

KINGDOM OF CAMBODIA

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Ministry of Health

**STANDARD OPERATING PROCEDURE
FOR HIV SELF-TESTING IN CAMBODIA**

June 2020



National Center for HIV/AIDS, Dermatology and STD (NCHADS)

Foreword

The Cambodian Ministry of Health takes great pride that Cambodia have achieved the HIV 90-90-90 targets in 2017, three years before the world's deadline¹. Cambodia's achievement on HIV and AIDS response was showcased.90-90-90 Targets Workshop in July 2017, in Paris where H.E. Minister Dr. Mam Bun Heng commented "We are proud of the expansion and coverage of life saving services that we have achieved. And we are committed to address the remaining challenges to sustain these results, and to eliminate HIV as a public health threat by 2025."

To reach the 95-95-95 targets by 2025, and to move toward elimination, the Ministry of Health has developed the National Consolidated Guidelines on HIV Testing Services. That guidance includes HIV self-testing (HIVST) for those who are reticent to access community-based or clinic screening for HIV. We know from our own studies and from other investigations around the world that HIVST can increase HIV testing among key populations who are especially high-risk for infection. Learning their status privately allows them the privacy they desire yet access the full counselling support of government clinics and community-based organizations to help them take the next appropriate steps.

The Ministry of Health hopes that all stakeholders will offer HIVST as a testing alternative to help Cambodia achieve the first 95 and link any positive individuals to care, treatment and viral suppression as part of our quest to achieve HIV transmission elimination by 2025.

Phnom Penh, 01/07/ 2020

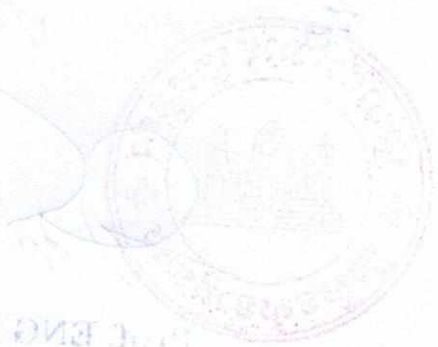
Minister of Health



Prof. ENG HUOT
SECRETARY OF STATE

¹ UNAIDS Press release, 2017.

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My thanks also go to NCHADS' staff and all individuals from NGOs for their contribution to the drafting of this document.



Phnom Penh, 19/06/ 2020



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Content

| | |
|--|-----|
| List of contributors to the development..... | iii |
| List of Abbreviations | v |
| Glossary | vi |
| 1 Introduction | 1 |
| 2 Rationale | 1 |
| 3 Goal and objectives of the HIVST SOP | 2 |
| 4 HIVST: basic principles | 2 |
| 4.1 HIVST: how do clients do it? | 3 |
| 4.2 HIVST access approaches | 3 |
| 4.3 Populations | 4 |
| 4.4 Geographical focus | 5 |
| 4.5 HIVST in the national HIV testing algorithm | 5 |
| 4.6 Pre-and post-test counseling | 5 |
| 4.7 Hotline and online support | 5 |
| 4.8 Linkages to services | 6 |
| 4.9 Follow-up of HIVST users | 7 |
| 4.10 HIV Promotion and Communication | 8 |
| 5 HIVST strategy | 10 |
| 5.1 National policy and regulations | 10 |
| 5.2 Registration process of HIVST products..... | 10 |
| 5.3 Communication strategy..... | 11 |
| 5.4 Quality Assurance and Improvement system | 11 |
| 5.5 M&E system | 11 |
| 5.6 Identification and selection of HIVST implementers | 11 |
| 6 Key steps for increasing HIVST access | 12 |
| 6.1 In person approaches | 12 |
| 6.2 Order online and receive by delivery service | 12 |
| 6.3 Through pharmacies | 13 |
| 6.4 Other Health Services | 13 |
| 6.5 Secondary Distribution of HIVST | 14 |
| 7 Quality Assurance & Improvement..... | 14 |
| 7.1 Quality assurance of HIVST kits..... | 15 |
| 7.2 Post marketing surveillance | 15 |
| 8 Monitoring & Evaluation..... | 16 |
| 9 Annex | 18 |

| | | |
|-----|--------------------------------------|----|
| 9.1 | Key messages for HIVST | 18 |
| 9.2 | Instructions for HIVST testing | 19 |
| 9.3 | Roles and responsibilities | 20 |
| 10 | References..... | 23 |

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List of Abbreviations

| | |
|---------|---|
| A | Assay |
| AE | Adverse Events |
| ANC | Antenatal Care |
| ART | Antiretroviral Treatment |
| B-IACM | Boosted Integrated Active Case Management |
| CBO | Community-Based Organization |
| EQA | External Quality Assessment |
| EW | Entertainment Worker |
| GBV | Gender-Based Violence |
| HIV | Human Immunodeficiency Virus |
| HTS | HIV Testing Services |
| HIVST | HIV Self-Testing |
| IBBS | Integrated Biological and Behavioral Surveillance |
| KP | Key Population |
| MoH | Ministry of Health |
| M&E | Monitoring and Evaluation |
| MSM | Men who have sex with Men |
| MSW | Male Sex Workers |
| NCHADS | National Center for HIV/AIDS, Dermatology and Sexually Transmitted Infections |
| NGO | Non-Governmental Organization |
| OW | Outreach Worker |
| PEP | Post-Exposure Prophylaxis |
| PMTCT | Prevention of Mother-to-Child Transmission |
| PNTT | Partner Notification, Tracing and Testing |
| PrEP | Pre-Exposure Prophylaxis |
| PLHIV | People Living with HIV |
| PWID | People who Inject Drugs |
| PWUD | People who Use Drugs |
| QA | Quality Assurance |
| QI | Quality Improvement |
| QR code | Quick Response Code |
| SOP | Standard Operating Procedures |
| TG | Transgender (transmen and transwomen) |
| TW | Transwomen |
| TWG | Technical Working Group |
| UNAIDS | The Joint United Nations Programme on HIV/AIDS |
| USAID | United States Agency for International Development |
| VCCT | Voluntary Confidential Counselling and Testing |
| WHO | World Health Organization |

Glossary

Assay: a complete procedure for detecting the presence or concentration of an analyte, including all the components of a test kit used to identify HIV p24 antigen or HIV-1/2 antibodies, in the case of HIV

Confirm: to issue an HIV status, initially reactive or invalid HIVST test results need to be confirmed according to the national validated testing algorithm.

HIV status: a collection of results from one or more assays as per the national HIV testing algorithm. An HIV status is similar to HIV diagnosis. It refers to reports of HIV-positive, HIV negative or HIV-inconclusive, whereas HIV diagnosis generally refers to HIV-positive diagnoses and in some cases HIV-negative diagnoses

HIVST provider: in the context of HIVST is a lay provider or trained health care worker that offers HIVST services.

HIV testing services: it indicates the full range of services that a client is offered together with HIV testing. This includes counselling (pre-and post-test); linkage to appropriate HIV prevention, care and treatment services and other clinical support services. Coordination with certified laboratory services to support quality assurance and delivery of to assure correct results is necessary.

Invalid Results: an invalid HIVST result means that the test did not work properly (e.g., the test is expired, the procedures were not properly followed). HIVST must be repeated with a new HIVST kit (when available) or the person should access HTS for regular HIV testing using the national algorithm.

Lay provider: any person, including peer outreach worker, who performs functions related to health-care delivery and has been trained to deliver specific services but has not received a formal professional or paraprofessional certificate or tertiary education degree

Non-reactive results: it means that the test indicates that HIV antibodies were not found in oral fluid or capillary blood sample. Anyone with a nonreactive self-test does not need further confirmatory testing but should be supported to re-test if they have had a recent potential HIV exposure or have on-going HIV risk behaviors.

HIV self-testing: a process in which an individual who wants to know his or her HIV status collects a specimen (oral fluid or capillary blood), performs a test and interprets the result by him- or herself, often in private either alone or with someone he or she trusts. Individuals with a reactive test result need to access HTS services for confirmatory HIV testing using national HIV testing algorithm. HIVST is considered as a *test for triage* and can be delivered through two approaches:

HIVST - Provider-assisted: refers to trained HIVST providers (lay or health care provider) giving individuals an in-person demonstration before or during HIVST of how to perform the test and interpret the test result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside HIVST kits.

