

HIV SELF-TESTING (HIVST)

IMPLEMENTATION MANUAL FOR DELIVERY OF DIRECTLY ASSISTED HIV SELF TEST SERVICE IN ETHIOPIA



FEDERAL MINISTRY OF HEALTH

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Executive Summary

Inadequate uptake of testing for HIV remains a primary bottleneck toward universal access to treatment and care as well as an obstacle to realizing the potential of new interventions for preventing HIV infection, including treatment for pre-exposure prophylaxis (PrEP).

HIV self-testing (HIVST) is a process whereby an individual conduct his or her own HIV test using a simple oral (nationally recommended) or blood-based test. It is an emerging approach that provides an opportunity for people to test themselves discreetly and conveniently, thereby empowering those who may not otherwise test, particularly among high-risk populations to know their HIV status.

HIVST has the potential of being a high impact, low cost intervention to reach population groups that are not testing, and to increase the number of people living with HIV who are identified and initiated on treatment. HIVST also provides an opportunity to provide linkages to HIV prevention services for those who test negative. Approaches to HIVST include community and facility based. Regardless of the approach applied, the testing model may either be directly-assisted by a provider or unassisted. Currently, we have been on the way to implement the directly assisted model of HIVST primarily using community-based approaches.

FMOH Ethiopia has been using different approaches and strategies for HIV testing in order to increase uptake of HTS. HIVST is one of the recommended innovative case detection strategies; and findings from the pilot implementation demonstrated its effectiveness in identifying HIV infection among the key and priority population groups. The coordination of HIV self-testing services will be a multi-faceted and multi-level activity that spans the national and lower level structures and needs to be done in line with the existing coordination mechanism.

These implementation manual outlines the programmatic approaches to HIV self-testing, describe the package of support services required under HIVST, describe commodity management system requirements and outline coordination mechanisms for HIVST. They also outline quality assurance strategies, and monitoring and evaluation for HIVST.

Forward

The current HIV epidemic in Ethiopia is a low intensity, mixed epidemic type with significant

heterogeneity across population groups and geographic areas. According to EDHS 2016, the

national HIV prevalence is estimated to be 0.9%. The 2018 HIV spectrum estimates and

projection show that there are an estimated 649,264 people living with HIV. New infections in

2018 were estimated at 13,488 while AIDS related-deaths during the same year were estimated

at 13,556 of whom approximately 3,600 were children.

In Ethiopia, HIV Testing Services (HTS) have been provided for decades with strong attention

from the government and partner organizations as these services are important entry points to

all other HIV prevention, treatment, care and support interventions. Recognizing this, FMOH

has been implementing different approaches and strategies for HIV testing to increase uptake of

HTS. HIVST is one of the recommended innovative case detection strategies and found to be

effective in identifying HIV infection among the key and priority population groups.

The development of this HIV self-testing implementation manual for innovative case finding

strategy to improve HIV testing among key and priority population has undergone multiple

consultations and continuous involvement of Federal Minister of Health and experts with

creditable contribution of partner organization in Ethiopia. Hereby, I would like to acknowledge

the experts for their outstanding contributions towards the realization of this implementation

manual. The Federal Minister of Health also owes appreciation to the core writing group who

developed the initial working document, reviewed and developed the final document and led

the overall development process.

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OPERATIONAL DEFINITION

HIV Testing Service: is the whole service package that enable provision of pre and post-test information/ counseling, rapid HIV testing with determination of final status to clients. It includes different modalities- provider-initiated, self-initiated, integrated/ targeted.

HIV self-Testing (HIVST): this is a process of HIV testing in which an individual collects his or her specimen (Oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting either alone or with someone he or she trusts.

Directly assisted HIVST: refers to when individuals who are performing self-testing for HIV receive an in-person demonstration from a trained provider 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 and only use an HIVST kit with manufacturer-provided instructions for use.

HIV status: is 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: is the immediate result from a single test on a given assay. It is not possible to tell ones HIV infection using one HIV test result.

Non-reactive results: It means that the test indicates that HIV antibodies were not found in the blood or oral fluid sample. Anyone whose result is non-reactive to a rapid HIV test (including a self-test) does not need further testing but should be supported to re-test after three months if they have had a recent potential HIV exposure or are at on-going HIV risk.

