

Overview—HIV self-testing

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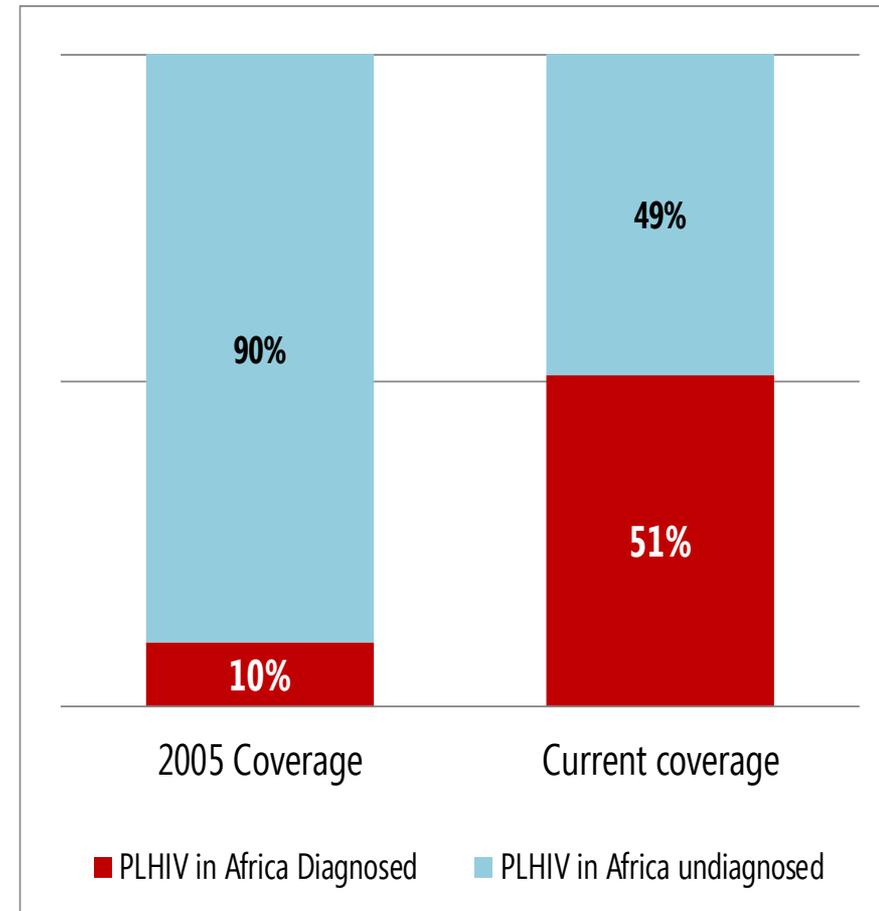
AIDSfree webinar
18 February 2016

We've come along way...

In 2005, 12% of people who wanted an HIV test were able & 10% of PLHIV in Africa knew their HIV status.

