

USAID considerations on sustainable, effective, and efficient HIV testing service programs

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Outline

- 1. HTS progress over 20 years has successfully driven us towards Epi control
 - HTS Progress and Programs today
 - Where are we with HTS programmatically
 - USAID/PEPFAR programs appear well optimized, diverse
- 2. Future HTS directions
 - Maintaining minimum standards and approaches
 - Innovations, access, and demand creation



Localization

We prioritize COUNTRY LEADERSHIP and LOCALIZATION to strengthen countries' planning, management, and financing of their HIV responses with optimized domestic resources coordinated with donor support.



Addressing Inequities

We strive to ADDRESS INEQUITIES in access to treatment, care, and prevention services for children, adolescents/youth, women, persons with disabilities, key populations, and other vulnerable populations.



Integration

We advance INTEGRATION of HIV systems and services to ensure person-centered comprehensive care.



Client-Centered Supply Chain

We partner with countries globally to ensure a responsive, CLIENT-CENTERED SUPPLY CHAIN that meets the needs of health systems and individuals.



Core Priorities to Sustain Impact and Accelerate **Progress of** the HIV Response

Resilient Workforce

We acknowledge and support the critical role played by a RESILIENT WORKFORCE in maintaining HIV gains and responding to future threats.





Optimized Health Financing

We advance solutions for optimizing country-level HEALTH FINANCING and support evidence-informed resource allocation aligned with local priorities.

USAID Advances to 2030 through Six Core **Priorities**



HTS Progress and Programs Today





Evolution of HTS: Demonstrable Progress towards Epi Control

The future of HIV testing in eastern and southern Africa: Broader scope, targeted services

Anna Grimsrud 1*, Lynne Wilkinson 1.2, Peter Ehrenkranz 3, Stephanie Behet 1. Thato Chidarikire 1. Tina Chisenga 5, Rachel Golin 1.4, Cheryl Case Johnson 1. Maureen Milanga 10, Obinna Onyekwena 11, Maaya Sundaram 1, Vincent Wong 1. Rachel Baggaley 1.

HTS: 2004

- Prevention paradigm (VCT)
- Extended time to diagnosis
- Limited treatment options
- Low knowledge of serostatus
- Stand alone services
- Limited PITC (outside of ANC)
- No index testing
- 3C focus consent/counseling/confidentiality
- Linkage/continuum not a focus.

HTS: 2024

- Clinical and Prevention paradigm
- Continuum and linkage critical
- Test and Start moved diagnoses and treatment closer together
- Overall higher rates of knowledge of serostatus
- HIVST expansion
- Highly effective use of index testing

Future of HTS?

- Maintenance of minimum approaches
- Testing for Prevention and Treatment
- Smart Integration
- Multiplex-testing
- Multiplicity of approaches to accelerating closing gaps (Men, KP, children/adolescents/youth)
- Deepen network models
- Private sector
- Al use
- Reengagement

- Knowledge of status steadily increased from 5.7% to 84%
- 12 countries reached the 90% target
- 2020: knowledge of status lower among men (79%) than women (87%)
- PLHIV aged 15–24 years were the least likely to know their status (65%)
- The largest absolute gap: men aged 35–49 years, with 701,000 undiagnosed
- Median time to diagnosis decreased from 9.6 years to <u>2.6 years</u>
- HIV testing positivity declined from 9.0% to 2.8%

Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000–20: a modelling study using survey and HIV testing programme data

Katia Giguère, Jeffrey W Eaton, Kimberly Marsh, Leigh F Johnson, Cheryl C Johnson, Eboi Ehui, Andreas Jahn, Ian Wanyeki, Francisco Mbofana, Fidèle Bakiono. Mary Mahy. Mathieu Maheu-Giroux



Of 46 countries, PEPFAR currently has:

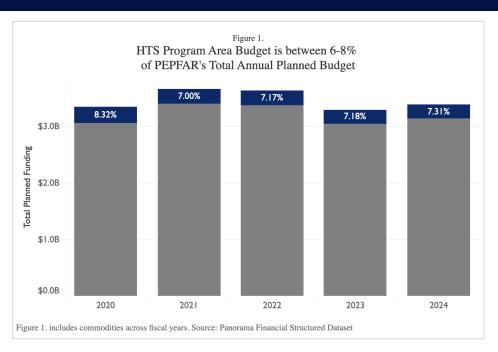
- 23 countries who have reached the 1st 90
- 9 countries who have reached or exceeded the 1st
 95

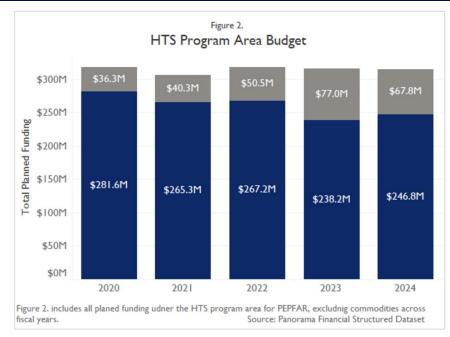
Steady Progress to the 1st 95 Over the Past 5 Years

