



HIV Self-Screening

Mpumalanga SAHCS



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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**



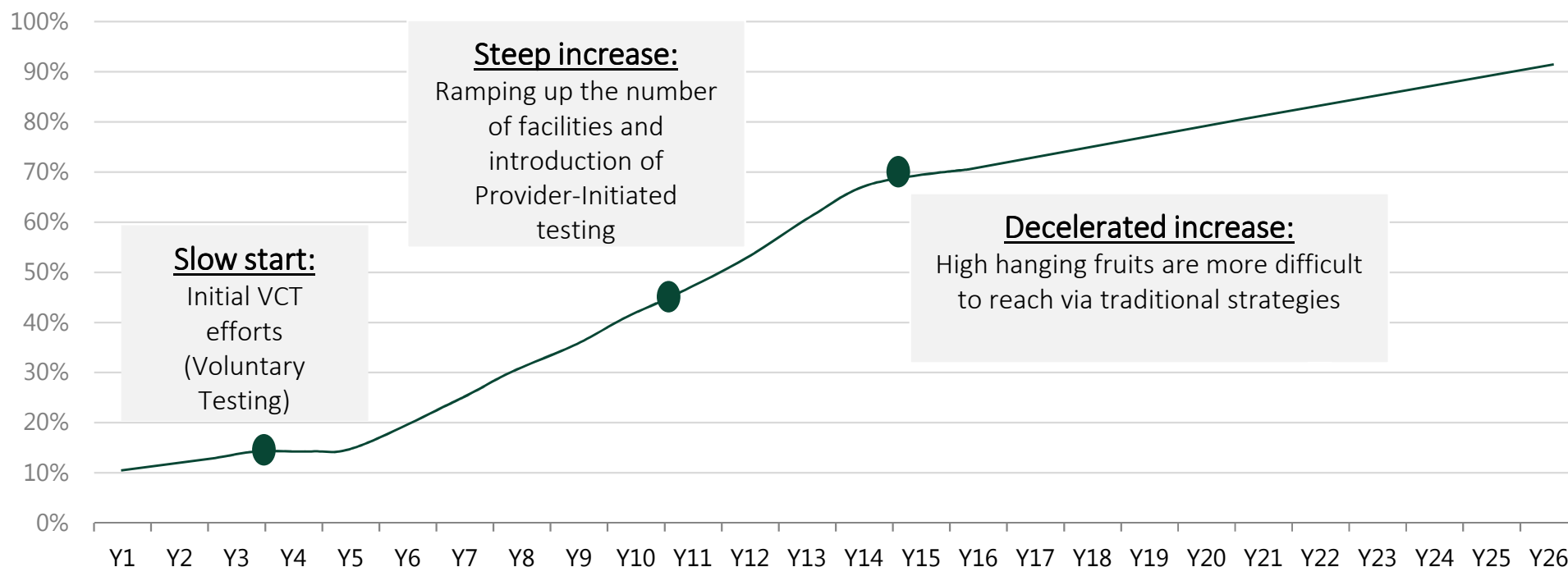


Understanding the **HIV testing gap**



HIV diagnosis over time

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



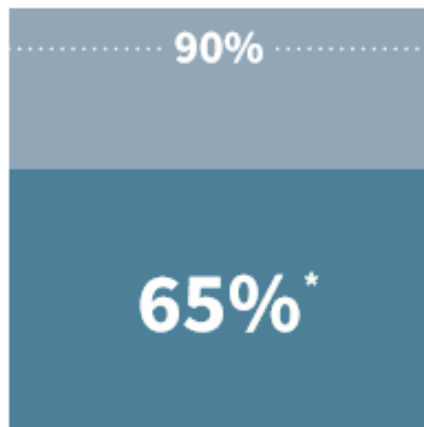
Projection suggests the earliest countries could identify 90% of PLHIV is 2026.

* By size of the epidemic

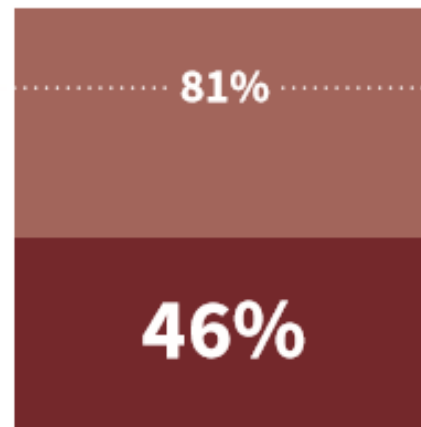
Source: Courtesy Frederic Seghers, CHAI Input data via [UNAIDS Aidsinfo](#); [DHS Statcompiler](#) – projections via CHAI NMOT modeling

South Africa towards the 90/90/90 goals

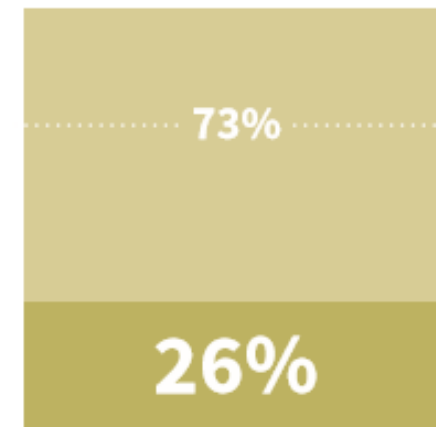
South Africa: HIV treatment cascade



Percentage of people living with HIV who know their HIV status



Percentage of people living with HIV who are on antiretroviral treatment

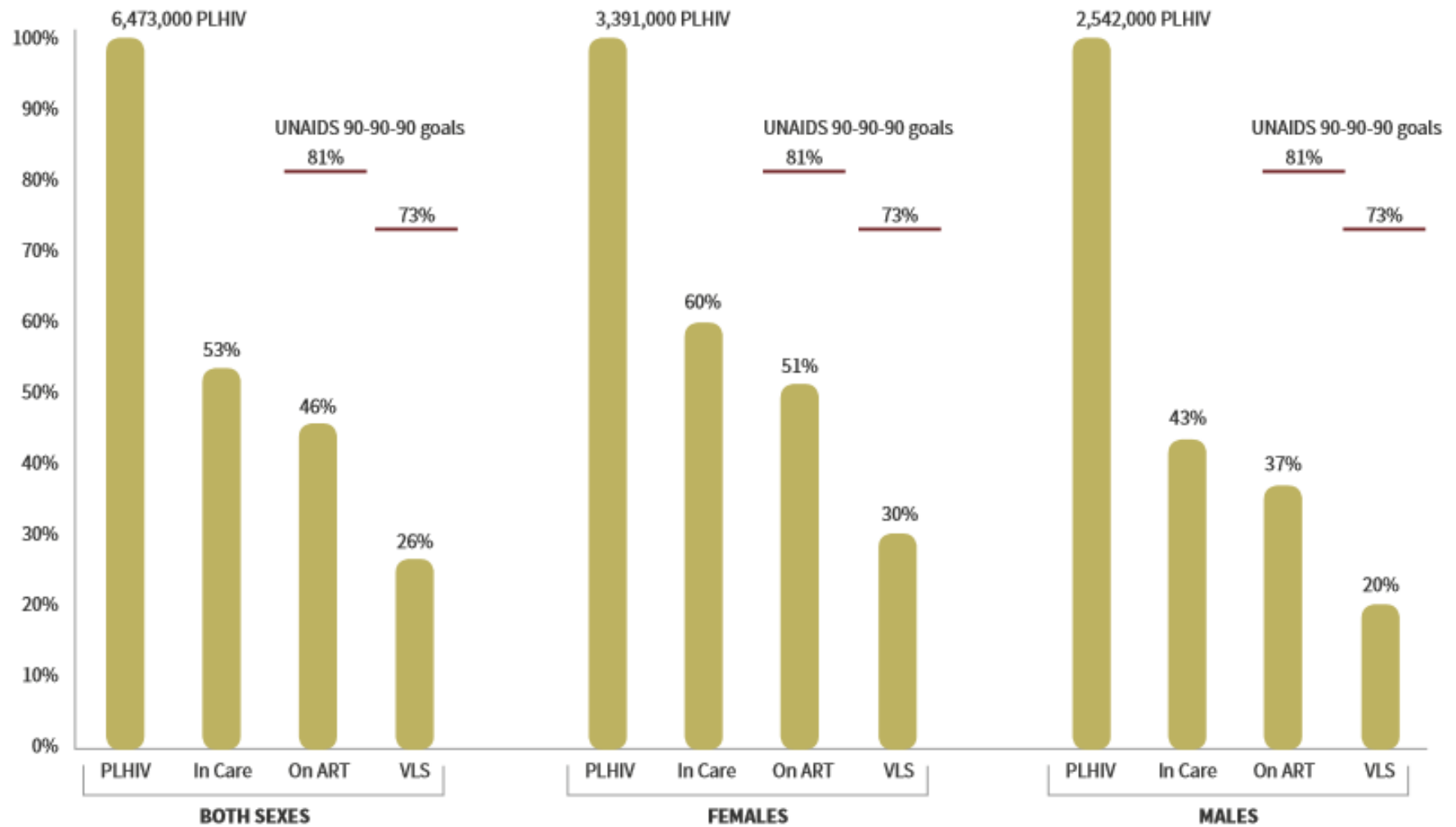


Percentage of people living with HIV who are virally suppressed

Source: Towards 90-90-90 Dec 2016



Unequal progress towards UNAIDS 90-90-90 targets



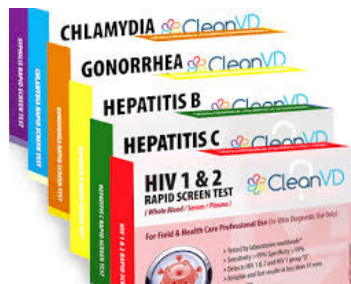


What is HIV self-screening?



What IS HIV self-screening ?

