Kingdom of Cambodia

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Ministry of Health

National Consolidated Guidelines on HIV Testing Services in Cambodia

2024

National Centre for HIV/AIDS, Dermatology and STD

Table of Contents

FOREWORD

At the UN General Assembly High Level Meeting on AIDS in New York in June 2021 Cambodia is committed to adopt the global goals and targets to end AIDS as a public health threat by 2030. To achieve these ambitious goals and targets the Ministry of Health (MOH) of the Kingdom of Cambodia through the National Center for HIV/AIDS, Dermatology and STD (NCHADS) and its partners has developed the boosted strategy for a combination of HIV prevention care and treatment among key populations and targeted general populations since 2012.

In addition, the Ministry of Health recommends that all HIV testing implementers put more effort into strengthening and expanding the implementation of approaches on boosted and integrated active HIV case management to detect 95% of total estimated people living with HIV to know their HIV status by 2025. Following the MoH recommendations, NCHADS and its partners developed in 2017 the consolidated national guidelines on HIV testing services (HTS). With recent development and newly adopted evidence-based guidance 2019, NCHADS updated this consolidated national guideline by adopting the most recent WHO HTS guidelines 2019 and the valuable inputs and good practices on HTS implemented in the country and in the region.

The Ministry of Health reviews and endorses these consolidated national guidelines on HTS being implemented in health facilities (public, private and NGOs) and in community settings with respect to the 5 C principles recommended by WHO including counsel, consent, confidentiality, correct test result and connection. MoH also expects that all HTS providers will use this document effectively and properly to ensure quality and effectiveness of HIV testing services in Cambodia.

Phnom Penh, 3.../Dec./2024

Minister of Health

Prof. CHHEANG RA

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This consolidated national guideline on HTS is successfully updated with active participation and inputs of members from the sub-technical working group on VCCT led by NCHADS.

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Anti-retroviral Therapy
ARV	Antiretroviral Drugs
B-IACM	Boosted Integrated Active Case Management
CMA	Case Management Assistant
CMC	Case Management Coordinator
CMP	Case Management Provider
CMS	Central Medical Store
COC	Continuum of Care
DBS	Dried Blood Spot
DNA	Deoxyribonucleic Acid
DPHI	Department of Planning and Health Information
EID	Early Infant Diagnosis
eMTCT	Elimination of Mother to Child Transmission
EQA	External Quality Assessment
EW	Entertainment Worker
FHI360	Family Health International 360
GP	General population
HIV	Human Immunodeficiency Virus
HPITC	Health Provider-Initiated Testing and Counseling
HIVST	HIV Self-Testing
HTC	HIV Testing and Counseling
HTS	HIV Testing Services
IPC	Pasteur Institute of Cambodia
KHANA	Khmer HIV/AIDS NGO Alliance
KP	Key Population
LOA	Letter of Agreement
MCH	Maternal and Child Health
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MSM	Men who Have Sex with Men
NBTC	National Blood Transfusion Center
NCHADS	National Center for HIV/AIDS, Dermatology and STD
NGO	Non-governmental Organization
NIPH	National Institute of Public Health
OD	Operational District
OW	Outreach Worker
HIV DNA PCR	Polymerase Chain Reaction
PASP	Provincial AIDS and STI Programme
PDI+	Peer Driven Intervention Plus
PEP	Post-Exposure Prophylaxis

PLHIV	People Living with HIV
PNTT	Partner Notification Testing
PMTCT	Prevention of Mother- to- Child Transmission
PrEP	Pre-Exposure Prophylaxis
PT	Proficiency Testing
PWID	People Who Inject Drug
PWUD	People Who Use Drug
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management System
RDT	Rapid Diagnostic Test
RTI	Reproductive Tract- Infections
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infections
TB	Tuberculosis
TG	Trans-gender
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCCT	Voluntary Confidentiality Counseling and Testing
WHO	World Health Organization

CHAPTER I. INTRODUCTION

1.1 Background

1.1.1 Overview of HIV epidemic in Cambodia

Cambodia has made a great progress against the HIV epidemic and has been a model for other countries in Asia and the Pacific region and beyond. These are evidenced by decrease in number of new HIV infections by 33% (from 2,000 to 14,00 in 2022), and AIDS-related deaths by 30% (from 1,600 to 1,100) between 2010 and 2022 according to AEM-Spectrum-UNAIDS/NCHADS-2023.

In addition, Cambodia acclaimed the highest HIV treatment coverage in Asia and the Pacific region with 86% of estimated total 76,000 PLHIV in the country on life saving treatment by the end of 2022 and 98% are virally suppressed. Achievement of 90-90-90 treatment targets (since 2017) is also the testament of putting people living with HIV and key populations community at the heart of the national HIV response coupled with innovative and people centered services.

These tremendous achievements are the results of the Political Commitment and leadership of the Royal Government of Cambodia, strong partnership with civil society organizations, UN and development partners, and active engagement of people living with HIV, and communities of key populations.

Cambodia has committed to ending AIDS as a public health threat by 2025, however, the last miles is often the hardest. HIV epidemic continues to affect key populations, more than others. These include female entertainment workers, men who have sex with men, people who inject drugs, and transgender people. In 2022, key Populations and their sexual partners account for 83% of total new HIV infections, and 48% of new HIV infections are among male sex workers and other men who have sex with men, which indicate a significant increase from the past years.

We see increasing vulnerability to HIV transmission among young key populations, particularly among young men who have sex with men and transgender women.

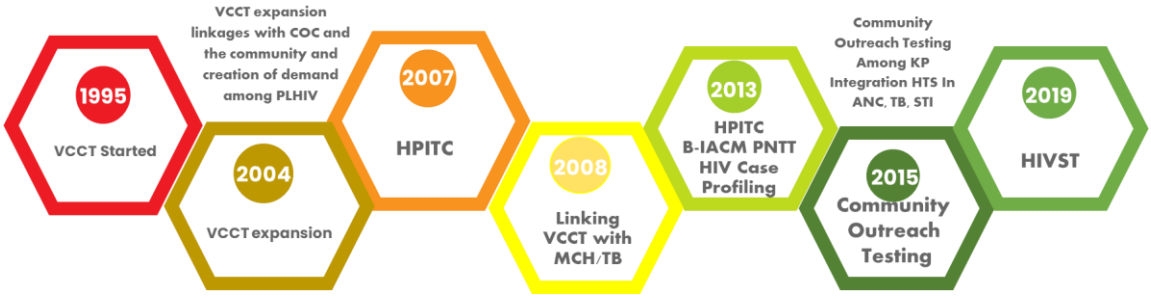
Though Cambodia has achieved the 95-95-95 target, but gaps remain to achieve the first 95 with only 86% of total estimated PLHIV knew their HIV status, and based on the NCHADS's database, there is testing gaps also exist among key population with only 75% estimated among MSM (87% among MSM have educated), 46% estimated among TG (84% TG have educated) 67% estimated among EWs (96% EW have educated) and lowest group among PWID accessed HIV testing in 2022 (NCHADS-NPD 2022)

1.1.2 Strategic priorities to end HIV epidemic.

It is important to note that at the UN General Assembly High Level Meeting on AIDS in New York in June 2021, Cambodia expressed its support to the global goals and targets in intensifying efforts to end AIDS by 2030. Building on the accomplishments made during the last decades, Cambodia has committed through a set of strategies clearly highlighting in Strategic Plan for HIV and STI Prevention and Care in Health Sector 2021-2025. These include 1) HIV Prevention, including combination HIV Prevention: PrEP which put particular focus on Key Populations, 2) HIV testing through differentiated HIV testing modalities, including HIV Self-Testing, 3) HIV care and treatment services, 4) eMTCT and 5) STI prevention and control.

1.1.3 Progress of HIV Testing Services

Figure 1. Evolution of HIV testing services over time, 1995-present



The first VCCT service was established in 1995 in Phnom Penh at the Pasteur Institute. Since then, with the assistance from French Cooperation by the end of 2001, 11 stand-alone VCCT services were made available and localized in capital cities and some provincial towns. Enzyme Linked Immune-Sorbent Assay (ELISA) tests were used for HIV diagnosis and were available at hospital laboratories [(7)]. The HIV test result was returned to the clients within two weeks. The first policy and guidelines for HIV counseling and testing (HTC) were officially approved in 2002.

To rapidly increase access to HIV care services, the continuum of care (COC) framework was approved and implemented at the operational district level in 2003. In addition, HTC was an important entry point for HIV prevention, care and treatment, and support services, and it contributed to reduction of stigma and discrimination of HIV. As a result, VCCT was rapidly expanded to cover all operational districts and even applied to the health center level. It is important to highlight that not only service expansion but systematic linkages with the community and creation of demand among people living with HIV (PLHIV) were also made.

HIV rapid tests were validated by NIPH laboratory in 2004, and the standard HIV testing algorithm was implemented at all VCCT services operated by public and NGO facilities. Since then, the three Rapid Diagnostic Tests (RDTs) including Determine HIV Early Detect, Stat-Pak HIV1/2, and Uni-Gold HIV1/2 have been used as the standard RDTs in Cambodia.

In line with WHO recommendations, Cambodia adopted and introduced the health provider-initiated testing and counseling approach (HPITC) in 2007 to increase the uptake of HIV testing and to provide early HIV diagnosis for the patients/clients attending health facilities [(10)]. This approach offered routine HIV testing at ANC and TB services, and the HIPTC model has been fully integrated since 2013 [(11)]. Before the integration of HTS in ANC and TB services, patients/clients were referred from these services using referral cards to the nearest VCCT or sending blood specimens to the hospital laboratory for HIV diagnosis. This process made the HIPTC coverage at other clinical settings (e.g. STI services and malnutrition wards) low in terms of clients registered. From 2017 onward, the term HTC is replaced by “HTS”.

The low service uptake led to an initiation of the community/peer-initiated testing and counseling approach which was developed to address the low uptake of HIV testing among KP and was endorsed by the Ministry of Health (MOH) in 2011. This approach was implemented through trained lay persons of each group of Key Populations.

1.2 Rationale

Cambodia is committed to achieve an ambitious goal to end the HIV epidemic by 2025. In the context of scarce resources implementing the "Identify and Reach" and "Treat All" strategies, Cambodia must focus on most effective, efficient, and innovative intervention models to detect 95% of total estimated PLHIV to know their status by 2025 [13].

From 2002, a range of documents on policies, strategies, and guidelines on HIV counseling and testing (HTC) were available in different papers developed by NCHADS and partners [7]. However, there are gaps and limitations in the HTC approaches implemented between 2002 and 2013 to provide a framework for all HTC modalities in order to identify and detect KP and high-risk GP, therefore, a solid consolidated guidelines on HTS was developed and adopted In June 2021.

With the evolution of HTS as mentioned in above section, including introduction of HIV self-testing, and WHO's latest guidelines on HIV prevention, testing, and treatment service delivery and monitoring published in July 2021 focusing on mixed HTS approaches, for which the accuracy of the test results and the improvement of the quality of the HTS in general are the central points. With this new WHO guideline, VCCT TWG led by NCHADS updates the adopted 2017 consolidated HTS guidelines to ensure reflection of HTS being implemented and alignment with the latest WHO guidance in delivering HTS.

1.3 Goal, Purpose, and Objectives

The overarching HTS goal is to detect all people living with HIV who do not know their status and to link and offer them quality HIV care services.

The primary purpose of the national consolidated guideline is to provide the standard guidance to the key actors who are involved in HTS management at all levels.

The specific objectives of the HTS consolidated guideline are as follows:

- To ensure consistent provision of quality HTC services at health facilities (public and private for profits or non-profits) and community outreach.
- To inform about the mix of approaches to delivering HTS that optimize the use of resources and will maximize impact.
- To reinforce the implementation of the strategic priorities of HTS models and strengthen the linkages to HIV prevention, care, and treatment services.
- To strengthen the quality assurance of HTS including the accuracy of the test results.

1.4 Target Audience

The HTS consolidated guideline targets HIV program managers at all levels and decision makers within the Ministry of Health who are responsible for the HIV response in the health sector including HIV testing, HIV prevention, care, and treatment services for general population as well as key populations.

This document also addresses healthcare providers working with the relevant programs to offer HTS such as maternal and child health, reproductive track-infections (RTI) including sexually transmitted infections (STI), tuberculosis, viral hepatitis, and chronic illnesses. It will be useful for other implementers of HTS such as clinical and non-clinical HTS providers including civil society organizations and community networks.

1.5 Guiding Principles

1.5.1 Human Right- Based Approach

A human right-based approach is essential for the success of HTS program. The program should prioritize gender equality, health related rights including accessibility, efficiency, quality of services, and universal health coverage. It also ensures that the essential elements of the HTS package address the rights of the people that use these standards. HTS will benefit tested individuals and simultaneously improve health outcomes of the population. Implementation of the guideline needs to be accompanied by efforts to promote an enabling environment and protect the human rights of people who need HIV services, including ensuring voluntary basis, informed consent, preventing stigma and discrimination in the provision of services, addressing laws and legislation that criminalize the behavior of people and create barriers for people to access HIV services, and promoting gender equity. The expansion of all HTS models should adopt a rights-based approach and should be in line with the rights highlighted in the 2002 Cambodian laws on HIV prevention and control of HIV/AIDS. It must also be ethical and conducted within a supportive environment that can be linked to prevention, treatment, care and support services to maximize individual and public health benefits. Furthermore, the implementation of the guideline should realize the rights and responsibilities of people living with HIV and promote the greater involvement of people living with HIV and meaningful involvement of people living with HIV principles.

1.5.2 The 5 Cs

The 5-C principle is the foundation of effective HTS that can be applied to all HIV counseling and testing models. These are consent, confidentiality, counseling, correct test results, and connection to prevention, treatment, and care services.

- **Consent:** Clients who receive HIV testing should be informed of the process for HTS and their right to decline testing. They should give consent before taking an HIV test and receiving HIV counseling.
- **Confidentiality:** Confidentiality is the right of an individual to privacy and dignity. The dialogue between HTS providers and the clients, and HIV test results should not be disclosed to anyone without the consent of the person being tested. Shared confidentiality with sexual partners or spouses and family members who are trusted should be encouraged.
- **Counseling:** Pre-test information can be given in a group setting, but a private setting is encouraged and should be provided to individuals who have questions that they do not wish to share with others. The high quality of post-test counseling must be provided in individual settings based on a specific HIV test result and HIV status reported.
- **Correct test result:** Quality Assurance (QA) mechanisms are crucial to ensure that clients receive a correct diagnosis. To ensure the quality of test result, QA mechanisms should be implemented.
- **Connection:** Linkage to prevention, treatment, and care services with effective and appropriate follow-up should be ensured and intensified.

1.5.3 Linking HTS to continuum of prevention, treatment, and care services

All HTS providers should understand and ensure that their clients are not lost in the HIV service cascade. For that reason, the continuum of linkages to care and prevention ensure the inclusion of:

- Demand creation and linking clients to HTS: Demand creation to increase HTS uptake and engage those in greatest need of services is a valuable tool for mitigating stigma, discrimination, and criminalization. Demand creation approaches may need to be prioritized, depending on the setting, focused population, and available resources, as part of a strategy to reach people living with HIV who do not know their status and who have high HIV-related risk. A wide range of demand-creation strategies have been rigorously tested to assess impact on HIV testing uptake and the proportion

of people living with HIV diagnosed, but often later outcomes related to linkage to care, or prevention have not been measured.

- Pre-test information including screening for TB: Pre-test counseling should be provided in a friendly and privacy environment, and ensure individual clients are able to clarify, raise questions and seek additional information for informed decision for HIV testing.
- HIV testing and result: with informed consent of individual, the test is performed following the national guidelines. The test result must be kept confidential in a close envelope and is provided to the individual with privacy ensured.
- Post-test counseling: Post-test counseling should be provided based on HIV test result and individual needs/concerns. Counseling on referral and linkage to confirmatory HIV testing is needed for individuals with HIV reactive test results and should be offered during post-test counseling. If a client tested negative, he/she should be also counselled on risk behaviors, follow up testing if needed and information on HIV prevention measures, including PrEP and other related services if relevant.
- Active referral and linkages to other HIV and health services: It is important to ensure individual clients who have HIV reactive test result access to confirmatory HIV testing and enrolled in HIV treatment and care service if confirmatory HIV test result is positive. Clients who have negative HIV test result should be encouraged and referred to HIV prevention services, including but not limited to PrEP.

CHAPTER 2. ETHICAL AND LEGAL CONSIDERATIONS

2.1 Human Rights

HTC services should be provided in an environment where human rights are respected to reduce vulnerability for both people living with HIV and people who are affected. The most relevant human rights principles in HTS include:

- **Right to privacy and confidentiality**
  Respect for confidentiality applies not only to a client's receipt of an HIV test and the test result, but also to any personal information, such as information concerning personal risk, sexual behavior or the use of drugs, and the identity of sexual or drug-injecting partners. Health workers and others who provide HIV testing may need special training and sensitization regarding the confidentiality of medical records and how to keep registers, records and documents with identifying information safe, particularly where key populations are concerned. All personal information of the clients regarding their HIV or health status should be kept confidential, unless ordered by the court of law or done so for the advantages of client's care and treatment. Providers should be sensitive to how and where they offer HTS, avoiding practices and situations that may lead to inadvertently revealing clients' personal information to others or that discourage individuals from asking for testing. Such harmful practices may include publicly asking personal questions about risk behavior or symptoms and offering testing and pre-test information in facility waiting rooms, outpatient departments or other settings that are not private.

- **Right to dignity and non-discrimination and equal protection**
  People have inherent dignity. So, the right to have their dignity should be respected and protected. No actions should be taken against any individuals solely on the basis of their HIV or key population status that will constitute stigma and discrimination.

