

Launch of the WHO Consolidated Guidelines on HIV testing services: An overview

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Testing, new directions in treatment, and measuring impact: New WHO guidelines (SUSA06) WHO IAS Satellite
Sunday 19 July 2015 12:30-14:30, room 211-214

WHO 2015 Guidelines. http://apps.who.int/iris/bitstream/10665/179870/1/9789241508926_eng.pdf?ua=1&ua=1

Rationale for HTS Guidelines

The 1st “90” is the most problematic

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

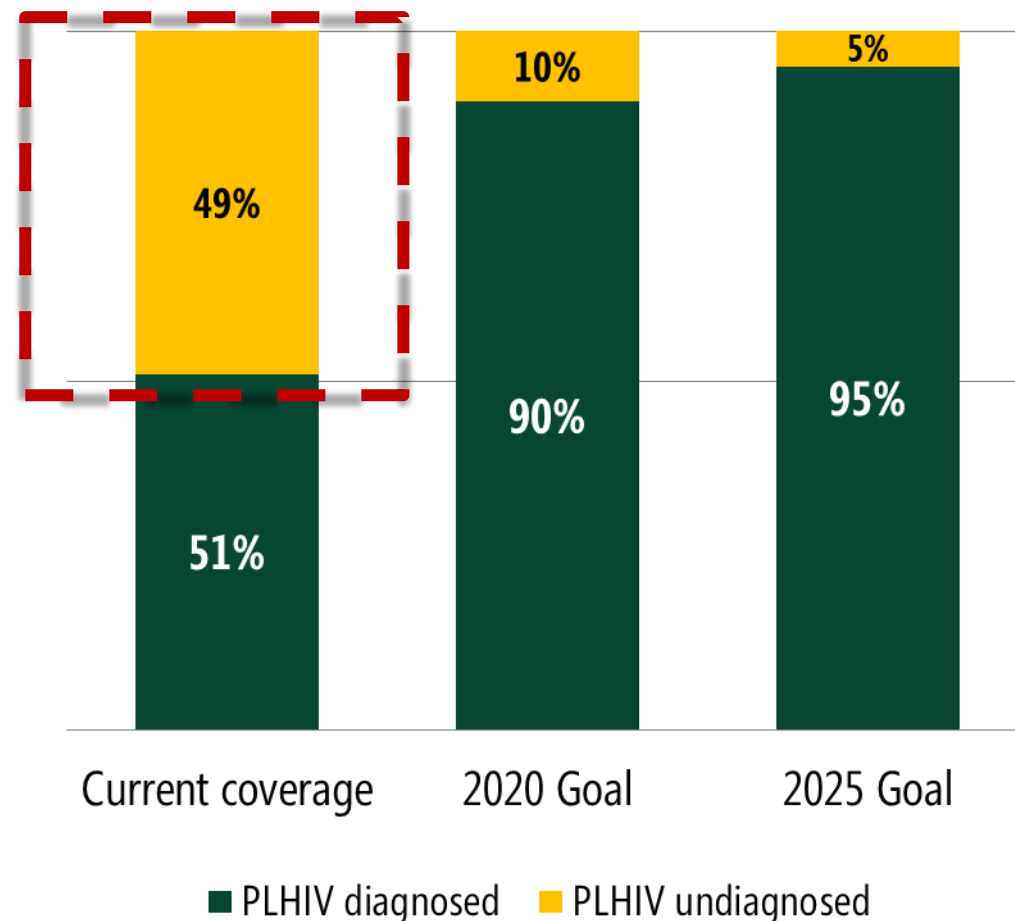
- ↓ men, adolescents, key populations

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

■ 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

■ New approaches

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

■ Preventing misdiagnosis

- Focus on QA & WHO recommended testing strategies
- Re-emphasise re-testing all +ve before ART initiation



