



# AIDSFREE NIGERIA

# HIV SELF-TESTING

# PROJECT REPORT

APRIL 2019





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## AIDSFree

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# ACRONYMS

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AIDSFree	Strengthening High Impact Interventions for an AIDS-free Generation
HIVST	HIV self-testing
HTS	HIV testing service(s)
MER	monitoring, evaluation, and research
NASCP	National AIDS and STI Control Programme
PEPFAR	U.S. President’s Emergency Plan for AIDS Relief
PNS	partner notification services
USAID	United States Agency for International Development





# BACKGROUND

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## The Situation

In December 2016, the World Health Organization, or WHO, released global guidelines recommending assisted partner notification services (PNS) and HIV self-testing (HIVST) as new strategies to reach high-risk and hard-to-reach populations with HIV testing (WHO 2015). HIV self-testing is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts. HIV self-testing does not provide a definitive diagnosis; rather, all reactive HIVST results need further testing by a health provider, following the national HIV testing algorithm. HIV self-tests are available in the United States and many countries in Europe, and increasingly throughout sub-Saharan Africa and other parts of the world.

Studies from Kenya, Lesotho, Malawi, Zambia, and Zimbabwe suggest that HIVST is feasible, acceptable, and performed with high-quality when certain conditions are met (Choko 2015, Indravudh 2017, Kurth 2016, Mavedzenge 2017, Sibanda 2017, Zanolini 2017, Zerbe 2015). HIVST can improve program outcomes, including identification of newly diagnosed people living with HIV and linkage with care and treatment (Johnson 2017, Moore 2017). It is cost-effective, and reports of social harms following HIVST are rare (Cambiano 2015, Choko 2015). Policies supporting HIVST exist in at least 12 sub-Saharan African countries to date, and are under development in at least nine more (WHO and Unitaid 2018). In October 2017, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) included a new HIVST indicator in its monitoring, evaluation, and research (MER) guidance for implementing partners (number of HIVST kits distributed), with recommendations for disaggregations and additional data elements for describing and tracking HIVST implementation (PEPFAR 2017). However, HIVST technical and monitoring and evaluation recommendations have not been widely implemented in Nigeria, and although the National HIV Testing Services (HTS) guidelines now reflect this new strategy, the broader National Prevention, Treatment, and Care guidelines do not. In Nigeria, HIVST has not been implemented to scale, and thus questions remain about whether this would be a successful approach for reaching new HIV-positive clients and linking them to care in Nigeria. The government of Nigeria and PEPFAR are working to improve the availability of HIVST products, the process for offering and distributing HIVST kits, and the quality and scale-up of these services in Nigeria.



# OBJECTIVES

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## Introduction

The primary objective of the AIDSFree HIVST technical assistance was to improve policy and implementation resources available for the scale-up of HIVST in Nigeria. The AIDSFree HIVST technical assistance project convened stakeholders to discuss key technical issues in HIVST and provide recommendations for consideration by PEPFAR and the federal Ministry of Health/National AIDS and STI Control Programme (NASCP) for incorporation into the national HIVST guidelines. The primary focus technical area is HIV testing services, which includes linkage to HIV care and treatment.



## Findings

### Stakeholder Meetings

An initial stakeholder meeting was held in June 2018 at the NASCP facilities. This half-day meeting allowed key stakeholders from donors, regulatory agencies, and implementing partners to discuss key technical issues related to HIVST in Nigeria. Kristina Grabbe (AIDSFree) presented a global status update on HIVST, providing evidence about the benefits and challenges of HIVST implementation worldwide. The meeting included representation from the following agencies:

- Federal Ministry of Health/NASCP
- National Agency for the Control of AIDS
- U.S. Centers for Disease Control and Prevention
- USAID
- U.S. Department of Defense, Walter Reed Project
- UNICEF
- Joint United Nations Programme on HIV/AIDS
- World Health Organization
- Clinton Health Access Initiative
- FHI 360
- Society for Family Health
- World Bank
- AIDS Healthcare Foundation
- AIDSFree
- Jhpiego/Maternal and Child Survival Program

Subsequently, a two-day meeting was held with the national HIV testing services task team to review an initial draft of the operational guidelines for HIVST prepared by Ms. Grabbe in August 2018. This meeting was held in September of 2018. NASCP Head of Prevention (Dr. Deborah Odoh) and National Coordinator (Dr. Sunday Aboje) opened the meeting, acknowledging the importance of HIVST as an additional HIV testing strategy and the opportunity it presents for reaching people who have not yet tested for HIV. Ms. Grabbe presented again on the state of HIVST globally, highlighting current evidence and policy issues arising from work in other countries and Nigeria. Dr. Sylvia Adebajo presented on a Population Council HIVST study with men who have sex with men in Nigeria, indicating OraQuick HIV self-tests are feasible and acceptable among this population. Joy Ogbu, Head of Laboratory, NASCP presented an update on the valuation of HIVST kits in Nigeria, reinforcing that there is currently only one approved HIVST for use in Nigeria (Amethyst) but that other kits are encouraged to undergo evaluation. OraSure Technologies was expected to submit its kit for evaluation in September 2018. Ima John-Dada and Ms. Grabbe presented the draft operational guidelines for HIVST chapter by

chapter, at which point the group broke into smaller groups to review and edit each chapter. At the end of day two, groups presented their edits and recommendations to the larger group and a timeline for completing the guidance (after the completion of the AIDSFree Project) was drafted.

# DISCUSSION & RECOMMENDATIONS

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The meetings facilitated by AIDSFree provided the opportunity to discuss key technical issues related to HIVST that will be incorporated into national HIVST operational guidance. It is recommended that following these meetings, guidelines be finalized, edited, and reviewed by the task team. The federal Ministry of Health shall host another meeting in November for the task team to adopt the guidelines, and guidelines shall be printed in January 2019 and disseminated nationwide.





# CONCLUSION

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The work completed under this AIDSFree program helped to initiate the development of national HIVST guidelines, bringing Nigeria into the fold of countries that have updated policy recommendations to recommend this innovative approach to case finding. Having a policy in support of HIVST will allow Nigeria to advance HIVST kit evaluation and approval and get more high-quality HIVST products on the market. The policy will also allow implementing partners to begin offering HIVST, and will outline standards to ensure high-quality service delivery.



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# ANNEX 1. JUNE 2018 HIV SELF-TESTING TECHNICAL CONSIDERATIONS PRESENTATION

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# **HIV Self-Testing Technical Considerations**

Kristina Grabbe and Michelle Willcox  
NASCP Conference Room, Abuja  
June 22, 2018  
[Jhpiego/MCSP/AIDSFREE](#)

# Objectives

- Review experiences and lessons learned with HIVST in multiple countries to date
- Identify priorities for HIVST implementation in Nigeria
- Outline donor and partner plans for HIVST support in Nigeria

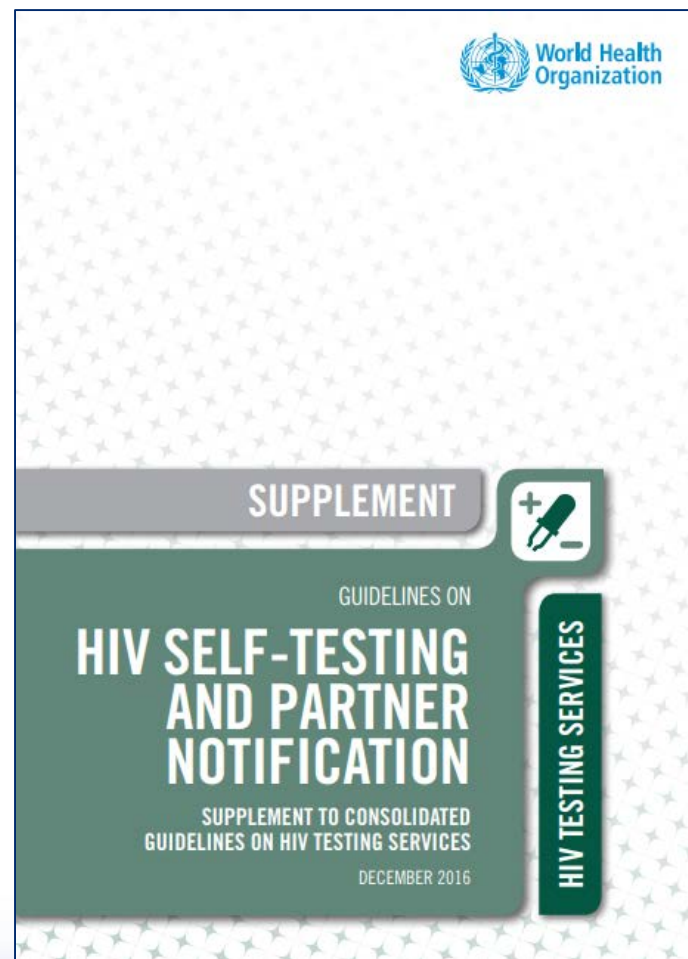
# Countries with Operational Guidelines and Implementation Materials