- **Ensuring consent and right to decline HIV testing.**
  Consent is giving verbal permission or agreement to test for HIV. Mandatory or coercive testing is never warranted. Every patient has the right to decline HIV testing without compromising their access to standard healthcare. Testing should not be a condition for obtaining other benefits and refusing testing should not be a reason for withholding other benefits. All HIV testing models shall remain voluntary with informed consent, even for the health provider-initiated testing or community outreach testing.

2.2 Stigma and Discrimination

In the context of HIV, stigma and discrimination refer to actions taken against individual solely based on their HIV status or perceived HIV status. The stigma is still attached to HIV that is a barrier to testing, especially among the communities that are stigmatized and discriminated by both communities and healthcare workers. Discrimination against people living with HIV undermines human dignity and encumbers an effective response to HIV. Therefore, HTS contributes to reducing discrimination by raising awareness and creating knowledge about HIV in communities.

HTS allows more people to know their status, which will reduce stigma and discrimination and foster normalization of HIV testing. Therefore, HTS providers should receive specific training and mentoring sessions to address the needs of PLHIV.

A person's HIV status should not be used to fire or deny them from their employment or educational opportunities. The employees become ill with HIV-related conditions should be treated in the usual manner of determining fitness for works.

The awareness on HIV and human rights issues should be raised among employers and their workers, and be reinforced to boost their adherence, based on the standards and practices of the Ministry of Labor and Vocational Training.

Within a facility, all staff members have a role in providing a safe, friendly, and welcoming environment. Healthcare worker training can be effective for reducing stigma and discrimination at facilities. To prevent violence, training and educating law enforcement agents can be effective. It can be important to screen for Intimate Partner Violence (IPV) before HIV testing and as part of partner services and to refer for available services as needed in line with national guidelines.

"Discrimination against person with HIV/AIDS in the hospitals and health institutions is strictly prohibited", according to the Law on the Prevention and Control of HIV/AIDS, enacted in 2002 (Article 41). The violation of this article shall be fined from 100,000 to 1,000,000 Riels with a penalty of imprisonment from 1 to 6 months (Article 52).

2.3 Informed Consent

Informed consent refers to a patient/client being given relevant and appropriate information regarding HIV testing. Based on the given information, the patient/client can make decisions either to accept or refuse to do HIV testing. Informed consent should be in written form and signed by the patient/client. This would prevent the HTS providers from any unintended disclosure of test results. Verbal consent is usually adequate, but all individuals should have a private opportunity to refuse testing. The patient/client should be able to consider the implications of a positive diagnosis on their personal and professional life.

2.3.1 Requirements of Informed Consent

The information that patients/clients require to give their informed consent may vary based on the service delivery approach and setting. The consent should include information about:

- benefits and implications of knowing HIV status and reasons for recommending HTS,
- client's rights to withdraw consent at any stage of the process,
- availability of prevention, follow-up treatment, care, and support services, and
- importance of disclosure, partner or family testing, and availability of couple HTS services

2.3.2 Capacity to Consent

In Cambodia, any person aged 18 years and older is sufficiently mature with the mental capacity to understand the benefits, risks, and social and other implications of HIV testing.
They can give consent for HTS and should:

- *know the reasons why they should be tested.*
- *understand and report on the consequences of a negative or positive test result.*
- *report how they are likely to respond to the test result.*

Khmer language should be used in informed consent.

In case that a patient/client who is assessed as being incapable of giving informed consent, a proxy consent may be considered. This informed consent is given by someone else who is acting in the best interests of the patient/client, for an example a senior clinician who takes care of the case. The test result must be

disclosed if the patient/client regains capacity. If the client has irreversible neurocognitive impairment, the test result can be shared with his/her caregiver. HIV testing must always be voluntary and free from coercion.

Informed consent should be documented in the following populations and settings:

- **Infants and children (<18 years old)**
  - HIV counseling should be provided to their parents or guardians as applicable, who should provide verbal or written informed consent. No person may disclose a child's HIV status without the parents' or guardians' consent.
  - The legal adult age in Cambodia is 18, yet under national law on prevention control of HIV/AIDS, in case written consent could not be obtained from the legal guardian of the minor, the HIV test could still be performed with the informed consent of the individual if testing is considered to be of interest to that individual.

- **Adults (>18 years old)**
  - Couples: Informed consent should be given by individuals who are willing to be tested as a couple
  - Research settings: Informed consent within research settings including clinical trials should be written and documented. For a client who wishes to do HIV testing and give signed consent, but he or she cannot write or has a disability that hinders his or her ability to write, his or her fingerprint can be used instead of a signature.

2.4. Empowering communities

Empowerment is a critical enabler for improving access to HTS among vulnerable communities, including key populations. Many different actions can support community empowerment, such as meaningful participation of people from key populations in designing and delivering services, peer education activities, legal literacy programmes, and fostering key population-led groups, programmes and service delivery.

CHAPTER 3. HIV TESTING SERVICE

HIV Testing Service (HTS) focuses on people living with HIV who remain undiagnosed and to diagnose and link them to treatment and care services as early as possible. People who are HIV-negative and at ongoing risk also need to be tested and linked to appropriate prevention services.

To maximize the impact of HTS and to maintain HIV epidemic control, Cambodia has applied a strategic mix of differentiated HIV testing approaches which include:

- Facility-based HTS approaches
- Community-based HTS approaches
- Network-based Testing (NBT) approaches, and
- HIV self-testing

To operationalize these differentiated HTS modality, key priority activities should be considered:

- The joint agreement between NCHADS and relevant clinical settings such as public and private/NGO facilities should be formulated, implemented, and regularly monitored. This includes clear roles and responsibilities of each party to make sure that HIPTC is smoothly implemented. The joint work plan for training activities for HTS as well as supervision and mentoring visits should be developed and implemented by both parties.
- HIV education materials and job aids for HTS should be produced for healthcare providers in clinical and community settings.

3.1 Facility-based HTS approaches

	Services	Key Activities
1	Voluntary Confidential Counseling and Testing (VCCT)	VCCT offers HIV testing and diagnosis to clients who voluntarily walk in, are referred from other health facilities, including from public, private, NGOs health facilities/clinics, and community-based testing for a confirmatory test.
2	*Routinely offered HTS at clinical sites	HTS is offered routinely to key populations, people living with HIV indicating conditions or at risk of acquiring HIV, clients with presumptive or confirmed TB, and in specific clinical settings such as malnutrition, ANC and STI, viral hepatitis, and TB services …
	2.1 Antenatal care, contraception/family planning, and pediatric services	- All pregnant attending antenatal care (ANC), and delivery services and are routinely offered HTS, as well as testing for HIV/syphilis in all settings, uses dual HIV/syphilis rapid diagnostic test (RDT) to screen women at their first ANC visit. They are then referred to a VCCT site if they are HIV-reactive and if they are syphilis reactive, they are treated at referral hospitals. - Their partners/ husbands of PW are counseled to get HIV tests while they visited clinics with their wives. See PMTCT guideline, 2020 for more details. - HTS offers to HIV-exposed infants and children who have a biological parent with HIV, and those infants and children with unknown HIV status who are admitted for inpatient care or attending outpatient,

	Services	Key Activities
		malnutrition, or immunization clinics. See Chapter 5 for special considerations for HTS among infants and children.
	2.2 TB Services	- TB is a leading cause of death among people living with HIV. Cambodia screens for TB among all PLHIV suspected or diagnosed with TB. - Currently TB services at referral, national, and provincial hospitals refer TB patients to VCCT for HIV screening and diagnosis. - For future considering rapid test HIV testing should be available at TB service at National and Referral Hospital. - TB patients are also screened for HIV at health centers. - Discussion is ongoing to integrate HIV test including HIVST at Provincial, Hospitals, Referral Hospitals and National Hospitals. All PLHIV are routinely screened for TB symptoms at ART sites and referred for diagnosis at TB ward. - All eligible PLHIV (both currently in care and newly identified HIV-positive) are given TB preventive treatment (TPT).
	2.3 Clinical and prevention services for key populations.	- These include drop-in centers, facilities where provide harm reduction services for people who inject drugs, PrEP service delivery sites. It is important to remember that key populations in many settings do access facilities for health services, and, when they do so, it is important to minimize missed opportunities for HTS. - See Chapter 4 for special considerations for HTS among key populations.
	2.4 Family Health Clinics provide STI testing and treatment.	- HIV and STI co-infections are common. Family health clinics (FHC) and STI integrated services in the health centers (HCs) offered HTS to all people with STIs. There were 38 FHCs and 12 NGO clinics across the country.
	2.5 STI treatment integration into Referral Hospital (RH).	- STI treatment is integration into Referral Hospital (RH). Currently the treatment syndromic approach (Syphilis Rapid test reactive will be treatment, however after treatment it needed to confirm RPR or other test at family health clinic) -
	2.6 Health Provider-Initiated Testing and Counseling (HPITC)	- HPITC is typically performed by health care providers to provide patients /clients with symptoms or signs of HIV infection at health services such as outpatient services, including antenatal care (ANC) services, TB treatment services, and medical services. STIs, etc. HPITC provides pre-test information and patient / client consent with opt-out choices Test.

* To ensure reliable test results, all VCCT sites are required to implement external quality assessment schemes (EQAS) and internal quality control (IQC). For details, please refer to Chapter 6 on EQAS.

Note: HTS is available in all health facilities including National Hospital (N =09), public municipal/provincial hospitals (n=26), district referral hospitals (n=94), health centers (n=1260), health posts (n=103), and some NGO hospitals/clinics (MOH, 2022).

3.2 Community-Based HTS Approaches

Working in the community increases early diagnosis by reaching the KP at higher risks and the targeted GP such as internal and external migrants, PW who never come to ANC, TB, and STI patients. It is important to notice that high confidentiality should be considered for community outreach HIV testing.

The routine community outreach model has been implemented and reached a huge number of KP groups, especially in providing HIV preventive education and condom distribution; however, referral to STI check-ups and HIV testing are limited, so community based HTS approaches have been useful to increase HIV testing uptake among key populations.

	Services	Key Activities
1	Community-Based HTS Model for KP	The key activities to support the implementation of the routine community outreach HTS model include the following: Select the laypersons from each group of KP by NGOs for HTS training to serve as the community outreach HTS providers. Build up the capacity of the laypersons (community HTS providers) through intensive and comprehensive training workshops on RDTs and pre and post-test HIV information. The use of simple messages to offer a proper and good quality of HTS during the training, conducted by NCHADS and NGO partners, is strongly encouraged. Conduct regular supervision and mentoring visits by NCHADS and NGO partners to community HTS providers on a quarterly basis. Ensure adequate and appropriate supplies of RDT kits and commodities; and Follow the national standard recording and reporting requirements for HTS. The test results should be returned to individuals in an envelope at the end of the HTS session. It is encouraged that community HTS provider should explain the test result to the client privately. Post-test education /information will be provided to all participants, regardless of their test results. The community HTS providers' telephone numbers and names are given to the patients/clients for further information, followed by detailed discussions about the available HTS services for HIV status confirmation. For the clients/patients with reactive test result, community HTS provider can provide a referral slip for the confirmatory HIV testing.
2	Community-Based HTS Model for Targeted General Population	2022 HIV estimates in Cambodia indicated that around 11,000 people living with HIV do not know their status in Cambodia as of the end of 2022 (2). Up to date, there is no clear evidence showing where and who these people are. They are the most essential groups, who should be prioritized under the "IR" of "IRIR" framework. The targeted GP within the community could be: Migrants and their partners In-country migrants such as construction workers, factory workers, taxi drivers, "Motodub", and three-wheel drivers Out-country migrants, who cross the borders for employment opportunities. PW who never visit ANC clinic or never test for HIV Partners or ex-partners of PLHIV or KP

To increase HIV testing coverage among KP, the community outreach HTS approaches using RDTs by finger prick were adopted by MOH and introduced by community HTS providers in early 2013 (12). With the technical and financial contributions from development partners, this strategic intervention model has been scaled up in high HIV-burden provinces since 2013.

Due to dwindling funding support to HIV programs and low uptake of HTS with low HIV positivity rate among certain sub-population groups of KP, an effective and efficient intervention model should be prioritized. PDI+ or social media implemented with small population of MSM and TG should be expanded to other KP sub-groups and extended to the high burden ODs.

It is interesting to note that since the B-IACM approaches and IRIR strategy were implemented, community-based outreach HTS using RDTs by finger prick has been applied only for KP, not for other population groups. These approaches are to increase the accessibility to HTS among the targeted GP by employing RDTs using a finger prick. The integration of these approaches into the primary health care system is essential, where confidentiality in the community is very critical to pay attention.

The existing village health volunteers, known as village health support groups (VHSG) should be selected and trained on HTS procedures and be mandated as community outreach HTS providers. There will be 2 options:

- ***Option 1:** VHSG will be used as the key informants to link the community to HTS services (including NGO and public health facilities)*
- ***Option 2:** Where needed and feasible depending on location, circumstance, and skill/capacity, VHSG will be selected and trained to provide HTS.*

HTS campaigns conducted in special events such as water festival, Pchum Ben, concerts in public areas are already good practices and they should be reinforced in terms of the linkages to further HIV testing services, particularly among those who are reactive to the tests.

The integration of HTS also is crucially important in ANC outreach sessions. If the test results reveal a reactive outcome, ensuring the linkages to further HIV testing services is necessary.

3.3 Network-based Testing (NBT) Approaches

The unequivocal prevention and life-saving benefits of ART necessitate testing strategies aimed at identifying undiagnosed PLHIV. This context focuses on index testing or contact testing, or it was known as partner notification tracing and testing (PNTT), and a social network strategy (SNS) known as peer-driven intervention plus (PDI+)

Based on the PNTT-VCCT database from 2020 to 2021, the comparison of the PNTT Cascade between RITA-Recent (n=196) and RITA Long-Term (n=3807). The partners of RITA recent was 39.0% and partners of long-term was 29.6%.

N	Services	Key Activities
1	*Partner Notification Tracing and Testing (PNTT)	PNTT was integrated into the ART and has been implemented since late 2017 countrywide. It is a case-finding approach that focuses on offering HIV testing to everyone exposed to HIV by the index case. This includes sexual partners and biological children of index clients who are less than 19 years old. They are referred via four approaches: **Index case' Referral**: index case tells his/her partner (s) about his HIV status and tells him to come to a health facility for an HIV test. **Contractual referral:** The index case and the counselor will work together to notify the client's partner, who will have 30 days to notify his or her partner, then the counselor will contact the partner. **Provider referral:** a counselor or other health care provider will call or visit the index's partner and inform them that they need to do an HIV test. **Referral by provider and index:** the counselor will sit with the client and his/her partner and support as the client tells his/her partner about the HIV diagnosis

N	Services	Key Activities
2	**Peer Driven Intervention Plus (PDI+)	PDI+ is an incentive-based, peer-centered, risk-tracing snowball approach where seeds with high-risk behaviors and large social networks are provided coupons to recruit peers within their networks to access HIV prevention education, testing, and referral to prevention and treatment services. Through physical and virtual referral chains, additional network members are brought in for testing in ways that ensure the privacy and confidentiality of KP members. PDI+ complements face-to-face outreach in improving HIV case detection and finding those who are hard to reach, have not been found by outreach workers for testing, or have not been contacted by existing HIV prevention programs.

**See the PNTT guidelines for further information*

*** PDI+ guideline for more detailed concept note on peer-driven intervention plus (PDI+) for new case detection among key population in Cambodia (NCHADS-2018).*

3.4 HIV Self-Testing (HIVST) Approaches

HIV self-testing is a process in which an individual who wishes to know his or her HIV status, collects a specimen, performs a test, and interprets the result by him or herself privately. HIV self-test is a pre-screening test and does not provide the definitive diagnosis. This approach does not replace the need for screening and confirmatory HIV test in the validated national testing algorithm [18].

The reactive self-testing result should be re-tested by additional testing conducted by trained HTS providers, following the national HIV testing guidelines. The HIV self-testing can be applied for the specific group of the KP or those who are hidden and not reached by other HTS approaches.

The result from HIVST study report in year 2019 found that more than 70% of participants had never been tested, and case finding from HIV self-testing was two to three times higher than usual outreach (more detail: Standard Operating Procedure for HIV-Self Testing, 2019). After the study, HIV self-testing was started from the end of 2019 up to date, which found the highest positive results among KP 10% in 2020, 13% in 2021, 10% in 2022. Especially MSM (13% in 2020, 17% in 2021, 10% in 2022) and TG (07% in 2020, 23% in 2021, 18% in 2022).

People with high risk of HIV may use HIVST. They can be sero-discordant couples and KP who are hard-to-reach, never been tested or have never been reached by peer outreach workers (OW) and PNTT and peer network. They could benefit from more frequent testing without needing more HTS visits. In this regard, HIVST can save time while reducing the burden of HTS providers [18].

Two approaches to HIVST can be used:

N	Services	Key Activities
1	**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 (healthcare workers or OW) during the delivery of the HIVST kit and assist clients 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 online or hotline support if the HIVST result is reactive and/or further assistance is needed.

N	Services	Key Activities
2	**Self-testing virtually assisted.**	If clients placed an online order and received their HIVST kit through private delivery services Users can rely on the instructions on 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.

3.5 Few key considerations for HTS approaches

3.5.1 Preventive testing

Testing for prevention is routine testing of individuals participating in prevention services including the persons who used pre-exposure prophylaxis (PrEP) and ANC services.

Routine testing of individuals participating in prevention services (i.e., PrEP, ANC) is critical for monitoring the impact of interventions in preventing new infections and maintaining epidemic control. PW should test at least once throughout their pregnancy period.

