Towards Sustainability and Scalability of HIV Self-Testing

HIV Self-testing Products, Technical Updates on Clinical Performance, Usability and Acceptability in Program Implementation

Moderators: Rachel Baggaley, WHO
Karin Hatzold, PSI, STAR Consortium

Presenters: Cheryl Johnson, WHO
Mohammed Majam, Ezintsha
Thato Chidarikire, NDOH
Kim Green, PATH
Doan Hong Anh, PATH
Agnes Sitta Kijo, WHO/REG/FPI
WHO guidance on HIVST and the global market and need forecast

Cheryl Johnson on behalf of HTS Team
Global HIV, Hepatitis and STI Programme
World Health Organization
15 October 2020

HTS Info on the Go: https://apple.co/2LAB8vt
WHO recommendations on HIV self-testing

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
- Comparable linkage and HIV+
- Empowering
- Can be affordable and cost-effective when focused

NEW remarks
- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis. Individuals with a reactive test result must receive further testing from a trained tester using the national testing algorithm.

Source: WHO 2019; Jamil et al 2020

WHO recommendation:

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

(Strong recommendation, moderate quality evidence)
### Qualitative values and preferences on HIVST kits

<table>
<thead>
<tr>
<th>All</th>
<th>General population</th>
<th>Key populations</th>
<th>Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Clear, simple, pictorial instructions</td>
<td>- Oral fluid sometimes preferred e.g.</td>
<td>- No clear preference between oral fluid</td>
<td>- Preference for quality assured</td>
</tr>
<tr>
<td>- Discreet packaging</td>
<td>noted to be considered pain-free and</td>
<td>or blood tests</td>
<td>tests</td>
</tr>
<tr>
<td>- Highly accurate test kits – clearly</td>
<td>perceived to be simple</td>
<td>- Some prefer and desire blood-based</td>
<td></td>
</tr>
<tr>
<td>indicated</td>
<td></td>
<td>kits or perceive blood tests to be more</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>accurate</td>
<td></td>
</tr>
</tbody>
</table>

**Take away:** Findings complement quantitative V&P. Preference for kits with clear and simple instructions with discreet packaging. Desire for high quality kits. *No clear preference for oral or blood tests.*

*Source: WHO 2019; Figueroa et al 2020*
Ensure products are quality assured
Choose *products with acceptable specifications*

- **HIVST products should be:**
  - highly sensitive and specific;
  - simple to use;
  - have necessary consumables (such as swabs and plasters);
  - provide results that are easy to read/interpret and that are available in a short period of time (1–20 minutes after the test is conducted);
  - disposable in general waste system

- **HIVST should be accompanied with:**
  - Contain clear pictorial instructions, support tools, info on what to do and where to go after self-testing
  - Products that include support tools – such as instructional videos, hotlines, websites and referral information – should be prioritized.
  - Products that do not have good stability (that cannot sustain suboptimal storage) or that are not robust (for example cannot sustain common user errors) may not be ideal for self-testing.

- **Other considerations**
  - Cost – consider cost of full service not just unit cost of kit
  - **Options (offering blood and oral)**
### HIVST products with WHO PQ, ERPD or approval from founding member of IMDRF*

<table>
<thead>
<tr>
<th>Test (manufacturer)</th>
<th>Specimen</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mylan HIV Self Test (Atomo Diagnostics, Australia)</td>
<td>Blood</td>
<td>WHO PQ</td>
</tr>
<tr>
<td>autotest VIH® ** (AAZ Labs, France)</td>
<td>Blood</td>
<td>CE mark</td>
</tr>
<tr>
<td>BioSURE HIV Self Test ** (BioSURE, United Kingdom Ltd)</td>
<td>Blood</td>
<td>CE mark ERPD-3</td>
</tr>
<tr>
<td>Exacto® Test HIV (Biosynex, France)</td>
<td>Blood</td>
<td>CE mark</td>
</tr>
<tr>
<td>INSTI® HIV Self Test ** (bioLytical Lab., Canada)</td>
<td>Blood</td>
<td>WHO PQ</td>
</tr>
<tr>
<td>OraQuick® In-Home HIV Test (OraSure Technologies, USA)</td>
<td>Oral fluid</td>
<td>FDA, CE Mark</td>
</tr>
<tr>
<td>OraQuick® HIV Self Test (OraSure Technologies, USA)</td>
<td>Oral fluid</td>
<td>WHO PQ</td>
</tr>
<tr>
<td>SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)</td>
<td>Blood</td>
<td>WHO PQ</td>
</tr>
</tbody>
</table>

- **WHO PQ products available for US$2.00-3.10 through Global Fund**
- **More information available via PAHO strategic fund**
- **Pipeline for products remains strong**
- **Blood and oral both WHO PQed**

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HIC, high-income countries; FDA, Food and Drug Administration; ERPD, Expert Review Panel for Diagnostics; Gen, test generation; LMIC, low- and middle-income countries, MRSP: maximum suggested retail price; NA, not available.

* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaid/Glmal Fund Expert Review Panel for Diagnostics. ** These products sold in more than one packaging format.

Note: Product details based on information provided by the manufacturers at the time of report preparation.

WHO-Unitaid 2020
Realizing the role of HIVST in COVID-19 Context

Considerations for HIVST

• HIVST may be acceptable alternative to maintain services while adhering to physical distancing guidance.

• Important to strategically implement HIVST prioritizing areas & populations with greatest needs and gaps in testing coverage.

• HIVST approaches include:
  • distribution for personal use and/or sexual and/or drug injecting partners of PLHIV and social contacts of key populations
  • in high HIV burden settings, pregnant women may also provide HIVST kits to their male partners.

