

HIV SELF-TESTING STRATEGIC FRAMEWORK

A GUIDE FOR PLANNING, INTRODUCING AND SCALING UP

OCTOBER 2018

HIV TESTING SERVICES



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HIV self-testing strategic framework: a guide for planning, introducing and scaling up

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ACRONYMS

ART	antiretroviral therapy
CBDA	community-based distribution agent
DHS	demographic and health survey
GAM	Global AIDS Monitoring
HIVSS	HIV self-screening
HIVST	HIV self-testing
HTS	HIV testing services
IBBS	Integrated HIV biobehavioural surveillance
LMIC	low- and middle-income countries
IVD	in vitro diagnostic
M&E	monitoring and evaluation
MHRA	Medicines and Healthcare products Regulatory Agency
PrEP	pre-exposure prophylaxis
PSI	Population Services International
Q&A	questions and answers
RDT	rapid diagnostic test
STAR	HIV Self-Testing Africa
STI	sexually transmitted infection
TASO	The AIDS Support Organization
TWG	technical working group
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	voluntary medical male circumcision
WHO	World Health Organization

1.0 INTRODUCTION

1.1 RATIONALE FOR INTRODUCING HIV SELF-TESTING

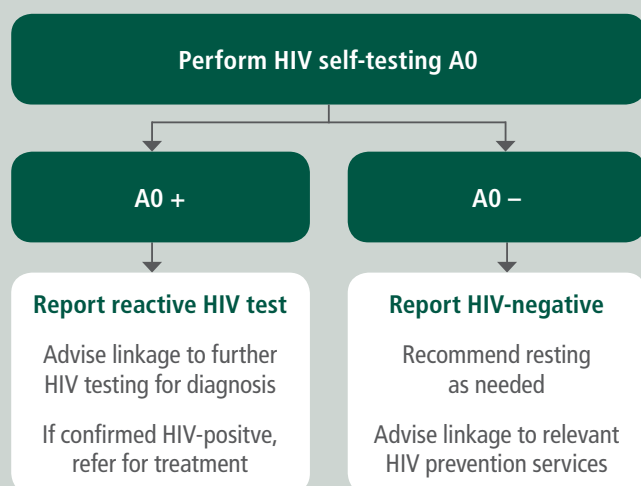
HIV testing services have been scaled up considerably worldwide. Between 2010 and 2014 more than 600 million people received HIV testing services in 122 low- and middle-income countries (LMIC) (1). In 2017, it was estimated that, globally, 75% of people with HIV were aware of their HIV-positive status, an increase from 67% in 2015 (2). Despite this progress, 9.4 million people – 25% of all people with HIV – remain unaware of their HIV infection (2). Many of those not currently benefiting from HIV testing scale-up are key populations¹, men and young people (aged 15–24) (2).

Recent modelling suggests the global 90–90–90 targets² will not be achieved by 2020 unless efforts are increased,

more focused, and innovations are used strategically (3). HIV self-testing (HIVST) is one innovation that has the potential to reach those who may not otherwise test (4, 5), as it offers a discreet, convenient and empowering way to test. HIVST is recommended by the World Health Organization (WHO) as an additional approach to delivering HIV testing services (Box 1) (5). Evidence to date has highlighted its role as a key strategy to increase uptake and frequency of testing among populations missed by existing services, particularly key populations in all regions and men and young people (aged 15–24), especially in eastern and southern Africa (5).

BOX 1. WHO RECOMMENDS HIVST

HIVST can be offered as an additional approach that complements and creates demand for existing HIV testing services.



A0 = Assay 0

may be in the “window period”³ and may have a nonreactive self-test result. They should seek testing at a facility in 14 days. If not feasible, they could consider self-testing again in 14 days. It is important messages are carefully crafted to ensure retesting among people who will benefit and linkage to relevant HIV prevention services such as condoms, harm reduction, voluntary medical male circumcision and pre-exposure prophylaxis.

Source: WHO (5).

HIVST is a process in which a person collects his or her own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets the result, often in a private setting, either alone or with someone he or she trusts.

A reactive self-test result is not equivalent to an HIV-positive diagnosis. All reactive results need to be followed by further testing by a trained provider starting with the first test in the validated national testing algorithm.

Nonreactive results should be considered negative. Messages following a nonreactive self-test result, as with all HIV testing, need to clearly recommend retesting at least every year to those at high ongoing risk (for example, key populations). People who have had potential HIV exposure within the preceding 6–12 weeks

¹ Key populations are defined by WHO as: people in prison or closed settings, people who inject drugs, men who have sex with men, sex workers and transgender people.

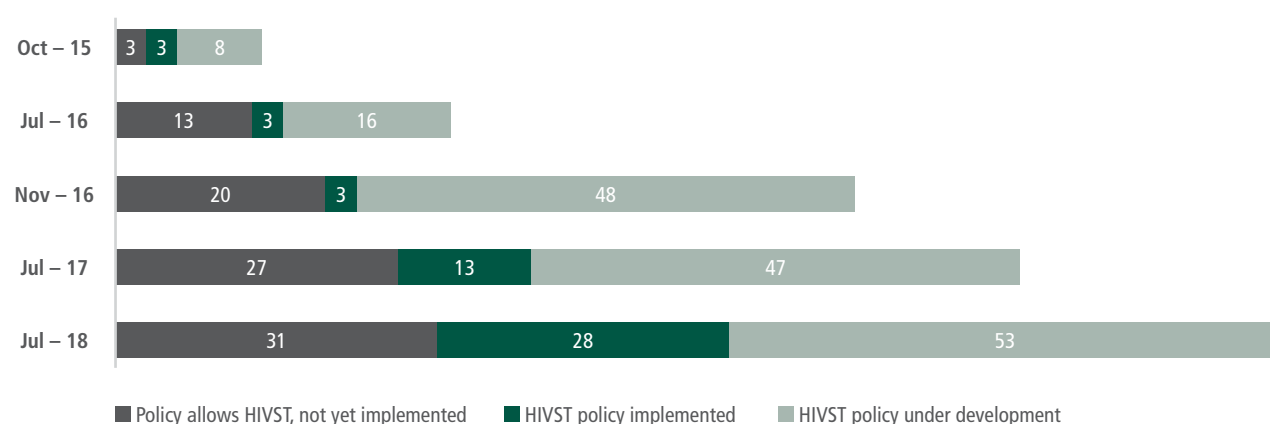
² United Nations’ targets: by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART), 90% of all people receiving ART will have viral suppression.

³ The window period is the time between potential exposure to HIV infection and the point when the test will give an accurate result. During the window period a person can be infected with HIV and be infectious but still test HIV-negative. Depending on the test used, the window can vary from approximately four weeks to approximately 12 weeks.

Globally, many countries have begun to develop and introduce HIVST policies (Fig. 1). By end 2018 it is estimated donors will procure at least 5 million HIVST kits in LMIC (6) and by 2020 the global market for HIVST will reach close

to 20 million kits. Despite these shifts, most countries are still developing the necessary strategic plans, regulations, implementation guidance and standard operating procedures needed for scale-up (6).

FIG. 1. NUMBER OF COUNTRIES WITH OR DEVELOPING HIVST POLICIES 2015–2018⁴



Source: Unitaidd (6).

4 As of July 2018 – **Countries with HIVST policies implemented (n=28)**: Austria, Belarus, Belgium, Brazil, Eswatini, Finland, France, Germany, Islamic Republic of Iran, Italy, Kenya, Lesotho, Luxembourg, Malta, Namibia, Nigeria, Poland, Republic of Moldova, Rwanda, South Africa, Spain, Switzerland, Uganda, United Kingdom, United States of America, Viet Nam, Zambia and Zimbabwe. **Countries with a supportive policy but HIVST not yet implemented (n=31)**: Armenia, Australia, Azerbaijan, Belize, Benin, Bosnia and Herzegovina, Botswana, Burkina Faso, Burundi, Cambodia, China, Côte d'Ivoire, Czech Republic, Democratic Republic of the Congo, Ethiopia, Ghana, Haiti, India, Ireland, Lao People's Democratic Republic, Latvia, Malawi, Mauritius, Mexico, Monaco, Morocco, Netherlands, Niger, Norway, Ukraine and United Republic of Tanzania. **Countries with HIVST policies under development (n=53)**: Afghanistan, Albania, Algeria, Angola, Argentina, Bahamas, Cameroon, Canada, Central African Republic, Chad, Cuba, Denmark, Gabon, Georgia, Guatemala, Guinea, Guinea-Bissau, Indonesia, Jamaica, Kyrgyzstan, Liberia, Libya, Lithuania, Madagascar, Malaysia, Mali, Mongolia, Mozambique, Myanmar, Nepal, New Zealand, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Portugal, Romania, Russian Federation, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Singapore, Somalia, South Sudan, Sudan, Suriname, Tajikistan, Thailand, Togo, Uruguay and Uzbekistan.

1.2 PRINCIPLES TO GUIDE HIVST IMPLEMENTATION

Costing and cost-effectiveness analyses done in LMIC show that to achieve impact with any additional HIV testing, including self-testing, efforts need to focus on populations with low testing coverage and who are at ongoing HIV risk (7-9). In some countries where the first 90–90–90 target (to diagnose 90% of all people with HIV) has been reached or nearly attained, diagnosing the few people with HIV who do not know their status may be challenging and costly. In other countries with slower progress toward achieving the first 90 target, a major shift will be needed in the approach to testing to improve effectiveness and efficiency in finding those with an undiagnosed HIV infection.

As with any additional HIV testing, it is recommended that approaches used 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.

HIVST can contribute to filling gaps in HIV programmes by:

- **Improving access and reaching people with high HIV risk and vulnerability who have not tested.** HIVST has been found to increase **testing uptake and frequency** (4, 10, 11) and to be **acceptable** to many of those currently unreached by existing testing services (key populations, men and young people) (12-14).
- **Creating demand for HIV prevention and increasing efficiencies for those who test HIV-negative.** Since

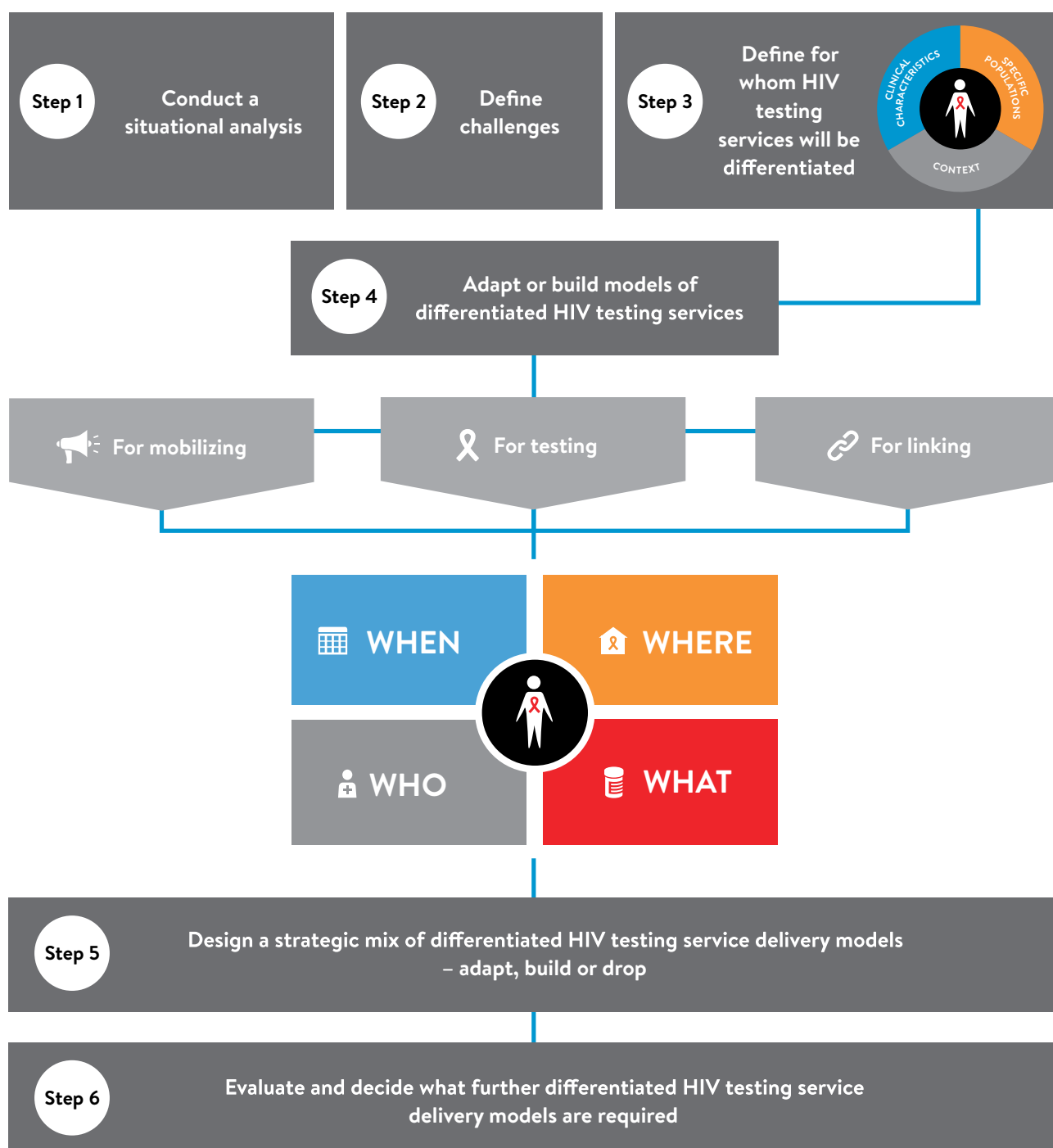
the majority of those with a negative self-test result will not immediately need further testing, HIVST can direct people who test HIV-negative to prevention services (such as condoms, harm reduction, voluntary medical male circumcision, pre-exposure prophylaxis, and the screening and treatment of sexually transmitted infections (STIs)) (5). Consequently, unnecessary testing or facility visits can be avoided, saving time and resources on the part of both those who have a HIV-negative self-test result and the health system.

- **Improving testing coverage through the integration of HIVST in clinical services where testing is needed but not routinely provided or where testing is poorly implemented,** for example, at high-volume clinics in high HIV burden settings and at STI or family planning clinics. Offering HIVST while clients wait for other clinical services maximizes their waiting time and ensures they have their test results on-site and, when relevant, can be offered further testing and treatment initiation.
- **Facilitating partner testing.** HIVST has been shown to facilitate couples and partner testing, which is an effective but often underutilized testing approach (5, 11). Providing HIVST kits to people with HIV or at high HIV risk so that they can offer HIVST to their partners or persons in their social network can be a highly effective and acceptable way to reach people with HIV who do not know their status. HIVST may also be used to support disclosure where beneficial and provide HIV prevention to serodiscordant couples (when one partner is HIV-positive and the other is HIV-negative).

(See **Section 3** Implementing HIVST and **Annex 1** HIVST case examples for further details.)

Several tools are available to identify programmatic gaps and guide HIVST implementation as part of broader HIV testing services such as, a decision-making framework developed by the International AIDS Society (Fig. 2) (15). The web-based SPECTRUM module for HIV testing, which includes HIVST, may be useful.

FIG. 2. SIX-STEP APPROACH TO DIFFERENTIATED HIV TESTING SERVICES



Source: IAS (15).

1.3 OBJECTIVES OF THIS STRATEGIC FRAMEWORK ON HIVST

This framework is intended to be a brief guide for countries and implementers that are planning, starting or scaling up HIVST implementation. It provides key considerations for: 1) preparing for HIVST; 2) implementing HIVST; 3) monitoring and optimizing HIVST implementation.