Adults/PEPFAR											
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Nicaragua								91%	94%		
Cambodia											90%
El Salvador							90%	90%	90%	90%	90%
Guatemala											90%
Nigeria											90%
DRC											91%
Peru											91%
Thailand											91%
Benin										91%	92%
Ethiopia										90%	92%
Burundi								90%	91%	92%	93%
Uganda					90%	91%	92%	92%	92%	92%	93%
Namibia						90%	92%	92%	93%	93%	94%
Nepal										91%	94%
Vietnam											94%
Lesotho			92%	95%	97%	97%	97%	96%	95%	95%	95%
Kenya				92%	93%	93%	93%	93%	94%	95%	96%
Malawi					90%	92%	94%	94%	94%	95%	96%
South Africa				90%	91%	92%	93%	95%	95%	95%	96%
Botswana						93%	94%	95%	96%	97%	97%
Rwanda	91%	90%	92%	93%	93%	94%	95%	95%	95%	96%	97%
Zambia						90%	91%	92%	92%	95%	97%
Zimbabwe					90%	92%	94%	95%	95%	97%	97%
Eswatini		90%	93%	95%	97%	97%	97%	96%	96%	97%	98%
Reach 90 0											
Reaction	0	0	1	2	3 3	6	9	9	8	8 7	14



PEPFAR HTS Financial Landscape: Three budget pictures





HTS Program Budget % of total

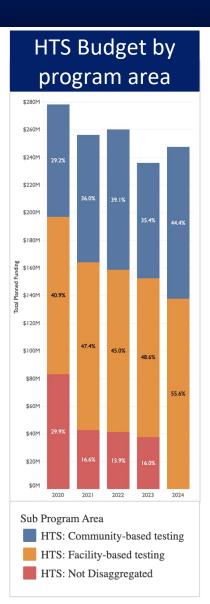
(w. Commodities; no M&O)

HTS Budget total

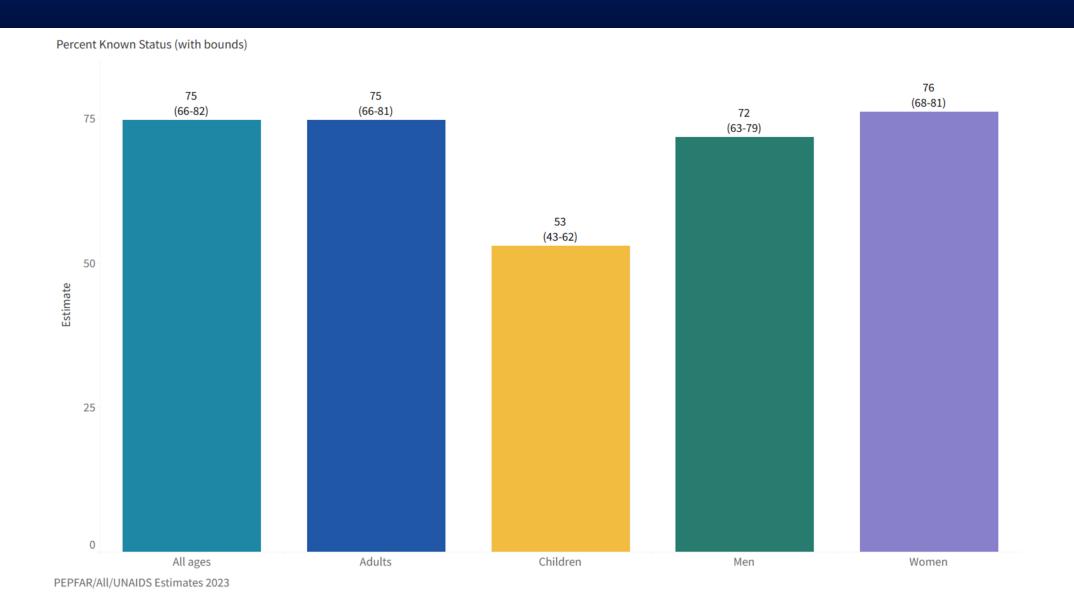
(commodities are added in grey)

Source: EA Structured Integrated DataSet

- Overall flatlined funding, including for HTS
- Commodity funding % have increased each year (includes HIVST)
- Funding for community-based approaches continues to be substantial proportionally.