The person on Pre-exposure prophylaxis (PrEP) is required to test for HIV before starting PrEP and every 3 months afterwards. PrEP services are rolled out in 20 sites with nearly 5,474 individuals enrolled on PrEP at the end of 2022.

3.5.2 Strengthening linkage requires a handshake between HIV testing and treatment and prevention providers.

HIV providers should:

- Support active linkage to prevention services (e.g., PrEP, etc.) for people who test negative.
- Support active linkage to confirmatory HIV testing and enrollment in HIV treatment for people who tested positive.
- Explain the importance of early initiation of HIV treatment.
- Provide information about where and when to go for HIV treatment.
- Facilitate enrollment in HIV treatment and follow up.
  - Physical accompaniment
  - Same-day ART initiation
  - SMS appointment reminders
  - Follow-up phone calls and home visits

3.5.3 Addressing Critical Enablers for HTS

HTS should be available in all healthcare facilities including public, private, NGO, and community settings. The norms and standards as highlighted below should be applied for HTS in facility and community settings:

- A primary role of all healthcare providers and community workers are to provide information and counsel their patients/clients, who are more likely to be affected by or at risk to HIV, about the benefits of HIV testing so that patients/clients can make informed decisions to do HIV testing. Healthcare providers should initiate and offer HIV testing to all patients/clients to identify PLHIV who do not know their status.
- Stigma discrimination and confidentiality issues should be addressed.

- Integration of HTS in the most relevant healthcare services should be introduced.
- Quality assurance for counseling and quality control for HIV testing and test kits should be subjected to the defined national standards and should be regularly monitored and evaluated.
- Effective partnership among HTS providers who provide first HIV test and VCCT through good coordination and communication should be maintained to ensure effective referral linkage, reporting, and QA and QC.

3.5.4 Improving Public-Private Partnership for HTS

There are some challenges in improving public-private partnership, especially the limited capacity of the public health system, including shortage of healthcare providers at public health facilities and lack of clients' choice used private health care services, are usually reported. It is obvious to note that there are two types of private healthcare services:

- Not-for-profit private healthcare services, i.e., NGO clinics
- For-profit healthcare facilities such as private hospitals and clinics, private maternity facilities, private laboratories, and private pharmacies.

Not-for-profit health services

NCHADS worked closely with not-for-profit private healthcare services such as Institute Pasteur du Camboges (IPC), SRHAC clinics, Angkor Children Hospital, Marie-Stopes STI/HTS clinics, Chhouk Sar clinics to start HTS within their health service deliveries. The letter of agreement (LoA) between NCHADS and these NGOs was signed by the two parties aiming at ensuring the roles and mutual responsibilities of individual parties, i.e., logistics supplies, joint monitoring, and training for specific activities. Most importantly, the LOA ensures that NGO clinics/hospitals follow the national HTS standards and procedures [(23)].

The implementation of HTS integrated settings such as NGO hospitals/clinics should be reinforced to increase the uptake of HTS and to improve the HIV case finding among targeted GP and KP. Supportive supervision and ongoing mentoring visits to NGO-HTS must be conducted regularly and efficiently to ensure the standard of the national HIV testing algorithm including RDTs and the high quality of HTS are met. In addition, standard reporting requirements of the national program must be followed. It is also suggested that the LOA between NCHADS and NGO partners should be regularly updated and properly implemented by both parties.

For-profit health services

In 2005, NCHADS worked hard with private for-profit companies including garment factories to offer HTS in its health services, but this attempt was abandoned for several reasons, including low-risk behaviors among garment factory workers and low commitment of private HIV testing providers which undermined the quality of HTS.

Private health services are growing very fast such as maternity clinics, polyclinics/hospitals, and laboratories where HTS can be integrated. In 2018 with technical support from PSI, NCHADS worked with twelve private hospitals/clinics in Phnom Penh, Battambang and Banteay Meanchey to offer HTC in their facilities. Because of poor or no pre-test counseling, all HTS sites operated by private clinics/hospitals were closed. Only one private hospital, “Chorey” signed LOA with NCHADS in 2014, and continues to offer HTS [(19)].

It is worth mentioning that some private hospitals/clinics/maternities/laboratories currently provide HIV testing to their patients/clients without collaboration with NCHADS. The main challenges facing these private HTS facilities are as follows:

- Unclear HTS procedures including national HIV testing algorithms.
- No QA for HTS including quality control of HIV testing and quality assurance on pre and post HIV testing counseling.
- The accuracy of the HIV test results is questionable.
- Unclear linkage and referral mechanisms for confirmed HIV positive to treatment and care services.

It is suggested that the national and sub-national HIV programs work closely with private hospitals/maternities/clinics or laboratories, where HTS are currently available to ensure that they follow the most up-to-date HTS national guidelines. The most important elements include:

- *following the national HIV algorithm*
- *providing correct HIV test results*
- *ensuring linkages and referral mechanisms for those tested HIV positive to treatment and care services*
- *following the national standard recording and reporting requirements.*

Exploring possibilities to involve the potential private health services such as maternities and laboratories to introduce HTS is crucial. A similar coordination model used with NGO-HTS, i.e. LOA, can be applied to these private health services.

3.5.5 Integration of HTS into illicit drug treatment facilities

HTS should be integrated into illicit drug treatment facilities to make HIV testing more accessible to people who inject drugs (PWID) and people who use drugs (PWUD). Particularly, HTS should be performed in MMT clinics, which locates in public hospitals.

The integration of HTS into health services of the correction or rehabilitation centers (where PWUD and PWID are presented) operated by either public or private entities is crucial. The health providers and lay persons from these centers should be selected to participate in HTS training programs. Ensuring adequate RDTs and commodities supplies made by NCHADS is necessary. Regular supportive supervision and ongoing mentoring visits from NCHADS and partners are essential to ensure HTS quality, especially the correct test results, and adherence to the standard recording and reporting requirements.

The implementation of HTS in correction/rehabilitation centers should be reinforced and expanded to the potential areas. Due to security problems, the following suggestions should be considered:

- *If the HIV test is reactive, the confirmatory test should be performed at the centers.*
- *If confirmed HIV positive, the patients/clients should be referred to the nearby HTS-ART sites.*

3.5.6 Strengthening HTS in Prison Settings

NCHADS, in partnership with NGOs, has a strong collaboration with health posts of all prisons at national and sub-national level. Currently, at least two trained health care workers or lay persons from these health facilities offer HTS to prisoners. NCHADS/PHD/CMS are responsible for supplying RDT kits and other consumables as well as providing supportive supervision visits *(for detail, refer to the current SOP for closed setting 2023)*. *Further, the recording and reporting requirement of HTS should be strengthened.*

3.5.7 Strengthening Linkage between HIV Testing in Blood Safety Programs and HIV Prevention, Care and Treatment Services

The National Blood Transfusion Center (NBTC) and the Provincial Blood Transfusion Center (PBTC) screen blood for some infectious diseases such as HIV, malaria, syphilis, hepatitis B and hepatitis C, using their testing strategy and algorithm. The LOA between NCHADS and NBTC has been validated since 2015 to ensure the linkage to HIV prevention, care, and treatment services [(26)].

The current referral and follow-up mechanisms for the active linkage to HIV prevention, care and treatment services should be further strengthened. Case Management Coordinators/Assistants (CMC/CMA) should work more closely with all NBTC and PBTC coordinators to make sure that all HIV reactive cases are referred to HTS-ART sites for confirmatory HIV testing. If the HIV test result is confirmed positive, the linkage for immediate ART enrollment is necessary.

CHAPTER 4. PRIORITY POPULATIONS

4.1 Key populations (KPs)

In 2022, 83% of new HIV infections in Cambodia were among key population and their sexual partners. In all settings, a comprehensive HIV response must include key populations. Due to risk behaviours and vulnerabilities related to stigma, restrictive policies and punitive laws, members of key populations and their partners often have poor access to health services and are at high ongoing risk for HIV in all settings.

- HTS and other HIV services should operate on the principles of medical ethics, avoidance of stigma, non-discrimination, and the right to healthcare. Testing services for key populations should also adopt practices that prioritize improving accessibility and acceptability and the capacity of providers to serve the needs of specific key populations in their communities.
- Services that employ peer and lay providers (sometimes called community outreach workers) from key populations are often crucial to providing friendly and accessible services in community and facility settings. These trained community providers can deliver HTS and support engagement in HIV prevention and treatment services.
- HIV testing (at least once annually) is advised for all people from key populations to reach those with undiagnosed HIV as early as possible and engage them in prevention, treatment, and care. More frequent retesting, that is every 3–6 months, may be warranted based on individual risks factors. For some key populations, more frequent testing may be required as part of routine monitoring in HIV prevention services – for example, harm reduction services, PMTCT or quarterly retesting for those taking PrEP.
- Facility-based HTS that are designed to serve members of key populations include stand-alone needle and syringe programmes or drug treatment services, drop-in centres, “one-stop shop” services and clinics that cater to the particular needs of key populations.
- Community-based HTS and HIV self-testing (HIVST) can be particularly effective at reaching members of key populations who may not test otherwise or who are at ongoing risk and may often be hesitant or unable to access facility-based services. There are many ways to implement and distribute HIVST kits among key populations, including through community and facility settings, online platforms, pharmacies, and private sector settings (for example, retail outlets), secondary distribution of test kits through partners or other contacts, and peer-distribution through sexual, drug injecting or social networks. Providing choice in HIVST service delivery models can improve access for various key population groups.

The low HIV testing rate and coverage (50%) among KP as reported by NPD and its implementing partners reflects the limited capacity of HTS programs to reach hard-to-reach or hidden KP, especially those who are at high risk. There will be the need to strengthen the capacity of outreach workers and the need to move beyond business as usual.

A 2019 HIVST study among KP in Phnom Penh have found that 70.7% of participants had never tested before and overall HIV reactive yield among those never-tested-participants was 5.9%. The reactive yield for these key populations is quite high compared to latest IBBS esp. for MSM (7.9% vs 4.0%) and TG (10.9% vs 9.6%). After the study, HIV self-testing was started from the end of 2019 up to date, which found the highest positive results among KPs 10% in 2020, 13% in 2021, 10% in 2022. Especially MSM (13% in 2020, 17% in 2021, 10% in 2022) and TG (07% in 2020, 23% in 2021, 18% in 2022).

KP should be encouraged to access HPITC services, where KP friendly principles exist without discrimination from healthcare providers. The KP's partners should also be encouraged to get tested. HIVST could also be proposed to KP as described in the community action framework.

HTS programs should review and revise the community-based outreach approaches for KP and must focus on strategic intervention models that can optimize the use of scarce resources to maximize impact, i.e. Peer Driven Intervention Plus (PDI+).

4.2 Couples and Partners of PLHIV

Testing partners of people with HIV is an effective way to reach people at high risk of HIV infection. It efficiently identifies additional people with HIV not yet diagnosed or on ART– particularly male partners in high HIV burden settings, who are substantially less likely to test than women. It also helps to offer HTS to sexual and/or drug-injecting partners of people living with HIV from key populations who may not otherwise test. HTS creates the opportunity to link couples to prevention interventions including PrEP and to safer conception or contraception. It can also facilitate uptake of and adherence to ART among HIV-positive partners and to PMTCT among HIV-positive pregnant women. As with all HTS approaches, couples, and partner HTS must be voluntary and not forced, and providers must recognize that some clients will not want to involve partners.

- Provider-assisted referral as the preferred way to support partner testing as part of a voluntary comprehensive package of care to reach partners. Provider-assisted referral, in which a trained provider, with consent of the index client, offers HTS to sexual and drug injecting partners, has been shown to lead to greater uptake as well as identification of additional HIV infections compared to patient referral.
- Updated HIVST has emerged as a safe, acceptable, and effective way to reach partners of HIV-negative ANC clients as well as partners of people diagnosed HIV-positive at facilities.
- Social network-based approaches can be offered as part of a comprehensive package of testing and care for key populations.
- Partner violence: partner testing, either together or separately, is recommended, with support for mutual disclosure were beneficial. Care is needed when delivering testing for couples and partners to minimize the risk of partner violence.
- For those who disclose sexual abuse within the first five days of incidence, clinical care should include first-line support, HIV post-exposure prophylaxis (PEP) (in the first 72 hours), STI prophylaxis or presumptive treatment, emergency contraception (in the first 120 hours) and access to safe abortion as legally permitted and hepatitis B vaccination.
- Providing the latest information on HIV prevention, treatment, and sexual and reproductive health options, as well as educational messages about how PrEP prevents HIV acquisition and how ART reduces the risk of HIV transmission to children and sexual partners is necessary. Delivering these messages may be important to prevent potential social harm among couples, particularly those that are sero-discordant.

HTS for couples and partners can be offered in different settings including ANC clinic, community outreach ANC, and community-based TB services. Those receiving ART services should be encouraged to bring their partners for testing. KP should be in the priority lists of couples and partners for HIV testing. It is suggested that the partner notification tracing and testing (PNTT) model that is officially adopted and implemented in some ART sites since 2015 should be reinforced and expanded.

HIVST can be offered for Index Case Partner Testing: CAC/ART counselor at ART site will counsel index case to bring a partner(s) in for testing using standard HIV testing options (refer to PNTT-SoP) or HIV

self-testing by starting with standard HIV testing algorithm. If the index case says their partners do not want to test or reject HTS testing, CAC/ART counselor should offer HIVST. If the index case accepts HIVST:

Index case should select one of the options below:

Option 1: index case delivers HIVST kit to partners by his/her own.

Option 2: index case offers contact information of his/her partners and CAC/ART counselor reach out to the partners (provider referral).

4.3 Adolescents and young women

Adolescence is a period of high risk for HIV infection. Generally, young women are at higher risk than young males. There are two groups of adolescents aged 14 to 24, who need access to HTS:

- Perinatally HIV-infected persons who were not diagnosed in infancy and have survived to adolescence, and young key population.
- Adolescents and young people who are vulnerable and need special attention, such as those who are homeless, orphans, adolescents in child-headed households, girls engaging in sex with older men or in multiple or concurrent sexual partnerships, adolescents and young people who are sexually exploited, and all adolescent girls and young women in high HIV burden settings.
- Adolescents should be counselled about the potential benefits and risks of disclosure of HIV-positive status and be empowered and supported to determine if, when how and to whom to disclose.
- Revisit age of consent policies, considering the need to uphold adolescents' rights to make choices about their own health and well-being.

Routine HIV testing, with linkage to prevention, treatment and care should be provided to adolescents at high risk. Adequate support for disclosure of HIV status should also be provided to them and to their family members.

HTS for adolescents should be integrated into all existing reproductive health services, with adolescent friendly principles to ensure that physical and psychological needs are addressed. Involving well-trained adolescent counselors are important to respond to their needs.

4.4 People in prison and close settings

HTS programs should provide routine HIV testing for people in prison and in other closed settings such as correction/detention and rehabilitation facilities for drug users. In these special locations, HTS can be offered by the health post staff or well-trained HTS providers with regular mentoring visits from NCHADS and partners.

People in prisons and other closed settings also need access to a comprehensive package of testing, treatment, care, and prevention services. It is essential that services give accurate information, obtain informed consent, maintain confidentiality, and ensure that use of services is voluntary. Discriminatory practices, such as forced segregation of prisoners diagnosed with HIV (unless as part of clinical management and efforts to prevent TB) must be avoided. Such practices are not effective in safeguarding health, and they also breach human rights. Also, linkage from testing to appropriate HIV prevention, treatment and care is essential. Those diagnosed with HIV must be linked to and provided with ART before release from prison, and continuity of care between prison and community must be assured in order to maintain viral suppression and prevent transmissions and the development of HIV drug resistance.

4.5 Men

In the last ten years of HTS programs, men were reported to test for HIV at lower rates than women. Consequently, men were more likely to start ART at later stages of HIV infection [26] resulting in high morbidity and mortality among men even after ART initiation. Men are less likely than women to use clinical health services and thus community-based HIV testing approaches are critical to reach them. These men include clients of entertainment venues, STI clients, partners of HIV positive women and other high-risk men. They might be reached by different HTS strategies including PNTT, HPITC and mobile HTS services at establishment venues as mentioned in the community action framework.

Differentiated HTS approaches that use a mix of facility-based and community-based approaches, are important for reaching men. Selecting a strategic combination of service delivery approaches for men requires thorough situational analysis consideration of men's preferences, local context, epidemiology, and available resources. In high HIV burden settings such as those of southern Africa, efforts to engage men from both general and key population groups are needed. In low HIV burden settings, approaches need to focus specifically on men from key populations including clients of sex workers, men with STIs or with confirmed or suspected TB, as well as men with partners with HIV who are not on ART and virally suppressed. Across all HTS approaches, men, like women diagnosed with HIV may need support to link to ART as soon as possible.

Community-based HTS is important for reaching men because in many settings they are less likely than women to use health facilities. Community-based approaches may be particularly useful for reaching men who have never tested and men from or with partners from key populations. Focused community and peer mobilization and mobile outreach with HIVST distribution may facilitate testing for men.

4.6 Pregnant women (PW)

Early provision of HTS in pregnancy enables PW to benefit from all relevant prevention interventions, care and treatment services. For those who tested HIV positive, immediate ART initiation and care will reduce the risk of HIV transmission to their infants and maintain good health. All women receiving antenatal care (ANC) should be offered voluntary confidential counselling and testing for HIV (additional Syphilis and HBV tests are offered as part of PMTCT program)

- All pregnant women should be screened for HIV (HBV and syphilis are also included as part of PMTCT) at the first antenatal care (ANC1) visit, ideally within the first times. If for any reason this was not done at the first ANC visit, it should be done at the next possible opportunity.
- All pregnant women, whose HIV status at delivery is still unknown, should systematically be offered voluntary counselling and testing during or after labor.

