

Update on the New WHO Guidelines for HIV Testing Services

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Consolidated guidelines on HIV testing services

<http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/>

Fact sheet to the WHO consolidated guidelines on HIV testing services

Policy brief: WHO recommends HIV testing by lay providers

Policy brief: WHO recommendations to assure HIV testing quality

Outline

- **HIV testing services (HTS)**— new name — what does this mean
- **Background**
 - HTS progress to date
 - Rationale for new HTS guidelines
- **Key issues in the new guidelines**
 - Strategic choices
 - New approaches
 - Better linkage
 - Improving quality and preventing misdiagnosis



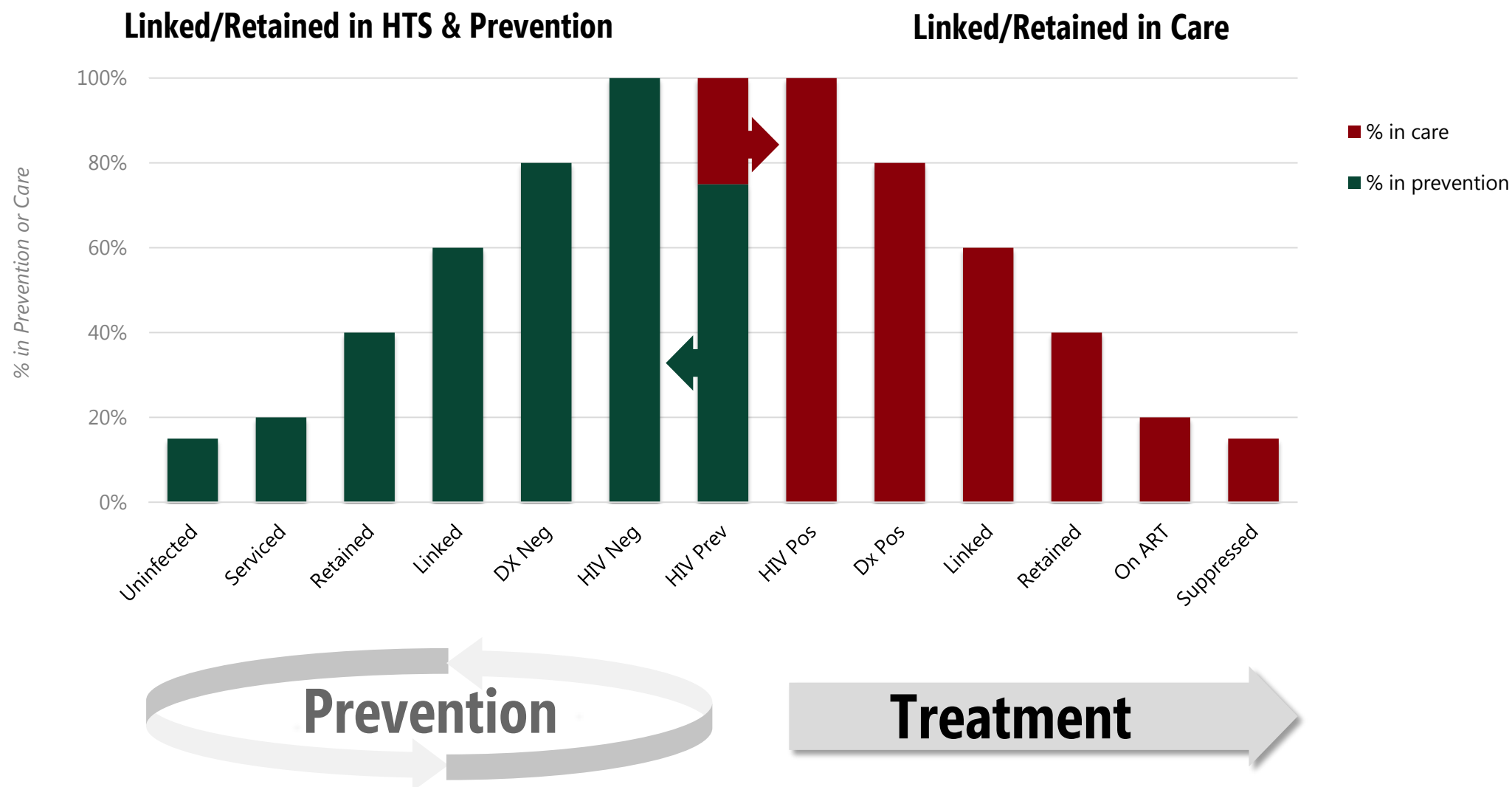
HIV Testing Services (HTS) - New Name

To embrace the full range of services provided together with HIV testing

- **Consent** - verbal consent sufficient
- **Confidentiality** – but not secrecy – sharing result often highly beneficial
- **Counselling** - Pre-test information & appropriate, high-quality post-test counselling, based on HIV test result
- **Correct** - provide high-quality testing services, and QA mechanisms so people receive a correct diagnosis.
- **Connection** - Linkage to prevention, treatment and care services.

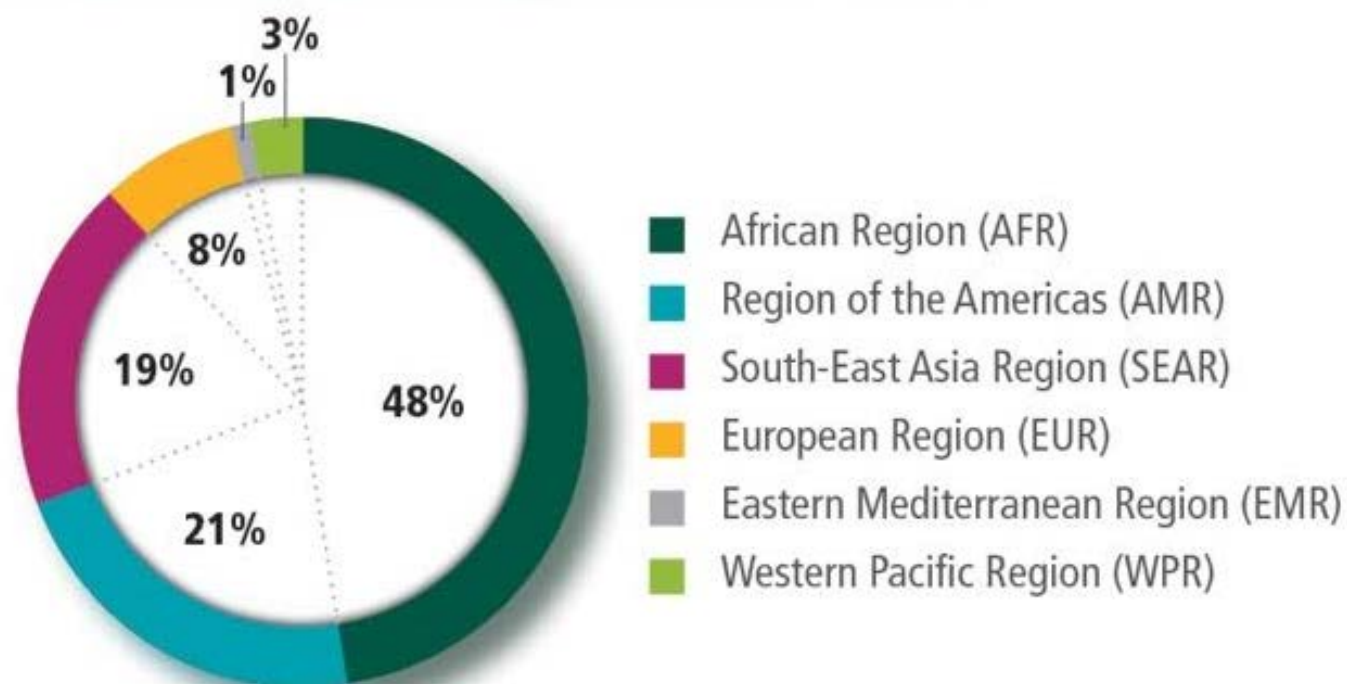
Providing HTS where there is no access to care, or poor linkage to care, including ART, has limited benefit for those with HIV.

HTS at core of prevention and care continuum



Background - Where we are with HTS

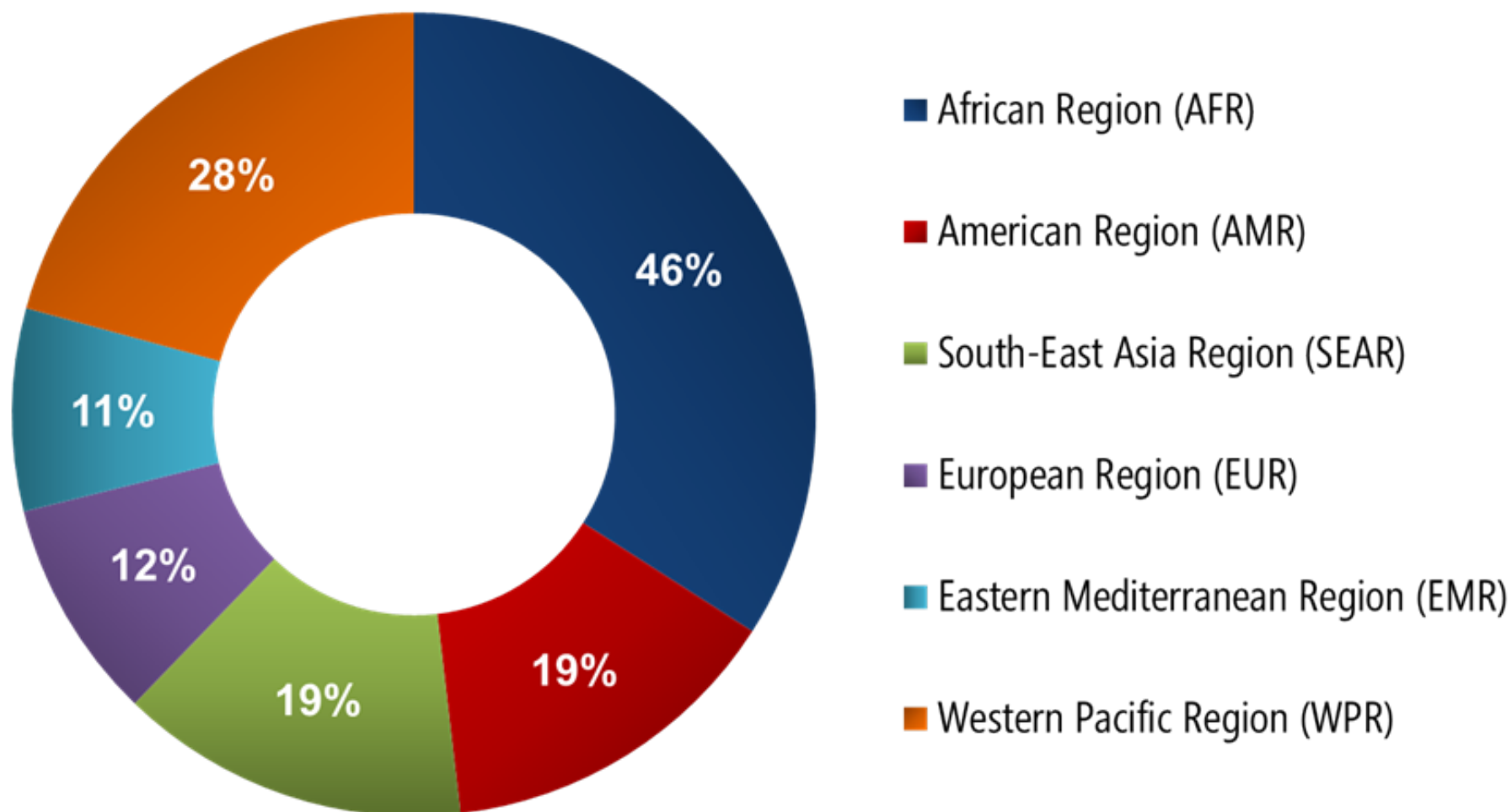
From 2010 to 2014, 600 million adults (ages 15+) were reported to receive HTS across 122 low- and middle-income countries.