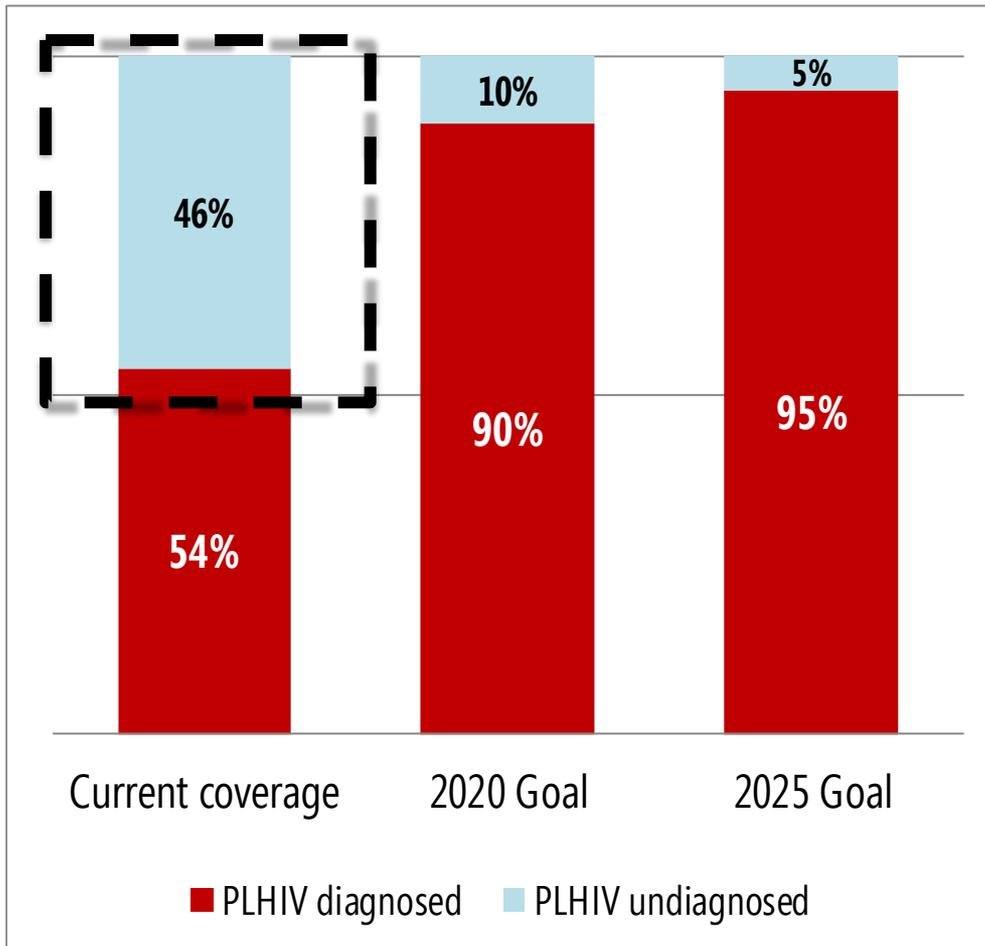
Now...

- In 2014 > 150 M people in reporting low- & middle-income countries received HTS
- UNAIDS estimates 51% of PLHIV in Africa now know their HIV status



...But we have a long way to go

UN First 90 - Diagnose 90% all PLHIV by 2020



More than 80% of PLHIV are on ART, but we are falling behind on HTS

Current HTS approaches not enough to get to 90

HIVST is an additional tool to create demand for HTS & potentially increase access, uptake & efficiency

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

What is HIV Self-Testing (HIVST)?



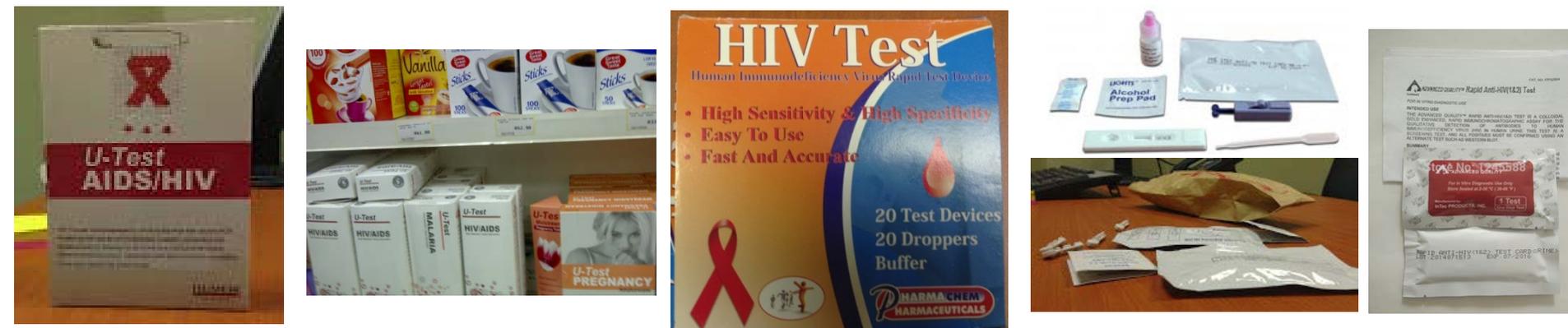
Reactive results need confirmation by health provider

