

**Kingdom of Cambodia  
Nation Religion King**



**Ministry of Health**

# **National Consolidated Guidelines on HIV Testing Services in Cambodia**

June 2017



National Centre for HIV/AIDS, Dermatology and STD

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## FOREWORD

At the UN general Assembly High Level Meeting on AIDS in New York in June 2011 and June 2016, Cambodia expressed its support to the global goals and targets in intensifying to virtual eliminate new HIV infections by 2030. To achieve this 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 had 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 to all HIV testing implementers to put more efforts to strengthen and expand the implementation of the approaches on boosted and integrated active HIV case management to detect 90% of people living with HIV who do not know their status by 2020. To follow the MoH recommendations NCHADS and its partners develop the consolidated national guidelines on HIV testing services (HTS) by adopting the most recent WHO HTS guidelines disseminated in 2015 and 2016 and the valuable inputs and good practices on HTS implemented in country and in the region from the national and international experts.

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

*URS @ HC*

Phnom Penh, *11 August* 2017



**Prof. ENG HUOT**  
SECRETARY OF STATE

## ACKNOWLEDGEMENTS

The National Center for HIV/AIDS Dermatology and STD (NCHADS) and its partners have developed a range of documents on policies, strategies and SOP including priority approaches for implementing the voluntary counseling and confidentiality and HIV testing (VCCT) since 2002. The most updated SOP for HIV testing and counseling (HTC) was endorsed officially in 2012. This document was not covered all aspects of HIV testing models, and was not targeted all population concerns.

To achieve the ambitious targets to detect 90% of PLHIV who do not know their status by 2020 NCHADS and partners develop the consolidated national guidelines on HIV testing services (HTS) which is adopted the relevant WHO guidelines disseminated in 2015 and 2016 and used the inputs and experiences on HTC from all HTC implementers. This document is successfully developed due to the active participation of the sub-technical working group on VCCT led by NCHADS and the inputs and good practices on HTC from the national and international experts.

NCHADS appreciates all those who involve in the development process of this document including all members of the sub-technical working group on VCCT and the national and international experts for their efforts and valuable technical guidance, patience and perseverance during this process. NCHADS also gives special thanks to development partners such as US-CDC, USAID, WHO, UNAIDS, KHANA, FHI 360, AHF, CHAI, CPN+ for their contributions in many ways especially providing financial and technical advices, reviewing the documents and giving valuable inputs towards the finalization of these consolidated national guidelines.

Phnom Penh, 7 August 2017

Director of NCHADS



Dr. LY PENH SUN

**Membership of Sub-Technical Working Group on  
“Voluntary Confidential Counseling and HIV Testing “in Cambodia**

1 .HE Dr. Mean Chhi Vun	Advisor of MoH	Technical Assistant
2. Dr. Ly Penh Sun	Director of NCHADS	Chairman
3. Dr. Ouk Vichea	Deputy Director (NCHADS)	Vice-Chair
4. Dr. Samreth Sovannarith	NCHADS	Member
5. Dr. Ngov Bora	NCHADS	Member
6. Dr. Kim Ratana	Director of PMTCT (NMCHC)	Member
7. Ph. Prok Kaheang	NCHADS	Member
8. Mr. Mom Chandara	NCHADS	Member
9. Mr. Leng Chanrattana	NCHADS	Member
10. Representative of	KHANA	Member
11. Representative of	FHI-360	Member
12. Representative of	US-CDC	Member
13. Representative of	CHAI	Member
14. Representative of	WHO	Member
15. Representative of	AHF	Member
16. Representative of	UNAIDS	Member
17. Representative of	USAID	Member
18. Representative of	CPN Plus	Member
19. Dr. Sok Panha	NCHADS	Member
20. Dr. Chea Chan Kosalmony	NCHADS	Member
21. Mrs. Lim Sophary	NCHADS	Secretariat

## ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Anti-retroviral Therapy
ARV	Anti-viral 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
EID	Early Infant Diagnosis
eMTCT	Elimination of Mother to Child Transmission
EQA	External Quality Assessment
EW	Entertainment Worker
FHI360	Family Health International 360
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 and 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 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
PDI+	Peer Driven Intervention Plus
PEP	Post-Exposure Prophylaxis
PLHIV	People Living with HIV
PMTCT	Prevention of Mother- to- Child Transmission
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 Track- Infections
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infections
TB	Tuberculosis
TG	Trans-gender
UN	United Nations
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 had one of the fastest growing HIV epidemics in Asia and the Pacific region in the mid-1990s and became one of the few countries to have HIV trend reversed within five years (1). The HIV estimations and projections conducted in 2016 indicated that the HIV prevalence among general adult populations fell from an estimated peak of 1.7% in 1998 to 0.6% in 2016 and will continue to reach 0.5% by 2020 (2). The number of HIV newly infected yearly is around 700 cases from 2016 to 2020 (2). The decline trend reflects a ten folds reduction in annual new infections in the last twenty years. It is also estimated that approximately 15,000 people living with HIV who do not know their status (2). Sex work used to be a dominant mode of HIV transmission in 1990's. This mode has changed over time and the transmissions between spouses and casual partners now account for around a half of the total new infection (2). For the past three years, Cambodia has been able to reach over 75% ART coverage and achieved high level of retention in treatment through a range of quality assurance activities (3).

Between 2014 and 2016, 15 operational districts (OD), implemented the boosted and integrated active case management (B-IACM) approach, reported that there were 4,530 reactive cases identified. Of these, 4,254 were confirmed HIV positive at HIV Testing Service-ART (HTS-ART) (4). Noticeably, among those confirmed cases, 9% of key populations (KP), 7% of Pregnant Women (PW), 3% of TB, 7% of partners of PLHIV and 74% of general population (GP) were identified (4).

In 2016, the National Maternal and Child Health Center (NMCHC) reported that out of 326,244 PW tested for HIV in ANC, 204 were confirmed HIV positive. The HIV positivity rate was 0.062% (5). At the same year, CENAT reported that among 15,590 TB patients/clients tested for HIV, only 257 received their test results (reactive result). Among them, 39 (0.25%) were confirmed HIV positive (5).

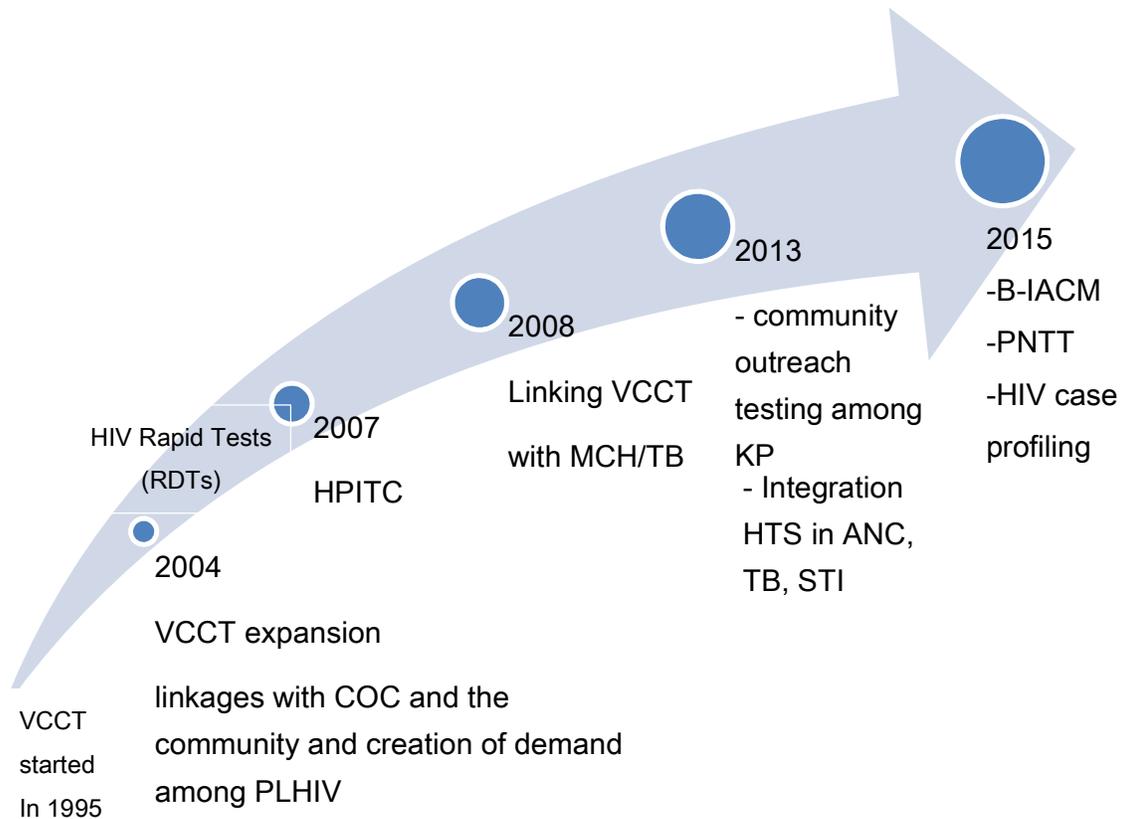
Despite a significant increase in HIV counseling and testing (HTC) coverage among KP in the past four years in Cambodia, KHANA and its implementing partners had reported among KP from January 2016 to December 2016, only 62% of 41,050 identified EWs, 60% of 17,961 identified MSM, 97% of 3,174 identified TG, 97% of 343 identified PWID, were tested for HIV through community finger prick HIV testing (6). The HIV positivity rates were 0.4%, 0.6%, 3.3% and 2.1% among EW, MSM, TG and PWID respectively (6).

#### **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 2011 and in June 2016, Cambodia expressed its support to the global goals and targets in intensifying efforts to virtual eliminate new HIV infections by 2025. Building on the accomplishments made during the last decade, the Cambodia 3.0 frameworks was initiated in 2012 consisted of three domains of work: (1) HIV prevention and links to health services for KP; (2) elimination of HIV Transmission from Mother to Child (eMTCT); and (3) ART as Prevention.

### 1.1.3 Evolution of HTC services

Figure 1. Evolution of VCCT services overtime, 1995-2013



The first VCCT service was established in 1995 in Phnom Penh at Pasteur Institute. Since then, with the assistance from French Cooperation by the end of 2001, 11 stand-alone VCCT services were available and localized in capital cities and some provincial towns (7). Enzyme Linked Immune-Sorbent Assay (ELISA) tests 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 (8).

To increase rapidly the access to HIV care services, the continuum of care (COC) framework was approved and implemented at operational district in 2003 (9). In addition, HTC was an important entry point for HIV prevention, care and treatment and support services, and it contributed to reduction of the stigma and discrimination of HIV. As a result, VCCT was rapidly expanded to cover all operational districts and even at 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 (7). Since then, the three Rapid Diagnostic Tests (RDTs) including Determine HIV1/2, Stat-Pak HIV1/2, and Uni-Gold HIV1/2 have been used as the standard RDTs in Cambodia (7).

In line with WHO recommendation in 2007 to introduce the provider initiated testing and counseling (PITC), Cambodia adopted the health providers 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, i.e. STI services, and malnutrition wards were low (in terms of clients registered). From 2017 onward, the term HTC is replaced by the “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 KP (12).