When planning and implementing in the real world, many of the steps detailed in this framework may occur

concurrently or in a different order. Therefore, it is recommended that this framework be used flexibly and adapted according to specific contexts and epidemics.

All programmes need to begin somewhere and should not be discouraged from exploring or getting started due to imperfect or evolving systems.



2.0 PREPARING FOR HIVST IMPLEMENTATION

When considering HIVST introduction, it is important to develop a plan that will guide implementation plans, policy and regulatory development. This section summarizes the following key actions to consider when preparing for HIVST while moving towards full implementation:

- Conduct an HIV testing services situational analysis.
- Develop HIVST national policy and regulations.
- Select and procure HIVST products.
- Identify approaches for HIVST distribution.
- Identify key considerations and messages for providers, users and communities.
- Establish quality assurance systems.
- Monitor adverse events and social harm.
- Finalize action plans and move to implementation.

2.1 CONDUCTING AN HIV TESTING SERVICES SITUATIONAL ANALYSIS

Carrying out an in-depth situational analysis of HIV testing services is an important step in assessing how to adapt existing services and/or introduce new testing approaches. Such analyses vary but often include a review of national HIV epidemiological data, programmatic data, and legal and policy documents. This process should be rapid and led by the ministry of health in coordination with key stakeholders, such as other government departments, communities, implementing partners, donors, health workers and lay or community providers.

An in-depth situational analysis of existing HIV testing services will also assess if HIVST is already informally available as unregulated or unregistered products sold by pharmacies or on the Internet. **Stakeholder mapping** can be conducted to identify relevant partners who can be engaged in HIVST introduction.

Efforts should be made to strengthen advocacy amongst those who can potentially influence programmatic implementation and consequent scale-up. Local communities, including the faith-based sector, need to be actively engaged early in the discussions and planning for HIVST implementation.

Convening consultations is important if HIVST is to be successful. Consultations provide a forum through which the communities and groups that will be most likely to use HIVST can be heard and engaged in discussions on the potential benefits and risks of HIVST, providing an opportunity to understand and address possible concerns, share information and ideas, and learn how (or how not) to implement HIVST.

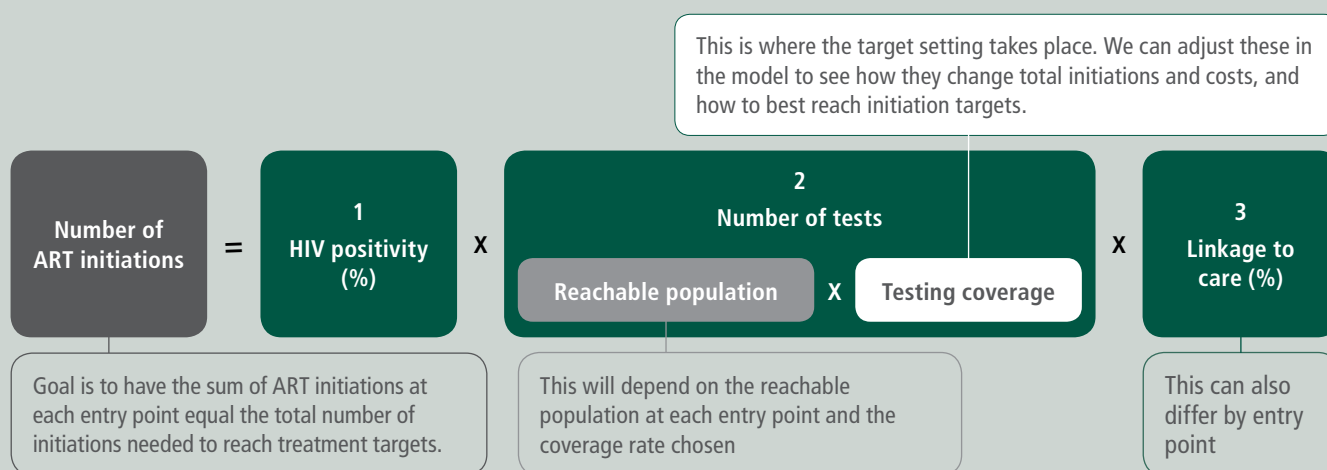
When looking at HIV testing services specifically, the analysis should examine **progress and gaps across national and subnational HIV epidemiology and programmatic data**, including HIV testing coverage, testing frequency/retesting, knowledge of status among people with HIV, number of persons testing HIV-positive (positivity rate), linkage to prevention and treatment, and HIV testing costs (disaggregated by sex, age, population group, testing approaches and geography). In addition, existing demand creation efforts as well as capacity, resources and quality assurance systems should be considered.

Information and statistics on past and current HIVST projects and pilots, both nationally and globally, should be reviewed to identify good practices. See **Annexes 1 and 2** for additional resources.

BOX 2. SITUATIONAL ANALYSIS FOR THE INTRODUCTION OF HIVST IN ZIMBABWE

Zimbabwe has effectively scaled up HIV testing services. Between 2007 and 2015 the number of people tested increased from 600 000 to 2.2 million. In 2015 approximately 74% of people with HIV knew their status, 87% of people with HIV were on treatment and 87% of those on treatment had an undetectable viral load. Due to the significant scale-up in HIV testing services, the proportion of people who tested HIV-positive declined from 22.7% in 2010 to 8.6% in 2015. Despite this progress, in the same period, only 68% of men and 50% of young people with HIV knew their status. To reach these groups and other people who do not know their HIV-positive status, more focused HIV testing approaches are required.

To address these gaps, the Zimbabwe Ministry of Health and Child Care with the support of the Clinton Health Access Initiative assessed 19 (new and existing) HIV testing approaches. National laws, policies and regulations related to HIVST were also reviewed with support from the Southern African AIDS Trust and the HIV Self-Testing Africa (STAR) Initiative. Multiple consultations with communities and healthcare workers were convened by STAR and inputs fed into a HIVST Technical Working Group.



Source: Ncube, G. April 2018

Through these processes, it was found that HIV testing could be further optimized by focusing mobile outreach on specific subpopulations and geographic areas, introducing index testing among the children and sexual partners of people with HIV, and strategically integrating HIVST into these new and existing services. HIVST alone was found to be costlier when compared to other HIV testing approaches.

As a result of the situational analysis, the Government of Zimbabwe decided to use HIVST to reach men and young people (aged 15–24), where testing coverage is low. HIVST is also being channelled through existing approaches to optimize implementation of index testing and at health facilities with suboptimal testing coverage. Key strategies include secondary distribution, that is, offering HIVST kits to people with HIV as well as pregnant and postpartum women to give to their male partners.

This situational analysis informed the 2017–2020 Zimbabwe national HIV testing strategy, which has also drawn from other reports, consultations and experiences with HIVST. Within this broader testing strategy, the following national targets, estimated costs and budget for publicly-funded HIVST were set:

	2017	2018	2019	2020	Total
Number of self-tests procured (aged 15+)	186 622	220 968	551 827	827 299	1 786 716
People with HIV diagnosed	4016	3559	7725	10 597	25 897
Commodity costs	US\$ 646 007	US\$ 761 474	US\$ 1 898 317	US\$ 2 843 139	US\$ 6 148 937
Operational costs	US\$ 92 949	US\$ 110 163	US\$ 275 217	US\$ 412 694	US\$ 891 023
Total costs	US\$ 738 956	US\$ 871 637	US\$ 2 173 534	US\$ 3 255 833	US\$ 7 039 960

Source: MOHCC (16), Sibande (17), Madanhire (18), SAT (19).

Identifying sustainable funding sources for HIVST in the public and private sector should be considered during a situational analysis of HIV testing services as it may affect implementation decisions.

Within the public sector, available government and donor funding for HIVST is generally part of a broader funding envelope for HIV testing services. Thus, it is important to use low-cost, high-impact approaches for HIVST implementation, with a focus on providing appropriate populations in strategic geographical areas with the services they need (Box 3). HIVST should be integrated into existing services as this is more likely to be cost-effective and sustainable. Standalone campaigns and resource-intensive HIVST distribution models will probably not be sustainable.

BOX 3. KEY FACTORS THAT DRIVE IMPACT OF HIVST IMPLEMENTATION

- Prevalence of undiagnosed HIV in priority populations and geographical areas
- Uptake of HIVST by high-risk groups and people with undiagnosed HIV
- Uptake of HIVST by low-risk groups and repeat testers, including those previously diagnosed with HIV
- Number of HIVST kits distributed
- Total cost of delivering HIVST to priority populations and geographical settings (compared to cost of existing or alternative testing approaches)
- Ability to link HIVST users with HIV prevention methods such as condoms, harm reduction, voluntary medical male circumcision or pre-exposure prophylaxis
- Ability to link HIVST users to further HIV testing for diagnosis and treatment
- Strategy adopted – either continuous availability of HIVST kits or seasonal provision of HIVST kits during specific periods and/or to particular populations or geographical areas.

Opportunities exist to use private sector resources for HIVST implementation, for example through pharmacies and other retail venues, the Internet and social media. These channels may be important for achieving scale. Although the sale of HIVST products through the private sector in LMIC has been limited to date, recent forecasting suggests there will be significant market growth in middle-income settings through 2020 (6). Moreover, in several settings private sector implementation of HIVST has catalysed the development of national policies and regulations on HIVST as well as public sector implementation (6).

To support financing for HIVST through the private sector, efforts to increase the availability and affordability of quality-assured products, as well as consumer awareness of and demand for HIVST, will likely be needed (6). Countries may find it useful to explore public–private financing schemes, such as public- or donor-supported social marketing, subsidies, rebates, vouchers and targeted incentives or discounts (5, 6). There are also significant opportunities for public–private partnerships through national health insurance and workplace programmes. Some countries implementing HIVST that have national health insurance programmes are reimbursing individuals who purchase HIVST kits in the private sector.

Ultimately, pursuing multiple sustainable financing models for HIVST will be the most effective strategy for securing resources. Countries may consider developing a simple HIV testing services investment case, or strategic plan, that as part of a broader HIV investment case or plan. Such an analysis and planning may help ministries of finance or donors to make decisions about funding of HIV testing services, including HIVST. Box 4 provides an example from South Africa where specific analysis on HIVST was undertaken to inform the procurement of HIV test kits.

BOX 4. SOUTH AFRICA'S INVESTMENT CASE FOR HIV SELF-SCREENING (HIVSS)⁵

The national tender for the procurement of HIV test kits in South Africa expires in 2019. To inform the new procurement budget and potential funding from donors, a cost and impact analysis was started in May 2018 with a view to developing a preliminary investment case for HIVSS. The analysis focused on HIVSS implementation through three broad distribution channels – workplaces, community settings and health facilities – and evaluated total and incremental costs to include HIVSS as a HIV testing option. The cost per HIVSS kit was based on available products priced between US\$ 2 and US\$ 3.40. This analysis is one part of a broader national investment case. The outcomes of the analysis, coupled with programmatic outcome and linkage data, will be used to inform implementation approaches and potential volumes and cost of procuring additional HIVSS kits.

Of the three approaches assessed, preliminary results suggest facility-based HIVSS to be the least expensive distribution model (see table). This preliminary analysis, as well as others, suggest HIVSS implementation should most likely be focused in six provinces with the highest HIV prevalence and among populations aged 15–19 and 30–44 years, in particular men, as these have the lowest testing coverage.

The National Department of Health, and partners, in South Africa are continuing to work on the investment case. The final investment case will likely be completed later in 2018. The outcome of the analysis will be used to inform the 2020 procurement budget and tender agreement for HIVSS in South Africa as well as other donor investments in HIVSS.

TABLE. ESTIMATED COST PER HIVSS KIT DISTRIBUTED, BY CHANNEL

Cost categories	Distribution channel (ZAR)		
	Community	Facility	Workplace
Test kits	26.00	26.00	26.00
Capital costs			
Training	1.20	0.71	0.24
Vehicles	8.42	-	1.68
Uniforms	1.17	-	0.23
Recurrent costs			
Information, education, communication materials (e.g. flyers, posters)	0.66	0.65	0.64
Personnel	24.60	10.46	24.60
Vehicle operation (i.e. fuel)	10.58	-	2.12
Other			
Reception	-	R 2.52	-
Consumables	-	R 5.06	-
Counselling room	-	R 0.28	-
Total cost	ZAR 72.63	ZAR 45.67	ZAR 55.51

All costs provided in South African Rand (ZAR) using US\$1=ZAR13.

Source: NDOH (20).

⁵ In South Africa, the National Department of Health refers to HIVST as defined in this document as HIV self-screening. The term is used to emphasize that all reactive self-test results need to be followed by further testing by a trained provider using the first test within the validated national testing algorithm.

Box 5 provides a suggested list of questions that countries should address when considering HIVST implementation or scale-up.

BOX 5. QUESTIONS FOR COUNTRIES CONSIDERING HIVST INTRODUCTION

- Does your situational analysis of existing HIV testing services indicate that HIVST would be beneficial for achieving national HIV testing targets?
- Are resources available, or are efforts underway to mobilize resources, to support HIVST implementation and scale-up?
- Do your community networks know about and understand HIVST? Are they in favour of and engaged in the introduction of HIVST?
- Are reliable HIV testing services available and accessible within and outside traditional health services to provide further testing to confirm any reactive (positive) self-test results?
- Is treatment available for those who are diagnosed with HIV?
- Is relevant HIV prevention (such as condoms, harm reduction, voluntary medical male circumcision, post- and pre-exposure prophylaxis) available and accessible for those with a negative self-test result?
- Does your country have clear policies and a legal framework to prevent coercive and mandatory testing and to fight stigma and discrimination, including in healthcare facilities?
- Are there national laws or policies regulating the marketing, distribution and use of HIVST kits?
- Are you able to procure quality-assured HIVST products (for example, WHO prequalified)?
- Are quality assurance systems in place that ensure the standard of in vitro diagnostics, including HIVST kits? Or does your country have plans to adapt or develop such systems?
- Do you have a post-market surveillance system to monitor social harm, adverse events or complaints? Or does your country have plans to develop one?



2.1.1 Integrate HIVST into existing working groups

The adaptation or development of national policies and regulations for HIVST should be considered by relevant **HIV planning committees or processes**. Many countries may already have established HIV testing working groups that can be leveraged for this purpose. In such cases, countries may find it useful to include HIVST within the terms of reference of an existing group and/or to establish an HIVST-focused subgroup.

Led by the ministry of health the group may be comprised of regulators and those identified and engaged through the stakeholder mapping exercise, such as: representatives from civil society and academia, implementing partners, providers including lay and community health workers, laboratory technicians, pharmacists, procurement and supply chain personnel, central medical stores, researchers, relevant donors and United Nations partners (for example, WHO and UNAIDS).

This group could inform and guide development of national policies, strategic plans (including sustainability), standard operating procedures, guidelines, monitoring and reporting tools, investment cases, communication materials, as well as advise on the priority research agenda. When implementation begins, the group could also routinely review programmatic data; examine reports of product misuse or failure, or social harm; provide updates on ongoing research; convene necessary consultations to maintain community engagement; and coordinate partners and broader HIVST scale-up. To ensure the group is effective, resources should be identified and budgeted to support its activities.

BOX 6. HIVSS TECHNICAL WORKING GROUP (TWG), SOUTH AFRICA

In 2016, the South African National Department of Health, with the support of WHO and partners, formed an official HIVSS TWG as it moved from HIVSS pilots to a broader national programme. The first task of this group was to draft national guidelines on HIVSS and to work with the South African Pharmacy Council and the South African Healthcare Products Regulatory Authority on the formulation of HIVSS regulations for both the public and private sector. During this process, the TWG began coordinating the activities of implementing partners, reviewing research findings and programmatic data, and advising on messaging and standardized communication on HIVSS. Consultations were also held with various other stakeholders, including communities, local nongovernmental organizations, and networks of people with HIV and key populations.