• Priority settings to consider
  • pick up at facilities or community sites
  • online platforms (e.g. websites, social media, digital platforms) and distribution through mail
  • pharmacies, retail vendors, vending machines

Countries with HIVST programmes

Expand and adapt HIVST

• replace facility with HIVST (to decongest health facilities)

• use HIVST for partner and social network testing

• Maintaining PrEP services

Countries yet to use HIVST

• Lobby for rapid HIVST approval

https://www.psi.org/project/star/hiv-self-testing-during-covid-19/
Countries implementing and developing HIVST policies, 2015-2020

Between 2017 and 2020 three times as many countries implemented HIVST

Source: GAM WHO, UNAIDS, UNICEF July 2020
40% (77/194) reporting countries have HIVST policies, of these only 49% (38) are implementing.
National HIVST policy and implementation 2020, by region

44% (86/194) reporting countries have HIVST policies, of these only 48% (41) are implementing

% Implementing

<table>
<thead>
<tr>
<th>Region</th>
<th># Countries</th>
<th>HIVST policy and implementation</th>
<th>HIVST policy and pilots</th>
<th>HIVST policy but no pilots or implementation</th>
<th>No HIVST policy</th>
<th>No HIVST policy but policy in development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia and Pacific</td>
<td>N=40</td>
<td>7</td>
<td>2</td>
<td>7</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Caribbean</td>
<td>N=16</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>East and Southern Africa</td>
<td>N=21</td>
<td>11</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Eastern Europe and Central Asia</td>
<td>N=16</td>
<td>6</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Latin America</td>
<td>N=17</td>
<td>8</td>
<td>8</td>
<td>5</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Middle East and North Africa</td>
<td>N=20</td>
<td>9</td>
<td>5</td>
<td>7</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>West and Central Africa</td>
<td>N=25</td>
<td>8</td>
<td>5</td>
<td>7</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Western and Central Europe and North America</td>
<td>N=39</td>
<td>18</td>
<td>13</td>
<td>18</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

Source: GAM WHO, UNAIDS, UNICEF July 2020
Number of HIV self-test kits procured and distributed by reporting countries, 2019

Number of HIV self-test kits procured and distributed by reporting countries, 2019

- Brazil
- Eswatini
- Guinea
- Mali
- Lao PDR
- Lebanon
- Malawi
- Republic of Moldova
- Tajikistan
- Kyrgyzstan
- Belarus
- Ukraine
- Senegal
- Ethiopia
- Lesotho
- Botswana
- Kenya
- South Africa
- Total

- **HIVST Procured**
- **HIVST Distributed**
Total HIVST need for LMICs is estimated to be 177m kits – growing to 192m kits by 2025

Source: WHO forecast 2020 – for more information email johnsonc@who.int
Confirmed volumes of 21 million HIVST kits 2020 – 2023

*Volumes are EIC analysis and not official figures and include estimates
Due to the nature of the PEFAR and Unitaid funding cycles confirmed volumes for 2022 and 2023 are not yet available for these organizations.

Source: WHO forecast 2020 – for more information email johnsonc@who.int
Opportunities for blood-based HIVST

Source: WHO special analysis of countries reporting oral vs blood procurement; WHO forecast 2020 – for more information email johnsonc@who.int
Low but increasing LMIC Demand volumes as a percentage of need is anticipated

Source: WHO forecast 2020 – for more information email johnsonc@who.int
Key takeaways

• **HIVST is a critical strategy** for reaching the first 95 target
  • Opportunities to expand in response to COVID-19 and maintain essential services – including PrEP
  • Future direction for testing more broadly

• **Growing market with many opportunities**
  • 4 WHO PQ products and strong pipeline
  • Procurement through Global Fund and PAHO Strategic Fund
  • Funding gap to reach current demand and need for HIVST

• **Offering quality options and both blood and oral HIVST can be beneficial**
  • Supply security
  • Reaching diverse group of users
Acknowledgements

Guidelines

WHO: Rachel Baggaley, Muhammad Jamil, Maggie Barr-DiChiara, Anita Sands, Arshad Altaf, Alison Wringe, Melanie Taylor, Teodora Wi, Mary Lyn Gafield, Virginia MacDonald, Bradley Mathers, Annette Verster, Niklas Luhman, Fatim Cham Jallow, Van Nguyen, Elena Vovc, Joumana Hermez, Maeve deMello, Anne Brink, Mukta Sharma, Andrew Ball, Tunga Namjilsuren, Belen Dinku, Veronique Millot and Valerie Amiel

Thank you to all All systematic and literature review teams WHO HTS Guideline Development Group, Steering Committee, external reviewers and key partners UNAIDS and UNICEF.

Forecasting

Thank you to the countries, manufacturers and donor partners who shared data.


Special thanks to funders Unitaid, USAID and Bill and Melinda Gates Foundation

More information and questions: Johnsonc@who.int
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Agnes Sitta Kijo, WHO/REG/FPI
HIV Self-Testing products, technical updates and use for program implementation and acceleration.

Mohammed Majam
Head: Medical Technologies
Ezintsha, a sub-division of Wits RHI, Wits Health Cons
mmajam@wrhi.ac.za
What are the current WHO PQ HIVST products?

How do they work?

What is our experience in the field?
Going back to basics!
What makes a good self-test?