## **1.2 Rationale**

Cambodia is committed to achieve an ambitious goal to end HIV epidemic by 2025. In the context of scarce resources to implement the “Identify and Reach” and “Treat All” strategies, Cambodia has to focus on most effective and efficient intervention models to detect 90% of those who do not know their status by 2020 (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 that had implemented between 2002 and 2013 to provide a framework for all HTC modalities in order to identify and detect KP and high risk GP. For this reason, the policy documents should be compiled and updated into a solid consolidated policy document.

The consolidated national guidelines on HTS adopts the most updated WHO 2015-2016 guidelines on HIV services focusing on a 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 (14).

## **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 offer quality HIV care services for them.

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

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

- To ensure consistent provision of high quality of 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 HTC 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 Audiences**

The HTS consolidated guideline targets HIV program managers at all levels and decision makers within the ministry of health who are responsible for HIV response in the health sector including HIV testing, HIV prevention, care and treatment services for GP as well as KP.

This document also addresses healthcare providers working with the relevant programs to offer HTC 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 like clinical and non-clinical HTS providers including civil society organizations and community networks.

#### **1.5 Guiding Principles**

##### **1.5.1 Rights Based Approach**

A human right based approach is essential for the success of HTC program that prioritizes 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 (14). HTS will benefit tested individuals and simultaneously improve health outcomes of the population. HIV testing for diagnosis should be voluntary and consented through pre-test information. The expansion of all HTS models should adopt 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 (15). It must also be ethical and be conducted within a supportive environment that can be linked to prevention, treatment, care and support services to maximize individual and public health benefits.

##### **1.5.2 The 5 Cs**

The 5 Cs principles 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 (14).

- **Consent:** clients who receive HIV testing should be informed of the process for HTC 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 should not be disclosed to anyone without the expressed 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 should be given in a group setting, but a private setting should be provided to individuals who have questions that they do not wish to share with others. The high quality of post-test counseling should be provided based on a specific HIV test result and HIV status reported in individual settings.

- **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 intensified.

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

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

- Demand creation and linking patients/clients to HTS
- Pre-test information including screening for TB
- HIV diagnosis
- Post-test counseling
- Active referral and confirmation linkages to other health services.

## **CHAPTER 2. ETHICAL and LEGAL CONSIDERATIONS**

### **2.1 Human Rights**

HTC services should be provided in an environment where human rights are respected that can reduce vulnerability for people living with HIV and those who are affected (14). The most relevant human rights principles in HTS include:

- **right to privacy and confidentiality**

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 clients care and treatment.

- **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 status that will constitute stigma and discrimination.

- **right to decline HIV testing**

Patients/clients have the right to decline HIV testing without compromising their access to standard healthcare. All HIV testing models shall remain voluntary with informed consent, even for the health provider initiated testing or community outreach testing.

Cambodia law on HIV prevention and control of HIV/AIDS enacted in 2002 (article 18) indicated that “Any practice or acts of those who are HIV positive, which have the intention to transmit HIV to other people, shall be strictly prohibited” (15). The violation of this article shall be punished to imprisonment from 10 to 15 years (15).

### **2.2 Stigma and Discrimination**

In the context of HIV, stigma and discrimination refer to actions taken against individual solely on the basis of their HIV status or perceived HIV status (14). 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 program contributes to reduce discrimination by raising awareness and creating knowledge about HIV in communities (14).

HTS program allow more people to know their status that, in turn, 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 fight 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 (16).

“Discrimination against person with HIV/AIDS in the hospitals and health institutions is strictly prohibited”, according 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 Riels to 1,000,000 Riels and with a penalty of imprisonment for 1 to 6 months (Article 52) (15).

### **2.3 Informed Consent**

Informed consent refers to a patient/client being given relevant and appropriate information or knowing about HIV testing (14). 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 patients/clients. This would prevent the HTS providers from any unintended disclosure of test result. 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 in order 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 HTC services

#### **2.3.2 Capacity to Consent**

In Cambodia, any person aged 18 years and older with be sufficiently mature and with the mental capacity to understand the benefits, risks, social and other implications of HIV testing.

*They can give consent for HTS and should:*

- *know the reasons why they are being 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 the informed consent.***

In case that a patient/client who is assessed as being incapable of giving informed consent, then 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, as an example a senior clinician who take care 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 be always voluntary and free from coercion. However, mandatory testing can be considered in special circumstances such as prescribed by a court of law or rape.

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

- **Infants and children (<18-year-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'/guardians' consent.

The legal adult age in Cambodia is 18 years and over, yet under national law on prevention control of HIV/AIDS (15), 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 provide most interest to that individual.

- **Adults (>18-year-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, the finger print can be used instead of the signature.

## **CHAPTER 3. SERVICE DELIVERY APPROACHES**

### **3.1 Approaches and Settings for HTS**

HTC could be provided in a variety of settings, in both health and community. It could be delivered in different ways and to different people as described bellows:

#### **3.1.1 Stand-Alone VCCT**

Stand-alone VCCT routinely offered HTC to patients/clients for HIV diagnosis, but there were no any linkages between the standalone VCCT and the healthcare services. It is no longer implemented.

#### **3.1.2 Health Provider Initiated Testing and Counseling (HPITC)**

PITC has been routinely conducted by healthcare workers to patients/clients presenting with signs or symptoms of HIV infections at healthcare services, such as inpatient services, outpatient wards including ANC, TB, and STI. PITC provides pre-test information and the consent depends on individuals to decline testing (17).

#### **3.1.3 Community-Based HTS**

Community-based HTS includes a number of approaches: (1) mobile outreach campaigns during special events, such as water festival, Khmer New Year, Pchum Ben; (2) testing at workplaces; (3) testing in places of worship, i.e. pagoda; and (4) testing in entertainment establishments.

*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/clients. It is important to notice that high confidentiality should be considered for community outreach HIV testing.*

#### **3.1.4 Strategic Mixed Approaches of HTS**

Health facilities and community-based settings facilitate the early diagnosis of HIV positive people. HPITC and community-based HTS are the two testing models that could be incorporated in both settings.

*As part of the B-IACM approaches, HTS program should actively link HIV positive people to treatment and care and support services, and HIV negative people to HIV prevention services.*

#### **3.1.5 HIV Self- Testing**

HIV self-testing is a process in which an individual who wish 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 who followed 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.*

### **3.2 Addressing Critical Enablers for HTS**

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

- A primary role of all healthcare workers is to provide information and counsel their patients/clients, who are more likely to be affected by HIV, about 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.
- Challenging stigma and discrimination should be addressed.
- Integration of HTC 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 through good coordination and communication should be maintained.
- Scientific evidence should be used to revise HTC strategic approaches among specific KP and targeted population.

### **3.3 HTS in Health Facility Settings**

Since the implementation of IACM approach has been introduced in 2013, HTS is available in all health facilities including public hospitals, health centers, and some NGO hospitals/clinics. HTS was introduced in one private for profit hospital namely Chorey Hospital, but not in private maternity clinics and laboratories (19). NCHADS and partners explore possibility to work with private hospitals/clinics and laboratories to make HTS available, especially for PW and suspected HIV cases in TB, STI, viral hepatitis and chronic care services.

#### **3.3.1 HTS in Client-Initiated Counseling and Testing at VCCT or HC**

Client-initiated counseling and testing refers to when an HTS is provided within healthcare facilities for patients/clients who intend to use the service. The patients/clients may voluntarily decide to know their HIV status as an individual, couple or family.

#### **3.3.2 HTS for Health Provider-Initiated Testing and Counseling (HPITC)**

Since 2007, HPITC is routinely offered by healthcare providers to the patients/clients attending healthcare services in both public and NGO hospitals/clinics. Initially, HTC was provided when healthcare providers suspected HIV infection in a symptomatic patient or when someone was identified to have a risk behavior that allowed the providers to make medical decisions. This HPITC model could either be health providers-initiated and HIV testing-performed by trained health providers or be patients/clients-referral to the nearest HTS within the health facility (10).

In late 2008, MOH endorsed the linked response approaches to rapidly increase the uptake of PMTCT cascade and to allow healthcare providers, especially ANC midwives to draw blood from their patients/clients and send the specimens to the nearest HTS (20). The test results returned to ANC clinics, where the blood samples were drawn, and then to the patients/clients within one week.

However, in practice healthcare providers provided pre-test information about benefits of HIV testing to their patients/clients and referred those who agreed to do testing to the nearest HTS.

Three main challenges were observed during the HPITC implementation:

- Not all patients/clients attending healthcare facilities were referred to VCCT nor all blood samples were sent to the hospital laboratory for HIV testing. Only 80% of ANC clients received information for HIV testing and 67% of patients/clients at STI and TB services received recommendation for testing (21). There were few patients/clients at other healthcare services that could learn/hear about HIV testing. As a consequence, many opportunities were lost to reach high-risk individuals.
- Not all patients/clients were ensured to receive their HIV test results and post-test counseling. To receive the test results, the patients/clients either had to come to the VCCT or they could collect the test results from healthcare services. Consequently, patients/clients incurred high costs for transportation and increased the turnaround time that contributed to loss to follow up, especially for those who may contract HIV.
- No feedback mechanism was implemented to follow up the patients/clients from the healthcare services such as ANC, maternity, STI, TB wards to VCCT services for HIV testing.

Since B-IACM approach and “IR” strategy for KP have been introduced in 2013, HIV finger prick testing was available in ANC and TB clinics (11). The patients/clients can receive the test results and post-test counseling within two hours. Those whose test results are reactive are referred to HTS, which co-locates within ART service, for confirmatory tests. The procedure follows the full HIV testing algorithm of the national program. The algorithm suggests that the HIV positive patients/clients are referred to ART sites for immediate ART initiation.

As a result of this HTS integration, the 2015 national PMTCT reports showed that 81.4% of PW attending ANC received pre-test information and finger prick HIV testing (22). Among them, more than 90% received test results and were referred to HTS, co-located with ART service, to confirm their HIV status.

*The good practices of this effective HTS integration in ANC and TB services can be applied to other most relevant healthcare services such STI, viral hepatitis, chronic illnesses, pediatric care/children malnutrition, surgery and dentistry.*

*To operationalize this HTS integration 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 monitored. This includes the role and responsibilities of each party to make sure that HIPTC is running smoothly. 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 HIV testing strategy should be produced for healthcare providers at clinical settings.*

**Two options** can be applied for HPITC at both public and private/NGO health facilities:

- **Option 1:** *HPITC could be performed in specific clinical setting using RDTs and finger prick in locations, where many patients/clients are presented with clinical signs and symptoms of HIV infection or when health providers suspect the cases. For example, dual HIV and syphilis rapid tests should be offered to STIs' patients/clients visiting family health clinics or NGO STI clinics, and among ANC clients. HIV RDTs should be performed at other clinical settings such as viral hepatitis, diabetes, under-5 malnutrition. The test results should be returned to the patients/clients on the same day.*
- **Option 2:** *For health facilities which have fewer clients, the healthcare providers may refer these patients/clients to the nearest HTS or draw the blood samples and then send the sample to the hospital laboratory for HIV diagnosis. A strong and clear message should be given to the patients/clients to return for their test results.*

### **3.3.3 Improving Public-Private Partnership for HTS**

There are some challenges to improve public-private partnership, especially limited capacity of public health system, for which the shortage of health care providers at public health facilities and lack of patients'/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.