Formally and informally HIVST is increasing

Available *Formally*



...& *Informally*



Credits: David Stanton, Vincent Wong, Cheryl Johnson, Matthew Rosenthal

Current Policy Environment

| Policies & Product(s) Approved for HIVST | Policies Explicitly Allowing HIVST | Policies Under Development | HIVST Available Informally |
|--|------------------------------------|----------------------------|-----------------------------|
| USA 2012 | Australia | Namibia | China |
| UK 2015 | Kenya | Peru | Namibia |
| France 2015 | Hong Kong SAR | Thailand | Russian Federation |
| Brazil 2015 | Macau SAR | Zambia | United Republic of Tanzania |
| | Malawi | Zimbabwe | Nigeria |
| | Rwanda | | Peru |
| | South Africa* | | Uganda |
| | | | Ukraine |

WHO/UNITAID landscape

- 15 RDTs for HIVST identified, 3 approved by founding member of GHTF, none WHO PQed yet
 - 10 RDTs use fingerstick/whole-blood
 - 5 RDTs use oral fluid
- Formal sales volumes increasing but reports are limited
 - 12,000 (Apr-Oct 2015, UK) & 750,000 (Jul 2012–Oct 2015, USA).
- Costs range from:
 - US\$ 28-40 (sale in high-income countries)
 - US\$ 3.50 – US\$ 16 (for research low- & middle-income countries)
 - US\$ 4-10 (sale informally in low- and middle-income countries)

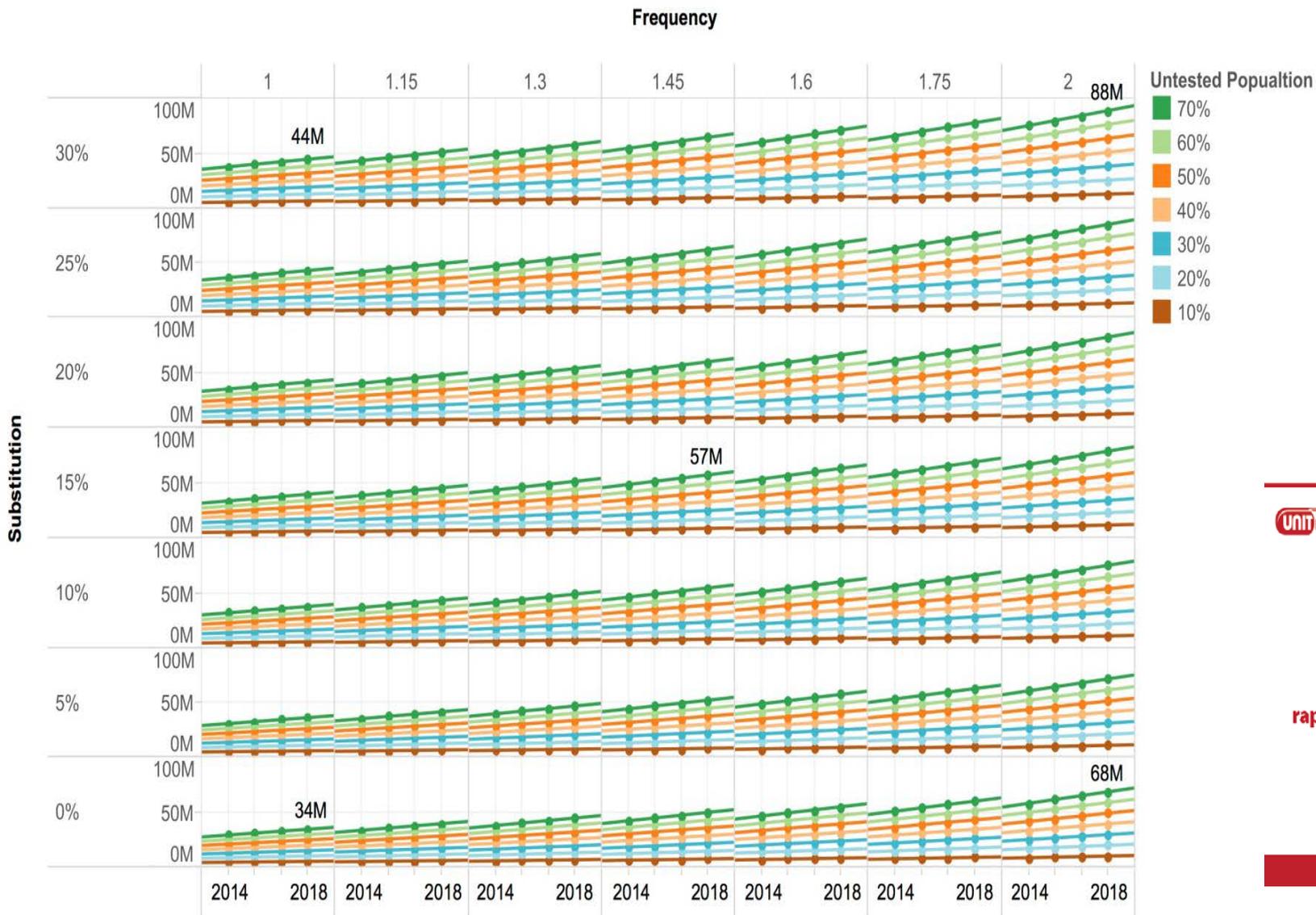
WHO / UNITAID
Landscape for HIV
rapid diagnostic tests for
HIV self-testing



