The international context of HIV self-testing

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http://www.who.int/hiv/en/
www.hivst.org

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South African Clinician’s Society
Outline

• Understanding the international context & testing gap
• What is HIV self-testing?
• WHO Guidelines
  – Evidence summary & Recommendations
• Landscape of HIVST products
• Implementation Considerations
  – Latest policy development
  – Implementation & lessons learned
• What’s are the gaps & what’s next?
Global Progress Toward the First 90, 2015

40% of PLHIV still remain undiagnosed worldwide

- 60% of PLHIV diagnosed
- 46% on ART
- 38% on ART & virally suppressed

> 80% of all diagnosed PLHIV are on treatment

Source: UNAIDS, 2016 – based on 2015 measure derived from data reported by 87 countries, which accounted for 73% of people living with HIV worldwide; 2015 measure derived from data reported by 86 countries. Worldwide, 22% of all people on antiretroviral therapy were reported to have received a viral load test during the reporting period.
Scale-Up of HIV Testing Services in Africa

From 2005 – 2015, there was a sharp increase in HIV-positive diagnoses in Africa. From 2010—2014, > 600 M people received HTS in 122 low- and middle-income countries – nearly half all tests were in Africa.

Source: WHO 2015; WHO 2016
Progress toward the first 90 by region, 2015

Source: UNAIDS, 2016
New HIV infections among people aged 15 years and over, by region, 2010–2015

Source: UNAIDS 2016 estimates.
Scale-up of Diagnosis of PLHIV Over Time

Average % of PLHIV Identified for Top 30 Countries*, Yearly, Starting 2001

Projection suggests the earliest countries could identify 90% of PLHIV is 2026.

* By size of the epidemic
Source: Courtesy Frederic Seghers, CHAI Input data via UNAIDS Aidsinfo; DHS Statcompiler – projections via CHAI NMOT modeling.
New adult HIV infections globally, 2015

~1.9 M new adult HIV infections in 2015

44% new HIV infections are among key populations and their partners

Source: UNAIDS, 2016. Data is for populations 15 years of age and above.
Women

Make Up
Approximately 70% of Those Tested in 2014

Much of all HIV testing is in ANC – even in low HIV prevalence settings

Source: WHO 2015, 76 reporting low and middle income countries. Data is for populations 15 years of age and above.
Proportion people never tested for HIV, 2013-16

~90% of the world’s HIV-positive adolescents (10–19 years of age) are in sub-Saharan Africa, where testing coverage remains low.

Testing coverage is often low due to:

- Age of consent laws
- Structural barriers
- Unfriendly services
- Stigma and discrimination
Innovation Needed to Close the Testing Gap
HIV Self-Testing (HIVST)

Collects  Performs  Interprets

Reactive results need confirmation by trained tester using a validated national algorithm.
WHO HIVST Strategy

- HIVST requires self-testers with a **reactive** (positive) result to receive **further testing** from a trained provider using a validated national testing algorithm.
- All 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.
- HIVST is **not** recommended for people taking anti-retroviral drugs, as this may cause a false non-reactive result.

*Any person **uncertain** about how their self-test result, should be encouraged to access facility- or community-based HIV testing*
Directly assisted HIV self-testing

Trained peer or health worker could provide a brief demonstration on how to use the kit and how to interpret results
- Provide face-to-face assistance during self-testing (optional)
- **Instruction-for-use &/or included in the kit:**
  - Pictorial/written
  - Including a hotline number or a link to a video
  - Multimedia instructions (tablet)
  - Remote support via SMS, QR code or mobile messaging applications

Unassisted HIV self-testing

**Instruction-for-use included in the kit:**
- Pictorial/written
- Including a hotline number or a link to a video
- Multimedia instructions (tablet)
- Remote support via SMS, QR code or mobile messaging applications
- Package inserts included in the kit
HIVST Service Delivery Approaches

- Community-based (door-to-door)
- Partner-delivered
- Facility-based (pick-up/self-test on site)
- Pharmacy-based
- Workplace programmes
- Integrated (e.g. VMMC, TB, STIs, reproductive health)
- Internet-based
- PrEP programmes
- Vending machines and kiosks
Knowledge
Latest evidence & policy
Developing Evidence-based Policy

2008
2012
2013
2015
2014
2016

Summary of clinical outcomes

UNITAID and the Global Fund expert panel approves the first HIV self-testing product

HIVST & PN Implementation Tools & Strategic Impact framework
WHO Guidelines on HIVST