#### **3.3.3.1 Not-for-profit health services**

NCHADS worked closely with not-for-profit private healthcare services such as Institute Pasteur du Cambodge (IPC), Center of Hope Hospital, RHAC clinics, Angkor Children Hospital, Marie-Stopes STI/HTS clinics, Chhouk Sar clinics to start HTS within their health service deliveries. The letter of agreements (LOA) between NCHADS and these NGOs were 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 procedures (23).

*The implementation of the HTS integrated settings like 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 standard of 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 LOA between NCHADS and NGO partners should be regularly updated and properly implemented by both parties.*

#### **3.3.3.2 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.

The private health services are growing very fast such as maternity clinics, polyclinics/hospitals, laboratories where HTS can be integrated. In 2010 with technical supports 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 HTC sites operated by private clinics/hospitals were closed. Only one private hospital, "Chorey" signed LOA with NCHADS in 2014, continues to offer HTS (19).

It is worth mentioning that some private hospitals/clinics/maternalities/laboratories currently provide HIV testing to their patients/clients without collaboration with NCHADS. The main challenges facing these private HTS 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 HIV post-counseling;
- Accuracy of the HIV test results is questionable;
- Unclear linkage referral mechanisms for HIV test positive to treatment and care services.

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

- *following the national HIV algorithm,*
- *providing correct HIV test results,*
- *ensuing linkages referral mechanism for the HIV test positive to treatment and care services, and*
- *following the national standard recording and reporting requirements.*

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

### **3.3.4 Integration of HTS into illicit drug treatment facilities**

HTS should be integrated in 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 the 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 the security problems, the following suggestions should be considered:*

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

### **3.3.5 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 (24). 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 close setting*). Further, the recording and reporting requirement of HTS should be strengthened.

### **3.3.6 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 (25). 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 Coordinator/Assistant (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 re-testing. If the HIV test result is confirmed positive, the linkage to immediate ART is necessary.*

## **3.4 Community-Based HTS Approaches**

The routine community outreach HTS model has been implemented and reached a huge number of KP groups, especially some outreach activities such as HIV educations and condom distributions; however, referral to STI check-up and HIV testing are limited.

### **3.4.1 Community-Based HTS Model for KP**

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

The key activities to support the implementation of the routine community outreach HTS model include the following:

- Select the lay persons from each group of KP by NGOs for HTS training to serve as the community outreach HTS providers;
- Build up the capacity of the lay persons (community HTS providers) through intensive and comprehensive training workshops on RDTs by finger prick and pre-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 the 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. For the clients/patients with reactive test result, HIV re-testing for HIV diagnosis can be made by community HTS provider's referral, if agreed by the clients/patients and should be accommodated by a referral slip. Group post-test education /information will be provided to all participants, regardless their test results. The community HTS providers' telephone numbers and names are given to the patients/clients for further information, followed by the detail discussions about the available HTS services for HIV status confirmation.*

In 2016, KHANA and its implementing partners reported that out of 62,528 people from all groups of KP, only 39,734 (64%) were tested for HIV through routine community-based outreach HTS with HIV positivity rate of 0.7% (27). The report might reflect two aspects/questions:

- Do the KP at higher risk or hard-to-reach KP is not reached?
- Do the remaining 36% of KP who did not test for HIV, are covered by other testing settings?

As a series of concept notes on B-COPCT approaches were officially endorsed in 2014 and translated into operational guidance for prioritizing B-COPCT among KP in 2015 (28), two projects were piloted by Flagship project (KHANA, FHI360 and PSI) in addition to the routine community- based outreach program to address the gap/above questions:

- Social media, including m-Health package such as Webpage, Facebook, Voices4U (hotline counseling) and other dating Apps to reach hidden KP for prevention key messages and link them to HTS;
- Peer driven intervention Plus (PDI+) model to increase new case detection among EW, MSM, TG and PWID (29).

The results of the PDI+ claimed that their models could detect more HIV positive cases and increase coverage among the study populations. KHANA reported between August 2016 and December 2016 that 1 of 82 tested EW found HIV positive result (or 1.2%), 19 of 1,187 tested MSM found HIV positive result (or 1.6%), 20 of 680 tested TG are positive (or 2.9%) and 4 of tested 133 PWID found HIV positive (or 3.0%).

*Based on the scarcity for funding support to HIV program and low uptake of HTS with low HIV positivity rate among certain sub-population groups of KP, an effective and efficient intervention models 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.*

### **3.4.2 Community-Based HTS Model for Targeted General Population**

Estimation by experts indicated that around 15,000 people living with HIV do not know their status in Cambodia as of end 2015, based on the national HIV estimations and projections performed in 2016 (2). Up to date, there is no clear evidence showing where, and who these people are. It was reported that more than 77% of these unknown HIV status populations may

be hidden in the GP (Dashboard of B-IACM) (4). They are the most essential groups, who should be prioritized under the "IR" framework. The targeted GP within the community could be:

- Migrants and their partners:
  - In-country migrants such as construction workers, factory workers, taxi drivers, Motos “dub”, and three wheels Remorks;
  - Out-country migrants, who cross the borders for employment opportunities
- PW who never visit ANC clinic or never test for HIV; and
- Partners or ex-partners of PLHIV or KP.

*It is interesting to note that since the B-IACM approaches and IRIR strategy 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 finger prick. The integration of these approaches into the primary health care system is essential, where the confidentiality in the community is very critical to pay attention.*

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

- **Option1:** *village and support group will be used as the key informants to link community to HTS services (including NGO and public health faculties)*
- **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.*

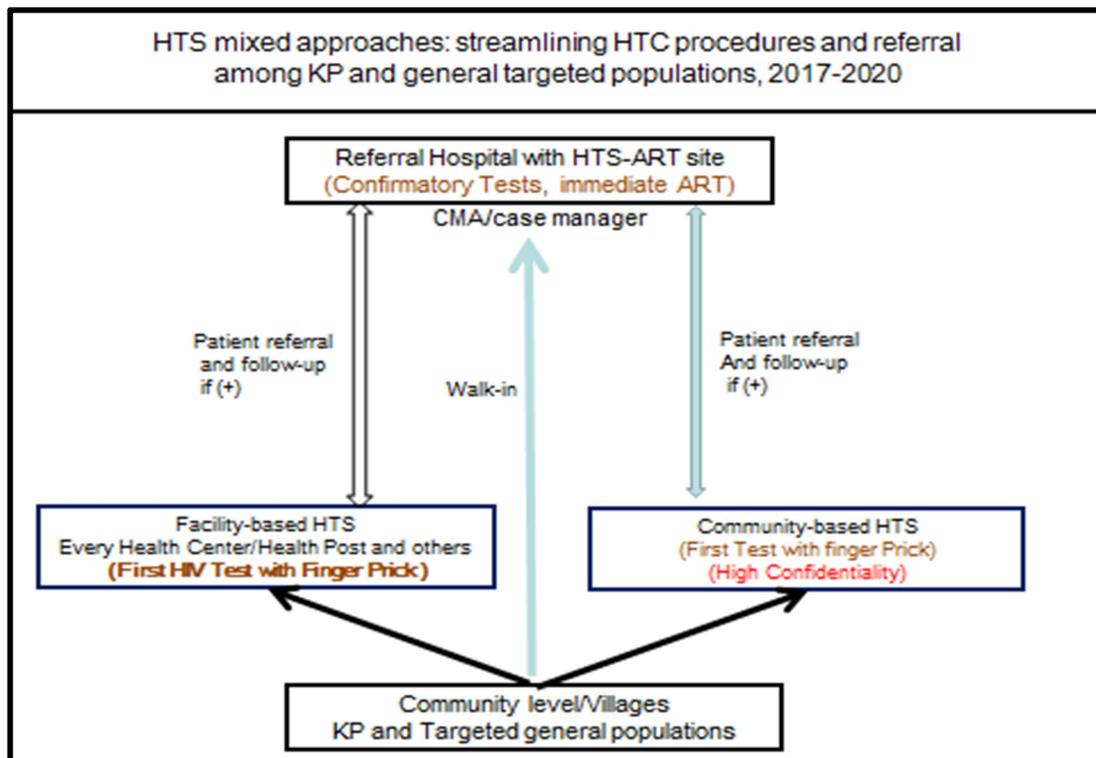
*The integration of HTS also is crucially important in ANC outreach sessions. If the test results reveal reactive outcome, ensuring the linkages to further HIV testing services is necessary.*

### **3.5 Mixed Strategic Approaches of HTS**

Mixed strategic approaches of HTS refer to facility- based HTS and community-based HTS that facilitate the early diagnosis of HIV positive people. For example, HPITC and community/peer-initiated testing and counseling (C/PITC) are the two testing models that can be incorporated in both settings where KP and GP often use.

*The mixed HTS models should support timely and complete linkage to prevention, treatment and care, and support services for those tested HIV positive. Meanwhile, the cases with HIV negative test result also need linkage to prevention services as well as to learn where and when to re-test.*

Figure 2 : A mixed strategic approaches of HTS



Community, including KP and targeted GP can receive HTS through three main ways:

- Community-based HTS (if reactive, referral to re-testing at HTS-ART sites)
- Facility-based HTS (public, NGO and private) (if reactive, referral to re-testing at HTS-ART sites)
- Walk-in HTS-ART sites

### 3.6 HIV Self-Testing (HIVST)

HIVST is a process in which an individual who wish to know his or her HIV status, collects a specimen (either oral fluid or blood) and then performs an HIV test, and interprets the test result by him or herself, often in private setting. HIVST should be voluntary, not coercive and mandatory (18).

