HIV Self-Screening
Mpumalanga SAHCS

Lynne Wilkinson
18.11.2017

Test yourself
The power is in your hands

University of the Witwatersrand
WITS RHI
Outline

• Understanding the testing gap
• What is HIV self-screening?
• Evidence to date
• WHO Guidance
• HIVSS products & WHO prequalification
• Oraquick and how it works
• Why HIV self-screening for SA?
• South African Guidelines
• Roll out in SA:
• Q&A
Understanding the HIV testing gap
HIV diagnosis 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
South Africa towards the 90/90/90 goals

South Africa: HIV treatment cascade

- 90%: Percentage of people living with HIV who know their HIV status
- 81%: Percentage of people living with HIV who are on antiretroviral treatment
- 73%: Percentage of people living with HIV who are virally suppressed

Source: Towards 90-90-90 Dec 2016
Unequal progress towards UNAIDS 90-90-90 targets

- **Both Sexes**
  - PLHIV: 6,473,000
  - In Care: 53%
  - On ART: 46%
  - VLS: 26%
  - UNAIDS 90-90-90 goals: 81% In Care, 73% On ART

- **Females**
  - PLHIV: 3,391,000
  - In Care: 60%
  - On ART: 51%
  - VLS: 30%
  - UNAIDS 90-90-90 goals: 81% In Care, 73% On ART

- **Males**
  - PLHIV: 2,542,000
  - In Care: 43%
  - On ART: 37%
  - VLS: 20%
  - UNAIDS 90-90-90 goals: 81% In Care, 73% On ART
What is HIV self-screening?
What IS HIV self-screening?
• A process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts

• HIVST is a “screening test” or Test for Triage
What HIVSS IS NOT

• It is **not here to replace other HTS modalities** from which the majority of the population learn their status.

• It is **not a definitive test**, but rather the first step towards learning a status. All POSITIVE results must be confirmed using the national algorithm.
Evidence on HIVSS

- **5 RCTs (2012-2016)** 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
HIVSS Doubled Uptake & Frequency compared to standard HTS

Moderate quality evidence that HIVST doubled 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>
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<tr>
<td>Gichagi 2016</td>
<td>3.08 [2.58, 3.69]</td>
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<tr>
<td>Thirumurthy 2016</td>
<td>1.77 [1.57, 2.00]</td>
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<tr>
<td>Wang 2016</td>
<td>1.77 [1.57, 2.00]</td>
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<td></td>
<td>2.12 [1.51, 2.98]</td>
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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>
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<tbody>
<tr>
<td>Katz 2015</td>
<td>1.70 [0.94, 2.46]</td>
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<tr>
<td>Jamil 2016</td>
<td>2.30 [2.27, 2.33]</td>
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<td>2.13 [1.59, 2.66]</td>
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Effect also shown for increase uptake of couples testing in Gichangi et al & Thirumurthy et al.

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

Across observational studies - HIV positivity ranged from
- 3–14% among the general population in sub-Saharan Africa
- 1–30% among key populations Africa, America, Asia, Europe

Studies in African region

Median HIV positivity

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<thead>
<tr>
<th>Median HIVST Positivity</th>
<th>Median HIV Prevalence</th>
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<tbody>
<tr>
<td>16%</td>
<td>9%</td>
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<tr>
<td>14%</td>
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<td>12%</td>
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<td>8%</td>
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<td>6%</td>
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<td>2%</td>
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<td>0%</td>
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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
Linkage to care

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

Effect also shown for increase uptake of couples testing in Choko et al & Thirumurthy et al.
HIVSS 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.
WHO Normative Guidance on HIV Self-Testing
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.
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:*

Unassisted HIV self-testing

*Instruction-for-use included in the kit:*
- Pictorial/written
- Including a hotline number or a link to a video
- 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**
- **Internet-based**
- **Workplace programmes**
- **PrEP programmes**
- **Integrated (e.g. VMMC, TB, STIs, reproductive health)**
- **Vending machines and kiosks**
HIVSS products & WHO prequalification
What is WHO Pre-Qualification?