Nearly half of all reported HTS delivered in the WHO African region.

Source: GARPR (WHO, UNAIDS, UNICEF) 6 July 2015.

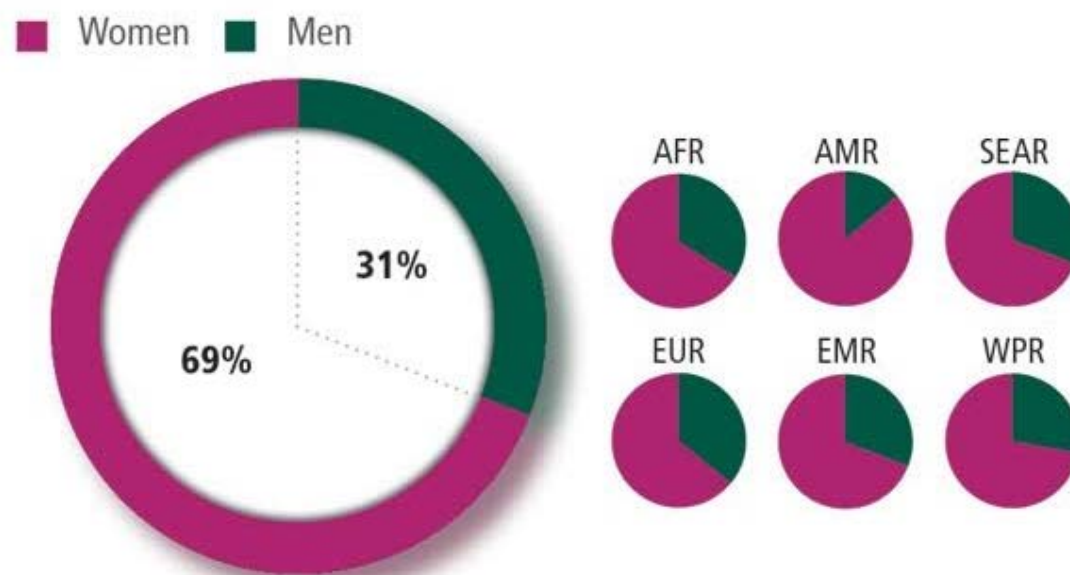
In 2014, across 129 LMIC, >150 million children & adults received HTS.



Women

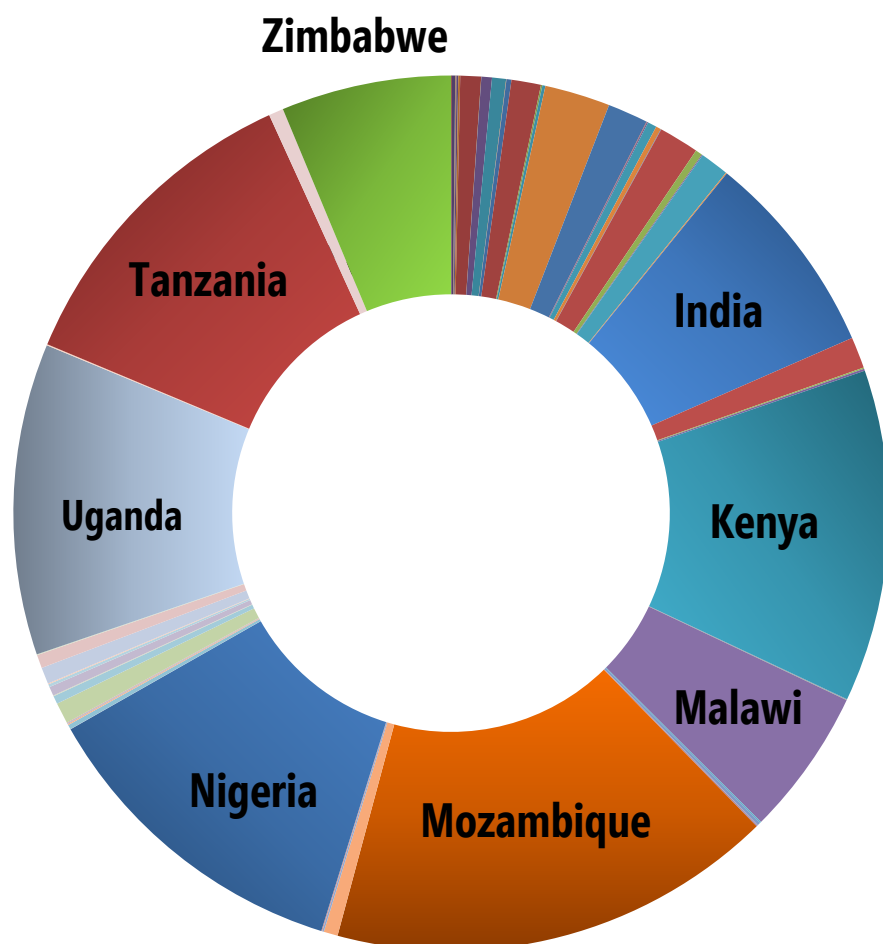
**Make Up Approximately 70%
of Those Tested
in 2014**

Much testing in ANC, even in low
and concentrated epidemics



Source: GARPR (WHO, UNAIDS, UNICEF) 6 July 2014. 76 reporting countries.

In 2014 \approx 3 million children & adults tested HIV +ve in 81 LMIC reporting on HIV+ve tests...but \approx 50% of people with HIV remain undiagnosed

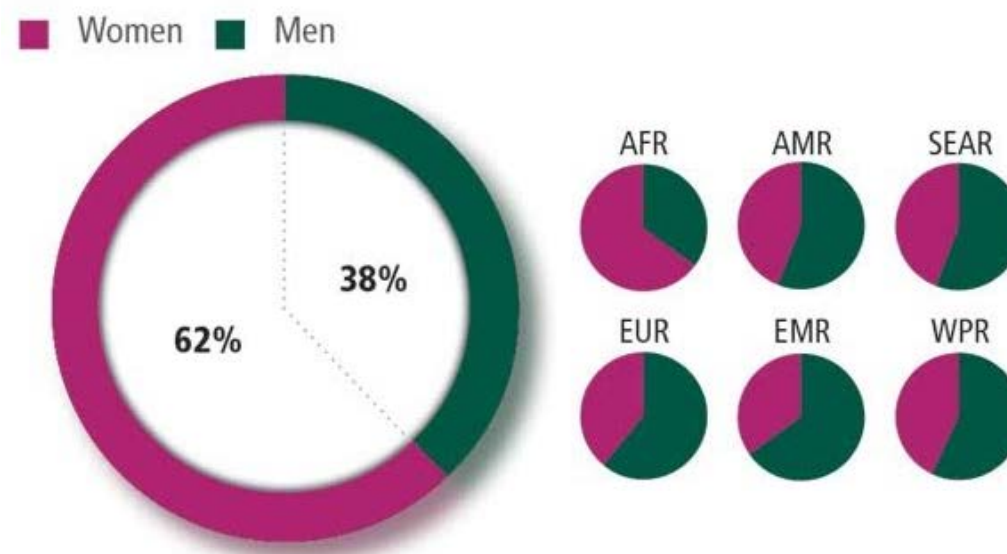


Majority of the reported HIV-positive tests occur in the WHO African region

Region	Tested	Positives	Positivity Rate	Countries
AFR	49,242,235	2,580,110	5.2%	30
AMR	3,704,951	45,317	1.2%	13
SEAR	27,844,749	278,310	1.0%	7
EUR	5,618,097	9,087	0.2%	13
EMR	5,459,838	8,936	0.2%	12
WPR	3,915,852	27,688	0.7%	6
Total	95,474,287	2,949,448	3.1%	81

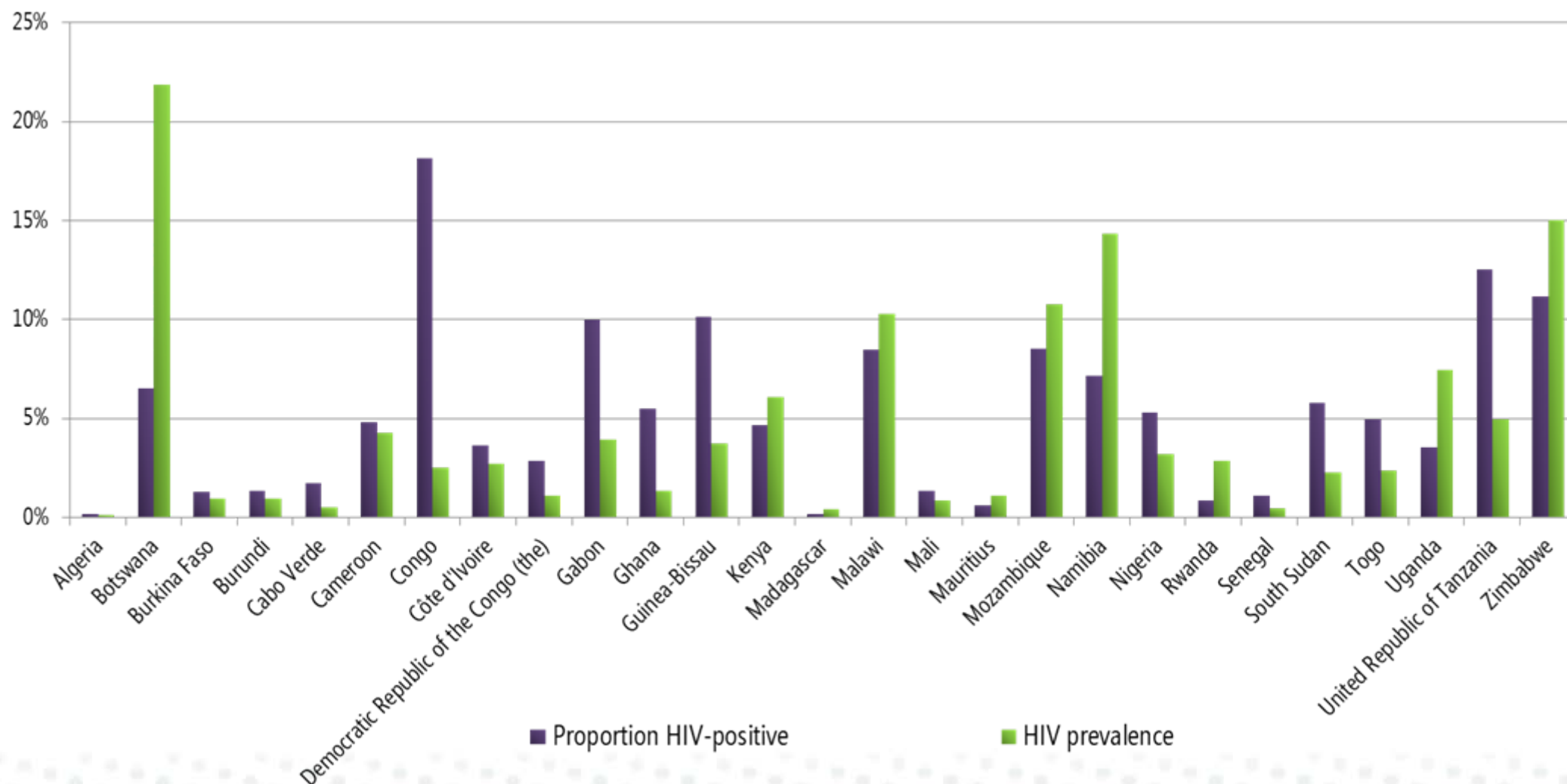
In 2014, in 65 countries reporting, approximately 2 million adults (15+) tested HIV+ve

Outside of Africa, in all other regions, those who test HIV+ve are more likely to be men