Retesting for HIV

- Pregnant women are recommended to retest HIV at the third trimester only for women at ongoing high HIV risk including those from key populations or have HIV+ partner who are currently not on ART or currently on ART but not virally suppressed or partner known to have high risk behavior or partner is key population)
- Retesting during pregnancy is not recommended otherwise.

Dual HIV/syphilis RDTs can be used as the first test in ANC. To optimize implementation and delivery, supply chain management, training and verification of testing algorithms need to be considered. Pregnant women who have already been diagnosed with HIV and are on ART or women already diagnosed with and treated for syphilis during their current pregnancy should not be tested with a dual HIV/syphilis RDT. Instead, women should be tested for HIV and syphilis using two different tests according to the national algorithm.

Pregnant women who are HIV-negative but at ongoing risk should be linked to comprehensive HIV prevention services. It is safe for pregnant and breastfeeding women to start or continue taking PrEP. Pregnant and breastfeeding women taking PrEP should receive HIV testing, alongside testing for STIs at quarterly facility visits.

- Women at substantial risk of HIV acquisition can start or continue PrEP during pregnancy and breastfeeding. Women taking PrEP should receive HTS alongside screening and testing for STIs, as part of quarterly facility visits
- Women with HIV, including those that are or who may become pregnant, should be provided with information about the benefits and risks of ART, medical guidance appropriate to their situation and support in making voluntary choices about initiating therapy, continuation, and adherence/retention in care as applicable. Health workers must help women to address their healthcare needs and those of their children.
- Pregnant women without any serological markers for HBV can be offered HBV vaccination. Follow-up should continue through the breastfeeding period to ensure that infants born to mothers with chronic HBV infection receive the recommended three doses of vaccine, especially if they did not receive the HBV birth-dose vaccination.

The package for ANC should is included HIV, Syphilis, and hepatitis B surface antigen (HBsAg) testing and treatment as part of PMTCT and the package of care for PW living with HIV should include systematic screening for TB symptoms, referral to TB diagnosis and treatment where necessary. All PW tested HIV positive should immediately initiate ART for their own and infants' health.

4.7 Infants and children

HIV-related mortality rate is very high among for untreated HIV-infected infants (under one year old). In this period, an effective PMTCT program with early HIV testing, a prompt return of test results, an early enrolment and immediate ART initiation with optimized regime is crucial. HIV testing among HIV exposed infants should follow the early infant diagnosis algorithm and guidelines.

4.7.1 Infants and children under 18 months of age

HIV diagnosis can be performed only by virological testing because maternal HIV antibodies remain in the infant's body until 18 months of age. The virological testing by nucleic acid testing (NAT) technologies can be conducted using dried blood spot (DBS) specimens that are collected by pediatric care staff and then sent to NCHADS laboratory for testing. There are two main challenges for this testing modality:

- Long turnover time to receive test results.
- Late initiation of ART

4.7.2 Children 18 months of age and older

For children aged 18 months and older who are not breastfed or who stop breastfeeding at least six weeks, standard and qualified HIV serological assays can be used. *It is suggested to integrate HIV antibody testing into child health programs such as immunization and nutrition services for HIV exposed infants who are not tested as part of PMTCT program.*

Priority activities to increase access to HIV testing.

To achieve virtual elimination of HIV transmission from mother to child by 2025, priority activities to be implemented among infants and children include [30]:

- *WHO recommends routine facility based HTS in inpatient care and malnutrition clinics for infants and children with unknown HIV status in high HIV burden settings.*
- *In high HIV burden settings, infants, and children with unknown HIV status should be offered HIV testing in outpatient or immunization clinics.*
- *Addition of nucleic acid testing (NAT) at birth to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants.*
- *NAT technologies that are developed and validated for use at or near the point-of care can be used for early infant HIV testing.*
- *HIV virological testing should be used to diagnose HIV infection in infants and children below 18 months of age.*
- *All HIV-exposed infants should have HIV virological testing at birth (0-2 days) and 4–6 weeks of age or at the earliest opportunity thereafter.*
- *In infants with an initial positive virological test result, it is recommended to start ART without delay and, at the same time, collect a second specimen to confirm the initial positive virological test result. Do not delay ART. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test.*
- *It is recommended that test results from virological testing in infants be returned to the clinic and child/mother/caregiver as soon as possible, but at the very latest within four weeks of specimen collection. Positive test results should be fast-tracked to the mother–baby pair as soon as possible to enable prompt initiation of ART.*
- *It is recommended that all infants with unknown or uncertain HIV exposure being seen in health-care facilities at or around birth, at the first postnatal visit (usually four to six weeks) or other child health visit have their HIV exposure status ascertained.*
- *It is recommended that children (18 months or older) with suspected HIV infection or HIV exposure have HIV serological testing performed according to the standard diagnostic HIV serological testing algorithm used in adults.*

Further good practices with strong recommendation and high-quality evidence:

- *In all settings biological children of a parent living with HIV (or who may have died of HIV) should be routinely offered HTS and, if found to be either infected or at high risk of infection through breastfeeding, should be linked to services for treatment or prevention and offered a broader package of voluntary provider-assisted referral.*
- *National regulatory agencies are encouraged not to delay adoption of point-of-care EID by conducting further evaluations but instead to adopt a rapid and streamlined registration and national approval process for immediate implementation.*

4.8 Other vulnerable populations

Other vulnerable populations are groups of people who are particularly vulnerable to HIV infection in certain situations or contexts but are not affected uniformly across all countries and epidemics. Depending on context, these may include orphans, street children, people with disabilities, and mobile or seasonal workers. Also, workers in certain industries, such as fisher folk and long-distance drivers, may face increased vulnerability to HIV. These vulnerable groups are often hard to reach and, typically, seldom use conventional HIV services.

CHAPTER 5. TESTING SERVICE

5.1 Pre-Test services

Cambodia is committed to achieving the 95-95-95 targets by 2025. To attain this ambitious goal and meet the targets, the "IR" strategy is a critical approach in diagnosing 95% of the estimated PLHIV and informing them of their status. The 2022 national HIV estimate clearly indicated that around 11,000 PLHIV with unknown status need to be identified.

5.1.1 Demand creation for HIV testing

A. Mobilization platforms for creating demand.

- Peer-delivered, participatory and community-led approaches, such as using peer educators, community groups and faith-based programmes
- Digital tools based on HTS approaches, setting and context, including but not limited to social media, text messages, mHealth, eHealth mass media and other digital media including short videos.

B. Mobilization strategies for creating demand.

- Targeted promotions, advertisements and messaging related to specific HTS attributes, such as unique setting or option, late-night or weekend hours.
- Educational programmes (for example, drama, sports-based or faith-centered);
- Counselling strategies (for example, motivational messages)
- Couples-oriented counselling and partner services (including provider-assisted referral and social network-based approaches)

Demand creation to increase HTS uptake and engage those in greatest need of services is a valuable tool for mitigating stigma, discrimination, and criminalization. It is part of a strategy to reach people living with HIV who do not know their status and who have high HIV-related risk. HTS programs have been promoted through routine mass media such as radio, television, leaflets, posters, billboards, and campaigns at special events. Although knowledge of HIV testing and where it is available are widespread, HIV prevention should be updated, reinforced, and more focused on the targeted GP and KP at high risk.

- HIV information and education through internet and electronic social media are useful to reach the young adolescents and should be adapted to target each KP group. These include Facebook, Twitter, Telegram, Messenger, Webpages, SMS, Hotline, and other social media platforms.
- Continued HIV prevention effort through national awareness campaign to promote HTS and early access to treatment.
- In addition to outreach and HIV promotion campaigns, HTS signboards that direct patients/clients to access HTS at HC and VCCT are important and can be applied at facility setting to combat stigma and discrimination.

5.1.2 Pre-test information for finger prick HIV testing

Prior to SOP-HTS introduction in 2017, HIV counseling was provided before and after HIV testing. During an intensive and lengthy pre-test counseling session, health care workers (who are trained to be HTS providers) spent more than twenty minutes in dialogue with their patients/clients to assist them in deciding whether to take an HIV test.

The minimum messages for pre-test counseling included:

- Providing clear information about HIV transmission and HIV prevention to correct any misconceptions.
- Discussing the benefits and potential challenges of HIV testing including stigma and discrimination as well as prevention, treatment, and care.
- Explaining the meaning of HIV test results and discussing the implications of a positive or negative test result.
- Benefits of early ART and the fact that people living with HIV who achieve and maintain an undetectable viral load cannot transmit HIV sexually to their partners.
- The importance of informing the provider if one was previously diagnosed with HIV.
- The potential for incorrect results if a person already on ART is tested and the services available if those on ART want further testing.
- The services available to those who test HIV-positive, including where ART is provided.
- The importance of disclosure and encouragement for partner testing.
- Prevention options including risk and harm-reduction information that are relevant and available, with a focus on those at high ongoing risk.
- The confidentiality of the test result and any information shared by the client.
- The client's right to refuse testing and that declining testing will not affect the clients.
- Access to HIV-related services or general medical care.
- The opportunity to ask the questions to the providers
- Exploring personal HIV risk behavior and options to reduce risk.
- Assessing patients'/clients' readiness for HIV testing and encouraging clients to return for their test results; and
- Obtaining verbal consent for HIV testing.

Since standard and qualified HIV rapid tests were used for HTS at both facility and community settings, patients/clients can receive the test results within the same day.

5.1.2.1 Provision of Pre-Test information through individual, couples or group sessions

Provision of pre-test information through individual or group sessions must be age-appropriate to ensure a comprehensive package, especially for children and adolescents. The messages used for these sessions must be simple, clear, and concise and specifically focus on:

- Benefits of HIV testing.
- Meaning of HIV positive and HIV negative test results.
- Linkages to HIV care services, including ART and community-based support services.
- Prevention options.
- Encouraging partner testing; and
- Confidentiality for the HIV test results, and any individual information shared.

Mass media and IEC such as leaflets, posters, brochures, or short video clips should be displayed and shown in the waiting areas.

5.1.2.2 Pre-test information for specific population

The pre-test information for pregnant or postpartum women should be conducted at ANC or post- delivery areas. The messages should include:

- From mother to infant during pregnancy, delivery, and breastfeeding ;
- Measures for PMTCT of HIV, including benefits of ART for mother and exposure prophylaxis and ART for infant.

- Benefits of infant feeding practices to reduce the risk of HIV transmission.
- Benefits of early HIV diagnosis for mothers and infants.
- Benefits and requirements of scheduled viral load testing for mother and PCR DNA testing for HIV exposed infant, and
- Inclusion of partner testing.

The pre-test information for KP

Stigma and discrimination against KP in health care settings still exists. The health care providers have limited knowledge, lack of experience or training on how to provide non- judgmental HTS to KPs.

Integrated messages can be effective and increase uptake of testing and onward care for HIV, HBV, HCV, TB and syphilis. Integrated messages should be prioritized for key populations and their partners and for pregnant women.

HIV pre-test information for KP through community-based support team and KP networks using social media should be strengthened and adapted to each population group. In addition, the training programs on HTS for KP for healthcare providers should include specific concerns and needs of KP, so that they can provide friendly and appropriate HTS to KP.

The pre-test information for couples or partners asking for joint testing.

The HTS providers who conduct pre-test assessment should be clear that both pre-test and post-test counseling can be provided. During the pre-test information session, HTS providers should not ask about past sexual behaviors that are unnecessary and may discourage couples from testing. Counseling should be offered to reduce partner's violence and its implication, addressing clients' needs and answering clients' questions.

In cases of serodiscordant couples, the joint couple counseling and partner testing promotes mutual disclosure of HIV status and increases adoption of prevention measures. The disclosure of couple's HIV status must maintain confidentiality.

5.1.2.3 Integration of TB symptoms screening in Pre-Test information at HTS to support intensified TB case finding.

The joint statement between NCHADS and CENAT (issued in July 2010 to reinforce the implementation of the "3 I strategy" for TB/HIV collaborative activities) clearly indicated the roles and responsibilities of each program. HIV program plays a critical role in screening for TB symptoms among all HIV positive cases. The integration of screening for TB symptoms into pre-test session at both facility and community settings is valuable for the HTS program. *All clients presenting with TB symptoms should be referred to thoroughly investigate the disease at HC or Referral Hospital (RH).*

5.1.2.4 STI, Viral Hepatitis and Diabetes linkage information in Pre-Test sessions

HIV co-infections with STI, viral hepatitis and other NCDs such as diabetes increase morbidity and mortality among PLHIV. *Pre-test information should highlight the importance of STI, viral hepatitis and diabetes diagnosis and treatment services and referral when possible.*

5.2 HIV testing process

5.2.1 HIV diagnosis

Two types of HIV tests are currently used in diagnosing adults and children in Cambodia:

- HIV serological tests or HIV antibody detection tests (rapid tests)
  - To increase the uptake of HTC and to improve its acceptability in both facility-based and community-based settings, MOH recommends the standard rapid diagnostic tests (RDTs) pre-qualified by WHO. These RDTs provide results within two hours. The standard RDTs can be performed with simple finger prick collection procedures and can be managed by well-trained HTS providers or community volunteers under the supervision and mentoring from the HTS providers to ensure the accuracy and reliability of the test results.
  - RDTs used for diagnosing adults can also be applied to children 18 months of age and older. Dual Rapid tests HIV/syphilis were approved by MOH and can be used to diagnose HIV and syphilis among PW, STI patients/clients and specific KP group such as entertainment workers, MSM, TG and PWID.
- HIV viral detection tests (HIV DNA PCR tests)

  HIV Polymerase Chain Reaction (HIV DNA PCR) can be used to diagnose early HIV infections for infants and children less than 18 months of age.

All HIV exposed infants are required to be tested with HIV DNA PCR testing at birth.

5.2.2 Serological testing strategy for HIV diagnosis

The serological testing strategy illustrated in Figure 4 and Figure 5, is currently used for HIV testing in both facility- based and community-based settings and Self-Testing in Cambodia. Three standard HIV assays for HIV diagnostic algorithm used to diagnose HIV have high sensitivity and specificity. All three assays able to use with finger prick whole blood, plasma, and serum.

At the HTS out of VCCT testing facility perform only one test as first test, such as health facility-based and community-based setting able use finger prick whole blood, and HIV self-testing use oral quick take from the mouth.

- If test show non-reactive reported result HIV Negative with posttest counseling,
- if test show reactive refer client to VCCT laboratory for confirm HIV status.

At VCCT laboratory based at or located with ART sites use 3 assays follow the national algorithm.
The figures below describe the sequence of assays and number of tests to be performed. The three assays include assay 1 (A1= Determine HIV1/2), assay 2 (A2= Stat-Pak HIV1/2) and assay 3 (A3= Uni-Gold HIV1/2).

- All blood sample are first tested with A1. non-reactive A1 (-) are reported result HIV negative to client with posttest counseling.
- Blood sample that are reactive on the first assay (A1) with HIV-Ab should be continues to perform with assays A2 and A3 parallel; if A1 reactive with only HIV-Ag will collect DBS and sent for the NAT test at NCHADS laboratory. Blood samples are reactive with all 3 assays A1 (Ab+), A2 (+) and A3(+) are reported result HIV Positive to client with posttest counseling.

Note: if A1 reactive only Antigen [A1(Ag+)] that client blood sample DBS should refer to NAT at NCHADS laboratory.

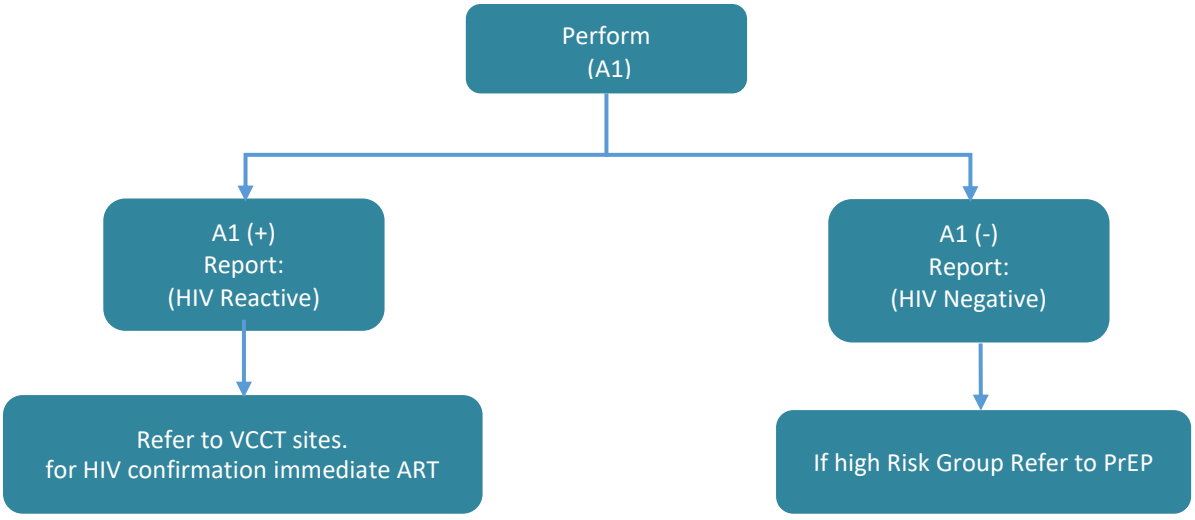
- If NAT test not HIV detected report HIV Negative
- If NAT Test HIV detected report HIV Positive

- Blood sample that are reactive on the first assay A1 (+), but second assay A2 and third assay A3 show result different from each other such as :[A1(+),A2(-),A3(-)]; [A1(+),A2(+),A3(-)] and [A1(+), A2 (-), A3(+)] should repeat all three A1 , A2 and A3 at the same blood sample.

