HIV Self-Testing in South Africa

The current landscape

Mohammed Majam

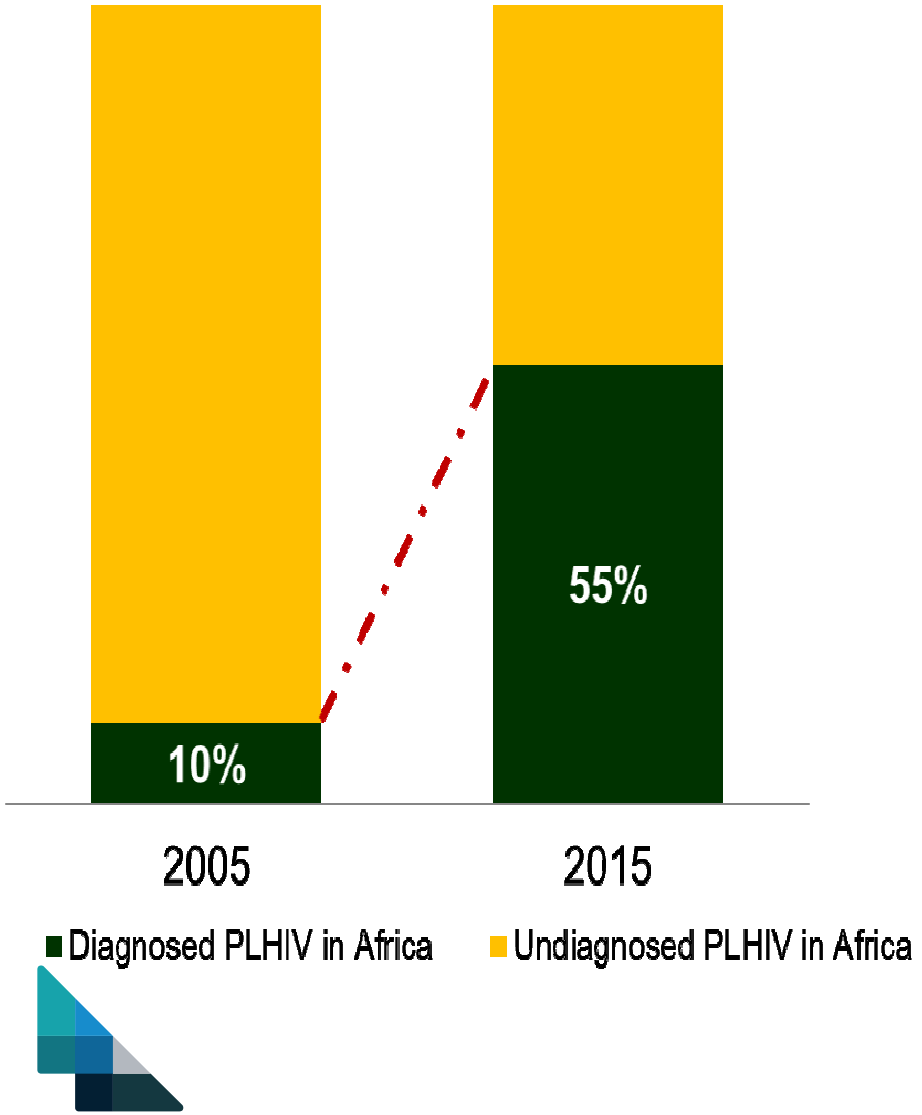
08.04.2017

Sunnyside Hotel,
Parktown

University of the Witwatersrand

WITS RHI

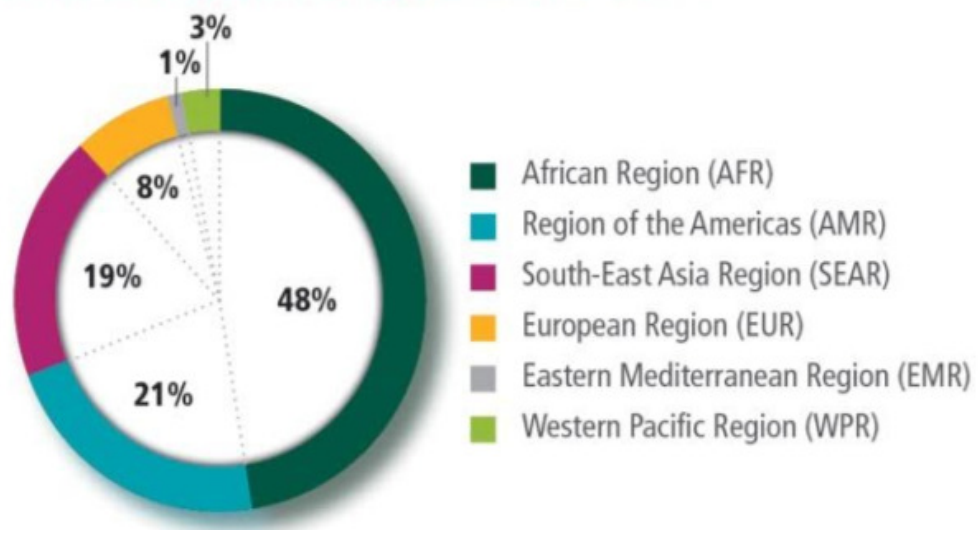
Scale-Up of HIV Testing Services



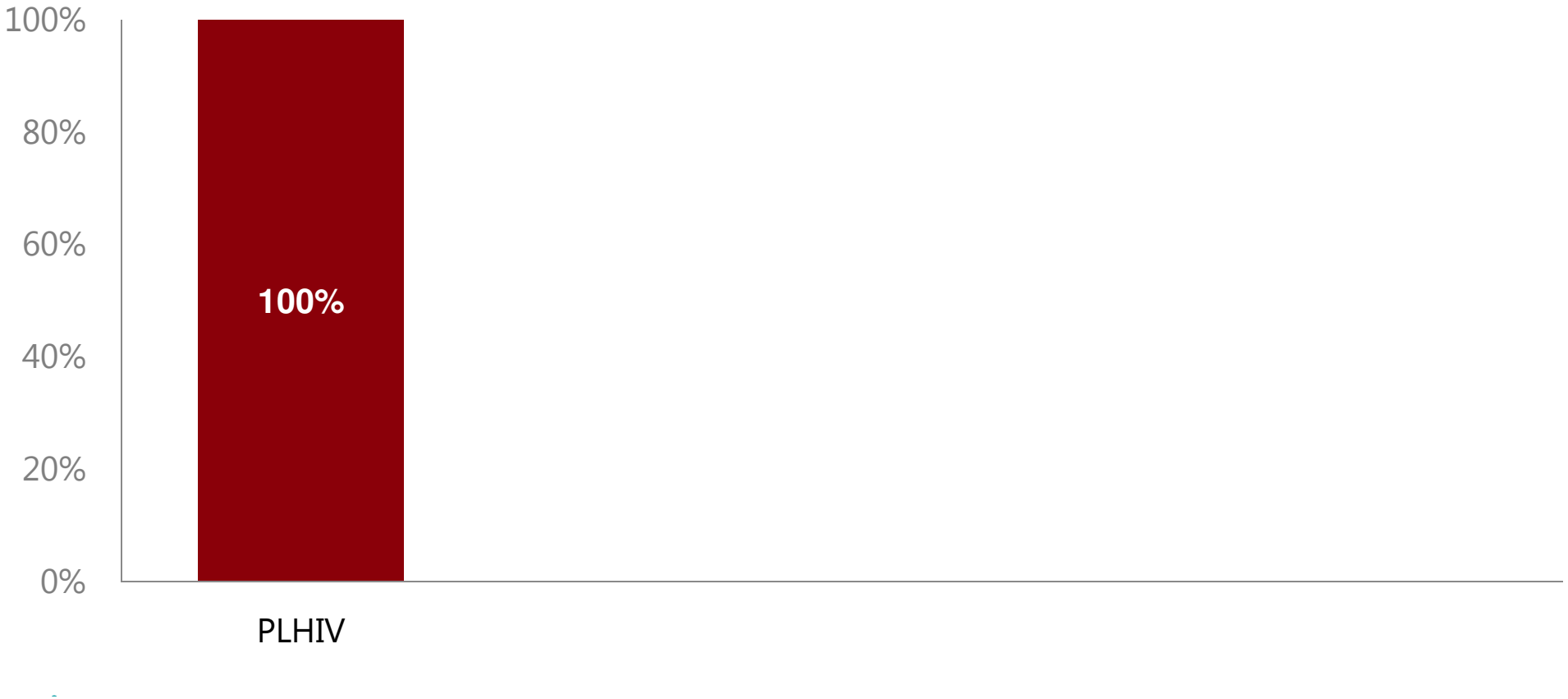
Source: WHO 2015; WHO 2016

From 2005 – 2015, there was a sharp increase in HIV-positive diagnoses in Africa

From 2010—2014, **> 600 M people** received HTS in 122 low- and middle-income countries – nearly half all tests were in Africa.

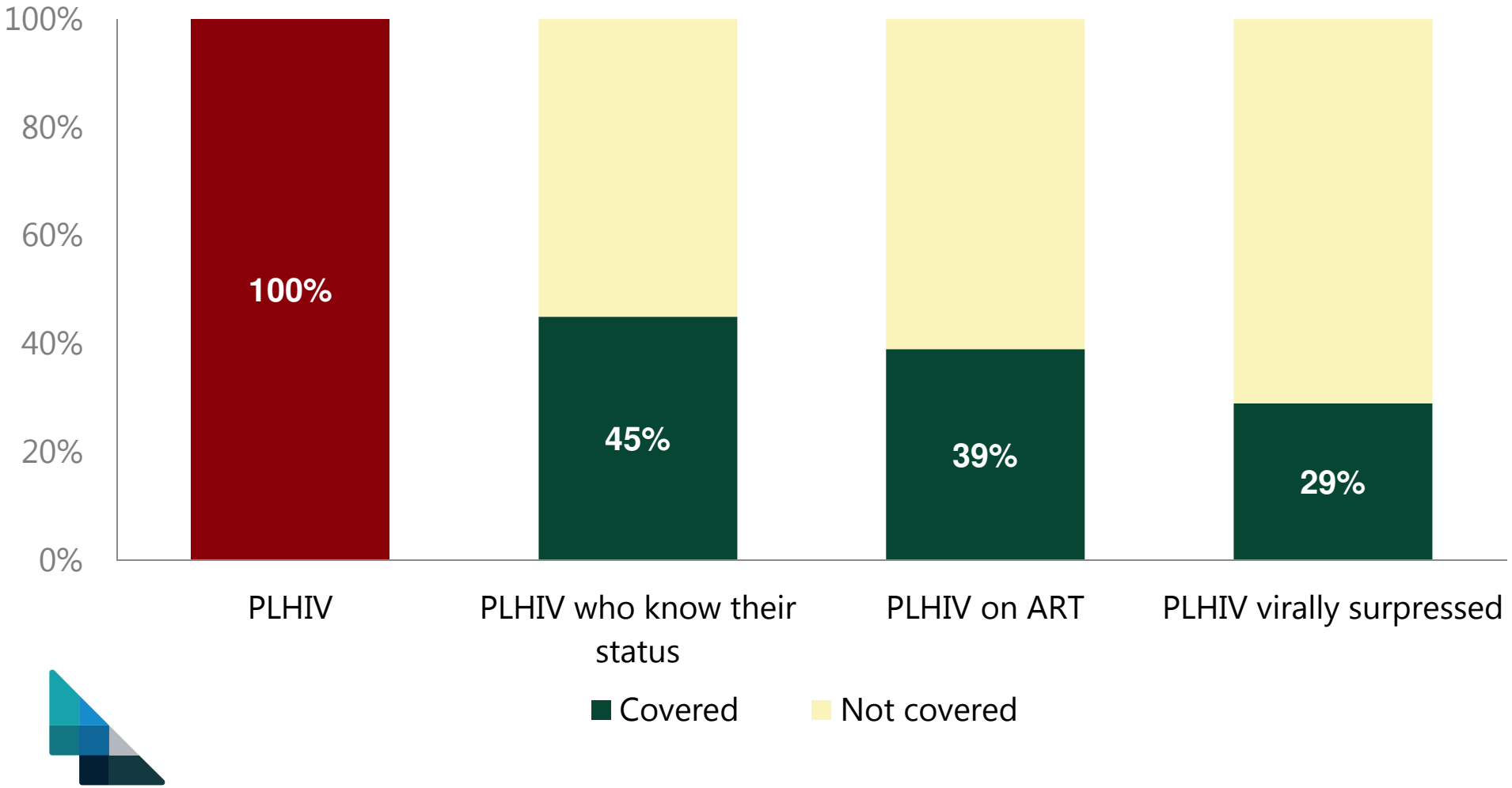


Why are we talking about HIV Self-Testing (HIVST)?



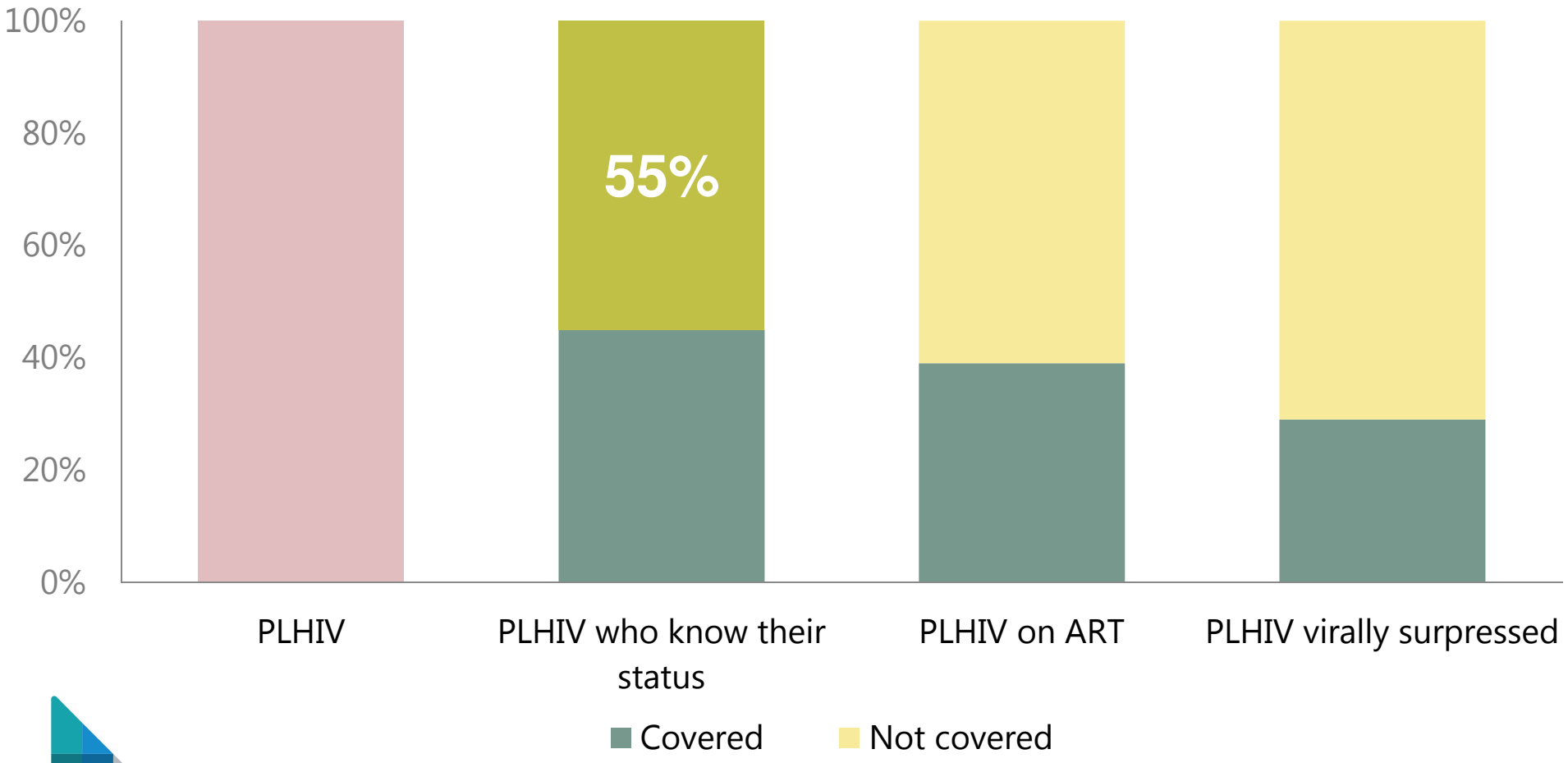
Source: UNAIDS, Gap report 2014

Why are we talking about HIV Self-Testing (HIVST)?