Products with GHTF approvals

| Product (supplier) | Specimen | Price (\$ US) | Regulatory Status |
|--|----------------|---------------|-------------------|
| Autotest VIH (AAZ, France) | Whole Blood | 28 | CE marked |
| Biosure HIV Self Test (Biosure, UK) | Whole Blood | 31 | CE marked |
| OraQuick In-Home HIV Test (OraSure Technologies, USA) | Oral Fluid | 40 | FDA/CE marked |

Demand for HIVST could be at least 4.8 M RDTs in 2018



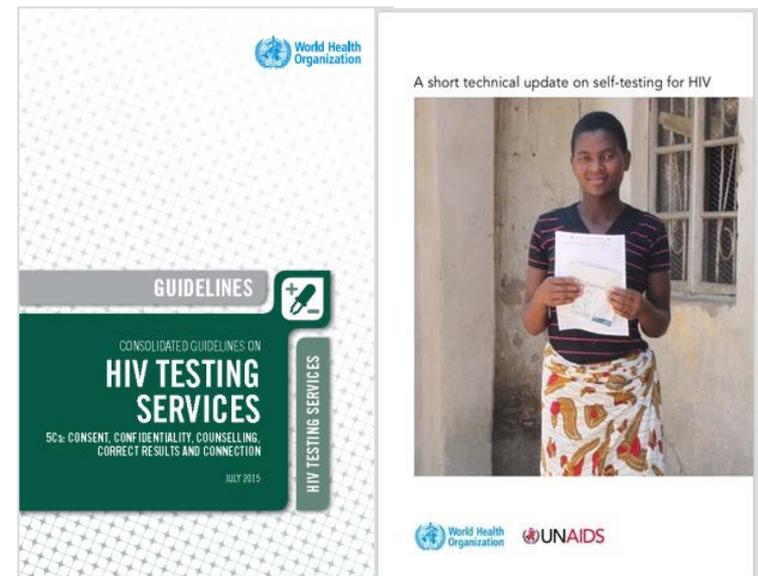
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Current WHO guidance on HIVST

Outlines models, priorities, policy issues & evidence gaps

Technical considerations for HIVST & encourages countries to conduct pilots/demonstration projects

