

Advancing HIV self-testing to increase HIV diagnosis in the Caribbean

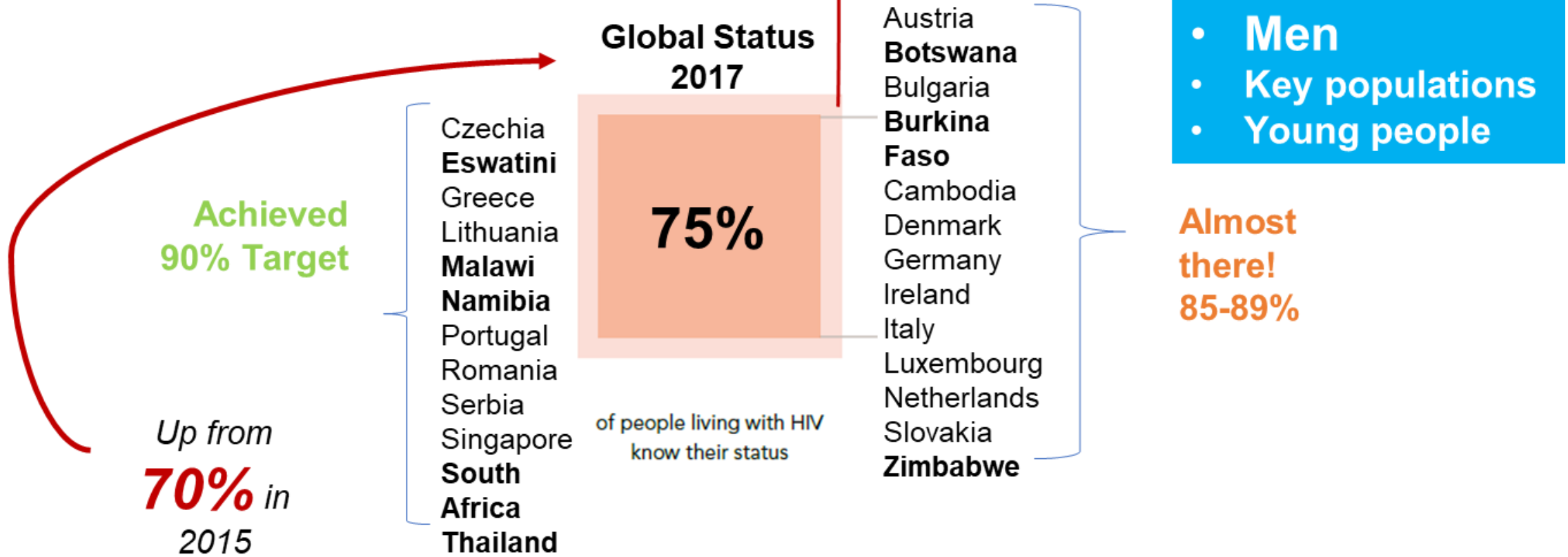
Global Evidence and Lessons Learnt

Cheryl Johnson
Technical Officer – HIV testing services
World Health Organization
8 November 2018

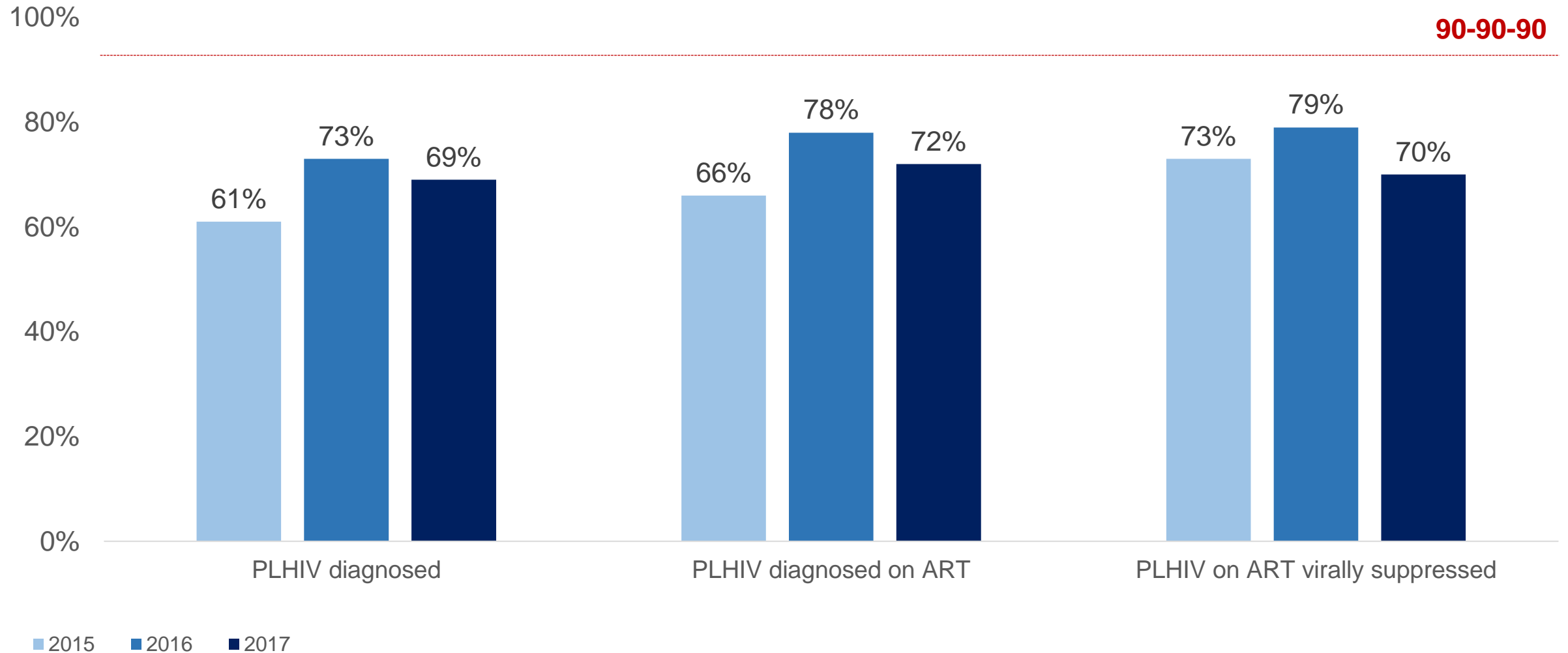


Progress toward first 90, 2017

Gap to reaching first 90: **5.7 Million people**

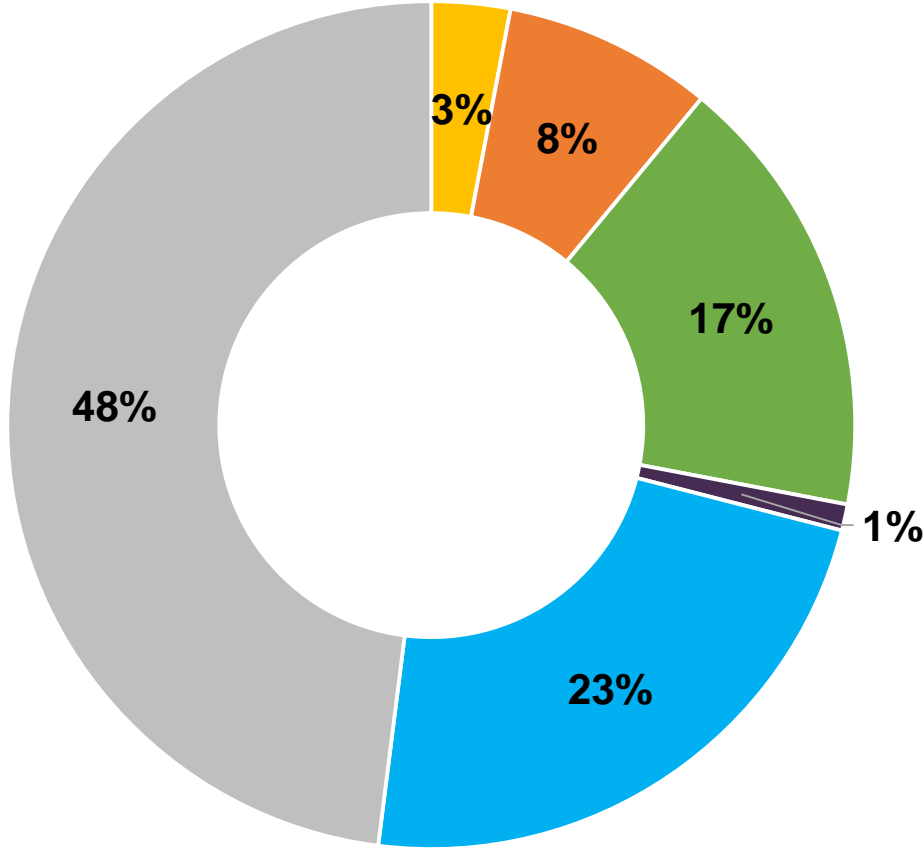


Progress toward 90-90-90 in the Caribbean



High proportion of new HIV infections are among key populations and their partners