WHO Consolidated Guidelines on HTS

New terminology –HTS

New emphasis on quality, efficiency, yield & linkage

Content

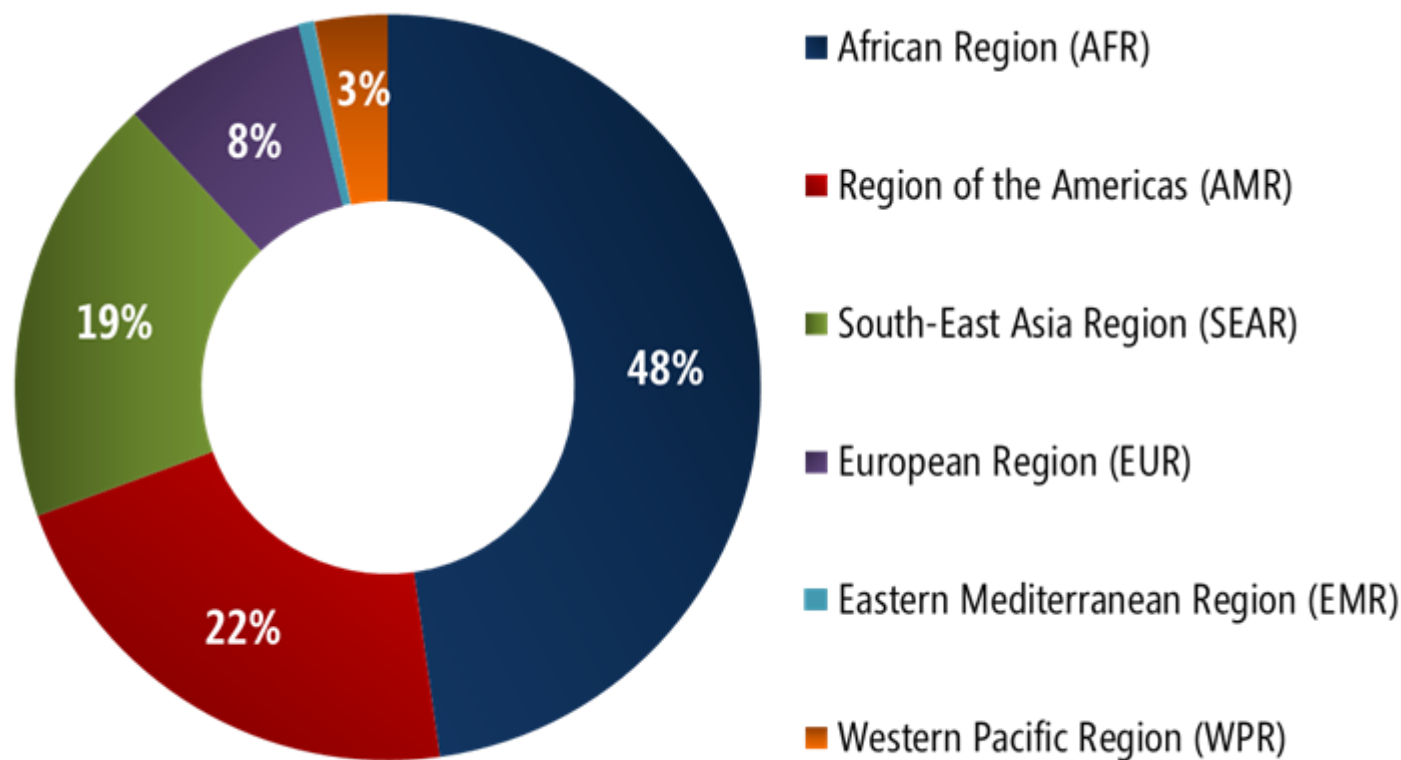
1. Pre & post-test services
2. Service delivery approaches
3. Priority groups:
 - key populations
 - infants, children, adolescents,
 - pregnant women;
 - couples & partners;
 - men
4. Strategic planning / focus for HTS
5. Diagnostics for HIV diagnosis
6. Quality assurance of HIV testing
7. HIV testing in the context of surveillance
8. Monitoring & evaluation

Background work

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

Where we are with HIV testing

Between 2010 and 2014 **600 million** adults (ages 15+), in 122 LMICs, reportedly received HIV testing services.

