



Ministry of Health
The Gambia

**OPERATIONAL GUIDELINES FOR THE
DELIVERY OF HIV SELF TESTING IN THE
GAMBIA**

September, 2022



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Suggested citation:

Operational Guideline for the delivery of HIV self-testing in the Gambia, September 2022

Foreword

The Gambia is a small West African country, bounded by Senegal, with a narrow Atlantic coastline. The country stretches approximately 400 km eastwards, and its width varies between 80km at the Atlantic and about 28km in the inland east. The country is divided horizontally by the River Gambia and the total land area is 11,295 square km. The total population in Gambia was estimated at 2.3 million people in 2020, according to the latest census figures and projections from Trading Economics.

The Gambia has made progress in combatting HIV and AIDS since its first detection in the country in 1986 when the Ministry of Health, Labor, and Social Welfare established the National AIDS Control Program (NACP). The first plan developed in 1987 was health-focused and led to the setting up of the National AIDS Control Programme (NACP) within the Ministry of Health. By the mid 1990s, the Government prepared a strategic framework for HIV as part of the National Health Policy (1994-2000) and the National HIV/AIDS Policies and Guideline, and launched programs to fight the epidemic which received support from internal and external development partners. However, the level of funding and coordination were vastly inadequate primarily due to limited visibility of the issue and a lack of commitment and leadership from the political strata till 2000.

In 2001 The Gambia got funding from the World Bank for the implementation of an HIV/AIDS Rapid Response Project (HARRP). Within the framework of this project, a National AIDS Council (NAC) and National AIDS Secretariat (NAS) was established under the Office of the President with The President being the chairman of the NAC. Great strides have been made in The Gambia since 1987 when rapid testing was first introduced, leading to rapid expansion in provision and utilization of HIV counselling and testing services to know their HIV status, to support prevention of mother to child transmission, and to encourage the population to reduce risky behaviour and gain earlier access to treatment, care and support services through the (NAC).

The Gambia can be described as having a generalized HIV epidemic. According to WHO, most generalized HIV epidemics are mixed in nature, in which key subpopulations are excessively affected. In The Gambia, HIV prevalence in the general population was 1.9% among adults (male and female) 15-49 years according to the 2013 DHS. The HIV prevalence in the Gambia is considered low in the general population as it falls below 2%. Geographically, the prevalence ranges from 1.1% in Banjul to 2.9% in Mansakonko (DHS 2013) and with the exception of Banjul, the prevalence of HIV is higher on the south bank of River Gambia. The prevalence among pregnant women attending antenatal clinic, however, was reported as 1.82%, according to the 2017 National Sentinel Surveillance (NSS).

The most recent (2018) Integrated Bio-Behavioural Surveillance Study (IBBS) among female sex workers (FSW) and men who have sex with men (MSM) in the Greater Banjul and neighbouring areas estimates an HIV prevalence among FSW of 11% and MSM 35.5%. The HIV prevalence among FSW has decreased by 4.9 percentage points, from 15.9% in 2011 down to 11% in 2018; whilst it increased more than three-fold among MSM from 9.8% in 2011 to 35.5% in 2018.

In 2018, the Gambia started implementing WHO's recommendation to provide all people living with HIV with lifelong antiretroviral therapy (ART) regardless of clinical status or CD4 cell count. Between 2015 and 2020, impressive progress happened as new infections were cut by half and new infections among children were reduced by 75% (National AIDS Strategic Plan, 2020-2025). All pregnant women attending antenatal clinics are routinely offered HIV tests, and all pregnant women living with HIV are eligible for ART (Option B+). Until the COVID-19 epidemic started, ART uptake had increased significantly. The country also adopted task shifting for HIV/AIDS and malaria—typically enabling nurses to dispense ART and capacitating community health workers to deliver a range of HIV services.

In July 2015, following the recommendation of the World Health Organisation (WHO) in the Consolidated Guidelines on HIV Testing Services, HIV Counselling and Testing nomenclature was changed to HIV Testing Services (HTS). This led to the review of the National Guidelines for HIV Testing Services in 2017, to accommodate the full range of services to be provided together with HIV testing to meet global standards. It also provided innovative strategies to increase uptake of HTS.

With deployment of innovative strategies, HTS coverage has progressively increased from 66% in 2016 to 95% in 2021, thus meeting up with the UNAIDS 90-90-90 targets. However, there is need to increase testing coverage in order to reach hard-to-reach populations and others not currently accessing testing; in particular men, children, partners of people living with HIV, key populations, Internally Displaced Persons, adolescent and young people.

One of the key ways of ensuring quality services provided to all clients accessing health facilities for HIV related services is through operational guidelines to ensure that they are up to date with current evidence and global best practices. This document provides the acceptable standard of service delivery models for effective HTS delivery. It also discusses key updates with a focus on new evidence, new recommendations, good practices and operational considerations that respond to the changing needs of national programs.

The Guideline also offers guidance for HIVST delivery approaches and the various modes of distribution for HIVST and recommends different strategies for the uptake of HIVST. These Guidelines therefore offers all that service providers require to deliver a comprehensive package of high-quality HTS that addresses the needs of individuals at high risk of acquiring HIV infection and the general population.

I therefore endorse and recommend this 2022 National HIV Testing Services Guidelines for use across all the health facilities and service delivery points in the country and also for individuals and organizations involved in HIV and AIDS programmes.

Honourable Dr. Ahmadou Lamin Samateh

Minister of Health

Quadrangle, Banjul

September 2022

Acknowledgments

The Ministry of Health wishes to express gratitude to and acknowledge the invaluable input of several individuals and partners whose efforts and contributions were essential in the production of this document.

Special thanks go to Action Aid International The Gambia in partnership with the Global Fund and UNAIDS for providing technical and financial support.

The Development of the guidelines was led by Lead Consultant Dr. Ali Johnson Onoja and a National Consultant, Dr. Sophie Ndow, who were supported by Sirra Ndow, The UNAIDS Country Director and Mam Kumba Ndow-Sise, The Global Fund Programme Manager ActionAid International The Gambia. We wish to thank them all for their hard work and dedication.

We are also grateful to the following Technical Working Group members who tirelessly worked towards the development of these guidelines:

NO.	NAME	DESIGNATION	INSTITUTION
1.	Dr. Sainabou Mbowe	Clinician	Hands On Care
2.	Jerreh K. Drammeh	Care Nurse	IDC,EFSTH
3.	Sheikh Hatab Tamba	Care Nurse	IDC,EFSTH
4.	Hamadi Sowe	Regional AIDS Cordinator	National AIDS Secretariat
5.	Halimatou Jeseourobo	Senior Nursing Officer	National AIDS Control Program
6.	Ansu Mboob	DIC Coordinator	World View
7.	Dr. Saihou Bah	Clinician	World View
8.	Aisha Babou	Peer Health Educator	World View
9.	Jack Jobe	Peer Health Educator	World View
10.	Modou Lamin Saïdy	Peer Health Educator	World View

Finally, I wish to thank all those individuals and organizations (not listed here) who had contributed to the successful development of these guidelines.

Pa Ousman Bah
Program Manager
National AIDS Control Program, Ministry of Health

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Acronyms

ACTafrica	AIDS Campaign Team for Africa
AIDS	Acquired Immuno Deficiency Syndrome
ARI	Accelerated Results Initiative
ART	Anti-retroviral Therapy
ARV	Anti-retroviral
BSS	Behavioral Surveillance Survey
CAS	Country Assistance Strategy
CBC	Community Birth Companions
CBD	Community-Based Distributors
CBO	Community-Based Organisations
CMU	Country Management Unit
CSO	Civil Society Organisations
DCA	Development Credit Agreement
FBO	Faith-Based Organisations
FM	Financial Management
FMA	Financial Management Agent
GFATM	Global Fund to Fight TB, AIDS and Malaria
GLF	Gambia Local Fund
HARRP	HIV/AIDS Rapid Response Project
HIV	Human Immuno Deficiency Virus
HIVST	HIV Self Test
IDPs	Internally Displaced Persons
IEC	Information Education and Communication
IPV	Intimate Partner Violence
KAP	Knowledge, Attitude, and Practice
KPI	Key Performance Indicator
LIL	Learning Innovation Loans
M&E	Monitoring and Evaluation
MAP	Multi-Country HIV/AIDS Program
MIS	Management Information System
MoBSE	Ministry of Basic and Secondary Education
MoH	Ministry Of Health
MSM	Men Who Have Sex with Men
MTR	Mid-Term Review
NAC	National AIDS Council
NACP	National AIDS Control Program
NAS	National AIDS Secretariat
NGO	Non-Governmental Organization
OI	Opportunistic Infection
PAD	Project Appraisal Document
PDO	Project Development Objective
PHPNP	Participatory Health, Population, and Nutrition Project
PLHIV	People Living with HIV
PMICT	Prevention of Mother-to-Child Transmission
PPF	Project Preparation Facility
PRSP	Poverty Reduction Strategy Paper
PWUDPWUD	People Who Use Injection Drugs.
QER	Quality Enhancement Review
RAC	Regional AIDS Committee
SBCC	Social and Behavior Change Communication
SSS	Sentinel Surveillance Survey
STI	Sexually Transmitted Infection
SWs	Sex Workers
TB	Tuberculosis
TC	Traditional Communicators
TG	Transgender
TTL	Task Team Leader
VHW	Village Health Worker
VSGs	Village Support Groups

Executive Summary

The Operational Guidelines for HIV Testing Services-(HTS) provide a framework and standard for the implementation of HTS in The Gambia. This policy document is a consolidation of the reviewed HTS guidelines of The current National Strategic Plan for HIV (2015-2020).