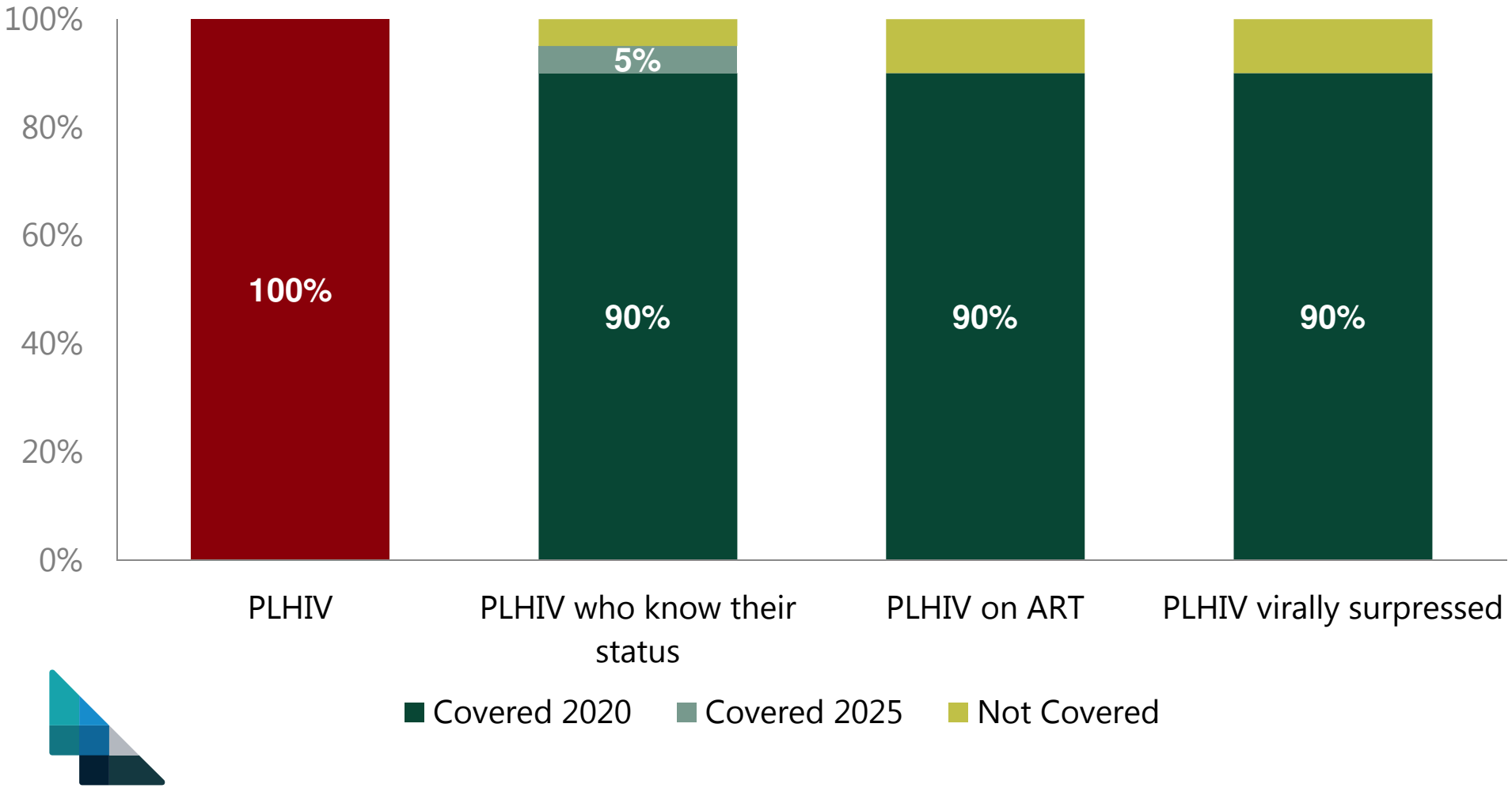
Source: UNAIDS, Gap report 2014

There is a testing gap.



Source: UNAIDS, Gap report 2014

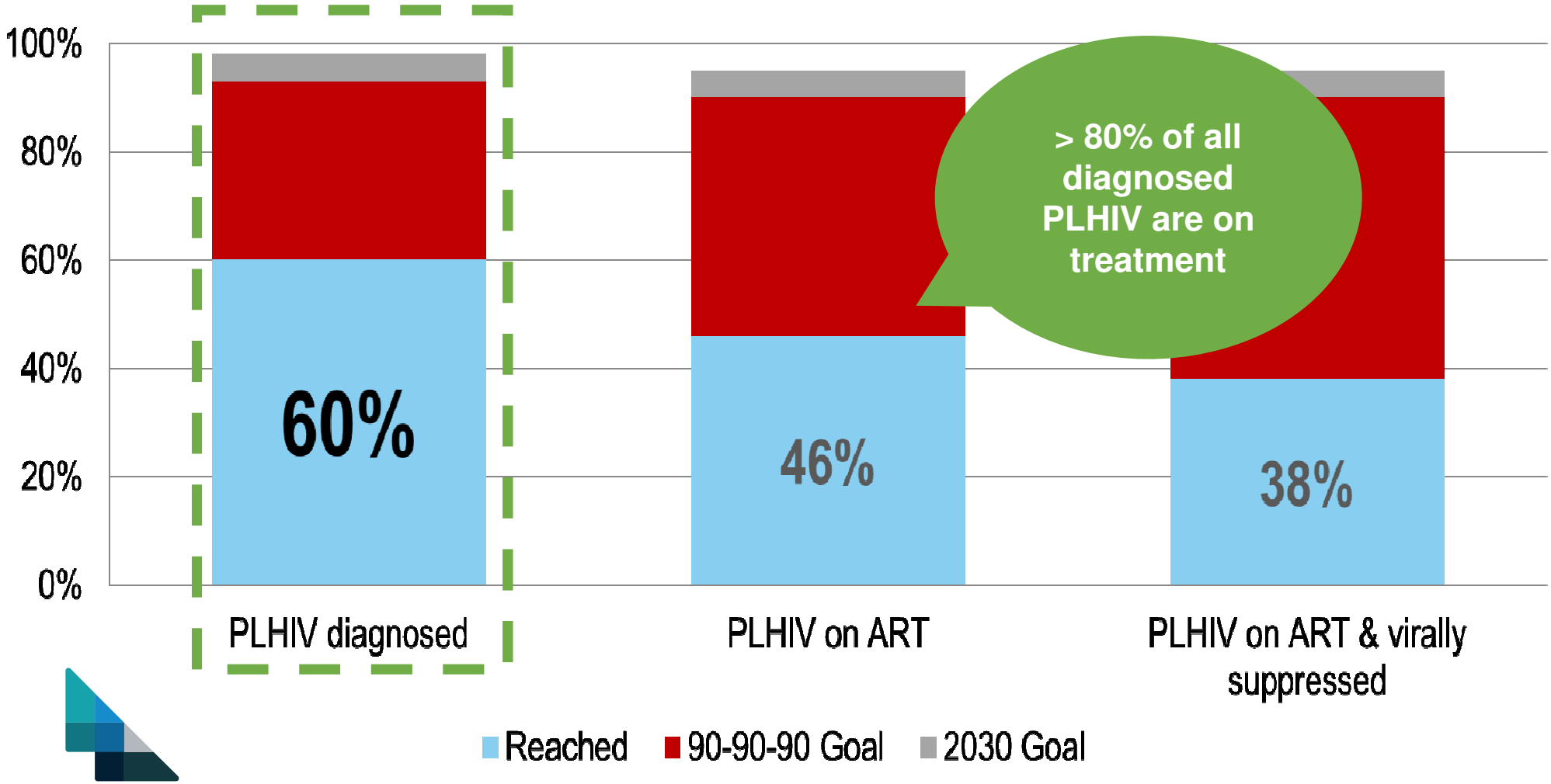
Proposed UNAIDS “90-90-90”



Source: UNAIDS, Ambitious treatment targets, 2014

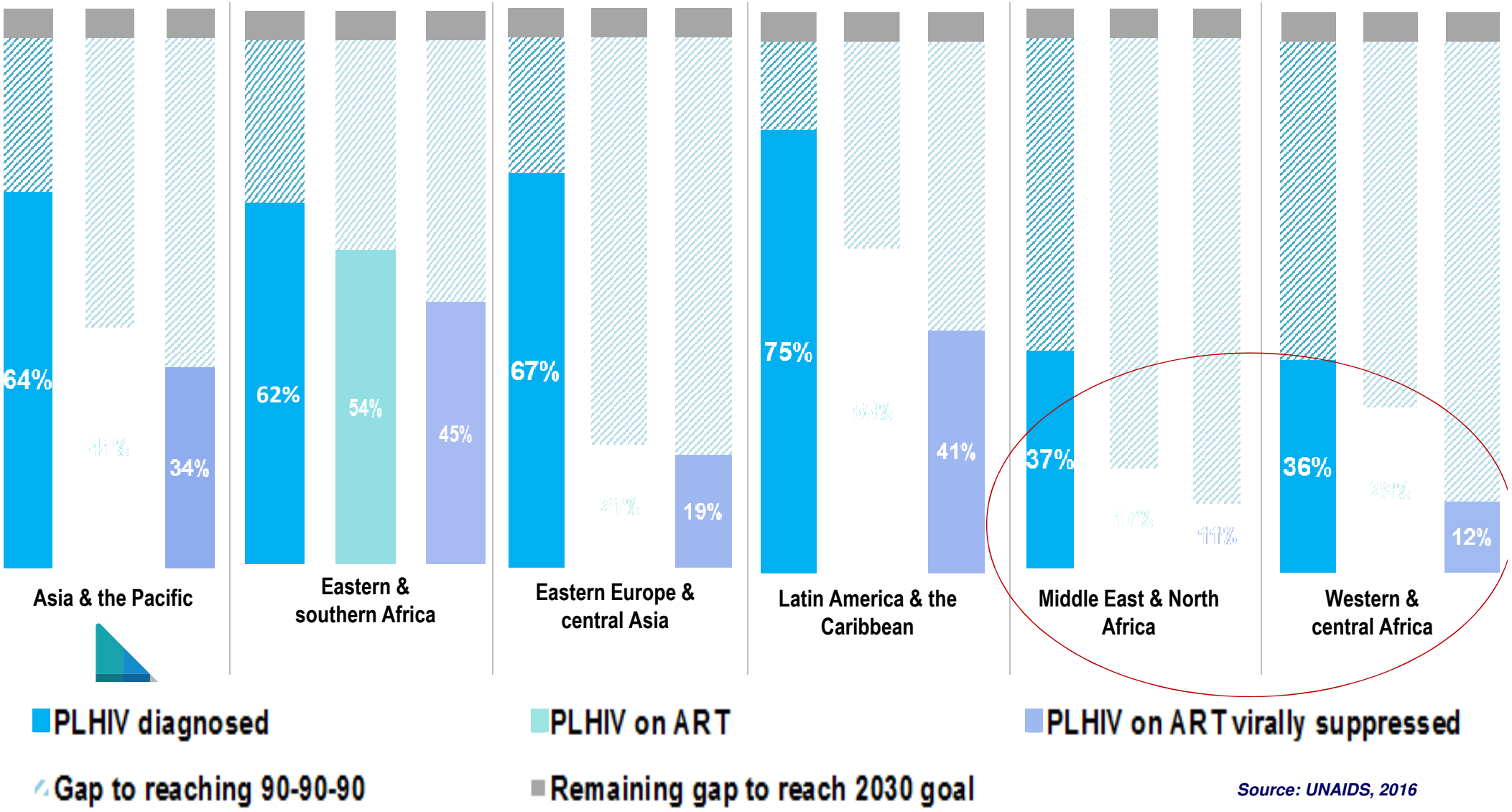
Global Progress Toward the First 90, 2015

40% of PLHIV still remain undiagnosed worldwide



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

Progress toward the first 90 by region, 2015

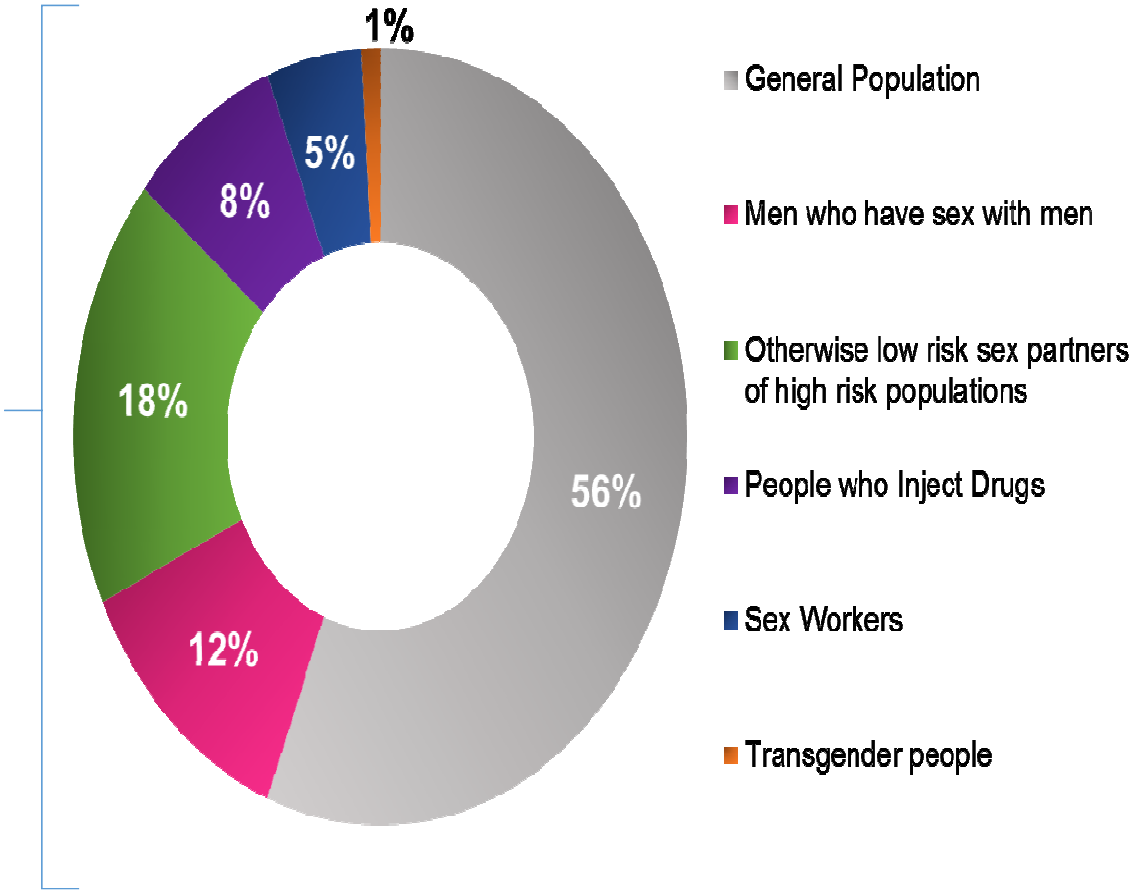


Source: UNAIDS, 2016

New adult HIV infections globally, 2015

~1.9 M new adult HIV infections in 2015

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



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

Innovation Needed to Close the Testing Gap

Photo Credit: http://fr.ubergizmo.com/2013/02/15/wifi-gratuit-metro-londonien-fin.html

So what is HIV Self-Testing?

- HIVST is a process by which an individual wanting to know his or her HIV status collects a blood or oral fluid specimen, performs a HIV test, and interprets the results by him or herself.
- HIVST is a “screening test” or Test for Triage
- As a new innovation that has significant potential to extend beyond the limitations of the HIV testing infrastructure and address existing barriers to testing, HIVST could play a substantial role in accelerating progress towards this goal of 90-90-90.

HIVST has been touted as a supplementary strategy to reach key and under-tested populations

It is a concept that requires optimization for the ‘lay’ person out in the community

What is HIVST NOT?

- It is not here to replace traditional HTS, and facility based HTS should continue to be the main modality through 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 and negatives retested in 3 months. MESSAGING MUST BE CLEAR


HIV Self Testing Assessments & Research

Current Wits HSTAR Programme

The HSTAR Programme, currently **funded by the BMGF and AIDS Fonds**, is evaluating HIV self-testing in the South African market, actively engaging with policy makers and communities, to pave the way for several well-tested products to enter the market, and facilitate the process towards World Health Organisation Pre-Qualification and National Guidance on ST.

The programme will address access, acceptability, product performance, implementation, assessment of social harms and linkage-to-care.

The programme has a multi-phased approach for the performance evaluation of potential devices:

- Phase 1: Usability Assessments of prospective HIV Self-Testing devices including Instruction for Use comprehension and result interpretation.
- ~~Phase 2: Evaluation of prospective HIVST devices in the hands of Trained Users.~~
- Phase 3: Evaluation of prospective HIVST devices in the hands of untrained users from the general population

Why WHO Pre-Qualification?