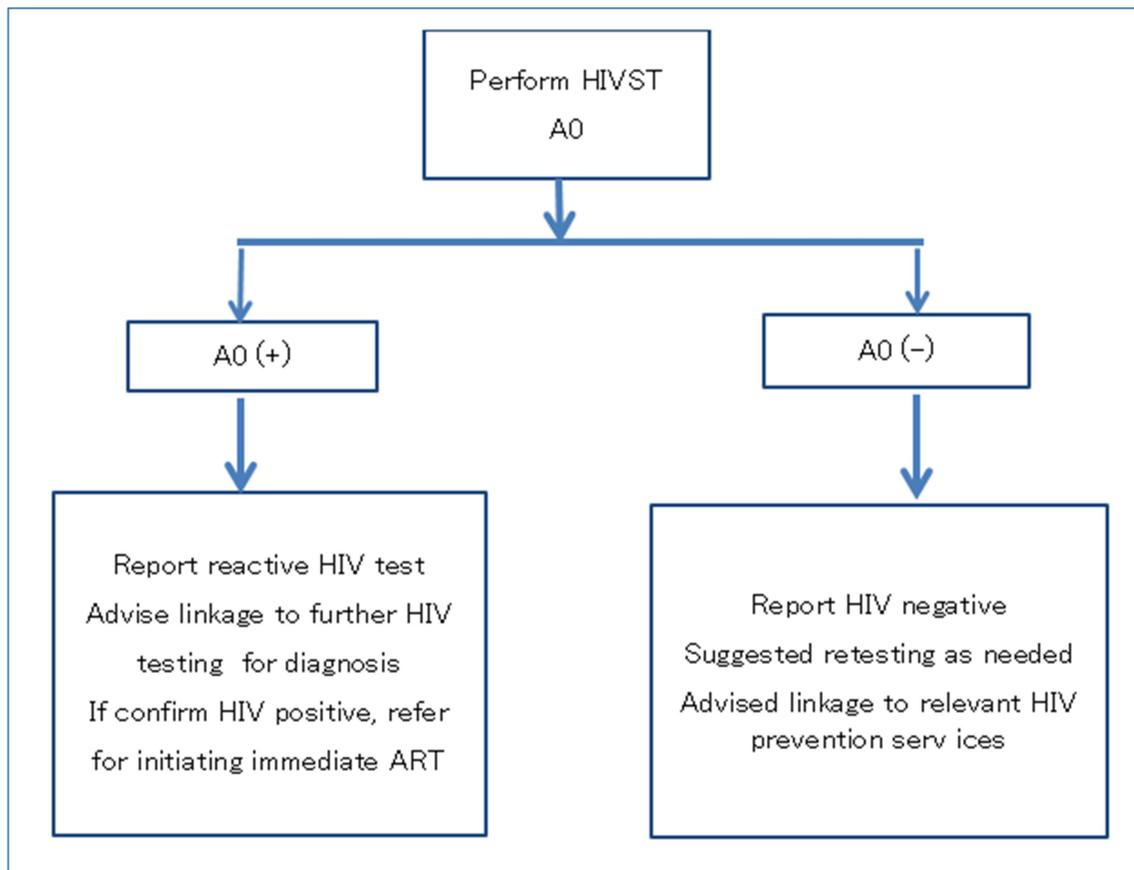
HIVST is a screening test, but it does not provide a definitive HIV positive diagnosis. HIVST does not replace the need for screening and confirmatory HIV test in the HTS where the validated national HIV testing algorithm is used. So, it is considered to be a test for triage that requires a reactive self-test result must be followed by additional testing performed by well-trained HTS providers. HIVST provides an opportunity to the people to test discretely and conveniently that may lead to increase the uptake of HIV testing among people who are hard-to-reach or not reaching by other HTS settings.

### **3.6.1 HIVST Strategy**

The HIVST strategy illustrated in figure 3 should be applied for individuals performing tests in private setting, either alone or with his or her trusted individual:

- Assay 0 is used as the test for triage.
- All specimens tested with Assay 0 (A0) that are non-reactive A0 (-) are considered HIV negative and reported as such. It is suggested that individuals with a non-reactive self-test result, who are at high risk of acquiring HIV, should disclose their test results to the HTS providers for further testing. Linkage to relevant HIV prevention services should be advised.
- Any specimens tested reactive A0 (+) should be reported as reactive. It is recommended that individuals with a reactive self-test result, who discloses their test result to HTS providers, should be referred to re-testing. If the HIV positive diagnosis is confirmed, then the case should be referred to initiate immediate ART.

**Figure 3. HIVST strategy**



### 3.6.2 Implementation Arrangement for HIVST

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

The HIV program personnel and NGO implementing partners, who are responsible for distributing the HIV RDTs for self- testing, should explain the community-based HTS providers (peer OWs) and the self-testers about the performance and the limitations of the HIVST kits in relation to the window period between HIV infection and the detection of HIV-antibodies. *Two types of support should be provided:*

- *Directly-assisted HIVST by trained and certified community-based HTS providers (i.e. OW), who demonstrate how to perform the test and interpret the test result to an individual before and during HIVST;*
- *Unassisted HIVST refers to when the HIVST testers use an HIVST kit and use the manufacture instruction provided;*

*Other means such as social media, telephone hotlines, SMS text messages, Webpage, may be useful for both directly-assisted HIVST and unassisted HIVST. In addition, both options ensure*

*that counseling and referrals to further HTS, HIV prevention, care and treatment, and other health services are needed.*

According to WHO review in 2016, the main outcomes of randomized controlled trials comparing HTS at facility setting to HIVST concluded that (18):

- Increased the uptake of HIV testing among male partners of PW and MSM;
- Increased the uptake of couples' HIV testing among male partners of PW;
- Increased the frequency of HIV testing among MSM by approximately two times in a year;
- Did not increase HIV risk behaviors such as less condom use for anal sex; and
- Did not increase social harm or other adverse events.

Other studies reported the values, preferences and feasibility related to HIVST among testers showed (30):

- The acceptability and intention to use HIVST was high among KP who cited the benefits of HIVST, such as:
  - convenience and privacy
  - easy to practice and painless testing option, and
  - no need of HTS providers.
- Preferences for oral fluid–based RDTs for HIVST among MSM and sex workers, because it was a painless testing option. Nevertheless, some testers preferred RDTs by finger brick for HIVST because of more accuracy of the test results.

The common concern for both policy makers and HIVST testers in introducing HIVST is the operational cost, especially the cost of HIV kits. UNITAID/WHO assessment of the market landscape in 2016 estimated that the price of HIV RDTs for self-testing in low and middle income countries ranged between US\$3 to US\$16 (for research purpose) (18).

Based on WHO recommendations for implementing HIVST and the good practices of HIVST among KP in many countries, *it is suggested that HIVST can be applied among the people who are hard-to-reach or never reach by the community-based outreach program (18).*

*This HIVST approach can be implemented as a demonstration project in some countries like Cambodia, which commits to achieve 90-90-90 target by 2020. Moving toward this HIVST approach in the country, the concept note for implementing HIVST should be developed. This should include clear objectives, strategic priorities, targeted populations, monitoring and evaluation and a clear road map on where and when to start this approach.*

## CHAPTER 4. PRIORITY POPULATIONS

### 4.1 Infants and children

The HIV related mortality rate is very high in the first year of life for untreated HIV infected infants. In this period, an effective PMTCT program including early HIV testing, a prompt return of test results and an early enrolment for initiating immediate ART are crucial. The purpose of HIV testing for infants should focus on identifying as many HIV infected infants as possible and as early as possible.

#### 4.1.1 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:

- Taking long time to receive test results
- Late initiation of immediate ART.

#### 4.1.2 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.*

#### 4.1.3 Priority activities to increase access to HIV testing

Toward achieving virtual elimination of HIV transmission from mother to child by 2025, priority activities to be implemented among infants and children include (30):

- *Early infant diagnosis (EID) should be offered to all HIV-exposed infants at birth;*
- *HIV testing should be performed for all infants and children presenting with symptoms such as failure to thrive, oral candidiasis, skin conditions, chronic cough, at pediatric care services and during the immunization sessions;*
- *HIV testing should be offered to all children attending TB and children malnutrition services;*
- *All children, whose one or both parents died of HIV, receiving orphan and vulnerable children (OVC) services should be offered HIV testing;*

### 4.2 Adolescents and young women

Adolescent 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 between 14 and 24, who need access to HTS:

- *Perinatally HIV infected adolescents who have not been tested for HIV in infancy. HIV diagnosis is needed for the perinatally HIV infected adolescents because they can receive immediate ART and link to other healthcare services;*
- *Adolescents acquiring HIV horizontally through early risk behavior, especially adolescents from young KP*

*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, where adolescent friendly principles exist to ensure that physical and psychological needs are addressed. Involving well-trained adolescent counselors are important to respond to their needs.*

#### **4.3 Pregnant women (PW)**

Early provision of HTS in pregnancy enables PW to benefit from all relevant prevention interventions. For those who tested HIV positive, immediate ART initiation and care will reduce the risk of HIV transmission to their infants.

*HTS for PW can be provided at both facility- based and community-based settings:*

- *HIPTC implemented in ANC since 2013 should be reinforced to routinely offer finger prick HIV and syphilis testing to all PW who regularly visit antenatal care, especially within the first trimester of their gestations.*
- *Finger prick HIV and syphilis testing should be performed through outreach ANC at the community level for PW who never come to ANC during their pregnancy.*

*All PW, whose HIV and syphilis status at delivery are still unknown, should be offered voluntary HIV and syphilis testing and counseling during labor and post-delivery.*

*PW assessed as at high risk of HIV/syphilis transmission are suggested to repeat test at the third trimester for HIV/syphilis.*

*Retesting HIV negative PW during pregnancy is not recommended. Unless they are from a KP group or are known to have an HIV-positive partner (14). In addition, PW who suspect themselves at risk of HIV infection or PW from sero-discordant couples can undergo the re-testing for HIV.*

*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 receive immediate ART across PMTCT cascade for their own and infants' health.*

#### **4.4 Couples and partners of PLHIV**

To identify more PLHIV, testing partners of PLHIV is an efficient and effective approach as they can benefit from treatment and care. A number of benefits which couples and partners participating in HTS are as follows:

- Adoption of prevention strategies the couples such as condom use, immediate ART
- Increase in uptake of PMTCT and improve adherence to follow PMTCT cascades
- Safer conception

*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 officially adopted and implemented in some ART sites since 2015 should be reinforced and expanded (11).*

#### **4.5 Key populations (KPs)**

Community outreach HIV finger prick testing and counseling among KP, conducted by community HTS providers, has been implemented countrywide since 2011. *The implementation of this HTS modality should be reinforced to reach more KP at high risk and can be used to detect more HIV cases in KP who do not know their statuses.*

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

*KP should be encouraged to access HPITC services, where KP friendly principles exist and without discrimination from healthcare providers. The KP's partners should also be encouraged to be 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 the strategic intervention models that can be optimized the use of scarce resources to maximize impact; i.e. PDI+.*

#### **4.6 Men**

In the last ten years of HTS programs, men reported ever testing for HIV lower than women and consequently men were more likely to start ART at later stages of HIV infection (26). Therefore, the morbidity and mortality among men are generally high after ART initiation. Men are less likely than women to use clinical health services, leading to community-based HIV testing approach critical to reach them. Those 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.

#### **4.7 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.

#### **4.8 Other priority populations**

These populations will be identified through case profiling and case control study in Cambodia. HTS services will be proposed to these targeted general populations to increase the identification rate, as described in the community action framework.

## CHAPTER 5. PRE-TEST, TESTING PROCESS AND POST-TEST SERVICES

### 5.1 Pre-Test services

Cambodia is very committed to achieve 90-90-90 targets by 2020. To attain this ambitious goal and targets, the “IR” strategy is a critical approach in diagnosing 90% of PLHIV who do not know their status. The 2016 HIV estimations and projections clearly indicated that around 15,000 PLHIV, who do not know their status, need to be identified by 2020.

#### 5.1.1 Demand creation for HIV testing

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 means.*
- *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 due to stigma and discrimination.*

#### 5.1.2 Ensuring confidentiality

According to the 5 Cs principles, confidentiality is critical when handling the HIV test result, reporting the HIV status and sharing any personal information, for instance, information about sex behavior and the use of illegal drugs. HTS providers should be cautious not to inadvertently reveal the patient's/client's test result or HIV status to others in the waiting areas of the public health facility or any other testing venues. The provision of HIV reactive / positive results must be counseled individually and be conducted in a private space by well-trained HTS providers. Lack of confidentiality discourages people from using HTS.

