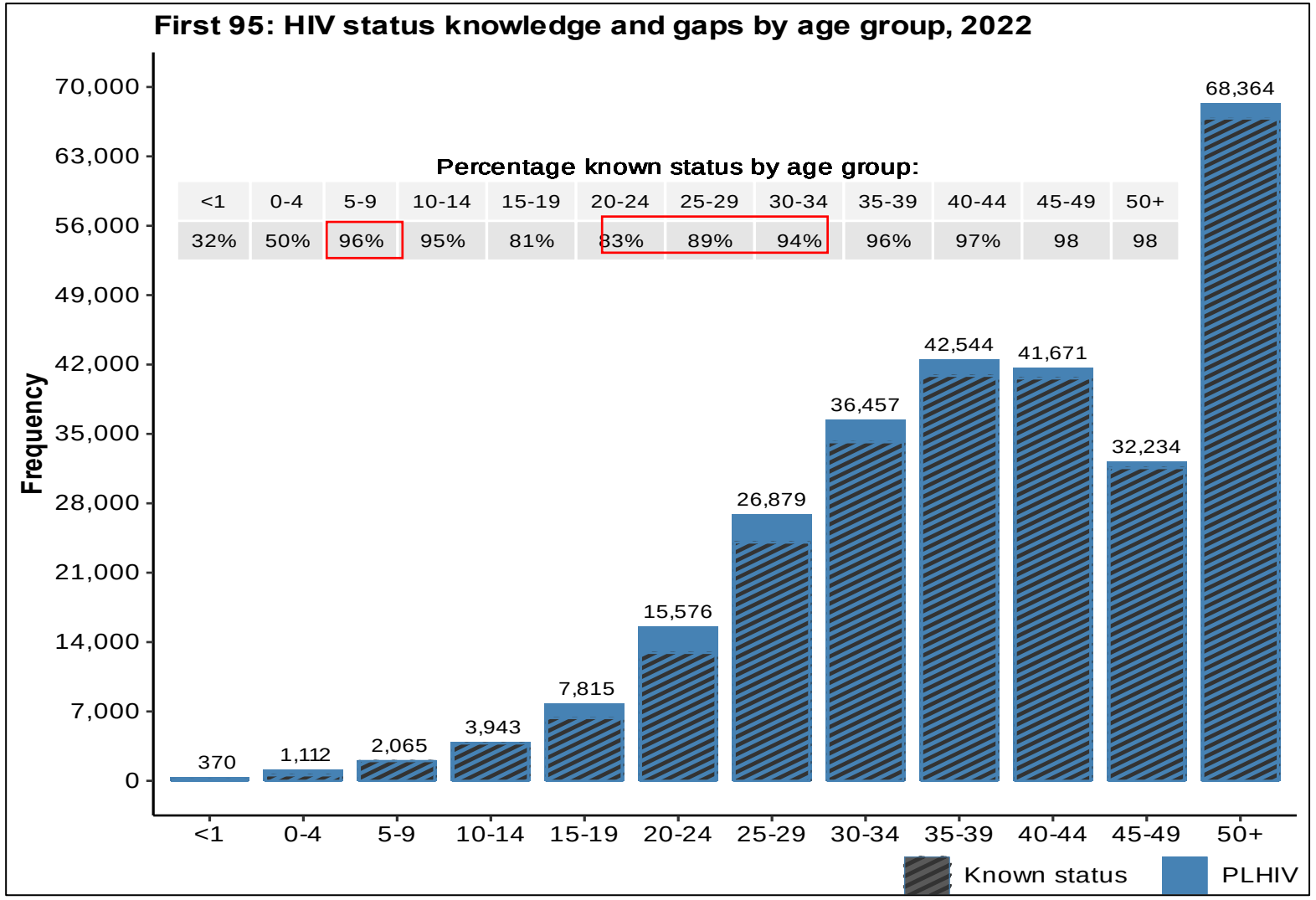
1st 95% by age



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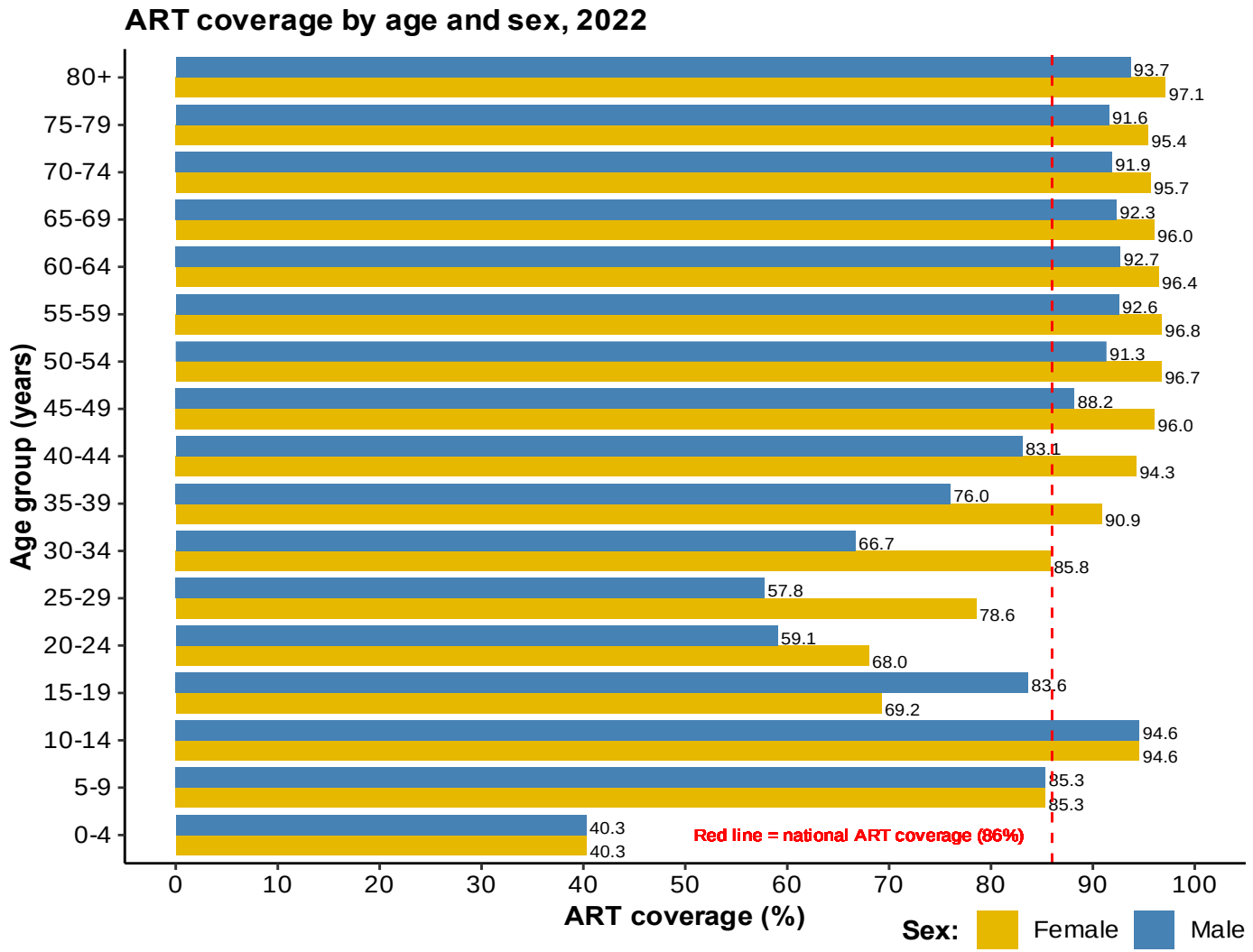
ART Coverage