Think back to 2014 and the Target Product Profile:
- High clinical and analytical sensitivity and specificity
- Low invalid and test failure rates
- Pictorial instructions for use with any text-based instruction translated into local languages
- Low number of test steps which could be achieved through integrated systems to deliver buffer or other such innovations
- Simple to interpret test results which require little instruction
- Reduction in time to result
- Increased stability of test results
Wits HSTAR Program Evaluations

• Kicked off in Dec 2015 with the aim of supporting independent data generation for HIV RDT Manufacturers looking to compile a dossier for HIV Self-Testing for submission to WHO PQ

• TSS updated to include requirements for HIVST in Dec 2016. WHO HIVST Guidelines launched Dec 2016.

• Part 3: Qualification of usability (self-testing)

PURPOSE: Assessment of product design, instructions for use and usability of RDTs for self-testing
Protocols designed to follow the requirements of the TSS for HP settings

**Protocol 1: Usability Assessment**

The purpose of the Usability Assessment is to document if “lay” people, non-professional and inexperienced in HIV self-testing, can successfully perform the steps to use a HIV Self-Test device, without product familiarization

- Label comprehension
- Mock Result Interpretation
- Overall usability and FMEA

NO demonstration provided prior to test use, and manufacturer provided information only (i.e. no additional job aids or IEC materials)

**Protocol 2: Clinical Performance Evaluation**

Evaluate the ability of untrained users to obtain accurate HIV test results using the XXXXXX Rapid HIV Self-Test when compared to professional users and ELISA.

- Additionally, assess test usability and successful completion rate
<table>
<thead>
<tr>
<th>Test (manufacturer)</th>
<th>Specimen</th>
<th>Approval</th>
<th>Markets</th>
<th>Price per test (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTI® HIV Self Test **</td>
<td>Blood</td>
<td>WHO PQ, CE mark</td>
<td>Several countries in Europe, Nigeria</td>
<td>LIC: $ 3–14</td>
</tr>
<tr>
<td>(bioLytical Lab., Canada)</td>
<td></td>
<td></td>
<td></td>
<td>HIC: $ 7–40</td>
</tr>
<tr>
<td>Mylan HIV Self Test</td>
<td>Blood</td>
<td>WHO PQ</td>
<td>To be updated</td>
<td>Public sector: $4.5–6</td>
</tr>
<tr>
<td>(Atomo Diagnostics, Australia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OraQuick® HIV Self Test **</td>
<td>Oral fluid</td>
<td>WHO PQ</td>
<td>Several countries in sub-Saharan Africa, Asia, Latin America and the Caribbean</td>
<td>LMIC ex-works: $ 2 for 50 countries</td>
</tr>
<tr>
<td>(OraSure Technologies, USA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SURE CHECK® HIV Self Test</td>
<td>Blood</td>
<td>WHO PQ</td>
<td>To be updated</td>
<td>To be updated</td>
</tr>
<tr>
<td>(Chembio Diagnostic Systems Inc., USA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>atomo HIV Self Test</td>
<td>Blood</td>
<td>CE mark, TGA ERPD-3</td>
<td>Australia</td>
<td>HIC: $ 17</td>
</tr>
<tr>
<td>(Atomo Diagnostics, Australia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>autotest VIH® **</td>
<td>Blood</td>
<td>CE mark</td>
<td>15 European countries</td>
<td>HIC: retail: $ 20–28; NGOs: $ 8–15</td>
</tr>
<tr>
<td>(AAZ Labs, France)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioSURE HIV Self Test **</td>
<td>Blood</td>
<td>CE mark, ERPD-3</td>
<td>South Africa, United Kingdom</td>
<td>HIC: retail: $ 25–40; NGOs: $ 6–10</td>
</tr>
<tr>
<td>(BiOSURE , United Kingdom Ltd)</td>
<td></td>
<td></td>
<td></td>
<td>LIC: retail: $ 10–18; public sector: $ 3.8–6</td>
</tr>
<tr>
<td>Exacto® Test HIV</td>
<td>Blood</td>
<td>CE mark</td>
<td>Austria, France, Gabon, Germany, Switzerland</td>
<td>To be updated</td>
</tr>
<tr>
<td>(Biosynex, France)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OraQuick® In-Home HIV Test</td>
<td>Oral fluid</td>
<td>FDA CE Mark</td>
<td>USA, Not yet marketed in Europe</td>
<td>HIC retail: $ 40</td>
</tr>
<tr>
<td>(OraSure Technologies, USA)</td>
<td></td>
<td></td>
<td></td>
<td>Public sector prices vary.</td>
</tr>
</tbody>
</table>

**WHO PQ products: https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/**


HIC, high-income countries; FDA, Food and Drug Administration; ERPD, Expert Review Panel for Diagnostics; Gen, test generation; LMIC, low- and middle-income countries, MRSP: maximum suggested retail price; NA, not available.

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Note: Product details based on information provided by the manufacturers at the time of report preparation.
Current HIVST with WHO PQ

<table>
<thead>
<tr>
<th>Test (manufacturer)</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTI® HIV Self Test ** (bioLytical Lab., Canada)</td>
<td>Blood</td>
</tr>
<tr>
<td>Mylan HIV Self Test</td>
<td>Blood</td>
</tr>
<tr>
<td>OraQuick® HIV Self Test (OraSure Technologies, USA)</td>
<td>Oral</td>
</tr>
<tr>
<td>SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)</td>
<td>Blood</td>
</tr>
</tbody>
</table>

Latest list of WHO prequalified products:  
https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/
HIV SELF-TESTING AFRICA INITIATIVE

Blood-based self-testing research in Malawi, South Africa and Zimbabwe

Euphemia Sibanda, Moses Kumwenda, Mohammed Majam
Common findings from all tests

- Collection of sample was challenging
  - Hardened skin making sample collection difficult - Insufficient blood
  - Instructions on where to position lancet on finger unclear

- Participant difficulties recognising lancet leading to inadvertent trigger
  “Where is the needle?”