#### 5.1.3 Pre-test information for finger prick HIV testing

Prior to HPICT introduction in 2007, HIV counseling was provided before and after HIV testing. During an intensive and lengthy pre-test counseling session, health care workers (who trained to be HTS providers) spent more than twenty minutes in dialogue with their patients/clients aiming to assist them in deciding whether to take an HIV testing. It is important to note that the test results were returned to clients within two to three weeks.

*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;*
- *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 the standard and qualified HIV rapid tests were used for HTS at both facility and community settings, patients/clients received the test results within the same day.*

#### **5.1.3.1 Provision of Pre-Test information through individual, couples or group sessions**

Provision of pre-test information through individual or group sessions is adequate, and 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.

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

#### **5.1.3.2 Pre-test information**

- **The pre-test information for pregnant or postpartum women** should be conducted at ANC or post- delivery areas. The messages should include:
  - HIV risk transmission from mother to infant;
  - Measures for PMTCT of HIV, including benefits of ART for mother and infant;
  - Benefits of infant feeding practices to reduce the risk of HIV transmission;
  - Benefits of early HIV diagnosis for mothers and infants; 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 KP.

*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 should teach healthcare providers about specific norms 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 testing all together**

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 behavior that is unnecessary and may discourage couples for testing.

*In case of sero-discordant couples, the joint couples 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.*

#### **5.1.4 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).*

#### **5.1.5 STI, Viral Hepatitis and Diabetes linkage information in Pre-Test sessions**

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

### **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 could 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 for children 18 months of age and older. Dual Rapid tests HIV/syphilis were recently 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) testing 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**

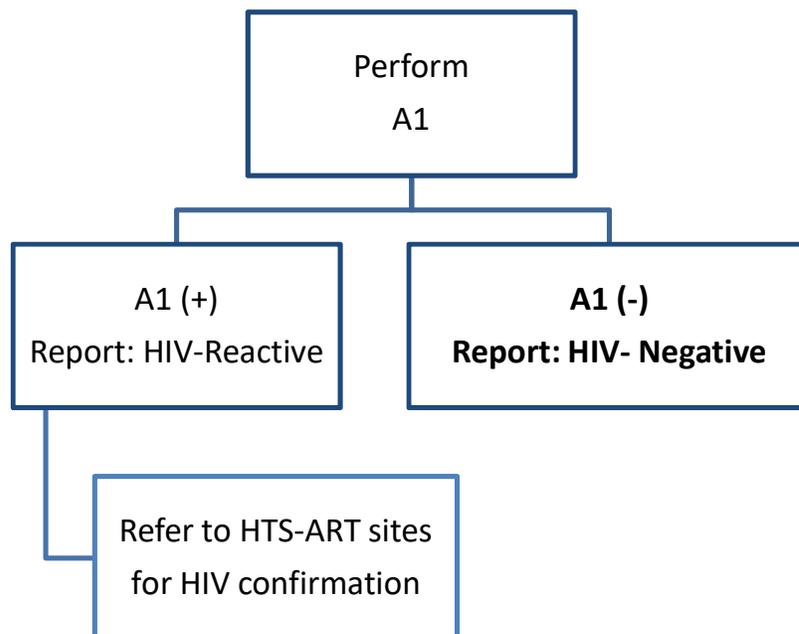
The serological testing strategy illustrated in figure 4 and figure 5, is currently used for HIV testing in both facility-based and community-based settings in Cambodia. Three standard HIV assays used to diagnose HIV have high sensitivity and specificity. It is important to note that the HIV assay uses finger prick whole blood. The first HIV assay is performed in both HTS

facility and community settings. The second and third HIV assays are used as confirmatory tests and are performed at HTS co-located in ART sites (HTS-ART site).

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).

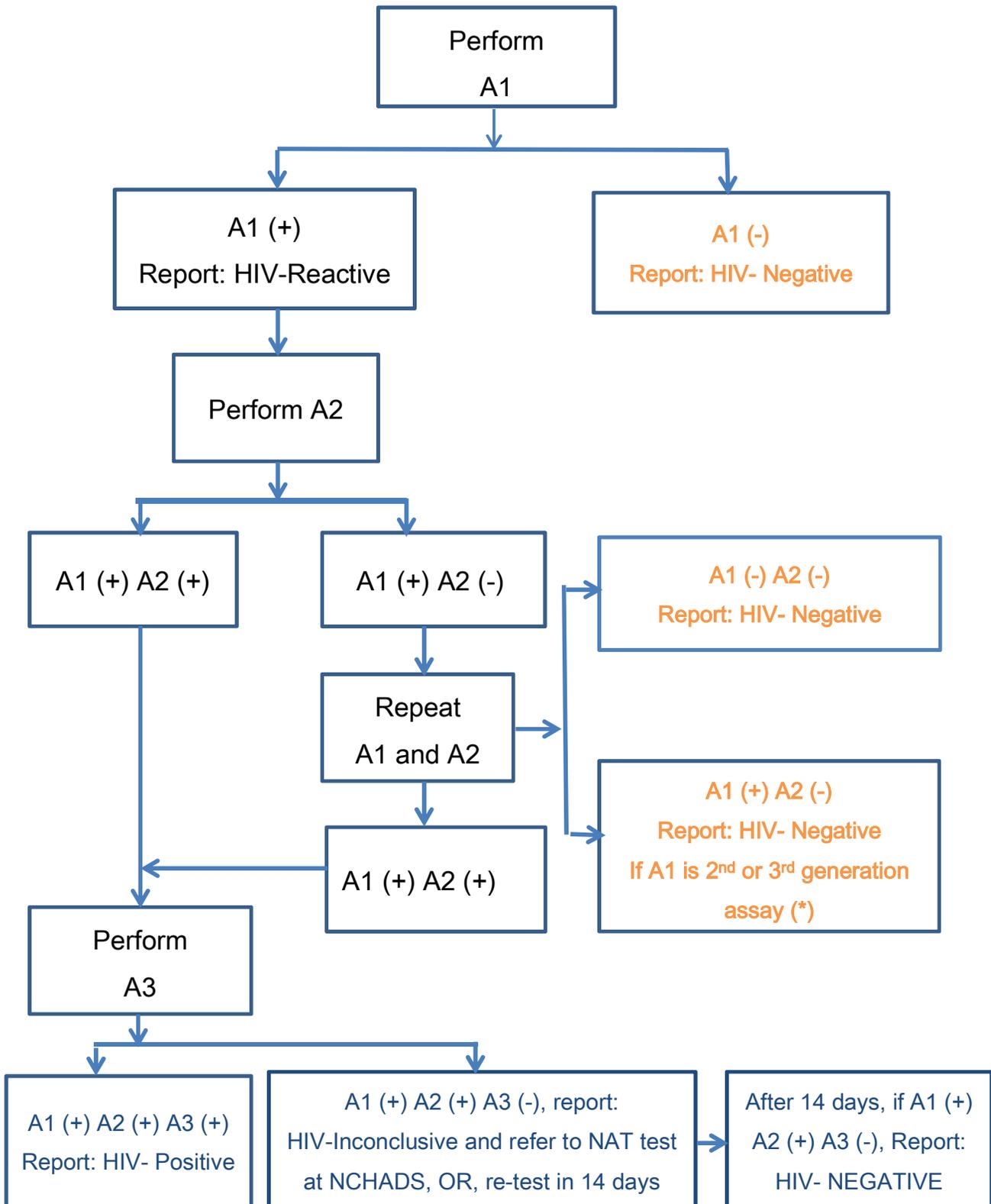
- All specimens are first tested with A1. The specimens testing non-reactive A1 (-) are reported HIV negative.
- Specimens that are reactive on the first assay (A1) should be confirmed with A2 and A3 at HTS-ART site. *However, if the reactive tests are referred from community or HC, then full algorithm should be followed (A1, A2, A3).*
- Specimens that are reactive on the first assay A1 (+), but non-reactive on the second assay A2 (-), [A1 (+); A2 (-)], should repeat A1 & A2.
  - If this results in A1(+) and A2 (-): report HIV negative result,
  - If this results in A1 (-) and A2 (-): report HIV negative result.
  - If this results in A1 (+) and A2 (+): need to perform A3.
    - If the third test result is also reactive [A1 (+); A2 (+); A3 (+)], the status is reported as HIV positive.
  - If the third test result is non-reactive [A1 (+); A2 (+); A3 (-)], the status is reported as an HIV- inconclusive. The blood sample should be sent to the NCHADS laboratory for NAT test. **Alternatively**, the clients/patients should be asked to return in 14 days for retesting (follow the national HTS algorithm). If the result consistently confirmed as [A1 (+); A2 (+); A3 (-)], the result should be concluded as NEGATIVE.

**Figure 4: Testing strategy at HTS sites**



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

Figure 5 : Testing strategy for HIV diagnosis (National HIV testing algorithm)



*(\*) Report HIV-inconclusive, if A1 is 4th generation assay (retest in 14 days)*

### **5.2.3 Pediatric HIV testing in HIV exposed and malnourished children**

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

- RDTs (HIV antibody detection tests)
- HIV DNA PCR (HIV cDNA proviral detection tests).

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. HPITC approach should be applied in infants/children when the health providers notice any signs or symptoms related to HIV infection.

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

Figure 6: Testing strategy for HIV diagnosis among exposed child <18 months of age