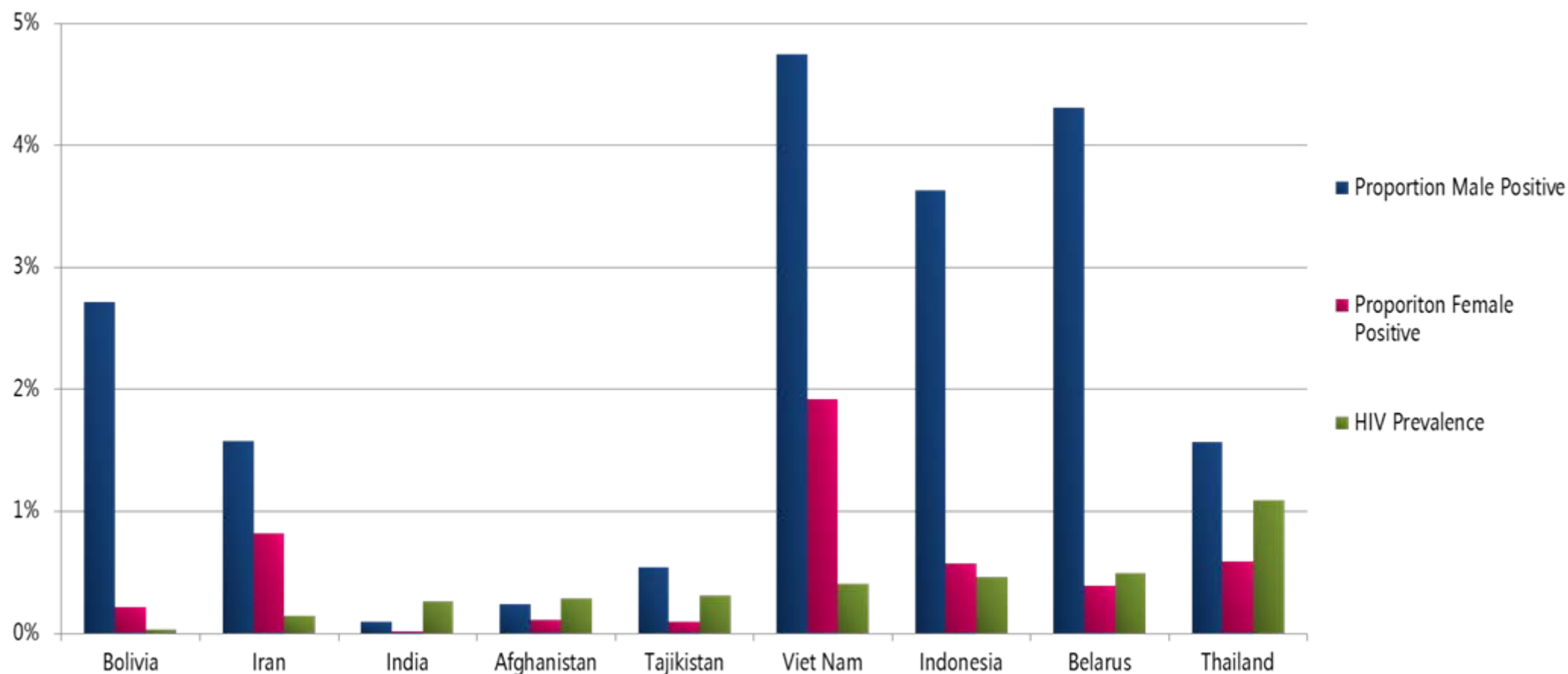
Source: GARPR (WHO, UNAIDS, UNICEF) 6 July 2015. 65 countries reporting men and women who received HIV testing services and who tested HIV-positive in 2014. Important to note this is not equivalent to new infections or HIV-prevalence as it includes people who were infected in previous years, not just those infected in 2014, and also individuals who are re-testing and who are known to be HIV-positive.

HTS positivity rate - proportion people testing HIV+ve & estimated national HIV prevalence, 27 reporting countries in WHO African Region



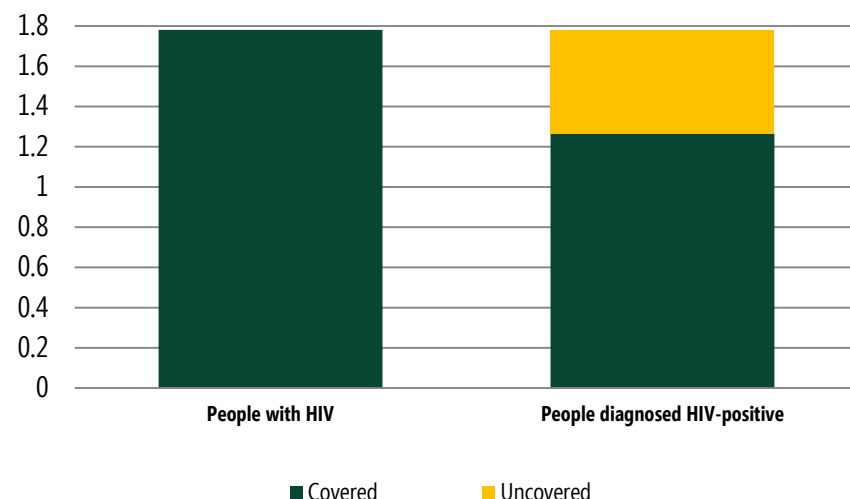
Source: GARPR 6 July 2014; 81 low and middle-income countries reporting both adults and children who tested HIV-positive in 2014. Important to note this is not equivalent to new infections or HIV-prevalence as it includes re-testers and known positives. GARPR 6 July 2015, select countries GARPR (WHO, UNAIDS; UNICEF); HIV prevalence estimates accessed 7 July 2015 UNAIDS AIDSinfo.org

In many low-prevalence settings adult (15+) men more likely to test HIV+ve than women—often exceeding national HIV prevalence estimates



Thailand

Cascade of people with HIV diagnosed and undiagnosed in Thailand (millions), 2014¹

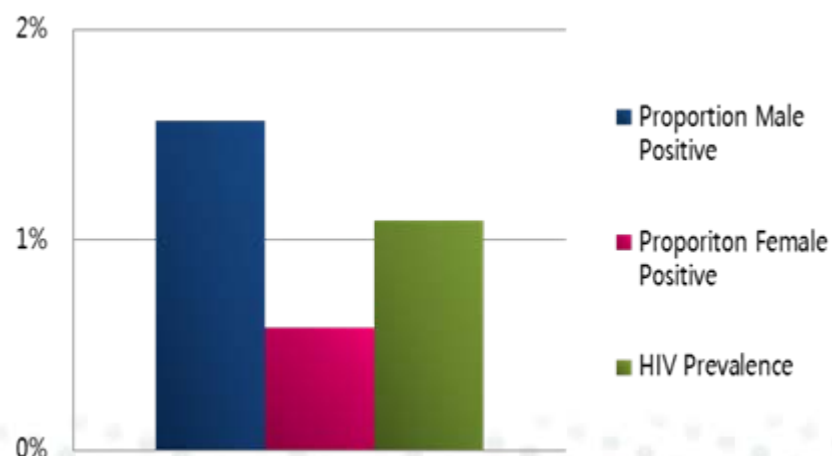


1.8 million people with HIV in Thailand & >70% have been diagnosed¹.

>1.3 million adult men and women received HTS and 1.3% tested HIV-positive, in 2014².

Majority adults receiving HTS services were women—but adult men were ~2x more likely to test HIV-positive cf adult women (Fig. 2.)².

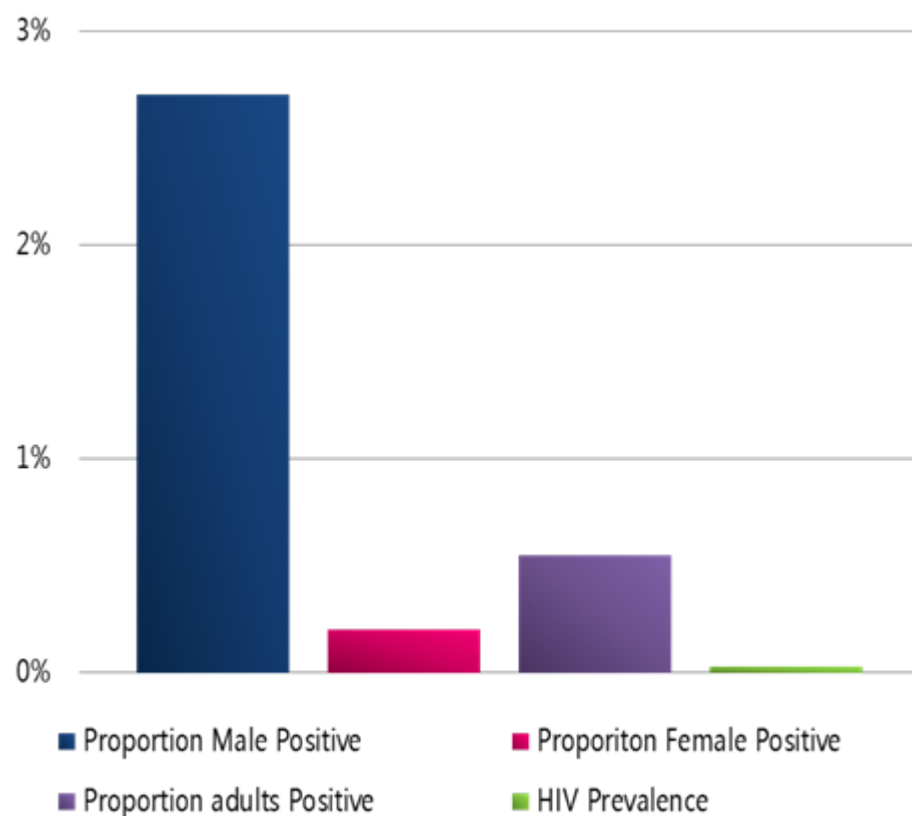
Proportion adults (15+) testing HIV-positive, disaggregated by men and women) compared to estimated HIV prevalence, 2014²



Adults 15+	Men	Women	Total
Total tested	332,012	1,009,029	1,341,041
Tested HIV- positive	12,038	5,742	17,780

Bolivia

Proportion adults (15+) testing HIV-positive, disaggregated by men & women) compared to estimated HIV prevalence, 2014²