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National AHD Program Overview

To drive sustainable delivery of the AHD care package, MOH has taken full stewardship of the AHD program from inception. Developing a program taking into consideration several domains, ranging from capacity-building to program monitoring.

AHD Evaluation Study

- The Ministry of Health (MoH) conducted an AHD evaluation study in 2019 in two hospitals. The study revealed a AHD prevalence of **28.8%** ,gaps in healthcare worker AHD knowledge and limited commodity availability.

Guideline development

- AHD manual was developed (2019) to define the AHD package of care and provide comprehensive treatment and management approaches towards AHD-associated opportunistic infections (OIs) and comorbidities.

Implementation planning

- The Ministry of Health (MoH) selected a ***Hub and Spoke*** model for implementation. Hubs (hospitals) provide pre-emptive therapy, screening, and treatment for all conditions. Spokes (health centers) provide screening and treatment of some diseases.
- Applying phased introduction, the care package was introduced, first in ***18 hospitals in 2020(Phase I sites)*** and subsequently in ***54 health centers (HCs) in 2022 (Phase II sites***). **Phase III** Facilities (158 HCs) to be activated in 2024.

Quantification

- MoH conducted an initial quantification exercise for focal commodities in 2021, including *TB LF-LAM, CrAg LFA, CD4 cartridges, Flucytosine, Fluconazole, and Liposomal Amphotericin B.*

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National AHD Program Overview

To drive sustainable delivery of the AHD care package, Lesotho developed a program taking into consideration several domains, ranging from capacity-building to program monitoring.

Procurement

- Initial orders were placed through a donor-funded catalytic procurement mechanism. Subsequent orders have been placed through a blend of national and donor budgets.

Healthcare worker training

- A blend of didactic and practical training sessions on AHD management were provided to medical officers, nurses, laboratorian technicians, pharmacists, and data clerks in Phase 1 and Phase 2 sites.
- Since the program's inception in 2019, four training sessions have been held.
- Continued health worker capacity building on AHD management is offered through virtual ECHO, a platform for sharing health information and data with health workers across different geographies.

Program monitoring

- The program is monitored using AHD data collected at sites by end-users, which is then entered on the e-register and aggregated on DHIS2. Supportive supervision by the MoH and partners is conducted at least bi-annually.

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Implementation Updates

Focal Activities

Strengthening Policy environment for AHD response ▶ *Scaling access to AHD Package of care* ▶ *Expanding AHD package of care* ▶ *Program monitoring*

Strengthening Policy environment for the AHD response

- CQUIN- AHD baseline staging conducted in August 2023
- Reduction of AHD-related deaths has been identified as a national priority and has been included in the **HIV/TB strategic plan (2023-2028),** with the goal to reduce AIDS-related mortality by >65% (<1,350 deaths) by 2028.
- Government financial investments have increased, with AHD commodities being obtained through national and partner financing mechanisms (GOL, Global Fund, PEPFAR).

Scaling access to AHD Package of care:

- The AHD care package has been **decentralized from 18 hospitals to an additional 54 health centers-** 31% of all facilities in Lesotho now provide AHD services. At health centers, clients are screened for AHD and provided with treatment for conditions that can be treated at the health center level (e.g., severe bacterial infections) patients are referred to Phase 1 sites for pre-emptive therapy and treatment of some conditions, such as cryptococcus disease.
- The government continues to ensure the availability of ancillary commodities requisite to AHD management and will provide **serum electrolytes testing** for clients on CM treatment in quarter 4, 2023.

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Implementation Updates

Focal Activities

Strengthening an enabling environment for AHD response ▶ Scaling access to AHD Package of care ▶ *Expanding AHD package of care* ▶ *Program monitoring*

Expanding AHD package of care

- Usage of VISITECT has been adopted, a measure which will reduce turnaround time for CD4 tests and encourage same-day OI testing and initiation of treatment/prophylaxis. Test kits have been procured and plans to distribute kits have been developed in conjunction with training plans.

Program monitoring

- New AHD registers have been distributed to sites. E-register and DHIS2 infrastructure have AHD reporting indicators.
- At least two national supportive supervision exercises have been conducted by MOH na da annually since the programmatic rollout.