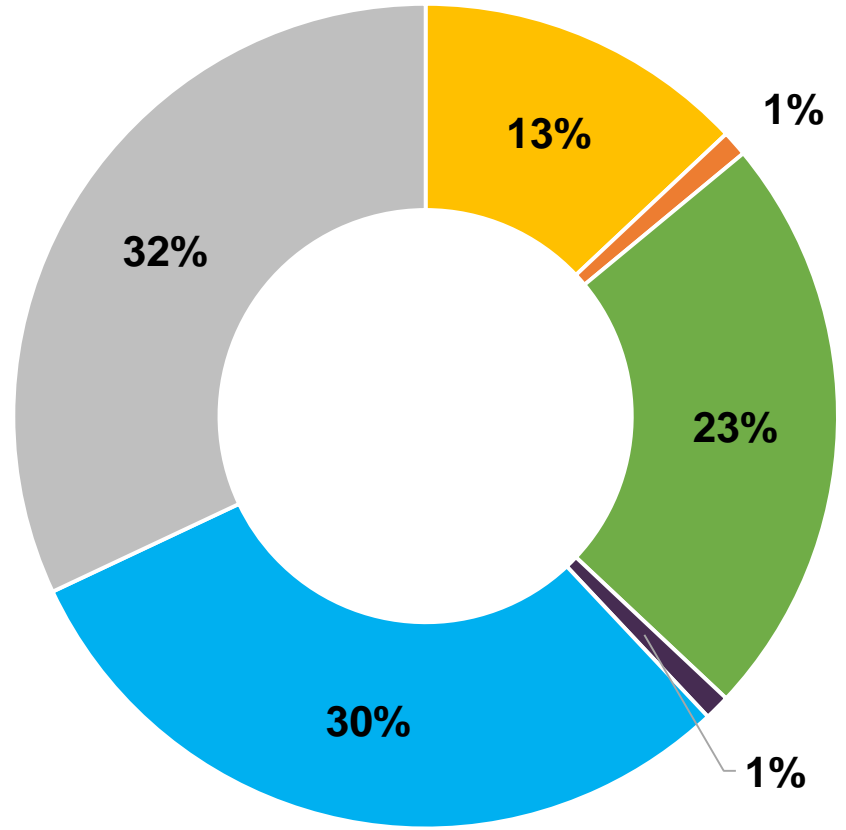
Global=52%



- Sex workers
- Transgender people

- People who inject drugs
- Sex partners of Key populations

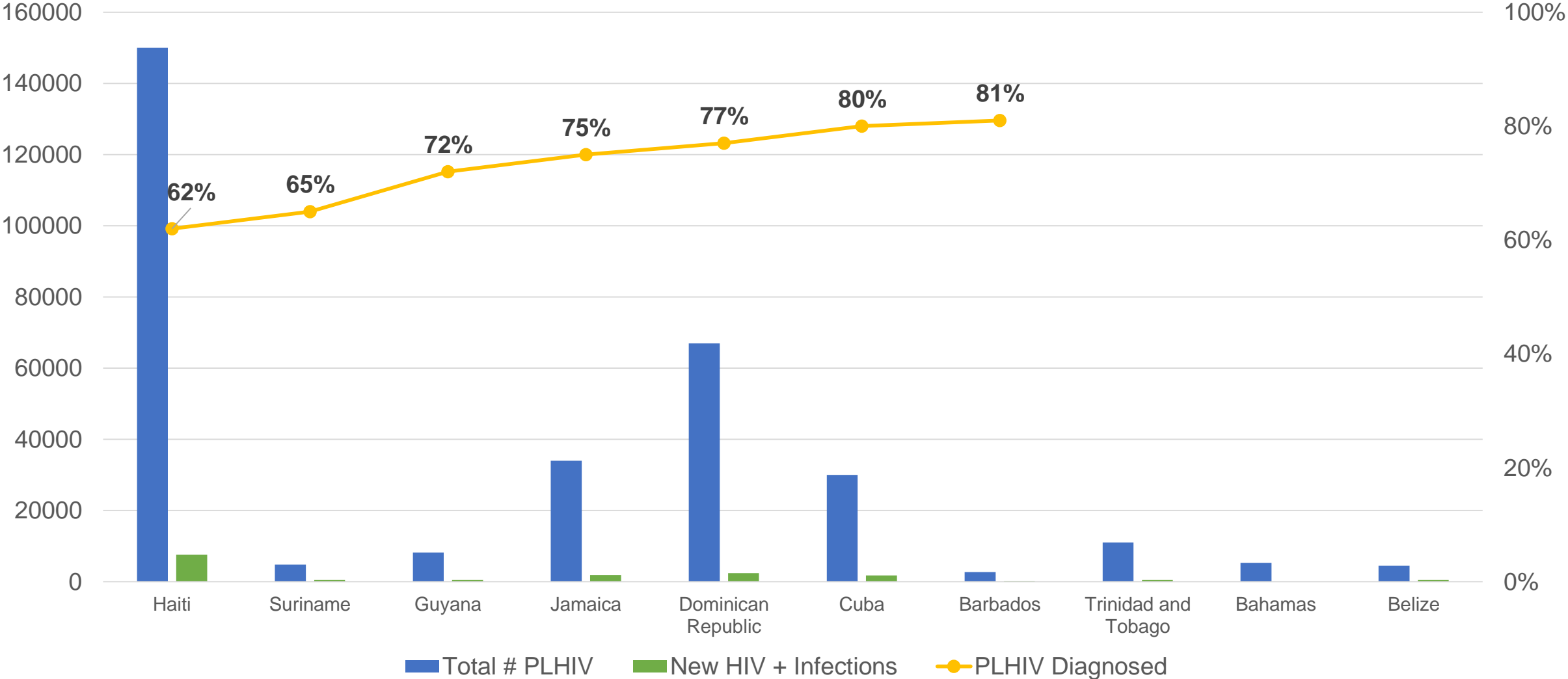
Caribbean= 68%



- Men who have sex with men
- Other - unreported risk

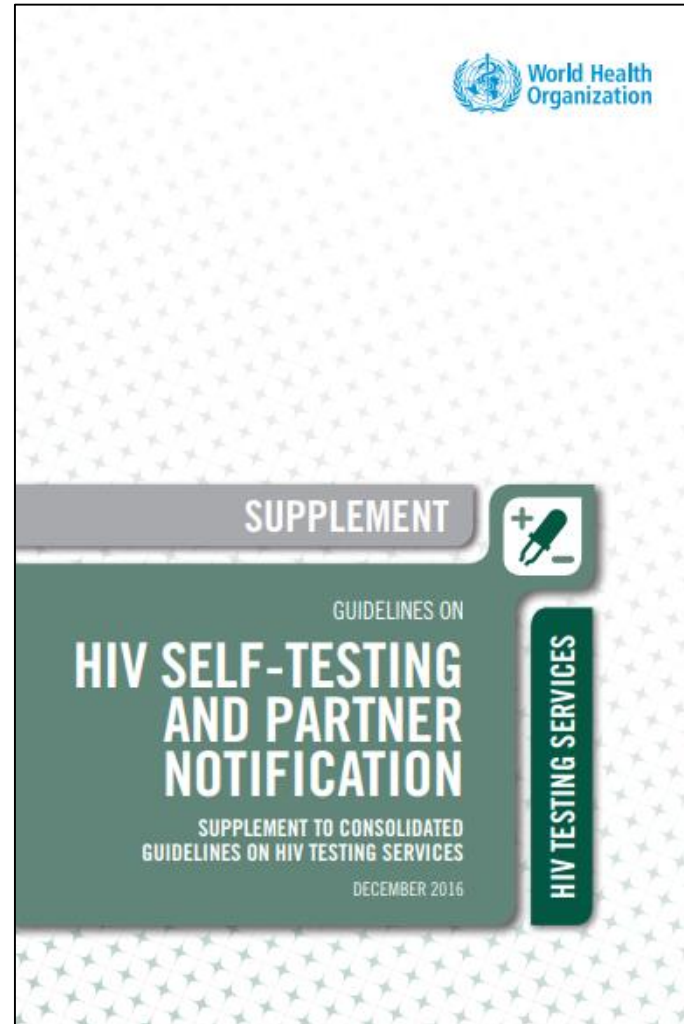
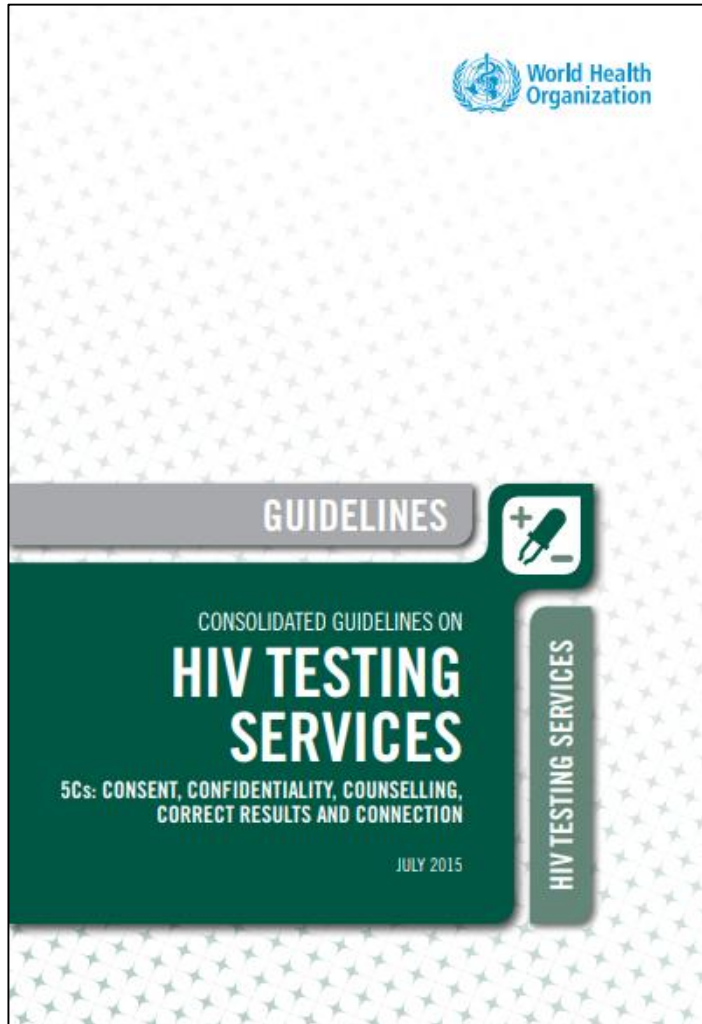
Source: UNAIDS 2018