Reactive results: It means that the test indicates that HIV antibodies are present in the blood or oral fluid sample. Anyone whose result is reactive to a rapid HIV test (including a self-test) must be followed by additional HIV testing services by a trained provider following the national HIV testing algorithm. Furthermore, self-testing users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos. This is confidently performed when there is adequate awareness and knowledge about HIV testing among the beneficiary community.

Window period: is the period between HIV infection and the early detection of HIV1/2 antibodies using serology assays, which marks the end of the diagnostic window period and the end of seroconversion. It is the early time of HIV infection when existing HIV testing kits cannot detect or show infection. It is the first 6-12 weeks of HIV infection.

Community care/support provider: is a person who is responsible for the HIV self-testing demand creation, kit distribution, counseling and assisting the client before, during and after self-testing, recording and referral/linkage of a tester. This can be trained community health care providers, health extension professionals, peer educator, peer navigator, peer supervisor, community resource person or community mobilizer.

Index testing: often referred to as index case, index patient or index partner HIV testing. This is a focused HTS approach in which the household, family members (including children under 15 years) and partners of people diagnosed with HIV are offered HIV Testing Service (including self-testing). However, children are not eligible for HIVST.

I. Background and Rationale

Along the progress over the HIV epidemic control, thirty years ago, HIV testing was one of the few interventions available to people living with HIV with limited benefits in the absence of treatment. Today, however, due to the extensive scale-up of HIV test—and-treat approach, knowing one's HIV status is a first step toward HIV prevention, care and treatment resulting in healthy life. consequently, this shift has resulted in tremendous progress toward controlling the epidemic.

According to the UNAIDS 2017 report, 36.9 million people live with HIV globally among which

- 75% of people living with HIV knew their status.
- 79% of people, who knew their status, were accessing treatment.
- 81% of people accessing treatment, were virally suppressed.

Despite this tremendous progress and considerable investment, ongoing efforts to increase testing were not reaching all those in need. More than twenty years into the epidemic, even with a large and growing number of HIV tests performed each year, key and priority populations, are still being missed. Key populations and their sexual partners remain disproportionately affected, contributing to nearly half of new HIV infections, but they are still largely unreached, due to fear of stigma and discrimination besides to inaccessibility and unfriendliness of the existing HIV testing service.

The 2016 WHO consolidated guideline on HIV testing service and the supplement on HIVST and partner notification provided guidance in the implementation and scale-up of ethical, effective, acceptable and evidence-based approaches to HIV self- test (HIVST) as a formal HTS intervention using quality-assured products. This will be integrated into both community-based and facility-based HTS approaches and be tailored to specific population groups that will contribute to closing the testing gap and achieving the UN's 90–90–90 targets and 2030 global goals.

As additional HTS approach, HIVST focuses on:

- Increasing acceptability, equity and demand by reaching those undiagnosed key and priority populations and spouse and non-spousal sexual contact of ICT by existing testing services,
- Ensuring cost-effectiveness (or cost-neutrality) and greater efficiencies for health systems and users; avoid unnecessary testing or facility visits
- Helping achieve existing national 90 90 90 targets
 Facilitating linkage to treatment for individual key and priority population who test HIV-positive and providing appropriately tailored prevention for those who test HIV-negative

According to the national HIV Road map in Ethiopia, the key population groups identified are female sex workers (FSW) and prisoners. The priority populations are widowed, separated or divorced women; distance drivers; PLHIV and their partners; mobile and resident workers in hotspot areas. HIV prevalence among FSW in Ethiopia is more than 23 times higher than the general population (EPHI, MARPS Survey, 2014). However, with the existing facility reports and available data, HTS coverage among key and priority populations including spouse and non-spousal sexual contacts of index cases remains low. This indicates that there is still gap in fully accessing these targeted groups by the existing HTS. To close the testing gap and reach high-risk individuals not accessing conventional HTS, HIVST is one of the recommended innovative case detection strategies which is effective in identifying HIV infection among these groups as revealed in the pilot period.