- **5 RCTs** directly comparing HIVST to HIV testing by a provider as of July 2016
- **25 studies** on HIV RDT for self-testing performance as of April 2016
- **125 studies** on acceptability/feasibility (including user values preferences) as of July 2016
- **4 studies** on cost/cost-effectiveness as of July 2016
HIVST Doubled Uptake & Frequency

Moderate quality evidence that HIVST doubled overall HIV testing uptake compared to standard HTS

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Risk Ratio</th>
<th>M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gichalgi 2016</td>
<td>3.08</td>
<td>[2.58, 3.69]</td>
</tr>
<tr>
<td>Thirumurthy 2016</td>
<td>1.77</td>
<td>[1.57, 2.00]</td>
</tr>
<tr>
<td>Wang 2016</td>
<td>1.77</td>
<td>[1.57, 2.00]</td>
</tr>
<tr>
<td></td>
<td>2.12</td>
<td>[1.51, 2.98]</td>
</tr>
</tbody>
</table>

Low quality evidence that HIVST resulted in 2 more tests in a 12-15 month period compared to standard HTS

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Katz 2015</td>
<td>1.70</td>
<td>[0.94, 2.46]</td>
</tr>
<tr>
<td>Jamil 2016</td>
<td>2.30</td>
<td>[2.27, 2.33]</td>
</tr>
<tr>
<td></td>
<td>2.13</td>
<td>[1.59, 2.66]</td>
</tr>
</tbody>
</table>

Effect also shown for increase uptake of couples testing in Gichang et al & Thirumurthy et al.

Jamil et al also showed HIVST increased the frequency of testing among non-recent testers compared to standard HTS.
HIVST identified 2x’s as many HIV-infections than only standard HTS

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<th>Study or Subgroup</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
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</thead>
<tbody>
<tr>
<td>Katz 2015</td>
<td>1.97 [0.37, 10.52]</td>
</tr>
<tr>
<td>Masters 2017</td>
<td>2.04 [0.62, 6.70]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>2.02 [0.76, 5.32]</td>
</tr>
</tbody>
</table>

Across observational studies - HIV positivity ranged from

3–14% among the general population in sub-Saharan Africa

1–30% among key populations in Africa, America, Asia, Europe

Median HIVST Positivity

Median HIV Prevalence
Linkage to care

50-56% in general populations in sub-Saharan Africa and 20-100% among key populations Africa, Americas, Asia, Europe

Original Investigation
Effect of Optional Home Initiation of HIV Care Following HIV Self-testing on Antiretroviral Therapy Initiation Among Adults in Malawi
A Randomized Clinical Trial

Percentage of all adult residents who initiated ART

- Home: 1.4% (2.10-4.12)
- Facility: 0.8%

RR: 2.94

- Optional home initiation after HIVST
- Facility initiation after HIVST
- No HIVST
No identifiable increased risk of social harm & adverse events

- Studies reported HIVST was empowering.
- Social harm due to HIVST was not identified in RCTs.
- Reports from studies were limited and did not suggest HIVST increased risk of harm.
- In Malawi, two-years of implementing HIVST found no suicides, no self-harm and no cases of IPV.
  - Reports of coercion identified were mostly among men who also reported that they would recommend HIVST.
- In Kenya 4 cases of IPV identified - unclear if due to HIVST. (41% of participants reported IPV 12 months prior to intervention).
Results of HIV RDTs performed by self-tester were similar to those performed by trained health worker.

Measured using kappa statistic – 16 studies
Achieved acceptable accuracy (sensitivity & specificity)

Sensitivity
as high as 98.8% (95% CI 96.6 – 99.5%)

Specificity
as high as 100% (95% CI 99.9 – 100 %)

n = 18 studies
Acceptability & Willingness

Generally good uptake
(median 76%, range 24-100%)

22 studies

Generally high acceptability & willingness
(median 73%, range 21-100%)

84 studies
HIVST Values & Preferences in Africa

- **HIVST is highly acceptable** across different populations & settings, e.g. men, young people, KP, couples
- Many users prefer oral HIVST— but others, e.g. men in South Africa and PWID reported a preference for fingerprick HIVST.
- **Preferences across service delivery approaches vary.**
  - Young people preferred community-based options, but key populations, reported preferences for pharmacies, the Internet, and over-the-counter approaches more appealing because they are more discreet and private.
HIVST Cost-effectiveness in Zimbabwe