- South Africa does not have a Medical Devices Regulatory Authority, or evaluation framework

- Yogan Pillay DDG Health “NDOH will not allow HIV Self-Tests into Public Health which have not been approved by the WHO PQ process”

WHO PQ TSS DEC 2016

WHO PREQUALIFICATION TEAM:
DIAGNOSTICS

World Health Organization

Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment

TSS-1

Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing

WHO PQ TSS April 2016

7.4.2.1 Part 2-a: Validation of label comprehension for finger stick and OMT job aid and IFU

Study objective

To validate the job aid and IFUs provided for self-testing in either fingerstick whole blood or OMT.

7.4.2.2 Part 2-b: Validation of result interpretation of results from pre-made Y1234-B/O cassettes

Study objective

The study will aimed to evaluate the ability of potential self-testers to interpret the results on non-functional devices pre-prepared with the following results:

7.4.2.3 Part 2-c Validation of device usability by observed self-testing in trained users

Study objective

To evaluate device performance (including collection materials, IFU and job aid, test result and result interpretation) in professional, trained testers conducting observed self-testing.

7.4.3 Part 3: Clinical performance evaluation – self testing

Study objective

The device is intended for self-testing by untrained individuals in resource limited settings. The design input documents require that the devices for OMT and for fingerstick blood, both must meet WHO performance validation criteria, in addition to meeting all the other input requirements.

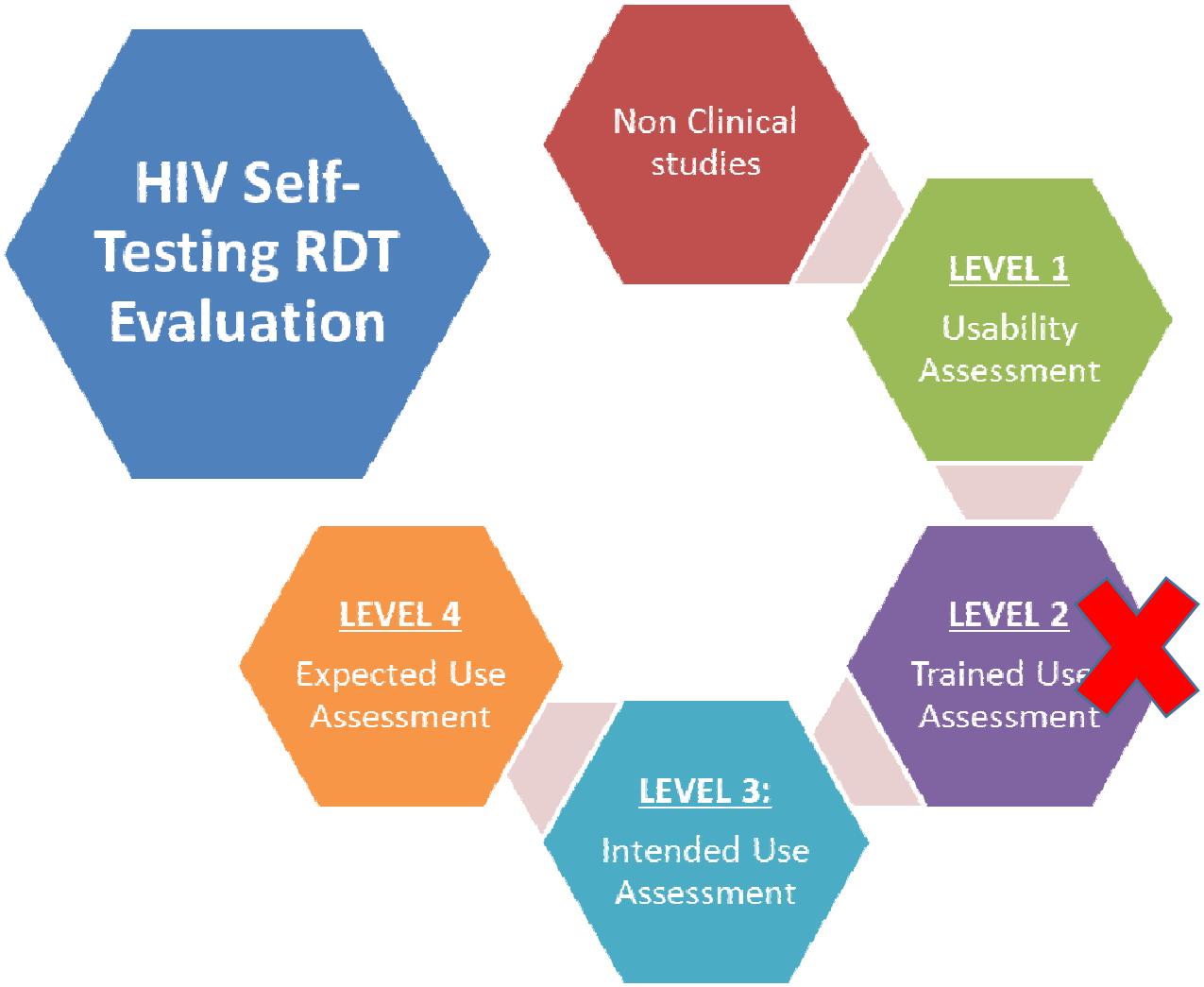
WHO PQ TSS DEC 2016

Part 3 Qualification of usability (self-testing)

PURPOSE: Assessment of product design, instructions for use and usability of RDTs for self-testing by analysis of the following:

- Results of questionnaire to assess whether key messages and instructions from packaging and labelling would be understood and easily followed by untrained intended users (i.e. self-testers).
- Results of interpretation of test-results by untrained users (i.e. self-testers) of simulated RDTs (e.g. pre-made and with contrived results).
- Test results and interpretations when assay is performed by untrained intended users (i.e. self-testers).
- For each of the studies summarized below the study group should comprise untrained subjects whose age, gender, level of education, literacy and additional, supplementary skills can challenge the usability of the IVD in intended users and in unfavourable operational settings (e.g. poor lighting).
- These assessment activities will determine the changes needed to optimize the IVD for use by self-testers. Changes may range from minor (simplification of instructions for use) to major. The impact of any change on safety and performance must be determined.
- Results from any one of the stages summarized below may indicate that assay redesign is necessary. This may in turn result in a need to revalidate the IVD or to perform additional specific performance studies and to update the risk analysis.

Aspect	Testing requirements	Comments	References
3.1 Qualification of usability (self-testing)			
3.1.1 Label comprehension study	Questionnaire-based testing of subjects, representative of end users, to assess ability of intended users to correctly comprehend key messages from packaging and labelling: • Proper self-selection (whether or not users understand if it is appropriate for them to undertake testing). • Understanding key warnings, limitations and/or restrictions. • Proper test procedure. • Test result interpretation. Questionnaire to be administered to at least 200 subjects, representative of end users, in order to demonstrate comprehension of key messages.	1. Instructions for use and labelling should be clear and easy to understand; use of pictorial instructional material is encouraged.	ISO 18113:2011 (16) ISO 15197:2013(en) (17) IEC 62366-1:2015 (18) MHRA (19) FDA (20); example of Summary of Safety and Effectiveness (21) EC CTS (2) European Directive 98/79/EC (22) FDA CLIA Waiver Requirements (23) WHO HIV testing
3.1.2 Results interpretation study	A minimum of 400 subjects to interpret the results of contrived IVDs (e.g. static/pre-made tests) to assess their ability to correctly interpret pre-determined test results. Contrived tests should be made to	1. The study group may include subject recruited as part of the label comprehension study.	


HIV Self-Testing RDT Evaluation
Non Clinical studies
LEVEL 1
Usability Assessment
LEVEL 2
Trained Use
Assessment
LEVEL 3:
Intended Use Assessment
LEVEL 4
Expected Use Assessment

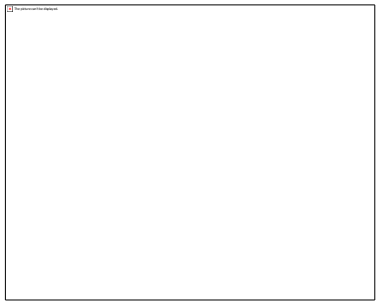
HIV Self Testing Assessments & Research

Product performance	***Implementation Res***	***Policy/Advocacy***
WHO PQ studies (Gates)	HSTAR004 (Aids Fonds)	WHO GDG
- HSTAR001	(n = 12000 – commence Q3 '17)	SA TWG
•Orasure (n = 250)		
•Biosure (n = 250)		
•Calypte (n = 200)		
•Biolytical (n = 200)		
•Atomo (n = 200)		
HSTAR001A – to follow		
- HSTAR003 (n = 900 pp)		

HIV Self Testing Assessments & Research

Product performance	***Implementation Res***	***Policy/Advocacy***
WHO PQ studies (Gates)	HSTAR004 (Aids Fonds)	WHO GDG
- HSTAR001	(n = 12000 – commence Q3 '17)	SA TWG
•Orasure (n = 250)		
•Biosure (n = 250)	STAR PHASE 2	
•Calypte (n = 200)	(n = 1.2 million)	
•Biolytical (n = 200)		
•Atomo (n = 200)		
HSTAR001A – to follow		
- HSTAR003 (n = 900 pp)		

Product Pipeline



atomo diagnostics

BioSURE HIV Self Test

CALYPTE

bioLytical LABORATORIES INSTI

Alere™

autotest VIH®

HSTAR 001 Objectives

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

- gain data regarding the usability (IFU comprehension and contrived results interpretation) of the device including any error[s] that may occur including modes of error, critical and non-critical errors, in a simulated “private” setting.

- Stratified for Age, Gender, Education level

Primary Objectives are to document and record:

- Label comprehension (understanding of Instructions for Use, test limitations, test goal, inspection of test components)
- Usability / user interaction with the devices [effectiveness and efficiency] and accuracy of testing process
- Results interpretation (contrived results, no actual diagnosis will be made)

EXAMPLE Section A: Test Performance

Number of participants enrolled (n)	50			
1. Did the participant read/use the IFU?	YES	94%	NO	6%
2. Did the participant have difficulty removing the test tube from the test pack?	NO	82%	YES	18%
3. Did the participant the remove the buffer pot and stand in upright in slot?	YES	76%	NO	24%
4. Did the participant have difficulty lancing their finger?	NO	78%	YES	22%
5. Did the participant have difficulty forming a blood droplet?	NO	78%	YES	22%
6. Was the participant able to fill the tube with adequate amount of blood?	YES	78%	NO	22%
7. Was the participant able to push the test tube right to the bottom of the buffer pot?	YES	68%	NO	32%
8. Was a control line present?	YES	86%	NO	14%
	AVE	80%		
BLUE: CRITICAL STEPS	AVE	75%		

Section B: Mock Result Interp

23 / 50 – 4/4 Correct
18 / 50 – 3/4 Correct
07 / 50 – 2/4 Correct
01 / 50 – 1/4 Correct
01 / 50 – 0/4 Correct

	Read correctly		
Result: NEGATIVE	42 / 50	84%	5 read POS, 3 read INVALID
Result: POSITIVE	44 / 50	88%	3 read NEG, 2 INVALID, 1 did not know
Result: FEINT POSITIVE	31 / 50	62%	12 read NEG, 7 read INVALID
Result: INVALID	44 / 50	88%	3 read POS, 2 read NEG, 1 did not know

Recommendations and responses…eg.

a. ***Issue: Buffer pot not been placed upright in the slot provided***

The majority of participants, after opening the packaging, do not open the IFU as one would a booklet, but rather as a leaflet. Figure 6 below demonstrates this.

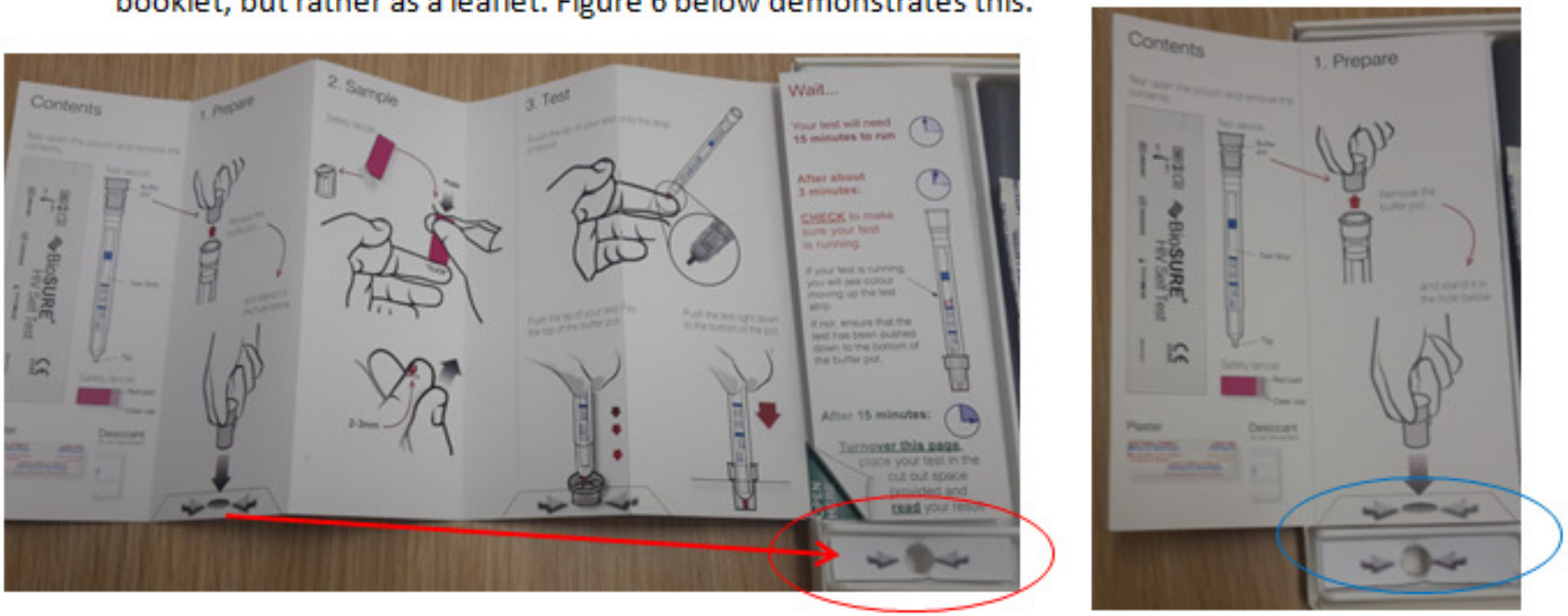


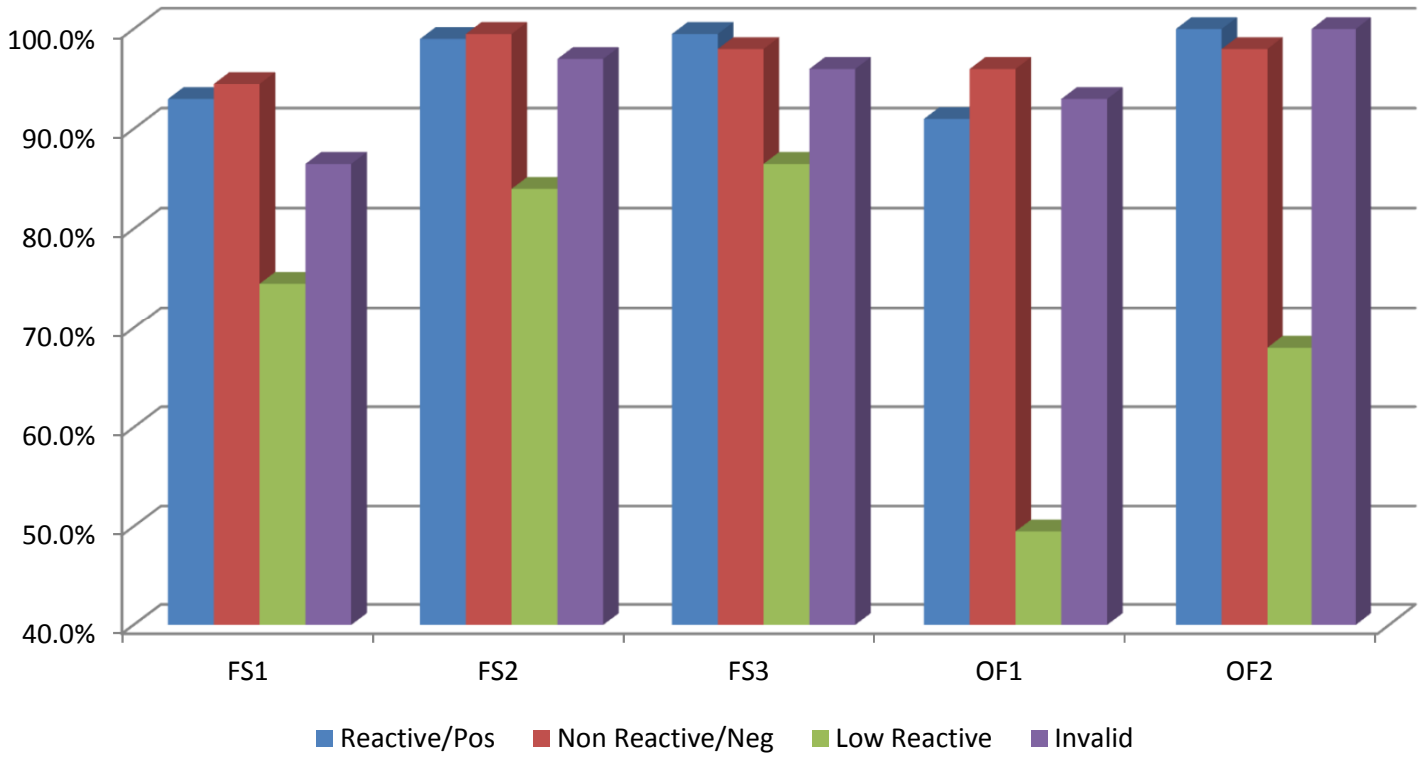
Figure 6: Opened as leaflet (left) vs. Opened as booklet (right)

As a result, some participants are not locating the slot (red circle) as easily as they would if opened as a booklet (blue circle). Therefore, those participants not locating the slot are standing the buffer-pot on the table, or holding it in their hands. This is not critical; however it does allow the possibility of falling over, spillage and not pushing the tube in correctly.