The effort of The Gambia Ministry of Health is focused towards achieving the UNAIDS 90-90-90 goals by 2030, which aims to ensure 90% of PLHIV know their status, 90% of those who know their status are receiving treatment, and 90% of those on treatment are virally suppressed.

The purpose of this document is to update the National Strategic Plan for HIV on HIV Testing Services to align with the 2020 National Guidelines for HIV Prevention, Treatment, Care and support current trends in HTS. It integrates recent advances in HTS delivery approaches such as Index testing, HIV self-testing, Recency testing as well as other testing technologies of valuable interest

These Guidelines comprise of twelve (12) chapters. Chapter (1) Introduces the document which includes HTS and HIVST; Chapter (2) provides the Guiding principles of HTS; chapter (3) talks about the Service delivery approaches of HTS; chapter (4) gives an overview of HIV self-testing, which includes delivery approaches for HIVST; chapter (5) provides information on Priority population to be considered for the HTS; chapter (6) discusses Demand creation and Pre and Post-test services for HTS; chapter (7) explains Conducting HIV test; chapter (8) Quality assurance for HTS is discussed in this chapter; chapter (9) Human resources for HIV testing service is outlined in this chapter; chapter (10) Logistic management which explains the process and management of HTS commodities; chapter (11) Monitoring and Evaluation for HTS which includes data collection, analysis, reporting and use; chapter (12) concludes the document by providing guidance for HTS Coordination and scale-up.

These guidelines shall be the basis for the establishment, provision, mentorship and supervision of HTS in The Gambia, and will enhance the realization of the UNAIDS global 90-90-90 targets by 2030 as adopted in The Gambia.

Key Definitions

HIV self-testing (HIVST) is a process whereby an individual collects his or her specimen, performs a test, and interprets the results, often in a private setting either alone or with someone he or she trusts. HIVST can be either directly assisted or non-assisted.

Unassisted HIV self-testing refers to an individual obtaining a kit for HIV self-testing and performing the HIV test following the instructions on the test kit insert or other informational resources such as leaflets or telephone helplines.

Directly assisted HIV self-testing - This refers to when individuals who are performing a self-test 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.

Reactive results This is when the test indicates that HIV antibodies are present in the blood or oral fluid sample. Anyone whose result is reactive to an HIV self-test (and any other rapid HIV test) must have additional testing following the approved national HIV testing algorithm, conducted by a trained HIV testing provider.

Non-reactive results This is when the test indicates that HIV antibodies were not found in the blood or oral fluid sample. Anyone whose result is non-reactive to an HIV-self test (and any other rapid HIV test) does not need further testing but should be supported to re-test in an appropriate time frame if they have had a recent potential HIV exposure or are at ongoing HIV risk.

HIVST distributor This refers to someone or an institution (public or private) who is trained to issue HIV self-tests to individuals for free. .

Chapter 1 Introduction

1.1 Background

As of 2018, almost 37.9 million people worldwide were infected with HIV with only 75% of people living with HIV (PLHIV) globally being aware of their HIV status. The Joint United Nations Programme on HIV/AIDS (UNAIDS) responded by developing an ambitious treatment plan to end the HIV/AIDS epidemic. The objective was for 90% of all PLHIVs to become aware of their HIV status, 90% of those be linked to sustained antiretroviral treatment (ART) so that 90% of people receiving ART could achieve viral suppression.

Despite remarkable progress in HIV treatment, annual new infections have hovered close to 2 million globally for several years, with an estimated 1.5 million new HIV infections in 2020 (UNAIDS 2021). Thus, large numbers of individuals including key populations (sex workers, men who have sex with men (MSM), People Who Use Drugs (PWUD and transgender people) remain at substantial risk for acquisition of HIV infection.

HIVST specifically refers to 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 self-testing is acceptable to many users across different contexts and can, therefore, increase uptake and frequency of HIV testing, particularly among populations at high ongoing risk of HIV, who are less likely to access testing or test less frequently than recommended. HIV self-testing can be used by partners of PLHIV as a strategy for Partner Notification Service, or for periodic re-testing in known discordant couples. HIV self-testing can be delivered through various approaches in the public and private sectors, including community-based, facility-based, and internet-based channels. HIVST may be done by an individual alone (unassisted) or with the assistance of a trained provider (assisted).

The Gambia is a small West African country along the Atlantic coastline with an estimated population of 2,273,665, and a human development index ranking of 174 out of 189 countries in 2019. The HIV epidemic in The Gambia like the situation in other West African countries is overall low—less than 2% of the general population—but highly concentrated among key populations such as men who have sex with men and female sex workers. Despite increased outreach activities, the testing coverage remains very low with less than 40% of the estimated PLHIV knowing their status. Inadequate investment in HIV prevention programmes and lack of access to prevention services, especially among key population groups, continue to impede progress in the national HIV response. HIV prevalence has increased more than three-fold among MSM from less than 10% in 2011 to over 35% in 2018 (IBBSS, 2018) and no program have been

designed to accelerate the uptake of pre-exposure prophylaxis as a prevention strategy among MSM.

The HIV-related human rights and gender situation in the Gambia has not improved in the past five years. Key populations suffer multiple burdens of frequent human rights violations, systematic disenfranchisement, stigma, and discrimination. The existence of punitive laws perpetuates barriers to accessing HIV services for key populations and further contributes to their social and economic marginalization. There remain lots to be done on promoting human rights literacy, putting in place mechanisms to monitor and report human rights violations, and advocate for policy reform and sensitization of lawmakers on human rights and gender-related issues.

Developing national guidelines for HIV self-testing (HIVST) has several benefits for the country's HIV response including promotion of the uptake of HIV self-testing for the prevention of new infections and reduction of the burden of HIV among individuals and groups particularly at high risk of acquiring the virus. HIV self-testing can empower individuals who might otherwise be dis-empowered in their lives either due to stigma or lack of access to facilities. HIV self-testing can really help people to take charge of their own lives and hold their destinies in their hands. Guidelines for HIVST will facilitate the effective implementation of the HIVST interventions available in the national response, by public health experts, healthcare workers, community groups and workers with targeted audiences for HIV prevention in the Gambia. It will address the challenges of low level of awareness, demand, and uptake of the HIV Self-testing and PrEP services in the country. HIV testing is an essential gateway to HIV prevention and treatment services.

However, HIV testing uptake remains low among men due to stigma, discrimination, and confidentiality concerns. HIV self-testing (HIVST) is an alternative HIV testing method that can address many of these barriers for men. In West Africa, only about 42 percent of people living with HIV know they have the virus. To meet the UNAIDS target—that 90 percent of people living with HIV know their status by 2030—we must move beyond conventional testing and invest in strategies such as self-testing.

1.2 Overview

In December 2016, WHO released global guidelines recommending partner notification services (PNS) and HIVST as new strategies to reach high-risk and hard-to-reach populations with HTS. HIV self-testing is 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. HIVST can either be assisted or un-assisted.

It is important to know that HIV self-testing is **a screening test and does not provide a definitive diagnosis; rather, all reactive HIVST results need further testing by a health provider, following the national HIV testing algorithm.** A person with a non-reactive result is advised to re-test if they have been exposed to HIV in the preceding

four weeks, or are at an ongoing risk of HIV exposure. It is also advisable they contact an HIV Testing Services (HTS) provider for prevention messages.