HIVST – Virtually assisted: refers to when individuals self-test for HIV using only a self-test kit that includes manufacturer-provided instructions for use and a link to online assistance to conduct his/her testing if virtual assistance is needed. As with all self-testing, users will be provided with links or contact details to access HTS services for a confirmatory HIV test if the result is reactive or invalid, additional support, such as telephone hotlines or instructional and educational videos.

Reactive results: it means that the test indicates that HIV antibodies are present in the oral fluid or capillary blood sample. Anyone whose result is reactive to a self-test must be followed by additional HIV confirmatory testing services in a government VCCT clinic following the national HIV testing algorithm.

Social harm: any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt from one person to another, a person to themselves, or an institution to a person, occurring before, during or after testing for HIV, including HIVST

Test for triage: an HIV testing approach whereby a trained provider or self-tester performs a single HIV rapid diagnostic test (e.g., *HIVST*). Individuals with a reactive test result are encouraged by a trained provider, or by written or pictorial information, to link to a facility for further HIV testing to confirm their status, and if confirmed HIV-positive, to prevention, treatment, care and other support. Individuals with a non-reactive test result are advised to link to appropriate HIV prevention services and retest if they tested within six weeks of possible HIV exposure or are at ongoing HIV risk.

1 Introduction

Cambodia is one of seven countries in the world that has achieved the 90-90-90 targets in 2017. HIV prevalence in the general adult population has declined from an estimated 1.6% in 1998 to 0.6% in 2017. In 2017 Cambodia announced its intent to further control the HIV epidemic by achieving the 95-95-95 targets (95% of people living with HIV know their status; 95% of those who know their HIV positive status received antiretroviral treatment (ART); 95% of those on treatment are virally suppressed) and moving towards the elimination of new HIV infection by 2025. Through its boosted integrated active case management (B-IACM) program, Cambodia has diagnosed approximately 82% of the estimated total people living with HIV (PLHIV) and placed 81% of PLHIV on ART and documented that 78% of PLHIV had achieved viral load suppression in 2018. However, the gap in HIV testing remains significant particularly among some hidden yet high risk populations. For instance, in 2019 the national program reported 33% of MSM and FEW had never tested and more than 50% of TGW had not tested in the past 6 months (HIVST study result in 2019).

2 Rationale

In 2017 Cambodia developed national consolidated guidelines on HIV testing services in which various approaches are recommended to increase the HIV test uptake, especially among hard-to-reach and key populations [1]. Currently, the Ministry of Health (MoH) and its National Center for HIV/AIDS, Dermatology and Sexually Transmitted Diseases (NCHADS) has implemented and rolled out assisted lay testing using fingerpick by trained outreach workers (OWs) since 2014 through a community-based approach, especially for key populations. The current assisted testing strategy follows the WHO recommendations where anyone screened reactive is referred to HIV testing services (HTS) for confirmation and, if confirmed HIV positive, the person is referred to treatment services and ART initiation. This model was strengthened by including a peer-driven intervention approach where people tested are asked to refer peers for HIV testing (PDI+) using a risk-tracing snowball approach.

The national consolidated guidelines on HIV testing services also includes HIVST as a strategy to reach hard-to-reach key populations and increase the uptake of HIV testing among these later populations. Focus group discussions held with 144 transgender women (TW), men who have sex with men (MSM), and entertainment worker (EW) representatives in Phnom Penh city, Kampong Cham, Battambang and Siem Reap provinces reported high willingness to use HIVST due to its confidentiality/privacy and convenience [3]. HIVST was piloted in Cambodia from December 2018-September 2019 to assess acceptability, feasibility and oral fluid vs blood-based approach in order to improve KP HIV testing rates. MSM, EW and TW declining CBO field-based finger prick or clinic referral for HIV testing were offered HIVST in either face to face or via online outreach. Eligible clients, after risk assessment, chose provider assisted or virtually assisted oral fluid or blood-based HIV self-testing. HIVST kits were given to clients directly or delivered to or were picked-up by clients at NGO offices or pharmacies. HIV test results were reported online. Clients with reactive results were referred for confirmatory testing and ART initiation. A total of 1,215 participants were enrolled face-to-face (F2F) by outreach workers or online. Most (1,208 or 99%) were enrolled F2F recruitment and of these 1,191 (98.6%) opted for provider assisted HIVST and 17 (1.4%) preferred the virtually assisted option. Of 27 participants enrolled online, 22 received a kit and 7 (32%) uploaded their test results. Remarkably, of the total participants enrolled in the study, 71.9% reported that they had never been previously tested for HIV and of those never tested 5.9% were found to be HIV positive. By KP, the overall HIV seropositivity was 8.1% for

MSM; 11.0% for TG; and 2.6% for EW and all rates significantly higher than the current average IBBS rates (IBBS 2019 MSM 4.0%, TG 9.6%). Notably, all participants reporting reactive HIVST results had confirmatory testing and initiated antiretroviral treatment.

These HIVST studies in Cambodia [3,4] document very real opportunities to increase HIV testing particularly for KPs having demonstrated a high level of acceptability of HIVST particularly for oral fluid-based HIVST; high rates of confirmation of HIVST positive at HTS and subsequent ART initiation. HIVST empowers individuals to test even in face-to-face settings and can reach hidden high-risk populations never or infrequently tested before with high positive yields.

This SOP is based on WHO recommendations [5,6] and the experience acquired during the implementation of the HIVST study in Cambodia. NCHADS and its partners are providing this guidance to establish policy and procedures around HIVST rollout and full implementation and to ensure that HIVST meets the HIV testing needs of hard-to-reach key populations or other populations with high-risk behaviors not reached by the current targeted interventions in Cambodia.

3 Goal and objectives of the HIVST SOP

Goal: Contribute to the elimination of new HIV infections and ending AIDS as a public health threat by 2025 achieving 95-95-95 targets through the added provision of alternative and more acceptable testing options for those at risk for HIV.

Objectives: The overall objective is to establish policy and procedures around HIVST rollout and implementation to create more HIV testing options to reduce barriers to accessing HIV testing for anyone at risk for HIV.

The following specific objectives will contribute to the achievements of the overall objective:

- Increase demand and HIV testing uptake among key and other populations with high-risk behaviors who are hard to reach or currently not reached by routine HIV testing service
- Implement HIVST in priority provinces
- Coordinate and support the delivery of HIVST in different settings
- Define HIVST monitoring and evaluation and data collection

4 HIVST: basic principles

- **A reactive self-test result is not equivalent to an HIV-positive diagnosis.** All reactive self-test results need further confirmation testing at a VCCT site by a trained provider following national testing algorithm.
- **Non-reactive results should be considered negative.** However, individuals who have had potential HIV exposure within the preceding 6 weeks may be in the “window period²”, when the test may be non-reactive. They should perform retesting in 14 days or seek

² The window period is the time between potential exposure to HIV infection and the point when the test will give an accurate result. During the window period a person can be infected with HIV and be infectious but still test HIV-negative. The window can vary from approximately 2-4 weeks and sometimes longer.

retesting at a facility. Those who have ongoing HIV risk (i.e., Key Populations) they should retest every 6 months

- **HIVST should not be performed by people taking antiretroviral drugs**, as this may cause a false non-reactive result.
- **Any person who is uncertain about how to correctly perform the self-test, or interpret the self-test result**, should be encouraged to access facility- or community-based HIV testing

4.1 HIVST: how do clients do it?

The *WHO* defines HIV self-testing as “where a person collects his or her own 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.”

Some well-informed clients who’ve read or learned about self-testing from friends who’ve tested will be well prepared and ready to do their test. Others may want more information directly from providers online and it may vary from a province to another based on the available resources:

HIVST - Provider assisted: refers to individuals who receive an in-person demonstration or assistance 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. Pre-and post-HIVST counselling is directly provided to the client.

HIVST – Virtually assisted: refers to individuals who self-test for HIV using a self-test kit that includes manufacturer-provided instructions for use and links to online assistance. As with all self-testing, users will be provided with contact details to access additional support, such as telephone counseling hotlines and instructional videos. Pre- and post-test counselling will be available for the users through educational videos posted on dedicated websites and linked through QR code placed onto package insert.

4.2 HIVST access approaches

In the Cambodian context, the HIVST would be accessible through the following approved options. Other approaches may be added in the future as the context may evolve.

Community-based approach: NGOs and CBOs already delivering testing services (indoors at drop-in centers or community-based clinics, or through virtual or outdoor outreach activities including PDI+) to key populations and populations with high-risk behaviors should integrate HIVST into their strategy/activities to get those individuals tested who might otherwise not.