We recommend that the arrows pointing to the slot be made bolder and more visible however

HSTAR 001 Results

	Overall Usability	Critical Steps
Orasure	91%	81%
Biosure	84%	81%
Calypte	93%	98%
Biolytical	97%	96%
Atomo	90%	85%



Other Notable UA in SA pops

Dong et al in KZN, showed 95% usability accuracy in a rural KZN population (35km out of PMB)

Deville et al demonstrated high usability, sensitivity (99%) and specificity (95%) in Moetse region in Groblersdal

HSTAR003

HSTAR 003 Objectives

Primary Objectives

- The primary objective of this study is to evaluate the ability of untrained users to obtain accurate HIV test results using the XXXXX Rapid HIV Self-Test when compared to professional users and ELISA

Secondary Objectives

- To evaluate the untrained users' interaction with the device in terms of effectiveness and efficiency, i.e. successful / unsuccessful completion and difficulty of the critical steps as per the Instructions for Use
- To assess the ability of the untrained users to correctly comprehend key messaging from device packaging and labelling, including the Instructions for Use
- Participants will be surveyed for user experience, and satisfaction with the overall process; in addition, users will be asked for comments and recommended improvements for test process

HSTAR 003 Progress

- Commenced 22 March 2017
- Orasure OF HIVST
- 147 participants completed to date

- Important study for OR PQ submission

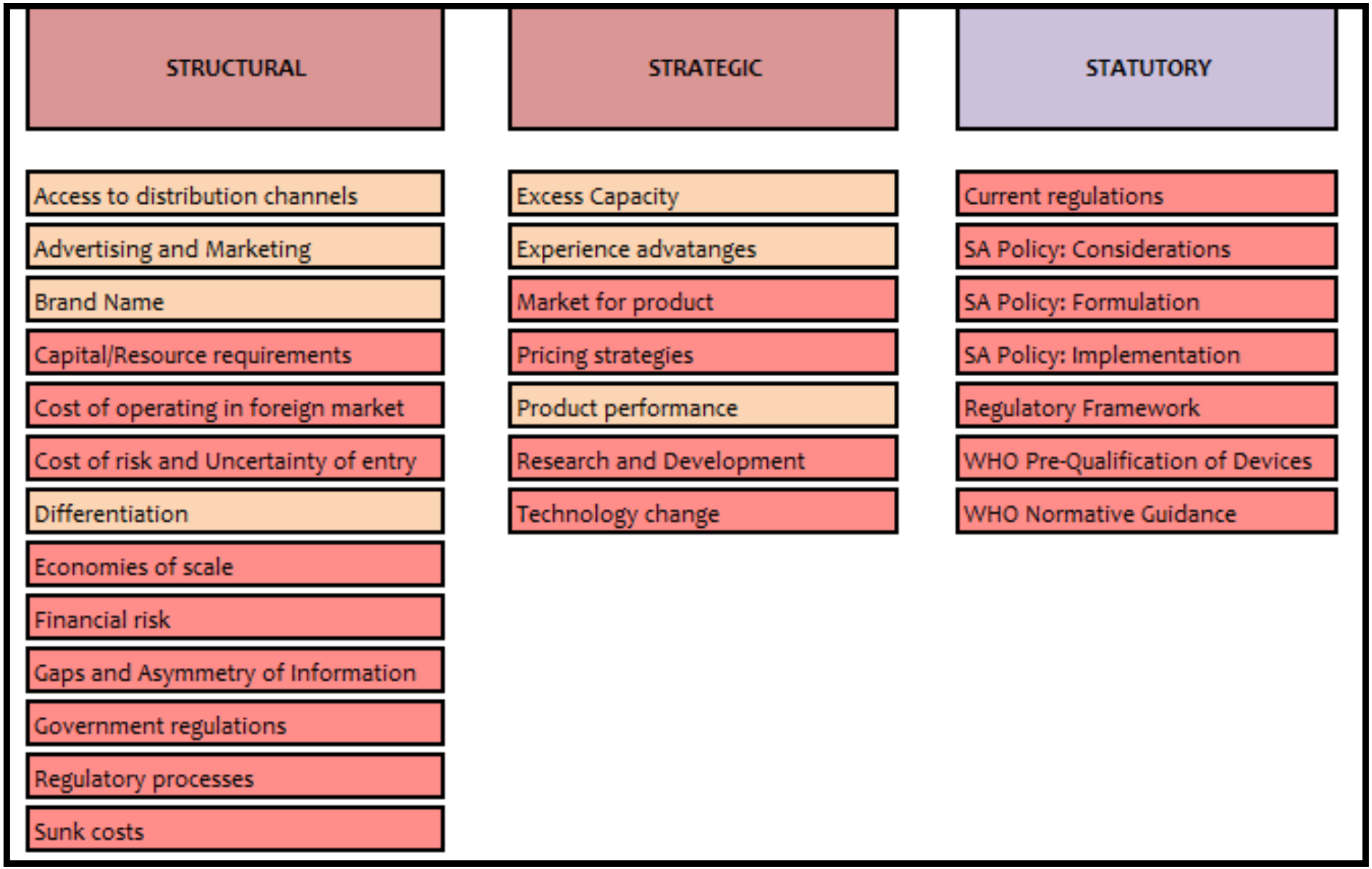
Visual Stability Study

- Embedded substudy of 003 where we are looking at the visual stability of the test line on the test kits are D1 – 7, wk 1 – 4, Mo 2 – 6.
- With Liverpool School Tropical Medicine
  - Duncombe, Watson, Taegetmayer

Where are we with HIVST in SA currently?

- Constraints/Barriers to Market Entry
- Target Product Profile
- Product Pipeline
- WHO Pre-Qualification
- Normative Guidance
- Regulatory pathways
- Clinical Research and Implementation Programmes
- SA TWG and Guidelines

Market Entry Barriers for HIVST in SA



Constraints/Barriers to Market Entry

- Barrier 1: Undefined Regulatory landscape‡
- Barrier 2: High cost of risk and uncertainty‡
- Barrier 3: Lack of demand for quality-assured HIVST translating into concrete purchase orders~
- Barrier 4: Price pressure form donors and governments~
- Barrier 5: Lack of incentives to innovate for further product development~
- Barrier 6: Lack of ownership of and investment in key market functions‡~

‡ Majam (2016), ~ PSI (2016)

Barriers? What barriers?

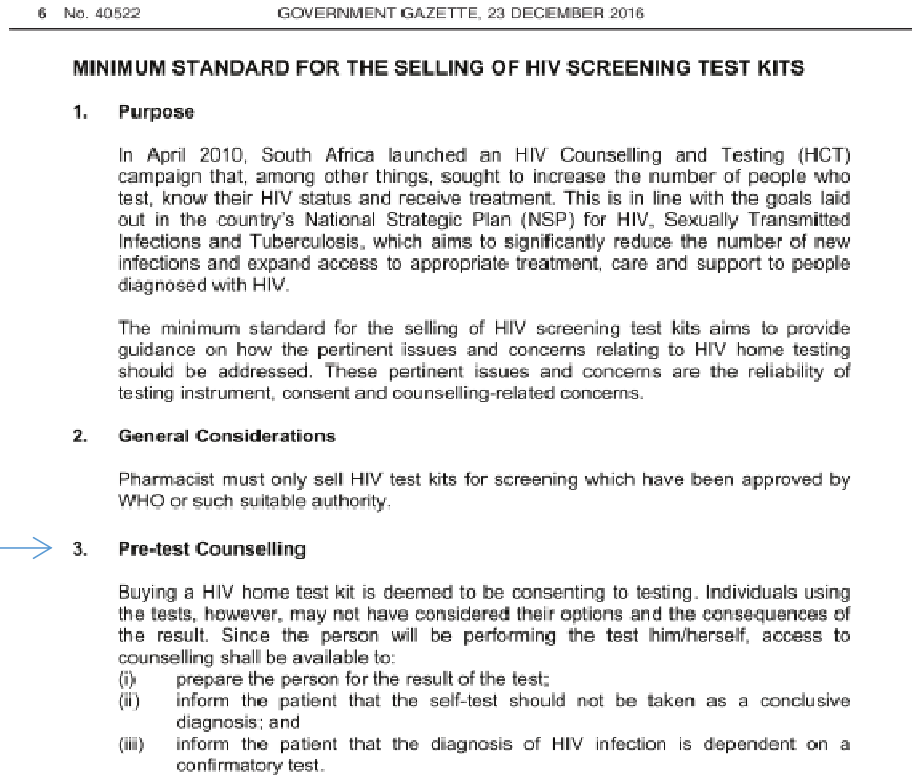
South African Pharmacy Council ruling

(g) All clients require and deserve the full attention of the person interviewing them. Rushed appointments, abbreviated counselling sessions and inadequate record keeping in no way serves the best interest of the patient.

(h) Pharmacists must not sell HIV tests for patients to perform at home.

(i) It is preferable that the infected person should tell his/her partners and family themselves. A counsellor can be pre-

23 Dec 2016



6 No. 40522 GOVERNMENT GAZETTE, 23 DECEMBER 2016

MINIMUM STANDARD FOR THE SELLING OF HIV SCREENING TEST KITS

1. Purpose

In April 2010, South Africa launched an HIV Counselling and Testing (HCT) campaign that, among other things, sought to increase the number of people who test, know their HIV status and receive treatment. This is in line with the goals laid out in the country's National Strategic Plan (NSP) for HIV, Sexually Transmitted Infections and Tuberculosis, which aims to significantly reduce the number of new infections and expand access to appropriate treatment, care and support to people diagnosed with HIV.

The minimum standard for the selling of HIV screening test kits aims to provide guidance on how the pertinent issues and concerns relating to HIV home testing should be addressed. These pertinent issues and concerns are the reliability of testing instrument, consent and counselling-related concerns.

2. General Considerations

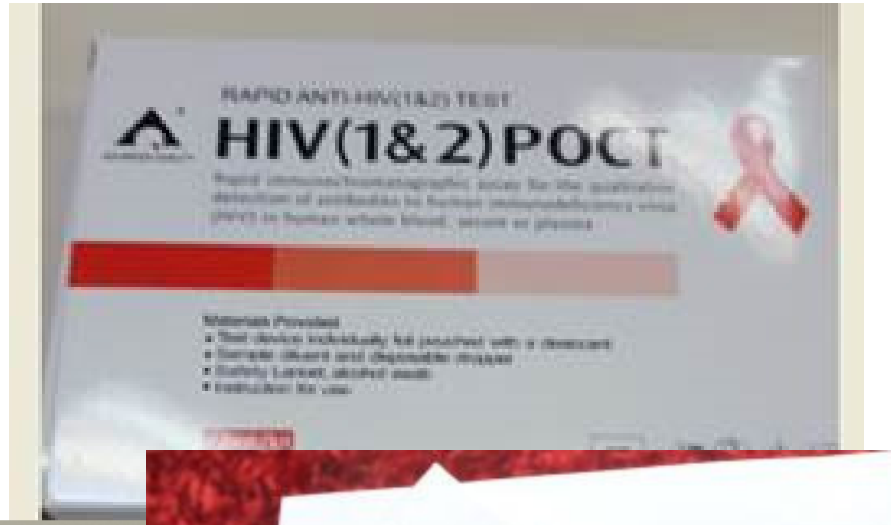
Pharmacist must only sell HIV test kits for screening which have been approved by WHO or such suitable authority.

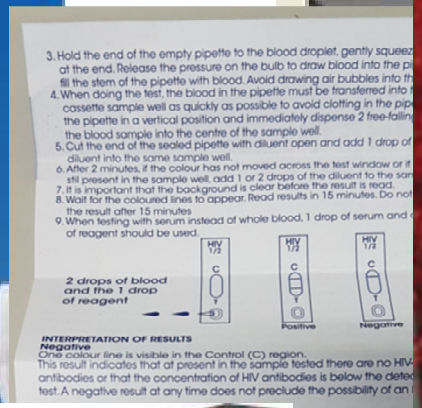
3. Pre-test Counselling

Buying a HIV home test kit is deemed to be consenting to testing. Individuals using the tests, however, may not have considered their options and the consequences of the result. Since the person will be performing the test him/herself, access to counselling shall be available to:

(i) prepare the person for the result of the test;
(ii) inform the patient that the self-test should not be taken as a conclusive diagnosis; and
(iii) inform the patient that the diagnosis of HIV infection is dependent on a confirmatory test.

On the market





The difference…

bioLytical

INSTI HIV SELF TEST INSTRUCTIONS

Questions? +1-604-204-6784

INSIDE YOUR TEST KIT

BOTTLE 1 | BOTTLE 2 | BOTTLE 3 | TEST DEVICE POUCH | LANCET

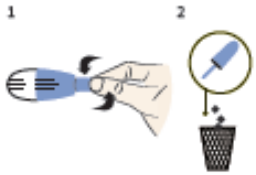
PREPARATION

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.

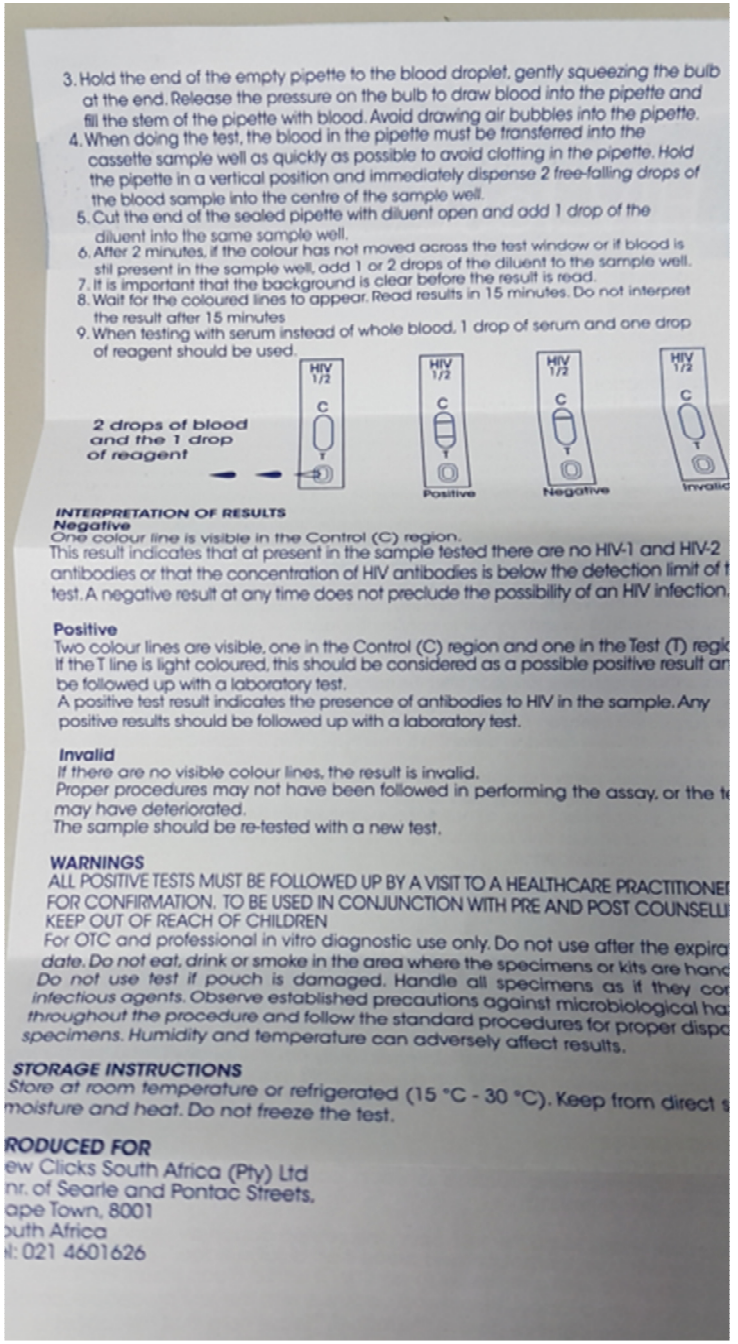
2. Rub finger until warm.