1.3 Evidence Base for HIV self-testing

HIV self-tests are available in the U.S. and many countries in Europe, and increasingly throughout sub-Saharan Africa and other parts of the world. Policies supporting HIVST exist in at least 12 sub-Saharan African countries to date, and are under development in at least 9 more (Unitaid and WHO, 2018).

HIV self-testing can improve programme outcomes, including identification of newly diagnosed PLHIV and linkage to care and treatment (Sibanda, 2017; Moore, 2017; Masters, 2016; Choko, 2015). It is cost-effective, and reports of social harms following HIVST are rare (Johnson, 2017; Cambiano, 2015; Mavedzenge, 2017). Studies have demonstrated that HIVST is acceptable and easy to use among different population groups in The Gambia (Tun 2018; Nwozuru et al 2019; NIMR 2019; Durosinmi-Etti et al 2021)

1.4 Benefits

HIVST is innovative strategy to increase uptake of HTS especially for underserved populations and persons who do not access conventional HTS. HIV self-testing has been shown to be acceptable to many diverse population groups in a variety of settings. It can be performed accurately when done with high-quality rapid diagnostic tests. Evidence shows that when it is provided in conjunction with adequate instructions for use and post-test support services, HIVST is also effective at case finding and is an efficient strategy requiring fewer human resources than other approaches.

HIVST has a number of benefits which are summarized as follows:

- Promotes access to HIV testing services, knowledge of HIV status and Pre-Exposure Prophylaxis (*PrEP*) uptake
- May reduce effects of stigma and discrimination by allowing key and vulnerable populations to test in private
- Easy to use with minimal waste generation
- Increases independence and self-sufficiency of HIV testing clients
- Promotes mutual partner testing
- Assures confidence in HIV test results because individuals interpret results on their own
- Convenient; clients can use HIV self-test kits in the privacy of their own home
- Cost free; The HIV self-test kits are free of charge in the Gambia.

Chapter 2 Delivery Approaches

There are many different ways in which HIVST can be delivered. This chapter outlines the different approaches and service delivery channels for HIVST.

2.1 Delivery Approaches

HIVST can be delivered through assisted and unassisted approaches.

a) Assisted Approach

Refers to when individuals using HIVST kits receive a demonstration from a provider or peer before or during HIVST, with instructions on how to perform a self-test and how to interpret result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside HIVST kits.

Note: Providers are not encouraged to perform an HIVST for a client.

b) Unassisted HIVST Approach

Refers to when individuals use HIVST kits without help from a provider or peer, but only using manufacturer-provided instructions. As with all HIVST, unassisted users may be provided with links or contact details to access additional support, such as telephone helplines or instructional videos (*WHO, 2016*).

2.2 Service Delivery Channels

In Gambia HIV self-testing will be delivered in the community and private sector distribution points. However, health facilities will serve as points for secondary distribution as well as avenues for referral and linkage services for persons who are reactive and non-reactive to HIVST.

2.2.1 Community based

In communities, HIVST can reach people who do not access conventional HIV testing services, in particular adolescent and young persons, men, key populations, IDPs, partners of PLHIV, and persons with special needs. Community distributors and peers can provide information and education about HIVST in groups or on a one-on-one basis, distributing kits to clients who express interest. They may target marketplaces, bus or taxi garages, IDP camps or places where target populations congregate. HIV self-testing in communities should focus on high priority populations, high-prevalence geographical areas (hotspots), and populations who have difficulty accessing other services

HIV self-tests can be distributed in the workplace or higher educational institutions, but it should be emphasized that HIVST is always voluntary. Some programmes have paired community-based distribution of HIVST with mobile HTS services, so that trained HTS providers are available to HIVST clients and users in case they need support conducting or interpreting the HIV self-test, or accessing follow-up services..

2.2.2 Private Sector

The private sector plays an important role in HIVST, since many people may choose to access HIV self-test kits on their own through community pharmacies, PPMVs, private clinics, private medical laboratories or other locations. Private sector providers should ensure they are only distributing high-quality HIV self-test kits that have been approved for use in Gambia, and that they provide sufficient information and education to HIVST users about how to conduct and interpret test results, and provide appropriate linkage to enable them access follow-up services.

2.2.3 Facility

Health facilities will serve as points for secondary distribution, and confirmation for reactive HIVST result as well as prevention services for non-reactive persons.

**HIVST kits should not be used as a first-line test for HTS.*

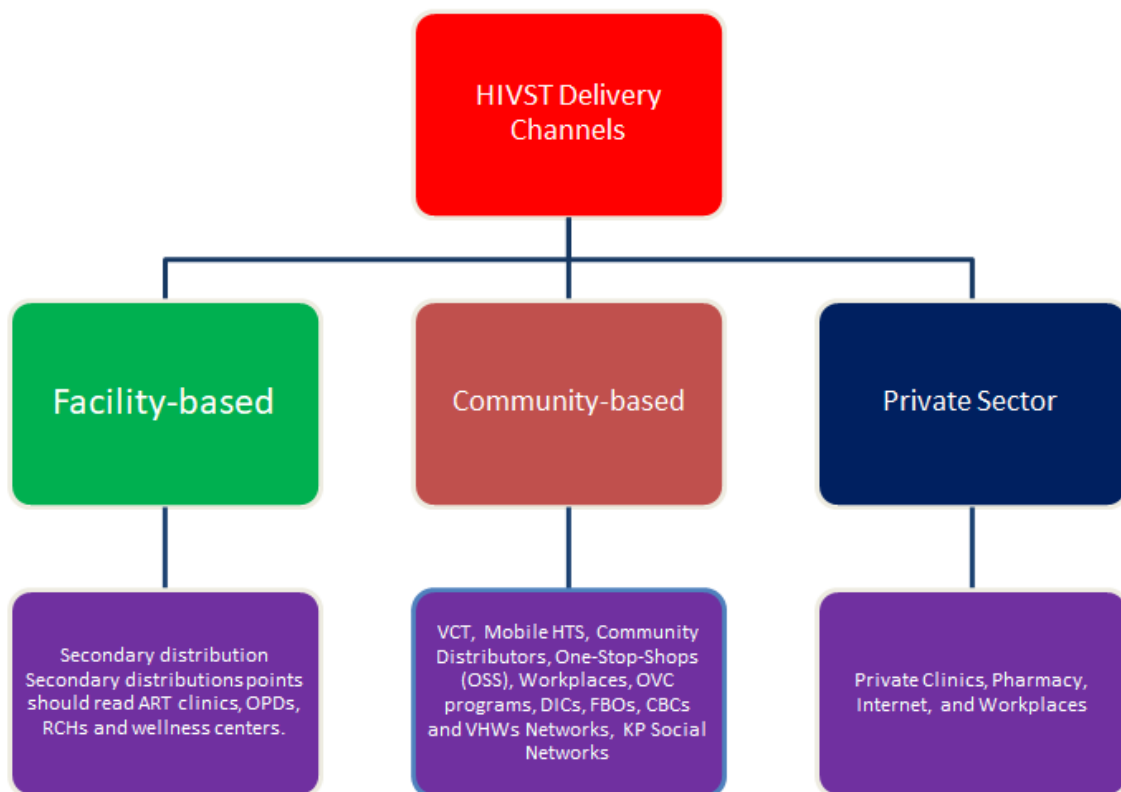


Figure 4: HIV Self-testing Service Delivery Channels

2.3 Primary and Secondary Distribution Approaches

HIV self-test kits may be distributed via primary or secondary distribution approaches.

- a) **Primary distribution** is when a provider distributes HIVST kits to persons who intend to use the kit themselves. The benefit of primary distribution is that the

provider has an opportunity to provide sufficient information and education to the intended HIVST user, and can also provide information about accessing follow-up services.

- b) **Secondary distribution** is when a provider distributes HIVST kits to persons who intend to give the kits to their sexual or needle sharing partner(s), peers, or family members. One benefit of secondary distribution is that it expands the reach of HIVST, giving access to hard-to-reach populations. When a provider is distributing HIVST kit to someone who intends to give it to his or her sexual partner(s), peers, or family members, they should ensure the person adequately understands how to use the kit and interpret the results, and how to explain this information to others. Printed or online information, education, and communication (IEC) materials can be helpful to ensure the secondary user performs the test correctly.

2.4 Modes of Distribution for Target Populations

Table 1 outlines HIVST delivery channels, entry points, target populations and possible distribution approaches for HIVST delivery.