Health facility-based approach (public and private): selected health facilities already providing HTS and ART services can provide access to HIVST kits and pre- and post-test counseling.

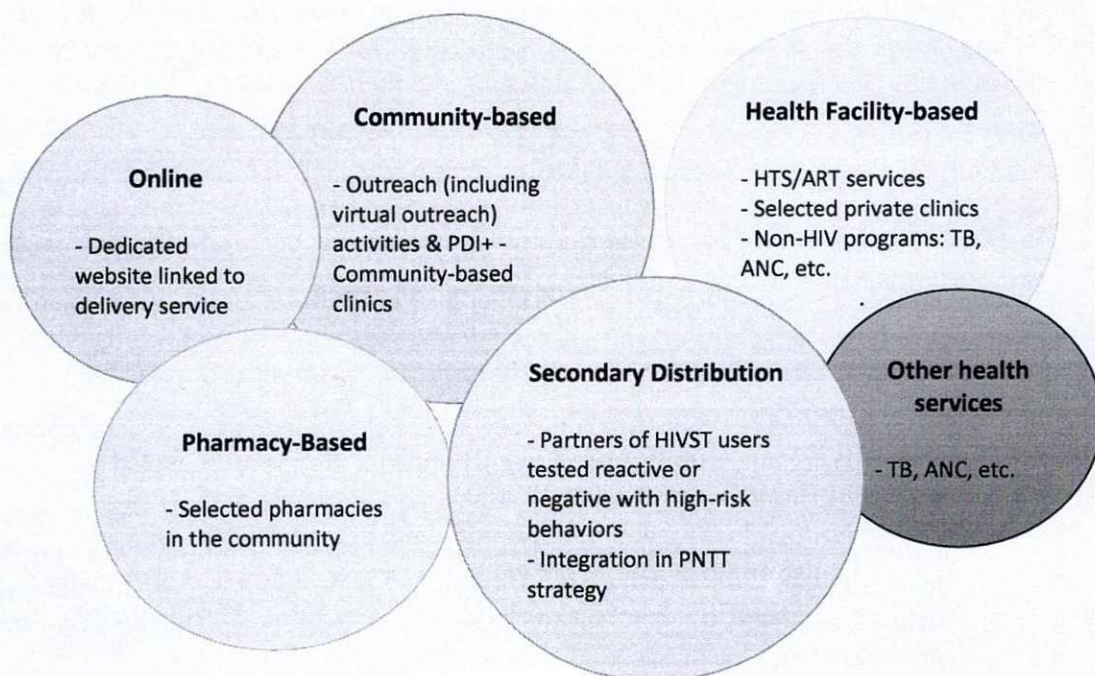
Secondary distribution of HIVST kits: HIVST providers (community or health facility-based) should consider secondary distribution to partner(s) of reactive, and non-reactive HIVST users reporting high-risk behaviors. HTS and ART services implementing PNTT could offer HIVST as an option for testing partner(s) who may not want to come to the test site.

Order online and receive by delivery service: Potential HIVST users should have the possibility to order the HIVST kit through a dedicated website (e.g., www.tohtest.org) or social media and receive it at home or in other preferred locations. The delivery could be initiated by selected NGOs and clinics using existing delivery services. While the HIVST kit will be free of charge, the person will be charged for the delivery cost.

Through pharmacies: selected pharmacies, particularly those valued by key populations and other populations at high-risk. Pharmacists can provide information on HIVST and linkages for those seeking confirmatory or facility-based testing.

Other Health Services: Integration of HIVST strategy in existing and relevant programs or health services such as TB, ANC, and PMTCT, STI services, chronic care and in-patient wards where HIVST could also offer another HIV testing option.

Figure 1: HIVST delivery approaches



4.3 Populations

The primary targets for HIVST in Cambodia include key populations (MSM, TG, EWs, PWID and high-risk PWUD), and other populations identified with high-risk behaviors, including but not limited to partners and clients of KPs, migrant workers, married women, and PWUD.

People below 15 years old, already known as HIV positive, under current antiretroviral therapy (ART), pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) or stopped PrEP or PEP less than 3 months before the test should not self-test. Treatment of any kind may reduce antibody levels below the threshold of the self-test sensitivity.

4.4 Geographical focus

HIVST will be promoted first in Phnom Penh where it has the highest number of KPs then extended, based on lessons learned to other larger areas where KP concentrated such as Sihanoukville, Siem Reap, Battambang and Banteay Meanchey provinces. Prior to scale-up to other provinces, lessons learned will direct adjustment of the HIVST strategy .

4.5 HIVST in the national HIV testing algorithm

HIVST is included as part of the national HIV testing strategy as a screening test or test for triage. Annex I describe its place and use in the national strategy.

4.6 Pre-and post-test counseling

Not all clients will want or desire pre and post test counselling. The program needs to assure that it is available online or face to face and it will be the option of the client to access it or not. It is important message that should let the users be aware of is the 5-Cs policy (consent, confidentiality, counseling, correct result, connect to prevention care and treatment).

All HIVST providers will be trained on providing pre-and post-test counselling for HIVST prior toward implementation of the HIVST strategy. Pre-and post-test counseling services will be provided by HIVST providers (health care or lay providers) according to the HIVST approaches and services delivery options selected by the HIVST users

Self-testing - provider assisted

Face-to-face contact or phone discussion prior to HIVST: pre-test and post-test counseling can be provided by HIVST providers (health care or OW) during the delivery of the HIVST kit and assist them in the execution of the test as needed. HIVST providers will remind their clients to follow the instructions of the package insert, to access educational pre-test counseling and HIVST procedures videos posted on a dedicated website, and/or seek for online or hotline support if the HIVST result is reactive and/or further assistance is needed.

Self-testing – virtually assisted

If clients order online and receive their HIVST kit through private delivery services, users can rely on the instructions from the package insert and can access educational pre-test counseling and HIVST procedures videos posted on a dedicated website, and/or seek for online or hotline support if the HIVST result is reactive and/or further assistance is needed.

4.7 Hotline and online support

Selected NGOs will be trained to provide hotline services and respond to HIVST users' questions and needs including guidance to access HIVST providers, pre- and post-test counseling, guidance to perform HIVST and interpret results and referrals. Similarly, lay providers from NGOS (outreach workers) will provide similar services through online social media using audio call or private message . The contact and operating hours of these hotline and online support services will be mentioned in the package insert and available on the dedicated website. These hotline and online support services will be also used as channels to report any social harms, complaints and adverse events

4.8 Linkages to services

In addition to delivery of effective HIVST services, specific strategies should be established to facilitate linkage to HIV prevention, including PrEP services, care and support and treatment services. Considering the possibility of adverse events (e.g. suicide ideation or suicide attempt) or social harms (e.g., gender based-violence, coercion) that could occur during HIV testing process, including HIVST, linkage to specific supportive services such as mental health, gender-based violence (GBV) and psycho-social, legal counseling and assistance should be, whenever possible, established by those delivering HIVST services, particularly HTS.

To minimize loss-to-follow-up users, HIVST providers should provide appropriate referral and linkage in line with the national HIV testing services guidelines. Directory of these referral services (contact and operating hours) should be available in the local package insert of the HIVST kit, printed materials and selected websites, as well as when making enquiries via the HIVST hotline service.

4.8.1 Linkage strategies for HIVST

- Interpersonal communication between HIVST users and community- and facility-based health care providers, peer supporters, case managers, or outreach workers through systematic follow-up of contacts and reminders via telephone, SMS, and social media applications (e.g., Facebook, WhatsApp, Twitter) if the client consents to sharing his/her contact.
- Counselling services and step-by-step instructions on what to do following a reactive or invalid HIVST result must be provided by phone (hotline or online support services) and through educational videos on pre- and post-test counselling posted in dedicated websites (linked with QR codes displayed in the package insert)
- Referral directory for HTS, care and treatment, mental health, legal counseling and assistance and GBV services could be posted on dedicated websites and printed materials that could be also used during community mobilization/awareness.