• Prequalification is an assessment made by WHO regarding the quality, safety, performance and suitability of an IVD/MD when it is used in WHO Member States

• WHO prequalification is a risk-based procedure founded on best regulatory practice

• WHO undertakes a comprehensive assessment of individual IVDs/MDs through a standardized procedure aimed at determining if the product meets PQ requirements.
Why WHO Pre-Qualification?

• The PQ decision is used by UN bodies and procurement agencies as a means for quality assuring IVDs/MD and other health products.

• The PQ decision can be used by Member States without strong regulatory systems or with limited resources to provide assurance of quality, safety and performance.

• The PQ decision is used by health implementing programmes to guide product selection.
First WHO PQ device

• 27 July 2017, OraQuick was granted pre-qualification after meeting all of the requirements of the WHO assessment process

• Currently, 3 products that are in the WHO PQ review pipeline, and we should have at least 1 blood-based PQ product by Q2 2018
OraQuick HIV self-screen
OraQuick HIV Self-Screening Kit

The kit includes:

• Instructions
• Bottle stand
• Bottle with testing liquid
• Testing pad
OraQuick HIV Self-Screening Kit

• Requires a swab of the gums → pain free!
• Takes 20-40 minutes
• Easy to read results

A positive result does not mean that a person is infected with HIV, they need to have additional testing with their health care provider.

If a person was exposed to HIV less than 3 months ago, they need to screen again to be sure that their status is truly negative.
How to self-screen

What you need:
- Test Kit
- Chair, Table/Privacy
- Clock

Screening process:
1. Insert the sample into the test kit.
2. Wait for 20 minutes.

Results:
- **POSITIVE RESULT**: You need to visit your healthcare provider for a follow-up test to confirm the positive result.
- **NEGATIVE RESULT**: If you haven't been exposed to HIV in 6 weeks, your result is NEGATIVE.
- **UNSURE RESULT**: You should visit your healthcare provider to re-screen.
1. Negative

2. Inconclusive

3. Inconclusive
What to do with a positive screen?

- Client needs to go to a health facility or community testing to have a rapid diagnostic test performed by a Health care provider.
- If that test is positive, the health care provider will perform an additional confirmatory rapid test.
- If that test is positive the client will be linked to care at the health facility for ART initiation.
What to do with a negative screen?

• If the client has been exposed to HIV in the last 3 months they will need to rescreen 3 months after exposure

• If the client has not been exposed to HIV in the last 3 months the client can consider themselves HIV-negative

• The client should be educated and linked to care for HIV combination prevention including VMMC and PrEP services
What is an inconclusive screen and what to do?
(Also : indeterminate, invalid, and unsure of result)

• If the client has an inconclusive screen they need to go to a health facility or community testing for repeat screening by a health care provider
HIVSS is not recommended for:

• Any client on ARVs or PREP – may give false negative result

• Has not been validated for use in children <12 years

• Limited userability assessment <15 years
Client Questions and Answers

**How does it work?**
The kit looks for HIV antibodies in the oral fluids you collect from your gums.

**How well does it work?**
The oral HIV self-screening kit is more than 90% accurate.

**How long does the test take?**
It is fast! Only 20-40 minutes.

**Does it hurt?**
Not at all! It is a pain free swab of your gums.

**Do I have to share my result?**
No. It is confidential. You can choose who you share your results with. BUT if you do have a positive result this doesn’t mean you definitely have HIV, you need to have a confirmatory test with a health care provider.

**Can the kit detect other diseases?**
No, it only detects HIV. If you need to be tested for pregnancy or for an STI you need to go see a health provider.
Why am I testing oral fluids, can HIV be spread through saliva?
HIV is not in saliva or oral fluids, but the antibodies your body makes to fight HIV can be detected there. This makes the kit a good option for people who don’t like their blood drawn.

I’m worried I have been exposed to HIV within the past 72 hours, can I still use the HIV self-screening kit?
No, you should not use the kit, you should visit your health care provider as soon as possible to access Post Exposure Prophylaxis (PEP).

I’m on PrEP, can I use the self-screening kit?
No, anyone using ARVs, for either treatment or prevention, should not use a self-screening kit as it can give you a false negative result.

