

Overview and Updates on HIV Self-Testing (HIVST)

What You Need to Know

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

Outline

- Background on epidemic and HTS situation
- Intro to HIV self-testing
 - Strategy and considerations
 - Products
 - Market
 - Future

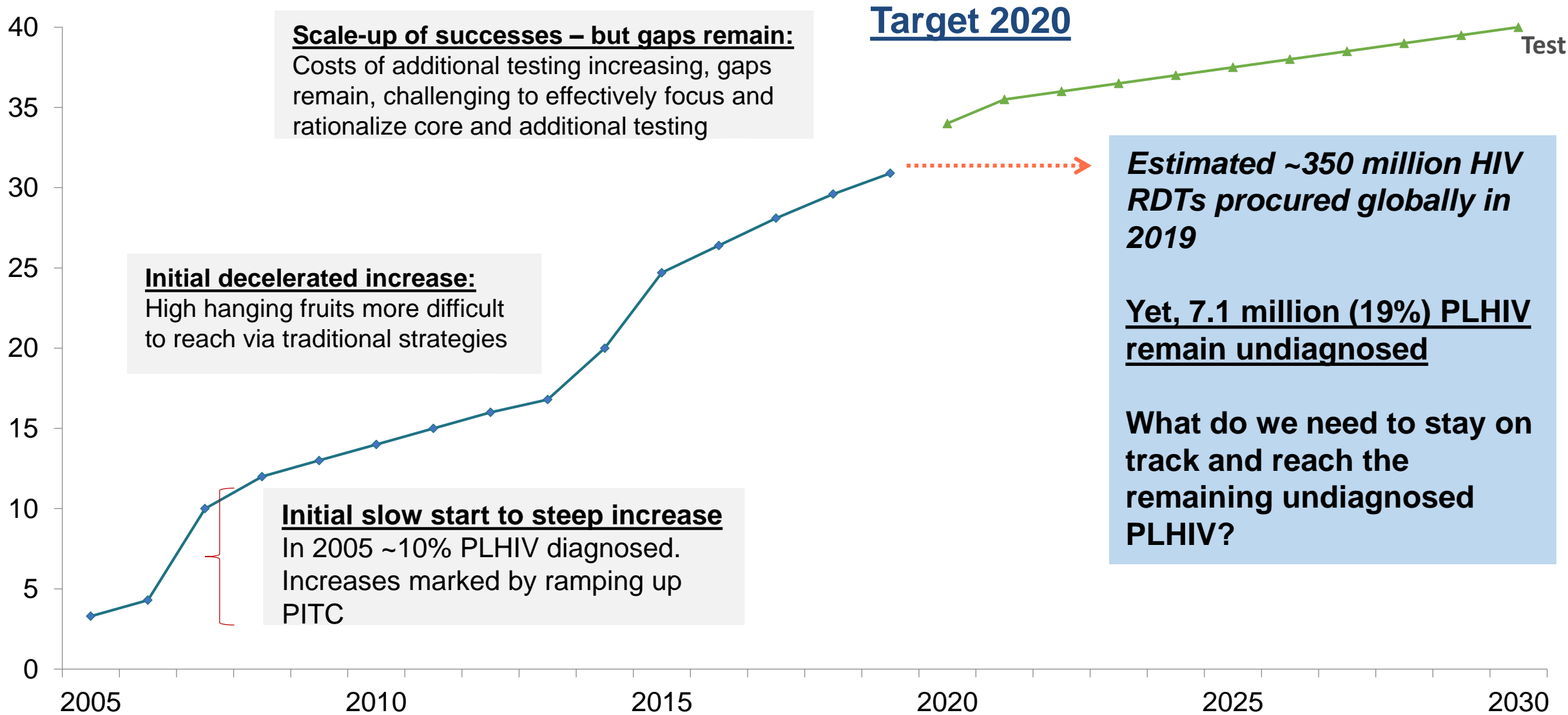
Self-learning

1. WHO HTS video. <https://www.who.int/hiv/mediacentre/news/hiv-self-testing-video/en/>
2. AIDS 2020 HIV self-testing innovations. <https://www.who.int/hiv/mediacentre/news/hiv-self-testing-video/en/>
3. WHO HIVST Policy brief: <https://www.who.int/publications/i/item/who-recommends-hiv-self-testing-evidence-update>
4. WHO systematic review 1: <https://www.sciencedirect.com/science/article/pii/S2352301818300444>
5. WHO systematic review 2: <https://onlinelibrary.wiley.com/doi/full/10.7448/IAS.20.1.21594>

Progress toward Global Targets: HIV testing

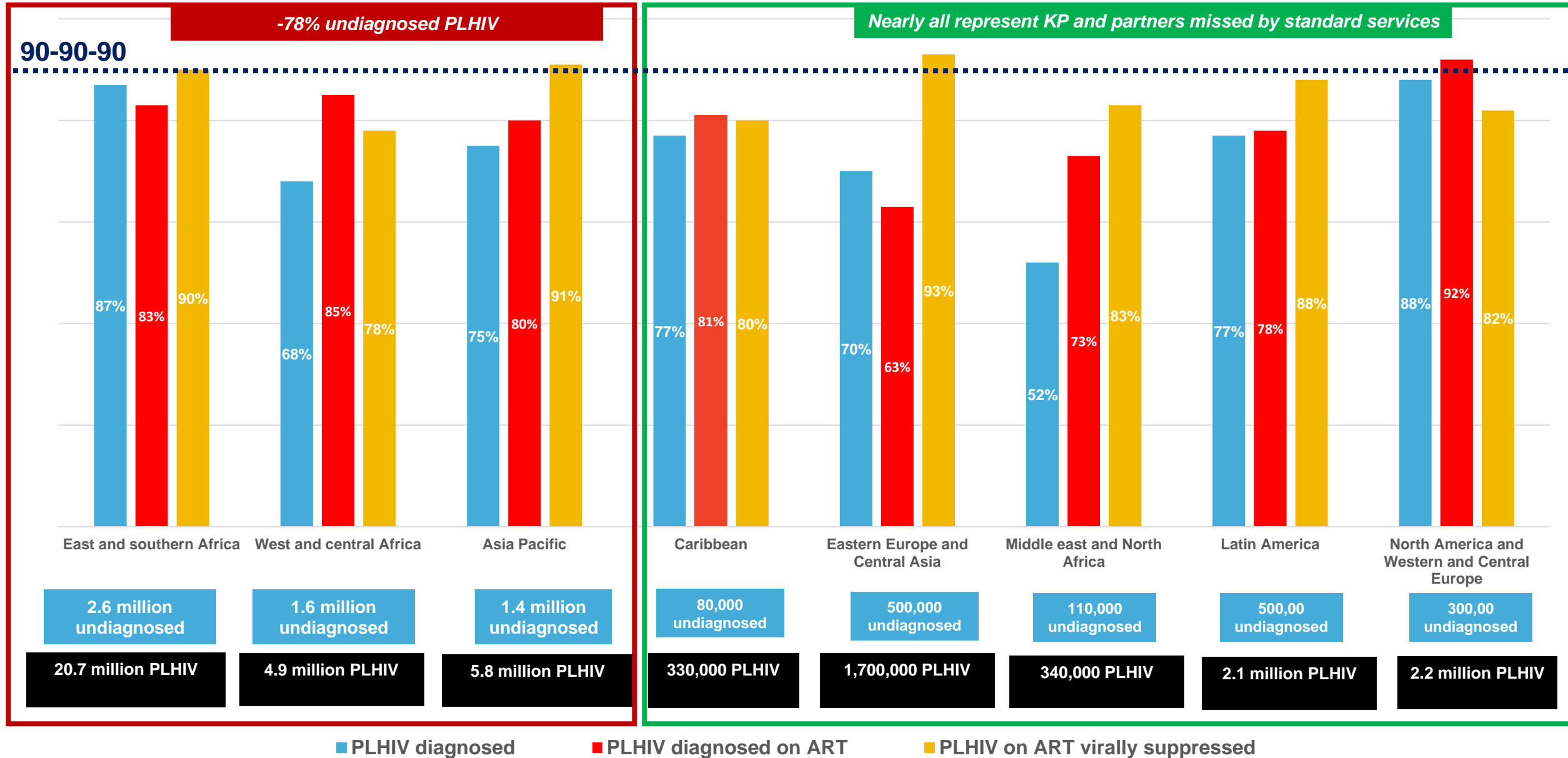


PLHIV Diagnosed (Millions)



Source: WHO forecast 2019; UNAIDS 2020; WHO 2005; CHAI 2015; WHO, UNICEF, PEPFAR, GFTAM 2018

Progress toward the 90-90-90, by region, 2019



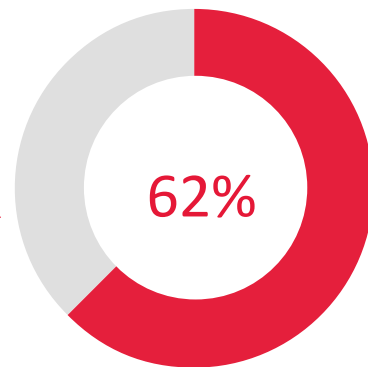
Number of new HIV infections (2019)



1.7 million

people newly infected
[1.2 million – 2.2 million]

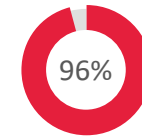
Proportion of new infections among key populations and their partners:



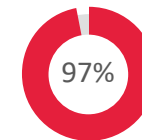
of new HIV infections from key populations and their partners (global)



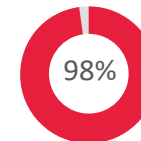
of new HIV infections in Eastern Europe and Central Asia



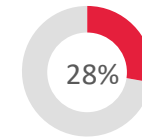
of new HIV infections in Western and Central Europe and North America



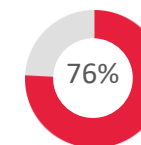
of new HIV infections in Middle East and North Africa



of new HIV infections in Asia and the Pacific

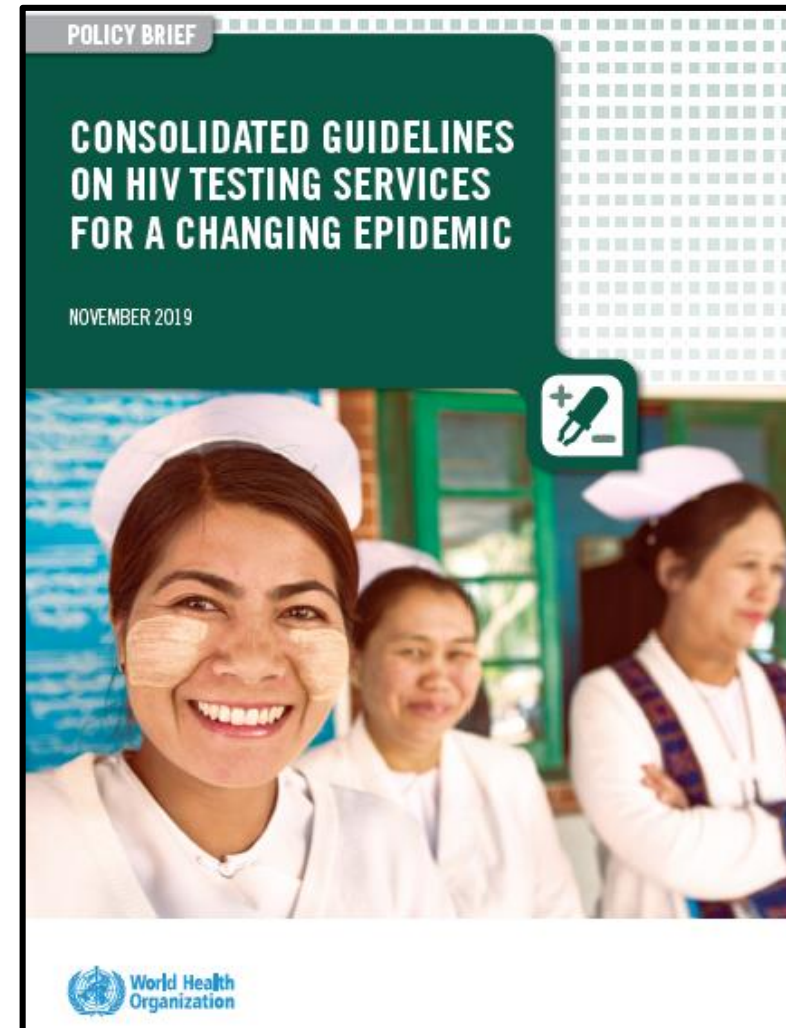
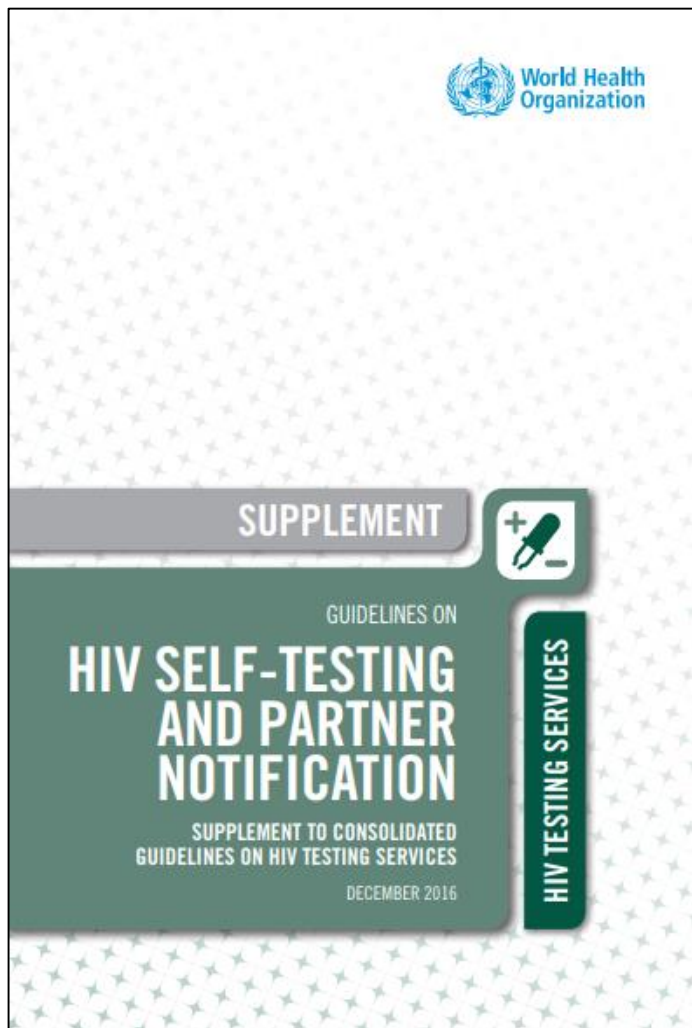


of new HIV infections in Eastern and Southern Africa



of new HIV infections in Latin America and the Caribbean

WHO HIV testing services guidelines



WHO HTS INFO

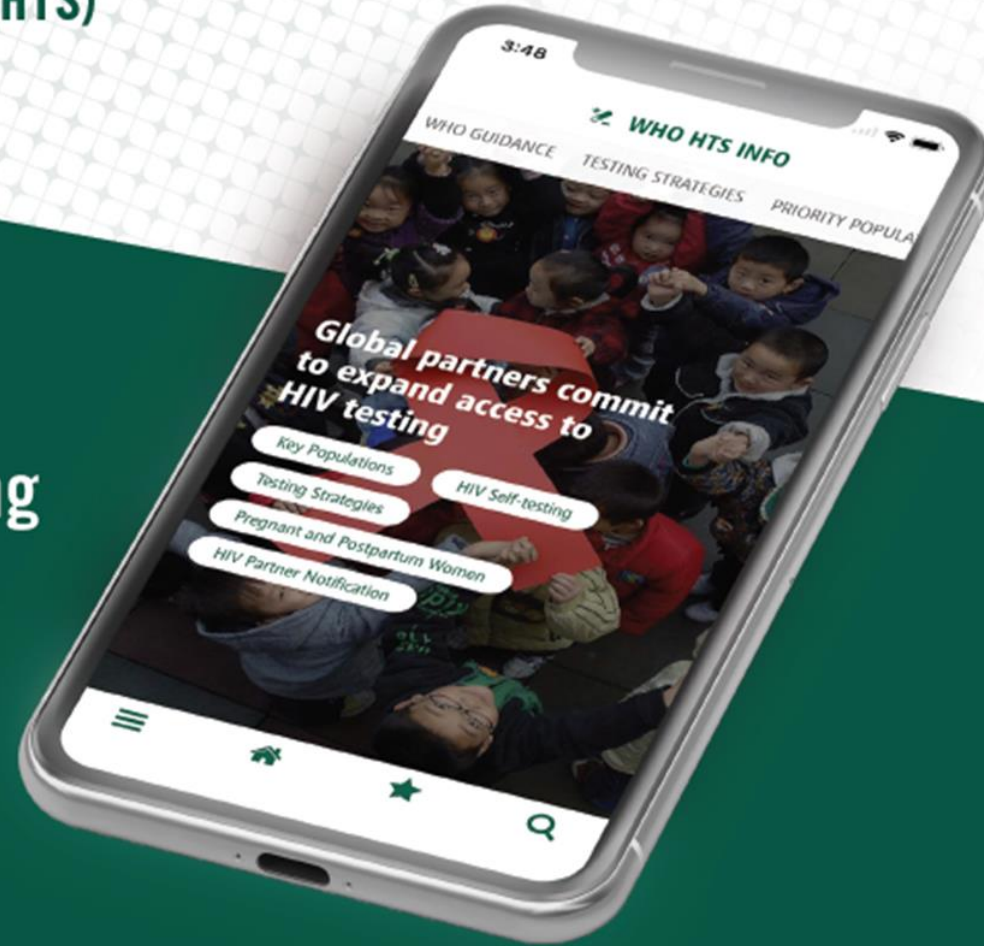
HIV Testing Services (HTS)