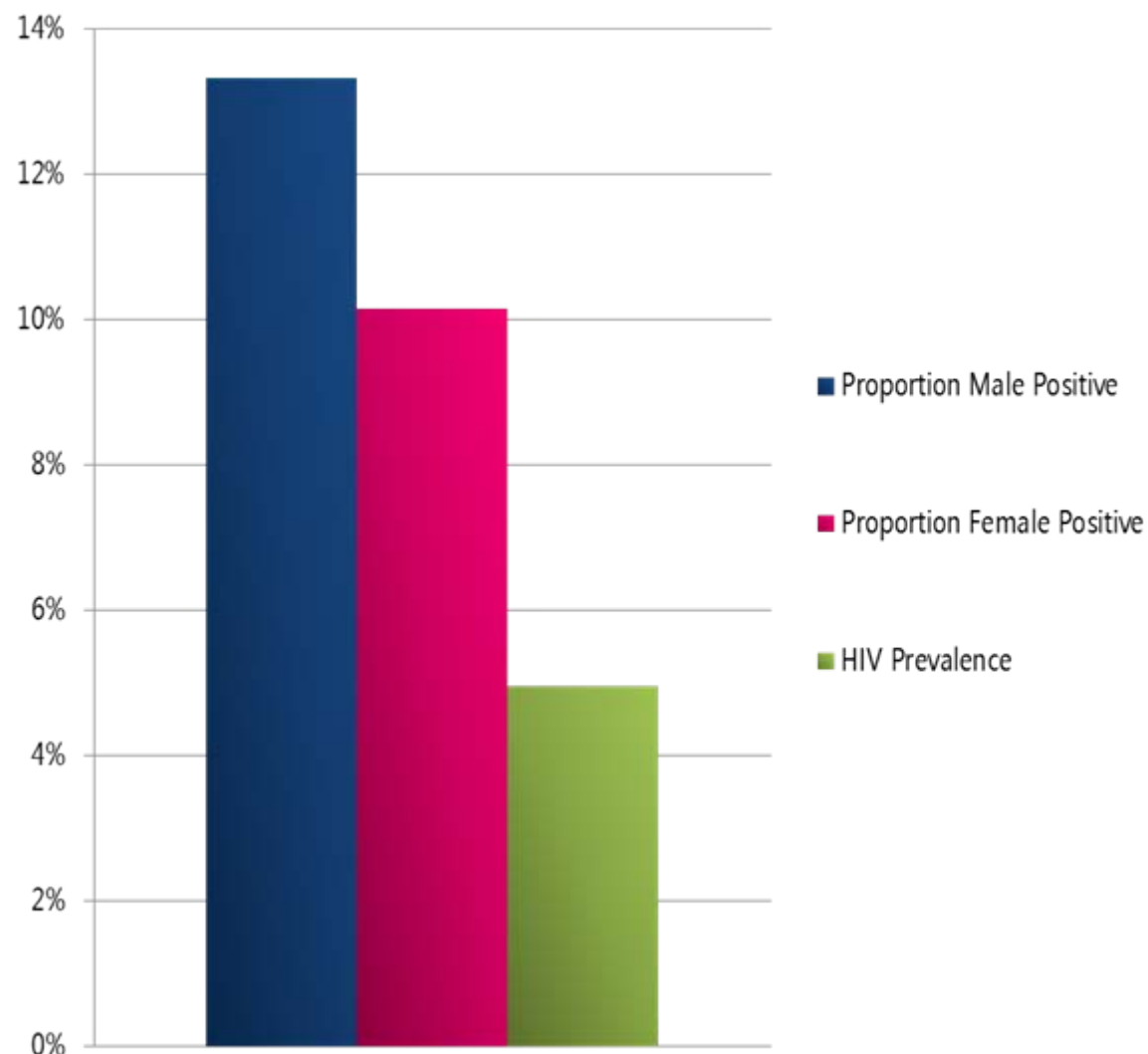
Estimated national HIV prevalence is 0.03%.

>372,498 adult men and women received HTS and 0.5% tested HIV-positive, in 2014².

Majority adults receiving HTS were women—but adult men were nearly 2.5x more likely to test HIV-positive compared to adult women (Fig. 2.)².

Adults 15+	Men	Women	Total
Total tested	49,654	322,844	372,498
Tested HIV- positive	1,345	691	2,036

United Republic of Tanzania



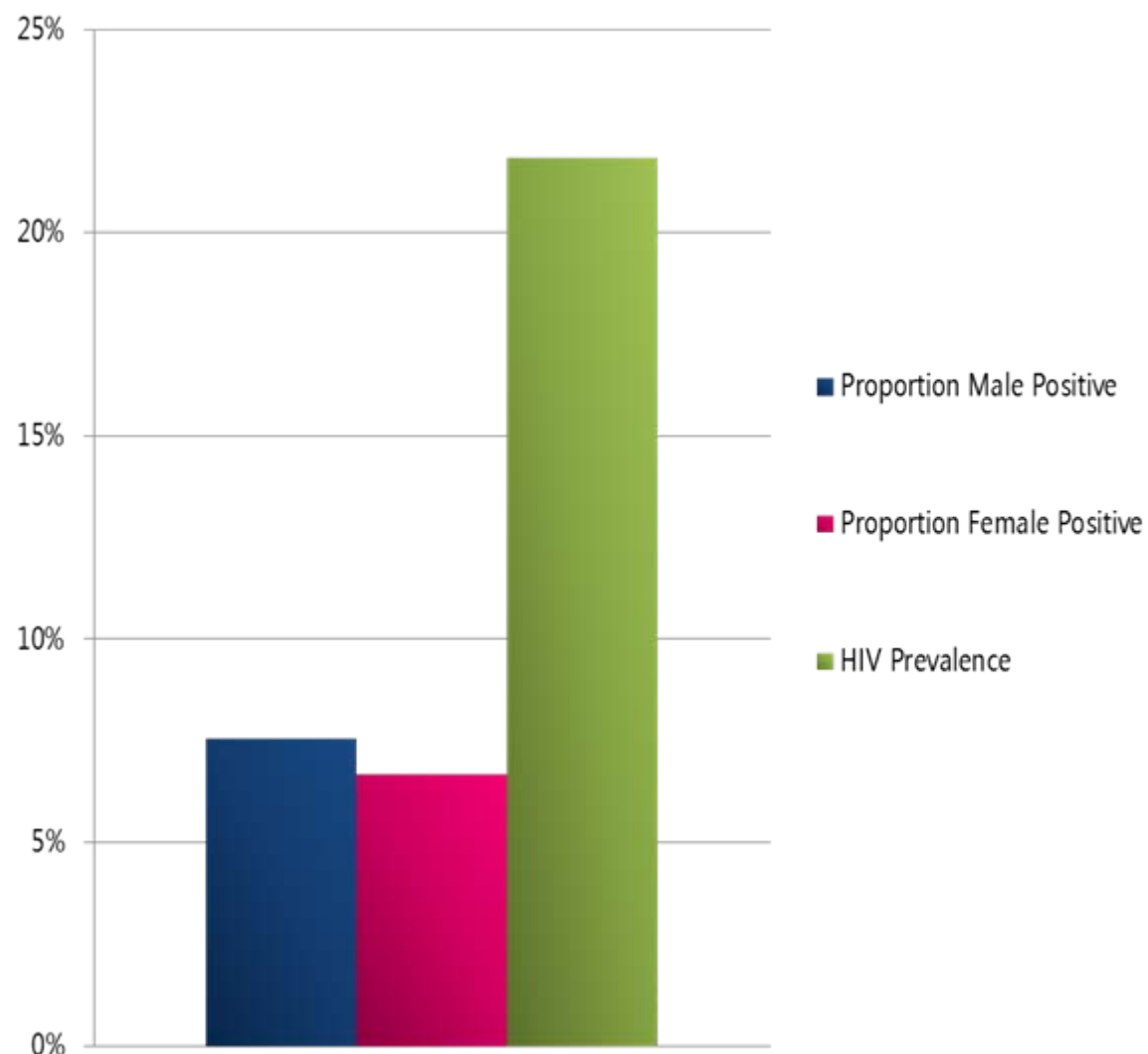
Estimated national HIV prevalence is 5%.

2.5 million adult men and women received HTS and 11% tested HIV-positive in 2014².

Majority adults receiving HTS were women—the proportion of adult men testing HIV-positive was 13% compared to 10% among adult women.²

Adults 15+	Men	Women	Total
Total tested	935,828	1,533,182	2,469,010
Tested HIV- positive	124,606	155,463	15,990

Botswana



Estimated national HIV prevalence is 22%.

>300,000 adult men and women received HTS and nearly 7% tested HIV-positive in 2014² cf national adult prevalence of >20%.

Adult men were 2x less likely to receive HTS than adult women—but the proportion of men testing HIV-positive was slightly higher 8% compared to 7%.²

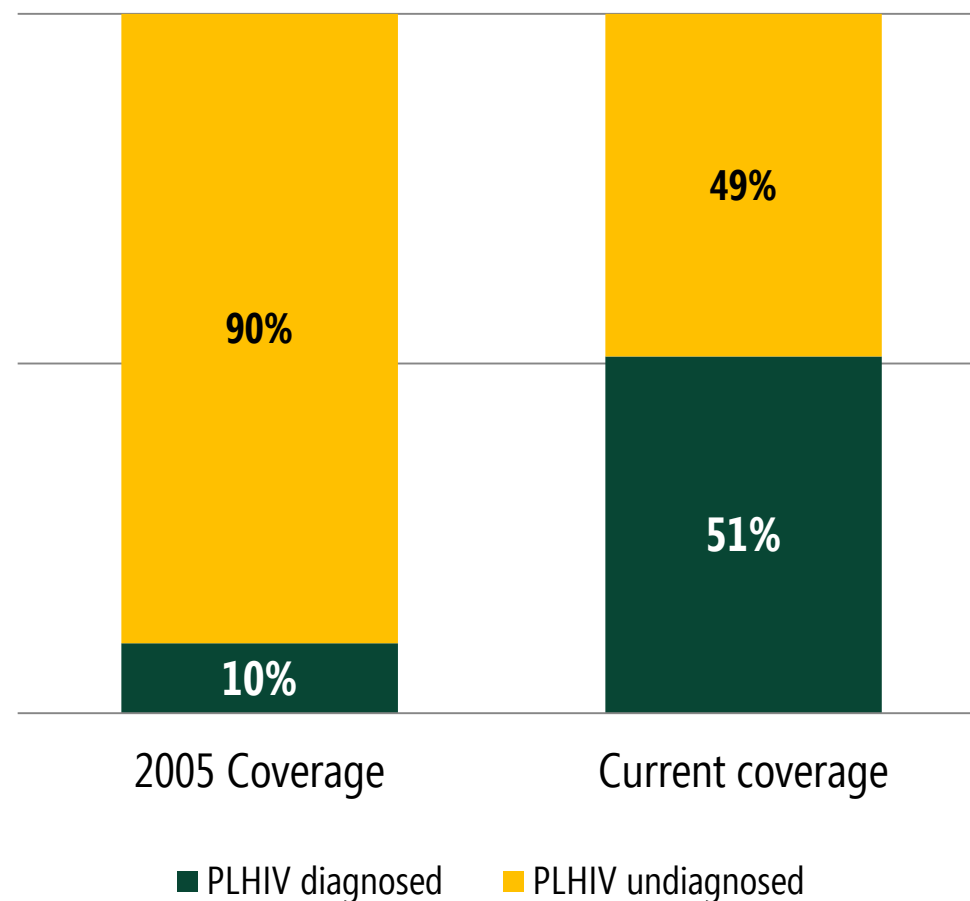
Adults 15+	Men	Women	Total
Total tested	107,563	207,622	315,185
Tested HIV- positive	8,132	13,866	21,998

How Far We Have Come

In 2005 a WHO report indicated that it was estimated that only 12% of people who wanted to be tested were able to do so.

2003-2005 household surveys in select high burden countries in Africa reported that only 10% of PLHIV knew their HIV status.