“Pricking instrument. The needle is inside; it cannot be seen”
Common findings from all tests...

- People don’t read introductory text

“It’s obvious you need to follow instructions so I didn’t need to read that”
Common findings all tests...(3)

• Challenges with translation to local languages
  • Warning against use among those on ART
  • Warning against use among those with bleeding disorder (Insti)

• Poor literacy limits understanding

• Need to use arrows to enhance clarity, e.g. showing the tear notch

• Use of clear pictures is important
  • “Pictures show that the red liquid has cut off or dissolved the finger”
A product-specific HIVST process checklist was developed to calculate a usability index that could be applied to each of the HIVSTs independently. This usability index was motivated by previous HIVST briefing documents from the Blood Products Advisory Committee, which quantified operational error rates by identifying and tracking errors based on the IFU. Instead of tracking erroneous steps to identify the error rate (expressed as a percentage), this study tracked successful steps, in order to identify usability with the usability index, which was also expressed as a percentage.

- Usability Index of Pre-qualified tests
  - Orasure 92,2%
  - Biolytical 97,4%
  - Chembio 93,7%
  - Mylan/Atomo 89,1%
BBST performance studies
## Performance studies

<table>
<thead>
<tr>
<th>Kits (n)</th>
<th>Zimbabwe</th>
<th>Malawi (n=714)</th>
<th>South Africa (900 each)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Biosure, Insti, Surecheck</td>
<td>Insti (and Oraquick)</td>
<td>Biosure, Insti, Chembio</td>
</tr>
<tr>
<td>Comparison test/s</td>
<td>• National algorithm • HIVST staff read</td>
<td>National algorithm</td>
<td>4th generation ELISA</td>
</tr>
<tr>
<td>Number of iterations</td>
<td>3, 4 and 3</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Population and recruitment sites</td>
<td>• Urban &amp; rural • HTS static &amp; mobile clinics + FSW clinic</td>
<td>Individuals seeking HTS at urban and rural clinics</td>
<td>Urban, in inner city Johannesburg</td>
</tr>
<tr>
<td>Information provided</td>
<td>• IFU &amp; video • IFU, video &amp; demonstration</td>
<td>IFU and demonstration</td>
<td>IFU only</td>
</tr>
<tr>
<td>Observation during testing</td>
<td>Video</td>
<td>None</td>
<td>Observer</td>
</tr>
</tbody>
</table>
## Performance results

<table>
<thead>
<tr>
<th></th>
<th>Zimbabwe (final iteration)</th>
<th>Malawi (n=714)</th>
<th>South Africa (900 for each kit)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biosure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agreement gen pop</td>
<td>47/50 (94.0%)</td>
<td></td>
<td>816 (90.7) successful HIV self-tests</td>
</tr>
<tr>
<td>Sens. 1/1 (100%)</td>
<td></td>
<td></td>
<td>Sensitivity: 126/129 (97.6%)</td>
</tr>
<tr>
<td>Spec. 46/49 (93.9%)</td>
<td></td>
<td></td>
<td>Specificity: 687/687 (100%)</td>
</tr>
<tr>
<td>Agreement FSW</td>
<td>49/51 (96.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sens: 4/5 (80.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spec: 45/46 (97.8%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Insti</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agreement gen pop:</td>
<td>45/51 (88.2%)</td>
<td>Agreement: 95.0%</td>
<td>849 (94.3) successful tests</td>
</tr>
<tr>
<td>Sens. 7/8 (87.5%)</td>
<td>Kappa: 0.91</td>
<td>Sensitivity: 98/99 (99.0%)</td>
<td></td>
</tr>
<tr>
<td>Spec. 38/43 (88.4)</td>
<td>Sensitivity: 95.2%</td>
<td>Specificity: 750/750 (100%)</td>
<td></td>
</tr>
<tr>
<td>Agreement among 50 FSW</td>
<td>42/50 (84.0%)</td>
<td>(95% CI: 76.2; 99.9%)</td>
<td></td>
</tr>
<tr>
<td>Sens: 5/6 (83.3%)</td>
<td>Specificity: 99.7%</td>
<td>(95% CI: 98.6; 100%)</td>
<td></td>
</tr>
<tr>
<td>Spec: 37/44 (84.1%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Performance results

<table>
<thead>
<tr>
<th></th>
<th>Zimbabwe (final iteration)</th>
<th>Malawi (n=714)</th>
<th>South Africa (900 for each kit)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surecheck</strong></td>
<td>Agreement gen pop</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>47/50 (94.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sens. 2/2 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spec. 45/48 (93.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agreement FSW</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>48/50 (96.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sens. 7/7 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spec. 40/43 (93.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chembio</strong></td>
<td></td>
<td></td>
<td>849 (94.3) successful tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sensitivity: 122/126 (96.8%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Specificity: 699/699 (100%)</td>
</tr>
</tbody>
</table>
Mohammed’s Independent scorecard!