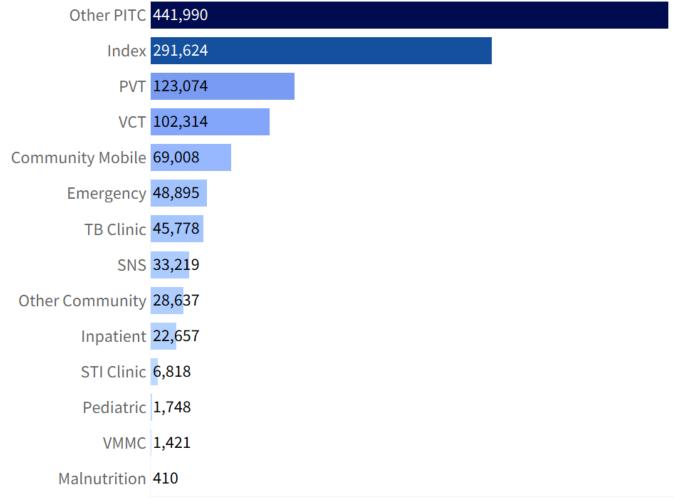


1st 95 is the biggest hurdle, particularly in younger ages



PEPFAR HTS Positives come from a diversity of modalities



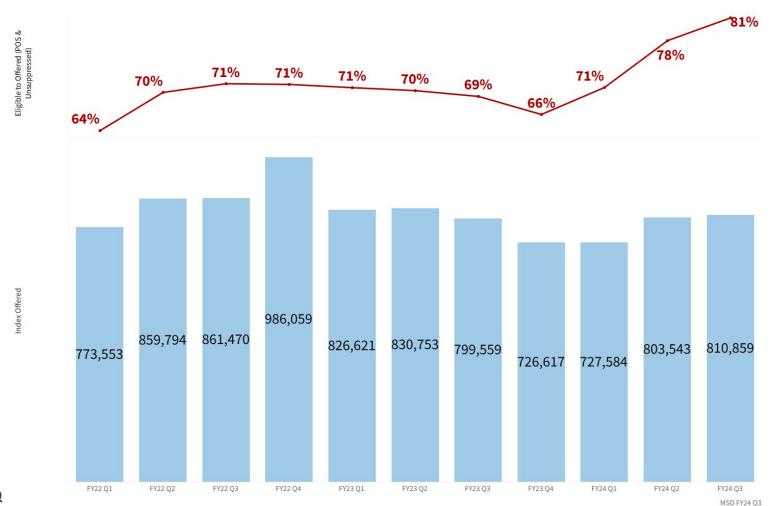


MSD FY24 Q3



Index testing is critical for success in facilities and community

PERCENT ELIGIBLE (POS & UNSUPPRESSED) WHO WERE OFFERED INDEX TESTING SERVICES



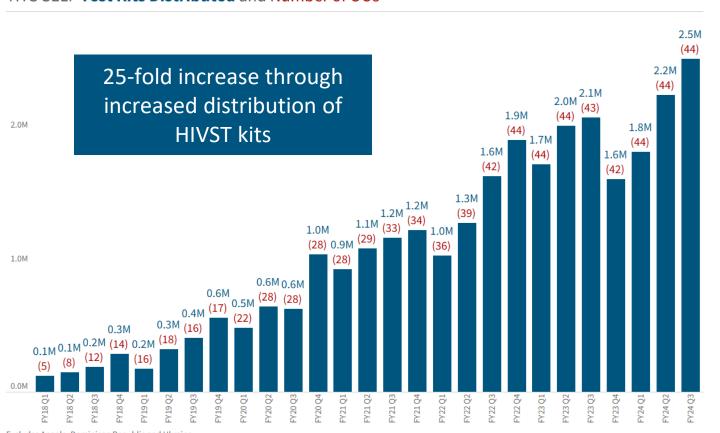
offer of index to all eligible (new POS and non-virally suppressed) individuals

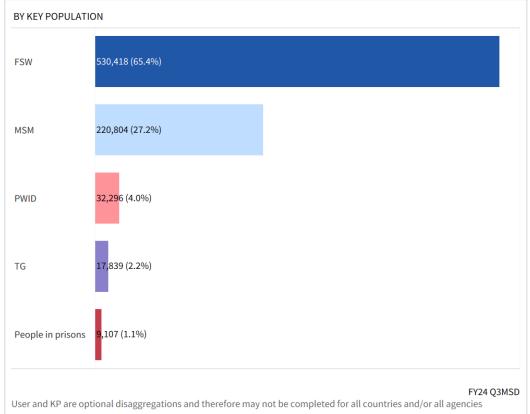
No other metrics are required by PEPFAR



Addressing Gaps through Increased Distribution of HIVST Kits

HTS SELF Test Kits Distributed and Number of OUs



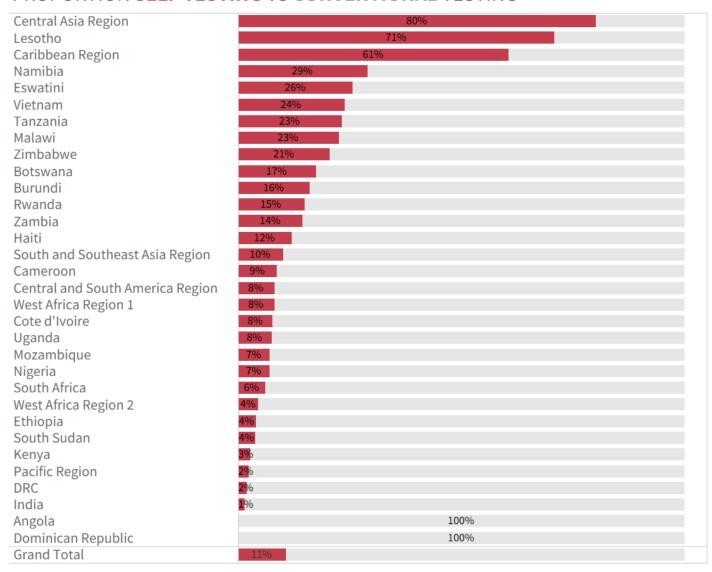






HIVST Expansion: Significant proportion of overall tests in 2024 (Q3)

