HIV Self-Testing in South Africa

MOVING FROM PRODUCT TO POLICY TO PROGRAMMES

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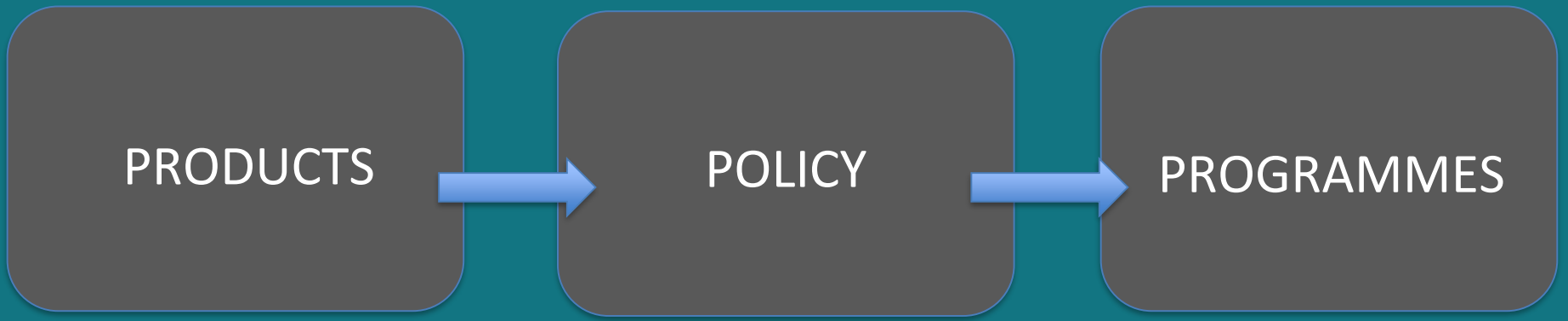
08.09.2017

AWAAC Conference

Elangeni Hotel

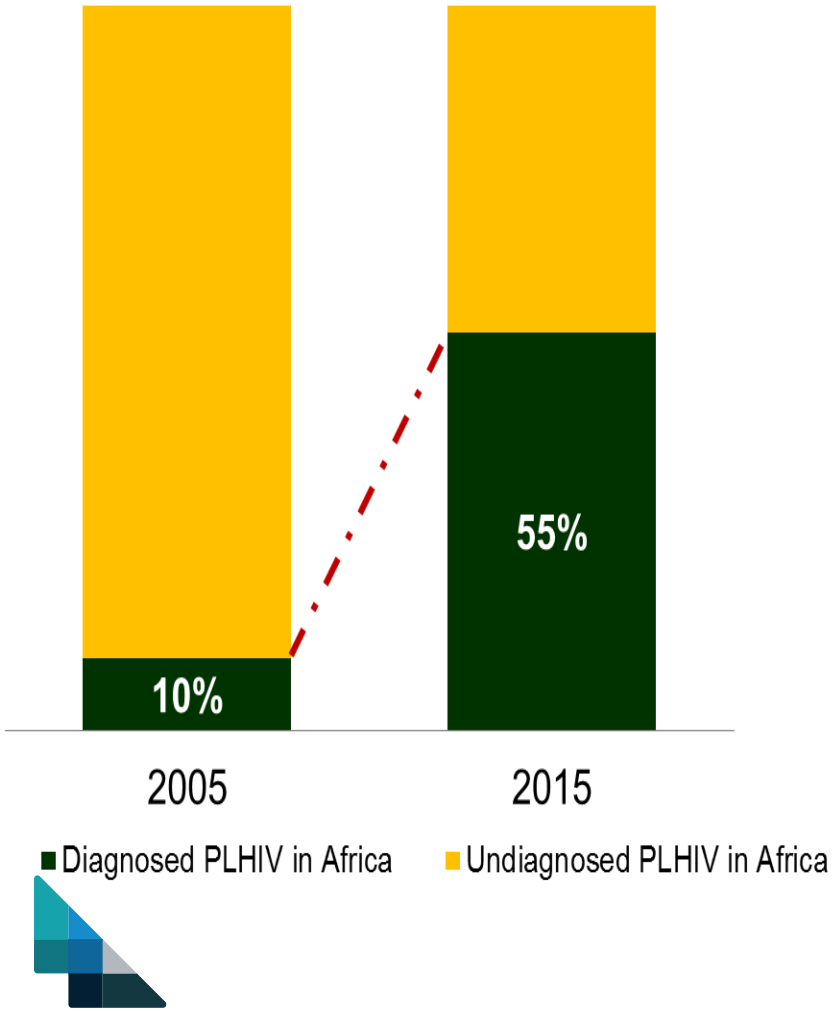
University of the Witwatersrand

WITS RHI


PRODUCTS
POLICY
PROGRAMMES

The perfect (HIV)STorm

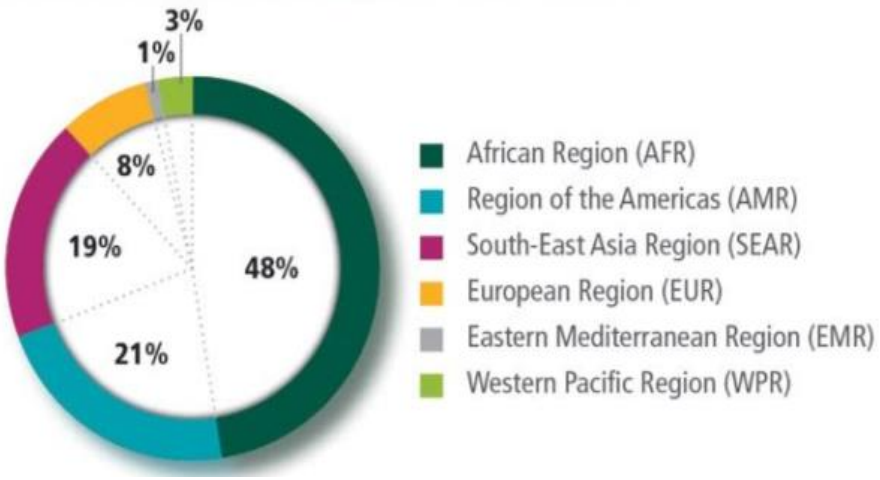
Scale-Up of HIV Testing Services



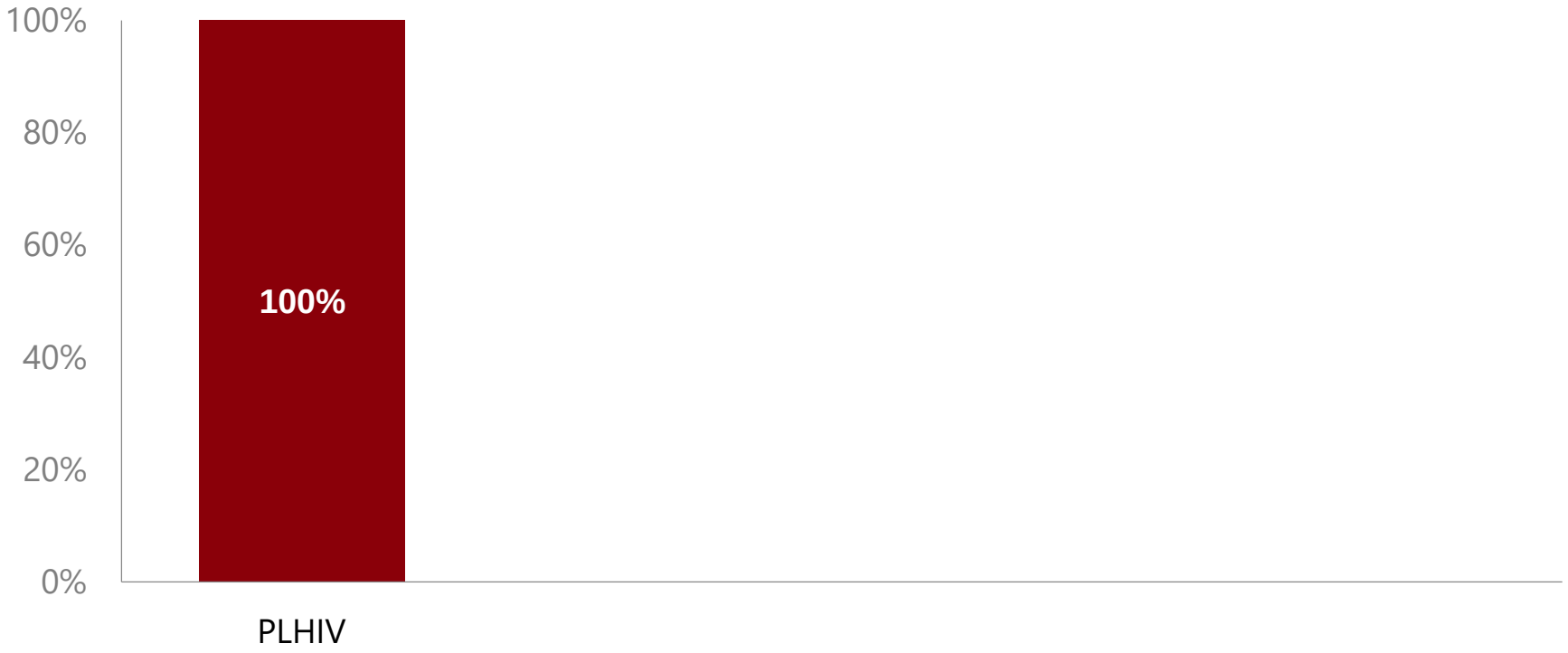
Source: WHO 2015; WHO 2016

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.

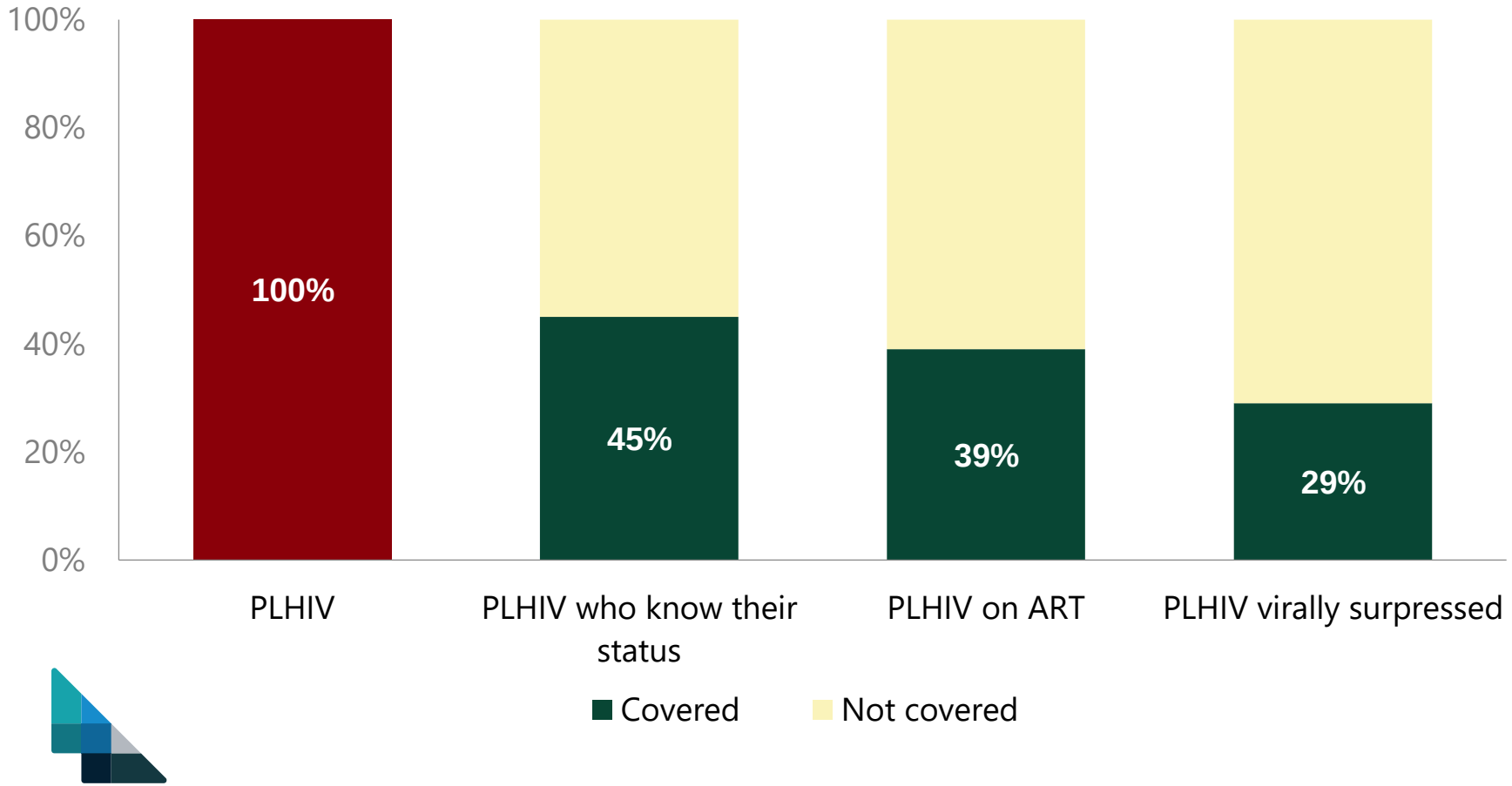


Why are we talking about HIV Self-Testing (HIVST)?