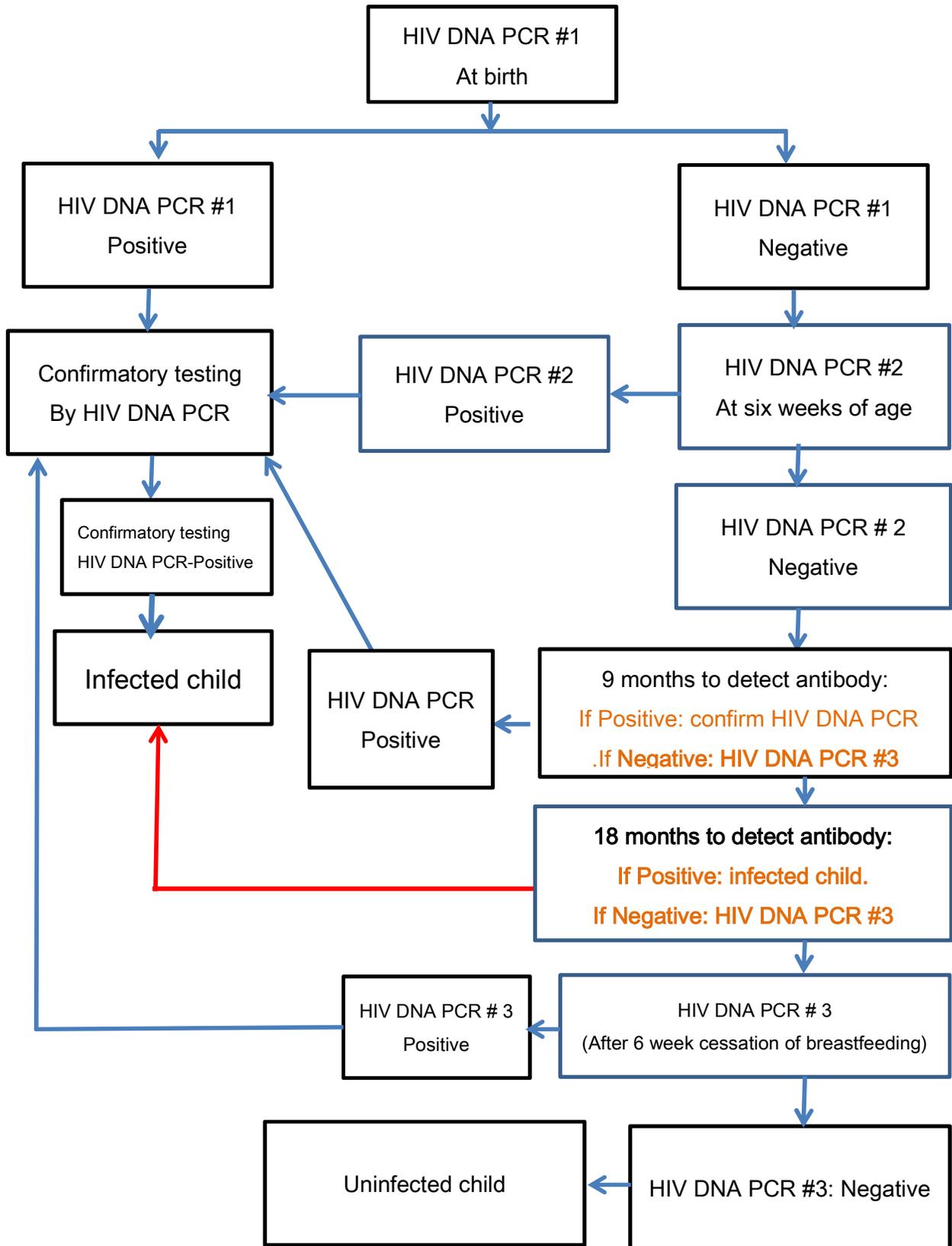


Figure 6 illustrates the testing strategy to diagnose HIV in exposed child <18 months of age:

- All HIV exposed infants require HIV DNA PCR testing at birth (HIV DNA PCR #1)
- If HIV DNA PCR #1 test is positive, this test should be immediately confirmed by HIV DNA PCR with a new sample.
- If HIV DNA PCR #1 test is negative, it does not mean the infant is uninfected, so the second HIV DNA PCR test (HIV DNA PCR #2) should be performed at six weeks of age:
  - If HIV DNA PCR #2 test is positive, this test should be immediately confirmed by HIV DNA PCR with a new sample. The result should be interpreted as POSITIVE.
  - If HIV DNA PCR #2 test is negative, breastfeeding status should be confirmed at the age of:
    - 9 months: if no breastfeeding in the past six weeks, a child is most likely not infected by HIV. However, the child needs a follow-up test in 9 months by an antibody HIV test.
      - If positive, a confirmatory test using HIV DNA PCR test is needed.
      - If negative, an HIV DNA PCR #3 is needed.
    - 18 months:
      - If the antibody test is positive, the child is infected by HIV.
      - If negative, an HIV DNA PCR #3 is needed.
        - If HIV DNA PCR #3 test is positive, the test should be confirmed immediately by HIV DNA PCR with a new sample. The result should be interpreted as POSITIVE.
        - If HIV DNA PCR #3 test is negative, the test result should be interpreted as NEGATIVE.

#### **5.2.3.2 HIV diagnosis for the child 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 5.2.3.1)*
  - *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**

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 required 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 including consistent condom use. It is important to note that a lengthy post-test counseling is not necessary or beneficial and may not be the best option in 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.

Minimum information for post-test counseling sessions should include:

- *Provision of HIV test results and reported HIV status;*
- *Discussion about window period for possible retesting of at risk clients;*
- *Education on risk reduction and uptake of preventive behaviors and provision of condoms if available;*
- *Discussion on referral and linkage to relevant HIV prevention services such PEP;*
- *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 for window period should be considered after four to six weeks from the possible date of exposure.

Additional retesting during window period is not necessary and may waste resources as most people's test will be negative.

#### 5.3.1.2 Re-Testing people who were diagnosed HIV negative, but remained at high risk of HIV acquisition

High risk KP may benefit from regular re-testing that gives them early HIV diagnosis and on going health literacy on HIV prevention. WHO recommends that KP at high risk of HIV infection need to be re-tested at least annually.

**Table 1 : Frequency of testing**

<b>Circumstance</b>	<b>When to re-test</b>	<b>Types of Tests</b>	<b>Frequency</b>
<i>Known positive partners</i>	At four weeks post exposure	<i>Antibody rapid test</i>	3 monthly
<i>Unknown HIV status of partners</i>	At four weeks post exposure	<i>Antibody rapid test</i>	6 monthly
<i>Sex workers</i>	At four weeks post exposure	<i>Dual HIV-Syphilis test</i>	6 monthly
<i>MSM/TG/PWID</i>	At four weeks post exposure	<i>Dual HIV-Syphilis test</i>	6 monthly

<i>Post rape</i>	At four weeks	<i>Antibody rapid test</i>
<i>Occupational exposure</i>	At four weeks	<i>Antibody rapid test</i>
<i>STI patients</i>	At four weeks	<i>Dual HIV-Syphilis test</i> 6 monthly

### **5.3.1.3 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.

### **5.3.1.4 Re-testing before initiating ART**

Retesting before initiating ART refers to the testing of a new specimen of each newly diagnosed individuals and current PLHIV on OI, conducted 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 (13). It indicates 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 related to 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 the HIV re-testing to verify the HIV diagnosis status of the case prior to ART initiation. If the 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.*

### **5.3.2 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 in order to refer them for confirmatory test at HTS-ART.

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 HTS-ART”
- 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 notice the strong feeling of patients/clients receiving the HIV reactive test result, then, HTS providers counsel patients/clients to comfort with the test results and cope with their emotions.*

### **5.3.3 Post-Test services for people with inconclusive test results or with test results 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 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.

### **5.3.4 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;
- 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;
- 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 including reducing transmission risk through viral suppression and consistent condoms use;
- Discussion on possible disclosure of the test results, and the risk and benefits of disclosure among partners or couples;
- Discussion on how to encourage and offer HIV testing to sexual partners, children of the HIV patients/clients.

The shock of receiving the HIV positive result may make it difficult for the patients/clients to accept, 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 for women;
- Assessing the risk of suicide, depression and other mental health consequences of diagnosis of HIV infection;
- Encouraging and allowing the patients/clients to ask additional questions or address further concerns.

### **5.3.5 HIV Disclosure**

Deciding about disclosure is a serious issue for a person who tests HIV positive. Three acceptable types of disclosure that can be discussed are:

- **Disclosure to a sexual partner, family member or close friend:**

When people learn their HIV positive result, they may need time to absorb and accept this diagnosis before they are ready to share it with other persons, so 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 to 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 inform their patients/clients who test HIV positive that their HIV status will be shared with medical workers under extreme medical condition that benefit for patients/clients. 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 in Cambodia 2015.

### **5.3.6 Post-Test counseling services for key populations (KPs)**

Well-trained community HTS providers should provide intensified post-test counseling combined with follow up counseling that could increase significantly the proportion of HIV infected KP to 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.

### **5.3.7 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 also 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 measure should be well explained to the couple such as condom use and ART adherence for viral suppression.

### **5.3.8 Post-Test counseling services for pregnant women**

The following messages should be added to the standard message described for people who are 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 HIV and people 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 care and treatment, 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 knowing one's status have limited value unless these are linked and connected to other services such as:

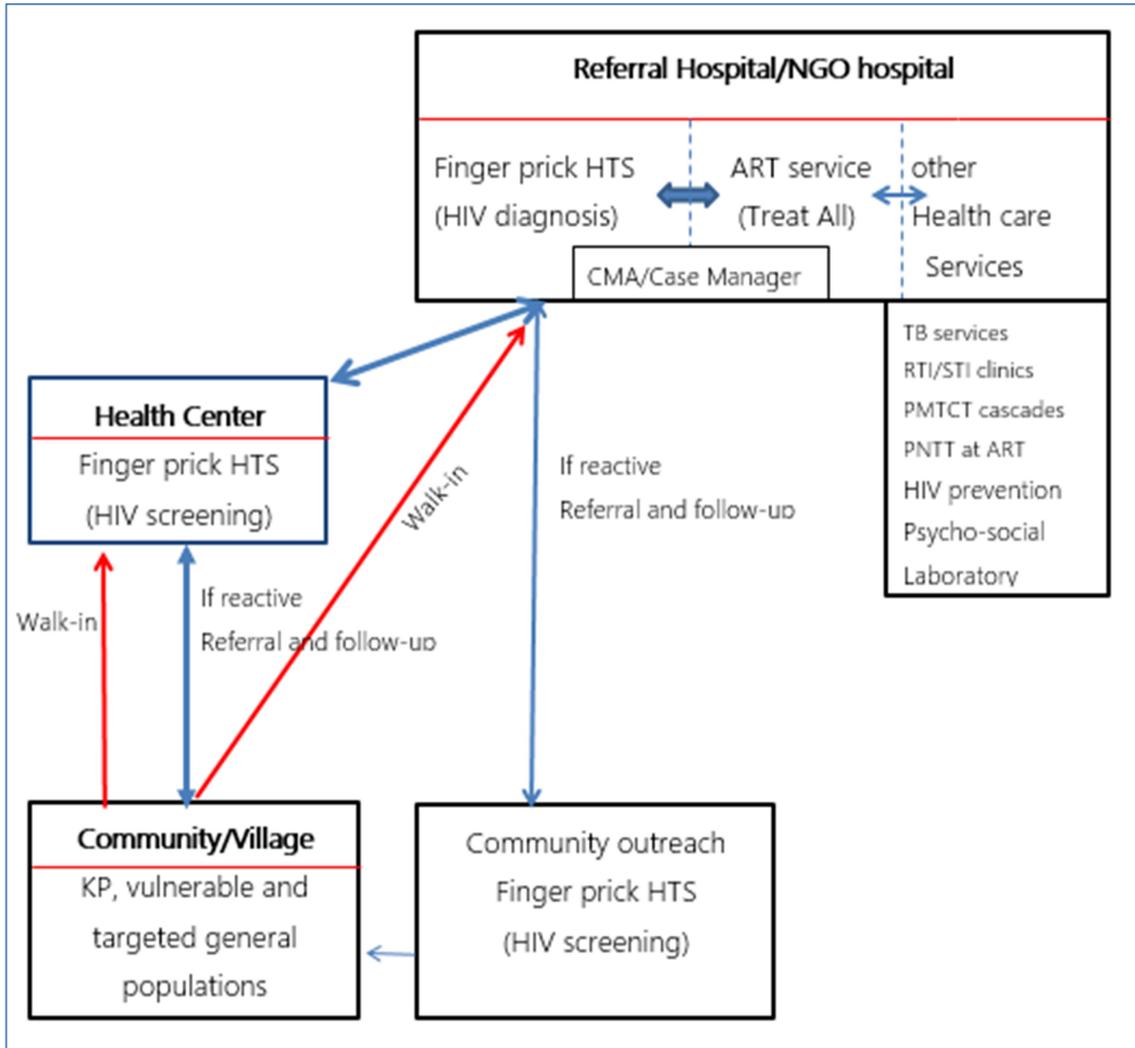
- Treatment and care, and management of diseases;
- Preventive services;
- Maternal and child health including sexual and reproductive health, birth spacing/family planning, PMTCT, STI services;
- HTS for partners and family members including partner notification tracing and testing (PNTT);
- Psycho-social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

The 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 HTS-ART 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 works closely with HTS-ART 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 7: Linkages between HTS (facility and community settings) and treatment and care services**



## 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 using rapid tests and testing for viral HIV detection in laboratory. HTS providers provide counseling and offer testing with respect to quality management system principles to ensure the highest level of quality and accuracy.

