

National HIV Testing Services (HTS) Guideline



**National AIDS/STD Control
Directorate General of Health Services
Ministry of Health and Family Welfare**



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December 2019



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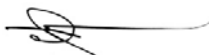
FOREWORD

Reaching the global strategy “Fast Track” 90-90-90 Bangladesh has been taken so many initiatives among its one of the major interventions is scale up of HIV Testing Services (HTS) across the country in public and private health services delivery point. In recent year AIDS/ STD Programme of DGHS established 28 HTS center in government medical college hospital, district general hospital made available the services for the people. The aim of this scale up is to increase case detection that will help us to reach first 90 which is 90% estimated case will be diagnosed by 2020. Besides this, a large number of NGO facility providing HTS services for the key population in the country since long. Trained human resources are providing the HIV testing services for the country people using rapid testing kits/ devise. To expand this service WHO recommended to ensure this testing using lay providers as well as soft testing method which has been addressed in this guideline.

A large number of tests are conducted every year in the country, the number of testing also increasing day by day. Although a degree of error and misdiagnosis can be expected, very few cases of false negative and false positive diagnoses have been reported in the country as per information of virology department of BSMMU. In this perspective quality of the testing is the major concern.

Ensuring quality of the HIV testing for the providers this guideline will play important role to maintain the standard testing, this guideline will be used by hospitals MT lab, Nurses, NGOs Counselor, Medical Assistant even Lay providers who received training on this issue with sufficient practical session. Other hand, this standard guideline will also help to the hospital manager, programme manager of the national programme, NGOs manager and management of the private sector health service providers for monitoring the testing process as part of the quality assurance.

I congratulate all the stakeholders who contributed for updating this guideline also expressing my good wishes to the users of this guideline in advance. I hope, we will able to reach our target “Ending AIDS by 2030”.



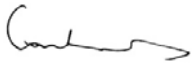
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ACKNOWLEDGEMENT

HIV Testing and Counseling (HTC) is a key component and entry point of HIV prevention, care and support programme. Counseling and testing is also a cost effective intervention for HIV prevention. Recently, AIDS/ STD Programme expanded the care, treatment as well as testing services covering all the divisional based medical college and district hospitals. Initially all 23 priority district hospital introduced testing service, gradually it will be expanded to all 64 districts.

The last National HIV Testing and Counseling (HTS) guideline was developed in 2013 by adopting testing algorithm as well as approach of the WHO guideline considering country context. Different components of the population require different HTS approaches in order to enhance access to available testing to reach the global target 90-90-90. ASP given emphasis the quality of the testing service in the public, NGOs and private health sector with adopting recent changes made by WHO and other competent agencies. Considering the importance, ASP taken the initiative to update the exiting HTS guideline. A technical working committee was formed to update this guideline consisting the members of different technical expertise including virologist, microbiologist, counseling, M&E, HIV programme managers, etc. Several consultations were organized to review the existing document as well as relevant updates of WHO, CDC.

I am sincerely expressing thanks to all the working group members who contributed for updating the HTS guideline. Also great full to the reviewers team for giving their time to review the guideline.



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ACRONYMS

ADR	: Adverse Drug Reaction	MSM	: Male having sex with male
AIDS	: Acquired Immune Deficiency Syndrome	MSW	: Male sex worker
ASP	: AIDS/STD Programme	NFM	: New Funding Model
BCC	: Behavior Change Communication	NGO	: Non-Governmental Organization
BSMMU	: Bangabandhu Sheikh Mujib Medical University	PITC	: Provider Initiated Testing and Counselling
CITC	: Client Initiated Testing and Counselling	PLHIV	: People Living with HIV
CSTC	: Care, Support and Treatment Center	PMTCT	: Prevention of Mother-to-Child Transmission
DBS	: Dried Blood Spot	PWID	: People Who Inject Drugs
DGHS	: Directorate General of Health Services	PSM	: Procurement and Supply Management
DIC	: Drop-in Centers	QA	: Quality Assurance
ELISA	: Enzyme linked Immuno Sorbent Assay	QI	: Quality Improvement
EQA	: External Quality Assessment	RCC	: Rolling Continuation Channel
FHI	: Family Health International	RDT	: Rapid Diagnostic Test
FSW	: Female Sex Worker	SOP	: Standard Operating Procedures
GFATM	: Global Fund to Fight AIDS, Tuberculosis, and Malaria	SP	: Service Provider
HCF	: Health Care Facility	SR	: Sub Recipient
HCP	: Health Care Provider	SSR	: Sub Sub Recipient
HIV	: Human Immunodeficiency Virus	STD	: Sexually Transmitted Disease
HIVST	: HIV Self-testing	STI	: Sexually Transmitted Infection
HTC	: HIV Testing and Counseling	TG	: Transgender

HTS	: HIV Testing Services	UNAIDS	: Joint United Nations Programme on HIV/AIDS
icddr,b	: International Centre for Diarrhoeal Disease Research, Bangladesh	UNFPA	: United Nations Population Fund
IEC	: Information Education Communication	UNICEF	: United Nations International Children's Emergency Fund
IP	: Infection Prevention	UP	: Universal Precaution
KP	: Key Population	VCT	: Voluntary Counselling and Testing
Lep	: Leprosy	WB	: Western Blot
LIA	: Line Immuno Assay	WHO	: World Health Organization
MBDC	: Mycobacterial Disease Control		



OPERATIONAL DEFINITIONS

Acute infection	The period in which an individual becomes HIV-infected and before HIV antibodies can be detected by a serological assay.
Analyte	A substance or chemical constituent that is analyzed, generally referring to a component of blood or another body fluid. In the context of HIV, analytes include HIV p24 antigen and HIV-1/2.
Community-based testing services	HIV This is an important approach to reach first-time testers and people who seldom use clinical services, including people from key populations in all settings. It also facilitates early diagnosis. Services may be offered in community sites such as community-based organizations, schools, workplaces and religious institutions. Mobile services can be provided through mobile vans or tents and in places of entertainment such as clubs.
Community	A community is a small or large social unit that has something in common, such as norms, religion, values, or identity.
Confirmed	To issue an HIV status, initially reactive test results need to be confirmed according to the national validated testing algorithm.
External quality assessment (EQA)	Inter-laboratory comparison to determine if the HIV testing service can provide correct test results and diagnosis.
HIV testing services (HTS)	The full range of services that should be provided together with HIV testing-counseling (pre-test information and post-test counseling); linkage to appropriate HIV prevention, treatment and care services and other clinical and support services; and coordination with laboratory services to support quality assurance and the delivery of correct results. The WHO 5 Cs are principles that apply all models of HTS in all circumstances.
HIV Self-testing (HIVST)	A process, in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him- or herself, often in private. Reactive test results must be followed by additional HIV testing services.
Key populations	Defined groups who, due to specific higher-risk behaviors, are at increased risk for HIV irrespective of the epidemic type or local context. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people.