Countries in the Caribbean by total number of PLHIV, New Infections and Proportion of PLHIV diagnosed



Source: AIDSinfo 2018

WHO HIV testing services guidelines



Recommended HIV Testing Services

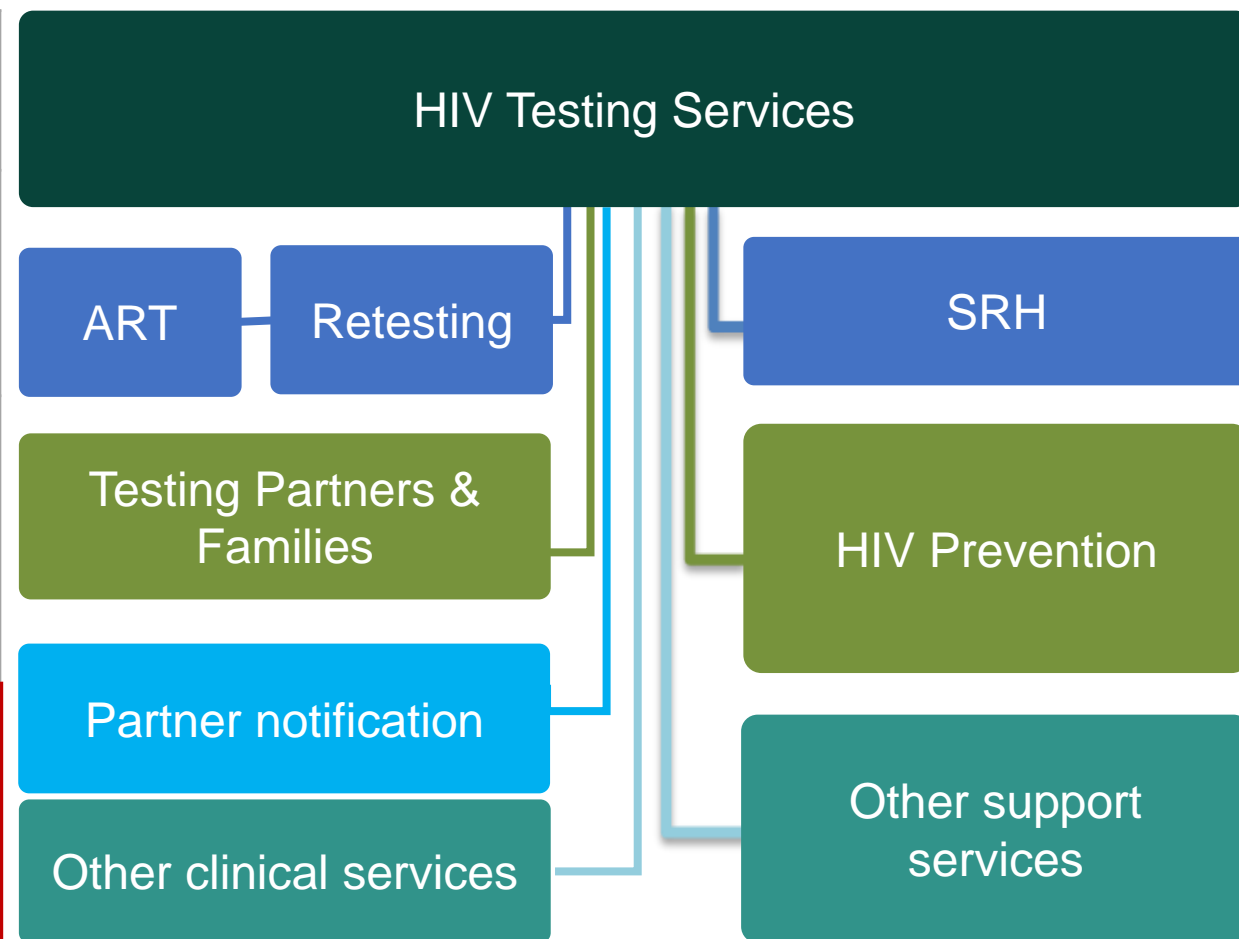
Important gateway to treatment and prevention for individuals, couples, and partners and families

Facility-based: Offering HIV testing in a facility, e.g. VCT, in-patient and out-patient clinics, ANC, TB, STI.

Community-based: Offering HIV testing in natural setting of the community, e.g. outreach, CBOs, workplace, clubs, bars.

Assisted partner notification: Assisting individuals with HIV by contacting their sexual and/or drug injecting partners and offering them HIV testing services.

HIV self-testing: Offering self-test kit for individual, and/or their partner, enabling them to collect their sample (oral or blood), perform test, and interpret results in private. **All reactive results need confirmation.**



Source: WHO 2015; WHO 2016

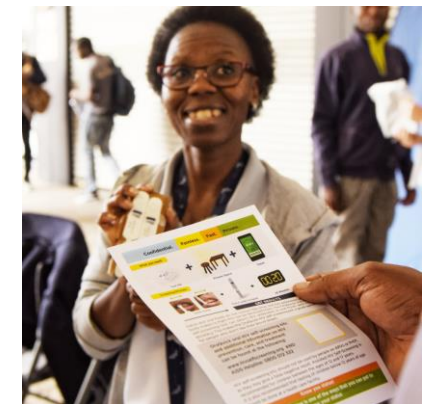
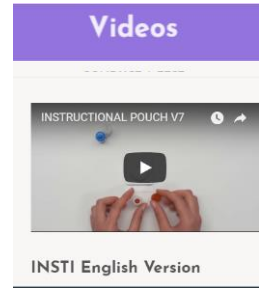
What is HIV self-testing (HIVST)?



When a person collects his or her own specimen, performs a rapid HIV test and interprets their result
All reactive self-tests need further testing

Variety of support tools for HIVST

1. In-person demonstration (one-on-one, with partners or in groups)
2. Demonstration video (including online links to videos)
3. Telephone hotline (can be integrated into existing national hotline services)
4. Short message service through telephone, Internet, social media
5. Educational information via radio, television, leaflets, brochures, the Internet, social media and applications for smartphones/tablets
6. Local information and resources, for example on counselling services, testing sites, treatment centres and where to access HIV prevention services like VMMC and PrEP.



HIVST products with WHO PQ, ERPD or approval from founding member of IMDRF*

Test (manufacturer)	Specimen	Approval	Markets	SENS	SPEC	Price per test (US\$)
atomo HIV Self Test (Atomo Diagnostics, Australia)	Blood	CE mark ERPD- Risk Category 3	Kenya, South Africa	99.7%	99.7%	Public sector: \$ 3
autotest VIH® ** (AAZ Labs, France)	Blood	CE mark	15 European countries	100.0%	99.8%	HIC retail: \$ 20–28 Distributors/NGOs: \$ 8–15
BioSURE HIV Self Test ** (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD-Risk Category 3	South Africa, United Kingdom	99.7%	99.9%	HIC retail: \$ 42–48 HIC public sector: \$ 7.5–15 LMIC retail: \$ 11.75
Exacto® Test HIV (Biosynex, France)	Blood	CE mark	Europe, Switzerland	99.99%	99.99%	Not available
INSTI® HIV Self Test ** (bioLytical Lab., Canada)	Blood	CE mark ERPD-Risk Category 3	Several countries in Europe, Nigeria	99.8%	99.5%	Price: \$ 3–12 MSRP: \$ 7–36
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA, CE Mark	USA, Not yet marketed in Europe	FDA: 91.7% CE: 100.0%	FDA: 99.98% CE: 99.8%	HIC retail: \$ 40 Public sector prices vary.
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ	Burundi, Kenya, South Africa, Uganda, Zambia, Zimbabwe	99.4%	99.0%	LMIC ex-works: \$ 2 for 50 countries
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc.,	Blood	ERPD- Risk Category 3	NA	NA	NA	NA