- If the results show:
  - A1(+), A2(-) and A3(-): refer new blood sample after 14 days or refer to NAT test.
  - A1(+), A2(+) and A3(-): refer new blood sample after 14 days or refer to NAT test.
  - A1(+), A2(-) and A3(+): refer new blood sample after 14 days or refer to NAT test.

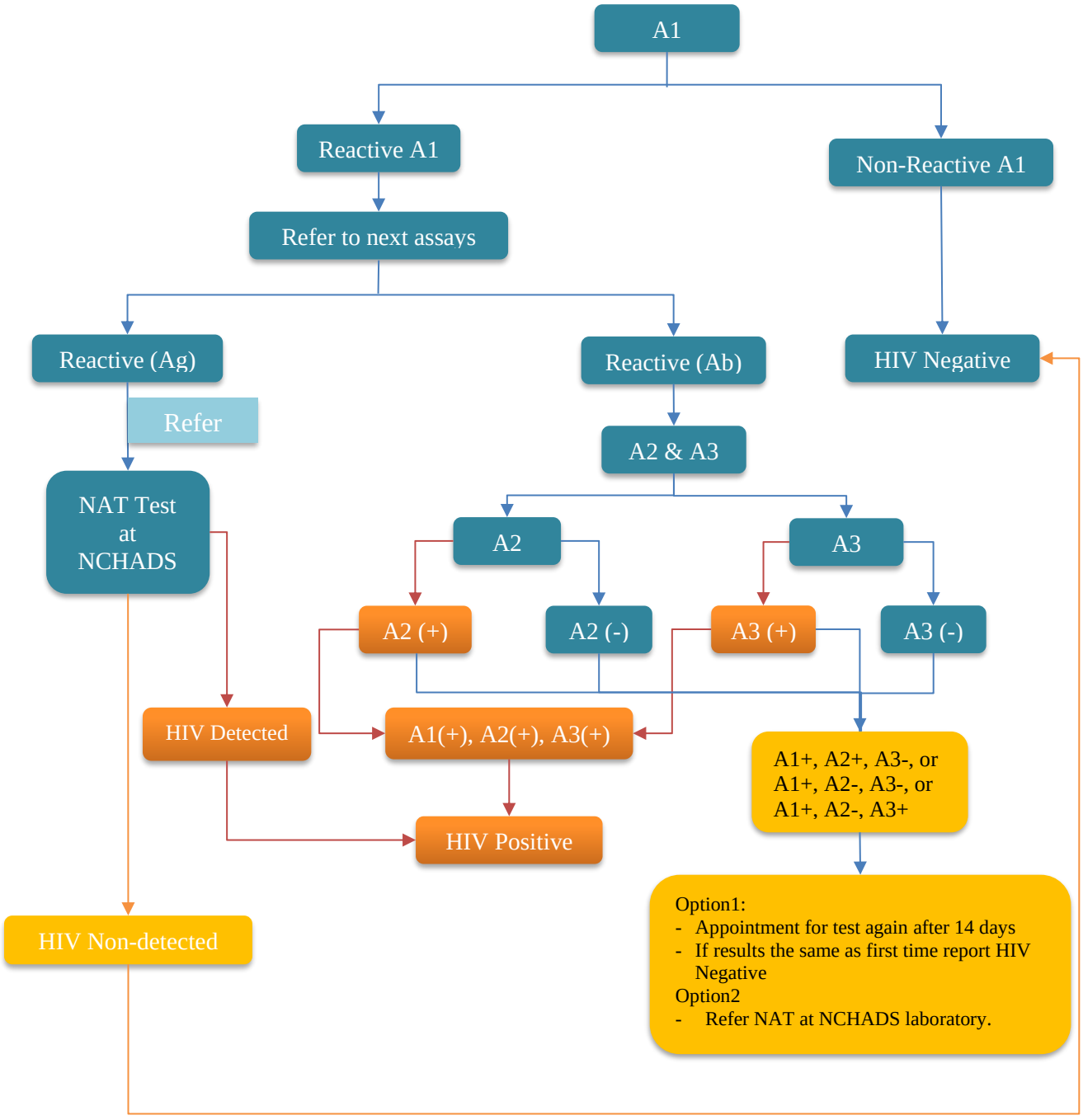
- New blood sample are collected after 14days and perform the HIV test that show the result still the same the first time as:
  - A1(-): report HIV Negative with posttest counseling
  - A1(+), A2(-) and A3(-): report the result HIV Negative with posttest counseling.
  - A1(+), A2(+) and A3(-): report the result HIV Negative with posttest counseling.
  - A1(+), A2(-) and A3(+): report the result HIV Negative with posttest counseling.
  - A1(+), A2(+) and A3(+): report the result HIV Positive with posttest counseling.

Figure 3: Testing strategy at HTS sites



This strategy can be applied for HTS at both facility-based and community-based settings.

Figure 4: Testing strategy for HIV diagnosis (National HIV testing algorithm)



5.2.3 Pediatric HIV testing in HIV exposed and malnourished children.

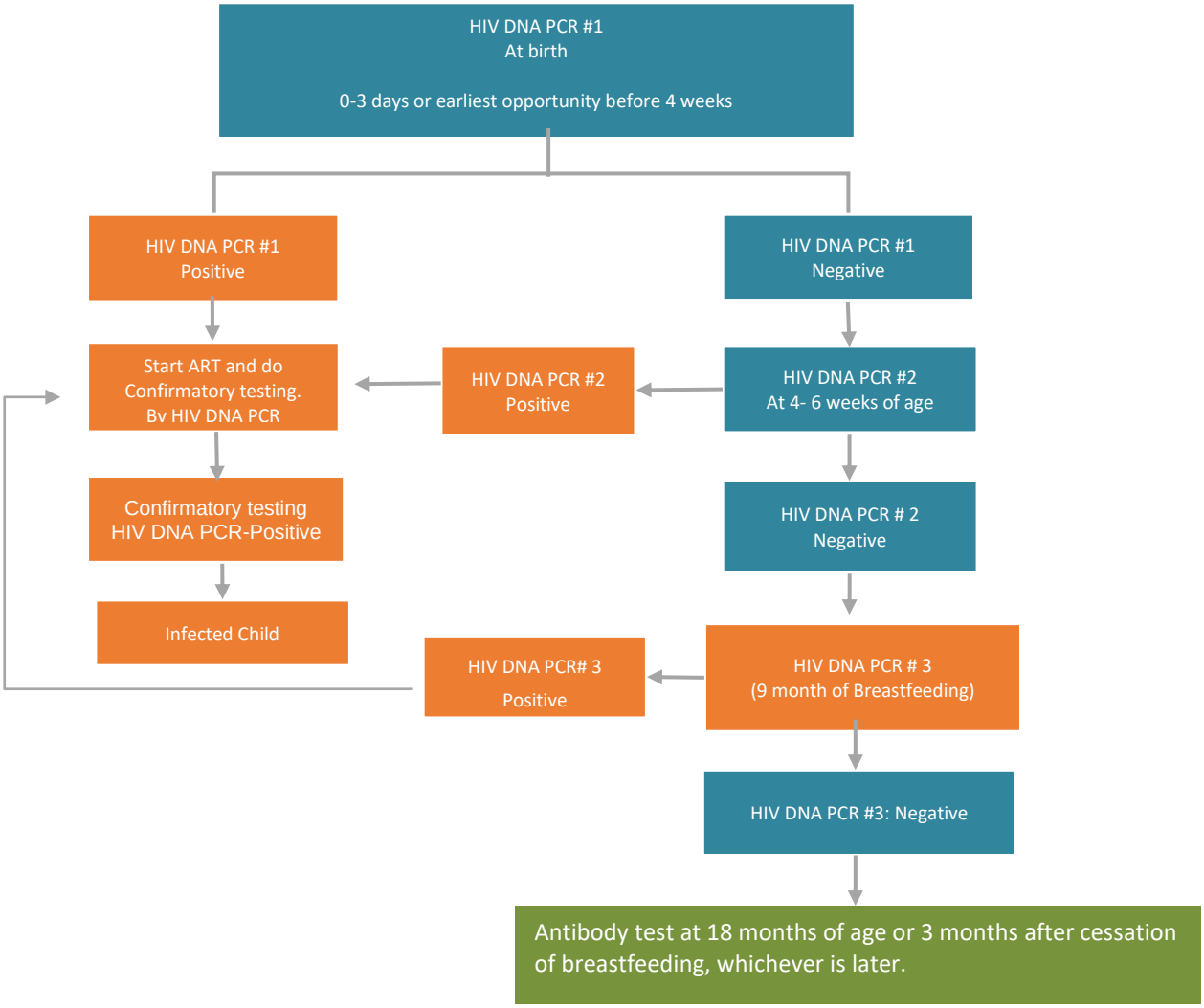
There are two types of HIV tests available for diagnosing children in Cambodia:

- RDTs (HIV antibody detection tests)
- HIV DNA PCR

Early HIV diagnosis and immediate ART initiation is very important for HIV infected infants/children. Therefore, all HIV exposed infants/children should be offered an HIV DNA PCR test through parents'/caregivers' consent. The follow up testing after 3 months of breast-feeding cessation is required to determine children's HIV status and management. HPITC approach should be applied in infants/children when the health providers notice any signs or symptoms related to HIV infection. Parents and community (CAA staff or VHSG) will help follow up and facilitate for the scheduled EID testing.

5.2.3.1 HIV diagnosis for HIV exposed child under 18 months of age

Figure 5: Testing strategy for HIV diagnosis among exposed child <18 months of age



All HIV -Exposed infants need to diagnostic for HIV infection as soon as possible after they are delivery and require HIV NAT (HIV DNA PCR) test. The diagnostic of infants breast-feeding should be performed as:

- First HIV DNA PCR test is collected blood the sample use DBS card and perform the test at days 0-3 days or earliest opportunity before 4 weeks.
  - If HIV DNA PCR non-detected the infant wait for second HIV DNA PCR at 4-6 weeks of age
  - If result show HIV DNA PCR detected report infant HIV Positive, then enfant is referred for ART treatment, that time ask for new blood collection as soon as possible for HIV DNA PCR confirmatory test.

  The confirmatory test result show:
  - HIV Positive that infant continues treatment as the national ART guideline for children,
  - HIV Negative stop ART treatment

- Second HIV DNA PCR test is collected blood sample use DBS card and perform the test at 4-6 weeks after delivery date.
  - If HIV DNA PCR non-detected the infant wait for third HIV DNA PCR
  - If result show HIV DNA PCR detected report infant Positive HIV, then enfant sent for ART treatment, that time ask for new blood collection as soon as possible for HIV DNA PCR confirmatory test. The confirmatory test result show:
    - HIV Positive that infant continues treatment as the national ART guideline for children,
    - HIV Negative stop ART treatment
- Third HIV DNA PCR test is collected blood sample use DBS card and perform the test at 9months of birth date.
  - If HIV DNA PCR non-detected the infant wait for next antibody at 18 months of age or 3 months after cessation of breastfeeding, which is the later.
  - (If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies)
  - If result show result is positive, child is infected, refer to start ART immediately and do confirmation test:
- For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirm infant is infected.

Please refer to the 2022 Amendment to the National HIV Clinical Management Guideline for Infant, Children, and Adolescents in Cambodia

5.2.3.2 HIV diagnosis for children under 18 months of age

The diagnosis among this age group (children <18 months from mothers who do not know their status) should be:

- Start HIV antibody test for the mothers (HIV testing algorithm for adults should be applied), and:
  - *If the test result is positive, the child is exposed to HIV infection (follow the guidance of figure 5*
  - *If the test result is negative, the child is not exposed to HIV infection.*

- If mother has died or is missing, test the infant/child with HIV DNA PCR, and:
  - *If the HIV DNA PCR test is positive, the child is infected.*
  - *If the HIV DNA PCR test is negative, the child is uninfected.*

5.3 Post-Test counseling

HIV testing services (HTS) are not complete without effective linkage to appropriate HIV prevention, treatment, and care services.

The core package of post-test services needs to include:

- clear and concise counselling messages
- referral and offer of rapid ART initiation.
- additional linkages to HIV prevention, care, support, and other relevant services

Post-test counseling is a confidential dialogue between well-trained HTS counselors and patients/clients with the aim to assist them to cope with the HIV test results and provide appropriate psychological and referral support. All patients/clients, regardless of the outcome of the HIV test results, should receive post-test counseling based on their test results. All test results must be communicated clearly. HIV test results can be given in individual or couple sessions. Patients/clients may specifically request that a family member, close friend, and other supportive person be present when they receive test results. *In this case, HTS counselors should be sure that this is truly desired by the patients/clients.*

5.3.1 Post-Test counseling for people who tested HIV negative

Patients/clients who test HIV-negative should receive health information about their test results. The health information should include HIV risk reduction counseling and recommendations on uptake of preventive behaviors and services including consistent condom use and PrEP. It is important to note that a lengthy post-test counseling is not necessary or beneficial and may not be the best option given the limited resource context.

For sero-discordant couples, counseling for those who test HIV negative should include education on methods and behaviors to prevent HIV acquisition, especially adhering to condom use and PrEP.

Minimum information for post-test counseling sessions should include:

- Acknowledging that HIV status and any other personal information that clients may share is confidential and will not be disclosed without their permission or consent.
- Provision and interpretation of HIV test results and reporting of HIV status.
- Reminding clients of the importance of informing the provider if one was previously diagnosed HIV-positive and is now taking ART as this may affect test results, messaging and follow-up services needed.
- Discussing the window period for possible retesting for at risk clients.
- The importance of knowing the HIV status of sexual partner(s) and the availability of partner testing services.
- Education on risk reduction and uptake of preventive behaviors and provision of condoms if available.
- Discussion on referral and linkage to relevant effective HIV prevention services such as PrEP; condoms and lubricants; STI testing and treatment. Harm reduction for people who inject drugs; other sexual and reproductive health services, including contraception/family planning and prevention of mother-to-child transmission (PMTCT)
- Opportunity for the patients/clients to clarify questions.

5.3.1.1 Re-Testing during the window period

The window period should be considered for HIV-negative patients/clients who report recent or ongoing risk of exposure. Re-testing during the window period should be considered after four to six weeks from the possible date of exposure.

5.3.1.2 Re-Testing people who were diagnosed HIV negative but are at high risk of HIV acquisition.

High risk KP may benefit from regular re-testing that provides them with early HIV diagnosis and ongoing health literacy on HIV prevention. WHO recommends specific groups of people in high-HIV-burden settings or individuals with HIV related risks to receive post-test counselling messages encouraging retesting at the appropriate intervals. WHO guidance recommends annual retesting for the following people. More frequent retesting, that is, every 3-6 months, may be warranted based on individual risk factors and as part of broader HIV prevention intervention, such as individuals taking PrEP who require quarterly HIV testing or key populations who present to services with a sexually transmitted infection.

Table 1: Frequency of testing

Circumstance	When to re-test	Types of Tests	Frequency
Known positive partners	*At four weeks post exposure*	*Antibody rapid test*	*3 monthly*
Unknown HIV status of partners	*At four weeks post exposure*	*Antibody rapid test*	*6 monthly*
EW/Sex workers	*At four weeks post exposure*	*Dual HIV-Syphilis test*	*6 monthly*
MSM/TG/PWID	*At four weeks post exposure*	*Dual HIV-Syphilis test*	*6 monthly*
Post rape	*At four weeks*	*Antibody rapid test*	
Occupational exposure	*At four weeks*	*Antibody rapid test*	
STI or viral hepatitis patients	*At four weeks*	*Dual HIV-Syphilis test*	*6 monthly*
individuals with a confirmed or presumptive TB diagnosis;		*Antibody rapid test*	*6 monthly*
outpatients presenting with clinical conditions or symptoms indicative of HIV		*Antibody rapid test*	*6 monthly*
individuals with recent HIV risk exposure.	*At four weeks*	*Antibody rapid test*	*6 monthly*

5.3.2 Re-testing adolescents who tested HIV negative

Information and education about healthy behaviors including correct and consistent condom use, reduction of risk-associated behaviors, and prevention of unwanted pregnancy are important for adolescents who test HIV-negative. If they have engaged in risky behavior, re-testing should be considered.

5.3.2.1 Re-testing before initiating ART.

Retesting before initiating ART refers to the testing of a new specimen from each newly diagnosed individual and current PLHIV on OI by different HTS providers using the same testing algorithm before starting ART. Re-testing should be conducted at HTS-ART to ensure that individuals are not needlessly placed on life-long ART (with potential side-effects, waste of resources, and psychological impact of misdiagnosis).

"Treat-All" strategy was officially endorsed by MOH in 2016. It calls for immediate initiation of ART regardless of CD4 count status among all HIV infected people. In practice, ART management team needs at least seven working days to receive an HIV patient's information on liver functions, kidney functions and TB diagnosis for those suspected of TB infection prior to ART initiation. Risk of misdiagnosis of HIV status due to technical or clerical errors is a critical concern among ART providers.

Thus, WHO recommends HIV re-testing to verify the HIV diagnosis status of the case prior to ART initiation. If HIV re-testing (following the whole three-test algorithms) is negative, the patient is not infected by HIV and should not start ART.

Note: WHO is not recommending retesting for individuals on ART. The effect of ART in suppressing viral replication may extend to suppression of the immune response and, thus, of antibody production. Therefore, non-reactive test results must be interpreted cautiously. Individuals undergoing HIV testing must be made aware of the risk of incorrect diagnosis if they do not disclose that they are on ART. All individuals receiving HIV testing should be asked if they have been tested previously and told they are HIV-infected and/or if they are now on ART or have ever received ART.