The guidelines on HIVSS have now been completed and disseminated. HIVSS is expected to feature prominently in a national campaign to scale up HIV testing approaches. An HIVSS investment case to inform the national strategy and targets is also under development and is expected to be completed by the end of 2018.

Currently, the TWG continues to meet and review programmatic data, and develop and coordinate standardized national messages and materials for HIVSS across implementers. A key priority for the group moving forward is to work on strengthening quality assurance and post-market surveillance for HIVSS.

2.2 INTEGRATING HIVST INTO NATIONAL POLICIES AND REGULATIONS

National health policies and regulations are essential to promote and support systematic implementation of good practices and evidence-based interventions.

National guidelines are often a pre-requisite for the development of regulations, including the capacity to procure and import products. In most settings, until an intervention is included in national guidance implementation and scale-up efforts are limited. However, in some countries even though an HIVST policy may be in place products are not registered and can only be used for research, preventing the roll-out of wide-scale HIVST implementation.

To effectively scale up HIVST and achieve impact, clear and supportive policies and regulations need to be developed, disseminated and implemented, particularly to enable access to quality-assured products specifically designed for self-testing. Dissemination of these policies and regulations in the health sector and among communities, particularly those who will be involved in HIVST implementation, should be prioritized. Efforts also need to be made to minimize the time gap between HIVST policy development and product availability in order not to delay implementation. Box 7 highlights some of the aspects that need to be given consideration when developing national policies on HIVST.

BOX 7. WHAT ISSUES RELATING TO HIVST SHOULD BE INCLUDED IN NATIONAL POLICIES?

- Clear definition of HIVST
- Priority populations and legal age of consent to self-test (in line with national policy)
- Clear HIVST strategy and diagram that links to the national HIV testing strategy, policies, regulations and laws and indicates that:
 - HIVST is considered a test for triage and cannot replace the first test within the validated national testing algorithm
 - Reactive (positive) self-test results must be followed by immediate further testing using the full national testing algorithm
 - Nonreactive (negative) self-test results should be considered negative with no need for immediate further testing to confirm a negative diagnosis unless referring for initiation of pre-exposure prophylaxis (PrEP)
 - Retesting following a negative self-test result is only necessary for those at high ongoing risk, such as key populations, and those reporting potential HIV exposure in the preceding 12 weeks
- Clear HIVST distribution models and implementation goals, including strategies for facilitating linkage to treatment and prevention
- Minimum communication package with key information messages for self-testers and the community
- Minimum training requirements, including key information and messages, for those officially distributing HIVST kits, healthcare workers and testing providers
- Minimum standards and requirements for the procurement and distribution of HIVST kits in the public and private sector
- System for quality assurance and post-market surveillance
- Monitoring and evaluation indicators and plan, including reporting system for complaints, adverse events and cases of social harm.

2.2.1 National registration and regulations

Establishing a clear and transparent national registration pathway for HIVST is important. WHO guidance and tools to develop and strengthen regulatory systems for medical devices, including for HIVST, can be used and adapted, particularly the global benchmarking tool http://www.who.int/medicines/regulation/benchmarking_tool/en/. It is recommended that a stepwise approach is adopted in the development of regulations and that the following components are included:

- **Market authorization (registration).** The procedure through which a test kit is released onto the market after its quality, safety and performance has been assessed. Licensing issued through this process applies to premises, facilities, establishments and/or companies throughout the supply chain including, but not limited to: manufacturers, distributors, wholesalers, importers and/or exporters.
- **Premarket controls.** The system by which the regulatory authority assesses devices, manufacturers and distributors before a device is placed on the market.
- **Market control.** The system that ensures a manufacturer's product complies with the national regulatory standards for quality, safety and efficacy.
- **Post-market surveillance.** The system a manufacturer should employ once the product is on the market to ensure monitoring continues with the aim of identifying and addressing potential complaints, including adverse events.
- **Market surveillance/control.** Through this system, national regulators survey products in the market place to ensure they continue to comply with national regulatory standards for quality, safety and performance.

To fast-track HIVST implementation, countries should consider having an expedited regulatory approval process for HIVST products already approved by a recognized authority such as WHO or one of the founding members of the Global Harmonization Task Force⁶. If fast-track procedures are not feasible, countries are encouraged to explore interim approaches that will provide access to HIVST, such as facilitating imports of WHO prequalified

products for donor programmes or providing support for operational research before national regulatory systems are fully developed.

It is important that all national regulations and registration requirements are made publicly available so that manufacturers, implementing partners and other stakeholders are aware of the procedures that need to be followed and which HIVST products have been approved for use.

2.2.2 Selecting and procuring HIVST products

There are many quality-assured HIVST products, both blood-based and oral fluid-based tests, that have WHO prequalification, meet the requirements of the Global Fund Quality Assurance Policy and/or are approved by one of the founding members of the Global Harmonization Task Force on Medical Devices. Several countries with national regulatory authorities also report the availability on the market of other products approved and registered for HIVST (6).

When selecting HIVST products for procurement, it is recommended that national programmes first determine if there are any products for self-testing listed by relevant national regulatory authorities. If no such products exist, or if listed products do not meet minimal standards, countries can select from those listed by WHO and the Global Fund. Selecting products from these lists will enable countries to forgo in-country performance evaluations because existing product assessments can be leveraged to fast-track national registration and product availability.

HIVST products for procurement are regularly updated and can be identified by reviewing those listed at the following links:

- WHO prequalification: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/
- Global Fund Quality Assurance Policy for Diagnostic Products: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/>

Additional information on these products and others in the pipeline is available in the 2018 Unitaid–WHO HIVST market and technology landscape report: <https://unitaid.org/assets/HIVST-landscape-report.pdf>.

⁶ The Global Harmonization Task Force is defunct and has been replaced by the International Medical Device Regulators Forum.

Some countries may be inclined to adapt and repackage professional-use HIV rapid diagnostic tests (RDTs) so that they can be used for self-testing. This procedure is not recommended. Only HIVST products with quality assurance should be procured and used for self-testing.

Using official products designed and intended for self-testing is important from both a regulatory and programmatic perspective. From a regulatory perspective, using or selling a professional-use HIV RDT for self-testing is considered off-label, unregulated use. From a programmatic perspective,

studies have shown that packaging, components and instructions for use impact a user's ability to correctly perform and interpret test results (21). Multiple independent manufacturer and implementation studies have been conducted to develop quality-assured HIVST products. Programmes cannot assume that using professional-use HIV RDTs for self-testing will achieve the same level of usability and performance.

Box 8 outlines key issues to be considered by countries when deciding which HIVST products to procure.

BOX 8. PRIMARY CONSIDERATIONS WHEN SELECTING HIVST PRODUCTS

- **Ensure products are quality assured.** All HIVST products should have been assessed and approved by a recognized national authority and/or an international body such as WHO, the Global Fund or a founding member of the Global Harmonization Task Force on Medical Devices. This will ensure the procurement of quality HIVST products without expensive and lengthy in-country validation studies.
- **Choose products with acceptable specifications** (such as those for WHO prequalification). HIVST products should be highly sensitive and specific; be 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); contain clear pictorial instructions and support tools, including information on what to do and where to go after self-testing.
- **Plan to procure more than one type of HIVST kit.** This is important to provide back-up options in the event of product issues, to accommodate user preferences and to provide users with choice. Because some users may prefer oral self-tests and others may prefer blood-based self-tests, provisions should be made to procure and offer both options. This may facilitate uptake among different users and, thereby, impact HIVST implementation.

Offering options early on may also be advantageous for exploring the market and planning for future procurement.

- **Unit cost per self-test.** Most procurement in the public sector will be supported by governments and donors, and a lower-cost HIVST kit may be key to achieving scale-up. When assessing costs in the public sector, however, it is important to consider the full cost of service delivery. This is particularly important when comparing the cost of HIVST to other testing approaches because the unit cost per HIVST kit will likely be higher than the unit cost per professional-use RDT. However, a higher unit cost will not always mean that HIVST is more costly than other HIV testing approaches using professional-use HIV RDTs.

Unit cost per self-test will also be important for successful private sector implementation. The higher the unit cost, the greater the value-added tax and retail fee mark-up, which will lead to increased costs to the consumers and may, thus, reduce uptake.

Although the price per self-test is an important consideration, it should not come before quality considerations.

Depending on the national HIV epidemiological setting and the population to be reached, it may also be important to consider what the self-test is capable of detecting (for example HIV-1, HIV-2, or combined HIV-1/HIV-2).

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. A self-test that cannot be disposed of in the general waste disposal system would also not be a good product to select.

2.2.3 Quality assurance and post-market surveillance for HIVST products

To prevent problems when delivering HIVST services to clients, it is recommended that quality assurance for HIVST products be integrated into existing monitoring, assessment and quality improvement processes. It is important that the supply chain system ensures products that are or have become unsuitable for self-testing are removed and returned to their supplier for destruction.

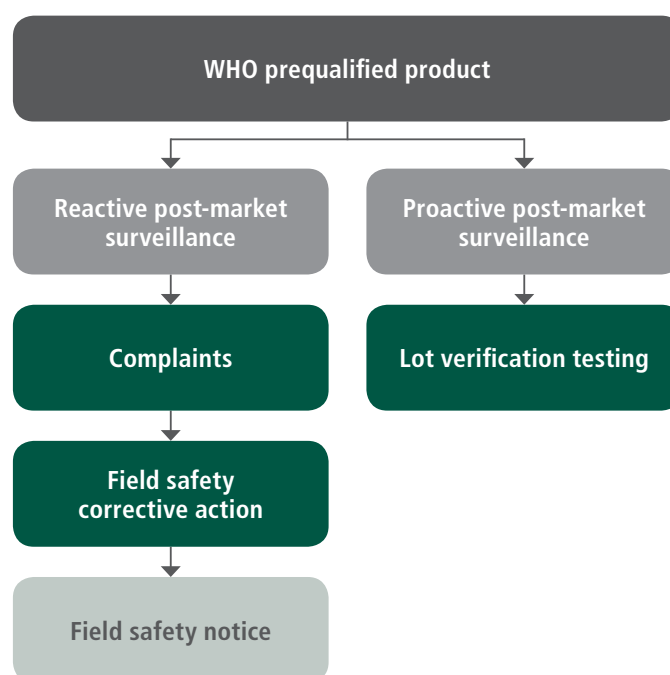
A risk-based approach to validating new lots of HIVST kits entering the country may be considered to ensure commodities meet national quality and regulatory standards.

Post-market surveillance of HIVST can be implemented through reactive and active approaches (Fig. 3). Reactive approaches, including the use of WHO complaint reporting systems, can be used to issue HIVST product-related complaints as well as to routinely check for WHO in vitro diagnostic (IVD) field safety notices related to HIVST products. In addition, active post-market surveillance can be periodically conducted by an authorized government agency to assess the quality and performance of the HIVST kits in use.

The following resources can be utilized to guide and implement post-market surveillance for HIVST:

- WHO IVD field safety notices: http://www.who.int/diagnostics_laboratory/procurement/complaints/en/
- WHO IVD complaint and adverse event reporting forms: http://www.who.int/diagnostics_laboratory/postmarket/en/
- WHO post-market surveillance guidance: <http://apps.who.int/iris/bitstream/handle/10665/255576/9789241509213-eng.pdf?sequence=1>

FIG. 3. POST-MARKET SURVEILLANCE FOR IVDs



Source: WHO (22).

BOX 9. YELLOW CARD POST-MARKET SURVEILLANCE SYSTEM

The Yellow Card Scheme is used by the Medicines and Healthcare products Regulatory Agency (MHRA) to monitor the safety of all healthcare products in the United Kingdom (UK). This system is utilized to ensure products are acceptably safe for those who use them by collecting information on suspected problems, counterfeit products and adverse incidents. When a suspected problem or incident is reported, the MHRA may decide to review the product and, if necessary, take action to minimize risk, protect public health and maximize benefit to the users.

Through this Scheme, in 2017 the MHRA identified an unauthorized HIVST product on the market and seized 114 of the kits in question from two UK-based suppliers. Following the incident, the MHRA encouraged consumers to check HIVST products for the CE mark that is required for all authorized medical devices in the UK, and to use the Yellow Card Scheme to report adverse issues: <https://yellowcard.mhra.gov.uk/>.

Source: MHRA (23), Siddique (24).

2.2.4 Identifying and selecting approaches to HIVST delivery

HIVST can be implemented in many ways (Table 1). Based on the situational analysis of HIV testing services that has been conducted, the national policy should

specify priority approaches, detailing the minimum package of services and support tools provided. (See also **Section 3.0 Implementing HIVST.**)

TABLE 1. APPROACHES TO HIVST DELIVERY (MOBILIZATION, TESTING AND LINKAGE)

	Mobilization	Testing	Linkage
WHEN (is HIVST delivered)?	What is the best time of day and/or day of the week to provide mobilization activities? How frequently should mobilization be done?	What is the best time of day and/or day of the week to provide testing? How frequently should testing be offered?	What is the optimal time period for linkage and follow-up?
WHERE (are HIVST kits distributed)?	Where should mobilization activities be focused?	Which sites should be prioritized for testing (for example, health facility, non-health facility, community)?	Where should linkage activities be located (for example, health facility, non-health facility, community)?
WHO (distributes HIVST kits)?	Who does the mobilization for HIVST?	Who distributes the HIVST kits?	to further testing and/or antiretroviral therapy (ART) following a reactive self-test result? Who supports linkage to prevention following a nonreactive self-test result?
WHAT (services and support tools are offered)?	For HIV testing alone? Or for HIVST with other services?	For HIV testing alone? Or with other testing services?	Could text message/phone or community-based tracing be used to support linkage to prevention or ART initiation, for example?

Source: adapted from IAS (15).

BOX 10. ASPECTS TO BE AWARE OF WHEN STARTING HIVST IMPLEMENTATION

- **HIVST kits may already be available** through the Internet, private pharmacies and other informal channels. Not all HIVST kits found in-country are quality-assured. It is important to inform and alert consumers on how to identify quality-assured self-tests, for example by offering advice on what to look for in terms of brand names, labels and/or markings related to expiry dates and quality assurance.
- **Both quality-assured blood and oral self-tests are available for procurement (6).** When used appropriately, both are safe and accurate (5, 21).
- **Not everyone needs or wants HIVST.** Alternative testing services in the community or in facility settings delivered by health workers or lay providers should continue to be available and actively promoted.
- **Plans change.** Plan to apply lessons learned early and continuously. Always look for ways to adjust a programme to reach the largest number of people with HIV who do not know their status and their partners, with a focus on those at greatest risk.
- **Fears and myths surrounding HIVST** exist and must be addressed early to facilitate implementation and scale-up. It is important to identify where there is support and where there is resistance to HIVST implementation so that barriers can be addressed, and supportive stakeholders engaged.

2.2.5 Key technical considerations and messages for providers, users and communities

Countries should consider adapting and developing messages on HIVST for providers, communities and users. These messages can be incorporated in informational tools and sessions, and training and counselling materials. WHO has developed a list of questions and answers (Q&A) on HIVST for communities, which can be adapted to national settings: <http://www.who.int/hiv/pub/self-testing/hst-questions-answer/en/>.

The following issues should be considered and, where necessary, adapted to better suit specific audiences and contexts.