Collects



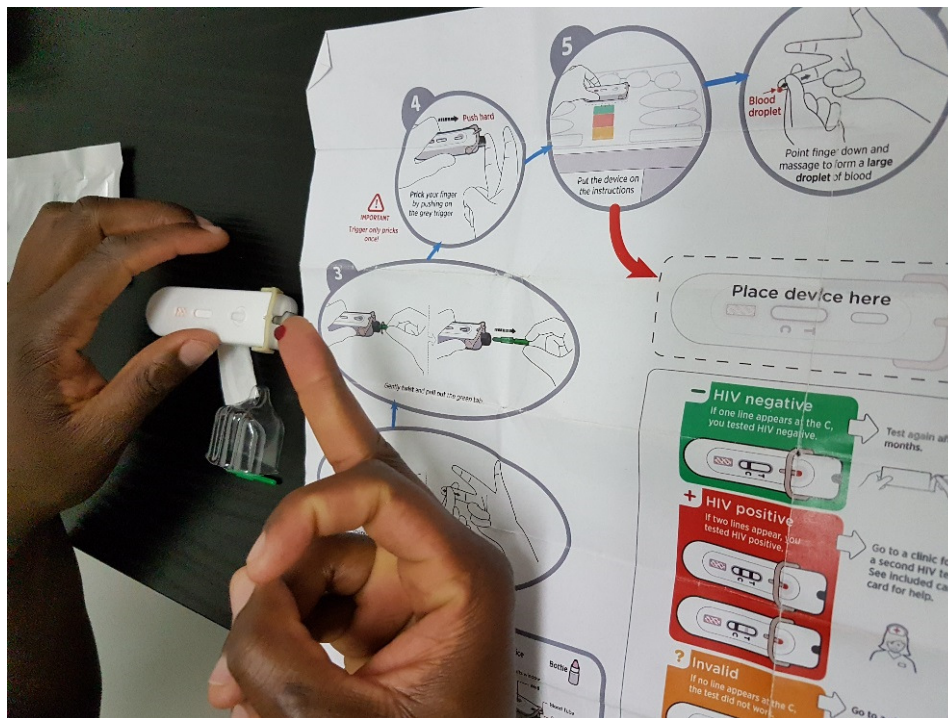
Performs



Interprets



- 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

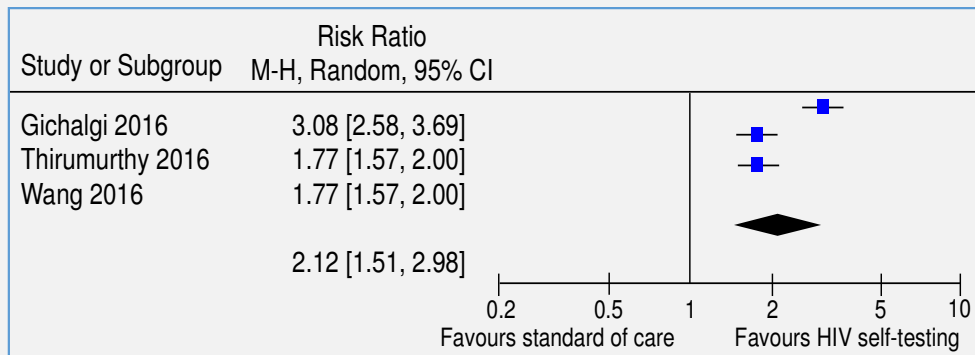
Evidence on HIVSS

- **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

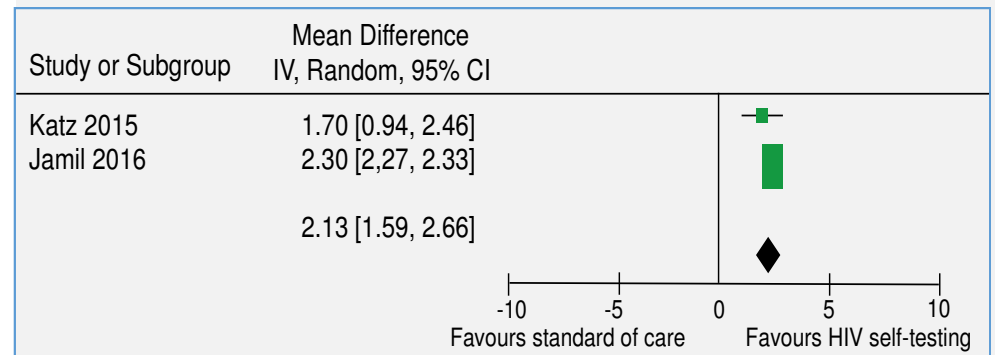
Moderate quality evidence that HIVST doubled HIV testing uptake compared to standard HTS



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

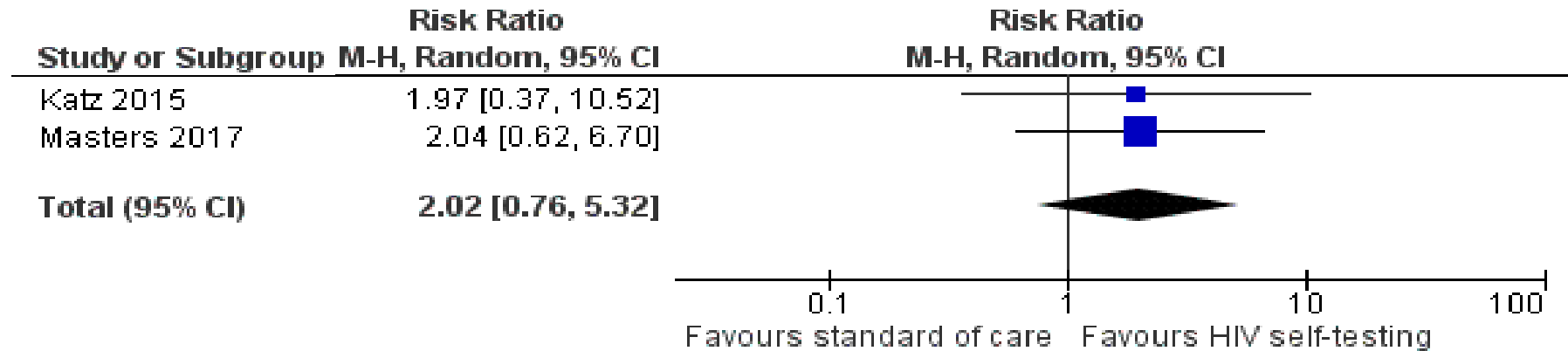


Low quality evidence that HIVST resulted in 2 more tests in a 12-15 month period compared to standard HTS



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

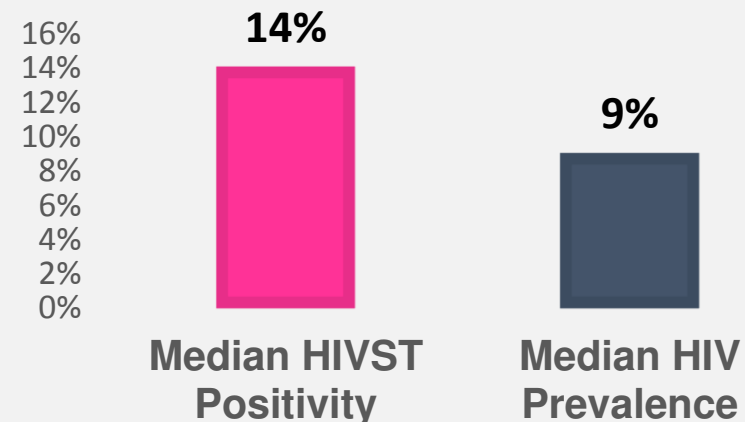


Across observational studies -
HIV positivity ranged from

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

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

Median HIV positivity Studies in African region



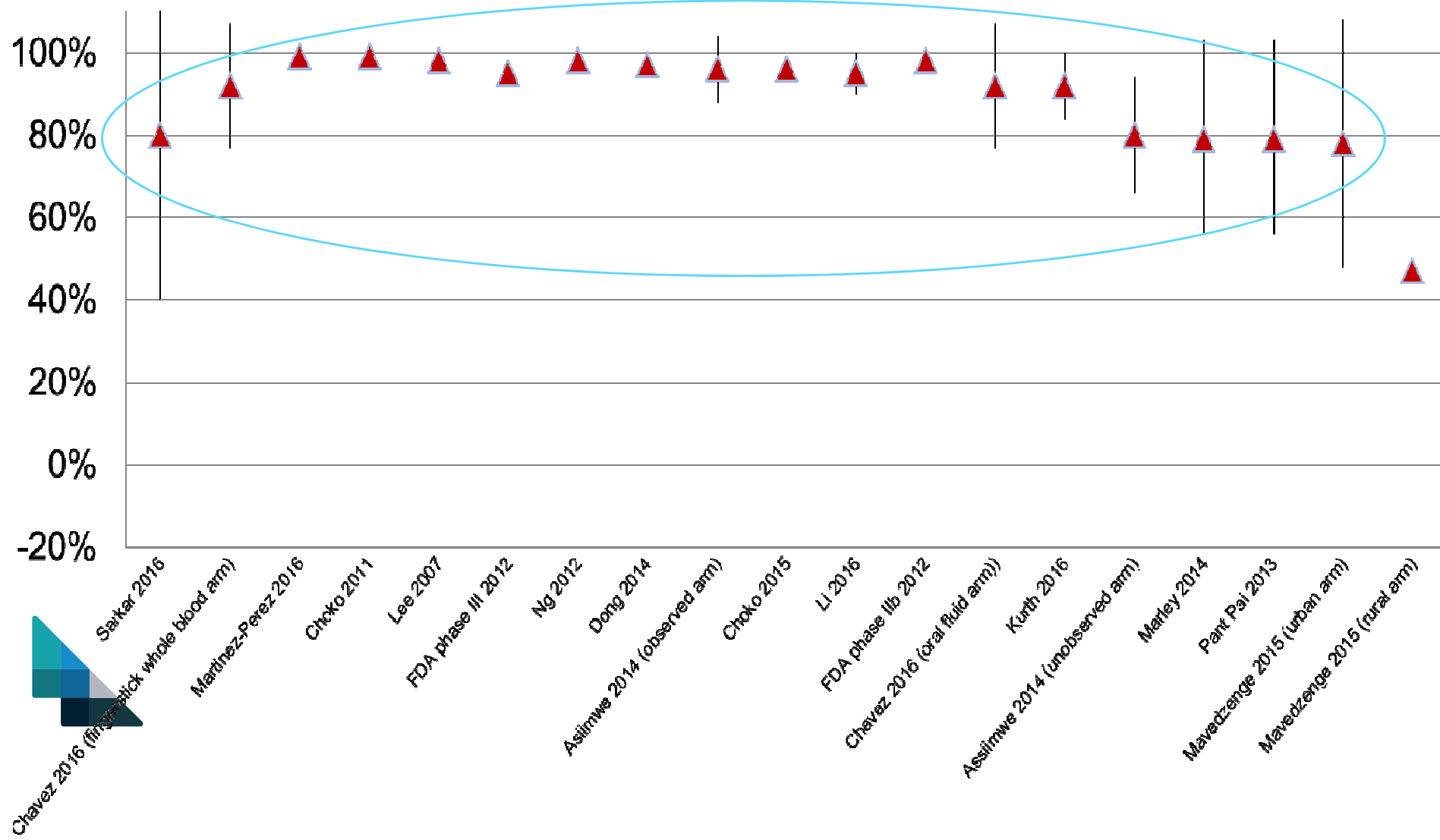
No identifiable increased risk of social harm & adverse events

- 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

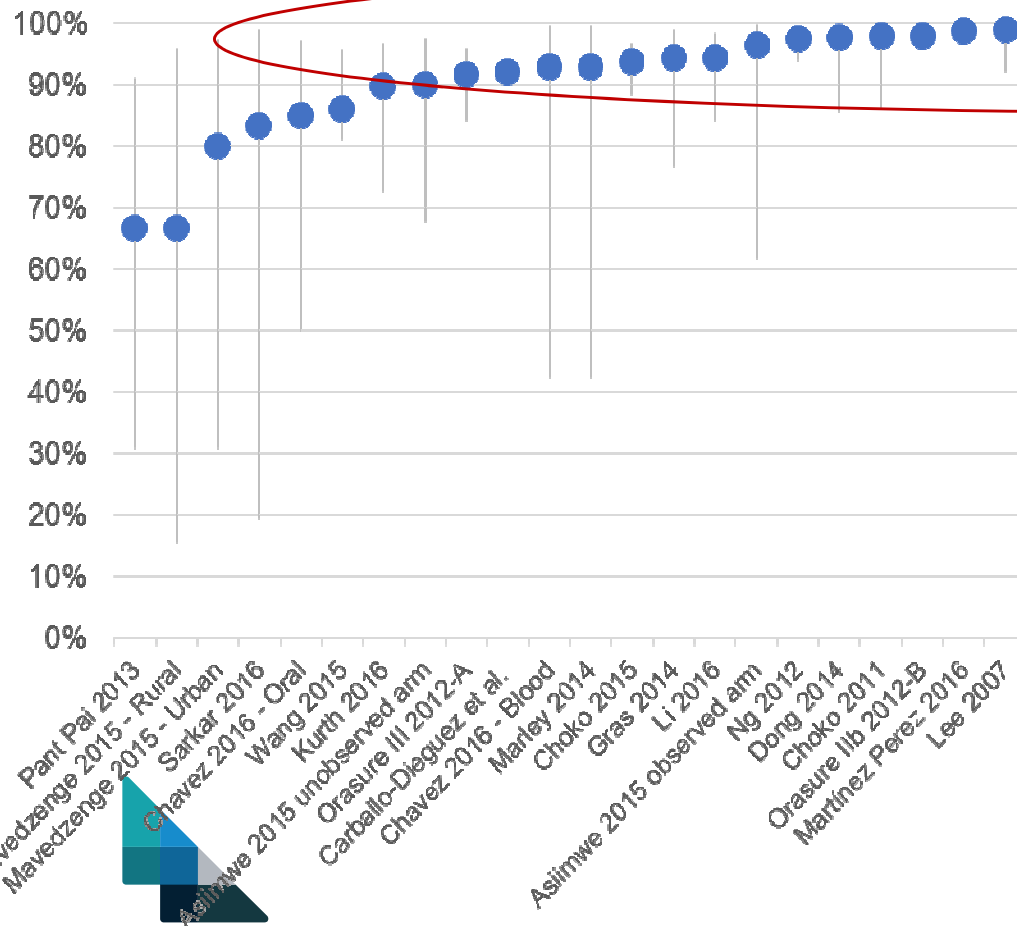
Measured using kappa statistic – 16 studies



Achieved acceptable accuracy (sensitivity & specificity)