Current coverage is estimated by UNAIDS and is based on DHS reports



Rationale for New HTS Guidelines

The 1st “90” is the most problematic

Nearly half all people w/ HIV unaware of HIV status, globally

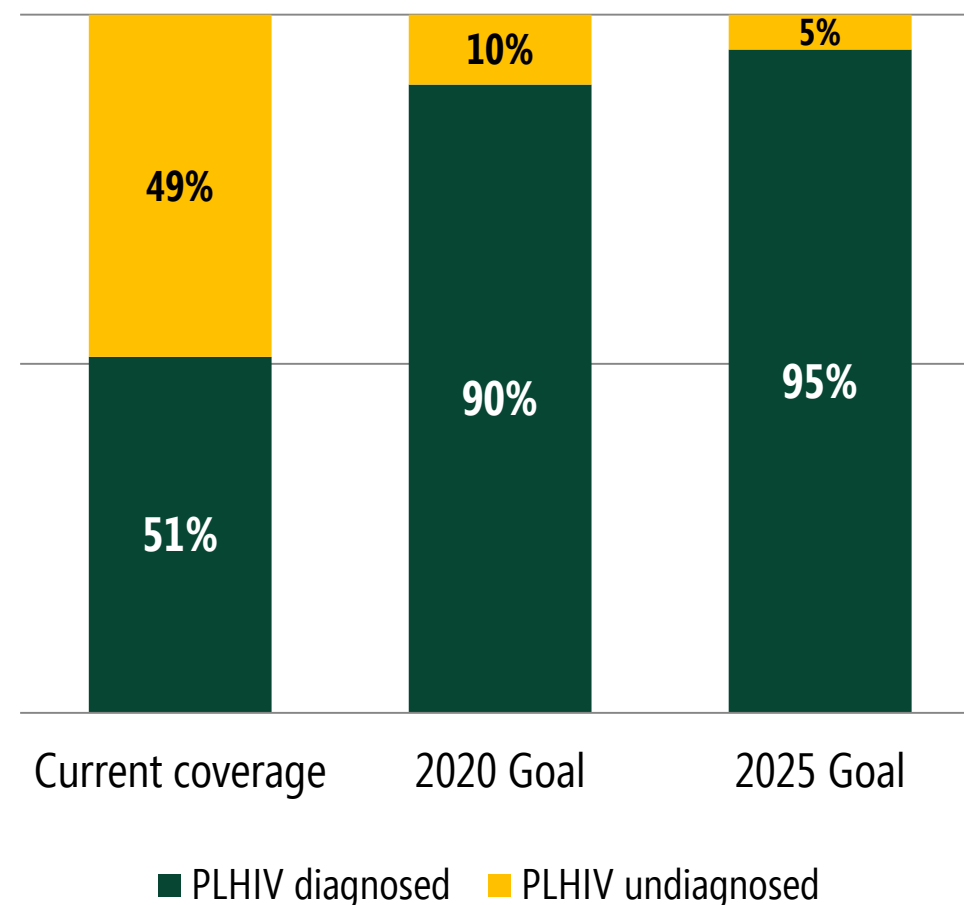
- ↓ men, adolescents, key populations

Suboptimal linkage post HTS to ART

- People delay & still initiate ART late

More focus and targeting

- Balance between HTS approaches in low & concentrated epidemics



Critical Issues Addressed in New HTS Guidelines

■ New approaches

- Trained lay providers testing (*new recommendation*)
- Test for Triage (*new testing strategy*)
- HIV self-testing (*push for implementation and monitoring*)

■ Better linkage

■ Preventing misdiagnosis

- Focus on QA
- Re-emphasise re-testing all +ve before ART initiation

■ Strategic choices

- Making tough choices about mix of testing approaches, for better cost effectiveness, earlier diagnosis and linkage and impact
 - including ANC testing in different epidemic setting
- Reinforcing appropriate testing in specific clinical settings & for indicator conditions
- Increasing access by supporting community testing
- Prioritizing index partner and family testing



Overview: Consolidated HTS Guidelines

Summary

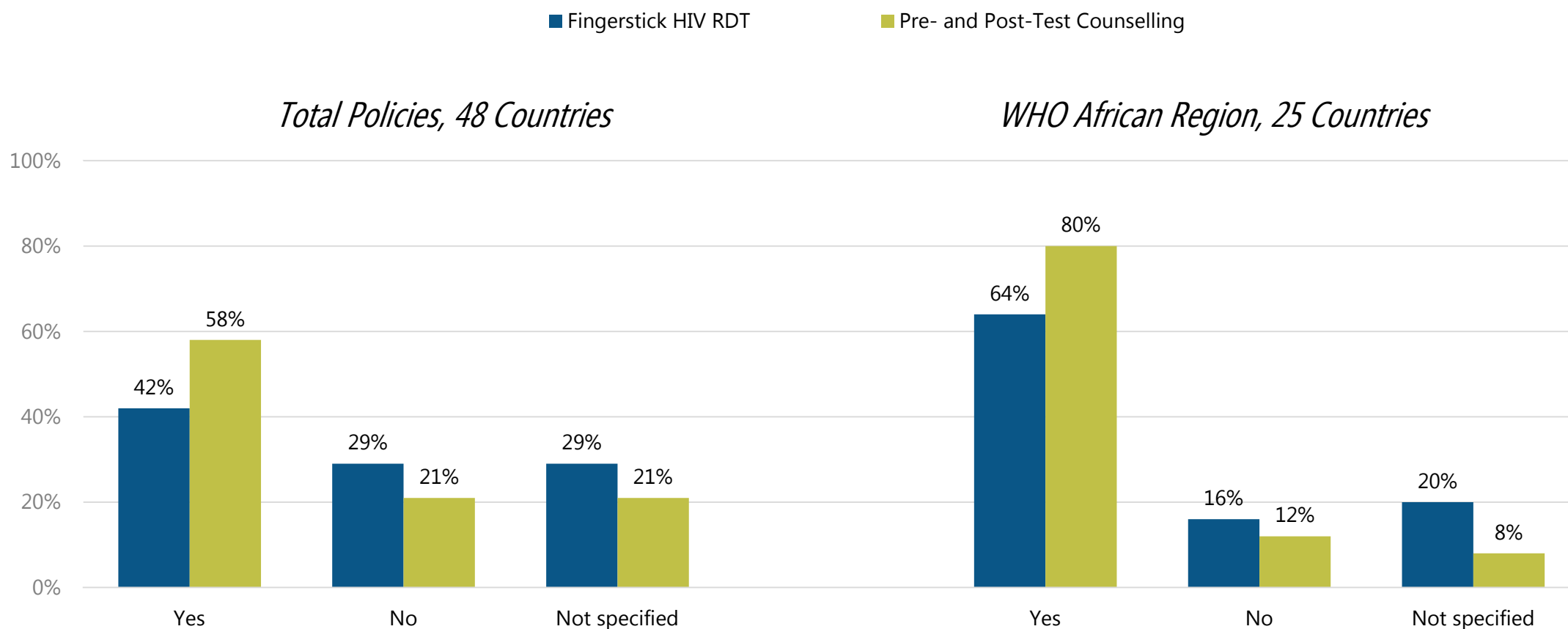
- 1. Introduction & Key issues**
- 2. Methodology**
- 3. Pre and post-test services**
- 4. Service delivery approaches**
- 5. Priority groups**
 - Infants & Children; Adolescents; Pregnant women; Couples & partners; Men; Key Populations; and Vulnerable/other populations
- 6. Strategic planning for HTS**
- 7. Diagnostics for HIV diagnosis**
- 8. Quality assurance of HIV testing**
- 9. HIV testing in the context of surveillance**
- 10. Monitoring and evaluation**

Background work

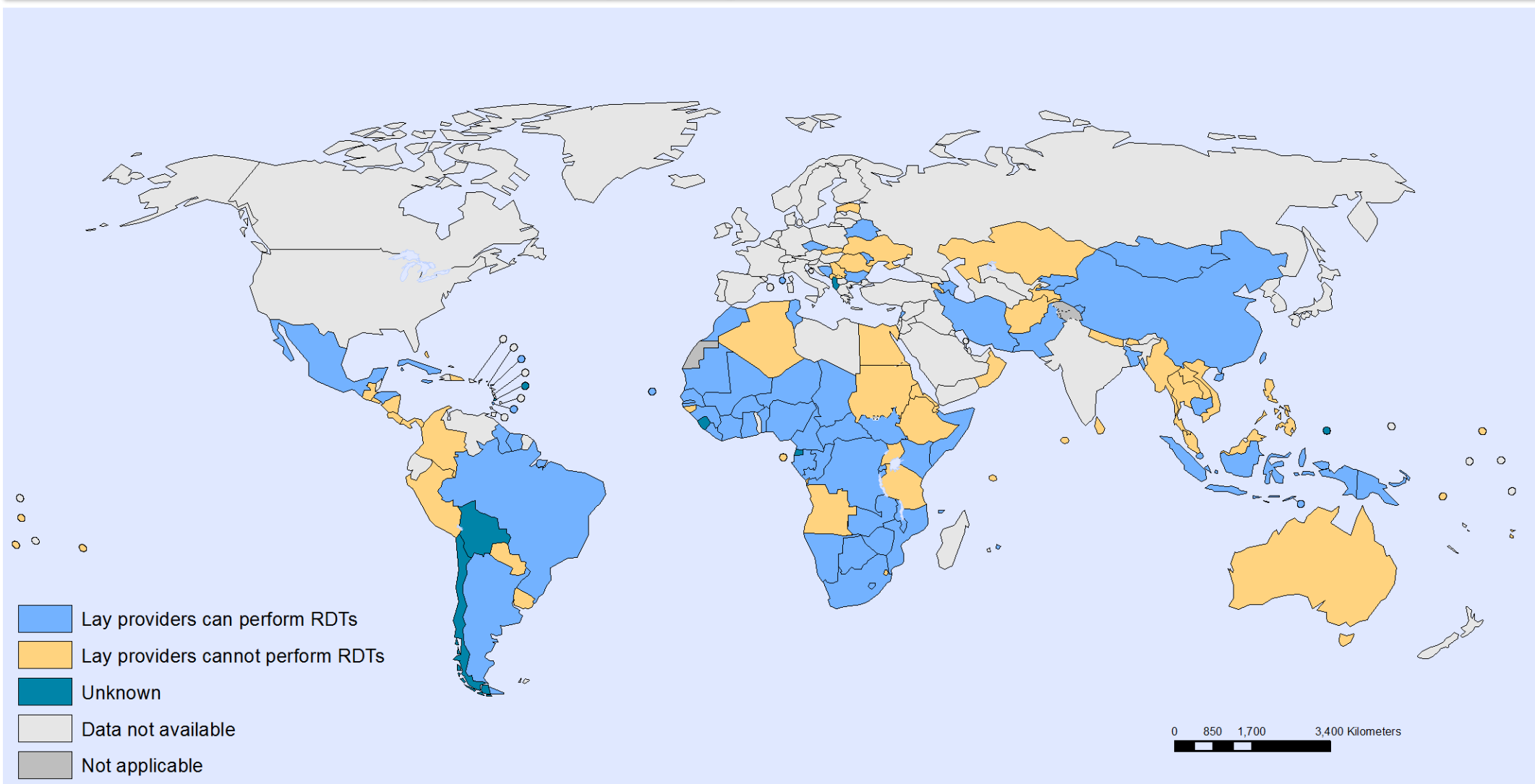
- Review lay providers testing services
- Test for Triage
- Review of community based HTS for general populations
- Review of community based HTS for KP
- Costing of different HTS approaches
- Cost-effectiveness of PITC in ANC in different prevalence settings
- Misdiagnosis of HIV status report
- Lit review of V&P around HIVST among KP

Highlight #1 Lay Provider HIV Testing Services

Some country policies already permit lay provider HIV testing; however, task sharing can be expanded.



Countries that report on policies that permit lay providers to perform rapid diagnostic tests (RDTs), 2014



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Health Statistics and
Information Systems (HSI)
World Health Organization



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New Recommendation

Should trained lay providers perform HIV testing services using HIV rapid diagnostic tests?

Studies identified: 1 RCT, 4 observational studies & 6 studies on values & preferences

Increased Uptake

- Uptake among ED patients was 57% (1,382/2,446) in the lay provider arm compared with 27% in the healthcare provider arm (643/2,409; RR: 2.12, 95% CI: 1.96 to 2.28)

Quality & Accuracy equivalent to health workers with longer training

- 3 observational studies report lay provider and laboratory staff test results were concordant in nearly all cases
- 2 observational studies comparing lay provider and laboratory staff test results, sensitivity was calculated as 98.0% (95% CI: 96.3-98.9%) and 99.6%, and specificity was calculated as 99.6% (95% CI: 99.4-99.7%) and 100.0%.

Values & Preferences

- General support for lay providers conducting HTS, particularly in RCT & other study measuring preferences among people who had actually undergone HTS with a lay provider.