- Kenya
- Malawi
- South Africa
- Tanzania



# WHO Guidance on HIV ST and PNS

- Original guidance 2015
- Updated guidance 2016
- Aims:
  - Support implementation & scale-up
  - Provide guidance on testing approach integration into HTS at community and facility levels
  - Support introduction of HIVST as a formal HTS intervention using quality-assured, locally and internationally approved products
  - Show new HTS approaches can contribute to closing the testing gap



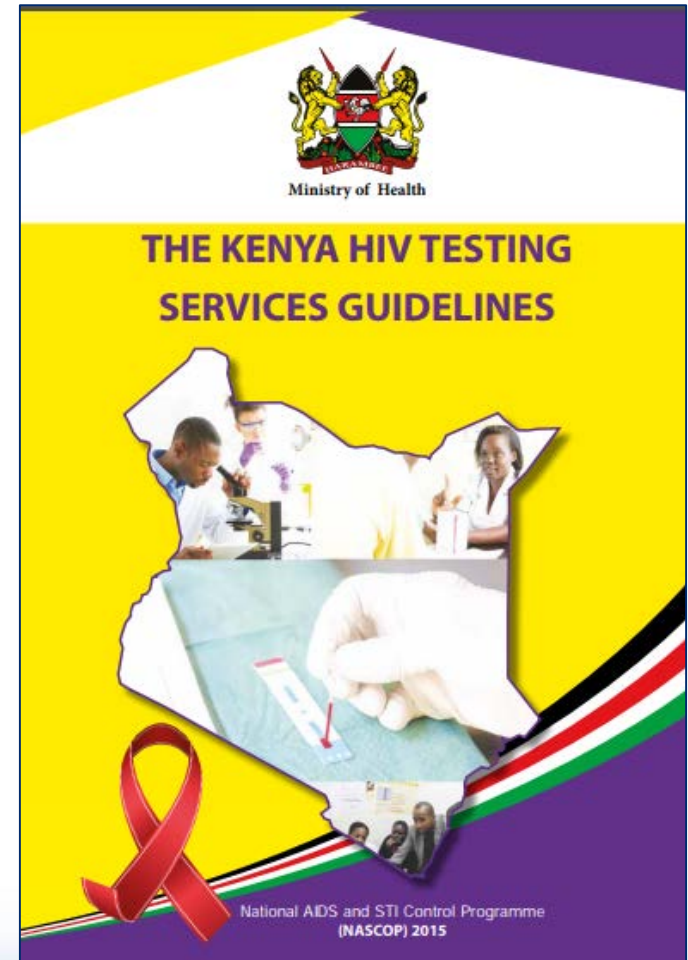
# HIV Self-Testing Recommendation (WHO, Dec 2016)



**HIV self-testing** should  
be offered as an  
additional approach to  
**HIV testing services**  
*(strong recommendation,  
moderate quality evidence)*

# Kenya Operational Guidance on HIV ST

- Original guidance 2015
- HIV ST included as an approach within HIV Testing Services
- Specific guidance included on use of self-testing to increase access to knowledge of HIV status in Kenya



# Kenya Journey to HIVST Roll Out

- HIVST first included in the national guidelines since 2009, but took 7 years for it be implemented
- 7 years of formative research on HIVST
  - 72% of respondents in last KAIS 2012 indicated that they would be willing to use a self test kit
  - Acceptability: 99% returned for confirmatory testing
  - Found a higher proportion of undiagnosed infection
  - 83% started ART on day of confirmation
  - Packaging
  - Social harms

# Progress in Kenya Towards Adoption of HIVST

- Inclusion in Kenya HIV Testing Guidelines 2015
- HIV Self Testing operational manual develop
- HIV Self testing to be launched together with PrEP at end of April
- Three HIV Self test kits registered in country by Pharmacy and Poisons Board
- Lab board listing ongoing
- Resource mobilization through PEPFAR, Global Fund and UNITAID

# Evidence on HIVST

- High uptake of self-testing has been reported among health care workers
- High uptake of HIVST specifically reported among youth, men and those who had not tested before
- Benefits: First time testers, privacy, convenience, reduced stigma
- Pharmacies identified as point of distribution
- Need to address pre-test information/counseling
- There is no significant harm associated with HIVST

# What is HIV Self-Testing (HIVST)?



Collects



Performs

Interprets

Reactive results need confirmation by trained tester using a validated national algorithm

# Guiding Principles for HIVST: 5Cs

- Consent
- Counseling
- Confidentiality
- Correct Test Results
- Connection



# Delivery Approaches

- **Unassisted HIVST:** Individual obtains an HIVST kit and performs the HIV test following the instructions in the package insert.
- **Directly assisted HIVST:** Individual performing HIVST receives in-person demonstration from a trained provider or peer before or during HIVST, including instructions on how to perform self-test and interpret the result.
  - This assistance is provided in addition to the manufacturer supplied instructions for use and other materials found inside HIVST kits.
  - May be observed or unobserved.

# Distribution Channels

- Open access
  - Pharmacies, Internet, Private Providers
- Community-based
  - CHW, Peer Educators, VCT
- Facility-based
  - PITC, ANC, Kiosks

# HIVST DISTRIBUTION MODELS

## Open Access

- Pharmacies, chemists
- Internet, social media
- Vending machines
- Private providers

## Community-based

- PE, CHW, Outreach
- Workplaces
- Colleges and Universities
- VCT

## Facility-based

- Integrated with PITC
- Kiosks
- Through ANC and PLHIV
- Integrated with KP services (including PrEP) and VMMC

### Directly Assisted

- Trained distributor provides brief demonstration, gives information
- Can observe or provide assistance during self-testing (optional)
- Instruction-for-use included in kit

### Unassisted

Instructions-for-use included in the kit:

- Pictorial/written
- Include a link to a video and/or hotline number
- Multimedia instructions (tablet)
- Remote support via SMS, QR code, or mobile messaging applications
- Package insert included in the kit