Ethiopia piloted HIVST among key population (FSW) in 2016-2017 under the USAID-funded MULU/MARPs HIV Prevention Project. Findings of the evaluation of the pilot indicated that HIVST is highly acceptable among FSW. It attracts new testers, showing that 18% of the self-testers were new. In addition, the finding of the pilot supports that HIVST can increase access of HTS to key populations and helps to reach the UNAIDS 90-90-90 goals, particularly reaching the first 90. FSW value both facility-based and community-based HIVST approaches; however, the pilot evaluation indicated that 18% of the participants prefer to conduct HIVST at home, 8% prefer at clinics/ private/ public facilities and the rest (74%) prefer community-based, i.e., Drop-In Centers (DICs).

The second approach of HIVST that WHO recommends is unassisted HIVST. Even though it is not currently implemented in Ethiopia, the ministry has planned to pilot unassisted HIVST at selected sites in the current fiscal year (2012 EFY).

1.1 Objectives

The general objective of this implementation manual is to provide guidance on HIVST service scale up at national level in order to maximize case detection and treatment uptake.

The specific objectives are:

 To enhance access of HIV testing among key and priority population who remains undiagnosed by providing alternative innovative HIV testing options

- To facilitate linkage of those who are tested positive to conventional HTS algorithm to confirm the diagnosis and to care and treatment based on their diagnosis.
- To implement and scale-up HIVST at national level

1.2 Target audience

The target audience for this manual are:

- Health care workers including counselors, pharmacy personnel, HEPs, community care/support providers
- Health program managers, Heath planners and researchers,
- Organizations involved in HTS commodities procurement, supply management and service delivery,
- Recipients of care- including PLHIV associations, and
- Those who involve in supporting the HIVST planning, implementation, monitoring and evaluation of HIVST

1.3 Guiding principles

The national HIV testing service align with a public health and human rights-based approach that highlights priority areas, including universal health coverage, gender equality and health-related human rights such as accessibility, availability, acceptability and quality of services.

For all HTS, regardless of approach, the public health benefits must always outweigh the potential harm or risk. Moreover, the main reasons for testing must always be to benefit the individuals tested and to improve health outcomes at the population level. HTS should be expanded primarily to provide access for all people in need to appropriate, quality HTS, which is linked to prevention, treatment and care services. HIV testing for diagnosis must always be voluntary, and consent for testing must be informed by pre-test information.

When the HIVST is considered as additional approach to the national HTS to reach those not accessing conventional HTS, there are concerns and risks/ miss-uses anticipated for which mitigation and close follow up are needed. Although no substantial evidences observed globally, the following anticipated concerns and worries are to think of with self-test.

- Wrongly taking HIVST as final diagnosis,
- Relentless use/ or miss use of HIVST by unintended population groups,
- Understanding and believes/ myths on HIV self-testing,
- Emotional and social consequences of those self-tested and knew their positive statusself-harm, anti-social/ revenge,
- Limited ways of bringing those self-identified HIV reactive clients to status confirmation and finally care and treatment (linkage),
- It might be difficult to monitor the proper use of HIVST kit and proper interpretation of results, including mandatory confirmation,
- Difficult to monitor distribution and utilization of HIVST kits

HIVST implementation shall follow balancing the above- mentioned concerns and the following key factors:

- Prevalence of undiagnosed HIV cases in key and priority populations and high prevalence geographical areas,
- Uptake of HIVST by high-risk groups to identify people with undiagnosed HIV,
- Uptake of HIVST among new couples and couples in long-term relations,
- Number of HIVST kits distributed compared to tested reported positive during the specific period,
- Lower cost of delivering HIVST to key and priority populations, spouse and non-spousal sexual contact of index and geographical settings compared to cost of existing tests provided at health facilities,

2. Implementation Approach

In Ethiopia, HTS for key and priority populations strive to serve unreached populations through evidence-based targeted interventions tailored for each population group. The current approach for HIVST delivery to reach different target populations will be with the direct assistance from trained community care/support providers. The community care/support

providers will directly assist self-tester by providing the information and demonstration and assisting before and during the procedure and interpretation of result, i.e., the assistant will automatically be aware of self-identified reactive client for linkage to confirmatory test at conventional testing site.