Table 1: Modes of Distribution for Reaching Select Populations

Distribution Channel	Entry Point	Target Population	Distribution Approaches
Community	Drop In Centers	<ul style="list-style-type: none"> Key populations (MSM, SWs, PWUDPWUD, TG,) Partners of KPs (sexual or needle sharing) Peers and social networks of KPs 	<ul style="list-style-type: none"> Primary distribution through peers at one-stop-shop Secondary distribution through KPs to reach partners and peers
	Mobilizers and Navigators	<ul style="list-style-type: none"> KPs (MSM, SW, PWUDPWUD, TG) and their partners Men Adolescents and young persons Persons with special needs 	<ul style="list-style-type: none"> Distribution through peers Targeting market places, taxi parks and bus stands, IDP camps and other places where KPs and men congregate Home-to-home testing in select communities where men and other high-risk populations reside To persons with special needs through peers or community distributors
	Social network testing	<ul style="list-style-type: none"> Peers and social networks of KPs and other vulnerable, unreached populations 	<ul style="list-style-type: none"> Secondary distribution through KPs, men, adolescents, persons with special needs to reach their peers and social networks
	Workplaces	<ul style="list-style-type: none"> Men/women 	<ul style="list-style-type: none"> HIVST available in

Distribution Channel	Entry Point	Target Population	Distribution Approaches
			<p>workplace clinics</p> <ul style="list-style-type: none"> HIVST kits distributed to employees for voluntary use as needed
	Mobile HTS Fixed Venues	<ul style="list-style-type: none"> Men and other high-risk populations 	<ul style="list-style-type: none"> HIVST kits distribution in same venue where conventional HTS is also offered, so providers can offer re-testing and linkage as needed
	Schools, Technical and Vocational Educational and Training institutions, Higher educational institutions, Religious Institutions, IDP camps and other closed settings (excluding inmates in correctional settings)	<ul style="list-style-type: none"> Adolescents and young persons 	<ul style="list-style-type: none"> Distribution via peers and well-trained HIVST kits distributors using the entry points listed
	Community Birth companions (CBCs) (non-formal actors) Traditional Communicators, village Health Workers, Village Support groups, Community Health Nurse	<ul style="list-style-type: none"> Pregnant and breastfeeding women who do not deliver in health facilities and their partners. Other clients that required services such as treatment for minor ailments as well as Family planning services at communal level. 	<ul style="list-style-type: none"> One-on-one distribution through trained CBCs, VHW, TCs, VSGss (non-formal actors) Secondary distribution for partners of pregnant and breastfeeding women
Private Sector	Community Pharmacies	<ul style="list-style-type: none"> Men Persons who self-diagnose without attending a clinic or hospital 	<ul style="list-style-type: none"> One-on-one information and education using IEC materials Primary distribution for persons willing to pay Secondary distribution to reach their partners
	Private Clinics and Medical Laboratories	<ul style="list-style-type: none"> Persons who may prefer private settings for convenience, confidentiality and privacy 	<ul style="list-style-type: none"> Primary distribution Secondary distribution to reach partners
Facility (The focus of facility-based is secondary distribution)	ART Clinic ANC, OPD	<ul style="list-style-type: none"> Partners of PLHIV Partners of pregnant and breastfeeding women 	<p>Secondary distribution to reach partners.</p>

Chapter 3: HIVST Delivery Package

HIV self-testing delivery starts with ensuring high quality HIVST kits are available, used, and accessed; that they are accompanied by simple, accurate, and clear instructions for use and IEC materials; and that HIVST distributors give clear and comprehensive pre-test information to HIVST users. HIVST distributors must also support linkage to confirmatory testing and treatment for persons with reactive HIVST results, and establish systems for supporting HIVST users who experience adverse events.

3.1 Delivery Package

HIV self-testing delivery package entails an array of services that results in testing for HIV using an HIVST kit. HIVST delivery package includes:

- Ensuring that high quality HIVST kits are available, accessible and used
- Ensuring that HIVST kits are accompanied by simple, accurate and clear instructions and information for use.
- Ensuring that HIVST kits users gets adequate support and linkage to confirmatory test in health facilities for persons with reactive results and preventive services for non-reactive results.
- Establishing systems for IPV screening, referrals, and linkages for GBV services

3.2 High-Quality HIVST Kits

Only HIVST kits are evaluated by the National Pharmaceutical Services/National Public Health Laboratory Services. and approved by the Ministry of Health should be distributed in the Gambia. This is to ensure that the highest quality products are available for use in the country.

3.2.1 Instructions for Use

HIV self-test kits approved in Gambia should include clear and tested instructions for use in English, and translated into local languages, as appropriate. Instructions for use should contain both written instructions and pictorial diagrams to help users understand how to perform and interpret HIVST results.

3.3 Information, Education, and Communication (IEC) Materials

HIV self-test kits should also be accompanied by tailored IEC materials containing key messages and pre-test information, Frequently Asked Questions, a referral card for facilitating access to confirmatory testing, HIV prevention, treatment, care, and other follow-up services (Appendices 3-4); contact information for the HIVST distributor; and helpline numbers, such as the National Call Centre on HIV/AIDS IEC materials should be tailored to the target audience, and may also include both written language and pictorial diagrams to ensure all HIVST users clearly understand the required information.

It is highly recommended that HIVST users have adequate support to correctly perform HIVST, interpret results, and access necessary follow-up services. This support should include a demonstration on how to use the HIV self-test kit, interpretation of results, post-test information, and clear referrals to additional services, and contact information for a provider or helpline in case the HIVST user has questions or experiences adverse events
(National Call Centre on HIV/AIDS 1223)

Providers and users should also be made aware that HIVST is NOT recommended for persons who are already taking ARVs or PrEP, because rapid HIV tests (including HIV self-tests) may give false negative results. This is because HIV antibody levels may be lower when people with HIV are on ART or PrEP.

HIVST users should also be informed that they may be required to provide some information to facilitate documentation and accountability of the HIV self-test kits. A short and simple tool will be used to document the details of the HIVST user and intended use; limited contact information about the client will be collected. Users should be assured of confidentiality.

Pre-distribution key messages

In addition to clear instructions for use and appropriate IEC materials, HIVST kits distributors should provide users with accurate, appropriate and comprehensive pre-test information. This information can be provided either verbally, in writing, or online and should address:

- Benefits and potential risks of HIVST
- Voluntary nature of HIVST: no one should be forced to use an HIVST kit
- Confidentiality of HIVST results: no one should be forced to disclose their HIVST result
- Handling and storage of the HIVST kit before using it
- Interpreting the HIVST results, including the meaning of reactive and non-reactive results
- Persons receiving a reactive HIVST results must access confirmatory testing in a health facility by a trained HTS provider following the national HTS algorithm
- Availability and importance of treatment for persons who are confirmed to be HIV-positive, including benefits for individual health and prevention to partner/s
- Non-reactive HIVST results can be interpreted as an HIV-negative result; clients should seek appropriate prevention services and re-testing based on risk
- Location and contact information for re-testing, prevention, care and treatment services
- Safe disposal of used HIVST kits by users
- Sites distributing HIVST should have a separate, private space that can be used for assisted HIVST.

Chapter 4: Linkage and Follow Up

4.1 Supporting Linkage and Follow-up

In addition to delivering high-quality HIVST in Gambia, strategies should be put in place to support HIVST users to access necessary HIV prevention, treatment, care, and support services following HIVST. These services can build upon existing linkage support services delivered as part of conventional HTS, but may require some modification and innovation to adequately ensure linkage.

Sufficient information should be given to HIVST users at the point of HIVST distribution, so that they are adequately prepared to access follow-up services as needed. This includes information about necessary follow-up services (i.e. confirmatory testing and treatment for persons with a reactive HIVST result) and where to access these services (i.e. with a local and current referral list or directory). HIVST distributors may also wish to give users their contact information and should give the number for the National Call Centre on HIV/AIDS in case the user has any questions or needs assistance accessing follow-up services.

Where feasible, providers may wish to get consent from HIVST users to follow up with them by phone, SMS, WhatsApp, Facebook, other social media, or in person to verify that the HIVST kit was used, to obtain the test results, and to confirm whether clients with reactive results accessed re-testing and treatment services. Ideally this should be done within 1-2 weeks of issuing the HIVST in order to expedite access to follow-up services, as needed. In places where internet access is high, mobile applications, virtual platforms or computer-based systems may be set up for clients to confirm their results and have access to follow-up services. However, because HIVST is voluntary, clients may also choose not to be contacted after the HIVST, and should not be forced or coerced into sharing their results or additional information.