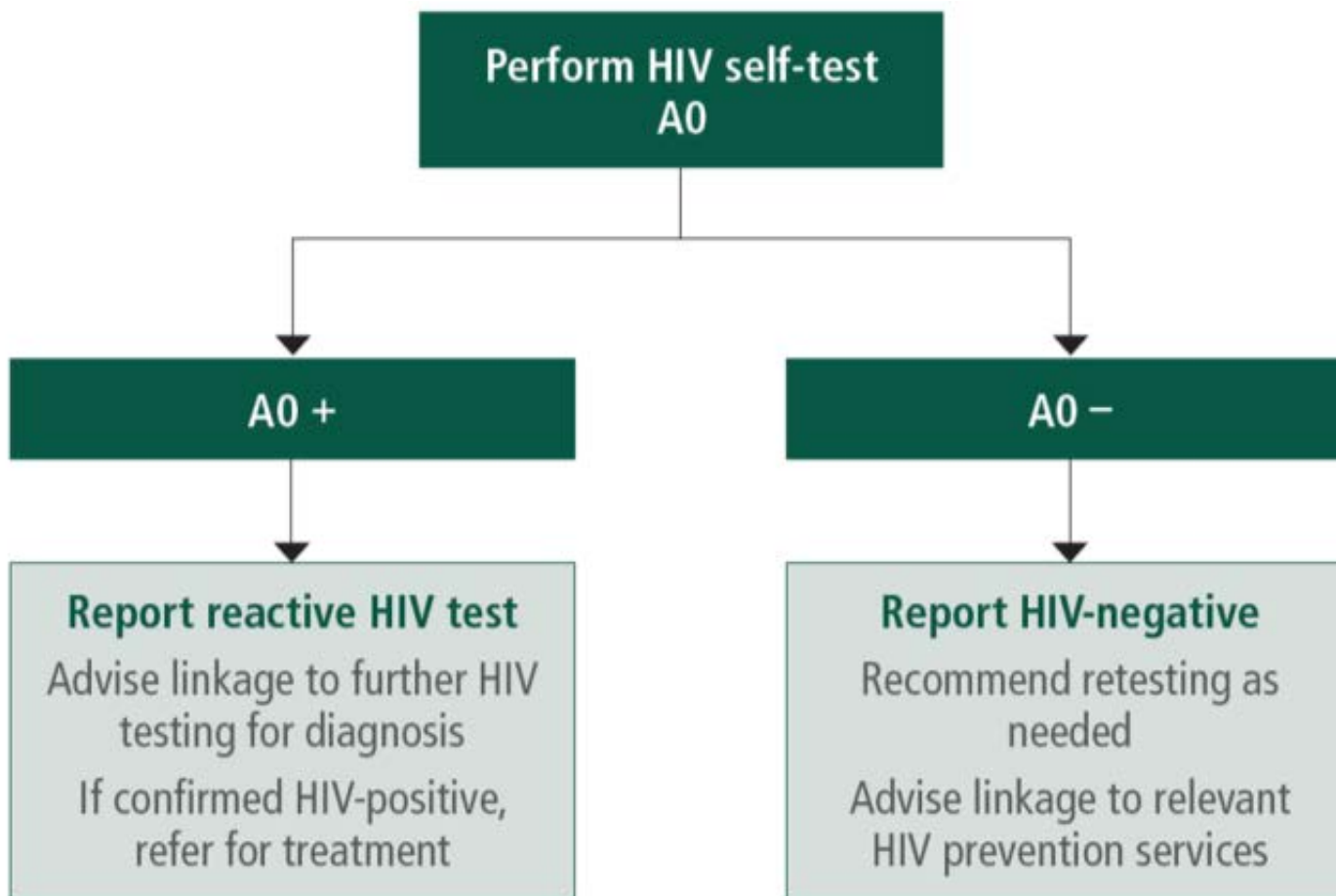
# Target Populations

- General Population
  - Partners of PLHIV, including male partners of women in PMTCT (PNS)
  - Men
  - Adolescents and/or Children
- Key Populations
  - FSW
  - MSM
  - PWID

# Definitions: HIVST Providers

- **Service provider:** In the context of HIVST is an organization, business or individual which offers service to others either in exchange for payment or for free.
- **Vendor:** In the context of HIVST is an outlet which sells directly to the consumer e.g. chemists.
- **Distributor:** An agent who supplies HIVST kits to stores and other businesses that sell to consumers e.g. wholesale.

# HIVST Algorithm



A0= Assay 0 (test for triage)

# Interpreting HIVST Results

- **Reactive results:** HIV antibodies are present in the blood or oral fluid sample.
  - Anyone with a reactive HIVST result must have their test confirmed by additional HTS by a trained provider following the national HIV testing algorithm
- **Non-reactive results:** HIV antibodies were not found in the blood or oral fluid sample.
  - Anyone with a non-reactive HIVST result does not need further testing but should be supported to re-test if they have had a recent potential HIV exposure or are at on-going HIV risk

# HIVST Diagnostics



Test Kit Name	Specimen	Approval Status	Sensitivity	Specificity
Atomo HIV Self-Test	Whole Blood	GF ERPD	On request	On request
INSTI HIV Self Test	Whole Blood	GF ERPD	On request	On request
Biosure HIV Self Test	Whole Blood	GF ERPD	On request	On request
SURE CHECK HIV Self-Test	Whole Blood	GF ERPD	On request	On request
OraQuick HIV Self-Test	Oral Fluid	WHO PQ	99.02%	100.00%



# OraQuick HIV Self-Test





Home	Company	Products	Innovation	Investors	News & Events	Contact
Infectious Disease		Substance Abuse Testing	Cryosurgery	Insurance	Toxicology/Forensics	OTC

Infectious Disease


- OraQuick® In-Home HIV Test
- OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test
- OraQuick® HCV Rapid Antibody Test
- OraQuick® Ebola Rapid Antigen Test
- OraQuick® HIV Self-Test
- OraSure QuickFlu® Rapid Flu A+B Test
- OraSure® HIV-1 Oral Specimen Collection Device

Patient Information



OraQuick HIV Self-Test - English

OraQuick HIV Self-Test\_English

 Download Instructions - English

English

Afrikaans	Bemba	Chichewa	Mu Kinyarwanda
Kiswahili	Luganda	Ndebele	Nyanja
Sepedi	Setswana	Shona	Tonga
Tsonga	Vietnamese	Zulu	

# Jhpiego/AIDSFree Technical Assistance

- Support development of operational resource package for HIVST
  - Operational Guidelines
  - Job Aids and Implementation Materials
  - IEC/Promotional Materials
  - Required Indicators
  - Process/Recommended Program Indicators
  - Data Collection and Reporting Tools

For more information, please visit  
**[www.mcspprogram.org](http://www.mcspprogram.org)**

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# Understanding the Market Based Challenges and Opportunities for HIV ST

# Market Constraints Globally (PSI, 2016)

1. Lack of demand for quality-assured HIVST translating into concrete purchase orders
2. Price pressure from donors and governments
3. Lack of incentives to innovate for further product development
4. Fragmented and uncertain regulatory environment for manufacturers
5. Lack of ownership of and investment in key market functions

# Relevant Recommendations from Global Market Analysis (PSI, 2016)

- Engage a market manager to help the market actively evolve from operational research studies to concrete demand and market development at scale
  - Coordination and advocacy
  - Go-to-market strategic planning
  - Regulatory support and guidance
  - Collection of market intelligence
- Conduct demonstration projects to understand the potential of specific distribution channels, especially through the private sector

# Total Market Approach

- TMA framework for developing and facilitating markets in improving efficiency and access for a specific product
  - Identification of all market players for service and product
  - Market segment identification and targeted strategies
  - Involvement of public and private (not-for-profit and for-profit) sectors
  - Programs and policies enhance the market and remain client-focused

# Total Market Approach (K4Health)

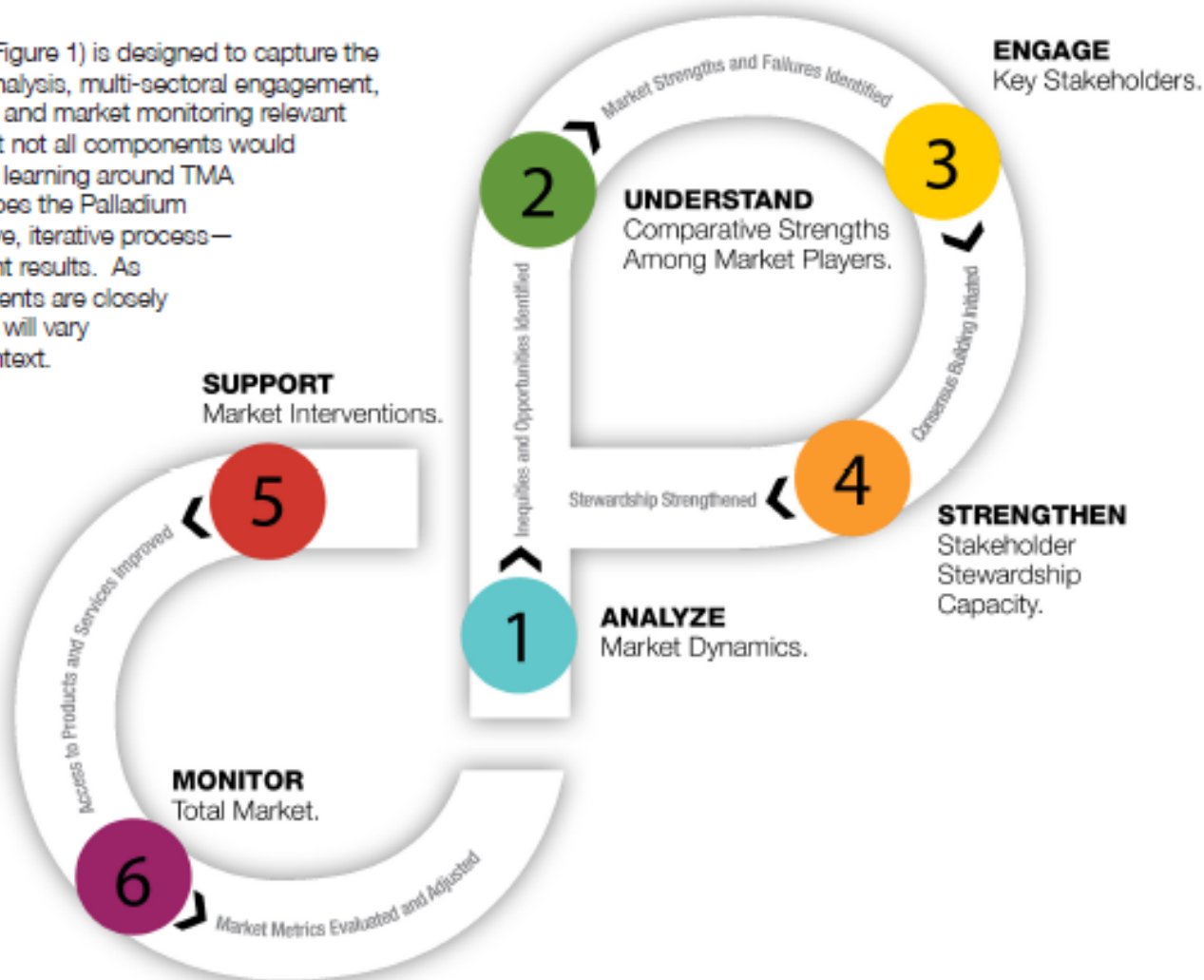




# Total Market Approach (Palladium Group)

## Our TMA Framework

Palladium's TMA framework (Figure 1) is designed to capture the complex process of market analysis, multi-sectoral engagement, market-shaping interventions, and market monitoring relevant to TMA, while recognizing that not all components would be applied in all situations. As learning around TMA implementation evolves, so does the Palladium framework. TMA is an intensive, iterative process—but one that leads to important results. As described below, the six elements are closely linked, often overlapping, and will vary depending on the country context.