PROPORTION SELF TESTING VS CONVENTIONAL TESTING

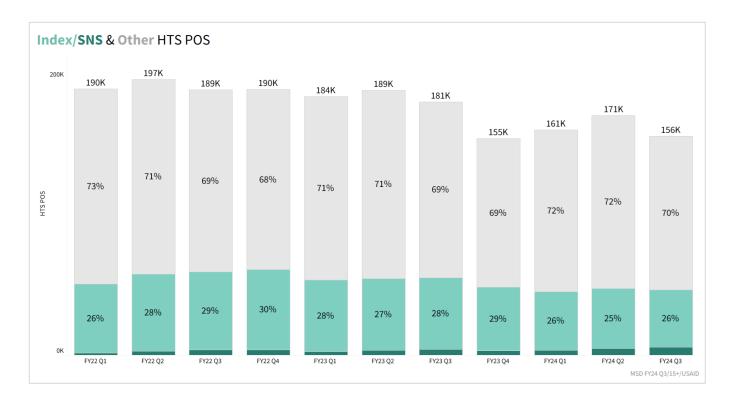


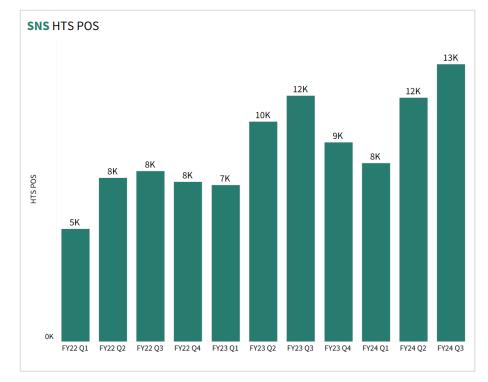


Moving Towards Network Based Testing

WHO Updated Recommendation: Network-based testing is recommended including the use of social network testing, family and household testing services and partner services.

Since the addition of SNS as the most recent HTS modality - OUs have continued to add and scale this strategy for use, with USAID conducting over 13K tests for SNS.

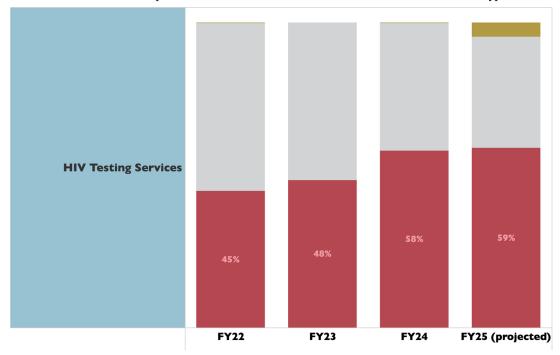


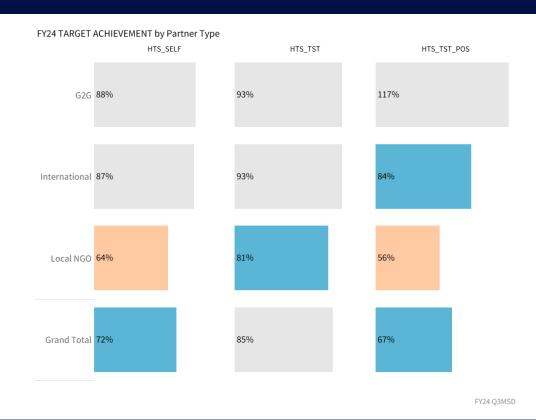


Shift to Local Partners has been effective at HTS



Local and TBD/Expected Local Not Local Not Awarded or TBD/Unknown Partner Type





- Funding proportions have increased globally to 59%
- Performance comparable to International IPs, lower POS results in 2023

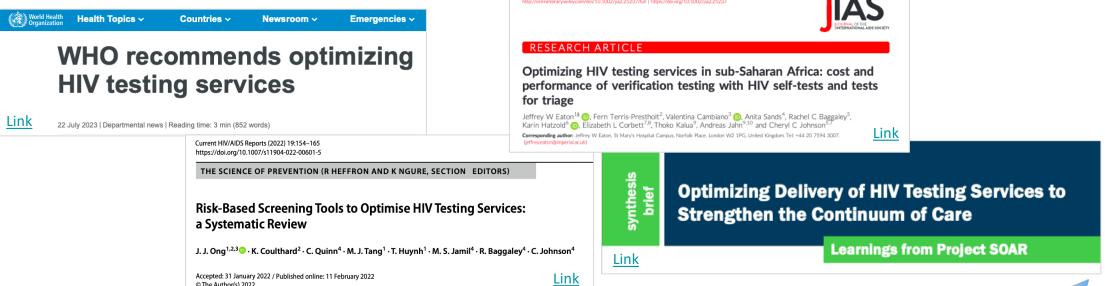


The Assumption: HTS is Already 'Optimized'

Eaton JW et al. Journal of the International AIDS Society 2019, 22(S1):e25237

"Optimize" has often been used in reference to HIV Testing Services and can have numerous different meanings: e.g. optimizing quality products and an accurate diagnosis vs. optimizing resources and case finding through positivity (at the expense of volume) vs. optimizing coverage with a highly targeted with a mix of strategies to reach people and populations at highest risk.