- **HIVST is not recommended for people with HIV on antiretroviral therapy (ART).** Self-testing, as well as retesting in general, should be discouraged in this population as false negative self-test results may occur. However, it is acknowledged that many people do and will use HIVST when they have an HIV infection and are on ART. The following messages can be used/adapted and included in training for providers and distributors and in counselling messages and informational brochures for communities and self-testers:
 - *“Once you are on ART, HIV testing using rapid tests, including self-testing, may not be accurate. A negative result while on ART will likely be false and you should not stop antiretroviral treatment.”*
 - *“An undetectable viral load test result means ART is successfully controlling the virus. It does not mean that the virus is gone and you are cured. It does not mean you can stop taking ART.”*
 - *“It is important to tell a person providing HIV testing or distributing self-tests that you are on ART as you may get a false negative result.”*
 - *“Talk to a counsellor or health worker if you have doubts or concerns about the accuracy of an HIV-positive diagnosis.”*
- **HIVST cannot currently replace initial, or subsequent, quarterly facility-based visits for people starting or already taking pre-exposure prophylaxis (PrEP).** However, HIVST may be useful between quarterly facility visits to help with adherence among PrEP users (25). HIVST distribution, such as through the partners and social network of people

taking PrEP, may also be useful for creating demand for PrEP among high-risk populations (5).

The potential use of HIVST within the context of PrEP is an important area for further research. Programmes interested in exploring the possible role of HIVST within the context of PrEP can consider conducting operational research. The following guidance is important for those developing policies on HIVST and implementing or scaling up HIVST:

- A nonreactive self-test result, unless followed by an HIV-negative test result at a facility conducted by a trained provider, is not sufficient to start PrEP.
- Once a person is taking PrEP, self-testing – particularly with kits using oral fluid-based specimens – will not always be able to reliably detect an HIV infection.
- Quarterly facility visits by those taking PrEP are not only occasions to provide HIV testing services but also opportunities to offer sexual and reproductive health services and screening for STIs and viral hepatitis.
- A reactive self-test result is an insufficient reason to stop PrEP. Individuals taking PrEP who have a reactive self-test result require further testing using the full validated national algorithm to confirm that result.
- Individuals taking PrEP should be made aware of the limitations of self-testing while taking PrEP so that they interpret self-test results with caution and understand the importance of continuing quarterly facility visits (26-28).

More information on PrEP implementation is available in the WHO implementation tool: <http://www.who.int/hiv/pub/prep/implementation-tool/en/>.

- **HIV cannot be transmitted through saliva or kissing.** HIVST kits that use oral fluid specimens do not detect the actual HIV virus but only the HIV-1/2 antibodies that the body develops against HIV. It is important that programmes using oral fluid-based self-tests explain this to users to combat myths and misinformation about HIVST.

It may also be useful to explain that oral fluid collected by a mouth swab is not saliva but a specimen found in the upper gums. Thus, oral tests would not provide a valid result if they were conducted using spit or saliva.

- **Storage and disposal information.** HIVST products should be stored according to national supply chain

management policies and the specified storage instructions for each kit. Most quality-assured HIVST products have a 24-month shelf life with recommended storage between 2 °C and 30 °C. (For details see the [Unitaid–WHO market and technology landscape report:
https://unitaid.org/assets/HIVST-landscape-report.pdf](https://unitaid.org/assets/HIVST-landscape-report.pdf).)

When dispensing HIVST kits, it is important that community distributors provide self-testers with some general guidance on where to store self-tests and where to find the expiry date so that they use the kit before it is out of date. Messages can include: *"Store the kit in a cool dark place"* and *"Be sure to check the expiration date on the kit before using it. If the date of use has passed, dispose of the test."*

HIVST kits should be disposed of according to the manufacturer's instructions. It should be possible to dispose of the test by depositing it in the general waste system (5). Some products also contain opaque bags to help users dispose of used kits confidentially. This applies to both blood-based and oral fluid-based tests.

- **Read the tests only in the read time suggested.** Self-testers should be advised to dispose of kits after interpreting their results. They should not re-read the results after the read-window has elapsed in order to avoid misinterpretations of their HIV status (29).
- **Self-testing means testing *yourself*.** HIVST is for individuals who want to test and learn their HIV status on their own. Offering a self-test kit to a sexual partner, friend or adult family member and encouraging him/her to self-test can often be a good way to help a person learn his/her HIV status. However, it is important a person is never coerced or forced to self-test. Coercive or mandatory use of an HIVST kit should never be supported or encouraged and is not considered self-testing.

WHO does not recommend parents or guardians use HIVST kits to test their babies or children. HIVST will not provide a correct result in children less than 18 months old because the mother's antibodies may still be present in the infant (30). It is recommended that women with HIV (whether or not they received treatment for the prevention of mother-to-child transmission when they were pregnant) seek community/facility-based testing for

babies soon after their birth and further testing as per the WHO guidelines (30). Older children who are under the age of consent and in need of HIV testing should receive traditional HIV testing by a trained provider in a community or facility setting. If a parent or guardian has concerns that a child in their care may have been exposed to HIV, they should consult a healthcare worker and obtain HIV testing from a trained provider.

Adolescents who have reached the age of consent for HIV testing should have access to HIVST that is delivered using a relevant and beneficial approach. Parents and guardians may be able to provide beneficial support to adolescents to facilitate their access to HIV services, including testing and self-testing, however, it is critical that parents and guardians do not attempt to coerce or pressure adolescents to self-test or to share their self-test results.

It is important that children and adolescents with a reactive self-test result are linked as soon as possible to a clinic where they can receive further testing and treatment.

- **Avoid social harm.** Self-testing should never be forced on people – whether deliberately or inadvertently. It is essential that this message is clearly understood by HIVST distributors and communities and that there are mechanisms in place to inform, monitor and report on forced or coerced testing, and to provide redress when necessary.

Current evidence on HIVST shows that social harm is very rare⁷. To date, studies and programmatic implementation reports indicate no suicides or self-harm due to self-testing (4, 5, 31).

Although many people have concerns about possible social harm following HIVST, most concerns are not unique to self-testing. People may experience emotions like sadness, stress or depression following an HIV-positive test result regardless of whether this result is obtained using a self-test kit or through a test conducted by a community- or facility-based provider. Unless people are aware of their HIV-positive status they cannot be linked to life-saving treatment or prevent ongoing HIV transmission.

⁷ Reported social harm following HIVST includes relationship difficulties and breakups. These may resolve with time or reflect underlying relationship problems. Understanding social harms may be complex; initially considered social harms may, with time, provide longer-term benefits, for example access to ART and prevention of HIV transmission within a serodiscordant partnership.

It is important to raise community awareness about the benefits of HIV testing – including self-testing – and subsequent linkage to treatment or prevention. Carefully developed messaging is essential for self-testers, especially those who intend to offer an HIVST kit to their partner(s) or social contacts to ensure they do not feel pressured to test if it would put them at risk of violence.

Countries can use or adapt existing screening tools for intimate partner violence or other forms of social harm.

Age of consent. Most countries have policies stating the age at which adolescents can access HIV testing without the consent of parents. Age of consent varies by country but is often between 15 and 18 years of age. In a few countries the age of consent is 12 or 13 years.

It is important that adolescents and young people who have reached the age of consent have access to HIVST and that sufficient safeguards and support are in place, for example, community-based HIVST, in-person demonstrations, counselling and follow-up.

To catalyse initial implementation, HIVST policies should align the age of consent to self-test with the national policy and legislation on the age of consent for HIV testing in general. In addition, communities, including adolescents, should be engaged in discussions and decisions about how best to implement HIVST for younger age groups.

Depending on the context, there may be opportunities to leverage HIVST to advocate for lowering the age of consent to test for HIV. This may be needed to achieve broader HIV testing goals, particularly when the age of consent is considered too high.

- **Partner testing.** HIVST has been effective in encouraging partners to test together and disclose their test results and HIV status (4). To ensure partner self-testing is safe and beneficial, information should be provided on HIV serodiscordancy and clear messaging disseminated that forced or coercive self-testing is unacceptable. Individuals vulnerable to abuse from a partner, particularly sex workers, should be advised about and helped to understand the risks of offering a self-test to, or self-testing with, their sexual partners or clients.

Some users may benefit from receiving a brief training session, including example messages, on how to bring up HIV testing and self-testing with their partner(s). Support tools and resources can be accessed in [Annex 2](#).

- **Linkage to further testing, prevention and treatment following HIVST is essential and can build on existing country strategies.** A reactive (positive) self-test result alone cannot provide an HIV-positive diagnosis. Linkage to further testing is essential and, if confirmed HIV-positive, to onward HIV treatment. For those with a nonreactive (negative) self-test result, linkage to relevant prevention such as condoms, harm reduction, voluntary medical male circumcision (VMMC) or PrEP is also needed. Linkage to prevention is particularly important for those at high ongoing risk and in need of periodic retesting, such as key populations and their partners.

National policies should include specific efforts that will be leveraged to facilitate linkage following HIVST, such as referral/appointment cards, peer navigators⁸, community-based follow-up, home-based assessment/treatment initiation and partner services.

- **Official distributors of HIVST kits require training.** Lay providers, peers, pharmacists and health workers with training may serve as official distributors of HIVST kits. Individuals trained to distribute HIVST kits do not need to be trained or qualified counsellors.

Minimum standards and requirements for different distributors should be established and aligned with existing national policies. Some countries may already have guidance and training materials on rapid HIV testing that can be adapted for self-testing. It is essential to tailor any training to the specific HIVST strategies adopted, the cadres distributing HIVST kits and the HIVST products utilized.

Official distributors of HIVST kits need to have a good understanding of how to self-test, including the ability to demonstrate the use of a kit and how to interpret results. Official distributors also need to be able to deliver clear and correct information about HIVST before, during or after self-testing, and be prepared to provide or refer individuals for counselling as needed. Distributors should also be trained on how to encourage

⁸ Peer navigator is an individual who has had experience with HIV testing services HIVST and has undergone training to guide others to the relevant services they need following standard HIV testing or self-testing.

and facilitate linkage to confirmatory testing, ART, prevention services, counselling and/or support groups. Further, they should be aware of legal considerations at the national level (including age of consent for HIVST) and issues related to social harm.

HIVST distributor training should also include guidance on how to identify when not to offer or provide a kit. HIVST should never be distributed to:

- Individuals under the age of consent without permission from a parent or guardian
- Individuals, including younger adolescents, who might need additional support to cope with reactive test results and linkage to further testing and ART if HIV-positive
- Parents or guardians who wish to test their children
- People to offer to a partner(s) in vulnerable situations who could experience violence
- Workplaces where voluntarism and confidentiality cannot be ensured (for example, when kits are given to brothel owners)
- Individuals who appear severely distressed or who are under the influence of substances such as drugs or alcohol, which might impair their judgement or their ability to perform the test and interpret results correctly.

BOX 11. BASIC STANDARDS FOR LAY PROVIDER OR PEER DISTRIBUTORS OF HIVST KITS

Depending on the setting, the following criteria should be considered when selecting individuals to serve as a community-based HIVST distributors:

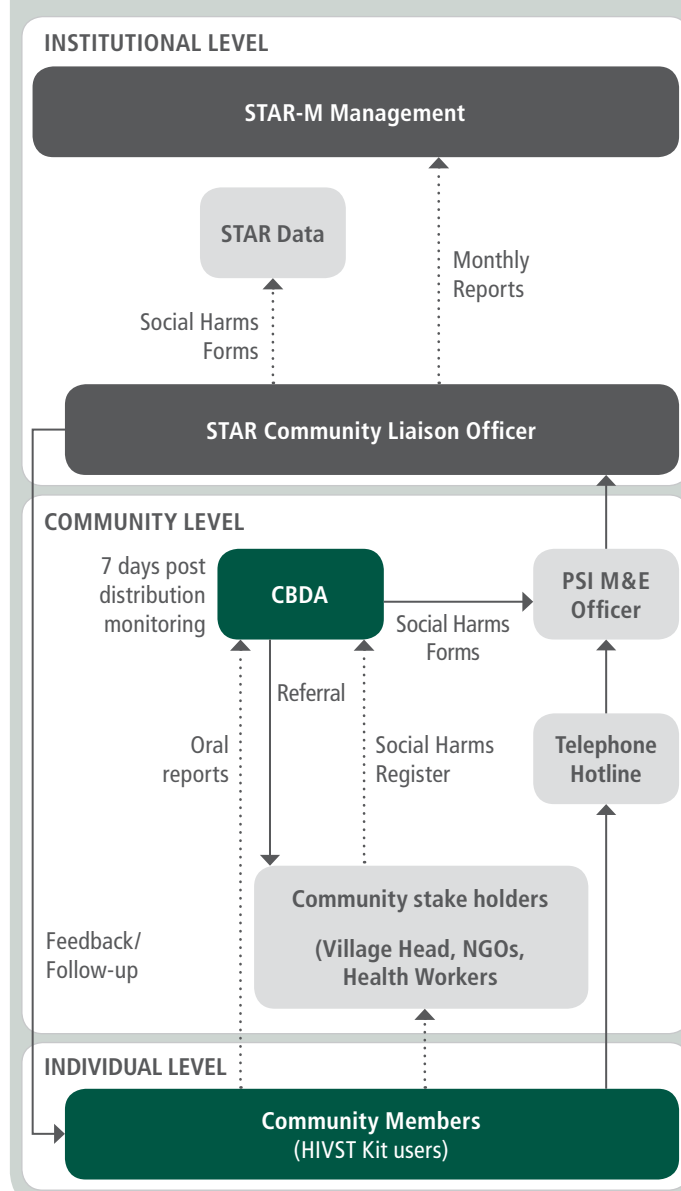
- Trusted by the local community, for example recommended or nominated by peers, including existing community-based providers or counsellors;
- Representative of the community the outreach is intended for, for example key populations, men and young people;
- Able to perform the self-test correctly and accurately demonstrate how to self-test and interpret results;
- Able to provide accurate information and additional support, for example to facilitate effective linkage to further HIV testing and prevention via referrals and other strategies employed in the country;
- Able to read and write;
- Able to complete monitoring and reporting tasks.

2.2.6 Social harm monitoring

HIVST has consistently been found to be accurate, safe and effective when used appropriately (5). Social harm following HIVST is very infrequent. Large-scale trials and implementation of HIVST have yet to identify any reports of suicide or self-harm following HIVST (4). Users continue to report HIVST as a preferred testing option, saying the convenience and privacy with self-testing prevents stigma and discrimination and the benefits outweigh possible risks (5, 12).

Although harm following HIVST is rare, it is still important to prevent and mitigate possible risks, including misuse. For this purpose, clear messages and simple monitoring and reporting systems can be developed. Community-led reporting systems can be a viable option in many settings (Box 12). In addition to the post-market surveillance approaches mentioned in Section 2.2.3, other mechanisms such as routine user satisfaction surveys, web-based tools and social media could potentially be used to report both adverse events and social harm.

BOX 12. IMPLEMENTING SOCIAL HARM MONITORING AND REPORTING IN MALAWI



Starting in 2015, HIVST was implemented among the general population and female sex workers in Malawi and included active social harm monitoring at the community level. Pre-existing community structures (such as village heads, police, community health workers, religious leaders, and marriage counsellors) were used to identify and report harms relating to HIVST.

When kits were distributed, self-testers were also encouraged to report any incidents of social harm directly to community stakeholders or community-based distribution agents (CBDAs). CBDAs followed up to address the issue and provide support where needed. They then reported the harm in a social harm register, which was submitted to the local Monitoring and Evaluation (M&E) Officer at Population Services International (PSI), the local implementing partner.

A telephone hotline was also made available to self-testers. Reports of harm made through the hotline were sent immediately to the PSI M&E Officer and the Community Liaison Officer at HIV Self-Testing Africa (STAR) Initiative, who followed up with individual self-testers, providing them with the necessary support. Reports of harm were aggregated into monthly reports by the M&E Officer.

While reports of harm were few, the system did pick up on some incidents. Encouragingly, no suicides or self-harm occurred during HIVST implementation and communities continued to report that the benefits of HIVST outweighed the potential risks. Efforts are currently underway to adapt this system to support broader HIVST implementation in Malawi.