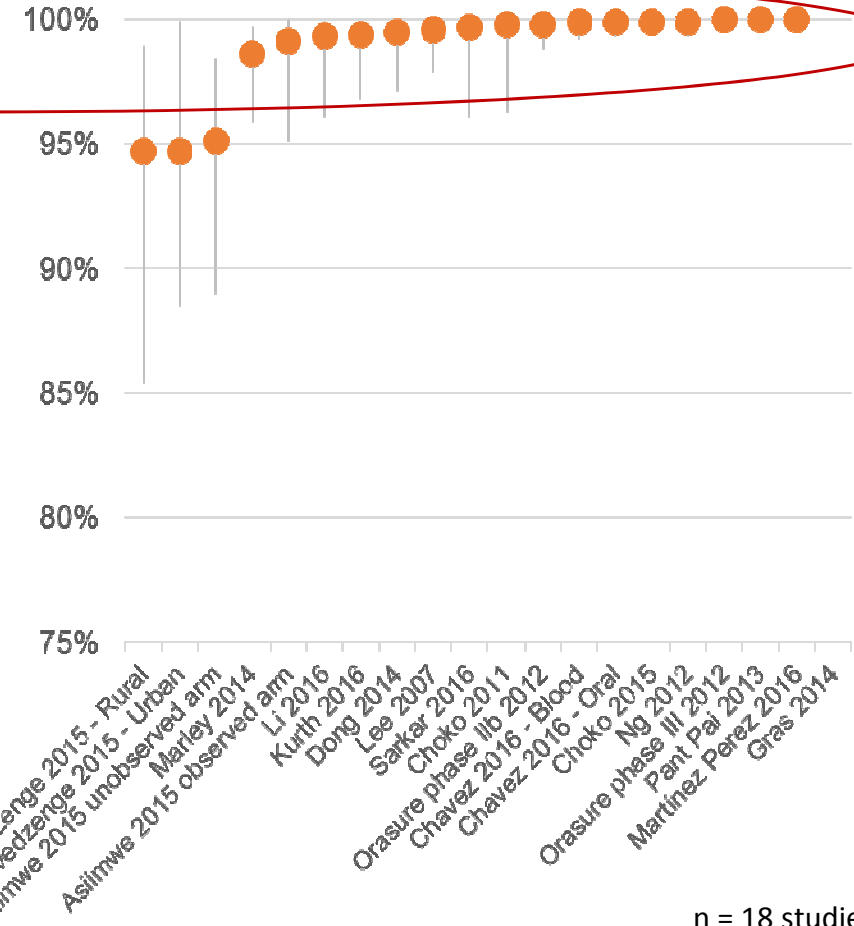
Sensitivity

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



Specificity

as high as 100% (95% CI 99.9 – 100 %)

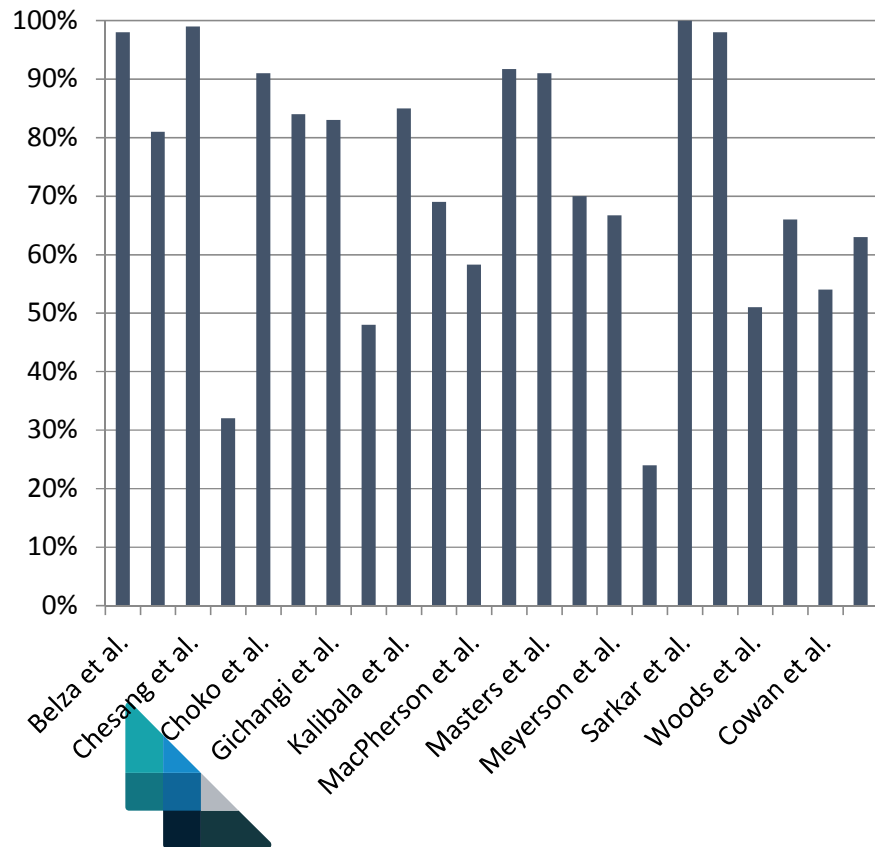


n = 18 studies

Acceptability & Willingness

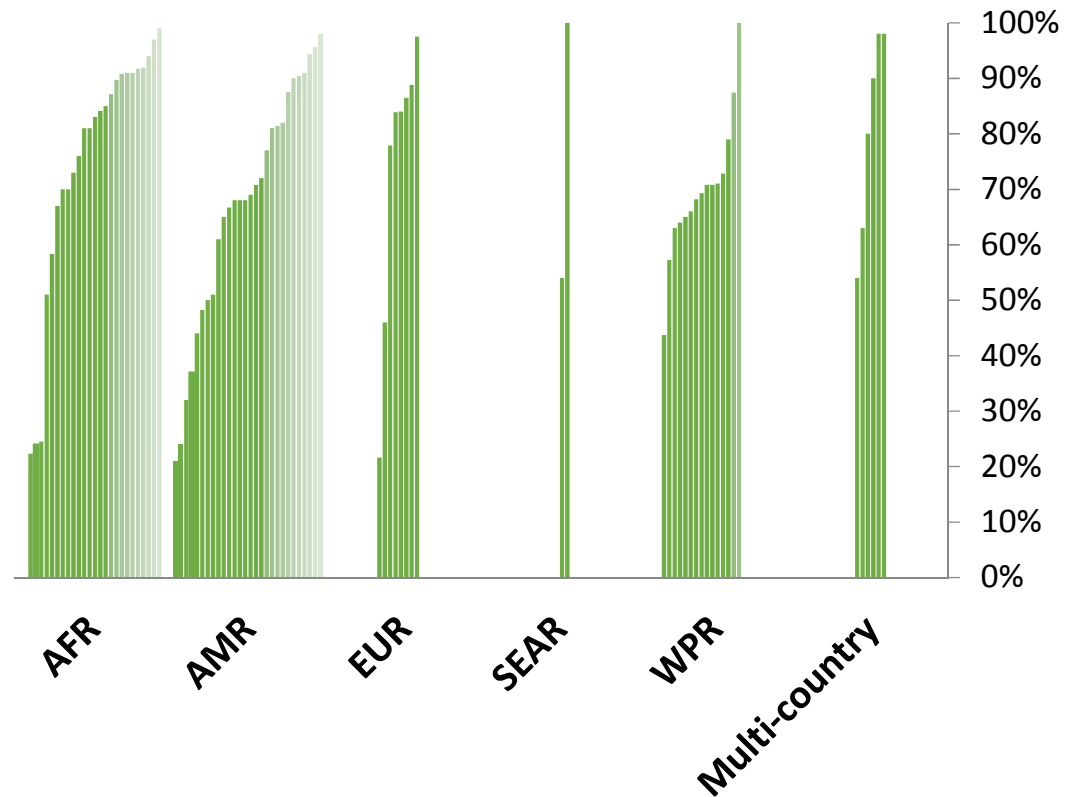
Generally good uptake
(median 76%, range 24-100%)

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

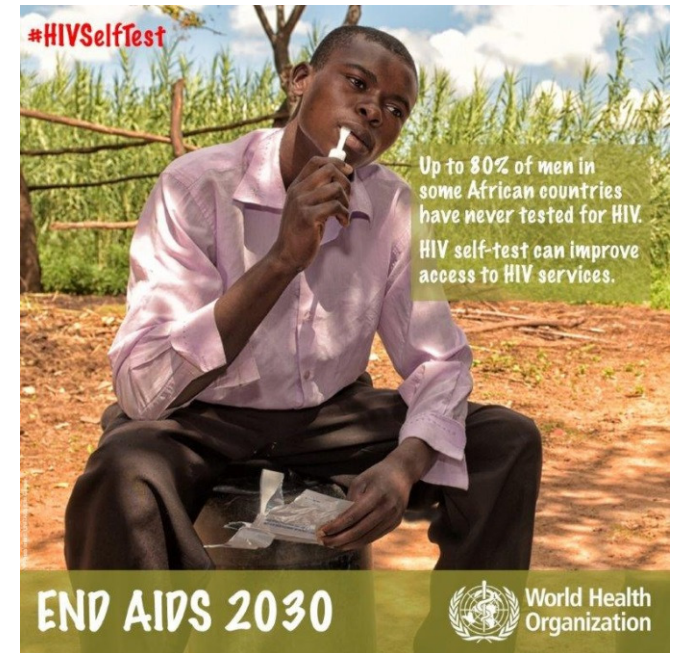
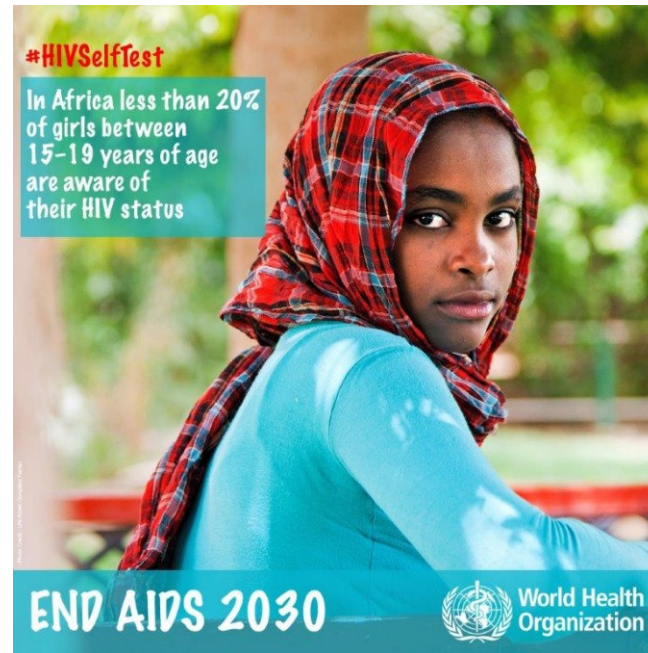
Effect also shown for increase uptake of couples testing in Choko et al & Thirumurthy et al.