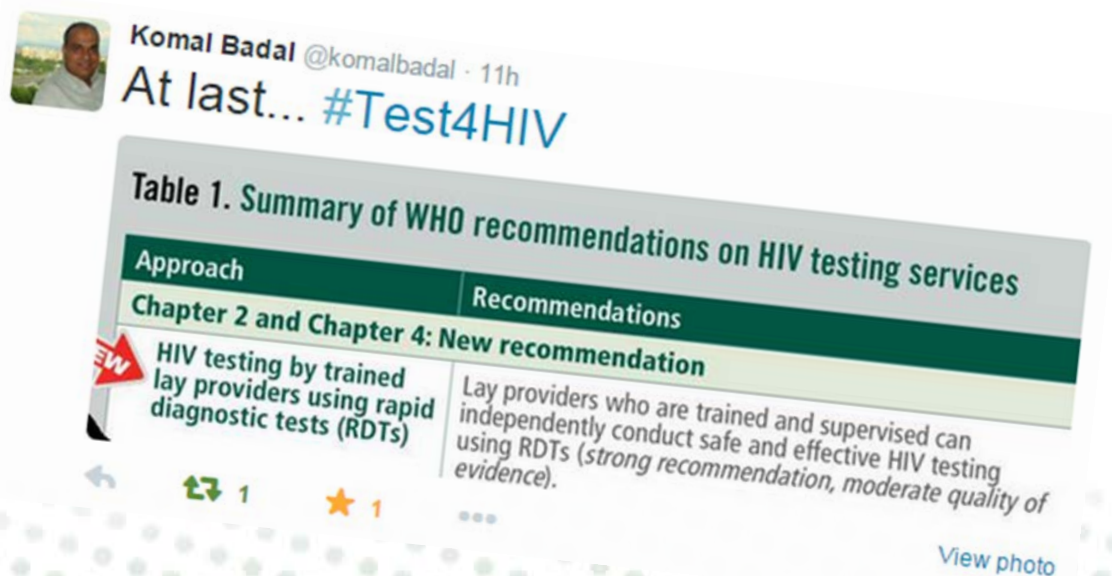
Cost

- Cost of trained lay providers vary but are generally lower than cost of health providers with longer training.

Trained lay providers can safely and effectively perform HIV testing services using rapid diagnostic tests. (*strong recommendation, moderate quality evidence*)

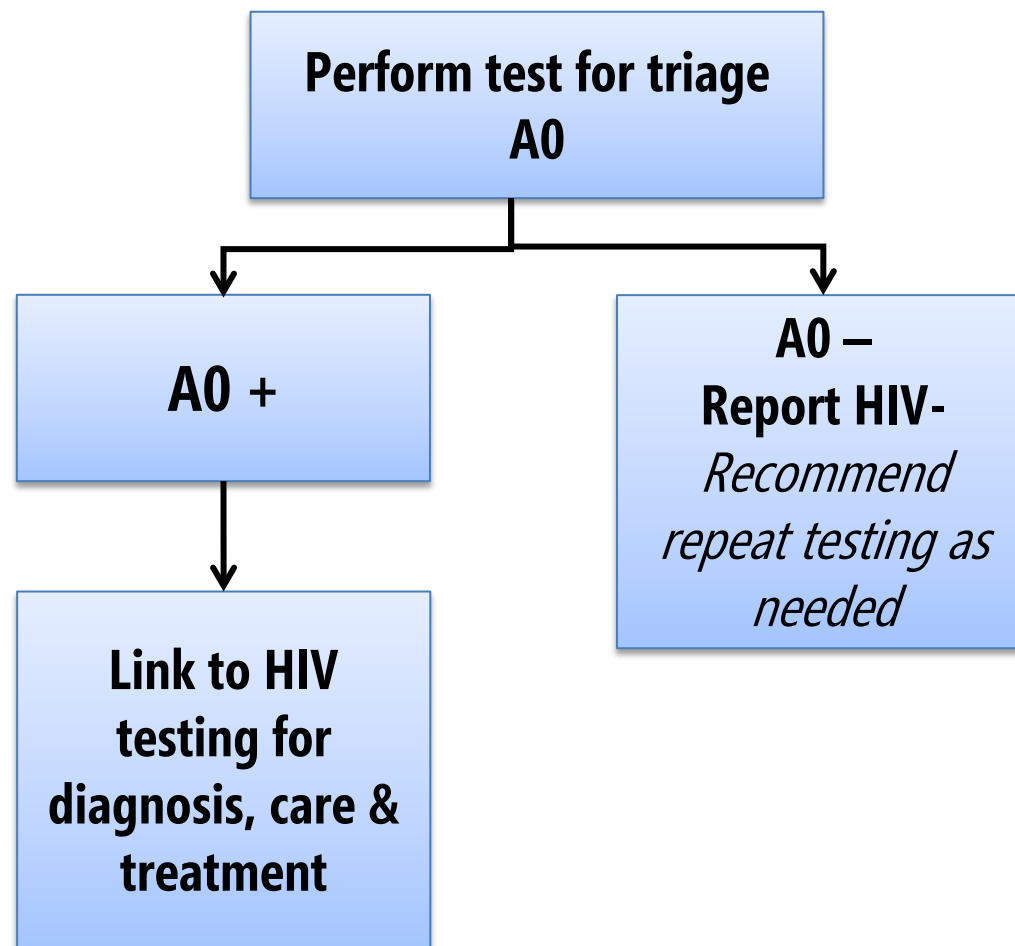
Lay Testers—Considerations for Success

- **Choose wisely**—select and train lay providers well-matched to clientele
- **Ongoing training**, mentoring and support is key—having a quality assurance system in place is essential
- **Adequate remuneration**—trained lay providers should receive adequate compensation
- **National policies** need to establish a role for trained lay providers to perform HTS



Test for Triage

- **A single rapid diagnostic test** in community-based HIV testing
- **Not a definitive test for those who test +ve**
- Emphasis on HIV diagnosis at health facility (start at A1)
- ***Triage*** – prioritize linkage following testing as appropriate

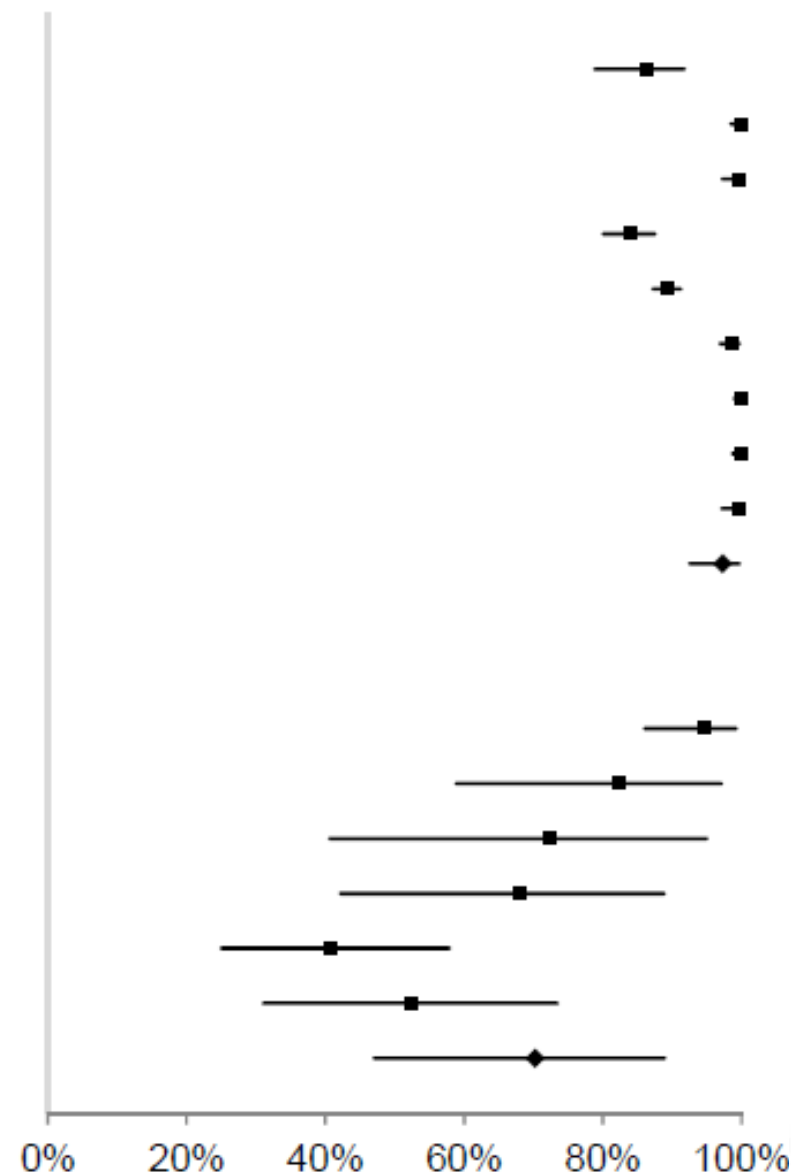


Highlight #2 Linkage

	<u>±</u>	<u>Total</u>	<u>Percentage (95% CI)</u>
<u>CD4 measured after HIV diagnosis</u>			
Feely (Workplace)	94	109	86.24 (78.82 - 91.75)
Chamie (Mobile)	140	140	99.82 (98.45 - 99.84)
Govindasamy (Mobile)	77	77	99.68 (97.21 - 99.71)
Van der Borght (Workplace)	311	370	83.96 (80.06 - 87.51)
Nglazi (Mobile)	798	893	89.32 (87.21 - 91.26)
Granich (Mobile)	255	258	98.66 (96.90 - 99.69)
Van Rooyen (House to house)	203	203	99.88 (98.93 - 99.89)
Shapiro (Index)	166	166	99.85 (98.69 - 99.86)
Shapiro (House to house)	76	76	99.67 (97.18 - 99.70)
OVERALL	2120	2292	97.27 (92.52 - 99.69)

Initiated ART after CD4 count indicated eligible

Feely (Workplace)	42	44	94.50 (86.04 - 99.18)
Van Rooyen (House to house)	11	13	82.28 (58.86 - 97.05)
Chamie (Mobile)	6	8	72.40 (40.61 - 94.96)
Govindasamy (Mobile)	9	13	67.91 (42.16 - 88.86)
Shapiro (Index)	13	32	40.90 (24.98 - 57.88)
Shapiro (House to house)	10	19	52.50 (31.07 - 73.46)
OVERALL	91	129	70.24 (47.04 - 88.91)