Lay provider	Any person who performs functions related to health-care delivery and has been trained to deliver specific services but has not received a formal professional or paraprofessional certificate or tertiary education degree.
Linkage	It is defined as a process of actions and activities that supports people testing for HIV and people diagnosed with HIV in engaging with prevention, treatment and care services as appropriate for their HIV status. For people with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment.
Non-reactive test result	A test result that does not show a reaction indicating the presence of analyte.
Outreach	Outreach is defined as performing HIV testing services in hot spots, workplaces, homestead, educational establishments, clubs, during mobile outreach campaigns and various national and cultural events.
Pre-test information	A dialogue and the provision of accurate information by a trained lay provider or health worker before an HIV test is performed.
Rapid diagnostic test (RDT)	In vitro diagnostic of immunochromatographic or immune-filtration format for, in the case of HIV diagnosis, the detection of HIV-1/2 antibodies and /or HIV p24 antigen.
Repeat testing	Refers to a situation where additional testing is performed for an individual immediately following initial test results, within the same testing visit, using the same assays and, where possible, the same specimen.
Re-testing	There are certain situations in which individuals should be retested after a defined period of time: (1) HIV-negative people with recent or on-going risk of exposure, (2) people with an HIV-inconclusive status and (3) HIV-positive people before they enroll in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription error and either ruling in or ruling out seroconversion.
Seroconversion	When an individual first produces a quantity of HIV antibodies sufficient to be detectable on a given HIV serological assay.
Sero-discordant couple	A couple in which one partner is HIV-positive and one partner is HIV-negative.
Testing algorithm	The combination and sequence of specific assays used within HIV testing strategies.
Test for triage	A community-based HIV testing approach involving trained and supported lay providers conducting a single HIV RDT. The lay providers then promptly link individuals with reactive test results to a facility for further HIV testing and to an assessment for treatment. Individuals with non-reactive test

results are informed of their results, referred and linked for appropriate HIV prevention services and recommended for retesting according to recent or on-going HIV risk and national guidelines (WHO consolidated guidelines, 2015).

Viral suppression It refers to a viral load below the detection threshold using viral assays.

Window period The period between HIV infection and the detection of HIV-1/2 antibodies using serological assays, this signals the end of the seroconversion period.



CHAPTER ONE: INTRODUCTION TO HTS SERVICES

1. Introduction
2. Purpose of the Guideline
3. Process of the HTS Guideline Development
4. Summary of chapters
5. Summary of chapters

1.1 Introduction

HIV testing is the gateway to HIV prevention, treatment, care and other support services. People's knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of the HIV response. The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) have endorsed global goals to achieve "zero new HIV infections, zero discrimination and zero AIDS-related deaths". Because of the potential serious medical, social and psychological consequences of misdiagnosis of HIV (either false-positive or false-negative), all programmes and people providing HIV testing must strive also for zero misdiagnoses.

The new global 90–90–90 targets call for 90% of all people with HIV to be diagnosed, 90% of people with HIV diagnosed to receive ART and 90% of those on ART to have a suppressed viral load by 2020 (20). The first 90 – diagnosis of HIV – is essential to the second 90 – initiation of ART among people with HIV – and the ultimate outcome of the third 90 – viral load suppression among people on ART, which improves client outcomes and prevents HIV-1 transmission. The challenge is to increase access to and uptake of HTS for those who remain undiagnosed and for those at greatest ongoing risk for HIV infection.

As essentials of national response to HIV/AIDS, a number of measures and interventions have been taken through AIDS/STD Programme (ASP) of Ministry of Health and Family Welfare (MOHFW). National AIDS Committee (NAC) was formed in 1985. National AIDS Policy has been approved by the cabinet in 1997, which covers many aspects of HIV/AIDS prevention and care. Government of Bangladesh (GOB) has taken leadership role through NASP with increasing partnership with NGOs, UN agencies and private sector under Health, Population and Nutrition Sector Development Program (HPNSDP) to combat HIV/AIDS. Several policy documents, strategies and guidelines have been formulated to scale up and accelerate the national response to HIV/AIDS. All those national documents are aimed to guide all partners and stakeholders and adopt them in HIV programming in a unified manner.

As per 4th National Strategic Plan For HIV and AIDS Response 2018-2022, with the aim to implement services to prevent new HIV infections by increasing program coverage and case detection and provide universal access to treatment, care and support services for the people living with HIV, ASP has planned to establish HTS centers and ART centers/refil centers in the identified propriety districts. As the HIV testing guideline was last updated on 2013 (unpublished), there are lots of progress has been

achieved in the HIV testing strategies, approaches and methodologies. To adopt the changes, ASP decide to update the existing manual and develop a comprehensive HIV testing guideline.

1.2 Purpose of the Guideline

HIV testing is the entry point to HIV prevention, care and treatment. The rapid expansion of care and treatment services has increased the need for HTS. Different components of the population require different testing approaches in order to enhance access to available care and treatment services. The National HIV Testing (HTS) Guideline 2019 will provide necessary information and guide to HTS providers, trainers, doctors and program managers to enable them conducting effective HIV testing services which would meet the medical, psychological and social needs of both the HIV affected and infected individuals and their families. This guideline will help making the providers' knowledge, attitude and practice perfect. As a result, HIV positive, even people with risk of HIV, would get proper information and inspiration to lead high quality, independent, productive life.

The overarching goals of HIV testing services are to:

1. identify people with HIV through the provision of quality services for individuals, couples and families;
2. effectively link individuals and their families to appropriate HIV treatment, care and support, as well as HIV prevention services, based upon their status; and
3. support the scale-up of high impact interventions to reduce HIV transmission and HIV-related morbidity and mortality, that is, antiretroviral therapy (ART), prevention of mother-to-child transmission (PMTCT), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

1.3 Process of the Guideline Development

National HIV Testing Services (HTS) guideline was developed through participatory process that includes-

1. A Consultative meeting with the relevant stakeholders was organized where a Technical Working Group was formed for developing the guideline.
2. The Technical Working Group developed a draft document with technical assistance from Save the Children, UNAIDS and WHO; the WHO consolidated Guideline for HIV testing services 2015 was the key document that the working group adopted from. Adaptation was done considering our country context and resource constraints.
3. Feedback and suggestions were taken from the other relevant stakeholders in all stages of developing the Guideline.
4. The draft document was shared with the stakeholders through a daylong workshop on March 2019 and recommendations incorporated in preparing the final document.

1.4 Summary of Chapters

Chapter 2 details the logistic, human resource and capacity building requirements of HTS site.

Chapter 3 describes the details of testing methodologies and procedure

Chapter 4 describes pre-test and post-test services, including linkage to prevention, treatment and care services.

Chapter 5 addresses HTS for specific populations – Key populations, infants and children, adolescents, pregnant women, couples and partners (including serodiscordant couples) and other vulnerable populations.