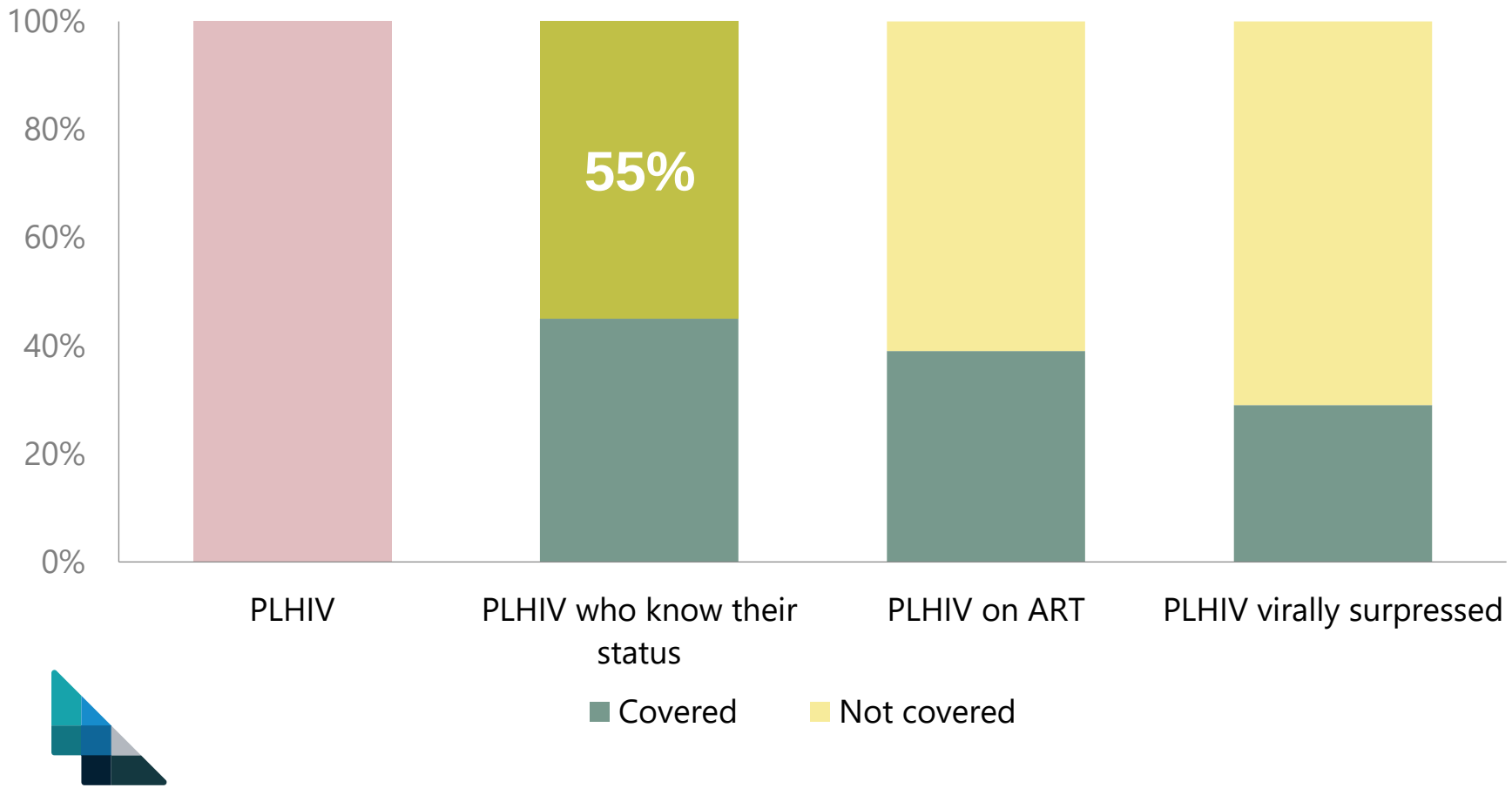
Source: UNAIDS, Gap report 2014

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



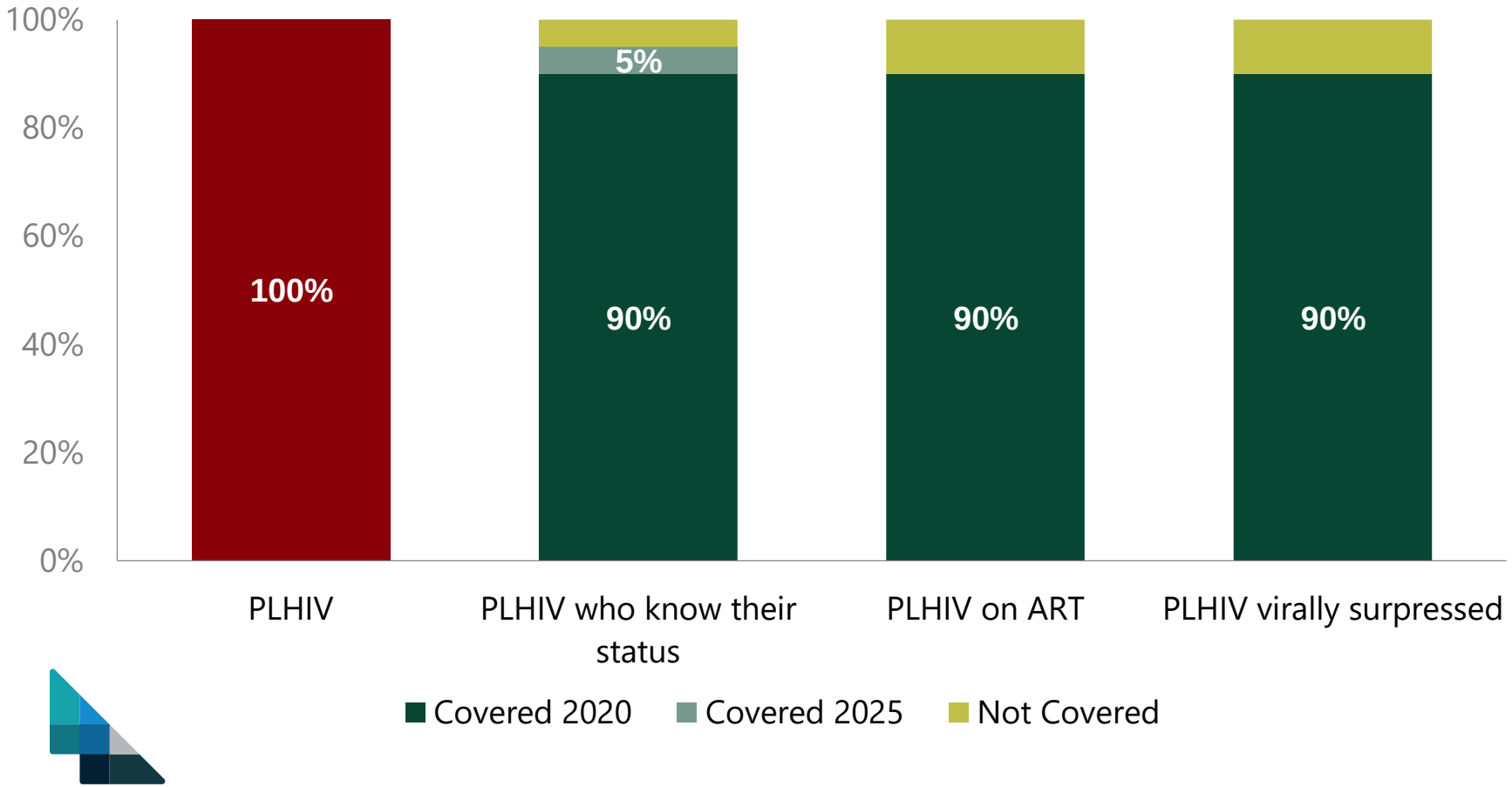
Source: UNAIDS, Gap report 2014

There is a testing gap.



Source: UNAIDS, Gap report 2014

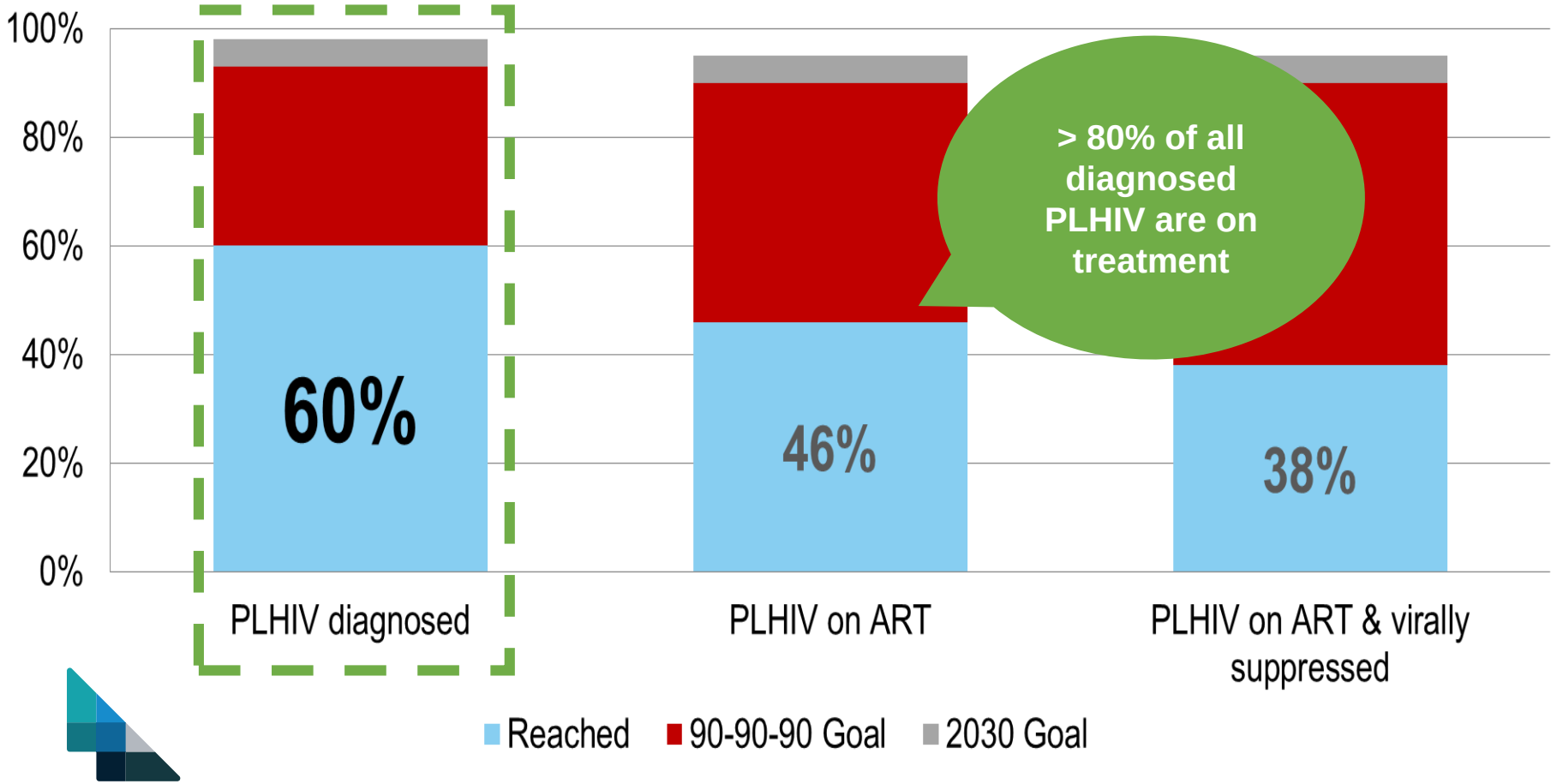
Proposed UNAIDS “90-90-90”



Source: UNAIDS, Ambitious treatment targets, 2014

Global Progress Toward the First 90, 2016

40% of PLHIV still remain undiagnosed worldwide



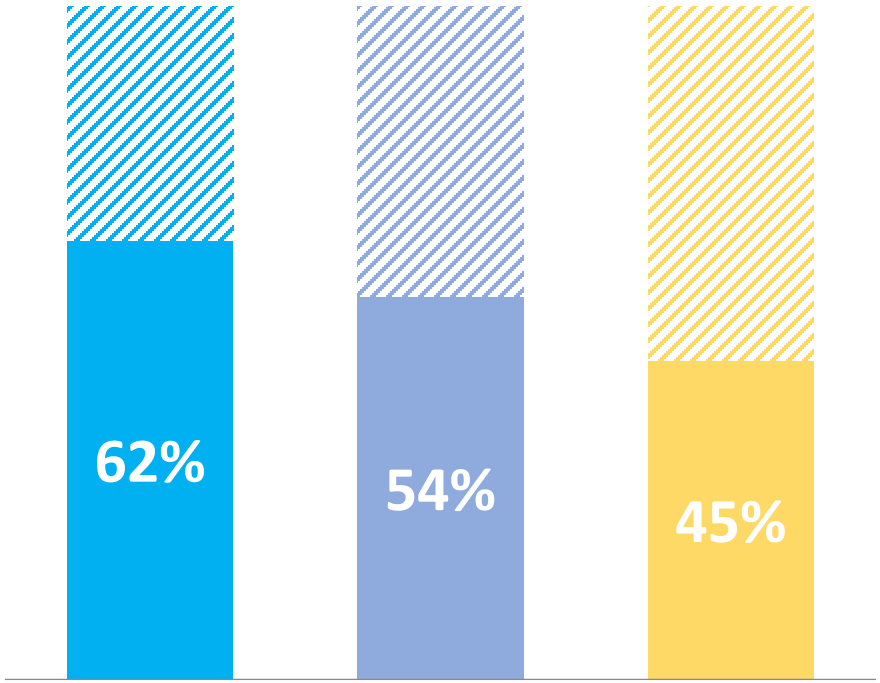
Source: UNAIDS, 2016 – based on 2015 measure derived from data reported by 87 countries, which accounted for 73% of people living with HIV worldwide; 2015 measure derived from data reported by 86 countries. Worldwide, 22% of all people on antiretroviral therapy were reported to have received a viral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