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

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

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

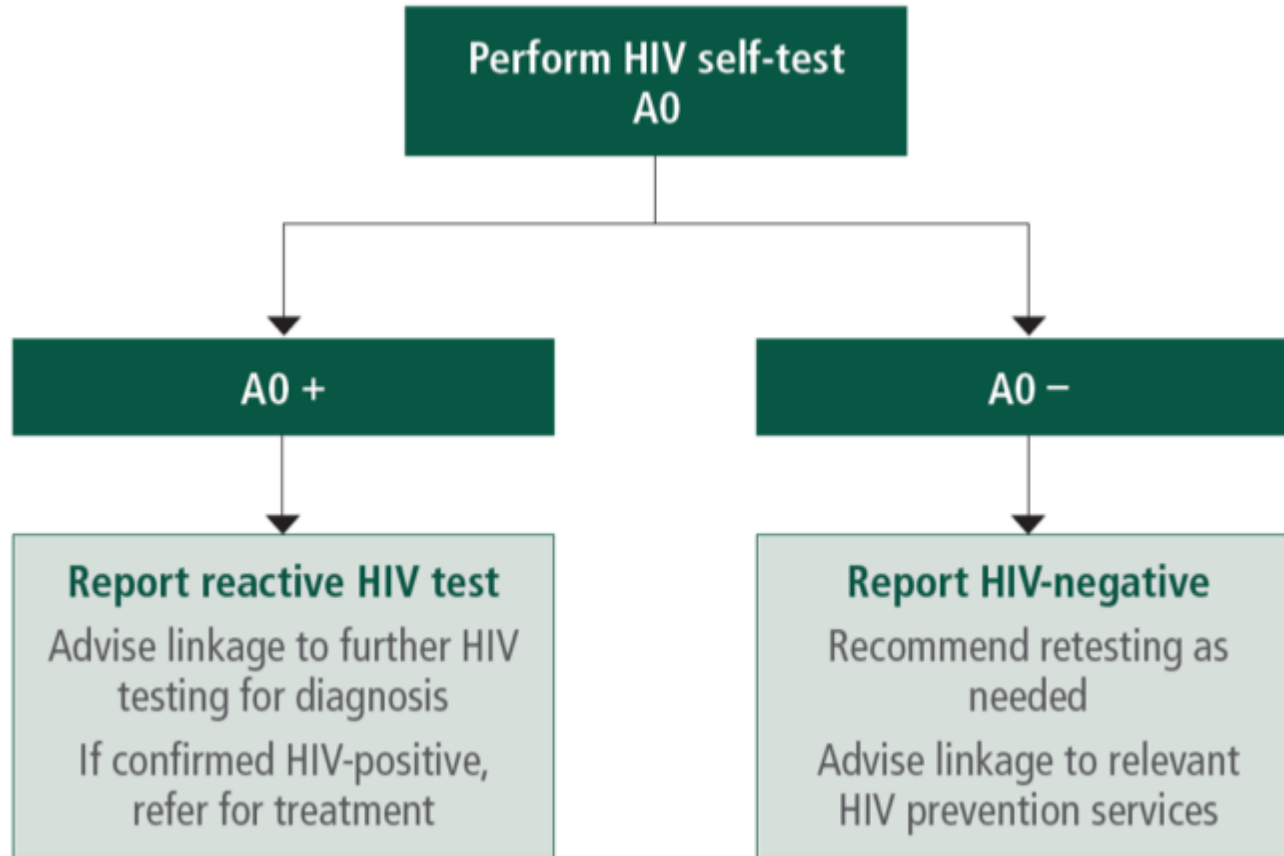
Ensure products are quality assured

Choose products with acceptable specifications

- **HIVST products should be:**
 - highly sensitive and specific;
 - simple to use;
 - have necessary consumables (such as swabs and plasters);
 - provide results that are easy to read/interpret and that are available in a short period of time (1–20 minutes after the test is conducted);
 - disposable in general waste system
- **HIVST should be accompanied with:**
 - contain clear pictorial instructions, support tools, info on what to do and where to go after self-testing
 - Products that include support tools – such as instructional videos, hotlines, websites and referral information – should be prioritized.
 - Products that do not have good stability (that cannot sustain suboptimal storage) or that are not robust (for example cannot sustain common user errors) may not be ideal for self-testing.
- **Other considerations**
 - Cost – consider cost of full service not just unit cost of kit
 - Options (offering blood and oral) important



WHO HIV Self-Testing Strategy



A0= Assay 0 (test for triage)



- HIVST requires self-testers with a **reactive** 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.

*Any person **uncertain** about how their self-test result, should be encouraged to access facility- or community-based HIV testing

Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis

Carmen Figueroa, Cheryl Johnson, Nathan Ford, Anita Sands, Shona Dalal, Robyn Meurant, Irena Prat, Karin Hatzold, Willy Urassa, Rachel Baggaley

Summary

Background The ability of individuals to use HIV self-tests correctly is debated. To inform the 2016 WHO recommendation on HIV self-testing, we assessed the reliability and performance of HIV rapid diagnostic tests when used by self-testers.

Methods In this systematic review and meta-analysis, we searched PubMed, PopLine, and Embase, conference abstracts, and additional grey literature between Jan 1, 1995, and April 30, 2016, for observational and experimental studies reporting on HIV self-testing performance. We excluded studies evaluating home specimen collection because patients did not interpret their own test results. We extracted data independently, using standardised extraction forms. Outcomes of interest were agreement between self-testers and health-care workers, sensitivity, and specificity. We calculated κ to establish the level of agreement and pooled κ estimates using a random-effects model, by approach (directly assisted or unassisted) and type of specimen (blood or oral fluid). We examined heterogeneity with the I^2 statistic.

Findings 25 studies met inclusion criteria (22 to 5662 participants). Quality assessment with QUADAS-2 showed studies had low risk of bias and incomplete reporting in accordance with the STARD checklist. Raw proportion of agreement ranged from 85.4% to 100%, and reported κ ranged from fair (κ 0.277, $p < 0.001$) to almost perfect (κ 0.99, $n=25$). Pooled κ suggested almost perfect agreement for both types of approaches (directly assisted 0.98, 95% CI 0.96–0.99 and unassisted 0.97, 0.96–0.98; $I^2=34.5\%$, 0–97.8). Excluding two outliers, sensitivity and specificity was higher for blood-based rapid diagnostic tests (4/16) compared with oral fluid rapid diagnostic tests (13/16). The most common error that affected test performance was incorrect specimen collection (oral swab or finger prick). Study limitations included the use of different reference standards and no disaggregation of results by individuals taking antiretrovirals.

Interpretation Self-testers can reliably and accurately do HIV rapid diagnostic tests, as compared with trained health-care workers. Errors in performance might be reduced through the improvement of rapid diagnostic tests for self-testing, particularly to make sample collection easier and to simplify instructions for use.

Lay users can perform HIV rapid diagnostic tests for self-testing as well as trained health workers

Instructions for use and packaging are important to optimise performance and reduce errors

Review article

Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis

Cheryl C Johnson^{1*}, Caitlin Kennedy⁷, Virginia Fonner³, Nandi Siegfried^{1,4}, Carmen Figueroa¹, Shona Dalal¹, Anita Sands⁵ and Rachel Baggaley¹

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Abstract
Introduction: HIV self-testing (HIVST) is a discreet and convenient way to reach people with HIV who do not know their status, including many who may not otherwise test. To inform World Health Organization (WHO) guidance, we assessed the effect of HIVST on uptake and frequency of testing, as well as identification of HIV-positive persons, linkage to care, social harm, and risk behaviour.
Methods: We systematically searched for studies comparing HIVST to standard HIV testing until 1 June 2016. Meta-analyses of studies reporting comparable outcomes were conducted using a random-effects model for relative risks (RR) and 95% confidence intervals. The quality of evidence was evaluated using GRADE.
Results: After screening 638 citations, we identified five randomized controlled trials (RCTs) comparing HIVST to standard HIV testing services among 4,145 total participants from four countries. All offered free oral-fluid rapid tests for HIVST and were among men. Meta-analysis of three RCTs showed HIVST doubled uptake of testing among men (RR = 2.12; 95% CI: 1.51, 2.98). Meta-analysis of two RCTs among men who have sex with men showed frequency of testing nearly doubled (Rate ratio = 1.88; 95% CI: 1.17; 3.01), resulting in two more tests in a 12–15-month period (Mean difference = 2.13; 95% CI: 1.59, 2.66). Meta-analysis of two RCTs showed HIVST also doubled the likelihood of an HIV-positive diagnosis (RR = 2.02; 95% CI: 0.37, 10.76, 5.32). Across all RCTs, there was no indication of harm attributable to HIVST and potential increases in risk-taking behaviour appeared to be minimal.

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ORIGINAL PAPER

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Attitudes and Acceptability on HIV Self-testing Among Key Populations: A Literature Review

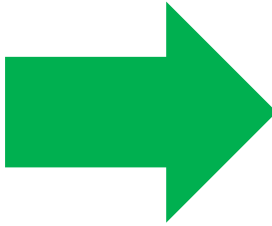
Carmen Figueroa^{1,2} · Cheryl Johnson² · Annette Verster² · Rachel Baggaley²

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Abstract HIV self-testing (HIVST) is a potential strategy to overcome disparities in access to and uptake of HIV testing, particularly among key populations (KP). A literature review was conducted on the acceptability, values and preferences among KP. Data was analyzed by country income World Bank classification, type of specimen collection, level of support offered and other qualitative aspects. Most studies identified were from high-income countries and among men who have sex with men (MSM) who found HIVST to be acceptable. In general, MSM were interested in HIVST because of its convenient and private nature. However, they had concerns about the lack of counseling, possible user error and accuracy. Data on the values and preferences of other KP groups regarding HIVST is limited. This should be a research priority, as HIVST is likely to become more widely available, including in resource-limited settings.

estos grupos de población. Analizamos los datos según el ingreso del país utilizando la clasificación del Banco Mundial, el tipo de muestra, la supervisión ofrecida y otros aspectos cualitativos. La mayoría de los estudios identificados fueron en países con ingresos elevados y con hombres que tienen sexo con hombres (HSH), quienes reportaron una alta aceptabilidad de la prueba casera, debido a su practicidad y privacidad; aunque les preocupaba la falta de asesoramiento, el posible error de usuario y la precisión de la prueba. Existe poca información sobre los valores y preferencias acerca de la prueba casera en otros grupos de población vulnerable. Considerando el aumento de su disponibilidad, incluso en países con pocos recursos, debería ser un área prioritaria en la investigación.