Figure 1. Proportion of people living with HIV diagnosed in 2020 and HIV infections and discounted DALYs averted per year

Source: Cambiano CROI 2017
HIVST to achieve 1\textsuperscript{st} 90 in Zimbabwe

Slide courtesy of Valentina Cambiano and STAR Consortium
**User Cost of Accessing Standard HTS**

<table>
<thead>
<tr>
<th>Cost Item</th>
<th>Males (USD)</th>
<th>Females (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Childcare</td>
<td>0.06</td>
<td>0.01</td>
</tr>
<tr>
<td>Transport</td>
<td>0.25</td>
<td>0.16</td>
</tr>
<tr>
<td>Consultation</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>Meal</td>
<td>0.18</td>
<td>0.13</td>
</tr>
<tr>
<td>Other</td>
<td>0.05</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td><strong>3.81</strong></td>
<td><strong>1.84</strong></td>
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- **User cost of HTS for men in Malawi is 154% more than daily wage.**

**Costing HIVST**

- **Health provider perspective: HIVST + Facility HTS v Facility HTS**
- **WTP = 3 X GDP per capita**
- **WTP = 1 X GDP per capita**

- **Cost-effectiveness analysis found implementing HIVST in Malawi was cost-effective (US$ 230/QALY gained)**

*Source: STAR Consortium; Maheswaran 2017*
New Recommendations

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

(Strong recommendation, moderate quality evidence)
# Countries with HIVST Policies

As of March 2017, 33 countries reported to WHO that they have HIVST policies – 11 of which are in Africa with other in development.

<table>
<thead>
<tr>
<th>Supportive HIVST Policy</th>
<th>Supportive HIVST Policy under development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chad</td>
<td>Rwanda</td>
</tr>
<tr>
<td>Burundi</td>
<td>South Africa</td>
</tr>
<tr>
<td>DRC</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Kenya</td>
<td>Zambia</td>
</tr>
<tr>
<td>Lesotho</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>Malawi</td>
<td></td>
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<tr>
<td></td>
<td>Botswana</td>
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<tr>
<td></td>
<td>CAR</td>
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<tr>
<td></td>
<td>Mali</td>
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<td></td>
<td>Namibia</td>
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<td></td>
<td>Nigeria</td>
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<td></td>
<td>Senegal</td>
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<td></td>
<td>Swaziland</td>
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</table>
WHO PQ: HIV RDTs for self-testing

- WHO PQ is actively accepting applications for HIV RDTs for self-testing

- Technical Specifications for HIVST are now available:

- 2 HIVST products currently under review
UNITAID - Global Fund
Expert Review Panel for Diagnostics

- ERP-D approval enables countries to immediately procure products through Global Fund and other donors – based on QA standards

Key Facts:
- ERP-D requires agreement to submit for WHO PQ
- Provides an ERP-D approval for 12-months
- To date, Global Fund has issued 2 expressions of interest for HIVST & provided approval for 2 products:
  - 1 for research (Biosure HIV self-test)
  - 1 for full programmatic use (OraQuick HIV self-test)
- ERP-D Round 2 for HIVST is currently underway
## HIV RDTs for self-testing

<table>
<thead>
<tr>
<th>Test Kit Name</th>
<th>Specimen</th>
<th>Approval Status</th>
<th>Suggested Price Per Test (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autotest VIH (AAZ Labs, France)</td>
<td>Blood</td>
<td>CE</td>
<td>25-28 (to consumer)</td>
</tr>
<tr>
<td>INSTI HIV Self Test (Bioanalytical, Canada)</td>
<td>Blood</td>
<td>CE</td>
<td>36 (to consumer)</td>
</tr>
<tr>
<td>Biosure HIV Self Test (Biosure, UK)</td>
<td>Blood</td>
<td>CE/GF ERPD</td>
<td>38-43 (to consumer) 7.50-15 (to public sector)</td>
</tr>
<tr>
<td>OraQuick In-Home HIV Test (OraSure Technologies, USA)</td>
<td>Oral</td>
<td>FDA</td>
<td>40 (to consumer)</td>
</tr>
<tr>
<td>OraQuick HIV Self-Test (OraSure Technologies, USA)</td>
<td>Oral</td>
<td>GF - ERPD</td>
<td>Available upon request</td>
</tr>
</tbody>
</table>

*With approval from a founding member of the GHTF. All information is provided by manufacturers (UNITAID/WHO Landscape July 2016/ Dec 2016). Other products are in the pipeline.*
Key messages for users and implementers