• So… which test should a country/program choose?
• Do we have a perfect test?
• How are we doing against the TPP?
PQ’d options vs TSS

- DISCLAIMER 1: All these tests have had to meet the stringent standards to achieve PQ
- DISCLAIMER 2: This is based on mine, and my team’s assessment and perception of the tests

<table>
<thead>
<tr>
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**PQ’d options vs TSS**

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<td>Chembio 99% stability with 1 - 6 month re-read</td>
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Supporting the Self-Tester

- Effective usage of digital tools, Job aids and other IEC Materials

Evaluation of a mobile application to support HIV self-testing in Johannesburg, South Africa

01. FIND
02. REGISTER
03. LEARN
04. JOURNEY
05. ENGAGE

Patient is guided by website, brochure or clinic staff towards online platform.
Patient registers and is explained their rights around data protections and anonymity.
Patient is provided information on their condition and upcoming journey.
Patients is guided through test and L2C by engaging with content and calls to action.
The patient can at any time access counselling by sending a message in-app for a call back.
Conclusion

• The HIVST pipeline is strong

• Competition is good and we should embrace it

• The variety of products available should be used to grow the market

• The tests are only as good as the program
Acknowledgements

• Tanya Shewchuk - BMGF
• Unitaid
• National Department of Health
• STAR Partners: PSI, SFH, CHAI, LSHTM
• Naleni Rhagnath and the Wits RHI Ezintsha STAR team
• WHO HIV and PQ teams
• Halteres Associates: Mickey, Laura and Rich
• All the HIVST manufacturers

CONTACT: MOHAMMED MAJAM, +27 82 826 0180, mmajam@wrhi.ac.za
Towards Sustainability and Scalability of HIV Self-Testing

HIV Self-testing Products, Technical Updates on Clinical Performance, Usability and Acceptability in Program Implementation

Moderators: Rachel Baggaley, WHO

Karin Hatzold, PSI, STAR Consortium

Presenters: Cheryl Johnson, WHO

Mohammed Majam, Ezintsha

Thato Chidarikire, NDOH

Kim Green, PATH

Doan Hong Anh, PATH

Agnes Sitta Kijo, WHO/REG/FPI
Experiences from HIV Self-Screening using blood-based products in South Africa

Dr Thato Chidarikire
DIRECTOR HIV PREVENTION PROGRAMS

Webinar on HIV Self-testing Products, Technical Updates on Clinical Performance, Usability and Acceptability in Program Implementation
90-90-90 Progress (September 2019)

Achievement of the 90-90-90 Goals among HIV-Positive Adults, by Sex - South Africa, Sep 2019

- **Adult Male**: 89% (64%)
- **Adult Female**: 94% (74%)
- **Total**: 91% (70%)

- **Total**: 83%
HIVSS Distribution models

- **Community-based**: door-to-door, HTS mobile integration, distribution at hot spots and transport hubs
- **Facilities-based**: Direct distribution to those not reached with PITC and secondary distribution to male partners of MCH client and sexual partners of newly diagnosed PLHIV and PLHIV on ART
- **Workplace programmes**: private/public partnership targeting men in the agriculture, industries and mining
- **Social Network Distribution**: Targeting FSWs, MSM, PWID
- **Distribution at pharmacies**
- **Online Ordering and Delivery**: Targeting MSM, Transgender people, Young women, Older men
SA HIVST Cumulative Distribution by model 2017-July 2020 (N=2,131,785)

- Community Based: 1,474,158, 69%
- Public Sector Facility: 205,344, 10%
- Public Sector ANC: 14,855, 1%
- Public Sector Index: 18,104, 1%
- Community Based: 205,344, 10%
- VMMC (Combined): 285, 0%
- Key Population: 36,697, 2%

Private Sector: 115,416, 5%
Work Place: 266,926, 12%
SA STAR Cumulative outputs by age & sex, % first time testers (2017-July 2020), N=2,109,800

67% Male
30% Female
14% % of first time testers (Male)
8% % of first time testers (Female)
Experience with Blood based HIVST products (1)

- Introduction of blood-based HIVSS products to the HIVSS program in South Africa in late 2019
  - Distribution initially restricted to facility direct distribution and assisted HIVSS (integration with HTS outreach)
  - Major scale up of blood-based product distribution during COVID-19 lock down
    - Distribution through pharmacies
    - Online Ordering and delivery

- High acceptability and ease of use reported by clients
- Operational advantages of blood-based products used due to short reaction time (2 minutes)
- Preference of blood-based products over oral fluid products with certain populations with online ordering/distribution
Experience with Blood based HIVST products - Facility based distribution (direct) in 4 districts

Introduction of HIVSS (blood-based products) through direct distribution at health facilities increased testing coverage among eligible clients and increased number of people diagnosed at health facilities as compared to before HIVSS was made available.
Online order and home delivery of HIVSS kits

**Step 1**
Online reach on social media platforms
- View HIVST advertisement
- Click on advert that diverts to ordering platform
- Self-identify HIV testing needs (self-screening)

**Step 2**
Online test order
- Fill out online HIVST delivery order (home delivery)
- Choice of Blood-Based or Oral Fluid HIVSS test

**Step 3**
HIVST kit delivery
- HIVST kits delivered to clients within 72 hrs
- Client confirms receipt via social media/followup call

**Step 4**
Follow-up HIVST
- Perform HIVST, using instructions-for-use and/or video
- If client gave permission to follow-up, feedback provided to distributors telephonically
- Client that didn’t not to be contacted were not followed up
HIVST Online Distribution Outputs: March – May 2020

- 62% of kits were delivered to clients aged 20-29 years
- 58% kits were delivered to men

- > 70% of clients prefer blood-based HIVST kits, of which 60% are ordered by men
Scale-up of HIVSS, Country Operational Plan

South African Government, Global Fund and PEPFAR - committed to the procurement of HIVSS test kits from 2020

- Never tested + not tested more than 12 months

- Phase-in approach – prioritising districts with the highest combination of: HIV incidence + TROA + testing gap