Update: UNAIDS Report 2017

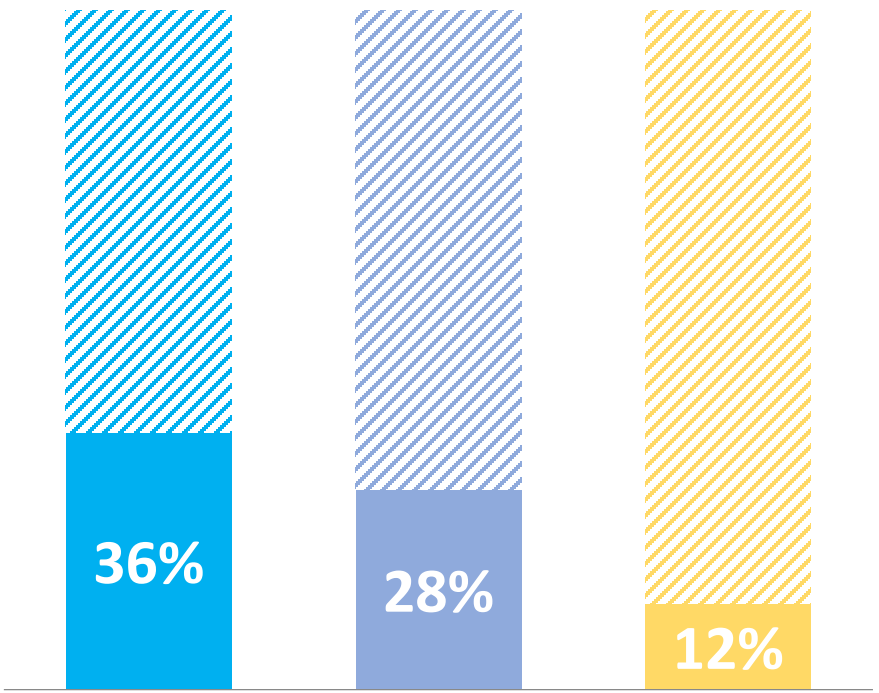
FIGURE 3.1. PROGRESS TOWARDS THE 90–90–90 TARGETS, GLOBAL, 2016

Source: UNAIDS special analysis, 2017; see annex on methods for more details.

Estimated progress toward the first 90 in the African Region, 2016



Eastern & southern Africa



Western & Central Africa

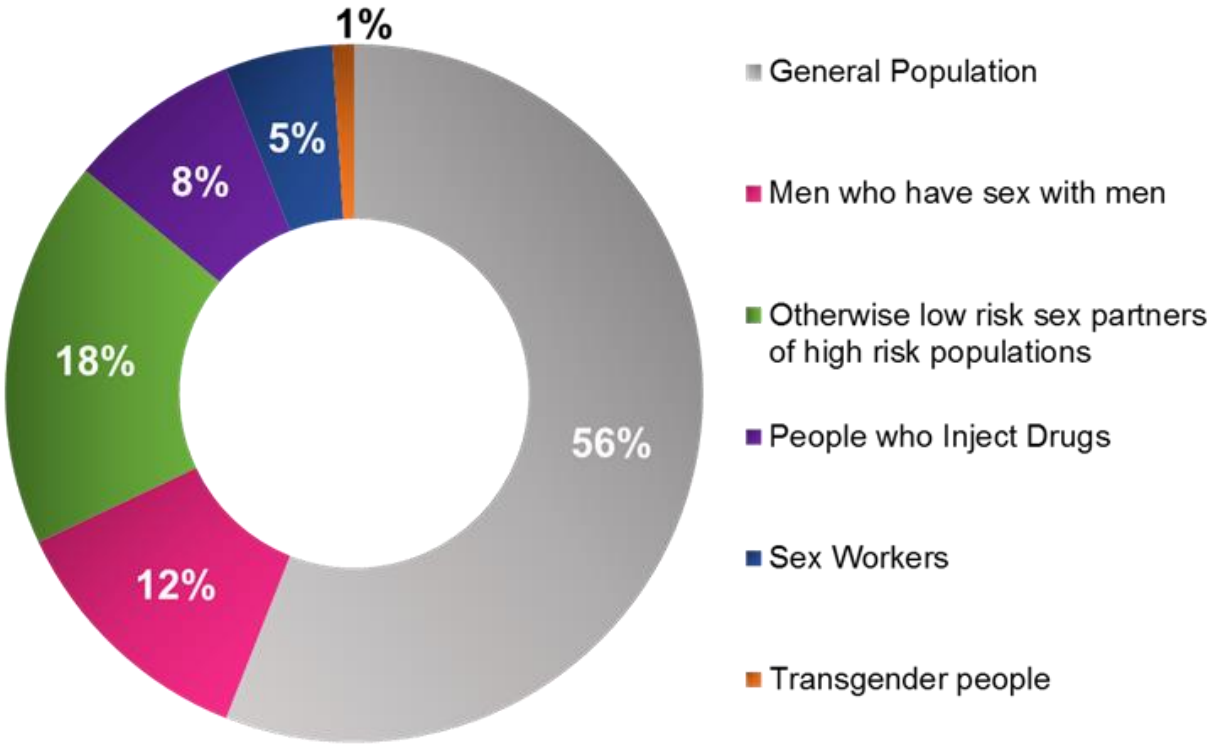
Source: UNAIDS, 2016

So who are we missing?

New adult HIV infections globally, 2016

~1.9 M new adult HIV infections in 2016

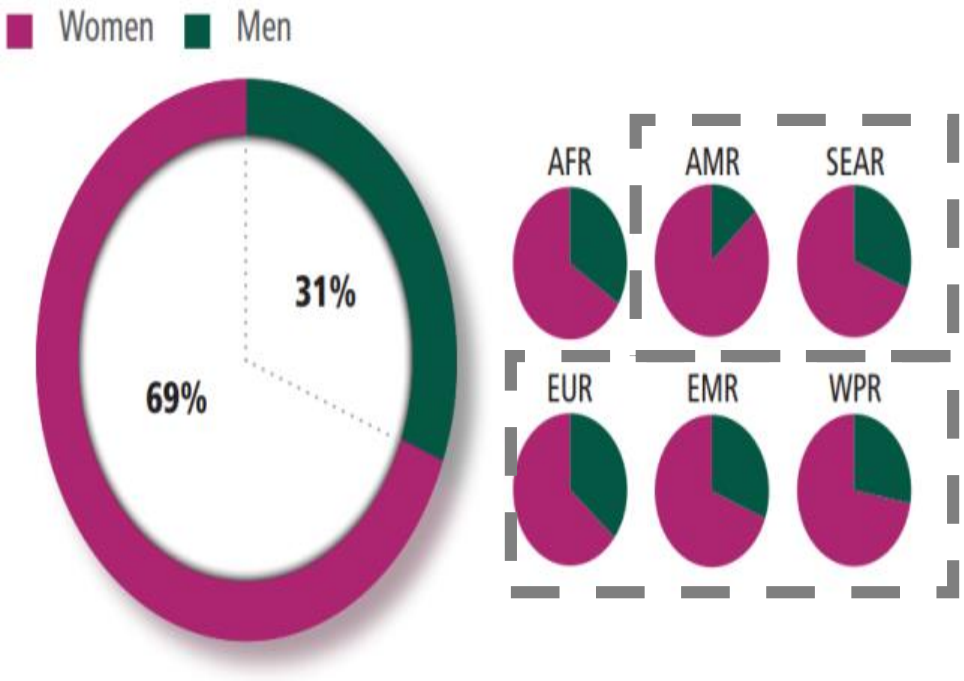
44% new HIV infections are among key populations and their partners



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

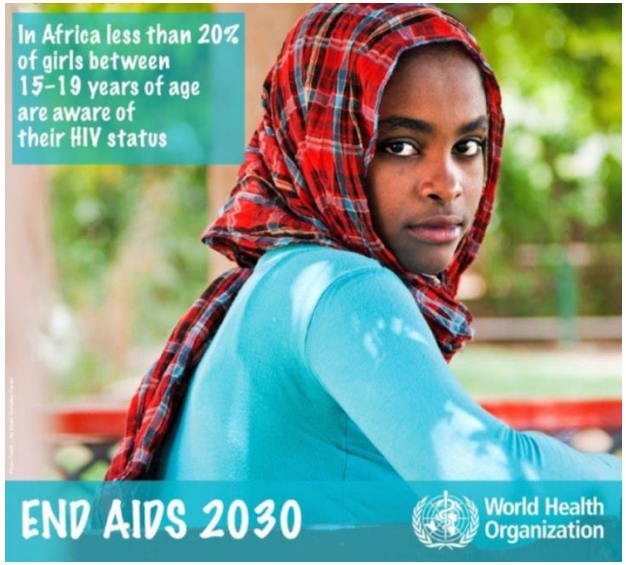
Women

Make Up Approximately 70% of Those Tested in 2015



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

Source: WHO 2015, 76 reporting low and middle income countries. Data is for populations 15 years of age and above.



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

Testing coverage is often low due to:

- Age of consent laws
- Structural barriers
- Unfriendly services
- Stigma and discrimination

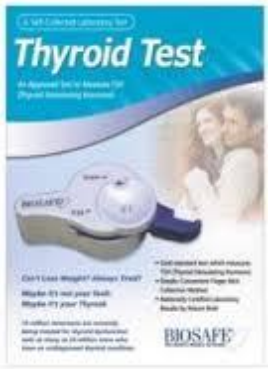
Innovation Needed to Close the Testing Gap

What is self-testing ?

Collects

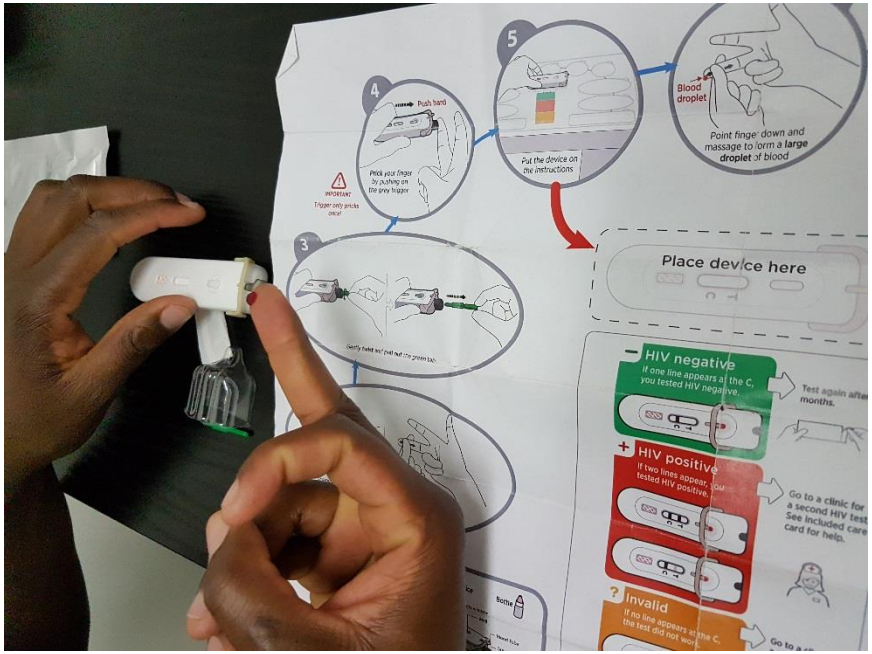
Performs

Interprets



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.
- WHO: HIVST is defined a “screening test” or Test for Triage



So what is HIV Self-Testing?

- 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.