Most current information available on HIVST.org

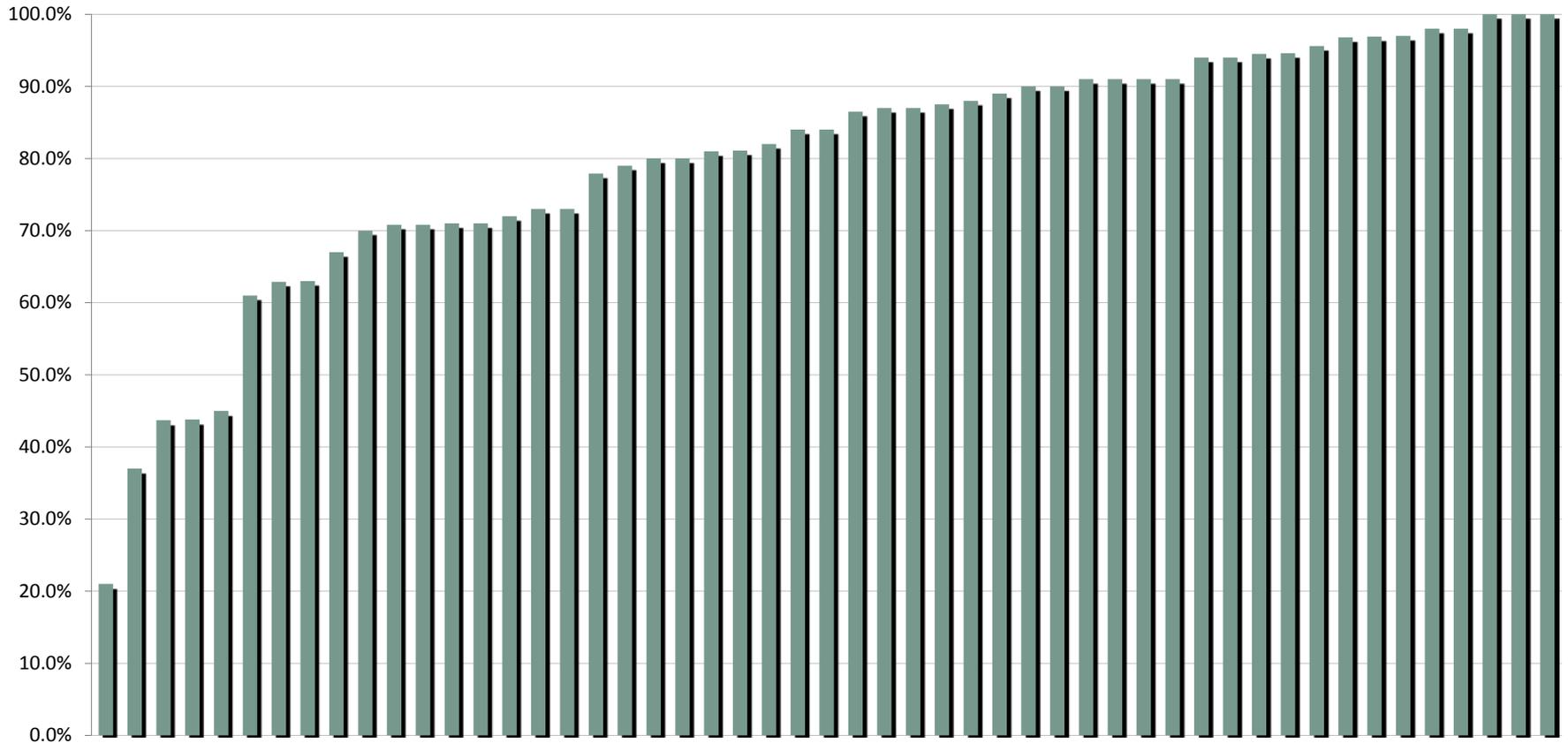




What we know?

