

MEETING TARGETS AND MAINTAINING
EPIDEMIC CONTROL (EPIC) PROJECT

COOPERATIVE AGREEMENT NO.
7200AA19CA00002

HIV SELF-TESTING OPERATIONAL GUIDE

FOR THE PLANNING, IMPLEMENTATION,
MONITORING AND REPORTING
OF HIV SELF-TESTING



ACKNOWLEDGEMENTS

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The work is aligned and based on the WHO Guidelines on HIV self-testing and partner notification,²⁴ the WHO HIV Self-Testing Strategic Framework,²⁶ the Considerations for HIV self-testing in the context of the COVID-19 pandemic and its response: an operational update, and PEPFAR 2021 COP guidance.

The work is based on evidence and best practice experience gathered by the Unitaid-funded HIVST Africa (STAR) Initiative and USAID funded HIVST implementation.

The work was funded by the United States Agency for International Development (USAID) through EpiC.

Editing was provided by Hannah Kikaya and Sonata.

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ABBREVIATIONS

ART	Antiretroviral therapy
CBDA	Community-based distribution agent
DHS	Demographic and health survey
HIV	Human immunodeficiency virus
HIVSS	HIV self-screening
HIVST	HIV self-testing
IBBS	Integrated bio-behavioral surveillance
IVD	In vitro diagnostic
IFU	Instructions for use
LMIC	Low- and middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
M&E	Monitoring and evaluation
MSM	Men who have sex with men
PLHIV	People living with HIV
PEP	Post-exposure prophylaxis
PMS	Post-marketing surveillance
PrEP	Pre-exposure prophylaxis
PSI	Population Services International
QA	Quality assurance
RDT	Rapid diagnostic test
SCM	Supply chain management
STAR	HIV Self-Test Africa Initiative
STI	Sexually transmitted infection
TWG	Technical working group
USAID	United States Agency for International Development
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

DEFINITIONS AND TERMS

Assisted partner notification services: Refers to when consenting HIV-positive clients are assisted by a trained provider to disclose their status or to anonymously notify their sexual and/or drug injecting partner(s) of their potential exposure to HIV infection. The provider then offers HIV testing to these partner(s). Assisted partner notification is done using contract referral, provider referral or dual referral approaches.

Client referral: The index client takes responsibility for disclosing their HIV status to partner(s) and encouraging partner(s) to seek HTS. This is often done using an invitation letter or referral slip.

Contract referral: An assisted partner notification service approach in which HIV-positive clients enter into a contract with a trained provider and agree to disclose their status and the potential HIV exposure to their partners by themselves, and refer their partners to HIV testing services (HTS) within a specific time period. If the partner(s) of the HIV-positive individual does not access HTS or contact the health provider within that period, then the provider will contact the partner(s) directly and offer voluntary HTS. Counsellors/providers offer voluntary HTS to partner(s) while maintaining the confidentiality of the index client.

Dual referral: An assisted partner notification service approach in which a trained provider accompanies and provides support to HIV-positive clients when they disclose their status and the potential exposure to HIV infection to their partners. The provider also offers voluntary HTS to the partner(s).

Directly assisted HIV self-testing (HIVST): Refers to when individuals who are self-testing for HIV receive an in-person demonstration from a trained provider or peer before or during HIVST, with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use (IFU) and other materials found inside HIVST kits.

Harm or social harm: Any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt from one person to another, a person to themselves, or an institution to a person, occurring before, during or after testing for HIV.

HIV self-testing: A process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts.

HIV status: The final report that is given to the patient; it is the final interpretation of the patient disease state and is based on a collection of testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or HIV-inconclusive.

HIV test result: The result from a single test on a given assay.

Index case testing (ICT): Index case testing refers to a process in which HIV testing is offered to everyone exposed to HIV by the index client (an individual newly diagnosed as HIV-positive and/or an HIV-positive or an individual who is enrolled in HIV treatment services). There

are four types of Index case testing all of which are defined separately in this list: (1) client referral; (2) contract referral; (3) provider referral; and (4) dual referral. All four ICT processes can be enhanced with HIVST.

In vitro diagnostic medical device: A medical device, used alone or in combination, intended by the manufacturer for the examination of specimens derived from the human body solely, or principally, to provide information for diagnosis, monitoring or determining compatibility. For example, an in vitro diagnostic medical device can be used for: diagnosis, as an aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

Intimate partner violence: Behavior within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship, including acts of physical violence, sexual violence, emotional or psychological abuse and controlling behaviors.

Key populations: Defined groups who, due to specific higher-risk behaviors, are at increased risk of HIV irrespective of the epidemic type or local context. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people.

Lay provider: Any person who performs functions related to health-care delivery and has been trained to deliver these services but has no formal professional or para-professional certification, nor a tertiary education degree.

Non-reactive test result: A test result that does not show a reaction indicating the presence of analyte, which in the context of HIV refers to HIV-1 p24 antigen or HIV-1/2 antibodies.

Partner notification services: Also known as disclosure or contact tracing; is defined as a voluntary process whereby a trained provider asks people diagnosed with HIV about their sexual partners and/or drug injecting partners, and then, if the HIV-positive client agrees, offers these partner(s) HTS. Partner notification is provided using passive or assisted approaches.

Passive referral: A partner notification service in which HIV-positive clients are encouraged by a trained provider to disclose their status to their sexual and/or drug injecting partners by themselves, and to also suggest HTS to the partner(s) given their potential exposure to HIV infection.

Point-of-sex testing: Refers to when individuals use an HIV rapid diagnostic test for self-testing to screen potential sex partners and determine his or her own HIV status and their partner(s)' HIV status.

Pre-test information: A dialogue and the provision of accurate information to a client by a lay provider or a health worker before an HIV test is performed.

Provider referral: An assisted partner notification service approach in which, with the consent of the HIV-positive client, a trained provider confidentially contacts the person's partner(s) directly, informs them that they have been exposed to HIV, and offers the partner(s) voluntary HTS while maintaining the confidentiality of the index client.

Quality assurance: Part of quality management focused on providing confidence amongst stakeholders that quality requirements will be fulfilled.

Quality control: The set of procedures designed to monitor the test method and results to ensure appropriate test system performance. It includes testing control materials, charting the results and analyzing them to identify source of error, and evaluating and documenting any remedial action taken as a result of this analysis.

Quality improvement: An element of quality management focused on increasing the ability to fulfil quality requirements.

Quality management system: A system to direct and control an organization with regard to quality. Systematic and process-oriented efforts are essential to meet quality objectives. Principles of quality management include categories such as documents and records, organization, personnel, equipment, purchasing and inventory, process control, information management, occurrence management, assessments – external and internal, process improvement, customer services and facilities and safety.

Rapid diagnostic test: In vitro diagnostic medical device of immunochromatographic or immunofiltration format for the detection of HIV-1/2 antibodies and/or HIV p24-1 antigen in the context of HIV. Reactive test result: a test result that shows a reaction indicating the presence of analyte, which in the context of HIV includes HIV-1 p24 antigen or HIV-1/2 antibodies.

Repeat testing: A situation in which additional testing is performed for an individual immediately following a first test, during the same testing visit, due to HIV-inconclusive status or discordant test results. The same assay(s) is used and, where possible, the same specimen.

Retesting: Refers to certain situations in which individuals should be retested after a defined period of time: (1) HIV-negative people with recent or ongoing risk of exposure; (2) people with an HIV-inconclusive status; and (3) HIV-positive people before they enroll in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription errors and ruling in or ruling out seroconversion.

Sensitivity: Denotes the probability that an HIV assay/algorithm will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV-1 p24 antigen. Seroconversion: is when an individual's immune system produces a quantity of HIV-1/2 antibodies sufficient to be detectable on a given HIV serology assay.

Sero-discordant couple: A couple in which one partner is HIV-positive and one partner is HIV-negative.

Specificity: The probability that the assay/algorithm will correctly identify specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Testing algorithm: The combination and sequence of specific assays used within HIV testing strategies.

Unassisted HIV self-testing: Refers to when individuals self-test for HIV using only a self-test kit that includes manufacturer-provided instructions for use. As with all self-testing, users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos.

HIV SELF-TESTING QUICK REFERENCE GUIDE

HIVST IN PRACTICE

When should HIV self-testing be used rather than conventional testing approaches?

Where are the gaps?

What is the potential impact?

HIV self-testing (HIVST) should be highly targeted to **individuals in groups not currently being reached by existing HIV testing services (HTS)**. HIVST distribution approaches should be tailored to populations with low testing coverage and at ongoing HIV risk. **For highest impact and cost effectiveness, HIVST should not replace conventional HTS but should be used to:**

- 1. Improve access for people with high HIV risk and vulnerability**, including people living with HIV who have been lost to follow-up (PLHIV LTFU), people who do not currently use HTS, adolescents, high risk men and hard-to-reach key populations.
- 2. Facilitate partner testing and index testing** by providing kits to people with HIV or at high risk of HIV so that they can offer HIVST to their partners or other people in their social networks.
- 3. Improve testing coverage by integrating it into clinical services** where testing is needed but not routinely provided or where testing is poorly implemented. **If the price of HIVST kits were to fall below \$1 per test, then PEPFAR would support the targeted use of HIVST at health facilities.** In this context, HIVST can replace components of provider-initiated HIV testing. Offering HIVST at

high-volume clinics in high-HIV-burden settings and at sexually transmitted infection (STI) or family planning clinics makes efficient use of clients' waiting time and ensures links to care services.

- 4. Create demand and increase uptake of HIV prevention services.** Those with a nonreactive self-test result will not need confirmatory testing, but HIVST is an opportunity to direct these people to prevention services (e.g., pre-exposure prophylaxis [PrEP], voluntary medical male circumcision [VMMC], condoms, and STI screening/treatment).

WHO?

Who are the target populations? Who could benefit from HIVST?

HIVST has the greatest impact when targeted at members of populations who do not access other forms of HTS.

The World Health Organization (WHO) and U.S. President's Emergency Plan for AIDS Relief (PEPFAR) have identified several populations as high priority for HIVST:

- Adult men in high-HIV-burden settings
- Adolescents and young people (ages 15–24 years) in high-HIV-burden settings
- PLHIV LTFU, as an easy way to re-enter treatment services
- Key populations: men who have sex with men (MSM), people who inject drugs (PWID), sex workers (SWs) and their sexual partners, transgender women, and people in prisons

- Other high-risk groups, including STI patients; women presenting for family planning services in high-burden settings; couples and partners, including partners of PLHIV; refugees; young at-risk men; and other groups that face high levels of stigma and discrimination

There may be other target groups depending on the country's HTS and antiretroviral therapy (ART) gaps.

AGE OF CONSENT FOR HIVST AND HIVST WITH YOUNG ADOLESCENTS

In most countries, the age of consent for HIV testing is 16 and this would also apply to HIVST.

In countries with the age of consent at 12-15 years (young adolescents), HIVST should always be assisted by a trained health care provider.

HIVST has a high acceptance rate among older adolescents and youth, and adolescents are more likely to accurately use oral self-test kits. Although HIVST holds potential to increase HTS coverage among adolescents, programs will need to ensure that adolescents who screen positive are linked to diagnostic HTS and treatment services, if confirmed positive.

USE OF RAPID HIV-1/2 SALIVA-BASED ANTIBODY TESTS IN CHILDREN 2-11 YEARS

Studies have shown that rapid HIV-1/2 saliva-based antibody tests have high sensitivity and specificity in children older than 2 years, and these tests have been approved by WHO for use in children starting at age 2 up to age 11 with the assistance of a trained health care worker.

WHAT?

Once national policy frameworks are in place, adequate HIVST service delivery requires careful planning. Effective HIVST approaches are based on three main components:

1. Demand creation and client mobilization
2. HIV testing process
3. Linkage process after HIVST

CORE HIVST PROGRAM COMPONENTS

1. **Demand creation/mobilization:** A comprehensive, user-centered communications and marketing strategy should increase awareness and demand among priority populations and engage with key stakeholders.
2. **Testing process:** Distribution is either direct (offered to the client who will use it) or indirect (offered to an intermediary) and can be unassisted or assisted—when a trained provider or peer gives information on how to use the kit and interpret the result and demonstrates use before giving it to the client. Assisted HIVST does not mean that provider directly assists the client and/or is present when client conducts the self-test. Self-test users can test on site or take the test kit home.
3. **Linkage:** Have tools available that support testers' links to confirmative testing, counseling, treatment, and/or prevention after a self-test. Tools should allow the tester to opt-in, use the highest level of technology available to the target population (e.g., phone, Internet, smartphone), offer the option of speaking to a human and direct community follow-up, and protect the privacy and confidentiality of the self-testing experience.

Tools should not pressure self-testing clients to disclose their test results nor compromise the privacy of the testing experience. People who use a self-test kit at a facility or community event should be offered confirmatory testing and linkage services on site. Linking self-testers who test off site is more challenging, so innovative follow-up approaches, such as calls, SMS, WhatsApp contact, or community outreach, might be required. The STAR Initiative has developed a range of tools to support linkage, available at: www.psi.org/project/star. Also see, USAID resources, available at: aidsfree.usaid.gov/resources/hts-kb/hiv-self-testing/all.

HIVST KITS

Where can HIVST kits be procured?

There are currently four WHO prequalified HIVST products:

- OraQuick HIV Self-Test (OraSure Technologies, USA); oral fluid
- INSTI HIV Self-Test (Bioanalytical, Canada); blood-based
- Mylan HIV Self-Test (Mylan, Atomo Diagnostics, Australia); blood-based
- SURE CHECK HIV 1/2 Assay (Chembio, USA), blood-based

All four kits can be procured with U.S. Government or Global Fund funds. To order, contact the Global Health Supply Chain-

Table 1. HIVST products with WHO PQ, EPRD or approval from founding member of IMDRF*

TEST (MANUFACTURER)	SPECIMEN	APPROVAL	PEPFAR UNIT PRICE EX WORKS
Mylan HIV Self Test (Atomo Diagnostics, Australia)	Blood	WHO PQ	\$1.99
autotest VIH*** (AAZ Labs, France)	Blood	CE mark	
BioSURE HIV Self Test** (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD-3	
Exacto® Test HIV (Biosynex, France)	Blood	CE mark	
INSTI® HIV Self Test** (bioLytical Lab., Canada)	Blood	WHO PQ	\$3.09
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA CE Mark	
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ	\$2.00
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	WHO PQ	\$2.99

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

* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaidd/GF Expert Review Panel for Diagnostics.

** These products sold in more than one packaging format.

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

Source: Unitaidd/WHO, 2019.

Rapid Test Kits (GHSC-RTK) via Dianna Edgil (dedgil@usaid.gov).

Selecting HIVST products for procurement from WHO's lists of prequalified HIVST kits will enable countries to forgo in-country performance evaluations. HIVST products for procurement can be identified by reviewing those listed at the following links: [WHO prequalification](#) and [GF Quality Assurance Policy for Diagnostic Products](#).

HOW?

There are many effective HIVST delivery mechanisms, in which individuals either test by themselves in private or in the presence of a sexual partner or peer, or distribute tests to partners and social contacts.

Figure 2 depicts the most frequently used HIVST distribution approaches. Evidence summarized by WHO demonstrates they all work in different contexts. Implementation arrangements must be tailored to the target population group and responsive to their preferences.

For help selecting optimal distribution models for the country context and health system structures, USAID Missions can contact Vincent Wong (vwong@usaid.gov) or Elisabeth Manfredini (emanfredini@usaid.gov) or access technical assistance through the EpiC (Judy Chen, juchen@usaid.gov) or RISE (Jacquie Firth, jfirth@usaid.gov) projects.

IMPACT FRAMEWORK

Investments in HIVST can result in broad health and social benefits. See Figure 1.

MONITORING AND EVALUATION

How should HIVST outcomes and impact be measured and reported?

Several indicators are recognized by WHO and PEPFAR for monitoring HIVST. Many of these metrics can be obtained using routine clinic data to provide a picture of HIVST's reach, outcomes, links to care and prevention, and measures of process efficiency. STAR sample monitoring tools can be found at:

- www.psi.org/project/star
- hivstar.lshtm.ac.uk
- aidsfree.usaid.gov/resources/hts-kb
- www.who.int/hiv/pub/self-testing/strategic-framework/en

MONITORING, EVALUATION, AND REPORTING (MER) INDICATORS

MER now includes an HTS_Self indicator to apply to HIVST kit distribution (required) and, where possible, use (recommended). Disaggregates of HTS_Self include age/sex of recipient, point of distribution, intended use (primary or secondary distribution); see datim.zendesk.com/hc/en-us/articles/360000084446-MER-Indicator-Reference-Guides

SPECIFIC HIVST INDICATORS

Reach

Which distribution strategies are most effective for reaching the priority populations?

- Uptake of HIVST by priority populations: adult males, adolescent girls and young women, adolescent boys and young men, key populations, other unreached populations

- HIV testing coverage among priority populations
- HIV testing uptake among index cases after HIVST

Reach data are:

- Disaggregated by sex and age
- Disaggregated by testing history (most recent test in the past three months, past 12 months, never tested)
- Disaggregated by approach (e.g., community-based, facility-based, secondary distribution)
- Type of sites (e.g., community outreach, door-to-door, mobile, workplace, antenatal clinic, primary care, outpatient department, STI clinic, family planning clinic)
- Self-testing by self, sex partner, other

Outcome of HIVST

- Measuring impact of HIVST on reaching the undiagnosed, links to HIV care/ treatment and prevention after HIVST
- Reactive and nonreactive (negative) HIVST results can either be collected through directly assisted, on-site HIVST or—if HIVST was conducted off site or the recipient received the test through secondary distribution—via direct follow-up with the self-tester.

Links to HIV care after HIVST

- Uptake of confirmatory testing (can be measured if self-testing is incorporated in clinic data or through direct follow-up of self-test users)
- ART initiation after HIVST (needs to be standardized, per clinic/day ideally)

Links to prevention services, VMMC, and PrEP uptake after HIVST

- Uptake of VMMC services after HIVST
- Uptake of PrEP services after HIVST

Process efficiency

- Measure different steps in the distribution and linkage processes for each of the distribution models to identify bottlenecks and to ensure fidelity of the planned HIVST service delivery approaches.

NOTE: Implementers should attempt to track adverse events associated with HIVST, including instances of self-harm and events related to secondary distribution, where possible.

Figure 1. How HIVST can turn investments into broad health and social impacts (source: WHO, 2019)

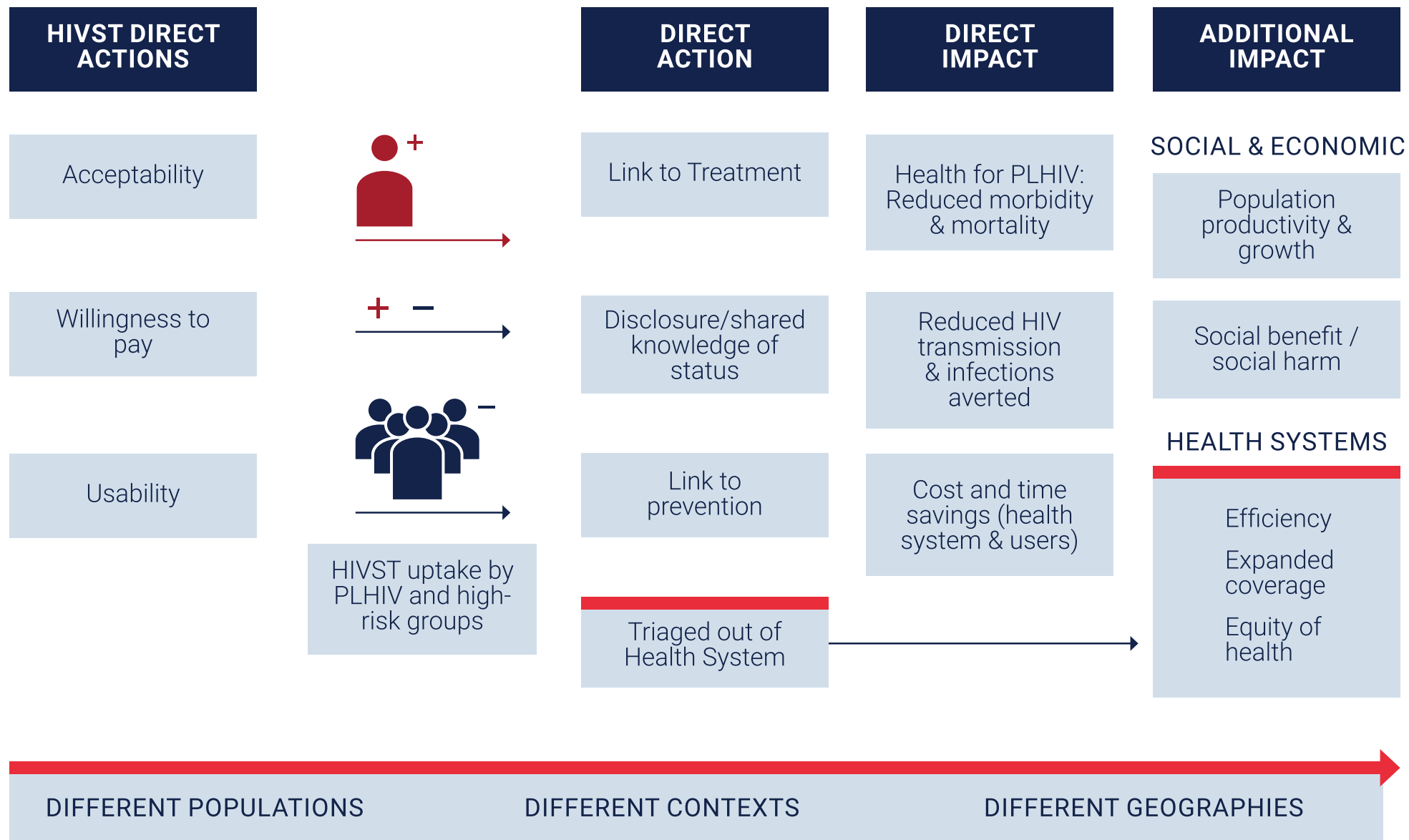
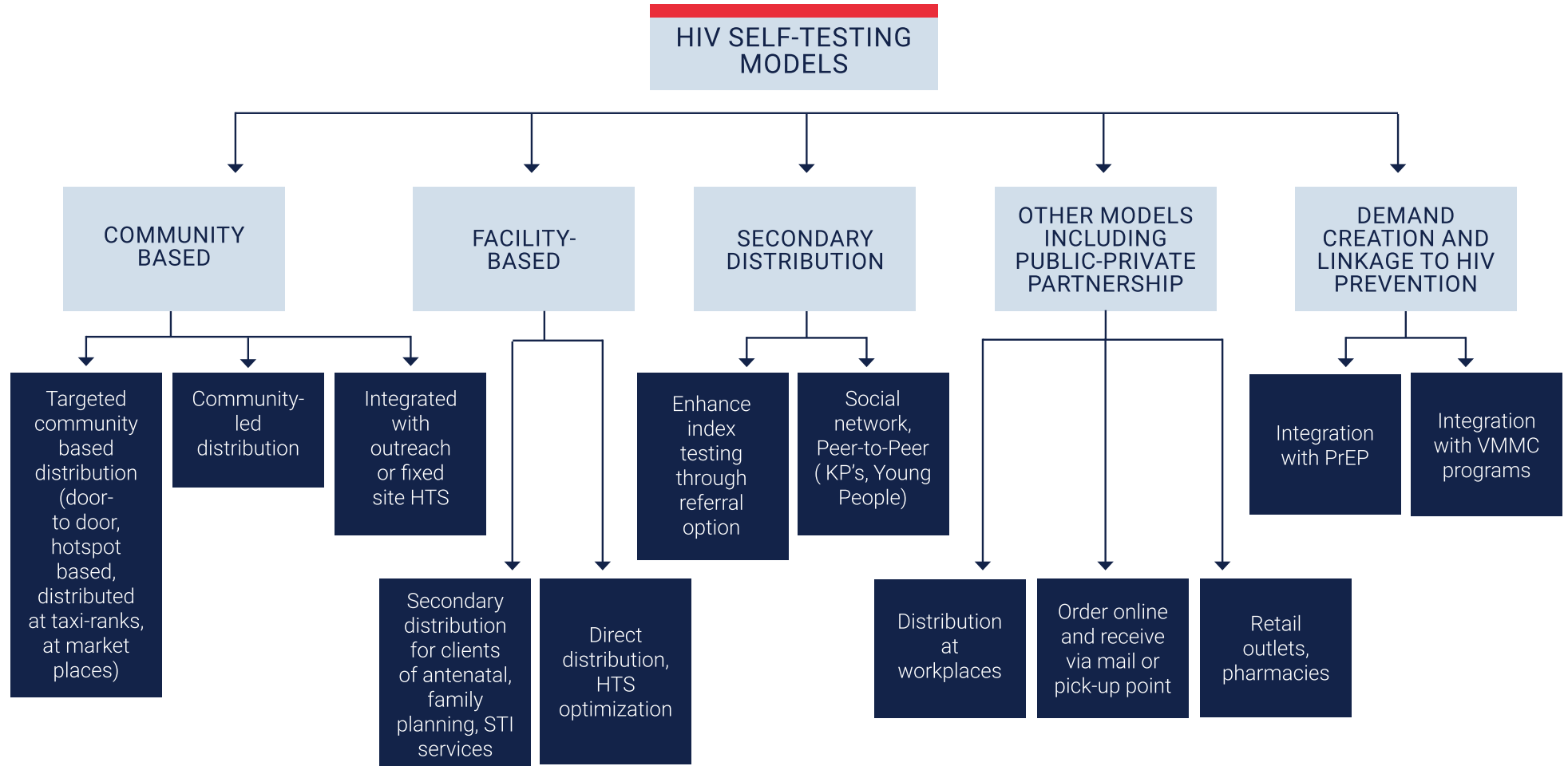


Figure 2. HIVST distribution models

1. INTRODUCTION

1.1. HIVST BACKGROUND

Over the past decade, great progress has been made in expanding HIV testing services. Between 2010 and 2014, more than 600 million people in low- and middle-income countries received HIV testing services, and by 2018 it was estimated that 79 % of people with HIV were aware of their status.¹

Yet, despite these achievements, 8.1 million people with HIV (PLHIV) remain unaware of their HIV positive status in 2019, particularly men and young people aged 15 to 24 years and key populations that are reluctant or unable to access existing services.² If the global 95–95–95³ targets are to be met then outreach to these key groups must be intensified and accompanied by innovations in methods for testing.⁴

HIV Self-Testing (HIVST) is a process whereby 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 themselves. This testing method has been endorsed by the World Health Organization (WHO) as an important complement to other testing strategies because it offers a discreet, convenient alternative for individuals who may otherwise not test.⁵

HIVST is highly acceptable,^{6, 7, 8, 9, 10} safe, and can be highly accurate.^{11, 12, 13} Adding HIVST to clinic-based HTS can increase coverage and frequency of HIV testing, including those less well served by established HTS approaches, such as rural populations, men, young people, and key populations.^{14, 15, 16} Current projections suggest that 15% of all 360 million HIV tests used each year, globally, will be self-tests by 2020, with highest percentages of 35%, 29%, 24%,

22% and 10% in Kenya, Malawi, Zambia, Zimbabwe and South Africa respectively.¹⁷

WHO conducted a systematic review to update the guidance on HIVST in December 2019 with the following key outcomes:

- Thirty-two randomized controlled trials (RCTs) showed that HIVST increases the uptake of HIV testing as compared to standard facility-based HIV testing
- Proportions of people diagnosed and linked to care with HIVST are comparable to those with facility-based testing.
- Misuse of HIVST and social harms associated with HIVST are rare. No suicides were reported. HIVST does not increase sexual risk behavior among men who have sex with men.
- A range of HIVST service delivery models and support tools are found to be effective.
- Many people are willing and able to perform HIVST with minimal support.
- HIVST is acceptable and feasible in a range of populations and settings.
- HIVST should complement other testing approaches in a number of ways, or in some situations replace other forms of testing altogether.¹⁸

The HIVST Impact framework on the following page demonstrates how HIVST can improve impact and health outcomes of HIV programming.