Persons with reactive HIVST results must seek confirmatory testing from a trained HTS provider following the national HTS algorithm. Persons with a confirmed HIV-positive result will be linked with HIV treatment, as needed. This information should be provided when HIVST kits are being distributed to users, together with an updated referral list or directory, contact information for the HIVST distributor.

4.2 Flow Chart for HIVST Users

The flow chart in Figure 5 outlines the steps that an HIVST user should take when performing their own HIV self-test.

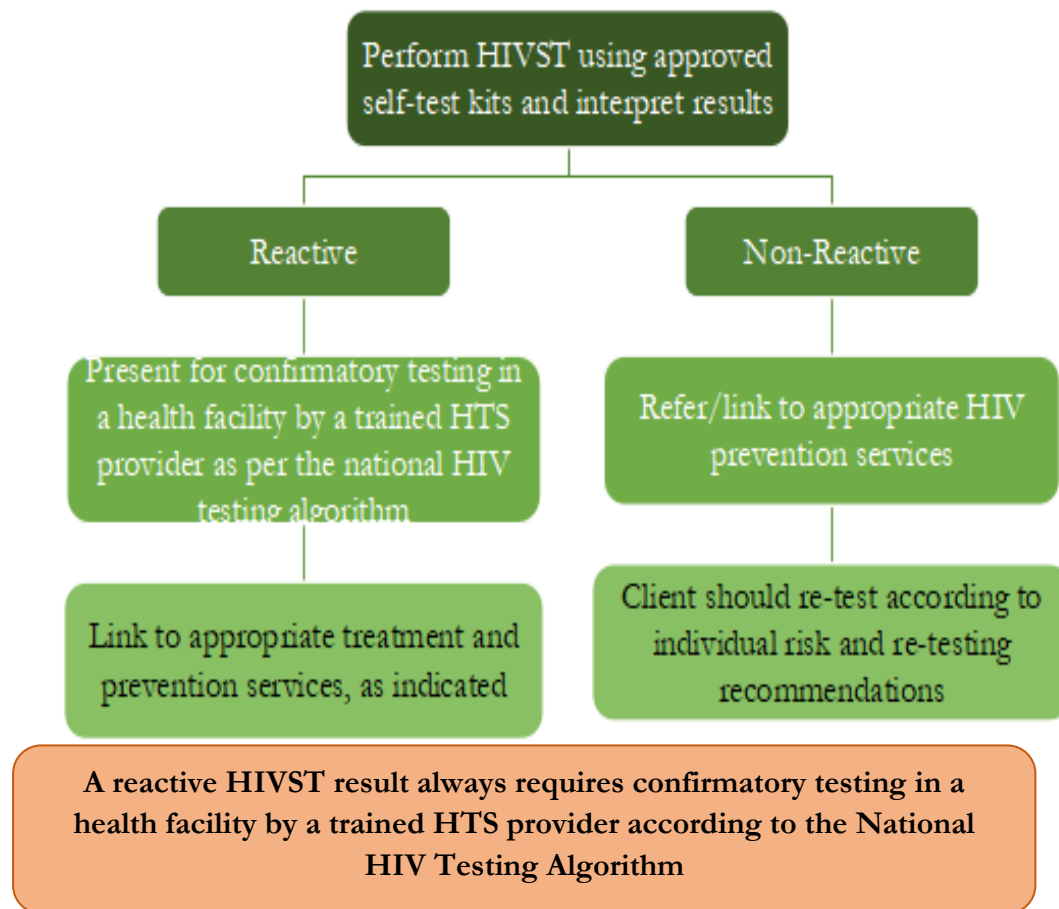


Figure 5: Flow Chart for HIVST Users

4.3 Support for Adverse Events

While current evidence suggests that there are many benefits to HIVST and the risk of harm is minimal, it remains true that coercion, intimate partner violence (IPV), or other social harms may be possible, depending on the context, setting, and relationship dynamics. As with any HTS, there is need for information and tailored messaging on disclosure in order to mitigate the risk of social harm and help couples and families to cope with a reactive self-test results or discordant self-test results.

IPV screening should be provided to all clients who are offered secondary distribution of HIVST kits. Individuals or couples who report IPV in their current relationship should be provided with or referred for GBV services. Secondary distribution of HIVST should occur only if the safety of both partners can be assured. Linkages to additional HTS, prevention, treatment and care, and services for gender-based violence (GBV) and IPV screening should be offered as part of HIVST, either during the pre-distribution messaging or in package inserts, instructions, and supplemental IEC materials.

HIV self-testing programmes should adapt monitoring and reporting systems (National Call Center for HIV and AIDS) to track social harm and other adverse events, as well as corrective action and follow-up, in order to address harm if and when it occurs.

4.4 Sustainable access to HIVST

All HIV Services in The Gambia including HIVST are offered free of charge. But in the future to ensure the sustainability of HIVST, the country would need to adopt a Total Market Approach (TMA) as a strategy to help grow HIVST market with a strong focus on coordination, partnership, and alignment of all related activities among key actors in the total market. A multi-sectoral coordinating mechanism (HIVST Technical Working Group), coordinated by NACP, AAITG and UNAIDS, should hold regular meetings with health care providers and suppliers from all three sectors - public, non-profit, and commercial to leverage the comparative advantages of the three sectors to meet clients' needs.

The TMA coordinating structures should ensure continuous data collection, sharing and analysis and use to inform programming and sustainable access to HIVST services. Regular monitoring and quality assurance of new brands/products is required to prevent influx of unregistered and unvalidated products. HIVST is relatively a new technology in Gambia, therefore it is essential that mechanisms to ensure competitive market are institutionalized.

Supply Chain for HIVST kits will be in line with the Total Market Approach (TMA).

- **Private Sector**

This would be in line with the NPS and MCA which ranges from the suppliers to the retailers across the various channel members who are licensed to distribute or dispense HIVST commodities/products.

- **NGOs/ Faith-Based Organizations**

This would mirror the current supply chain processes which is aimed at providing access to the communities where they operate at subsidized rate or distributed freely.

- **Public Sector**

The government working with CBDs and CBOs would provide fully subsidized HIVST kits to the hard-to-reach population and the indigent.

Chapter 5: Demand Creation and Sensitization

5.1 Demand Creation for HIVST

Demand creation for HIVST is a process that ensures willingness and ability to request, access, uptake and utilize available services. Demand creation approaches depend on the settings, target and available resources. This would be part of a strategy to reach people with HIV who do not know their status and those who are at high risk of being infected with HIV. A wide range of demand creation strategies have been tested to assess impact on HIV self-testing and the proportion of people with HIV diagnosis. Results from WHO have shown that there are evidence-based platforms for demand creation and approaches for increasing demand for HIVST.

Evidence-based platforms for delivering demand creation

- Peer-delivered, participatory, and community-led approaches such as using peer educators, community groups and faith-based programmes
- Digital tool based on HIVST approach including social media, SMS, mass media and other digital media including short videos.

Approaches that show evidence of increasing demands

- Advertisement of specific HIVST attributes
- Brief key messages
- Motivational messages that encourage self-testing
- Messages related to risk reduction

Enabling Environment for demand creation

- Preventing social harm, stigma, discrimination, and criminalization
- Protecting confidentiality
- Ensuring appropriate age-of-consent policy
- Empowering communities

Strategies for creating demand

- Targeted promotions, advertisements, and messaging
- Educational programs for example drama, sport and faith-based
- Social Network based approaches

5.2 Social and Behavioral Change Communication (SBCC)

Social and Behavioral Change Communication (SBCC) is the systematic use of interactive and evidence-based communication processes and techniques to equip and empower target audiences to embrace and use HIV Self-Testing at the individual, community, and social levels.

SBCC Goal and Objectives for HIVST

The SBCC goal is for people to accept and demand HIV Self-Testing services.

The objectives include:

- To increase HIV risk perception among target audiences.
- To address barriers and motivate target audiences to demand and utilize HIVST services.
- To provide a supportive environment for HIVST uptake at individual, family and community level.
- To motivate HIV reactive clients to confirm their status at a health facility, if positive, initiate ART on the same day and if negative, adopt risk reduction practices.

Justification for SBCC

- Misconceptions and Myths about HIV
- Poor health seeking behavior and low HTS uptake
- Low HIV risk perception
- Inadequate information on HIVST
- Poor linkage to care after HIVST
- Limited Knowledge and skills on HIVST
- Fear of distress following reactive results
- Doubts about accuracy of HIVST results
- Fear of Violence from peers, partners and others.
- Failure to interpret results
- Negative attitude of the service providers
- Limited resources/ inconsistent supply of HIVST kits

Target audience for HIVST

All SBCC interventions will be targeted to reach specific HIV self testing audiences including leaders, service providers and the community. SBCC will consider the specific characteristics of each audience such as gender, age, location, socio-economic status, education, culture, sexual orientation and behavioral pattern.