HIVSS Values & Preferences in Africa

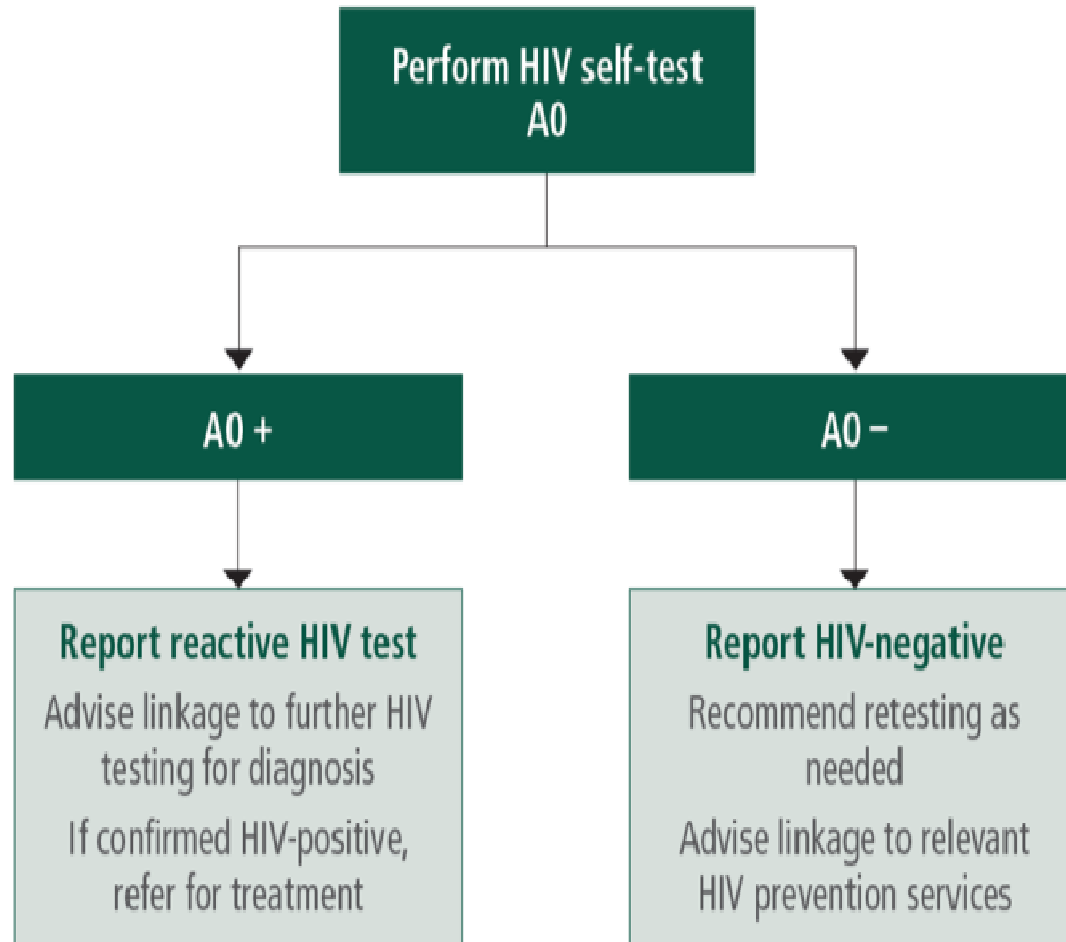
- **HIVST is highly acceptable** across different populations & settings, e.g. men, young people, KP, couples
- Many users prefer oral HIVST– but others, e.g. men in South Africa and PWID reported a preference for fingerprick HIVST.
- **Preferences across service delivery approaches vary.**
 - Young 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**

WHO HIVST Strategy



A0= Assay 0 (test for triage)



- 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

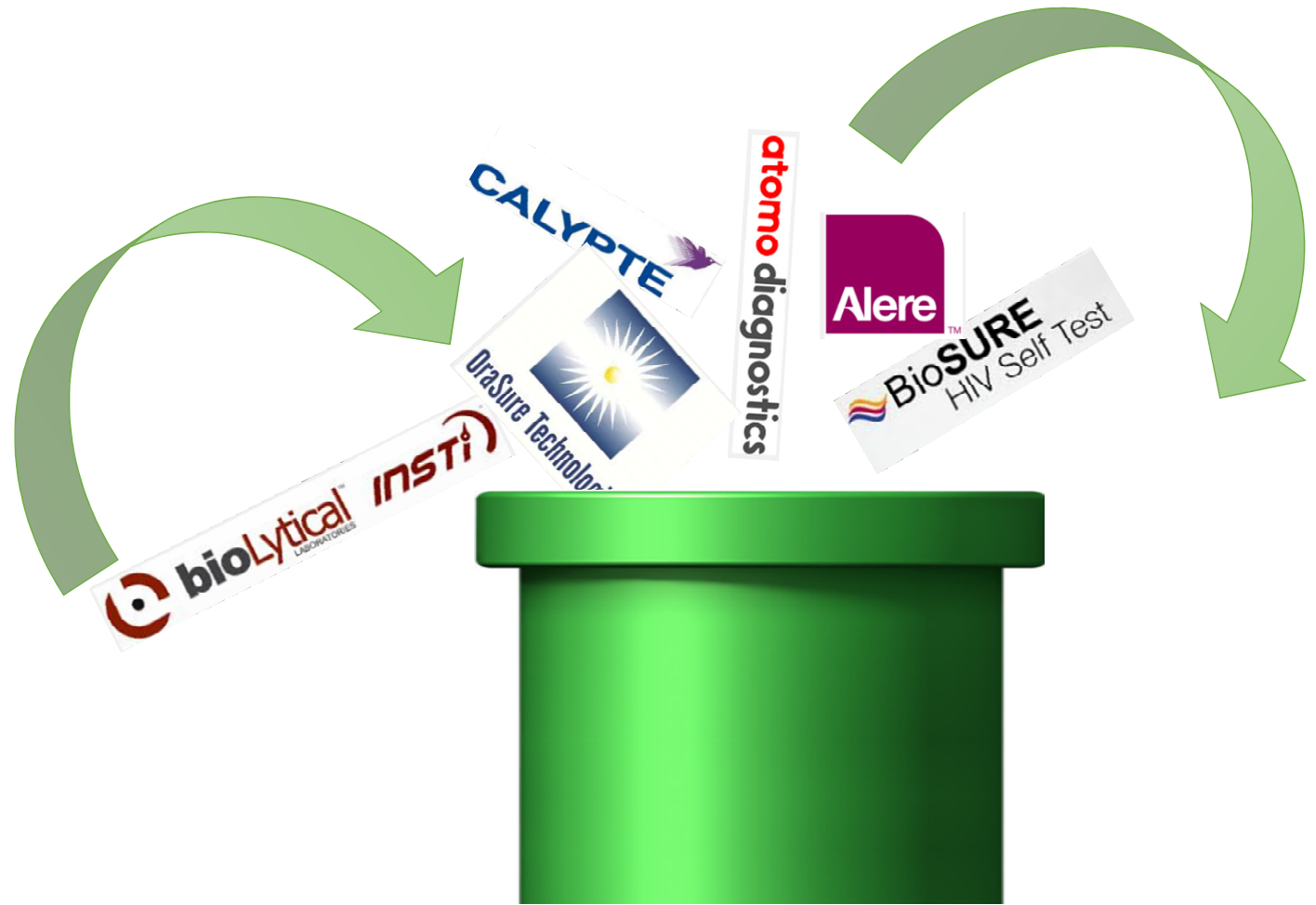
Instruction-for-use included in the kit:

- 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





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

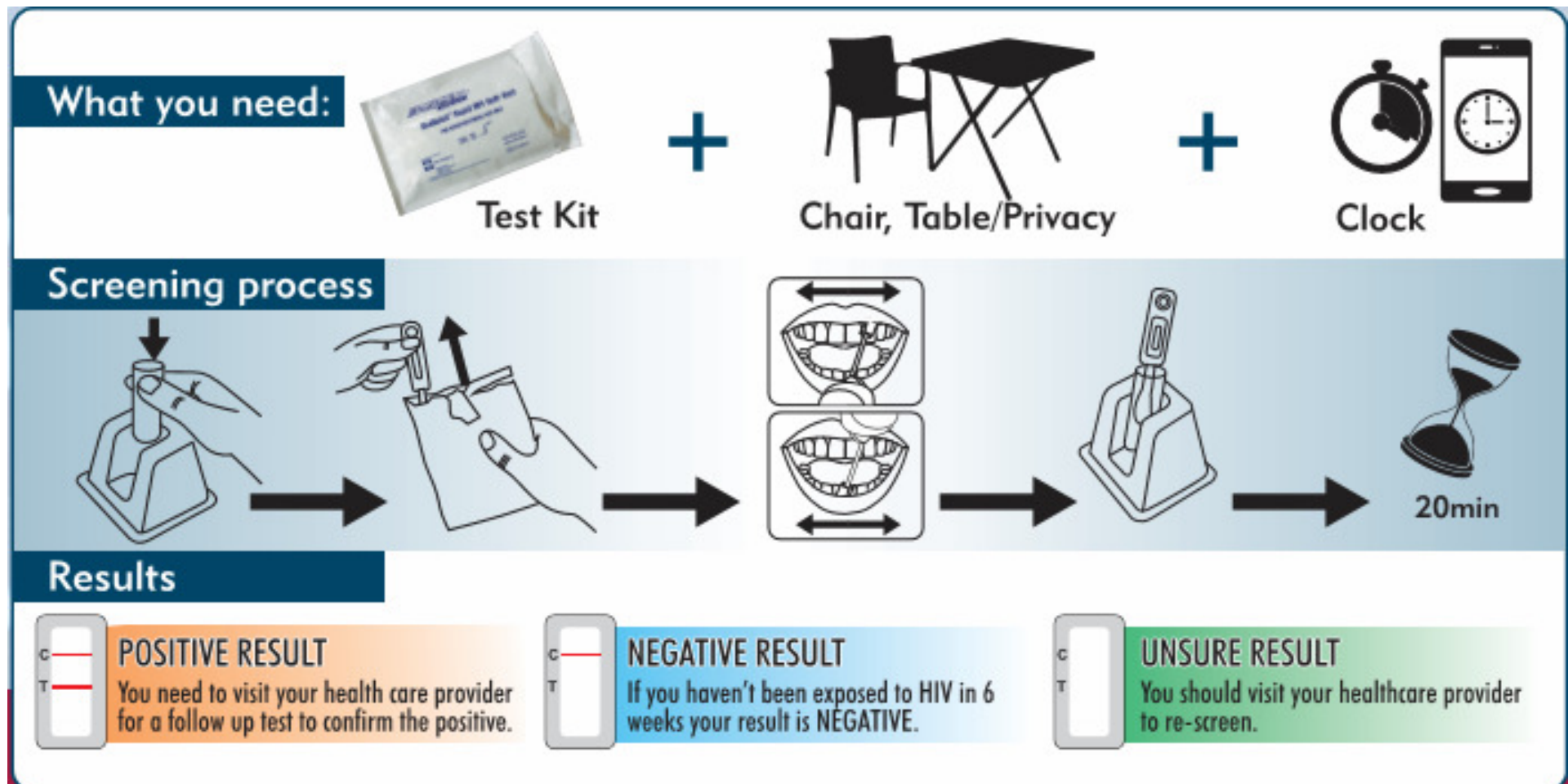
- Requires a swab of the gums → pain free!
- Takes 20-40 minutes
- Easy to read results

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



Negative



1

Inconclusive



2

Inconclusive



3



Inconclusive



Positive



Inconclusive



4

5

6

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



TAKEN DAILY,
PrEP IS AN ADDITIONAL
PREVENTION
OPTION

- Condoms
- PrEP
- Counselling
- Post-exposure prophylaxis
- Healthy lifestyles
- Treatment for STIs
- Male medical circumcision
- ART for partners living with HIV

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 usability 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.

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.

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.

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 on PrEP, can I use the self-screening kit?