Unmonitored distribution of HIVST kit without demonstration and direct assistance to clients on result interpretation is strictly- prohibited to avoid loss of self-identified reactive cases before confirmation and linkage to care & treatment.

The directly assisted HIVST approach will be implemented by a combination of Community and facility-based distribution taking the sexual networks reached through index case testing (ICT) approach.

Community-based distribution through DICs and Community based organizations:

- Different groups of KPPs and their sexual networks can be addressed through community care /support providers based at community centers/ DICs or home-tohome
- Widows and divorced women can be addressed through HEPs, community health workers
- Youths engaged in risk behaviors can be addressed through the youth center clinics.

Facility-based distribution through community care/support providers working for KPP friendly services in public health facility:

• Sero-discordant couples, partners and partners of ANC/ PMTCT clients, can be addressed through community care/support providers.

Therefore, an in-person demonstration before and during HIVST on how to perform the test and interpret the test result is provided by a trained community care/support provider.

Eligible population group for HIVST are:

- FSW and their partners,
- Sexual partners and networks of index cases
- Long distance truck drivers and their assistances
- Daily Laborer, mobile workers

- Index families and spouse/ discordant (children not included for HIVST)
- Widowed/ divorced/ remarried
- Partners of PMTCT/ANC clients
- Vulnerable adolescents and youth clients (18- 24)

2.1 HIV Self-Testing Package

The HIVST package is the whole service package for self- test including making standard rapid test kit available, procedure for HIVST, Information for users, the referral linkage and finally the monitoring process.

2.1.1 Standards and procedure

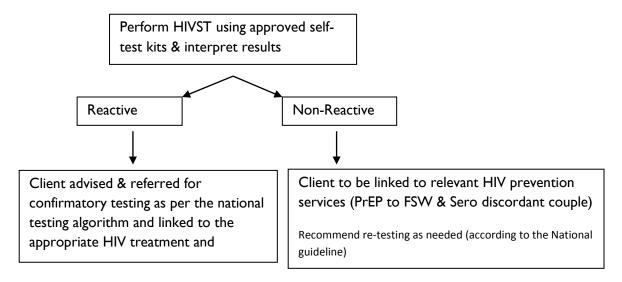
HIVST must be conducted using the nationally approved HIV rapid self-test kit(s). The kit(s) will include instructions in English and local language as well as pictorial diagrams to aid ease of use and correct interpretation of results. All HIVST kits should be distributed must also be accompanied with client education material.

All service delivery points where HIV self test is conducted should display illustrations or instructions on HIVST procedures should a tester require further explanation or testing support. In addition, all outlets must have a separate, private space to perform the test. The assistant will provide pretest information, demonstration and interpretation of the result with possibility of linkage to conventional test for confirmation based on the test result.

Individuals with non-reactive self-test results, the assistant should advise the self-tester to retest as per their risk to HIV infection as outlined in the national HTS guideline retesting recommendations.

If the HIVST test result is reactive, the assistant should link the self tester to conventional HIV testing for confirmation, where the approved national HIV testing algorithm is utilized. And the assistant will also follow whether the confirmation test performed and whether the client is enrolled to ART if test result turns out to be positive.

Figure 1. HIVST Flow chart



A reactive HIV self-test result always requires additional HIV testing according to the national HIV testing algorithm

2.1.2 Information package

When providing HIVST, the following information should be included:

- ✓ The general instructions on how to use the test kit, with demonstration of the procedures that includes:
 - How to perform while undertaking the test
 - How to interpret the test results
 - What to do after reading the results, including information on available post-test services, such as counseling, further testing and care and treatment
 - How to safely dispose of the used test-kits
- ✓ The ethical and legal obligations, such as that no one should test a third party without their consent
- ✓ Be aware that HIVST is NOT recommended for people who are already taking ARV drugs, because rapid HIV tests (including HIVST) may give false negative results as antibody levels may be lower when people with HIV are on ART.
- ✓ Be informed that some information will be required to facilitate documentation and accountability of the kits, assuring any information provided will be treated confidentially.