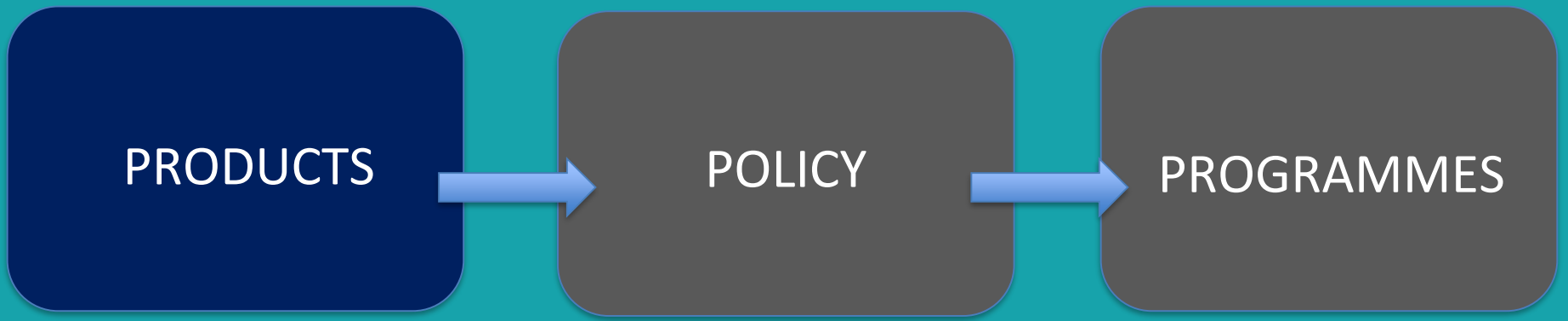
HIVST has been touted as a supplementary strategy to reach key and under-tested populations

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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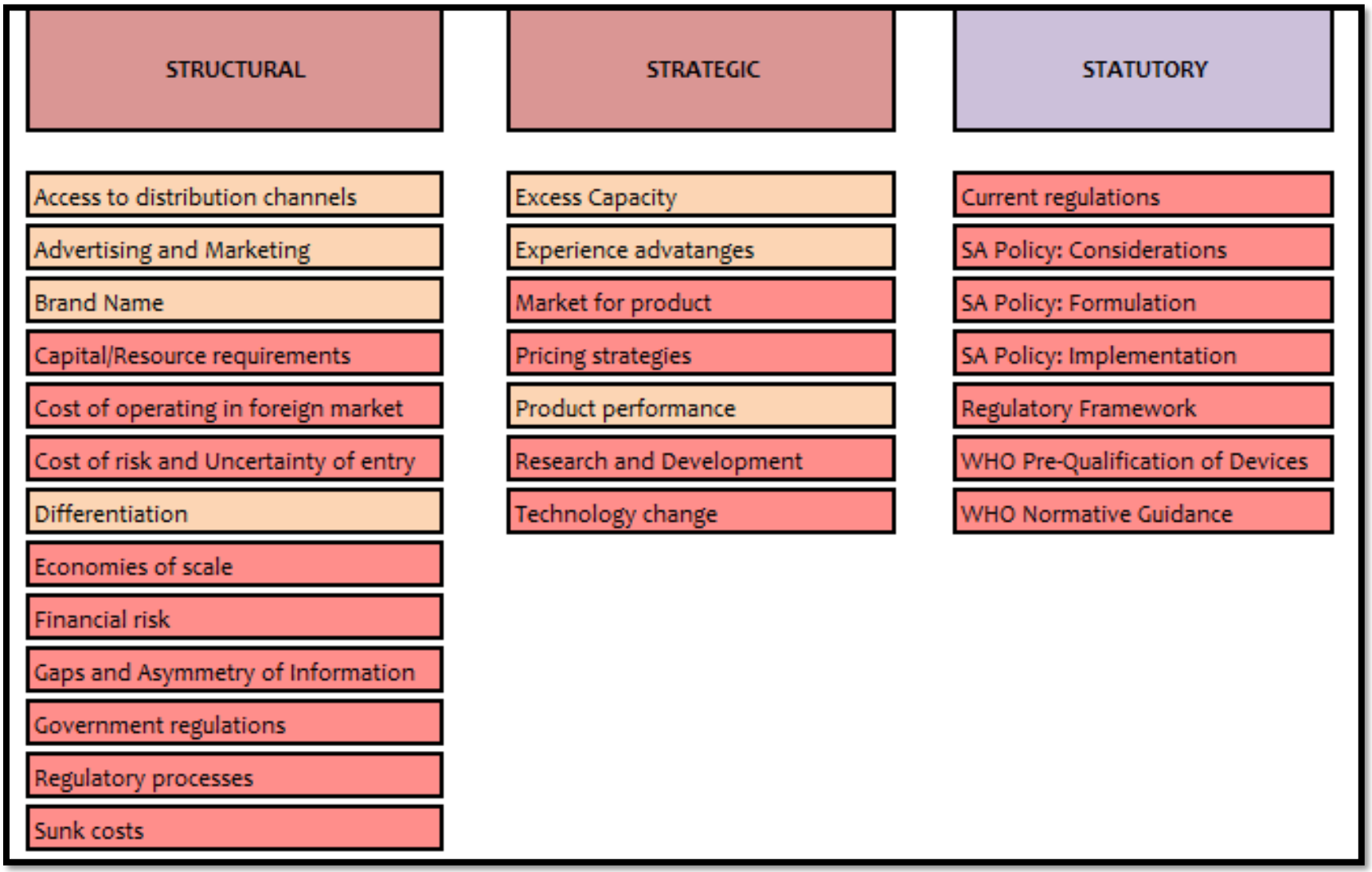
Market Entry Barriers for HIVST in SA



What has been the greatest barrier to market entry in SA?

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

- South Africa ~~does not~~ did not have a Medical Devices Regulatory Authority, or evaluation framework
- SAHPRA formally constituted 02 JUNE 2017

Wits RHI 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.

Product performance	***Implementation Res***	***Policy/Advocacy***
WHO PQ studies (Gates)	HSTAR004 (Aids Fonds)	WHO GDG
		SA TWG

Why 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?

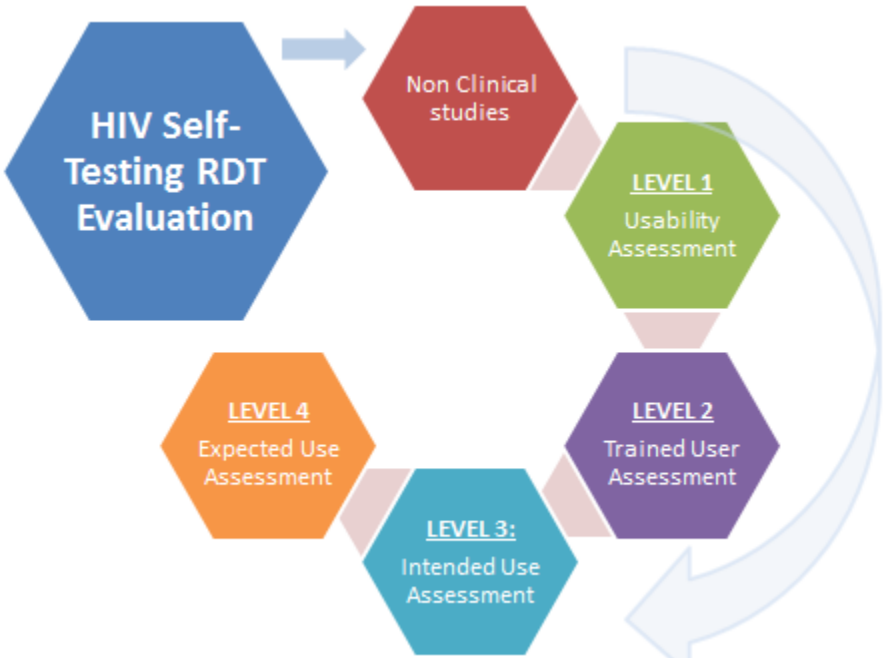
- The PQ decision is used by UN bodies and procurement agencies as a means for quality assuring IVDs/MD and other health products
- The PQ decision can be used by Member States without strong regulatory systems or with limited resources to provide assurance of quality, safety and performance
- The PQ decision is used by health implementing programmes to guide product selection

But PQ only finalised the TSS in Dec 2016

- The FDA had approved Orasure in 2012 after a lengthy, robust and intense evaluation process
- Biosure received CE marking in UK in 2015

- Using a combination of study designs from these two Regulatory Authorities, the programme was designed which was proposed to WHO PQ. The essence of the programme remained:
  - Usability of products
  - Label Comprehension
  - Mock Result interpretation
  - Product performance by Untrained Users vs Lab Gold Std

Programme designed to mirror PQ



WHO PREQUALIFICATION TEAM: DIAGNOSTICS

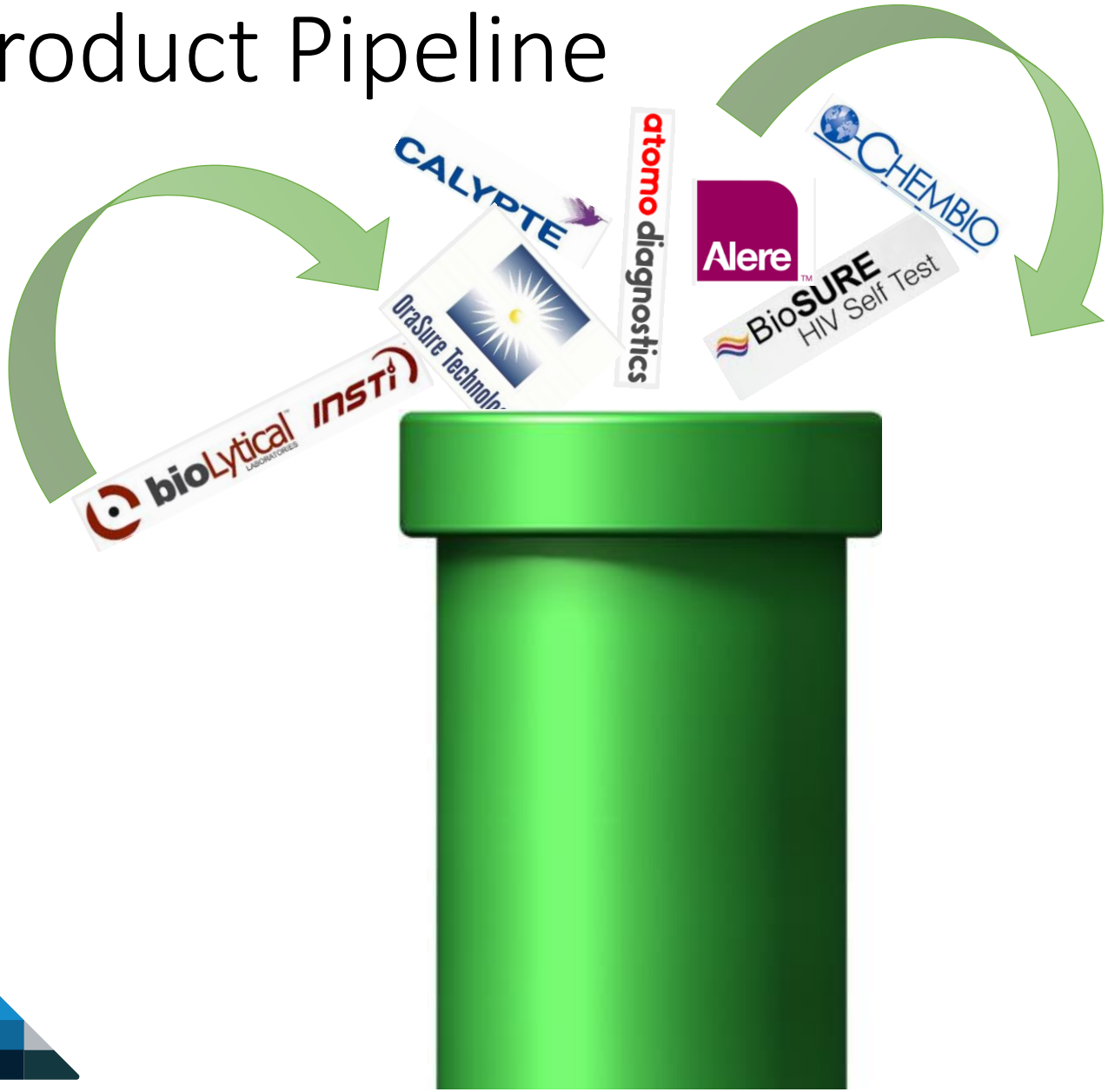
World Health Organization

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

MIRROR

Product Pipeline



HSTAR 001 – USABILITY ASSESSMENT

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

- gain data regarding the 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
- Usability / user interaction with the devices and accuracy of testing process
- Results interpretation (contrived results, no actual diagnosis will be made)

5 Devices: 3 Finger Stick, and 2 Oral Fluid

Table 1: Demographics of usability studies (N=200 for each device study, 5 devices total)

Gender	
Male	48-57%
Female	43-52%
Age Band	
18 – 25 years	19-33%
26 – 35	31-44%
36 – 45	15-32%
46 – 55	6-11%
56 – 65	1-6%
65+	0-1%
Education Level	
≤ Grade 7	30-33%
≥ Grade 8 to Grade 12	34-37%
Grade 12 +	33-34%

Nationality	
SA	63-70%
Zimbabwe	24-32%
Other	3-13%
Last HIV Test	
Tested in 2016	35%
Tested in 2015	23%
Tested in ≤2014	31%
Never	11%

1) Accuracy of testing process

- Participant provided test kit and instructions for use
- NO demonstration/familiarization provided
- Observer will record device specific step performance
- Tests were all mocks (no result conferred)

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%		

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.