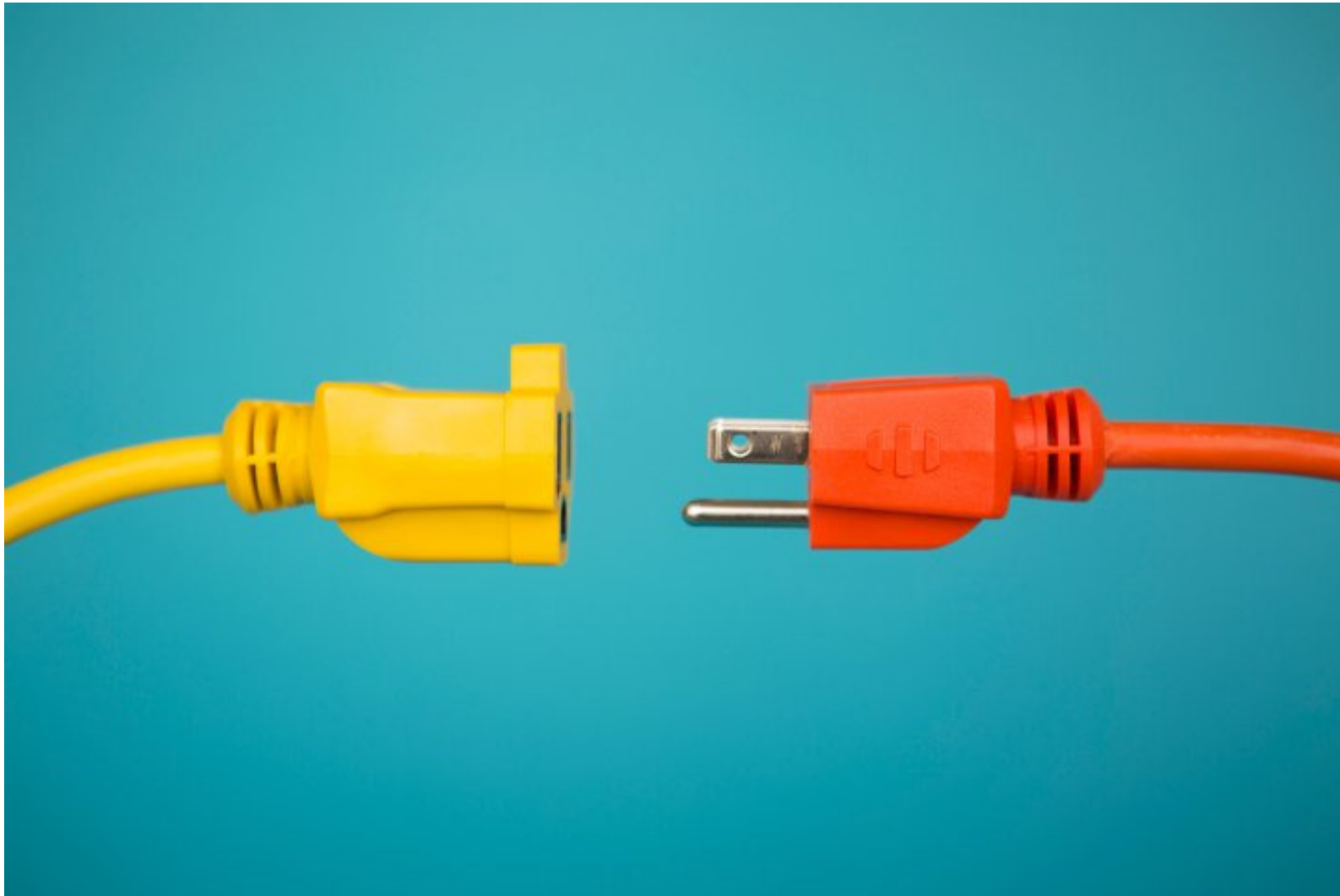
No, anyone using ARVs, for either treatment or prevention, should not use a self-screening kit as it can give you a false negative result.

I'm 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).

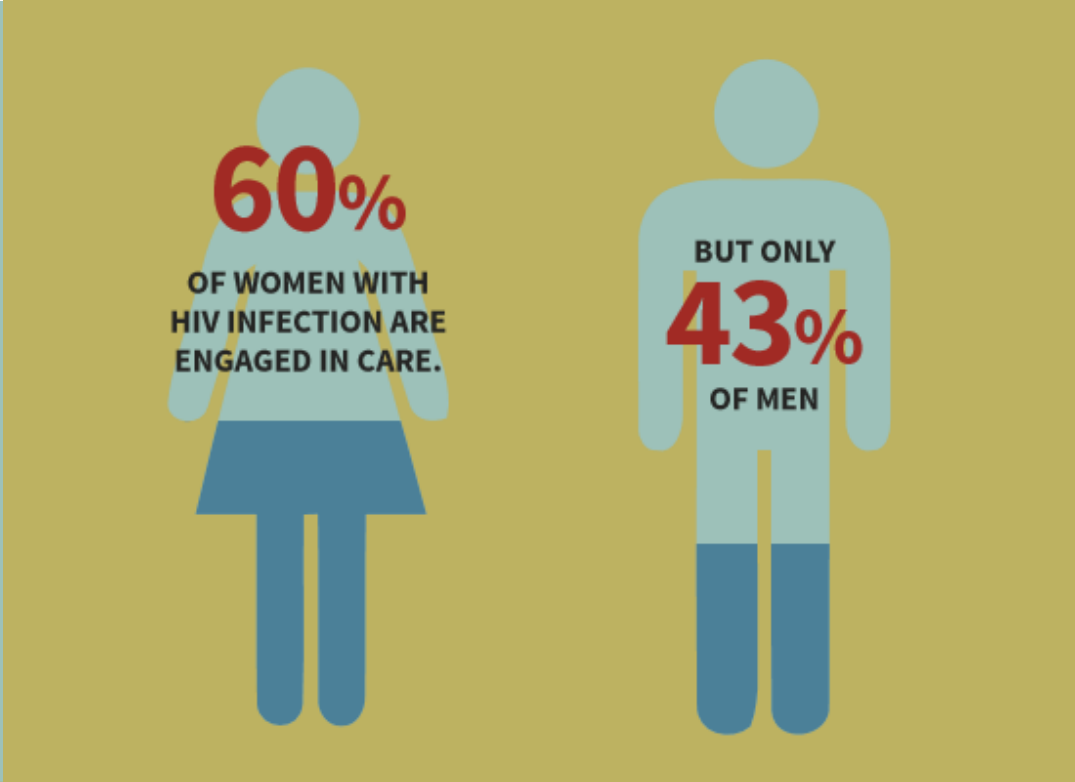
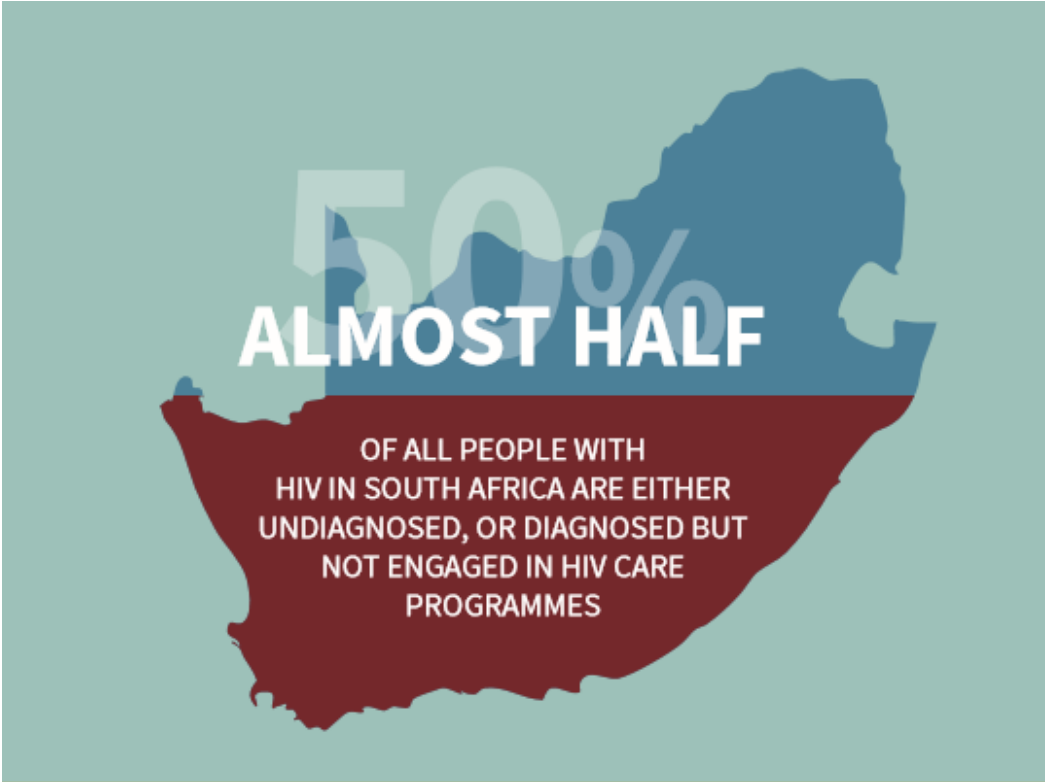
I'm on ARVs, can I use the self-screening kit?

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





Source: Towards 90-90-90 Dec 2016







Asianewsphoto



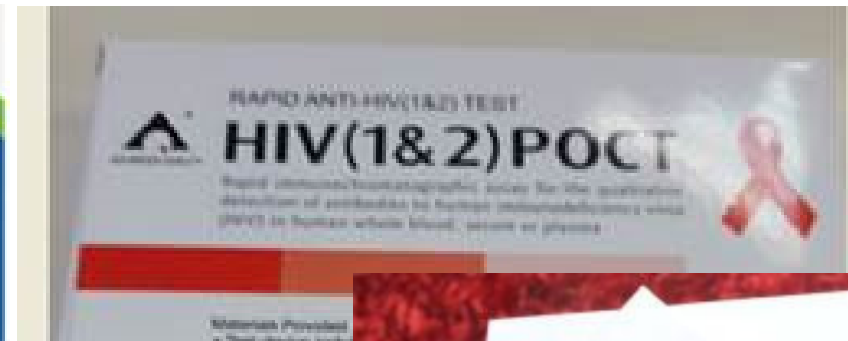


NOW WE HAVE: a WHO PQ device



SA regulation of medical devices:

SAPRHA constituted 2 June 2017



3. Hold the end of the empty pipette to the blood droplet, gently squeeze at the end. Release the pressure on the bulb to draw blood into the pipette. Fill the stem of the pipette with blood. Avoid drawing air bubbles into the pipette.

4. When doing the test, the blood in the pipette must be transferred into the cassette sample well as quickly as possible to avoid clotting in the pipette. Hold the pipette in a vertical position and immediately dispense 2 free-falling drops of the blood sample into the centre of the sample well.

5. Cut the end of the sealed pipette with diluent open and add 1 drop of diluent into the same sample well.

6. After 2 minutes, if the colour has not moved across the test window or if still present in the sample well, add 1 or 2 drops of the diluent to the sample well. It is important that the background is clear before the result is read.

7. Wait for the coloured lines to appear. Read results in 15 minutes. Do not read the result after 15 minutes.

8. When testing with serum instead of whole blood, 1 drop of serum and 1 drop of reagent should be used.

2 drops of blood and the 1 drop of reagent

INTERPRETATION OF RESULTS
Negative
One colour line is visible in the Control (C) region. This result indicates that at present in the sample tested there are no HIV antibodies or that the concentration of HIV antibodies is below the detection limit of the test. A negative result at any time does not preclude the possibility of an HIV infection.

Positive
Two colour lines are visible in the Control (C) region and one in the Test (T) region. This result indicates a positive result as a possible positive result. This result should be confirmed as a possible positive result by a laboratory test.

Negative
No colour lines are visible in the Control (C) region and one in the Test (T) region. This result indicates a negative result as a possible positive result. This result should be confirmed as a possible positive result by a laboratory test.



The difference...



INSTI HIV SELF TEST INSTRUCTIONS

Questions? ☎ +1-804-204-8784

INSIDE YOUR TEST KIT



BOTTLE 1



BOTTLE 2



BOTTLE 3



TEST DEVICE POUCH



LANCET

PREPARATION



1. Open test device pouch.

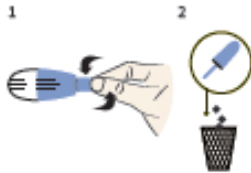


2. Place the test device down on a flat surface.



3. Remove cap of Bottle 1. Place on flat surface.

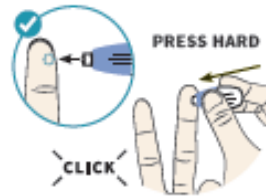
STEP 1: COLLECT BLOOD



1. Twist off tip. Throw away tip in waste bin.



2. Rub finger until warm.



3. Place lancet on the side of finger tip.



4. Rub finger to get larger round drop of blood.



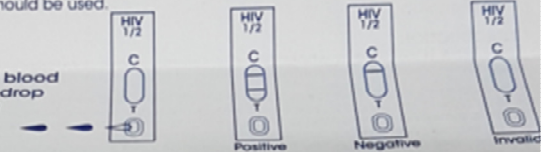
5. Let 1 drop fall into Bottle 1.



6. Twist on cap of Bottle 1.

- Hold the end of the empty pipette to the blood droplet, gently squeezing the bulb at the end. Release the pressure on the bulb to draw blood into the pipette and fill the stem of the pipette with blood. Avoid drawing air bubbles into the pipette.
- When doing the test, the blood in the pipette must be transferred into the cassette sample well as quickly as possible to avoid clotting in the pipette. Hold the pipette in a vertical position and immediately dispense 2 free-falling drops of the blood sample into the centre of the sample well.
- Cut the end of the sealed pipette with diluent open and add 1 drop of the diluent into the same sample well.
- After 2 minutes, if the colour has not moved across the test window or if blood is still present in the sample well, add 1 or 2 drops of the diluent to the sample well.
- It is important that the background is clear before the result is read.
- Wait for the coloured lines to appear. Read results in 15 minutes. Do not interpret the result after 15 minutes.
- When testing with serum instead of whole blood, 1 drop of serum and one drop of reagent should be used.