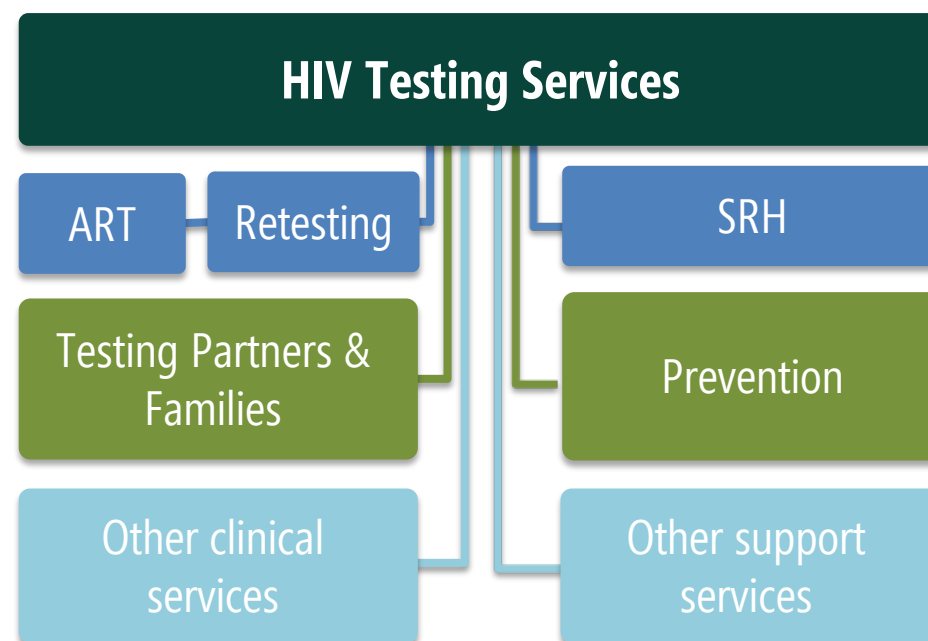
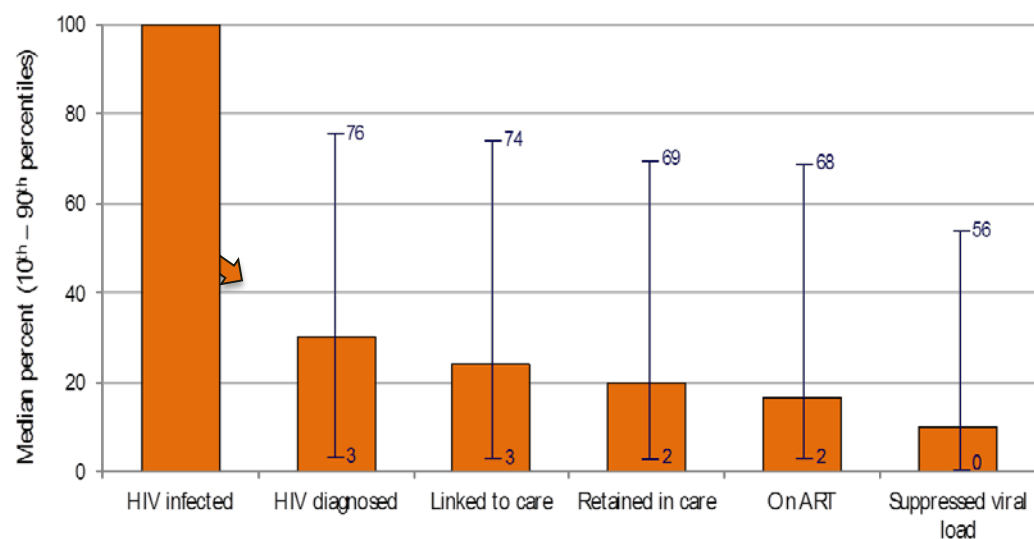
% linkage following various testing approaches, WHO 2013

Linkage to Prevention, Treatment and Care

Linkage to ART

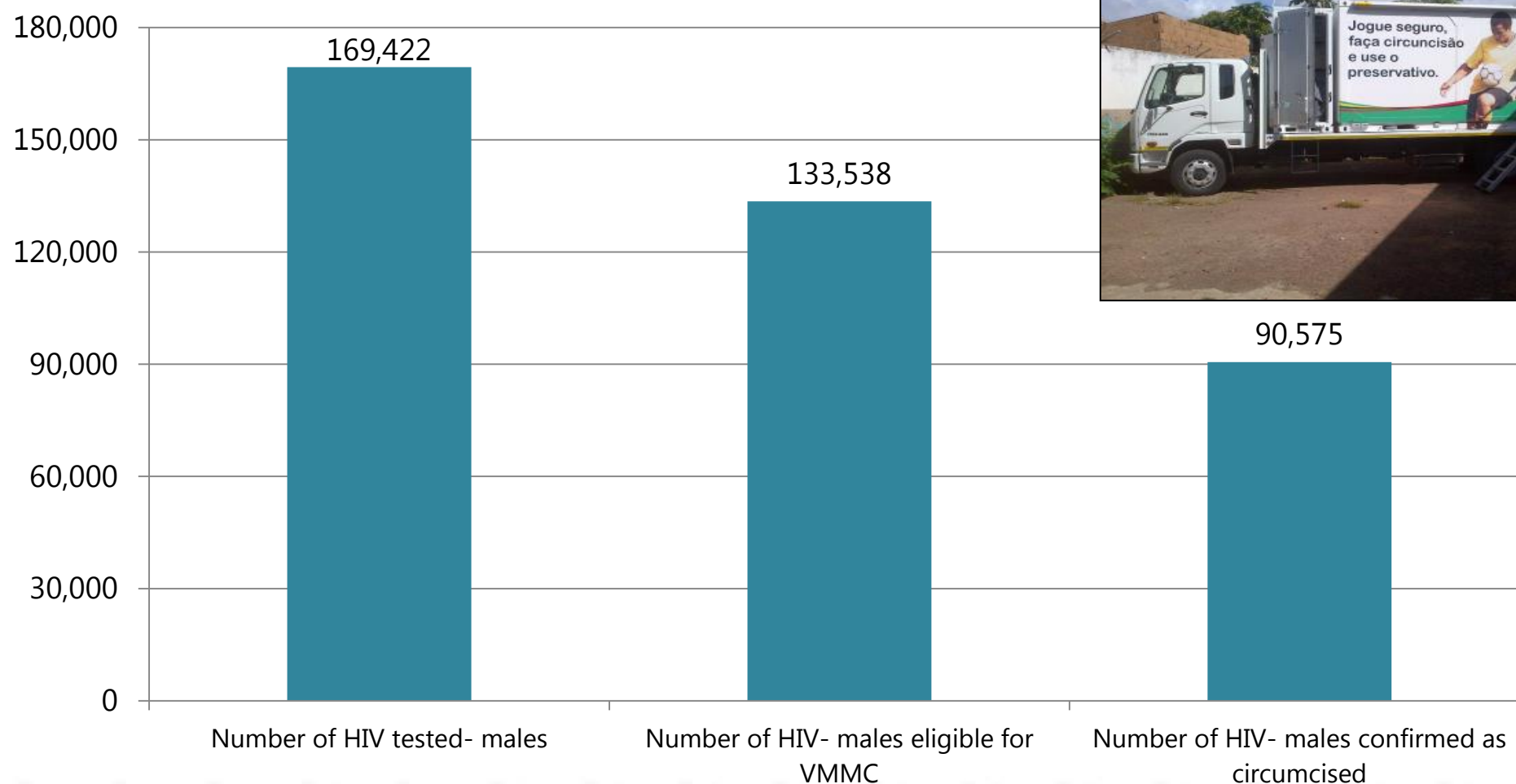
HIV Care Cascade among MSM From 12 Sites In India

n = 1,146 HIV Positive



Linkage to Prevention

Mozambique: tracking VMMC referrals from home-based HTS

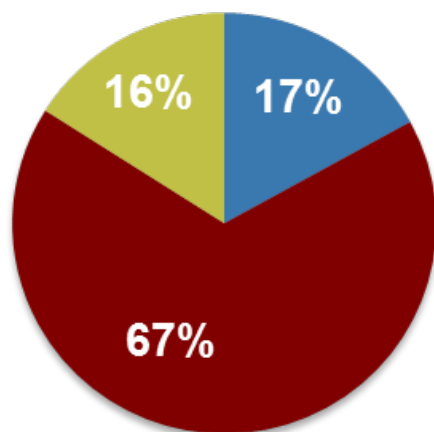


Strategies to Consider for Improving Linkage

- Comprehensive home-based HIV testing, home-based ART and/or home-based ART assessment
- Integration of services at a single facility
- On-site or immediate CD4 testing with same day results
- Transport vouchers
- Decentralized ART provision
- Use of trained lay providers to act as peer navigators, expert patients/clients and community outreach workers to support, identify and reach people lost to follow-up
- Brief strengths-based case management
- Partner testing promotion
- Intimate partner notification

Highlight #3 Improving Quality, Reducing Misdiagnosis

National Testing Policies in Line with WHO
Recommendations
48 Countries



■ Yes ■ No ■ Insufficient Information

Review identified various studies with quality issues. Few studies reported on misdiagnosis, but 2 MSF studies report misclassification range from 2.6% to 10.3%^{1,2}

Studies (N=44) Identified in a Literature Review, Reporting
Factors Related to Misdiagnosis

Category	#	%
Clerical/technical errors (e.g. mislabeling, poor recordkeeping, clerical mistakes)	14	32%
User error (e.g., errors performing RDT or interpreting results, misapplication of buffer, inaccurate reading time and other human errors)	21	48%
Cross-reactivity (e.g., antibodies from inter-current infection, environmental exposure to test components, HIV subtype, or late-stage AIDS)	8	18%
Incorrect / suboptimal testing strategy or algorithm (e.g. tiebreaker testing strategy)	22	50%
Poor management and supervision (work load stress, staff shortages, lack of training, poor adherence to testing strategy or testing algorithm, substandard operating procedures, testing in window period)	20	45%

WHO Retesting Recommendations

1. Retesting HIV-negative people at ongoing risk for HIV infection

- people from key populations
- people with a known HIV-positive partner
- people with known recent HIV exposure
- pregnant and breastfeeding women in high incidence/prevalence settings
- individuals seen for a diagnosis or treatment of STIs
- TB patients with a possible recent HIV exposure or who are at higher risk for HIV exposure
- outpatients with clinical conditions indicative of HIV infection

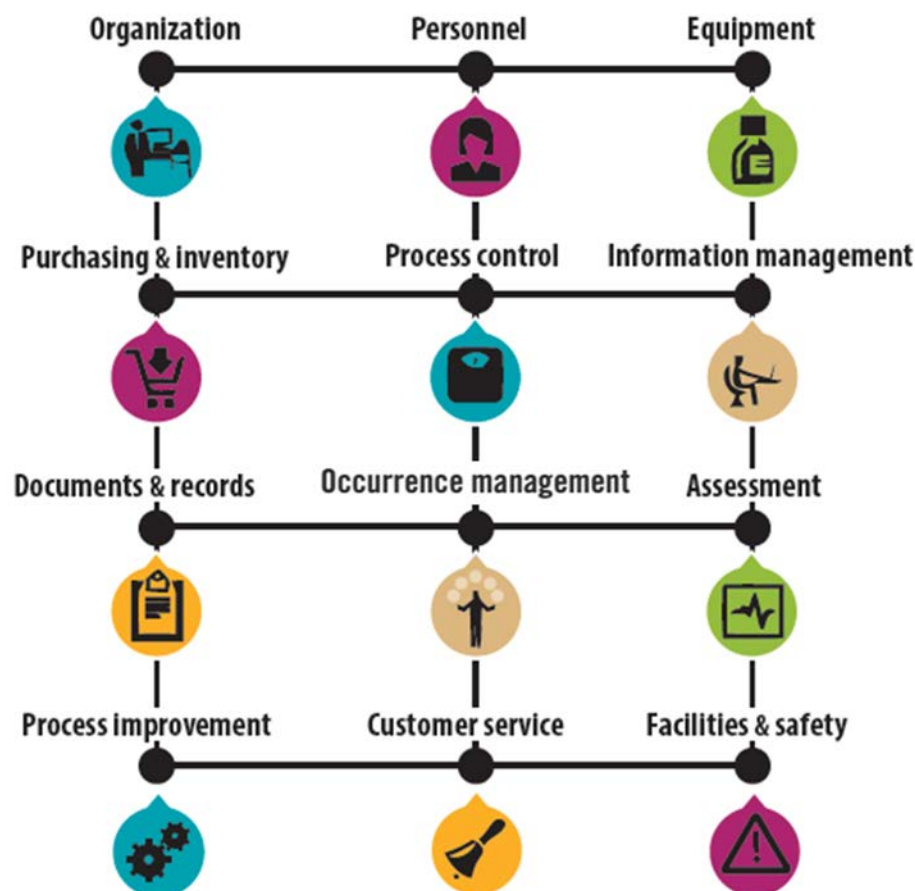
It is important to note that in **low prevalence settings retesting of pregnant women is not recommended**, unless they are from a key population group or is known to have an HIV-positive partner.

2. Retesting people with HIV-inconclusive test results after 14 days; and

3. Retest to verify an HIV-positive diagnosis before initiating care and/or ART.

- Retesting people who are already on ART is *not* recommended.