✓ HIVST shall not be implemented at facility level. The facility works as means of distribution channel only.

The HIVST kit shall be accompanied with the following information education materials.

- Manufacturer's instructions for use (IFU)
- Information Brochure in local language, pictorial presentation on steps to do and interpret the results,

And for the client who performs the assisted HIVST, the following provisions shall be available:

- Brief in-person demonstration (one-on-one or group) before testing And also, in-person assistance during procedure
- Demonstration using wall charts on the procedure and result interpretation
- And if available and Video show on the test procedure before testing

All clients of HIVST shall be provided with the following information at the point where they can access the test kit and before they perform the test. HIVST is provided by trained person (health care provider, Health extension professional, community service provider) who is expected to ensure clients have understanding on the following information:

- Purpose of the Self-Test
- Plan if a Test result is non-reactive (negative result):
 - When to retest
 - Prevention service packages available
- Plan if a Test result is reactive:
 - Confirming the positive result
 - Referral linkage to HIV treatment
 - Partner and family testing

2.1.3 Partner Notification and Disclosure

- Clients should be informed about the potential health benefits of disclosing their HIV status to significant others and also encourage them to accept assisted self-test prior to receiving their self-testing kits. This information should be included in the clients' information pack.
- Clients with reactive HIVST results should be encouraged to visit a conventional HTS service point with their partners for further testing for confirmation of screening result

as per the national HTS testing algorithm and receive supported disclosure. Clients whose test result is non-reactive should also be encouraged to disclose their status to their sexual partners and encourage their partners to know their HIV status through use of HIVST kits or a visit to an HTS service point.

 Health care providers should assess for possible social harm and/or violence following disclosure, such as intimate partner violence, and provide guidance and referral as appropriate.

2.1.4 Referral and Linkage

In addition to identifying the best approach for delivering HIVST, programs/ implementers need to consider how to facilitate linkage to prevention, treatment and care following HIVST.

Linkage strategies following HIVST:

- Proactive, community-based follow-up by trained community care/support providers
- Assistance and /or accompanied referral to confirmatory testing service of clients who are reactive for HIVST to conventional HTS facilities
- Appointment cards and referral slips given to clients may facilitate linkage by including the day and time of an appointment or the name and phone number of a contact person and facility where services can be sought.
- Use of video step-by-step instructions on HIVST and what to do following a reactive self-test
- For additional information the clients can contact Hot lines (952) on linkage to HTS, prevention and treatment services
- Mobile phone text message services to provide information, reminders and linkage messages

3. HIV Self-Testing Promotion and Communication

To create awareness and increase utilization of HIVST, advocacy and communication strategies should aim to emphasize on correct usage of the self-test kits, and ensure correct interpretation of results and create awareness on the need for linkage for additional testing

(confirmation), HIV prevention, care and treatment. These can be enhanced through the following communication strategies:

3.1 Healthcare providers

- Orientation of healthcare providers on directly assisted HIVST as an additional strategy for increasing access for HTS. This can be done through implementation manual dissemination, off/ on site training, IEC materials, etc.
- Integration of Directly assisted HIVST into existing programs like ART, PMTCT, HTS (VCT/PITC), and key population programs. Although the HIVST is not performed in the health facilities, health care providers do link eligible clients for HIVST assisted by community care/support providers.
- Encouraging healthcare providers to advocate for use of HIVST to increase testing among ART, PMTCT clients, partner testing and key populations

3.2 Target groups/ prime clients

Sensitization and awareness creation among KPPs who are undiagnosed and cannot access the conventional HTS in healthcare settings is taken as the prime activity with directly assisted HIVST approach. This can be done through one on one or group approach by trained community care/support providers, organizing campaigns/social forums/medias and infotainment events according to their specific contexts.

3.3 Community education and Demand Creation

This include involvement of networks of people living with HIV and community-based organizations/actors is critical in order to increase the uptake of self-testing and minimize the misuse. It is also important to communicate to providers that HIVST can serve as a tool to create demand for existing services and, thereby, enhance their role in delivering HTS. Information tools such as brochures, job aids can also be useful in increasing understanding and raising awareness.