The below definitions of the quality of services may be useful for HTS providers and HIV program management team at 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 and priority element of the 5 Cs principles of WHO and UNAIDS is to ensure the correct test results of HIV testing. In spite of availability of excellent RDTs (high sensitivity and specificity) the reliability of the test results depends on the correct use and stock conditions of RDTs as well as commodities. Some errors can occur at any point of testing along with the process of diagnosis that could contribute to incorrect test results, i.e. 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 result of HIV status.

Rapid scale up of HTS at both facility and community settings should consider the following keys 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 including quantification and forecasting for RDTs kits and commodities to avoid stock-outs;
- Strong strategic information system including standard monitoring tools, records keeping (standard registers, log-books).

*A comprehensive and standard training package on HTC including QA should be regularly updated according the HTS policy and used for training that focus on ensuring the competency of HTS providers. The SOP for specific practices such as how to perform individual assays, QA for HIV testing, 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:

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

Since 2004, the experiences of QA implemented in Cambodia focused on ensuring the quality of HIV counseling and testing that was 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 laboratory recognized by MOH such 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 continue to strengthen, but supervision or mentoring should be reinforced and focused on HTS effectiveness and efficiency to ensure the 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 limited resources settings.

Cambodia is encouraged to continue the use of WHO pre-qualified RDTs, especially the three standards 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 twelve elements illustrated in figure 8.

**Figure 8. Twelve elements of QMS**



#### 6.3.1 Organizations

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**

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 follows:

- *Develop job descriptions indicating clear roles and responsibilities of all HTS providers;*
- *Keep training checklists for all HTS providers;*
- *Encourage the performance assessment to discuss the 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;*
- *Standardize and update training curriculums and produce 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 that incorporated training courses for community-based workers (lay persons). In the past ten years, a lot of progress on human resource development for VCCT/HTC program had 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 the main 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, following suggestions should be considered:

- *Update the inventory lists of trained HTS providers at both facility and community-based settings including education background, when and where training was providing and place of work;*
- *Update training curriculum, course syllabus and training manual for HTS program according to the updated national guidelines on HTS;*
- *Conduct initial training activities using the updated training documents for the new recruited HTS providers;*

- *Conduct refresher training activities at least every year for the HTS providers on specific subjects that could strengthen their capacities and improve 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:**

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 box if the ambient temperature according to manufacturer's recommendation is exceeded.*

HTS providers should be responsible to:

- Maintain an inventory of equipment and commodities for HIV testing;
- Ensure that equipment and commodities in the inventory is subject to preventive and correct storage on an appropriate cycle;
- Ensure that faulty equipment and commodities are not used in any process to provide test results;
- Make sure that SOPs exists for all equipment with clear instructions.

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

Purchasing refers to activities at the programmatic level to ensure that HTS have 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, 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 requirement Provide full sets of test kits to testing sites without separating or splitting the kits;
  - Place order every 5 monthly
  - Maintain reserved buffers of RDT (for 3 month)
  - 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 reserved buffers of RDT, for 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 correctly and on time (sent to NCHADS every quarter)
  - Maintain a list of inventory requirements for HIV test kits, consumables
  - Ensure enough space to store test kits, especially at OD level (access to cool box or refrigeration, if room temperature is above the manufacturer 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 take it into consideration that this issue needs to be addressed, especially distribution systems of HIV test kits to HTS settings.*

### 6.3.5 Quality Control (QC)

QC or process control refers to processes and activities to ensure that testing procedures are performed correctly with 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 before 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, they are:

- testing the 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, before 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 place  
[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 (follow the Procedure of Test or Job Aids)
  - Ensure double checking 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 waste disposal management properly (refer to the SOP of MOH, Medical Waste Management Control)

### **6.3.6 External Quality Assessment Scheme (EQAS) and Proficiency Testing (PT)**

EQAS including PT refers to the inter-laboratory comparison to identify if the HTS can provide the correct test results. PT involves testing of unknown samples at regular intervals by the testing sites. EQAS assures that HTS sites' performance, 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:

- Evaluate testing competence;
- Assess performance of specific HTS providers;
- Evaluate the reliability of HIV testing procedures;
- Ensures accuracy HIV test results
- Provide information for self-evaluation

How to implement EQAS:

- All HTS at both facility and community-based settings should actively participate in 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 a number of 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 has been officially endorsed in 2009.

All registered VCCT sites (around 300 sites) and HIV testing laboratories, which participated in the HIV serology EQAS with NIPH, were provided with the serum panel twice per year. NIPH collected the results of the panel from the sites and analyzed and finally reported back to the sites. Currently, EQAS program is implemented in only 65 VCCT sites and they 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 sites selection criteria, where HIV screening were performed*
  - *EQAS procedures*

### **6.3.7 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.

### **6.3.8 Documents and Records**

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 that are describe each test procedure, how to read the test results according to the validated testing algorithm and how to refer for retesting. Records generated as a result of performing testing activities should be filled correctly.

Records required for a quality system practice are in the followings:

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

The implementation arrangements of documents and records 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 that existing documents should be used consistently and properly for improving the quality of HTS in order to ensure the reliability and accuracy of test results. These should be revised or updated within an appropriate time according to clear assessment outcomes and other evidences in country or globally.*

### **6.3.9 Quality assurance (QA) for HIV counseling**

The HTS providers' counseling skills have the greatest impact on the clients' HTS experiences. High quality of counseling is defined as non-judgmental, accessible, and client-center. Having systems to ensure the quality of counseling is important for ensuring that human right is respected and the client's needs are met. Counseling should increase the knowledge of HIV prevention, benefits of early treatment for HIV positive individuals, and help 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 HTC (HTC). *Supportive supervision, ongoing mentoring and on site observations to HTS counselors should be conducted effectively and regularly on the quarterly basis.*

#### **6.3.10 Quality improvement (QI) for HIV testing**

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

NCHADS and partners launched 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 as part of this COC- CQI process that currently contains 11 indicators to identify HIV infected individuals through providing HTS (32).

*It is suggested that tracking individual patients/clients instead of visit interactions is a critical issue to monitor those who are reached or accessing to 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 and unique identifier using finger print 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 by linking the individual's records in HTS database, ART database for adults, and STI database through a unique identifier system, should be considered.*

#### **6.3.11 Occurrence management**

Errors or problems occur in the most carefully conducted and monitored testing environment. To reduce and minimize errors, the national QA/HTS team should apply steps as follow:

- Investigate the error or problem to determine cause
- 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. This information is useful for those mentors.
- Use Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist

#### **6.3.12 Facility and Safety**

**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, and personnel must follow, procedures 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.
- A PEP procedure must be available at the testing sites.

## CHAPTER 7. LOGISTIC SUPPLY MANAGEMENT

### 7.1 Forecasting HIV test kits and commodities

Quantification and forecasting is the process of estimation on how much of the HIV test kits and other commodities that the program needs to reach the population served. Accurate forecasting is crucial for effective HIV testing services.

Quantification and forecasting tool was developed to ensure the accuracy of HIV test kits and commodities to be quantified and forecasted. The current forecasting tool is based on:

- Estimated populations to be tested
- Timeframe needs to be forecasted, and
- Previous consumption analysis and report.

### 7.2 Logistic and supply management

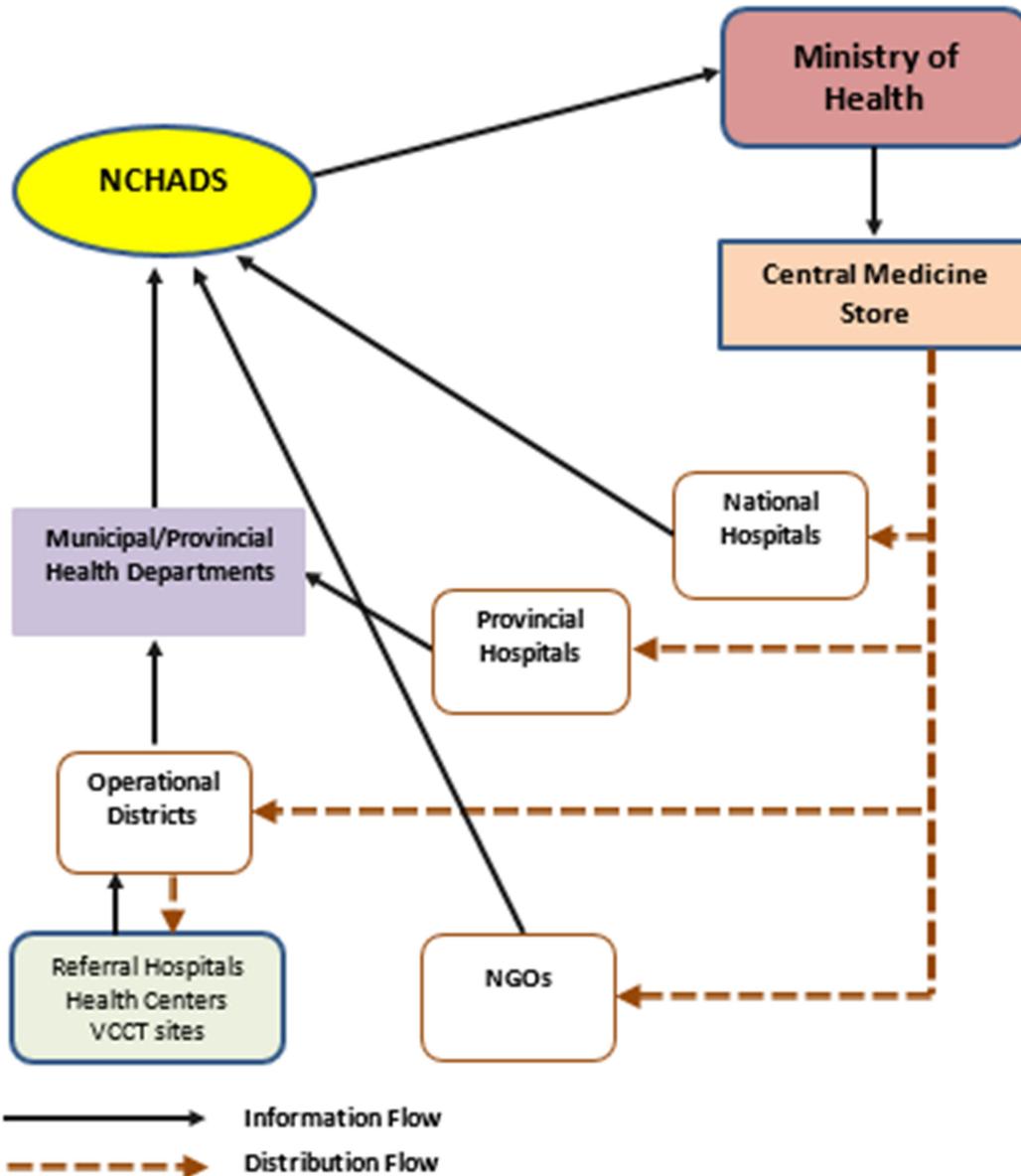
Logistic Supply Management Unit (LMU/NCHADS) of NCHADS is a national level focal point to closely work with provincial/municipal health departments, national hospitals, and NGOs to collect the request form, validate the data, and create the distribution plan for HIV test kits and commodities. In order 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 per for each group.