Chapter 6 discusses essential and standards required for referral and linkage for people identified as HIV positive through HTS

Chapter 7 outlines core monitoring and evaluation considerations for HIV Testing services

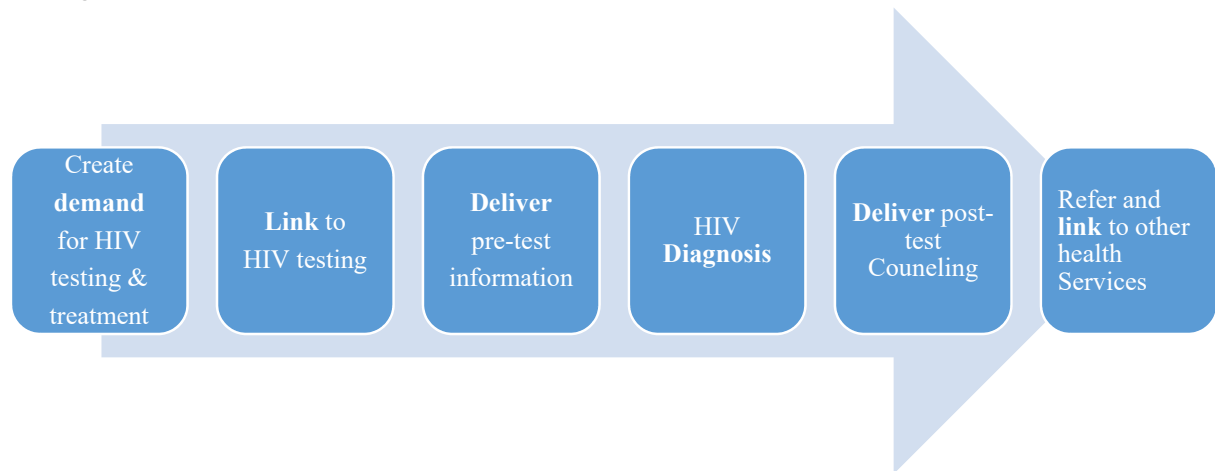


Figure 1. Continuum of linkage to care and prevention

1.5 Guiding Principles¹

A public health and human rights-based approach is important to delivering HTS. A human rights-based approach gives priority to such concerns as universal health coverage, gender equality and health-related rights such as accessibility, availability, acceptability and quality of services. For all HTS, regardless of approach, the actual public health benefits must always outweigh the potential harm or risk. Moreover, the chief reason for testing must always be both to benefit the individuals tested and to improve health outcomes at the population level. HTS should be expanded not merely to achieve high testing uptake or to meet HIV testing targets, but primarily to provide access for all people in need to appropriate, quality HTS that are linked to prevention, treatment, care and support services. Thus, HIV testing for diagnosis must always be voluntary, consent must be informed by pre-test information, and testing must be linked to prevention, treatment, care and support services to maximize both individual and public health benefits.

All forms of HIV testing should adhere to the WHO 5 Cs: Consent, Confidentiality, Counselling, Correct test results and Connection (linkage to prevention, treatment and care services) (44). Coerced testing is never appropriate, whether that coercion comes from a health-care provider, an employer, authorities (such as immigration services) or a partner or family member.

¹ WHO consolidated guideline for HTS 2015

The 5 Cs are principles that apply to all HTS and in all circumstances

Consent: People receiving HTS must give informed consent to be tested and counselled. (Verbal consent is sufficient; written consent is not required.) They should be informed of the process for HIV testing and counselling and of their right to decline testing.

Confidentiality: HTS must be confidential, meaning that what the HTS provider and the client discuss will not be disclosed to anyone else without the expressed consent of the person being tested. Confidentiality should be respected, but it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with a partner or family members – trusted others – and health- care providers is often highly beneficial.

Counselling: Pre-test information can be provided in a group setting, but all people should have the opportunity to ask questions in a private setting if they request it. All HIV testing must be accompanied by appropriate and high-quality post-test counselling, based on the specific HIV test result and HIV status reported. Quality assurance (QA) mechanisms as well as supportive supervision and mentoring systems should be in place to ensure the provision of high-quality counselling.

Correct: Providers of HIV testing should strive to provide high-quality testing services, and QA mechanisms should ensure that people receive a correct diagnosis. QA may include both internal and external measures and should receive support from the national reference laboratory. All people who receive a positive HIV diagnosis should be retested to verify their diagnosis before initiation of HIV care or treatment.

Connection: Linkage to prevention, treatment and care services should include effective and appropriate follow-up, including long-term prevention and treatment support. Providing HTS where there is no access to care, or poor linkage to care, including ART, has limited benefit for those with HIV.

CHAPTER TWO: HIV TESTING SERVICE (HTS) DELIVERY APPROACHES

1. Introduction
2. HIV Testing Services (HTS) Delivery Approaches
3. Characteristics of ideal HIV Testing Services
4. Administrative Structure and Operational Procedure
1. Training of the HTS Service Provider

Key Messages	
1.	Approaches of HIV Testing Services (HTS) includes Facility based HIV testing services, Community based HIV testing services, and HIV self testing (HIVST).
2.	A HTS facility must be easily accessible to target clients, ensure privacy and confidentiality and have a reliable HIV testing.
3.	The HTS provider must have adequate knowledge and skills on HTS services. S/He must receive five day long basic training, ongoing mentoring and yearly refreshers training
4.	AIDS/STD Programme (ASP) will be responsible for overall coordination and quality assurance of the HTS.

2.1 Introduction

HIV testing is the gateway to HIV prevention, treatment, care and other support services. People's knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of the HIV response. The HTS sessions should take place in a quiet and undisturbed atmosphere where people can concentrate, and where they will be able to absorb the content of the discussions. Therefore, it is very important to take into consideration several factors while planning for HTS, such as:

1. A separate space ensuring privacy for providing pre-test, HIV test and post-test services
2. System for regular quality assurance of testing
3. Referral linkages for prevention, care, support and treatment services
4. Accuracy and confidentiality of all client related information
5. Alignment and linkage of MIS (Management Information System) of HTS with national information system
6. An adequate supply of rapid tests kits and consumables, commodities and information, education & communication (IEC)/behavior change communication (BCC) materials.

2.2 HIV Testing Service Delivery Approaches and Models

HIV testing services are offered in a diverse range of settings following different models. PITC model refers to HIV testing and counseling which is routinely recommended by health care providers to persons attending health care facilities as a standard component of medical care. Outside clinical settings HTS can be offered through client-initiated testing & counseling model (CITC).

As per the global needs to increase the case detection of HIV through provider initiated testing for strengthening the treatment as prevention approach, AIDS/STD Programme (ASP) will adopt all testing

services approaches, such as facility based, community based and self-testing approaches. The models are grouped as facility or community based services as shown below:

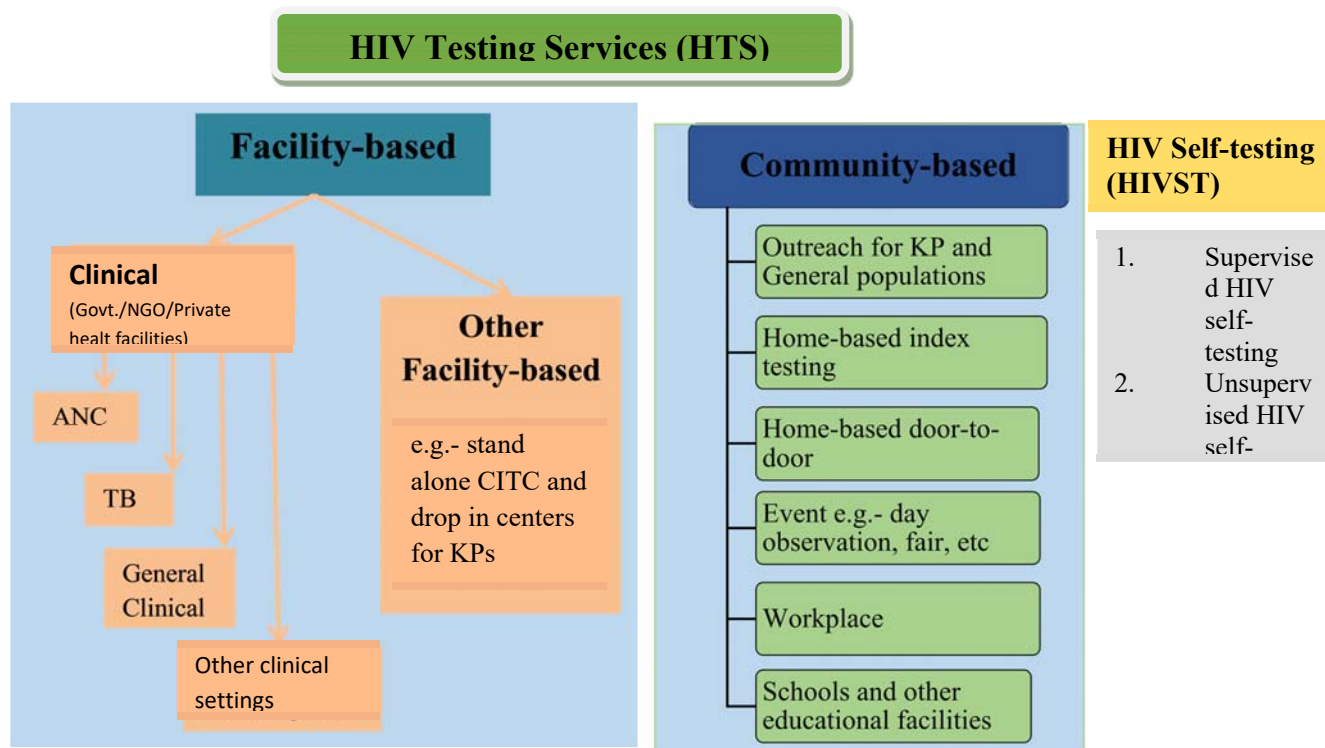


Figure 2. HIV Testing Services (HTS)

Facility-based approach includes stand-alone CITC in a fixed site. It usually does not take place in clinical settings, and the model is more closely aligned with community-based approaches. Stand-alone sites usually are situated in the community and thus are more accessible to their target populations than many other health-care facilities. In the first two decades of the HIV response, CITC was the predominant model through which individuals learnt their HIV status.

However, in regards to facility-based approach, PITC has been the predominant model in a number of settings through which individuals have learnt their HIV status and obtained access to HIV services. Beginning in ANC clinic, PITC has been integrated in other clinical settings, such as TB services, STI clinics, services for key populations including opioid substitution therapy (OST) and needle syringe programmes (NSP) for people who inject drugs (PWID).

When facilities are concentrated in urban areas, PITC may be inaccessible to rural, hard-to-reach, and key populations. So, it is particularly needed to introduce other models of HTS that extend service availability and delivery beyond facility settings. So, Community-based and/ or community led HTS delivery is the implementation option in a variety of settings and with various approaches.

HIV self-testing (HIVST) is a process in which an individual who wants to know his or her HIV status collects specimen, performs a test and interprets the result by him or herself, often in private. HIVST does not provide a definitive diagnosis. By giving people the opportunity to test directly and conveniently, HIVST may increase uptake of HIV testing among people not reached by other HIV testing services.

2.3 Characteristics of Ideal HIV Testing Services

It is generally recommended that a HIV testing services should have at least the following facilities and resources:

A. Space, Furniture & Equipment

Reception area: The minimum requirement at the reception area includes desk and chair; file cabinet and if possible, a computer for data entry, communication gadgets e.g. telephone, and IEC material.

Waiting area: A comfortable sitting facility, availability of safe drinking water, open display area for educational materials and audiovisual equipment.

Pre-test and post-test service room: This area should be equipped with minimum three chairs, small round or semicircular table, lockable cupboard, registers, stationeries and IEC/BCC materials.

Laboratory/Testing Area: Area to be equipped with a desk, chair washable work counter, safe storage space for medical consumables and test kits, refrigerator for test kits and/or reagents needing refrigeration, post exposure prophylaxis (PEP) kits, waste disposal containers, sink with elbow taps with running water. This room may be separate one or the may be the same room where pre-test and post-test counseling services will be conducted. List of consumables, supplies and equipment is attached as annex-1.

Toilets: Provision for separate toilets for clients and staff.

B. Staffing

Key staff to be considered for a HIV testing services:

Management: A designated/assigned person is essential to ensure standard HIV testing services. Responsibilities include planning, coordination, supervision and supporting staff at the site.

Technical staff:

Counselor cum Test: There must be an adequate number of trained personnel to provide pre-test, test and post-test services. S/he should receive periodic supervision and ongoing mentoring services.

In health facilities, where available, laboratory technologist/technician can be trained to facilitate HTS. However, in order to support the expansion of HIV testing services in Bangladesh, medical assistants, nurses, midwives, counselors and other health service providers who have received the requisite training will be authorized to provide HTS (including pre-test, test and post-test services).

Designated personnel for data entry: Assigned personnel will be responsible for incorporating data in to the national MIS system on periodic basis (please see the M&E section- for further clarification).

Ancillary staff: These include general service staff such as cleaners, security guards, etc. They are responsible for the general house-keeping and other duties at the facility.

Key Requirement for HTS services	
1.	HTS sites:
1.	Must be easily accessible to target clients
2.	Must ensure privacy and confidentiality
3.	Must have a reliable HIV testing facility
4.	HTS provider:
1.	Must have standard training on HIV testing services
2.	The HTS provider needs to have good knowledge of HTS and be motivated
3.	Must be accessible, available and reliable to their respective clients
4.	Must have basic communication skills
5.	Should be intelligent, and with an empathic character
6.	Must follow the professional code of conduct and maintain high standard of professional ethics
7.	Academic qualification will widely vary according to HTS approach and facility
8.	HTS sessions:
1.	Must be well organized and structured, and appropriate checklists should be used
2.	Must be flexible in order to meet the requirements of individual clients and/or population subset

2.4 Administrative Structure and Operational Procedure for HTS

Administrative structure: AIDS/STD Programme (ASP) will be responsible for overall coordination and quality assurance for HTS. The services will be implemented by both government and non-government organizations. Each HTS facility will be managed by designated personnel, to whom all HTS staff will be accountable. There will be regular liaison between implementing organization and AIDS/STD Programme for updating progress and ensuring efficient and effective service delivery. ASP will be responsible for global data requirements.

Site Security and Confidentiality Requirements:

1. All client records including registers will be kept in a locked cabinet.
2. Access to client records is restricted to HTS provider and his/her technical supervisor, any other personnel will have the access on “need to know basis” under shared confidentiality approach

3. All testing supplies, consumables, IEC materials and commodities will be kept in a safe storage, having access only to the HTS providers and designated person.