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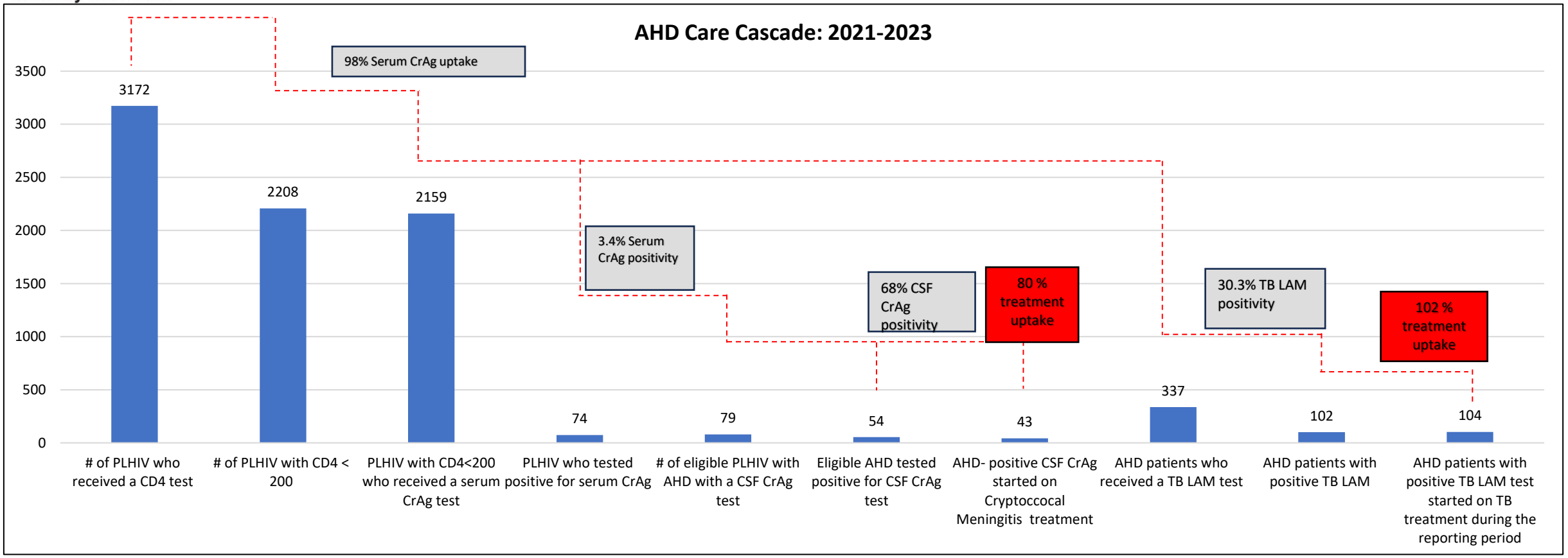
AHD Cascade



- 70% of patients who took a CD4 test had a CD4 cell count below 200 cells/mm^3.
- Uptake of TB LAM lags far behind serum CrAg testing for eligible clients.
- Data verification is critical to ensure that treatment and testing uptake figures are accurate.

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Challenges-Lessons Learnt

Despite the overall progress in rolling out the AHD package of care, optimal program monitoring, treatment uptake, and full access to focal commodities are yet to be achieved.

Program Monitoring

- Under-reporting of AHD client data on E-register/DHIS-2, AHD register, paper-based, and other client monitoring tools.
- Fragmented data systems: lack of interoperability and standardization between electronic data reporting systems and other electronic platforms (such as LMIS, LIS etc.).

Clinical Implementation

- Uptake of AHD testing and treatment commodities remains low.
- Uptake of TB LF-LAM has improved marginally since its re-introduction in March 2023, but still lags far behind serum CrAg testing for eligible clients.
- Treatment adherence remains poor due to a number of contributing factors, including internal and external migrations, financial burden, and lack of social and psychological support.

Supply Chain

- Supply of some AHD focal commodities remains intermittent with stockouts reported.

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Next Steps-Priorities

Over the next few months, MoH will implement tactical activities to improve data reporting, clinical implementation, and increase access to AHD focal commodities.

Program Monitoring

- Review AHD indicators in the E-register and DHIS2 and harmonize with other platforms.
- Conduct on-site training (supportive supervision) on AHD reporting in hospitals and health centers.
- Engage IT personnel to facilitate the interoperability of the data reporting systems.
- Collect outcome data.

Clinical Implementation

- Conduct refresher training targeted towards hospitals, health centers providing AHD package of care and AHD evaluation study
- Monitor and improve quality of AHD services through routine mentorship visits and establish of QA initiatives.
- Pilot AI to aid diagnosis and management of clients with AHD.
- Establish linkage between the MoH and the Ministry of Social Welfare to assist indigent clients with AHD.
- Integration of other health services in the AHD package (including mental health assessment, cervical cancer screening, and welfare support for indigent AHD clients) to provide quality and comprehensive client-centered care.

Supply Chain

- Expand the informed push system module to include pull components for 5FC, L-AmB, and other AHD commodities.
- Distribute VISITECT to increase same-day diagnosis and treatment/prophylaxis initiation for OIs.

Kea leboha

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The role of VISITECT CD4 line assay in triaging of HIV infected subjects into Test and Treat and Delivery of AHD Package of care services: Experience from Nigeria

Akanmu AS

Chairman: AHD technical Working Group

Chairman: National Task Team on ART

Summary

- Describe Evolution of Test and Treat Strategy in Relation to discontinuation of CD4+ Cell assay at baseline
- Highlight the effect of initiation of ART at any CD4+ Cell count and the Cancellation of Baseline CD4+ Cell Count- The Basis of AHD
- Itemise the Role of CD4+ Cell Count in AHD Diagnosis
- List Laboratory Techniques for CD4+ Cell Count Assay
- Highlight Nigeria Experience validating VISITECT CD4 Line assay
- Discuss the Nigeria's Experience using VISITECT CD4+ Line Assay in the Implementation of AHD package of care in 28 facilities across 4 staes in Nigeria