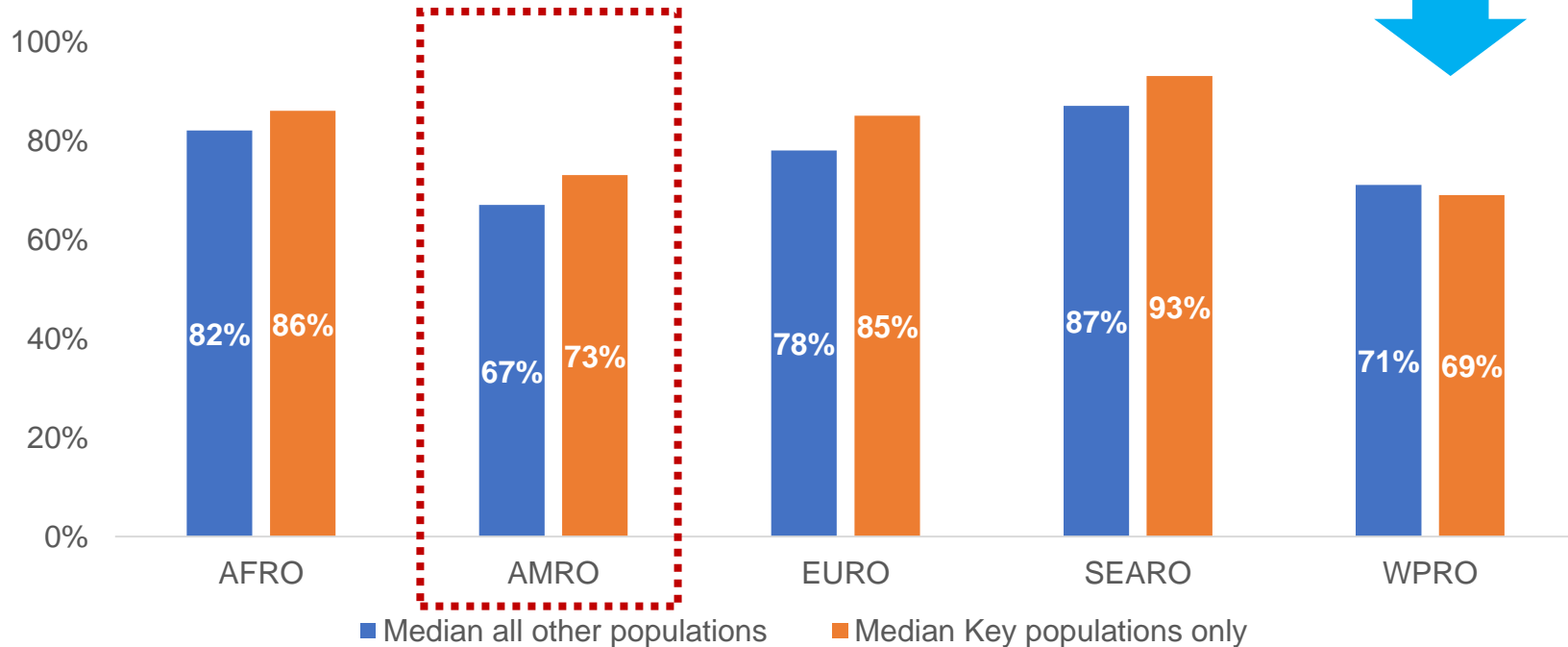
Keywords Key populations · Acceptability · HIV self-testing · Values · Preferences



HIVST (compared to standard HTS):

- Doubled uptake of HIV testing;
- Doubled partner testing;
- Doubled frequency of testing among high-risk MSM;
- Diagnosed more HIV+ people
 (4 RCTs to date have shown HIVST had greater proportion HIV+ vs facility-based HTS)

HIVST is high acceptability globally – and in AMRO – particularly among key populations

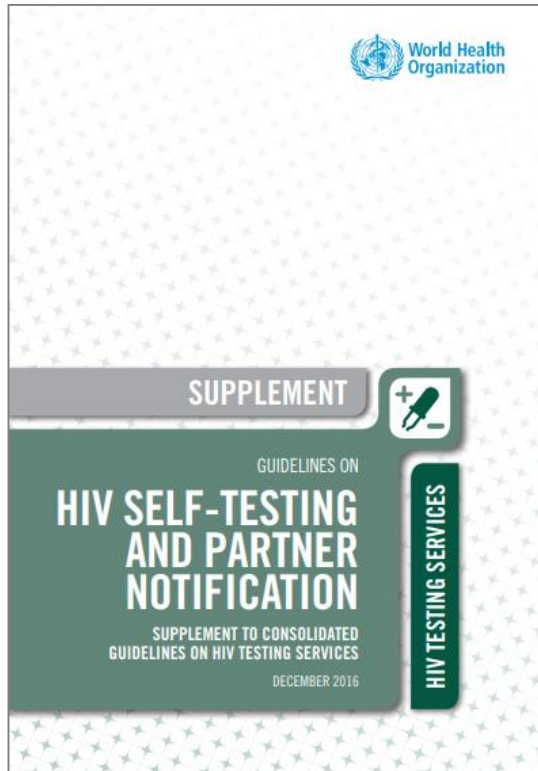


Potential Social Harm & Adverse Events

- **Studies report HIVST can be empowering**
- **Social harm due to HIVST was not identified in RCTs –reports from other observational studies were limited and did not suggest HIVST increased risk of harm**
- **Over 1 million HIVST kits distributed with close monitoring in 6 countries. No suicides or self-harm.**
 - Cases of social harm reported not directly related to HIVST, but issues affecting communities, e.g. serodiscordant couples with break-up, those with history of IPV prior to HIVST
 - Individuals and communities continue to report potential benefits outweigh the potential risks
- **Programmes need to provide clear messages to address potential harm**
 - **Monitoring & reporting system for HIVST are key**
 - Tools such as hotlines/mobile phones, community-based monitoring systems, computer programmes, post-market surveillance systems, etc. can be utilized
 - WHO forms for IVD complaint reporting can also be adapted and used:
http://www.who.int/diagnostics_laboratory/procurement/complaints/en/



WHO recommendations on HIV self-testing (HIVST)



Key evidence showed HIVST is:

- Safe and **accurate**
- Highly acceptable
- Increased access
- Increased uptake and frequency of HIV testing among those at high risk and who may not test otherwise
- Diagnosed more HIV+

WHO recommendation:

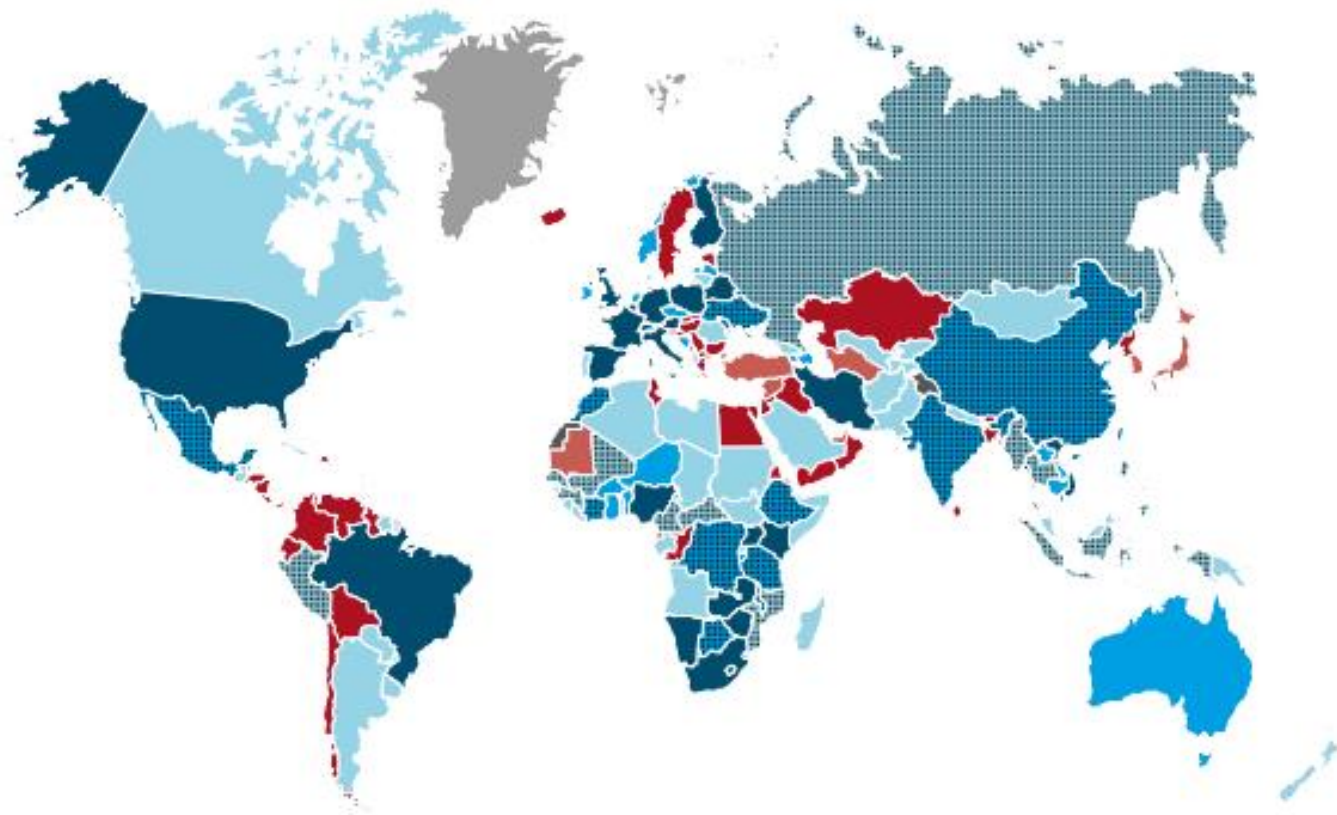
HIV self-testing should be offered as an additional approach to HIV testing services

(strong recommendation, moderate quality evidence)

Many different models – ranging from community-based, facility-based, partner-delivered, social network-based, pharmacies, workplace depending on context and who needs testing.