Specifically, HIVST can:

- Improve access and reach to people with high HIV risk and vulnerability who have not tested and link them to care and treatment services. HIVST has been found to increase testing uptake and frequency and to be acceptable to many of those currently unreached by existing testing services (key populations, men and young people).
- **Create demand for HIV prevention and improve linkages into HIV prevention** (voluntary medical male circumcision [VMMC], pre-exposure prophylaxis [PrEP], condom use), STI screening and treatment, family planning and sexual and reproductive health services for people who have non-reactive self-test results.
- **Increase efficiencies for those who test HIV-negative (non-reactive).** Those with a negative self-test result and no recent HIV exposure will not immediately need further testing, but HIVST is an opportunity to direct these people to access prevention services (such as condoms, harm reduction, VMMC, PrEP, and the screening and treatment of other sexually transmitted infections). Consequently, unnecessary testing or facility visits can be avoided, saving time and resources on the part of both the clients and the health system.
- Improve testing coverage through the integration of HIVST in clinical services where testing is needed but not routinely provided or where testing is poorly implemented. In these contexts, HIVST can replace components of provider-initiated HIV testing and counseling. For example, offering HIVST at high-volume clinics in high HIV burden

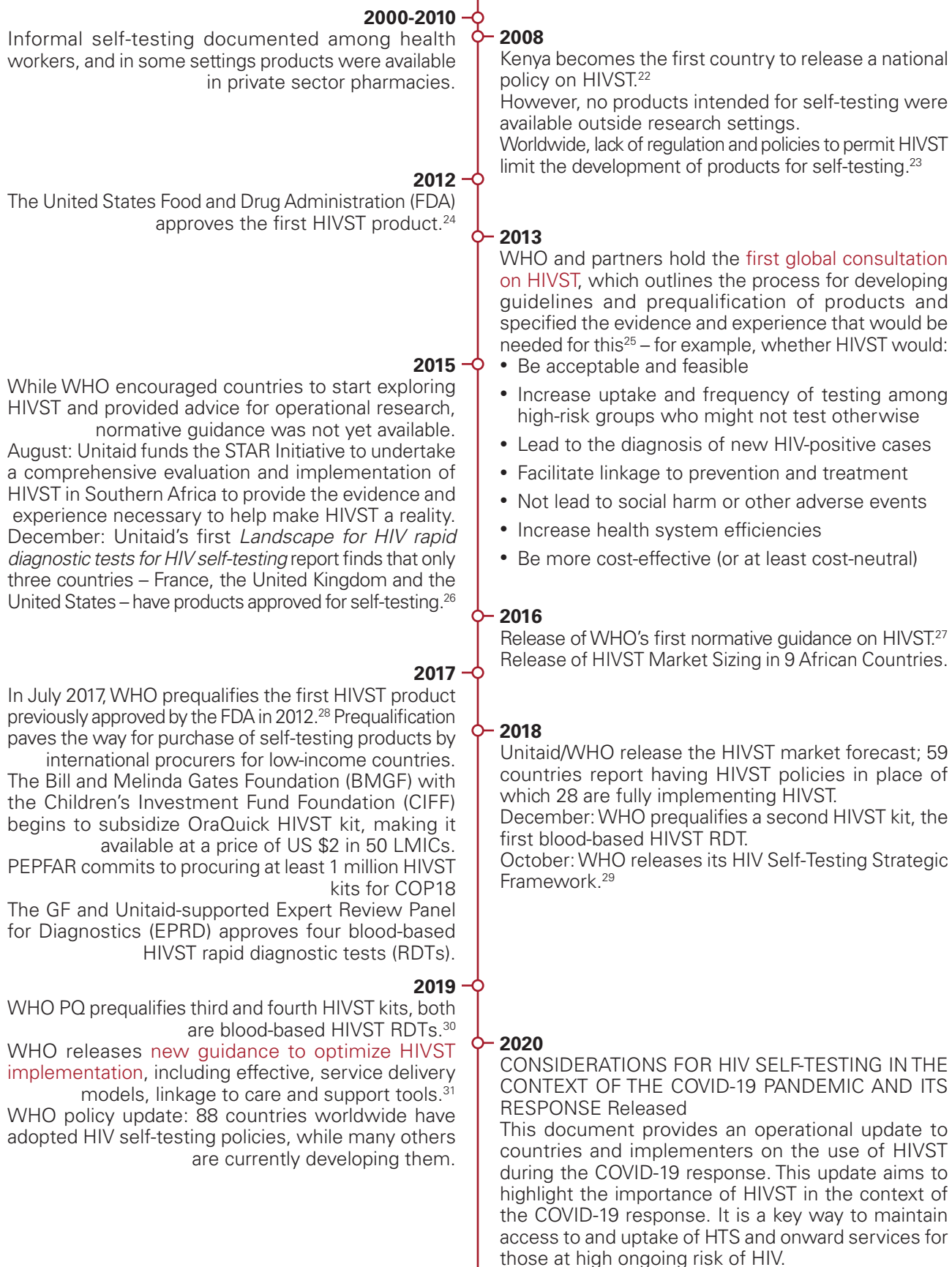
settings and at STI or family planning clinics while clients wait for other clinical services makes beneficial use of their waiting time and ensures they have their test results onsite and, when relevant, can be offered further testing and treatment initiation.

- Facilitate partner testing. HIVST has been shown to facilitate couples and partner testing, which is an effective but often underutilized testing approach. 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 sero-discordant couples (when one partner is HIV-positive and the other is HIV-negative).

These advantages, which are especially beneficial in countries with large testing gaps or hard-to-reach population groups, are driving the current interest in expanding HIVST for countries that need to increase the reach and effectiveness of their HIV programs.

1.2. TIMELINE OF HIVST

Although momentum for implementation has built up only recently, HIVST as a testing method is not new. The idea has been discussed since early in the epidemic as a discreet and convenient option for those seeking to know their status. This table summarizes some of the major chronological milestones that led to its introduction as an innovative component of effective testing campaigns.



1.3. HIVST PRODUCTS

As of December 2020, there are four WHO prequalified (PQ) HIVST products: the INSTI HIV Self-Test (Bioanalytical, Canada); the Mylan HIV Self-Test (Mylan, Atomo Diagnostics, Australia); and the OraQuick HIV Self-Test (OraSure Technologies, USA) and the SURE CHECK HIV 1/2 Assay (Chembio, USA), and several others may be expected to come to market.¹⁹

An additional six HIV self-tests have been approved by a stringent regulatory authority in one of the founding member countries of the International Medical Device Regulators Forum (IMDRF) or recommended for procurement by the Unitaid/GF EPRD.²⁰

Additional locally manufactured HIVST kits with national-level approval have emerged in some countries (six products identified), including Belarus, Brazil and Nigeria. The quality and performance of these products are largely unknown. There are other HIV self-tests under development, using either whole blood specimens, oral fluid specimens or urine specimens.

Despite this encouraging progress toward international approvals, manufacturers remain concerned that in some countries the regulatory process remains opaque, with a lack of clarity about which authorities are responsible for the registration of HIVST products and lengthy in-country validation and registration processes for products even after they have achieved WHO PQ status.

Table 1 lists those that have either been prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of the Unitaid/Global Fund EPRD.

1.4. HIVST POLICY ENVIRONMENT

Following the release of WHO's first HIVST normative guidance in 2016 and dissemination of HIVST evidence through the STAR initiative globally, many countries have begun to develop and introduce HIVST policies. As of December 2020 eighty eight countries worldwide are actively implementing HIVST. Many more are still developing the necessary strategic plans, regulations, implementation guidance and standard operating procedures needed for scale-up of HIVST and have not reached the stage of large-scale implementation.²¹ This guide is intended to be a resource for those considering HIVST introduction to help reduce or eliminate barriers to progress. It is hoped that by documenting lessons learnt from experience so far, and by collecting together all the core HIVST program-related tools and guides in one place, that we will support the expansion of HIVST implementation.

1.5. HIVST PEPFAR COP GUIDANCE

PEPFAR started to integrate HIVST into their future financing plans for countries, including by incorporating HIVST into its Country Operational Plans (COP) since 2017. The COP guidance recommends the use of HIVST strategies to complement and enhance conventional HIV testing.

Importantly, HIVST should be part of the HTS portfolio especially in high-burden settings and should be strategically deployed to screen adolescent girls and young women (AGYW) and their partners, male partners of ANC clients, KPs and their partners, and other priority populations (e.g., refugees, prisoners, young at-risk men) that face high levels of stigma and discrimination.

Where feasible, messages and materials should be tailored to the barriers and drivers of particular groups and it is vital to

Table 1. HIVST products with WHO PQ, EPRD or approval from founding member of IMDRF*

TEST (MANUFACTURER)	SPECIMEN	APPROVAL	PEPFAR UNIT PRICE EX WORKS
Mylan HIV Self Test (Atomo Diagnostics, Australia)	Blood	WHO PQ	\$1.99
autotest VIH^{®**} (AAZ Labs, France)	Blood	CE mark	
BioSURE HIV Self Test^{**} (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD-3	
Exacto[®] Test HIV (Biosynex, France)	Blood	CE mark	
INSTI[®] HIV Self Test^{**} (bioLytical Lab., Canada)	Blood	WHO PQ	\$3.09
OraQuick[®] In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA CE Mark	
OraQuick[®] HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ	\$2.00
SURE CHECK[®] HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	WHO PQ	\$2.99

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

* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaidd/GF Expert Review Panel for Diagnostics.

** These products sold in more than one packaging format.

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

Source: Unitaidd/WHO, 2019.

engage community groups to advocate for, design, implement, and analyze the success of HIVST. Programs should anticipate the internal and external barriers and challenges that clients may face in deciding whether to link to care and aim to address those barriers. Based on positive outcomes (e.g., linkage and initiation on ART), HIVST should be taken to scale, especially in high yield geographic locations to increase testing of young men. Index clients should also be offered self-testing kits for partners if they do not volunteer to bring them in for index client testing. It is important that individuals who receive the HIVST on from a peer or

sexual partner understand how the HIVST is used and feel comfortable demonstrating this to their partners. IPs may develop and explore emerging linkage support tools (e.g., digital or community-based) for unassisted self-testing.

Within the context of COVID-19, distribution of self-testing kits may help reach individuals who otherwise would be reluctant go to a facility. Additionally, self-testing kit distribution in facilities may help decongest facilities and reduce client-provider interactions. Where feasible and effective, programs should consider distributing HIV self-testing kits

to index clients so that partners can screen themselves prior to coming to the facility. This may help ensure that only partners who are most likely to have HIV will come to the facility for confirmatory HIV testing per the national testing algorithm. National policies may limit the feasibility of partner notification through index testing in light of the COVID-19 pandemic and, as such, programs should take this into account. Countries may consider accelerating their plans for scaling HIVST kit distribution for those with increased risk of HIV infection which may include extending COVID-19 adaptations such as providing oral testing kits to index clients screen biological children >2 years of age for HIV. Programs may need to develop alternate workflows to ensure that patients can receive confirmatory testing per the national testing algorithm.

There is some evidence that HIVST as a screening tool is highly sensitive, has lower HRH requirements, can increase testing uptake, and can catch clients missed by PITC or risk-based screening, and decrease perception of coercion.

Importantly, self-testing implementation should be strategic and based on epidemiologic environment. Programs may consider accelerating plans for scaling HIV self-testing kit distribution in the following settings, if appropriate based on their epidemiological context:

- Reaching priority populations within the community or facilities
- Providing an HIVST to an index client for their partner
- Providing parents (index clients) with HIVST to screen biological children >2 years of age
- Scale of HIVST for KP and clients of FSW
- Providing HIVST for high-risk PBFW

1.5.1. MONITORING HIVST

PEPFAR's MER includes an HTS_SELF indicator that measures distribution of HIVST kits and, where possible, measures intended use of HIVST. Disaggregates of HTS_SELF include age/sex of recipient, point of distribution, intended use (primary or secondary distribution). HTS registers can be adapted to include reason for visit, including at HTS sites, in both community and facility settings, as well as at treatment sites. Reason for visit can include having a reactive

HIV self-test and needing confirmatory testing. This is a proxy measure to assess whether individuals with a reactive HIV self-test have actually linked to HTS for confirmatory testing. HIVST indicators or metrics that indicate downstream clinical impacts (e.g., numbers and proportions linked to confirmatory testing, both in PEPFAR and non-PEPFAR-supported sites, and to ART initiation) should be developed by OU teams. Methodologies to track outcomes of HIVST may include activities such as survey questions on HIVST use at treatment and testing intake, follow-up surveys or tracking among a sample of HIVST kit recipients (this can be done via phone, SMS, or direct in-person follow-up), return of kits to provider to estimate positivity on the same day, or drawing inferences from target HIVST population and increase in uptake of testing and treatment within that population. In addition, programs should attempt to track adverse events associated with HIVST, including instances of self-harm or intimate partner violence, and including events related to secondary distribution where possible.

See section 5 on Monitoring and Evaluation of HIVST.

2. HIVST OPERATIONAL GUIDE

2.1. PURPOSE AND OVERVIEW

This guide and associated tools are intended as a practical manual for program teams to guide them in planning, implementation monitoring and reporting of HIVST. It is based on the evidence and experience gathered by the HIV Self-Test Africa (STAR) Initiative, supported by Unitaid and USAID-funded HIVST pilot implementation, and is intended to provide detailed practical guidance for implementers to complement the [WHO Guidelines on HIV self-testing and partner notification](#),²⁴ the [WHO HIV Self-Testing Strategic Framework](#)²⁶ and PEPFAR COP guidance.

The guide will help program teams and implementers to establish programs that are well-designed, sustainable, effective and with measurable impact. The information contained in this guide is derived from extensive field experience. It draws together the techniques, tools, planning and management approaches that have proved successful during HIVST roll out and provides a systematic “how to” guide for program managers that want to introduce HIVST to new markets. The practical part of the guide is divided into three parts.

Part 1: HIVST service delivery planning and implementation

Part 2: HIVST demand creation and communication

Part 3: HIVST monitoring and evaluation and reporting

This guide covers the core components that all HIVST programs should include in order to establish sustainable effective interventions. When planning and implementing HIVST programs many of the steps detailed in this guide may occur concurrently or in a different order. We recommend taking a flexible

approach, accepting that no implementation is ever perfect, and adapting the framework as you go to suit specific contexts and epidemic profiles.

2.2. GUIDING PRINCIPLES FOR HIVST IMPLEMENTATION

2.2.1. OBJECTIVES

The major objectives and considerations for HIVST are generally the same as for any HIV testing program:

- Improving health outcomes (including testing coverage and linkage to counseling, confirmative HIV testing, treatment and prevention)
- Achieving national program targets (e.g., 95-95-95)
- Influencing national policy and regulations
- Prioritizing key population segments
- Optimizing the testing process
- Achieving cost-effectiveness (or cost neutrality) and greater efficiencies for the health systems and users
- Establishing quality assurance standards and systems
- Minimizing unintended consequences/ social harms

Since the purpose of HIVST is to complement and amplify existing testing approaches, program design teams should take into account the status of current testing programs, the demographics of key populations and groups least likely to be reached by other testing methods, and facilitating linkage to HIV prevention services for those who are non-reactive on self-tests.

There are several important lessons learnt from HIVST implementation experience of planning, rolling out and scaling up HIVST which are likely to be useful for other teams intending to introduce HIVST to their programs. The following practical, ethical and cost considerations highlight some key points to think about as program teams begin the planning process.

2.2.2. PRACTICAL CONSIDERATIONS

It is important to start the planning process from an informed perspective, both in terms of the country in which the program will be implemented and the lessons learnt from other countries. The core practical considerations for establishing a new HIVST program include understanding the regulatory framework (or lack of one) with respect to medical devices, understanding the processes and impediments for getting the selected products into the country, and confidence that it will be possible to provide a safe, effective and reliable delivery system.

For any country where HIVST has not previously been available, it may be necessary to undertake program evaluations to study the prospective acceptability of the testing approach, preferences of potential clients, language and cultural issues that could affect the success of the program, and studies to ascertain whether an HIVST program could achieve the intended health goals.

Much work has been done to answer some core programmatic implementation questions and understand the factors that determine its overall impact. For example, modelling and investment scenarios developed as part of STAR demonstrated that the impact and cost-effectiveness of HIVST is sensitive to the prevalence of undiagnosed HIV in the sub-population and the overall costs of service delivery.

Studies of data from Malawi, Zambia and Zimbabwe showed that the greatest epidemiological impact can be achieved with the most cost-effective use of scarce resources when HIVST focuses on adult men and when targeted at women having transactional sex.

Providers of HIVST testing should put in place quality assurance (QA) mechanisms to ensure that individuals who self-test get a correct diagnosis. Those who self-test HIV positive (reactive) must undergo confirmatory testing using approved algorithm.

Distributors of HIVST should ensure that users are provided with information and tools to support effective linkage and referrals to confirmatory testing, treatment and prevention. Recommended models for linkages can be found in the "Implementation" section of this guide.

Other key findings from experience to date with HIVST led to the recommendations that in all programs:

- Those who receive a reactive (potentially positive) result should be referred to confirmatory testing and, if confirmed, linkage to ART; and,
- Those who test negative (non-reactive) should still receive referrals and linkage to HIV prevention, as well as other health information on tuberculosis, other sexually transmitted diseases (STIs) and hepatitis. This can be done using user guides, frequently asked questions brochures and materials delivered in addition to the HIVST kits (and IFU included in the HIVST kits).

When distributing HIVST kits, users should be provided with appropriate and high-quality pre-test information and demonstrations. Key messaging should include:

- How to collect the specimen and how to conduct the test
- How to interpret the result of the HIVST (reactive, non-reactive, or invalid)
- Where to get confirmatory testing if the result is reactive
- How to link to prevention, treatment and other HIV-related services

In the STAR HIVST pilot studies it was found that most errors arose from users' inability to comprehend the IFU and correctly interpret results. While these issues were discovered during studies of oral fluid HIVST kits, it is likely that they would also occur during sample collection and transfer for blood based HIVST kits.

Some important caveats should be borne in mind before HIVST programs are scaled up:

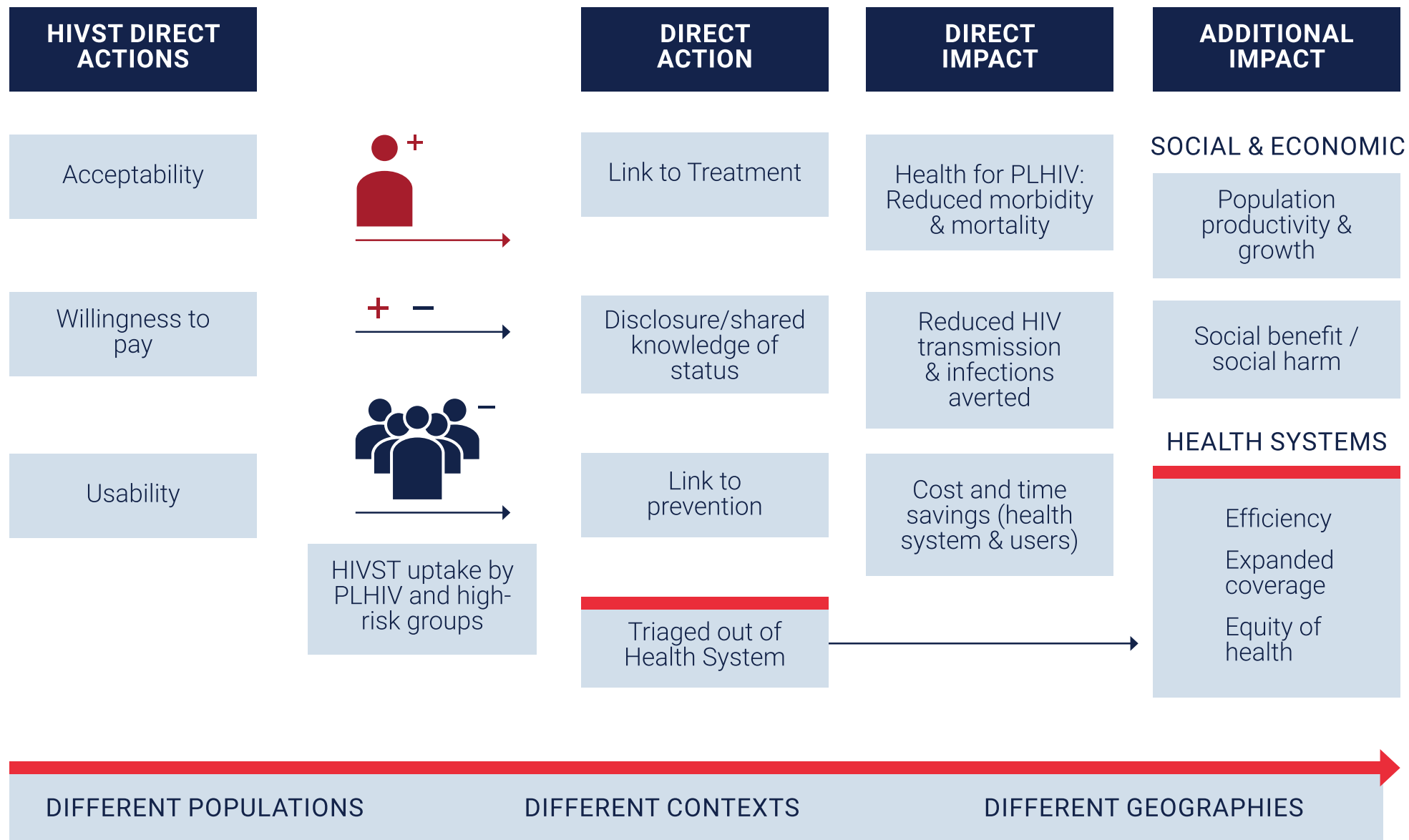
- 1. HIVST is not for people living with HIV and receiving ART.** Self-testing, as well as retesting in general, should be discouraged in this population as false negative self-test results may occur. Specific messages promoting HIVST kit use should emphasize on this (see below HIVST demand creation and communications).
- 2. Retesting following a negative self-test result is only necessary for those at ongoing risk,** such as people from key populations and those reporting potential HIV exposure in the preceding 12 weeks.
- 3. HIVST cannot replace facility-based visits for people starting PrEP.** A negative (non-reactive) self-test result, unless followed by a negative test at a facility, is not sufficient to start PrEP. Once taking PrEP, self-testing, particularly with kits using oral fluid specimens, might not be able to reliably detect an HIV infection.³² Recent

recommendations from WHO, especially in the context of COVID-19, suggest: While lab-only visits for assessment of HIV infection and other indicated tests for the provision of PrEP are preferred, when these are not available or feasible, WHO recommends considering two additional options: home specimen collection kits, which are sensitive enough to detect recent HIV infection; or self-testing via quality assured oral or blood-based HIVST kits. Although HIV self-tests are usually not recommended for PrEP patients due to their lower sensitivity in detecting recent HIV infection during PrEP use, clinicians could consider use of these tests when other options are not available. In addition, HIVST can be valuable tool for creating demand for PrEP and reaching high risk populations, including the partners and social network of people on PrEP (see distribution models and HIVST impact framework in Figure 1).

2.2.3. CONSIDERATIONS FOR COSTS

Overall evidence has shown that HIV self-testing can be cost-effective when targeted toward populations where fewer people with HIV know their status and for whom treatment coverage is low. The costs of HIVST however have generally appeared to be higher than costs of facility-based conventional provider delivered testing, and the cost of community- or home-based HIVST distribution tended to be higher than that of facility-based HIVST distribution. The incremental unit costs of community-based HIVST distribution in Zimbabwe and Zambia for example were estimated to be two and three times higher than facility based HIVST incremental costs, respectively (\$14.69 vs \$6.10 in Zimbabwe and \$17.00 vs \$5.37 in Zambia) with major cost drivers being personnel and commodity costs.