The Evolution of the Test and Treat Mantra

1. **Early Days of the Epidemic:**
    a) limited treatment options available, and the
    b) Focus was primarily on managing opportunistic infections and prolonging survival.
    c) ARV came late 1980s and early 1990s, but they were very toxic
2. **Emergence of Effective Antiretroviral Therapy:**
    a) The mid-1990s greeted the arrival of HAART, now cART
    b) This laid the foundation for the concept of treating HIV as early as possible after diagnosis.
3. **HIV Treatment as Prevention (TasP):**
    a) Then the ground-breaking HPTN 052 clinical trial, that started in 2005
    b) Demonstrated that early initiation of ART significantly reduce the risk of transmitting the virus
    c) The concept of "treatment as prevention" was born
4. **UNAIDS 90-90-90 Targets:**
    a) In 2013, UNAIDS set the 90-90-90 targets, now 95, 95, 95.
    b) These targets underscored the importance of widespread testing and immediate treatment initiation without consideration for CD4+ cell count

Test and Treat strategy gained momentum globally BUT…….

1.Implementation and Scaling Up:

a) Countries adopted test and treat Strategy
b) Efforts were made to reduce barriers to testing, such as stigma and discrimination, and
c) To increase access to antiretroviral therapy.

2.U=U (Undetectable = Untransmittable) Campaign:

a) This further emphasized the importance of early treatment without recourse to CD4+ cell count

3.Benefits and Challenges:

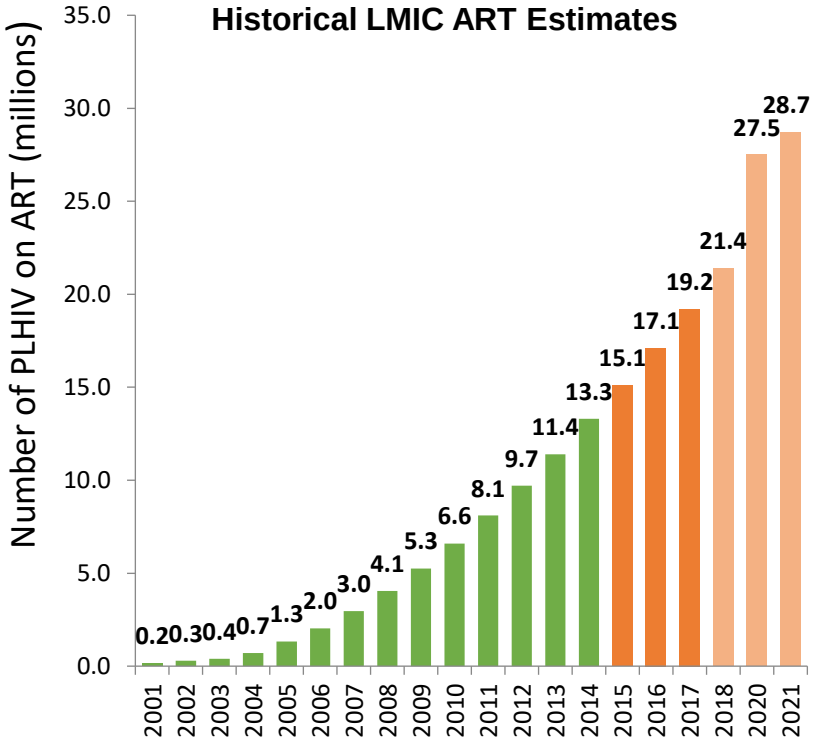
a) Reduced morbidity
b) Decreased transmission rates, and
c) Improved community health.

4.BUT

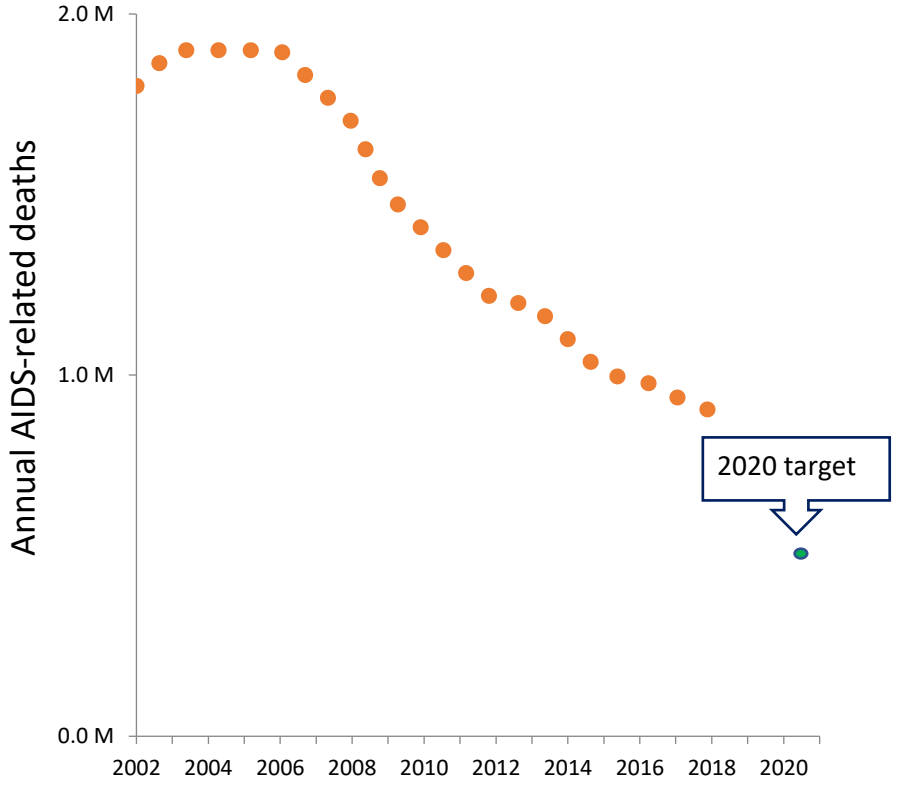
a) Death Rate Plateaued

ART has scaled up dramatically since 2000, reaching over 28M people living with HIV (PLHIV) in 2021

Historical scale up of PLHIV on ART in low- and middle-income countries (LMICs)