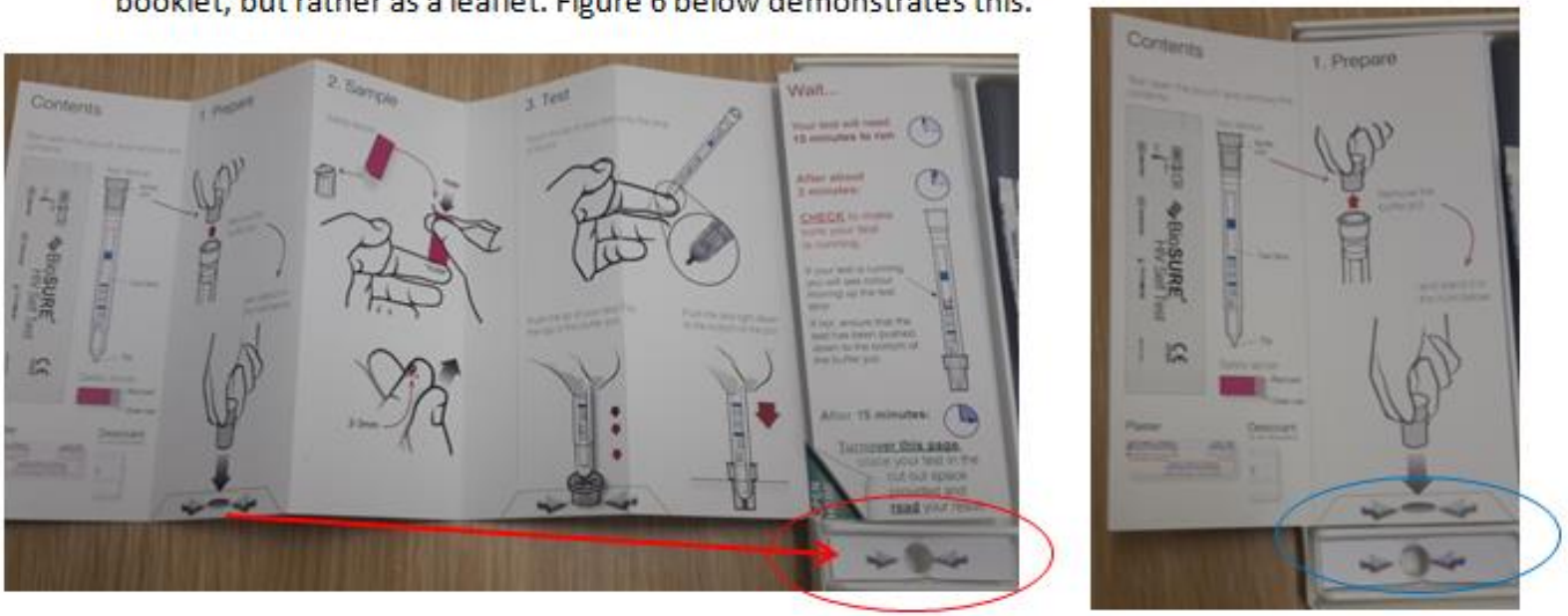


Figure 6: Opened as leaflet (left) vs. Opened as booklet (right)

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

Usability scores

Table 2: Key observer data for HIVST process

Observer checklist:	FS1	FS2	FS3	OF1	OF2
Did the participant read/use the IFU?	96.5%	100%	100%	100%	100%
Did the participant have any difficulty with the kit packaging?	11.5%	5%	1%	10%	1.5%
Was the participant able to obtain and transfer the specimen?★	79%	85.5%	63%	76%	97%
Did the participant quit the process at any point?	11%	0.5%	1.5%	0.5%	0%
Critical IFU steps completed	81.3%	96.3%	85.5%	87.5%	98.3%
All IFU steps completed	84.2%	97.3%	89.1%	91.3%	93.6%

★ Since mock devices were used to assess the product in terms of each process step individually, we could not ascertain whether under- or over loading of the specimen would result in a actual result being obtained

Types of errors

- Critical errors were noted when participants had difficulty obtaining and transferring the specimen
- For the FS devices, the most common sampling errors including:
    - lancing the thumb instead of finger,
    - not acquiring enough of a blood droplet, or
    - not filling the transfer capillary to the fill mark.
    - There were several cases where the lancet was not pressed firmly against the finger, resulting in a too-shallow cut. Notably, many of the “quits” were because of lancet misfire.
- For the OF devices, the most common sampling errors came from placing the sample collector in the mouth instead of moving/swiping, or inserting the wrong end of the collector.

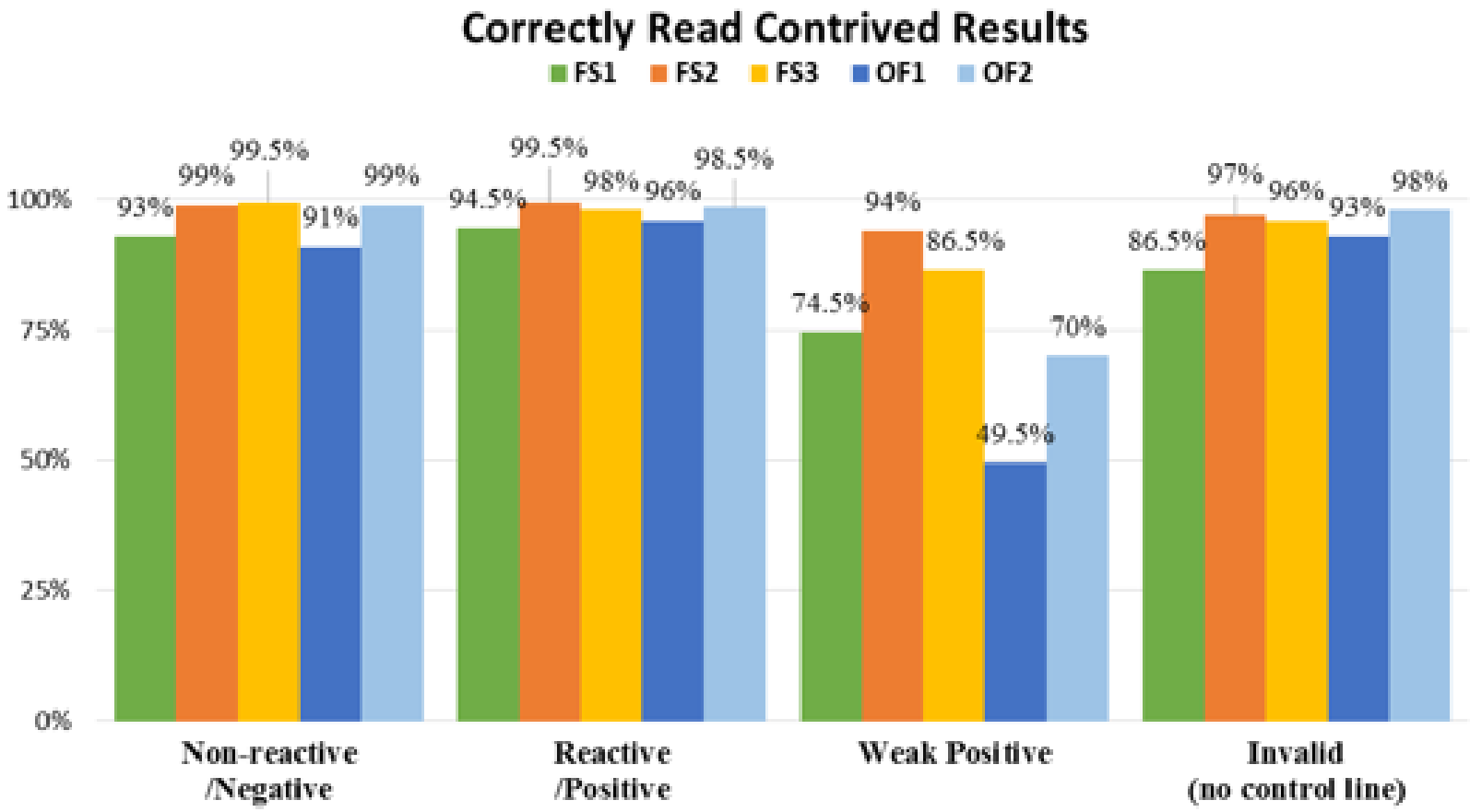
2) Interpretation of contrived results

- To evaluate the participant's ability to read and interpret the device results, contrived tests were provided by each manufacturer to represent the four possible test outcomes:

1) non-reactive/negative,
2) reactive/positive,
3) weak positive, and
4) invalid (no control).

- Participants were provided with all four contrived devices (serially, in random order) to interpret each result

Interpretation scores



Observations

- Participants achieved the best result interpretation when the test device could be placed next to "life sized" examples of the possible test outcomes in the IFU.
- Overall, participants could correctly interpret the non-reactive/negative and reactive/positive results accurately for each of the devices.
- For the weak positive result, some devices were contrived darker and easier to read, others were quite faint – there was no universal standard for intensity of a weak positive. Most of the weak positive errors were called as non-reactive/negative.
- The invalid test result was called correctly in most cases, but for some participants this was a new and confusing concept, and several of the invalid tests were marked as "not sure."

3) Label Comprehension

- How long should you wait before reading the test?
- What is the maximum time to read the result?
- How should you dispose of a used test kit?
- What should you do if you have a negative/non-reactive result?
- What should you do if you have a positive/reactive result?
- What should you do if you have an invalid result?
- What should you do if you do not know/unsure of your result?

Results

Table 3: Participant responses for what to do after HIVST

	FS1	FS2	FS3	OF1	OF2
What should you do if you have a non-reactive/negative result?					
Re-test in 3 months	29.5%	81%	81%	51%	82.5%
Condomize	43.5%	13%	16%	22.5%	17.5%
Other (no answer, partner test, celebrate)	27%	6%	3%	27%	0%
What should you do if you have a reactive/positive result?					
Visit clinic/seek treatment/counselling	94.5%	99%	99.5%	94%	100%
Other (condomize, re-test, stress, acceptance)	5.5%	1%	0.5%	6%	0%

Observations

- Most of the IFUs provided simple recommendations for test results with the pictured examples, such as “go to clinic” for a reactive/positive result, and “re-test in 3 months” for a non-reactive/negative result.
- Some IFUs did not include recommendations for the non-reactive/negative test result, and the corresponding study participants had a higher percentage of “other” responses, suggesting the value of a clear IFU recommendation in lieu of a detailed explanation about the window of seroconversion.
- In the “other” category, some participants provided an emotional response: celebrate if good news (negative test result), with stress or acceptance if bad news (positive test result).

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 . (UNASSISTED HIVST)

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

CONFIRMATORY DATA COMPARISON

		CONFIRMATORY TEST (EIA + DNA)	
HIV SELF TEST		Positive	Negative
	Positive	76	3
	Negative	0	321

		RDT ALGORITHM	
HIV SELF TEST		Positive	Negative
	Positive	76	3
	Negative	0	321

Sensitivity and Specificity Calculation

True Positive	76
False Negative	0
True Negative	321
False Positive	3
SENSITIVITY	100%
SPECIFICITY	99.1%

FIRST WHO PQ DEVICE

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

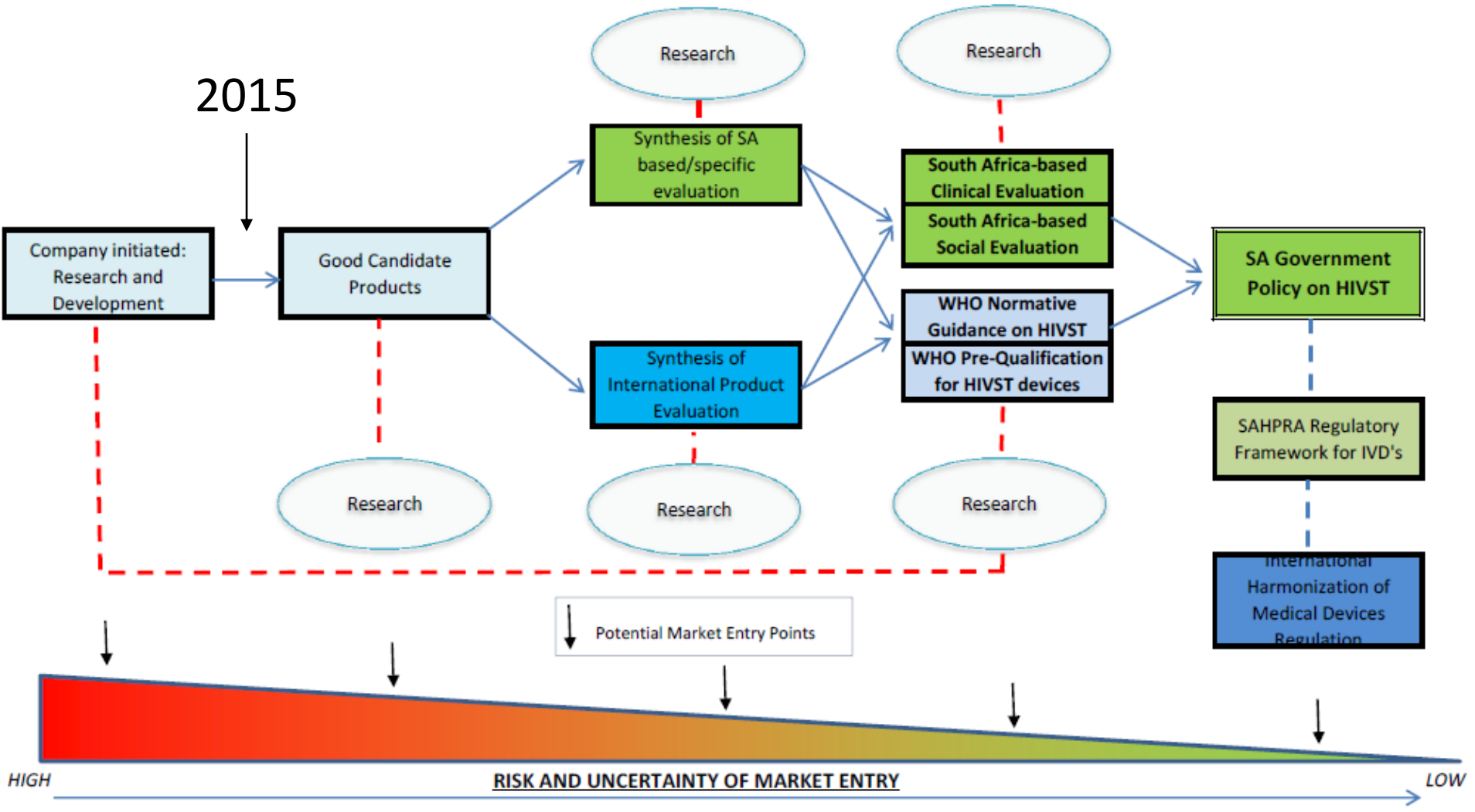

PRODUCTS
POLICY
PROGRAMMES

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)

HIVST Regulatory Pathway



Barriers? What barriers?