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/>



Guiding principles for HTS



WHO 5Cs encourage all testing to include

- Consent
- Confidentiality
- Counselling (pre-test information and post-test messages)
- Correct results and
- Connection (linkage)



Supportive policies are essential

- Critical enablers



- Task-sharing HIV testing services with lay providers (**WHO recommended**)

- High uptake
- Accurate
- Often preferred
- Low cost

WHO recommends:

- Initiatives to protect and enforce privacy
- Prevent discrimination
- Promote tolerance



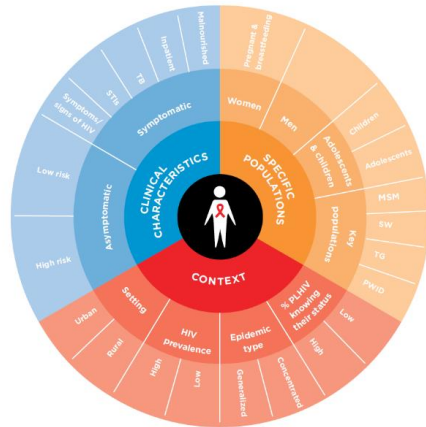
Strategic principles for HTS

HTS approaches need to consider three dimensions for implementation:

1. **Mobilizing** and creating demand for testing
2. Testing **service delivery**
3. **Linkage** to post-test services



Approaches are then adapted based on the context, population and epidemic



	Mobilizing and creating demand	HTS implementation	Linkage to care
When	Continuous, intermittent or focused	Time of day and frequency	Time period for linking and frequency of monitoring
Where	Location of mobilization activities	Health facility, other facility, community	Location of linkage activities
Who	Who does the mobilizing? Who is the focus for messages and mobilization?	Who does the HIV testing? Who is the focus for testing?	Who supports linkage to prevention or ART initiation?
What	What package of services and demand creation interventions?	What HTS approach?	What linkage intervention?

HIV testing for reaching undiagnosed PLHIV

Effective Focused Facility-based HTS

High burden settings:
HTS in every health contact –
integration

Low burden settings:
HTS in hotspots/select
services (TB, STI, key pops)

HIVST & Community Approaches

High burden settings:
outreach for key pops,
partners PLHIV, hotspots,
consider workplace, strategic
outreach

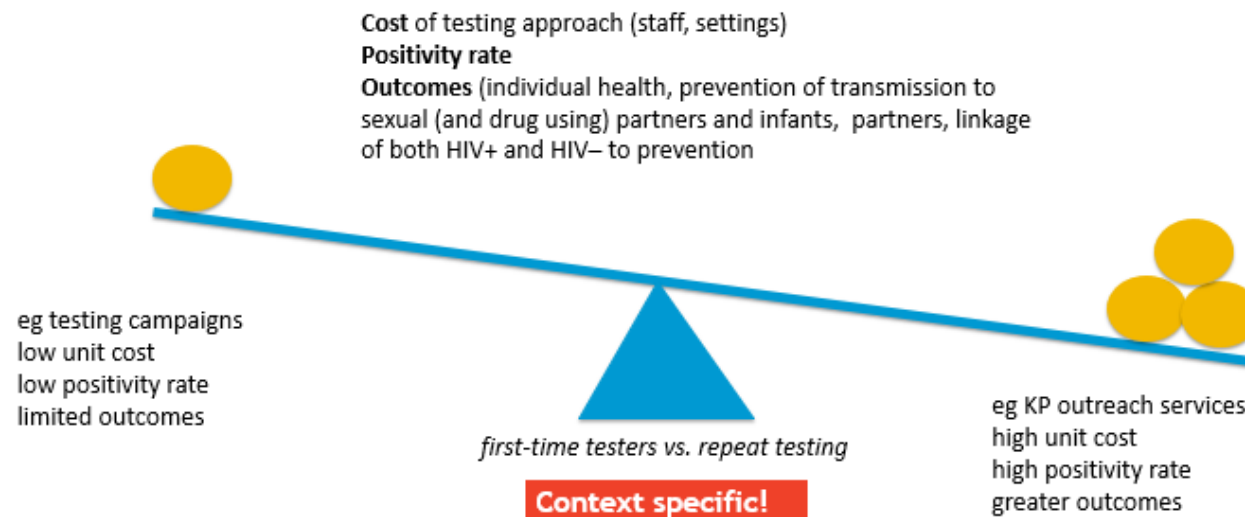
Low burden settings:
outreach to key pops,
partners PLHIV

Couples and Partners

High burden settings:
offer all, and for partners of
KP and PLHIV

Low burden settings:
offer to KP and partners of
PLHIV

Balancing efficiency and impact



- Reorienting HTS to reach the most PLHIV (#) who don't know their status as effectively and efficiently as possible (%)
- A strategic mix of HTS approaches and options needed to reach priority populations
 - Key populations and their partners
 - Partners PLHIV
 - Young people (15-24) and men in ESA

HIV testing within prevention

HIV testing services are also part of implementing and monitoring prevention services to help:

1. **HIV-negative** ppl stay negative (monitoring)
2. **Diagnose PLHIV at high risk** and start ART as soon as possible

Core **HIV Prevention** packages with HTS:

- **PMTCT** (1st ANC visit test for all, late pregnancy 3rd trimester only for KP or in high burden settings)
- **PrEP** – quarterly testing
- **Key populations** testing at least annually (up to 3-6 month based on risk)
- **Serodiscordant couples** package of services annually (up to 3-6 month based on risk)

ACCESS++ the prevention toolbox to end HIV



- A**wareness and education
- C**ondom use
- C**ircumcision for boys and men
- E**nding stigma and discrimination
- S**afe blood and injections
- S**terile equipment and harm reduction for people who use drugs
- + HIV medicines used before and after exposure
- + HIV treatment and viral suppression

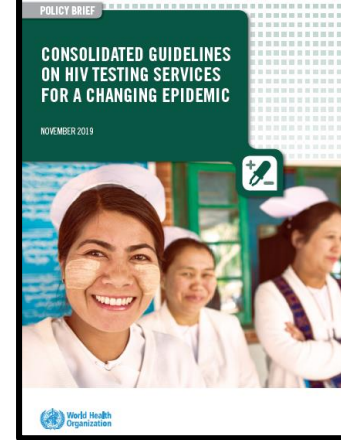


World Health Organization



Recommended HIV Testing Services

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

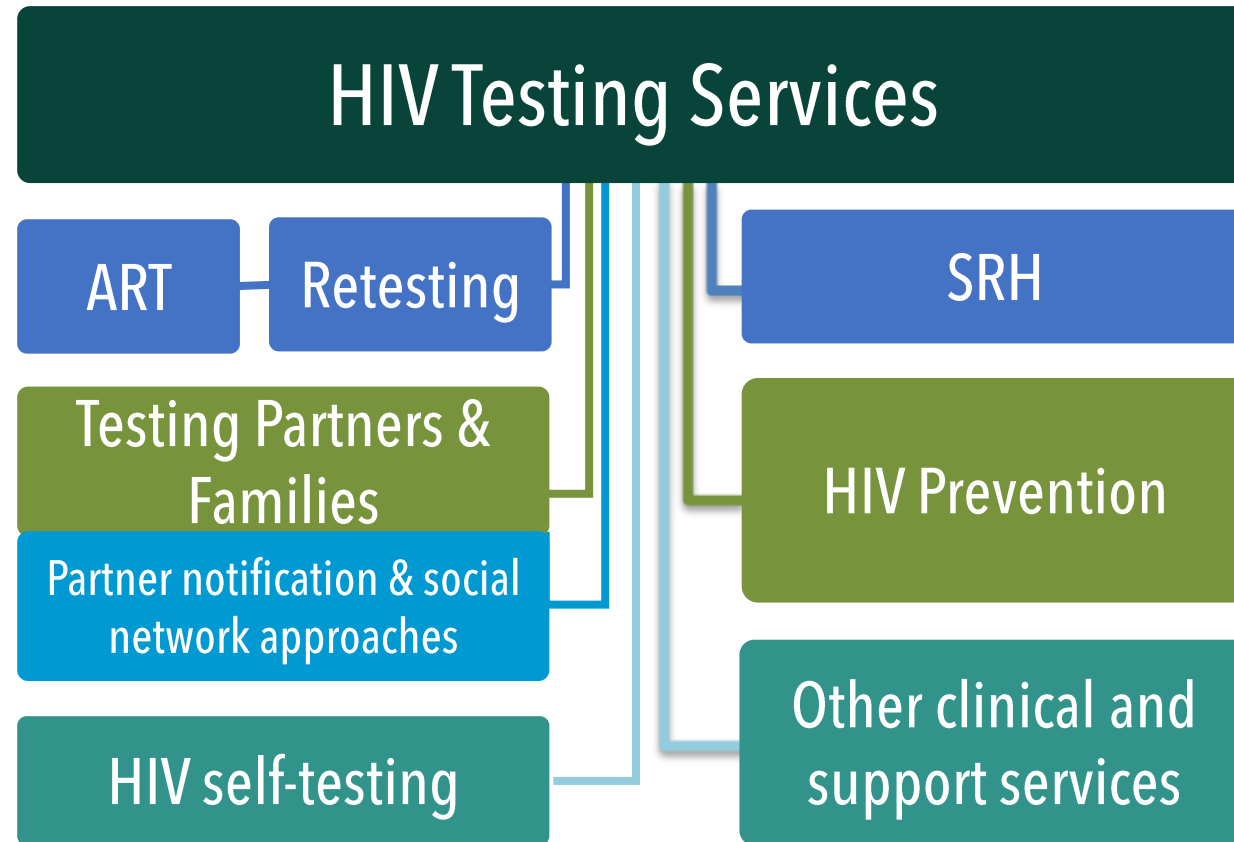


Facility-based: Offering HIV testing in a facility, e.g. VCT, in-patient and out-patient clinics, ANC, TB, STI.

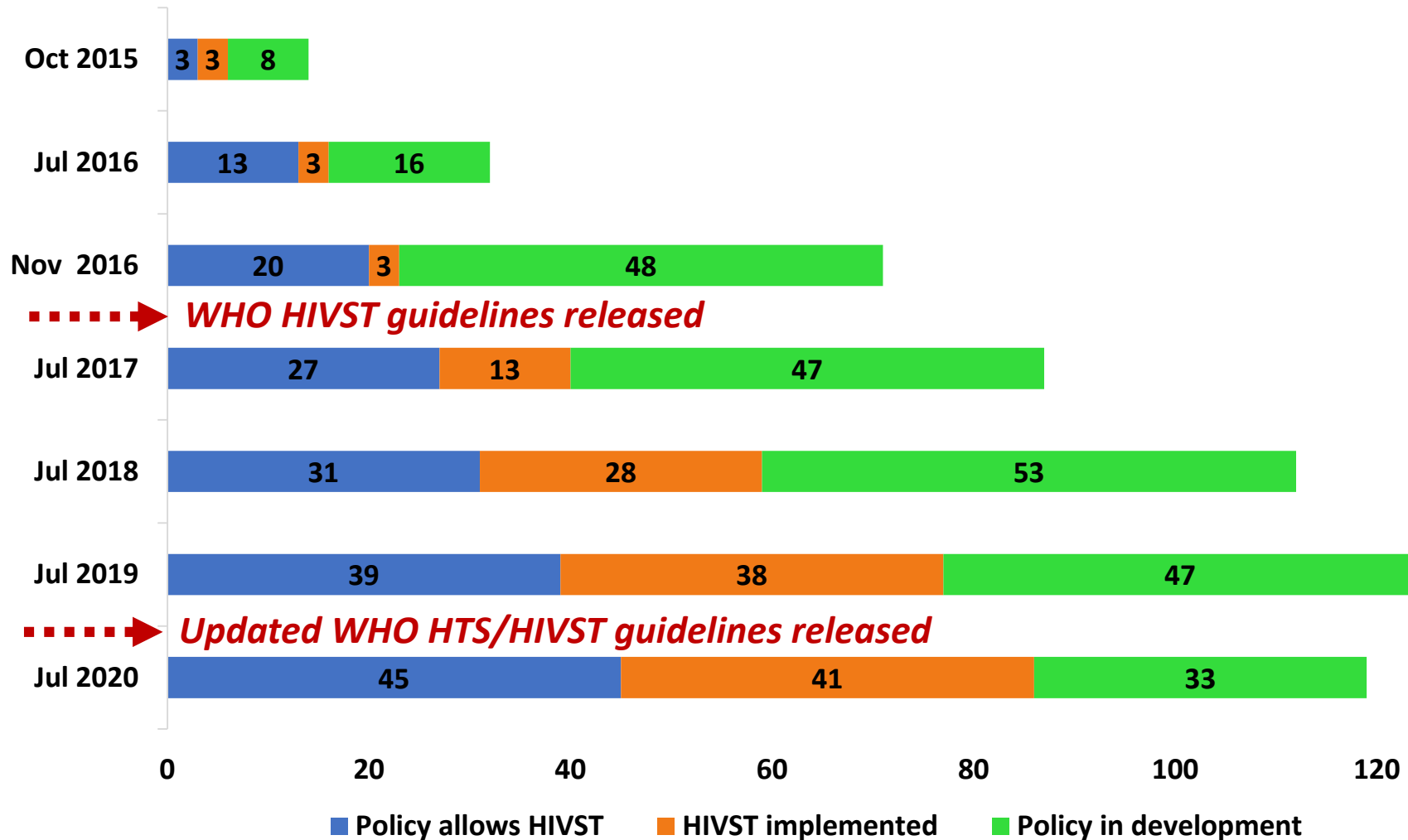
Community-based: Offering HIV testing in natural setting of the community, e.g. outreach, CBOs, workplace, clubs, bars.