- Use of approved HIV RDT for self-testing, either by national or international authority
- Use HIVST kits with appropriate, validated, clear and concise instructions for use – demonstrations and support tools may be particularly useful for rural populations and those with low levels of education and literacy
- Clearly state reactive results need further testing, provide information on what to do after a reactive self-test result
- Make sure pre-test information and post-test counselling messages are accessible and available to all self-testers – and that health workers and providers are trained to deliver these messages
- Integrate HIVST into comprehensive sexual health service programmes and provide messages and information on tuberculosis, STIs and viral hepatitis.
## Where to Begin with HIV Self-Testing

<table>
<thead>
<tr>
<th>Know your epidemic &amp; testing gap</th>
<th>Approaches</th>
<th>Considerations</th>
</tr>
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<tbody>
<tr>
<td><strong>Couples &amp; Partners</strong></td>
<td>Community-based (outreach, door-to-door)</td>
<td><strong>Benefits &amp; Risks to Populations</strong></td>
</tr>
<tr>
<td></td>
<td>Facility-based (PITC, drop-in centres)</td>
<td><strong>Support tools</strong></td>
</tr>
<tr>
<td><strong>Men</strong></td>
<td>VMMC programmes</td>
<td><strong>Linkage</strong></td>
</tr>
<tr>
<td><strong>Key populations</strong></td>
<td>Workplace programmes</td>
<td><strong>Increased access</strong></td>
</tr>
<tr>
<td><strong>Young people</strong></td>
<td>Integrated in KP Programmes</td>
<td><strong>Increased coverage</strong></td>
</tr>
<tr>
<td><strong>Other At risk populations</strong></td>
<td>Internet &amp; Apps</td>
<td></td>
</tr>
<tr>
<td><em>(SDC, partners of PLHIV, migrants etc.)</em></td>
<td>Vending machines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Partner-delivered</td>
<td></td>
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</tbody>
</table>
Where to Begin with HIV Self-Testing

Know your epidemic & testing gap

Couples & Partners
Men
Key populations
Young people
Other At risk populations (SDC, partners of PLHIV, migrants etc.)

Approaches

Community-based (outreach, door-to-door)
VMMC programmes
Pharmacies & Kiosks
Internet & Apps
Vending machines

Facility-based (PITC, drop-in centres)
Workplace programmes
Integrated in KP Programmes
Integrated in RHS & Contraceptive Services
Partner-delivered

Considerations

Benefits & Risks to Populations
Support tools
Linkage
Increased access
Increased coverage
Where to Begin with HIV Self-Testing

**Know your epidemic & testing gap**

**Approaches**

- Community-based (outreach, door-to-door)
- VMMC programmes
- Pharmacies & Kiosks
- Internet & Apps
- Vending machines
- Partner-delivered

**Facility-based (PITC, drop-in centres)**
- Workplace programmes
- Integrated in KP Programmes
- Integrated in RHS & Contraceptive Services

**Considerations**

**Benefits & Risks to Populations**
- Support tools
- Linkage
- Increased access
- Increased coverage

**Couples & Partners**

**Men**

**Key populations**

**Young people**

**Other At risk populations**
(SDC, partners of PLHIV, migrants etc.)
Where to Begin with HIV Self-Testing

Know your epidemic & testing gap

Approaches

Community-based (outreach, door-to-door)

VMMC programmes

Pharmacies & Kiosks

Internet & Apps

Vending machines

Facility-based (PITC, drop-in centres)

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Integrated in RHS & Contraceptive Services

Partner-delivered

Considerations

Benefits & Risks to Populations
Support tools
Linkage
Increased access
Increased coverage
What’s Next & What are the gaps?
Priorities

• Support more countries to implement & scale-up HIVST – and including national policies, strategies and implementation plans
  • Including GF funding request & COP
  • Work to negotiate lower prices, pooling procurement

• WHO PQ HIVST kits – and additional ERP-D round to fast-track approval of more products (blood and oral)

• WHO Developing Strategic framework for Implementation & impact.
Critical Gaps

• Optimized service delivery & linkages to prevention & treatment

• How to scale-up the most cost-effective HIVST models to achieve national/global public health goals and for reaching specific populations in specific settings?

• Regulatory policy & frameworks
  • Public & Private Sector – opportunities & challenges

• Integrated and routine implementation and monitoring systems

• Affordable WHO PQed products available in LMIC (blood and oral options)
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