GREY ZONE

Public health vs Private Sector Strategies

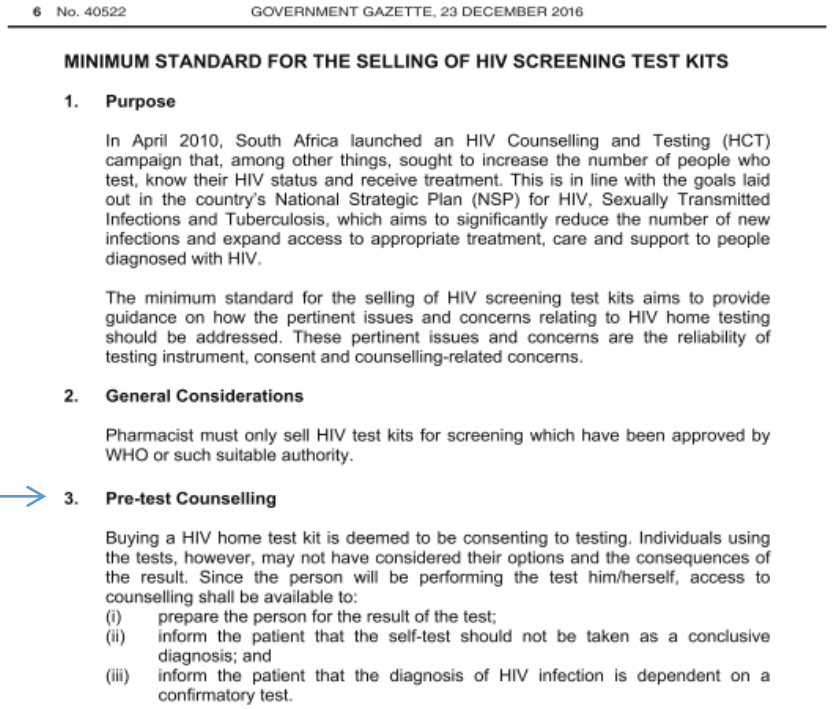
South African Pharmacy Council ruling

(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

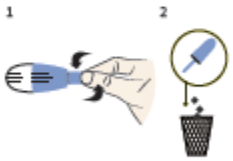
PREPARATION

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.

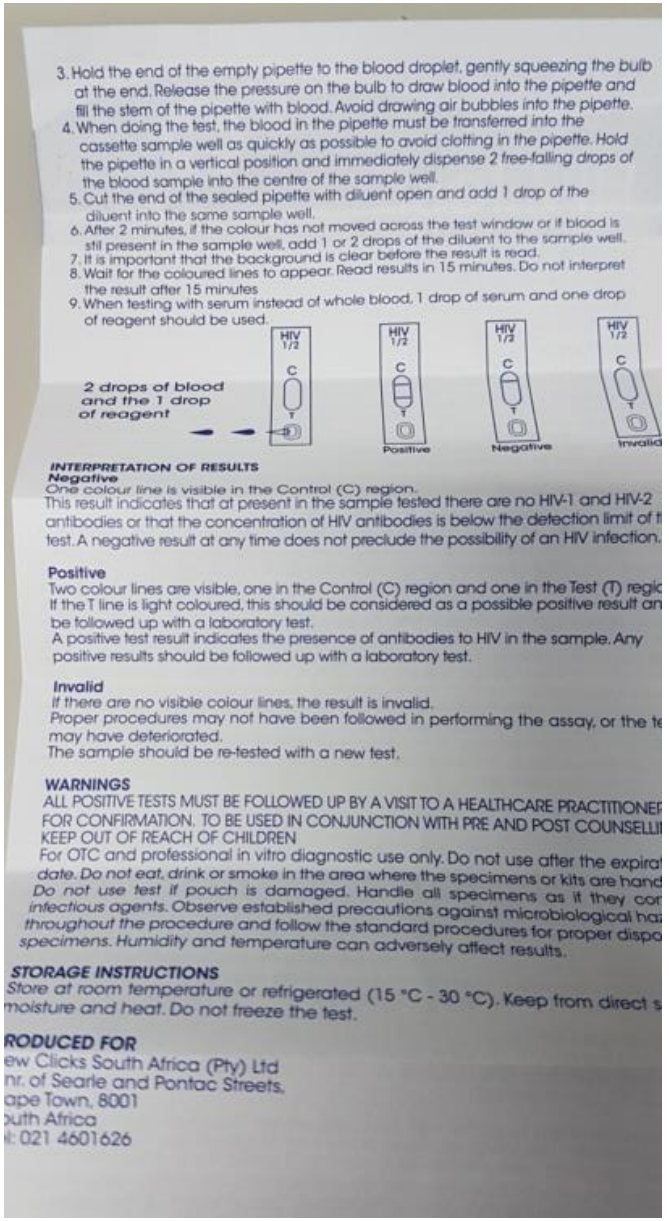
2. Rub finger until warm.

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) regio If the T line is light coloured, this should be considered as a possible positive result an 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 te 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 COUNSELLI
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 s moisture and heat. Do not freeze the test.

RODUCED FOR
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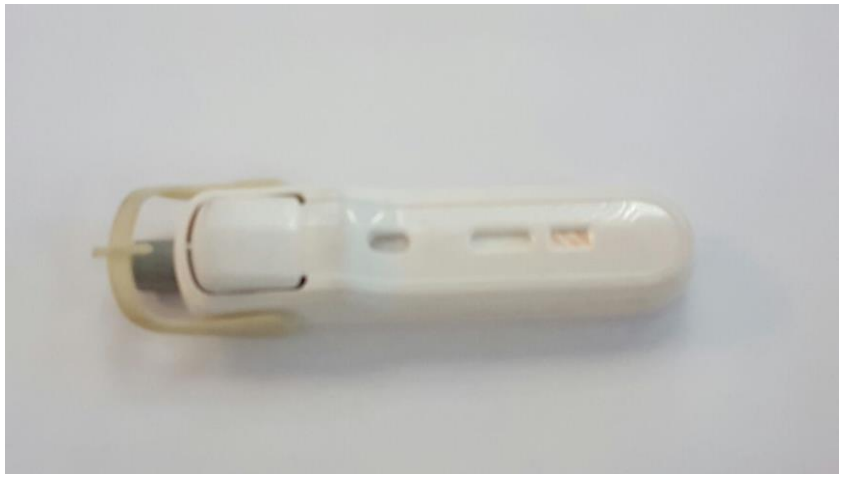
nr. of Searle and Pontac Streets,
ape Town, 8001
outh Africa
: 021 4601626

ST manufacturers have brought innovation to a stagnant industry



All in one test

Flow through technology
Results in seconds

National Dept of Health Supportive

- HIVST included in the National HTS Policy 2016
- Supplement to HTS 2016 on HIVST
- HIVST included in the NSP 2017 – 2022
- Minister of Health included HIVST in his IMC slides in Feb 2017

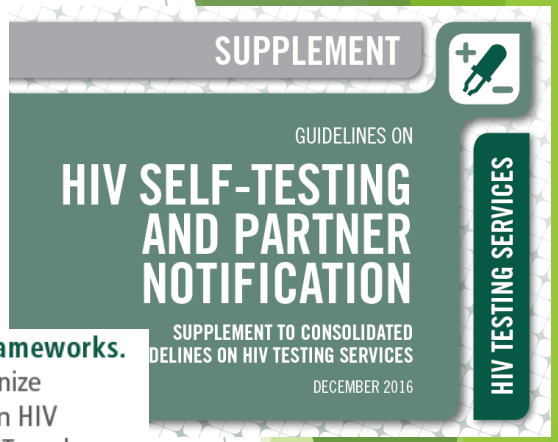
Guideline:
South African HIV Self-Testing Policy and Guidance Considerations

A supplement to the National HIV Testing Services Policy 2016

A publication of the Southern African HIV Clinicians Society

WHO Guidelines – Dec 2016

- Launched on 1st December 2016
- Recommendation:



Recommendation NEW

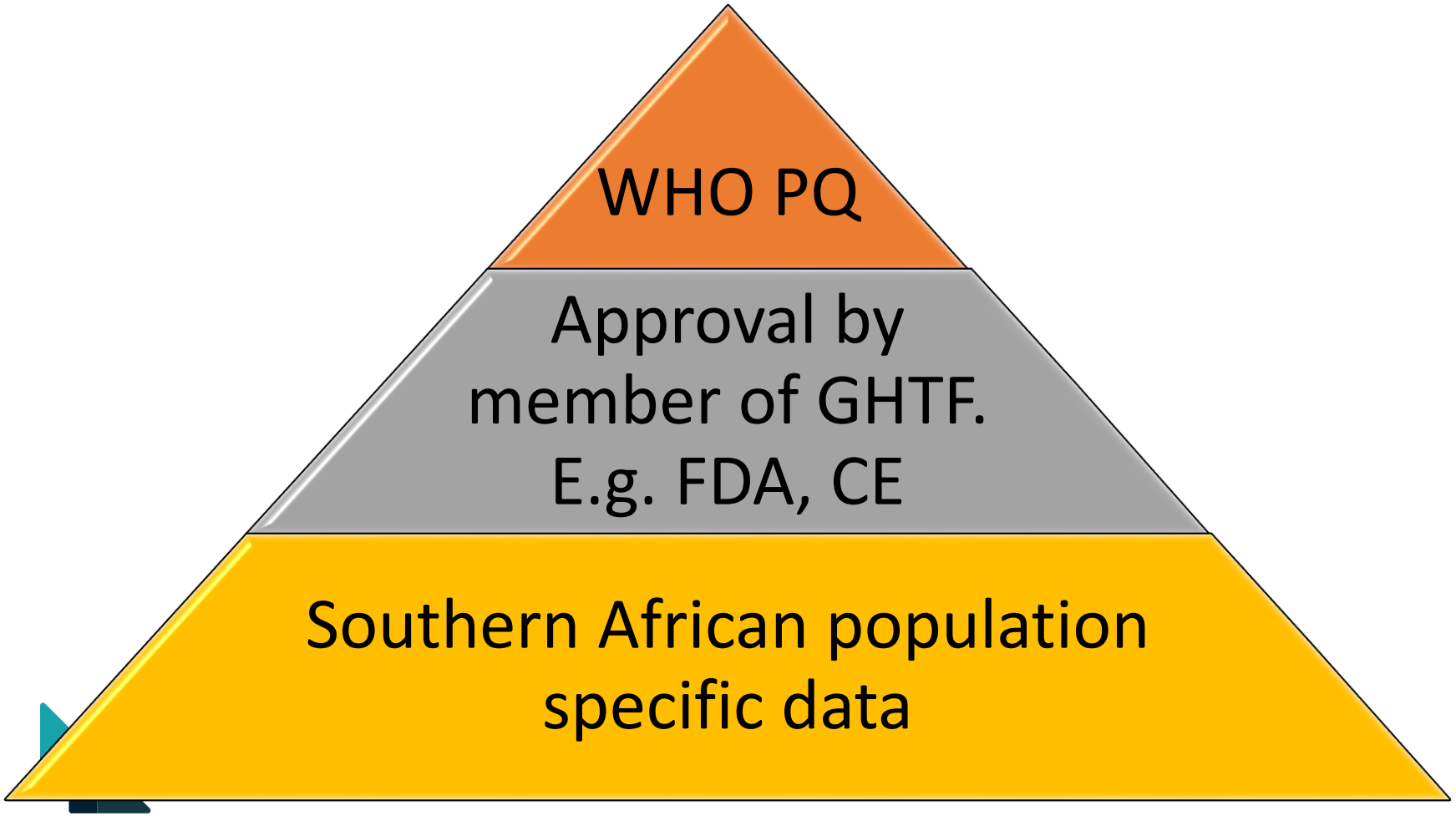
HIV self-testing should be offered as an additional approach to HIV testing services.