2.5 Training of the HTS service provider

Pre placement basic training for HTS: All staff providing HIV testing services (HTS) must undergo the basic HTS training course. In case of turn over or any other situation, the HTS service provider may receive an on-site hand on training until next training course become available. The basic HTS training course will be of five days duration with practical sessions using the standard curriculum developed/endorsed by AIDS/STD Program (ASP). Participants will receive certificate after successful completion of the training.

On-going mentoring /Refresher training: After the initial training and certification, the HTS service provider need to maintain competency, build their skills, and refresh their knowledge on new approaches. Post training mentorship, supervision, and regular communication are important elements of ongoing quality of counseling and testing. Therefore, refresher training will be conducted at-least once yearly that would cover new developments in this field and thereby continue professional development to ensure quality of HTS.

CHAPTER THREE: HIV TESTING SERVICES

1. Introduction
2. HIV Testing Strategy in Bangladesh
3. Different HIV Antibody Assays
4. HIV Rapid Tests
5. Testing Algorithms
6. Understanding of HIV test results
7. Retesting
8. Quality assurance of HIV Rapid Testing

Key Messages

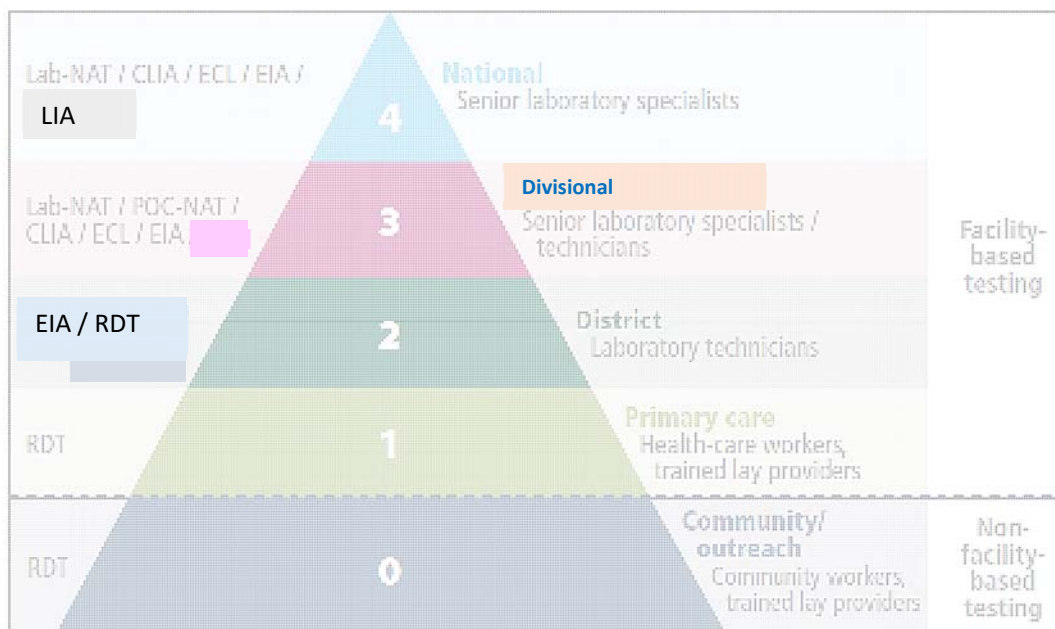
1. HIV can be detected by HIV antibody tests or HIV antigen test
2. The three groups of HIV Antibody Assays are: Enzyme linked immunosorbent assay (ELISA/EIA); Line immune assay (LIA)/Western blot (WB) assay; and Rapid Tests.
3. The three types of specimens used for diagnostic tests are: Serum and Plasma Specimens, Whole Blood (Finger-stick) Specimens and Oral and Other Fluids
4. Rapid diagnostic tests (RDTs) are a critical tool for scaling up HIV testing services. They can be performed by trained lay providers, health-care workers and laboratory professionals in various settings, irrespective of the infrastructure, as they do not require specialized equipment or specimen collection by venipuncture.
5. There are two commonly used algorithms for rapid testing—serial/sequential and parallel testing. The testing algorithm is currently being in use in Bangladesh is serial testing where three different rapid test kits are used as A1, A2 and A3 respectively
6. The first assay (A1) for any testing algorithm should be the most sensitive assay available, with more specific assays used as second (A2) and third (A3), irrespective of the assay format.
7. **A negative result in RTD** indicates that no antibodies to HIV have been detected in the blood meaning the person is not infected or may be infected but antibodies to the virus are yet to high up to be detected
8. **A positive result in RDT** indicates that antibodies to HIV have been detected in the person's characteristics blood meaning the person has been infected.
9. Retesting is also recommended for certain individuals with ongoing risk who test HIV negative.
10. Retesting is not recommended for individuals on ART. For individuals who have taken PEP, for infants exposed to PMTCT regimens via their mothers and for individuals taking PrEP, negative status should be interpreted with caution.
11. The **window period** represents the period of time between initial infection with HIV and the time when HIV antibodies can be detected in the blood stream by currently available diagnostic tests.

The window period can last up to 12 weeks and may vary between different assays using different methodologies or due to different types of HIV.

12. For EQA, after following the Rapid test algorithm, all positive samples and 3-5% of negative samples should be sent to the reference laboratory for “Retesting” by ELISA/EIA and/or WB/LIA periodically from each HTS site

3.1 Introduction

HIV testing is the entrance to HIV prevention, treatment, care and other support services. People’s knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of the HIV response. HIV testing will take place at any level of the health-care facility (Govt./Non-Govt./NGO/Private) and also in the community. Fig. A depicts how HIV testing services are organized and shows the different testing types that could be available at each level (for both facility-based and community-based testing).



Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; CLIA: chemiluminescence immunoassay; ECL: electro chemiluminescence immunoassay; EIA: enzyme immunoassay; LIA: Line immune assay, RDT: rapid diagnostic test.

Figure 3. A tiered testing service, with assay format menu and staff qualifications

Type of HIV Testing:

1. Antibody tests-
 1. Rapid tests (RDT)
 2. EIA/ELISAs

2 WHO consolidated HTS Guideline 2015

3. LIA/WB
2. Virological/Antigen tests –
 1. PCR (Polymerase chain reaction)
 2. Lab-NAT: Laboratory-based nucleic acid testing;
 3. POC-NAT: Nucleic acid testing at point-of-care
 4. Viral culture