I’m on ARVs, can I use the self-screening kit?
No, HIV self-screening kits are not suitable for those who are on ARVs as they may give a false negative result.
WHY HIV self-screening for SA
50% of all people with HIV in South Africa are either undiagnosed, or diagnosed but not engaged in HIV care programmes.

60% of women with HIV infection are engaged in care.

But only 43% of men.

Source: Towards 90-90-90 Dec 2016
NOW WE HAVE: a WHO PQ device
SA regulation of medical devices:

SAPRHA constituted 2 June 2017
The difference...
SA guidance
South African policy on HIV self-screening

4.4 Self-testing

HIV self-testing (HIVST) is a process in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him or herself, often in private. HIVST is a pre-screening test and does not provide a definitive diagnosis. It does not replace the need for the screening and confirmatory HIV test in the validated national testing algorithm. A reactive self-test result must always be followed by additional testing conducted by a trained provider who operates according to the validated national diagnostic testing algorithm.

HIVST provides people an opportunity to test discretely and conveniently and may increase uptake of HIV testing among people not reached by other HIV services. HIVST is currently under policy consideration in South Africa.

Clients participating in clinical vaccine trials should be referred back to their research site for appropriate testing to avoid misdiagnosis.
## Translating Policy into Practice – Enabling Environment for HIVST in South Africa

### National HIVSS guidelines will be published in Nov 2017, through a multi-stakeholder consultative process and in alignment with broader national HTS priorities

**Development of SA national guidelines currently underway:**

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### Timeline

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### Key Milestones

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<td>Policy Development</td>
<td>SA HTS Policy recommends inclusion of HIVST to increase testing among hard-to-reach populations</td>
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<tr>
<td>Guideline Development</td>
<td>Multi-stakeholder consultative process with WHO buy-in, establishment of TWG to provide oversight</td>
</tr>
<tr>
<td>Implementation Planning</td>
<td>Development of implementation models and distribution channel selection</td>
</tr>
<tr>
<td>NDoH Annual Budgeting Process</td>
<td>Implementation costing to inform future national, provincial, and district level budgeting</td>
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To be finalized mid November 2017
HIV SELF-SCREENING:
What it is and how to integrate it into HIV Testing Services

HIV self-screening refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, either in a private setting, either alone or with someone he or she trusts.

All healthcare providers should support clients who have self-screened by conducting a rapid HIV screening test and if positive, a confirmatory rapid HIV test together with appropriate pre- and post-test counselling.

A reactive (positive) result always requires confirmatory testing by a trained tester following the national testing algorithms. Interpretation of a non-reactive (negative) result will depend on the ongoing risk of HIV exposure. Individuals with possible exposure within the past 3 months should be encouraged to re-screen 3 months after possible HIV exposure. If this result is still negative, it should be encouraged to re-screen regularly. No confirmatory test can be done with an HIV self-test or a facility-based rapid test.

A person may also get an invalid result or may have struggled to interpret their result. If this is the case, a person should immediately seek a health facility where a trained tester will conduct testing following the national testing algorithm.

HIV self-screening is not recommended for anyone on ART or PEP, as it may lead to a false negative result. It has also not been validated for any person under the age of 15 years.

HIV self-screening is acceptable to many people across different contexts and can therefore increase uptake and frequency of HIV testing, particularly among populations at high ongoing risk of HIV, who may be less likely to access testing or test less frequently than recommended.

HIV self-screening kits used by self-testers can perform as accurately as when used by a trained tester.

Reference:
CLIENT PERFORMS HIV SELF-SCREEN AT HOME

Reactive (Positive) Result

Home based: Client needs to seek confirmatory testing.

Clinic based: Client needs to seek confirmatory testing.

Non Reactive (Negative) Result

Client advised:
- To retest if HIV exposure in past 3 months or less, and
- To seek linkage to relevant HIV prevention services

Additional HIV Combination Prevention:
- Condoms
- PrEP
- Counseling
- PEP
- Healthy Lifestyles
- Treatment for STIs
- MMC
- ART for partners living with HIV
Also important in SA HIVSS guidelines:

• Do not use if on ARVs or PREP

• Do not use <12 years old

• If 12-17 years ensure demonstration provided and post HIVSS support available
Referral Card

Dear Sister in charge,

This client has screened for HIV using an HIV self-screen and may have received a reactive (positive) result. Please ensure that the client is provided with confirmatory testing and appropriate counselling in terms of the national HIV testing algorithm.