The target audiences include:

- Key Populations -MSM, SW, PWUDPWUD, TG
- Men
- Couples and Partners
- Sero-discordant couples
- Partners of PLHIV
- Displaced persons
- Migrants
- Persons with special needs (persons with disabilities)

- Health care Service Providers
- Inter-Personal Communication Agents: Village/Ward Development Committees , peers, linkage facilitators, para social workers, traditional communicators and expert clients
- Leaders: Cultural, Political, , Religious and Opinion

5.2.1 Channels of Communications

Demand creation for HIVST becomes effective when the relevant channels of communication are used to reach the target audiences. The channels of communication include Print and electronic media, Healthcare workers peer educators and HIVST champions, social media and internet as well as helplines among others.

5.2.2. Print and Electronic media

Printed and audio-visual materials such as posters, leaflets, information cards, bill boards, radio and TV spots, neon-signs and others may be developed and used at the programme level to support HIVST demand creation and distribution. Programmes should develop print and electronic media materials with language and pictorial graphics that are appropriate for their target audience. Special considerations should be given to persons with special needs in order to ensure that they have access to accurate and appropriate information on HIVST.

5.3. Mobilizers and health navigators

Peers can be effective for communicating information about new health services such as HIVST. Persons who have used HIVST kits and had good experiences can be engaged as peer educators or HIVST champions, to share their experiences and educate others in the community. HIV self-testing champions can also be engaged to promote HIVST in both private sector and community settings. These champions may be peer educators, key populations, or expert clients who are trained on communication skills and HIVST kit usage in a manner that is appropriate and client-centered.

Existing workplace and faith-based wellness programmes may be leveraged to promote HIVST among persons who are hesitant to access existing HTS in the workplace due to stigma and discrimination. Additionally, local leaders, religious leaders, and civil society groups can be engaged to inform their networks, create demand, normalize HIVST, offer HIVST support, and encourage linkage in a manner that is appropriate and client-centered.

5.4 Social Media and Internet

Social media platforms such as WhatsApp, Facebook, Instagram, Twitter, and other internet-based platforms provide a good avenue for reaching many people, especially young people who are a priority population for HIVST kits distribution.

5.5 Helplines

Operators of the National Call Centre on HIV/AIDS will provide information and education about HIVST to persons calling with related questions. HIVST kits distributors and other community members should refer HIVST kits users to the National Call Centre for HIV information as needed. The Call center will be decentralized by NACP and NAS to regional levels to reach additional HIVST kits users.

Chapter 6: Special Considerations

6.1 Disclosure to sexual partners

Clients should be informed about the potential health benefits of disclosing their HIV status to sexual partners, partners who share needles and other family members, as part of pre-test information for HIVST. However, HIVST does not provide a definitive HIV-positive diagnosis and therefore, disclosure of a reactive result may not be relevant until confirmed by a trained provider. This information should also be included in the clients' information pack. Clients with reactive HIVST results should be encouraged to visit an HTS provider with their partner(s) for additional testing following the National HTS Algorithm, so that their partner(s) may also be tested. Clients with non-reactive HIVST results should also be encouraged to disclose their HIV status to their sexual partners and encourage their partners to know their HIV status through use of HIVST or a visit to an HTS provider.

Providers should assess for risk of possible social harm and/or violence following disclosure, such as Gender Based Violence (GBV) and Intimate Partner Violence (IPV), and provide services or referral to appropriate support services. Referral services include health facilities, civil society organizations (CSOs), and sexual and gender-based response teams. Recommend a national hotline

In some instances, clients may request HIVST kits for their partners, high-risk peers, or other family members. This strategy of *secondary distribution* of HIVST kits can be an effective complement to index testing, and can increase uptake of HTS among populations at high risk, but clients must be informed that HIVST is voluntary, and they should not coerce or force anyone to use HIVST Kit. If someone has been coerced or forced to use an HIV self-test kit, they should contact the nearest health facility, CSO, sexual or gender-based response team or contact The National Call Center for HIV.

6.2 Key Populations

Key populations include sex workers (SW), men who have sex with men (MSM), and persons who use injection drugs (PWUDPWUD), Transgender (TG) and persons in closed settings (PICS). These populations are at high risk for HIV infection, and their behaviours are highly stigmatized and sometimes illegal. This may limit access and uptake of HTS. Due to stigma, discrimination and criminalization, key populations may also be less likely than general populations to access health care services through public clinics and hospitals. HIV self-testing can be an effective means of reaching this vulnerable group with HTS, by distributing HIVST kits through peers and community settings, one-stop-shop (OSS), community pharmacies online platforms that are acceptable and well frequented by KPs.

When distributing HIVST kits to KPs, special considerations may be needed to ensure tests are performed with accuracy, results are interpreted correctly, and follow-up services are accessed.

6.3 Men

Men are less likely than women to know their HIV status, and less likely to access HIV care and treatment services. HIVST is an important strategy for increasing knowledge of HIV status among men. Peer distribution of HIVST kits among men may be a highly effective approach for reaching men and supporting them with linkage to follow-up services. Community HIVST kits distribution should focus on places where men are likely to congregate, including workplaces, taxi garages and mini-bus stations, marketplaces, sport centres, mechanic workshops, and other community venues.

When men are engaged in secondary distribution of HIVST kits to their female partners, it should be reinforced that HIVST is voluntary, and partners should not be forced to use an HIVST kits. Screening for IPV may focus both on the man's risk of violence, and risk of perpetuating violence against his partner if he/she declines to use HIVST, and providers should counsel men accordingly.

6.4 Women

Although more women know their HIV status than men, there are still many opportunities for HIVST to reach women who are not currently tested, or who may need re-testing. Additionally, secondary distribution through women living with HIV can reach men who may be at risk of having HIV but who do not know their status.. It may be more difficult for women to notify their partners of their own HIV-positive status, and so additional counselling may be needed with women to help build their skills for talking about HIVST with their male partners, and identifying strategies for successful HIVST delivery. Women may also be more comfortable using HIVST kits together with their male partners, and so could be given two HIVST kits – one for themselves, and one for their male partners – to use together.

Women at risk of IPV with their partner(s) should not be denied HIVST, but should have the opportunity to decline HIVST for their partners if they wish. Alternative strategies for notifying the partner and getting him tested – if indicated – should be explored. Women should also be appropriately provided with or referred for IPV support services, as available.

6.5 Adolescents and Young Persons

Young persons who are eligible for HTS either because they have attained the age of consent (16 above), can be granted access to a self-test.. Providers could offer assistance to young persons where appropriate. Many young persons will be able to perform the test accurately and HIVST can be a good option for increasing knowledge of HIV status amongst young persons who may not feel comfortable accessing HTS in other settings.

6.6. Persons who are Incarcerated

HIV self-testing is not recommended to persons in incarceration rather increased access to HTS should be promoted.

6.7. Persons with Special Needs

Persons with special needs (for example development disability, autism, communication disorder, attention deficit disorder, dyslexia etc) should also have access to HIVST as part of comprehensive HIV service delivery. Provisions should be made for persons with special needs to access appropriate information and educational materials about HIVST, and to receive support conducting HIVST. Special attention should be given to ensure that persons with special needs are not being coerced or forced to perform HIVST.

6.8. Emerging Issues (Internally Displaced Persons)

Due to the vulnerability and peculiarity of internally displaced persons (IDPs), HIVST is recommended due to poor access to conventional HTS. Reactive individuals should be linked to settings where they can get confirmatory test while the non-reactive individuals are linked to prevention and other services.

6.9. Persons taking ARVs, including PrEP

HIV self-testing is NOT recommended for persons who are already taking ARVs, whether for their own health or for HIV prevention (PrEP). This is because HIV antibody levels may be lower when people with HIV are on ART and so rapid HIV tests (including HIVST kits) may give false negative results. However, HIVST can be a useful tool for creating demand for PrEP, such that persons who receive a non-reactive HIVST result may be eligible for PrEP and can be given information about their eligibility and the availability of this service. Persons on PrEP may choose to use HIVST in order to test more frequently than is required by their clinician, but they should understand the possibility of receiving a false result and should continue to receive regular clinical appointments as scheduled by their PrEP provider.