2.3 DEVELOPING AND STARTING ACTION PLANS

Once the preparatory work for HIVST introduction has been completed, it is important that direct action steps are taken. The following box provides a checklist to consider when working to move from the planning phase to implementation.

BOX 13. CHECKLIST BEFORE HIVST IMPLEMENTATION

- ✓ Completed situational analysis of HIV testing services, including review of national laws, policies and regulations, key population mapping, stakeholder mapping, and clear community engagement
- ✓ Under the leadership of the ministry of health, define mandates, roles and responsibilities of key stakeholders, for example regulatory authorities
- ✓ Minimum standards and criteria for HIVST products in the public and private sector established, as well as the pathway to formal national registration
- ✓ Quality-assured HIVST kits procured in preparation for implementation and scale-up
- ✓ Short-, medium- and long-term plans for HIVST implementation established, with criteria for the development or updating of necessary laws, policies and regulations, including the age of consent for HIVST
- ✓ Identified approaches and strategies that will be utilized to facilitate linkage to further testing, prevention and treatment following HIVST, such as referral/appointment cards, peer navigators, community-based follow-up, home-based assessment/treatment initiation and partner services
- ✓ Harmonized messages on HIVST included across national strategic plans, HIV testing guidelines, implementation guidance, regulations, standard operating procedures, job aids, demand creation tools and promotional materials
- ✓ Guidelines, policies, regulations and national registration pathway for HIVST disseminated through an easy-to-access, publicly available platform such as the Internet
- ✓ Training on guidelines, policies and regulations completed with relevant audiences, such as communities, regulators, national agencies, implementing partners, HIVST kit distributors and healthcare workers.

3.0 IMPLEMENTING HIVST

3.1 IMPLEMENTING DIFFERENTIATED HIVST

As with any additional HIV testing, HIVST introduction needs to be strategic and focused. Based on the findings of the situational analysis of HIV testing services, it is important to review and select different approaches that will most effectively reach people in need of HIV testing, prevention and treatment.

The following sections outline some considerations for determining how to implement HIVST in a differentiated way, including priority populations, where and when to deliver HIVST, who can distribute HIVST kits (including mobilization and linkage) and which other services and support tools can be offered.

3.1.1 Priority populations

It is essential to differentiate HIV testing services to meet the needs of specific populations. HIVST has the potential to increase HIV testing coverage and frequency of testing among groups that are currently unreached. Strategies to effectively mobilize different groups to self-test and to link to further testing, prevention and treatment following self-testing need to be considered.

Based on the situational analysis conducted, it should be clear which groups need further testing and would likely benefit from HIVST. Table 2 highlights some priority populations that may benefit from HIVST. Depending on a country's context, there may be other country-specific populations that could also benefit from HIVST.

TABLE 2. EXAMPLES OF PRIORITY POPULATIONS FOR HIVST

Key populations, particularly men who have sex with men, people who inject drugs, sex workers, transgender people and people in prison	HIV testing coverage is disproportionately low among key populations (32). These populations can benefit from access to HIVST in all settings as it can increase testing coverage as well as frequency of HIV testing to at least annual testing, followed by linkage prevention and treatment (30).
Men	HIV testing coverage and knowledge of HIV status among men with HIV is substantially lower than in women with HIV worldwide (1, 2). This discrepancy is due to many issues, including fewer facility visits or opportunities for HIV testing. HIVST in studies has been shown to be beneficial in increasing testing among men (4).
Adolescents and young people (aged 15–24 years)	Approximately one third of new HIV infections globally are among young people in southern Africa (2, 33). Young key populations are especially vulnerable and affected by HIV. These most affected groups of young people have remained largely unreached by traditional HIV testing services. HIVST offered through community or peer support is considered highly acceptable and when offered has reached a large proportion of young people (31, 34–38).
Couples and partners, including partners of people with HIV	Couples and partner HIV testing, including index testing and assisted partner notification, with a view to reaching the sexual and drug injecting partners of people with HIV, is highly beneficial but under-implemented (39, 40). Partner testing in antenatal care and family planning clinics can be considered. When coupled with intimate partner violence screening, HIVST is an acceptable and effective tool for increasing partner testing and disclosure where beneficial (11, 41–45).
Other high-risk groups, for example people with STIs or those attending family planning clinics	Some groups at high ongoing risk of HIV may continue to be missed by existing HIV testing services, such as individuals presenting for family planning and/or for STI screening services. HIVST when integrated in outreach services or at healthcare facilities can potentially increase HIV testing, prevention and treatment coverage among these groups. In high HIV burden settings, offering HIVST at family planning and reproductive health clinics could have the important added benefit of helping women make informed choices about contraception and safer conception.
Pregnant and postpartum women in high HIV burden settings	In high HIV incidence and prevalence settings, although retesting in pregnant and postpartum women through the breastfeeding period is recommended and cost-effective (46), it is not usually consistently or routinely implemented. Offering partner testing and encouraging men to test during this period is also important. Offering HIVST during this heightened period of HIV risk has increased couples and partner testing (4). There are ongoing studies assessing the role of HIVST in optimizing retesting among pregnant and postpartum women and their partners (47).

3.1.2 Where can HIVST be implemented?

HIVST can be offered in many different settings depending on the HIV testing coverage gap, the population to be reached and the epidemic context. HIVST implementation across all settings should be focused and tailored using national and subnational epidemiological data, for example by focusing on geographical areas with a high HIV burden (referred to as hotspots) and/or low population/subpopulation testing coverage (Table 3).

It is important to routinely monitor HIVST implementation in order that programmatic approaches can be further optimized to achieve impact and reach national testing targets.

HIVST kits can be distributed through the following channels:

- **Communities:** HIVST kits can be distributed by trained lay providers, peer educators or community workers. Depending on the context, HIVST kits can be distributed to individuals at home (in high HIV prevalence settings), at community venues or through mobile outreach services (key populations and hotspots in high or low HIV prevalence settings).
- **Workplace/educational establishments:** HIVST kits can be offered in the workplace or at educational institutions as part of health and wellness initiatives (in high HIV prevalence settings). A health worker or trained community/peer provider can promote HIVST alongside many other health services – including HIV prevention, treatment and care – to staff and students of age of consent. In workplaces without wellness programmes, HIVST may be appealing to employers and employees as it can save time by providing a quick way to test on-site or in private at home.
- **Facilities:** HIVST kits can be distributed by a trained provider (lay provider, health worker, nurse, doctor, etc.) at a health facility. To improve testing coverage, testing volumes and efficiency of services, in some contexts HIVST kits may also be distributed in private areas while an individual or couple wait for other health services (for example, in high volume facilities with low HIV testing coverage in high HIV prevalence settings; or in health facilities that serve high-risk populations such as key populations, clients with STIs, clients with suspected or confirmed tuberculosis, and clients attending reproductive health or family planning services).
- **Pharmacies:** HIVST kits can be provided at public or private pharmacies, either over the counter by a trained staff member or through a vending machine. A trained pharmacist, or a nurse offering services at a pharmacy, may also be able to provide additional testing on-site to confirm a person's HIV status or to provide referral for further testing and, where indicated, HIV prevention and treatment services.

TABLE 3. POTENTIAL SETTINGS FOR HIVST IMPLEMENTATION

Priority populations	Low testing coverage, high HIV burden	Low testing coverage, low HIV burden	High testing coverage, high HIV burden	High testing coverage, low HIV burden
Key populations	✓	✓	✓	✓
Men	✓		✓	
Adolescents and young people (age 15–24 years)	✓		✓	
Couples and partners	✓		✓	
Partners of people with HIV	✓	✓	✓	✓
People with STIs	✓	✓	✓	✓
Family planning clients	✓		✓	
Pregnant and postpartum women	✓		✓	

- **Internet and social media:** HIVST kits can be offered for retail over the Internet or through social media channels, including dating apps. Individuals can purchase HIVST kits by paying the full retail price or by using vouchers, coupons or rebates. The kits can then be sent to a safe location for pick-up, for example a home address, office, community organization or pharmacy.
- **Retail venues (kiosks, vending machines, etc.):** HIVST kits can be made available during working hours, or at any time of the day, inside or outside distribution points such as pharmacies, sex-on-premises venues, clinics or hospitals, workplaces and educational establishments. Kits can be purchased by paying the full retail price or by using coupons, vouchers or rebates.

In all settings, approaches that have the potential to reach key populations and partners of people with HIV should be prioritized. In most settings, facility- and community-based HIVST approaches can be good options when there is a focus on hotspots and high-risk populations unreached by existing services (Box 14). HIVST kits can be made available via the Internet or through pharmacies and other retail venues in many settings regardless of HIV testing coverage or epidemic setting (Box 15).

Integrating HIVST within networks of existing drop-in centres for key populations (45, 50) and in Internet-based and social media outreach (48, 51-55) has been successful in many settings. In eastern and southern Africa, workplace and university programmes as well as short-term community-based outreach have been particularly useful in reaching men and young people with HIVST (Box 16). In Zimbabwe, HIVST has been an efficient way to achieve greater HIV testing coverage in public sector healthcare facilities, particularly those in a high HIV burden setting with poor testing coverage, long wait times and few staff (Box 17).

Linkage to confirmatory testing and treatment following self-testing may be facilitated where HIVST kits are distributed and/or where HIVST is performed. HIVST also has the potential to link users to prevention services, for example linking key populations and other populations at high ongoing risk to PrEP (5, 28). In eastern and southern Africa, where VMMC is a priority HIV programme intervention, HIVST may be an effective tool in increasing HIV testing uptake among men and their friends who

accompany them to circumcision. HIVST may also overcome a barrier to VMMC by removing the requirement of facility-based HIV testing as men can attend for VMMC already being aware of their test result (42).

Possible ways to increase linkage following self-testing include:

- **Referral/appointment cards.** Distributing referral/ appointment cards together with HIVST kits – with information and contact details on where to access further HIV testing, prevention and treatment – can help facilitate linkages. Depending on the setting, these cards can either be included by manufacturers inside the HIVST kits or provided as supplementary materials by implementing partners.
- **Community outreach and follow-up.** Follow-up by trained peers or community workers can be a useful strategy for facilitating linkage to further testing, prevention and treatment (42). This can include offering community-based confirmatory testing, prevention and treatment while HIVST kits are distributed or on an ad hoc basis (31, 56). Community workers and peer navigators may also accompany those with a reactive self-test result to receive further testing and care in a facility (48).
- **Telephone calls, text messages or social media counselling messages and reminders.** Follow-up counselling, messages and reminders can be used to encourage self-testers to link to further testing, prevention and treatment. These follow-up messages can be integrated in a variety of HIVST approaches as well as within existing HIV testing services.
- **Compensation or financial incentives.** Small incentives offered to self-testers – such as the reimbursement of transport costs and/or financial compensation for the time lost to travel to a clinic for further testing, prevention or treatment services – may be useful, particularly for men (57, 58). However, issues of feasibility, equity and sustainability need to be considered.

BOX 14. USING HIVST TO REACH MEN WHO HAVE SEX WITH MEN, FEMALE SEX WORKERS AND PEOPLE WHO INJECT DRUGS IN VIET NAM

In 2016 it was estimated that 27% of people with HIV in Viet Nam were undiagnosed, the majority of whom were key populations and their sexual partners. During this period conventional HIV testing coverage remained low in these groups, with only 36% of people who inject drugs, 41% of female sex workers and 43% of men who have sex with men receiving an HIV test. To achieve the first of the 90–90–90 targets – diagnosis of 90% of people with HIV – the Government of Viet Nam estimated that HIV testing coverage among key populations needed to increase to at least 80%.

Starting in January 2017, lay provider HIV testing, HIVST, index partner testing, and rapid hepatitis C virus and syphilis testing were implemented in Thai Nguyen and Can Tho provinces. Trained peer educators from key populations led and conducted all services, including HIVST kit distribution. Mobilization promoting HIVST was done through social media and social networks and

included efforts to encourage the partners of people with HIV to test. Since this was a pilot initiative, all HIVST was observed and supported by peers. Testing uptake and linkage data were routinely collected through logbooks.

Between January and December 2017, through this community-led approach to HIVST, 426 people self-tested and 7.7% (33/426) were diagnosed with HIV; 88.8% (29/33) of those diagnosed with HIV received ART.

Following the success of this pilot and others conducted in Viet Nam during this period, the Viet Nam Ministry of Health committed to scale up self-testing nationwide, including through open access (the purchase of HIVST kits via the Internet, social media, private sector retail, etc.) and unobserved approaches. In April 2018, the government of Viet Nam formally endorsed and released national guidelines supporting HIVST.

Source: Nguyen (48).

BOX 15. SAFE BOX – HIVST KITS REACH MEN WHO HAVE SEX WITH MEN AND TRANSGENDER PEOPLE IN RUSSIA

In the context of growing stigma and discrimination towards men who have sex with men and transgender people in Russia, providing convenient, discreet or anonymous HIV testing and referral options is essential. The Safe Box project was launched in 2017 in five large cities (Moscow, St. Petersburg, Yekaterinburg, Omsk, Orel), where men who have sex with men and transgender people can access free HIVST kits from community organizations, clinics, private pharmacies, clubs, saunas, as well as via the postal system and volunteers. HIVST users can provide feedback and receive support through a free telephone hotline, social media channels or the project's website: <http://gaytest.info/>.

In 2017, over 10 000 HIVST kits were distributed through this project. While only 28% of self-testers reported their results, 15% of these had a reactive result, suggesting the project is reaching high-risk men who have sex with men and transgender people. To date, 230 people have

reported receiving further testing to confirm their HIV status and 81% of these have been enrolled in care at local treatment centres.

Men who have sex with men and transgender people participating in the Safe Box project were initially reluctant to visit community organizations, even in big cities, preferring to access an HIVST kit in a neutral place such as a pharmacy, where they only had to speak to a pharmacist instead of to a community representative. Additional HIVST kit distribution sites are now being set up.

Efforts to promote the project through social media platforms and "gay-friendly" websites increased demand for HIVST. For example, within one month of using Hornet, a gay dating app, to inform people about the possibility of self-testing, coverage increased by 25%.

Source: Pisemsky (48).

BOX 16. WORKPLACE PROGRAMMES THAT INCLUDE HIVST IN SOUTH AFRICA

Numerous approaches are currently being adopted to implement HIVST in South Africa. Workplace HIVST is being explored as a strategy to help achieve national targets to reach more men with HIV who do not know their status. As a first phase in this strategy, male-dominated industries – including formal and informal employment in mining, construction, security, petroleum and agriculture – were prioritized in three provinces.

Between January and June 2018, 110 114 HIVST kits were distributed; 66% of these were provided to men. Nearly half (47%) of the HIVST kits distributed reached people who reported not having tested in the preceding 12 months or never having tested.

Key lessons learned from this first phase in workplace HIVST include:

- A substantial amount of time is needed to plan, coordinate and negotiate with companies on how to offer HIVST in the workplace.

- It is important to develop a comprehensive stakeholder engagement plan and to include worker unions.
- HIVST information sessions, including demonstrations on how to self-test, and distribution events should be conducted in the language(s) of the employees and must be timed to not affect workflow. Shift worker schedules need to be taken into consideration.
- Partnerships with public health services and existing workplace wellness programmes – including mapping of public health services for companies – is critical to facilitate linkages to further/confirmatory testing, prevention and treatment.

Based on the lessons learned from this first phase in the workplace HIVST strategy, implementation is being rolled out with a view to reaching even more men who have never tested.