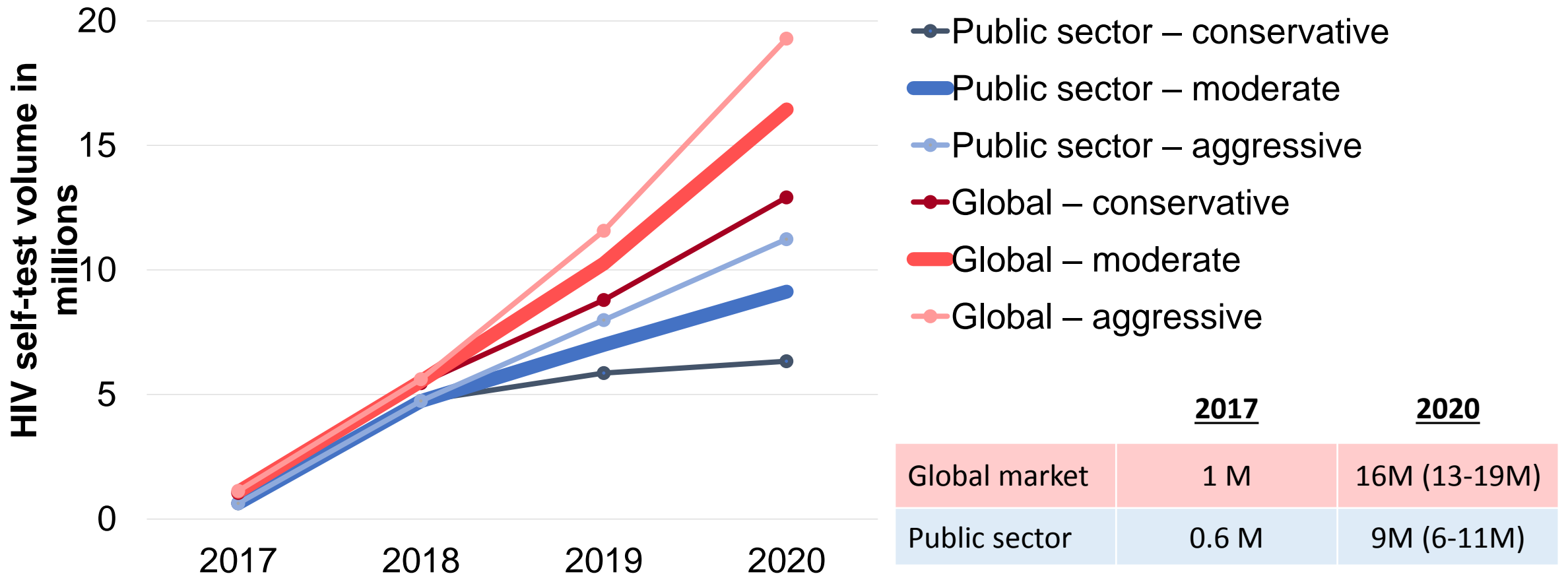
Countries are scaling-up HIVST

*59 countries with policies, of which 28 are implementing.
In addition to 32 piloting HIVST and 53 with policies under development.*



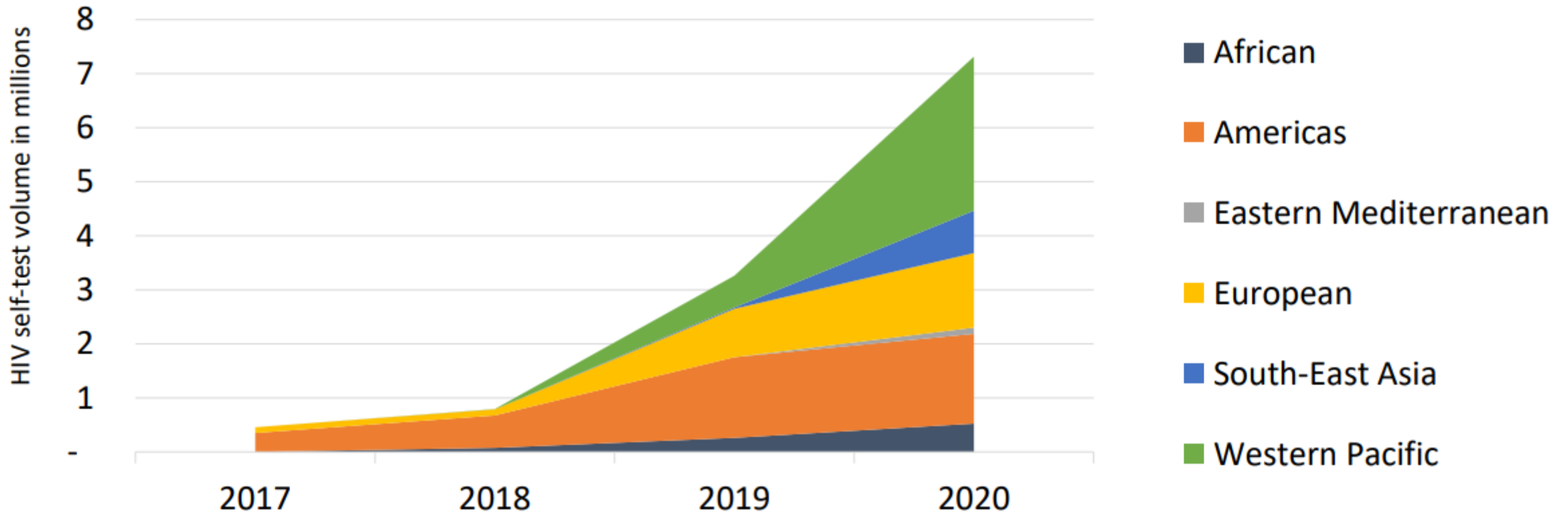
Countries	HIVST Policy Status (July 2018)
Brazil	HIVST policy Implemented
Belize	HIVST policy – but not yet implemented
Haiti	HIVST policy – but not yet implemented
Bahamas	HIVST policy in development
Canada	HIVST policy in development
Cuba	HIVST policy in development
Jamaica	HIVST policy in development
Paraguay	HIVST policy in development
Peru	HIVST policy in development

Global HIVST forecast



Private sector forecast, by WHO region

- Americas is expected to provide a strong foundation for private sector volumes.
- Eastern European and Western Pacific markets are expected to present significant growth.



Source: Unitaid 2018

New HIVST should be focused



As with any additional HIV testing, recommended to introduce HIVST focus on:

1. Reaching the largest possible number of people with HIV who remain undiagnosed;
2. Increasing acceptability, equity and demand by reaching “those left behind”, including key populations;
3. Ensuring cost-effectiveness (or cost-neutrality) and greater efficiencies for health systems and users (including through improved targeting);
4. Helping achieve existing national programme targets (for example, the 90–90–90 and other fast-track prevention targets);
5. Facilitating linkage to treatment for individuals who test HIV-positive and providing appropriately tailored prevention for those who test HIV-negative

Where to Begin with HIV Self-Testing

**Know your epidemic
& testing gap**

Approaches

Considerations

Couples & Partners

Men

Key populations

Young people

**Other
At risk populations**
(SDC, partners of PLHIV, migrants etc.)

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

**Demand creation for PrEP
programmes**

Pharmacies & Kiosks

Internet & Apps

Vending machines

**Facility-based
(PITC, drop-in centres)**

Workplace programmes

**Integrated in KP
Programmes**

**Integrated in RHS &
Contraceptive Services**

Partner-delivered

**Benefits & Risks to
Populations**

Support tools

Linkage

Increased access

Increased coverage

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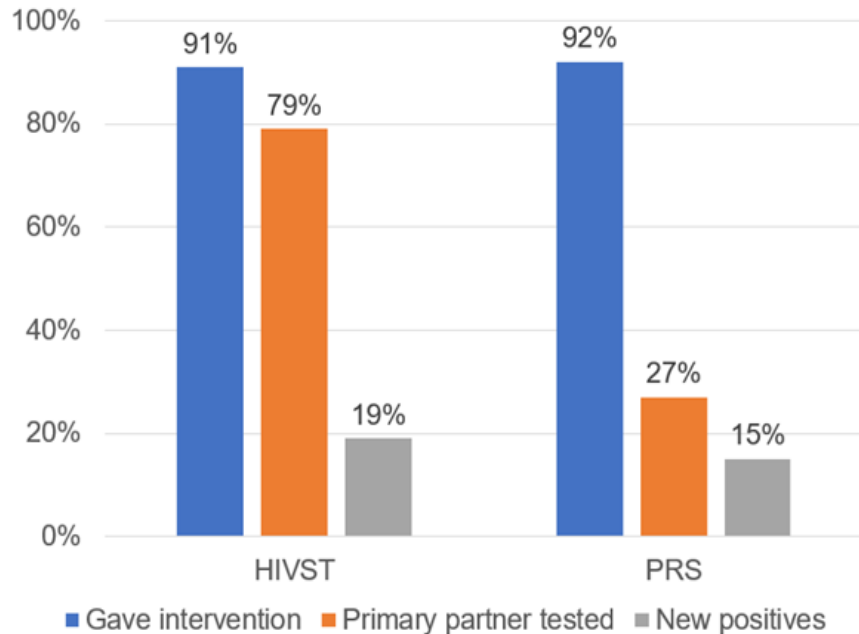
Increased coverage