HIVST.org

Acceptability & Willingness



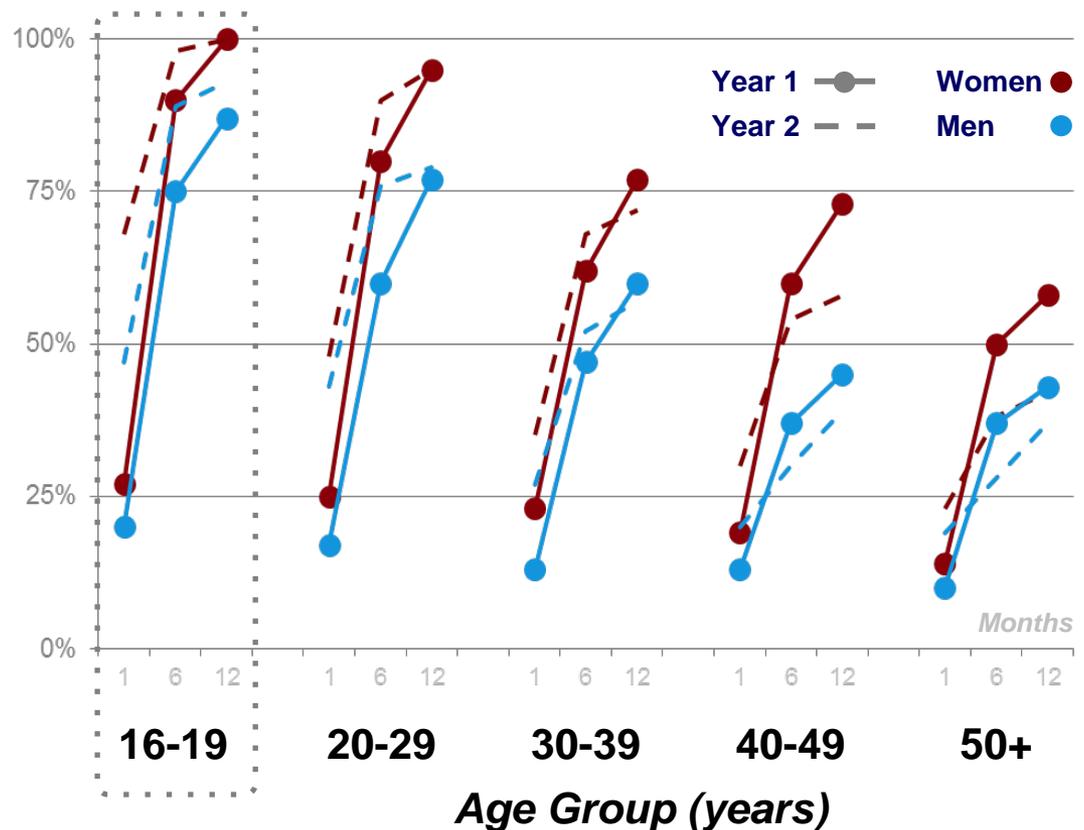
Source: 1 www.hivst.org , Evidence Map, accessed 15 Feb 2016 – 51 reporting studies

Uptake Amongst All Residents in Malawi

Since HIVST Made Available

Highest uptake among young people & adolescents

- 76% in months 1-12
- 74% in months 13-24
- 44% first-time testers
- ~90% returned kits with self-completed questionnaire



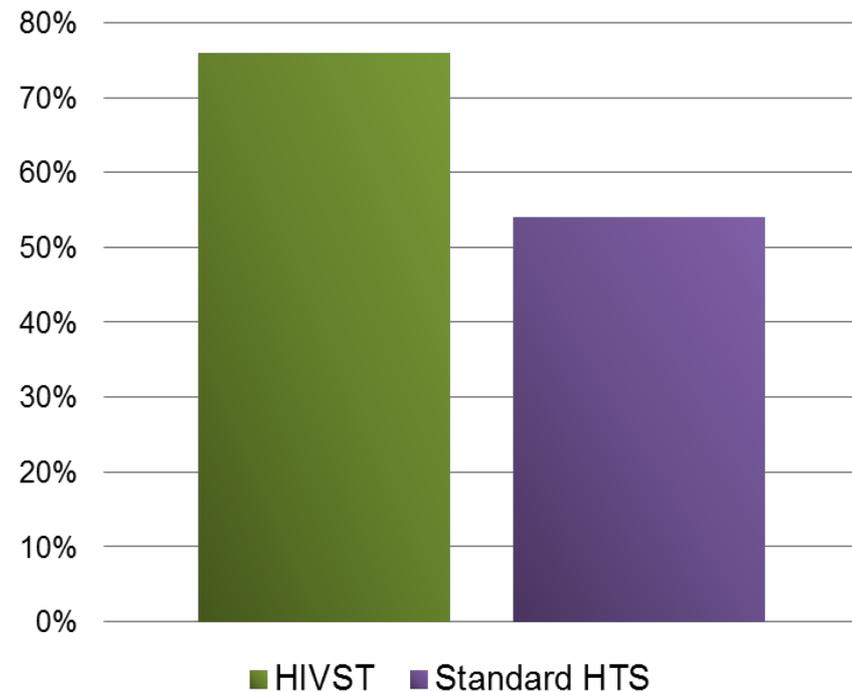
Increased Frequency of Testing among MSM

In Brazil, **MSM** who were **less frequent testers** and considered testing but failed to test were more likely to **prefer HIVST**.