- 15% of all distribution outcomes should be recorded

- Facility
  - Clients accessing health facilities, eligible not tested

- TVET’s
  - Adult men, key Populations young people and other vulnerable

- Workplace
  - Adults man

- Pharmacy/Online
 Significant increase in the national HIVST need after COVID 19 – Republic of South Africa

### National HIVST Need: Pre-Covid 19 Forecast (Q1, 2019)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of HIVST Kits</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>2.2 Million</td>
</tr>
<tr>
<td>2021</td>
<td>2.3 Million</td>
</tr>
</tbody>
</table>

### National HIVST Need: Post-Covid Forecast (Q4, 2020)

- Need based HIVST forecasting model is under the update process (Nov 2020).
- Latest model will include COVID 19 assumption: to analyze the impact of COVID on conventional testing/HIVST need at national and sub-national.
- HIVST forecasting experience from other countries in the region indicates - **Significant increase** in the need and demand for HIVST after COVID 19 (Eswatini: - 35%, Lesotho 27%).
- **In 2020**: NDOH, STAR and other partners are procuring HIVST kits (significant share for BB kits). NDOH procurement: Tentative 44% blood-based products/ total procurement* (WIP)
Acknowledgements

• Unitaid
• STAR
• Implementing partners
• WHO
• DOH
• NDOH
• All who participated in one way or another towards success of HIVSS
THANK YOU
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Scaling-up access to blood-based HIVST in Vietnam and Uganda

Ms. Doan Hong Anh, HIV Testing Lead, USAID/PATH Healthy Markets
Dr. Kimberly Green, Global HIV & TB Director, PATH
Differentiated HIVST strategies pre-COVID19

Virtual ordering platforms
- Kenya, Uganda, Vietnam

Pharmacy-based distribution
- DRC, Uganda, Vietnam

Index and social network testing approaches
- DRC, Kenya, Uganda, Vietnam

*Coming soon in Indonesia and India
How to maintain HIV testing services during COVID-19?

HIVST to continue index testing in Ukraine

Safe HIV self-testing services at pharmacies in the DRC

HIVST 3.0: Self-testing goes virtual in Vietnam

Community- and home-based distribution of HIVST in Kenya
HIVST scale-up: A phased approach

2015: Assessed preferences and willingness to pay

2016: Launched oral and blood-based HIVST

2017/8: National HIVST guidelines, product performance assessments, demand creation

2019: Registration of HIVST products

2020: Evolution of models: online, secondary distribution, pharmacy, social-enterprise
HIVST acceptability and preferences

Intention to use HIVST

- **FSW (N=1248)**
  - Yes: 44%
  - No: 56%

- **PWID (N=1296)**
  - Yes: 31%
  - No: 69%

- **MSM (N=1528)**
  - Yes: 36%
  - No: 64%

Prefer oral fluid or blood-based HIV self-test?

- **PWID**
  - Mouth saliva swab: 59%
  - Finger prick: 43%
  - Either, does not make a difference: 17%

- **FSW**
  - Mouth saliva swab: 29%
  - Finger prick: 49%
  - Either, does not make a difference: 36%

- **MSM**
  - Mouth saliva swab: 29%
  - Finger prick: 49%
  - Either, does not make a difference: 47%

Source: USAID/PATH Healthy Markets project, HIV commodity and service consumer preferences, utilization and willingness to pay, December 2015, Hanoi, Vietnam
HIVST pilot and evaluation (2016-2017)

- HIVST offered from May 2016 through 15 KP CBOs
- Within the pilot was an embedded evaluation that assessed HIV lay and HIVST acceptability, feasibility and linkages
- KP CBO clients offered a choice of lay or self-testing (assisted or unassisted)
  - 15 key population-led CBOs (MSM, TGW, FSW, PWID) in Ho Chi Minh City (5/2016), Hanoi (9/2016), Vinh City, Nghe An (1/2017)
- And a choice of tests:
  - Oral fluid assay (OraQuick Rapid HIV 1/2), August 2016
  - Blood-based assay (Alere Determine HIV 1/2), May 2016
- Inserts, posters and video tutorials developed in Vietnamese
HIVST introduction and scale up in Vietnam: HIVST guidelines support blood-based and oral-fluid tests

- MOH approved community HIV testing pilot in 6 provinces (Oct 2015)
- National launch of HIVST (Aug 2016)
- MOH approved national guidelines on community HIV testing/HIVST (Apr 2018)
- GVN approves Decree 155 enabling delivery and sale of lay testing & HIVST services (Nov 2018)

- Lay testing introduced (Dec 2015)
- Self-testing introduced (May 2016)
- Index testing/PNS introduced (June 2017)
- Community HIV testing scale up in 33/63 provinces since 2018 (PEPFAR, GFATM)
- First HIVST product (INSTI) registered in VN (July 2019)
Enabling local HIVST product registration and generating data for WHO PQ

5 HIVST products evaluated in Vietnam for WHO pre-qualification

New blood-based HIVST product evaluation in process

2 HIVST product registered for use in Vietnam
# Blood-based HIVST preferences and willingness to pay*

<table>
<thead>
<tr>
<th>Questions</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D14. Prefer to use test at home or a clinic?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At home</td>
<td>313</td>
<td>52.3</td>
</tr>
<tr>
<td>At clinic</td>
<td>193</td>
<td>32.2</td>
</tr>
<tr>
<td>Both of them are fine</td>
<td>93</td>
<td>15.5</td>
</tr>
<tr>
<td>D15. Recommend the test for sexual partners or friends?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>65</td>
<td>10.9</td>
</tr>
<tr>
<td>Yes</td>
<td>526</td>
<td>88.1</td>
</tr>
<tr>
<td>Do not know</td>
<td>6</td>
<td>1.0</td>
</tr>
<tr>
<td>D16. Use the test again?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>38</td>
<td>6.4</td>
</tr>
<tr>
<td>Yes</td>
<td>543</td>
<td>91.1</td>
</tr>
<tr>
<td>Do not know</td>
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*Performance and acceptability of x blood-based HIVST, Vietnam, 2019
Adapting HIVST distribution models and increasing choice during COVID-19