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BOX 17. HIVST INTEGRATION IN PUBLIC SECTOR HEALTH FACILITIES IN ZIMBABWE

In June 2017, HIVST was introduced at 43 clinics and district hospitals in Zimbabwe to increase the HIV testing capacity of public sector healthcare facilities. HIVST is offered as an alternative option to provider-delivered HIV testing services to patients accessing other health services at outpatient departments. Eligible clients, those who have not recently tested for HIV, are unaware of their status and are not already receiving ART, are offered HIVST while waiting to see their healthcare provider.

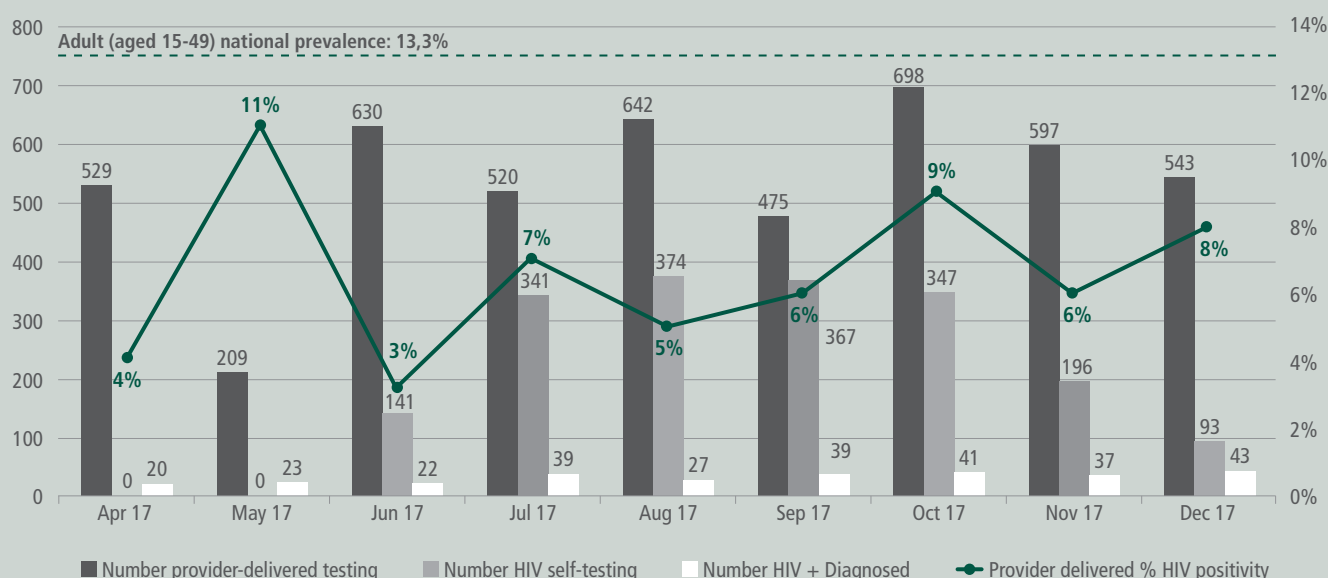
HIVST demonstrations are either conducted in person by a lay counsellor or nurse or through videos screened in the waiting area. Two to three HIVST booths are set up in the outpatient department to provide clients with the necessary privacy to test on-site. Additional written and pictorial information on how to perform the test and interpret the result, as well as a clock to serve as a timer alerting users when they can read the test results, are provided inside each booth. Clients are asked to present their self-test results to the provider. In case of a reactive result the provider offers further testing on-site and if confirmed HIV-positive ART is initiated on the same day. Those who test HIV-negative are informed about prevention interventions such as VMMC and PrEP and safe sexual behaviour.

From June to December 2017, following the introduction of HIVST at public sector health facilities, the number of patients tested for HIV in Zimbabwe more than doubled (see chart). Approximately 30% of all those tested at the facility opted for self-testing over provider-initiated testing. Prior to HIVST introduction, the HIV positivity rate was between 3% and 4% within the facilities. Between June and December 2017, during HIVST implementation, HIV positivity was consistently higher than before HIVST was made available. The number of HIV-positive cases identified increased by 80%, from a monthly average of 20 cases in April 2017 to an average of 43 cases in December 2017.

Overall, offering HIVST at public sector healthcare facilities is feasible and acceptable among both providers and clients. HIVST increases testing coverage at facilities and frees up time spent by providers on testing HIV-negative clients, who can be screened out efficiently, allowing providers to focus their work on confirmative testing, counselling and education for HIV-positive clients, including the initiation of ART. Further efforts by ministry of health are needed to ensure healthcare workers do not see HIVST as competing with their work requirements, especially if they are remunerated based on their performance in testing and counselling clients for HIV.

HIV SELF-TESTING AND PROVIDER-DELIVERED TESTING IN PUBLIC SECTOR CLINICS AND HOSPITALS IN ZIMBABWE, APRIL TO DECEMBER 2017

n=6364 people tested, 4.6% HIV-positive



3.1.3 Who can deliver HIVST (mobilization, distribution and linkage)?

HIVST kits can be distributed by many people, such as trained peers, healthcare workers, pharmacists, as well as individuals who directly deliver self-tests to their social networks, including their sexual and drug injecting partners.

Trained community workers, peers and peer educators have been shown to be effective in mobilization efforts and the distribution of HIVST kits as well as in facilitating linkages through social networks, health facilities and community outreach, particularly in key populations, men and young people (48, 59-64). Although health workers and pharmacists are also able to distribute HIVST kits, studies indicate they require additional training and information about HIVST to be able to provide adequate support and facilitate linkage to further testing, prevention and treatment (18, 65, 66).

Using community mobilizers selected by the local community has been effective for achieving good HIVST uptake and linkage to VMMC and ART in southern Africa (42, 67, 68). Trained health workers, counsellors, peers and other cadres can also facilitate linkages by providing information and counselling through telephone hotlines and messaging services via the Internet or social media (Box 18) (63).

All HIVST approaches can include secondary distribution of self-tests (sometimes referred to as partner-delivered) from one individual to those in his/her social network, including sexual or drug injecting partners. To effectively implement this approach, it is important that initial HIVST kit distribution includes screening for intimate partner violence and adequate information on how to self-test, how to offer and demonstrate a self-test and the importance of avoiding noncoercive practices.

Secondary distribution of HIVST, when done appropriately, can increase testing uptake and potentially help facilitate linkages (4, 59-61, 64). In some population groups, HIVST via secondary distribution can also provide an opportunity for individuals to receive additional support by testing with a partner or peer that they trust (35, 43, 69). Secondary distribution to the male sexual partners of pregnant and postpartum women in high prevalence settings, and to the sexual partners and social networks of key populations as well as the partners of people living with HIV in all settings should be encouraged (5).

When HIVST kits are distributed directly to the user by retailers or manufacturers, via the Internet for example, it is imperative that sufficient instructions, information and support, as well as contact details – such as telephone hotlines or websites – are provided with the kit.

BOX 18. REACHING FISHERMEN IN UGANDA USING PEER-TO-PEER HIVST WITH TELEPHONE COUNSELLING AND LINKAGE TO CARE

To increase uptake of HIV testing and linkage to care among fishermen in Uganda, in 2018 The AIDS Support Organization (TASO), a local non-governmental organization, began offering HIVST kits among this population. TASO expert clients mobilized 19 fishermen (10 who were HIV-positive and on ART, and 9 who had not tested for a year or more) and trained them on how to distribute the self-test. The fishermen were each given five HIVST kits together with instruction leaflets to deliver to other fishermen. The leaflets provided information on what to do after self-testing, including how to contact a counsellor at a health facility or how to access telephone counselling.

During the initial implementation phase, 95 out of the 115 fishermen offered a HIVST kit accepted. Approximately 4% (4/95) had a reactive self-test result. Of these, one reported to a counsellor via telephone that he already knew his status and was on ART. The other three called the telephone hotline to share their self-test result and receive counselling, after which they obtained further testing at a facility to confirm their HIV-positive diagnosis and initiate treatment.

The results of the TASO initiative suggest that telephone counselling is acceptable to fishermen who are HIV-positive and can successfully encourage them to receive further testing and treatment. Other mobile or online counselling services can also be considered for facilitating linkage following self-testing.

Source: Nanfuka (63).

3.1.4 When can HIVST be delivered?

It is important to make HIVST available at different times based on the needs of the populations to be reached.

HIVST has been shown to be an effective tool in improving the frequency of HIV testing (4, 5). The frequency of retesting, including HIVST, should be determined by an individual's risk of acquiring HIV. Retesting, at least every year, is needed in groups at high ongoing risk, such as key populations (30). Providing access to multiple HIVST kits per year helped high-risk men who have sex with men achieve quarterly testing in both Australia and the United States (4, 70, 71). Retesting targets should be carefully considered as retesting is only beneficial if there are strong linkages to HIV prevention (for those who have a nonreactive self-test result).

Several open access options – such as the Internet, social media and private sector retail – can make HIVST available 24 hours a day. In health facilities, educational establishments and workplace programmes, HIVST can be accessible to individuals during general operating hours. Active distribution of HIVST in community settings can complement other HIV testing services by making HIVST kits available during non-traditional hours, such as late at night and on weekends, to reach men, key populations and young people currently missed by existing services. In some settings, a community-based HIVST strategy may be implemented periodically using a campaign style approach, for example annually or every three to five years (72). Secondary distribution may also enable individuals to offer HIVST kits to their peers and partners at their convenience. Because of the variety in the times when HIVST can be available, it is important that support services, including counselling and referrals, that are offered during/after self-testing are also accessible at these times, for example through telephone hotlines.

3.1.5 What other services and support tools can be offered with HIVST?

HIVST implementation involves more than distributing a test kit; it also requires the delivery of a package of services that include demand creation and support tools. Depending on the population and setting, different types of demand creation strategies and support before, during or after HIVST may be needed.

Demand creation strategies. Multiple strategies can be used to increase demand for HIVST among different priority population groups. As a first step, while HIVST is being distributed across various approaches, increasing visibility is important to create awareness. However, efforts may be needed to target demand for HIVST to prevent unnecessary retesting in low-risk groups. To amplify awareness and knowledge of HIVST the following approaches can be utilized:

- Mass media (radio, television), social media, websites and print-based materials
- Local celebrities, politicians and HIVST champions in the community
- Community outreach and engagement, including dissemination meetings, consultations, special events
- Trusted and trained peers, health workers and community leaders who can mobilize for HIVST, as well as other health services, and distribute HIVST kits
- Secondary distribution of HIVST kits, including through invitation letters, to mobilize sexual partners, drug injecting partners and peers to test.

Support tools. When focusing on reaching adolescents and young people, first-time testers, populations in rural settings and those with low literacy or education levels, using support tools such as in-person demonstrations will most likely be needed.



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The first time that people self-test they may require more support and information to become familiar with the process – with less support needed as awareness increases and after they have had the experience of self-testing. Early implementation studies found users preferred receiving assistance when self-testing the first time (42, 73). In eastern and southern Africa, particularly in rural settings with low literacy and education levels, brief in-person demonstrations have been shown to be very important to achieve correct self-test results (17, 74). Adolescents and young people may desire HIVST and be able to self-test and interpret the result correctly, however, they may prefer and need greater support from a trained peer or counsellor.

When starting HIVST implementation, programmes may require self-testers to be observed and intensely supported during the testing process. This is mainly due to initial concerns users might have, as well as the need to provide sufficient evidence to inform national policy and implementation. Such approaches, while potentially needed, should be time-limited. Once sufficient evidence has been provided, it is important that programmes move toward defining a minimum package of support tools as part of a sustainable and routine implementation model.

The following list highlights a core package of tools to assist and support self-testers that can be considered:

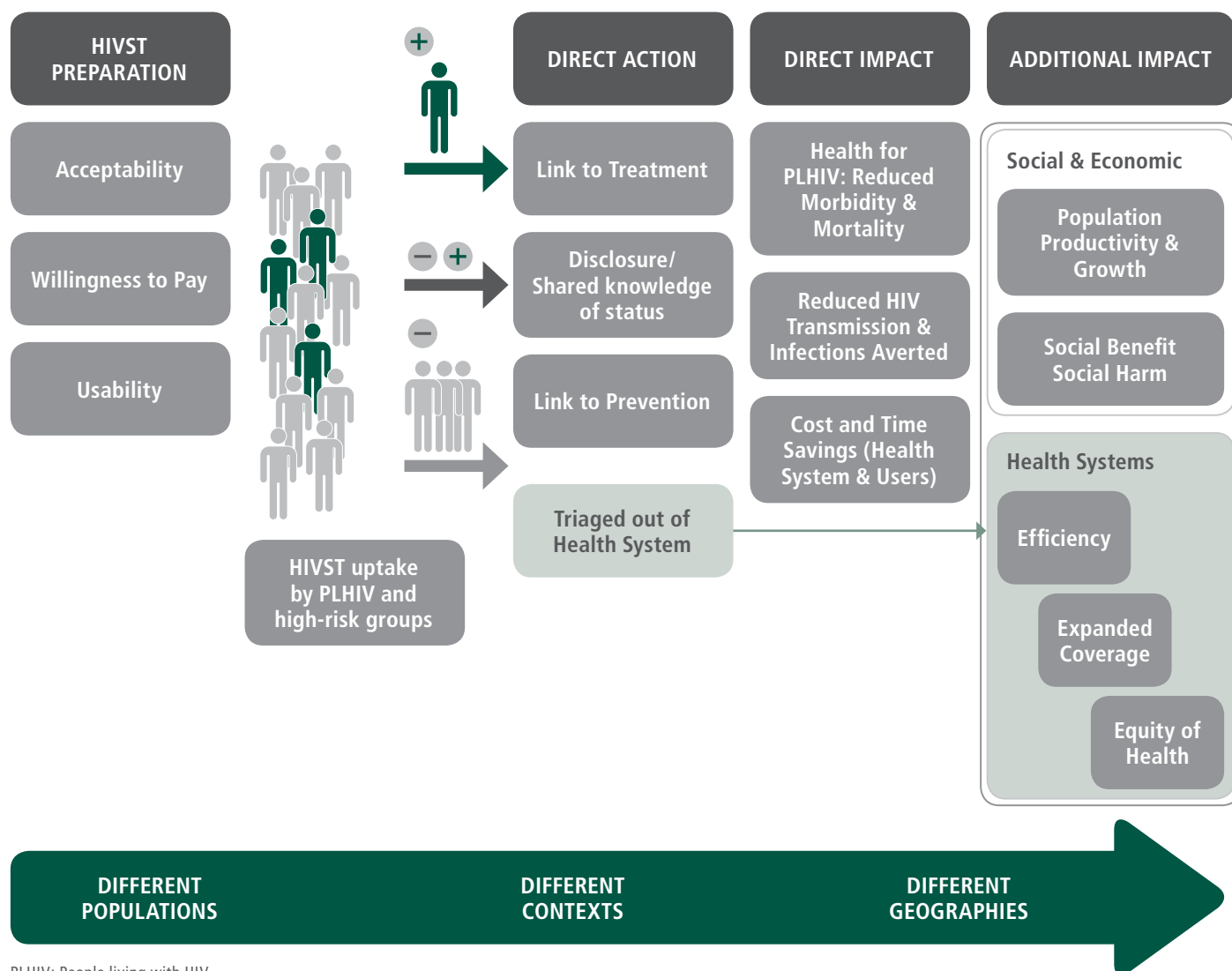
- In-person demonstration (one-on-one, with partners or in groups)
- Demonstration video (including online links to videos)
- Telephone hotline (can be integrated into existing national hotline services)
- Short message service through telephone, Internet, social media
- Educational information via radio,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

4.0 MONITORING TO OPTIMIZE HIVST

As previously indicated, the key objective of HIV testing service implementation, including HIVST, is to contribute to national and global HIV goals such as the 90–90–90 targets. By reaching people with HIV who do not know their status and population groups at high ongoing risk, HIVST can enable linkage to further testing (for early diagnosis) and HIV prevention and treatment services. As a result, HIV-related morbidity and mortality, including the number of new HIV infections, can be reduced, particularly among populations that may not have otherwise been reached. Additional indirect social, economic and health system benefits – such as potential cost and time savings and greater equity – can also emerge (Fig. 4).