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.**



Countries implementing and developing HIVST policies, 2015-2020



.....➔ *WHO HIVST guidelines released*

.....➔ *Updated WHO HTS/HIVST guidelines released*

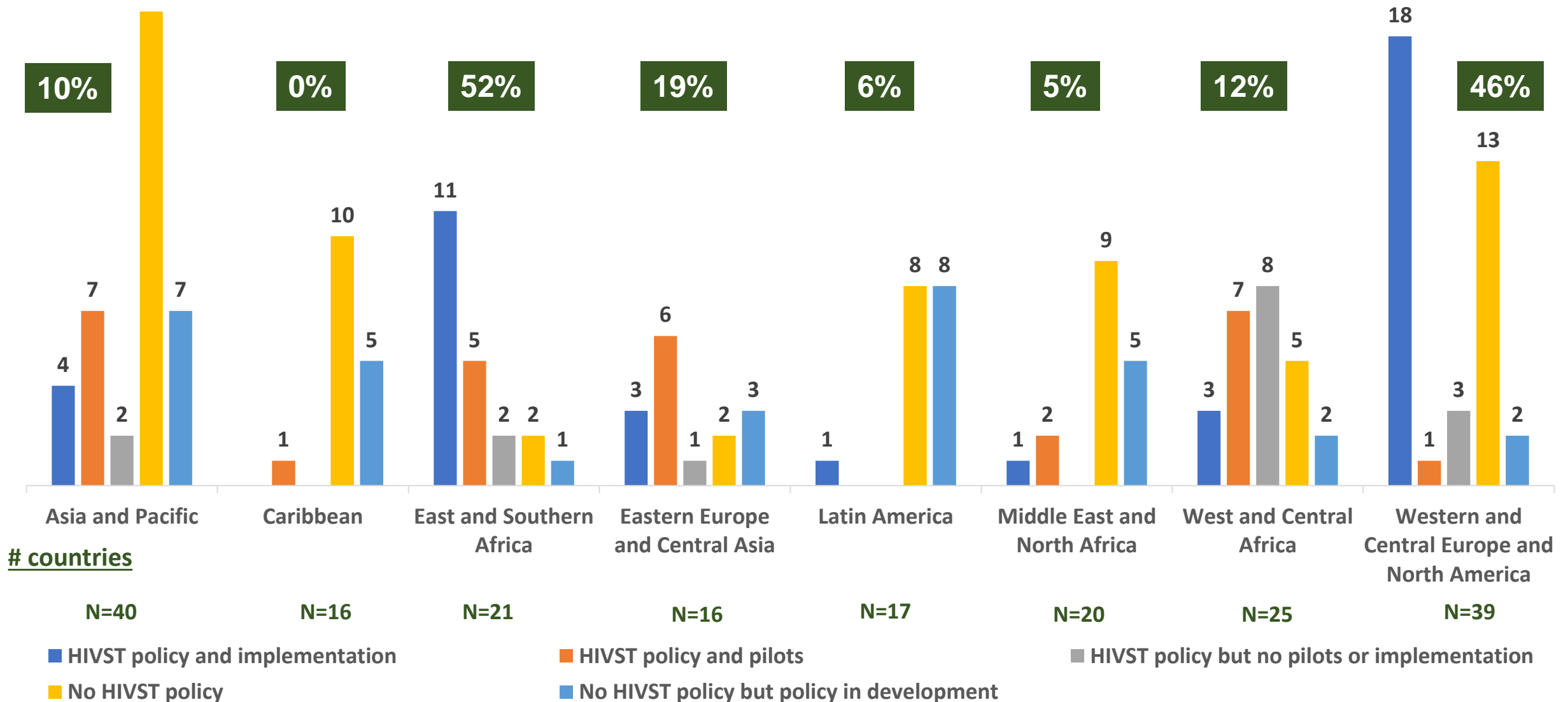


*Between 2017 and 2020
 three times as many
 countries implemented
 HIVST*

National HIVST policy and implementation 2020, by region

44% (86/194) reporting countries have HIVST policies, of these only 48% (41) are implementing

% Implementing

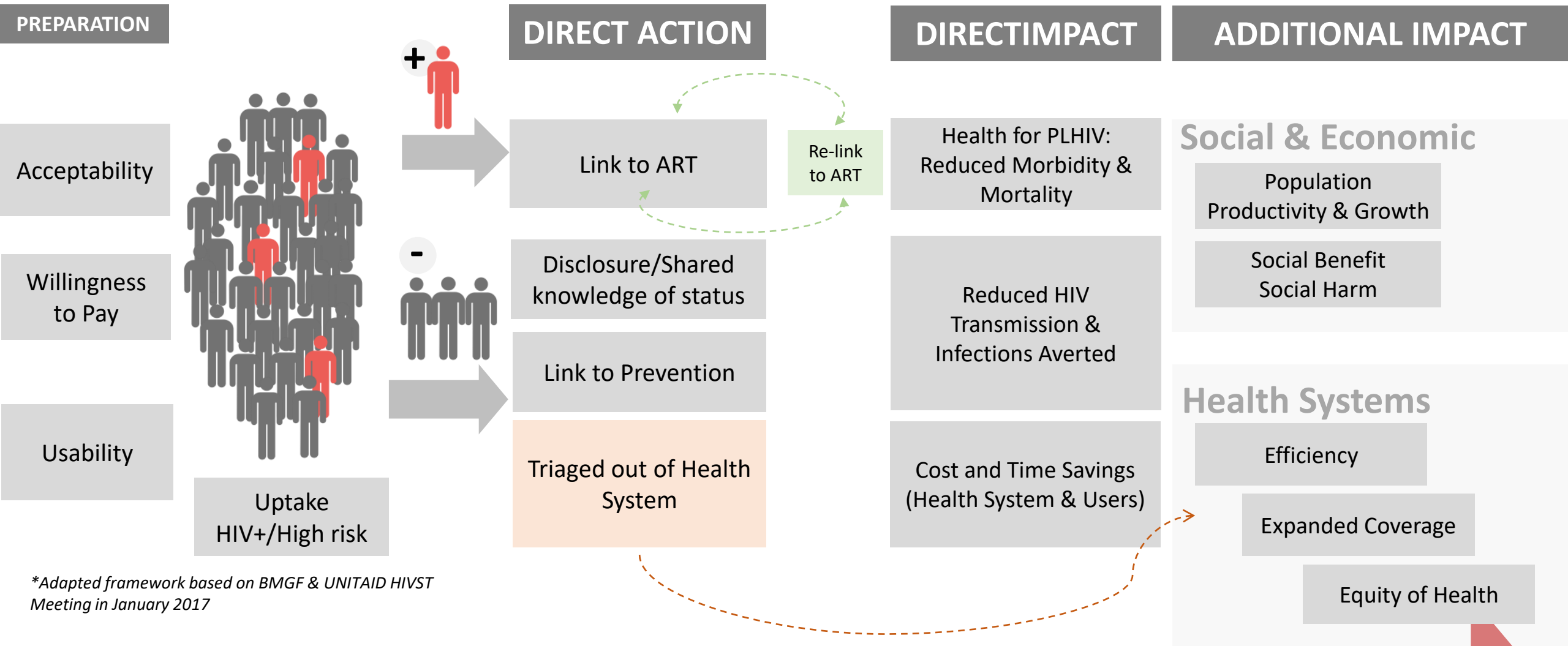


What is HIV self-testing (HIVST)?



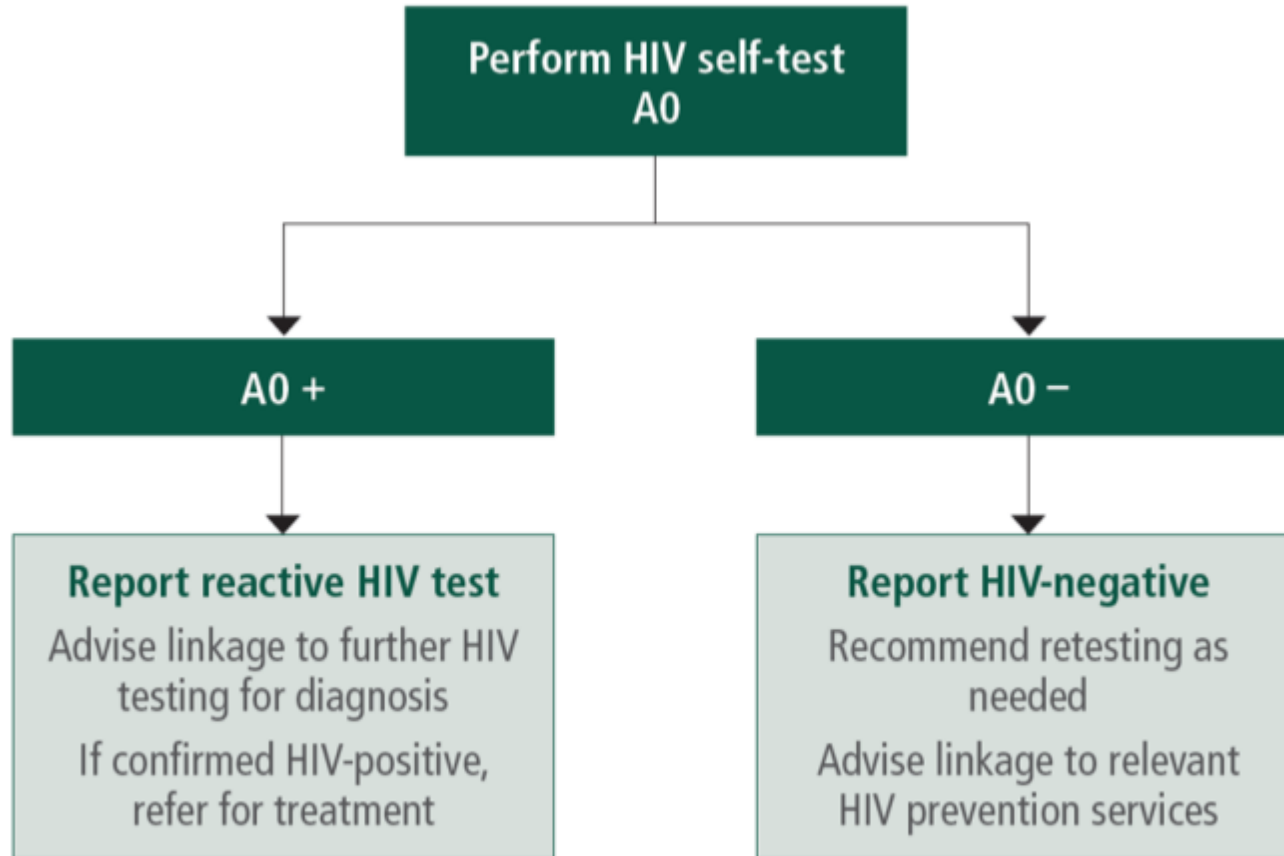
When a person collects his or her own specimen, performs a rapid HIV test and interprets their result
All reactive self-tests need further testing

HIVST Investment Case Framework



**Adapted framework based on BMGF & UNITAID HIVST Meeting in January 2017*

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

WHO recommendations on HIV self-testing



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**
- Comparable linkage and HIV+
- Empowering
- Can be affordable and cost-effective when focused

WHO recommendation:

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

(strong recommendation, moderate quality evidence)

NEW remarks

- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis. Individuals with a reactive test result must receive further testing from a trained tester using the national testing algorithm.



Synthesis of latest evidence

GRADE Review: summary of included RCTs

Category	n
Total	32
General population	21
Key population	11
MSM	8
FSW	3
Individual RCT	17
Cluster RCT	15
Region	
Africa	23 (7 Malawi, 5 Kenya, 4 Zambia, 3 Zimbabwe, 2 Uganda, 2 South Africa)
Americas	5 (all in USA)
Western-Pacific	4 (3 China/Hong Kong SAR, 1 Australia)

- A very small proportion of participants in MSM studies were transgender people (TG)
- No RCTs exclusively among TG, people in prison, or people who inject drugs (PWID)

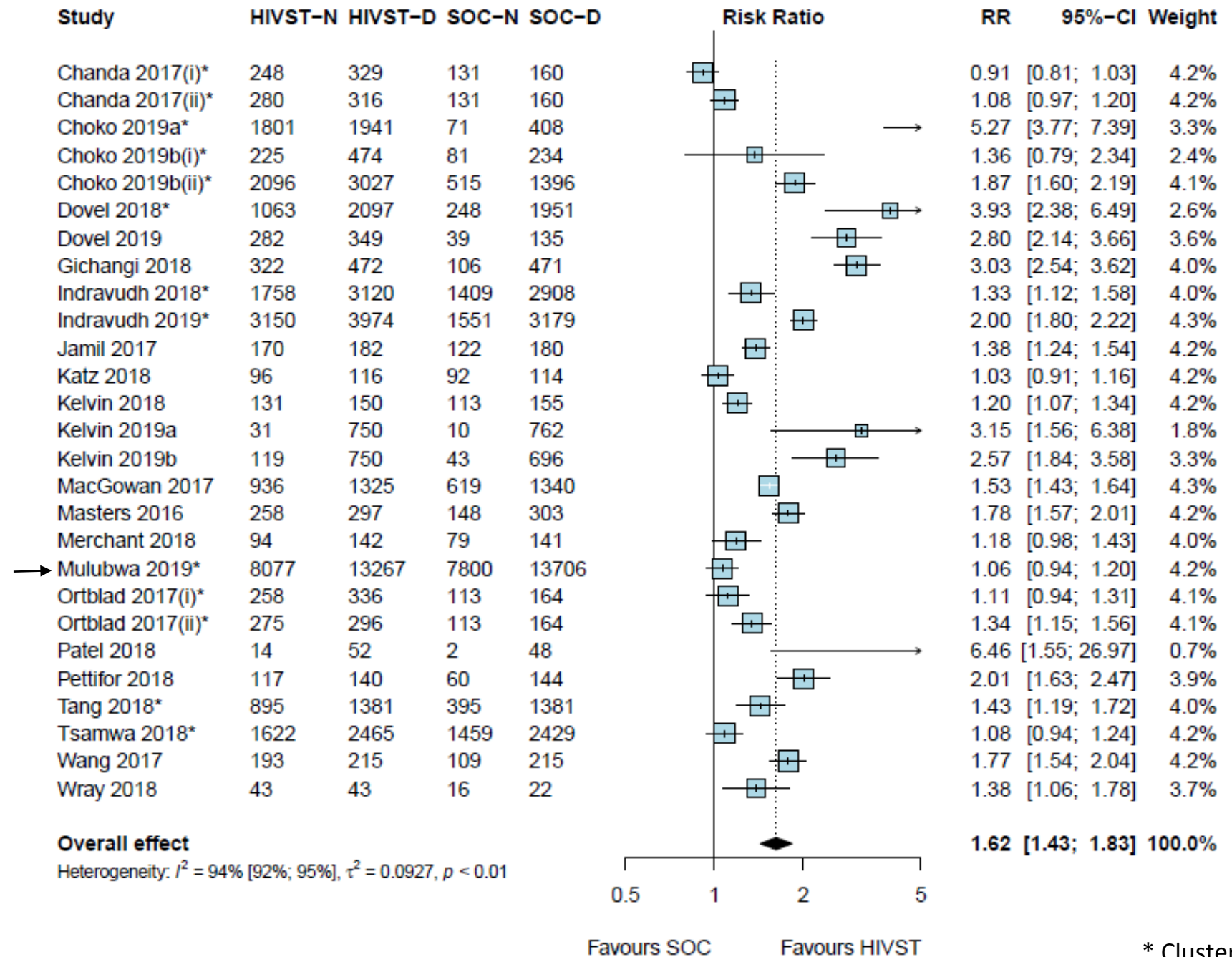
- 3 RCTs exclusively among 15-24 years
- 3 additional RCTs with stratifications for 15-24 years
- No RCTs in < 15 years