Note that PEPFAR has taken steps to recalibrate prior hyperfocus on optimizing positivity (i.e. 'yield' and risk screening tools)



PITC Already Widely Optimized

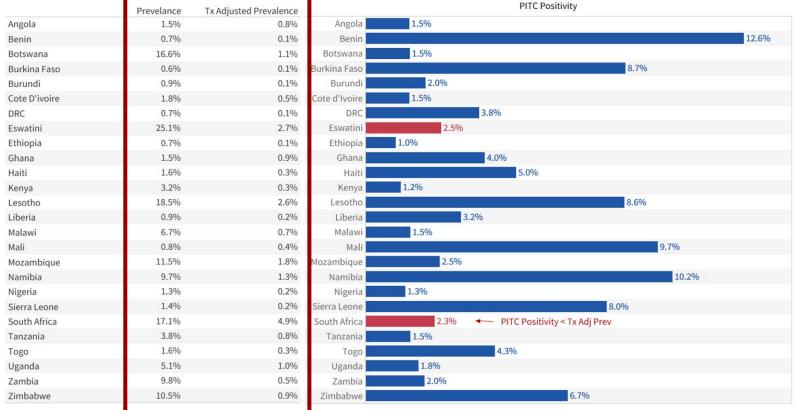
Treatment Adjusted Prevalence

=

Estimated Number of Adult PLHIV - Number of Adult PLHIV on ART

Total Adult Population - Number of Adult PLHIV on ART

FY24 PITC Positivity vs Dec 2023 Treatment Adjusted Prevalence



Note: Treatment-adjusted prevalence estimates the expected positivity in a testing program by accounting for both national HIV prevalence and ART coverage. The treatment-adjusted prevalence is calculated to account for individuals with HIV who are a) diagnosed, b) previously diagnosed and treated naive, or c) previously diagnosed with an interruption in treatment. To account for 2nd 95 achievements, individuals who are on ART are excluded from the calculation.



COUIN 8^t

HTS Future Directions for USAID HTS Programs



Chongwe Rural Health Center, Zambia



The Underlying Span of Testing That Must Be Maintained

Routine access to testing through a mix of modalities must be maintained to ensure we're not diagnosing people late in disease progression.

From Grimsrud et. al. (Link):

"HTS programs use a **strategic mix of modalities focused on people most likely to have undiagnosed HIV**, those who are not on
ART, and people who are more vulnerable to HIV acquisition".

"HTS programs should not reduce the volume of HIV testing. Rather HTS programs should broaden the scope of testing to encapsulate both prevention and treatment objectives and prioritize services to the people at the highest risk of HIV".

PLOS MEDICINE

DOLLOV FORU

The future of HIV testing in eastern and southern Africa: Broader scope, targeted services

Anna Grimsrudo 1*, Lynne Wilkinson 12*, Peter Ehrenkranzo 3*, Stephanie Behei 4, Thato Chidarikire 3*, Tina Chisenga 6*, Rachel Golin 7*, Cheryl Case Johnson 3*, Maureen Milanga 10*, Obinna Onyekwena 11*, Maaya Sundaram 3*, Vincent Wong 9*, Rachel Baggaley 3*

1 IAS-International AIDS Society, Cape Town, Western Cape, South Africa, 2 University of Cape Town, Cape Town, Cape Town, Cape Town, South Africa, 3 Bill A Minion States Foundation, Seatifite, Weshington, United States of America, 4 Cantres for Disease Control and Provention, Allarria, Georgia, United States of America, 5 South Africa, National Department of Health, Precional, Gastlering South Africa, 6 Zambia Ministry of Health, Lusakia, Zambia, 7 Office of the Global AIDS Coordinator and Health Dipionnecy, Washington Dc, United States of America, 8 United States appropriate International Development, Washington Dc, United States of America, 8 United States Agency for International Development, Washington Dc, United States of America, 9 World Health Organization, Geneva, Switzerland, 10 Health GAP, Nairobi, Kenya, 11 The Global Fund, Geneva, Switzerland, 10 Health GAP, Nairobi, Kenya, 11 The Global Fund, Caperva, Switzerland, 10 Health GAP, Nairobi, Kenya, 11 The Global Fund, 11 August 11 August 12 A



G OPEN ACCESS

Citation: Grimsrud A, Wilkinson L, Ehrenkranz P, Behel S, Chidarkire T, Chisenga T, et al. (2023) The future of HIV setting in eastern and southern Africa: Broader scope, targeted services. PLoS Med 20(3): e1004182. https://doi.org/10.1371/journal. pmd. 1104182.

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Competing interests: The authors have declared that no competing interests exist.