To achieve impact, a minimum reliable set of data is required to guide and further optimize HIVST implementation. The following information is intended for those responsible for monitoring HIV testing services – including HIVST – at the global, national and site levels. Since HIVST implementation is still new for most settings, monitoring indicators and guidance are currently being field tested. More detailed guidelines and tools for HIVST monitoring and reporting will be provided in early 2019.

FIG. 4. IMPACT FRAMEWORK FOR HIVST



PLHIV: People living with HIV

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

4.1 ROUTINE MONITORING AND REPORTING FOR HIVST PROGRAMMES

4.1.1 National-level HIVST monitoring

Prior to starting HIVST implementation, it is recommended that programmes conduct a baseline assessment to identify which populations will most benefit from self-testing using existing routine indicators for HIV testing and linkage to prevention and treatment. Detailed guidance and reference sheets on these routine HIV testing and linkage indicators is available in the WHO *Consolidated Strategic Information Guidelines for HIV in the Health Sector*: <http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en/>. All existing HIVST indicators are summarized in **Annex 3**. Additional considerations to guide programmatic efforts and initial target-setting are available in **Section 2.1** on conducting an HIV testing services situational analysis.

During HIVST implementation, it is important to integrate HIVST monitoring into existing tools and approaches used to monitor HIV testing services, such as HIV testing and ART registers. In some countries, revising these HIV testing and ART registers, for example by adding an additional column, has been seen to be a simple way to streamline HIVST monitoring and the reporting of HIVST uptake, test results and linkage to treatment or prevention services. Questions on HIVST can also be included in special surveys, such as in a demographic and health survey (DHS) or in integrated bio-behavioural surveillance (IBBS).

Additional HIVST-specific monitoring and reporting tools will sometimes be needed. Tablet- or paper-based tools can be used, particularly for collecting data on people receiving HIVST kits across various service delivery points. For instance, when distributing self-test kits a client data card (Fig. 5) or HIVST register (Fig. 6) can be used to determine who is accessing HIVST.

When collecting information on HIVST indicators it is important to consider the quality of the data. It is recommended that routine quarterly reviews be conducted to ensure the accuracy of any data collected and to further optimize implementation. The following considerations should be kept in mind when monitoring HIVST implementation:

- Collecting data on HIVST kit distribution, including the persons who receive these kits, will provide essential information on the target populations reached, for example key populations, men, first-time testers.
- Retesting is an issue with all routine HIV testing data. Since all reactive self-test results should be followed by further testing, it is important to ensure estimated numbers of tests are deduplicated when calculating the total number of people tested and diagnosed with HIV.
- Some testers may have been previously diagnosed with HIV and some may already be on ART. Therefore, it is important to utilize existing monitoring systems to measure testing and self-testing among these individuals, including when assessing any data on linkage to care as some testers may already be on treatment.
- Surveys conducted by telephone or through apps or short messages could be feasible options in some settings to estimate HIV positivity and linkage following HIVST. This approach requires further field testing and research, however.
- Early studies used late reads of self-test kits (after the manufacturer read window has lapsed) to estimate HIV positivity. This should no longer be done, particularly with oral fluid-based tests, as evidence suggests it may overestimate HIV positivity (29).

FIG. 5. EXAMPLE HIVST CLIENT DATA CARD FROM KENYA

Thank you for taking this bold step to perform your own HIV testing. This information will remain anonymous and will assist in improving Self-testing services. Please do not include your name or your phone number

Age (years): [____]

Gender: Female [____] Male [____]

Have you ever tested for HIV before?:
Yes [____] No [____]

How long ago did you have the HIV test
Never [____] Last three months [____] Last one year [____] Longer than one year [____]

What Type of HIV self-test kit have you purchased today:
Oral [____] Blood [____]



What is the main reason for testing?
(select one only):

- To understand illness/ symptoms that I have/had
- Advice from the pharmacist/ my doctor
- I recently had a possible exposure to HIV
- To plan the future/ take charge of my own health/ getting married
- Encouraged by sex partner
- It has been longer than 1 year since I last tested
- Other reason (please indicate): _____

Source: NASCOP (75).

FIG. 6. EXAMPLE HIVST CLIENT DATA REGISTER

Name of service delivery point					Type of service delivery point: Public [] Private [] Hospital [] Clinic [] Pharmacy/chemist [] Voluntary counselling and testing site [] Drop-in centre [] Other/specify_____							
Serial	Date	Client name	Sex	Age	Marital status	Tel Number	Kit information			Referred [Y/N/NA]	Received HTS	Remarks
					S/M/D/Se/W		Name	Batch No.	Exp. Date			
							Test result: P/N/I					

S/M/D/Se/W: Single/Married/Divorced/Separated/Widowed

P/N/I: Positive/Negative/Inconclusive

Y/N/NA: Yes/No/Not applicable

Source: NASCOP (75).

Table 4 details existing national indicators that can be considered for routine monitoring and reporting on HIVST implementation.

TABLE 4. NATIONAL-LEVEL INDICATORS FOR MONITORING HIVST

Status	Indicator	Numerator (N)/ Denominator (D)	Measurement method and issues	Source
Required ★	Number of HIVST kits distributed	N: Total number of HIVST kits distributed	Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population if collected; approach, for example: community-based, facility-based, secondary distribution (key partner, index case, male partner); type of sites, for example: community outreach, door-to-door, mobile, workplace, antenatal clinic, primary care, outpatient department, STI clinic, family planning clinic; and self-testing by self, sex partner, other See Annex 3 for detailed indicator reference sheet	Self-reported during HIVST kit distribution (for example, using tablet- or paper-based collection tools) Adapted from PEPFAR Monitoring, Evaluation and Reporting Indicator Reference Guide
Optional (also global-level)	Number of individual HIVST kits approved / registered by authorized body at national level	N: Total number of individual HIVST kits approved/registered by authorized body at national level	Disaggregation by oral and blood-based self-tests, WHO prequalification, and other approvals	National register of approved/regulated IVDs WHO prequalification and Global Fund lists
Optional	Number of sites distributing HIVST kits	N: Total number of sites distributing HIVST kits	Disaggregated by geography, private sector and public sector	National programme data Manufacturer and Pharmacy Council data
Optional	Percentage of the population aware of HIVST	N: Total number of people reporting they have heard of test kits people can use to test themselves for HIV D: Population surveyed	Question: Have you heard of test kits people can use to test themselves for HIV? Disaggregation by age (10–14, 15–19, 20–49, 50+ years) and sex	Self-reported responses to special survey (DHS)
Optional	Percentage of the population who has ever self-tested	N: Total number of people reporting they have self-tested D: Population surveyed	Question: Have you ever tested yourself for HIV using a self-test kit? Disaggregation by age (10–14, 15–19, 20–49, 50+ years) and sex	Self-reported responses to special survey (DHS)
Optional	Percentage of the population willing to self-test if available	N: Total number of people reporting they would self-test if they had the opportunity D: Population surveyed	Question: If a self-test kit was available, would you be willing to test yourself for HIV? Disaggregation by age (10–14, 15–19, 20–49, 50+ years) and sex	Self-reported responses to special survey (DHS)
Optional	Percentage of people presenting at HIV testing sites reporting prior self-testing in the past 12 months	N: Total number of people self-reporting self-testing prior to presenting at HIV testing site in the past 12 months D: Total number of people presenting for HIV testing in the past 12 months	Disaggregation by age (10–14, 15–19, 20–49, 50+ years), sex, key population and self-test result (reactive or nonreactive) if collected	Self-reported self-testing documented in clinic logbooks (for example, HIV testing register)

Status	Indicator	Numerator (N)/ Denominator (D)	Measurement method and issues	Source
Optional	Percentage of those tested in the last 12 months reporting self-test as their last test	N: Total number of people reporting self-testing as their last test in the last 12 months D: Total number of people reporting HIV testing in the past 12 months	Question: Please think back to the last time you tested for HIV. Did you go somewhere, or did someone come to you, or did you test yourself for HIV? Disaggregation by age (10–14, 15–19, 20–49, 50+ years), sex and if collected by key population	Self-reported responses to special survey (IBBS)
Optional	Percentage of new ART initiations among people diagnosed with HIV who report prior self-testing in the past 12 months	N: Total number of people self-reporting self-testing who have documented HIV-positive diagnosis newly initiating ART in the past 12 months D: Total number of new ART initiations in the past 12 months	Disaggregation by age (10–14, 15–19, 20–49, 50+ years), sex and by key population if collected	Self-reported self-testing documented in clinic logbooks (for example, ART register) at ART sites and clinics Note: important to exclude people previously diagnosed with HIV reinitiating ART
Optional	Percentage of male circumcisions among people who report prior self-testing in the past 12 months	N: Total number of people self-reporting self-testing who have documented VMMC in the past 12 months D: Total number of male circumcisions in the past 12 months	Disaggregation by age (10–14, 15–19, 20–49, 50+ years)	Self-reported self-testing documented in clinic logbooks
Optional	Percentage of PrEP initiations among people who report prior self-testing in the past 12 months	N: Total number of people self-reporting self-testing who have documented PrEP initiation in the past 12 months D: Total number of PrEP initiations in the past 12 months	Disaggregation by age (10–14, 15–19, 20–49, 50+ years), sex and key population if collected	Self-reported self-testing documented in clinic logbooks
Optional	Percentage of self-testers reporting they self-tested with a sex worker prior to having sex in the past 12 months	N: Total number of people reporting they self-tested with a sex worker prior to having sex in past 12 months D: Total number of people reporting they self-tested in past 12 months	Question: There are home HIV test kits available. Have you ever tested for HIV with a sex worker before having sex? Disaggregation by age (10–14, 15–19, 20–49, 50+ years), sex and key population	Self-reported responses to special survey (IBBS)

4.1.2 Global-level HIVST monitoring

At the global level, HIVST monitoring is conducted through the Global AIDS Monitoring (GAM) system. Current indicators focus primarily on tracking countries that report they are: 1) implementing HIVST; 2) have a policy on HIVST; or 3) are developing an HIVST policy. Global reporting on these policy indicators is updated biannually. Further details on the GAM guidelines and indicators are available: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf.

In addition, WHO monitors the number of HIVST product failures and complaint reports, and the number of HIVST kits that are registered or approved by a founding

member of the Global Harmonization Task Force, WHO prequalification or the Global Fund/Unitaid Expert Review Panel for Diagnostics. WHO forms for collecting product complaints and adverse events are available: http://www.who.int/diagnostics_laboratory/postmarket/en/.

Data on product failures, complaints and adverse events are collected directly from donors and manufacturers and validated with WHO's Department of Essential Medicines and Health Products. In addition, this information is aggregated with global HIVST policy and implementation data and donor procurement data to provide an annual HIVST forecast – see, for example, the Unitaid-WHO landscape report: <https://unitaid.org/assets/HIVST-landscape-report.pdf>.

Table 5 detail existing global indicators that can be considered for routine monitoring and reporting on HIVST implementation.

TABLE 5. GLOBAL-LEVEL INDICATORS FOR MONITORING HIVST

Status	Indicator	Numerator (N)/ Denominator (D)	Measurement method and issues	Source
Required	Number of countries implementing HIVST	N: Total number of countries reporting they are implementing HIVST	Question: Which of the following HIV testing approaches are used in your country (please select all that apply): • client-initiated testing and counselling; • provider-initiated testing and counselling; • routine antenatal testing; • community-based testing and counselling; • home testing; • lay provider testing; • self-testing; • assisted partner notification; • other index case-based testing (for example, family, social network contacts)?	Global reporting through GAM system
Required	Number of countries with HIVST in a national policy or plan	N: Total number of countries that have included HIVST within a national policy or plan	Question: Has your country adopted or included HIVST as a national policy or plan?	Global reporting through GAM system
Required	Number of countries planning to include HIVST in future national policy or plan	N: Total number of countries planning to include HIVST in future national policy or plan	Question: If your country has no HIVST policy, does it have plans to include self-testing in its national policy in the future? Question: If your country is planning to include HIVST in its future policy, please indicate in which year this will be done: 2019, 2020, 2021, no planned year?	Global reporting through GAM system
Optional (also national level)	Number of individual HIVST kits approved / registered by authorized body at national level	N: Total number of individual HIVST kits approved/registered by authorized body at national level	Disaggregation by oral and blood-based self-tests, WHO prequalification, and other approvals	National register of approved/regulated IVDs WHO prequalification and Global Fund lists
Required	Number of HIVST product failures and/or adverse events	N: Total number of HIVST product failures and/or adverse events reported to WHO by users	Measured based on the total number of complaints related to an HIVST product reported to WHO.	WHO IVD complaint reporting forms completed by users and collected and validated by WHO Department of Essential Medicines and Health Products

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ANNEXES

ANNEX 1. HIVST CASE EXAMPLES

A. 1.1 Zhuhai Xutong Voluntary Services Centre launches innovative service to provide HIVST to men who have sex with men in China

Limited resources for HIV testing services in China hinder sufficient community outreach, particularly among men who have sex with men, who often distrust the healthcare system and lack appropriate resources to access testing in the private sector. The low HIV testing rate among men who have sex with men is an obstacle to achieving the first global 90–90–90 target in the country.

Since 2016, Zhuhai Xutong Voluntary Services Centre, a community organization based in Zhuhai city, has offered HIVST through an online platform. The website is tailored to men who have sex with men and offers a confidential and trusted channel through which to order HIVST kits and be informed about HIV and the testing and treatment services that are available. Users have the option of ordering additional HIVST kits for other persons in their social circle.

From July 2016 to March 2018, 3370 HIVST kits were distributed to 915 users; 93% of these kits (3138/3370) were returned by 1193 individual self-testers. The majority of those who tested HIV-positive were linked to other testing services and care. Self-testers aged less than 20 years and those 20–39 years reported preferring HIVST to standard HIV testing services.

Based on these results, the Chinese Centre for Disease Control and Prevention and Zhuhai Xutong Voluntary Services Centre are evaluating the broader introduction of HIVST and how to further tailor the programme to reach more men who have sex with men.

A. 1.2 A Hora É Agora (The Time is Now), Brazil

In 2014 a web-based platform (e-testing site) was developed to enable men who have sex with men in Curitiba, Brazil, to order HIVST kits online. The service is anonymous and provides free HIVST packages that include condoms and two self-test kits. The HIVST packages ordered on the website are sent to the address provided by the user or can be collected from a local pharmacy.

Since the project's inception in 2014, 8800 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, a city where this population group is estimated to number 17 000. 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. Ninety-six per cent of users 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.

The success of the project in Curitiba has led to increased HIVST implementation at the national level. As of May 2018, two men-only clinics (one at a public healthcare facility and one in Curitiba's most active meeting point for key populations) are providing HIV testing services, including HIVST, followed by immediate treatment for people diagnosed as HIV-positive, as well as diagnosis and treatment of STIs, and immunization against the human papillomavirus and hepatitis B virus. In addition, 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.

Source: Grinsztejn (76); Lentini (77); Benzaken (78).

A. 1.3 HIVST distribution through lay providers to increase HIV testing among key populations in Ukraine

In Ukraine, lay providers are not permitted to deliver HIV testing services. The HIV epidemic in the country is highly concentrated among key populations, therefore, community-based approaches are needed. To bridge this gap, assisted HIV self-testing is being provided with support from AIDS Alliance. Trusted peers are trained to provide direct support to people so they can self-test for HIV, whilst also offering them syringes and condoms. These lay providers can refer and follow up with clients who have a reactive self-test result to facilitate linkage to confirmatory testing and treatment.