- All used oral fluid HIVST kits

Uptake of HIV testing: HIVST vs. SOC

19 of 27 comparisons showed a significant increase

Comparator = Home-based rapid testing (PopART trial)



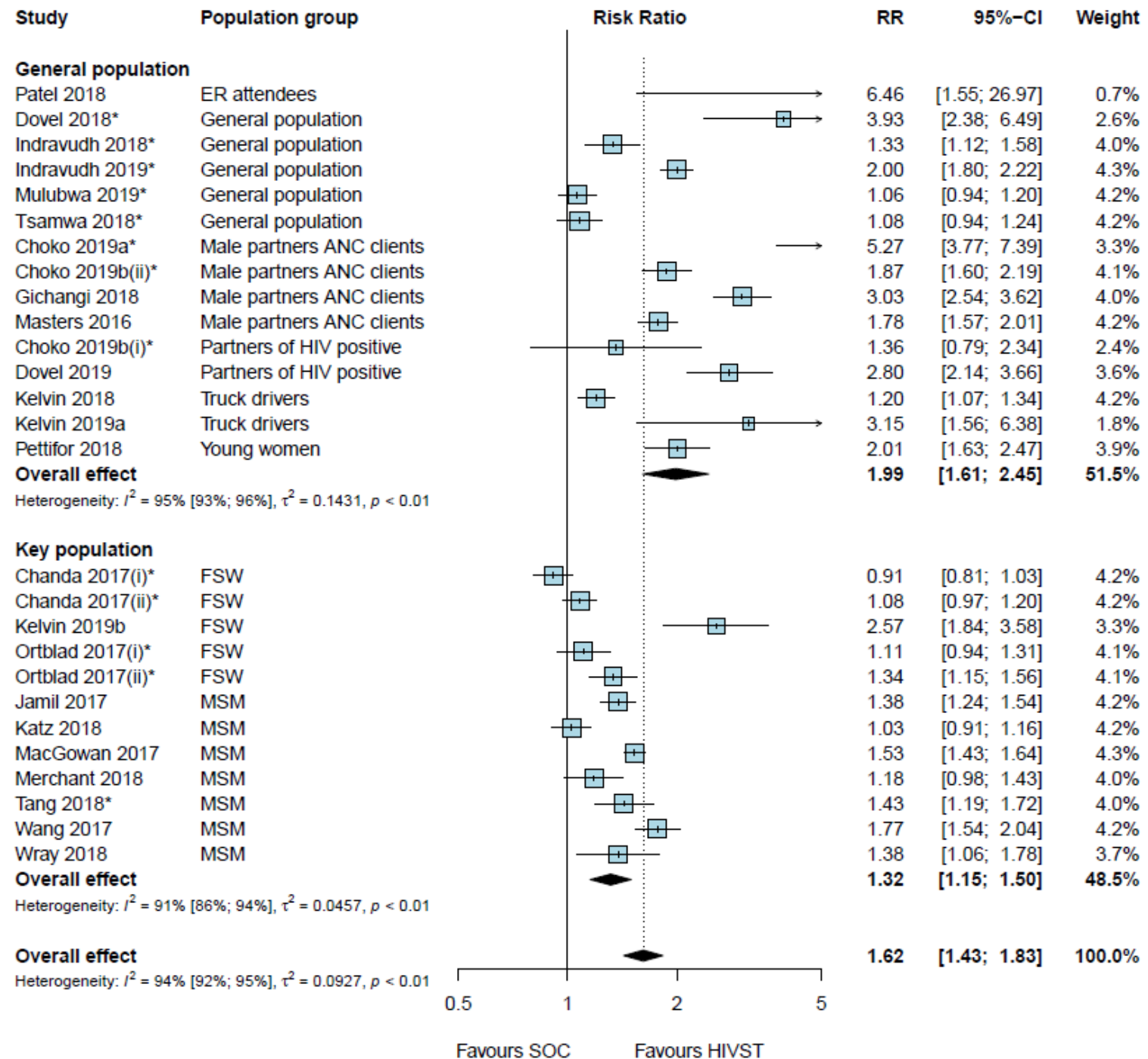
Mean score: 8
Ranking: 1

* Cluster RCT

Uptake of HIV testing: HIVST vs. SOC, by population

Strong effect in

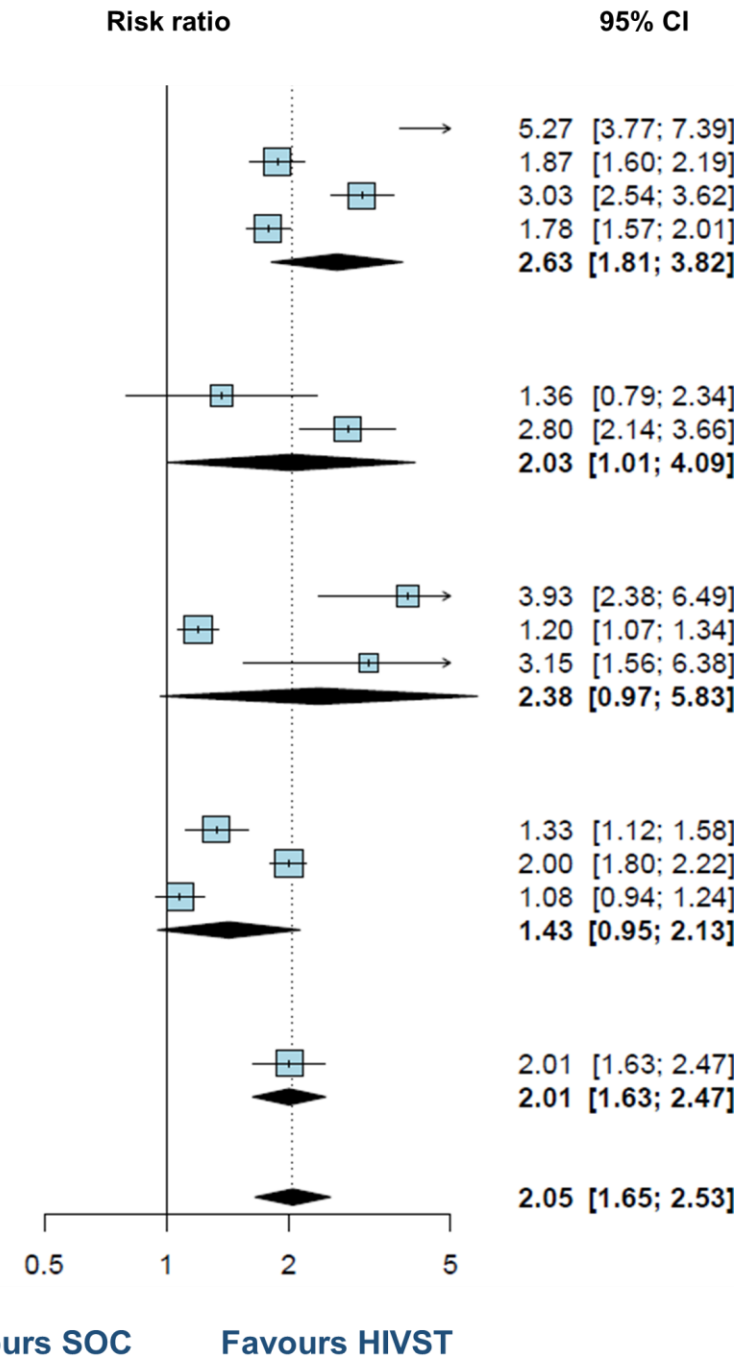
- general populations
- key populations



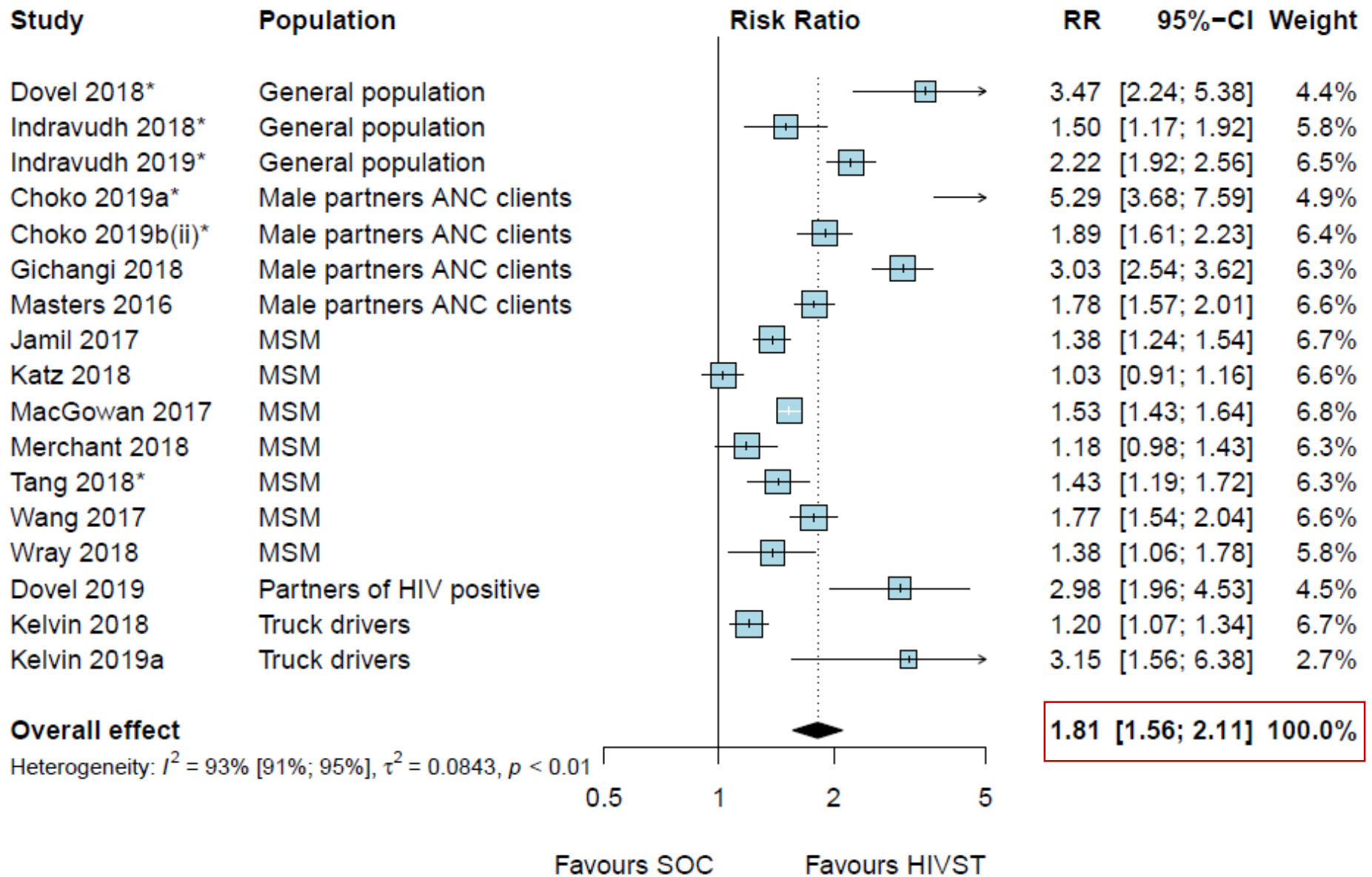
* Cluster RCT

Many HIVST distribution models work well depending on context and population

Study	HIVST		SOC	
	n	N	n	N
Secondary distribution: women to male partners				
Choko 2019a*	1801	1941	71	408
Choko 2019b(ii)*	2096	3027	515	1396
Gichangi 2018	322	472	106	471
Masters 2016	258	297	148	303
Overall effect				
Heterogeneity: $I^2 = 94%$ [89%; 97%], $\tau^2 = 0.1328$, $p < 0.01$				
Secondary distribution: HIV-positive to partners				
Choko 2019b(i)*	225	474	81	234
Dovel 2019	282	349	39	135
Overall effect				
Heterogeneity: $I^2 = 82%$, $\tau^2 = 0.2107$, $p = 0.02$				
HIVST at facilities				
Dovel 2018*	1063	2097	248	1951
Kelvin 2018	131	150	113	155
Kelvin 2019a	31	750	10	762
Overall effect				
Heterogeneity: $I^2 = 92%$ [81%; 97%], $\tau^2 = 0.5685$, $p < 0.01$				
Community or home based distribution				
Indravudh 2018*	1758	3120	1409	2908
Indravudh 2019*	3150	3974	1551	3179
Tsamwa 2018*	1622	2465	1459	2429
Overall effect				
Heterogeneity: $I^2 = 96%$ [92%; 98%], $\tau^2 = 0.1219$, $p < 0.01$				
Facility based distribution				
Pettifor 2018	117	140	60	144
Overall effect				
Heterogeneity: not applicable				
Overall effect				
Heterogeneity: $I^2 = 94%$ [92%; 96%], $\tau^2 = 0.1316$, $p < 0.01$				