4.8.2 Linkages to care: how, who and where?

- HIVST users with an **HIVST reactive result** should be referred to HTS services for HIV confirmatory testing. Referrals can be by OWs, providers, online or by phone.
- HIVST users **confirmed HIV positive at HTS services** should be immediately linked to treatment services for ART initiation. This referral is usually initiated and supported by the HTS provider (facility or community based HTS services).
- HIVST users **reporting any adverse/undesired event** (e.g., suicide ideation, cognitive stress, etc.), **social harm** (e.g., GBV), **coercion**, should be evaluated for urgency and referred first to emergency care if needed and when appropriate to HTS services by community or facility-based services where professional counsellors can decide the need for further referral to specific services. Follow-up should be organized to ensure they are stable and to identify additional support.
- User-initiated HIVST users with an **invalid HIVST result** or who cannot **understand the instructions** or how to **interpret the HIVST results** should contact helpline or online counsellors for further guidance or decide to access any HIVST provider for

obtaining a new HIVST kit, receiving a provider-initiated HIVST or for a referral to HTS (community or facility-based services) for routine HIV testing using national algorithm. Arrangements should be made to ensure easy access to online, phone support that doesn't force individuals to reveal their identity.

- HIVST users reporting a **non-reactive HIVST result and high-risk behavior(s)** with possible exposure to HIV (unprotected anal or vaginal sex or needles sharing) in the preceding 12 weeks should be advised to retest at 4 weeks. A referral to HTS services or to any HIVST providers could be discussed and planned in this situation. More importantly, a referral to existing PrEP services should be discussed and offered to these HIVST users.
- HIVST users reporting lack of trust or doubts on the HIVST non-reactive result should be offered a referral to HTS services for HIV confirmatory test. This referral should be proposed to the clients if after addressing these distrusts they are still concerned about the accuracy of the HIVST non-reactive result.

4.9 Follow-up of HIVST users

Follow-up contacts with HIVST users should be organized by HIVST providers where possible. Many HIVST clients want to hide their identity and may be unwilling to give phone, email or other personal identifiers. Follow-up will be only possible if the **HIVST user consents** 1) sharing his or her telephone number or social media username; and 2) receiving calls or private messages from HIVST provider. Note that HIVST users who do not consent to share their contact information **are still eligible for HIVST**, but no active follow-up could be organized. However, HIVST users not consenting to share their information, should be advised to contact hotline or online support services. Referral/ appointment cards can be included in HIVST kits that include information and contact details on where to access further HIV testing, prevention and treatment. Depending on the setting, these cards can either be included by manufacturers inside the HIVST kits or provided as supplementary materials by implementing partners. For those consenting, the frequency of follow-up calls or private messages should be adapted as per the user's wishes (e.g., once a week after 6 p.m.) and stopped whenever the HIVST user decides. Kits could be coded to track source and interval between delivery and presentation to VCCT.

HIVST providers must ensure that information collected from HIVST users during these follow-up contacts are stored in a secure location or device to minimize the risk of breach of confidentiality. It is critical that the HIVST results are not stored in the same tools where users' identifiers are already recorded.

Type of follow-up contacts:

- **HIVST – virtually assisted - opting for private delivery service:** confirm the reception of the kit and if they have already performed the test
- **HIVST – provider-assisted - who have already performed the test:** can discuss their HIVST result and linkage to HTS for confirmatory HIV testing (if reactive result), to prevention services (if non-reactive and do not report on-going risk), to PrEP services (if non-reactive and do report on-going risks).
- **HIVST –. provider-assisted - diagnosed HIV positive at HTS:** support linkage to treatment service if not done at the time of confirmation.

- **HIVST – virtual or provider-assisted - with non-reactive result and reporting high-risk behaviors:** support linkage for a second test (HIVST or regular HIV testing) at 4 weeks and linkage to PrEP services
- **HIVST – virtual or provider-assisted - who report any undesired, social harm, coercion event:** support emergency care as needed and linkage to HTS for meeting professional counsellors
- **HIVST – virtual or provider-assisted - who report any challenge or difficulty in interpreting the results:** support linkage to an HIVST provider or HTS as per the user's choice.
- **Secondary distribution:** confirm the delivery of the HIVST kit to partner and explore whether HIVST has been already performed or the possibility to return the self-test kit.

4.10 HIV Promotion and Communication

To increase awareness, demand and utilization of HIVST, a communication strategy should be developed, if possible, prior to rollout the HIVST strategy. The communication strategy should be tailored to specific target audiences susceptible to receive HIVST services.

4.10.1 Health care and lay providers

Information on HIVST as an additional strategy for increasing access for HTS should be widely available to media, lay community, lay providers as well as health care providers. A specific curriculum should be developed to train HIVST providers and training courses organized.

Pre-and post-test counselling procedures should be strengthened by integrating HIVST strategy and related HIVST key messages (see key messages in Annex 9.1) that should be discussed with all clients when requesting HIVST option.

Encouraging health care and lay providers to advocate through interpersonal communication and with printed materials (e.g., leaflets, flyers and digital platforms) the use of HIVST

4.10.2 Key populations

Community awareness development through NGOs and CBOs working directly with key populations. The goal of community awareness is to increase the community's knowledge on HIVST including discussion on HIVST benefits and possible harms, addressing misconceptions generated by oral fluid-based HIVST kit, key procedures to perform HIVST, the meaning of HIVST results (invalid, non-reactive and reactive) and actions to be taken, and the referral directory.

The activities for community awareness should include off- and online for a (using social media), Facebook Live, educational materials (such as educational videos on pre- and post-test counselling, short video from HIVST users or champions sharing experience HIVST, etc.) posted on dedicated website (campaign "Toh Test"), interpersonal communications (outreach workers/peer educators) and printed materials.

Endorsement/support from MoH/NCHADS on any communication products should be visible to increase the level of trust from the targeted populations on

HIVST (e.g. logos, short video talk of high-level and known authorities of MoH, etc.)

4.10.3 Other populations with high-risk behaviors

Care providers in targeted national programs or departments (e.g., TB, ANC, FHCs, etc.) should promote HIVST as an option for HIV testing.

Integration of HIVST awareness on existing workplace prevention programs to promote HIVST to reach those who are hesitant to access existing HTS services due to stigma and discrimination as well as to reach other key populations or Package insert of the HIVST kit. Dedicated website for HIV testing (campaign “*Toh Test*”) will include pages on HIVST

4.10.4 Package insert developed by the manufacturer

- **Language:** the content of the insert should be in Khmer language but useful to request the manufacturer to add QR code(s) to add instructions in other relevant languages such as Chinese, Vietnamese, and English.
- **Pictures/text describing procedures and how to interpret results:** pictures and content should be large enough for a comfortable reading. Each step of the procedure for the preparation and the execution of the test and the interpretation of the HIVST result should be displayed in the insert.
- **Critical instructions and key messages:** critical instructions, warnings and contraindications should be on the top of the insert to be sure that the people read them first. Key messages (see Annex 9.1) should be also mentioned for the users.

Important instructions for the preparation and execution of the test should be visible and in other font color (for instance, wait 20 minutes before reading the results; or in case of oral-fluid-based test, do not drink or eat prior to the test). Meaning of possible HIVST results (reactive – non-reactive – invalid) and related actions to be taken should be clearly explained. The insert could also include a short description of the performance of the kit and a list of frequent questions & answers

Any video instructions provided by the manufacturer should be available on YouTube with Khmer subtitles.

4.10.5 Package insert (or sticker) developed locally

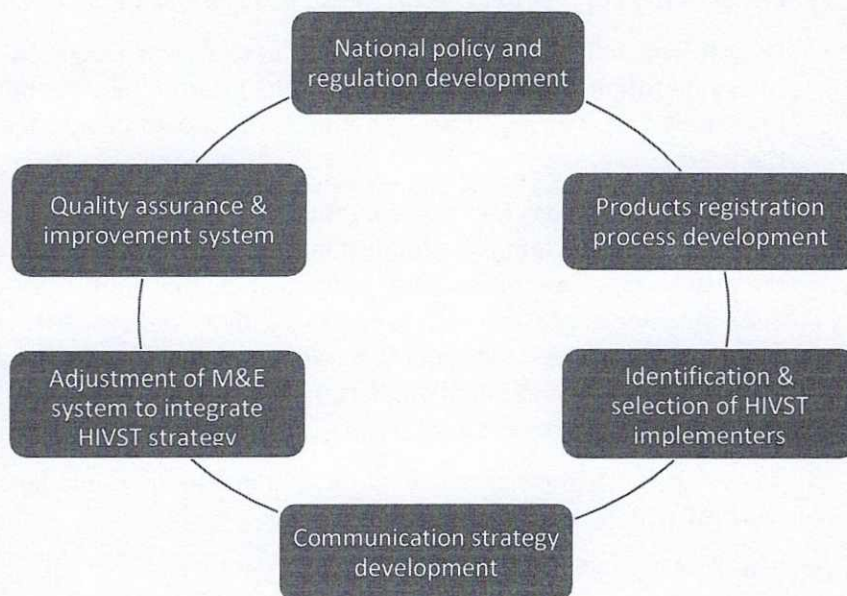
- **Contacts for assistance and linkages:** since these contacts will change from a province to another, additional and tailored insert including contacts for assistance (hotline services and HIVST providers such as NGOs, HTS services, etc.)
- **QR codes** to access educational videos for pre and post counselling and step-by-step instructions to perform the HIVST all in Khmer with English subtitles.
- **Logos of MoH/NCHADS** endorsing HIVST and confirming the legal registration and use of this HIVST kit in Cambodia: branding registered products versus products illegally sold in Cambodia.