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.



3. 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.
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 the diluent into the same sample well.
6. 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.
7. It is important that the background is clear before the result is read.
8. Wait for the coloured lines to appear. Read results in 15 minutes. Do not interpret the result after 15 minutes
9. 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

HIV 1/2 C T — Positive — Negative — Invalid

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 t 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) regi If the T line is light coloured, this should be considered as a possible positive result ar 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 t 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 PRACTITIONE FOR CONFIRMATION. TO BE USED IN CONJUNCTION WITH PRE AND POST COUNSELL KEEP OUT OF REACH OF CHILDREN
For OTC and professional in vitro diagnostic use only. Do not use after the expira date. Do not eat, drink or smoke in the area where the specimens or kits are hand Do not use test if pouch is damaged. Handle all specimens as if they cor infectious agents. Observe established precautions against microbiological ha throughout the procedure and follow the standard procedures for proper dispo 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.

RODUCED FOR
ew Clicks South Africa (Pty) Ltd
nr. of Searle and Pontac Streets,
ape Town, 8001
outh Africa
l: 021 4601626

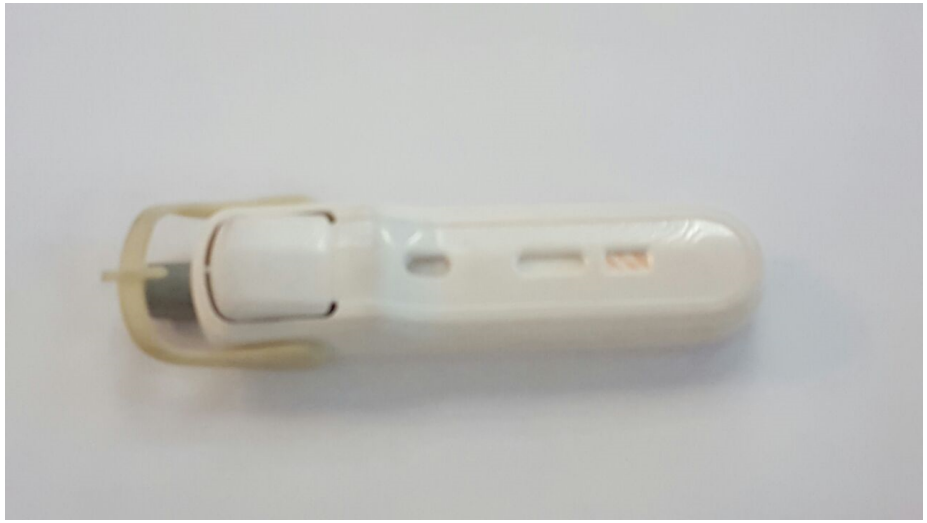
HIVST Target Product Profile (PATH, 2014)

- Unlike HIV RDTs for professional-use, HIV RDTs for self-testing are often employed by lay users who must collect a whole-blood or oral fluid specimen, perform the test, and interpret the results, potentially with little to no assistance.
- This requires that products be designed for ease of use to achieve accuracy, to facilitate interpretation of results, and to support linkage to care.

TPP…cont

- 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 to 5 minutes or less (time from test performance to interpretation)
- Increased stability of test results

ST manufacturers have brought innovation to a stagnant industry



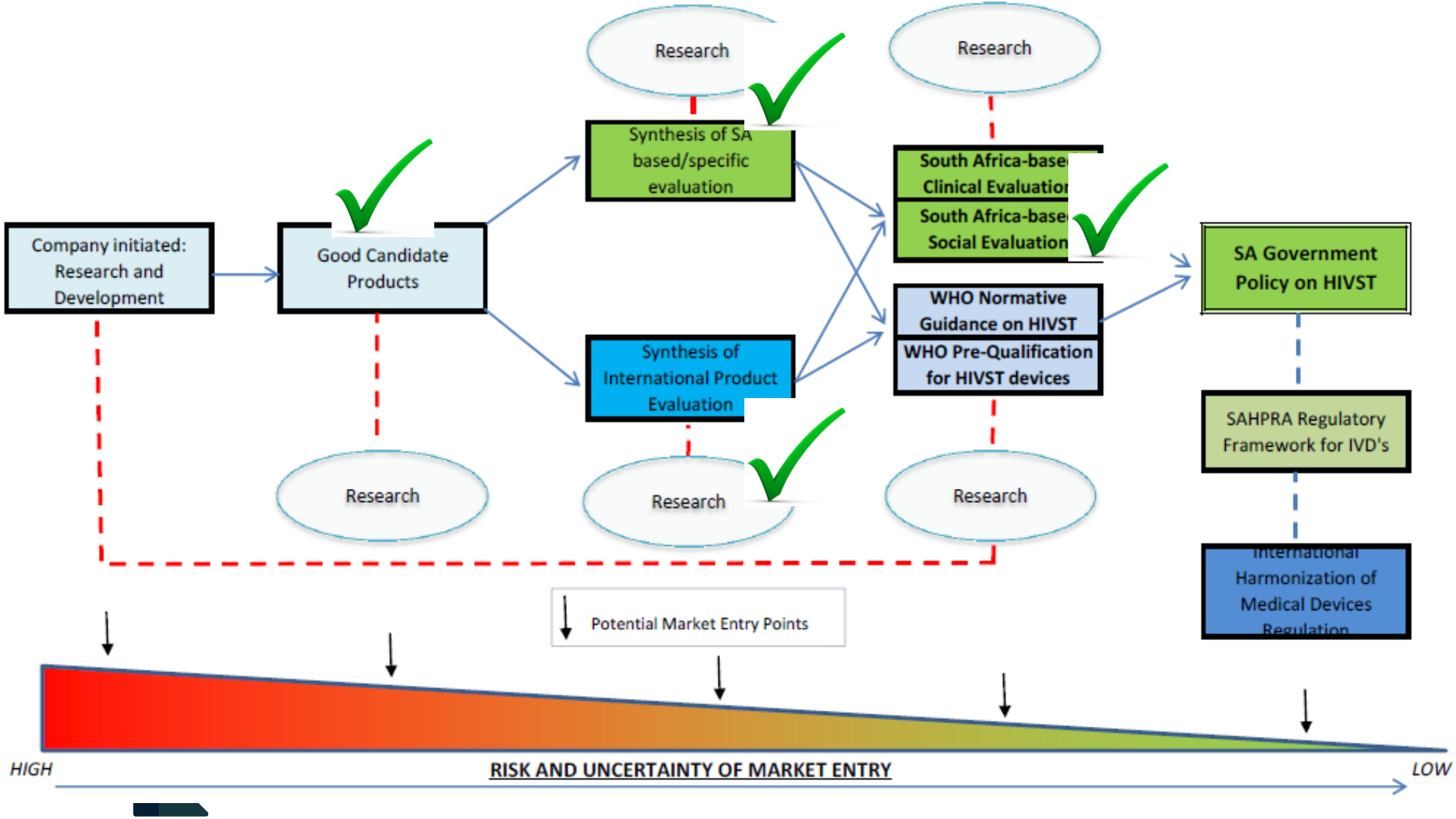
All in one test

Flow through technology
Results in seconds

On-going research into ST

- STAR Project
- Choko et al - Malawi
- Australia, Thailand, Brazil, Kenya programmes
- HSTAR programme (FDA studies, and WHO PQ)

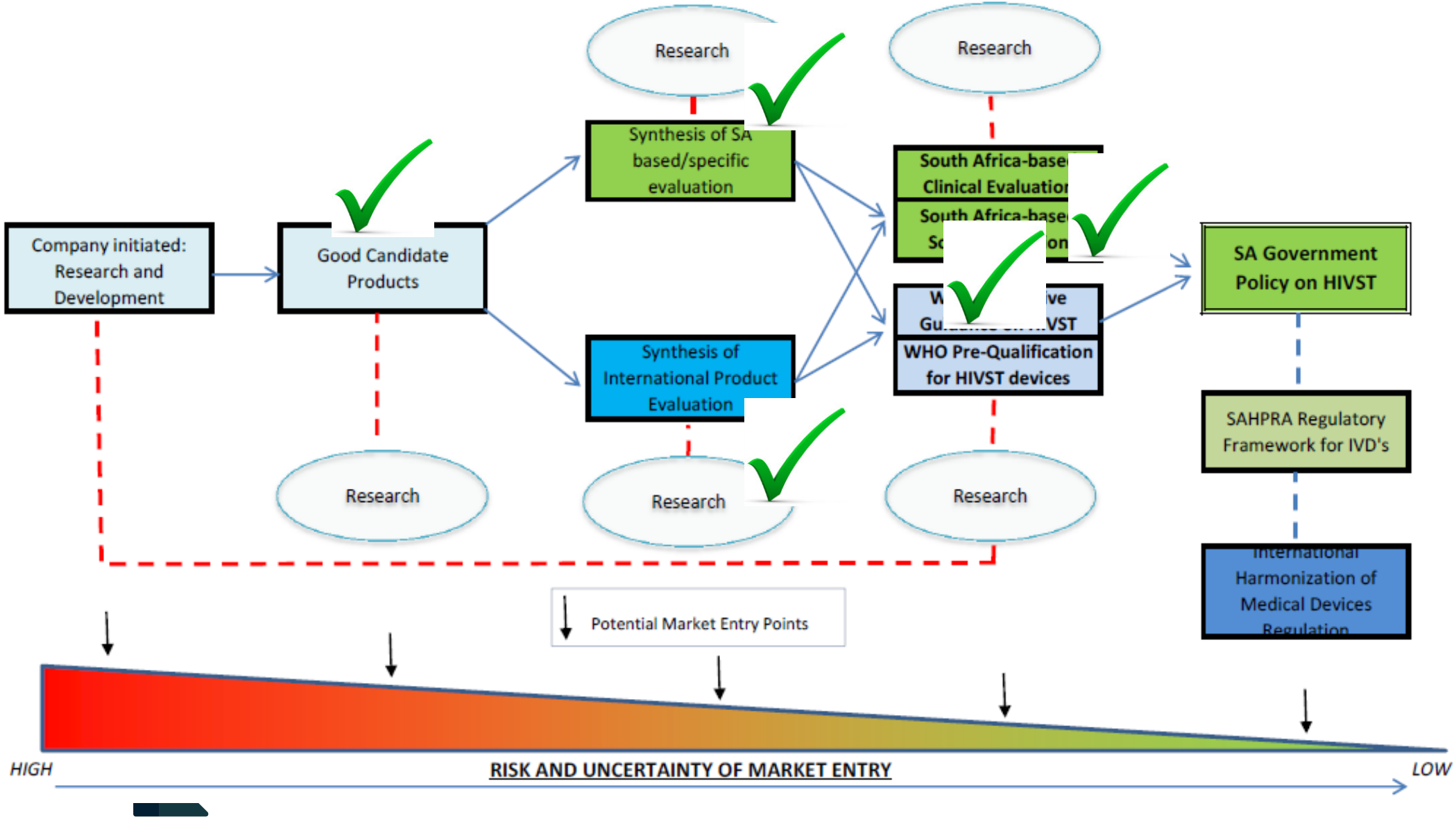
HIV Self-Testing landscape...3



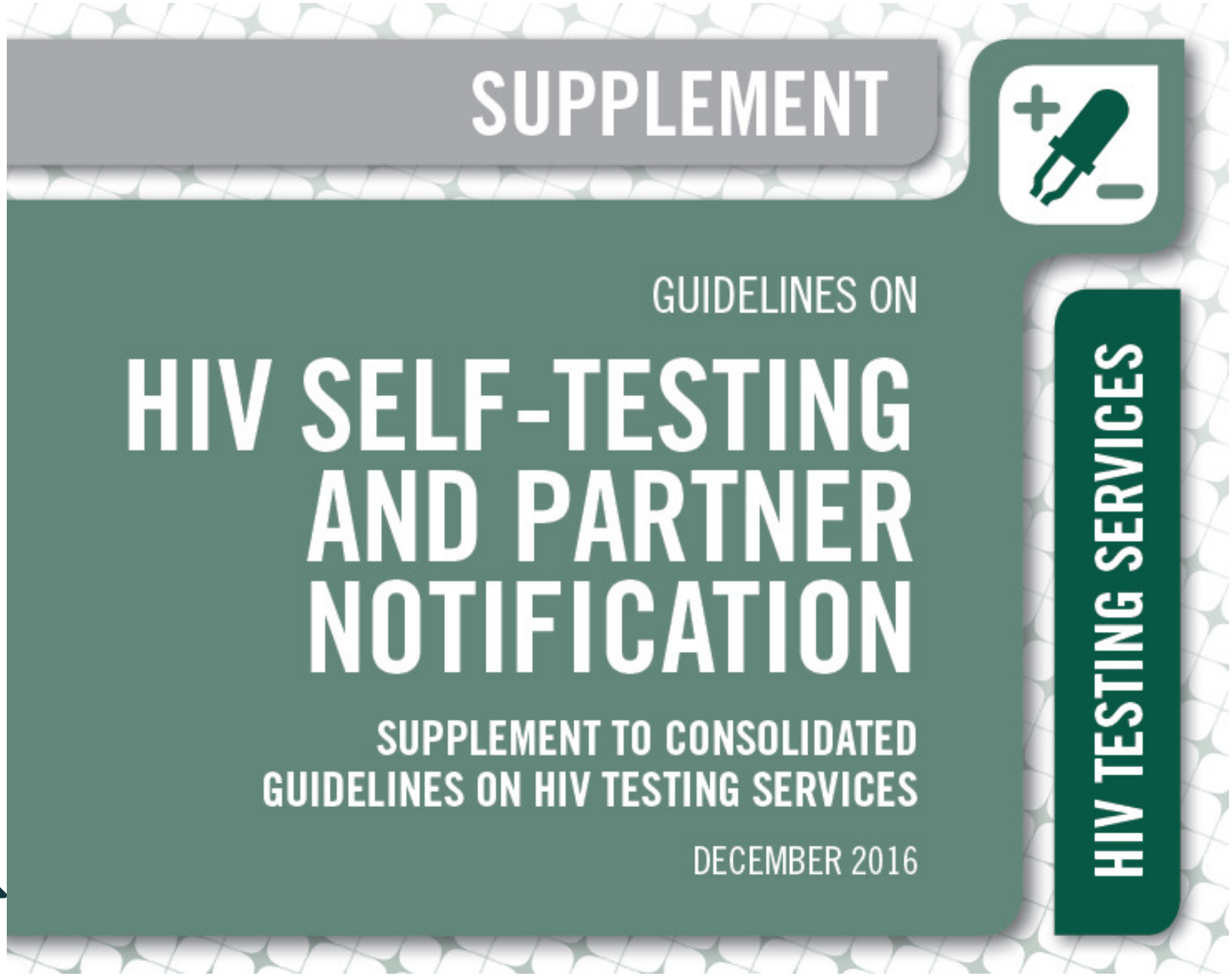
South African ST data

- Ndlovu Health (Limpopo)
  - High usability, concordance, Sens and Spec in rural population
- HSTAR (Gauteng)
  - High usability in Oral Fluid and Finger stick products in Inner City Johannesburg
- iTEACH (Gauteng, Mpumalanga, KZN)
  - High concordance, but low LTC in Truck Drivers
- UCT (Western Cape)
  - High acceptability in MSM, and demonstrated utility of online platforms for sale and distribution
- Anova (North West)
  - High acceptability in MSM