High yield HIVST approaches

Partner-delivered approaches
(including as part of partner services e.g. index)

- **Social networks** (distributing kits via risk networks – e.g. key populations)
- **Focused facility- or community-based outreach** toward groups at risk and with low HIV testing coverage

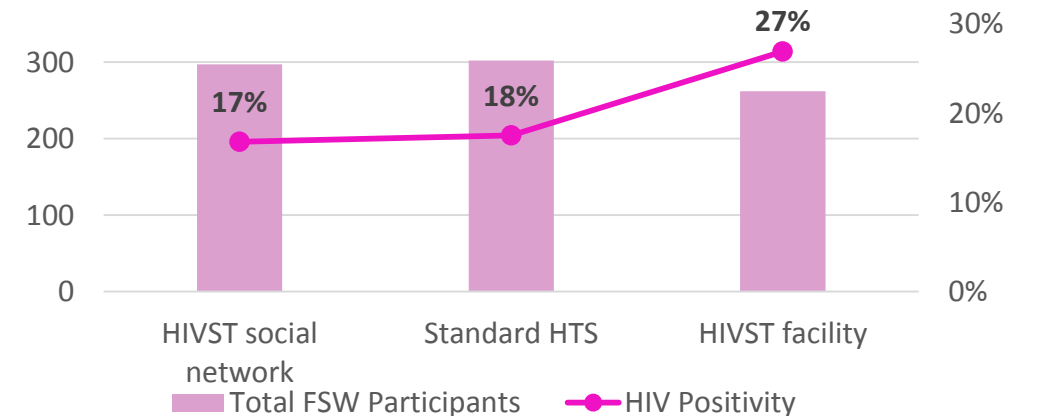
440 HIV+ Clients enrolled, 367 (83%) completed follow-up survey



FSW Uganda

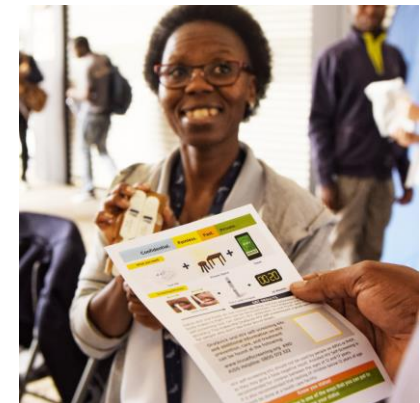
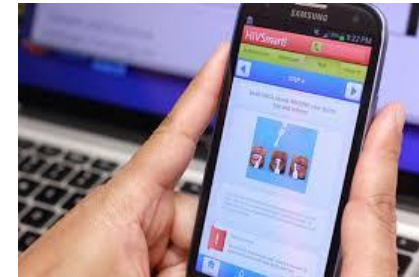
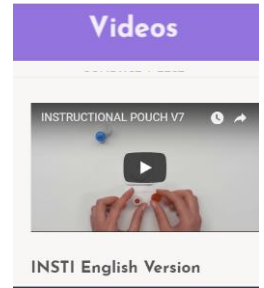
MSM in Kenya

Community-based HTS	HIV self-testing via social network
690 MSM	337 self-test kits
690 MSM	333 (99.1%) returned for confirmatory testing
Median age: 27	Median age: 26
24 (3.5%) newly diagnosed	29 (8.7%) confirmed HIV-positive
20 MSM (83.5%) started ART after median of 5 days (IQR: 3-14 days)	24 (82.8%) started ART on the day of confirming HIV-positive status



Variety of support tools for HIVST

1. In-person demonstration (one-on-one, with partners or in groups)
2. Demonstration video (including online links to videos)
3. Telephone hotline (can be integrated into existing national hotline services)
4. Short message service through telephone, Internet, social media
5. Educational information via radio, television, leaflets, brochures, the Internet, social media and applications for smartphones/tablets
6. Local information and resources, for example on counselling services, testing sites, treatment centres and where to access HIV prevention services like VMMC and PrEP.



Internet-based HIVST in Brazil



Since the project's inception in 2014, 8,800 HIVST kits (in response to the 10, 219 requests made on the website) have been delivered to men who have sex with men in Curitiba.

The sharing of test results through the website is optional as the project prefers to focus on expanding access to HIVST, even if this means never knowing the results of the self-tests conducted. Nonetheless, 201 men who have sex with men have voluntarily reported a HIV-positive self-test result since 2014.

A Hora É Agora also offers confirmatory testing through the public healthcare network, linkage to care through health system navigators, and a 24/7 hotline to answer questions and provide crisis management support.

To date, 99% of users report having had a positive experience interacting with the project and say they will recommend the website to friends. **96% report their main concern with the website is that they would like to be able to order a larger number of test kits and to be able to do this on a more frequent basis.**



Scale-up and pilots
in Brazil

Sistema Único de Saúde acquired 400,000 HIVST kits in 2018, which will be distributed to key populations, including prisoners, via inmate visits, peer-led distribution, as part of demand creation for PrEP, as well as via increased online distribution through A Hora É Agora in Curitiba and São Paulo.

Unitaid-funded Fiotec implementation of HIVST to generate demand for PrEP (*ongoing*)

HIVST in Peru, Mexico and Argentina



Peru

Nearly 82% of all participants (n=192) were willing to use the HIVST if offered for free (95% transgender women and 78% men who have sex with men).

When asked about preferences 19% preferred blood test at a facility to self-testing (oral fluid). 78% of participants preferred getting the HIVST kit in a clinic or by mail.

HIVST available for US\$18 in some pharmacies. Willingness to pay for HIVST was around US\$5.00.

TG women preferred to get the HIVST kit at home (63%), whereas MSM preferred self-test kit delivered to a friend's house (46%).

Source: Bustamante 2017

Mexico

The majority of MSM (94.3%, n=4537) indicated they would self-test if it were available.

Source: Oldenburg 2017

Argentina

74% of MSM in Buenos Aires reported they were likely to buy HIVST kits, test themselves more frequently than they currently do (77%), and that the procedure would simplify testing (70%).

71% reported they would probably use it alone, 66% would use it with a steady partner, and 56% with a friend/partner.

Those likely to buy HIVST were older and more likely to identify as gay.

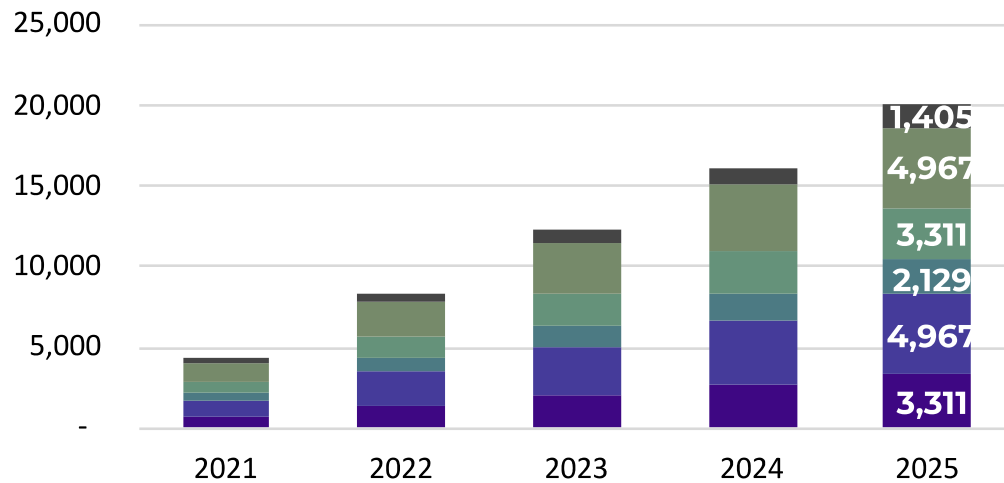
Source: Pando 2017

Both Peru and Mexico are now piloting HIVST to guide future implementation and scale-up under Unitaids-funded project

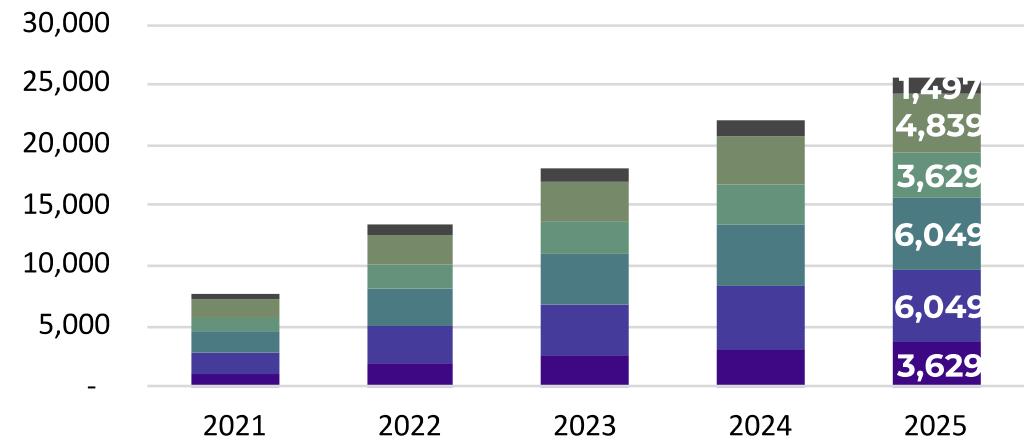
Preliminary Forecasting for Central America HIVST

- In the Ideal scenario NGO provider testing and online channels are the primary channels for HIVST volumes with 24% share of total HIVST volumes.
- In the Improved scenario both NGO testing and Community outreach channels provide 25% of total HIVST volumes.