# Guiding Questions for TMA

- Are we maximizing participation of all service provision actors?
- What populations are currently served and where?
- What types of service delivery approaches can each do best for each segment?
- How can we grow the whole market?

# ANNEX 2. SEPTEMBER 2018 HIV SELF-TESTING: THE GLOBAL LANDSCAPE PRESENTATION

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# HIV Self-Testing: the Global Landscape

Presentation to Nigeria HIV Testing Services Task Team

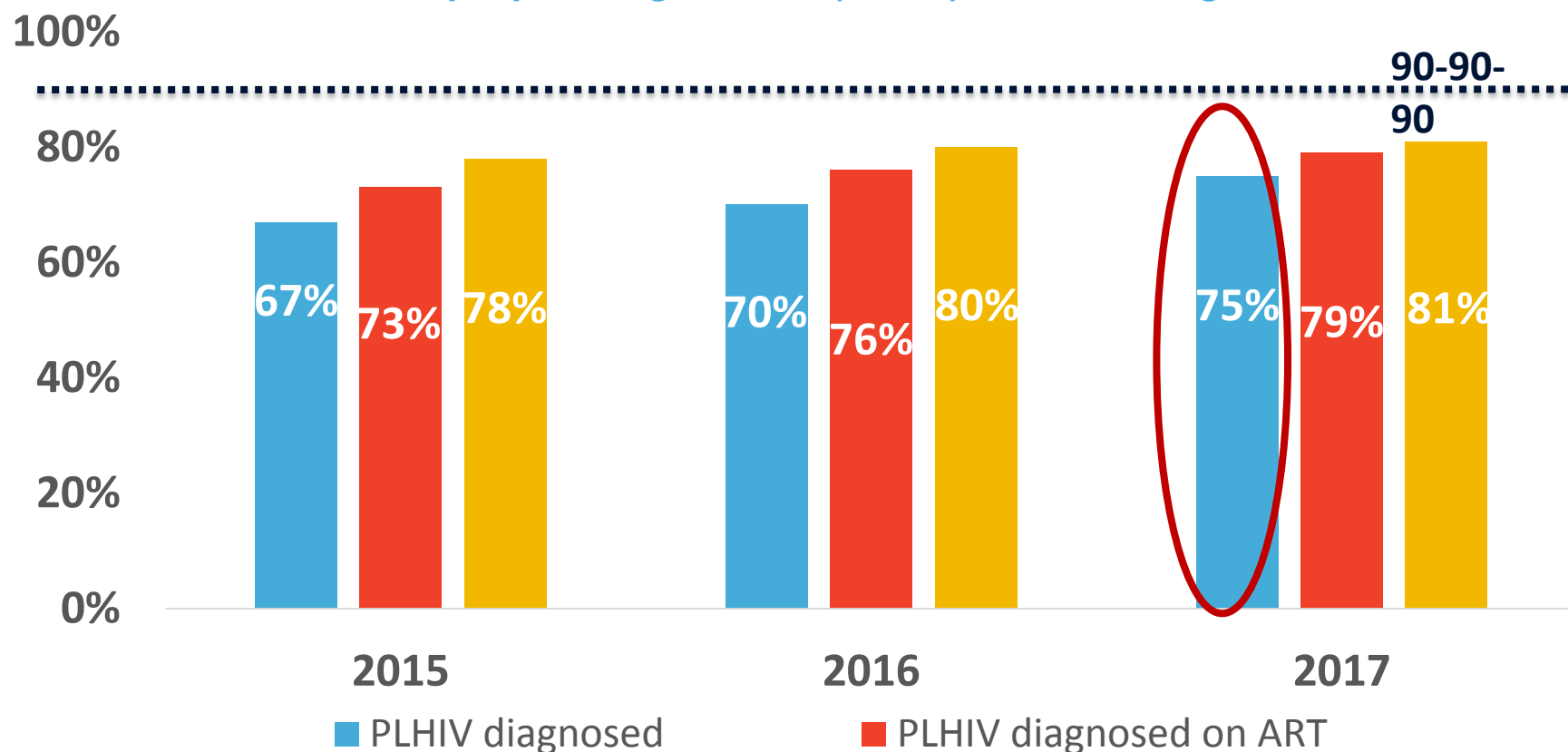
September 6, 2018

Kristina L. Grabbe, Jhpiego/MCSP/AIDSFree

Setting the Stage: The 'First 90'

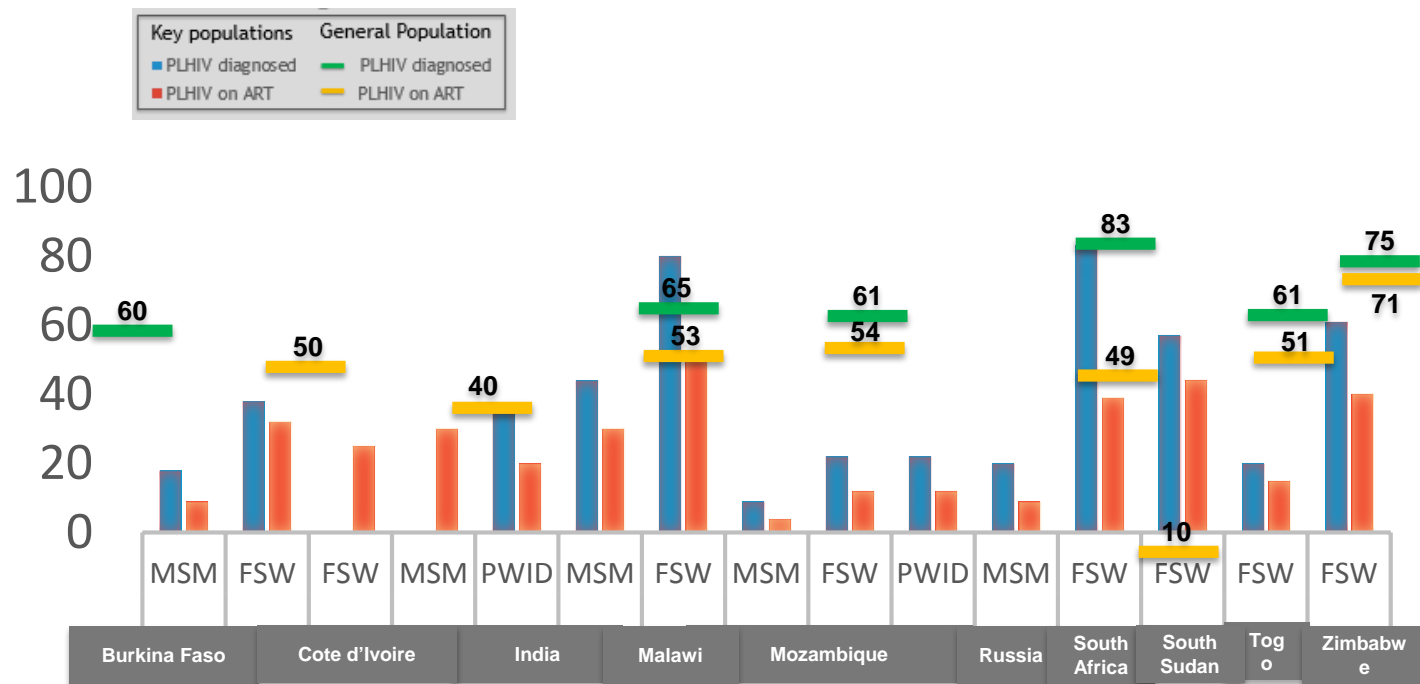
# Progress toward the 90-90-90, 2015-2017