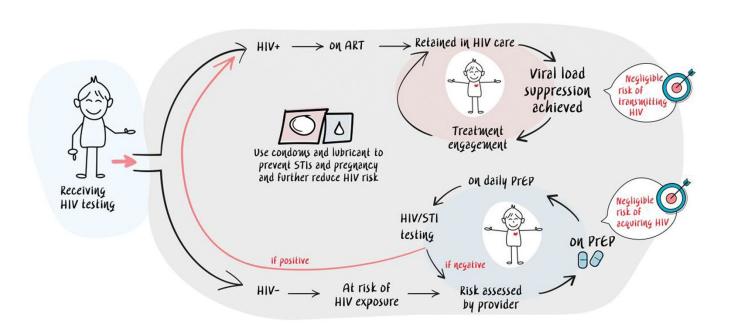
Summary points

- Scale-up of HIV testing services (HTS), primarily through routine offer of HIV testing in health services, has led to an increase in the proportion of people with HIV who know their status and are accessing HIV treatment.
- In eastern and southern Africa (ESA), home to more than half of people living with HIV globally, many countries are close to reaching global targets for HIV treatment and viral suppression, with slower progress towards the global target that 95% of people should know their HIV status. Given this, it is critical to update the approach to HIV testing to reflect changes in the HIV epidemic, the response to it, and to acknowledge ongoing resource constraints.
- An expert consultation series defined this updated approach as a shift to "broader scope, targeted services." Over the next decade, HTS in ESA should implement a status-neutral approach that maintains once testing services to reach the greatest number of people with HIV not on treatment, while broadening the scope to support linkage to appropriate prevention and treatment. It is important that HTS programs use a strategic mix of modalities focused on people most likely to have undiagnosed HIV, those who are not on ART, and people who are more vulnerable to HIV acquisition.
- Ten key themes for the future of HTS were articulated. The most critical are: promote a status-neutral approach to HTS; realize the potential of HIV self-testing (HIVST); prioritize facility-based HTS; reframe retesting among those previously diagnosed but not currently on antiretroviral therapy (ART) as an opportunity; and involve and invest in community leadership and community-led monitoring (CLM) to ensure HTS meets the needs and preferences of clients.

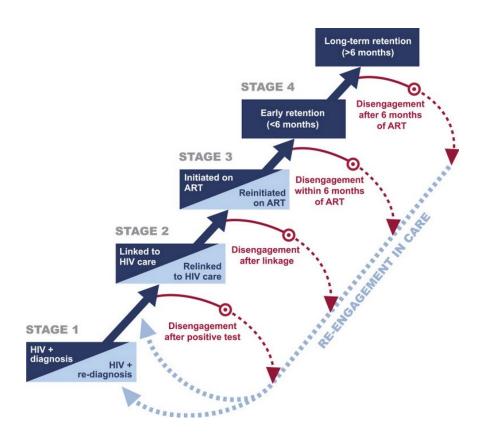
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Evolution of HTS: Refining Program Models, How can HTS programming be better leveraged?



HTS and Linkage to Prevention/Treatment Phanuphak et al. 2020



Re-engagement along the cascade Ehrenkranz et al. 2021



5C's as PEPFAR minimum standards for HTS

The WHO Minimum Standards set forth in the 5 C's apply to all HTS in any setting and circumstance and must be maintained.

- Consent: People receiving testing services must give informed consent to be tested and counseled.
- **Confidentiality**: HTS must be confidential. Any client/provider discussions will not be disclosed to anyone else without the express consent of the person tested.
- Counseling: HTS must be accompanied by appropriate and high-quality post-test counseling based on the specific test result and status reported.
- **Correct**: HTS providers would strive to provide high quality testing services and QA mechanisms should ensure that people receive a correct diagnosis. All people who receive a seropositive HIV diagnosis should be retested to verify their diagnosis before initiation of treatment.
- **Connection**: Linkage to prevention and treatment services must be offered with effective and appropriate follow-up.

Sustainability beyond the 1st 95: Basic Essential HIV Testing Services that must be Maintained

- ANC (including maternal retesting)
- Early Infant Diagnosis
- High risk pediatric testing (e.g. malnutrition, inpatient, etc)
- Clinical and symptomatic provider initiated testing (incl. TB & STI)
- Facility based index testing
- Testing within key populations
- Testing to initiate and continue PrEP
- HIV self-testing (including oral fluid and blood based options)
- * These services should be maintained according to applicable WHO recommendations and standards.
- ** No individuals who seek HTS should be denied services.