HIVST forecast by channel for IMPROVED Scenario (El Salvador)



HIVST forecast by channel for IDEAL Scenario (El Salvador)



■ Traditional health facility testing
 ■ NGO testing
■ Online
 ■ Social referral (offline)
■ Community outreach
 ■ Private sector pharmacies / labs

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Countries piloting

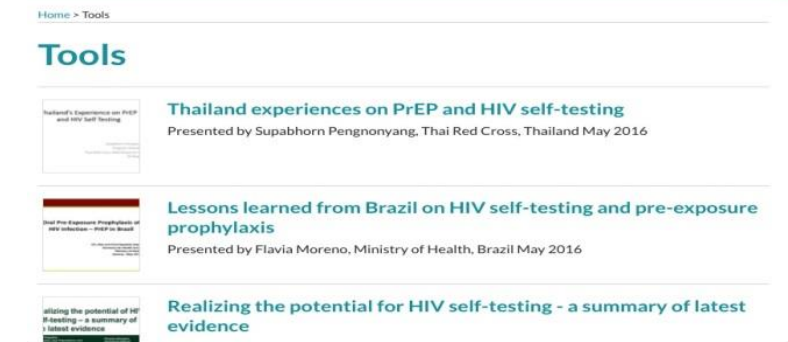
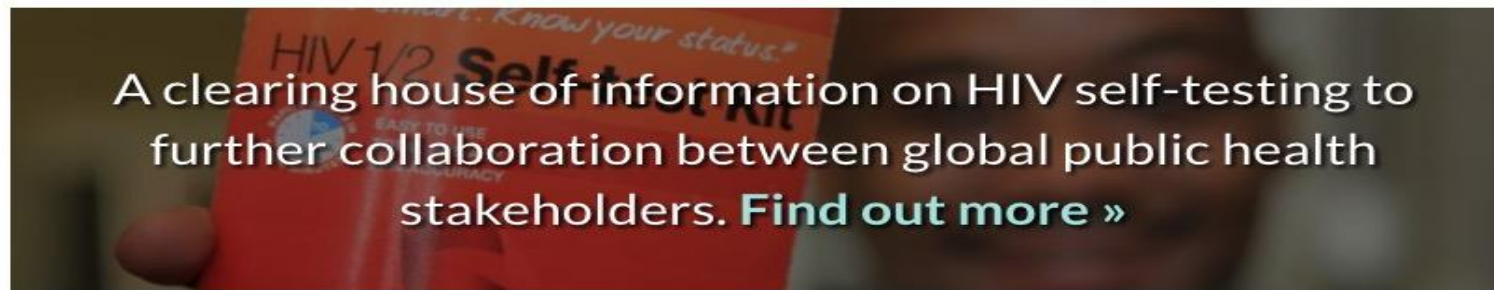
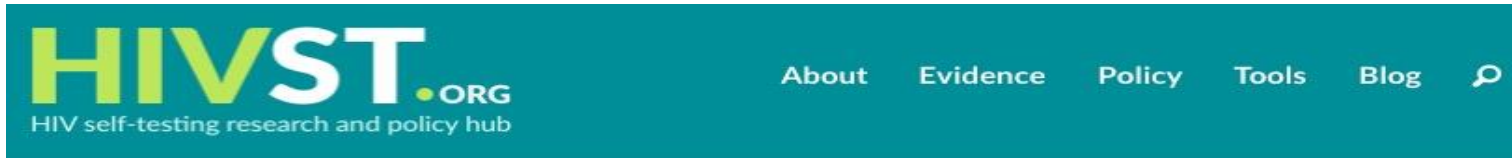
Haiti (Jhpiego)

- Two health facilities in Port-au-Prince (ICC Grace Children's Hospital and Hospital de l'Universite d'Etat d'Haiti) will offer directly HIV self-testing as an alternative to conventional HIV rapid testing, for clients presenting and/or eligible for HIV testing services.
- Home-based HIVST also offered in the catchment areas near facilities by community health workers who currently provide community-based health information as part of routine service delivery.

Central America (PSI)

- Landscaping activities
- Acceptability and feasibility studies

HIVST.org



WHO HTS INFO

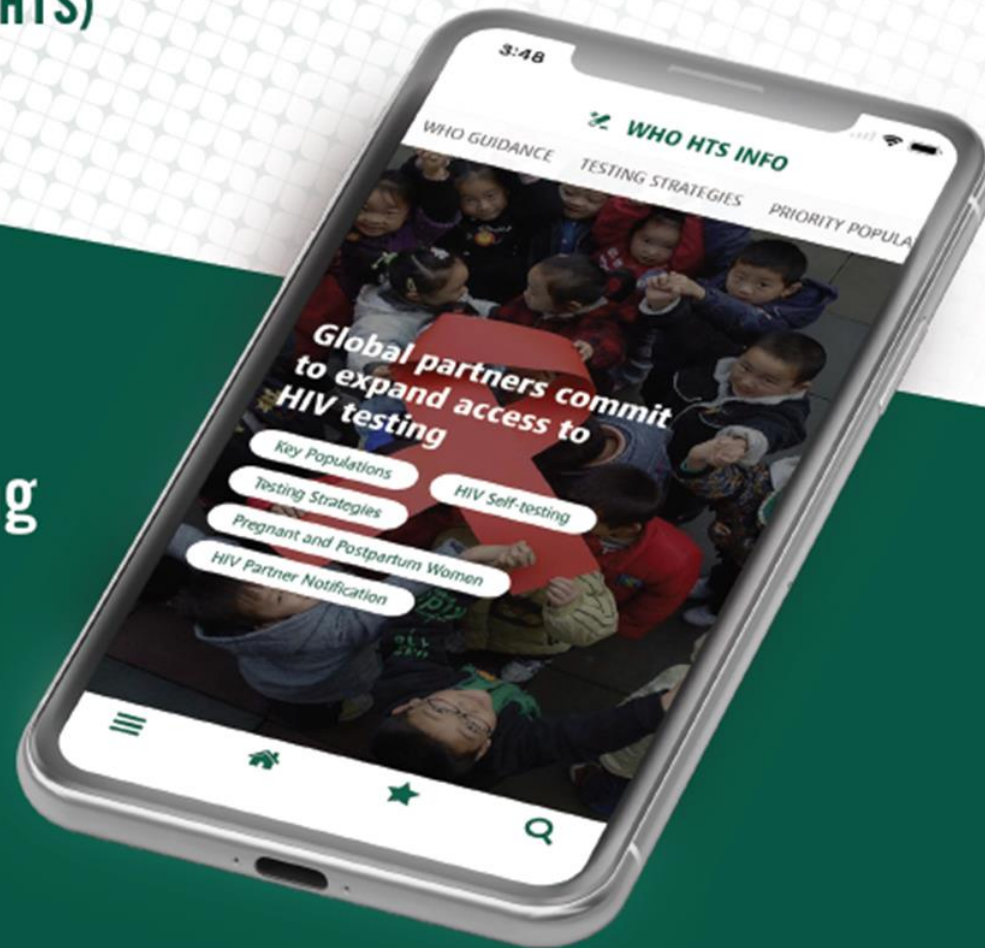
HIV Testing Services (HTS)



World Health Organization

French, Russian, Spanish,
Chinese coming soon!

WHO HTS Info makes it easy to view WHO guidance on HIV testing on smartphones and tablets, online or off, everywhere.



Download now!

Search “HTS Info”
In [App Store](#) /
[Google Play](#)

Or Try the link:

<http://www.who.int/hiv/mediacentre/news/hts-info-app/en/>



Additional HIVST Resources

- WHO Guidelines on HTS Info: [App Store](#) / [Google Play](#)
- HIVST Strategic Framework: <http://www.who.int/hiv/pub/self-testing/strategic-framework/en/>
- WHO-Unitaid landscape on HIVST technologies and market: <http://www.who.int/hiv/pub/self-testing/hiv-self-testing-2018-edition4/en/>
- WHO PQ HIVST: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/
- Global Fund list: https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf
- Latest HIVST Information: <http://www.who.int/hiv/pub/self-testing/en/>
- HIVST.org <http://www.hivst.org/>

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