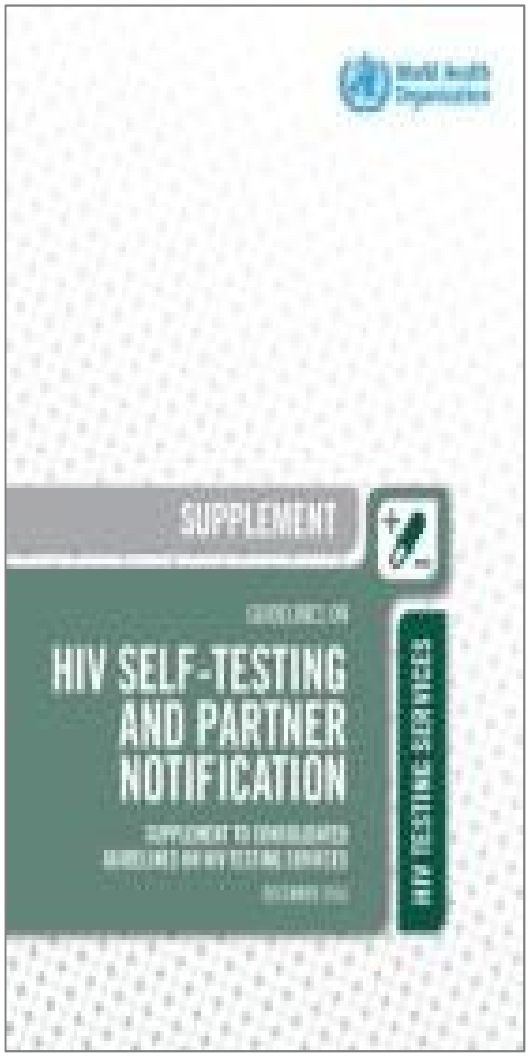
HIV Self-Testing landscape...4



Normative Guidance



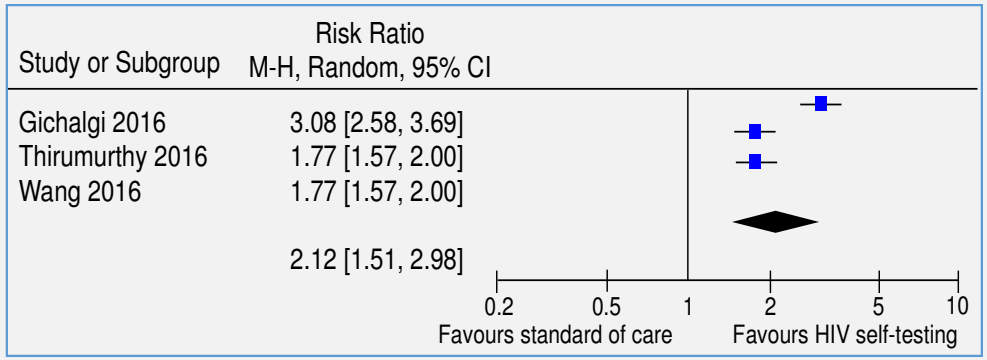
WHO Guidelines on HIVST



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

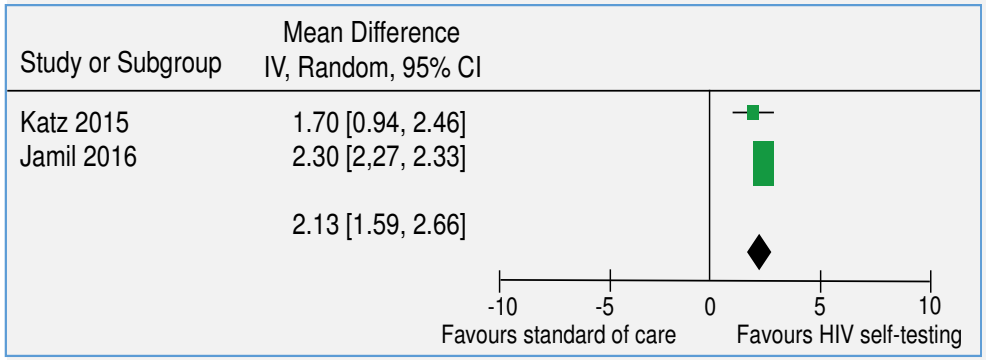
HIVST Doubled Uptake & Frequency

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



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

No identifiable increased risk of social harm & adverse events

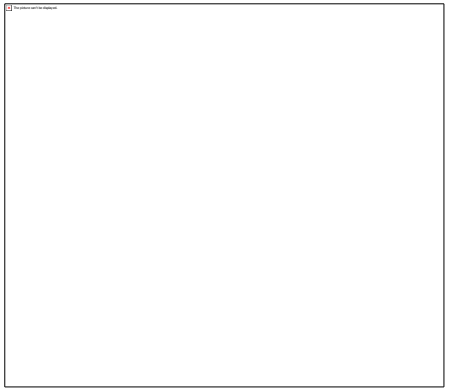
- Studies generally report **HIVST can be empowering**
- **Social harm due to HIVST was not identified in RCTs**
- Reports from other studies were limited and did not suggest HIVST increased risk of harm
- In Malawi, two-years of implementing HIVST found no suicides, no self-harm and no cases of IPV.
  - 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).*

However, Social Harms remain a concern and will be continually assessed through current and on-going research

- STAR Phase 1: Over 300 000 tests distributed through various modalities with no incidence of GBV, IPV or Suicide
- Malawi unobserved, unassisted study (n = 14000), no reports of social harm
- Much of the concern regarding suicide after a positive HIV test comes from speculation and anecdotal reports on the Internet. These remain a concern but no evidence to support the link.

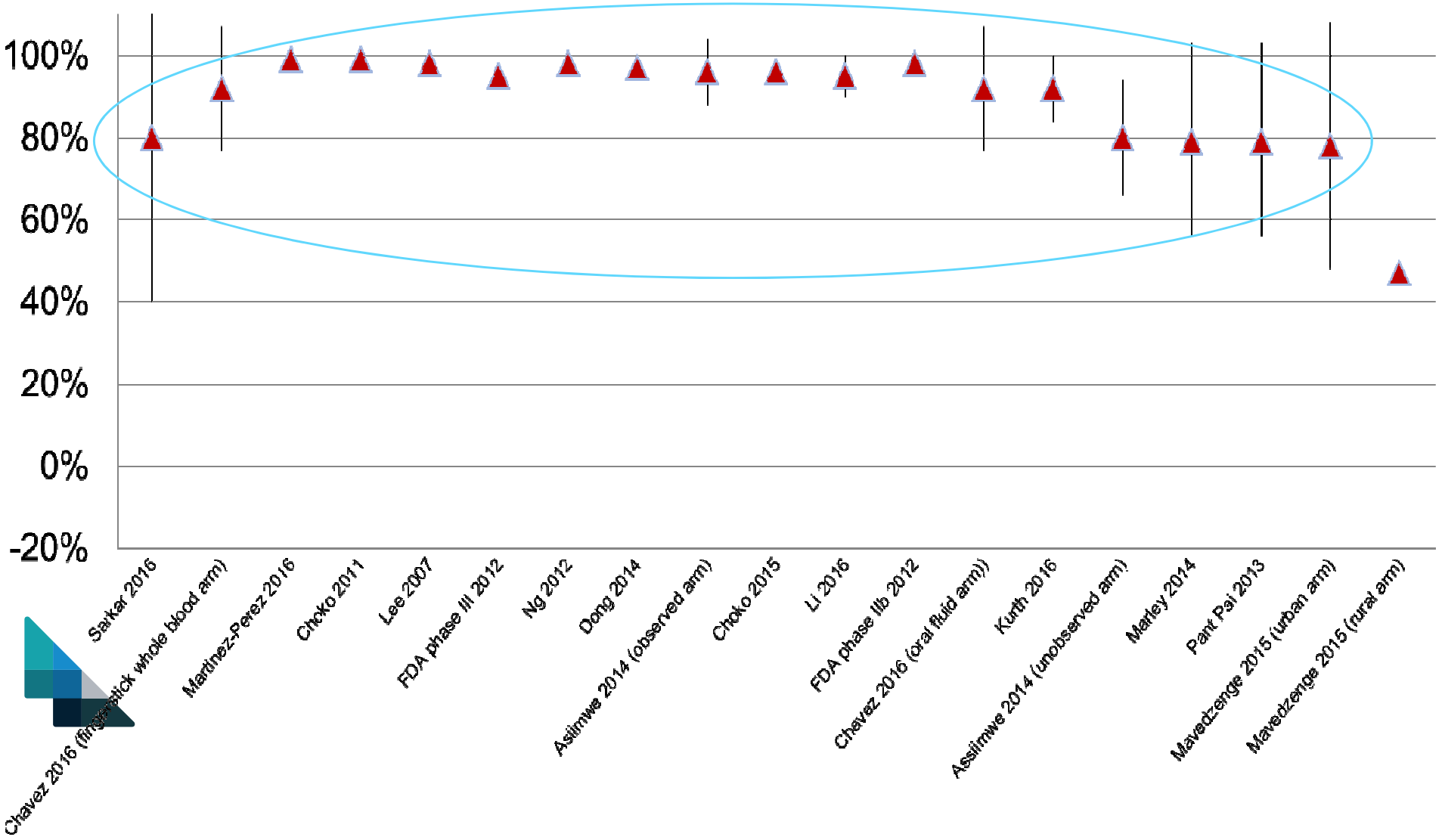
Summary of Values & Preferences

- **HIVST is highly acceptable among many different groups and across different settings** – but some concern about potential lack of counselling and support, accuracy of test results, and related costs
- **Individuals surveyed about HIVST had concerns about possible harm, but most had not self-tested, and concerns were not founded in evidence –despite concern most still found HIVST acceptable**
- **Many users prefer oral HIVST (e.g. painless) – but many studies did not inform respondents about performance.**
  - Some studies show when participants are informed they may actually prefer fingerprick/whole blood-based HIVST.
- **Preferences across service delivery approaches vary**
  - Key populations, in particular, reported preferences for pharmacies, the Internet, and over-the-counter approaches more appealing because they are more discreet and private



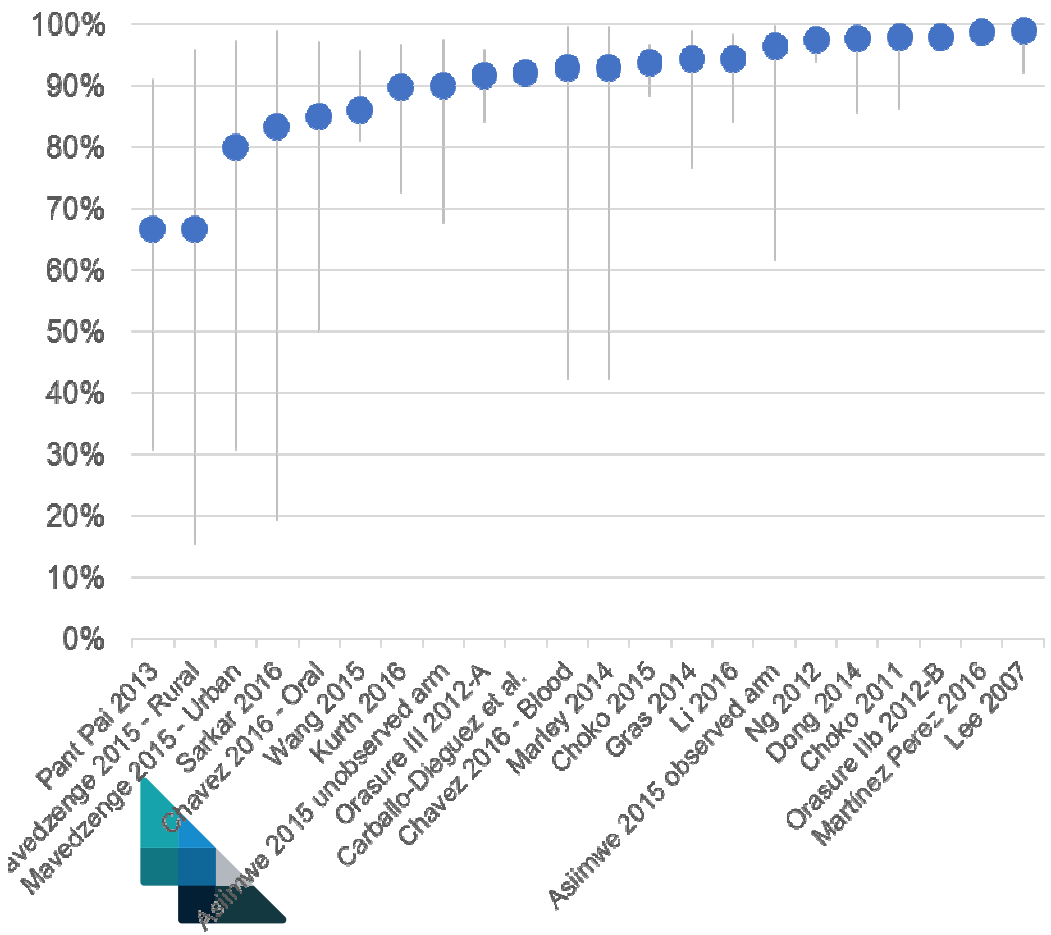
Results of HIV RDTs performed by self-tester were similar to those performed by trained health worker

Measured using kappa statistic – 16 studies

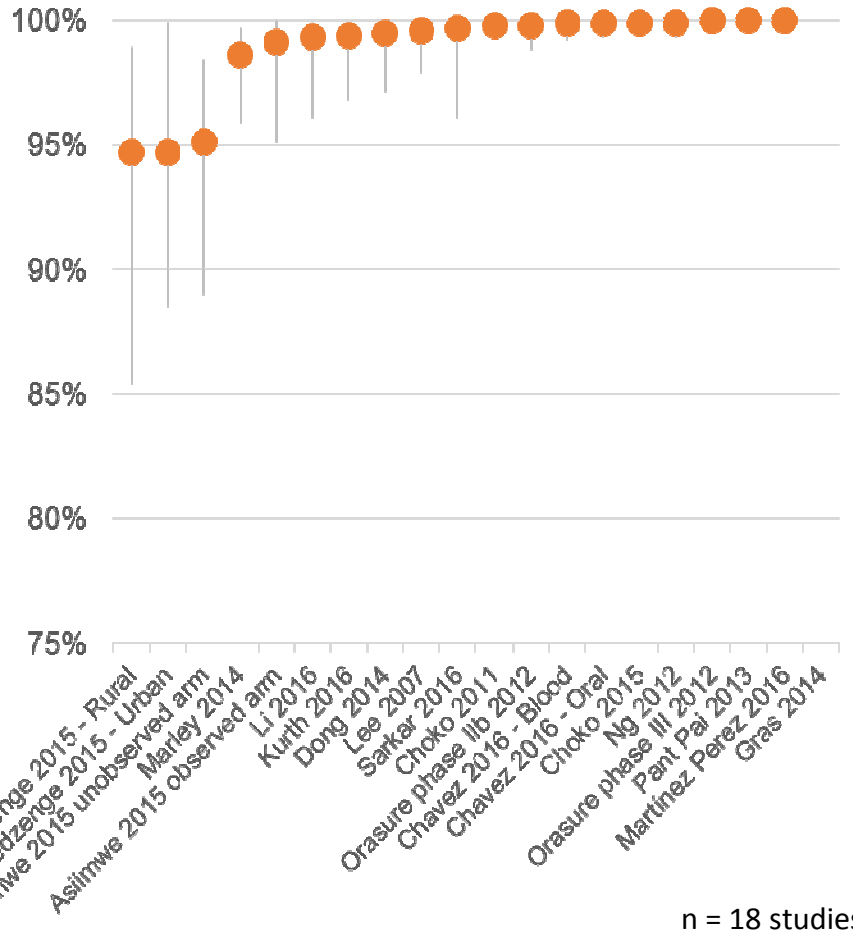


Generally acceptable levels of sensitivity and specificity were achieved

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

Strong recommendation

NEW

Recommendation

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

[STRONG RECOMMENDATION, MODERATE QUALITY OF EVIDENCE.]

- **Policy and regulatory frameworks.** Adapt, develop and harmonize existing national policies on HIV testing to incorporate HIVST, such as:
  - Laws permitting the sale, distribution, advertisement and use of quality-assured RDTs for HIVST;
  - Age of consent to self-test;
  - Human rights laws, policies and regulations to protect individuals and address misuse of HIVST if and when it occurs;
  - National policies on how to confirm an individual's HIV status following HIVST;
  - Quality assurance and post-market surveillance systems for RDTs used for HIVST.