*9.4 million people living with HIV (PLHIV) remain undiagnosed*



# Many of those unreachable are key populations

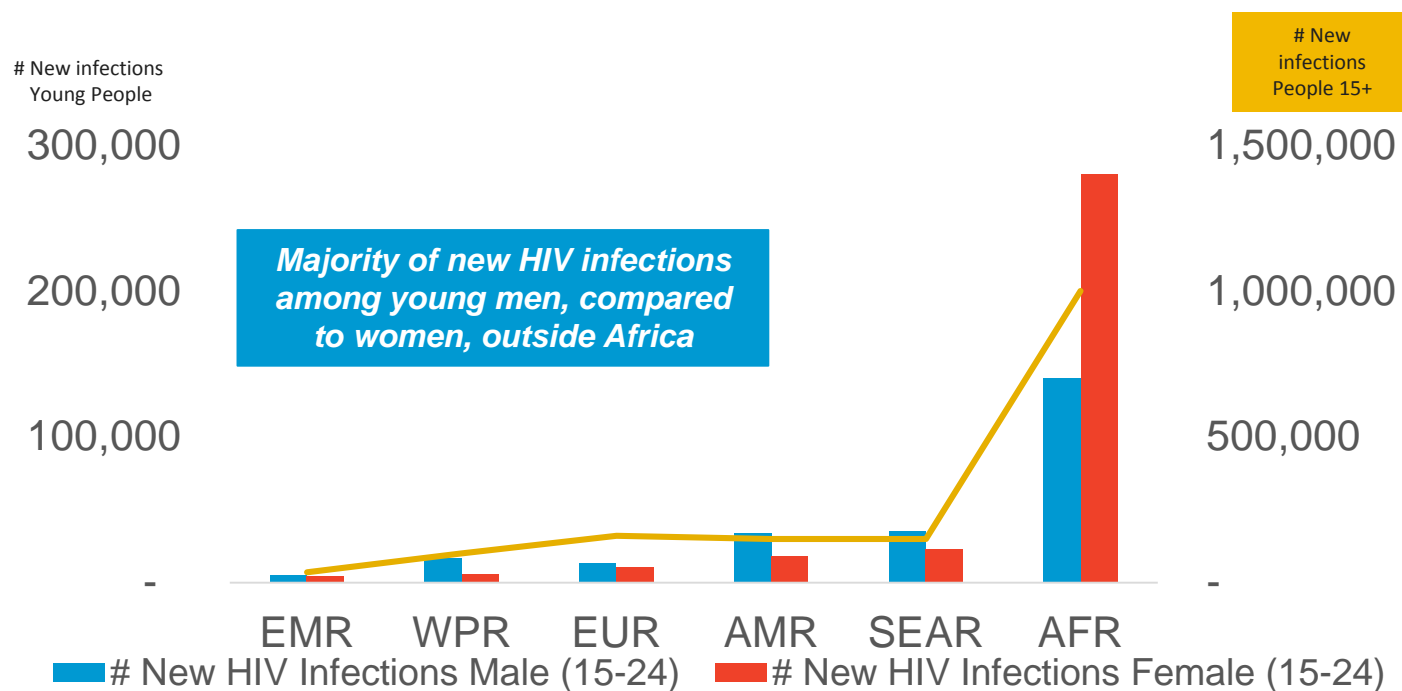
*Proportion of key populations diagnosed and/or on treatment compared to general populations, by country*



Special analysis using UNAIDS Global AIDS Monitoring data vs available key population data (data published in peer reviewed journals and IBBS) matched for year; C Johnson AIDS 2018

# Many of those unreachable are young people

*In 2017 there were 1.8 million new HIV infections in people  
37% were among 15-24 year olds – most in southern Africa*

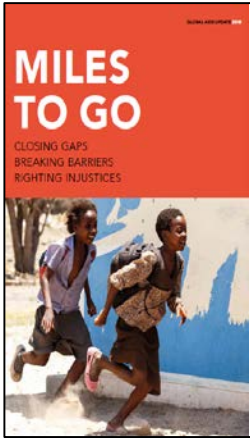


Source: WHO/UNAIDS 2018; C Johnson AIDS 2018



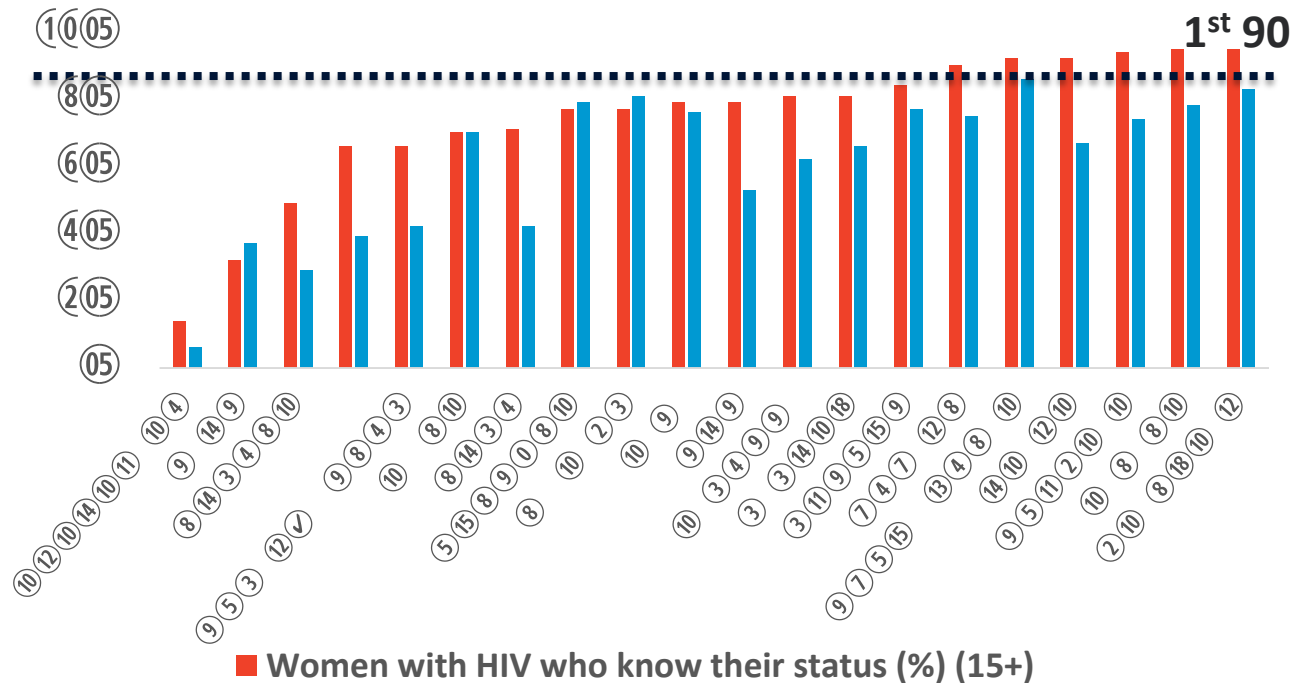
# Many of those unreachable are men

*Proportion of people with HIV who know their status, by sex  
20 reporting African countries, 2017*