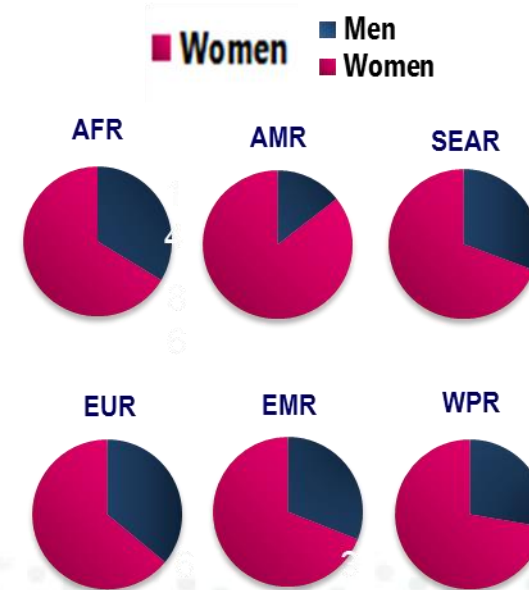
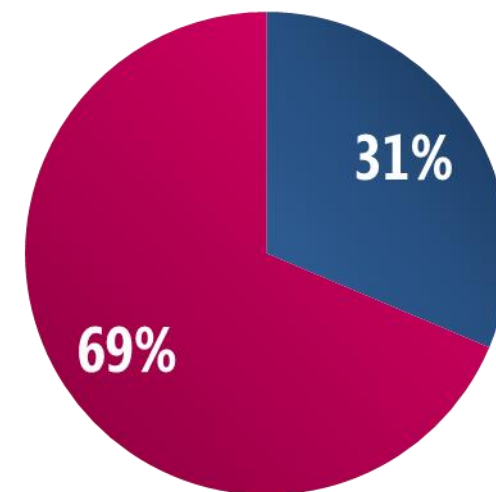


Nearly half of all reported HIV testing services have been delivered in the WHO African region.

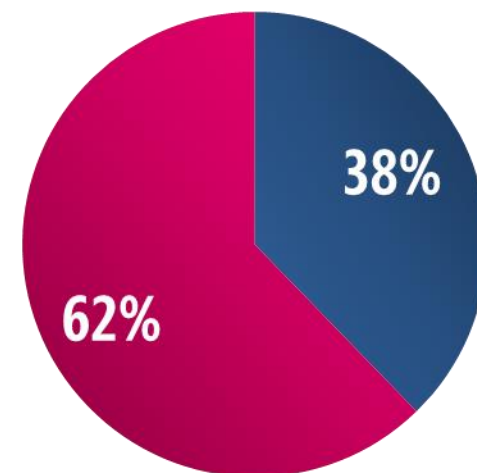
Women

Make Up Approximately
70% of Those Tested in
2014

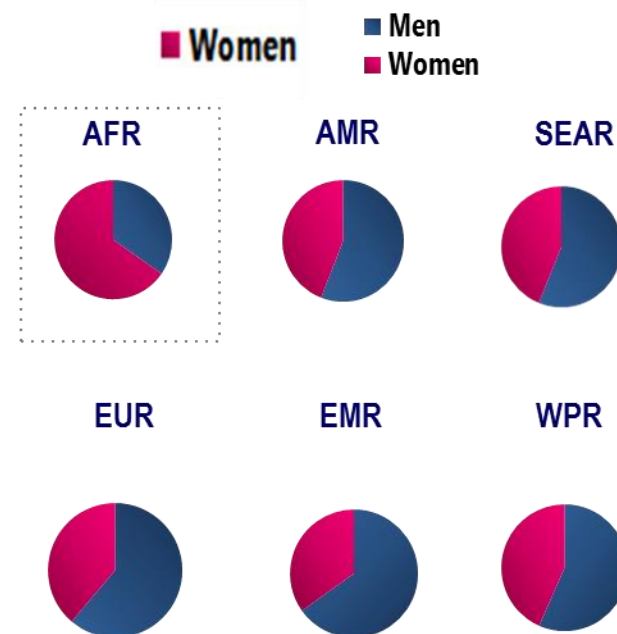
Much testing in ANC, even in low
and concentrated epidemics



In 2014, approximately 2 million adults (15+) tested HIV-positive in 65 reporting LMICs