The demand creation on HIVST to the specific target group will be conducted by community care/support providers. In addition, service providers at DIC & public facilities will provide information on HIVST kits to social and sexual networks of index cases. FSW who are diagnosed HIV positive at community, DICs or public health facility and clients who attend ART

clinics who request for HIVST service for sexual partner(s) might take BCC materials for demand creation among target groups.

The use of in-person demonstrations and other support tools, such as video demonstrations and printed procedures, will be used to enhance the performance of HIVST. Manufacturer's instructions and brochures, brief in-person demonstration (one-on-one or small group) before testing, pictorial/written guide on the procedures and package inserts can be applied.

4. HIVST Kits distribution Channels

The HIVST distribution channels will include community and facility-based to different target groups. Unlike the community-based distribution channel where both the distribution and service are provided at the site. Facility based distribution serves only as a means of HIVST kit distribution i.e. **HIVST service delivery should not be performed in the health facility.**

Community based

Integrated with Community outreach, Ider

HIVST Distribution Channels

Facility based

Integrated with KP friendly public health facility

Figure 2. HIVST kits distribution Channels

Facility based Distribution

When it meant by facility level distribution, KP friendly service providing HF will provide HIVST kits from the facility Pharmacy store to community level FSW peer navigators to provide HIV self-test for willing female sex workers at their living / working areas. This will be done by moving community workers from KP facilities to hotels, bars youth centers, development

schemes etc; where FSWs work/ reside and the approach helps us to test more FSWs because the number of FSW willing to visit health facility for HIV test is very low.

The HIVST kits available at KP facility will be used by community care/support providers for community level testing for FSW, and their social and sexual networks as an alternative testing option. This approach can be used among elicited partners of index cases where community care/support providers collect the kit from HFs and provide assisted HIVST in the community up on the preference and convenience of clients.

Community providers accessing HIVST kit from KP friendly public health facility shall keep basic documentation of the self-testers including HIVST result and referral.

Figure 3. Facility-based Distribution Implementation Flow chart

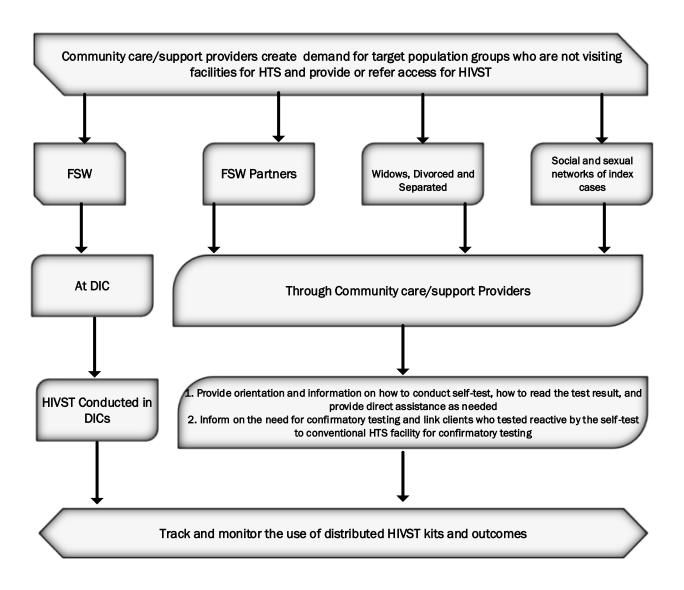
Health care Providers at ART/PMTCT/VCT/KP friendly service Elicit potential eligible for HIVST among their clients, provide information on availability of HIVST through community care/support providers near their vicinity Refer/ Link identified partners of indexes, eligible FSW and their partners to respective community care/ support providers for HIVST at their community Direct provision of HIVST kit to community care/ support providers Community care/support providers give information and direct assistance on conducting HIVST, and interpreting of test result Refer/link to conventional HTS for confirmation and ART service if the result is reactive on HIVST If the result is non-reactive and the client is on substantial risk refer/link to PrEp

- Document basic information from HIVST clients
- Track and monitor the use of distributed kits and outcome reporting

Community based Distribution

Community distribution will be done by community level health service outlets like DICs or community service points (LIPs serving in the communities). These community service outlets conduct community-based demand-creation for high-risk target populations who are not visiting health facilities for HTS through community care/support providers.