- **Referral card** with a unique ID that HIVST users should give to health care providers at HTS services when referred for confirmatory HIV testing. These referral cards will be collected by the HIVST implementers for M&E purposes. These cards could be linked to small incentive e.g. phone card to ensure their submission at time of confirmatory testing.

5 HIVST strategy

HIVST roll out plan has been developed under the guidance of the National Technical Working Group (TWG) for HTS led by NCHADS and consists of members from key partners organizations, including key populations community representatives. This TWG has played a critical role in preparing and guiding the implementation of the HIVST strategy and coordinating with other existing TWGs for the integration of the HIVST strategy in other strategies aimed to reduce HIV incidence in Cambodia. To implement and scale up the HIVST strategy, essential activities (Figure 2) should be clearly understood and roles and responsibilities clear.

Figure 2: Essential activities to be established during the pre-implementation phase



5.1 National policy and regulations

NCHADS and MOH should ensure that clear and supportive policies and regulations are developed, approved and disseminated in the health sector, including provincial health offices, and communities, particularly for those who will be involved in HIVST implementation. Regulations should also highlight the eligibility criteria of HIVST implementers.

5.2 Registration process of HIVST products

To fast-track HIVST implementation, MoH and NCHADS should provide support for establishing an expedited regulatory approval process for HIVST products (capillary blood- and oral fluid-based kits) that are already approved by a recognized authority such as WHO. Then, a final national registration pathway for HIVST should be established and publicized for manufacturers. Specifications of the HIVST kits for this HIVST strategy in Cambodia include:

- Capillary blood and/or oral-fluid based HIVST products
- Performance of the kit should be above 99% for sensitivity and 99% for specificity
- Easy to use and no additional material/equipment should be bought by the users for collecting specimen (capillary blood or oral fluid), performing the test or interpreting the HIVST result
- Instructions for HIVST users should be in Khmer language
- Rapidity to get the final HIVST result should not exceed 20 minutes (excluding time to prepare and collect specimen)
- Storage condition should be between 2-30 degrees Celsius and shelf-life for at least 9 months.
- Packaging should be solid enough to avoid damage during transport/distribution

5.3 Communication strategy

A communication strategy aimed to magnify awareness and knowledge of HIVST and increase demand should be developed and implemented (see Section 4.10). The implementation of the communication strategy should be initiated prior to implementing the HIVST strategy to prepare the populations targeted by the strategy. Furthermore, training curriculum should be developed and all identified HIVST implementers (including pharmacists) should be trained prior to the implementation.

5.4 Quality Assurance and Improvement system

To prevent problems and ensure and sustain optimal HIVST performance, a quality assurance and improvement system, including post-marketing surveillance should be in place (see Section 7)

5.5 M&E system

HIVST should be integrated into the existing M&E system for HIV testing in Cambodia. New indicators (see Section 8) and tools to collect data to compute these indicators should be adapted or developed.

5.6 Identification and selection of HIVST implementers

NCHADS and partners should identify and select HIVST implementers at community and facility level to cover different HIVST service delivery approaches (see Section 4.3) and targeted populations proposed under the HIVST strategy in Cambodia. All HIVST implementers will be trained prior to initiated the implementation of the strategy

6 Key steps for increasing HIVST access

This section summarizes the key steps for increasing HIVST access by approach: community-based; facility-based; online; pharmacies; other services; and secondary distribution. Detailed standard operating procedures must be developed by each site according to their settings where HIVST will be implemented and include the below key steps as standard procedures for quality assurance. Specific instructions to perform HIVST are placed in Annex 9.2

6.1 In person approaches

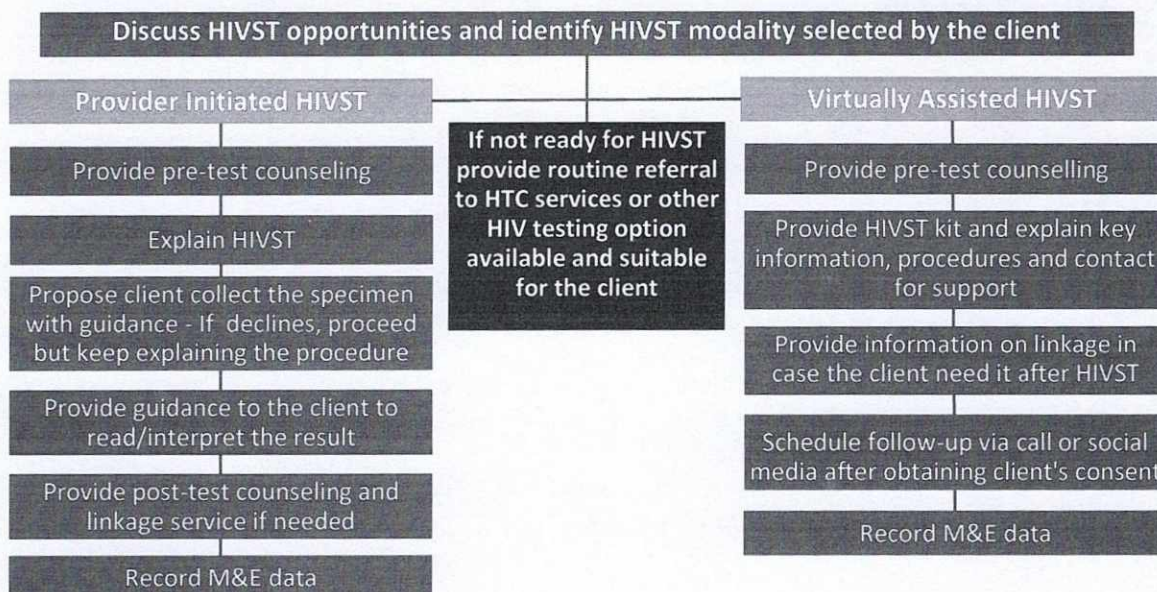
6.1.1 Community access

NGOs and CBOs already delivering testing services (indoors at drop-in centers or community-based clinics, or through virtual or out-door outreach activities including PDI+) to key populations and populations with high-risk behaviors should integrate HIVST into their strategy/activities to get those individuals tested who might otherwise not.

6.1.2 Health facility-based access (public and private)

Selected health facilities already providing HTS and ART services can provide access to HIVST kits and pre- and post-test counseling