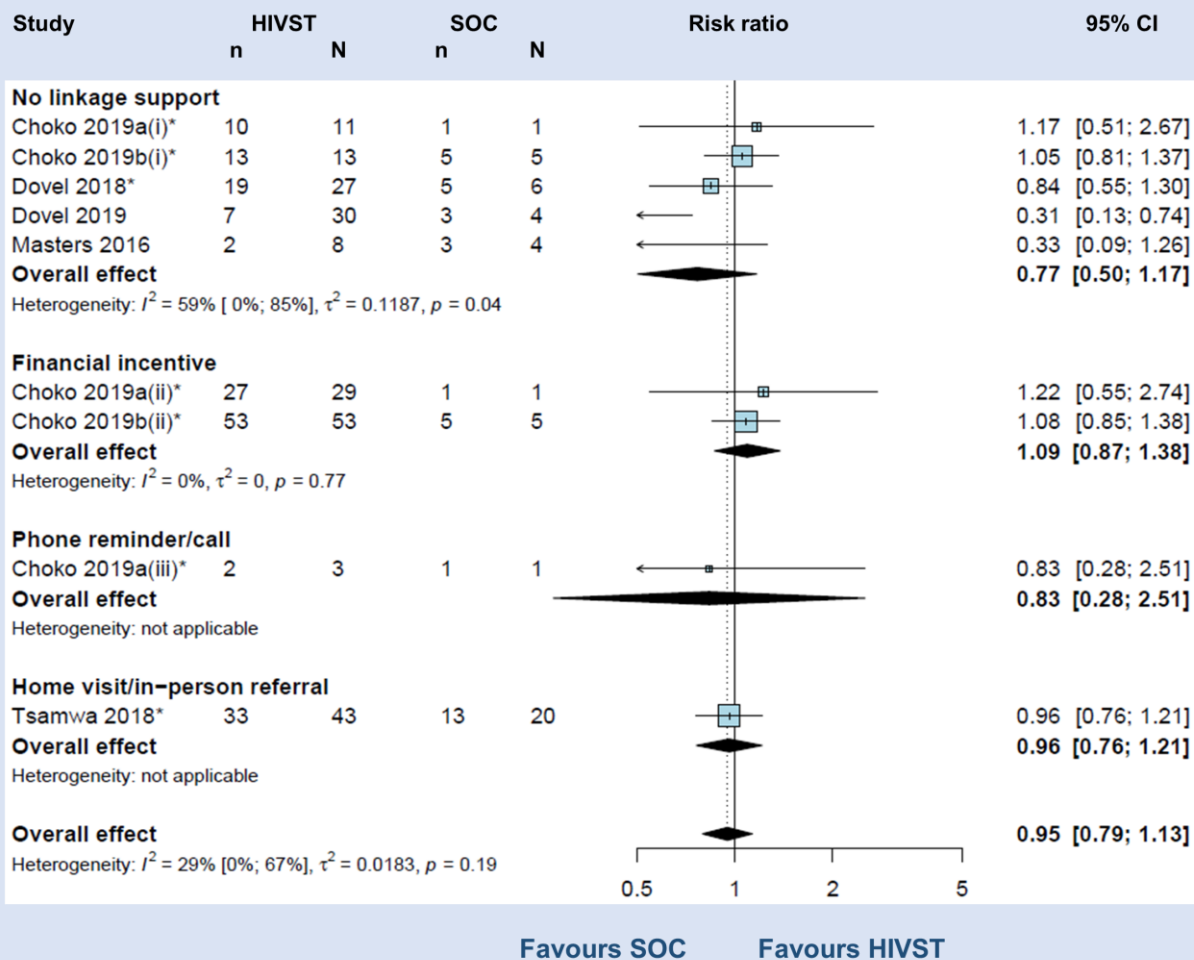


HIVST vs Standard HTS results in ~2-fold increase in uptake among men

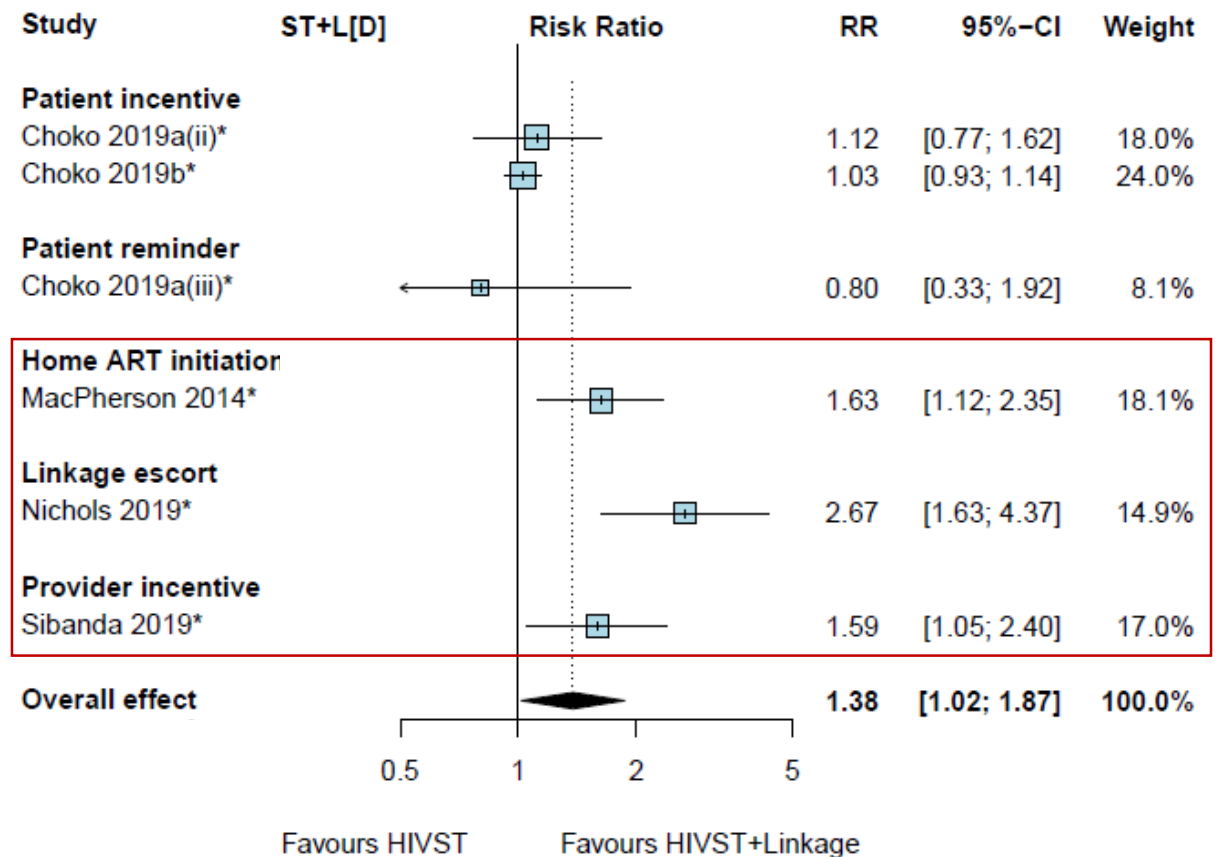


Post-HIVST linkage not significantly different, but linkage support likely helps

Overall linkage to care post-HIVST compared with standard testing



Linkage to care post-HIVST with support intervention compared with standard testing



Linkage to prevention (1)

		Among negative	Among all
Choko 2019a (VMMC referral)	SOC	28.3% (15/53)	3.7% (15/408)
	HIVST only	41.9% (31/74)	7.0% (31/442)
	HIVST + \$3*	32.6% (47/144)	12.4% (47/380)
	HIVST + \$10*	33.3% (84/252)	16.4% (84/512)
	HIVST + lottery	23.1% (6/26)	3.9% (6/155)
	HIVST + phone reminder	48.1% (39/81)	8.6% (39/452)
Hatzold 2019 (VMMC uptake per IPC-agent month, mean)	Standard community mobilization (SCM)	34.1	27.7
	SCM + HIVST	22.4	13.8
	SCM + HCD-informed demand generation	35.4	26.9
	SCM + HCD + HIVST	16.7	10.3
	No effect of intervention: HCD-informed IRR = 0.87 (95% CI: 0.38-2.02); HIVST IRR = 0.65 (95% CI: 0.28-1.50)		
	The linkage rate was significantly lower in the IPN arm compared to SOC, but similar between PND and SOC		

*Significant difference compared to SOC according to authors when combining linkage among HIV positives

Linkage to prevention (2)

		Among negative	Among all
Shahmanesh 2019 (PrEP screening 18-30 women)	SOC (peer-navigator distribute referral slips)		6.7% (46/686)
	HIVST - incentivized peer-network		0.6% (4/632)
	HIVST - peer-navigator distribution		47/898 (5.2%)
	The linkage rate was significantly lower in the IPN arm compared to SOC, but similar between PND and SOC		
Sibanda 2019**	HIVST + fixed incentive	1.4% (12/853)	
	HIVST + fixed & conditional incentive	2.2% (19/854)	
Wray 2018 (PrEP referral)	SOC		13.6% (3/22)
	HIVST		9.1% (2/22)
	eTest		3.8% (8/21)
	eTEST participants were significantly more likely to have received PrEP referrals than either control.		
Wray 2018 (PrEP prescription)	SOC		4.5% (1/22)
	HIVST		4.5% (1/22)
	eTest		9.5% (2/21)
	Higher among eTEST participants but non-significant.		

**Non-significant difference

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**
- **Millions HIVST kits distributed with close monitoring in 6 African 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/



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



Quantitative V&P – summary of findings

All populations (n=73)	Key populations (n=36)	HCW/providers (n=12)
<ul style="list-style-type: none"> • Willingness* to use HIVST: 44% - 100% • Would recommend HIVST to a partner, friend, family or their clients: 8 - 100% • Majority found HIVST kits easy to use • HIVST gives them more power and control over their health and choices • Some valued confidentiality provided by HIVST • Some desired support for testing and for reactive results. • No clear preference for oral or blood tests (some prefer oral as pain-free and perceived simple; some consider blood to be more accurate) • Willingness to pay for HIVST: US\$0.5 – 30 • Social harms or adverse events very rare. • No reports of suicide 	<ul style="list-style-type: none"> • Would recommend HIVST to a partner, friend, family or their clients: 39 - 100% • Very few reported emotional challenges when using HIVST • One study reported forced testing (coercion) with HIVST <div data-bbox="817 486 1951 605" style="background-color: #2c5e8a; color: white; text-align: center; padding: 5px;"> General population (n=23) </div> <ul style="list-style-type: none"> • Would recommend HIVST to a friend or family: 8-97% • Some valued convenience of HIVST (e.g. fast results, no need for appointments) <div data-bbox="817 768 1951 886" style="background-color: #333; color: white; text-align: center; padding: 5px;"> Other vulnerable populations** (n=14) </div> <ul style="list-style-type: none"> • Would recommend HIVST to others: 85 - 97% • Some concerns about confidentiality, misuse and disclosure – more so than other groups • Willingness to pay ranged 3.3 -15 USD 	<ul style="list-style-type: none"> • 64-73% would welcome the introduction of HIVST • Very few fear job losses due to HIVST • Very few reported concerns about inaccurate results • HIVST was perceived to be safe for various populations • Some early concerns about unsafe disposal, suicide, human rights issues or other social harm. • Willingness to pay ranged 0.1–6.3 USD, a few thought this service should be free for users

Take away: high willingness to use HIVST, easy to use, convenience valued. Many would recommend HIVST to others. Some concerns about confidentiality, misuse and disclosure. Preference for free or low cost kits. Social harms were very rare. HCW support HIVST introduction, some concerns about job security.

* Likelihood to use HIVST, willingness to use HIVST in the future, preference to use HIVST over other HTS

** include: pregnant women (2), fishermen (1), PLHIV (2), truck drivers (1), uninfected couples of PLHIV (3), black Africans (1), young people (4)

HTS programme costs per person tested vary widely

by setting, population and approach

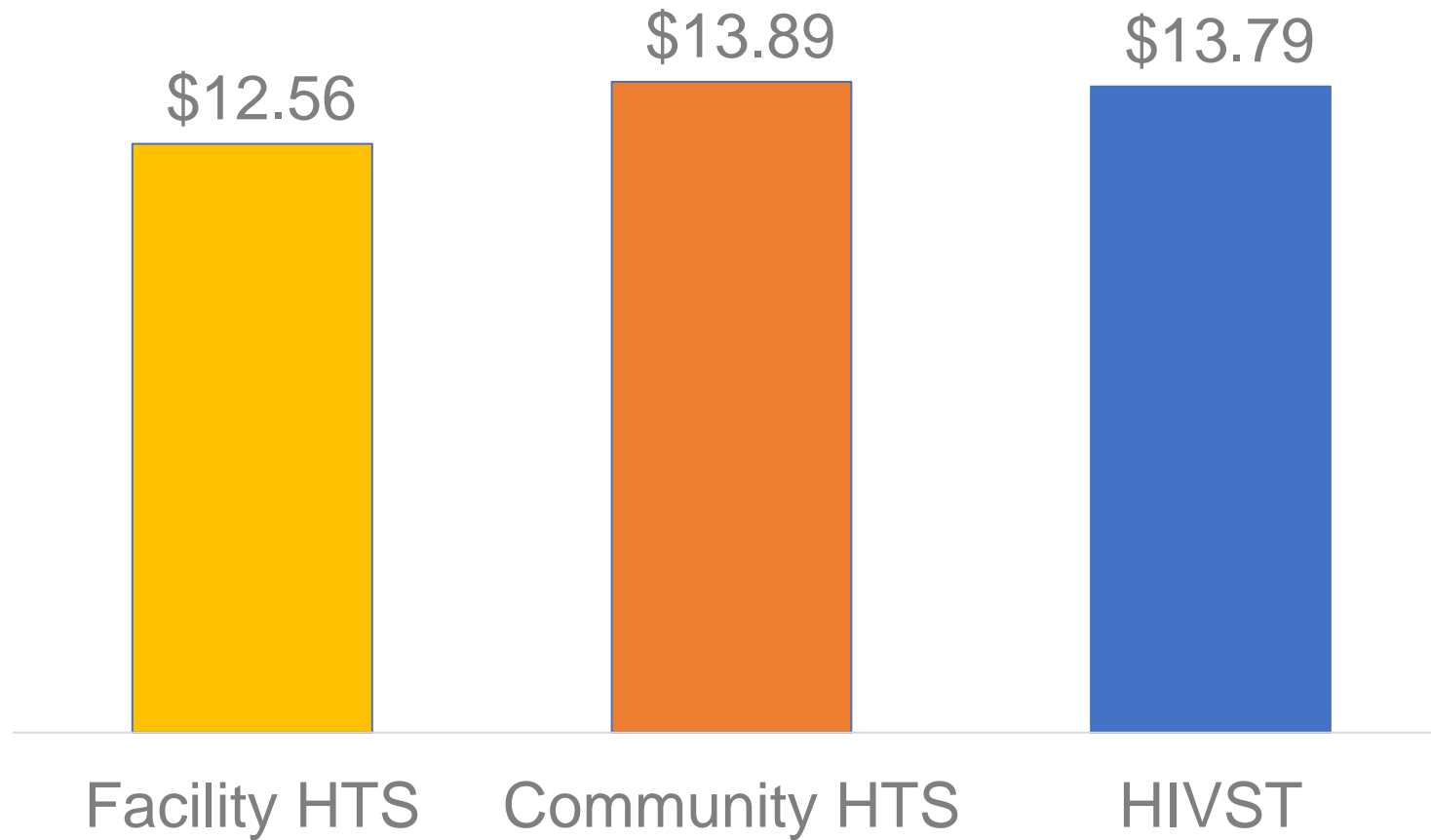
Previous
review

	Low- to upper-middle income countries		High-income countries			All settings
Approach	General pop	Key pop	General pop	Key pop	Other at-risk pop	All pop
Mobile	Median: \$20 Range: \$7–\$46	Median: \$5 Range: \$3–\$6		Median: \$231 Range: \$96–\$709	Median: \$999 Range: \$520– \$1529	Median: \$114 Range: \$3–\$1529
Facility	Median: \$10 Range: \$2–\$58	Median: \$11 Range: \$6–\$43	Median: \$56 Range: \$20– \$115	Median: \$177 Range: \$93–\$209	Median: \$109 Range: \$90–\$129	Median: \$16 Range: \$2–\$209
VCT standalone	Median: \$50 Range: \$26–\$147	Median: \$7 Range: \$4–\$9				Median: \$31 Range: \$4–\$147
Home-based	Median: \$11 Range: \$7–\$19					Median: \$11 Range: \$7–\$19
Other				Median: \$67 Range: \$34–\$160	Median: \$803 Range: \$52–\$1642	Median: \$83 Range: \$34–\$1642
Totals	Median: \$13 Range: \$2–\$147	Median: \$6 Range: \$3–\$43	Median: \$56 Range: \$20– \$115	Median: \$123 Range: \$34– \$709	Median: \$803 Range: \$52– \$1642	Median: \$28 Range: \$2–\$1642

HIVST and HTS programme costs in sub-Saharan Africa may not be too different

Previous review

Median cost per person tested reported



- Costs represent crude programme costs and do not take into account
 - Efficiency (HIV+%)
 - Equity (KP and untested pops)
 - Opportunity cost (cost to testers)
- HIVST reaches those who never come to facilities or where additional cost to get to facilities is considerable

Source: Sharma Nature, 2015; Mangelah JIAS 2019. *Costs are not directly comparable, only illustrative.* Sharma reports across approaches. Mangelah only reports on community-based HIVST and substantial start-up costs.

Products and usability for HIVST

Accuracy and Usability

- Nearly all HIVST products available have been adapted from existing WHO PQed HIV rapid diagnostic tests used for professional use.
 - In this way – many are highly accurate and meet the WHO $\geq 99\%$ sensitivity and $\geq 98\%$ specificity when evaluated in the hands of professional testers.
- Usability, however, is when we are looking at these tests in the hands of self-testers who are a diverse and non-uniform group with varying literacy, education levels etc.
 - In this way – a highly accurate rapid HIV test for professional use may perform poorly when used by self-tester. Not because the technology is different, but because of issues such as design, labelling, packaging.