USAID aligns w WHO: Not Support Using 15+ Screening Tools

WHO Stance: HIVST can replace risk screening tools to optimize testing among those presenting at health facilities. (pg 88 of 2024 Guidelines)

PEPFAR Stance:

For programs that are currently utilizing highly sensitive, validated, **screen-in** tools, efforts should be maximized to **support prompt re-engagement** for individuals identified as having an interruption in treatment. Due to 1) the lack of screen-in tools that are validated with appropriate sensitivity, 2) the increased availability of highly sensitive, highly specific, and more affordable HIV self-test (HIVST) assays, all programs are encouraged to optimize the use of HIVST within PITC and in other testing sites where staff and HTS coverage may be limited. (FY24 Tech Cons Pg 168)

HIV risk screening tools should NEVER be used to reduce testing volume

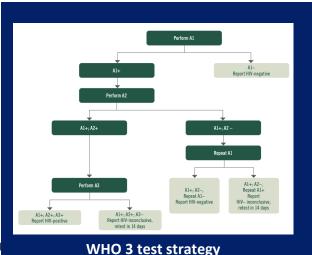
Relevant publications and links:

- Should HIV self-testing be offered as an additional testing option in health facilities?: A systematic review and metaanalysis, McGee, July 2023 IAS
- Systematic Review on the use of risk based screening tools, Ong et. al., Feb 2022
- Slide deck from WHO Webinar on the use of risk



Expanding African Manufacturing While Ensuring Quality

- PEPFAR aims to procure 15 million HIV tests produced by African manufacturers in 2025 at an estimated cost of \$20 million
- PEPFAR will make key adjustments to its procurement policies to better support emerging African manufacturers to scale-up over time
- WHO PQ is the current standard for PEPFAR RDT Procurements
 - ≥99% Sensitivity
 - ≥98% Specificity
- National regulatory approval required for countries



Verification of Testing Algorithms is Essential

- Verifying testing algorithms provides evidence that a specific combination of three products will accurately diagnose HIV infection
- Prior to making procurement decisions, countries should conduct a verification study that assesses the level of shared false reactivity among products
- Tests used in the algorithm should share the least, or no, common cross-reactivity



GF ERDP Request



Testing for Prevention and Treatment

HTS for Prevention and Treatment is an approach that ensures individuals are referred to prevention services and linked to treatment services appropriate to their individual needs, *regardless of their serostatus*.

- HTS for Prevention & Tx DOES NOT equal universal testing.
- HTS for Prevention & Tx is:
 - A 'whole person' approach, emphasizing high quality care to engage and retain people in services regardless of if the services are for prevention or treatment.
 - Is centered on supporting a person's needs through timely linkage to person-centered HIV treatment initiation, reengagement, and/or referral to prevention services.

HIV testing for treatment and prevention

- Broader scope than case finding
- Actively supports linkage to and engagement in prevention programs

Terminology Differences:

WHO: Testing for Treatment and Prevention

UNAIDS: Status Neutral



WHO Recommends against Recency Testing w/in HTS

WHO Recommendation: HIV recency testing is not recommended as part of routine HIV testing services (pg 132)

Remarks: This recommendation is to exclude recency testing from routine HTS. HTS is defined as a package of services including brief pre-test information and post-test counselling; linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.

Recency assays have been used to estimate HIV incidence in representative cross-sectional surveys and in epidemiological studies, which can facilitate more strategic targeting of testing and prevention interventions, optimize allocation of resources and measure progress in the HIV response. WHO and UNAIDS have issued guidance on this use of recency assays for HIV surveillance

Relevant publications and links:

- PEPFAR SAB report
- AMFAR 'Blinded by our own data' report
- UNAIDS technical guidance on recency surveillance

WHO 2024 Guidance



Dual HIV/Syphilis Testing Recommended w/ in ANC & KP

WHO Recommendation: Dual HIV/syphilis RDTs can be the first test in HIV testing strategies and algorithms in ANC settings and for key populations (pg. 22)

Dual tests should not be used among people with HIV on ART or among people already diagnosed and treated for syphilis during pregnancy

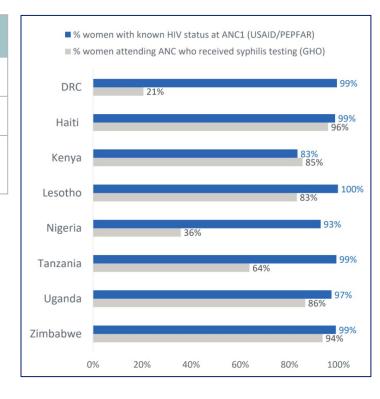
WHO aiming to release multiplex guidance in 2025

WHO PQ Dual Tests	Manufacturer	Price
Bioline HIV/Syphilis Duo	Abbott Diagnostics	\$1.50 USD
Standard Q HIV/Syphilis Combo Test	SD Biosensor, Inc	\$0.95 USD
First Response HIV 1+2/Syphilis Combo Card Test	Premier Medical Corporation	\$0.95 USD

Use of dual tests allows for cost saving measures as well as expanded coverage of diagnostic services.

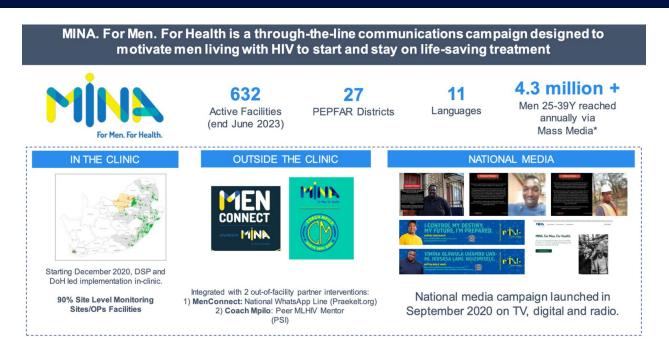
If using a dual HIV/syphilis test, it is **imperative that treatment w/ BPG be available** at the site level.