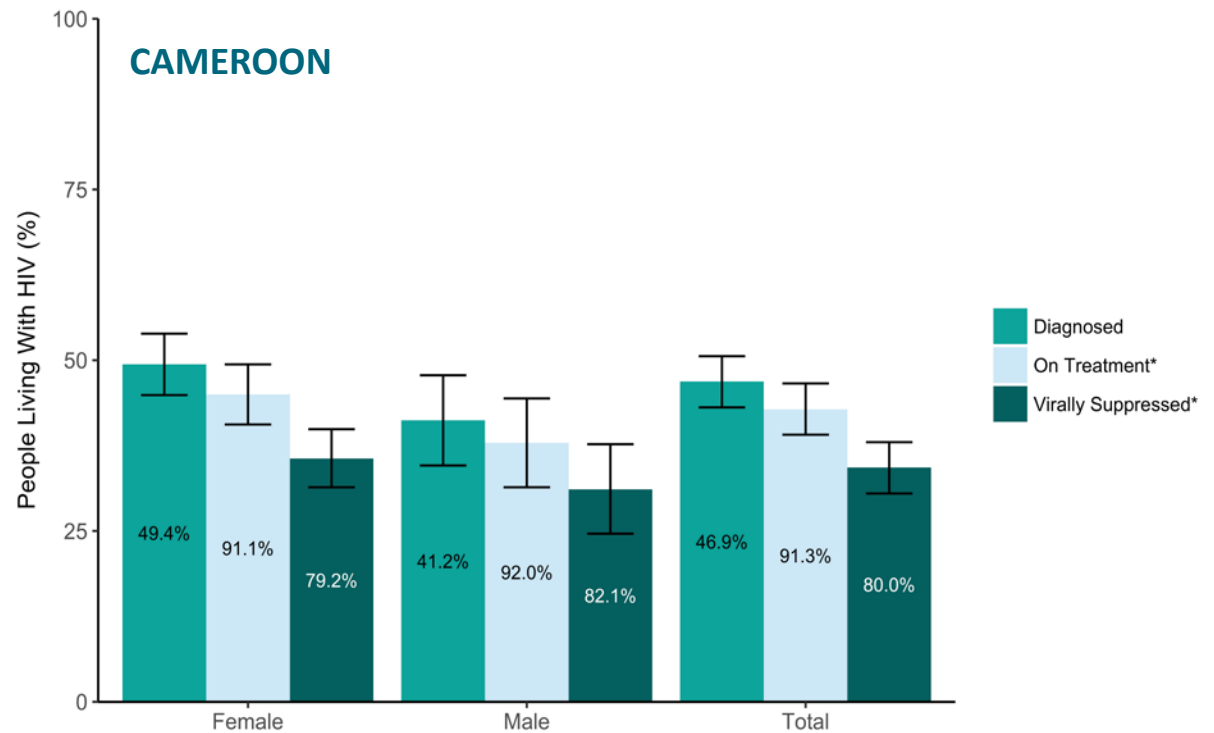


*“Despite higher disease burden among women, more men living with HIV are dying”*

Source: WHO/UNAIDS 2018; C Johnson AIDS 2018



Newly released population-based surveys indicate decreased incidence and progress towards 90-90-90 but reinforce the need for differentiated models of service delivery targeting unreached populations, with particular emphasis on ‘First 90’ and reaching men.

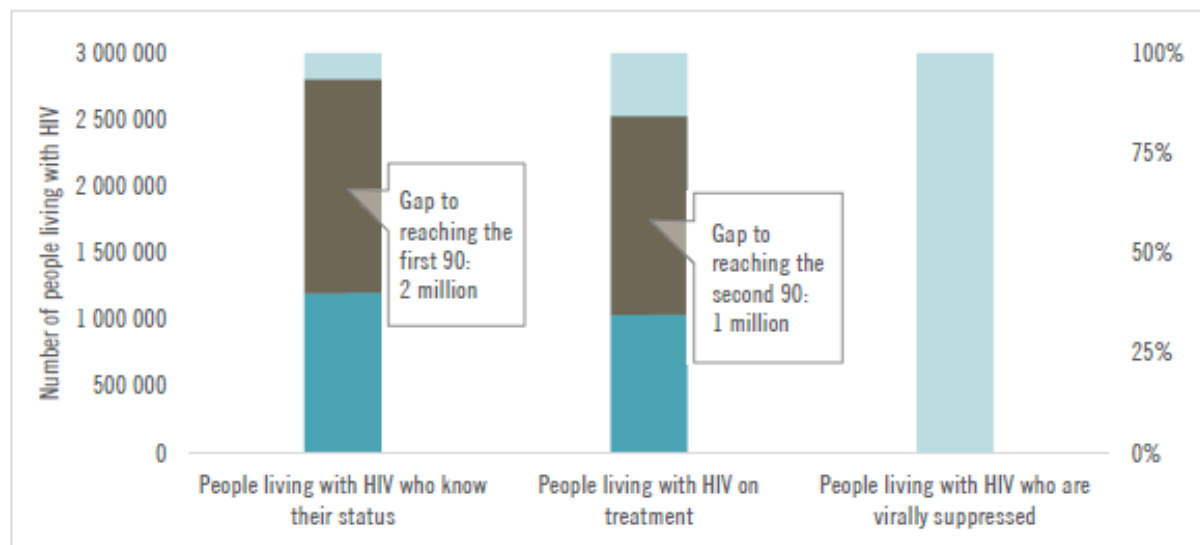


Source: <https://phia.icap.columbia.edu/>; HSRC AIDS 2018

## Nigeria Progress to 90-90-90

- 38% PLHIV know their HIV status (49% women, 29% men)
- 1 million PLHIV are on treatment (44% women LHIV, 22% men LHIV)
- Viral suppression estimates unknown
- Regional and population disparities

## HIV TESTING AND TREATMENT CASCADE



All ages	38% [26–54%]	33% [22–47%]	...% [...–...%]
Children (0–14)	25% [14–37%]	26% [15–39%]	...% [...–...%]
Women (15+)	49% [33–68%]	44% [30–61%]	...% [...–...%]
Men (15+)	29% [18–42%]	22% [14–32%]	...% [...–...%]

## Innovation is needed to close this gap

Find the 62% of PLHIV in Nigeria who don't know their status



Link the 67% of PLHIV in Nigeria who are not on ART



Link HIV-negatives to effective prevention to stay negative!



What got us here, won't get us there.



# International Guidance on HIVST

# HIV Self-testing Recommendation (WHO, Dec 2016)



**HIV self-testing** should  
be offered as an  
additional approach to  
HIV testing services  
*(strong recommendation,  
moderate quality  
evidence)*

# What is HIV Self-Testing (HIVST)?



Collects



Perfor  
ms

Interpr  
ets

Reactive results need confirmation by trained tester using a validated national algorithm

# HIV self-testing: an important innovation

*Individual collecting their specimen (oral or blood), performing a rapid test and interpreting their result often in private or with someone they trust*



## Key evidence showed HIVST is:

- Safe and accurate
- Highly acceptable
- Increased access
- Increased uptake and frequency of HIV testing among those at high risk and who may not test otherwise (men, KP, young people, partners of PLHIV)

## WHO recommendation:

HIV self-testing should be offered as an additional approach to HIV testing services

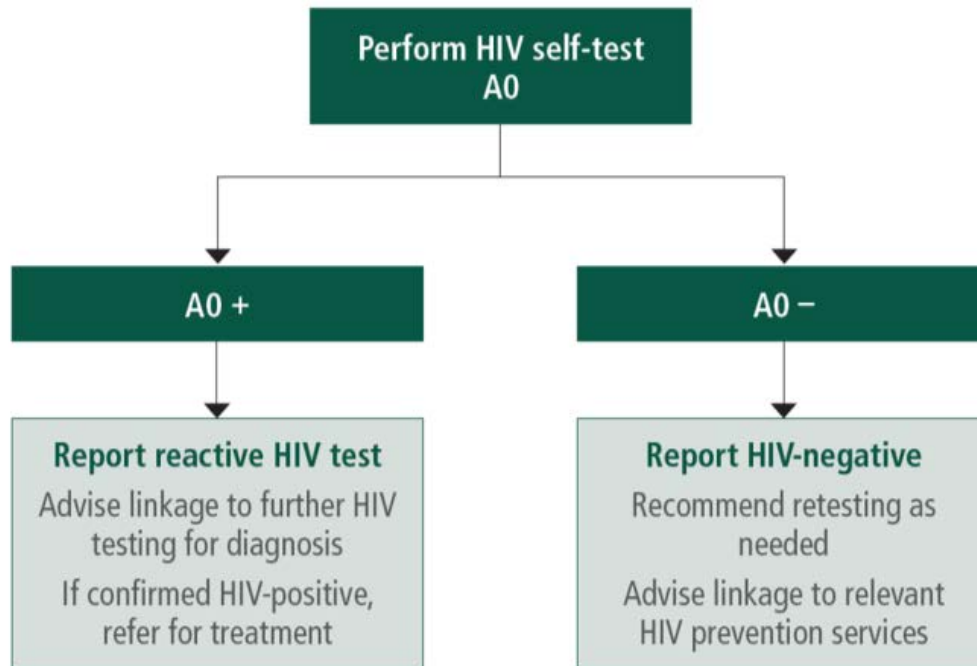
*(strong recommendation, moderate quality evidence)*

**Many different models – ranging from community-based, facility-based, partner-delivered, social network-based, pharmacies, workplace**