5.3.3 Post-Test Services for People Tested HIV Reactive

The well-trained HTS providers should always keep in mind the 5 Cs principles recommended by WHO, particularly correct test results before giving HIV-reactive test results to their patients/clients. HTS providers should provide clear messages to refer them for confirmatory test at VCCT. HTS-ART is change to VCCT instead.

The minimum messages for reactive patients/clients at the post-test counseling include the followings:

- clear explanation about the test result, i.e. "this is the result of the first test only, you need to confirm diagnosis with other tests at VCCT"
- clear information about the need of getting confirmatory test at the same day and the benefits of immediate ART initiation, if the test is confirmed positive, and
- clear information regarding the importance of partners testing.

It is important to note that HTS providers should look out for any strong feelings displayed by patients/clients when receiving the HIV reactive test result. Where relevant, HTS providers should counsel patients/clients on their test results and help manage their emotions.

5.3.4 Post-Test services for people with inconclusive test results or with test results that are not yet confirmed.

An HIV-inconclusive/indeterminate results means that the first HIV results were not confirmed by subsequent test using RDTs (i.e. screening test was reactive but confirmatory test was non-reactive or the first two test results were reactive, but the third test was non-reactive). The patients/clients with

inconclusive test results should be informed that a definitive diagnosis cannot be provided the same day and they should return in 14 days for additional testing to confirm their HIV status, or the provider can choose to send specimen to NCHADS for NAT test. In such cases, individuals or couples may be stressed and confused; thus, they need clear explanation and guidance for the follow-up test.

5.3.5 Post-Test services for people tested HIV positive.

All post-test counseling should be client-centered, responsive, and tailored to the unique situation of each individual or couple. The patients/clients may have difficulties absorbing the information/counseling provided by trained HTS providers in one session, so follow-up counseling sessions are needed.

The minimum messages for post-test counseling include the following:

- Clear explanation about the test results and diagnosis, and that HIV is a chronic, manageable condition requiring lifelong treatment; with treatment most, people will live healthy lives and will usually live as long as people who do not have HIV.
- Psychological support to live positively with their status.
- Clear information about the benefits of immediate ART initiation, and where and how to enroll in this important treatment service; and that if they remain **adherent** to treatment and become virally suppressed, they will not transmit HIV to their partner(s); also, that ART is **safe, and side-effects are minimal**.
- For **women living with HIV**, as relevant, provide information on safe conception, ART use during pregnancy to prevent mother-to-child transmission and breastfeeding.
- Importance of ART adherence.
- Active referral with a specific time and date to social and community-based support.
- Information on how to prevent transmission of HIV through viral suppression and consistent condom use as well as PrEP.
- Discussing the possible disclosure of test results to partners, and the risks and benefits of doing so.
- Discussion on how to encourage and offer HIV testing to sexual partners and children of the HIV patients/clients.
- **Invite questions** throughout and provide time for the client to ask them.

The shock of receiving the HIV positive result may make it difficult for the patients/clients to process, so HTS providers should also provide the necessary emotional support as follows:

- Giving time for the patients/clients to consider the test results.
- Helping the patients/clients to cope with their emotions regarding the HIV positive result.
- Discussing patients'/clients' immediate concerns, providing psychological support, and informing them about the availability of social networks to offer immediate support services.
- Discussing and offering guidance to individuals with barriers to immediately enrolling in ART such as transportation, stigma, and discrimination, etc.
- Assessing the risk of intimate partner violence, including physical safety of female clients.
- Assessing the risk of suicide, depression, and other mental health consequences of HIV positive diagnosis.
- Encouraging and allowing the patients/clients to ask additional questions or address further concerns.

5.3.6 HIV Disclosure

Deciding about disclosing one's HIV status is a serious issue for a person who tests HIV positive. The three acceptable types of disclosure that are often considered include:

- **Disclosure to a sexual partner, family member or close friend:**
  When people learn about their HIV positive result, they may need time to absorb and process this diagnosis before they are ready to share it with others. As such, they need clear counseling about disclosure. HIV disclosure can benefit sexual partners, but the social context of an individual should be considered. In this regard, well trained HTS providers should assess the risk of partner violence and make appropriate referral if necessary.

- **Disclosure by the HTS providers to a sexual partner of the individual:**
  The HTS providers need to be sensitive to patients/clients who may be susceptible to adverse outcomes of disclosure such as discrimination, violence, abandonment, or incarceration and should adapt counseling accordingly. Such patients/clients may need additional counseling both before and after testing.

- **Disclosure by the HTS providers to other health workers involved in the patient/client's care:**
  To ensure appropriate clinical management, HTS providers should seek consents from their patients/clients who test HIV positive to share their HIV status with medical workers involved in their care, and that such disclosures are done with the utmost consideration for patients'/clients' benefits and their quality of care. This special disclosure should respect the client's basic right to privacy and confidentiality of all medical information. The process of disclosure should be based on the National Guidelines on Diagnosis and Antiretroviral Treatment of HIV Infection in Infants, Children and Adolescents (National Center for HIV/AIDS and Dermatology, Cambodia, 2015).

5.3.7 Post-Test counseling services for key populations (KPs)

Well-trained community HTS providers should provide intensified post-test counseling in combination with follow up counseling to increase the proportion of HIV infected KP who enroll in HIV care and treatment services. KP who tested HIV positive may need counseling and peer support services to cope with the HIV diagnosis status and to access linkage to care and treatment services.

5.3.8 Post-Test counseling services for couples and partners of PLHIV

Couples counseling requires additional training and enhanced counseling skills. HTS providers may have challenges providing post-test counseling to sero-discordant couples because it is difficult to explain the HIV positive test and hard for the couple to accept the HIV status. The trained HTS providers should ensure that HIV positive partner is enrolled in care and treatment services for immediate initiation of ART. At the same time, the HTS provider should ensure that the negative partner receives further HIV testing. In addition, preventive measures such as condom use and ART adherence for viral suppression should be explained to the couple.

5.3.9 Post-Test counseling services for pregnant women

The following messages should be added to the standard message described for people who tested HIV positive and be used for PW who are tested HIV positive:

- **Childbirth plans:** HTS provider should encourage HIV-positive PW to deliver in a health facility co-located with ART for their own health and to ensure access to PMTCT services.
- **Access to ART:** ART management team should provide immediate ART to PW who are tested HIV-positive and provide ARV post exposure prophylaxis to babies for PMTCT.
- **Partner testing:** HTS providers should explain the importance of partner testing and provide information on where HIV testing services are available.
- **Ensuring screening for TB.**

5.4 Linkage to prevention, care, and treatment services

Linkage and connection to HIV care is defined as a process of actions and activities that support people testing for and diagnosed with HIV to engage with prevention, treatment, and care services as appropriate for their HIV status. Therefore, linkage to appropriate services following a diagnosis is a key factor of the success of HTS program.

For PLHIV, linkage service should run from the HIV diagnosis stage to enrolment stage in treatment and care, and other health services. All HTS providers are responsible to ensure that patients/clients are linked and connected to appropriate prevention, care, and treatment. HIV testing and knowledge of one's status have limited value unless these are linked and connected to other services such as:

- Treatment and care, and management of diseases.
- Preventive services.
- Maternal and child health including sexual and reproductive health, birth spacing/family planning, PMTCT, STI services.
- HTS for partners and family members including partner notification tracing and testing (PNTT);
- Psycho-social support services.
- Other relevant medical services, i.e. laboratory

The following table illustrates linkage services for both HIV + and negative individual.

Table 4.1. HIV prevention, treatment, and care services

<table>
<tr><th></th><th>People living with HIV</th><th>People testing HIV-negative</th></tr>
<tr><td>Treatment</td><td>Treatment</td><td>N/A</td></tr>
<tr><td rowspan="6">Prevention</td><td colspan="2">Male and female condoms and condor-compatible lubricants</td></tr>
<tr><td></td><td>PrEP for people at substantial ongoing risk of HIV infection</td></tr>
<tr><td></td><td>Post-exposure prophylaxis (PEP) following suspected exposure</td></tr>
<tr><td></td><td>Voluntary medical male circumcision (VMMC) (in 14 priority countries)</td></tr>
<tr><td colspan="2">Harm reduction for people who inject drugs (needle and syringe programmes, opioid substitution therapy, other drug-dependence treatment, and opioid overdose prevention and management)</td></tr>
<tr><td colspan="2">Behavioral interventions to support risk reduction, particularly for people with HIV and members of key populations.</td></tr>
</table>

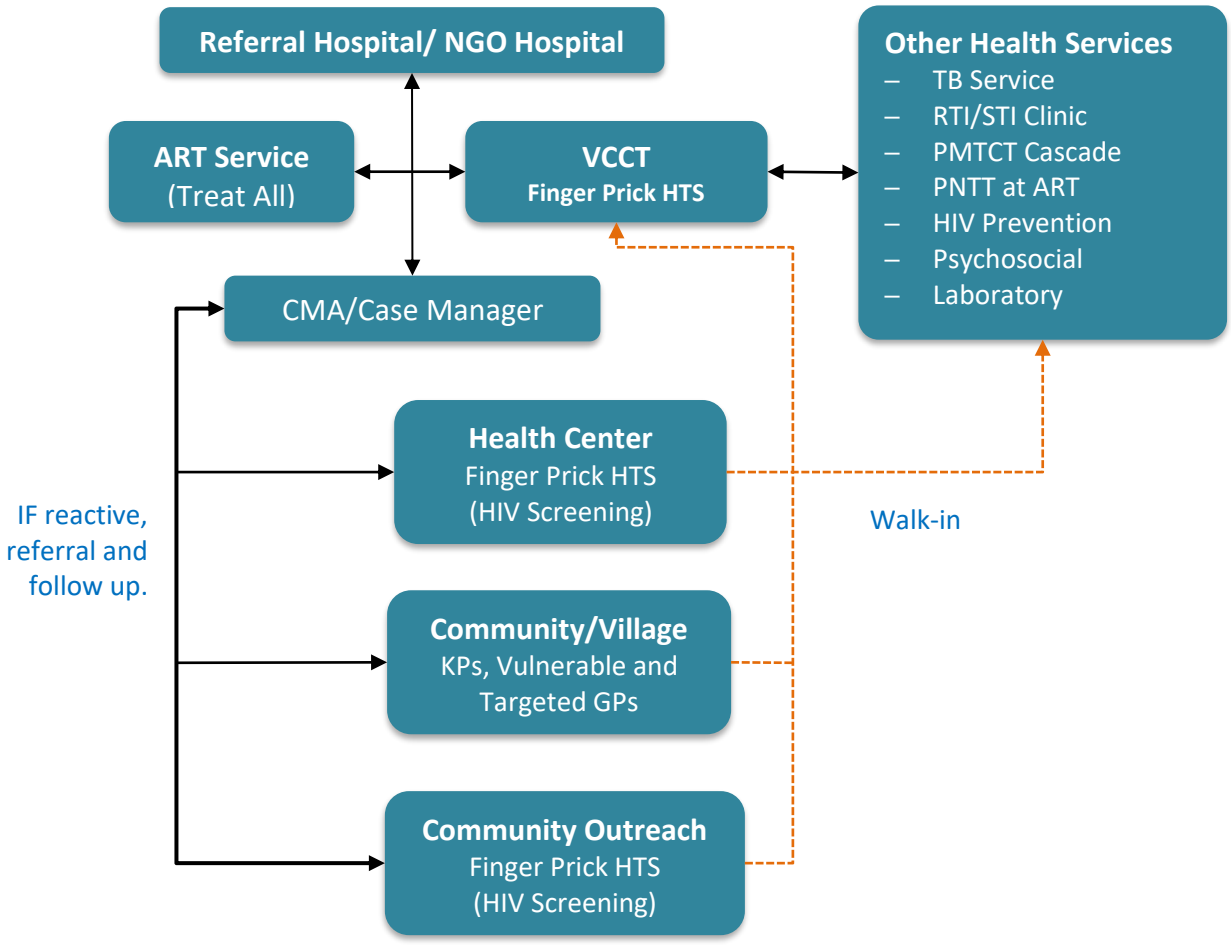
	People living with HIV	People testing HIV-negative
Sexual and reproductive health	Contraception and family planning	
	Prevention of mother-to-child transmission	N/A
	Cervical cancer screening and treatment	
	Anal cancer screening (for men who have sex with men)	
	STI testing and treatment	STI testing and treatment for those with ongoing risk, including people from key populations
Testing for all partners and biological children	Testing for all partners and biological children (includes partner services and index case testing)	For partners and social contacts of people from key populations, where appropriate
Retesting and Confirmatory testing	Retest before ART initiation Confirmatory testing following reactive testing (positive) community-based test-for-triage. or HIVST result	Retest at least every 12 months if at high ongoing risk, particularly people from key populations
Other clinical services	Assessment and provision of vaccinations, such as for hepatitis B virus (HBV) for people from key populations, pregnant women, and infants; and, where appropriate, tetanus vaccination for adolescent boys and men receiving VMMC	
	HBV testing and vaccination and hepatitis. C virus (HV) testing and treatment	HBV and HV testing particularly for members of key populations, according to epidemiology, and treatment or vaccination
	Co-trimoxazole chemoprophylaxis to prevent Pneumocystis carinii pneumonia	
	Intensified TB case finding and linkage to TB treatment	
	Provision of isoniazid preventive therapy if person does not have TB	
	Malaria prevention (such as bed nets and prophylaxis), depending on epidemiology	
Other support services	Mental health services	
	Psychosocial counseling, support, and treatment adherence counseling	
	Support for disclosure and partner services	
	Legal and social services	
	Services for responding to violence against women, including first-line support and psychosocial support, post-rape care, and other support services including shelters, legal services, and women and child protection services.	

NA = not applicable

The current mechanism for linkage to HIV prevention, care and treatment services is indicated in Figure 7:

- More effort is needed to link people who have a reactive test result in the community-based and facility-based HTS to VCCT services for additional testing and an HIV diagnosis. For those diagnosed HIV positive, re-testing to verify diagnosis is crucial before ART initiation.
- All people who test HIV positive need immediate linkage to care to maximize the benefits of ART.
- All people who test HIV-negative with ongoing HIV risk need to be linked to prevention services.
- In each OD, CMA/Case Manager and outreach worker/peer educator of KP works closely with VCCT team and all case management providers (CMP) of all HTS (facility and community settings) to ensure that patients/clients are linked to the relevant HIV services such as HIV diagnosis, prevention, and care and treatment, and other health services as needed.

Figure 6: Linkages between HTS (facility and community settings) and treatment and care services
This diagram will be update follow national algorisms.



CHAPTER 6. QUALITY ASSURANCE OF HIV TESTING

The implementation of quality assurance through quality management systems is crucial for all HTS modalities including HIV testing in both health facility and community-based settings that uses rapid tests and in laboratory testing for viral HIV detection. HTS providers provide counseling and offer testing with respect to quality management system principles to ensure the highest level of quality and accuracy.

The following definitions relating to the quality of services may be useful for HTS providers and HIV program management teams at the national and sub-national level:

- Quality management system: a system to direct and control an organization with regards to quality.
- Quality assurance (QA): a part of quality management focused on providing confidence that quality requirements are fulfilled.
- External quality assessment scheme (EQAS) including proficiency testing: inter-laboratory comparison to determine if the HIV testing service can provide the correct test status.
- Quality control (QC) or process control: a material or mechanism which, when used or as part of the test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.
- Quality improvement (QI): a part of quality management focused on continuous increase in the ability to fulfill quality requirements. (Source: WHO, 2010).

6.1 Quality of HIV test results

A crucial priority element of the 5 Cs principles of WHO and UNAIDS is to ensure correct test results from HIV testing. Despite the availability of excellent HIV reagent (high sensitivity and specificity), the reliability of the test results depends on the correct use and stock conditions of reagents as well as commodities. Some errors can occur at any point of the testing and diagnosis process which t could contribute to incorrect test results. Examples of such errors may include poor quality of HIV assays, transcription errors, improper storage of test kits, and inadequate quality training program for HTS providers.

Misdiagnosis of HIV status, i.e. false positive or false negative, may have severe consequences for individuals and for the community. These are the main challenges in HTS program. It is a priority for the national HIV program to implement robust quality management systems to deliver high-quality and accurate results of HIV status.

Rapid scale up of HTS at both facility and community settings should consider the following key aspects to ensure the quality of HIV diagnosis:

- A national HTS policy that is regularly updated and linked to HIV strategic plan in the health sector.
- Pre- and post-market regulatory controls.
- Validated national testing algorithm with back-up options.
- Quality management systems ensuring QA practices for all HIV testing in all settings.
- Good quality training with supportive supervision and mentoring for HTS providers.
- Ensure logistic supply management includes quantification and forecasting for RDTs kits and commodities to avoid stock-outs or over-stock.
- Strong strategic information system including standard monitoring tools and records keeping (standard registers, logbooks).

A comprehensive and standard training package on HTC including QA should be regularly updated according to the HTS policy and used for training to ensure the competency of HTS providers. The SOP for specific practices such as how to perform individual assays, QA for HIV testing and national testing algorithms should be developed in line with the updated national HTS policy. These documents should be available at HTS sites and HTS providers.

In addition, strengthening strategic information on HTS is crucial, and the training should also include the following:

- Keeping all records and reports using standardized logbooks/forms such as registers, referral slips, lab test results, appointment cards, QC forms and temperature monitoring sheets.
- Understanding the importance of QC system for all HIV testing, including internal quality control (IQC) and external quality control (EQC);
- Conducting effective supervision or mentoring visits with informed corrective actions to HTS at both facility and community settings; and
- Improving the quality of counseling (pre & post- tests)

Since 2004, QA implementation in Cambodia has been focused on ensuring the quality of HIV counseling and testing that are conducted at VCCT. To do so, qualified national supervisors or mentors including NCHADS teams, and their partners have conducted regular supervision or mentoring visits to HTS providers using QA checklists. Besides, the national referral laboratories recognized by MOH such as NIPH, NCHADS, and IPC laboratories, in collaboration with NCHADS' relevant units, have planned and implemented the QA activities every six months to monitor and improve the quality of testing.