Protect your privacy, self-test for HIV!
Differentiated models of distribution…
HIVST pharmacy, clinic and social enterprise distribution

- Blood-based HIVST sold and distributed by:
  - 7 key population-owned clinics and social enterprises.
  - 48 pharmacies across Ho Chi Minh City and Hanoi.
- TA for product marketing/promotion through online channels and through peer influencers.
- Developing commercial HIVST sales/use data capture system.
- Price a barrier.
Co-packaging blood-based HIVST kits with PrEP promotional materials and PPE
Uganda
Uganda and blood-based HIVST snapshot

- National HIVST guidelines in place that are broad and encompass blood-based and oral-fluid products – responsive to HIVST product preferences among different populations.
- Stewardship by the MOH and oversight with regard to product registration, pricing and placement.
- SureCheck and INSTI registered and available.
- HIVST kits available through pharmacies and clinics, as well as through implementing partners.
- Blood-based HIVST included overall forecasting and procurement plan-and in Global fund program.
- But…the price of blood-based HIVST remains challenge.
Key take-aways

Making blood-based HIVST kits available:

- Increases choice and options
- Diversifies the HIVST market
- Can be a portal to PrEP
- May be more acceptable to some during a respiratory pandemic such as COVID-19

“The packaging is convenient, small and easy to carry, with clear instruction of how to use. Some clients think a blood-based test is more accurate and is preferred these users. – KP-led clinic in Hanoi/HCMC (Glink)
Acknowledgements

- Vietnam MOH/VAAC
- Uganda MOH
- CBOs/clinics/social enterprises/pharmacies
- USAID Vietnam
- Bill & Melinda Gates Foundation
- Ezintsha/Wits RHI
- Unitaid
- WHO
- PATH colleagues
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WHO Collaborative Registration Procedure for in vitro diagnostics

Agnes Sitta Kijo, WHO/RPQ/REG/FPI

15 October 2020
Objective

Understand the basis, key principles and benefits of the CRP in accelerating access to quality assured diagnostics.
How regulators can best contribute to the public health with the (limited) resources they have?

✓ Avoid doing things that do not give added value, concentrate on things that do give added value;

✓ Concentrate on high risk areas/products;

✓ Be pragmatic: "Nice to know" – forget it, "Need to know" – get it! And learn making difference between the two;

✓ Cooperate with partners in order to increase regulatory capacity by elimination of duplicated activities - facilitated by comparable standards and administrative requirements.
Defining Reliance and Recognition

**Reliance**: act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision.

**Recognition**: the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B.
Regulatory decision making

• Unilateral or mutual recognition: mutual recognition is based on treaties or equivalent, providing maximal benefits but partial loss of sovereignty with regard to decision-making

• Reliance on regulatory decisions performed by other competent and trusted agencies and/or cooperation/collaboration with other regulators to reduce the workload, with independent final decision-making

• NRA makes independent decisions based on its own reviews or inspections

Regulatory cooperation based on convergence/harmonization to improve the quality of decision making process

Normal standard processes

WHA resolution 67.20 (2014)
The underlying principles of facilitated regulatory pathways

- timely and equitable access to quality-assured products;
- science-based, risk-based, transparent regulatory decision-making;
- better use of available, often limited, regulatory resources on value-added regulatory processes;
- reducing duplication of efforts and resources through reliance on the work products of trusted counterpart regulatory agencies and institutions to inform local regulatory decision-making;
- respecting national sovereignty.
Facilitated pathways to “transfer” regulatory information & knowledge

- Sharing information (assessment, inspection and testing results) that serve as basis for national decisions – avoiding duplication.
- Voluntary participation – reference authorities, participating authorities and manufacturers/sponsors

**PRINCIPLES**

- **WHO collaborative procedure**
  - Vaccines: 2004
  - Medicines: Started in 2012
  - Diagnostics: Pilot 2019
  - Vector control: Pilot 2020

- **“SRA” collaborative procedure**
  - Initiated in 2015
  - European Medicines Agency (EMA)
  - Medicines and Healthcare Products Regulatory Agency (MHRA)
  - 20 African NRAs

- **Regional networks**
  - African Medicines Regulatory Harmonization Project (AMRH)
  - ASEAN SIAHR Project
  - AVAREF

---
WHO CRP - mechanism

- Voluntary
- Product and registration dossier in countries are 'the same' as prequalified by WHO
- Shared confidential information to support NRA decision making in exchange for accelerated registration process
- 'Harmonized product status' is monitored and maintained.
WHO PQ CRP
In vitro Diagnostics

IVD
EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva 19 to 23 October 2020

COLLABORATIVE PROCEDURE BETWEEN THE WORLD HEALTH ORGANIZATION (WHO) AND NATIONALREGULATORY AUTHORITIES IN THE ASSESSMENT ANDACCELERATED NATIONAL REGISTRATION OFWHO-PREQUALIFIED IN VITRO DIAGNOSTICS (IVDS)

NOTE:

This document has been prepared for the purpose of inviting comments andsuggestions on the proposals contained therein, which will then be considered by theExpert Committee on Biological Standardization (ECBS) and by the ExpertCommittee on Specifications for Pharmaceutical Preparations (ECSSP).