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.

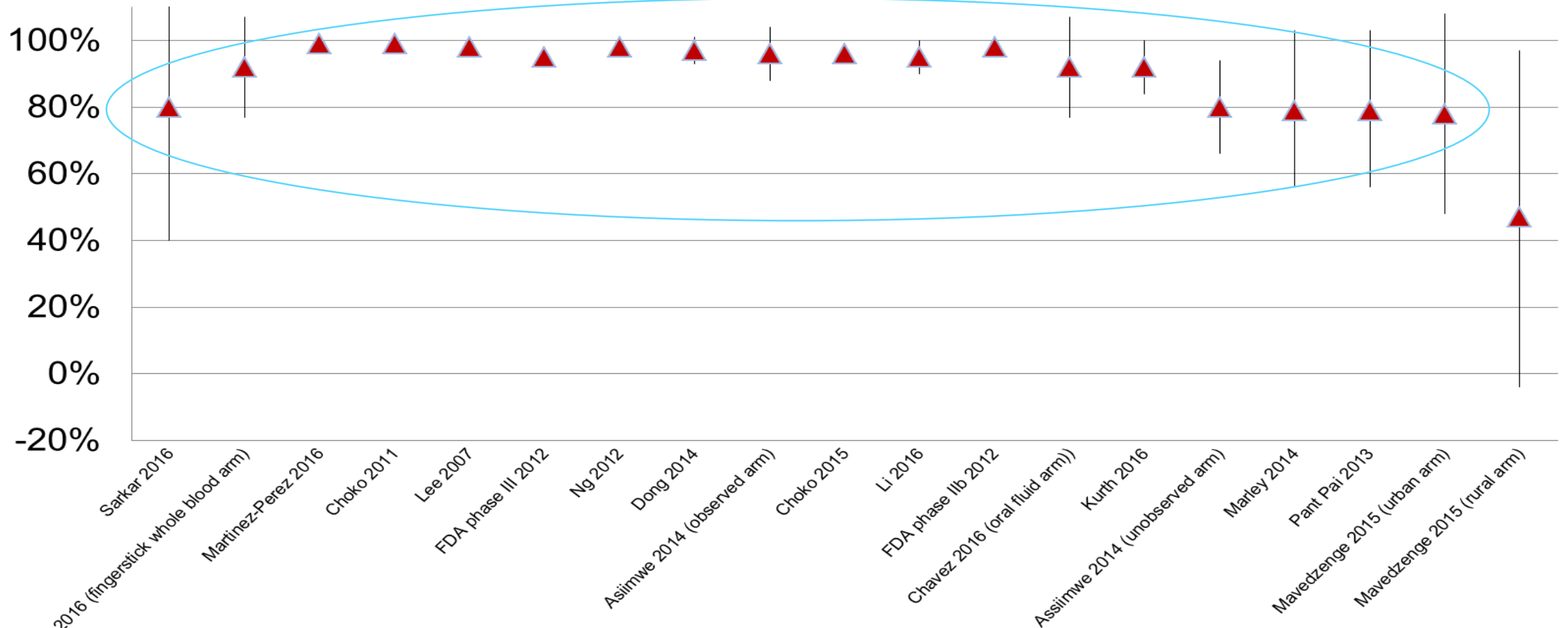
Interpretation Self-testers can reliably and accurately do HIV rapid diagnostic tests, as compared with trained health-care workers. Errors in performance might be reduced through the improvement of rapid diagnostic tests for self-testing, particularly to make sample collection easier and to simplify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

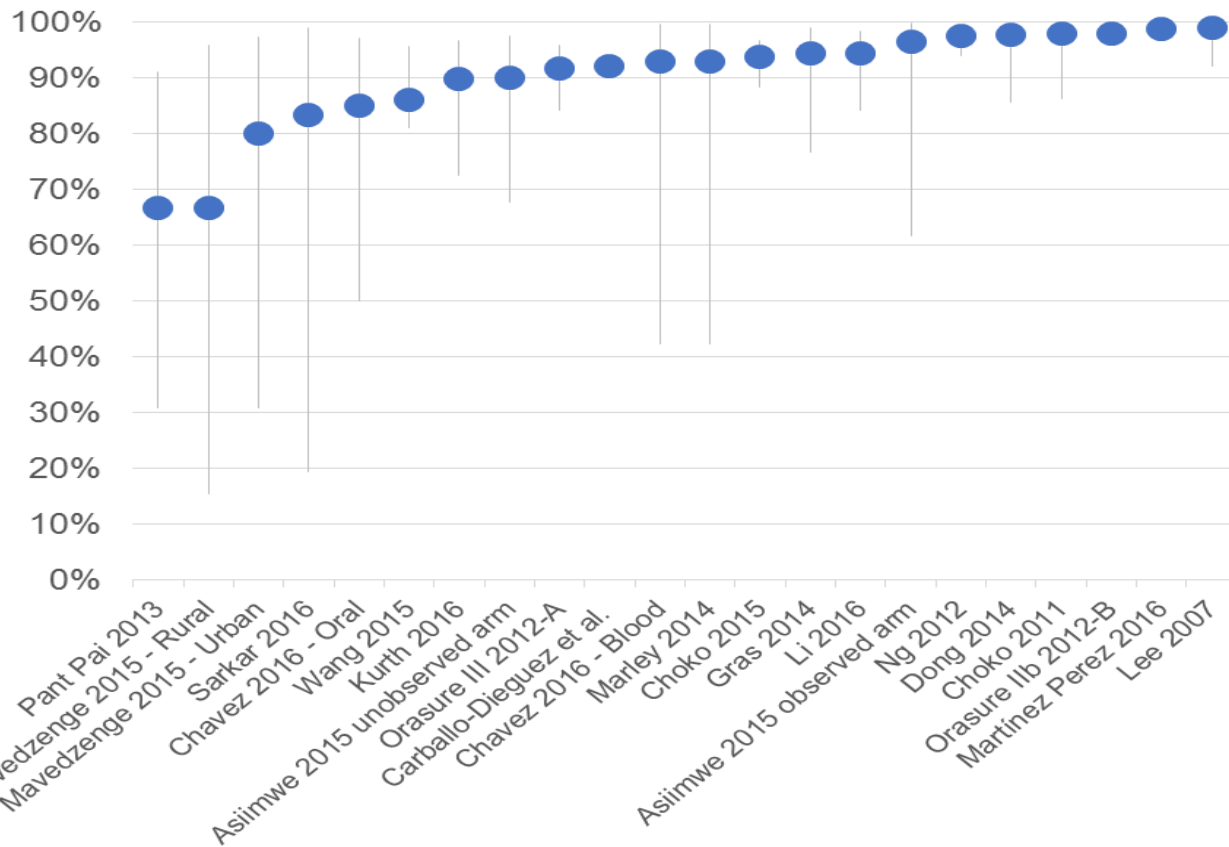
Concordance of HIV RDT result performed by self-tester compared to trained health worker

Measured using kappa statistic – 16 studies

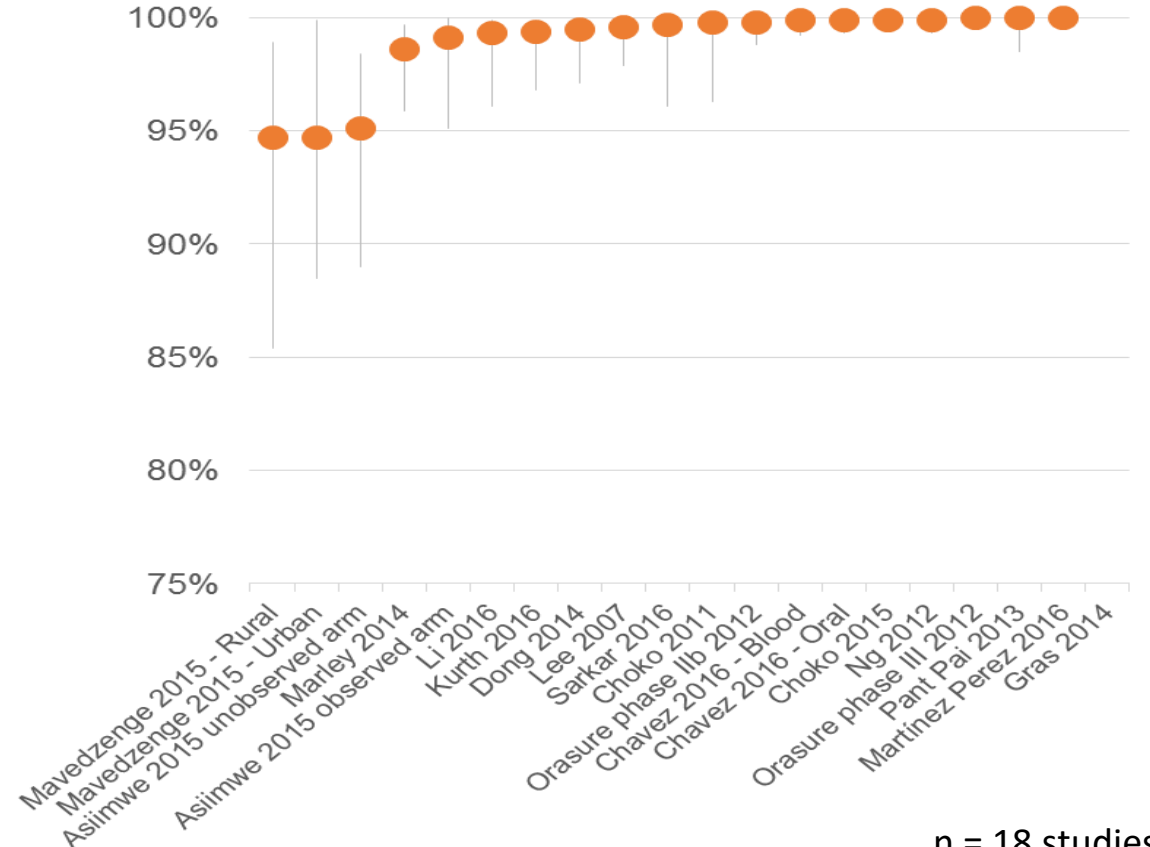


Sensitivity and Specificity

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



Specificity
as high as 100% (95% CI 99.9 – 100 %)



n = 18 studies

A clinical utility risk-benefit analysis for HIV self-testing

AUTHORS:

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1. World Health Organization, Department of HIV, Geneva, Switzerland; 2. London School of Hygiene and Tropical Medicine, London, UK ; 3. University College London, London, UK; 4. World Health Organization, Essential Medicines and Health Products, Geneva, Switzerland; 5. Malawi Liverpool Wellcome Trust, Blantyre, Malawi; 6. Population Services International, Harare, Zimbabwe; 7. Liverpool School of Tropical Medicine, Liverpool, UK

BACKGROUND
 HIV self-testing (HIVST) offers a new way to diagnose HIV infection. Many countries are adopting HIVST, and evidence is growing that it can improve HIV testing rates. However, the clinical utility of HIVST is not clear, and it is important to understand the risks and benefits of HIVST compared to other HIV testing options. This study conducted a risk-benefit analysis to estimate the net clinical utility of HIVST compared to other HIV testing options.

METHODS
 We used a decision-analytic model to estimate the net clinical utility of HIVST compared to other HIV testing options. The model included HIVST, self-testing, and other HIV testing options. We varied the sensitivity and specificity of HIVST, the linkage to prevention and treatment services, and the prevalence of HIV. We calculated the net clinical utility of HIVST compared to other HIV testing options for different scenarios.

RESULTS
 In most scenarios, the net clinical utility of HIVST was positive, indicating that the benefits of HIVST outweighed the risks. The net clinical utility of HIVST was highest in high-prevalence settings with high linkage to prevention and treatment services. The net clinical utility of HIVST was lowest in low-prevalence settings with low linkage to prevention and treatment services.

Table 1a. Percent of situations with net positive results, overall

Prevalence	Sensitivity				Linkage	Total
	95%	90%	85%	80%		
10%	80%	70%	60%	50%	50%	60%
20%	85%	75%	65%	55%	50%	65%
30%	90%	80%	70%	60%	50%	70%
40%	95%	85%	75%	65%	50%	80%
50%	100%	90%	80%	70%	50%	90%
60%	100%	95%	85%	75%	50%	100%
70%	100%	100%	90%	80%	50%	100%
80%	100%	100%	95%	85%	50%	100%
90%	100%	100%	100%	90%	50%	100%
100%	100%	100%	100%	100%	50%	100%

Table 1b. Percent of situations with net positive results, overall (95-100%)

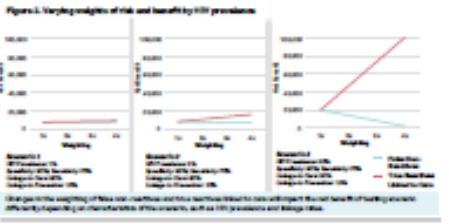
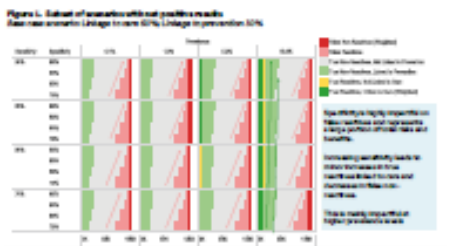
Prevalence	Sensitivity				Linkage	Total
	95%	90%	85%	80%		
10%	80%	70%	60%	50%	50%	60%
20%	85%	75%	65%	55%	50%	65%
30%	90%	80%	70%	60%	50%	70%
40%	95%	85%	75%	65%	50%	80%
50%	100%	90%	80%	70%	50%	90%
60%	100%	95%	85%	75%	50%	100%
70%	100%	100%	90%	80%	50%	100%
80%	100%	100%	95%	85%	50%	100%
90%	100%	100%	100%	90%	50%	100%
100%	100%	100%	100%	100%	50%	100%

Table 1c. Percent of situations with net positive results, according to HIV prevalence, linkage to prevention and care

Prevalence	High HIV Prevalence (70% and 80%)				Linkage	Total
	95%	90%	85%	80%		
10%	80%	70%	60%	50%	50%	60%
20%	85%	75%	65%	55%	50%	65%
30%	90%	80%	70%	60%	50%	70%
40%	95%	85%	75%	65%	50%	80%
50%	100%	90%	80%	70%	50%	90%
60%	100%	95%	85%	75%	50%	100%
70%	100%	100%	90%	80%	50%	100%
80%	100%	100%	95%	85%	50%	100%
90%	100%	100%	100%	90%	50%	100%
100%	100%	100%	100%	100%	50%	100%

Table 1d. Percent of situations with net positive results, according to HIV prevalence, linkage to prevention and care

Prevalence	Low HIV Prevalence (10% and 20%)				Linkage	Total
	95%	90%	85%	80%		
10%	80%	70%	60%	50%	50%	60%
20%	85%	75%	65%	55%	50%	65%
30%	90%	80%	70%	60%	50%	70%
40%	95%	85%	75%	65%	50%	80%
50%	100%	90%	80%	70%	50%	90%
60%	100%	95%	85%	75%	50%	100%
70%	100%	100%	90%	80%	50%	100%
80%	100%	100%	95%	85%	50%	100%
90%	100%	100%	100%	90%	50%	100%
100%	100%	100%	100%	100%	50%	100%



CONCLUSION
 In the majority of scenarios, HIVST was exceeding the benefits of diagnostic linkage to HIV prevention and treatment services. While HIVST's clinical utility is greater when performance is greater, this study suggests that net benefits can be achieved even with performance below commonly acceptable standards (80% sensitivity and 95% specificity) in most settings considered, provided services linking self-testers to HIV prevention and treatment services are functional. For very high prevalence settings, such as those among female sex workers in Johannesburg, South Africa (72%), arbitrary low linkage (23%), 80% sensitivity and specificity would be needed to achieve a net positive benefit. This emphasizes the need to focus on effective linkage following HIV self-testing, as well as testing services.