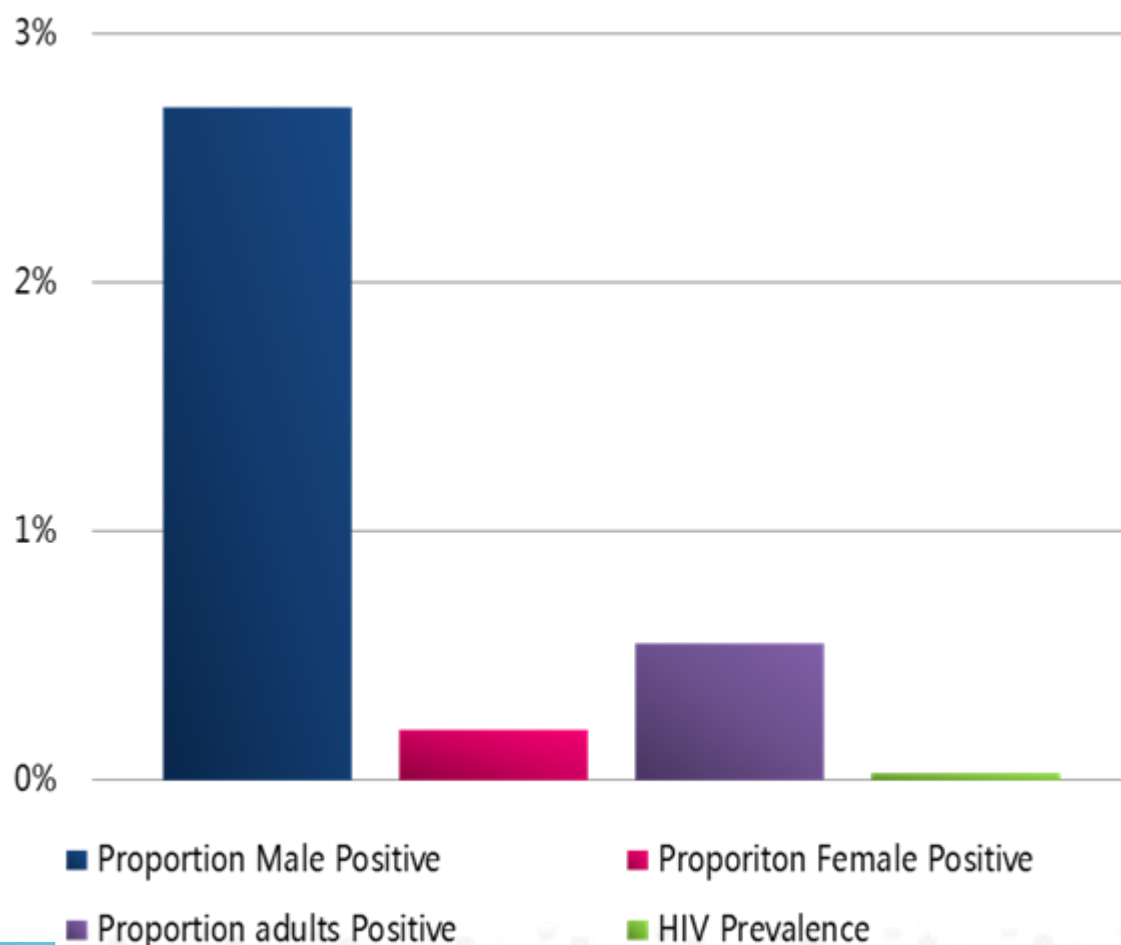


Outside of Africa, those who tested HIV-positive were more likely to be men in all regions



Bolivia

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



Estimated national **HIV prevalence 0.03%**.