Figure 1. How HIVST can turn investments into broad health and social impacts (source: WHO, 2019)





However, there are important limitations to such comparisons, given that cost data come from different sources and settings, therefore, are not directly comparable. Especially as these costs are general program costs and do not consider opportunity costs to testers or accessibility and equity issues. HIV testing costs can vary substantially, and it is important to consider the most efficient and effective ways to distribute self-test kits and achieve impact. In addition, cost of diagnosing additional infections through standard testing services can be substantial, especially in settings with generally high testing and treatment coverage.

2.2.4. ETHICAL CONSIDERATIONS

Providing individuals with the means to determine their own HIV status without

clinical supervision raises a number of ethical issues. HIV testing has, until recently, been confined to facility-based and community-based programs where testers have direct access to counselors and follow-up services as necessary. In a self-testing scenario, clients should be well informed about what the results of the test mean for them and should only undertake testing voluntarily, without any form of coercion. Verbal consent for HIVST is sufficient, however, so no paper record of consent is required to be maintained by distribution outlets.

As with all HIV testing, HIVST must be confidential. If an individual asks for support in conducting a self-test, it is important to obtain the individual's consent for the person assisting to read the test results. A person's HIV status can only be disclosed to others if

the client specifically consents. HIV status can be disclosed to other health workers if relevant to the clinical management of a client's disease, but otherwise kept confidential.

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 program managers are aware of the legal restrictions on consent and HIV testing from the start of the planning process.

In addition to efforts to monitor the overall success of the program, ethical considerations require that specific data is collected throughout the program's implementation to ensure that any potential for social harm is identified at an early stage and can be addressed. At a minimum, programs should include a gender analysis, gender-specific monitoring and evaluation indicators, collection of sex and age disaggregated data, and a portion of program budgets allocated to conduct these activities. Collecting this data will help to ensure that harmful cultural or social norms are not perpetuated through HIVST programs, and that program managers understand and address systemic and structural biases that lead to inequalities. It is vital that those who have been marginalized are able to engage with HIVST programs, otherwise the program will not succeed in being effective.

Gender analyses will also inform program designers of any relevant risk for gender-based violence to program beneficiaries, as well as the potential risk for exacerbating these risks for beneficiaries by program activities, enabling appropriate risk mitigation and planning.

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. In addition to the post-market surveillance approaches, 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.

2.3. IDENTIFYING POPULATIONS, PRODUCTS AND HIVST DISTRIBUTION MODELS

2.3.1. HIVST PRIORITY POPULATIONS

As stated before, HIVST is not intended as a replacement for conventional HIV testing, efforts should focus on populations who cannot access other forms of HIV testing. During an initial situational analysis before starting on program design, the populations missed by current testing programs should be identified, or segments of the population where HIV risk is particularly high and testing needs to be done frequently. This information should be used to define the target populations for HIVST and delineate groups according to how one intend to reach them with services.

WHO and PEPFAR identify a number of populations as generally high priority for HIVST:

- Adult men in high HIV-burden settings
- Adolescents and young people (aged 15–24 years) in high HIV-burden settings
- Couples and partners, including partners of people living with HIV (PLHIV)
- Individuals with STIs
- Individuals attending family planning services

- Pregnant and postpartum women in high HIV burden settings
- Men who have sex with men and their sexual partners
- Transgender women and men and their sexual partners
- People who inject drugs and their sexual partners
- Sex workers and their sexual partners
- PLHIV who are lost to follow up (LTFU) to facilitate re-entering treatment and care.

These populations will be covered in greater detail in the implementation section of this operational guide. Additionally, there may be country-specific populations at high risk, targeted by the national government and the donors or that you identify in your research and situational analysis who could also

benefit from HIVST. Prior to starting HIVST implementation, it is recommended that programs 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 (refer to the [WHO Consolidated Guidelines for Strategic Information in the Health Sector](#)³³ for specific information on these assessments.

Properly understanding your target populations is critical for making decisions about selecting an appropriate combination of HIVST products and distribution models for your program that meets their needs, is adapted to population preferences and meets any legal or regulatory requirements for the country.



2.3.2. HIVST PRODUCTS

Selection of which HIVST products to use must first take account of the regulatory situation in the country, whether there are already regulations governing the use of medical devices or, if not, which substitute regulatory body's decisions will be used instead. Your situational analysis and additional operational research should also have generated data on the preferences of your target populations for various different types of test kits and culture-specific issues, which will influence product choices.

Regardless of the final decision, all HIVST products should have been assessed and approved by a recognized national authority and/or an international body such as WHO, 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, including adequate sensitivity (proportion of people with the disease correctly identified as reactive by the test) and specificity (proportion of people without the disease correctly identified as non-reactive) of above 95%. HIVST products should be highly sensitive and specific, so that the results are accurate, be simple to use; include all necessary consumables; provide results that are easy to read/interpret within a short period of time and contain clear pictorial instructions and support tools (including information on what to do and where to go after self-testing).

HIVST kits should be easy to use. Sample preparation should be simple and only a small number of operator steps, especially timed steps, should be required to perform the test. Each step for HIV testing, from the

specimen collection to interpreting the final result, is critical for ensuring a correct result. The more steps, the greater the risk is for user error, which may in turn increase the risk of an incorrect test result. Collecting and transferring specimen has been shown to be particularly prone to error for self-testers, resulting in test system failures, invalid results and suboptimal performance. Thus, an HIV RDT for self-testing with few steps, or ideally one single step, could substantially reduce the risk of a number of user errors.

An ideal RDT for self-testing should provide a result in one to twenty minutes and have a read-window where results are stable for more than 60 minutes, after which they give an invalid result. Result windows should be clear and easy to read to facilitate correct interpretation of results.

You should avoid products that have poor stability (i.e., that cannot sustain suboptimal storage), are not robust (e.g., cannot sustain common user errors). It is particularly important that the end-reading point is stable, meaning that the results can be accurately read for a significant time after the test is first done and results are visible. You should prioritize products that offer support tools such as instructional videos, hotlines, websites and referral information to help clients.

Furthermore, it is important to identify not only first choice products but also alternative products and suppliers to avoid service interruptions due to product or supply issues. There could also be cases where you might want to introduce multiple products to accommodate a variety of user preferences and increase choice as a strategy for promoting uptake among different users and priority populations (e.g., some users may prefer oral self-tests and others may prefer blood-based self-tests). You might also want to offer multiple

options early on as a way of testing the market and planning for future procurement.

Note that previous guidance and recommendations on monitoring of sero-conversions in people who are taking PrEP with HIV self-testing has changed in the context of the COVID-19 pandemic and the availability of WHO requalified blood-based HIVST kits. HIVST can now be used for self-monitoring of sero-conversions with PrEP users.

2.3.3. HIVST DELIVERY MODELS

Once target populations and products have been identified and selected, it is important to identify the most appropriate model of delivery of HIVST kits based on the population you are trying to reach and the health impact you are trying to achieve (see Figure 2). Considerable research on different types

of delivery models has been conducted, which models are suited to which priority populations, how to mobilize clients with each approach, and the best mechanisms for linking clients to HIV prevention or treatment services after they receive their results. Detailed descriptions of how to operationalize these models are described below in the implementation section of the guide; however, the following figure and table summarize the key features of the currently used HIVST distribution models and their appropriateness for different contexts, health and program impact and priority populations. The models described are based on the HIVST impact framework (Figure 1). This summary should serve as a guide for narrowing down the options at the planning stage.



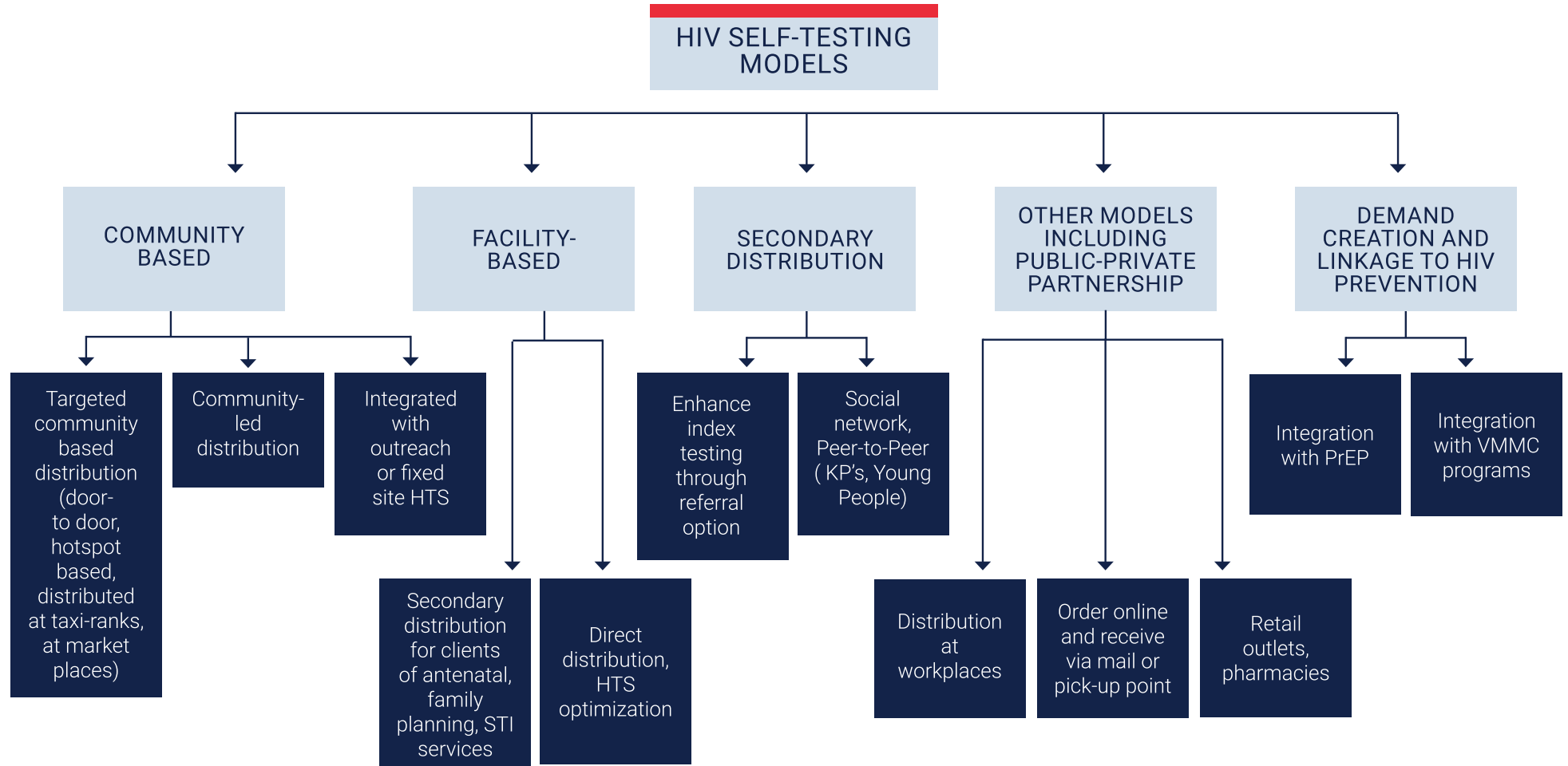
Figure 2. HIVST distribution models

Table 2. Summary of HIVST distribution models and their key features

COMMUNITY-BASED DISTRIBUTION	
TARGETED COMMUNITY-BASED DISTRIBUTION	
Model Description	<ul style="list-style-type: none"> • HIVST kits offered at community level through targeted distribution, either at household level, at transport hubs, marketplaces, at hotspots, bars, nightclubs and in areas where priority populations can be found. • HIVST distribution campaigns. • Community-led HIVST distribution, where communities are themselves responsible for the distribution of HIVST to beneficiaries in their community have demonstrated to be highly effective in increasing testing coverage, yield and linkage to care and treatment, ART coverage. • Targeted HIVST distribution to index cases (sexual partners of index clients) at community level by community health care workers or peer-navigators, expert clients and other cadres of lay providers as pre-screening test, index cases with reactive result are followed up with confirmative testing by health providers or are referred to health facility for confirmative testing.
Rationale	<ul style="list-style-type: none"> • Increases testing coverage, linkage to care and treatment, ART coverage, uptake of prevention services among populations who would otherwise not seek or have access to testing services, including in rural areas and among populations at high risk of HIV infection. • Index case pre-screening with HIVST can increase uptake of HIV testing (higher acceptance, more convenient), only those with reactive test results require confirmative testing by provider, increases testing coverage among index cases, reduces workload in tracking index cases, reduces resources required for index case tracking.
Priority Populations	<ul style="list-style-type: none"> • Underserved high-risk rural populations, especially high-risk adult men and young people unable to access conventional testing services. • Key populations such as sex workers, MSM, transgender people and people who inject drugs, etc. who can be reached through HIVST distribution at hotspots. • Sexual partners of PLHIV (index clients) from all target groups.
Mobilization Strategy	<ul style="list-style-type: none"> • Mobilization through community sensitization by community-based distributors, peer-educators, health promotion officers, community leadership and other cadres.
Linkage Strategy	<ul style="list-style-type: none"> • Referral notes, linking self-testers to prevention and treatment services, provided at delivery of the test kit together with information on where and how to link. • Voluntary, active follow up option with via telephone, SMS and WhatsApp. • Referral registers at health facilities in the catchment areas of HIVST distribution collect data on self-referral of HIV self-testers.

HIVST INTEGRATED WITH MOBILE SERVICES OR HIVST FIXED SITES	
Model Description	<ul style="list-style-type: none"> • Distribution at urban and rural community hotspots, where HTS outreach or fixed site testing services are provided. Individuals can choose HIVST or provider delivered testing (opt-in). • Confirmatory HIV testing, and in some cases, ART initiation is provided on site (for individuals with reactive HIVST). • Individuals from priority population can test themselves in a cubicle/tent at the distribution point or HTS clinic (with assistance available) or take the test kit home for self-testing at home. • Individuals (irrespective of status) can receive HIVST kits for their partners (restriction to number of HIVST distributed to individuals), unassisted HIVST/secondary distribution. • HIVST kits offered to those who test positive (index case) to take home to their sexual partner(s). Follow-up with index or partner for confirmatory testing; unassisted HIVST/secondary distribution.
Rationale	<ul style="list-style-type: none"> • Fast-track pre-screening, triaging out those who self-test HIV negative, who do not require health care provider counseling and testing. • Providers can shift attention to index testing and assisted partner notification and follow up with sexual partners, confirmatory testing, initiation of ART. • Increase in demand for HTS if mobile or fixed HTS clinic services are promoted as outlets for HIVST kits. • More capacity for index testing and assisted partner notification, increases potential for case finding through high yield testing strategies. • Reduces workload of providers at health facilities and potentially reduces costs.
Priority Populations	<ul style="list-style-type: none"> • High-risk adults, adult men, adolescents, especially adolescent girls and young women • Sexual partners of HIV positive people diagnosed at testing sites (secondary distribution/ unassisted HIVST). • Sexual partners of HIV negative or of unknown status individuals (women) accessing the testing sites (secondary distribution/ unassisted HIVST). • Key populations such as sex workers, MSM, transgender people and people who inject drugs (PWID), etc. who can be reached through HIVST distribution at hotspots, where HIVST distribution integrated with HTS is offered.
Mobilization Strategy	<ul style="list-style-type: none"> • Mobilization and demand creation for HIVST at community, hotspot, targeted geographic area, level through different cadres. • Index clients offer HIVST to sexual partners • Pregnant/lactating women offer HIVST to sexual partners • KP offers HIVST to peers, sexual partners or network partners.

Linkage Strategy	<ul style="list-style-type: none"> • Confirmatory testing offered at site; referral to treatment with referral note after confirmed HIV positive status. <p>For directly assisted HIVST, where client decides to take test kit home for self use:</p> <ul style="list-style-type: none"> • Referral notes, linking self-testers to prevention and treatment services, provided at delivery of the test kit together with information on where and how to link. • Voluntary, active follow up option with via telephone, SMS and WhatsApp. • Referral registers at health facilities in the catchment areas of HIVST distribution collect data on self-referral of HIV self-testers. <p>For unassisted, secondary distribution:</p> <ul style="list-style-type: none"> • Referral form included in information materials when HIVST kit is handed to sexual partner. Referral information provided via index client. • Voluntary, active follow-up through index client or recipient of self-test kit or if partner consents, direct follow up with self-test user, follow-up option with via telephone, SMS and WhatsApp.
FACILITY-BASED MODELS	
FACILITY-BASED SECONDARY DISTRIBUTION	
Model Description	<ul style="list-style-type: none"> • HIVST kit offered to HIV positive clients to take to sexual partner(s). Follow-up with index or partner for outcome and if required confirmatory testing. • HIVST kit is offered to all pregnant/lactating women regardless of HIV status to take to male partner. Follow-up with women or partner for outcome and if required confirmatory testing. • HIVST offered to STI patients, TB patients, Family Planning clients to take to sexual partner(s). Follow-up with client or partner for outcome and if required confirmatory testing.
Rationale	<ul style="list-style-type: none"> • Secondary distribution through clients accessing health care facilities (often women) can reach priority populations. • Increased risk of HIV infection during pregnancy and breastfeeding period due to infection acquired by the sexual male partner during this time, important to reach male sexual partner for testing, who might not visit health facility. • Secondary distribution through index client to sexual partners can increase likelihood of uptake of testing services by the partner, high yield testing strategy. Requires follow up with sexual partner or index client for confirmative testing.
Priority Population	<ul style="list-style-type: none"> • Sexual partners of HIV positive index diagnosed at health facility or taking ART (secondary distribution) • Partners of pregnant/lactating women using public sector maternity services (secondary distribution) • Sexual partners of STI, FP and TB patients (secondary distribution).
Mobilization Strategy	<ul style="list-style-type: none"> • Health-care providers actively promote HIVST at health facilities, option of individuals to take test kit for partner home testing • Index clients offer HIVST to sexual partners • Pregnant women offer HIVST to sexual partners

Linkage Strategy	<ul style="list-style-type: none"> • Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via index client • Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via index client.
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FACILITY-BASED DIRECT DISTRIBUTION

Model Description	<ul style="list-style-type: none"> • Facility-based counsellors and health care workers directly promote HIVST at entry points of the health delivery system, for example, outpatients, in-patients, clients accessing family planning services, etc. • Individuals from priority population can test themselves in a cubicle/tent at the health facility. • Individuals present their HIVST test result to the provider at the health facility. • If self-test is negative, referral to prevention services. • Self-testers with reactive result receive confirmatory testing on site, initiation on ART (test and treat).
Rationale	<ul style="list-style-type: none"> • Increases testing capacity and testing coverage at health facility level. • Fast-track pre-screening, triaging out those who self-test HIV negative unless confirmatory testing desired. • Providers can shift attention to those most in need, for example, index testing and assisted partner notification, confirmatory testing, initiation of ART. • Increase in demand for HTS if mobile or fixed HTS clinic services are promoted as outlets for HIVST kits.
Priority Population	<ul style="list-style-type: none"> • Individuals (in priority men, adolescents, KP), who are accessing health care facilities and who are eligible after pre-screening for HIV testing due to their risk pattern and testing history (never tested, tested more than 12 months ago).
Mobilization Strategy	<ul style="list-style-type: none"> • Awareness creation and promotion at health facility, routine offer/ opt-out approach after pre-screening.
Linkage Strategy	<ul style="list-style-type: none"> • On-site confirmatory testing and linkage into on-site treatment services, linkage to VMMC and PrEP services provided on site if HIV negative.

OTHER HIVST DISTRIBUTION MODELS, INCLUDING PUBLIC/PRIVATE PARTNERSHIPS

HIVST OFFERED AT WORKPLACES/THROUGH PHARMACIES/RETAIL OUTLETS

Model Description	<ul style="list-style-type: none"> • HIVST kits are offered to employees at workplaces employing mostly men after buy-in and agreement by employer. Employees can perform HIVST in a private space provided at the workplace where assistance is available or take the HIVST kit home. • HIVST kits are offered to clients accessing pharmacies to buy drugs or condoms, lubricants, etc. Pharmacists would prompt and promote HIVST (especially in combination with family planning products, emergency contraception, condoms, STI treatment) and offer test kit to the client (test kits can be provided for free, or at nominal subsidized price). Pharmacists are trained in HIVST use and can conduct demonstration and are providing also referral information. • HIVST kits are offered at retail outlets in hotspots and areas where the priority populations can be reached. Shop owner promotes HIVST kit use, demonstrates use and provides additional user information together with the HIVST kits.
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Rationale	<ul style="list-style-type: none"> Increases testing in populations that would otherwise not seek testing services. Could potentially, rapidly increases testing coverage. Good opportunity to reach high risk populations and those *MISSING TEXT*
Priority Population	<ul style="list-style-type: none"> High-risk adults, men at workplaces and their sexual partners. High risk AGYW, FP and emergency contraception users. KPs at hotspots, who access pharmacies, retail outlets.
Mobilization Strategy	<ul style="list-style-type: none"> Peer educators and counsellors at workplaces promote HIVST Pharmacists and shop owners promote HIVST General advertisement and community mobilization HIVST Campaigns
Linkage Strategy	<ul style="list-style-type: none"> Referral form included in information materials given when HIVST kit is offered. Potential for direct follow-up.

SECONDARY DISTRIBUTION ICT

Model Description	<ul style="list-style-type: none"> HIVST kit offered to HIV-positive clients to take to sexual partner(s) Index clients are shown how to perform the self-test and receive information materials to give to their sexual partners. Follow-up with index or partner for confirmatory testing and referral/linkage into care and treatment. Follow up can be done at community level via peer navigator, expert client, community health care workers, etc.
Rationale	<ul style="list-style-type: none"> Increases numbers tested and more targeted provider-initiated testing to maximize HIV positive diagnoses, ART initiation and uptake of prevention service. Increases likelihood that sexual partner will test. Increases opportunity for partners of pregnant women to test for HIV and link to care, treatment or prevention.
Priority Population	<ul style="list-style-type: none"> Sexual partners of HIV positive index diagnosed at HTS (secondary distribution) Sexual partners of PLHIV on ART PWID (needle sharing) with HIV positive index client
Mobilization Strategy	<ul style="list-style-type: none"> Index clients offer HIVST to sexual partners/PWID partners.
Linkage Strategy	<ul style="list-style-type: none"> Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via index client Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via index client. Voluntary, active follow up through index client or recipient of self-test kit or if partner consents, direct follow up with self-test user, follow-up option with via telephone, SMS and WhatsApp.

DEMAND CREATION AND LINKAGE TO HIV PREVENTION (VMMC/PrEP)

Model Description	<ul style="list-style-type: none"> HIVST offered to men mobilized for VMMC to use at home before VMMC, VMMC awareness, promotion and referral done in combination with HIVST offer. HIVST is offered to potential beneficiaries of PrEP services, PrEP awareness, promotion and referral done in combination with HIVST offer.
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Rationale	<ul style="list-style-type: none"> • May reduce fear of testing that discourages men from taking up VMMC services. • HIVST can also function also as an entry point to PrEP if targeted at potential beneficiaries of PrEP, e.g. AGYW at increased risk of HIV infection, KPs (FSWs, MSM, Transgender people), heterosexual high-risk men.
Priority Population	<ul style="list-style-type: none"> • Adult uncircumcised men, aged 20 and above. • High risk AGYW, heterosexual men, key populations.
Mobilization Strategy	<ul style="list-style-type: none"> • Mobilizers for VMMC offer HIVST as option to conduct pre-screening before VMMC. • Mobilizers and health promotion officers.
Linkage Strategy	<ul style="list-style-type: none"> • VMMC mobilizers may directly follow up with clients on successful referral for HIVST (telephonic, SMS, WhatsApp follow-up). Mobiliser checks with VMMC referral clinic whether mobilized client has presented for VMMC. • PrEP mobilizers may directly follow up with clients on successful referral for HIVST (telephonic, SMS, WhatsApp follow up). Mobiliser checks with PrEP referral clinic whether mobilized client has presented for VMMC.
HIVST INTEGRATED WITH HTS SERVICES FOR KPS (E.G. FEMALE SEXWORKERS, MSM, PWID)	
Model Description	<ul style="list-style-type: none"> • HIVST offered as alternative to HTS to clients accessing sex worker clinics or health services for men who have sex with men. • HIVST distribution through social networks of female sex workers and their sexual partners (and clients), men who have sex with men or PWID. • Online ordering of HIVST kits and delivery at home or place of convenience for the KPs.
Rationale	<ul style="list-style-type: none"> • Test-for-triage approach. HTS clinic can shift attention to other tasks. Increases numbers tested and more targeted provider-initiated testing to maximize HIV positive diagnoses, ART initiation and uptake of prevention service. • Increases uptake and frequency of testing among key populations. • Note that HIVST distribution to KPs should be targeted at those hard to reach, most at risk and those refusing conventional testing.
Priority Population	<ul style="list-style-type: none"> • Female sex workers and men who have sex with men, PWID.
Mobilization Strategy	<ul style="list-style-type: none"> • Health-care providers actively promote HIVST at health facilities. • Peers of key populations promote HIVST.
Linkage Strategy	<ul style="list-style-type: none"> • Self-testers with reactive result receive confirmatory testing on site, initiation on ART (test and treat). • Referral form included in information materials given with HIVST kit.

3. HIVST PLANNING AND IMPLEMENTATION

3.1. INTRODUCTION

In order to achieve the desired outcomes of increasing the impact of current testing strategies and targeting populations that are not reached with traditional approaches, HIVST implementation must be strategic and focused. With this goal in mind, all decisions should be based on evidence gathered with careful planning completed before implementation begins. In this part, we will cover strategies for planning and implementing differentiated HIVST and discuss key considerations through the following components:

- Tailoring services for priority populations
- Distribution models, SOPs and training
- Follow-up and linkage to counseling, treatment and prevention
- Supply chain planning and execution.