[STRONG RECOMMENDATION, MODERATE QUALITY OF EVIDENCE.]

- Urged member countries to "Adapt, develop and harmonize existing national policies on HIV testing to incorporate HIVST
  - Included use of Quality assured products
  - Consent and rights
  - Confirmatory algorithms
  - QA and Post Marketing Surveillance

- **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.

Pyramid of requirements



Key points from the Guidelines

- The need for appropriate, validated, clear and concise instructions for use. This is critical in terms of the products usability to ensure that critical errors are minimised and accuracy is maximised.
- Instructions for use and packaging materials must be translated and available in local languages, as well as English
- Clear messaging: Users must understand that a reactive/positive result must be confirmed through further testing by a health care worker as well as where to access services
- Manufacturers should include a “care card” with the packaging which the user can take to a local clinic as evidence of having self-tested. Care card information should include the DoH logo, the contact details for the National Aids Helpline, the HIV self-testing website (www.hivselftesting.co.za) and/or the manufacturer’s website that can provide any additional information on linkage to care as needed.

Key points from the Guidelines…cont

- All products must ensure on the basis of a conformity assessment certificate issued by a Conformity Assessment Body, a body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body recognized by the Medicines Control Council, according to a standard as determined by the Council
- Post Marketing Surveillance and lot number tracking to ensure device failures can be reported, lot numbers may be recalled and manufacturing quality can be assured. All kits must clearly show the expiry date of the product.
- All HIVST devices must provide disposal instructions and disposal supplies e.g. sealable plastic bags

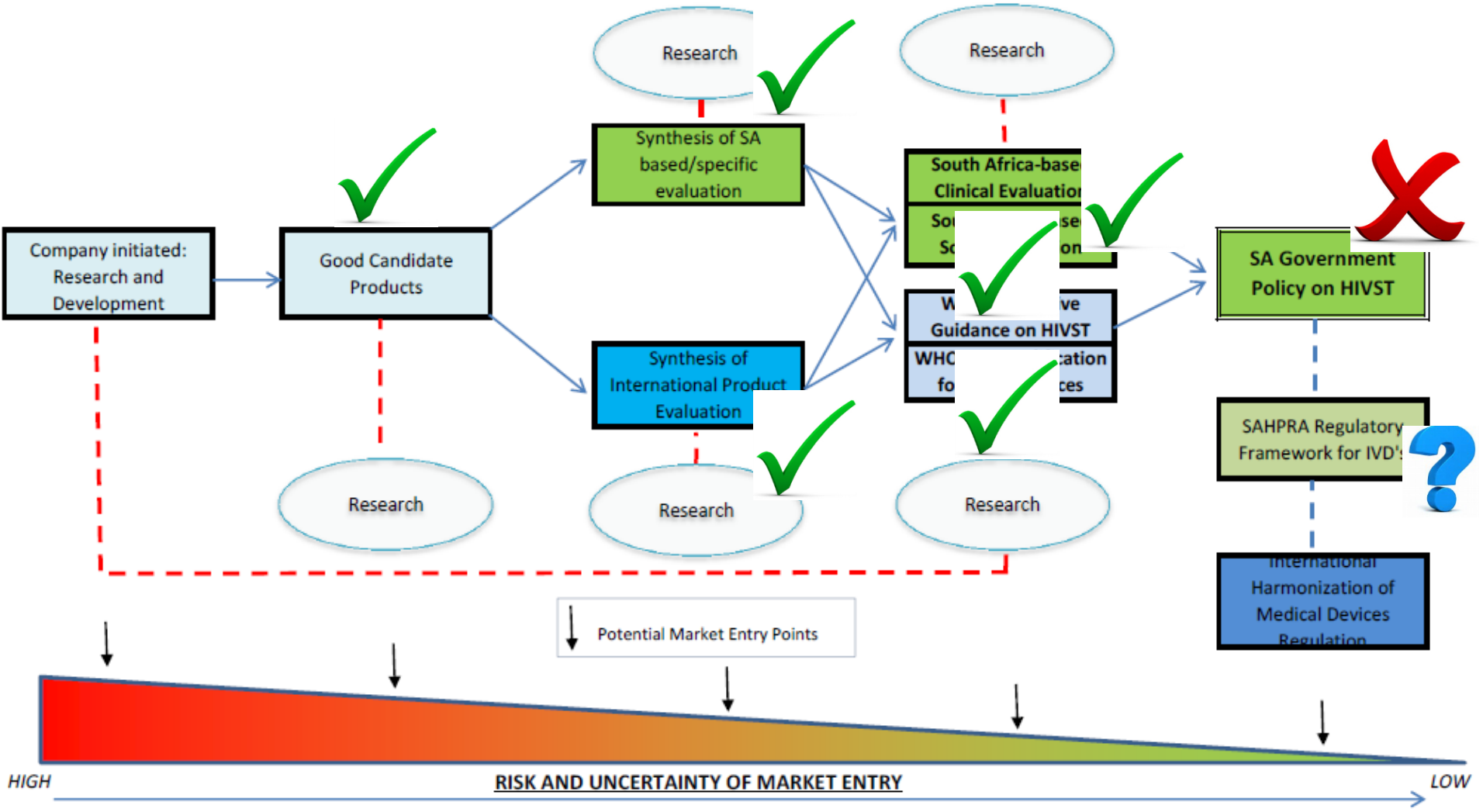
HIVST IMPLEMENTATION

- **IMPLEMENTATION CONSIDERATIONS**
  - There are several models through which HIVST may be delivered, and will depend on the target population:
  - These would include Primary Health Care facilities, Hospitals and pharmacies. Less traditional access points could be through internet distribution, workplace programmes, and Vending machines. In terms of community based outreach Self-Testing can be offered as part of a package to clients visiting PrEP facilities, VMMC, Sexual and reproductive health centres, Outreach TB/STI clinics, and campaign multi-diseases.
  - Secondary distribution includes Peer-to-peer and Couples and partners

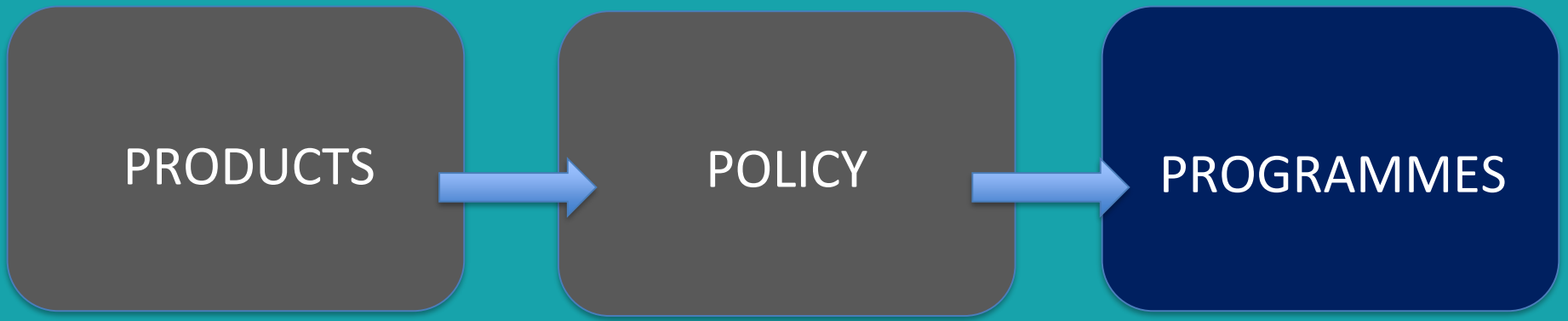
- Within the spectrum of channels for distribution of HIVST, there are also varying levels and type of support that can be offered to self-testers.
  - The following tools can be utilised for assistance or demonstration:

  Pictorials, Videos, Hotlines, Apps, Multimedia, SMS

HIV Self-Testing landscape…6



2017


PRODUCTS
POLICY
PROGRAMMES

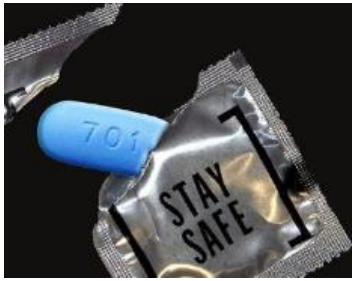
So who are the under-tested and high risk pop that we want to target

MEN

AGYW

KEY POPS: FSW, MSM, IDU, TRANSG

HIVST Service Delivery Approaches



Pharmacy-based

Community-based *(door-to-door)*

Internet-based

Workplace programmes

Partner-delivered

PrEP programmes

Integrated *(e.g. VMMC, TB, STIs, reproductive health)*

Facility-based *(pick-up/self-test on site)*

Vending machines and kiosks

STAR Phase 2

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

HIV SELF-TESTING AFRICA

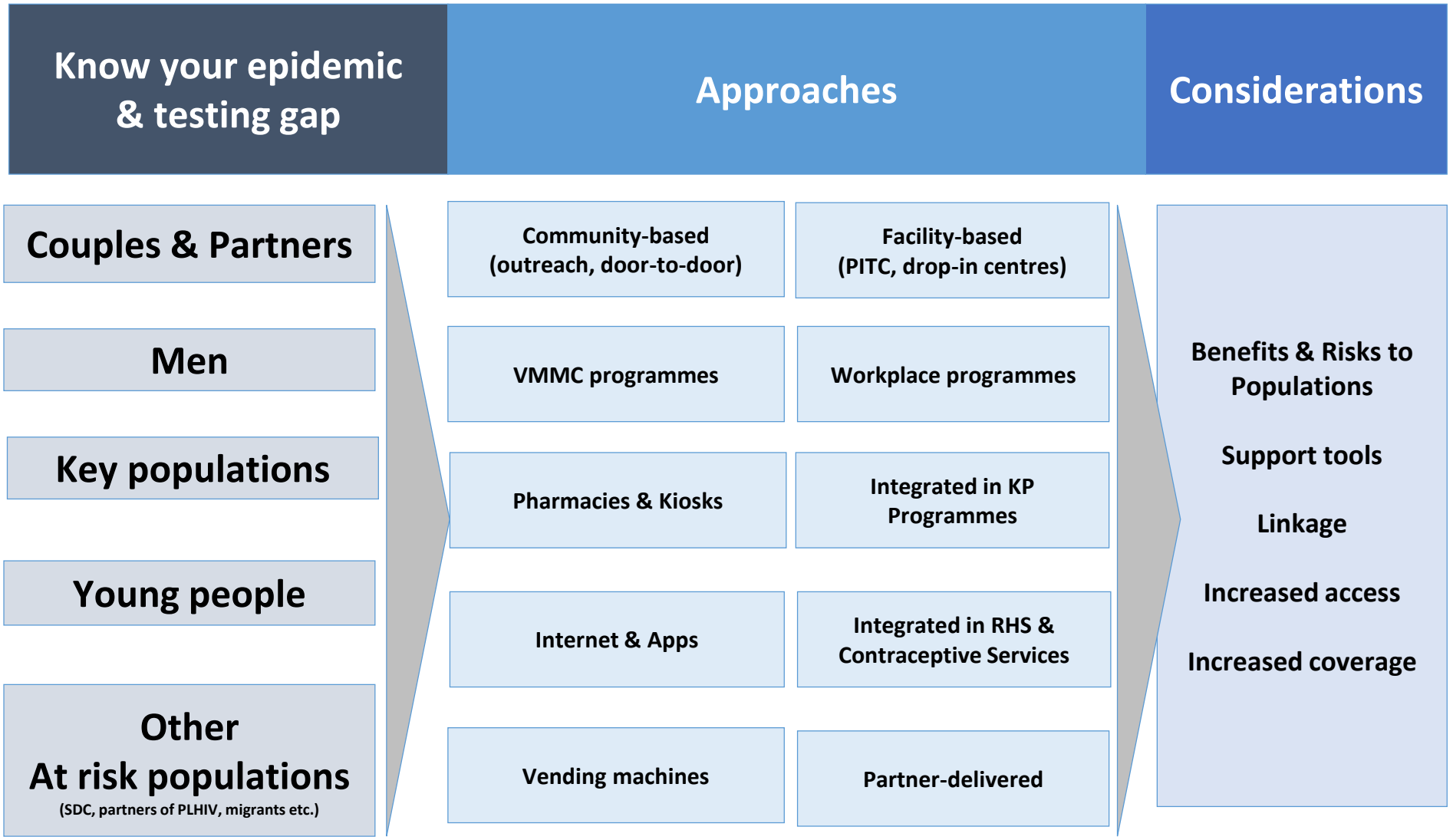
Project Objectives

- Integrating HIVST into national HIV testing policies, developing evidence-based strategy and implementation plans, and facilitating regulatory approvals of HIVST products to drive scale-up;
- Scaling-up equitable and sustainable HIVST models across health sectors and supporting the transition to country implementation;
- Building a sustainable supply of multiple, quality-assured and affordable HIVST products;
- Engaging other funders, including local governments, PEPFAR and the Global Fund to accelerate the expansion and sustainable operation of the HIVST market.