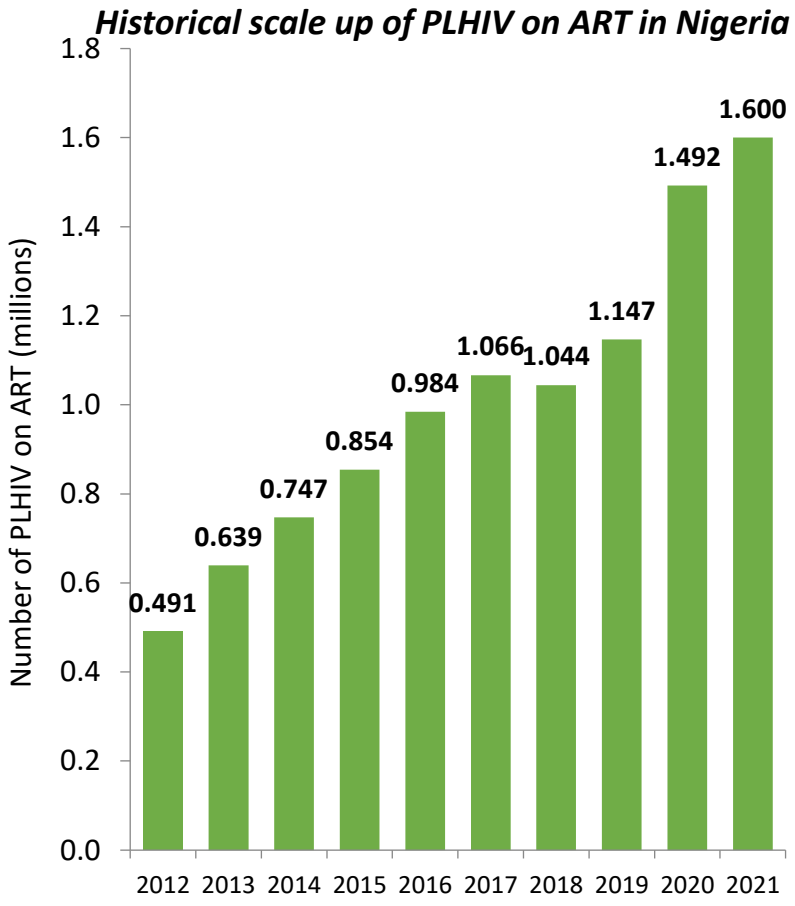
Number of AIDS-related deaths, global, 1990–2017 and 2020 target

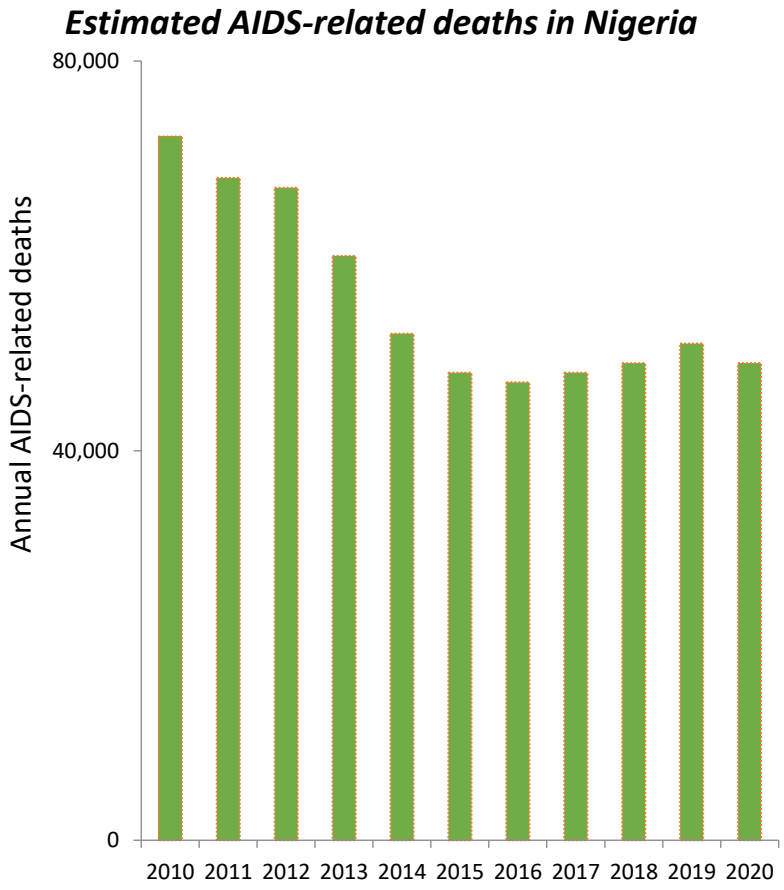


Source: WHO/UNAIDS for historical estimates

Note: 2010-2018 ART coverage figures calculated for LMICs using 2019 World Bank Income Classifications and UNAIDS AIDSinfo database, accessed August 29, 2019 (only includes countries with both ART and PLHIV numbers reported)

Nigeria ART coverage and AIDS-related deaths





Source: NASCP

Mortality in the Year Following Antiretroviral Therapy Initiation in HIV-Infected Adults and Children in Uganda and Zimbabwe

A. Sarah Walker,[1] Andrew J. Prendergast,[1,2] Peter Mugyenyi,[3] Paula Munderi,[4] James Hakim,[5] Addy Kekitiinwa,[6] Elly Katabira,[7] Charles F. Gilks,[8] Cissy Kityo,[3] Patricia Nahirya-Ntege,[4] Kusum Nathoo,[9] and Diana M. Gibb[1]; for the DART and ARROW trial teams

[1]MRC Clinical Trials Unit, London, [2]Queen Mary University of London, United Kingdom; [3]Joint Clinical Research Centre, Kampala, [4]MRC/UVRI Uganda Research Unit on AIDS, Entebbe; [5]University of Zimbabwe Clinical Research Centre, Harare; [6]Baylor-Uganda Pediatric Infectious Disease Centre, Mulago, [7]Infectious Disease Institute, Makarere University, Kampala, Uganda, [8]Imperial College, London, United Kingdom, and [9]University of Zimbabwe Medical School, Harare

Background. Adult mortality in the first 3 months on antiretroviral therapy (ART) is higher in low-income than in high-income countries, with more similar mortality after 6 months. However, the specific patterns of changing risk and causes of death have rarely been investigated in adults, nor compared with children in low-

Some Literatures cited by WHO to describe AHD

1. Anderegg N, Kirk O on behalf of IeDEA-Global Adults and COHERE. Immunodefciency at the start of combination antiretroviral therapy in low-, middle- and high-income countries. 21st International Workshop on HIV and Hepatitis Observational Databases, Lisbon, Portugal, 30 March–1 April 2017. Abstract 12.