These QA practices should be continually strengthened, and supervision or mentoring should be reinforced and focused on HTS effectiveness and efficiency to ensure the delivery of correct test results. These can be applied to all HTS at both facility and community-based settings.

6.2 Regulations of HIV Diagnosis

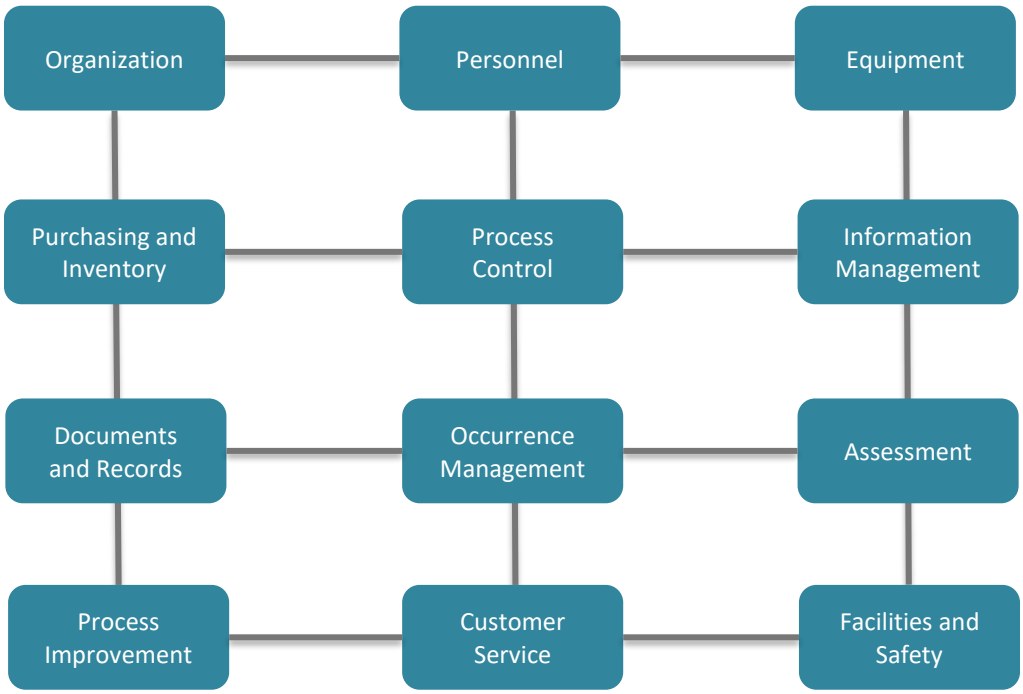
The WHO pre-qualification of *in vitro* diagnosis promotes and facilitates access to safe, appropriate, and affordable diagnosis with good quality HIV tests. Lists of WHO pre-qualified and USA-FDA qualified RDTs are available in markets for use in resource scarce settings.

Cambodia is encouraged to continue the use of WHO pre-qualified RDTs, especially the three standard HIV rapid tests that were validated by NIPH laboratory and supported technically and financially by US-CDC in 2004. The validation of any new RDTs for replacing the current HIV rapid tests should be conducted by the national referral laboratory.

6.3 Quality Management System (QMS)

QMS can be implemented in varying degrees, but the basic principles still apply to any HTS which provides HIV diagnosis. QMS implemented in any HTS should incorporate the 12 elements illustrated in figure (8).

Figure7. Twelve elements of QMS



6.3.1 **Organizations**

In order to have a functioning quality management system, the structure and management of the laboratory must be organized so that quality policies can be established and implemented. These must be a strong supporting organizational structure-management commitment is crucial- and there must be a mechanism for implementation and monitoring.

HTS at both facility and community settings should assure quality of HIV testing and should have policies that specify these quality issues such as:

- Ensuring the competencies of all HTS providers.
- Ensuring quality of HIV test kits, equipment and commodities (purchasing and inventory);
- Creating and managing documents (information management);
- Keeping confidentiality of records (information management);
- Recording and following up the patient/client's complaints (occurrence management);
- Evaluating and following up on results of EQA schemes, proficiency testing and on-site verification/supervision.

6.3.2 **Personnel**

The most important laboratory resource is competent, motivated staff. The quality management system addresses many elements of personnel management and oversight and reminds us of the importance of encouragement and motivation.

HTS providers should be trained and certified to conduct all HTS components such as counseling, testing, linkage to care, etc. HTS providers should be trained in RDTs stock monitoring and management in order to request the correct amount of RDTs and consumables needed in a given time period.

The training program for HTS providers including lay persons should consist of pre-service and in-service training and periodic refresher courses. In addition, regular supportive supervision, and ongoing mentoring from the national level to HTS sites should be strengthened.

Activities to improve the capacity and ensure the competencies of HTS providers are as follow:

- *Developing job descriptions indicating clear roles and responsibilities of all HTS providers.*
- *Keeping training checklists for all HTS providers.*
- *Encouraging performance assessments to discuss issues that may affect a provider's ability to perform his or her assigned tasks.*

For the national level, it is critical to have:

- *Human resources development, planning, and management systems including personnel information systems.*
- *Standardized and updated training curriculums and production of handbooks for participants for pre-service and in-service training.*

In Cambodia, the VCCT training manual was officially endorsed and used in 2004 to train VCCT staff working at public and NGO facilities [31]. The VCCT training manual was revised in 2013 and incorporated training courses for community-based workers (lay persons). In the past ten years, a lot of progress on human resource development for VCCT/HTS program had been reported. However, the shortage of health workers at public health facilities (especially at health centers and referral level one hospitals) and the turnover of trained community-based HTS providers (lay persons) were additional challenges. Those challenges affected the HTS program as well as the QA of HIV testing.

Therefore, training curriculum and training materials including handbooks for participants should be regularly updated according to the latest national guidelines on HTS. Quality of HIV training program is one of the critical issues that need to be addressed.

To ensure the competencies of HTS providers, the following suggestions should be considered:

- *Updating the inventory lists of trained HTS providers at both facility and community-based settings, including their education background, when and where training was provided and place of work*.
- *Updating training curriculum, course syllabus and training manual for HTS program according to the updated national guidelines on HTS.*
- *Conducting initial training activities using the updated training documents for newly recruited HTS providers.*
- *Conducting refresher training activities at least every year for the HTS providers on specific subjects that could strengthen their capacities and knowledge to ensure the quality of HIV testing results.*
- *Enable supervision and ongoing mentoring visits to HTS, efficiently and effectively.*

It is important to note that certified trainers should be able to conduct HTS training to HTS providers at both facility-based and community-based settings. The trainers should follow the national HTS training curriculum/manual.

6.3.3 **Equipment, HIV test kits and consumables:**

Many kinds of equipment are used in the laboratory and each piece of equipment must function properly. Choosing the right equipment, installing it correctly, ensuring that new equipment works properly, and having a system for maintenance are all part of the equipment management programme in a quality management system.

Availability of fully functional equipment and adequate and unexpired test kits and consumables are critical for HTS at all settings. *For HTS performing both HIV test screening and HIV diagnosis using RDTs, HTS providers should have timers and have access to cold boxes if the ambient temperature exceeds the manufacturer's recommendation*.

HTS providers should be responsible for:

- Maintaining an inventory of equipment and commodities for HIV testing.
- Ensuring that equipment and commodities in the inventory are subject to preventive and correct storage on an appropriate cycle.
- Ensuring that faulty equipment and commodities are not used in any process to provide test results.
- Making sure that SOPs with clear instructions exist for all equipment.

6.3.4 **Purchasing and Inventory of HIV test kits and commodities**

The management of reagents and supplies in the laboratory is often a challenging task. However, proper management of purchasing and inventory can produce cost savings in addition to ensuring supplies and reagent are available when needed. The procedures that are a part of the management of purchasing and inventory are designed to ensure that all reagents and supplies are of good quality and that they are used and stored in a manner that preserves integrity and reliability.

Purchasing refers to activities at the programmatic level to ensure that HTS has adequate supplies of HIV test kits and commodities.

Inventory refers to an itemized catalog of HIV test kits and commodities available at HTS sites.
Shortage or stock-outs of HIV test kits and essential consumables such lancets, buffer, gloves and alcohol swabs are the main concerns leading to poor quality and patient's/clients' dissatisfaction.

It is important to ensure that there is an adequate system in place to track procurement for test kits and consumables. Each HTS site should track consumption of all test kits and consumables so that they can report to Operational District (OD), PHD and NCHADS when there is a need to replenish stock.

How to improve purchasing and inventory:

- **National level:**
  - Monitor the purchases and stock based on the requirements.
  - Provide full sets of test kits to testing sites without separating or splitting the kits.
  - Place order every 5 months.
  - Maintain reserve buffers of RDT (for 3 months)
  - Ensure correct and timely RDT Standardized Reporting Tool
  - Strengthen supervision visits and on-site verification (update checklist routinely)
  - Develop and revise job aides for national, OD and sites separately for stock management and request.

- **Sub-national level:**
  - HTS site to review and report the stock level on monthly basis to OD
  - Maintain reserve buffers of RDT (2 months for OD and 15 days for site level).
  - For NGOs, the request and report should be under the monthly management of their umbrella NGO.
  - Fill the RDT Standardized Reporting Tool on a correct and timely basis (sent to NCHADS every quarter)
  - Maintain a list of inventory requirements for HIV test kits and consumables.
  - Ensure sufficient space to store test kits, especially at OD/HC/community level (access to cool box or refrigeration, if room temperature is above the manufacturer's recommendation)
  - Provide full test kits to testing sites without separating or splitting the kits.

Since the HTC at both facility and community-based settings were expanded countrywide in 2013, some HTS have reported inadequate supplies or stock-outs of HIV test kits and some essential consumables. *The HTS program at all levels should note that this issue (especially the distribution systems of HIV test kits to HTS settings) needs to be addressed*.

6.3.5 Process control

Process control is comprised of several factors that are important in ensuring the quality of the laboratory testing processes. These factors include quality control for testing, appropriate management of the sample, including collection and handling, and method verification and validation.

The elements of process control are very familiar to laboratorians; quality control was one of the first quality practices to be used in the laboratory and continues to play a vital role in ensuring accuracy of testing, and to make sure the quality of laboratory need to participate with EQAS program, as describe bellow:

6.3.5.1 Quality Control (QC)

QC or process control refers to processes and activities to ensure that testing procedures are performed correctly under suitable environmental conditions and that the HIV tests perform as expected. QC is crucial to detect, evaluate, and correct errors due to assay failure, environmental conditions or HTS providers' performance prior to giving test results. QC should be implemented in all HTS sites and records should be kept accordingly [14]. There are two levels of internal QC (IQC) for HIV rapid testing:

- Testing samples with known results to verify if the procedure is working properly, and
- Interpreting the presence or absence of the control lines/bands within the device itself

Corrective action is required if any problems/errors occur prior to giving the result to patients/clients. This is a multi-step testing process:

- **Before testing (pre-analytic)**
  - Prepare the space and test kits and other necessary materials before testing.
  - Prepare client for the sample collection.
  - Check that job aids are available at the testing site [For detail, refer to Stepwise process for improving the Quality of HIV Rapid Testing (SPI-RT) Checklist, October 2016].

- **During testing (analytical)**
  - Prepare test devices.

- Run IQC to make sure the quality of the test devices and that the results are within IQC acceptance criteria.
- Perform the test (following the Procedure of Test or Job Aids)
- Double checking of all read assays by two people.

- **After testing (post-analytic)**
  - Record the HIV test results correctly on the testing forms/registers/logbook.
  - Prepare monthly report.
  - Ensure all clients' documents and records are confirmed and kept securely throughout all phases of the testing process.
  - Ensure proper waste disposal management (refer to the SOP of MOH, Medical Waste Management Control).

6.3.5.2 External Quality Assessment Scheme (EQAS) and Proficiency Testing (PT)

EQAS including PT refers to inter-laboratory comparisons to ascertain the provision of correct test results by HTS. PT involves testing of random samples at regular intervals by the testing sites. EQAS assures HTS sites' performance by ensuring that results are reproducible, and errors are detected and corrected to avoid misdiagnosis of HIV status.

The purposes of participating in EQAS schemes are as follows:

- Evaluating testing competency.
- Assessing performance of specific HTS providers.
- Evaluating the reliability of HIV testing procedures.
- Ensuring accuracy HIV test results
- Provision of information for self-evaluation

How to implement EQAS:

- All HTS at both facility and community-based settings should actively participate in the EQAS program.
- The qualified supervisors or mentors should provide regular supportive supervision to HTS settings.
- All HTS settings should be recognized by NCHADS/MOH based on EQA performance and participation results.

The 2006 SOP for quality improvement (QI) on HIV counseling and QC for HIV testing was implemented in several VCCT sites. There were several QC procedures such as random sampling and serum panel through internal and external evaluation. Based on cost effectiveness and reliability principles, NCHADS and partners have selected serum panel and regular sampling as a QC method. As part of QC, the SOP on EQAS developed by NCHADS in collaboration with NIPH and its partners had been officially endorsed in 2009.

All registered VCCT sites (around 300 sites) and HIV testing laboratories (which participate in the HIV serology EQAS with NIPH) are provided with the serum panel twice per year. NIPH collects and analyzes the results of the panel from the sites before reporting back to the sites. Currently, EQAS program is implemented in only 65 VCCT sites which are co-located with ART sites.

Since the finger prick HIV testing policy was implemented for HTS in both facility and community-based settings in 2013, more than thousands of HTS sites have been offered HTC countrywide. These are the challenges facing NCHADS and partners in conducting EQAS in all HTS sites.
How to implement EQAS in all HTS at both facility and community settings:

- *Develop SOP/Protocol addressing countrywide EQAS implementation, i.e.*
  - *HTS site selection criteria, where HIV screening is performed.*
  - *EQAS procedures.*

6.3.6 Information management

The product of the laboratory is information, primarily in the form of test reporting. Information (data) needs to be carefully managed to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health care providers. Information may be managed and conveyed with either paper systems or with computers; both will be discussed in the section on information management.

Paper-based and/or electronic databases are used for storing HIV records. They will protect the confidentiality of patients/clients undergoing HIV testing. It is critical that all information be kept confidential with access restricted only to people who provide HIV services. Linking a series of HIV test results is crucial when retesting is used to verify a client's HIV positive diagnosis or to resolve a client's HIV-inconclusive status and clients' initial codes.

6.3.7 Documents and Records

Many of the 12 quality system essentials overlap. A good example is the close relationship between "Documents and records "and "Information management". Documents are needed in the laboratory to inform how to do things, and the laboratory always has many documents. Records must be meticulously maintained so as to be accurate and accessible.

The documents are policy, process, and procedural documentation for all aspects of HTS and its quality management system. The documents should be officially endorsed prior to use and should be revised if necessary.

Job aids are useful for HTS providers. The messages used in these documents should be simple, short, and concise and describe each test procedure, how to read the test results according to the validated testing algorithm, and how to refer for retesting. Records generated from testing activities should be filled correctly.
Records required for quality system practice include the following:

- Testing logbooks and registers should be used to identify the person undergoing testing and their test results.
- Referral slips for retesting and other post-test services.
- RDTs and commodities inventory records
- QC results of all testing for that period

The implementation arrangements of documents and records should include:

- SOPs of all HIV testing processes such as testing algorithms should be updated and available at all HTS.
- Equipment maintenance records should be kept properly.

- Standard testing logbooks, registers, and other reporting forms used to record testing results should be retained.

*It is suggested th*at existing documents should be used consistently and properly to improve the quality of HTS in *order to ensure the reliability and accuracy of test results. These should be revised or updated within an appropriate timeframe according to clear assessment outcomes and other evidence from the country or globally.*

6.3.8 Assessment

The process of assessment is a tool for examining laboratory performance and comparing it to standards, benchmarks, or the performance of other laboratories. Assessment may be internal (performed within the laboratory using its own staff) or it may external (conducted by a group or agency outside the laboratory). Laboratory quality standards are an important part of the assessment process, serving as benchmarks for the laboratory.

6.3.9 Quality improvement (QI) for HIV testing

The primary goal in a quality management system is continuous improvement of the laboratory processes and this must be done in a systematic manner. There are several tools that are useful for process improvement.

HIV program management team at all levels and HTS providers must monitor and evaluate their programs continually and use evidence to improve the quality of services. All key players should be actively involved in every level to monitor quality and make improvements towards a coherent, functioning quality management system to address national, sub-national, facility and community concerns.

NCHADS and partners launched a continuous quality improvement (CQI) program within continuum of care (COC) in 2008 and the SOP for the CQI process was officially adopted in 2013. CQI of HTC is part of this COC-CQI process that currently contains 11 indicators to identify HIV infected individuals through provision of HTS (32).

It is suggested that tracking individual patients/clients instead of visit interactions is critical to monitoring those who are reached or accessing HTS. The implementation of the two innovative approaches to track individual patients/clients should be reinforced or expanded. These are unique identifier code used for KP, unique identifier using fingerprint for PLHIV at ART sites, and integration of data system (papers or electronic database). It is also recommended that another integrated approach for CQI of HTS linked to CQI-COC is to link the individual's records in HTS database, ART database for adults, and STI database through a unique identifier system.

6.3.10 Occurrence management

An occurrence is an error or an event that should not have happened. A system is needed to detect these problems or occurrences, to handle them properly and to learn from mistakes and take action so that they do not happen again.