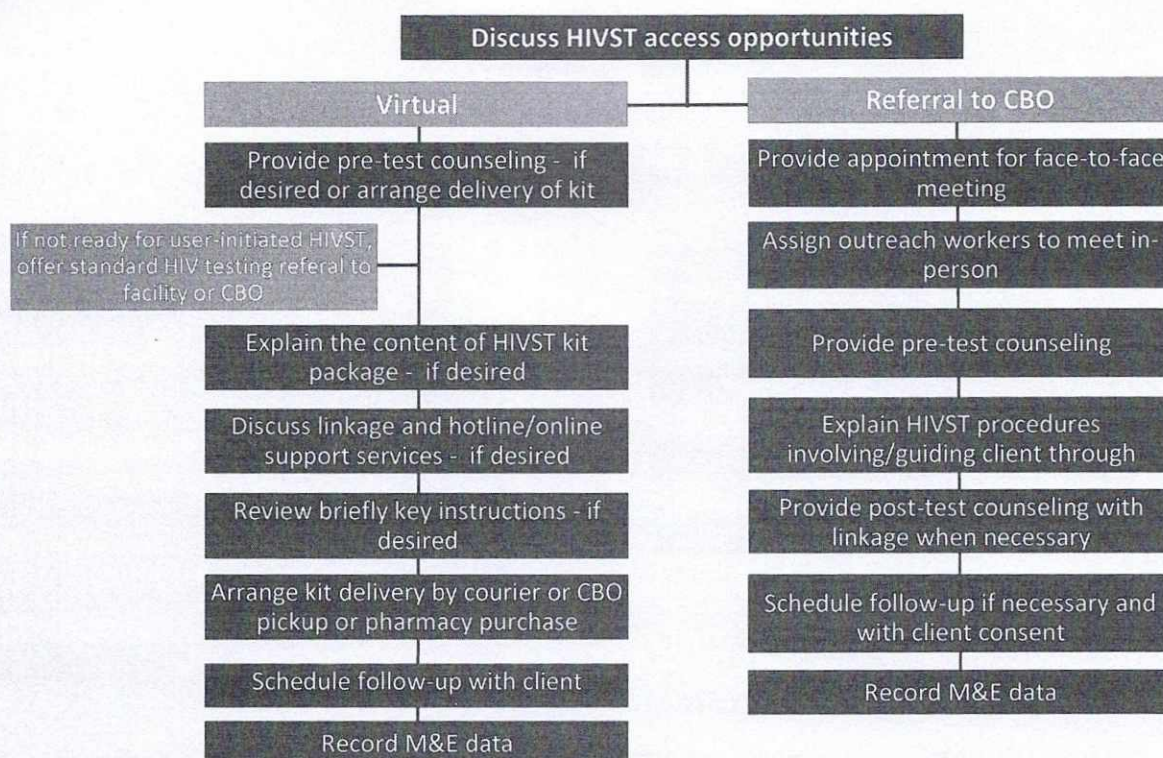
Figure 3: In-person approaches by CBOs and HTS/ART services



6.2 Order online and receive by delivery service

Potential HIVST users should have the possibility to order the HIVST kit through a dedicated website (e.g., "Toh Test") or social media and receive it at home or in other preferred locations. The delivery could be initiated by selected NGOs and clinics using existing delivery services. While the HIVST kit will be free of charge, the person will be charged for the delivery cost.

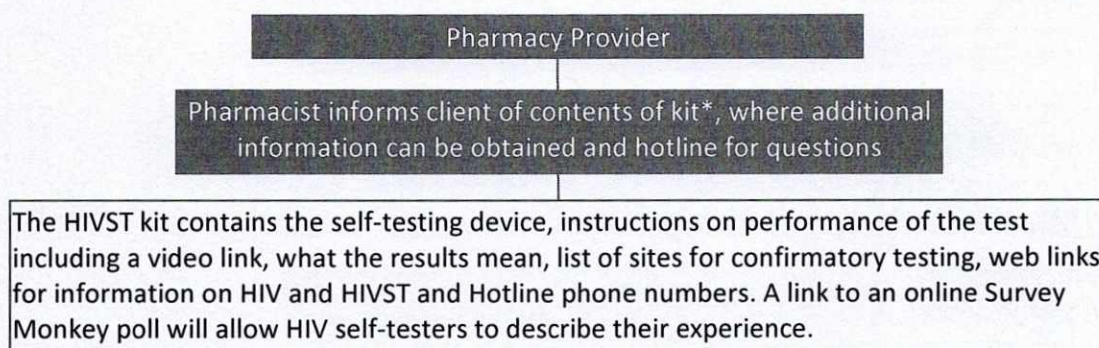
Figure 4: Online access



6.3 Through pharmacies

Selected pharmacies, particularly those valued by key populations and other populations at high-risk. Pharmacists can provide information on HIVST and linkages for those seeking confirmatory or facility-based testing.

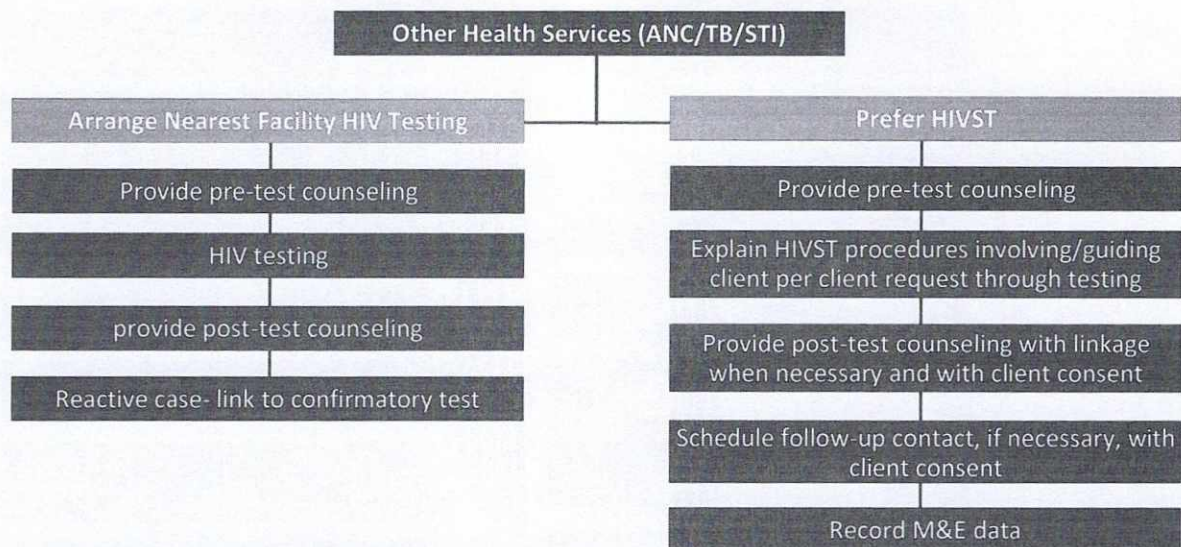
Figure 5: Pharmacy Approach



6.4 Other Health Services

Integration of HIVST strategy in existing and relevant programs or health services such as TB, ANC, and PMTCT, STI services, chronic care and in-patient wards where HIVST could also offer another HIV testing option.

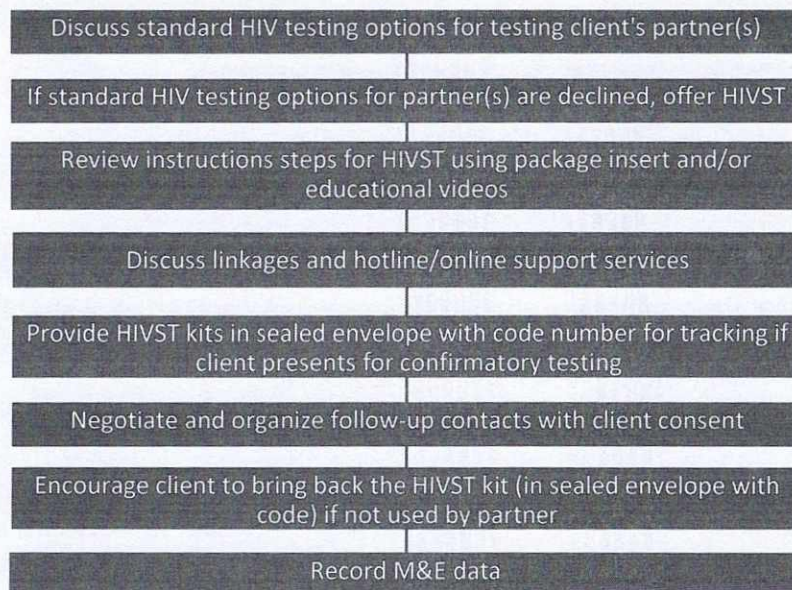
Figure 6: Other Health Service Access



6.5 Secondary Distribution of HIVST

Secondary distribution of HIVST will occur at community and clinic facilities, including sites where PNTT is implemented. The secondary distribution of HIVST kits should be offered to clients (HIV positive or negative and reporting high-risk behaviors), if other standard HIV testing options for their partner(s) are declined HIVST should be offered. HIVST providers will follow the below key steps for the delivery of HIVST under secondary distribution

Figure 7: Secondary Promotion Approach



7 Quality Assurance & Improvement

Quality assurance and improvement procedures should be established and include the following components:

7.1 Quality assurance of HIVST kits

HIVST kits for national procurement must be pre-qualified by WHO and should be registered in the country following MoH regulatory affairs for registration of in vitro diagnostic devices as other HIV test kits currently used in Cambodia.

This registration process, as well as the identification of in-country distributor(s) of the product should be initiated and supported by the manufacturer of the HIVST kit.