2 drops of blood and the 1 drop of reagent



INTERPRETATION OF RESULTS

Negative

One colour line is visible in the Control (C) region. This result indicates that at present in the sample tested there are no HIV-1 and HIV-2 antibodies or that the concentration of HIV antibodies is below the detection limit of the test. A negative result at any time does not preclude the possibility of an HIV infection.

Positive

Two colour lines are visible, one in the Control (C) region and one in the Test (T) region. If the T line is light coloured, this should be considered as a possible positive result and be followed up with a laboratory test. A positive test result indicates the presence of antibodies to HIV in the sample. Any positive results should be followed up with a laboratory test.

Invalid

If there are no visible colour lines, the result is invalid. Proper procedures may not have been followed in performing the assay, or the test may have deteriorated. The sample should be re-tested with a new test.

WARNINGS

ALL POSITIVE TESTS MUST BE FOLLOWED UP BY A VISIT TO A HEALTHCARE PRACTITIONER FOR CONFIRMATION. TO BE USED IN CONJUNCTION WITH PRE AND POST COUNSELLING. KEEP OUT OF REACH OF CHILDREN. For OTC and professional in vitro diagnostic use only. Do not use after the expiration date. Do not eat, drink or smoke in the area where the specimens or kits are handled. Do not use test if pouch is damaged. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Humidity and temperature can adversely affect results.

STORAGE INSTRUCTIONS

Store at room temperature or refrigerated (15 °C - 30 °C). Keep from direct moisture and heat. Do not freeze the test.

PRODUCED FOR

New Clicks South Africa (Pty) Ltd
nr. of Searle and Pontac Streets,
Cape Town, 8001
South Africa
Tel: 021 4601626



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

A long and
healthy life for all
South Africans



SA guidance

South African policy on HIV self-screening



NATIONAL HIV TESTING SERVICES: POLICY AND GUIDELINES 2015

Prepared by the national C

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.

A k 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.

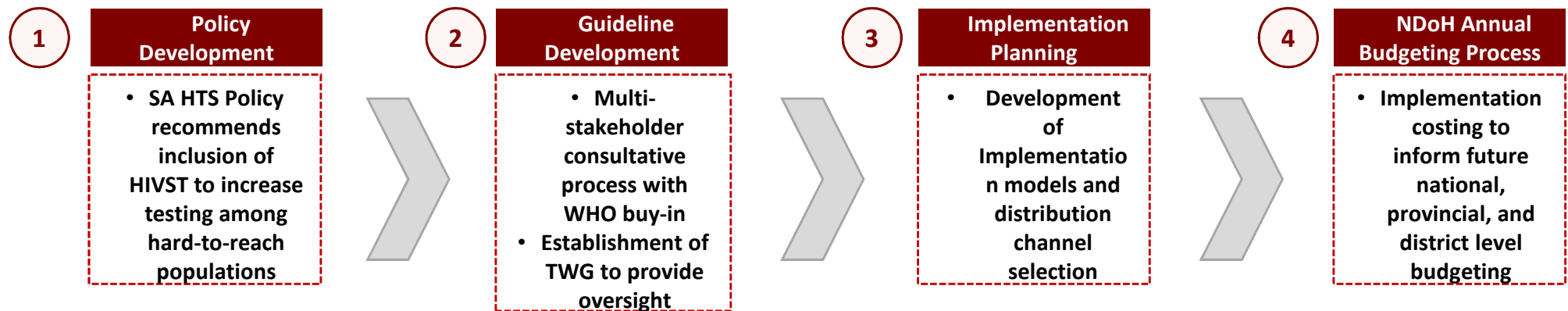


health

Department:
Health
REPUBLIC OF SOUTH AFRICA

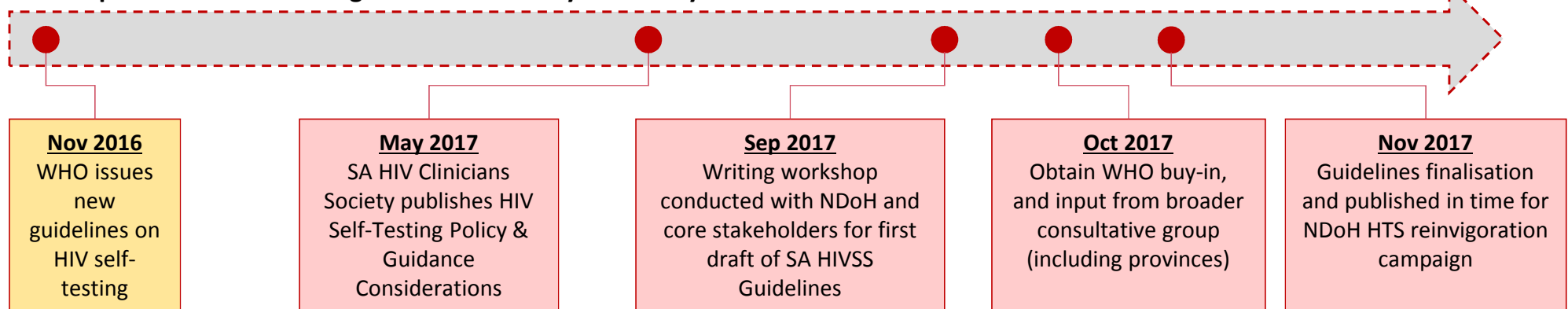
Clients participating in clinical vaccine trials should be referred back to their research site for appropriate testing to avoid misdiagnosis.

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 :



Guideline:

DRAFT NATIONAL HIV SELF SCREENING



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

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Head of Department
Mpumalanga Health
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NELSPRUIT
1200

**REQUEST SUPPORT FOR IMPLEMENTATION OF THE STAR PHASE 2
PROJECT FOR HIV SELF SCREENING IN MPUMALANGA**

Dear Dr Mohangi



A publication of the Southern African HIV Clinicians Society

To be finalized mid
November 2017

HIV SELF-SCREENING:

What it is and how to integrate it into HIV Testing Services

The National Department of Health and the South African Pharmacy Council supports the use of WHO-approved HIV self-screening kits for people who may not be able to access facility-based testing for different reasons. HIV self-screening provides an opportunity for such people to screen themselves in private and in their own time.

HIV self-screening is not intended to displace facility-based HIV testing but is rather a complementary approach to reach previously untested, hard-to-reach, and test-averse populations.

Currently, the WHO-approved OneQuick-cool HIV self-screening kit is approved for the South African market. The OneQuick-cool HIV self-screening kit detects HIV antibodies in oral fluids collected from a gum swab.



Any positive result from a self-screening kit requires confirmatory testing using the national HIV testing algorithm.

Display algorithm NOW including HIV self-screening.

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 algorithm.

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. While individuals with high ongoing risk, should be encouraged to re-screen regularly. Re-screening 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. Instructions in the kit recommend attending a health facility where a trained tester will conduct testing following the national testing algorithm.

HIV self-screening is not recommended for anyone on ARVs or PrEP, as it may lead to a false negative result. It has also not been validated for any person under the age of 12 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 frequent than recommended.

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

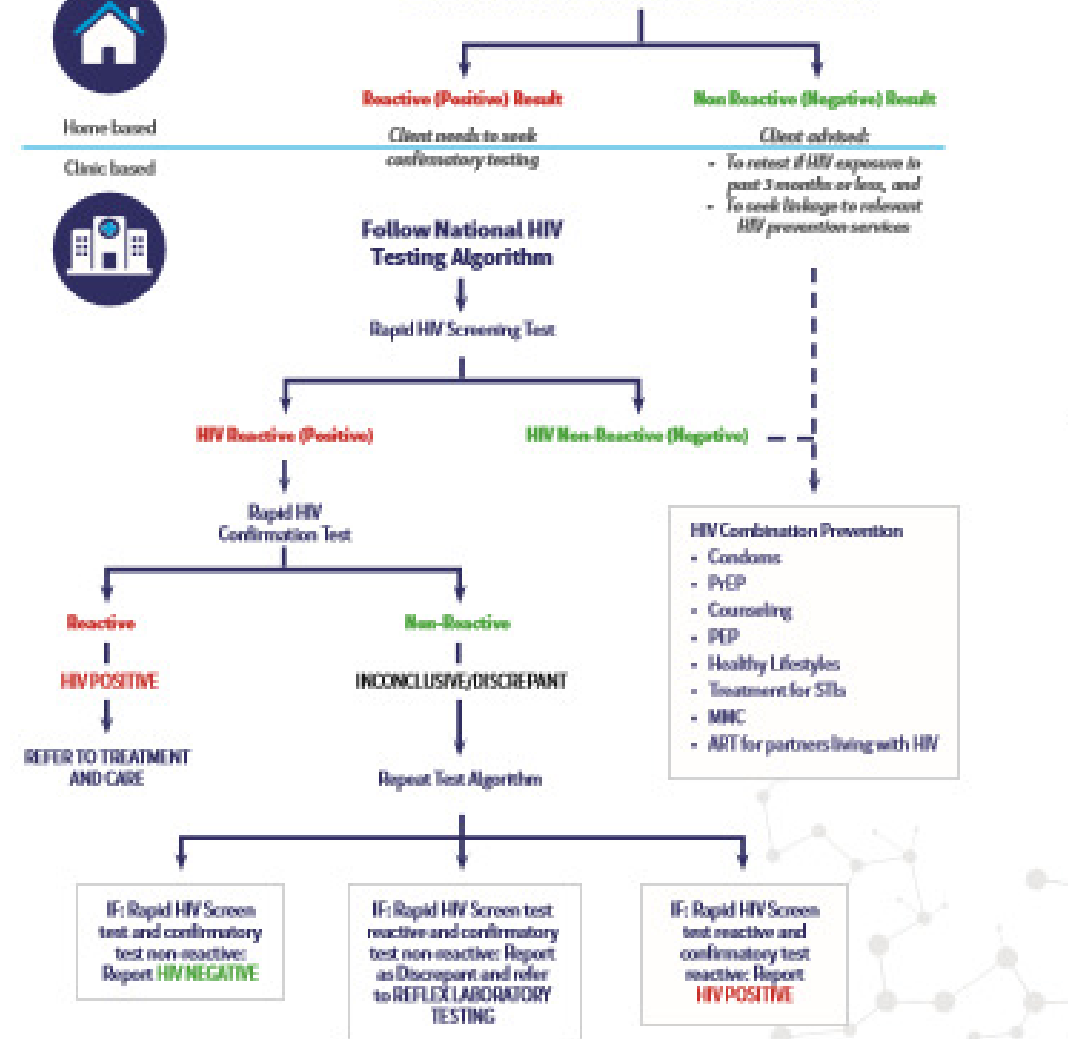


Home based

Clinic based



CLIENT PERFORMS HIV SELF-SCREEN AT HOME



References
 *Guidelines on HIV self-testing and partner notification: supplemental to consolidated guidelines on HIV testing services. World Health Organization, 2016.
 *National HIV testing service policy. South Africa National Department of Health, 2016.