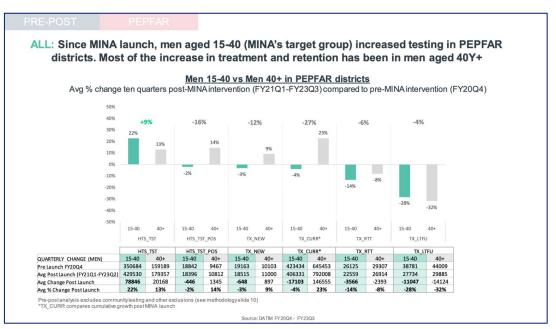
Note that there is only one <u>WHO PQ BPG</u> which is manufactured by Laboratorio Reig Jofre.



From: USAID Poster on dual HIV/syphilis efforts at AIDS2024 #TH-PE-E-600

Applying Social/Behavior Change and Behavioral Science to address 1st 95 and Testing/Tx Challenges





- PEPFAR and USAID emphasizing leveraging behavioral science/ social and behavior change (SBC) interventions for 1st 95 goals.
- MINA/South Africa: example increasing testing/diagnoses among adult men.
- Provider and client behavior how best to leverage for target gap populations?
- Small investments may help amplify HTS results in uptake, diagnosis, linkage

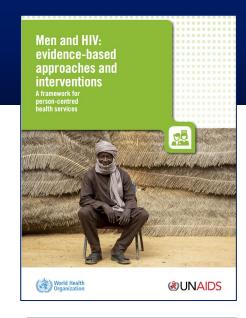


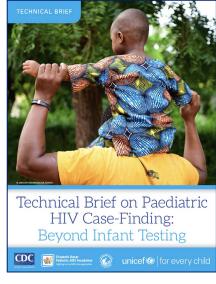
HTS effectiveness: Addressing gap populations: children, adols, men

- "What got us here won't get us there"
- Lots of frameworks no "silver bullets".
- What's effective may not be efficient
- Behavioral/SBC interv.: communication, HCD, marketing
 - Provider behav, demand, disclosure, barriers/facilitators etc.
- HTS Accessibility/Acceptability:
 - modalities to meet populations where they are, and reflect their needs.
 - multiple approaches will be critical
- Ensuring Linkage to Tx & Prevention



<u>Circle of Care</u>: SBC supports thentire service continuum







Conclusion

Current PEPFAR/USAID *HTS Programming has evolved and achieved much*

- Evolved over 20 years: diversity of access and impact (1st 95!)
- PEPFAR HTS funding stable, flatlined, with some shifts.
- Increased local partner proportions

The **future of HTS** is coming into focus (but cost neutral?)

- WHO recommendations maintained: 5Cs, guidelines, 3-RTK, etc
- Multiple approaches that align with gaps, geographies
- Increased focus on linkage to prevention
- Reengagement
- Leveraging social and behavior change (SBC) interventions
- Utilization of multiplex w/ treatment availability.
- Local manufacturing of RDTs expands

"the future is already here, it's just not evenly distributed"

William Gibson

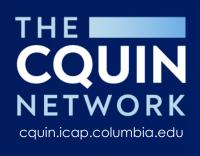












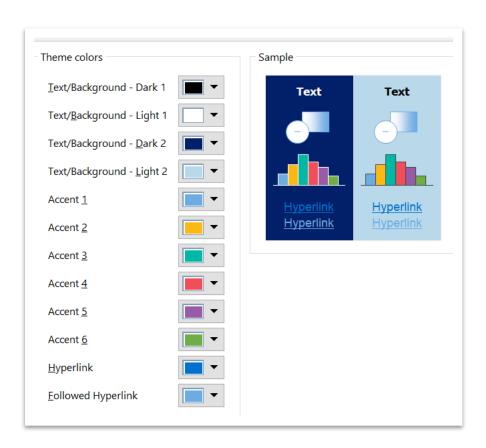
Thank You!

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Context and Objectives-SLIDE TO BE DELETED-1

Background

- Adoption of a 3-RTK algorithm is ongoing in some countries (e.g. Uganda, Nigeria) and is yet to start in others
 e.g. in Rwanda. Irrespective of the country's epidemic profile (High or Low burden, High or Low testing
 coverage), WHO recommends the use of a 3-RTK algorithm to reduce misdiagnosis of HIV.
- Attaining the 2030 goal of ending HIV/AIDS as a public health threat requires country programs to deliver sustainable, effective and efficient HIV services. In the testing space, effectiveness and efficiency can be attained through a systematic application of tools and frameworks in a differentiated approach. In this session, panelists will discuss guidance and tools that promote delivery of sustained effective and efficient HIV testing services, and the progress on adopting a 3-RTK algorithm to minimize HIV misdiagnosis.

Session objectives:

- Understand global guidance that promotes delivery of sustained effective and efficient HIV testing services amidst dwindling financial resources
- Review country updates on:
- Adopting a 3-RTK based algorithm