2. Tanuma J, Lee KH, Haneuse S, Matsumoto S, Nguyen DT et al. Incidence of AIDS-defning opportunistic infections and mortality during antiretroviral therapy in a cohort of adult HIVinfected individuals in Hanoi, 2007–2014. PLoS ONE. 2016;11:e0150781.

3. Kranzer K, Ford N. Unstructured treatment interruption of antiretroviral therapy in clinical practice: a systematic review. Trop Med Int Health. 2011;16:1297–313.

4. McMahon JH, Spelman T, Ford N, Greig J, Mesic A, Ssonko C et al. Risk factors for unstructured treatment interruptions and association with survival in low to middle income countries. AIDS Res Ther. 2016;13:25.

5. Meintjes G, Kerkhoff AD, Burton R, Schutz C, Boulle A, Van Wyk G et al. HIV-related medical admissions to a South African district hospital remain frequent despite effective antiretroviral therapy scale-up. Medicine (Baltimore). 2015;94:e226

The Effects of Packaged Interventions for Advanced HIV Disease

REALITY study	27% reduced death
	Reductions in incident morbidity
	Reductions in hospitalization
REMSTART study	28% reduced death
	Improved adherence to ART at 6 months

Role of CD4+ cell count testing in identifying and managing people with advanced HIV disease

- The 2016 WHO consolidated ARV guidelines recommend starting ART regardless of CD+4 cell count and
- That the use of CD4 cell+ count for ART response monitoring can be stopped in settings where routine viral load monitoring is available and people are stable on ART.
- However, CD4 cell count testing at baseline for all people living with HIV remains important
- Relying on clinical staging alone risks missing substantial numbers of people living with HIV with severe immune suppression.
- In a study from Kenya, Malawi, Uganda and Zimbabwe, almost half the people with CD4 count <100 cells/mm3 were classified as having WHO clinical stage 1 or 2 disease (45).

Current Recommendation Screening and diagnosis of AHD – CD4+ lymphocyte count

❖CD4 + lymphocyte count testing at baseline is **MANDATORY** for
- All patients newly diagnosed with HIV
- All patients with suspected treatment failure
- LTFU (IIT) returning to care

❖CD4+ lymphocyte count should be done **immediately** and results **should** be obtained on same day

All patients with CD4+ lymphocyte count <200cells/mm^3 should be screened for OIs associated with AHD

Methods of CD4 + lymphocyte count estimation

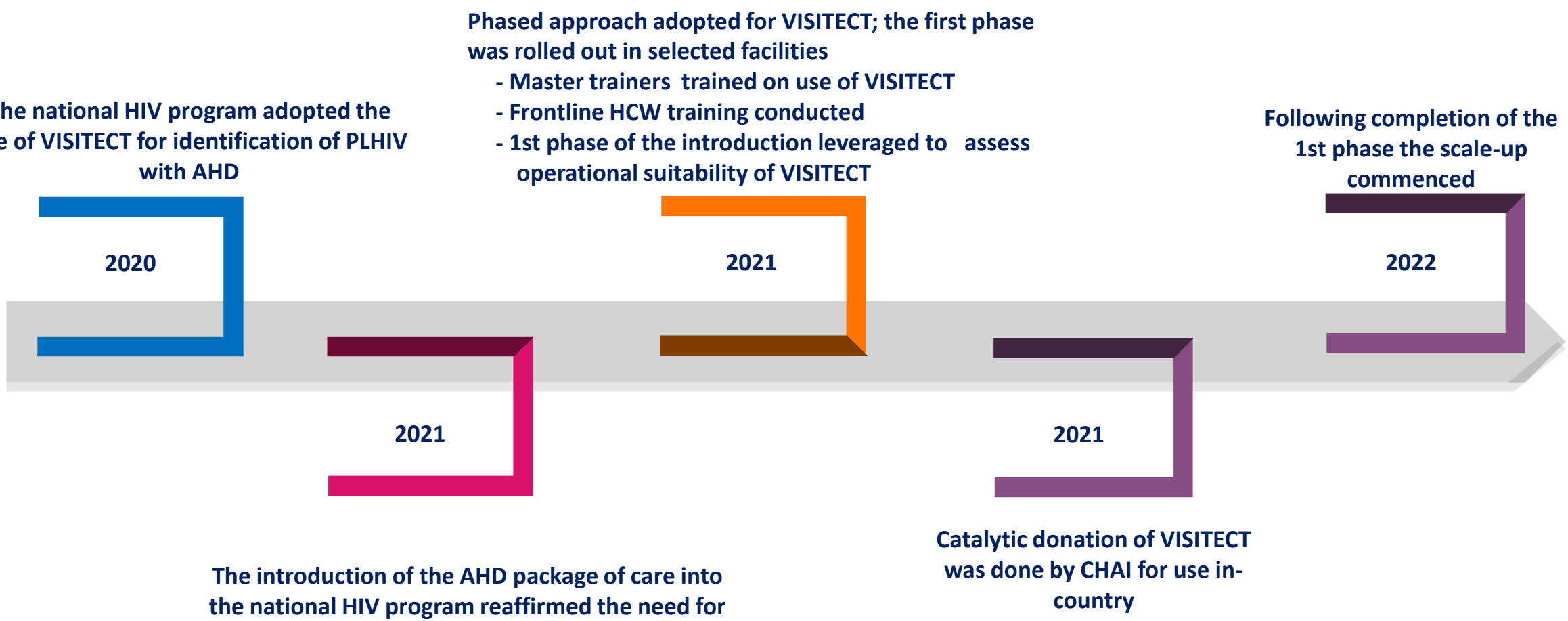
Flow cytometry is fast and available - Partec cyflow and BD FACSCount/FACSPresto