Publication of this draft is to provide information about the proposed Guidelines forCollaborative Procedure between the World Health Organization (WHO) andNational Regulatory Authorities in the assessment and accelerated NationalRegistration of WHO-Prequalified In Vitro Diagnostics to a broad audience and toimprove transparency of the consultation process.

The text in its present form does not necessarily represent an agreed formulationof the ECBS. Written comments proposing modifications to this text MUST bereceived by 15 July 2020 using the Comment Form available separately andshould be addressed to: Department of Health Products Policy and Standards (HPS),World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland.Comments may also be submitted electronically to the Responsible Officer:
gmalad@who.int.

The outcome of the deliberations of the ECBS and ECSSP will be published in theWHO Technical Report Series. The final agreed formulation of the document willbe edited to be in conformity with the second edition of the WHO style guide(KMS/WHP/131).
Table of Contents

1. Background ............................................................................................................. 4
2. Introduction ............................................................................................................. 6
   2.1. Aims and objectives of the Collaborative Procedure ........................................ 6
   2.2. Scope ................................................................................................................. 8
   2.3. Glossary ............................................................................................................ 8
3. Principles and general considerations ................................................................. 10
   3.1. Participating parties .......................................................................................... 10
   3.2. Sameness of the prequalified product and nationally registered product .......... 10
   3.3. Submissions format and content of product dossiers to NRAs ......................... 11
   3.4. Information shared under the Collaborative Procedure ................................. 12
   3.5. Applicable national registration fees .................................................................. 13
   3.6. Participating authority commitments ............................................................... 13
   3.7. Regulatory decision(s) on a prequalified product ............................................. 15
   3.8. Manufacturer commitments ............................................................................. 16
4. Steps in the collaboration for national registration of a prequalified in vitro diagnostic ................................................................. 17
5. Collaboration mechanisms for post-prequalification and/or post-registration variations/changes ................................................................. 24
6. Withdrawals, suspensions or de-listings of prequalified IVDs and national deregistrations ................................................................. 28
7. References .............................................................................................................. 30

Appendix 1 National regulatory authority participation agreement and undertaking for national regulatory authority focal point(s) ................................................................. 32
Appendix 2 Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure ................................................................. 44
Appendix 3 Expression of interest to national regulatory authority (NRA) in the assessment and accelerated national registration, acceptance by NRA and notification of Procedure outcomes ..................................................................................................... 47
Appendix 4 Report on post-registration actions in respect of a product registered under the Procedure ................................................................. 50

Key features of the CRP Guidelines
Steps of the procedure

Agreement

• NRA confirms to WHO PQT its interest to participate in collaborative procedure and respect its conditions;
• One or two focal persons are designated at each interested NRA, sign confidentiality undertaking and are given access to the WHO managed restricted access platform (MedNet).

Registration

• Manufacturer submits MA application to participating NRA for the PQ-ed medicine and informs the authority about the interest to follow the collaborative procedure. Same data submitted as for PQ;
• Manufacturer informs WHO PQT about the application for national registration and, for each product, provides written agreement to exchange of information between the participating NRA and WHO PQT;
Steps of the procedure:

- Participating authority confirms to WHO PQT its interest to apply the procedure for given medicinal product;

- Within 30 days, WHO PQT provides focal person (s) in the participating NRA with assessment and inspection reports via restricted-access website (MedNet) and provides additional explanation, if requested;

- Within 90 days participating NRA decides upon the national registration, informs WHO PQT about the outcome of national registration and, when divergent from PQT decision, provides explanations;

- Within 30 days of having taken its decision, the participating authority informs WHO/PQT and the applicant of this decision;

- WHO PQT lists products registered by participating NRAs according to this procedure on its public website.
Objectives

• Use the WHO –prequalification obtained for m-PIMA HIV-1/2 VL as a basis for country registration

• Assess feasibility of new WHO collaborative Procedure including impact on registration timelines and requirements for additional country specific studies.

Participating countries

• Nigeria, Ivory Coast, Tanzania, Ethiopia, Cameroon and Ghana (recently included.

• Two countries were able to register the product within 90 days.

Lessons learned

Collaborative registration procedure for diagnostics has proved to be great innovative mechanism that can accelerate registration of diagnostics and facilitate timely availability of IVDs.
Win-Win outcome

Win-win outcomes for all stakeholders

- **Manufacturers**
  - Harmonized data for PQ and national registration
  - Facilitated interaction with NRAs in assessment, inspections & testing
  - Accelerated and more predictable registration
  - Easier post-registration maintenance

- **Procurers**
  - Time, assurance, availability

- **NRAs**
  - Having data well organized in line with PQ requirements
  - Availability of WHO assessment, inspection & testing outcomes to support national decisions and save internal capacities
  - Having assurance about registration of the same product as is prequalified

- **WHO**
  - Prequalified products are faster available to patients
  - Feedback on WHO prequalification outcomes
Towards Sustainability and Scalability of HIV Self-Testing

HIV Self-testing Products, Technical Updates on Clinical Performance, Usability and Acceptability in Program Implementation

Moderators: Rachel Baggaley, WHO
Karin Hatzold, PSI, STAR Consortium

Presenters: Cheryl Johnson, WHO
Mohammed Majam, Ezintsha
Thato Chidarikire, NDOH
Kim Green, PATH
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