**Table 2 : Name of provinces by delivery groups**

<b>GROUP</b>	<b>PROVINCES</b>
GROUP 1	Battambang, Banteay Menchey, Kampong Chhnang, Pursat, Pailin, Siem Reap, Oddor Menchey, Svay Rieng and Phnom Penh
GROUP 2	Kampong Thom, Kampong Cham, Thbong Khmum, Kandal, Kampong Speu, Kep, Kampot, Koh Kong, Sihavouk 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 9. 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 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 have to send the request form to OD in a specific time period. OD is responsible to compile all request forms, and contact HTS sites in case of errors occurred. After compiling and verifying, OD sends the request form to PHD for approval. Provincial hospital sends the request form directly to PHD. After receiving request forms from ODs and provincial hospital, PHD submits the request forms to LMU/NCHADS based on schedule (table 3) in order to ensuring the HIV test kits and commodities will be delivered on time.

**Table 3. Schedule for submitting the request form by groups**

GROUP	QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
GROUP 1	Before 5 <sup>th</sup> December	Before 5 <sup>th</sup> March	Before 5 <sup>th</sup> June	Before 5 <sup>th</sup> September
GROUP 2	Before 5 <sup>th</sup> January	Before 5 <sup>th</sup> April	Before 5 <sup>th</sup> July	Before 5 <sup>th</sup> October
GROUP 3	Before 5 <sup>th</sup> February	Before 5 <sup>th</sup> May	Before 5 August	Before 5 <sup>th</sup> November

At national level, after receiving 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 and provincial hospitals to clarify any error or concern on the request form. After verifying, LMU/NCHADS creates the distribution plan based on the requests and submits to MOH for approval and ultimately be forwarded to CMS. If the ODs and provincial hospitals are unable to submit the request form on time, they should contact LMU/NCHADS immediately to discuss about 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 and national hospitals based on schedule (Table 4). NGOs 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 and NGOs check every pallet/box in order to ensure no any damage and expiry dates, and quantities matched with invoice.

In case, the quantity does not match with request, national hospitals, ODs and NGOs contact LMU/NCHADS to solve the issue immediately.

It is important to note that ODs ensure that referral hospitals, health centers and health posts collect HIV test kits and commodities from OD warehouse. In case the referral hospitals, health centers and health posts do not collect HIV test kits and commodities, ODs have to follow up.

### **7.3 Emergency request of HIV test kits and commodities**

The emergency request is typically occurring when there is a huge increase of unexpected number of testing kits and HTS sites. In this regards, national hospitals, ODs and NGOs should provide reasons for the emergency request, so LMU/NCHADS can find the possible ways to solve the problem immediately.

### **7.4 Stock Management**

RDTs National Dashboard (annex 1) was created with a purpose of improving the stock management and strengthening the supply management to minimize the stock-outs and wastages. Also, it has a capacity to see the stock status and identify the stock tensions.

#### **7.4.1 Receive 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 warehouse

#### **7.4.2 Storage Practice of HIV Test Kits and Commodities**

- Check every lots and expiry of new stock
- Update the stock card
- Stock the new products based on the require temperature and expiry date.

#### **7.4.3 Management of Expiry Stock**

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

## **CHAPTER 8. MONITORING AND EVALUATION**

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

Monitoring is the routine tracking of service 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 Quality Assurance Indicators in HTS Register**

QA indicators in the HTS register is used in recording the specific result of each individual HIV test kit used, and it allows smooth monitoring of the lot number, names and number of test kits used and the expiry date. It could help HTS providers to address HIV test kits problems (expiry date of test kits) or inconclusive test results.

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

### **8.2 Data Management**

Data management is very important for the effective management and improvement of HTS program. *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 be compiled at provincial level. Data Management Unit of NCHADS plays a critical role to do HTS data analysis and data dissemination through NCHADS websites on the quarterly basis.

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

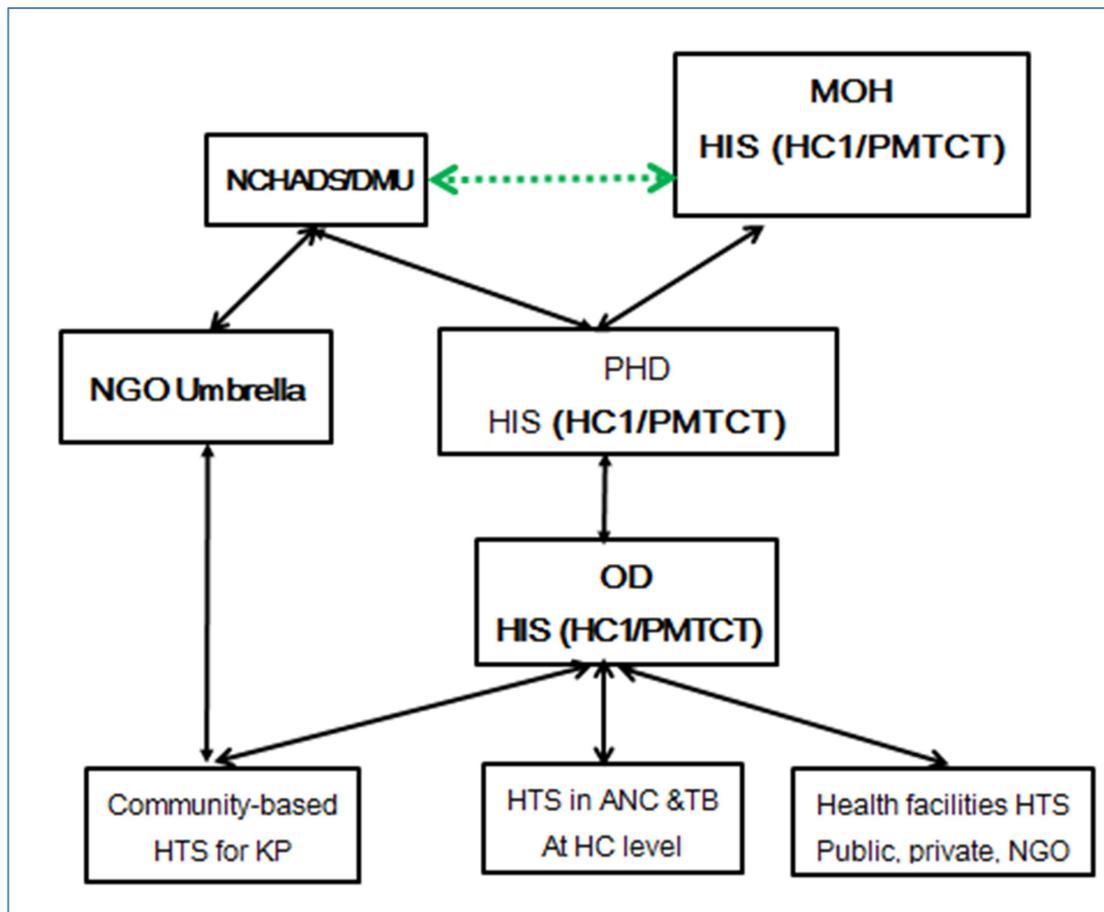
### **8.3 Recording and Reporting Requirements**

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.*

#### 8.4 HTS Data Flow

Figure 10. 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 performed by OD within 10 working days. NCHADS/DMU retrieves HIV data from HIS for further analysis and reporting. NCHADS send the data analysis to subnational level to improve the quality of HTS every three months.

#### 8.5 Monitoring Indicators

Monitoring of 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 National Strategic Plan 2016-2020.

## **8.6 Data Quality Assurance (DQA)**

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

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## ANNEXES

### Annex 1: RDTs National Dashboard



NCHADS, Logistics Management Unit

Date of Stock Status update -->

1-Nov-15

#### Diagnostic Commodities Stock Management

#### CMS Warehouse and NCHADS - Months of Stock on Hand by Formulation (including all current pipeline orders set to arrive in next 9 months)

Note: Months of stock on hand for each month reflect remaining months of stock (MOS) at the end of each month after any deliveries arrive and average monthly distribution is made.

National: Includes deliveries and expected consumption over 15 month period

Months of Stock	Unit	AMC	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16
<b>Rapid Diagnostic Test</b>								
Determine HIV 1/2 test	Test	600	5.8	4.8	8.8	7.8	6.8	5.8
Stat-Pak for confirmation	Test	37	15.6	14.6	28.5	27.5	26.5	25.5
Unigold for confirmation	Test	31	1.7	0.7	8.9	7.9	6.9	5.9
EID Reagents and Consumable	Test	1	7.0	6.0	11.4	10.4	9.4	8.4
<b>Reagents for CD4 Test</b>								
FACSCOUNT Reagent CD4 and CD4%	Test	126	1.5	0.5	2.6	1.6	0.6	0.0
FACSCOUNT Control	Test	-	0.0	0.0	0.0	0.0	0.0	0.0
Facsflow Sheath fluid	Btl	-	0.0	0.0	0.0	0.0	0.0	0.0
BD Facs Clean 5L	Btl	-	0.0	0.0	0.0	0.0	0.0	0.0
BD Facs Rinse 5L	Btl	-	0.0	0.0	0.0	0.0	0.0	0.0
PIMA reagents	Cartridge	-	0.0	0.0	0.0	0.0	0.0	0.0
<b>Reagents for VL Test</b>								
Viral Load Reagent	Test	50	1.0	0.0	2.0	1.0	0.0	0.0
<b>Reagents for STD Test</b>								
Syphilis Determine test	Test	247	1.1	0.1	3.3	2.3	1.3	0.3

Serodia TPPA	Test	-	0.0	0.0	0.0	0.0	0.0	0.0
RPR	Test	-	0.0	0.0	0.0	0.0	0.0	0.0
Gramstain Ready for use Bio-Meieux	Set	-	0.0	0.0	0.0	0.0	0.0	0.0
Xylen	Btl	-	0.0	0.0	0.0	0.0	0.0	0.0
Potassium Hydroxide	Btl	-	0.0	0.0	0.0	0.0	0.0	0.0
Ethanol, Denatured Solution, 72%	Case	-	0.0	0.0	0.0	0.0	0.0	0.0
PH Vaginal test	Test	-	0.0	0.0	0.0	0.0	0.0	0.0
Immersion Oil	Btl	-	0.0	0.0	0.0	0.0	0.0	0.0
<b>Condom</b>								
Male Condom	Pcs	-	0.0	0.0	0.0	0.0	0.0	0.0

<b>Stock Out Risks and Recommendation/Action</b>	
<b>Expiry Risks and Recommendation/Action</b>	