South African Guidance Document

SA TWG:

SAHIVSOC

Wits RHI

NHLS

NICD

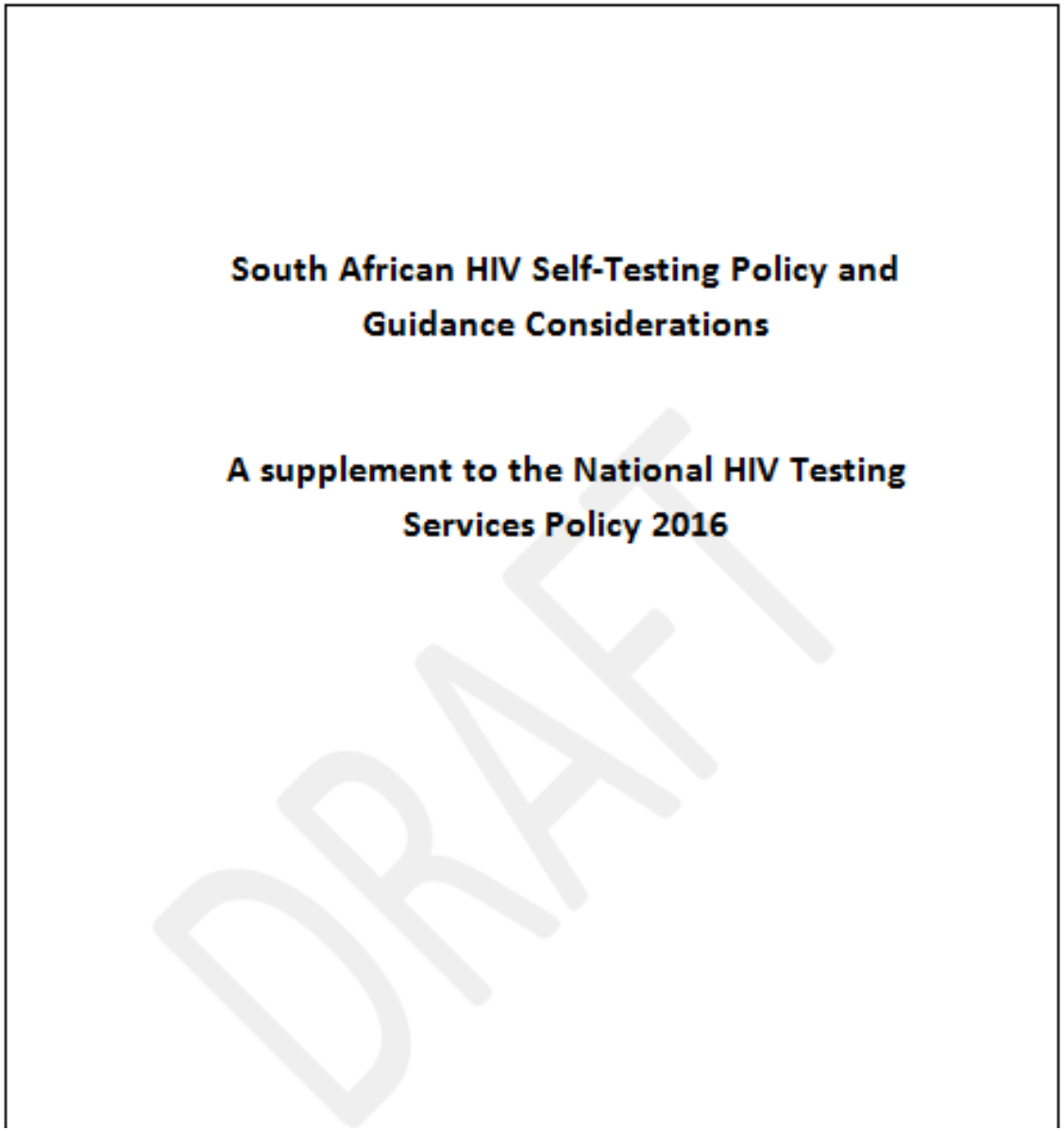
MRC

MSF

iTEACH

NDLOVU

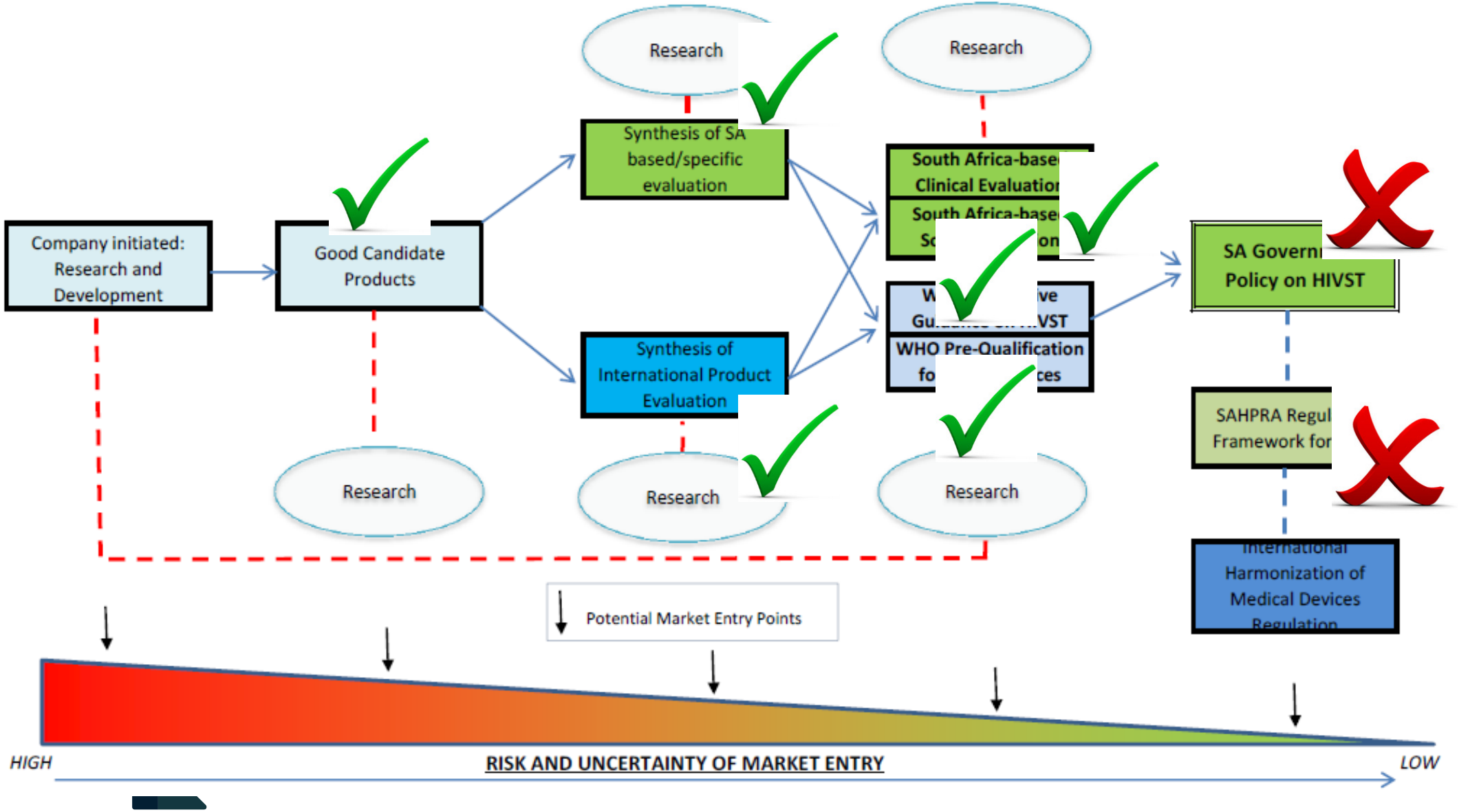
… others



SA Specific Guidance

- Guidance for Implementation
- Guidance to Manufacturers
- Implementation Messaging
- Provision for access to information through various mechanisms in the absence of counselling
- Support systems
  - Websites
  - Apps
  - Helpline
  - Social Media
- Post Marketing Surveillance

HIV Self-Testing landscape...6



HSTAR004

HIV Self-Testing: A supplementary strategy towards achieving the first 90 in inner city Johannesburg

- This programme addresses the following two interlinked problems:
  - Inadequate HIV testing options, with poor linkage to care
  - Inadequate testing of men, transgender, discordant couples and other key and under-tested populations
  - Using innovative Health Communication Platforms
  - Opportunity to pilot in proposed STAR populations

Distribution of HIV Prevention Packages that include:

HIV Self-test, Male and Female Condoms, Prevention pamphlets

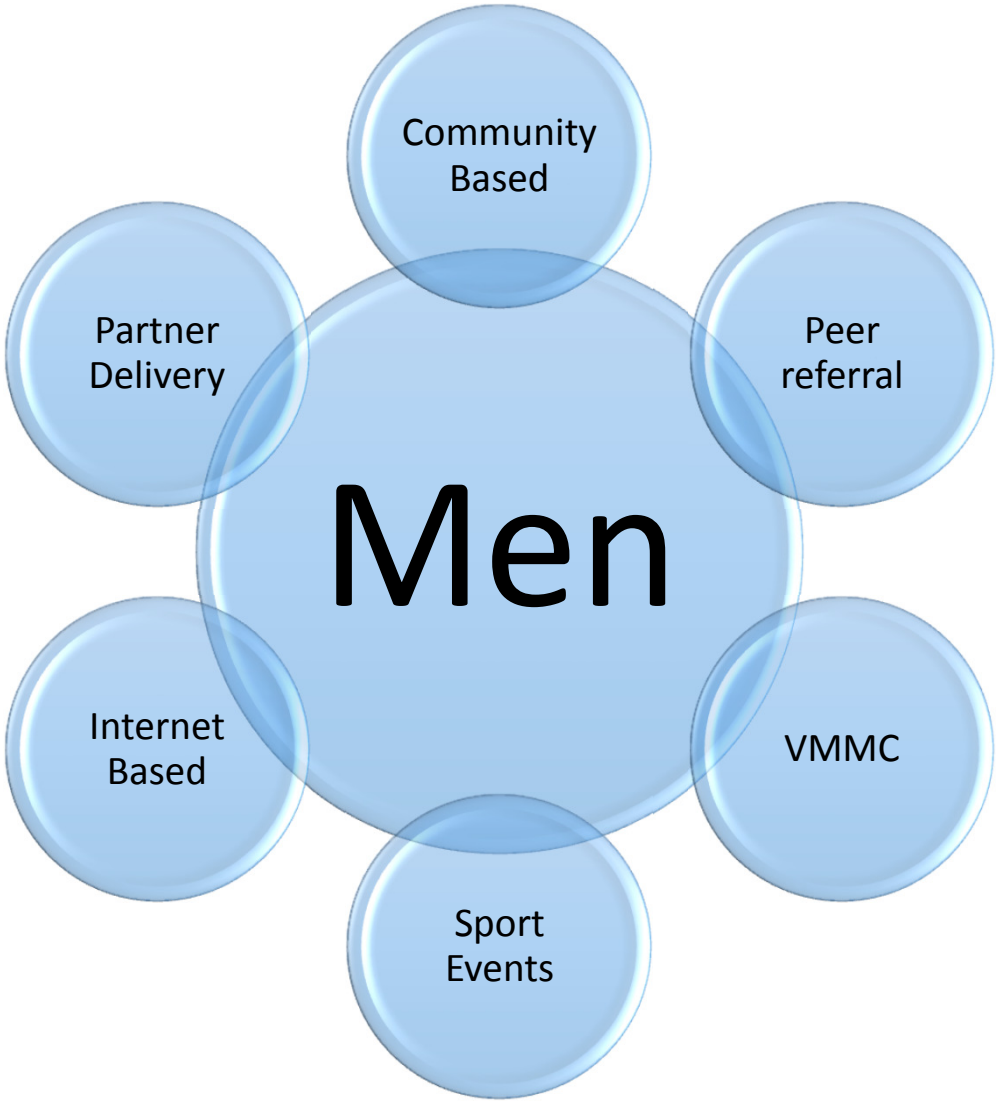
So who are the under-tested and high risk pop that we want to target

MEN

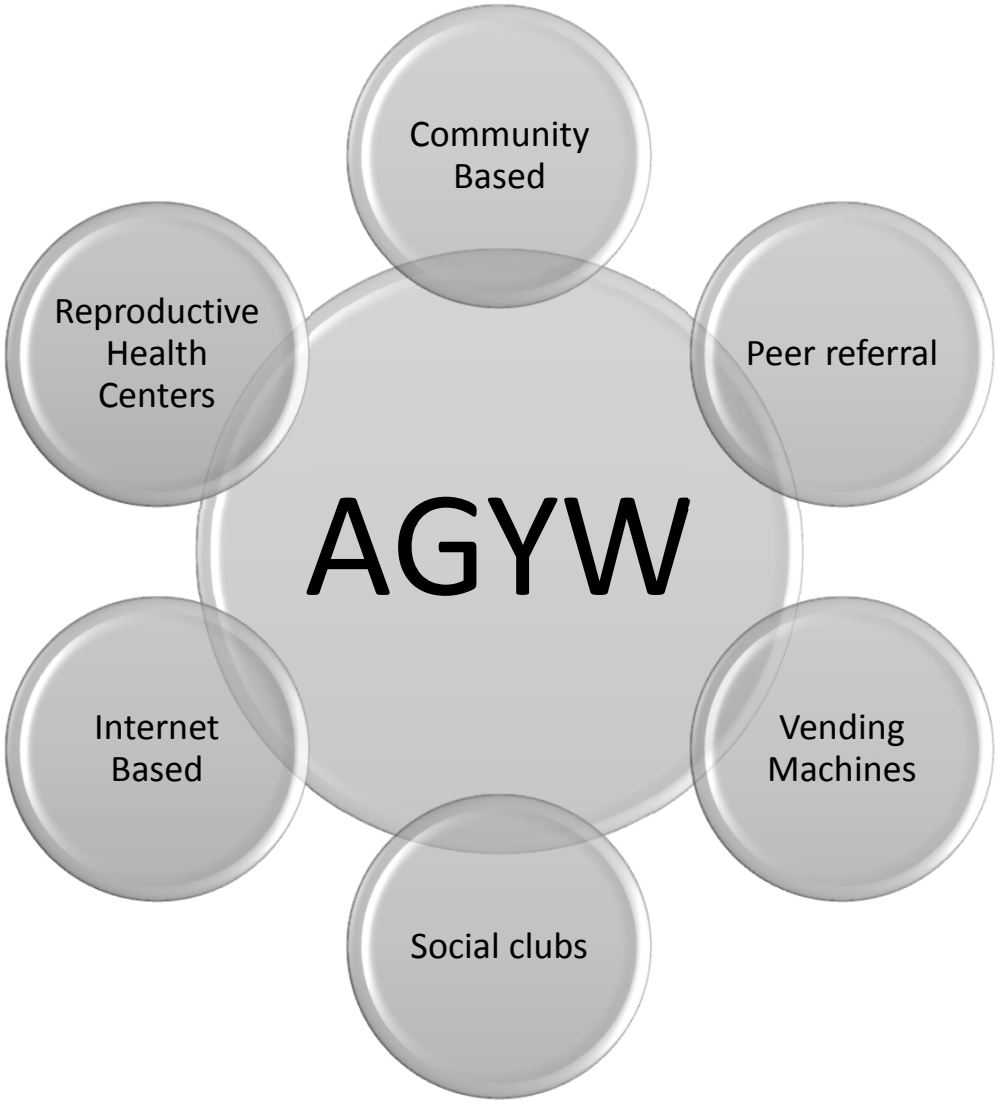
AGYW

KEY POPS: FSW, MSM, IDU, TRANSG

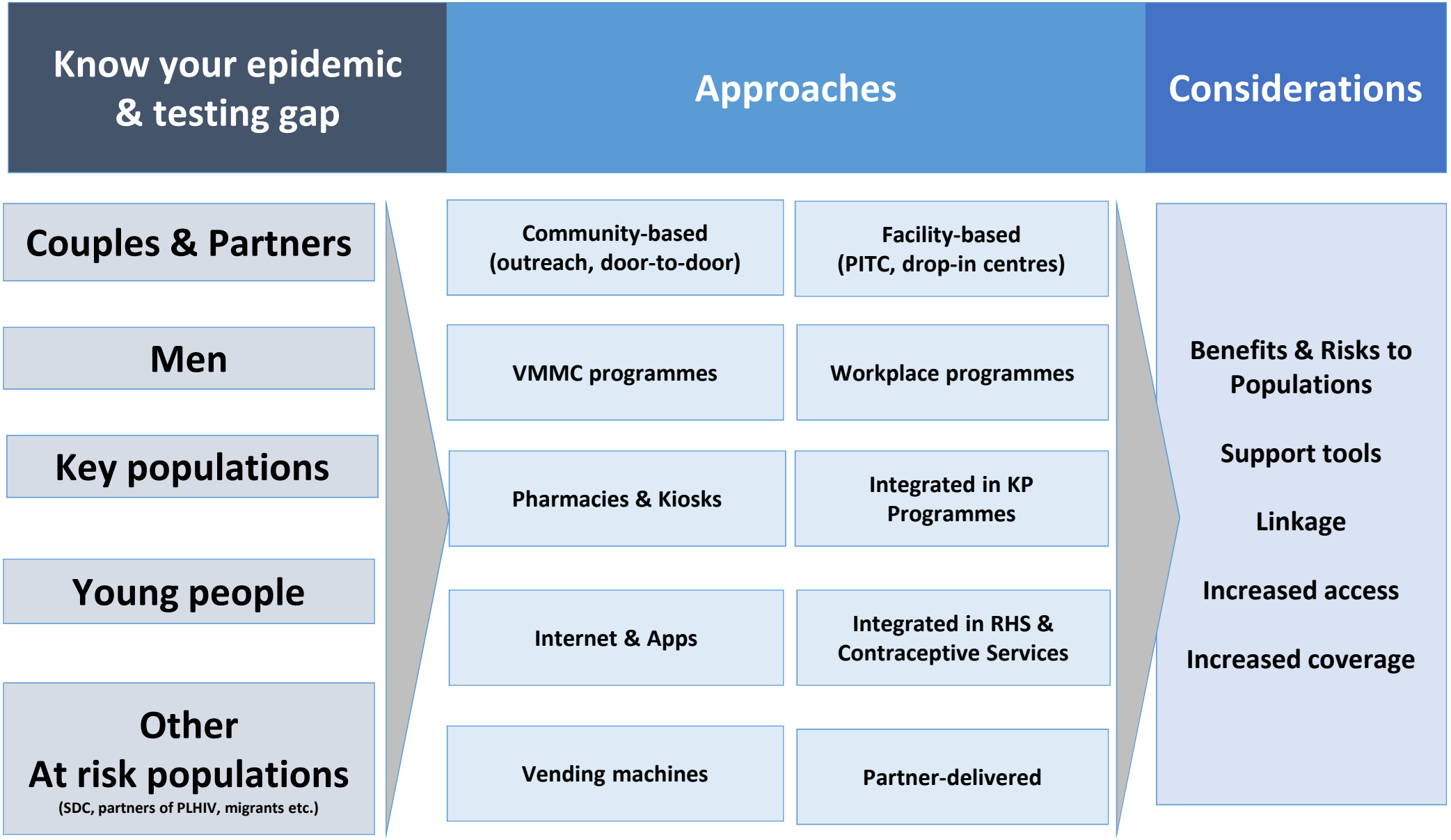
What would a Distribution Model look like? Men