3.2. TAILORED SERVICES FOR PRIORITY POPULATIONS

To achieve maximum impact, it is important that the delivery mechanisms and implementation arrangements used are specifically designed for the population group you intend to reach. HIVST has the potential to increase HIV testing coverage and frequency of testing among groups that are currently unreached. Based on situational and gap analyses, it should be clear which population groups could potentially benefit from HIVST. The list below outlines the priority populations for whom we have evidence that HIVST can improve HIV testing coverage and consequently linkage into care, treatment and prevention. There may be other groups of populations dependent on country context and specific testing and ART gap.

Men: HIV-testing coverage and knowledge of HIV status among men living with HIV is substantially lower than among women worldwide. Differences in knowledge of HIV status stem from near-universal provision of HTS at health facilities which women are more likely to frequent.³⁴ Men have lower rates of healthcare utilization in general, which reduce their opportunities to test for HIV through routine services.³⁵ Furthermore, masculine norms promoting physical strength, economic role as breadwinner, and sexual primacy can lead men to underestimate HIV risk, disregard symptoms of illness or stigmatize use of HIV services.^{36, 37, 38, 39} Studies have shown that HIVST is beneficial in increasing testing among men.

Adolescents and young people (aged 15–24 years): Approximately one-third of new HIV infections in the world occur among young people in Southern Africa. Young KPs are especially vulnerable and affected by HIV. These most-affected groups of young people have remained largely unreached by traditional HTS. For adolescents and young adults, their status as dependents can limit their ability to consent or pay for HIV services or generate fears of social and economic marginalization from families.^{40, 41} Concerns around implicit revelation of sexual debut and stigma and discrimination from health care providers can also limit uptake.⁴² HIVST offered through community or peer support is considered highly acceptable and when offered has reached a large proportion of young people.

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.

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.

Pregnant and postpartum women in high HIV burden settings: Pregnant and postpartum women are at increased risk of HIV infection in high HIV incidence and prevalence settings. Re-testing in pregnant and postpartum women and their sexual partners through the breastfeeding period is recommended and cost-effective, it is not usually consistently or routinely implemented and uptake of partner testing has been very low. Offering HIVST during this heightened period of HIV risk has increased couples and partner testing in studies conducted through STAR and is currently scaled up most countries that have adopted HIVST as part of their testing programs.

KPs (men who have sex with men (MSM); people who inject drugs, sex workers, transgender people and people in prison): HIV testing coverage is disproportionally low among KPs. 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 to prevention and treatment. Acceptability and willingness to use HIVST is generally high among key populations despite some reported concerns about the potential lack of support, possible social harm, the level of accuracy of test results, and the related costs which could hinder access. Overall, the benefits of HIVST most commonly cited by KPs are convenience and privacy, followed by HIVST being an easy and painless testing option.

Other high-risk groups, including STI patients, women presenting for family planning services: Some groups at high ongoing risk of HIV are missed by existing HIV testing services. These include clients presenting for STI screening and treatment and women, especially young women, presenting for family planning and SRH services, including emergency contraception. Often these populations do not get offered HIV testing and HIVST presents an excellent opportunity to those populations to test for HIV and to receive HIVST kits for their partners to test as well. Integrating HIVST at health care facilities out-patients departments, at STI and FP clinics provide good entry points.

3.3. DELIVERY MODELS AND TRAINING

3.3.1. OVERVIEW

At the most general level, HIVST distribution is either direct (primary) or indirect (secondary) and HIVST distribution can be assisted and unassisted.

Primary distribution: This approach employs trained providers, either health professionals (e.g. healthcare workers, pharmacists, counselors) or lay providers (e.g. community-based distribution agents, peer-educators, community health care workers, expert clients, peer navigator, etc.) Even though they are professionals, healthcare workers and pharmacists still require additional orientation, training and information about HIVST to be able to provide adequate support and facilitate linkage to further testing, prevention and treatment.

Meanwhile, studies have shown that, with proper training, non-professionals such as CBDAs and peer educators can be highly effective in mobilization efforts and the distribution of HIVST kits as well as in facilitating

linkages to health facilities and community outreach with all priority populations.

Secondary distribution: This refers to distribution among partners (including sexual and drug injecting partners) and via social networks by individual (either HIV positive or negative), who present at health care facilities or HIVST distribution points at community level and workplaces, pharmacies, etc. This approach can increase testing uptake among people who would otherwise not test and are at high risk of HIV infection (e.g. sexual or drug injecting partners of HIV positive index clients) and potentially help facilitate linkages to care and treatment. However, for this approach to be effective, it is important that the initial HIVST kit distribution include (see also detailed SOP for secondary HIVST distribution):

- Screening for intimate partner violence
- Information on how to self-test
- Information on how to offer and demonstrate a self-test
- Verbiage on the importance of avoiding non-coercive practices
- Information on linkage into confirmative testing, Care and Treatment or HIV prevention
- If indicated: consent for provider follow up with the self-tester directly

Assisted HIVST refers to when individuals who are self-testing for HIV receive an in-person demonstration from a trained provider or peer before or during HIVST, with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside HIVST kits.

Unassisted HIVST: Refers to when individuals self-test for HIV using only a self-test kit that includes manufacturer-provided instructions

for use. As with all self-testing, users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos. A typical example for unassisted HIVST is when a client purchases an HIVST kit at the pharmacy without a provider explaining on how to use the test or if an individual receives an HIVST via mail after ordering it over the internet. In this context we are also referring to unassisted HIVST if the HIVST is received by a sexual partner, who has not been specifically trained on how to demonstrate performing the test. Secondary HIVST distribution is therefore always unassisted.

HIVST products and related services can be distributed in a variety of ways, some of which might be better suited for certain contexts and priority populations than others. 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 (for example telephone hotlines or websites) are provided with the kit.

A range of HIVST distribution and linkage models that use a combination of primary and secondary distribution approaches have been developed by the STAR initiative and other USAID funded implementing partners. The models have been piloted and are now scaled up. This experience was used to define five distinct distribution settings targeting different priority populations. These models, and the implementation considerations specific to each, are described detailed below:

- Community-based HIVST distribution
- Facility-based HIVST distribution
- Secondary HIVST distribution
- HIVST distribution at workplaces/retail outlets and pharmacies
- HIVST to increase uptake of HIV prevention interventions

3.3.2. COMMUNITY-BASED HIVST DISTRIBUTION

Community based distribution comprises of two models, targeted community-based distribution and HIVST distribution at community level that is integrated with conventional HTS, either through outreach or fixed HTS sites.

Targeted Community-Based Distribution

In this model HIVST kits are offered at community level through targeted distribution (targeting areas with HIV testing coverage and ART coverage gaps or where priority populations can be found) via home delivery or in social venues such as marketplaces, transport hubs, busy streets, bars and beer halls. This model relies on providers including lay providers, to promote HIVST and offer (free) test kits to users. Self-test kit users can also collect kits from the community-based distributors home or from other more permanent distribution points, if preferred. In addition to providing kits, CBDs and other HIVST distributors can support users throughout the testing process, as necessary.

While CBDs do not need to be medical professionals, they should have a minimum of level of education and reside in the community they will serve. In the STAR initiative, we found participatory approaches to be effective, with community members nominating candidates following community sensitization meetings. For the STAR initiative, CBDs completed a two-day training, including basic facts about HIV transmission and treatment, antibody-based diagnosis, discordancy and the principles of consent and confidentiality, as well as familiarization with the kits and how to demonstrate use to recipients, and data capture tools.

All trainees had to undergo competency testing at the end of the training course

when training skills were assessed. Once they have completed training and successful competency testing, CBDs should be able to: provide clients with brief health information about HIV; information on the test; IFU in local language, optimized for the priority population; and an in-person or video-clip demonstration of how to use the kit, to supplement manufacturer's instructions.

Clients can choose to perform the test alone, or with the help and guidance of the CBD. This is particularly helpful for illiterate and semi-literate participants, who might need the CBD to read the IFU and help them to complete any other paperwork that might be involved in the distribution process (e.g., a user survey, in which case the CBD would explain the questions then let the user complete the checkboxes in private). CBDs can also provide support and guidance post-test, such as answering questions and providing self-referral cards with locally adapted options to facilitate linkage to confirmatory testing, HIV care and prevention services. Establishing a toll-free hotline to answer questions about the testing process, results and referral options is also good practice for a CBD-driven model.

Community-based distribution also includes distribution at hotspots, in taxi ranks, at market places and other through social venues. Dependent on the distribution area and the priority population to be reached, different providers can be used for the promotion and distribution of HIVST kits, including peer-educators and peers of key populations, vendors and other lay-cadres.

HIVST campaigns, when HIVST kits are offered during specific time periods to achieve high saturation, are also considered community-based distribution programs. This campaign-style distribution has been used successfully in Zimbabwe, where HIVST were distributed over a period of 6 weeks at household level in

rural areas with testing coverage gaps. Another example includes the distribution at taxi ranks in urban areas in South Africa, where high HIV testing coverage was achieved, especially among high risk men over a campaign period of 6 to 8 weeks.

Community-led HIVST distribution has been evaluated in two randomized controlled trials in Malawi and Zimbabwe. In this HIVST distribution model, communities are themselves responsible for the distribution of HIVST to beneficiaries in their community without the need for external distributors. These models have demonstrated to be highly effective in increasing testing coverage, yield and linkage to care and treatment, ART coverage and are sustainable with limited external funding.

Community based index case testing is another model of targeted community based HIVST, whereby HIVST kits are offered by community health care providers, peer-navigators, expert clients or other community based outreach workers, who are conducting contact tracing, to sexual partners of HIV positive index clients at community. This model has shown to be effective.

HIVST Integrated with Mobile Services or HIVST Fixed Sites

Integrating HIVST into the service offerings of HTS clinics and mobile outreach operations can expand choice for users and improve efficiency for service provision through increased testing capacity and higher throughput of clients. In the model HIVST is offered in parallel to conventional provider delivered HTS (PDHTS) either as opt-out or opt-in approach. HIVST is offered to clients of HTS clinics and mobile outreach services near “hot spots” such as bus and truck stops, mining areas, urban shopping malls, and other informal workplaces. Clients can conduct HIVST on-site or can take the test kit home.

Those who accepted the HIVST kits received a brief demonstration (either by video or by a trained provider) and information about post-test support services and referral forms (confirmative testing, HIV treatment including ART, information about prevention services) prior to HIVST. Clients who choose to self-test on-site can use private space that has been created through individual tents and private cubicles. Counsellor assistance with HIVST is made available. After HIVST, clients are advised to see a counselor to report on their test results or have the option to leave the site and leave their used self-tests in an envelope at exit (for same day rereading by providers). Self-testers with non-reactive results are counseled referred for HIV prevention services (VMMC, PrEP, family planning, condom use). Self-testers with reactive results will receive confirmative testing on-site with a provider. If confirmed, people with HIV are referred for ART according to national guidelines, with immediate initiation if ART services are either available onsite, or through direct and facilitated linkage services to ART services at public and private sector health care facilities.

HIV positive index clients diagnosed at the HTS site are offered index testing, including self-test kits for secondary distribution to all their sexual partners. Clients taking kits for secondary distribution are talked through the process of supporting their partner to use and interpret the kit correctly, how to access follow-on HIV services, and the need to maintain voluntariness.

3.3.3. FACILITY-BASED MODELS

HIVST distribution at health facility level can either through direct distribution to clients and patients accessing the health care facility for any medical reason (OPD) or are admitted in the hospital and who have been pre-screened and found eligible for

Figure 3. Community based distribution Flowchart for HIVST integrated with HTS

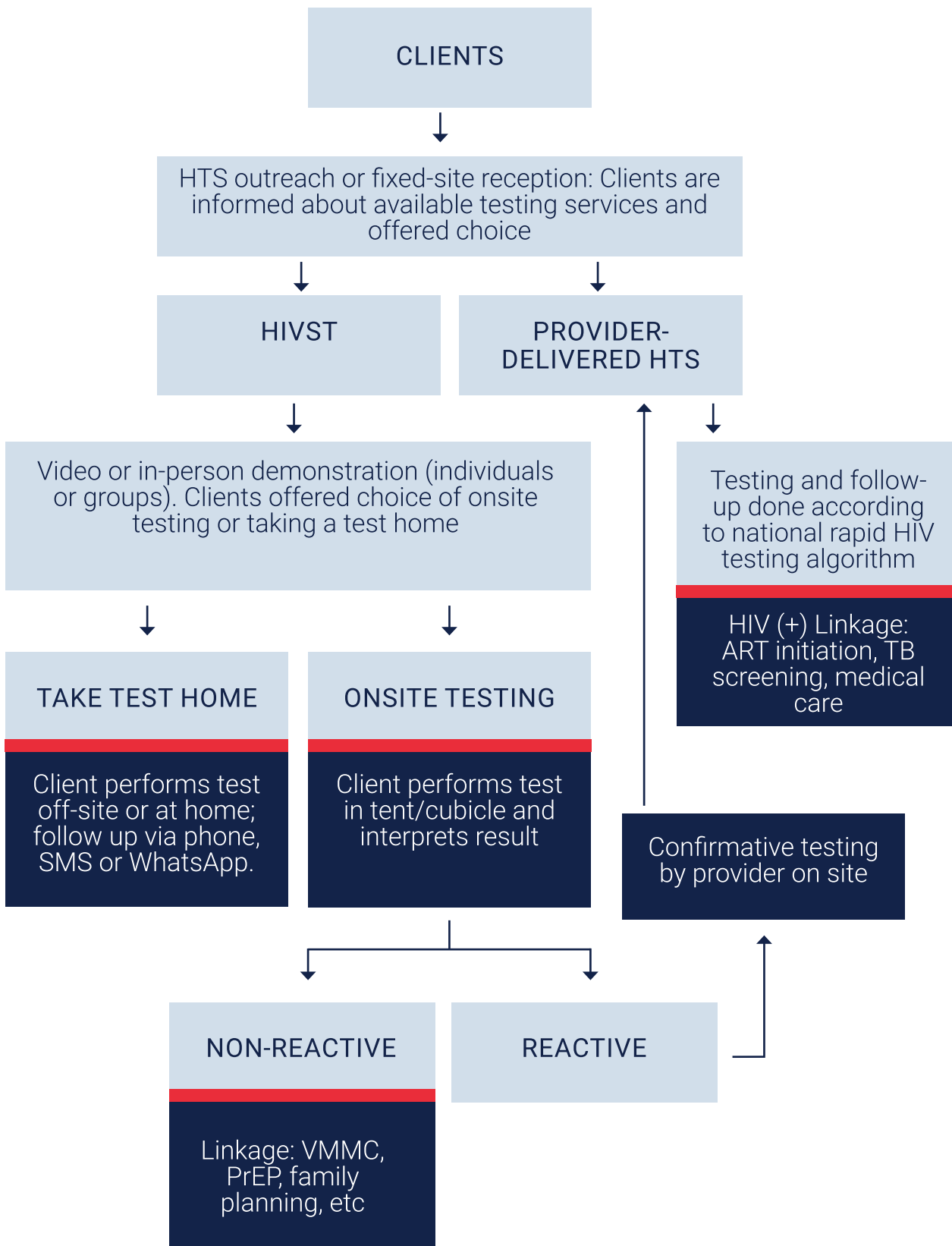


Figure 4. Facility-based direct distribution flowchart

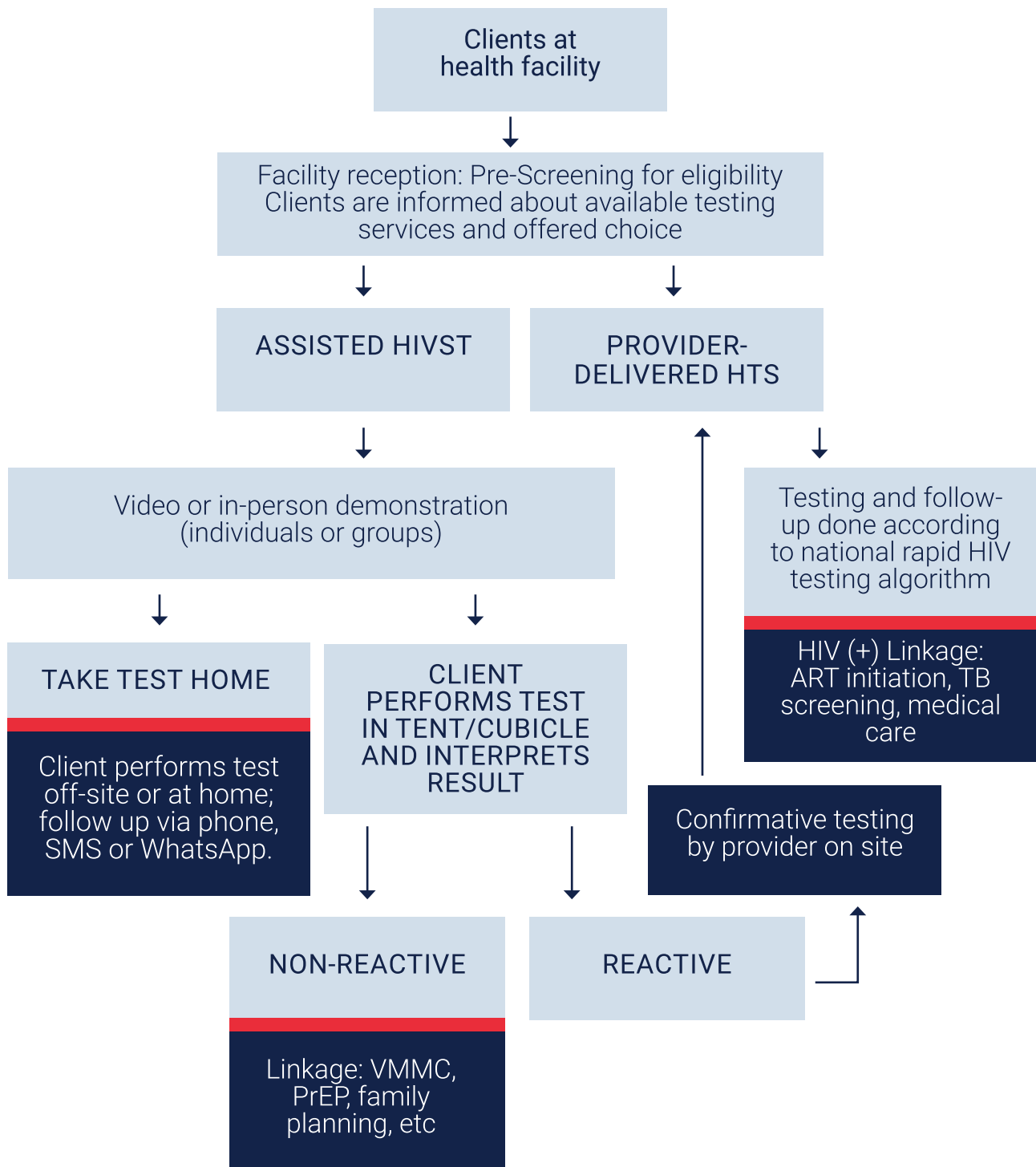
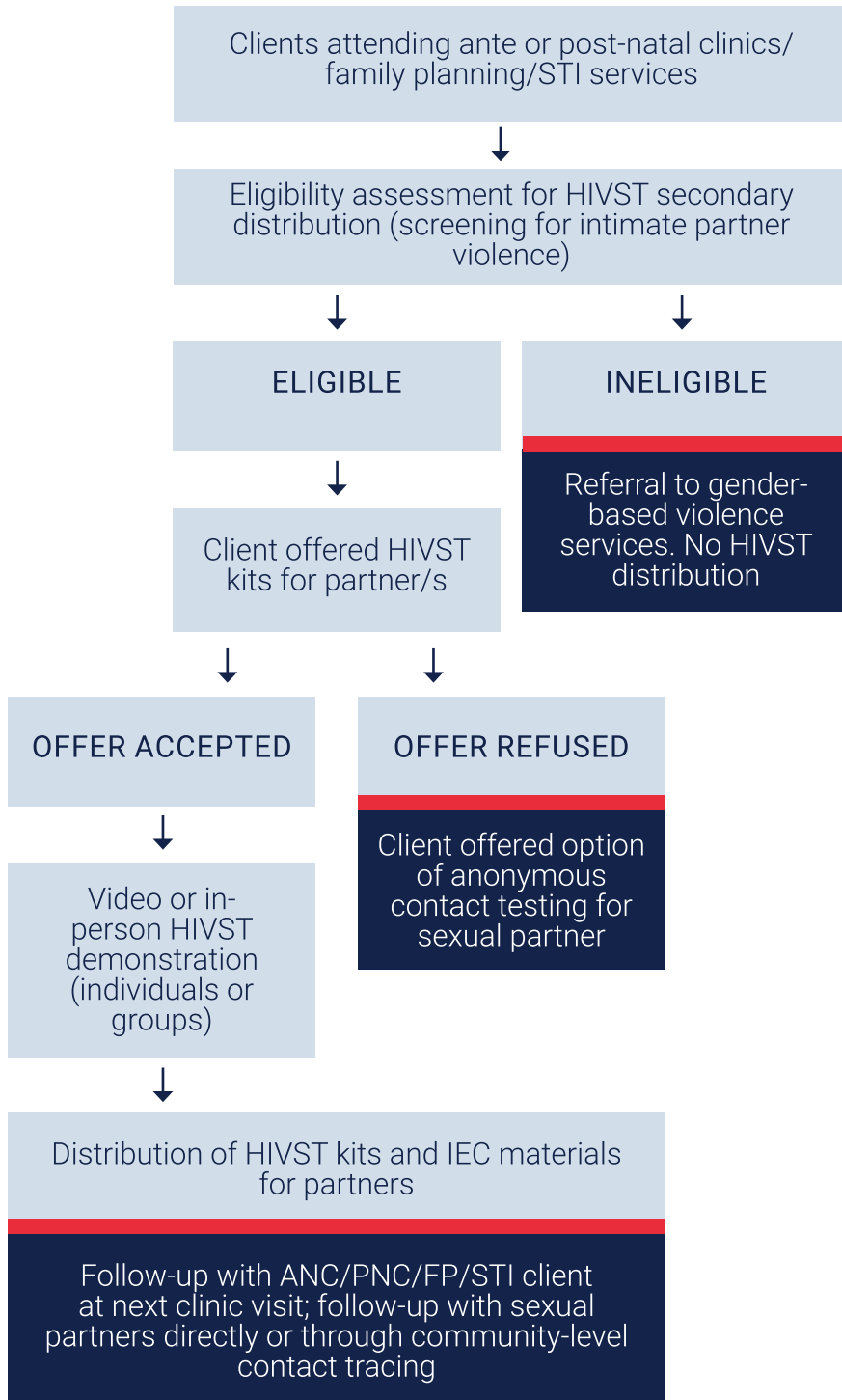


Figure 5. Facility-based secondary distribution flowchart



HIV testing as alternative option to provider delivered HTS (PITC) or through secondary distribution of HIVST kits to sexual partners of pregnant and post-partum women (or women accessing FP and SRH services, etc) or through secondary distribution through HIV-positive index clients, who have been newly diagnosed or who are accessing ART services at the health facility (including HIV-positive pregnant women).

Facility-Based Direct Distribution

In this model, which can be beneficial in terms of cost and time for the health system and the users, and can be a good fit for health facilities with limited HIV-testing capacity, facility-based counsellors and health-care workers directly promote HIVST at entry points of the health delivery system. These entry point can include: outpatient and in-patient departments, clients accessing

family planning services, etc. HIVST is then offered to individuals that are eligible for HTS based on their testing history and sexual risk behavior. Individuals from priority populations can test themselves in a cubicle/tent at the health facility during their waiting time. After HIVST, individuals present their HIVST test result to the provider at the health facility. If self-test is non-reactive, clients receiving counseling and information on HIV prevention services available and are referred and linked to HIV prevention services (PrEP, VMMC and other prevention). Self-testers with a reactive result receive confirmatory testing on site and, if feasible and acceptable, initiation on ART immediately (test and treat).

Facility-based secondary distribution means distribution HIVST kits to male partners of pregnant and post-partum women accessing health facilities.



3.3.4. OTHER HIVST DISTRIBUTION MODELS, INCLUDING PUBLIC/ PRIVATE PARTNERSHIPS

HIVST offered at workplaces/through pharmacies/retail outlets

Evidence has shown that HIV testing coverage among men and adolescents can be increased through the HIVST option. To reach high risk men and adolescents, HIVST should be provided through targeted efforts in locations where these priority populations can be found. HIVST distribution at male dominated workplaces, through pharmacies and retail outlets at no-or nominal cost to the beneficiaries has proven to be successful in increasing coverage. HIVST kits can be distributed at larger male dominated workplace through peer-promoters or HTS outreach workers. As part of the STAR initiative, HIVST kits are distributed at worksites for the mining and farming industry. Peer promoters and outreach workers are providing pre-test information and in-person demonstrations of the self-testing process. Clients can self-test on-site or take the HIVST home and can take an additional test kit for their partner to use, with support for secondary distribution as described above. Confirmatory testing might be available on site or can be provided through HTS outreach teams or through self-referral forms providing information on local private and public-sector health services. Confirmed PLHIV are referred for ART at public or private sector providers. A toll-free hotline number can be provided to all clients for additional information or counseling.