*Source: WHO 2016* **depending on context and who you are trying to reach**



# WHO HIVST Strategy: “Test for Triage”

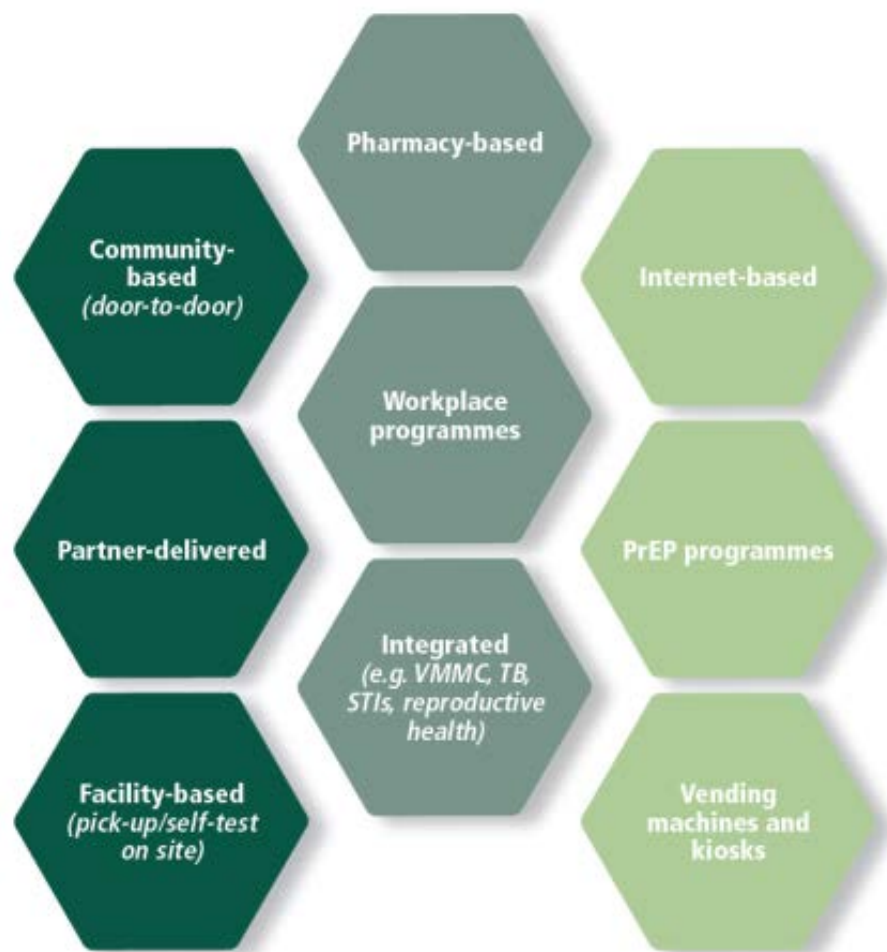


A0= Assay 0 (test for triage)

- HIVST does not provide a definitive HIV-positive diagnosis.
- HIV self-testers with a **reactive** (positive) result to receive further testing from a trained provider using a validated national testing algorithm.
- HIV self-testers with a **non-reactive** test result should retest if they might have been exposed to HIV in the preceding six weeks, or are at high ongoing HIV risk.
- Any person who is **uncertain** about their HIV self-test result should access facility- or community-based HIV testing.
- HIVST is **not** recommended for people taking anti-retroviral drugs, as this may cause a false non-reactive result.

# Strategic Planning HIVST Service Delivery

- There are many possible public and private sector HIVST approaches.
- Programmes should evaluate existing HTS approaches to determine where and how to implement HIVST, so that it is complementary and addresses gaps in current coverage.
- Aim to reach untested populations: men, KP, young people, partners of PLHIV.



# Global Policy and HIVST Implementation

- HIVST is an acceptable, safe, accurate, and effective way to reach people who are at risk and may not otherwise test.
- 59 countries now have policies supporting HIVST.
  - Additional 53 countries are developing policies on HIVST, many of which will be completed in 2018.
- Despite rapid policy development, implementation of HIVST is limited to 28 countries worldwide, increased from 13 in July, 2017.
- About 2/3 (18) of countries implementing HIVST are upper middle or high-income countries.

# HIVST Implementation

## Linkage following HIVST

- Evidence suggests linkage to additional testing to confirm HIV status and treatment initiation following reactive self-test results can be at least equivalent to national linkage rates.
- HIV self-testing can also facilitate linkage to other prevention services, such as preexposure prophylaxis (PrEP).
- Support tools and innovative technologies, such as smartphone apps and a hotline, may also improve linkages to prevention and care after self-testing.

# Monitoring and Evaluation for HIVST

- Ensure HIVST is:
  - Reaching the right people (i.e. target populations), and
  - Facilitating access to confirmatory testing and ART for persons who test HIV-positive
- HIV self-test distribution is easy to track, but HIV self-test use and linkage to ART requires follow-up
  - Proactive, community-based follow up (in-person, via phone, text, social messaging)
  - Home-based treatment assessment and initiation
  - Brochures and flyers distributed together with HIV self-tests
  - Telephone hotlines
  - Internet and computer-based programs and applications
  - Vouchers, coupons, or rebates
  - Appointment cards and referral slips

# Monitoring Impact of HIVST Over Time

- HIVST is private and discreet, makes it difficult to collect information on effectiveness of HIVST programs, but monitoring is important!
- Possible tools for monitoring and tracking HIVST include:
  - Monitor and analyze calls to HIV self-test hotlines and messaging services, including pictures of test results
  - Add question(s) to population-based surveys (DHS, AIS, PHIA)
  - Modify site-level and facility-level logbooks and testing registers to include HIVST, i.e. “Have you ever used an HIV self-test before?”
  - Internet and mobile phone surveys and tools for clients to report experiences using HIV self-tests
  - Focused follow-up with target populations
  - Implementation evaluation and studies to track HTS coverage and enrollment on ART for hard-to-reach populations
  - Financial or in-kind incentives to encourage users to report on their HIVST experiences

## Case Example: Namibia

- 2018 Namibia endorsed HIVST in national guidelines and developed SOPs
- Peers from KP groups were trained to distribute self-tests
- Manufacturer instructions for use were provided in 4 local languages
- Peers provided demonstrations and issued HIV self-tests to FSW in their communities
  - FSW could receive 2 kits to encourage partner testing
  - Peer distributors helped link people to further testing, treatment, and prevention services (including PrEP)

*Source: Taimi Amaambo, Society for Family Health, Denis Mali, USAID*



## Namibia: Results

- Between March and May 2018, peer distributors gave out 1,475 kits
- 813 recipients disclosed their test results to peer distributors
  - 24 (2.9%) were HIV-positive
  - 23 (96%) were linked to treatment
  - 62 (8%) of those who were confirmed HIV-negative were linked to PrEP services

# Lessons from Kenya shift from VCT to HIVST

1. We have to start and learn as we go along! – don't let fears get in the way of progress
2. The most invested (policy makers, providers) are sometimes the barriers
3. We have to trust that people will do what is best for them when they have accurate information, technology, and are motivated
4. We must actively focus on couples/partners
5. We need an open and saturated market - relinquish some control of distribution models and points, leverage other sectors
6. We need to invest in systems:
  - Regulation, evaluation, approval
  - Forecasting and quantifications
  - Commodity supply and management systems
  - Data collection and collation

## Current Evidence

# Priority Area: HIV Self-Testing

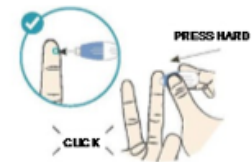
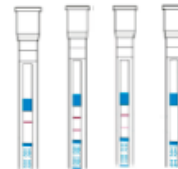
- Secondary HIVST distribution to male partners of young women leads to increased male partner and couples testing, no increased risk of IPV
  - Agot et al, Kenya
- Community Based Distribution Agents effectively delivered HIVST in Malawi, leading to increased coverage of HIVST in rural populations
  - Indravudh et al, Malawi
- Persons at risk for any adverse event following HIVST are those with prior history of violence in relationship
  - Cowan et al, Zimbabwe
- Blood-based HIVST is feasible and acceptable for semi-supervised HIVST
  - Cowan et al, Zimbabwe and Malawi

## Aim

To evaluate feasibility and acceptability of HIVST with blood based RDTs in Malawi and Zimbabwe.

## Methodology

- Mixed-methods study observing the distribution and use of BB and OF self-test kits at rural and urban primary health centres / HIV testing sites.



**Global Market for HIVST**

**Unitaid/WHO: Market and technology landscape, 4<sup>th</sup> edition**

# The Global Market

- Procurement forecast suggests significant growth for HIVST in both public and private sectors beyond 2020.
- Volumes are expected to grow from 1 million tests globally in 2017 to an estimated 16.4 million tests by the end of 2020.
  - Public sector is expected to contribute around 9.1 million.
  - Private sector is expected to account for remaining 7.3 million.

# HIV Self-test Diagnostics

- As of July 2018, 8 HIVST (2 oral fluid, 6 blood-based) have received some degree of international approval
  - Either prequalified by WHO, approved by a regulatory authority/International Medical Device Regulators Forum, or recommended for procurement by Unitaids/Global Fund Expert Review Panel for Diagnostics.
- Only 1 HIV self-test, an oral fluid test, has been prequalified by WHO.
- Locally manufactured HIV self-test kits with national-level approval in some countries (6 products identified), including Belarus, Brazil, and **Nigeria**, but quality and performance of these kits vary.
- There are at least 6 other HIV self-tests under development – 3 use whole blood specimens, 2 use oral fluid specimens, and 1 uses urine specimens.