In Australia **2/3 HIV-negative MSM** said they'd **test more frequently if HIVST was available**.

Models suggest increases in frequency using HIVST among MSM, especially in settings with low testing coverage, could have a public health impact.

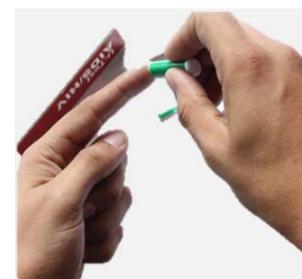
HIVST increased frequency of HTS among MSM in USA



Accuracy can be good, but not always

As high as 99.1% sensitivity and 100% specificity, but depends on RDT used, IFUs, populations and settings

| Studies | Sensitivity | Specificity | HIV Prevalence | Type of population |
|---|-------------------|-------------------|------------------|--|
| | Estimate (CI 95%) | Estimate (CI 95%) | | |
| Asiimwe (2014) supervised arm | 96.4% (61.6-99.8) | 98.6% (93.6-99.7) | 10.6% (13/123) | GP (100%) |
| Asiimwe (2014) unsupervised arm | 90.0% (67.6-97.5) | 95.1% (88.9-98.0) | 16.3% (20/123) | GP (100%) |
| Dong (2014) | 97.7% (85.6-99.7) | 99.5% (96.3-99.9) | 18.9% (44/233) | GP (100%) |
| Gras (2014) | 96.4% (84.1-99.3) | n/a | 100% (40/40) | PLHIV (100%) |
| Kurth (2014) | 89.7% (72.4-96.6) | 99.4% (96.0-99.9) | 14.6% (35/239) | GP (100%) |
| Pant Pai (2013) | 65.0% (33.6-87.2) | 99.8% (96.8-100) | 3.6% (9/249) | Health care workers (100%) |
| Phase III OraQuick (2012) | 91.7% (84.2-95.8) | 100% (99.9-100) | 2.12% (120/5662) | GP (86.9%) and KP (13.1%) |
| Lee (2007) | 98.8% (92.0-99.8) | 99.6% (97.3-99.9) | 25% (88/350) | GP (90%) and KP (10%) |
| Choko (2015)* | 94.0% (88.9-96.8) | 99.9% (99.5-100) | 8.6% (141/1649) | GP (100%) |
| Choko (2011) | 96.9% (86.2-99.4) | 99.8% (96.3-100) | 16.9% (48/283) | GP (100%) |
| Marley (2014) | 77.5% (62.1-87.9) | 99.7% (97.7-100) | 5.6% (13/229) | GP (29%) |
| Napierala (2015) urban arm ⁺ | 80.0% (30.9-97.3) | 97.8% (86.1-99.7) | 9% (16/172) | GP (100%) |
| Napierala (2015) rural arm | 66.7% (15.4-95.7) | 94.7% (84.9-98.3) | 8% (5/62) | GP (100%) |
| Ng (2012) | 97.4% (93.9-98.9) | 99.9% (99.1-99.8) | 19.3% (192/994) | GP (63.7%), PLHIV (20%), and KP (16.3%) |
| Phase II OraQuick (2012) | 97.9% (96.2-98.9) | 99.8% (98.5-100) | 51% (526/1031) | GP (42.4%), PLHIV (51.3%), and KP (6.3%) |
| Sarkar (2015) | 83.3% (19.4-99.0) | 99.7% (96.1-100) | 0.9% (2/202) | Pregnant women (100%) |
| Mkwamba (2015) | 99.1% (96.5-99.8) | 99.9% (99.1-100) | 21.9% (221/1005) | KP (100%) |