What would a Distribution Model look like? Adolescent Girls Young Women



Where to Begin with HIV Self-Testing



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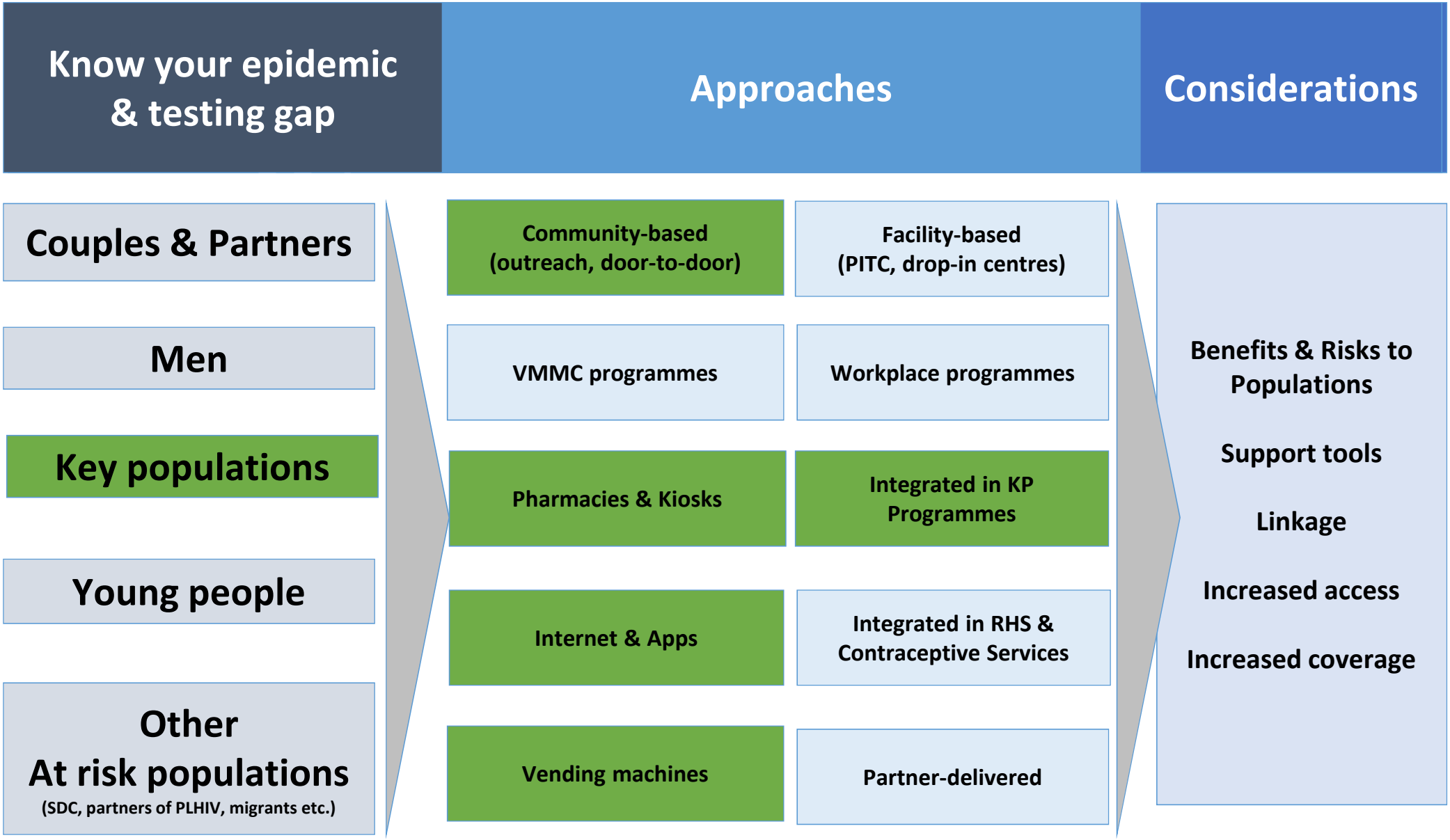

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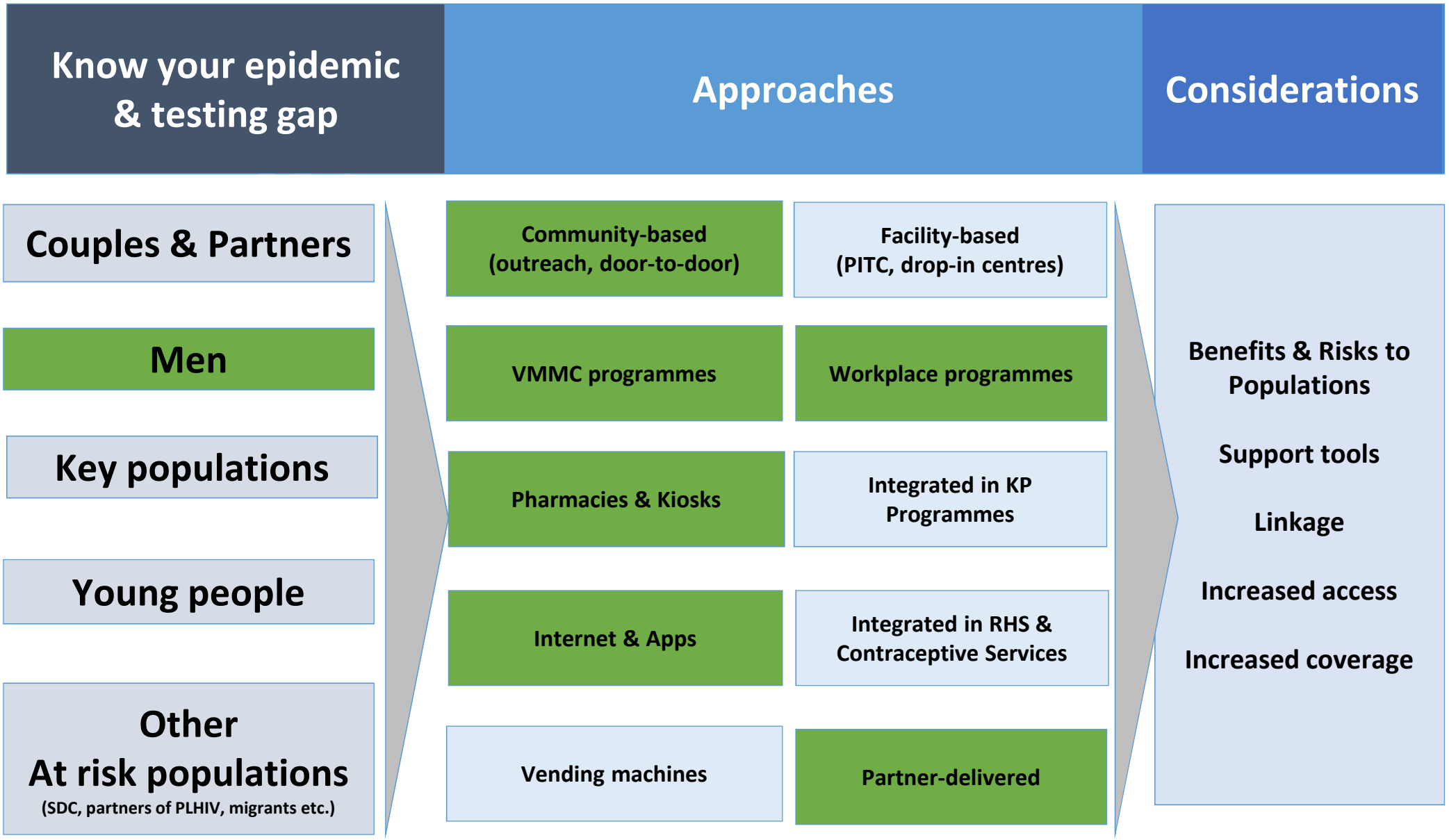

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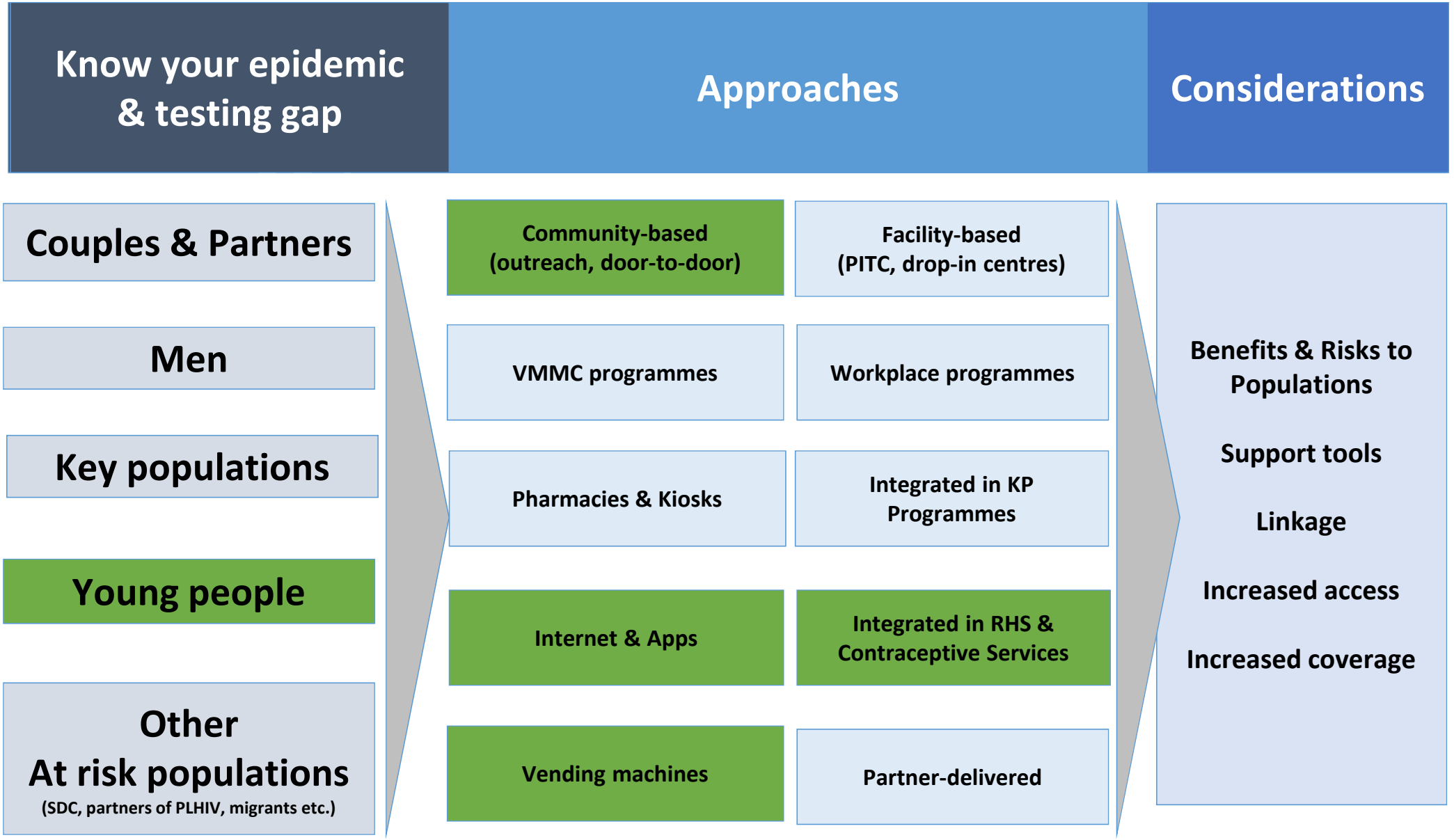


Policy and Advocacy

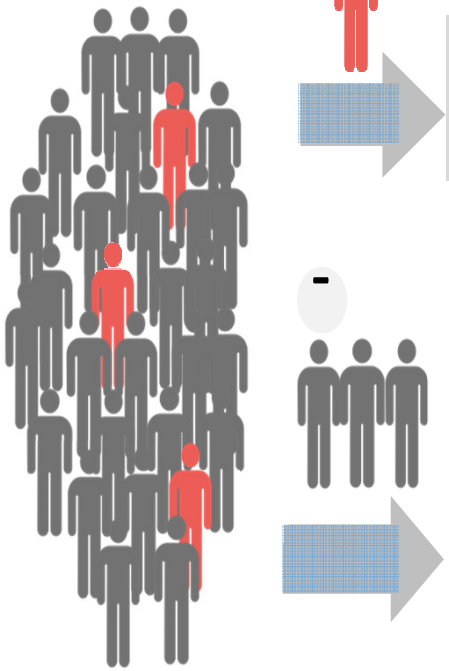
- South African Guidelines and TWG
  - Final Draft with WHO HIV Dept for review
- WHO TWG
- Engagement with Pharmacy Council and Pharmacy Groups
- TAC
- SANAC
- South African Stakeholder Symposium

WHAT STILL NEEDS TO BE DONE IN THE HIVST WORLD???

QUITE A BIT

HIVST PREP

- Acceptability
- Willingness to Pay
- Usability



DIRECT ACTION

- Link to Treatment
- Link to Prevention
- Triaged out of Health System

DIRECT IMPACT

- Health for PLHIV: Reduced Morbidity & Mortality
- Reduced HIV Transmission & Infections Averted
- Cost and Time Savings (Health System & Users)

ADDITIONAL IMPACT

Social & Economic

- Population Productivity & Growth
- Social Benefit Social Harm

Health Systems

- Efficiency
- Expanded Coverage
- Equity of Health

Evidence Available

DIFFERENT POPULATIONS → **DIFFERENT CONTEXTS** → **DIFFERENT GEOGRAPHIES**

To do list!

- Learn what distribution model works in which populations
- LINKAGE TO CARE!
- How do measure impact of HIVST on National numbers?
- Is this modality cost effective?
- Have we adequately addressed all the concerns of social harm?

STAR Phase 2

- Wits RHI, SFH, PSI and CHAI
- 2.2 million HIVST Kits over 3 years
- Test and research distribution models over the next three years to make both investment and operational implementation recommendations to NDOH

Finally

We don’t have all the answers yet, and we don’t profess a perfect science, but we are moving forward in a responsible and inclusive manner in the hopes of achieving a positive public health impact

Acknowledgements

- Dr Yogan Pillay and Dr Thato Chidarikire
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- UNITAID
- STAR Consortium

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