Figure 4. Community distribution for scaleup flow chart



5. Supply Chain Management for HIVST

This represents the set of practices that must be coordinated to ensure that appropriate, high quality supplies are available whenever and wherever they are needed. It requires proper coordination and management of commodities in order to ensure availability and utilization of the kits. All the HIVST kits used in the country shall be WHO pre-qualified and validated for use in-country in order to maintain the quality of self- tests and results. The HIVST kits must be registered as per the national procedures, validated through EPHI standards and supply chain management. Like any other pharmaceuticals, the storage and distribution of HIVST kits shall follow the national system. After kits are procured, a proper distribution plan must be done at all level. This will make the monitoring of HIVST test kits easier. Parallel to this, service delivery outlets must have reports on the amount of kits distributed to beneficiaries.

6. Quality Assurance

While delivering HIVST services to clients, it is recommended that quality assurance for HIVST products be integrated into existing monitoring, assessment and quality improvement processes. Having qualified, trained staff that perform and monitor the quality of HIVST and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. All HIVST service providers should be trained per the HIVST training package. The safety, quality and performance of HIVST should be further verified upon delivery and before distribution to the target groups. The procurement agency must ensure that any new shipments and lots of HIVST test kits coming into the country are evaluated to ensure that products delivered meet criteria for quality and performance.

7. Coordination

FMOH

- Lead the development of HIVST strategic guidance, Standard operational procedures, training materials and implementation manuals.
- Coordinates the implementing partners who provide HIVST services at all levels.
- Ensure availability of WHO approved and nationally validated test kit in the country.

- Follow the implementation process of HIVST service and provide technical guidance.
- Monitor the performance of HIVST
- Generate evidence and utilize evidence for decision making
- Conduct supportive supervision and workshop

EFDA:

- Ensure the registration and importation of WHO approved HIVST kit(s) in the country,
- Monitor the proper storage and transportation of HIVST kits in the country,

EPHI:

- Overall quality assurance in HIVST services
- Test Kit validation and new lot verification
- Conduct post distribution surveillance HIVST test kit

EPSA:

- Incorporate the quantification and procurement of HIVST kit(s) in the national regular procurement process for pharmaceuticals and RTKs,
- Engage in the distribution of the test kits

RHB:

- Cascade the implementation of HIVST using the manual
- Promote HIVST community education and demand creation activities to the target group
- Coordinate the HIVST implementation at all level
- Monitor the implementation progress of HIVST with stakeholders
- Coordinates the implementing partners who provide HIVST services at all levels

PARTNERS and HTS TWG

- Technically support the development of HIVST guidance document, training materials
- Facilitate HIVST demand creation activities to the target group
- Provision of training to service providers and CBDA
- Printing and distributions of distribution & tracking tools
- Conduct supportive supervision with MOH & RHB
- Ensures the provision of quality HIVST services
- Performance monitoring and reporting
- Collect and send report to FMOH

SERVICE PROVIDERS:

- Ensure provision of necessary information on HIVST to clients
- Provision of quality HIV Self testing services
- Commodity management and reporting
- Community mobilization and advocacy
- Provision of referral for follow up confirmatory HIV testing
- Data collection and reporting

8. Monitoring and Evaluation

This section outlines the monitoring and evaluation (M&E) requirements to inform the demand, uptake and utilization of HIVST by the targeted groups. Although the service is provided at different level with different channels, there shall be selected minimum information flowing to monitor the service.

8.1 Indicators for M&E In HIVST

The national DHISTI system shall incorporate the reporting of HIVST service implemented in health care facilities. Until fully integrated into the national DHISTI system, there shall be parallel reporting system for HIVST implementation. Community level HIVST service shall be reported by implementing partners.

As per the national reporting system, HIVST implementing health facilities and community service outlets shall compile basic reports and report to next level, and accordingly the report shall be visible at FMOH level for program monitoring.