Source: UNITAID 2018

HIV self-test kits with international approval (WHO PQ, approved by regulatory authority in one of founding member countries of International Medical Device Regulators Forum, or eligible for procurement on recommendation of Unitaid/GF ERPD)

Test name (manufacturer/supplier)	Test generation <sup>a</sup>	Specimen	Sensitivity	Specificity	Approval status	Markets	Price in US\$ per test
<b>atomo HIV Self Test</b> (Atomo Diagnostics, Australia)	3 <sup>rd</sup>	Whole blood	99.7%	99.7%	CE mark, ERPD (Category-3) <sup>a</sup>	Kenya, South Africa	Public sector: \$ 3 (depends on volume)
<b>autotest VIH®</b> (three packaging formats) (AAZ Labs, France) <sup>c</sup>	2 <sup>nd</sup>	Whole blood	100.0%	99.8%	CE mark	Registered and available in 15 European countries <sup>d</sup>	HIC retail: \$ 20–28 Distributors/NGOs: \$ 8–15 (depends on packaging format)
<b>BioSURE HIV Self Test</b> (hard case & soft case) (BioSURE, United Kingdom Ltd) <sup>c</sup>	2 <sup>nd</sup>	Whole blood	99.7%	99.9%	CE mark, ERPD (Category-3) <sup>a*</sup>	South Africa, United Kingdom	HIC retail: \$ 42–48 HIC public sector: \$ 7.50–15 LMIC retail: \$ 11.75
<b>Exacto® Test HIV</b> (Biosynex, France)	3 <sup>rd</sup>	Whole blood	99.99%	99.90%	CE mark	Europe <sup>d</sup>	Not available
<b>INSTI® HIV Self Test</b> (box & pouch) (bioLytical Lab., Canada) <sup>c</sup>	2 <sup>nd</sup>	Whole blood	Box: 100.0% Pouch: 99.8%	Box: 99.8% Pouch: 99.5%	CE mark, ERPD <sup>c</sup> (Category-3) <sup>a</sup>	Several countries in Europe, Nigeria	Price: \$ 3–12 MSRP: \$ 7–36 (Prices depend on packaging format, volumes and market region)
<b>OraQuick® In-Home HIV Test</b> (OraSure Technologies, USA)	2 <sup>nd</sup>	Oral fluid	FDA: 91.7% <sup>a</sup> CE: 100.0%	FDA: 99.98% CE: 99.8%	FDA, CE mark	USA	HIC retail: \$ 40 Public sector prices vary. Not yet marketed in Europe
<b>OraQuick® HIV Self Test</b> (OraSure Technologies, USA)	Not available <sup>a</sup>	Oral fluid	99.4%	99.0%	WHO PQ <sup>a</sup>	Burundi, Kenya, South Africa, Uganda, Zambia, Zimbabwe	LMIC ex-works <sup>i</sup> : \$ 2 for 50 countries <sup>j</sup>
<b>SURE CHECK® HIV Self Test</b> (Chembio Diagnostic Systems Inc., USA)	2 <sup>nd</sup>	Whole blood	Not available	Not available	ERPD (Category-3) <sup>a</sup>	Not available	Not available



HIV self-test  
kits with  
national-level  
approval in  
selected  
countries

Test name (manufacturer/supplier)	Specimen	Approval status	Availability	Price in US\$
<b>Action!</b> (Orangelife Comércio e Indústria LTDA, Brazil)	Whole blood	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Free-on-board*: \$ 9.80
<b>Alerta</b> (Wama Diagnóstica, Brazil)	Whole blood	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Not available
<b>Amethyst HIV 1&amp;2 Test Kit</b> (Bedford Biotech Nigeria Ltd., Nigeria)	Oral fluid	Approved in Nigeria	Nigeria	\$ 14 recommended market price. Prices for public sector and NGOs may vary.
<b>HIV Detect</b> (Eco diagnóstica, Brazil)	Oral fluid	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Not available
<b>Saliteste</b> (Ebram Produtos Laboratoriais, Brazil)	Oral fluid	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Not available
<b>Unnamed test</b> (Belarus)	Not available	Manufactured and approved in Belarus	Belarus	Not available

## HIV self-test kits under development

Test name (manufacturer/supplier)	Specimen	Plan for regulatory approval
<b>Asanté™ HIV Self Test</b> (Sedia Biosciences Corporation, USA)	Oral fluid (also, a version is under development that can test either an oral fluid or whole blood specimen in a single device)	Not available
<b>Aware™ HIV-1/2 OMT Oral HIV Self Test</b> (Calypse Biomedical, USA)	Oral fluid	Plan to apply for WHO PQ and CE mark
<b>First Response HIV 1-2.0 Card Test (Self Test)</b> (Premier Medical Corporation, India)	Whole blood	Plan to apply for WHO PQ
<b>To be named</b> (Abbott Laboratories, USA)	Whole blood	Not available
<b>To be named</b> (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China)	Urine	National regulatory approval in China pending
<b>To be named</b> (Trinity Biotech, Ireland)	Whole blood	Not available

## Future directions for HIVST diagnostics

- Improve existing technologies through open market and increased competition
- Optimize and improve self-test product performance
  - Simplify sample collection, clear instructions, demonstrations and support tools, fewer steps, faster and easy to read results
- Multiplex self-tests with ability to test simultaneously for more than one disease using a single specimen and one test procedure or test run
  - Possible combinations include HIV, syphilis, hepatitis B and C, among others
- Self-testing for STIs
  - Self-collection systems exist for certain STIs, but no approved self-test currently

## Cost of HIV self-tests

- Price of HIVST kits with WHO PQ or stringent regulatory authority varies considerably, depending on setting, market sector, and product packaging.
  - High income countries, private sector prices range from \$20 to \$48 per test; public sector NGO procurement range from \$7.5 to 15 per test.
  - In LMIC self-tests are available at a lower price, ranging from **\$2 to \$12** per test in public sector, and **\$7 to 12** per test in private sector.
- Lowest price per test (\$2) is available in public sector in 50 high-burden LMIC settings, including **Nigeria**, for a limited time through an agreement between BMGF and the manufacturer of the only WHO PQ'd self-test.

Source: UNITAID 2018

## Public Sector Financing and Procurement

- Depending on funding source and procurement method, process for financing, procurement, and delivery of HIV self-tests can be complex and time consuming.
- Financing through Global Fund – estimated time from grant evaluation to estimated procurement date is 503 days.
  - Does not include time required to prepare grant submission.
- Global Health Supply Chain (GHSC) is main procurement agent for PEPFAR/USAID.
  - Average lead-time to process and deliver HIV self-tests is **115 days** across 21 countries in 2017 and 2018.

## Public Sector Forecasting

- Moderate forecast assumes countries scaling up HIVST achieve self-test volumes of 2.5% to 5% of total RDT volumes
- Aggressive forecast scenario assumes a range of 5% to 7.5%.
- This proportion may increase over time, but HIV self-tests will likely remain a small fraction of all HIV RDTs even by 2020.
  - In 5 key countries (Kenya, Malawi, South Africa, Zambia, Zimbabwe) public sector moderate forecast is 18.8% of RDT volumes in 2020.

## Challenges with HIVST Scale-up

- Consumer choices and market competition is limited, due to only one WHO PQ'd self-test
  - In Nigeria, only one nationally approved test, not WHO PQ'd
- Lack of clarity, or absence of national regulatory pathways in some settings hinders market entry for new products
  - Registration processes can be lengthy or expensive, or may allow substandard products to enter market
- Awareness of HIVST remains low in target populations in many settings
  - Large-scale promotion campaigns are needed to generate and sustain demand

Source: UNAIDS 2018

# HIVST User Preferences

- Privacy, convenience, and immediacy of results are appealing
- Cost and accuracy drive demand.
  - In Zambia, adults and adolescents indicated a willingness to pay for HIV self-tests.
    - Those who had tested in last 12 months were willing to pay ~\$3.30 for a self-test kit.
    - Those who had not tested recently were willing to pay ~\$4.60.
- Specimen type – oral fluid or blood – does not seem to have major influence on choice, but some population groups may prefer one over the other (MSM, FSW, PWID).
  - Diversifying choice and specimen types will make testing more accessible and appealing and strengthen security of supply.



For more information, please visit  
**[www.mcspprogram.org](http://www.mcspprogram.org)**

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