Batch testing of procured HIVST kits could be also organized, prior to the distribution, on a sample of kits randomly selected from each batch of HIVST kits received from the manufacturer. Furthermore, an EQA system for HIVST could be developed to compare HIVST and HIV testing results.

7.2 Post marketing surveillance

Post-marketing surveillance should be established to ensure that the procure HIVST kits are safe, efficacious and effective:

7.2.1 Distribution and supply of HIVST kits

Licensed and regulated distributors of HIVST kits have responsibility to comply with good storage and distribution practices. This system should be developed and monitored by the distributor in collaboration with MoH/NCHADS and their partners

7.2.2 Social harm/ undesired events reporting

The rapid reporting of these events is critical for the safety of HIVST users. HIVST users will have the possibility to report these events either through hotline services or NGOs/CBOs providing HIVST services (information in the package insert). Their contact will be listed in the package insert. Report forms will be completed by these organizations receiving calls and submitted to NCHADS in Phnom Penh):

- **Social Harm (e.g., intimate-partner violence, denying access to household, coercion, etc.):** support referral to professional counsellors at HTS services) (community or facility-based services) for further referrals to specific services and report
- **Undesired event such as cognitive stress, suicide ideation or attempt, binge drinking, etc.):** support referral to professional counsellors at HTS services (community or facility-based services) for further referrals to specific services and report
- **HIVST kit package damaged, incomplete, or device not performing properly:** support referral to HIVST providers (community or facility-based services) to receive a new kit in exchange, whenever is possible, of the damaged/incomplete kits (batch/lot number of the damaged/incomplete HIVST kit should be recorded in the form)

7.2.3 Quality assurance of HIVST procedure

All HIVST service providers, including outreach workers, health care providers, counselors from HTS services or hotline services, should be trained per the HIVST training package that could be developed by NCHADS and relevant partners. This includes capacity building and knowledge on how to conduct the tests and to interpret result, and where to refer

clients to for linkage for additional testing and further support. Training could be organized by national trainers (e.g., NCHADS, LINKAGES) or organized by in-house trainers once they are certified. The distributors will be in charge of training pharmacist on appropriate use of the product.

All promotional and educational materials (printed material or videos), SOP and reporting tools (M&E and undesired/social harm events) should be discussed during the training and available in each HIVST provider site.

Quality assurance for HIVST procedure could be assessed in the field or at the clinic when HIVST providers perform provider initiated HIVST with a client. Specific tools for assessing the quality of the HIVST procedure should be developed.

7.2.4 Quality Improvement

Triangulation of data from M&E and other relevant sources (e.g., data from HTS services, post marketing surveillance, quality assurance, etc.) should be used to develop a quality improvement plan. NCHADS and relevant partners could lead the process and discuss the findings and recommendations for with the national HTS TWG.

8 Monitoring & Evaluation

National and institutional specific standard tools should be developed and utilized by the HIVST implementers to collect and report data.

Disaggregation of these indicators (age-group, gender, population, etc.) should be done for all these indicators as per the guidance of the national M&E system and donors' requirements.

Data flow and frequency of reporting should follow national M&E guidance for reporting HIV testing-related indicators.

The following indicators could be reported:

- Number of HIVST kits distributed to implementers (breakdown by type of implementer)
- Number of HIVST kits distributed to clients (breakdown by HIVST approach and by delivery model)
- Number of HIVST users reporting their results (breakdown by HIVST approach, delivery model and HIVST result)
- Number of first-time testers (breakdown by HIVST approach, delivery model and HIVST result): never been tested prior HIVST. Monitored with Universal Unique Identifier Code (UUIC) if operational in Cambodia or asked to each HIVST user when they come to request HIVST (reported)
- Number of frequent HIVST testers i.e., at least more than one HIVST in the preceding 12 months (breakdown by HIVST approach, delivery model and result) monitored with Universal Unique Identifier Code (UUIC) if operational in Cambodia or asked to each HIVST user when they come to request HIVST (reported)
- Number of HIVST users screened reactive successfully referred to HTS services for confirmatory tests (breakdown by HIVST approach and delivery model)

- Number of HIVST users screened but results invalid and referred for testing using the national algorithm (breakdown by HIVST approach, delivery model and HIV test result: positive, negative or inconclusive)
- Number of newly diagnosed HIV positive linked to treatment services for ART initiation
- Number of HIVST users reporting non-reactive HIVST results linked to prevention services
- Number of HIVST users reporting non-reactive HIVST results and ongoing risk linked to PrEP services
- Number of HIVST users reporting adverse/undesired events or social harm (breakdown by HIVST approach, delivery model and results and by type of event)
- Number of HIVST users reporting issue with device: kit incomplete, damaged, or not performing as expected (breakdown by HIVST approach and delivery model)

Reporting tools

HIVST tools for compiling and reporting data should be developed. These tools could include:

- HIVST Register for the implementer (managed by the focal point or health care providers) – or integrated in the existing HTS register, if any
- HIVST weekly reporting form for outreach workers
- Adverse and social harm events and other complains reporting form
- Quarterly report from implementer (follow national report)
- Stock control cards

9 Annex

9.1 Key messages for HIVST

- *Most people feel a little bit anxious and stressed when taking an HIV test. But, if you feel very anxious about taking the test, you may want to wait until you are calmer to take it, call hotline or online services to receive assistance (see list of available services), or to get tested at HTS services (see list of available services)*
- *If you are already on treatment for HIV (antiretroviral treatment) or prophylactic treatment for HIV (PrEP and PEP), HIVST is not for you as the results may be false.*
 - *Once you are on ART, HIV testing using rapid tests, including self-testing, may not be accurate. A negative result while on ART will likely be false and you should not stop antiretroviral treatment*
 - *An undetectable viral load test result means ART is successfully controlling the virus. It does not mean that the virus is gone and that you are cured. It also does not mean you can stop taking ART and that your HIV test will turn out negative.*
 - *It is important to tell a person providing HIV testing or distributing self-tests that you are on ART as you may get a false negative result*
 - *Talk to a counsellor, health worker, or a trained outreach worker if you have doubts or concerns about the accuracy of the HIVST results or need any assistance (see list of available services)*
- *Please follow the testing directions carefully to be sure the results are correct. If you are not sure about the instructions or you face a problem during the execution of the test you can call the hotline services (see list of available services) to receive assistance. These calls are anonymous meaning that we will not ask your name or other identifiers.*
- *You should be 15 years old or older to use this HIVST test*
- *A reactive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done at HTS (see list of available services)*
- *A non-reactive result with this test does not mean that you are definitely not infected with HIV, particularly when exposure to HIV may have been within the preceding 12 weeks. In this case, you should retest at 4-weeks*
- *If your test is non-reactive and you engage in activities that put you at risk for HIV on a regular basis, you should test regularly and talk to your health care provider the possibility to get a treatment to prevent HIV infection that is called pre-exposure prophylaxis treatment or PrEP (see list of available services)*
- *This product should not be used to make decisions on behavior that may put you at increased risk for HIV*
- *HIVST testing should always be voluntary, never mandatory, or performed under coercion*

9.2 Instructions for HIVST testing

For Outside USA Use Only • In Vitro Diagnostic Use • Do Not Reuse

INSTRUCTIONS FOR USE

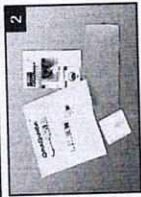
The OraQuick[®] HIV Self-Test is an in vitro diagnostic medical device (ID) that is used for self testing of individuals for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals. You must follow the test directions carefully to get an accurate result. **WARNING: If you are on HIV treatment you may get a false negative result. Do not use this test if you are on HIV treatment. You must follow the test directions carefully to get an accurate result.**

DO NOT eat or drink for at least 15 minutes before you start the test or use mouth cleaning products 30 minutes before you start the test.

HOW TO USE THE ORAQUICK[®] HIV SELF-TEST KIT



YOU WILL NEED A WAY TO TIME THE TEST



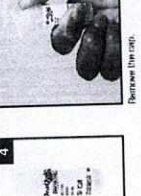
Kit contains: test kit, test device, instructions for use and disposal bag. Follow these steps to begin testing.



Your seal kit contains two vials.



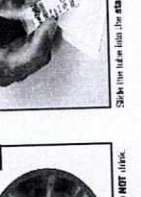
Tear open the results envelope.