The following indicators will be reported to the national level:

- Total number of HIVST service delivery points/ outlets (Disaggregated to entry-point community/ DIC/ work place/ higher institution)
- Total number of test kits issued/ distributed (Disaggregated to channel) /per month or year
- Total number of clients accessed HIVST kits (Population categories) /per month or year
- Total number of persons reporting having done self-testing (Disaggregated to population categories/ entry-point, on-site/ assisted)
- Number of people reporting HIV positive results by HIVST
- Number of people reporting HIV positive results by HIVST accessing confirmation through conventional HIV testing service (HTS) using the national algorithm
- Number of people reporting confirmed HIV positive results through conventional HIV testing service (HTS) using the national algorithm

Other indicators that can be collected at service delivery and program levels:

- Number of persons referred for HIVST by age and gender/ pre-test information provided
- Number of persons offered HIVST by age and gender
- Number of people accessing HIVST by age and gender
- Number of people reporting results (disaggregated to results/outcomes)
- Number of people reporting reactive results accessing confirmation through conventional HIV testing service (HTS) using the national algorithm
- Number of people diagnosed with HIVST and confirmed HIV positive who are linked to treatment

Reporting tools and systems

The following M&E tools shall be developed and available at IVST service delivery point and program coordination level.

- HIV Self- test Register
- HIVST kit distribution tracking logbook
- HIVST activity monthly reporting form/ template

Using the recording & reporting forms, all clients who undergo HIVST services and the number of HIVST kits distributed will be recorded daily and reported on a monthly basis. RHB, implementing partners and program managers will monitor the performance and kit utilization using the monthly reports.

Annex I: HIV Self- Test Register

	1	H	IV	Self	Testing	g serv	ice p	rovisi	ion r	egist	er, d	lraft 20	19	ı	T-
S. No	Clie nt Nam e	Cli ent cod e	Ag e (yr s)	Sex (M/ F)	*Target population category (A/B/C/D/ E/F/G/H)	Inform ation on HIVST provide d (Yes/ No)	HIVS T kit provi ded (Yes/ No)	Self- Test perfor med (on- site/ off- site)	Nam e of assist ant	HIV ST resu lt (R/ NR)	Link ed to HTS for react ive HIVS T resul t (Yes/ No)	Confirm ed HTS result by conventi onal national algorith m	Linke d to PrEP for HIVS T NR (Yes/ No)	If link ed, Stat e id. nu mb er	Rema rks

*Target population category:

- A. FSW
- B. Partners and Sexual networks of FSW
- C. Long distance truck drivers (LDTD) and their assistances
- D. Daily Laborer, mobile workers

- E. HIV negative partners of PLHIV
- F. Widowed/ divorced/ remarried
- G. Partners of PMTCT clients
- H. Vulnerable adolescents and youth clients (18- 24) years old

Annex 2: HIVST monthly reporting template

Monthly reporting template for HIV Self-Testing service

Reporting Month:		
Name of Facility/ community service point:		
Types of population categories serviced:		
		
total number of outlets/ channels:		

	Indicator	Result						
1.	Total number of Self-test kits issued/ distributed							
2.	Total number of persons/clients reported having done self-testing							
3.	3. Total Number of persons/clients reported self-test results							
4.	Total Number of persons/clients reported having reactive self-test result							
	Total Number of persons/ clients reported having reactive result and							
	linked to conventional HIV testing service (HTS) using the national							
5.	algorithm							
	Total Number of clients reported reactive result and confirmed							
	positive through conventional HIV testing service (HTS) using the							
6.	national algorithm							
	Number of people diagnosed with HIVST & confirmed HIV+ who are							
7.	linked to treatment							

Annex 3: HIVST referral slip

HIV Self Testing Referral Slip

Date:						
Region:	Zone:					
Woreda/ Sub City:	Town:					
Referring HIV self-testing Site:	Referred to:					
Age: Sex:	Unique ID No:					
Target Population Category:						
Date HIV Self tested:	Reason for Referral: -					
Feedback Date:						
Region:	Zone:					
Woreda/ Sub City:	Town:					
Name Health Facility:	To: Testing Sit					
Age: Sex: Target Popu	lation Category:					
Unique ID No: MRN						