GP: general population, KP: key population, PLHIV: people living with HIV, n/a: non available, * 4 participants were on ART, + 1 participant was on ART

Linkage

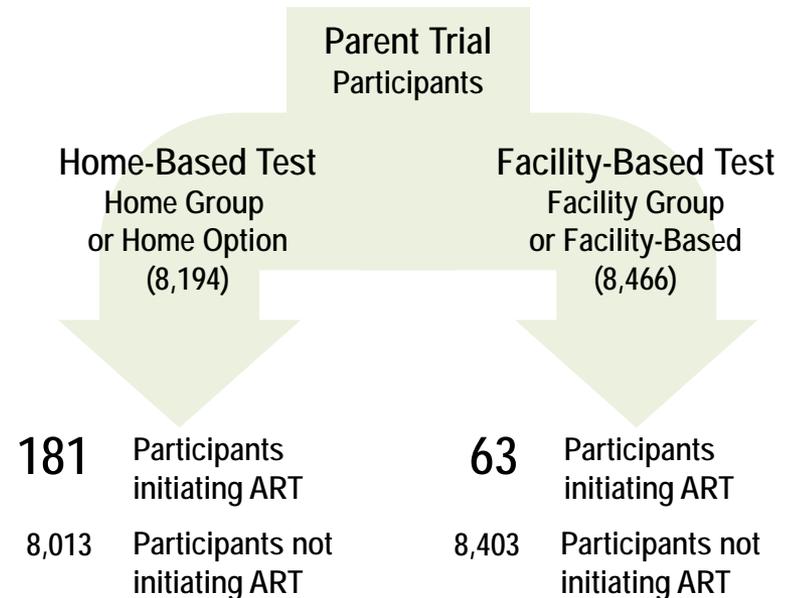
Evidence is limited, but promising^{1,2}

- Especially when coupled with a proactive approach (e.g. home-based assessment, ART initiation)
- 80-100% of MSM report they would link to further testing and care, if they had a reactive self-test result³



Higher ART among Home Self-test Clusters than Facility-based

MacPherson 2014 (Malawi)



Adverse Events

HIVST can be empowering.

No serious adverse events as a result of self-testing for multiple diseases and conditions, including HIV, reported in published literature¹.

Monitoring and reporting systems are important to identify and address issues when and if they occur

Information and messages for communities, particularly for vulnerable populations are key.

Tools include: Hotlines, Mobile phones & SMS, Community-based monitoring systems, computer programmes, post-market surveillance systems



What's needed to get HIVST going?

Implementation pilots addressing gaps:

- | | |
|---|-------------------------------------|
| • Public health impact? | • Social harm? |
| • Uptake those at risk & who may not otherwise test? | • Accuracy? |
| • Optimize? | • Quality? |
| • Case-finding? | • Monitoring? |
| • Early diagnosis? | • Low cost? /Cost-effective? |
| • Linkage? / Support? | • Demand? / Supply? |

- **WHO normative guidance** (Dec 2016)
- **ERPD & WHO PQ ed RDTs for HIVST** – urgent need
- Support from GF, PEPFAR & BMGF for country implementation (*operational note GF , forthcoming*)
- Price reduction of RDTs for HIVST
- Country policy & regulatory change
- Create awareness & demand

PSI/UNITAID STAR Project

Catalysing HIVST in Southern Africa

Implementation-research Partnership Tackling Market Barriers **by:**

- Multiple sites, models, & populations
- Normalizing HIVST in Southern Africa
- Providing evidence for scale-up
- Developing WHO Guidelines
- Encouraging policy change
- Enabling the regulatory environment
- Shaping market to reduce barriers & increase entry of low-cost HIVST products available for purchase & on recommended diagnostic commodities list



UNITAID·PSI
HIV SELF-TESTING AFRICA



Closing thoughts on HIVST

Current approaches not enough to get to 90.

Additional tool to create demand for, not substitute, HIV testing services.

HIVST is an innovation for implementation, but could stimulate new technological advances & further optimization

Potential to **increase reach, frequency & efficiency**

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

WHO guidance on the way!

Use what we have, work toward quality, WHO PQed, low cost RDTs for settings & populations who can benefit most.

Think big.