Table 1. HIV assays and their operational characteristics¹

Type	Format	Time to result	Specimen type	Storage condition
Rapid diagnostic tests	Immunofiltration (vertical flow)	< 3 minutes	Serum, plasma, venous/capillary whole blood	2-30°C or 2-8°C
	Immunochromatographic (lateral flow)	15-30 minutes	Serum, plasma, venous/capillary whole blood, oral fluid	2-30°C
Simple assays	Indirect solid phase enzyme immunoassay	< 30 minutes	Serum, plasma	2-8°C
	Agglutination	2 hours	Serum, plasma	2-8°C
Immunoassay	Enzyme immunoassay (microtitreplate)	2-3 hours	Serum, plasma	2-8°C
	Enzyme immunoassay (simple immunoanalyser)	< 2 hours	Serum, plasma	2-8°C
	Random access chemiluminescence and electrochemiluminescence immunoanalysers	< 2 hours	Serum, plasma	2-8°C
Nucleic acid testing	Qualitative nucleic acid testing (laboratory based)	< 2 hours	Whole blood, dried blood spot	Cold chain
Assays for supplemental use only	Western blot, Line immunoassays	< 8 hours	Serum, plasma	2-8°C
	RDTs for supplementary use only	Depents on format	Depents on format	2-30°C or 2-8°C
	Qualitative nucleic acid testing (point of care)	< 1 hours	Whole blood	2-30°C
	Qualitative nucleic acid testing (laboratory based)	< 5 hours	Whole blood, dried blood spot	Cold chain

Table 2. Generations of HIV serological assays³

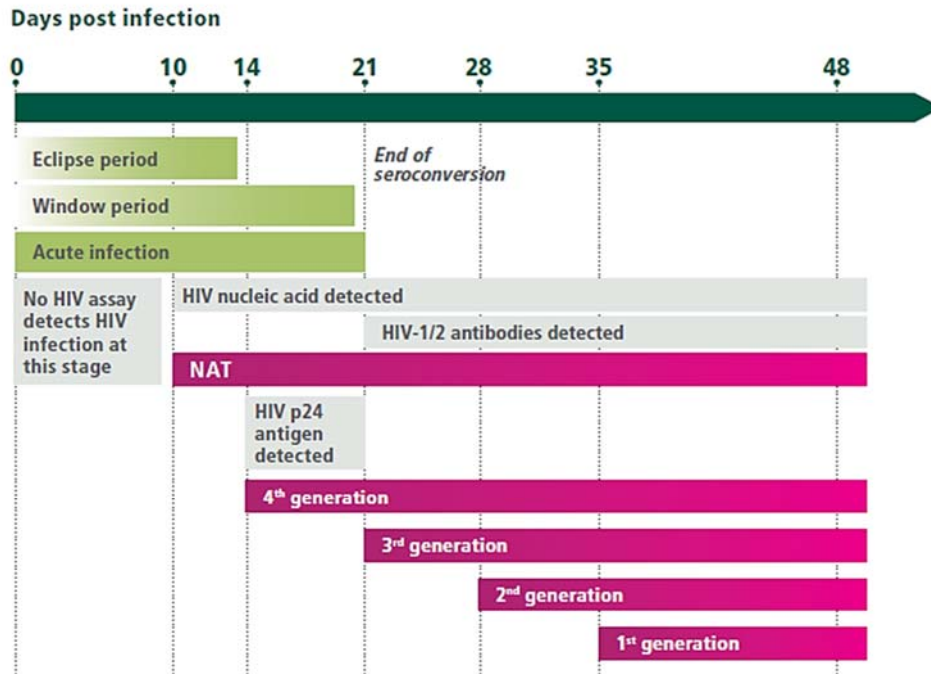
Generation	Antigen source and attributes of the assays
First generation	Crude viral lysate as antigen
	Relatively sensitive but lacked relative specificity. Detects immunoglobulin G antibodies (IgG) only.
Second generation	Recombinant proteins and synthetic peptides as antigen
	Improved specificity and sensitivity. Detects IgG only.
Third generation	Recombinant proteins as antigen, with same antigen conjugated to enzyme (antigen sandwich)
	Further refines sensitivity and specificity. Detects IgG and immunoglobulin M antibodies (IgM).
Fourth generation	Recombinant proteins as antigen and monoclonal antibodies
	Detects IgM and IgG antibodies and HIV p24 antigen; therefore, increased sensitivity in early infection, that is, during seroconversion.

Due to the high sensitivity of both third and fourth generation serological assays, a certain low level of false reactivity is to be expected. Therefore, any testing algorithm using a third or fourth generation serological assay as the first-line assay should include more specific second-line and third-line assays to verify the HIV diagnosis and rule out false reactivity.

Fourth generation serological assays (RDTs, EIAs, CLIAs, ECLs) that detect both HIV p24 antigen and HIV-1/2 antibodies have the potential to identify infected individuals earlier in the course of disease. In other words, these assays greatly shorten the diagnostic window period (Fig. 7.2). Thus, fourth generation serological assays are a suitable choice for a first-line assay when seroconversion sensitivity is preferred, such as in blood screening. Certain fourth generation serological assays can produce a result that indicates whether the assay is reactive to HIV p24 antigen or to HIV-1/2 antibodies, rather than combined detection of these markers. Thus, it is theoretically possible to identify individuals with acute infection (HIV p24 antigen present but non-reactive for HIV-1/2 antibodies).

However, recently published data show that the HIV p24 antigen detection component of some fourth generation RDTs lacks analytical and diagnostic sensitivity (242–245). A further caveat is that the presence of HIV p24 antigen should not always be interpreted as acute infection. This is because levels of free and circulating HIV p24 antigen can be detected again late in the course of HIV infection, when the immune (antibody) response wanes and a lack of HIV-1/2 antibodies (and, therefore, rising titres of HIV p24 antigen) are observed.

³ WHO consolidated HTS Guideline 2015, Page-94



Source: Rosenberg et al., 2015 (1).

Figure 4. Detecting HIV-infection with various formats and generations of in vitro diagnostics over the natural history of infection⁴

For a period of about 10 days following HIV infection, known as the eclipse period, no currently available serological or virological assay can detect any marker of HIV infection. The end of the eclipse period is marked by the appearance of HIV RNA or DNA detectable by nucleic acid testing (NAT) and then HIV p24 antigen, detectable by immunoassay (IA). The period prior to detection of HIV-1/2 antibodies is often referred to as “acute infection”. The number of HIV virus particles rises rapidly during acute infection and may be associated with higher infectivity and rate of transmission.

As the level of HIV-1/2 antibodies increases, these antibodies form immune complexes with free HIV antigen circulating in the bloodstream. Thus, free HIV antigen is captured (complexed) and, therefore, unable to bind to monoclonal antibody presented on the test device. As a result, the level of detectable HIV antigen decreases. The detection of HIV-1/2 antibodies by serological assay signals the end of seroconversion and, therefore, the window period for diagnosis. The duration of the window period depends on three main factors: (1) the genetics of the virus, (2) the genetics and immunocompetence of the host and (3) what exactly the assay detects (antigen, antibodies). In particular, the format of the assay determines its ability to detect early HIV antibodies (including IgM, IgA, IgG); this may also depend on the specimen type, such as oral fluid, venous or capillary whole blood and serum/plasma. The shortest window period is generally observed with fourth generation serological assays, followed by third and then second generation assays, with first generation assays

⁴ WHO consolidated HTS Guideline 2015, Page-93

having the longest window period. Among RDTs, those using oral fluid specimens exhibit the very longest window period, irrespective of their generation, likely because the concentration of HIV-1/2 antibodies is lower in oral fluid than in other specimen types. However, they have been successfully used in many settings, particularly where high HIV incidence is not expected.

3.2 HIV Testing Strategy of Bangladesh

In alignment with WHO/UNAIDS recommendations, government of Bangladesh has also provided the following guidance on HIV testing strategies. Any of the three⁵ testing strategies can be followed for HIV diagnosis.