The likelihood of achieving a high level of clinical utility using HIVST should be high as studies have shown HIVST sensitivity (80–100%) and specificity (95.1–100%).

LIMITATIONS
 This clinical utility analysis assessed HIVST risk and benefit based on performance data and did not consider additional health or economic harms.

In addition, the weightings utilized in the model were derived from expert opinion due to the absence of sufficient data. It was an early step in exploring the analysis using data from the HIV self-test utility (HIVSTU) program to more accurately model the consequences of false results and non-results, as well as the benefits of current health services.

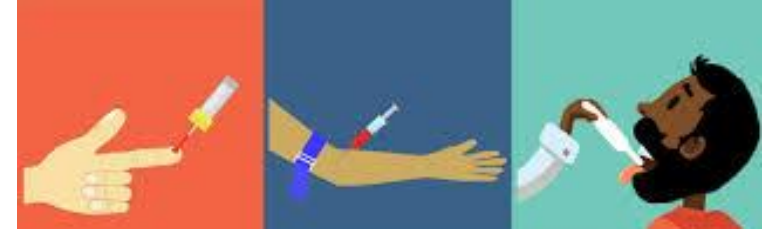
In the majority of scenarios, risks were exceeded by the benefits of diagnosis and linkage... Analysis suggests that net benefit can be achieved even with **≥90% specificity and ≥70% sensitivity** in most all settings considered; provided services linking self-testers to HIV prevention and treatment services are functional.

For very high prevalence settings, e.g. sex workers in Johannesburg (72%), with very low linkage (23%), **≥90% sensitivity and specificity** would be needed.

The likelihood of achieving a high-level of clinical utility using HIVST should be high as studies have shown HIVST kits can achieve sensitivity (80–100%) and specificity (95.1–100%).

ARVs for treatment or prevention can impact self-test results

- ARV drugs work to suppress the HIV virus and can impact the production of HIV antibodies.
- People with HIV who are on ART (or those who acquire HIV while taking PrEP) may have a false nonreactive (negative) self-test result.
- Important people are made aware and those on ART and PrEP can be directed to appropriate services.



Public health approach to quality HIV testing in the context of antiretroviral drugs

Meeting report

12-13 December 2017 | Centre for the AIDS Programme of Research in South Africa, Durban, South Africa

ART may impact HIV testing technologies, programmatic and surveillance considerations

The following key information was identified in a WHO review of the literature and by meeting participants:

- While not recommended by WHO, and usually not beneficial, many people with HIV and receiving ART do retest.
- ART impacts sensitivity of HIV serology tests, but review of evidence suggests effects are not substantial.
- Some HIV tests may perform better, or worse, than others, among a population on ART. Second generation serology tests and oral fluid-based RDTs, including those used for HIV self-testing, are likely to be most affected.

Ensure products are quality assured

Choose *products with acceptable specifications*

Professional use \geq 99% Sensitivity and \geq 98% Specificity in laboratory evaluation

1. Labelling study - Ensure self-testers understand questions. Given to at least 200 subjects, representative of end users, in order to demonstrate comprehension of key messages.

2. Result interpretation study – Ensure self-testers can read result. A minimum of 400 subjects to interpret the results of contrived IVD (e.g. Non-reactive; Range of invalid results; Reactive and Weak reactive) among diverse high and low prev, education etc.

3. Observed untrained user study – Testing by at least 900 self-testing subjects comprising: at least 200 self-testers in each of two high-prevalence ($>5\%$), geographically diverse population and at least 500 self-testers from a low-prevalence.

WHO PREQUALIFICATION TEAM:
DIAGNOSTICS



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

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

Test (manufacturer)	Specimen	Approval
Mylan HIV Self Test (Atomo Diagnostics, Australia)	Blood	WHO PQ
autotest VIH® ** (AAZ Labs, France)	Blood	CE mark
BioSURE HIV Self Test ** (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD-3)
Exacto® Test HIV (Biosynex, France)	Blood	CE mark
INSTI® HIV Self Test ** (bioLytical Lab., Canada)	Blood	WHO PQ
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA, CE Mark
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	WHO PQ

- WHO PQ products available for US\$2.00-3.10 through Global Fund
- More information available via PAHO strategic fund
- Pipeline for products remains strong



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.

WHO PQed HIVST

Essential medicines and health products

In the lead-up to Paris AIDS conference, WHO prequalifies first generic hepatitis C medicine and first HIV self-test

INSTRUCTIONS FOR USE
You must follow the test directions carefully to get an accurate result. Do not eat or drink for at least 15 minutes before you start the test or use mouth cleaning products 30 minutes before you start the test.

WARNING: If you are on HIV treatment (ARVs) you may get a false result.

HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

INTERPRETING RESULTS

HIV POSITIVE RESULT
Two complete lines, even if the line is faint, means you may be HIV POSITIVE and you need to seek additional testing. **As soon as possible...** Visit your nearest HIV testing Centre or Health Facility.

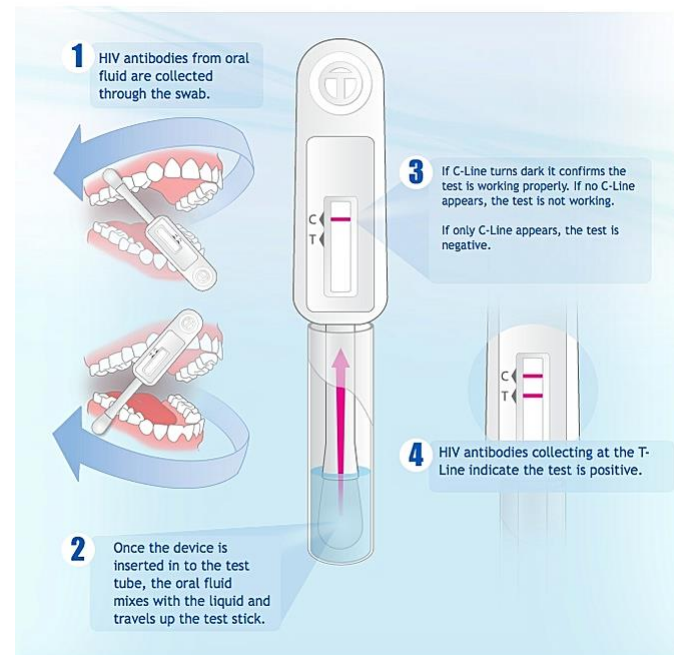
INVALID RESULT
No line next to the "C" (even when there is a line next to the "T"), or a red background makes it impossible to read the test, the test is not working and should be repeated. **You will need to obtain another test.** Visit your nearest HIV Testing Centre or Health Facility to test again.

HIV NEGATIVE RESULT
IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT
ONE LINE next to the "C" and NO line next to the "T", your result is HIV NEGATIVE. **Seek regular testing. If you may have been exposed to HIV, test again in 3 months.**

NOT SURE OF RESULT
You do not know your result or you are unsure of your result. **Visit your nearest HIV Testing Centre or Health Facility to test again.**

DISPOSE
Remove the test stick, put the cap on the test tube and throw away all contents in the normal trash.

Item# 3001-3001-PQ Rev 07/18

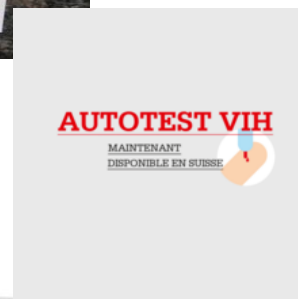


HIVST in Switzerland

- 3 products available
- Internet and Pharmacy-based (50-60 CHF)
- NGOs, like Groupe Sida Geneve



Product in France with slightly different packaging



Self-testing HIV kit goes on sale in Switzerland

Health

See in other languages: 6

JUN 18, 2018 - 14:55



The screening tests can be obtained in pharmacies and drugstores nationwide and are also available via the internet.

(Keystone)



Ensure products are quality assured

Choose products with acceptable specifications

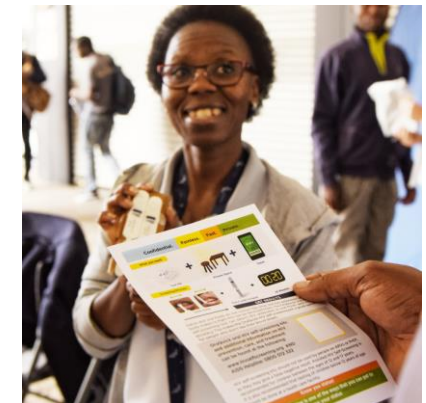
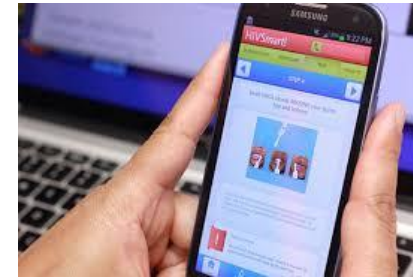
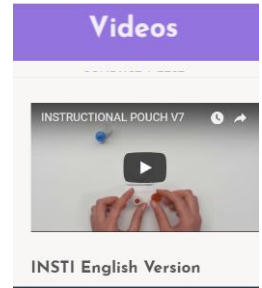
- **HIVST products should be:**
 - highly sensitive and specific;
 - simple to use;
 - have necessary consumables (such as swabs and plasters);
 - provide results that are easy to read/interpret and that are available in a short period of time (1–20 minutes after the test is conducted);
 - disposable 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)



Implementation considerations for HIVST

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.



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)

VMMC 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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HTS in Context of COVID-19

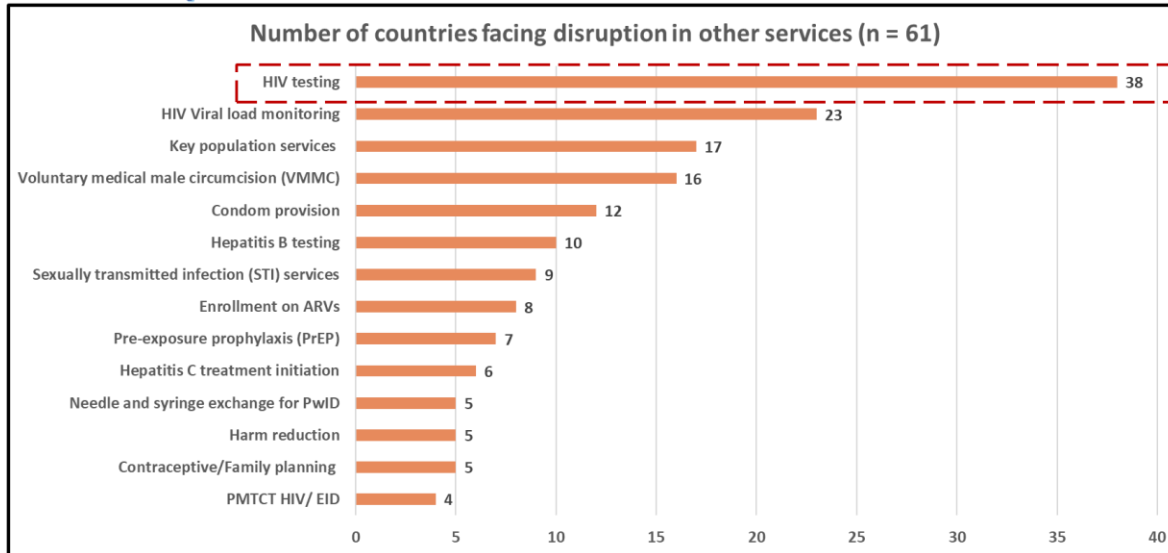
- **But need to also try and maintain testing services**

- to avoid losing substantial HIV gains
- to support people with HIV who are undiagnosed or unlinked to ART → test & link

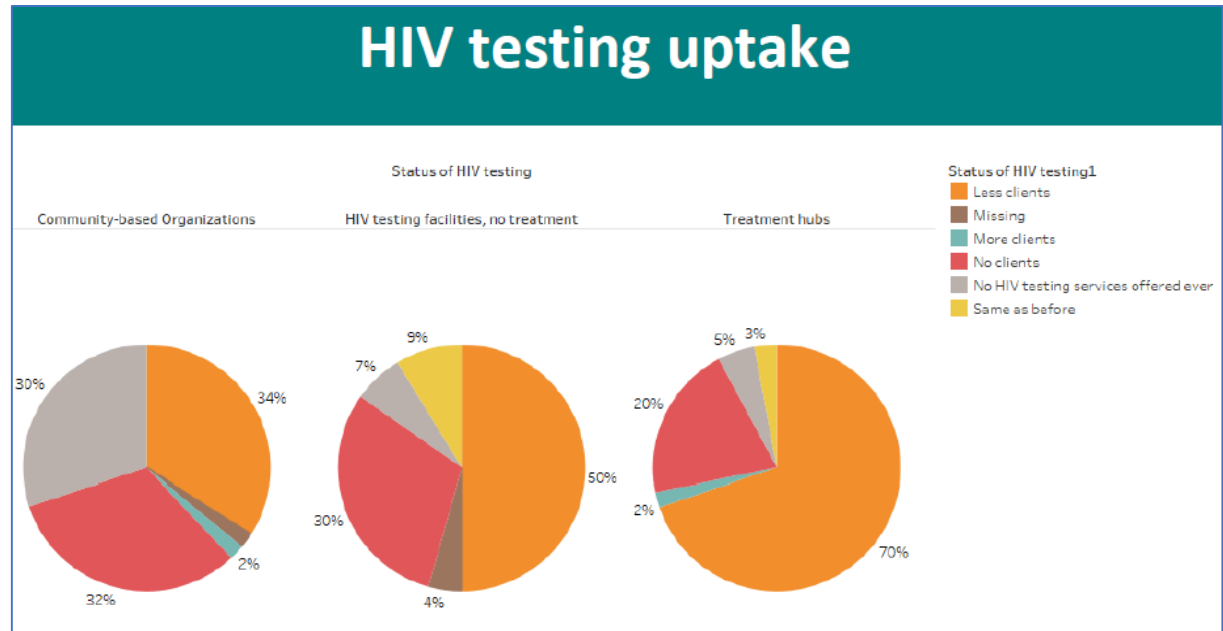
Planning needed to avoid stockouts



Disruptions in other services due to COVID-19



Global Fund survey highlighted COVID-19 affecting HIV testing services – w/ 80% of respondents with fewer or no clients.