3.3.5. SECONDARY DISTRIBUTION INDEX CASE TESTING (ICT)

HIVST can be used in different ways to potentially increase uptake of HIV testing among sexual partners of HIV positive index clients, increase coverage of index testing and contact tracing and increase efficiency and convenience through screening of index cases at community level using HIVST offered by community health care workers and lay providers. The different approaches can potentially enhance client referral options of index testing (client referral and contract referral) as well as provider referral options (provider referral and dual referral). This is depicted in Figure 6. HIVST can enhance index testing through index client referral of sexual contact. Evidence has shown that HIVST can facilitate disclosure of status from the HIV positive individual to their sexual partners. In this model HIVST kits are offered to the HIV-positive clients to take to their sexual partner(s) for testing (screening) outside the facility. Index clients are shown how to perform the self-test and receive information material and user guides to give to their sexual partners to facilitate the HIV self-testing process without the assistance of a trained provider as well as facilitating referral and linkage to confirmative testing, care and treatment in case of a reactive self-test and to prevention services in case of an HIV negative self-test. Follow-up after HIVST is either conducted with index client or directly with the sexual partner, if he/she has consented. Partners are invited to return to the health facility for confirmatory testing and referral/linkage into care and treatment. Follow up of index clients and referral/linkage facilitation can also be done at community level via peer navigator, expert client, community health care workers, etc.

Figure 6. Steps for index partner testing services demonstrating opportunities where HIVST could enhance each method of partner notification (client referral, contract referral, provider referral and dual referral)

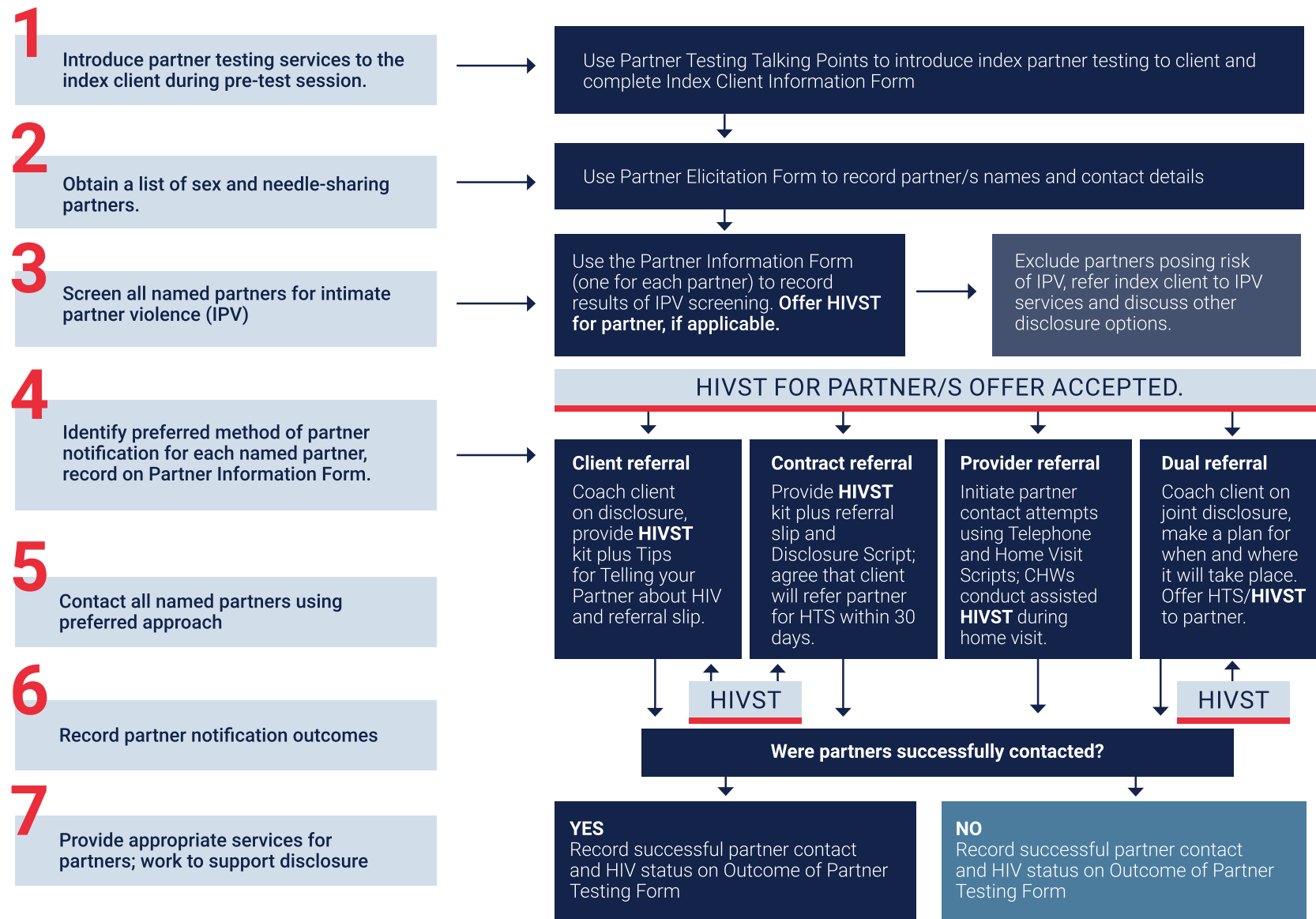
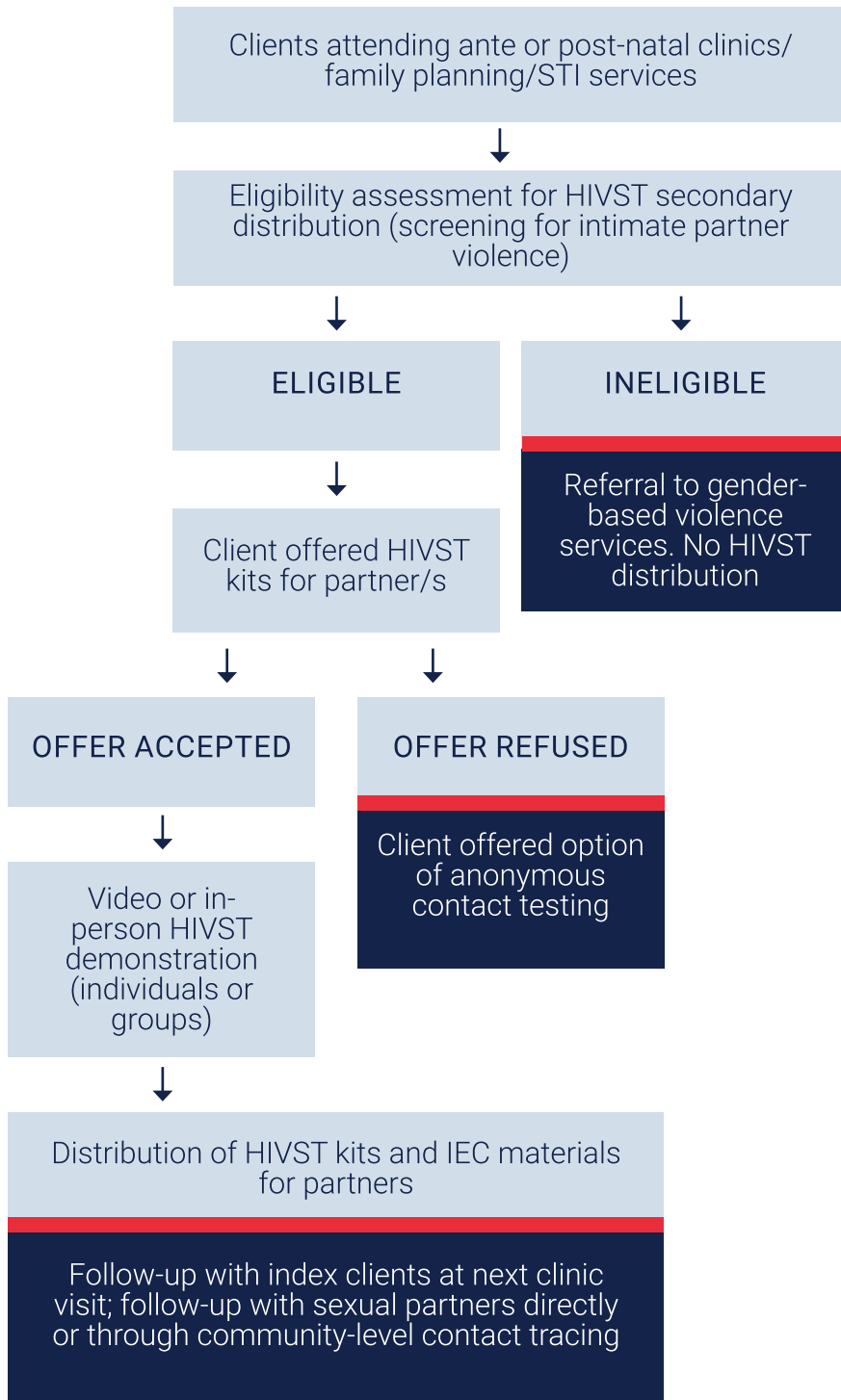


Figure 7. Secondary distribution ICT flowchart



3.4. IDENTIFYING, SELECTING AND PLANNING HIVST SERVICE DELIVERY

Adequate HIVST service delivery is based on three main components: 1) mobilization, demand creation and client awareness and information; 2) the HIV testing process; and 3) the linkage process after HIVST. For all three components, adequate design and steps in terms of planning and coordination need to be developed to ensure smooth operations. When described as a service delivery model of HIVST, all three

components are necessary and should be included in the design of the model. Figure 8 illustrates how these components should be used to design an HIVST service delivery model. It has been adapted from IAS differentiated HIV testing framework and has been useful for program managers and implementers to guide implementation. It can be adapted to each model of HIVST targeting specific priority populations. Below Figure 8 presents the HIVST planning framework and Figure 9 presents an example for HIVST implementation.

Figure 8. HIVST planning framework

	MOBILIZING	TESTING	LINKING
WHEN	What is the best day/week to distribute HIVST and mobilize the largest number of clients?	What is the best time of the day to provide testing? How frequently should testing be offered?	What is the best time period and interval for linkage and follow up?
WHERE	Where should mobilization activities be focused?	Which sites should be prioritized? Community, health facility, outreach, private sector, etc.	Client preferred facility or IP community services
WHO	Who does the mobilization?	Who distributes the best kits and performs the best test kits?	Who links the client to confirmatory testing or treatment following a reactive self-test result or linkage to prevention for non-reactive results?
WHAT	What is being distributed? HIVST kits alone, or a combination of services and information?	Is HIVST being done alone or in combination with other services?	Could text message, phone or community-based follow up be used to support linkage to prevention or ART initiation?

Figure 9. Example of use of the framework to guide HIVST distribution through taxi ranks

	MOBILIZING	TESTING	LINKING
WHEN	Advertising on/in taxis for 6 weeks prior to distribution. Active mobilization at distribution sites during implementation.	Peak commuter hours. Downtime for taxi drivers.	Linkage options provided with HIVST kit, along with consent to follow up via SMS 3 days later then call centre 5 days later.
WHERE	On taxi routes traveling from targeted high-volume rank sites.	At a place convenient to client, determined by the client.	Client preferred facility or IP community services.
WHO	Mobile and fixed point distributors.	Done by client themselves.	Client-let linkage from referral information. IP field supervisors. Call centre/HIV national hotline.
WHAT	Advertising on/in taxis. Clearly labelled promoter trays.	HIVST demonstration. HIVST distribution. Offer HIVST for male partners.	Identify referral sites for confirm testing and VMMC. Referral card. IP call centre/supportline/WhatsApp/SMS. HIV national hotline support.

3.5. FOLLOW-UP AND LINKAGES TO COUNSELING, TREATMENT AND PREVENTION

Protocols must be in place prior to distribution of HIVST kits to ensure that individuals are referred and linked to counseling, treatment and/or prevention as appropriate following a self-test.

Users who receive a reactive result must be immediately referred and linked to confirmatory testing using conventional, professionally administered approaches, according to national standards. If the follow-up testing confirms the HIV-positive status, appropriate counselling and treatment options should be provided including anti-

retroviral treatment and other care options. As with all HIV testing, users who receive a non-reactive result should be encouraged to retest at least every year dependent on their individual risk exposure.

Prevention options should also be recommended including: condom use, uptake of VMMC for male HIV negative self-testers, and PrEP. Care must be taken to develop clear messages for each contingency tailored to each priority population. Following up of self-test users who chose to test off-site and for users who received the HIVST kit through their sexual partner or peers can be more challenging, and innovative approaches such as direct voluntary telephonic follow up or follow-

up via SMS, WhatsApp or through community outreach might be required. Nevertheless, without active follow up and linkage facilitation it will be very difficult to measure the impact of HIVST programs according to the HIVST impact framework. It is also important that follow-up data is linked to the individual HIVST kit distribution (see M&E section below).

Possible ways to improve linkages to care following self-testing include:

- **Referral/appointment cards:** Distributing referral/appointment cards together with HIVST kits – with information materials and brochures and contact details on where to access further HIV testing, prevention and treatment can help facilitate linkages. These materials should be adapted to the local context and ideally directly link to existing health care facilities in the catchment areas of HIVST distribution, provided as supplementary materials by implementing partners.
- **Community outreach and follow-up:** Follow-up community health care workers, peer educators, peer navigators, referral facilitators and other community-based cadres can be a useful strategy for facilitating linkage to further testing, prevention and treatment. This approach is in particular important for follow up of sexual partners of index clients, who received HIVST kits through their HIV positive partners and for male sexual partners of pregnant and post-partum women, who received HIVST kits through secondary distribution. This can include offering community-based confirmatory testing, prevention and treatment while HIVST kits are distributed or on an ad hoc basis. Community workers and peer navigators may also accompany those

with a reactive self-test result to receive further testing and care in a facility

- **Telephone calls, text messages or social media counselling messages and reminders** (e.g. through WhatsApp and WhatsApp for business) and digital platforms for self-reporting of outcomes and linkage facilitation: Follow-up counselling, messages and reminders can be used to follow up with self-test users on their individual test results through self-reporting and to facilitate linkage to further testing, prevention and treatment. Several mhealth follow-up systems for HIVST have been evaluated through the STAR Initiative in South Africa, including website based solutions, interactive voice response systems, WhatsApp and WebApp systems, all of which are linked with a back-end data base, where follow up outcome data is captured and linked to HIVST distribution. All tools can be adapted to local contexts.

3.6. SUPPLY CHAIN PLANNING

Supply chain management (SCM) refers to how we manage the flow of products, in this case HIVST kits, from manufacturers to importers, local distributors, retailers/providers and, eventually, our intended users. There are two dimensions to SCM:

- **Supply Chain Planning**, which focuses on accurately forecasting, monitoring and balancing supply and demand to avoid stockouts, overstock and/or expired product.
- **Supply Chain Execution**, which involves sourcing and distributing the product according to plan, as well as proper handling, transportation and storage.



3.6.1. SUPPLY CHAIN PLANNING

The fundamental point of supply chain planning is to make sure there is enough stock available, where and when it is needed, to meet the priority population's needs. Ideally, supply of a product in a market and demand for that product would be perfectly balanced, so that consumer needs are met without any shortages nor waste, though in reality supply can often exceed demand and vice versa. Proper planning as well as efficient and smart responses to unforeseen circumstances can ensure better balance overall.

Supply planning is a monthly process that uses current forecasts, existing inventory, on-order procurement quantities and due dates, and probable stock obsolescence to calculate how much stock will be available

each month into the future. The purpose of supply planning is to properly balance product supply with consumer demand and therefore avoid stockouts and excess inventory.

The planning horizon is usually two years, but it may be more or less depending on the needs of the particular country and/or project duration. Proper supply chain planning involves forecasting and monitoring.

Forecasting

Effective SCM starts with making informed decisions about your operational forecasts. Forecasting is an activity that uses data, information, assumptions and market insights to predict demand. You need to make sure you are placing funds as wisely as possible so you don't over or under invest in different areas. Forecasts are simply estimates: actual

numbers will never exactly match them. The purpose of forecasts is to provide a basis to make the best supply chain decisions possible, using the most up-to-date information known about true consumer demand at the time each supply-related decision gets made.

Forecasts should use the most current information known at the time. During a product's lifecycle, more information becomes known about the market and the consumer, and that information gets used to fine-tune the forecasts. It is easy to confuse forecasts with targets, but there is a very important difference between the two:

- **Targets** rarely change from when they are initially set and when they are finally evaluated, because their purpose is goal-setting.

- **Forecasts** usually start out being the same as the target but evolve and improve over time as real-time data is accumulated.

It is important that forecasts are as accurate as possible, not an over-optimistic view of the potential to move stock. Being over-optimistic in forecasting leads to negative consequences for stock management and wasted money. Many organizations are quite happy to increase their operational forecasts if they are overachieving the set expectations, provided it does not affect the current period metrics target. However, there does tend to be a cultural aversion within the humanitarian sector to reducing a forecast. In this case, people may prefer to wait and hope the situation improves.



The risk of delaying a forecast reduction can and has caused obsolete stock. It is strongly advised that even if the forecast owner may be disappointed about a product's current market performance, it is far better to accept the reality of it, adjust the forecasts for the time being, and work on tangible demand-generation strategies. If real-time supply decisions such as procurements are not based on realistic forecasts, this can lead to mistakes such as:

- Procurements being made too late, causing limited supply and even stockout.
- Procurements being made too early, causing overstock, space constraints, increased cost to store if storage costs are variable, and even obsolete stock and expired product, which is wasteful.
- Limited procurement budget. With poor forecasting, monies may get used to purchase one product at the expense of another, which may cause excess inventory of one product and stockout of another that the target consumer prefers for the same or similar use.

Furthermore, having forecasts that are unrealistic can hide or exaggerate how much stock is really at risk of becoming obsolete or set to expire.

- If a forecast is unrealistically high, the Expiry Monitoring tool may calculate that no stock is at risk of becoming obsolete until the risk is imminent, thereby limiting the opportunity to find the best strategy to address the issue.
- If a forecast is unrealistically low, the Expiry Monitoring tool may calculate and flag to the supply planner that more stock is at risk than really is the case, resulting in unnecessary give aways or discounted stock.

Forecast accuracy is usually measured by evaluating how accurate the forecast was over the last 6 months rather than as single monthly events. Problems arise when we are consistently overselling the forecast (risk of stockout) or consistently underselling it (risk of excess inventory and obsolete stock).

When we see consistent over-and under-estimates occurring, it is necessary to engage with program and/or sales and marketing to evaluate the forecast and change it if necessary. It may not always be necessary to change the forecast, but it is always recommended to seek to understand why discrepancies are occurring.

While some stockouts cannot reasonably be prevented, for example, when there is a major manufacturer quality incident, stockouts are normally indicative of poor supply management processes and practices and can damage your program's reputation with donors. Fortunately, most stockouts can be prevented with appropriate foresight and proper supply chain planning.

Expiry Monitoring

If an oversupply situation arises due to forecast undersells or other reasons and it is significant enough to cause product obsolescence, this should be highlighted through the Expiry Monitoring tool, linked at the top of this section.

During this phase, by-lot stock holdings are monitored individually to see if there is a likely risk that stock will become obsolete before it would normally be used, based on the current forecast. Stock is considered obsolete when it does not have enough months of remaining shelf life before its expiry date for it to safely pass through the various levels of the supply chain.

This period of time is referred to as the stop-ship period or stop-ship date. We recommend a stop-ship policy of 6 months before expiry.



Under no circumstances should expired HIVST kits be dispatched from a warehouse or distributed to users!

Safety Stock

Safety stock is a planned amount of stock that is held as contingency supply to help protect programs from stockout in case of forecast oversells and/or delays in procurement and delivery. Safety stock levels should be set when supply plans are created.

Safety stock is normally expressed as a certain number of months' worth of planned stock cover. Levels should be set high enough that all of the facilities in the country are unlikely to run out of stock, but not so high that it will put stock at risk of expiring in the warehouse or cause excessive amounts of space to be required to store inventory.

For health commodities that are imported, network members are generally encouraged to keep central warehouse safety stocks at between 4 and 6 months' cover per product if practical. You should also give consideration to the following:

- **Predictability of sales and distributions:** How predictable is the demand for this product normally?
- **Product lead times and substitutability:** How long does it take to source more product? Do we have equivalent or similar products that may be substituted in case of stockout?
- **Supplier and agent reliability:** How reliable is the supplier at delivering on the date they committed to? Are

customs clearance or delivery delays suffered routinely, and if so how long does the disruption normally last?

- **Budget/funding constraints:** What is the procurement budget for the item(s)?
- **Warehousing/storage space constraints:** Do we have sufficient space to store the required stock without needing additional warehousing space?
- **Product shelf life:** How many months are there between the date of manufacture and the expiry date of the product? What is the demand expected to be during that period?

Once safety stock levels have been set, the supply planner schedules new deliveries to arrive at the time that projected stock balances begin to fall below safety stock minimums.

Each month when the plan gets reviewed, the supply planner checks existing planned deliveries to make sure they are still scheduled to arrive as the projected stock balance falls below safety stock. The supply planner may need to move planned orders forwards or backwards, if possible, to account for underselling or overselling the forecast or other events that have affected stock availability.

3.6.2. SUPPLY CHAIN EXECUTION

Supply Chain Execution requires being familiar with the rules and guidelines that govern best practices for sourcing, storing, and distributing products. This section will focus on:

- Procurement
- Customs Clearance & Delivery
- Warehousing & Inventory Management
- Reporting for Replenishment

Procurement

Procurement refers the acquisition of material goods or the acquisition of services, in our

case, HIVST kits. The procurement process involves selecting appropriate products and then balancing quality, quantity and price to deliver products to the right place in time to meet the target consumer's needs.

Before the three stages of procurement are considered, procurement lead times must be assessed in order to have a realistic expectation of when you will have your HIVST kit in stock. Once you have identified your procurement lead times, there are three stages to consider: (1) initiating procurement; (2) carrying out procurement; and (3) monitoring procurement.

The procurement lead time defines how far in advance orders must be placed to arrive on time so that the stock balance doesn't fall below the safety stock level that has been set. For imported health commodities, procurement lead times can be lengthy: usually between about 6 months all the way up to 9 and even 12 months for a single procurement. The amount of time needed will vary by product and by country and sometimes even by donor as certain donors require extra steps in the procurement process that others may not require.

Factors affecting procurement lead time include:

- Drafting and floating tenders (including bid evaluation and supplier selection)
- Manufacturing of HIVST kits
- Quality sampling and testing, which can be both pre-shipment and post-shipment if country import regulations require it;
- Delivery to the country.

Other sources of delays may include regulatory complications (particularly for new products), pre- and post-shipment quality testing (reliant on third party quality tester), and customs clearance. The party

responsible for executing the procurement can provide lead time estimates for the country team to use for planning, but it is important to recognize that these are only best-guess estimates.

Depending on procurement lead times and delays, the supply planner should try to move orders forward or backward if possible to ensure proper stocking.

Monitoring Procurement

Once a procurement is underway and you are sure that it is on track to be delivered at the requested time, it's important to make sure it stays that way. The status of open procurements should be consistently monitored. Never assume that a simple agreement of a delivery date will automatically be adhered to.

Deliveries have been delayed by such events as:

- Facilitating tax exemptions
- Funder non-objections
- Manufacturer plant shut down
- Quality assurance issue

By monitoring open procurements, you may reduce the possibility of a delay.

Customs Clearance and Delivery

Customs clearance and delivery is an important component of your procurement considerations and typically involves a third party.

Customs clearance arrangements are usually made by contracting a reputable Customs Clearance Agent. Customs clearance is a highly specialized job which is why it is outsourced and not performed in-house.

When contracting out to a third party, it's extremely important to ensure that a delegate from your organization is explicitly responsible for managing the relationship and

ensuring that the agency acts in accordance with your expectations and cost efficiency. Contract management is also a specialized skill set. It is worth your consideration to enroll team members who are assigned to such oversight in a professional development course designed to teach these skills.

Other considerations to be made when arranging for customs clearance may include: Certain countries may require that a pharmacist employed by your organization be registered with one or more agencies in order for certain HIVST kits to pass through customs. It may be necessary to secure a tax exemption certificate before the supplier can release the kits for shipment.

Warehousing and Inventory Management

Successful warehousing and inventory management practices support the supply chain by effectively and efficiently managing the control and storage of products within a warehouse, and the movement of products through transactions such as receiving and dispatch.

Four important goals for warehouse management are identified below:

- **Inventory Record Accuracy:** Maintaining accurate inventory records makes it possible to make decisions that are well informed, including decisions about resupply.
- **First-Expiry-First-Out (FEFO) Stock Storage & Rotation:** Using FEFO principles to store and rotate stock reduces the amount of stock that may need to be disposed of due to product expiry.
- **Ensuring Product Quality:** Good storage practices keep product in good condition and help ensure that target consumers receive products that are of high quality.

- **Monitoring Slow Moving Stock:** A process to monitor and report slow moving stock helps manage stock close to expiry and prevents accumulation of obsolete stock.

Warehousing and inventory management activities can be arranged into two groups:

- 1. Stock Movement Activities**, including receiving, dispatch, production (kitting), and customer returns.
- 2. Stock Administration Activities**, including stock tracking, storage, safety and security, physical inventory, and stock disposal.

Stock Movement Activities

Receiving Inbound Deliveries: Receiving involves taking delivery of goods into the

warehouse from suppliers, external packing facilities, other internal storage facilities, and occasionally from customers or sales staff in the event of a customer return.

Production/Kitting: Production, otherwise known as kitting, packing or assembly, is the value-adding process of converting raw goods, including commodities, packaging materials and consumer information leaflets into finished goods that are ready for sale or distribution to the target consumer.

Dispatching Outbound Deliveries: Dispatch involves preparing stock to be delivered or picked up from the warehouse for delivery to an external location, such as a customer, sales representative, outsourced packing facility, or a separate internal warehouse or store.



Processing Customer Returns: Customer Returns are a form of receiving that occurs when stock has previously been dispatched from the warehouse to either an internal sales representative or an external customer and then it is returned back to the same location. It is critically important to carefully inspect all customer returns. Returning stock to inventory and/or to the damaged and obsolete stock location in the warehouse is likely to have financial implications and therefore it is very important to validate and clearly document on the correct paperwork the product, quantity and condition of the customer return.