From 2014 to 2017, since the introduction of this community-based approach, HIV testing coverage among key populations has increased from 40% to 120% (60% of clients reached self-test twice a year). In 2015, more than 149 000 people who inject drugs tested for HIV using this assisted self-testing approach, which represents 67.5% testing coverage in this population, compared to 66 481 people who inject drugs in 2014, representing 31.6% testing coverage. Efforts to explore and scale up unassisted HIV self-testing are now underway.

Source: Denisiuk (79).

A. 1.4 Community-based HIVST kit distribution to men who have sex with men in Kenya

Six men who have sex with men in Malindi, Kenya were provided training on how to use an oral fluid-based HIVST kit, including messages emphasizing the need to confirm self-test results and the importance of confidentiality. They were then closely monitored and supported in their task of distributing HIVST kits to their peers, and offered feedback on a daily basis. Amkeni, a local nongovernmental organization run by men who have sex with men mobilized peers in the community to take up self-testing through this initiative. Given this was a pilot, all men who have sex with men who took an HIVST kit were asked to return for further testing.

From March to June 2016, the six trained men who have sex with men distributed 337 HIVST kits to their peers, averaging four to five kits per week. The majority of men who have sex with men who took up HIVST were younger adults (aged 26 years, IQR: 23–32). 99.1% (333/337) of men who have sex with men who took a self-test kit returned for further testing and 8.7% (29/333) of these were confirmed HIV-positive; 88.8% (24/29) started treatment the same day their HIV-positive diagnosis was given.

More men who have sex with men were diagnosed with HIV through this HIVST initiative than through other previously implemented community-based approaches to HIV testing using peer providers (8.7% vs. 3.5%; $P < 0.001$).

Men who have sex with men who participated in this initiative reported HIVST as an acceptable way to test. Confirming a reactive self-test result through a peer provider and, thereafter, starting ART immediately – if made available – also appeared to be acceptable and feasible.

Source: van der List (61).

ANNEX 2. HIVST RESOURCES

2.1 TECHNICAL GUIDELINES AND POLICY BRIEFS

- WHO HIVST: <http://www.who.int/hiv/topics/self-testing/en/>
- WHO HIVST Q&A: <https://youtu.be/BA5E9wsEbPw>
- WHO HIVST – key questions, answers and messages for community organizations: <http://www.who.int/hiv/pub/self-testing/hst-questions-answer/en/>
- WHO HIVST guidelines and partner notification: <http://www.who.int/hiv/pub/self-testing/hiv-self-testing-guidelines/en/>
- WHO HIVST policy brief: <http://www.who.int/hiv/pub/vct/who-recommends-hiv-self-testing/en/>
- WHO global benchmarking tool for evaluation of national regulatory systems: http://www.who.int/medicines/regulation/benchmarking_tool/en/
- WHO guidance on post-market surveillance of IVDs: <http://apps.who.int/iris/bitstream/handle/10665/255576/9789241509213-eng.pdf?sequence=1>
- WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices: <http://apps.who.int/medicinedocs/documents/s23213en/s23213en.pdf>
- WHO regulation of medical devices – a step-by-step guide: <http://apps.who.int/medicinedocs/documents/s22503en/s22503en.pdf>

2.2 EXTERNAL RESOURCES AND REFERENCES

The following external implementation materials and tools on HIVST can be found at the following websites.

- HIVST implementation tools: <https://aidsfree.usaid.gov/resources/hts-kb/>
- HIVST research and policy hub: <http://hivst.org/>
- Differentiated service delivery: <http://www.differentiatedcare.org/>
- STAR protocols and tools: <https://hivstar.lshtm.ac.uk/protocols/>
- Pharmaceutical Society of Kenya resources: <http://www.besure.co.ke>
- WHO IVD complaint reporting forms: http://www.who.int/diagnostics_laboratory/postmarket/en/
- SPECTRUM module: <http://beta.avstaging.org/gt/>
- PEPFAR monitoring, evaluation and reporting indicator reference guide: <https://datim.zendesk.com/hc/en-us/articles/360000084446-MER-2-0-Indicator-Reference-Guide->

2.3 HIVST PRODUCT INFORMATION

- WHO prequalification list: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/
- Global Fund list of eligible diagnostic products: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/>
- Unitaid HIVST market and technology landscape: <https://unitaid.org/assets/HIVST-landscape-report.pdf>
- WHO IVD field safety notices: http://www.who.int/diagnostics_laboratory/procurement/complaints/en/
- WHO post-market surveillance guidance: http://www.who.int/diagnostics_laboratory/postmarket/en/

ANNEX 3. MONITORING AND EVALUATION BEFORE AND DURING HIVST IMPLEMENTATION

Indicator	Numerator/Denominator	Programme relevance and interpretation	Measurement method and issues
Percentage of population ever tested for HIV	N: Number of people reporting that they have ever been tested for HIV D: Number of people surveyed Disaggregated by test result, sex, age (<1, 1–4, 5–9, 10–14, 15–19, 20–49, 50+ years)	Measures trends in scale-up of HIV testing services among first-time testers	Self-reported in special survey (DHS) Question: I do not want to know the results, but have you ever been tested for HIV?
Percentage of population tested for HIV in the past 12 months	N: Number of people who were tested for HIV and received their results within the past 12 months D: n/a. Although not required for this indicator, a denominator may be gauged by using the general population size in generalized epidemics or the sizes of key populations and other priority populations in low-level and concentrated epidemics Disaggregated by test result, sex, age (<1, 1–4, 5–9, 10–14, 15–19, 20–49, 50+ years), key population (where available), other target populations if relevant	Measures trends in scale-up of HIV testing and counselling	D&N: Programme records, for example HIV testing service registers Count only people's first test or else subtract retesters to calculate the number of individuals tested
Number of people who were retested for HIV within the past 12 months	N: Number of people who were tested and received their results more than once within the past 12 months D: n/a. Although not required for this indicator, a denominator may be gauged by using the general population size in generalized epidemics or the sizes of key populations and other priority populations in low-level and concentrated epidemics Disaggregated by sex, age (<1, 1–4, 5–9, 10–19, 20–49, 50+ years), key population (where available), other target populations if relevant Type of retester: 1. Retesting (at ongoing risk); 2. Retesting after discrepant result; 3. Retesting to verify diagnosis	Quantifying the number of retesters and subtracting retesters from the total number of testers helps to determine the number of individuals tested. Knowing the reasons for retests can help explain retesting patterns	Programme records
Proportion of HIV-positive adults receiving HIV care whose partner's status is known	N: Number of HIV-positive adults receiving HIV care within the past 12 months whose sexual partner's HIV status is documented in their patient record D: Number of HIV-positive adults who received HIV care within the past 12 months and who have a sexual partner Disaggregated by specific population of interest.	Measures the programme's ability to identify and test the sexual partners of people receiving HIV care who are at high risk for HIV infection, to: 1. Prevent ongoing transmission in serodiscordant couples, and; 2. Identify HIV-positive partners with the aim of enrolling them in HIV care services	N&D: programme records, for example, patient clinical records. Data can be collected during annual review at all facilities or at a sample of sentinel sites (Interpret results appropriately)

Indicator	Numerator/Denominator	Programme relevance and interpretation	Measurement method and issues
Percentage of people diagnosed with HIV	N: Number of people living with HIV who have been diagnosed and have received their test results D: Number of people living with HIV Disaggregated by sex, age (<1, 1–4, 5–9, 10–19, 20–24, 25–49, 50+ years), key populations, other target populations	Assesses effectiveness of HIV testing programmes in reaching people living with HIV A more detailed review, identifying which subpopulations are undiagnosed can help tailor HIV testing strategies to improve and increase diagnosis of people living with HIV	Best estimate based on the following data sources if available: 1. Facility data: N: cumulative number of reported new HIV diagnoses minus deaths; D: national estimate for the number of people living with HIV based on internationally consistent modelled estimates, for example, Spectrum AIM 2. Population-based surveys that collect data on HIV serostatus with a question to assess whether respondents know their HIV-positive status. The indicator will be calculated as people living with HIV who report knowing their status 3. Population-based surveys that collect data on HIV serostatus without a question to assess whether respondents know their HIV-positive status. Construct a plausible range and midpoint based on: the higher value of the percentage of respondents in the survey who are living with HIV and have been tested in the past 12 months and received their results, with the percentage of all people living with HIV on care as the lower end of the range and the percentage of people living with HIV ever tested as the upper end of the range Other surveys, related programme data and modelled estimates can be used as additional data sources for developing and triangulating estimates
Percentage of people with HIV who know their status and are on ART	N: Number of people living with HIV who received HIV care in the past 12 months (as proxied by receipt of at least one of the following during the past 12 months: clinical assessment (WHO staging) or CD4 count or viral load or currently receiving ART) D: Number of people living with HIV	Measures the proportion of people living with HIV who are receiving care (both ART and pre-ART services). Time trends can be monitored to assess the increase in the proportion of people in care. Reviewing the number of people who are receiving HIV care out of the number of people living with diagnosed HIV can be useful as well	N: Programme records, for example, pre-ART and ART registers, visit records D: Internationally consistent modelling estimates, for example, Spectrum AIM

Indicator	Numerator/Denominator	Programme relevance and interpretation	Measurement method and issues
Number and % of newly diagnosed HIV-positive people newly enrolled in and receiving care LINK.1a (preferred): Number and % of newly diagnosed people linked to HIV care (individual-level linkage) LINK.1b (if LINK.1a not feasible): Number of HIV-positive people newly enrolled in and receiving care and ratio relative to number of people who test positive for HIV (cross-sectional proxy for linkage)	N: Number of people who were newly enrolled in HIV care and received clinical HIV care services in the past 12 months (as proxied by receipt of at least one of the following during the reporting period: clinical assessment (WHO staging) or CD4 count or viral load count or currently receiving ART) D: Number of people newly diagnosed with HIV within the past 12 months. Includes pregnant women and tuberculosis patients diagnosed HIV-positive Disaggregated by age (<1, 1–4, 5–14, 15–19, 20–49, 50+ years), ART, sex, key population, pregnant women, breastfeeding women	Indicates programme performance in linking people diagnosed HIV-positive to care Where possible, individual-level linkage to care should be measured to accurately determine the percentage of newly diagnosed people who were linked to care Where it is currently not possible to measure individual-level linkage, a cross-sectional numerator and denominator can be compared to get a broad sense of linkage from testing to HIV care (Different individuals are counted in the numerator and denominator and, therefore, this figure is a ratio, not a true proportion)	N: Programme records for HIV care, including pre-ART registers, ART registers, other facility registers (for example, for HIV testing, antenatal care, tuberculosis) and case-based surveillance data D: Programme records, for example HIV testing registers, laboratory records, case reporting Track individuals' linkage to care through recording in a testing register or through case reporting or electronic M&E systems that link data on patient diagnosis with data on HIV care (facilitated by the use of unique IDs) If that is not possible, try to review the cross-sectional proxy for linkage: compare the number of newly in HIV care (including ART) with the number diagnosed HIV-positive within the reporting period (12 months). Includes pregnant women and tuberculosis patients diagnosed HIV-positive
Number of male circumcisions in past 12 months (where appropriate)	N: Number of medical male circumcisions within the past 12 months performed according to the national standard Disaggregated by age (<1, 1–9, 10–14, 15–19, 20–24, 25–49, 50+ years), HIV status, male circumcision method (surgical, elastic collar compression type device, collar clamp type device) Optional: type and location of facility cadre of provider	The total number of male circumcisions carried out over time indicates change in the supply of services and/or change in demand Comparing current results with previous values shows where male circumcision services have been newly instituted or where male circumcision volume has changed When numbers of male circumcisions are disaggregated by HIV status and age, it will be possible to adjust inputs used in models to determine the impact of male circumcision programmes on HIV incidence and, if a country has prioritized services or set targets for age groups, determine success in meeting those targets Disaggregation by age can help determine how well age-specific strategies to increase demand are working	Programme records, VMMC registers

ANNEX 4. HIVST INDICATOR REFERENCE SHEET

Description	Number of individual HIVST kits distributed	
Numerator	Number of individual HIVST kits distributed	This indicator aims to monitor trends in the distribution of HIVST kits within a country at the lowest distribution point
Denominator	N/A	
How to use	To monitor HIVST implementation approaches. HIVST is when a person collects his/her own specimen (oral fluid or blood), performs an HIV test and then interprets the results. This is often done in a private setting, either alone or with a trusted person. Self-test kits can be distributed in many ways, as specified by the national programme, to facilitate and enhance access to and uptake of HIV testing services for populations where HIV test uptake is low and undiagnosed HIV infection is high. This indicator aims to monitor trends in the distribution of HIVST kits within a country at the lowest distribution point (that is, between the distributor and the intended user(s)/recipient).	
How to collect data	The suggested data source is an HIVST register or logbook. If a standalone HIVST register or logbook is not possible, revise existing registers for HIV testing services, log books and reporting forms already in use to include very clear labels indicating self-testing. Ensure information on HIVST entered in an HIV testing services register is not counted and reported as standard HIV testing. Data for the numerator should be generated by counting the number of individual HIVST kits distributed and NOT the number of individuals receiving an HIVST kit. This is because one individual can receive multiple self-test kits (for example, one for themselves and one for their partner(s)). Number of self-test kits distributed should be captured and reported at the lowest distribution point. The lowest distribution point refers to the individual/site giving out self-test kits and capturing data for monitoring purposes. This is to prevent double counting between the various higher supply chain levels. The disaggregation by type of self-testing provides information about the proportion of test kits distributed through each model. Further disaggregation by “number of tests distributed to a person by age/sex” and “test kit distributed for use by” can provide information about what subpopulations are receiving HIVST kits and who the test kit is intended for use by (that is, self, sex partner, other). The findings can support national government programmes to assess how efficient different distribution approaches are at reaching target populations. These data may also be useful for projecting programmatic commodities (for example, self-test kits) and systems needs (such as, staffing resources). Although not required, attempts to document and report information about actual use of self-test kits are encouraged. This includes who used the test kit, the result of the self-test and linkage to retesting (if result is reactive), particularly when directly assisted HIVST occurs.	
Reporting level	Facility and community	
Reporting frequency	Quarterly	
How to review for data quality	Data should be reviewed regularly for the purposes of programme management, to monitor progress towards achieving targets, and to identify and correct any data quality issues. For example, the number of test kits distributed should not be greater than the number of test kits a provider was allocated during the reporting period. Pay careful attention to the number of HIVST kits distributed at pharmacies and online. Careful attention should be paid to ensure HIVST is not being counted as part of standard HIV testing data.	
How to calculate the annual total	Sum results across quarters.	
Data elements and disaggregates		
Number of individual HIVST kits distributed	HIVST approach	Approach as specified by national programme, for example, community-based, facility-based, secondary distribution (key partner, index case or male partner)
	HIVST kit distribution channel	Type of sites specified by national programme, for example, community outreach, door-to-door, mobile, workplace, antenatal clinic, primary care, outpatient department, STI clinic, family planning clinic
	Number of HIVST kits distributed to a person by age/sex	10–14 M, 10–14 F, 15–19 M, 15–19 F, 20–24 M, 20–24 F, 25–29 M, 25–29 F, 30–34 M, 30–34 F, 35–39 M, 35–39 F, 40–49 M, 40–49 F, 50+ M, 50+ F
	Number of test kits distributed to key populations [optional]	• People who inject drugs • Men who have sex with men • Transgender people • Sex workers • People in prison and other closed settings
	Test kit distributed for use by	Self-testing by: self, sex partner, other



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