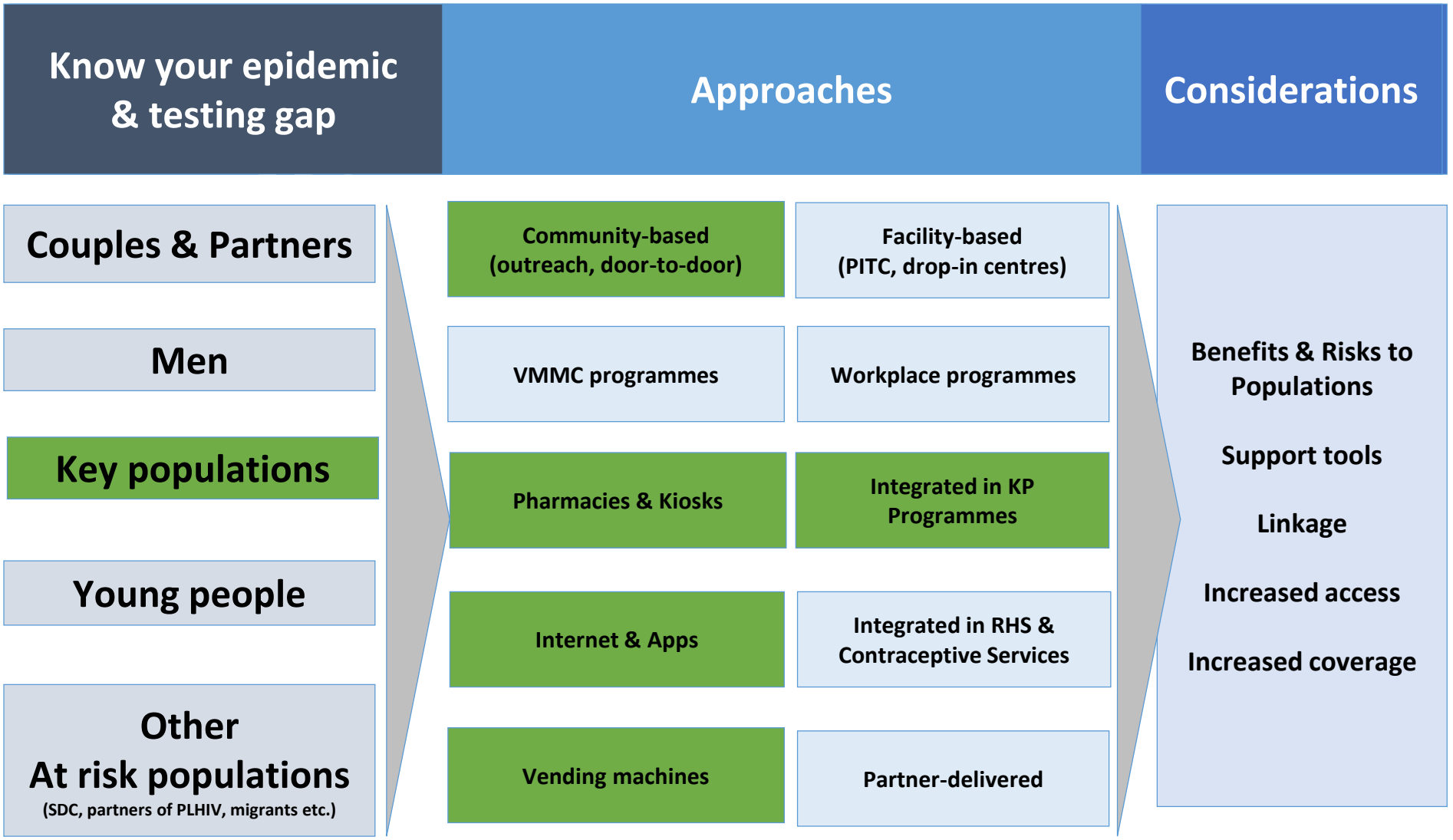
STAR 2 implementation plan

- **Men**: 60% of the 1.2m would be split evenly among what we identified as the top 20 industrial districts in SA
- **AGYW**: 30% split evenly between the DREAMS, GAP YEAR and SHE CONQUERS projects
- **Key pops**: 10% split evenly between the 8 metropolitan municipalities (assuming that key pops are sex workers, MSM, PWID)

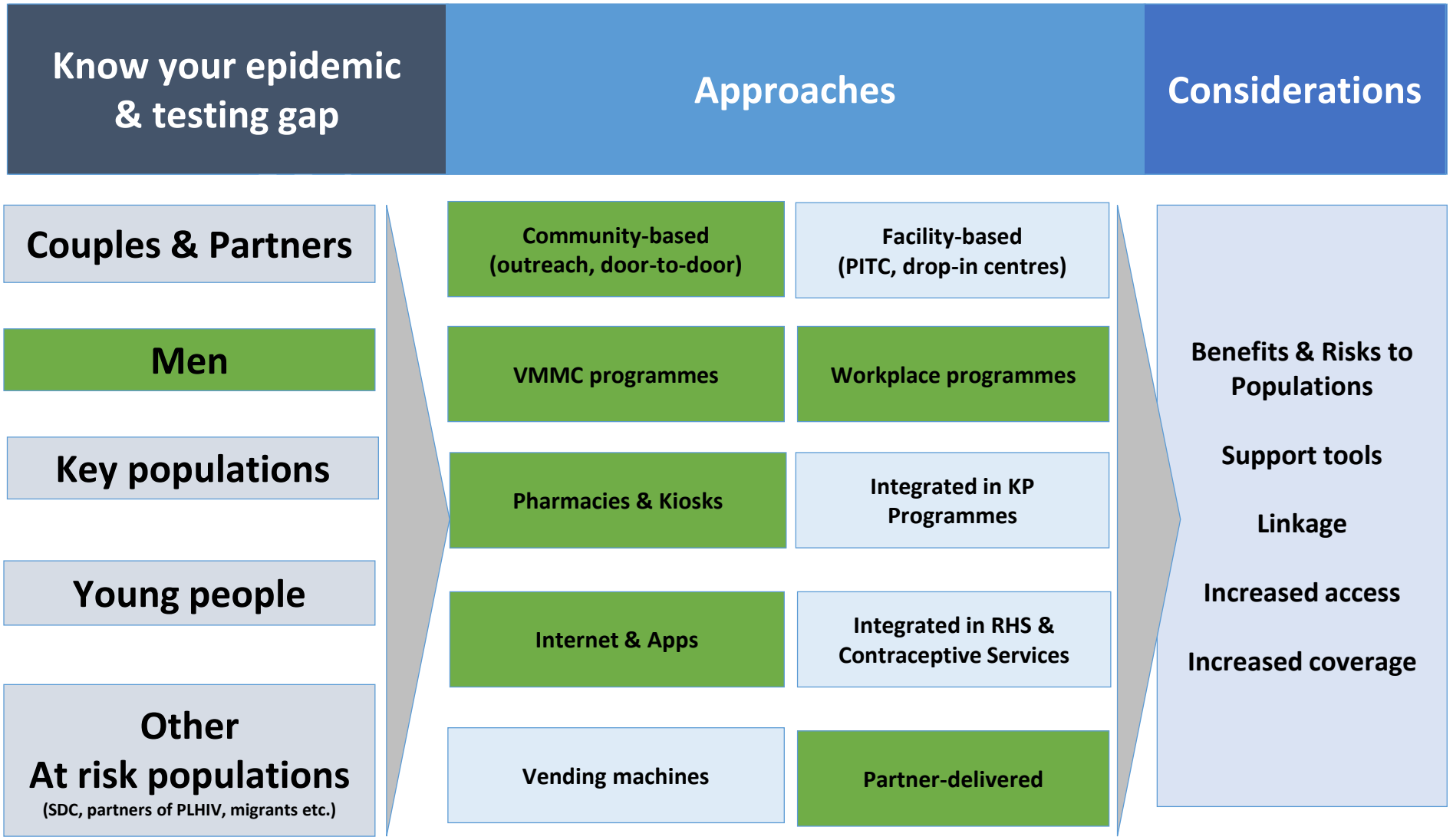
Where to Begin with HIV Self-Testing



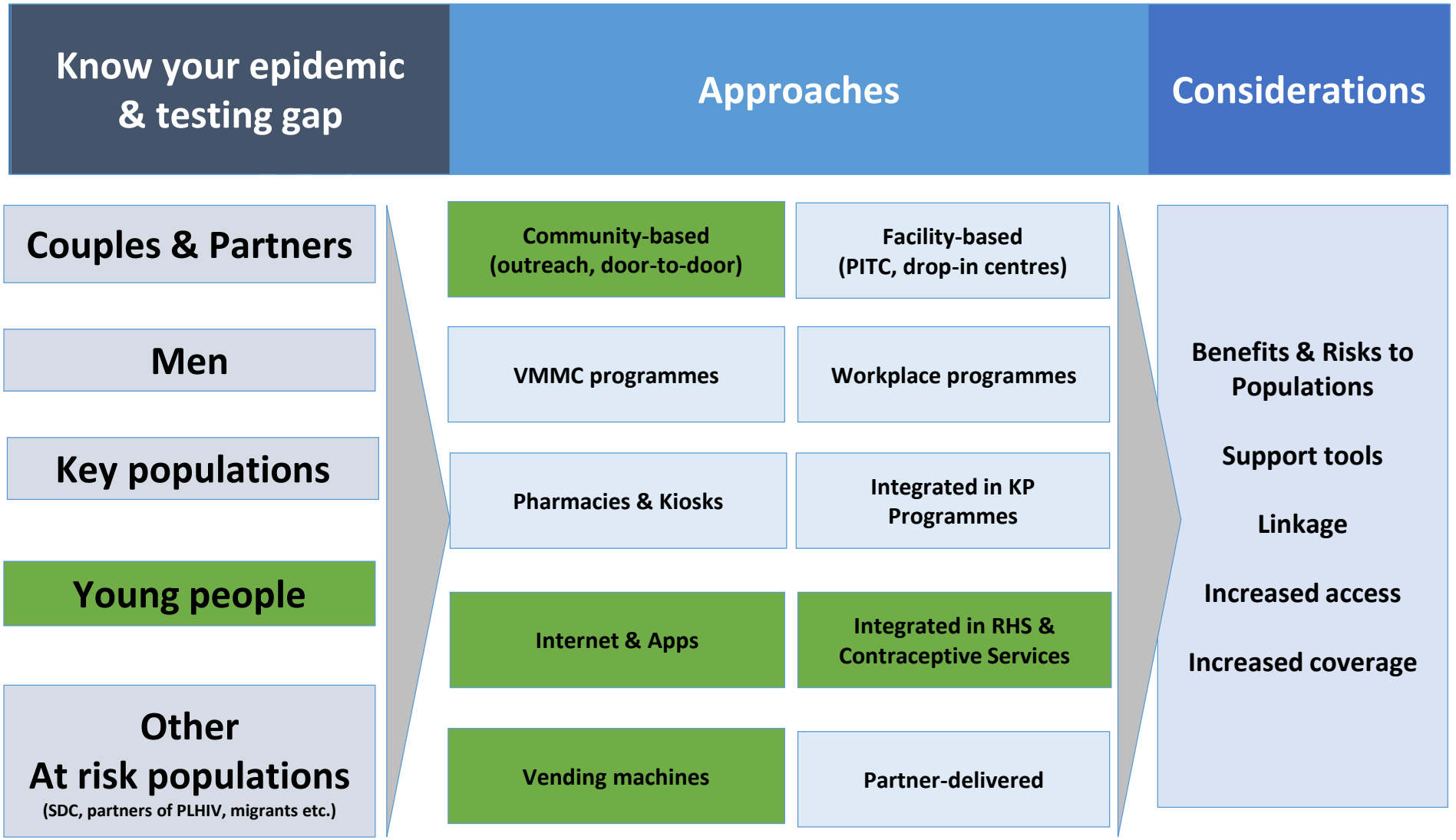
Where to Begin with HIV Self-Testing



Where to Begin with HIV Self-Testing



Where to Begin with HIV Self-Testing



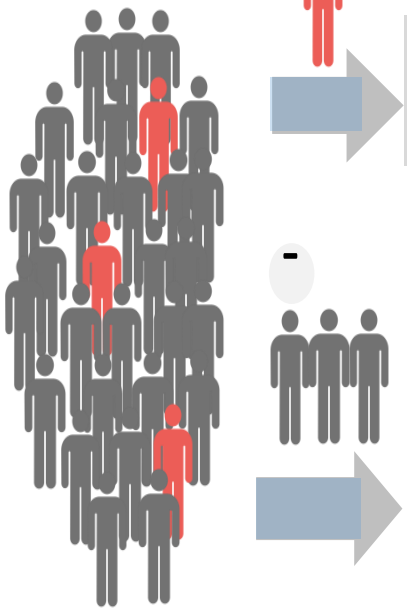
WHAT STILL NEEDS TO BE DONE IN THE HIVST WORLD???

QUITE A BIT

SOURCE: Johnson, C (CROI, 2016)

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**

Critical Gaps

- Optimized service delivery & linkages to prevention & treatment
- How to scale-up the most cost-effective HIVST models to achieve national/global public health goals and for reaching specific populations in specific settings?
- Regulatory policy & frameworks
  - Public & Private Sector – opportunities & challenges
- Integrated and routine implementation and monitoring systems
- Affordable WHO PQed products available in LMIC (blood and oral options)

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?

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 - NDOH
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- UNITAID
- STAR II Consortium Partners – PSI, CHAI and SFH

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