Rapid test kits for estimation of CD4+ lymphocyte counts

POC machines can be used if available e.g. m-PIMA

LF VISITECT CD4+ Cell count

Process of VISITECT introduction in Nigeria



Validating VISITECT CD4 line assay

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Nigeria introduced VISITECT CD4 Advanced Disease rapid test (VISITECT), a semi-quantitative point of care test pre-qualified by WHO, to address gaps in CD4+ cell count coverage.

Conducting VISITECT test requires time-sensitive procedural steps and visual acuity for interpretation, and there was no experience with its use in Nigeria.

To allay concerns of the impact of operational differences on the quality of VISITECT results in the Nigerian context, we compared results from VISITECT to CD4 flow cytometry, the current gold standard in-country.

Lessons from the VISITECT Implementation

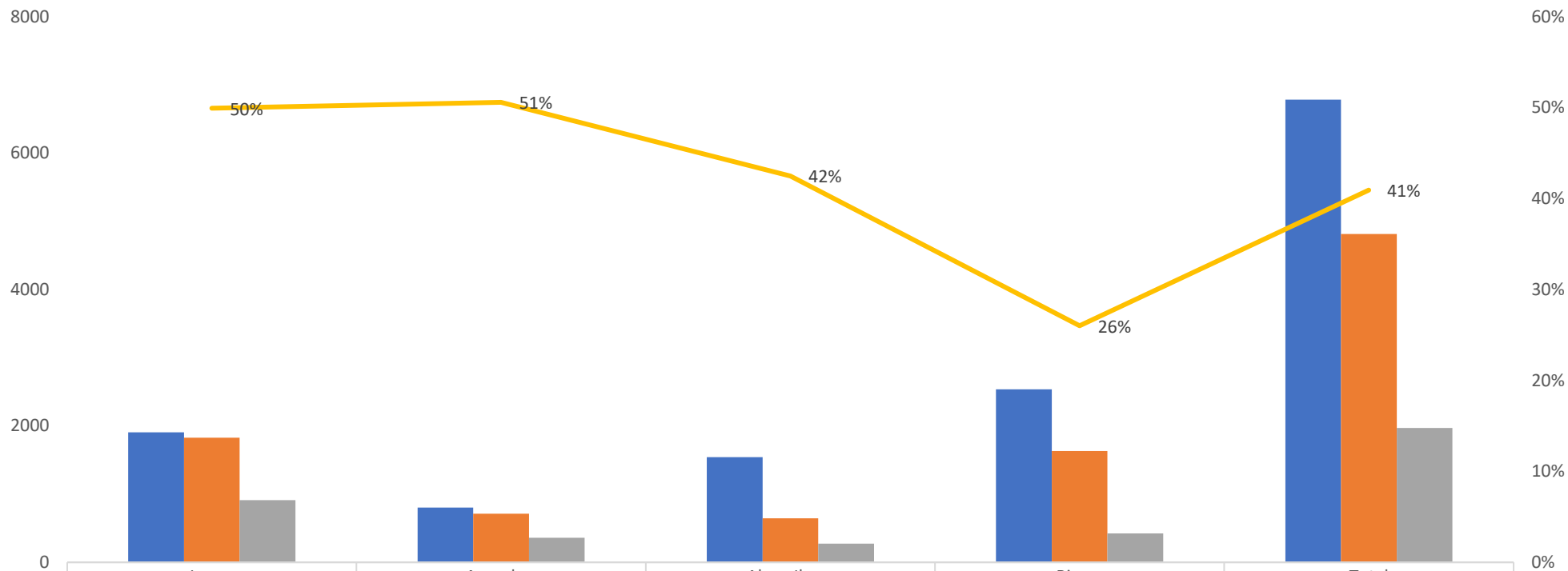
Comparison of VISITECT® and Flowcytometry results

		CD4+ cell count Flow cytometry result		
		<200cells/mm^3	>200cells/mm^3	Total
VISITECT result	<200cells/mm^3	765	104	869
	>200cells/mm^3	37	1069	1106
	Total	802	1173	1975

Using Cohen's Kappa test, the chance agreement between VISITECT and Flowcytometry was 51% whereas the actual agreement was 92.86%. A high agreement was established between the 2 sets of values [kappa=0.854], P<0.01)

The positive predictive index of VISITECT® is 88%. However, the negative predictive index is high (96.6%) as only 37 of the 1,106 that VISITECT® identified as having CD4 cell count >200cells/mm3 was shown by flowcytometry to have CD4 cell count <200cells/mm3.