Stock Administration Activities

Stock Tracking: Stock Tracking spans all warehousing activities. Stock tracking involves creating and maintaining paper and electronic records of stock movements and perpetual stock balances to create a thorough and accurate audit trail. It also makes it possible to regularly report stock balances to relevant departments to inform business decisions.

Storage of Inventory: Storage best practices should be followed to protect HIVST kits in warehouse from damage, theft, obsolescence or other issues that might compromise quality. Specifically:

- Keep test kits in a clean organized and locked shelf/cabinet
- Store according to manufacturer's instructions
- Place in a well-ventilated room
- Store away from direct sunlight
- Organize supplies by expiry dates (FIFO Principle – First to Expire, First Out)

Physical Inventory: Regularly counting the inventory of HIVST kits at each warehouse or distribution point helps ensure stock balances in our database match the actual quantities of products available at any given point in the chain.

Stock Disposal: Damaged and expired/obsolete HIVST kits can be disposed of in a normal waste bin, out of the reach of children.

Inventory and Reporting for Replenishment

Consistent, accurate reporting of opening and closing stock balances is critically important to support continuous supply. Make sure there is a system in place for collecting this data at every point in the supply chain. Having this information will help you calculate when to order more stock and determine when it needs to be delivered., preventing stockouts and facilitating shelf life management across the supply chain.

Supply Review

Each month the supply planner fills out the supply plan and the expiry monitoring tool (examples linked at the top of this section). Doing so triggers the supply review process, as it produces signals and information that tell the planner and team members from other departments which parts of the supply chain they need to pay attention to and correct any imbalances.

The Supply Review Forum is the (usually monthly) forum by which you keep your demand and supply in check with each other. The Supply Review Forum is typically led by a member of your supply chain or operations team with support from HQ. Any issues raised by the supply plan and the expiry monitoring tool must be discussed between departments, and players must agree on how to take action so that all tasks and responsibilities are clear to everyone.

Examples of some of the actions that may come out of the supply review are as follows:

- A procurement is needed: This requires various people to assess how much stock needs to be purchased or donated, and where and when to create a



requisition. They must check on funding and make sure budget is available for the purchase, then authorize and submit a requisition or request to donor.

- Stock is at risk of becoming obsolete: This requires the Program Manager and/or sales and marketing teams to assess how much stock is at risk and when. The program manager must also evaluate how big or small the problem is relative to normal demand. They then need to develop a tangible strategy for clearing or otherwise using the stock before it's too late and the product would get wasted.
- An order isn't on track for on-time delivery as planned: If the delay is caused by unfinished work within your country — such as artwork that hasn't been finalized or approved — it will require

the program manager and/or marketing team to resolve that promptly, so no further delays are incurred. If the delay is on the procurement side, it will require the planner to follow up with the person who is executing the procurement to understand why there is a delay and help them clear the blockage if possible.

- A product is in stockout or has limited supply: This requires the program manager and/or sales and marketing teams to assess whether they need to implement strategies to cap or limit supply to certain customers. Such options may include trying to substitute one product or variant for another similar product or variant in the market, or potentially borrowing stock from a partner or the government until the replenishment arrives, etc.

4. HIVST DEMAND CREATION AND COMMUNICATIONS

HIVST addresses key barriers to the uptake of HIV testing services, especially among priority populations that are currently not reached with conventional testing. Testing barriers include people's concerns about confidentiality, stigma, discrimination and, in some contexts, criminalization. HIVST can also reduce opportunity costs that are common to conventional testing services, including inconvenience, missed work and cost.

However, in order to realize the potential of HIVST to address these gaps and barriers, demand for the service needs to be stimulated among the target groups in such a way that unreached populations seek out HIVST from providers.

A healthy market for HIVST requires solid demand from end users and wholesale buyers including national governments and donors. The objectives of a comprehensive, user-centered communications and marketing strategy are to:

- Increase awareness and demand among priority populations to take advantage of HIVST and related referral and services (counseling, treatment, prevention).
- Engage with key stakeholders in the local healthcare market (governments, providers, businesses, communities) to ensure that HIVST products and related services are made available and accessible to priority populations, in a sustainable way through several entry points.

Elaborating an effective strategy that achieves these goals requires understanding of all relevant actors to ensure that messaging, content, channels and approaches are all targeted to the right groups in ways they will respond to.

Making HIVST products available in a market is only half of the challenge. In this section we will discuss strategies for raising awareness and encouraging members of priority populations to use HIVST kits as well as developing support tools for clients using HIVST kits.

For HIVST programs to have an impact, we need persuade members of priority populations to take advantage of HIVST and related services (counseling, confirmative HIV testing, treatment, prevention) and engage with key stakeholders in the local healthcare market (governments, providers, businesses, communities) to ensure that HIVST products and related services are made available and accessible to priority populations, in a sustainable way.

To accomplish these goals, we need to develop demand creation strategies that account for

- The needs and motivations of the intended users
- The personal relationships and social influences that shape users' decisions.
- The needs and motivations of players in the commercial value chain
- The concerns of policymakers, regulators and funders.

4.1. UNDERSTANDING THE INTENDED USERS

Convincing individual members of priority populations to make use of HIVST requires a deeper understanding of HIVST users as people, beyond their superficial demographic characteristics. By developing personal empathy with HIVST users we can gain insight

into their lives, thought process, hopes and concerns that can help us influence their behavior. In the sections that follow, we will review a number of practical exercises for developing greater empathy and insight.

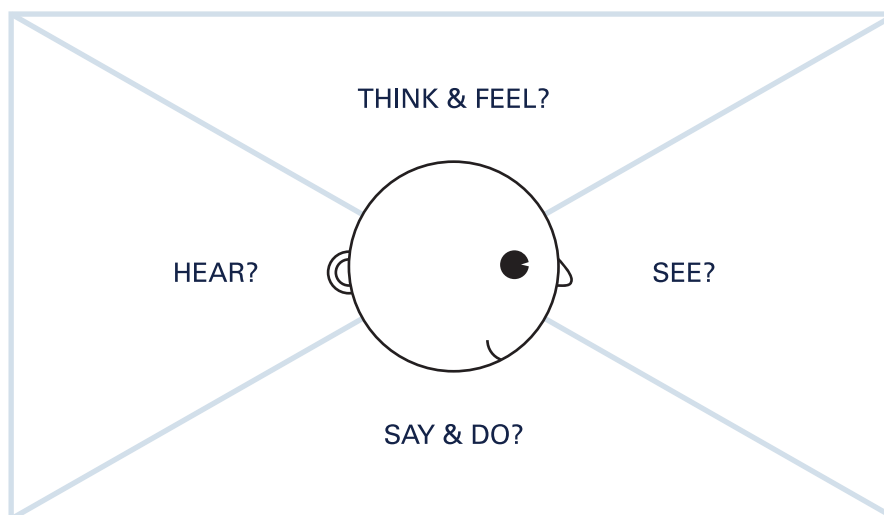
4.1.1. EMPATHY MAPPING

Empathy mapping is a quick exercise that can help you start to see the world and HIVST from an intended user's perspective. Start by selecting a specific priority population (e.g., MSM or postpartum women in high HIV burden settings). Then, sit down with other

members of your team who have worked with that priority population before, and — based on what you know — fill out a chart like the one below, describing what the target user sees, hears, thinks and feels and says and does related to HIVST.

By viewing our intended users' world in these terms, we can get a clearer sense of the challenges they face related to HIV testing and the messages they might need to receive before adopting HIVST. Empathy mapping is supposed to be a quick exercise, which you can complete in one sitting. If,

Figure 10. Graphic representation of the empathy mapping process



For example:

	MSM	POSTPARTUM WOMEN
Sees	Partners and acquaintances testing positive for HIV.	Friends having relationship problems during pregnancy.
Hears	Homophobic messages from the culture around him, including friends and family.	Warnings from her doctors about elevated HIV risks.
Thinks and Feels	Feels concerned about his HIV status.	Feels pressured to have sex with her partner.
Says and Does	Avoids testing for fear of stigma.	Has unprotected sex with her partner during pregnancy.

when attempting to develop an empathy map, you find that you don't know your intended users well enough to imagine yourself in their situation, then you might need to do some research or recruit team members with more experience working with the group in question.

4.1.2. JOURNEY MAPPING

Journey Mapping is an exercise where we analyze an individual's experience of using a health product/service or adopting a healthy behavior by dividing it into several distinct stages:

- **Awareness** - How did they first learn of the product, service or behavior?
- **Decision** - What events or influences made them decide to use the product/service or adopt the healthy behavior?
- **Uptake** - When did they finally act on their intention and start using the product/service or practicing the behavior?

- **Continued Use** - What was their subsequent experience using the product/service or maintaining the behavior, day to day?
- **Advocacy** - To what extent did they influence others to use the product/service or adopt the behavior?

By viewing the intended user's experience as a journey from initially learning about HIVST to eventually making use of it and, ideally, advocating HIVST to others, we gain a clearer sense of how their views might change over time and how we could potentially influence them at each stage, for example by informing local providers such as pharmacists about the benefits of HIVST or engaging with intended users on social media.

To give examples of journey maps for linkages to counseling, treatment and prevention:

Figure 11. Graphic representation of the journey mapping process

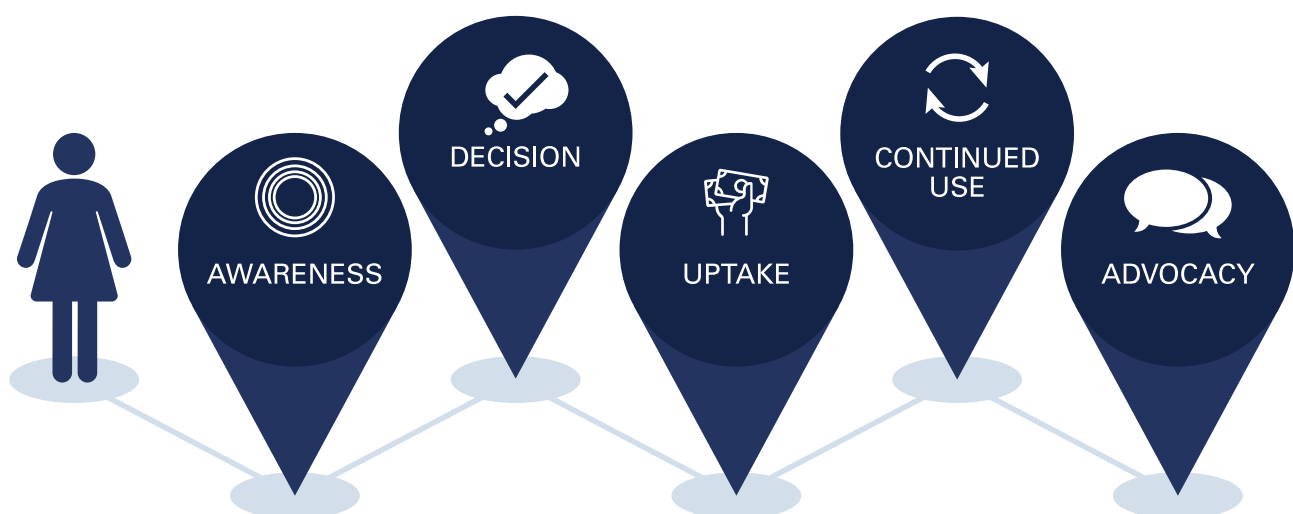
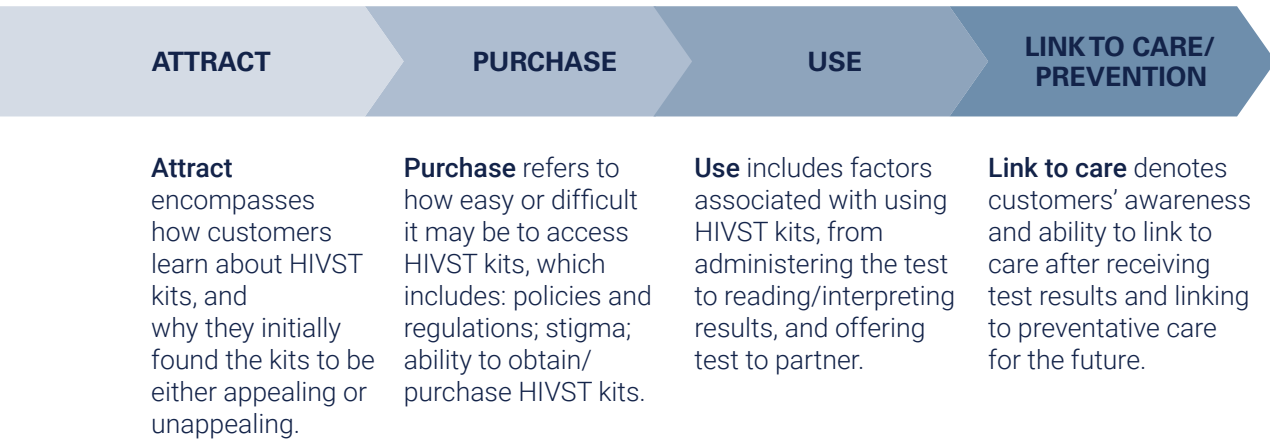
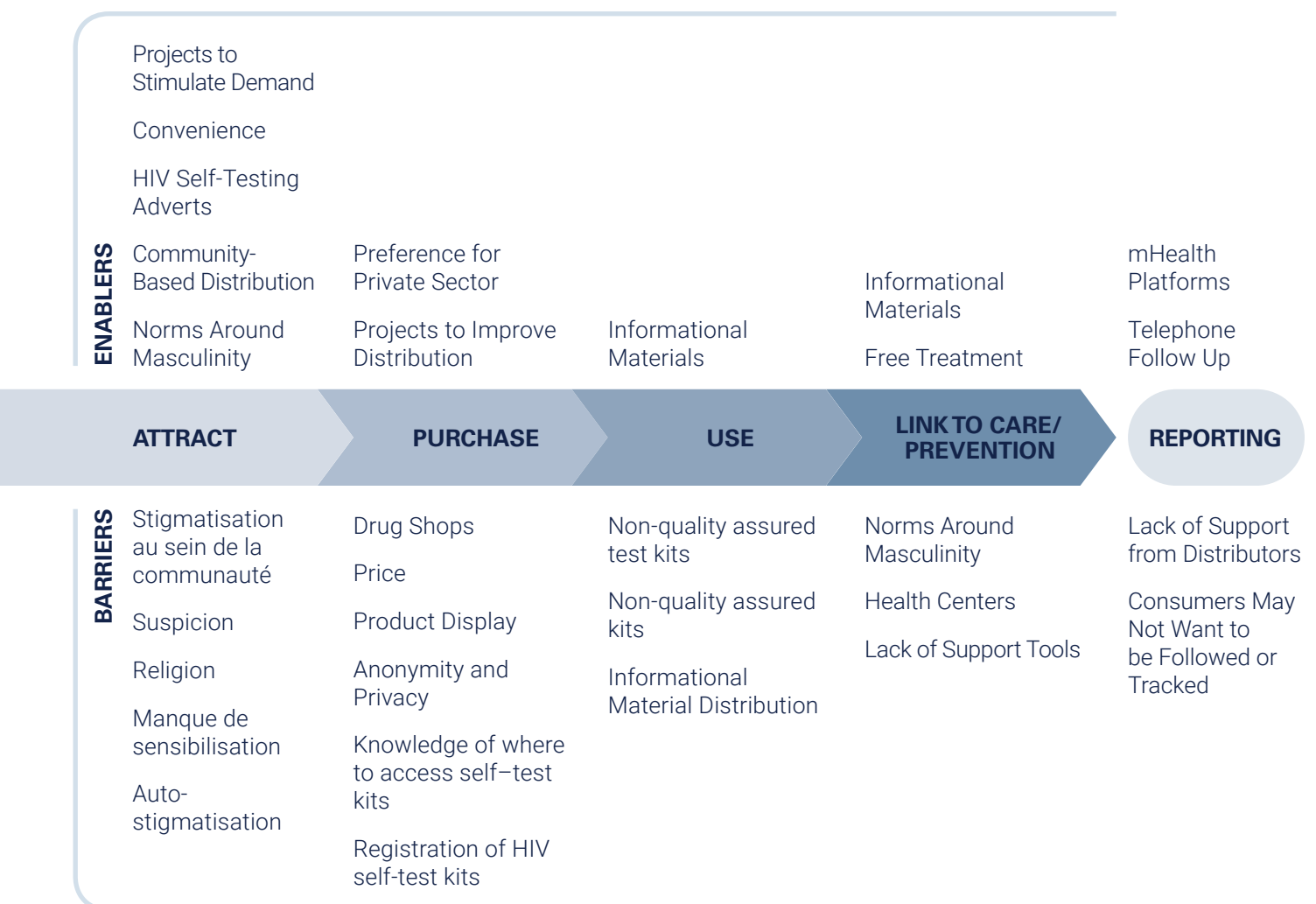


Figure 12. HIV Self-Testing Client Journey



Mapping Enablers and Barriers Along the HIVST Client Journey



The examples given above represent ideal user journeys - in other words, the path we would like intended users to take towards using HIVST and related services. However, the reality might be a great deal more complicated. There might be unanticipated barriers, and our understanding of intended users' decision-making process and motivations might be inaccurate, outdated or incomplete.

You will want to validate your ideal journey against the experiences of real users and, if necessary, create an "actual" journey map that reflects the current reality. This can help you identify gaps and develop strategies to bring users' actual journeys more in line with your ideal.

Journey mapping requires more detailed knowledge of users and their day-to-day experience than simple empathy maps. At least some research will be required, including:

- Primary research in the form of in-depth interviews with priority population members, focus group discussions or surveys
- Secondary research such as census data, DHS, BSS, media consumption studies or commercial market research data
- Observations by peers, IPC agents or other field workers who regularly interact with the priority population

4.1.3. PROFILING ARCHETYPAL USERS

It is often helpful to create detailed profiles of fictional people representing "typical" members of your priority population. Doing this can make a priority population more relatable, which makes it easier to develop effective demand creation communications tailored to their specific needs and preferences. Some examples of user archetypes are:



LUFUNO - YOUNG WOMAN, 25 YEARS OLD

Lufuno has multiple sexual partners and she uses sex to generate income. She does not feel comfortable to discuss her private issues with friends or colleagues. Anonymity is important to her willingness to access HIV testing services.

HIVST value proposition:

HIVST allows her to know her status without sharing her sexual behavior with anyone (e.g. Counsellor)

Messages:

- You can take the test at your own time
- No need to queue at the clinic to know your HIV Status
- Total confidentiality of test result
- HIVSS put you in control of your HIV Status and whom to share your status with
- After knowing your HIV status, it is important to practice safe sex.

TSHEPO - YOUNG MAN, 20 YEARS OLD

Tshepo is a vibrant young man with an active sex life. Tshepo does not want to be counseled however he wants to know his HIV status. He is not willing to share his risky behavior with a counselor. He is open to share his sexual history with friends.

HIVST value proposition:

Tshepo does have to go through counseling for him to know his HIV status.

Messages:

- No pre-test counseling session
- After self-screening, you can seek post-test counseling services at your own convenience
- Know your HIV results and have a peace of mind
- Knowing your HIV status will help protect you and your sexual partner
- HIVSS helps you know your status at your convenience

ZANELE - FAMILY WOMAN, 35 YEARS OLD

Zanele draws her joys and happiness from her children. Her major aspirations are centered on her children's education, health and their wellbeing. Zanele does not solely depend on her husband for financial support and hence ventures in entrepreneurial activities to make ends meet for her family. Zanele knows that her husband has affairs but she is afraid to confront him. She wants her husband to test but she is afraid of asking him because that could be interpreted as an accusation of infidelity. She also wonders about her own HIV status and would get tested; however, she is concerned about the level of confidentiality maintained by nurses and their judgmental attitudes.

HIVST Value Proposition:

HIVST can at least offer Zanele a way to check her own status.

Messages:

- Your partner's HIV test results may not reflect your status
- Some couples live with different HIV status
- You can take an HIVST test without provider's presence
- Know your results and have a peace of mind
- Knowing your HIV status will put you in control of your health and plan for the wellbeing of your family.

These profiles or “archetypes” should be based on data collected during empathy mapping, journey mapping and situational analysis. Once an archetype for a particular priority population has been thoroughly researched and validated, it will likely remain relevant for a long time and should not need to be recreated for a few years.

A simple archetype document should tell a story about a hypothetical member of the priority population as a real person. While the archetype might represent a group with a range of characteristics, the archetype itself should represent a specific person with enough personal detail to help you imagine how this particular person might behave in real-life situations.

In addition to creating archetypes for intended users, it is sometimes helpful to create archetypes for other actors in the HIVST market (manufacturers, regulators, pharmacists, CBDs, etc.). In these cases, you will want to understand the key drivers of a business or the broader policy objectives and alternatives facing donors and policymakers.

Not all archetypes need not look the same nor contain the exact same information. The output should be concise (about 1 or 2 pages long) and easy to understand, with key insights and considerations clearly highlighted.

Most archetypes will contain the following core components:

- Giving your archetype a **name** immediately makes them more relatable as an individual
- **Basic demographic information** such as age, marital status, geographic location and wealth quintile to give you a clear idea of their place in society (you can use data collected during the Target Consumer Segmentation activity in the Diagnose phase)
- **Attitudes, perceptions and risk behaviors** as they relate to the target behavior, to give you a sense of their relationship to the health need (again, you can use data collected during the Target Consumer Segmentation activity in the Diagnose phase)
- **Motivators and barriers** to the target behavior, to clarify their thought process
- **Media habits** to help us know how to reach them and who else might be influencing them
- **Goals and aspirations**, especially as they relate to the desired behavior, so we can position the solution as being in line with their personal interests
- A brief **narrative of a typical day in their life** to help us think of new ways to engage them
- **Influencers** who shape their perceptions and beliefs

Example of HIVST archetype used for demand creation planning in South Africa:



Nandi Nkabinde

South African adolescent

GENDER

Female

AGE

20 years old

MARITAL STATUS

Single

CHILDREN

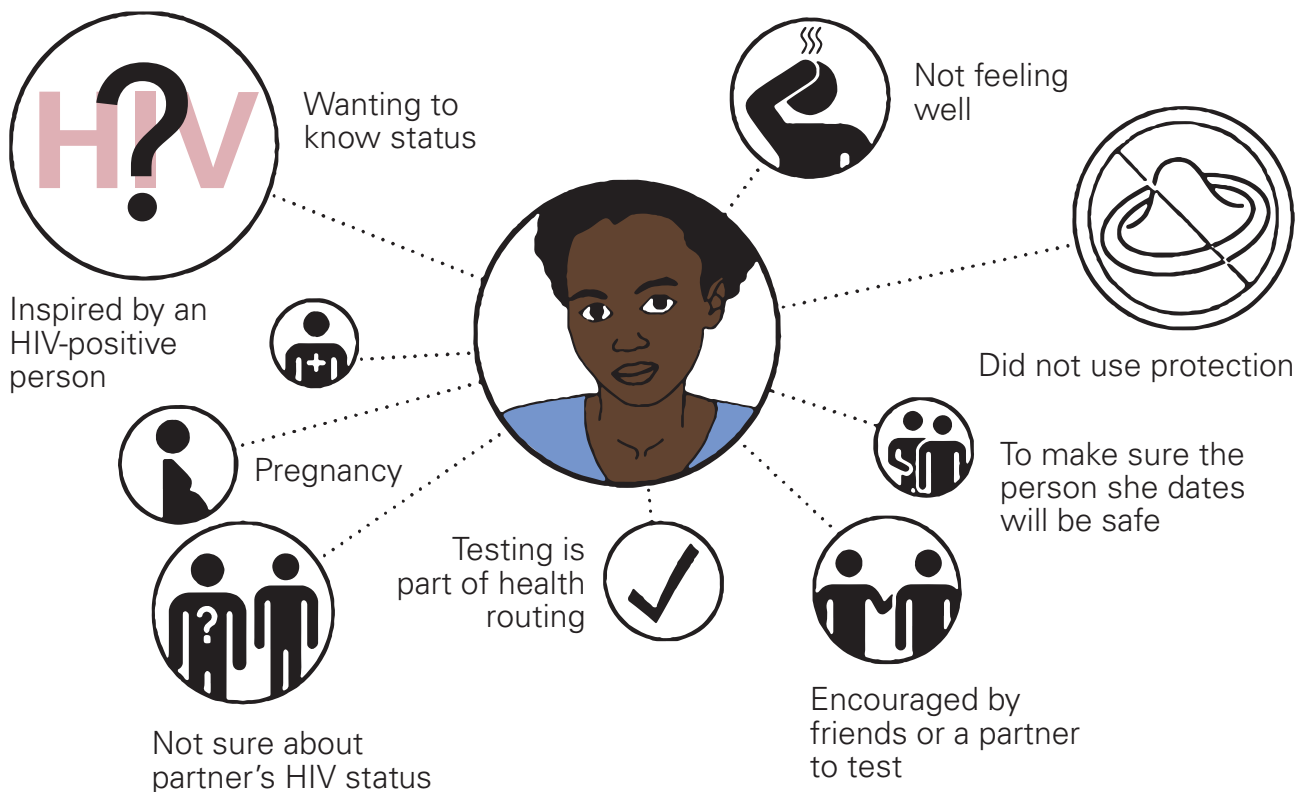
None

HOME

Nandi lives in a township in South Africa, where she grew up. She was raised by her grandparents and her mother, who is a domestic worker. Nandi lives in a small home with five other family members.

LIFE

Nandi is out of school but not working. She completed Grade 12 at the high school near her township.