This requires a rapid HIV screening test and if positive, a further rapid confirmatory test. Where the client is confirmed HIV positive, please ensure the client is prepared and scheduled for ART initiation as per national guidelines.

Please also reflect that the client HIV self-screened in the new column in your HIV testing register (if not at your clinic yet - please indicate “HIVSS” next to the client’s name).

Should you have any questions, please contact:
Implementation South Africa
HIV Self-Testing Africa: The STAR Initiative
Introduction to the STAR Initiative

- Multiple sites, models, and populations
- Normalizing HIV self-screening in Southern Africa
- Providing evidence for scale-up
- Encouraging policy change
- Enabling the regulatory environment
- Reducing barriers

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<tbody>
<tr>
<td>Zimbabwe, Zambia, Malawi</td>
<td>Zimbabwe, Zambia, Malawi + South Africa, Swaziland, Lesotho</td>
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</table>
Number of HIV Self-Screen kits distributed by channel (2015-2017)

681,791 HIV self-screen kits distributed as of Aug 2017
3 Objectives in SA

1. Enabling environment
2. Pilot, implement and learn from HIVST distribution models
3. Facilitating transition into and scale-up within national system (costed plan/supply/national and donor budgets/M&E etc)
Workplace distribution models

Target service: Workplace

Target service location: Gauteng & NW
- Mining construction & security companies

Target pop:
- Employed men
- Sexual partners

Distribution channel:
- DD to employees
- SD through employees to SP
- DD in workplace associated communities
## Community distribution models

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<tr>
<th>Target service</th>
<th>Target service location</th>
<th>Target pop</th>
<th>Distribution channel</th>
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<tbody>
<tr>
<td><strong>Community</strong></td>
<td><strong>Region F, Gauteng &amp; DKK district, NW</strong></td>
<td>General population &amp; Men (through twilight service)</td>
<td>DD through triage screening</td>
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<tr>
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<td>Mobile outreach HIV testing services</td>
<td>Sexual partners</td>
<td>SD by clients testing HIV+</td>
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<td><strong>Region F, Gauteng</strong> VMMC men’s dialogues</td>
<td>Men</td>
<td>DD at dialogues</td>
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<td><strong>Hillbrow, Gauteng</strong> Fixed collection points</td>
<td>General population &amp; Men &amp; Students</td>
<td>DD at collection point</td>
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<td><strong>Bree &amp; Noord St taxi and Park station, Gauteng</strong> Fixed point collection &amp; campaign</td>
<td>Men &amp; General population</td>
<td>DD through campaigns</td>
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<tr>
<td></td>
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<td>DD from collection points</td>
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</tbody>
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Community distribution models

- **Community**
  - **Target service**
  - **Target service location**
    - Region F, Gauteng & DKK district, NW
      Mobile outreach
      HIV testing services
    - Region F, Gauteng
      VMMC men's dialogues
    - Hillbrow, Gauteng
      Fixed collection points
    - Bree & Noord St taxi and Park station, Gauteng
      Fixed point collection & campaign
  - **Target pop**
    - General population & Men (through twilight service)
    - Sexual partners
    - Men
    - General population & Men & Students
    - Men & General population
  - **Distribution channel**
    - DD through triage screening
    - SD by clients testing HIV+
    - DD at dialogues
    - DD at collection point
    - DD through campaigns
    - DD from collection points
Facility distribution models

- Target service: Facility
- Target service location: Region F, Gauteng Ante-natal service
- Target pop: Sexual partners
- Distribution channel: SD through 1st visit ante-natal attendees
Acknowledgements

• WHO HIV Dept: Cheryl Johnson and Rachel Baggaley
• Mohammed Majam & Wits RHI Colleagues
• SA HIV Clinicians Society and the Guidelines TWG
• Funders: BMGF, Aids Fonds & UNITAID
• STAR II Consortium Partners – PSI, CHAI and SFH

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