Strategy 1: Three ELISA/EIA run on different kits are adequate to confirm HIV status of the individuals. If the results of two ELISA/EIA kits differ, LIA/WB as supplementary test is indicated.

Strategy 2: Three rapid tests run on different approved kits and algorithm are also sufficient to confirm HIV status.

Strategy 3: Positive result on ELISA/EIA or rapid test followed by LIA/WB should be considered confirmatory.

In the beginning, HIV diagnosis was possible centrally only in Dhaka following strategy 3 with ELISA and Western Blot. In 2006 there was major shifting in testing approach. Due to felt need for rapid scaling up of HIV testing (HTS) services for Key Population (KP), an algorithm using three rapid test kits was validated following WHO guideline. The result of the validation study was immediately fed into interventions implemented for KP. Currently, three rapid tests are used in number of HTS centers for HIV diagnosis. At present, strategy 3 is used for Quality Assessment of HIV rapid test by reference laboratory.

Till 2014, the HIV testing was only center based where tests were done using serum. From 2015, considering the global strategy of 90-90-90 and previous years experiences, fingertip whole blood testing was also adopted in Bangladesh and satellite testing was introduced which increases uptake of HIV testing and new case detections; lay provider testing was also introduced from 2017 which increases the access and uptake of HIV testing.

3.3 HIV Antibody Testing

A variety of HIV antibody assays are available. These assays can be broadly classified into three groups: Enzyme Linked Immunosorbent Assay (ELISA/EIA); Western Blot Assay; and Rapid Tests. Most current HIV antibody tests are capable of detecting antibodies to both HIV-1 and HIV-2.

1. **Rapid tests:** A variety of rapid tests are available and employ a wide range of techniques including particle agglutination; Immuno chromatography (lateral flow); Immuno

5NASP. National Policy on HIV/AIDS and STD Related Issues. DGHS.MoHFW. 1996.

concentration (flow-through device) and comb or dipstick-based assay systems. Rapid tests are most appropriate for the smaller health institutions where only a few samples are processed each day. Rapid tests are quicker and do not require specialized equipment. Most rapid tests have sensitivities and specificities of over 99% and 98% respectively.

2. **ELISA/EIA:** HIV antibodies in the test serum are detected using an antibody sandwich capture technique. Essentially HIV antibodies if present in the test sample (Whole blood, serum or plasma) are 'sandwiched' between HIV antigen, which is fixed to the test well, and to 'enzymes' that are added to the test well following addition of the test serum.
3. **Line Immunoassay (LIA)/Western Blot (WB):** HIV antibodies in the test sample are detected by reacting to a variety of HIV viral proteins. To prepare WB strip, the HIV proteins are initially separated into bands according to their molecular weight on an electrophoresis gel. These proteins are then transferred or 'blotted' to nitrocellulose paper. In LIA the proteins are 'blotted' directly to nitrocellulose paper. The WB/LIA strips are then incubated with the patient's sample. HIV antibodies to specific HIV proteins bind to the WB or LIA strip at precisely the point to which the target protein migrated or blotted.

During the early stage of HIV pandemic, HIV diagnosis was dependent on testing procedures using ELISA to screen a specimen, and if it is reactive, the result was confirmed by testing the specimen with a LIA/Western Blot which is treated as Gold Standard test for diagnosis of HIV. However, studies have shown that the latest generation of ELISAs and rapid tests are as reliable for confirmation as Western Blot. In addition, compared with Western blots, ELISAs and rapid tests are less expensive, do not require as high a level of technical expertise to perform and interpret, and produce fewer indeterminate results.

WHO/UNAIDS recommends three tests (ELISA or rapid) for use in diagnostic testing in populations with an HIV prevalence $\leq 10\%$ among asymptomatic persons. These are the kits recommended by WHO and duly validated by Government

Therefore, UNAIDS and WHO recommend alternative testing strategies using combinations of EIAs or rapid tests to confirm initial positive tests. The first test (screening test) should be highly sensitive to provide reliable detection of antibodies in a specimen. The second and/or third test should be highly specific to confirm that the specimen truly does not contain antibodies specific to HIV.

3.4 HIV Rapid Tests

Most rapid tests contain antigens to both HIV-1 and HIV-2 and therefore can detect antibodies to both HIV types. However, most tests do not distinguish between HIV-1 and HIV-2 but these are useful for diagnostic purposes. Rapid tests are useful for small laboratories that routinely perform fewer HIV tests per day, for laboratories without electricity or equipment, and for geographic areas with limited laboratory infrastructure. HIV testing with rapid tests is also useable to detect HIV in community based/satellite session. Rapid tests may be appropriate for testing among KPs (e.g., injecting drug users, female sex workers) or geographically remote populations. In these populations, opportunities

for provision of results may be limited after the initial encounter; therefore, testing (screening and confirmatory) may need to be performed on site on the same day as specimen collection.

The major advantage of the rapid HIV test is that it allows results to be given on the same day as testing thus reducing the number of visits made by the clients. A further benefit is that individuals are more likely to receive their results from the same health care worker who performed pre-test information.

HIV rapid tests have the following advantages:

1. Increases access to prevention interventions
2. Supports increased number of testing sites
3. Same-day diagnosis and Counseling
4. Robust and easy to use
5. Test time less 30 minutes
6. Most require no refrigeration
7. None or one reagent (a substance used in a chemical reaction to detect or produce other substances)
8. Minimal or no equipment required
9. Minimum technical skill

Most of the rapid test kits have 99% sensitivity and 98% specificity or even higher

However, HIV rapid tests also have a few disadvantages:

1. Small numbers for each test run
2. Requires quality Assurance/Quality Control at multiple sites
3. Test performance varies by product
4. Refrigeration required by some products, e.g., Capillus
5. Reader variability in interpretation of results

Specimens for HIV Antibody Testing: Usually diagnosis of HIV infection is based on the detection of HIV antibodies in the whole blood or plasma/serum or oral fluid of infected persons. When deciding which type of specimens (Table-3) will be used for same-day diagnostic rapid tests, it must be kept in mind that specimen collection should be compatible with a non-laboratory setting where rapid testing is most useful. Further, sample processing should be avoided in order to speed up the testing result. Several types of samples could be used for HIV testing which are discussed below.

a. Whole Blood Finger-stick Specimens: Most of the assays available on the market can use whole blood collected by finger stick. This specimen is easy to obtain, requires no special equipment, and can be performed by appropriately trained personnel. In addition, this method of specimen collection reduces the risk of infection for staff as no needles are used and there is minimal waste disposal. However, depending on the algorithm used by the country, more than one finger stick may be necessary to complete the testing required by the algorithm.

b. Serum and Plasma Specimens: Serum or plasma specimens can be used with rapid tests as well as with conventional HIV tests (ELISA and confirmation tests), but requires that venous blood be drawn by means of syringes and collection tubes (e.g., Vacutainers). In addition,

whole blood must be centrifuged to separate the serum/plasma from the red blood cells.

c. Oral and Other Fluids: Tests using oral mucosal transudate (oral fluids) also currently available and is a non-invasive and convenient method for screening.