Errors or problems can occur even in the most carefully conducted and monitored testing environment. To reduce and minimize errors, the national QA/HTS team should take the following steps:

- Investigate the cause of the error or problem.
- Take action to address the cause of problem. Corrective actions may result in changes in policy or procedures to help ensure that the error will not re-occur.
- Keep a record of all circumstances related to the error or problem. Also, keep a record of corrective action taken and any communication with affected persons.
- Use Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist.

6.3.11 Customer Service

The concept of customer service has often been overlooked in laboratory practice. However, it is important to note that the laboratory is a service organization; therefore, it is essential that clients of the laboratory receive what they need. The laboratory should understand who the customers are and should assess their needs and use customer feedback for making improvements.

6.3.12 Facility and Safety

Many factors must be a part of the quality management of facilities and safety. These include:

- Security – which is the process of preventing unwanted risks and hazards from entering the laboratory space.
- Containment – which seeks to minimize risks and prevent hazard from leaving the laboratory space and causing harm to the community.
- Safety – which includes policies and procedures to prevent harm to workers, visitors, and the community.
- Ergonomics – which addresses facility and equipment adaptation to allow safe and healthy working conditions at the laboratory site.

Facility: Physical space appropriate for HIV testing should be maintained at each fixed site/setting (refer to Chapter 3).

Safety: HTS sites must have available procedures that personnel must follow to safely handle bio-hazardous material. This includes:

- Instructions on use of gloves, hand washing, handling, and disposing of sharps, and spill containment and disinfection must be provided.
- Basic safety procedures should be clearly posted or visibly available in the testing site.
- General policies such as “no eating, drinking, or smoking,” “no unauthorized persons in the testing area,” must be enforced.
- Procedures for safe disposal of all specimens and materials used in testing must be available and must be observed at each site. This is essential for protecting those performing the tests as well as others who might be exposed to discarded materials. All specimens and materials must be handled as if they are capable of transmitting an infectious disease.
- PEP procedure must be available at the testing sites.

6.4 Quality assurance (QA) for HIV counseling

The counseling skills of HTS providers have the greatest impact on the clients’ HTS experiences. High quality counseling is defined by non-judgmental, accessible, and client-centered counseling. Having systems to

ensure the quality of counseling is important to ensure that human rights are respected, and the client's needs are met. Counseling should increase the knowledge of HIV prevention and benefits of early treatment for HIV positive individuals, whilst also helping clients to focus on achievable steps to reduce their risk.

HTS providers who provide post-test counseling must understand the QA for HIV counseling as part of the 2012 NCHADS (SOP on HTS). Supportive supervision, ongoing mentoring, and on-site observations of HTS counselors should be conducted effectively and regularly on a quarterly basis.

CHAPTER 7. LOGISTIC SUPPLY MANAGEMENT

7.1 Forecasting HIV test kits and commodities

Quantification and forecasting are the processes of estimating how many HIV test kits and other commodities the program needs to reach the population served. Accurate forecasting is crucial for effective HIV testing services.

A quantification and forecasting tool were developed to accurately predict the demand and supplies of HIV test kits and commodities at each site. The current forecasting tool is based on:

- Estimated population that needs to be tested
- Timeframe within which stock is required,
- Previous consumption analysis and report.

7.2 Logistic and supply management

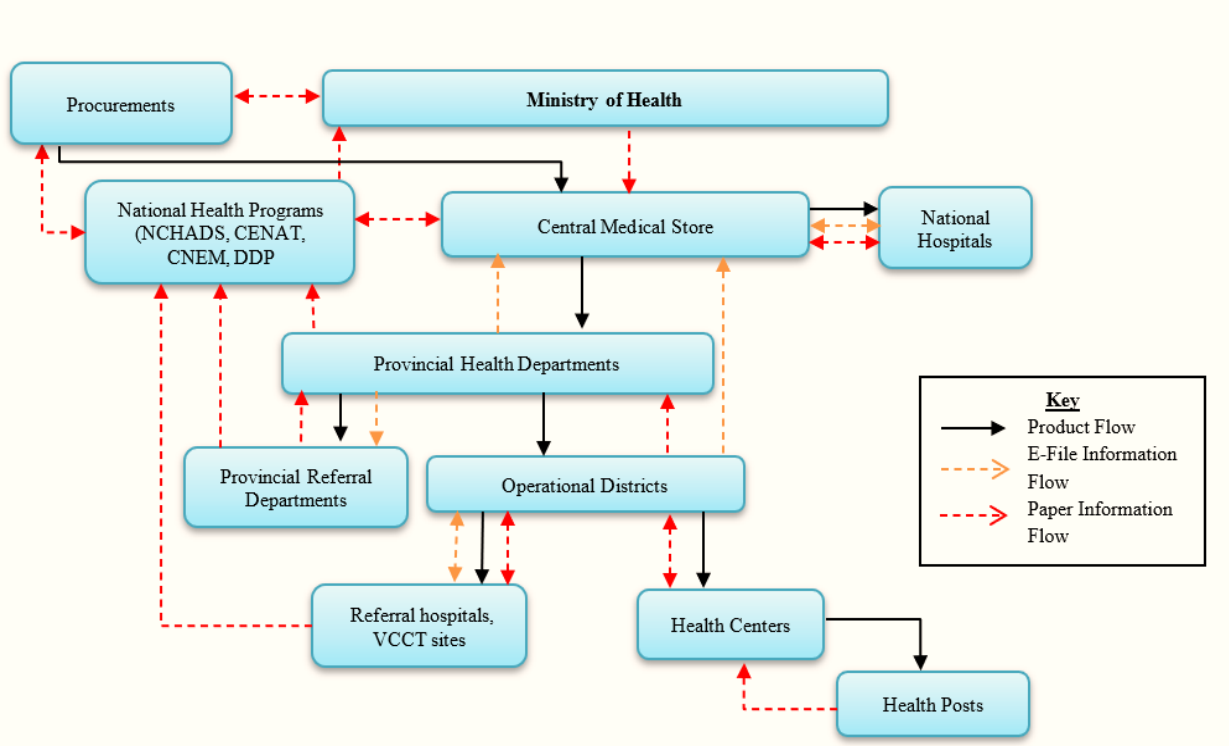
Logistic Supply Management Unit (LMU/NCHADS) of NCHADS is a national level focal point that works closely with provincial/municipal health departments, national hospitals, and NGOs to collect the request form, validate the data, and create the distribution plan for HIV test kits and commodities. In order to easily manage and effectively distribute HIV test kits and commodities, the 25 provinces have been divided into 3 groups (Table 2) and distribution is done quarterly for each group.

Table 2: Name of provinces by delivery groups

Group	Provinces
Group 1	Battambang, Banteay Meanchey, Kampong Chhnang, Pursat, Pailin, Siem Reap, Oddor Meanchey, Svay Rieng and Phnom Penh
Group 2	Kampong Thom, Kampong Cham, Thbong Khmum, Kandal, Kampong Speu, Kep, Kampot, Koh Kong, Sihanouk Ville, Stung Treng and Rattanakiri
Group 3	Prey Veng, Takeo, Kratie, Preah Vihear and Mondulkiri

7.2.1 Flow of logistic and supply management

Figure 8. In-country laboratory logistic and supply flowchart (including information flow and distribution flow)



Logistics and supply management involves multiple parties (MOH, CMS, NCHADS, municipal/provincial health departments, national hospitals, provincial hospitals, operational districts, referral hospitals, health centers, VCCT clinics and NGOs) in the information sharing, request, and distribution processes. The process of request submission and distribution flow of the HIV test kits and commodities are divided according to the agreed timeframe and procedure.

7.2.2 Information and distribution flow for HIV test kits and commodities

7.2.2.1 Request flow

All referral hospitals, health centers and health posts under the OD must send the request form to OD in a specific period. OD is responsible for compiling all request forms and contacting HTS sites when errors occur. After compiling and verifying the request, OD sends the request form to PHD for approval. Provincial hospitals send the request form directly to PHD. After receiving the request forms from ODs and provincial hospitals, PHD will submit the request forms to LMU/NCHADS based on the schedule listed in Table 3 to ensure timely delivery of the HIV test kits and commodities. National Hospitals and NGOs will send the request form directly to LMU/NCHADS based on the same schedule (Table 3).

Table 3. Schedule for submitting the request form by groups

Group	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Group 1	Before 5th December	Before 5th March	Before 5th June	Before 5th September
Group 2	Before 5th January	Before 5th April	Before 5th July	Before 5th October
Group 3	Before 5th February	Before 5th May	Before 5 August	Before 5th November

At the national level, after receiving the request forms from PHDs, the request forms will be reviewed and verified by LMU/NCHADS in order to ensure that the request forms are filled correctly. LMU/NCHADS will contact the focal person of ODs, provincial hospitals, national hospitals, and NGOs to clarify any error or concern on the request form. After verification, LMU/NCHADS will create the distribution plan based on the requests and submit it to MOH for approval and ultimately forward it to CMS. If the ODs, provincial hospitals, national hospitals, and NGOs are unable to submit the request form on time, they should contact LMU/NCHADS immediately to discuss options for alternative delivery or vice versa.

7.2.2.2 Distribution Flow

At CMS, after receiving the distribution plan, CMS will create the invoices and dispatch the HIV test kits and commodities to ODs, provincial hospitals and national hospitals based on the following schedule (Table 4). NGOs will collect the HIV test kits and commodities directly from CMS.

Table 4. Schedule of dispatching to sites

Group	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Group 1	15 to 30 January	15 to 30 April	15 to 30 July	15 to 30 October
Group 2	15 to 30 February	15 to 30 May	15 to 30 August	15 to 30 November
Group 3	15 to 30 March	15 to 30 June	15 to 30 September	15 to 30 December

When receiving HIV test kits and commodities from CMS, national hospitals, ODs, provincial hospitals, and NGOs should check every pallet/box in order to ensure that there is no damage, that the products have sufficiently long expiry dates, and that quantities match with those listed on the invoice.
In the event that the quantity does not match the request, national hospitals, ODs, provincial hospitals, and NGOs should contact LMU/NCHADS immediately to resolve the issue.

It is important for ODs to ensure that referral hospitals, health centers and health posts collect HIV test kits and commodities from OD warehouses. In cases where the referral hospitals, health centers, and health posts do not collect HIV test kits and commodities, ODs need to follow up.

7.3 Emergency request for HIV test kits and commodities

- Emergency requests typically occur when there is an unexpectedly huge increase in demand of the testing kits at HTS sites. In this regard, national hospitals, ODs, provincial hospitals, and NGOs should provide justification attached with e-request form (R&R form) for the emergency request so that LMU/NCHADS can find possible ways to resolve the problem. The paper request should be submitted one month after regular schedule for submitting the request form for each group (see Table 3).
- If the commodities are available at NCHADS warehouse, LMU is distributing the commodities right immediately to sites. The paper request form should be submitted as soon as possible.
- If the commodities aren't available at NCHADS warehouse, but at CMS, LMU is preparing an official request latter, based on the request from sites to MoH for approval, and CMS will proceed in accordingly. By going through CMS process, the turnaround would take a month.

7.3.1 Stock Management

RDT National Dashboard (annex 1) was created with the purpose of improving the stock management and strengthening of the supply management to minimize stock-outs and wastages. It also has the capacity to track the stock status and identify any stock tensions. The dashboard tracks products distributed at all relevant hospitals and HC's as well as NGO clinics/sites.

7.3.2 Receiving New HIV Test Kits and Commodities

- Ensure all required documents are included (invoice, packing list)
- Check the products to avoid any damage/leakage.
- Count the products and compare the actual quantity with the invoice/packing list.
- Sign the confirmation of reception.
- Enter new stock into the warehouse.

7.3.3 Storage Practices of HIV Test Kits and Commodities

- Check every lot.
- Expiry date of new stock
- Update the stock card and verifies.
- Stock the new products based on the required temperature actually and expiry date.

7.3.4 Management of Expired Stock

- Report the expiry date of each product in the request form.
- Keep the expired date test kits separate from the non-expired with labels to show expired stocks.
- Keep disqualified or damaged HIV test kits separate from other stocks.
- Request MOH to incinerate the expired, disqualified, and damaged stocks.

CHAPTER 8. MONITORING AND EVALUATION

Monitoring and evaluation (M&E) is a necessary component of the implementation and management of the HTS program to ensure that resources are utilized, service operations are accessed, and the expected results are achieved. Routine monitoring of the HTS program ensures that service quality is improved and maximum health benefits for the populations are derived.

Monitoring is the routine tracking of services and program using input, process and outcome information that is collected on a regular and ongoing basis. This process makes use of HTS program tools such as supervision checklists, registers/logbooks, referral slips, result cards, appointment cards, stock cards and reporting forms.

Evaluation is the periodic assessment of results that can be attributed to program activities. It uses advanced data analysis and indicators that are not collected through routine information systems. It also assesses whether the program is effective in achieving its objectives.

8.1 Data Management

Data management is very important for the effective management and improvement of HTS services. *Clients/patients data should be used to monitor each HTS site at both facility and community-based settings, at district, provincial and national level. A standard HTS register should be used by all HTS providers as a data collection tool.*

In practice, data collection takes place at the HTS sites, both facility and community-based settings, where patients/clients are presented. The data sent from all HTS sites are collated at OD level and are compiled at provincial level. Data Management Unit of NCHADS plays a critical role in HTS data analysis and data dissemination through NCHADS websites on a quarterly basis.

It is important to note that NCHADS works closely with MOH/DPHI to integrate HTS information system at all levels into HIS of the MOH. The NGO report should be incorporated into the OD report. The reports should be prepared on monthly basis.

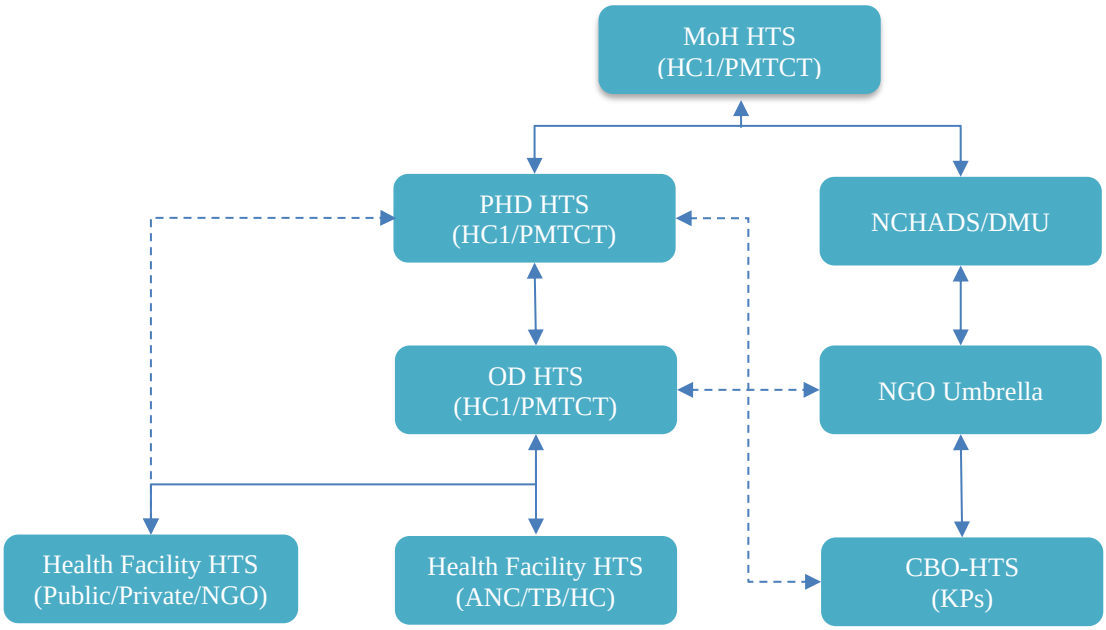
8.2 Recording and Reporting Requirements

Standardized HTS registers, logbooks and case report forms are the basis of service delivery information from which aggregated reports are collected.

HTS providers have to complete all HTS record-keeping forms and registers. These completed documents should be well maintained at HTS sites. The HTS providers should prepare the monthly reports on HIV testing activities and submit those reports to OD.

8.3 HTS Data Flow

Figure 9. Current HTS reporting flow.



The reporting system should follow the HTS information flow as mentioned in figure 9. At health center level, community-based HTS for KP and HTS facilities submit monthly reports to OD. OD HIS officer performs data entry. The data will be automatically run and can be viewed and retrieved by MOH/DPHI.

For HIV information, the data verification can be carried out by OD HIV coordinator. PASP ensure the complete, correct, and timely data entry by OD within 10 working days. NCHADS/DMU retrieves HIV data from HIS for further analysis and reporting. NCHADS sends the data analysis to the subnational level to improve the quality of HTS every three months.

8.4 Data Quality Assurance (DQA)

NCHADS and its partners should select HTS sites to be visited for data verification on a quarterly basis to assure the quality of the data that is reported. A data verification tool should be developed to assist this process.

8.5 Monitoring Indicators

Monitoring of the HTS program has evolved from measuring coverage in terms of the number of the tests performed to measuring knowledge of HIV status among different populations and estimating the proportion of people with HIV who know their status.

HTS indicators are included in the M&E Framework and the Strategic Plan for HIV and STI Prevention and Care in the health sector 2021-2025.

8.6 Quality Assurance Indicators in HTS Register

QA indicators in the HTS register is used in the recording of specific results from each individual HIV test kit used, and it allows smooth monitoring of the lot number, names, number of test kits

used and the expiry dates. It could help HTS providers address HIV test kits problems (expiry date of test kits) or inconclusive test results.

The HTS providers should complete the HTS register immediately after conducting the HIV rapid test with patients/clients. This register should be checked by the national and sub-national supervisors.

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