6.10. HIVST and PEP

Persons with an acute exposure to HIV who are eligible for PEP should seek medical consultation as soon as possible after the exposure. Because of the importance of starting PEP within 72 hours after exposure, it is recommended that HIV testing to initiate PEP be conducted by a trained HTS provider. However, some people may still choose to use HIVST before seeing a provider, to ensure they are not HIV infected as this may not be their first exposure.

Chapter 7: Commodity Management

This chapter addresses the management of HIVST commodities and Supply Chain Management for HIVST across public and private sectors. HIVST commodities should be managed according to standard. Supply Chain Procedures, to ensure that the right commodities are procured in the right quantities, in the right condition, delivered to the right place at the right time, and for the right cost.

7.1 HIVST Kit Selection

Selection of HIVST kits to be procured nationally will be guided by HIVST selection criteria in order to assure high quality products are procured. HIVST kits must be evaluated and validated by the Gambia National Laboratory Quality Assurance Team using the National External Quality Assessment Laboratory or other authorized government laboratory.

7.2 Quantification and Procurement

For the public sector, quantification of HIVST will be done through the annual national forecasting and quantification process. In the private sector, quantification will be based on demand. Procurement will be managed by Ministry of Health through National Pharmaceutical Services (NPS) for both public and private sector, using the supply chain management system.

7.3 Allocation and HIVST Kit Distribution

The Supply Chain Management System will be adopted to include HIVST kits. These test kits will be allocated initially based on estimates and subsequently based on consumption reports. Data on the number of HIVST kits distributed will be generated through local reporting and allocation mechanisms. Rationalization of kits allocated will be done by the national procurement committee through NPS before distribution.

7.4 Inventory Management

The management of HIVST kits will be aligned to the existing Logistics Management Information System (LMIS). This will include receipt of HIVST kits, storage according to the manufacturer's instructions or in adherence to the recommended storage guidelines, and distribution to HIVST sites. Proper record keeping shall be ensured by the use of existing tools and commodity management reporting systems.

Chapter 8: Quality Assurance

This chapter provides guidance on ensuring the quality of HIVST kits and the HIVST process and procedures.

8.1 Benefits of Quality Assurance in HIVST

Focusing on quality assurance in HIVST will:

- Ensure that clients receive the correct test result
- Ensure standardization to facilitate consistent service delivery
- Instil confidence in HIVST users
- Increase demand for HIVST
- Ensure the needs and expectations of clients and communities are met regarding HTS
- Identify places for improving HIVST processes

8.2 Quality Assurance of HIVST Kits

All test kits for national procurement must obtain in-country laboratory validation to ensure that they meet the minimum inclusion criteria. WHO pre-qualification is an added advantage.

a) Regulatory bodies:

All HIVST kits must be validated, certified, and registered by relevant national regulatory authorities before being introduced into the market.

b) Lot – to - lot validation

All entities procuring HIVST kits must ensure that any new lots coming into the country are validated to ensure that products delivered meet criteria for quality and performance. Only lots with satisfactory results should be distributed.

c) Post-market surveillance

Post-market surveillance will be conducted periodically by the Medicine Control Agency (MCA) to assess the quality and performance of HIVST kits in use, in compliance with the established standards.

8.3 Quality Assurance of HIVST Process and Procedure

a. Capacity building and sensitization on HIVST

All HIVST providers should be sensitized according to the HIVST training package. This includes capacity building and knowledge on how to conduct the test, and where to refer clients for linkage for additional testing and support.

Testing aids, instructions for use, and Standard Operating Procedures (SOPs) should be readily available to providers and clients at all HIVST kits distribution points. This should include how to conduct HIV self-test, the meaning and interpretation of HIVST results. All clients must also be aware of the need to confirm a reactive HIVST result, by seeking HTS from a trained provider, following the National HTS algorithm.

b. Infection Prevention and Control.

While the risk of HIV transmission through HIV self-tests has been demonstrated to be minimal, clients should be made aware of the correct practices to minimize biosafety risks. Waste should be disposed according to manufacturer's instruction and in line with the National guideline on infectious waste management.

c. Referral and Linkages.

Information on referral and linkage to appropriate HIV Services should be made available to all clients during pre-test information. In the event of a reactive HIVST result, clients should know where to access additional HTS. A national referral directory should be available for HTS and other prevention, treatment, care, and support services.

Chapter 9: Monitoring and Evaluation

This chapter outlines the monitoring and evaluation requirements that should be in place to track HIVST uptake and utilization.

9.1 Indicators for M&E in HIVST

The following indicators will be tracked at the national level:

1. Total number of HIVST distribution sites/outlets
2. Total number of HIVST kits distributed/given (disaggregated by age, gender)
3. Total number of persons given test kits
4. Total number of persons reporting that they have done HIVST (by age, gender)

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

- ❖ Number of persons referred for HIVST (by age, gender)
- ❖ Number of persons offered HIVST (by age, gender)
- ❖ Number of persons accessing HIVST (by age, gender)
- ❖ Number of people reporting results (by age, gender, reactive or non-reactive results)
- ❖ Number of people reporting reactive results who accessed HTS from a trained provider following the national algorithm

9.2 Reporting Tools and Systems

HIVST tools should be developed to capture and report on data at the HIVST distribution sites. These tools should include:

1. HTS register with HIVST incorporated
2. eLMIS tools
3. HIVST daily distribution sheet`
4. Linkage register
5. Incorporation of HIVST into DHIS reporting tools

Chapter 10: Coordination

This section outlines the roles and responsibilities of key stakeholders in the coordination of HIVST in The Gambia.

10.1 Roles and Responsibilities

The coordination of HIVST in The Gambia will be aligned with the roles and responsibilities outlined in the relevant Government policies and guidelines. Other key actors such as regulatory bodies, professional associations, development partners, and private sector distributors and vendors will also be involved, particularly related to coordination in the private sector.

HIVST responsibilities span the national, regional, and local levels. At each level, various bodies are responsible for different functions as outlined below:

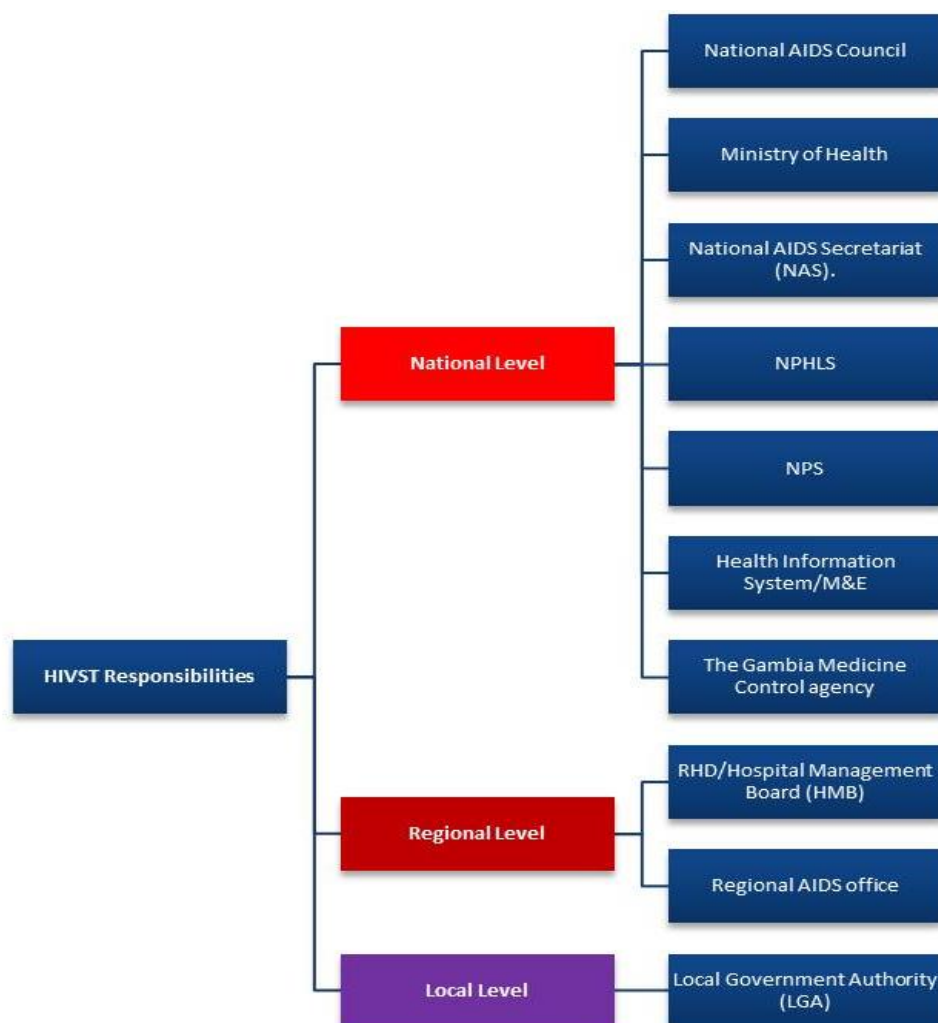


Figure 6: HIVST responsibilities

The Gambia - NATIONAL LEVEL

Institution	Roles and Responsibilities
Ministry of Health National AIDS Secretariat (NAS).	<ul style="list-style-type: none"> • Development and dissemination of policy documents • Technical assistance and capacity building • Implementing partner coordination • Leadership of national technical working groups • Monitoring trends of the HIV epidemic • Performance monitoring and reporting (national and international) • Development of M&E tools and indicators • Development of training curricular • Technical guidance on procurement and supply chain management • Carrying out coordinating and disseminating research • Advocacy and resource mobilization • HTS promotion activities • Quantification, procurement, forecasting, supply plan, distribution, Storage
NAC	<ul style="list-style-type: none"> • Strategic guidance on the HIV response • Multi-sectoral coordination • Advocacy and resource mobilization
NPHLS	<ul style="list-style-type: none"> • National quality assurance <ul style="list-style-type: none"> • EQA through PT and DTS validation • Test kit validation • Post-market surveillance • Evaluating new testing technologies • Supplemental and specialized testing (i.e. Early Infant Diagnosis, P-24 antigen, Polymerase Chain Reaction) • Development of training material for HIV testing • Technical assistance and capacity building in HIV testing • Performance monitoring and reporting on QA indicators
NPS	<ul style="list-style-type: none"> • Forecasting, quantification and data management of HIVST commodities. Storage and distribution of HIVST commodities
Health Information System/M&E	<ul style="list-style-type: none"> • Development of data collection and reporting systems • Data storage and management • Registration of M&E tools • Data quality audits
The Gambia Medicine Control agency	<ul style="list-style-type: none"> • The Authority to ensure that the HIVST test kits are certified and fit for use as evidence by the presence of the authority • The Authority to Conduct Post marketing surveillance activities of the test kits • The Authority to Conduct surveys on safety and quality of the test kits. • The Authority to regulate the importation, manufacturers sales and stocking of invitro diagnostics.

REGIONAL LEVEL	
Institution	Roles and Responsibilities
RHD/Hospital Management Board (HMB)	<ul style="list-style-type: none"> • Management of service delivery • Human resource management • Training of healthcare workers • Monitoring of LGA HIV epidemic trends and programme performance Storage and distribution of HIVST commodities • Printing and distributions of M&E tools and national IEC materials • Development and revision of key M&E indicators • Infrastructure support • Data quality audits • HTS promotion activities • Participate in EQA (External quality assurance)
Regional AIDS office	<ul style="list-style-type: none"> • Reporting through DHIS • Supervision of service delivery • Data quality audit • Participate in EQA • HIVST promotion activities

LOCAL LEVEL	
Institution	Roles and Responsibilities
Local Government Authority (LGA)	<ul style="list-style-type: none"> • Community mobilization and advocacy • Provision of quality HIV services • Data collection and reporting • HIVST promotion activities

10.2 Public-Private Partnerships (PPP)

This is a cooperative arrangement between public and private sectors, typically of a long term nature for the purpose of advocacy, communication and social mobilization to ensure the success of HIV self-testing. For this to succeed government should work with the following:

- Religious leaders/organizations; to mobilize and educate their members on HIVST acceptability, availability, benefits and adherence to the National guideline on HIVST.
- Opinion and Community leaders (NGO's, CBO's, Hotels, etc.): to mobilize and educate their members on HIVST acceptability, availability, benefits and adherence to the National guideline on HIVST.
- CSO's including the Network of People Living with HIV; to sensitize various communities including rural communities.

- Private facilities (Hospitals, Patent medicine vendors, pharmacists, Private laboratories, etc.): take up the services of HIVST using the HIVST guideline
- Corporate organizations: take up the services of HIVST using the HIVST guideline and also promote the services.

Appendices

Appendix 1: Re-testing Recommendations for Persons with Non-Reactive HIVST Results

Who should be retested?	When should they be retested?
Persons with a known, specific recent HIV exposure (i.e. within the last 4 weeks)	Within 3 months of the specific HIV exposure incident, or 4-6 weeks after receiving their initial HIV-negative results. After ruling out HIV infection from the specific incident, resume annual retesting.
General population with low or no risk	Annually or with a new risk of exposure.
Persons from key populations (FSW, MSM, PWID, TG)	Every 3-6months, depending on their risk.
Persons with a known HIV-positive partner	Retest every 3 months until HIV-positive partner achieves viral suppression on ART. Once viral suppression is confirmed, re-test every 6-12 months, depending on their risk. <i>Recommend other prevention services, including condoms. Assess eligibility and willingness for PrEP.</i>
Survivors of rape, or sexual or gender-based violence	If on PEP, retest per PEP guidelines. If not on PEP, retest 4 weeks after the incident and again at 3 months after the incident.
Pregnant and breastfeeding women in high incidence/prevalence areas	in third trimester or at labour and delivery.
Individuals seen for a diagnosis or treatment of STIs	6-12 weeks after receiving their initial HIV-negative results. After ruling out HIV infection, resume annual retesting.
TB patients with a possible recent HIV exposure, or who are at higher risk of exposure	6-12 weeks after receiving their initial HIV-negative results. After ruling out HIV infection, resume annual retesting.
Outpatients with clinical conditions indicative of HIV infection	6-12 weeks after receiving their initial HIV-negative results. After ruling out HIV infection, resume annual retesting.
Individuals taking PrEP (Pre-exposure prophylaxis)	Every 3 months, or as guidance indicates
Individuals taking PEP (Post-exposure prophylaxis)	According to PEP guidelines

*Individuals are encouraged to self-test more frequently than indicated based on their risk to HIV.

Appendix 2: Client Data Card

The client data card can be used to capture data on who is accessing HIVST services. Clients can complete the client data card on their own, and should leave it at the HIVST distribution site or outlet. They should be informed that all data will remain anonymous and confidential.

<p>Thank you for taking this important step to perform your own HIV test. We are collecting information on HIVST use so that we can continue improving our services. This information we are collecting will remain anonymous—please do not include your name or phone number.</p> <p>Age (years) : [_____]</p> <p>Gender : Female [_____] Male [_____]</p> <p>Have you ever tested for HIV before ? Yes [_____] No [_____]</p> <p>How long ago did you test for HIV ? Never [_____] Last 3 months [_____] Less than 1 year [_____] More than 1 year [_____]</p> <p>What type of HIVST kit did you receive/purchase today ? Oral fluid [_____] Blood [_____]</p>	<p>What is your main reason for accessing HIVST today ? (select one only)</p> <p><input type="checkbox"/> To understand illness/symptoms that I have had</p> <p><input type="checkbox"/> Advice from the pharmacist/my doctor</p> <p><input type="checkbox"/> I recently had a possible exposure to HIV</p> <p><input type="checkbox"/> To plan the future/take charge of my health/getting married</p> <p><input type="checkbox"/> Encouraged by sex partner</p> <p><input type="checkbox"/> It has been longer than 1 year since I last tested</p> <p><input type="checkbox"/> Other reason (please indicate) : _____</p> <p>_____</p> <p>_____</p>
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Appendix 3: Key Messages

Key Messages for HIVST Users :

- Always obtain an HIV self-test kit from an authorized provider or outlet
- Always follow the manufacturer's instructions provided in the HIV self-test kit
- HIVST is a screening test ; reactive HIVST results are not conclusive, and a person should seek further HIV testing from an HTS provider at the facility or community level
- Always adhere to proper infection prevention and control measures

Safety :

- Maintain proper mouth and hand hygiene
- In oral HIVST, the risk of HIV infection transmission is minimal
- Where blood-based HIVST kits are used, biosafety and infection prevention control measures should be adhered to, as per manufacturer's instructions
- Used HIVST kits should be disposed of per manufacturers' instructions and in line with National guideline on infectious waste management.

Referral and Linkage :

- HIVST is a screening test
- The HIVST distributor or provider should map and identify facilities that can provide further HIV testing
- Clients should be counselled on the importance of additional HIV testing in case of a reactive HIVST result
- Clients with substantial risk of HIV acquisition should be counselled on how to stay HIV-negative and/or referred to facilities for additional prevention strategies, as needed

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