4.2. UNDERSTANDING THE MARKET

4.2.1. SITUATIONAL ANALYSIS

Some of the key questions related to demand creation that should have been included are:

- What conventional HIV testing services are available to our target users? To what extent do they take advantage of these services and what are some possible reasons why everyone who needs HIV testing might not be receiving it / seeking it out?
- Who - if anyone - is currently delivering HIV testing services to our priority populations and who pays for it? Do they have adequate funding? Do they ever make money from providing these services (e.g., private physicians)?
- What are the channels through which HIV testing services are currently delivered (e.g., hospitals, pharmacies, mobile clinics, etc.)? Are our priority population(s) aware of these channels? Are they accessible and affordable?
- What is the availability of related services for counseling, treatment and prevention? Who is providing them and where can they be accessed? For example:
 - » Condoms
 - » VMMC
 - » PMTCT
 - » ARVs
 - » PEP
 - » PrEP

4.3. DESIGNING A DEMAND CREATION CAMPAIGN

Once you have a solid understanding of your intended users and the larger market around HIV testing, you can start designing your demand creation campaign. The major steps in designing a campaign are:

- Identifying target audiences
- Discovery of best practices
- Planning your campaign
- Implementation

4.3.1. IDENTIFYING TARGET AUDIENCES

While most of our discussion so far has been about intended users, there are many potential audiences for demand creation messaging, including:

- **Intended users** / members of priority populations
- **Influencers** who can impact intended users' decision-making about HIVST (partners, friends and family, community members and leaders, peers, faith-based sector, media, including social media influencers, primary care providers, etc.)
- **Distributors** (pharmacists, doctors, CBDs, etc.)
- Policymakers, regulators and funders

You will need to make a decision about how much time, effort and resources to allocate to each of these groups. Ideally, the insight you gained through your consumer and market research will help you evaluate their relative importance in terms of convincing more intended users to take advantage of HIVST and related services.

4.3.2. DISCOVERY OF BEST PRACTICES

Before designing your own demand creation campaign, take a moment to review literature from past programs that addressed similar audiences in a similar market context, and ask if any aspects of their demand creation campaigns could be reused or adapted for your own program. You should feel free to “steal with pride” and copy successful programs if there is reason to believe they will translate to your current market context.

4.3.3. PLANNING YOUR CAMPAIGN

In the following sections, we will review various methods for adapting existing models to your context or - if you can't find a proven model that translates to your context - developing a demand creation campaign from scratch.

When promoting HIVST and related services, it can help to approach the task with the same mindset as a commercial marketer. At the highest level, demand creation strategies can be divided into two categories:

- “Push” strategies that encourage distributors and other influencers to actively promote products and services to the target consumer
- “Pull” strategies that seek to generate demand among consumers.

Your campaigns for HIVST and related services will likely employ a combination of both.

Traditionally, commercial marketers think in terms of the “Ps”: Proposition, Product, Place, Price, and Promotion. An explanation of each of these “Ps” is provided in the table below.

THE 5 “PS” OF EFFECTIVE MARKETING CAMPAIGNS	
Proposition	<ul style="list-style-type: none"> • How can we frame the value of HIVST (and HIV testing in general) in terms our audience will appreciate? Should we focus on convenience? Privacy? The ability to reach underserved populations? Something else? • How can we best frame the value of counseling, treatment and prevention?
Product	<ul style="list-style-type: none"> • How can you inspire confidence in the quality and reliability of HIVST kits? • What counseling, treatment and prevention options are available and are they appropriate for your target audience?
Place	<ul style="list-style-type: none"> • Where will HIVST kits be available? Where will we display our messages? For example, can you place brochures or signs in local pharmacies? Can you coordinate promotional events when mobile services with HIVST kits are in town? • Where can intended users access counseling, treatment and prevention services? Should they be provided with literature when they receive their HIVST kits? How else can you raise awareness?
Price	<ul style="list-style-type: none"> • This guide assumes that HIVST products will be made available free of charge. • Are there costs associated with counseling, treatment and prevention options? Are the costs reasonable for your intended users?
Promotion	<ul style="list-style-type: none"> • What channels are you using to create demand for HIVST and related services (e.g., social media, billboards, events, brochures, etc.) and will the messages resonate with your intended audiences and move them to take advantage of HIVST and related counseling/treatment/prevention services?

In the following sections, we will review each of the P's as they relate to HIVST and related services.

P1: Value Proposition

Demand creation is ultimately about making a promise to the consumer regarding the value of a particular product or service - in this case, HIVST and related services. Commercial marketers refer this as the product or service's "value proposition" or "positioning".

An effective value proposition has the following elements:

- Target (the audience you are addressing)
- Context (the circumstances in which your priority population uses the product)
- Points of Difference (why your product is better than the alternatives)
 - » Emotional (required) – How people experience the product. (e.g., "Knowing your status helps you protect your loved ones" or "HIVST is private and discreet")
 - » Functional (optional) – While it might seem logical to point out the functional reasons why your product is better (e.g., HIVST lets you know your status), for the consumer they are but a means for achieving the emotional experience, and are thus of secondary importance in consumer-facing demand creation communications.

Typically, a positioning statement is constructed as follows: [Target] uses [product] in [context] because [points of difference]

For HIVST, your value proposition might be "[HIV self-testing] offers [married people] a way to check their HIV status [in private], so they can [protect their loved ones]."

Alternately, depending on your audience, you might choose to emphasize the privacy aspect, for instance "[HIV self-testing] offers [incarcerated people] a convenient way to learn their status [without having to leave their facility] so they can [receive necessary services and treatment while in prison]."

Again, the above examples are only suggestions. Your proposition should be informed by the insight you gained from researching your intended users, then validated and refined through subsequent prototyping and testing. You should also be mindful of any local regulations on what, exactly, manufacturers and distributors can say about a health product's benefits.

P2: Product

While the options for HIVST products are relatively limited, we want to make sure to select the most appropriate option for our intended audiences, and that everything we do to promote it presents an image of quality and reliability.

As for counseling, treatment and prevention, we want to present an appropriate range of options for our target audience. For example, some MSM might prefer to receive counseling anonymously via social media rather than attending public support groups.

There are three components to a successful brand:

- **Proposition/positioning** - A clear value proposition that identifies the most compelling and unique benefits of the product or service for the target audience
- **Personality** – 2 to 4 adjectives that define the tone of voice for all brand communications targeting a particular audience. Do you want it to be formal and authoritative? Warm and caring? Honest and discreet?

- **Execution** – Tangible brand elements such as logos, colors, symbols, etc.

All aspects of brand strategy should be driven by consumer insights and present the brand as a solution to whatever problems are preventing the consumer from getting what they need or want.

P3: Placement Strategy

“Place” or Placement Strategy focuses on making products, services, and communications available in places where they will attract consumers’ attention and be convenient for consumers to access.

There are two main dimensions to Placement strategy:

- **Making products and services available.** Simply distributing HIVST kits and making counseling, treatment and prevention services available to your intended users can be a challenge, depending on your country’s infrastructure and other practical considerations. That’s why it’s critical to select the most appropriate distribution model(s), practice effective supply chain management and create effective linkages to support services.
- **Making products and communications visible.** Consumers in nearly all markets are exposed to an increasing amount of marketing messaging. Your challenge is to place your products and communications in areas where they will catch the consumer’s attention among everything else competing for their attention, both in terms of HIV testing/treatment/prevention, and in general.

To determine appropriate placement, we should ask:

- Where does the target consumer typically go in a day? Can we make products available or display communications in their workplace or in the neighborhoods where they live? What types of events do they attend, and could we sponsor them?
- Specifically, where do consumers go for products or services related or similar to HIV testing? Do they visit a clinic or pharmacy when they are feeling sick? Do they visit brothels? Can we make HIVST kits and/or communications available in those places, and can we educate the staff to “push” HIVST kits towards intended users?

P4: Price

While this guide assumes that HIVST kits are being made available to intended users free of charge, we still want to ensure that adequate incentives are in place for stakeholders involved in the distribution and/or promotion of HIVST to do their jobs.

Price might also be an issue when it comes to counseling, treatment and prevention options. We want to make sure that we are in a position to provide effective yet reasonably priced options for all our target audiences. For instance, PrEP might be less affordable than condoms for adolescents, and incarcerated people might have very few options for support and treatment.

P5: Promotion Strategy

Now that you have determined your Proposition, Product, Price, and Placement strategies, you are ready to move on to the most intensive part of the demand creation process: Promotion. Promotion strategy involves designing marketing materials that engage and motivate your target audience and distributing the marketing materials through the most effective channels. Before

you begin working on your Promotion strategy, review past promotional campaigns for HIVST in similar markets, if possible. Copying successful campaigns that worked for a similar target audience in a similar context can greatly improve your chances of success.

The standard steps for developing a promotion strategy include:

1. Develop communications objectives and key messages
2. Develop a campaign strategy and produce communication assets
3. Identify priority channels
4. Consider pre- and post- communication testing
5. Implement the communication/ promotional campaign

4.3.4. DEVELOPING COMMUNICATIONS OBJECTIVES

A communications objective states how your promotion strategy will support your intervention objectives. For example, a communications objective for a safe water brand might be to make consumers more aware of the risks of dehydration, or of water-borne pathogens.

For HIVST, we might want to make intended users aware that they can find out their HIV status in the privacy of their home (or wherever they might live), without having to visit a clinic or risk public exposure (again, this is just an example: the objectives you develop for your target audience could be different).

Communications objectives often relate to:

- Driving awareness of a product, service or behavior
- Educating the target audience about a product, service or behavior

- Convincing the audience to use a product/service or adopt a behavior
- Shaping attitudes and perceptions of a product, service or behavior

Identifying the “Call to Action”: A communications program will typically have one core objective or “call to action” representing the action that you want the target audience to take in response to the communication. In the case of HIVST, we typically want the target audience to acquire and use an HIVST kit or take advantage of counseling, treatment or prevention services.

Developing Key Messages: Next, think about the key messages you need the consumer to take from your communications. What is the most compelling message that you could tell your audience? What will convince the target audience to take the desired action? You should test your messages up front, to check they are relevant and compelling to your target audience. This can be done through the Prototyping process described later in this section or more formal research.

A key message:

- Is the idea or belief that the target consumer should retain after she is exposed to the communication piece,
- Is not necessarily the actual text that will appear in the communication piece, but a summary of what that text should convey,
- Will be used again in the creative brief to describe the core idea upon which the advertising agency (or internal creative department) will build their concepts,
- Should be single-minded and focused. Remember, the audience may not have a long time to digest the message (depending on the channel), so it is important to create a key message that is easily understood and immediately compelling.

Apply the insights you gained from researching your intended user / target audience to develop your key message.

Examples of possible HIVST messages might include:

- HIVST is convenient and can be used anywhere
- HIVST is private and confidential
- HIVST lets you know your status, and knowing your status protects the people you love
- [For providers] HIVST should be offered as an additional approach to conventional HIV testing
- With proper treatment, millions of people live long and fulfilling lives with HIV
- U=U, People infected with HIV who are virally suppressed cannot sexually transmit the virus to others.
- Practicing safer sex can dramatically reduce risk of HIV infection
- VMMC is a highly effective way to lower your risk of HIV acquisition
- PrEP is a highly effective way to lower your risk of HIV acquisition

Branded vs. Generic Communications:

Communications and promotion campaigns can be branded or generic (i.e., promoting HIVST in general, without any reference to a particular brand). This choice will depend both on the program objectives and the brand's credibility with the audience.

4.4. IMPLEMENTATION OF DEMAND CREATION CAMPAIGNS

4.4.1. ENGAGING KEY PARTNERS

Even with the best materials and a generous marketing budget, there is only so much you

can accomplish without the buy-in and support of other stakeholders. Efforts should be made to strengthen advocacy amongst those who can potentially influence programmatic implementation and consequent scale-up including government officials, healthcare providers, community leaders and leaders of faith-based institutions.

Involving these groups in initial ideation sessions or inviting them to participate in promotional events can help secure their buy-in and support for the campaign.

4.4.2. EVALUATION

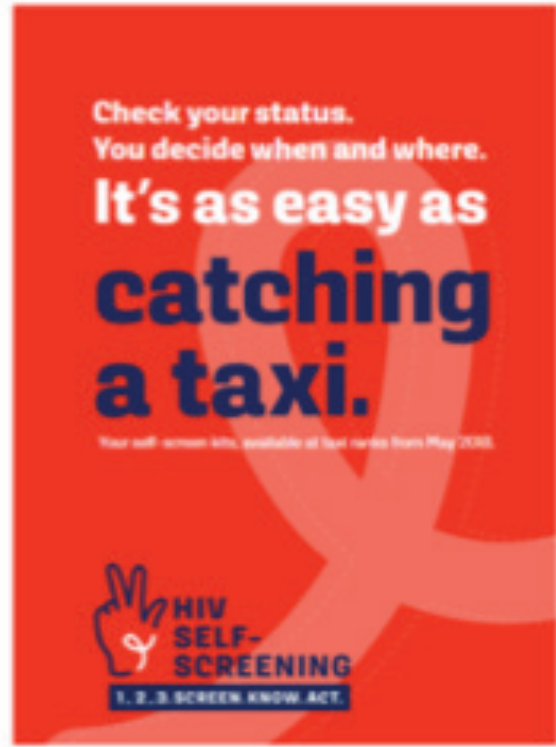
You will want to evaluate the effectiveness of your communications campaign through various methods including:

- Qualitative studies (focus groups) help you find out how well the communications assets impacted individuals.
- Quantitative studies (surveys) give you performance scores against key indicators. These surveys can often be conducted/collected at the point of distribution.

If budget and scheduling allow, you might want to conduct pre-testing to ensure the effectiveness of your materials with a limited audience before rolling out the full campaign.

Regardless, you will need to conduct post-testing will help you find out how effective your campaign has been in delivering services and products to the target audience. Based on the results, you may need to refine your messaging and materials before launching the next campaign.

Examples for Communications Campaigns:



5. MONITORING AND EVALUATION

Monitoring and evaluation (M&E) are a critical part of any public health intervention, including HIVST. The M&E framework has a core function as part of the implementation process to ensure that the program is proceeding as planned; it provides routine information for decision making at all levels; and help to highlight areas where there are challenges or unexpected delays so that these can be identified and resolved quickly.

Regular reports of program performance are required by donors and government representatives and other stakeholders on a pre-determined schedule in order to keep all relevant partners informed about progress and any necessary changes to the initial roll-out plan and in the HIVST models chosen to reach the priority populations. However, in order for the system to function effectively, it is crucial that the right indicators are chosen for monitoring to ensure that data is reflective of the actual status of operations, that there are mechanisms for collecting reliable figures on a routine basis, and that review and checking processes are in place to ensure consistent data quality.

The main goal for HIVST is to reach populations who remain undiagnosed and to link them to treatment and care services. First, all reactive HIVST results need to be confirmed through further testing by a trained provider. Then, those confirmed HIV-positive are linked to care. For those who test HIV-negative but face ongoing risk of HIV infection, HIVST may facilitate periodic HIV testing and linkage to effective prevention options. HIVST monitoring may require data collection across this HIVST delivery cascade, including:

1. HIVST kit distribution
2. HIVST use and results
3. linkage to appropriate services following HIVST.

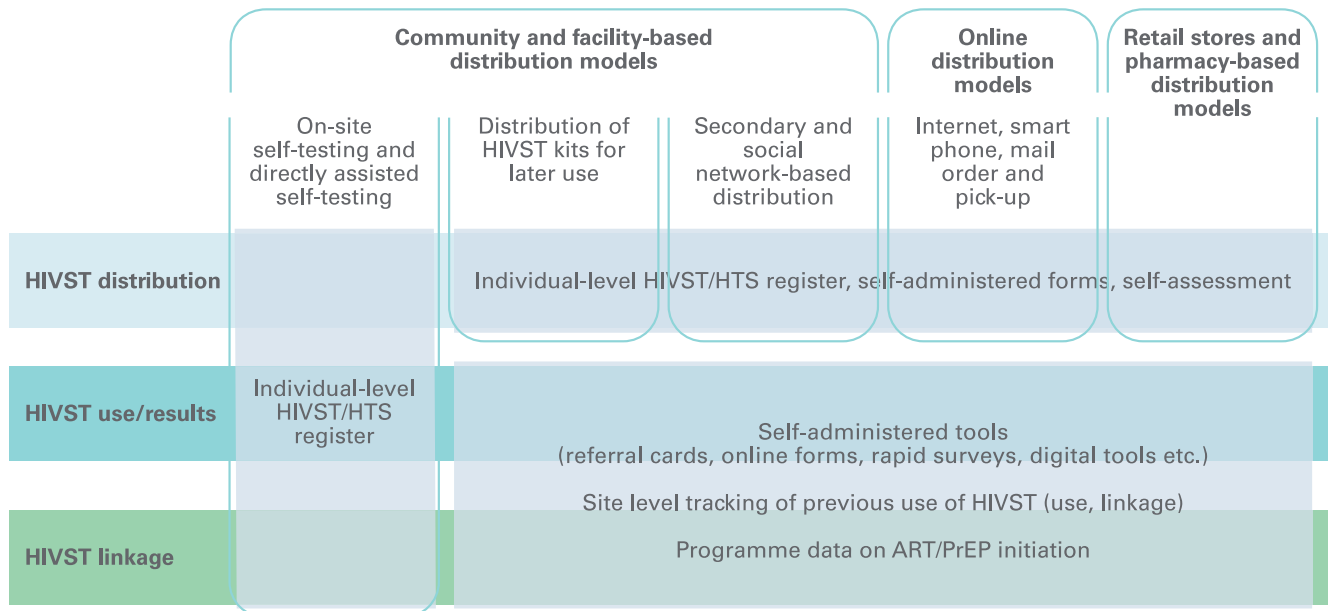
In standard facility-based HTS or when HIVST is offered in a facility or supervised by a provider in the community or online, appropriate linkage can be provided in a single visit or testing session. However, for many HIVST models, HIVST use and linkage are not likely to happen immediately after HIVST kit distribution or in the same place. This leads to challenges for routine data collection to track the progression from HIVST kit distribution through use, initial test result, confirmatory testing and linkage. Despite such challenges, there are pragmatic ways that program can collect M&E data, depending on local context and distribution model.

5.1. M&E FRAMEWORKS FOR HIVST

5.1.1. HIVST OBJECTIVES

The key objective of HIVST implementation is to contribute to national and global HIV goals such as the 95–95–95 targets. As outlined in the HIVST Impact Framework (see figure 1), HIVST can have impact on several public health outcomes that guide the different models of HIVST distribution: 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 treatment services and enhance uptake of HIV prevention services by HIV negative self-testers. As a result, HIV-related morbidity and mortality, including the number of new HIV infections, can be reduced, particularly among

Figure 13. Examples of routine data collection for various HIVST distribution models



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 be achieved.

To measure the impact of HIVST, a minimum reliable set of data is required to guide and further optimize HIVST implementation. For each model of HIVST distribution specific indicators will be collected that are outlined in the M&E framework.

HIVST implementers need to develop comprehensive M&E plans to:

- Standardize monitoring and evaluation across the program
- Ensure that the program is doing what it intends to do
- Ensure that all relevant stakeholders are making evidence-driven decisions
- Ensure that the program acts as a platform for future learning.

5.1.2. HIVST INDICATORS

There are a number of established indicators recognized by the WHO and PEPFAR to track the success of HIVST in particular, along with linkage to prevention and treatment. Many of these metrics can be obtained using routine clinic data, specifically:

- **Reach:** Which distribution strategies are most effective for reaching the undiagnosed?
 - » Uptake of HIVST by priority population: adult males, adolescent girls and young women, adolescent boys and young men,
 - » HIV testing coverage among priority populations
 - » HIV testing uptake among index cases following HIVST
 - » Uptake of HIVST among first-time testers

- **Outcome of HIVST: reactive and non-reactive (negative) HIVST** (can be collected with directly assisted, on-site HIVST and via direct follow up with the self-tester (if HIVST was conducted off-site) or the recipient of the HIVST for secondary distribution (pregnant and post-partum women, who receive HIVST for partner or index clients, who received HIVST kits for distribution among their sexual contacts).
- **Linkage to HIV care following HIVST:**
 - » Uptake of confirmatory testing (can be measured if self-testing is incorporated in clinic data or through direct follow up of HIV Self-test users)
 - » Level of ART initiation following an HIVST (needs to be standardized, per clinic/day ideally)
- **Linkage to Prevention Services, VMMC and PrEP uptake following HIVST**
 - » Uptake of VMMC services following HIVST
 - » Uptake of PrEP services following HIVST
- **Process:** Measuring different steps in the distribution and linkage processes for each of the distribution models to identify bottlenecks to ensure fidelity of the planned HIVST service delivery approaches.

The following table summarizes the indicators used for the different HIVST distribution and linkage models described above:



HIVST DISTRIBUTION MODEL	INDICATOR (* = WHO/PEPFAR REQUIRED)	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
All HIVST distribution models	Number of HIVST kits distributed*	N: Total number of HIVST kits distributed	<p>Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population, if collected.</p> <p>Disaggregated by testing history (last test in the last 3 months, last 12 months, never tested for HIV before HIVST)</p> <p>Disaggregated by approach (e.g., community-based, facility-based, secondary distribution (key partner, index case, male partner);</p> <p>Type of sites (e.g., 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)</p>	Routine program data based HIVST registers filled during HIVST kit distribution (for example, using tablet- or paper-based collection tools)PEPFAR Monitoring, Evaluation and Reporting Indicator Reference Guide
Targeted Community-based HIVST Distribution and other models of HIVST distribution including private/public partnerships	<ol style="list-style-type: none"> Percentage of HIVST users with reactive results Percentage of HIVST users with reactive results, confirmed HIV positive Percentage of HIVST with confirmed positive results initiated on ART 	<ol style="list-style-type: none"> D= Total number of HIVST used by priority population followed up N= Number of HIVST users who have a reactive/ non-reactive test result of those followed up D= Total number of HIVST users who have a reactive test result of those followed up. 	<p>Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population, if collected.</p>	Self-reported outcome data based on follow up Routine program data based HIVST registers and individual client data forms filled during HIVST kit distribution and follow up (for example, using tablet- or paper-based collection tools)

HIVST DISTRIBUTION MODEL	INDICATOR (* = WHO/PEPFAR REQUIRED)	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
		<p>2. N= Number of HIVST users who have a reactive test result and have received confirmative HIV testing by a provider of those followed up</p> <p>3. D= Total number of HIVST users with confirmed HIV positive status</p> <p>3. N= Number of HIVST users confirmed positive and started on ART</p>		
HIVST integrated with HTS outreach and fixed site	<p>1. Percentage of HIVST users with reactive results</p> <p>2. Percentage of HIVST users with reactive results, confirmed HIV positive</p> <p>3. Percentage of HIVST with confirmed positive results initiated on ART</p> <p>4. Percentage of HIVST users of total clients tested for HIV through outreach and fixed site HTS.</p>	<p>1. D= Total number of HIVST used by priority population followed up</p> <p>1. N= Number of HIVST users who have a reactive/ non-reactive test result of those followed up</p> <p>2. D= Total number of HIVST users who have a reactive test result of those followed up.</p> <p>2. N= Number of HIVST users who have a reactive test result and have received confirmative HIV testing by a provider of those followed up</p> <p>3. D= Total number of HIVST users with confirmed HIV positive status</p> <p>3. N= Number of HIVST users confirmed positive and started on ART</p>	Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population, if collected.	Routine program data based on HIVST registers and individual client data forms filled during HIVST kit distribution and follow up (for example, using tablet- or paper-based collection tools)

HIVST DISTRIBUTION MODEL	INDICATOR (* = WHO/PEPFAR REQUIRED)	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
		<p>4. D= Total number of individuals tested for HIV.</p> <p>4. N= Number of clients tested through HIVST</p>		
Facility-based direct distribution	<p>1. Percentage of HIVST users with reactive results</p> <p>2. Percentage of HIVST users with reactive results, confirmed HIV positive</p> <p>3. Percentage of HIVST with confirmed positive results initiated on ART</p> <p>4. Percentage of HIVST users of total clients tested for HIV at public sector health facilities.</p>	<p>1. D= Total number of HIVST used by priority population followed up</p> <p>1. N= Number of HIVST users who have a reactive/ non-reactive test result of those followed up</p> <p>2. D= Total number of HIVST users who have a reactive test result of those followed up.</p> <p>2. N= Number of HIVST users who have a reactive test result and have received confirmative HIV testing by a provider of those followed up</p> <p>3. D= Total number of HIVST users with confirmed HIV positive status</p> <p>3. N= Number of HIVST users confirmed positive and started on ART</p> <p>4. D= Total number of individuals tested for HIV at facility.</p> <p>4. N= Number of clients tested through HIVST</p>	Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population, if collected.	Routine program data based on HIVST registers and individual client data forms filled during HIVST kit distribution and follow up (for example, using tablet- or paper-based collection tools)

HIVST DISTRIBUTION MODEL	INDICATOR (* = WHO/PEPFAR REQUIRED)	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
Facility-based secondary distribution	<ol style="list-style-type: none"> 1. Percentage of pregnant and post-partum women accepting HIVST for distribution to their partners 2. Percentage of partners of pregnant and post-partum women testing with HIVST kit. 3. Percentage of partners of pregnant and post-partum women using HIVST kit, with reactive result. 4. Percentage of partners of pregnant and post-partum women with confirmed HIV positive status. 5. Percentage of partners of pregnant and post-partum women with confirmed HIV positive status initiated on ART. 	<ol style="list-style-type: none"> 1. D= Total number of pregnant and post-partum women 1. N= pregnant and post-partum women accepting HIVST for distribution to their partners. 2.2.D= Total number of partners of pregnant and post-partum women offered HIVST by their partners. 2. N= partners of pregnant and post-partum women testing with HIVST kit. 3. D=Partners of pregnant and post-partum women using HIVST kit 3. N= Number partners of pregnant and post-partum women using HIVST kit, with reactive result 4. D= number partners of pregnant and post-partum women using HIVST kit, with reactive result 4. N=Number partners of pregnant and post-partum women with confirmed HIV positive status 5. D=Number of partners of pregnant and post-partum women with confirmed HIV positive status 		

HIVST DISTRIBUTION MODEL	INDICATOR (* = WHO/PEPFAR REQUIRED)	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
		5. N=Number partners of pregnant and post-partum women with confirmed HIV positive status initiated on ART		
Secondary Distribution ICT	<ol style="list-style-type: none"> 1. Percentage of index clients accepting HIVST for distribution to their partners 2. Percentage of partners of index clients testing with HIVST kit. 3. Percentage of partners of index clients using HIVST kit, with reactive result. 4. Percentage of partners of index clients with confirmed HIV positive status. 5. Percentage of partners of index clients with confirmed HIV positive status initiated on ART. 	<ol style="list-style-type: none"> 1. D= Total number of positive index clients offered HIVST for their partners. 1. N= index clients accepting HIVST for distribution to their partners. 2. D= Total number of index clients offered HIVST by their partners. 2. N= Number of index cases testing with HIVST kit. 3. D=Number of Partners of index clients using HIVST kit 3. N= Number of partners of index clients using HIVST kit, with reactive result 4. D= number of partners of index clients using HIVST kit, with reactive result 4. N=Number of partners of index clients with confirmed HIV positive status 5. D=Number of partners of index clients with confirmed HIV positive status 	Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population, if collected.	Self-reported outcome data based on follow up Routine program data based HIVST registers and individual client data forms filled during HIVST kit distribution and follow up (for example, using tablet- or paper-based collection tools)

HIVST DISTRIBUTION MODEL	INDICATOR (* = WHO/PEPFAR REQUIRED)	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
		5. N=Number of partners of index clients with confirmed HIV positive status initiated on ART		
Demand Creation and linkage to HIV Prevention	1. Percentage of potential VMMC/PrEP users mobilized accepting HIV self-test kit 2. Percentage of potential VMMC/PrEP users mobilized using HIVST kits, accessing VMMC/PrEP services	1. D= Total number of individuals mobilized for VMMC/PrEP. 1. N= Number of mobilized clients taking up HIVST 2. D=Total number of HIVST users (of those mobilized) 2. N= Number of mobilized HIVST users accessing VMMC/PrEP.	Disaggregation by: age (10–14, 15–19, 20–49, 50+ years), sex and key population, if collected.	Self-reported outcome data based on follow up Routine program data based HIVST/ VMMC/PrEP registers and individual client data forms filled during HIVST kit distribution, VMMC/PrEP service delivery and follow up (for example, using tablet- or paper-based collection tools

The following table summarizes the indicators commonly used with various distribution models.