A long and healthy life for all South Africans





Home based

Clinic based

CLIENT PERFORMS HIV SELF-SCREEN AT HOME

Reactive (Positive) Result

*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*



HIV Combination Prevention

- Condoms
- PrEP
- Counseling
- PEP
- Healthy Lifestyles
- Treatment for STIs
- MMC
- ART for partners living with HIV



Clinic based



Follow National HIV Testing Algorithm

Rapid HIV Screening Test

HIV Reactive (Positive)

HIV Non-Reactive (Negative)

Rapid HIV Confirmation Test

Reactive

Non-Reactive

HIV POSITIVE

INCONCLUSIVE/DISCREPANT

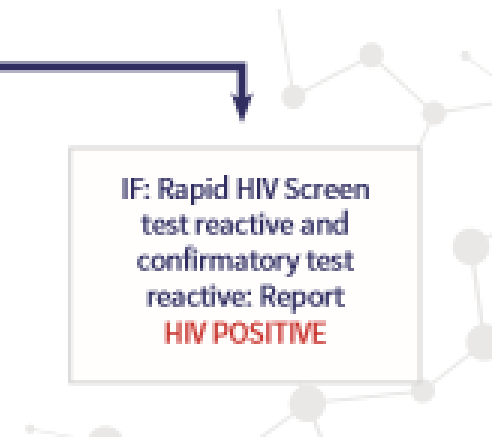
REFER TO TREATMENT AND CARE

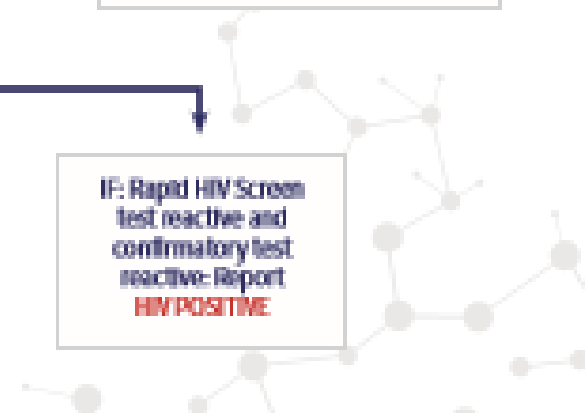
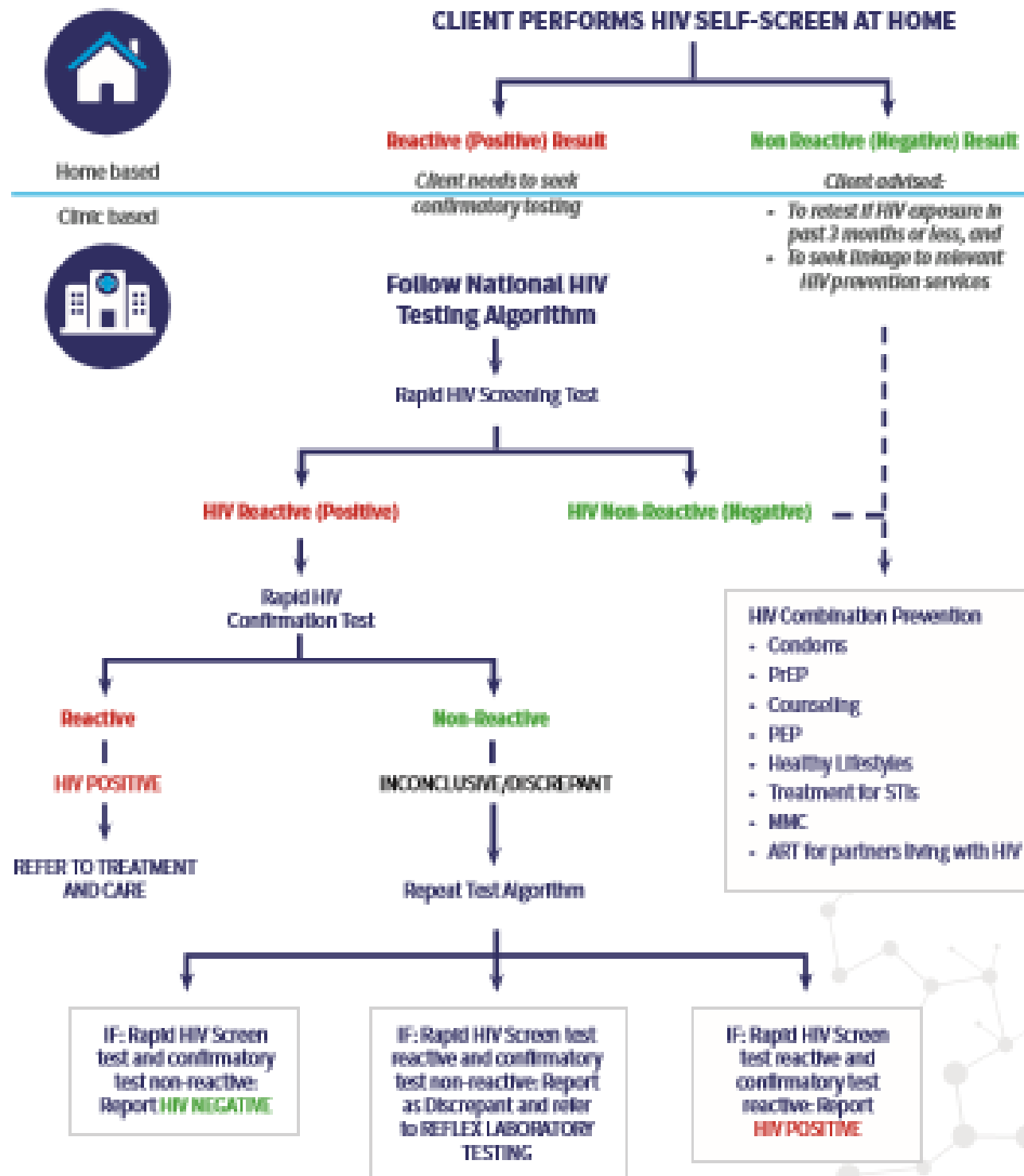
Repeat Test Algorithm

IF: Rapid HIV Screen test and confirmatory test non-reactive: Report **HIV NEGATIVE**

IF: Rapid HIV Screen test reactive and confirmatory test non-reactive: Report as Discrepant and refer to REFLEX LABORATORY TESTING

IF: Rapid HIV Screen test reactive and confirmatory test reactive: Report **HIV POSITIVE**





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



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Dear Sister in charge

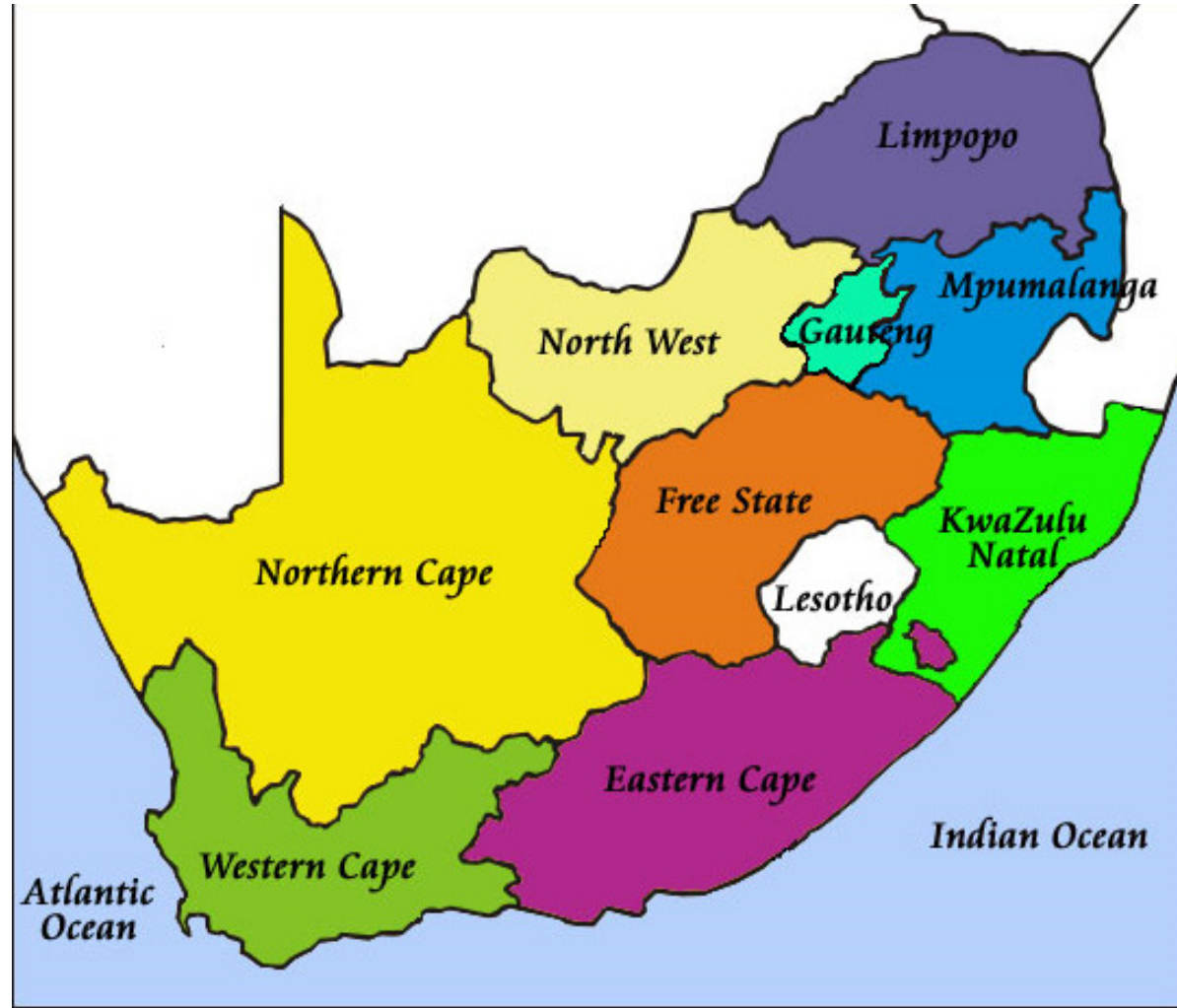
This client has screened for HIV using an HIV self-screen and may have received a reactive (positive) result. Please ensure that the client is provided with confirmatory testing and appropriate counselling in terms of the national HIV testing algorithm.

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:

A large, empty rectangular box with a thin orange border, intended for contact information.



Implementation South Africa



HIV Self-Testing Africa: The STAR Initiative

UNITAID

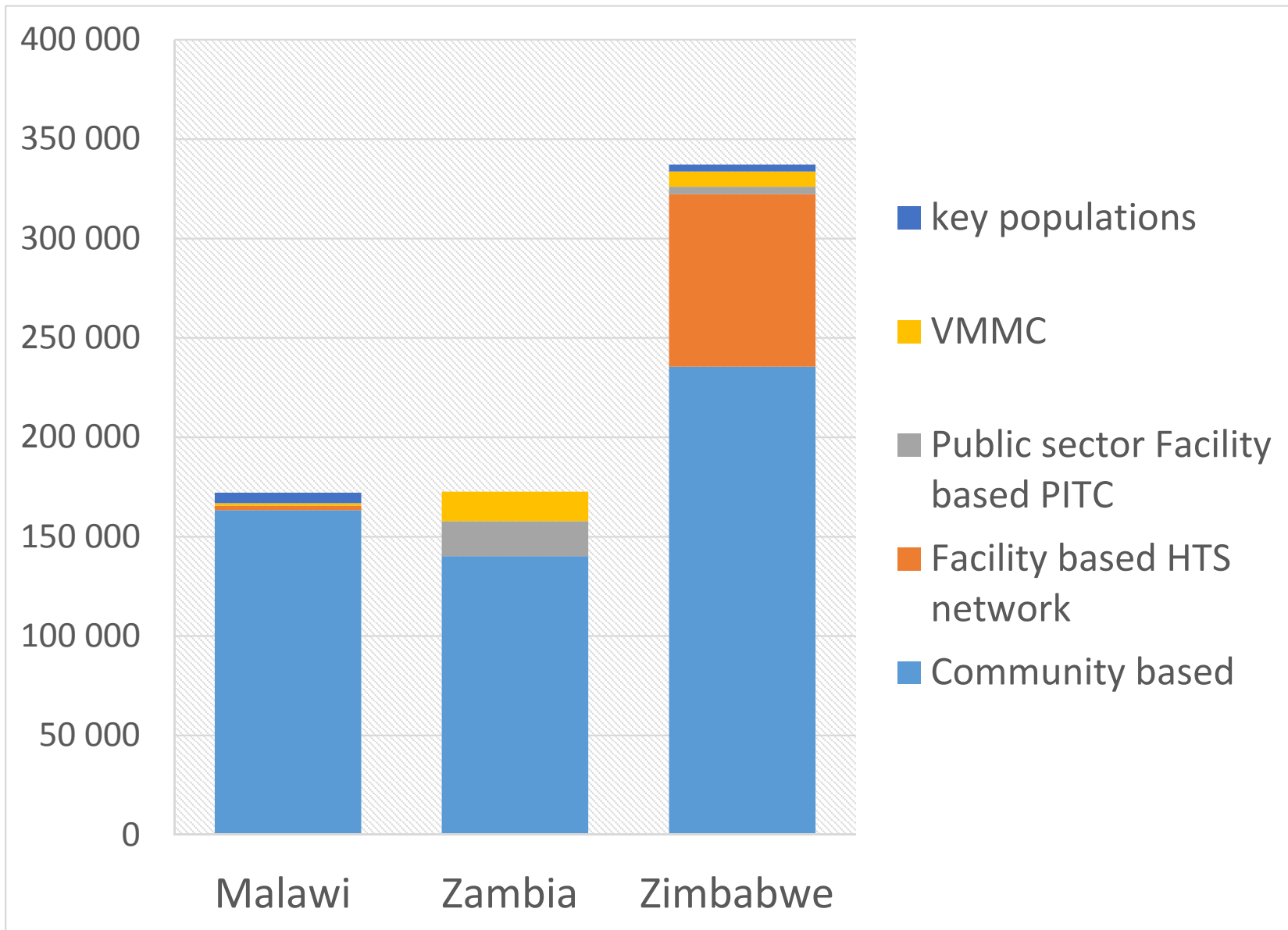


Introduction to the STAR Initiative

- 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

Phase 1 (2015 – 2017)	Phase II (2017 – 2020)
Zimbabwe, Zambia, Malawi	Zimbabwe, Zambia, Malawi + South Africa, Swaziland, Lesotho