HIVST procurement increasing in some settings



CONSIDERATIONS FOR HIV SELF-TESTING IN THE CONTEXT OF THE COVID-19 PANDEMIC AND ITS RESPONSE: AN OPERATIONAL UPDATE

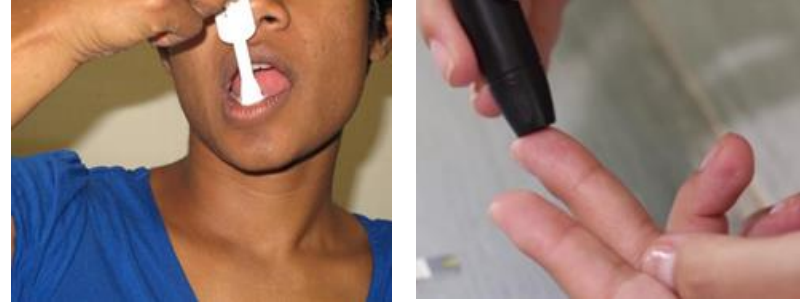


- Way to maintain essential HIV testing services – especially with limited staff and restrictions.
- Continue index partner testing and social network testing
- Enable retesting for populations (e.g. KP groups)
- Digital support tools and models increasingly used

Realizing the role of HIVST in COVID-19 Context

Considerations for HIVST

- HIVST may be acceptable alternative to maintain services while adhering to physical distancing guidance.
- Important to strategically implement HIVST **prioritizing areas & populations** with greatest needs and gaps in testing coverage.
- **HIVST approaches include:**
 - distribution for personal use and/or sexual and/or drug injecting partners of PLHIV and social contacts of key populations
 - in high HIV burden settings, pregnant women may also provide HIVST kits to their male partners.
- **Priority settings to consider**
 - pick up at facilities or community sites
 - online platforms (e.g. websites, social media, digital platforms) and distribution through mail
 - pharmacies, retail vendors, vending machines



Countries with HIVST programmes

Expand and adapt HIVST

- replace facility with HIVST (to decongest health facilities)
- use HIVST for partner and social network testing

Countries yet to use HIVST

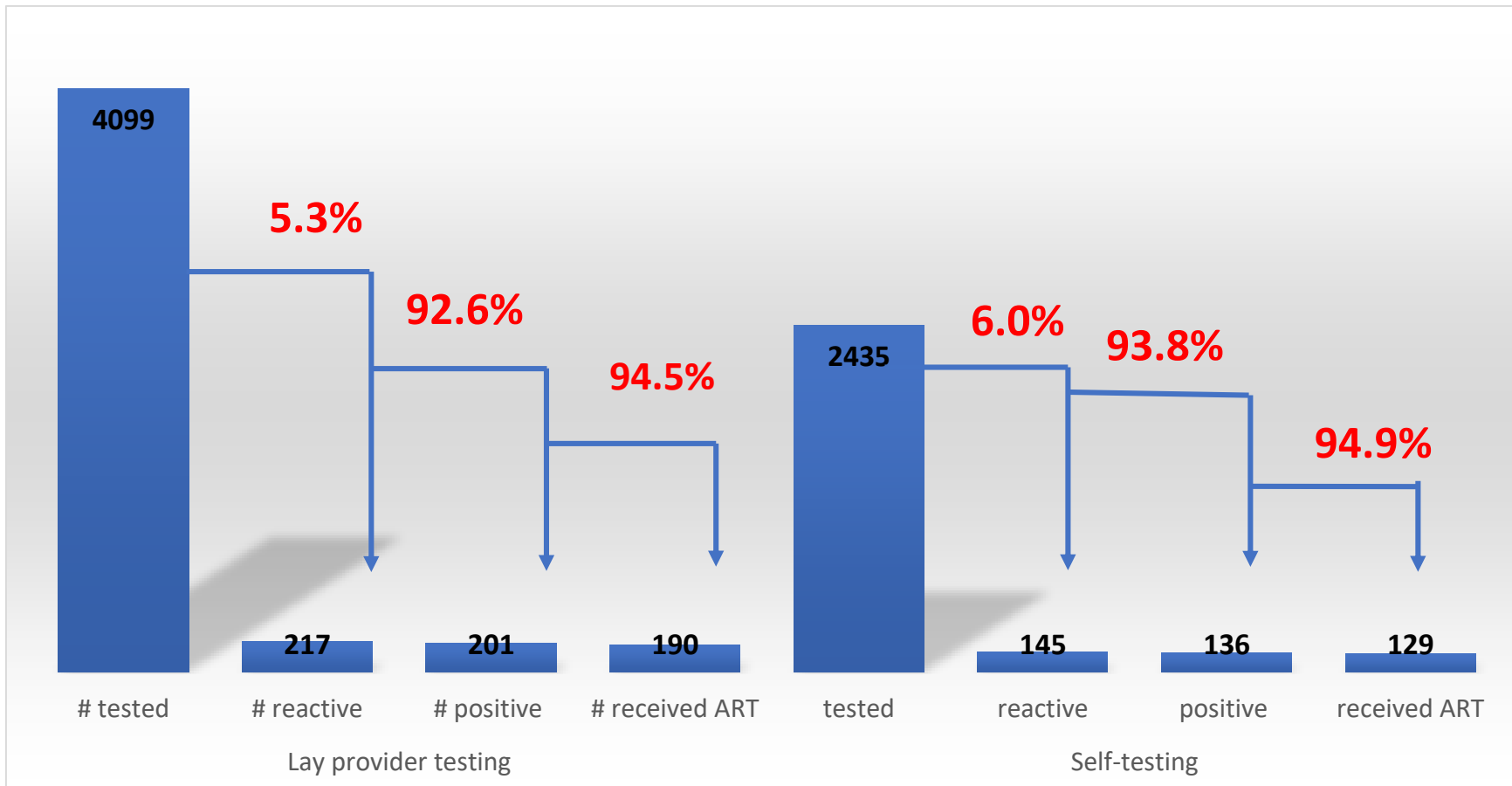
- Lobby for rapid HIVST approval



CONSIDERATIONS FOR HIV SELF-TESTING
IN THE CONTEXT OF THE COVID-19
PANDEMIC AND ITS RESPONSE:
AN OPERATIONAL UPDATE



Community-led model from Viet Nam using HIVST, lay providers and partner notification, 2017-18



Nguyen TT *et al.*, *Journal of the International AIDS Society* 2019, **22**(3):e25301
<https://onlinelibrary.wiley.com/doi/10.1002/jia2.25301> | <https://doi.org/10.1002/jia2.25301>



RESEARCH ARTICLE

Community-led HIV testing services including HIV self-testing and assisted partner notification services in Vietnam: lessons from a pilot study in a concentrated epidemic setting

Van Thi Thuy Nguyen^{1†}, Huong TT Phan², Masaya Kato³, Quang-Thong Nguyen³, Kim A Le Ai⁴, Son H Vo², Duong C Thanh⁵, Rachel C Baggaley⁶ and Cheryl C Johnson^{6*}

*Corresponding author: Van Thi Thuy Nguyen, WHO, 304 Kim Ma, Ba Dinh District, Hanoi, Vietnam. Tel: +84 24 39500314. nguyentv@who.int

Abstract

Introduction: The HIV epidemic in Vietnam is concentrated in key populations and their partners – people who inject drugs, men who have sex with men, sex workers and partners of people living with HIV. These groups have poor access to and uptake of conventional HIV testing services (HTS). To address this gap, lay provider- and self-testing and assisted partner notification (aPN) were introduced and delivered by the community. We explored the feasibility and effectiveness of implementing aPN as part of community testing services for key populations.

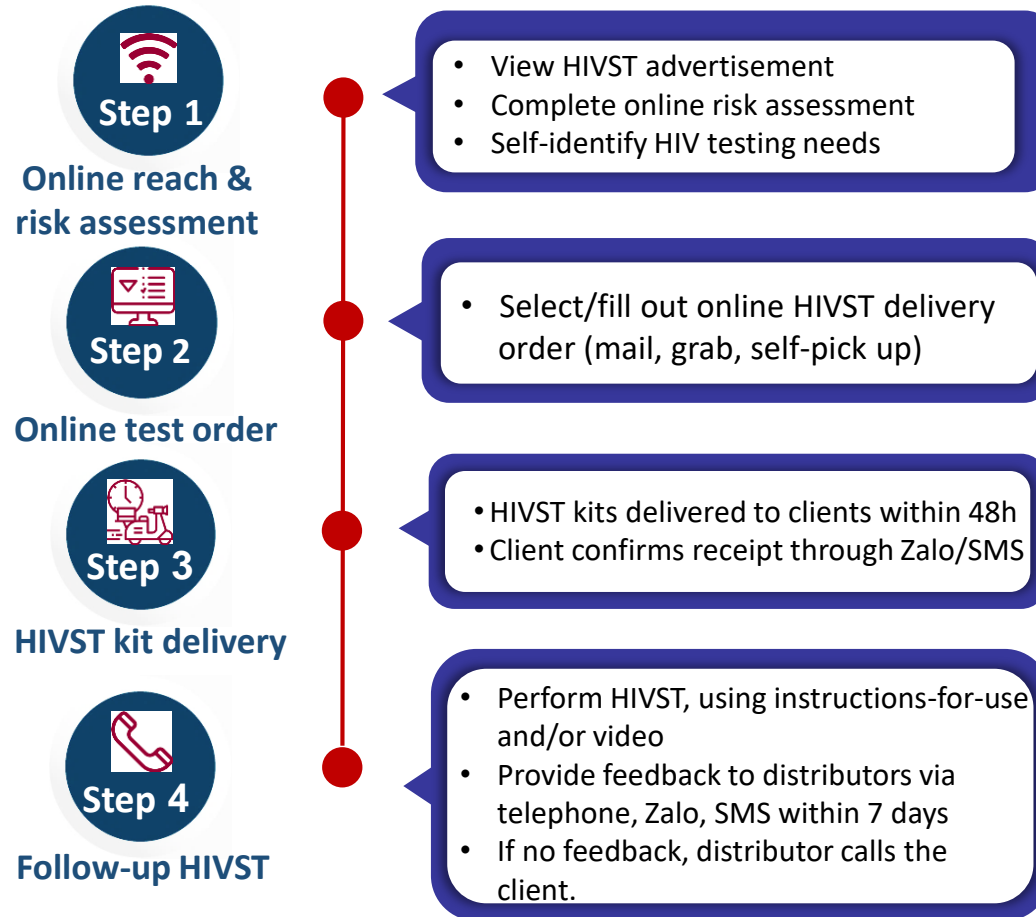
Methods: Lay provider testing and self-testing was started in January 2017, and targeted key populations and their partners. Since July 2017, aPN was introduced. HTS was offered at drop-in houses or coffee shops in Thai Nguyen and Can Tho provinces. All self-testing was assisted and observed by peer educators. Both in-person and social network methods were used to motivate key populations to test for HIV and offer HTS to partners of people living with HIV. Client-level data, including demographic information and self-reported risk behaviour, were collected on site by peer educators.

Results: Between January 2017 and May 2018, 3978 persons from key populations were tested through community-led HTS; 66.7% were first-time testers. Of the 3978 clients, 3086 received HTS from a lay provider and 892 self-tested in the presence of a lay provider. Overall, 245 (6.2% of tested clients) had reactive results, 231 (94.3%) were confirmed to be HIV positive; 215/231 (93.1%) initiated antiretroviral therapy (ART). Of 231 adult HIV-positive clients, 186 (80.5%) were provided voluntary aPN, and 105 of their partners were contacted and received HTS. The ratio of partners who tested for HIV per index client was 0.56. Forty-four (41.9%) partners of index clients receiving HTS were diagnosed with HIV, 97.7% initiated ART during the study period. No social harm was identified or reported.

Conclusions: Including aPN as part of community-led HTS for key populations and their partners is feasible and effective, particularly for reaching first-time testers and undiagnosed HIV clients. Scale-up of aPN within community-led HTS for key populations is essential for achieving the United Nations 90-90-90 targets in Vietnam.

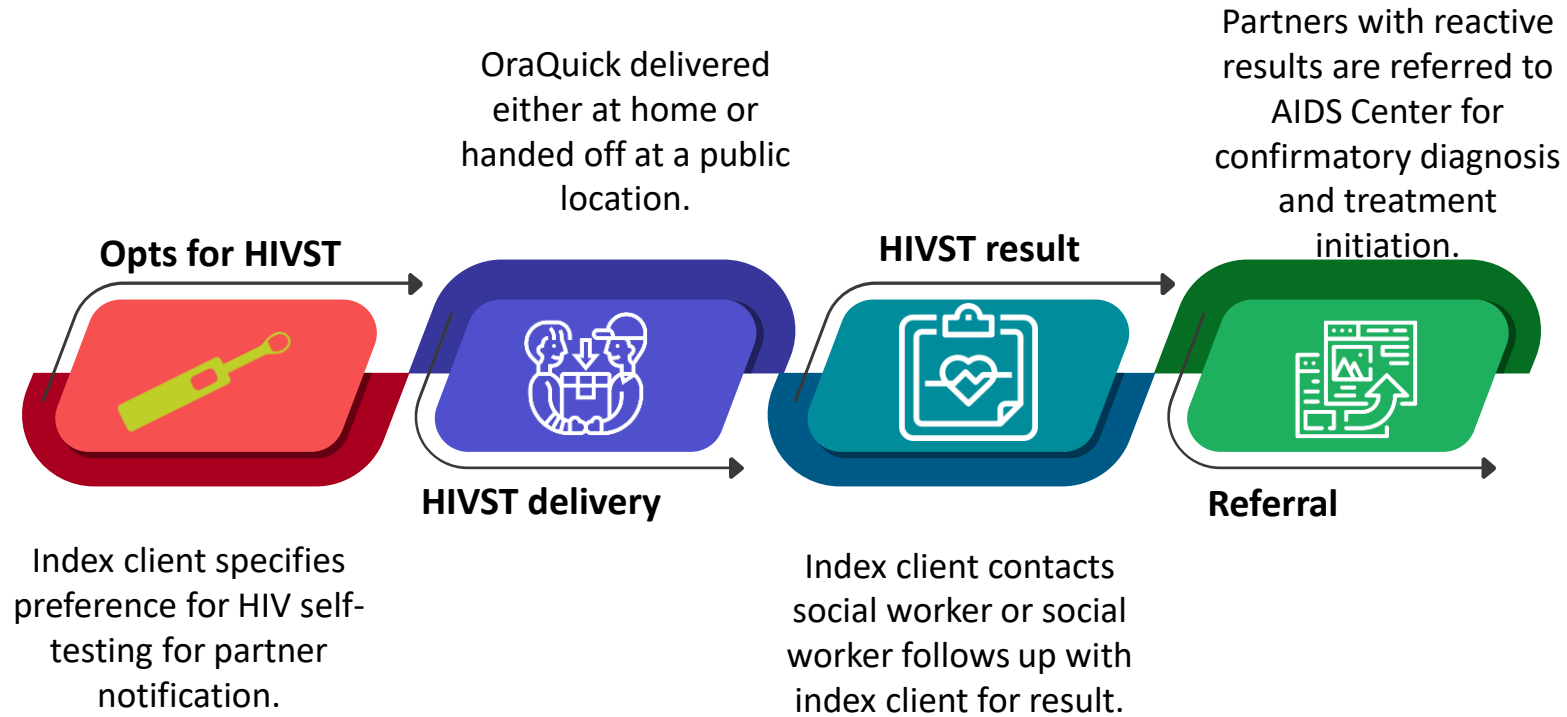
Keywords: HIV; community; lay provider; self-testing; partner notification; key and vulnerable populations; Vietnam

Viet Nam (USAID/PATH Healthy Markets): Client-directed online HIVST



'Grab' delivery

Ukraine (Serving Life): HIVST to continue index testing during COVID-19



Slide curtesy Dr. Kimberly Green, Global Director
– HIV & TB, PATH

PATH
10::▲0♦//2□0



Background references

1. *Guidance and implementation resources:*

- **WHO 2019 guidance policy briefs :** <https://bit.ly/3eXnMaB>
- **Full WHO guidelines on HTS Info:** <https://apple.co/2LAB8vt>
- **WHO HTS webpage:** <https://www.who.int/hiv/topics/vct/en/>
- **HIVST Framework:** <https://www.who.int/hiv/pub/self-testing/strategic-framework/en/>
- **IAS decision framework for differentiated HIV testing:** <https://www.iasociety.org/HIV-Programmes/Programmes/Differentiated-Service-Delivery/Resources>
- HIVST in COVID-19 context: <https://www.psi.org/project/star/resource-library/considerations-for-hiv-self-testing-in-the-context-of-the-covid-19-pandemic-and-its-response-an-operational-update/>

2. *Data resources*

- **UNAIDS 2020 Report:** <https://www.unaids.org/en/resources/documents/2020/global-aids-report>
- **AIDSinfo:** <https://aidsinfo.unaids.org/>
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Questions?

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