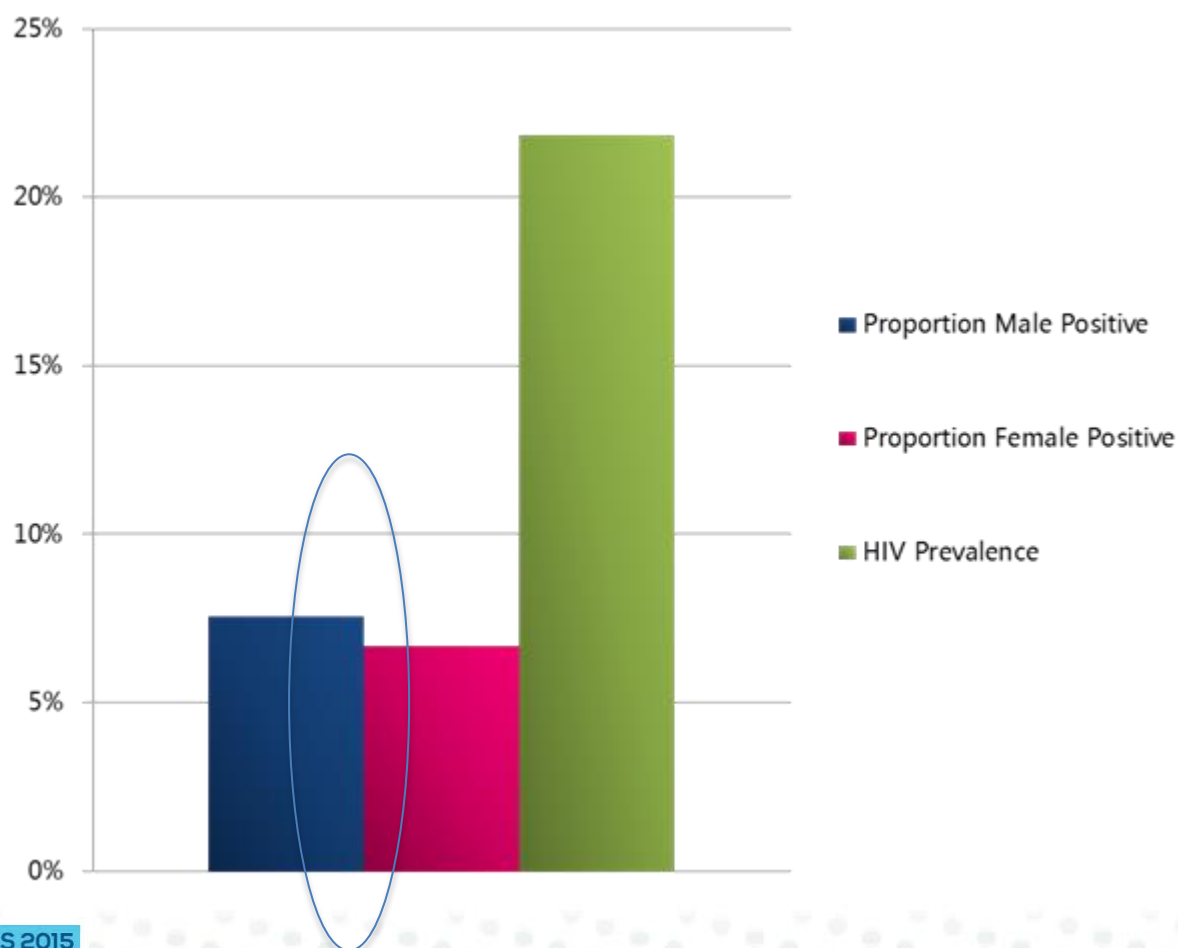
Over **372,498** adult men and women received HIV testing services and **0.5% tested HIV-positive**, in 2014².

Majority adults receiving HIV testing services were women—but **adult men were nearly 2.5x more likely to test HIV-positive compared to adult women**².

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

Botswana

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



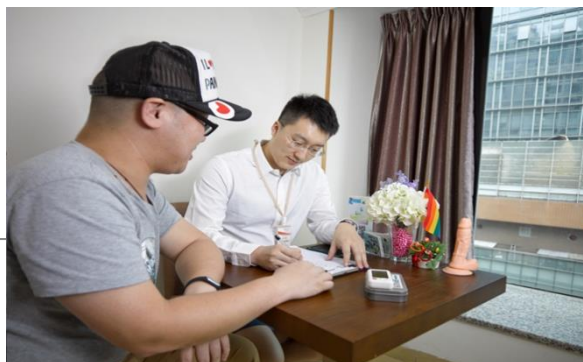
Estimated national **HIV prevalence is 22%**.

Over **300,000 adult men and women received HIV testing services** and nearly **7% tested HIV-positive** in 2014².

Adult men 2x less likely to receive HIV testing services 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