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

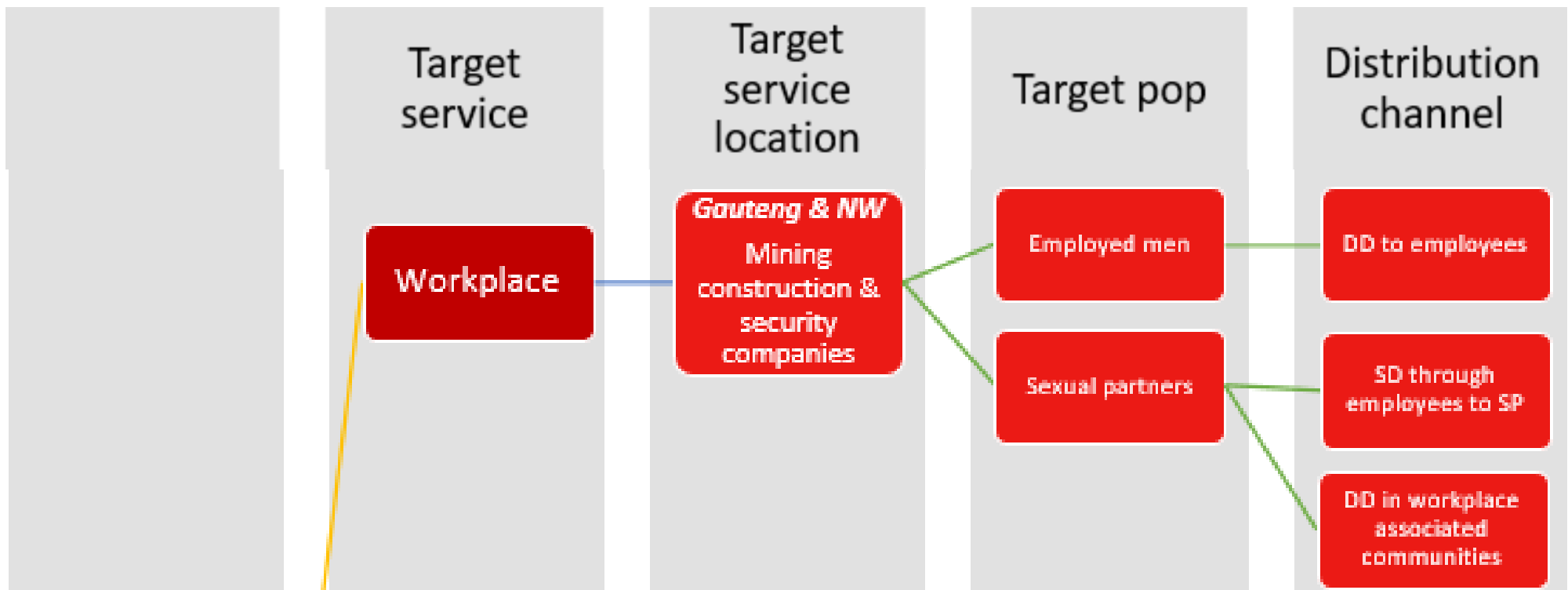
1. Enabling environment
2. Pilot, implement and learn from HIVST distribution models
3. Facilitating transition into and scale-up within national system (*costed plan/supply/national and donor budgets/M&E etc*)



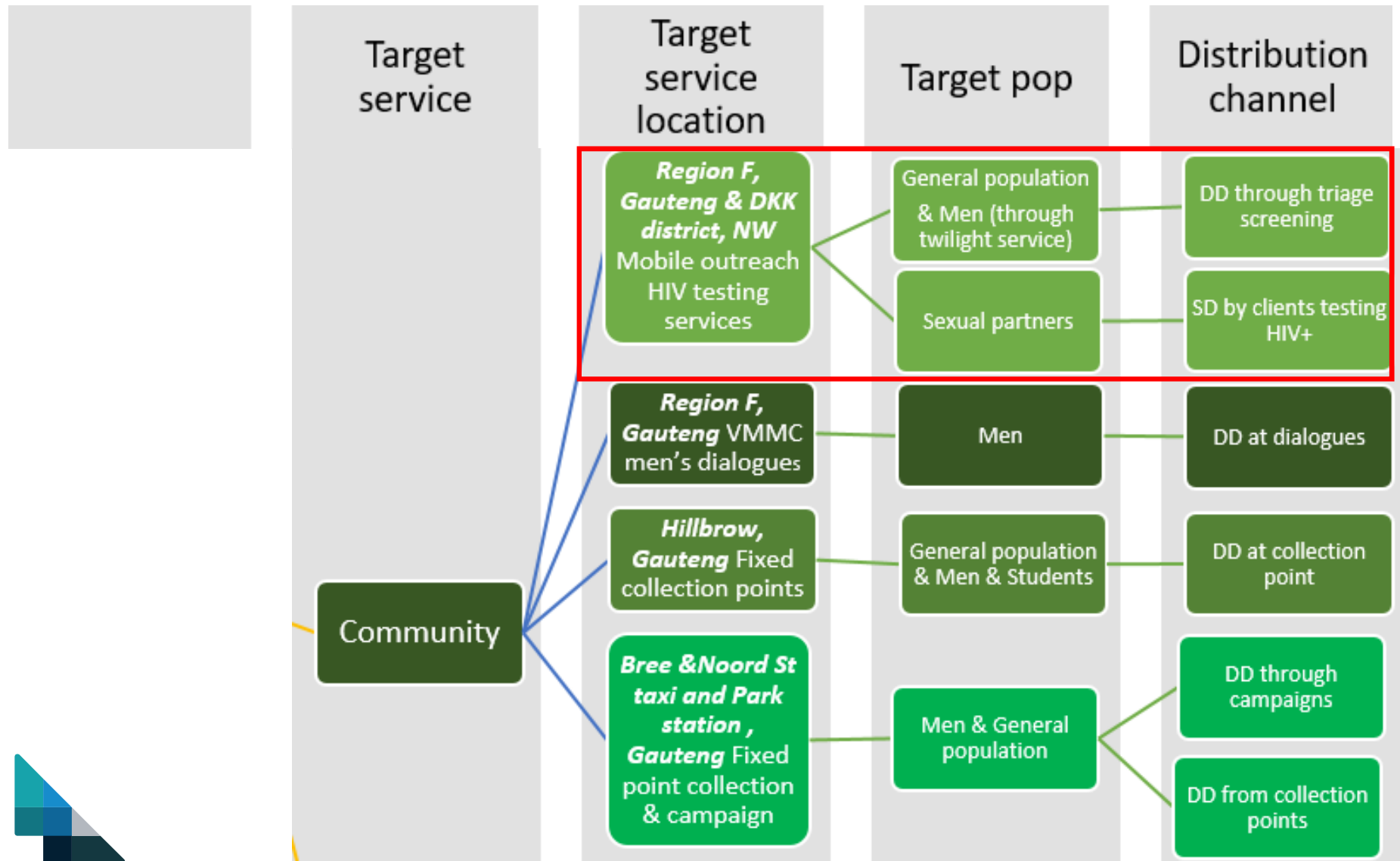
WITS RHI Year 1 distribution models



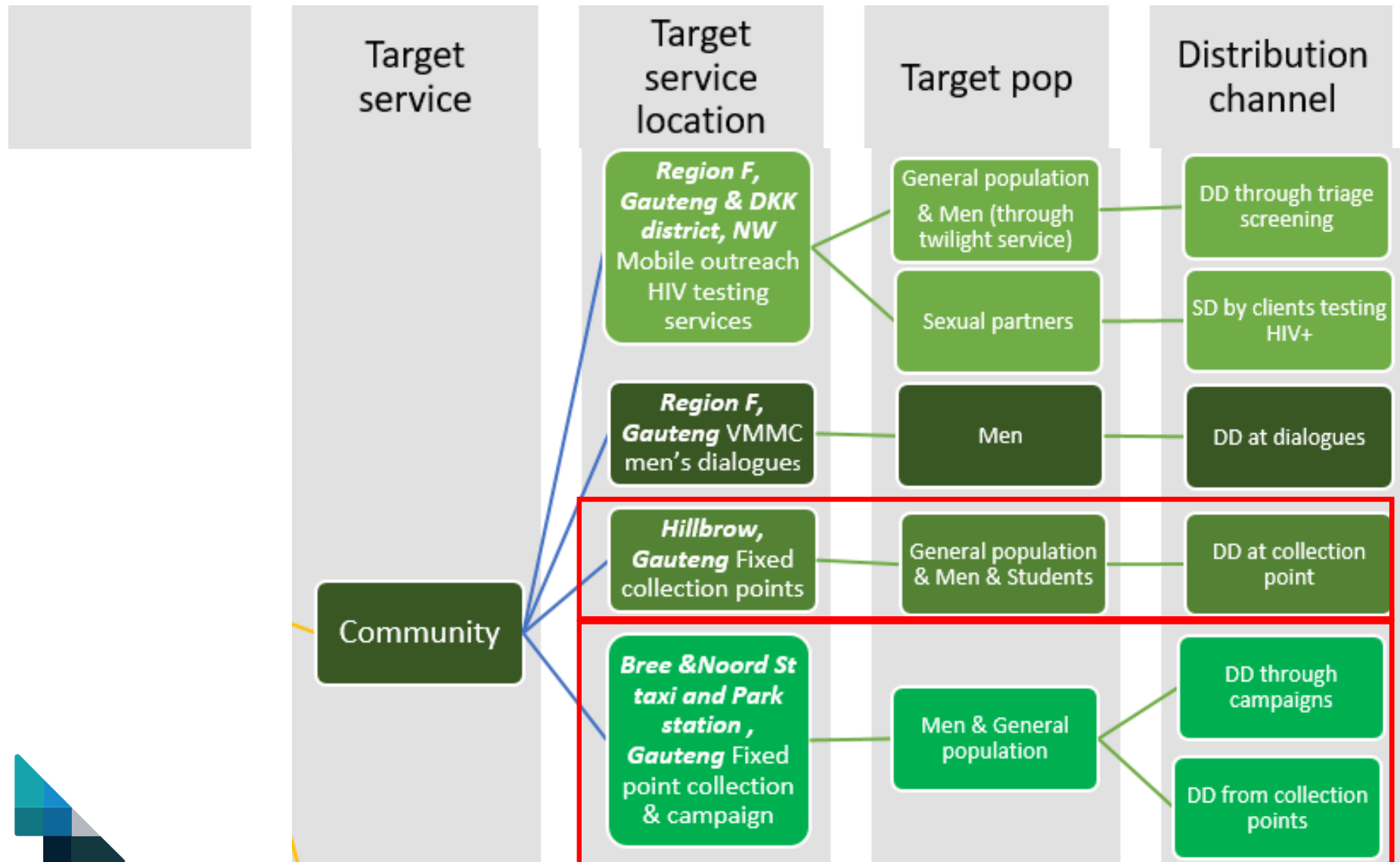
Workplace distribution models



Community distribution models



Community distribution models



Facility distribution models





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- WHO HIV Dept: Cheryl Johnson and Rachel Baggaley
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