AHD identification cascade (February – September 2021



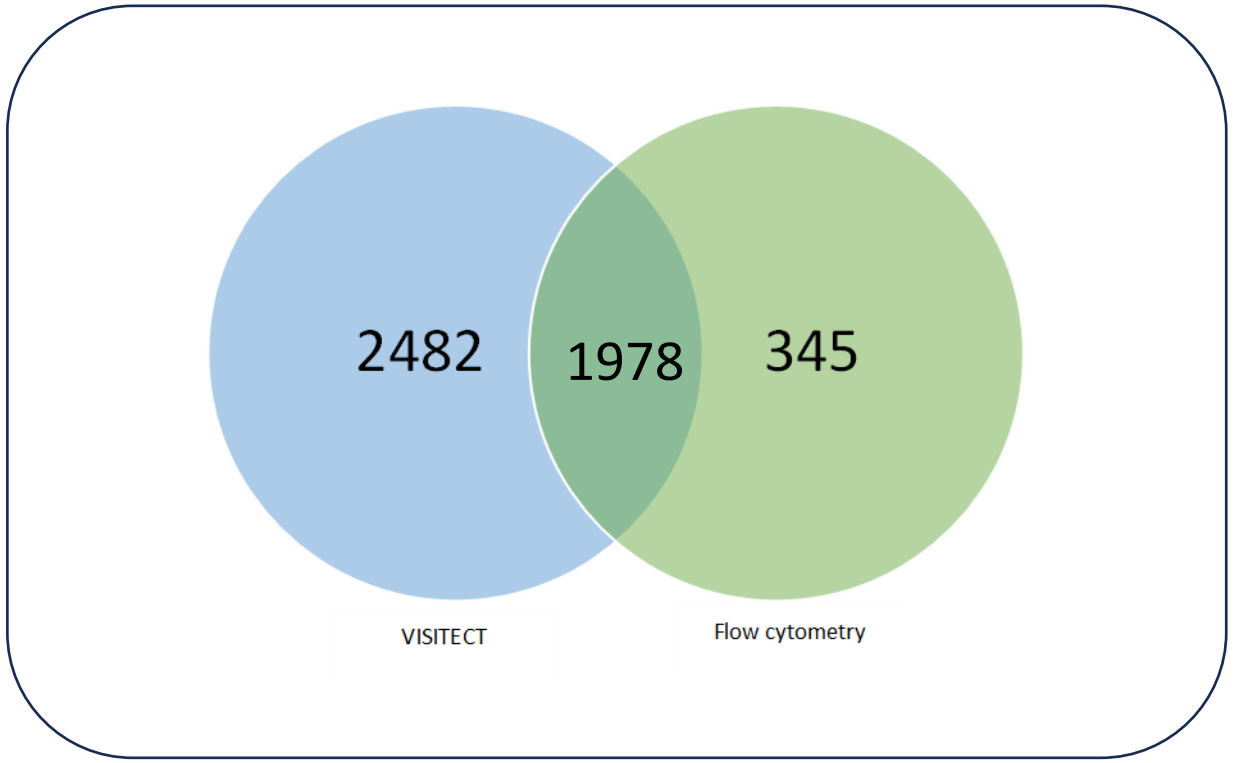
	Lagos	Anambra	Akwa Ibom	Rivers	Total
No of PLHIV enrolled	1903	801	1542	2535	6781
No with CD4 test	1827	710	645	1630	4812
CD4 <200	912	359	274	424	1969
AHD prevalence	50%	51%	42%	26%	41%

Any Conccurence Between CD4+ Cell Count and WHO Clinical Staging?

- A review of the WHO clinical staging for all the new patients showed that:
- 6,541 (96%) of 6,781 had a documented clinical staging.
- Of this, 854 (13%) had stage 3 or 4 disease.
- Of the 854 patients with WHO clinical stage 3 or 4, 821 (96%) had a documented CD4+ cell count result.
- Unexpectedly, 186 (23%) had a CD4+ cell count >200, while
- Of the 4,820 WHO clinical stage 1 or 2 patients with a baseline CD4+ cell count result, 1,254 (26%) had a CD4+ cell count <200.

Lessons from the VISITECT Implementation

- Prior to the commencement of the AHD package of care, CD4 flow cytometry device was available in 17% (322 of 1,866) of ART sites in the country.
- Of the total 4,812 CD4+ cell count tests conducted,
  - 51.6% were enumerated using VISITECT alone,
  - 7.3% were enumerated using a flow cytometry device alone, while
  - 41.1% were enumerated using both VISITECT and a flow cytometry device.
  - Facilities with flow cytometry devices still conducted more CD4+ cell count tests using VISITECT (4,293) than with flow cytometry device (2,335).
- VISITECT enabled same day CD4 test result for prompt clinical decisions.



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Thank you!

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Regional Manager
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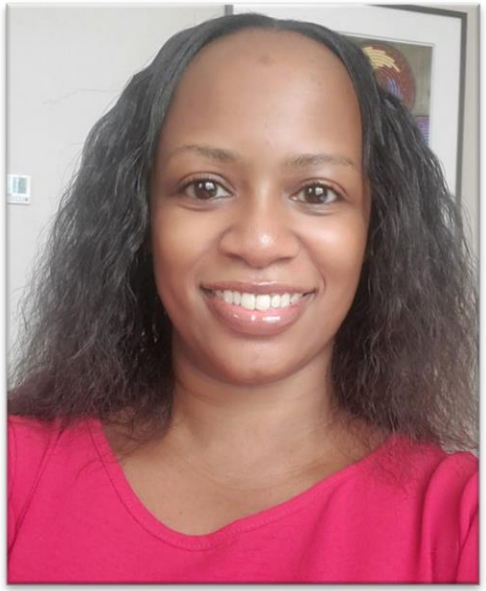
Presenters



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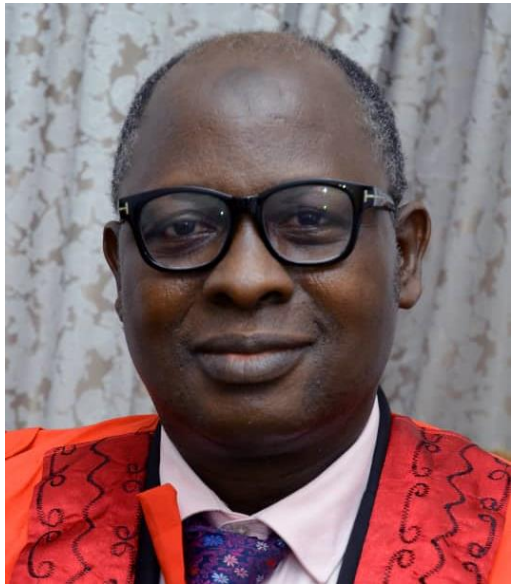

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Slides and recordings from today's session will be posted on the CQUIN website:
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Join us for the next CQUIN webinar:

October 3rd = Integrating HIV & NCD services: data from Malawi, South, Africa, and Zambia

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Thank you/Merci/Obrigado/Asante