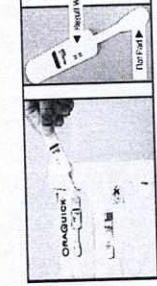
Remove the cap.



DO NOT FOR 20 MINUTES before reading the results. DO NOT drink, eat, or use mouth cleaning products during this time.



Stick the test in the stand.



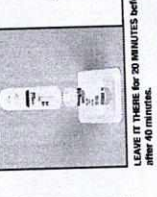
Test open pouch containing the test device and control. DO NOT touch the test pad with your fingers. DO NOT eat or drink for 15 minutes after testing.



Read the test results in a well-lit area.



Wait 20 minutes.



Read the test results in a well-lit area.



Dispose of the test device.

INTERPRETING RESULTS

Read test results in a well-lit area.

HIV POSITIVE RESULT

Two complete lines, even if the line is faint, means you may have HIV. If you are HIV positive, you need to seek medical attention as soon as possible. 98.4% of people (150 out of 153) correctly reported their result as positive. This means that 1 out of 153 people infected with HIV reported a negative result. This is called a false negative.

HIV NEGATIVE RESULT

ONE LINE, not to the "C" and NO line means you are HIV negative. 99.0% of people (147 out of 148) correctly reported their result as negative. This means that 1 out of 148 people not infected with HIV reported a positive result. This is called a false positive.

INVALID RESULT

IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT. ONE LINE, not to the "C" and NO line means you are HIV negative. 99.0% of people (147 out of 148) correctly reported their result as negative. This means that 1 out of 148 people not infected with HIV reported a positive result. This is called a false positive.

DISPOSE

Remove the test stick, put the cap on the test stick, place in the disposal bag provided and throw away all contents in the disposal bag.

NOT SURE OF RESULT

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

PRODUCT INFORMATION

184-1000, 184-1001, 184-1002

WARNINGS AND PRECAUTIONS

• DO NOT use the test if you are HIV positive. • Do not use the test if it has been opened for more than 12 months. • Do not use the test if it has been opened for more than 12 months. • Do not use the test if it has been opened for more than 12 months.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

If you are HIV, HCV, or HTLV (HIV) positive, you may get a false result. It is recommended that you discuss this with your healthcare provider.



www.oraquick.com

| Item Code | Lot Number | Expiration Date | Use By |
|------------------------|------------------------|------------------------|------------------------|
| LOT | EXP | EXP | EXP |
| On the Result | On the Result | On the Result | On the Result |
| Temperature / Location | Temperature / Location | Temperature / Location | Temperature / Location |

EXPLANATION OF SYMBOLS

| | |
|--|--|
| Caution: Consult Accompanying Instructions | Caution: Consult Accompanying Instructions |
| Do Not Reuse | Do Not Reuse |
| Temperature / Location | Temperature / Location |



OraQuick HIV Self-Test

184-1000, 184-1001, 184-1002

9.3 Roles and responsibilities

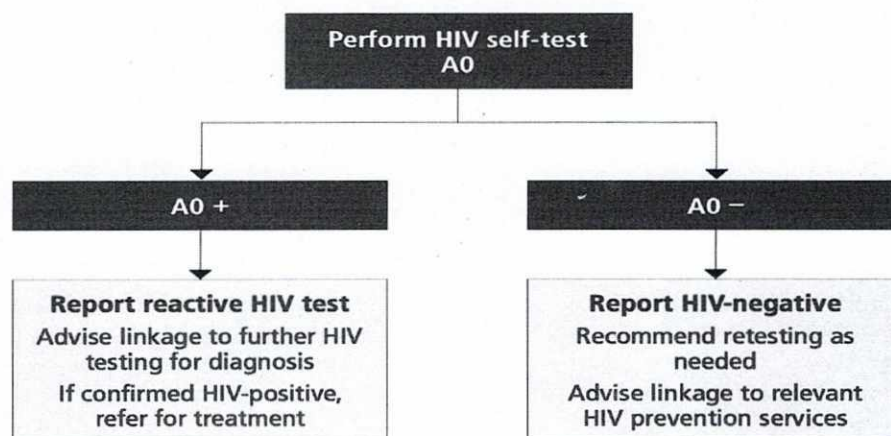
| Level | Agencies and their Role | Staff | Responsibilities |
|----------------|---|-------------------------------------|---|
| National Level | NCHADS <i>Role: Leadership, technical assistance and coordination of all stakeholders involved in the implementation of the HIVST</i> | Focal points for HIVST | <ul style="list-style-type: none"> * Review and endorse the materials (training, promotion, etc.) and tools developed for the HIVST strategy * Lead the M&E and quality assurance (QA) and quality improvement (QI) teams to ensure that the system is operational * Review M&E, QA, QI plans, and other reports (adverse/undesired events, social harm, external quality assessment, etc.) before the submission to the HIVST TWG * Coordinate with other department of MoH and national program to explore the feasibility of integrating HIVST in relevant programs |
| | NCHADS' partners (GOs, UN agencies, INGOs, NGOs, and other national agencies (TDB) supporting HIVST strategy) <i>Role: Provide technical assistance and support for the implementation of HIVST strategy</i> | Assigned staff(s) of these agencies | In collaboration with NCHADS <ul style="list-style-type: none"> * Provide TA for development of training and promotional materials, educational video, M&E and other reporting forms (adverse/undesired events, social harm, etc.), and QA/QI * Provide TA and support for the development of the promotion, including community awareness and demand for HIVST * Provide TA for training trainers of implementers agencies * Provide TA for the implementation of quality assurance system * Compile data (triangulation of data) to monitor and evaluate the HIVST strategy and provide preliminary analysis and QI plan |
| | HTS Technical Working Group (TWG) <i>Role: Provide technical support and guidance for the successful implementation of the HIVST strategy</i> | Members of the TWG | <ul style="list-style-type: none"> * Convene regular meeting with members of the TWG to discuss the progress of the implementation, challenges and opportunities * Review different reports and provide recommendations on quality improvement and needs to develop and update the SOP, relevant guidelines and tools |
| | Distributor of HIVST kits (should be proposed by the manufacturer importing HIVST kits) <i>Role: Ensure the supply and distribution of safe and effective HIVST kits</i> <i>(Note: could be also found at provincial level)</i> | Representative and staff | <ul style="list-style-type: none"> * Ensure the procurement and distribution of HIVST from national to provincial level * Add any material (insert package) developed and endorse by the HIVST TWG * Collaborate with MoH to develop batch test procedures before the distribution and an EQA system. * Ensure the training of pharmacists distributing/selling HIVST kits |

| | | | |
|--|--|--|---|
| | clinic to reach key populations and vulnerable groups accessing services | | <ul style="list-style-type: none"> * Manage the delivery of HIVST kit to users who would like a face-to-face delivery (at office or in the community) and provide pre-test counselling when delivering the kit * Organize follow-up of HIVST users in need of referral to services and provide support for successful referral. * Propose HIVST as an HIV testing option in the PNTT strategy (secondary distribution) * Collect and compile M&E data and reports and participate to M&E and QA/QI activities |
|--|--|--|---|

9.4 The National Testing Strategy

Following WHO recommendations, HIVST is considered as a test for triage (screening test) and as "Assay 0" (Figure 8) in the HIV testing algorithm. A reactive HIVST result is not considered to an HIV- positive diagnosis.

Figure 8: HIVST strategy



A0 = Assay 0 (test for triage).

Source: WHO 2016 Guidelines

The following situations should be considered:

- HIVST users with a **non-reactive HIVST result** should be considered as negative and advised to retest in 6 months if no risks have been reported in the preceding 12 weeks. However, if high-risk behaviors (e.g., unprotected anal or vaginal sex and sharing needles for injection) in the preceding 6 to 12 weeks or ongoing risk of HIV infection are reported by the users, the person should be retested at 4 weeks
- Users with a **reactive HIVST result** should be referred to HTS services for confirmatory HIV testing using the national HIV testing algorithm (2017's National HIV testing strategy) where specific assays (A1, A2, A3) could be used to confirm the diagnosis.
- Users with **invalid HIVST result** should be referred to an HIVST provider (community or facility-based) for a provider-initiated HIVST or referred to HTS services for a standard HIV test.

10 References

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- 6 World Health Organization. *Guidelines on HIV self-testing and partner notification: supplement to Consolidated guidelines on HIV testing services.* ; 2016.
7. World Health Organization. *HIV Self-testing Strategic Framework. A guide for Planning, introducing and scale up HIV testing services.*; Oct 2018