Highlight # 1 Lay provider HIV testing services

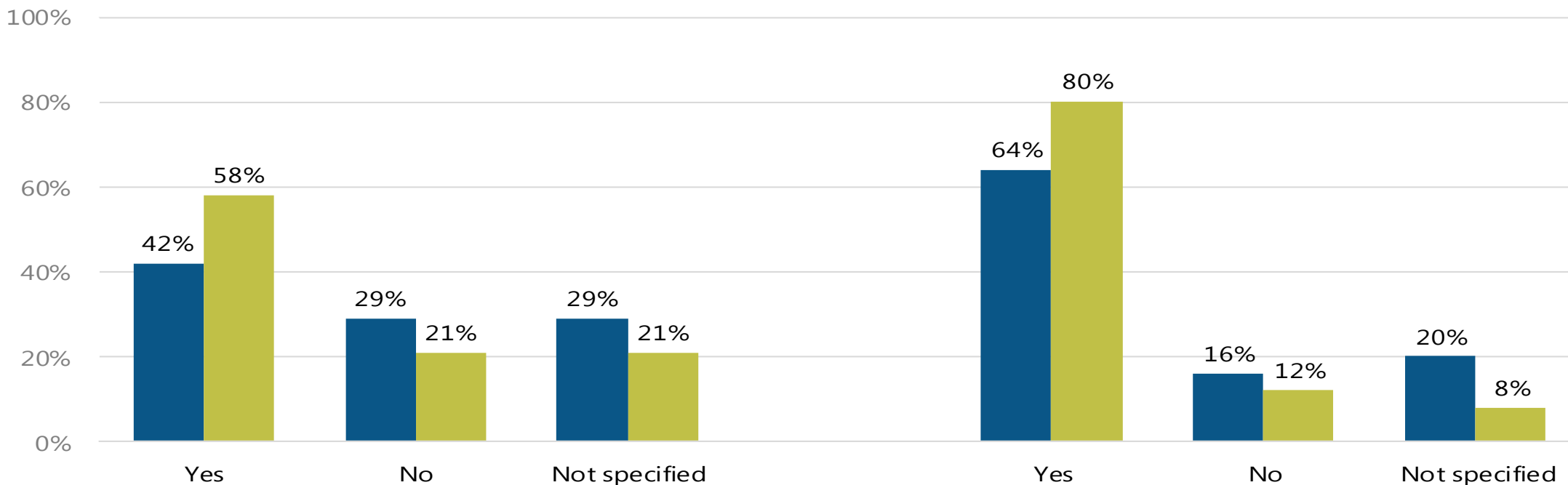


Some country policies already permit lay provider HIV testing; however task sharing can be expanded.

■ Fingerstick HIV RDT ■ Pre- and Post-Test Counselling

Total Policies, 48 Countries

WHO African Region, 25 Countries



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



Komal Badal @komalbadal · 11h
At last... #Test4HIV

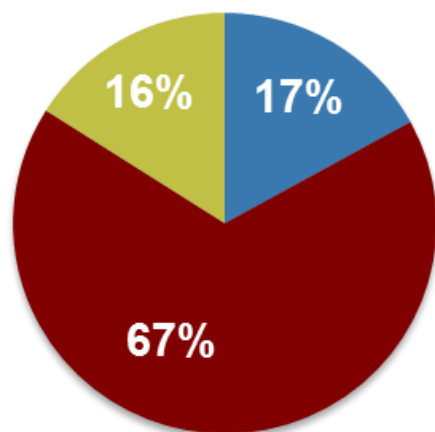
Table 1. Summary of WHO recommendations on HIV testing services

Approach	Recommendations
Chapter 2 and Chapter 4: New recommendation	
HIV testing by trained lay providers using rapid diagnostic tests (RDTs)	Lay providers who are trained and supervised can independently conduct safe and effective HIV testing using RDTs (<i>strong recommendation, moderate quality of evidence</i>).

View photo

Highlight # 2 Improving Quality reducing Misdiagnosis

National Testing Policies in Line with WHO Recommendations 48 Countries



■ Yes ■ No ■ Insufficient Information

Review identified reports of 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. mis-labelling, 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)	11	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%

Source: 1. Shanks PLoS One 2013; 2. Klarkowski PLoS One 2009; WHO 2015 forthcoming

Appropriate Retesting Recommendations

1. Retesting HIV-negative people at on-going risk for 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.

Guidance to improve quality

Highlight # 3 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

Effective Focused PITC

Generalized epidemics
PITC in every health
contact

Low and Conc
epidemics PITC in
select services (TB, STI,
Key pops)

Couples and Partner Testing

Generalized epidemics
- offer to all

Low and Conc
epidemics - offer to
partners of +ves

Community Approaches

Generalized epidemics
- outreach for key
pops, consider door to
door, workplace,
schools augmented by
campaigns

Low and Conc
epidemics - outreach
to key pops

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 



Remembering Glenn Thomas

Acknowledgements

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