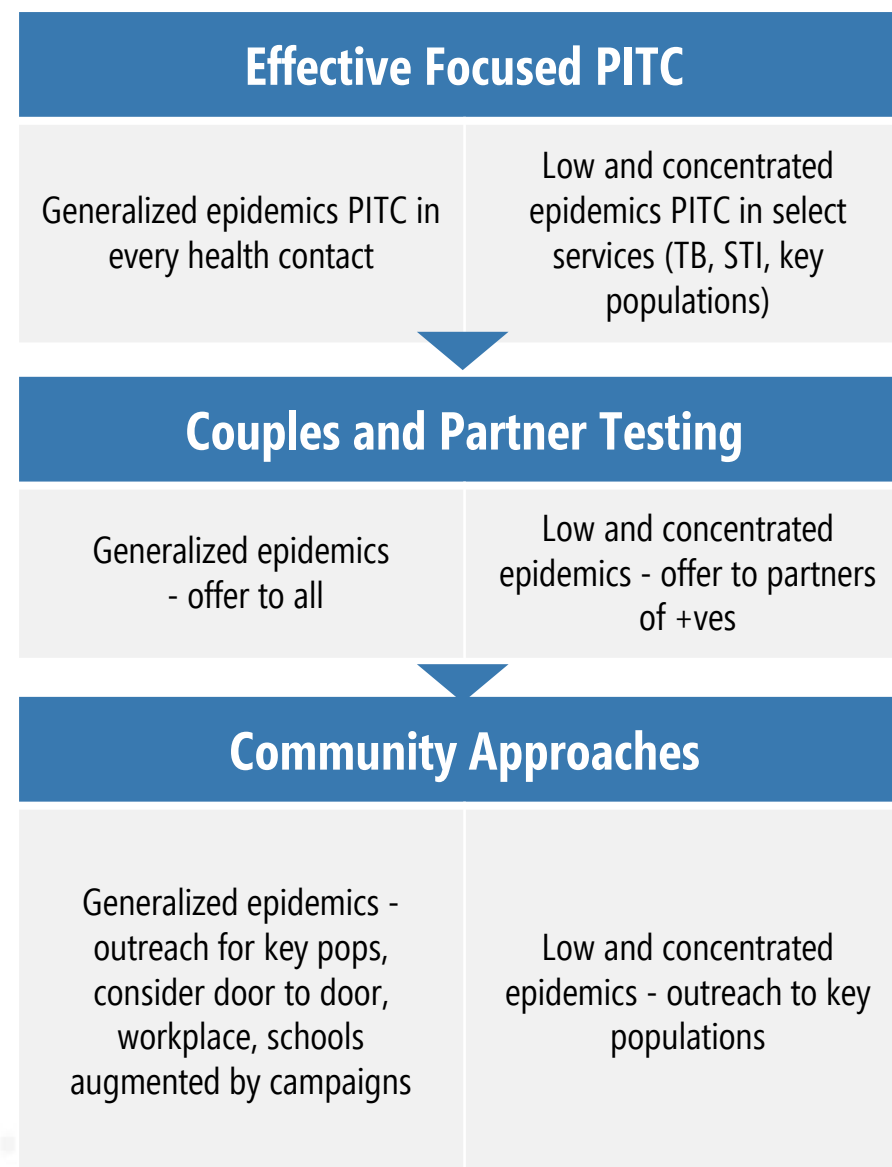
12 Quality System Essentials



To assure the quality of HIV testing services it is critical that all sites follow 12 QSEs—regardless of whether HTS takes place in laboratories, facilities or in community-based (non-facility) settings

Highlight #4 Focusing HTS

- **Strategic use of PITC** in low and concentrated epidemics
- **Where to stop testing** and re-prioritize
- Focusing on **diagnosing the undiagnosed**, underserved & those with ongoing risk
- Strategies to reach **men**
- Overcome reluctance to provide **partner testing**/index partner testing
- Legitimize lay provider/peer testing for outreach, esp. for KP



Highlight #4 Expanding Community-Based HTS

Highly Acceptable



- Home based **82%** (#18)
- Index partner **93%** (#6)
- Mobile/outreach **93%** (#9)
- Workplace **59%** (#4)

Earlier Diagnosis



- 11 studies (3190 participants) CD4 >350 cells—pooled **59%**.

Missing Populations



- Men
- Key Populations
- Young women (not pregnant)

Linkage to Care

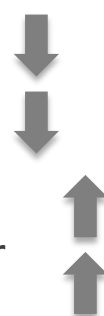


- Highly variable and problematic

Positivity Rate



- Home based
- Campaigns
- KP outreach
- Index partner



Unit Cost



- But cost effectiveness may be acceptable especially for KP

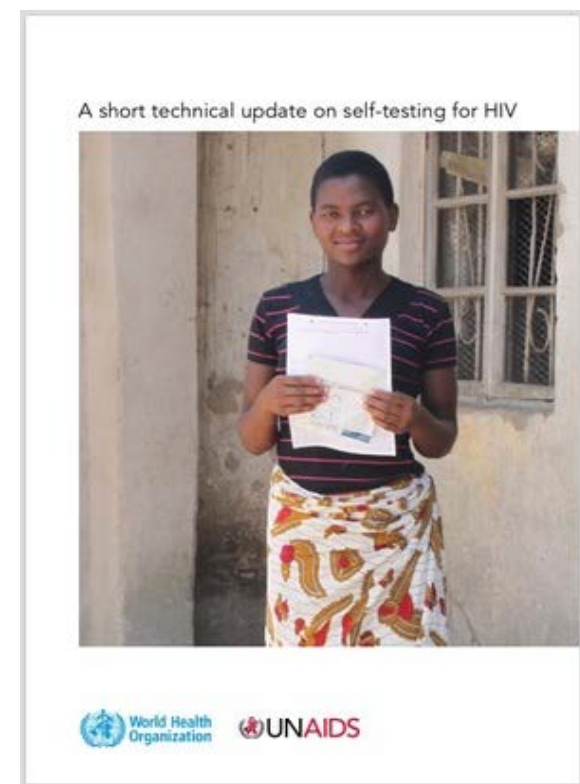
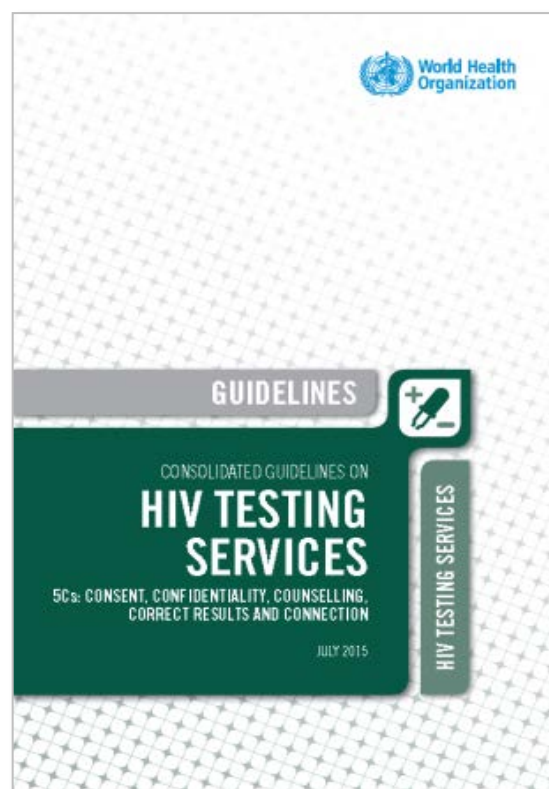
Current WHO Guidance on HIVST

Many models, priorities and policy issues, and evidence gaps

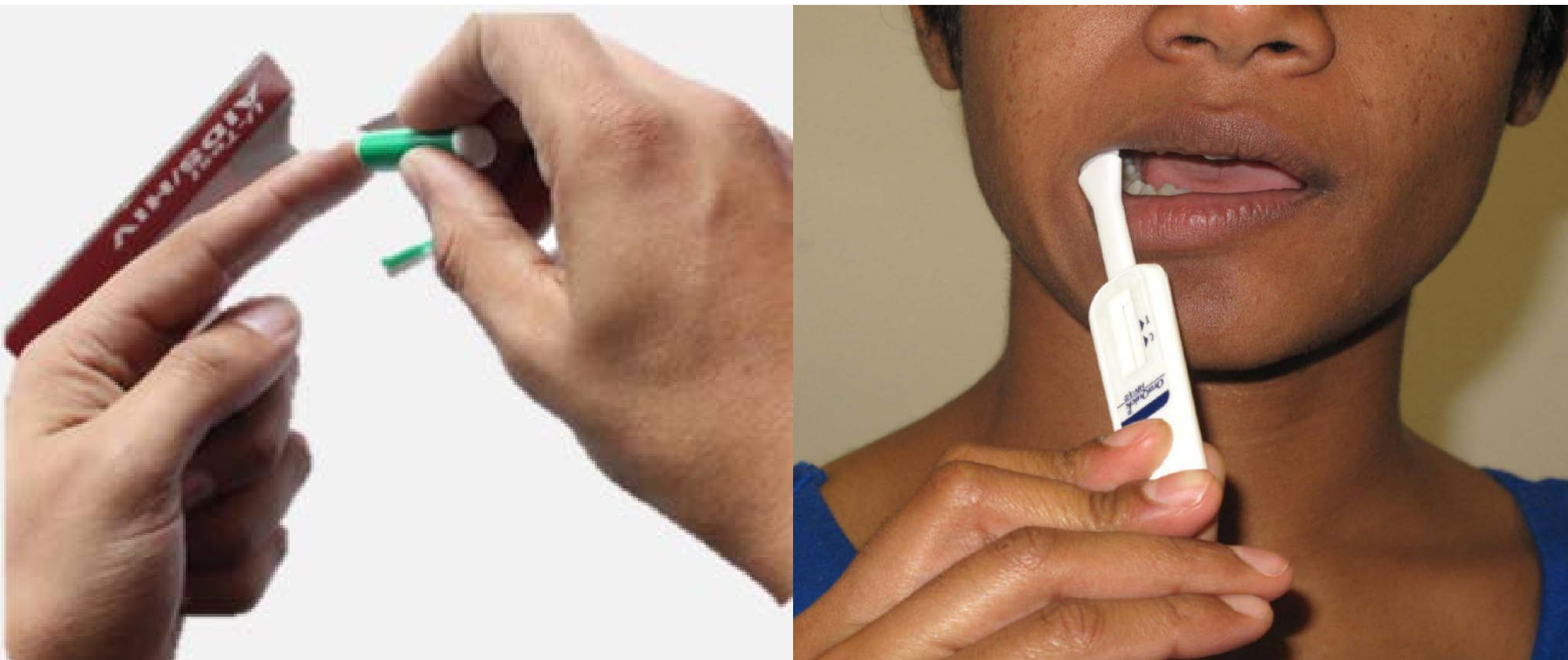
Outlines the issues & technical considerations for HIVST & **encourages countries to conduct demonstration projects**

Normative guidance on HIVST is **planned for 2016**

Most current information available on **HIVST.org**



What is HIV Self-Testing (HIVST)?



Reactive results need confirmation by health provider

Key Concepts & Next Steps

Current HIV testing services are not enough to get to 90.

- **Community based testing** implemented widely but not always most appropriately or effectively and barriers exist
- **Facility based testing** – still many missed opportunities
- **Couples and partners** – prioritize and normalize
- **Self-testing** is not new
 - HIVST –an additional tool to *create demand for, not substitute*, HIV testing services
 - WHO guidance forthcoming
 - Countries encouraged to start implementing - different models & for different populations

Public health response lags behind public demand—need to catch up

Countries and implementers need to choose a strategic, cost effective mix of HTS approaches.

Improve quality, stimulate technological advances, better tests & innovations in implementation

Acknowledgments

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