INDICATOR	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
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
Number of sites distributing HIVST kits	N: Total number of sites distributing HIVST kits	Disaggregated by geography, private sector and public sector	National program data Manufacturer and Pharmacy Council data
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)

INDICATOR	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
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)
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)
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)
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)
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

INDICATOR	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT METHOD AND ISSUES	SOURCE
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
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
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)

5.2. DATA COLLECTION AND MANAGEMENT

Once you have identified which indicators to track (specific to distribution models implemented, outcome, output and the impact to be achieved), you will need to integrate data collection into your implementation plan.

General guidelines for data collection include:

- Collect data as close to the source as possible to ensure accuracy
- Ensure data is entered correctly
- Review Standard Operating Procedures (SOPs) for data collection with all staff assigned to enter data
- Implement systems checks such as data format checking, edit validations, and mandatory checks to prevent invalid data from being entered
- Enter only the minimum amount of personally identifiable information necessary for program activities
- Maintain data in a secure environment and only transmit through secure methods
- Limit the number of persons and entities granted access to identifiable data

5.2.1. DATA COLLECTION TOOLS

During HIVST implementation, it is important to integrate HIVST monitoring into existing tools and monitoring programs. For instance, some testers may have been previously diagnosed with HIV and some may already be on ART. Revising national HIV testing and ART registers to include an additional column for HIVST is a simple way to streamline HIVST monitoring and the reporting of uptake. Questions on HIVST can also be included in special surveys, such as in a demographic and health survey (DHS) or in integrated bio-behavioral surveillance (IBBS).

Additional HIVST-specific monitoring and reporting tools may be needed, such as providing distributors with tablet- or paper-based tools to collect data on people receiving HIVST kits across various service delivery points. For instance, when distributing self-test kits a client data card or HIVST register can be used to determine who is accessing HIVST.

Surveys conducted by telephone or through apps or short messages are feasible options in some settings to estimate HIV positivity and linkage following HIVST, as indicated in the M&E indicator table for the different distribution models.

See examples of HIVST Data collection tools in the Annexes.

5.2.2. DATA MANAGEMENT, REPORTING AND QUALITY ASSURANCE

When collecting information on HIVST indicators it is important to ensure quality. Routine quarterly reviews should be conducted to ensure the accuracy of any data collected. Below find a suggested workflow for data collection and quality assurance:

- Collection
- Verification
- Revision
- Approval
- Reporting

Data will typically be collected by HIVST distributors and counselors, then collated and verified by field officers/senior counsellors and verified further by M&E officers. The program manager and M&E manager will work with other executive stakeholders and technical experts to analyze data and prepare reports.

Reporting

Your M&E team should report monthly on:

- The number of people issued with HIVST kits by model
- The number of people tested with HIVST
- The number of people who tested reactive and linked to care and treatment services
- The number of people who tested non-reactive and linked to HIV prevention services, e.g. PrEP.
- The number of males who test non-reactive and are linked to VMMC services

Providing this information (along with narrative interpretation) to key stakeholders on a monthly, quarterly and/or annual basis as appropriate to enable them to assess progress made against routine indicators and make informed decisions. An example of a monthly data report such as this is linked at the top of this section.

Data Quality

You should develop a robust data quality assessment plan to verify the quality of the data; assess the system that produces that data and develop action plans to improve both quality of data as well as the system that produces it if there are any concerns.

Recommended data quality activities include:

- Routine data quality checks as part of ongoing supervision
- Initial and follow-up assessments of your data management and reporting system
- Strengthening program staff's capacity in data management and reporting
- Conducting formal data quality audits on a quarterly basis to identify and address weaknesses within your data collection and reporting systems.
- External assessment by partners of the quality of data

Data quality audits should be done regularly to confirm the availability and completeness of source documents. During this process, the reported numbers should be verified against the numbers in the source documents and any discrepancies explained. These activities can be conducted by your own team or external auditors (budget permitting).

In order to ensure that data integrity is maintained, staff should be trained on data quality. Proper training will ensure that staff is able to identify barriers to data quality and make attempts to avoid them. Staff training should emphasize the importance of good quality data and how staff can contribute to it; individual responsibility regarding data collection, analysis, and reporting; the implications of poor data quality in their area in terms of their own accountability and policies related to data quality on security and data protection.

Improving data quality is a long-term task and should be a priority from the start of the implementation process. Some of the data quality improvement measures which you might need to adopt as part of your implementation process are:

- Changes in data collection forms, harmonization of forms
- Promoting information use at local level, where data is collected
- Developing routines on checking data quality
- Including data quality in training
- Implementing data quality checks in your system

For HIVST programs in particular, 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.

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.

6. CONSIDERATIONS FOR HIVST DURING COVID-19

6.1. HIV TESTING SERVICES IN THE CONTEXT OF COVID-19

The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a major global health threat. It has caused worldwide disruptions, such as economic slow-downs, travel restrictions, interruptions to the global supply of medical, diagnostic and infection prevention commodities, and has severely impacted public health in many countries.

There is limited evidence to suggest that the risk of infection or complications of COVID-19 among people living with HIV (PLHIV) who are clinically and immunologically stable on antiretroviral therapy (ART) may be comparable with the general population. However, people with HIV who are not on ART and those with advanced disease have an increased risk of infection and related complications in general. Moreover, some people with HIV have comorbidities that are known risk factors for the complications of COVID-19, such as lung disease (e.g. due to active or previously treated tuberculosis), diabetes, cardiovascular disease, chronic kidney and liver disease, chronic obstructive pulmonary disease (COPD), certain other noncommunicable diseases and pregnancy. As such, they may be at increased risk for COVID-19 not directly related to HIV.

To control the pandemic and prevent the spread of SARS-CoV-2 infection, many national and local governments are implementing measures such as physical distancing, travel restrictions and stay-at-home orders. Such changes have had important implications, particularly for maintaining health services, including HIV services.

The World Health Organization (WHO) has recently issued key updates, which include information on [HIV, antiretroviral therapy and COVID-19](#) as well as [operational guidance for maintaining essential health services in response to COVID-19](#). As part of this guidance, **WHO highlights the importance of ensuring continuing access to essential HIV services – including HIV testing services (HTS) and linkage to prevention, treatment and care services** – in all settings. These include areas where there is community transmission and measures of physical distancing and restricted movement are being implemented within the public health response to the COVID-19 pandemic.

During this time, it remains critical to **support people with undiagnosed or untreated HIV to get tested and linked to ART**. While access to HTS followed by linkage to care must be maintained, evidence-based measures need to be implemented for both clients and providers to reduce possible transmission when adapting services. These include environmental surface cleaning, practicing hand hygiene and respiratory hygiene such as the use of face masks, and physical distancing measures. Additionally, for health-care workers and providers, including lay and community workers, it is essential to practice infection prevention and control (IPC) measures and use appropriate personal protective equipment (PPE) when delivering services. Maintaining existing HTS with these measures and at current scale is challenging for many settings, however, and innovative strategies and tools are urgently needed.

6.2. HIV SELF-TESTING IN THE COVID-19 CONTEXT

Since 2016, WHO has recommended HIV self-testing (HIVST) as a safe, accurate and effective way to deliver HTS and to reach people who may not otherwise get tested. Given the possibility that general health services may be overburdened due to the number of patients with COVID-19, as well as reduced access to HIV services in many settings, HIVST – whereby a person who wants to know their status collects their specimen (oral fluid or blood), performs a rapid test and interprets their result – has many advantages.

First, HIVST provides a way to maintain access to HTS while adhering to physical distancing guidance and helping to reduce the number of people attending and in need of HTS in health facilities. Following HIVST, those with a reactive result can be directed to appropriate service sites and tools, including confirmatory testing, ART access and support. Self-testers with a non-reactive result may also benefit by avoiding an unnecessary health facility visit and reduce the risk of exposure to SARS-CoV-2. People at high ongoing HIV risk may also be able to utilize HIVST as a way to test more frequently and as part of their ongoing HIV prevention efforts, such as those taking pre-exposure prophylaxis (PrEP). It is important to strategically implement HIVST, **prioritizing geographical settings, clinics and populations** with the greatest need and where there are gaps in testing coverage.

Second, implementation of HIVST can be easily adapted to the COVID-19 context. It can be used in facilities and community settings, and test kits delivered through the Internet, mail-order systems and the private sector. Strategies include personal use of HIVST kits, as well as secondary distribution of HIVST kits to a sexual or drug-injecting

partner among PLHIV and social contacts among key populations. In some high HIV burden settings, pregnant women may also provide HIVST kits to their male partners. Where access to facility-based testing is limited due to COVID-19, several programmes are evaluating the use of HIVST as a way to maintain PrEP programmes and caregiver testing for children (≥ 18 months of age) of people with HIV (e.g. an approach that is not self-testing, but whereby a parent, guardian or community outreach worker uses an HIVST kit to provide follow-up HTS).

As the COVID-19 response evolves, countries and programs will need to be flexible and adapt to specific contexts and epidemics. Thus, this guide provides key considerations for implementing and monitoring implementation of HIVST in the COVID-19 context and illustrates this with country examples and experiences.

While many countries have developed and are implementing HIVST policies, **several countries have yet to fully introduce HIVST**. Considering this new context and the effect of COVID-19 on individuals, communities and health systems, countries should **urgently overcome policy and regulatory barriers to HIVST implementation and enable widespread access to HIVST**. Such efforts are key to ensuring the continuity of HTS and access to prevention, treatment and care services, which are public health priorities, and are critical to global goals to achieving and maintaining low HIV incidence by 2030.

BRIEF REFERENCE GUIDE: HIV SELF-TESTING (HIVST) IN THE CONTEXT OF COVID-19

<p>When should HIV self-testing (HIVST) be used in the context of COVID-19?</p>	<p>HIVST continues to be a safe, effective and acceptable HIV testing approach. As part of the COVID-19 response, it is an important tool and acceptable way to maintain access to HIV testing services (HTS) while adhering to physical distancing guidance and efficiently triaging HTS clients seeking services at health facilities. It is critical to use HIVST where there is access to further confirmatory testing and linkage to prevention, treatment and care services.</p>
<p>Which are the populations that should be reached with HIVST specifically in the COVID-19 context?</p>	<p>Priority populations in need of access to HIVST will vary by context. While wide-scale access to HIVST may be beneficial for physical distancing and for reducing client volumes at facilities, it remains critical to reach those at ongoing risk, such as:</p> <ul style="list-style-type: none"> • key populations¹ and their partners, who may not be able to access HIV • testing services routinely or as frequently as needed; • sexual and drug-injecting partners of a person with HIV; • people with HIV-related symptoms; • individuals in high HIV burden settings who are sexually active and have not tested in the past 12 months.
<p>What does adequate HIVST service delivery require and what needs to be considered in the context of COVID-19?</p>	<p>Demand creation/mobilization: adapted, user-centred communication and demand creation tools that increase awareness and demand among priority populations should be available. These engage with key stakeholders and also provide information about COVID-19 and its potential risks for PLHIV who are not on treatment.</p> <p>Testing process: distribution is either direct (offered to the client who will use it) or indirect (secondary distribution) and should be largely unassisted to reduce in-person contact with the provider. Adequate information and demonstration videos should be provided through the social media or user-friendly inserts. Self-testers may have the option to test on-site at a facility or take the test kit home.</p> <p>Linkage: tools that support testers' links to information, counselling, treatment and/or prevention after a self-test should be available. Linkage information should be updated to inform clients about health facilities that provide safe services, which might require booking and scheduling due to COVID-19. Tools should allow the</p>

1. WHO defines key populations as: men who have sex with men, people who inject drugs, people in prison or closed settings, sex workers and transgender people.

	<p>tester to opt-in, use the highest level of technology available to the target population (e.g. phone, Internet, smartphone), offer the option of speaking to a human and allow for direct community follow up, and protect the privacy and confidentiality of the self-testing experience.</p> <p>Tools should not pressurize self-testers to disclose their test results nor compromise the privacy of the testing experience. Linking self-testers who test off-site is more challenging, so innovative follow-up approaches might be required, such as calls, SMS, WhatsApp contact, or community outreach.</p>
<p>What HIVST approaches can be applied in the context of COVID-19?</p>	<ul style="list-style-type: none"> • Facility-based direct distribution of HIVST kits and drop-off sites at health facilities • Secondary distribution through PLHIV to their sexual or drug-injecting partners, pregnant women to their male partners, and social, sexual or drug-injecting contacts of key populations • Pick up or purchase at kiosks, pharmacies or vending machines • Internet or mail-order system (e.g. e-commerce) • Integrating HIVST into SARS-CoV-2 testing and COVID-19 contact tracing and/or screening at facilities or community settings <p>Due to disruptions in services following the COVID-19 pandemic, some countries are evaluating:</p> <ul style="list-style-type: none"> • HIVST use in PrEP programmes. While HIVST is not being promoted over HTS, when available, it is important to carefully consider and monitor implementation. • caregiver HTS, whereby a parent, guardian or community outreach worker uses an HIVST kit to provide follow-up HTS for children of PLHIV. While this approach is not self-testing, high HIV burden countries considering this approach will need to carefully monitor implementation.
<p>Where and how can HIVST kits be procured?</p>	<p>There are currently four WHO-prequalified HIVST products, including both oral fluid- and blood-based rapid diagnostic tests. These are available at: www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en.</p> <p>All manufacturers have local distributors at country level in selected countries in Africa, Asia and Latin America through whom HIVST kits can be locally purchased at affordable prices. A list of local distributors can be obtained from each of the manufacturers. HIVST kit orders can also be placed directly with the manufacturers or through the procurement mechanisms of major donors, e.g. PEPFAR and the Global Fund.</p>

How should HIVST outcomes and impact be measured and reported?

Several indicators are recognized by WHO and PEPFAR for monitoring HIVST and are available at: www.who.int/hiv/pub/self-testing/strategic-framework/en. Many of these metrics can be obtained using routine clinic data.

In the context of COVID-19, it might be necessary to adapt data collection processes to limit the time of direct interaction between the provider and the beneficiary. Additional process indicators may be useful to also identify bottlenecks in implementation and to ensure fidelity of the planned HIVST service delivery approaches.

COVID-19: coronavirus disease 2019; HIVST: HIV self-testing; HTS: HIV testing services; PEPFAR: US President's Emergency Plan For AIDS Relief; PLHIV: people living with HIV; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

6.3. POPULATIONS THAT MAY NEED INCREASED ACCESS TO HIVST

HIVST should be offered to selected groups of populations who are at increased risk of HIV infection and have the greatest need for testing coverage, as well as in areas where there are gaps in coverage.

The table below outlines the populations that may need increased access to HIVST and for whom there is evidence that HIVST can improve HIV testing coverage and consequently linkage to care, treatment and prevention. There may be other groups of populations, depending on the country context and specific testing and ART gaps.

Populations in need of increased access to HIV self-testing and considerations regarding COVID-19

PRIORITY POPULATION	RATIONALE	DISTRIBUTION DURING THE COVID-19 PANDEMIC
Key populations (i.e. men who have sex with men, people who inject drugs, sex workers, transgender people and people in prison)	HTS coverage is disproportionately low among key populations globally. Maintaining and increasing HTS coverage among key populations is critical to preventing new HIV infections and achieving low incidence.	Delivering HIVST kits through virtual online distribution with home delivery or delivery at drop-off sites, social networks or distribution through peers, free distribution at pharmacies or retail outlets that are accessible during the COVID-19 pandemic or health facilities and drop-in centres that reach key populations represent excellent opportunities for HIVST distribution. In settings where PrEP is being disrupted by COVID-19, HIVST with close monitoring can be considered to maintain services.

PRIORITY POPULATION	RATIONALE	DISTRIBUTION DURING THE COVID-19 PANDEMIC
Men	<p>Worldwide, HIV testing coverage and knowledge of HIV status among men living with HIV is substantially lower than among women. Men in southern Africa and from key population groups are an important population to reach.</p> <p>Men have lower rates of health-care utilization in general. This reduces their opportunities to test for HIV through routine services.⁴³</p>	<p>Several HIVST access points could be considered for reaching men during the COVID-19 pandemic, especially those offered through secondary distribution, by sex workers to their clients, female partners who access health facilities or who access pharmacies where HIVST kits are offered through promotions.</p> <p>Men can also be reached through workplaces and the private sector, including pharmacies and the Internet. Internet-based and mail-order delivery of HIVST may be options in many settings.</p>
Couples and partners, including partners of people with HIV	<p>Couples and partner HIV testing, particularly for sexual and drug-injecting partners of PLHIV, is highly beneficial but under-implemented.</p>	<p>Offer HIVST to PLHIV for secondary distribution.</p> <p>This offers an opportunity to integrate HIVST distribution within adapted ART distribution at community level (3–6 months – WHO recommendation in the COVID-19 context). This is currently implemented in several countries.</p>
Pregnant and postpartum women in high HIV burden settings	<p>Offering HIVST during this heightened period of HIV risk has increased couples and partner testing in studies conducted through STAR and is currently being scaled up in most countries that have adopted HIVST as part of their testing programs.</p>	<p>Provide HIVST kits to pregnant women to encourage their male partners to test. Countries implementing maternal retesting can also consider providing HIVST kits to implement retesting in late pregnancy or in the postpartum period. Such approaches should be prioritized for high HIV burden settings or for women living with HIV or with a partner from a key population.</p>
Adolescents and young people (aged 15–24 years)	<p>Approximately one third of new HIV infections in the world occur among young people in southern Africa.</p> <p>Young key populations are especially vulnerable to and affected by HIV.</p> <p>For adolescents and young adults, their status as dependents can limit their ability to consent or pay for HIV services or generate fears of social and economic marginalization from families.^{44, 45}</p> <p>Concerns around implicit revelation of sexual debut and stigma and discrimination from health-care providers can also limit uptake.⁴⁶</p>	<p>Virtual online distribution with home delivery or delivery at drop-off sites and free distribution at pharmacies or retail outlets that are accessible during the COVID-19 pandemic or drop-off distribution at health facilities represent excellent opportunities for young people to access HIVST kits.</p>

ANNEX 1. SUMMARIZING HIV SELF-TESTING IN THE CONTEXT OF COVID-19

- **HIVST models suggested in the context of COVID-19. Strategic facility-based testing remains an important HTS approach and should be continued with appropriate precautions.** HIV testing using rapid diagnostic tests at facilities can provide same-day results and facilitate prompt initiation of ART or relevant prevention services to clients.
 - Facilities and other fixed health services sites continuing to offer HIV testing and HIVST services should develop standard operating procedures and implement standard precautions. These include triage, early recognition and source control (isolating patients with suspected SARS-CoV-2 infection/ COVID-19); adequate ventilation; maintaining the recommended physical distance among patients and providers; correct and consistent cleaning and disinfection procedures; and appropriate use of personal protective equipment (PPE) by health-care workers and other providers.
 - Clients seeking HTS at facilities can be given HIVST kits for use within the facilities or for later use to reduce facility burden and minimize contact with health-care workers.
 - In high HIV burden settings, HIVST kits can be given to women presenting for antenatal care (ANC) so that they can provide a kit to their male partner.
 - People with HIV can be provided with HIVST kits to distribute to their sexual and/or drug-injecting partners.
 - Key populations, whether HIV-positive or HIV-negative, can be provided HIVST kits to distribute to their sexual and/or drug-injecting partners, peers or social contacts.
 - People taking pre-exposure prophylaxis (PrEP) can be given HIVST kits where access to routine facility-based HTS is limited to prevent disruption of services.
 - Consider easy-to-access HIVST kits and other prevention materials (condoms, lubricants and relevant educational materials) for distribution in pre-packaged bags at health-care facilities or outside in proximity of health-care facilities for clients to take to minimize contact.
 - Consider the use of digital tools for delivering pre-test information and post-test counselling, including videos, social media, applications and other media.
- HIVST kits can be **targeted and distributed through community-based fixed sites** or through mobile or community outreach. However, **community-based, mobile and outreach distribution models** should be **managed with great caution and adapted** to comply with national authorities' recommendations on physical distancing. The frequency of community or outreach visits, number of clients participating in outreach sessions, contact tracing associated with partner services and pattern of participation (e.g. staggered to minimize contact) can be adapted depending on the local context. Additionally, consider the use of social networks for HIVST distribution among key populations (with appropriate caution to clients on physical distancing when distributing HIVST kits) to maintain community-based HTS. HIVST kits can be provided to HIV-positive clients to distribute to their sexual and/or drug-injecting partners.
- **HIVST availability through online platforms.** Making HIVST kits available to clients through online platforms (websites, social media, digital platforms) and distribution through mail can be a particularly attractive option in the context of the COVID-19 pandemic, ensuring ongoing access to HTS. HIVST kits through this model typically come at a price to clients; however, efforts should be made to provide kits to those in need for free or at an affordable price.
- **Availability of kits through retail outlets, pharmacies and vending machines.** Availability of HIVST kits through retail outlets, pharmacies or vending machines can ensure ongoing access to HTS in settings where restrictions on movement are being implemented. Efforts are needed to ensure supply at an affordable cost and through innovative financing initiatives such as through public-private partnerships and distribution of coupons or vouchers to those at increased risk.

All programmes using HIVST, as with standard HTS, need to ensure that confirmatory HIV testing is available for those with a reactive test. This is essential for diagnosing and treating all people with HIV. Access to HIV prevention, such as condoms and lubricants, and PrEP should also be assured where possible for those provided HIVST kits. Information and access to other sexual health services will continue to be important, including contraceptive services. Special attention and provisions for key populations and other populations vulnerable to both HIV and COVID-19 will need to be considered and supported.

Support package and tools for HIVST

In collaboration with civil society organizations, countries and programmes can develop a support package and tools that accompany HIVST kits. Some tools that can be considered to support correct HIVST usage and facilitate linkage to HIV confirmatory testing (if needed) and care in the context of the COVID-19 pandemic are as follows:

- standard, manufacturer-provided instructions for use (and local adaptations or translations where appropriate) and manufacturer-provided telephone hotline or other customer support;
- virtual real-time support through online platforms (such as messaging, social media, videos);
- new digital, social media, clear print media and video or messaging platforms tailored for different audiences (such as young persons, key populations). These may be readily acceptable, especially to young people.

Considerations for successful HIVST implementation

- **Develop simple, clear and supportive policies, regulations and standard operating procedures** and disseminate them to distribution sites and providers. These should ensure the registration and availability of quality-assured HIVST products and adequate post-market surveillance. The most up-to-date list of WHO-prequalified HIVST kits can be accessed on the WHO website at: www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en
- **Empower and effectively engage communities** in developing and adapting HIVST delivery and support models, including information about where people can link to further testing for diagnosis and ART services. The meaningful participation of community members and people from key populations in HIVST services in the context of COVID-19 can also be ensured using **virtual platforms and simple, clear print media**.
- **Create messages and communication strategies for dissemination of HIVST with key stakeholders, including communities and civil society organizations**. It is important to ensure that messages and materials provide accurate information and raise awareness about HIVST, minimize misuse and eventual harms in relation to HIVST, and offer information on ways of reporting and addressing complaints and adverse events through the national post-market surveillance system. **It will be important for these messages to also provide correct information on COVID-19 and address misinformation and myths at the community level**. Community action plans may be an important tool to develop and utilize.
- **Ensure that messaging reinforces the fact that a positive HIVST result does not confer a positive HIV diagnosis** until a confirmatory test is conducted, which also yields a positive result.
- **If possible, offer a choice of HIVST service delivery options and the type of test kit** (such as kits using oral fluid or blood).

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