Note: Clinical evaluations/external quality assessment (EQA) mechanism are required for whole blood specimen from finger-stick and saliva samples for HTS setup in Bangladesh.

Table 3. Specimen types and processing requirements⁶

Specimen type	Time to processing/storage/time to testing
<p>Venous whole blood Whole blood freshly collected by venepuncture.</p>	Use the specimen immediately.
<p>Capillary whole blood Capillary (finger-stick) whole blood is collected using a lancet and a specimen transfer device.</p>	<p>Use the specimen immediately, with the specimen transfer device recommended by the instructions for use. Note that the specimen transfer device may or may not include an anticoagulant. An anticoagulant contributes to accuracy. The hanging drop method, whereby blood is dropped directly from the fingertip onto the test device, is not recommended, as it does not ensure that the specimen volume is accurately added.</p>
<p>Serum Freshly collected whole blood is allowed to coagulate, and the serum fraction is collected away from the clotted red blood cells.</p>	Collect whole blood, mix by hand 4–5 times immediately, and let stand for the clot to form. Process within 30 minutes of collection. Store at 2–8 °C, and test within 5 days or as specified by the instructions for the assay to be used.
<p>Plasma Freshly collected whole blood is added to the recommended anticoagulant, such as EDTA, heparin or citrate. After centrifugation, the plasma is separated. Use only anticoagulants validated by the assay manufacturer.</p>	<p>Collect whole blood, mix by hand 8–10 times immediately, and centrifuge for up to 10 minutes. Process within 6 hours of collection. Store at 2–8 °C, test within 5 days or as specified by the instructions for the assay to be used.</p>
<p>Oral fluid Oral mucosal transudate (not saliva) is collected from the gums using a collection device.</p>	Use the specimen immediately, with the specimen transfer device recommended by the instructions for use.

⁶ WHO consolidated HTS Guideline 2015, Page-99

Dried blood spot (DBS)

Venous or capillary whole blood is applied to a filter paper by hanging drop or micro capillary. Whole blood is later eluted from the filter paper and used for the test procedure.

Store at 4 °C for up to 3 months, at –20 °C for longer.

The use of specific assays with DBS should be validated by the manufacturer. When the manufacturer has not validated their assay for DBS, the use of DBS is considered “off-label”, or unauthorized for returning medical results.

HIV testing for infants and children (below 18 months): In general, a child may be tested for HIV under a number of circumstances. These include:

1. shortly after birth for early diagnosis of HIV acquired prenatally;
2. for the purposes of individual diagnosis in a child who is ill (e.g. those presenting with an symptoms of AIDS);
1. in cases where a child has either been exposed or is potentially exposed to HIV e.g. through mother-to-child transmission, sexual abuse, sexual activity; exposed within a healthcare setting e.g. through contaminated needles or receipt of potentially infected (un-screened) blood) or through other means/blood product; and in orphans whose parents died of AIDS and have other indication of suspicion of HIV infection.

Early infant diagnosis (EID) refers to making of HIV diagnosis in infants and young children before 18 months of age. Research shows that EID followed by treatment has substantial positive impact on survival among HIV-positive children. The Children with HIV Early Antiretroviral Therapy (CHER) study conducted in South Africa demonstrated that, for infants infected at or around birth but with no signs of Immune-deficiency, early mortality was reduced from 16% to 4% by starting treatment early. EID gives an opportunity for early identification of HIV-exposed and infected infants (due to sub-optimal PMTCT service or lack of it) and early linkage to prevention for the exposed and care and treatment for the infected.

As antibodies are transferred from the mother to baby in-utero, conducting serological tests may be falsely HIV-positive. These antibodies persist in the infants for 12 to 18 months. Studies from both developed and developing countries show that the mean and/or median age at the time of sero-reversion ranges between 9 and 16 months of age. These data indicate that maternal antibody may remain detectable through the first 6 months of life but significant decay occurs by 9-12 months of age. Most HIV-uninfected children do not have detectable antibody at 12 months of age. While the majority of uninfected non-breastfed children will have cleared maternal antibody by the age of 12 months, a small percentage of children do not sero-revert until the age of 18 months and, in rare instances, even beyond. Therefore, virological tests are recommended for HIV diagnosis of the infant/children aged below 18 months. HIV serological tests are only recommended for HIV diagnosis of children aged above 18 months.

In infants with in utero HIV infection, HIV DNA and RNA can be detected in venous blood specimens obtained within 48 hours of birth. However, in infants with peripartum acquisition of HIV, HIV DNA

7 National Guidelines for the Prevention of Vertical Transmission of HIV and Congenital Syphilis 2013

and RNA are not detected in early venous blood specimens but become detectable at or after 1 to 2 weeks of age. By six weeks of age, almost all infants infected prior to, at, or around birth can be identified by virological testing.

Infants and children of HIV-infected mothers who continue to breast-feed are at ongoing risk for acquiring HIV-infection and hence negative virological test results are difficult to interpret if the infant is still feeding. Once breastfeeding is completely discontinued, it is considered that virological tests conducted at least six weeks after discontinuation of breastfeeding are indicative of true HIV-infection status, i.e. the window period for virological testing after stopping breastfeeding is up to six weeks.

For infants with an initial positive virological test result, it is strongly recommended that ART be started without delay and, at the same time, a second specimen be collected to confirm the initial positive virological test result.

HIV self-testing (HIVST)⁸: To date, three commercial HIV RDTs specifically labelled and packaged for self-testing are available; several others are in development. In general, these RDTs use oral fluid or capillary whole blood specimens. Development of assays for HIVST that meet regulatory standards is critical to both reducing the cost of and improving the quality of assays available for HIV self-testing. The positive result of self-testing to be confirmed by retesting of the client (whole blood/serum) using the approved HIV testing algorithm.

3.5 Testing Algorithm

There are two commonly used algorithms for rapid testing - serial / sequential and parallel testing. The testing algorithm is currently being in use in Bangladesh is serial testing.⁹ Three different rapid test kits are used. These are- Determine HIV-1/2, Uni-Gold TM Recombigen® HIV and First Response HIV -1-2-0 as denoted as A1, A2 and A3 respectively.

All HIV testing should be performed in accordance with the assay manufacturer's instructions for use (the package insert). In addition, SOPs and job aids has been adopted (see in annex-1) that help testing providers to minimize testing and reporting errors and, thus, to improve the quality of the testing results.

Recommended serial testing algorithm is portrayed below:

1. If this first test (A1) result is non-reactive, there is no need to perform a second test; the result is given to the client as HIV-negative.
2. If the first test (A1) result is reactive or positive, the sample to be tested again using a different brand of rapid HIV test (A2).
3. If the second (A2) test is reactive then another rapid test (A3) should be performed. If the result is reactive then HIV-positive result will be given to the client.

⁸ WHO consolidated HTS guideline 2015, page-101

⁹ National HIV Counseling Manual 2009.

4. a. If the second test is negative (A2 -), first and second tests (A1, A2) should be repeated. If on repeating both the tests turned positive (A1+A2+) then another test (A3) will be performed. On the other hand if both the test turned negative then report as “Negative”.
 - b. if the result remain same (A+, A2-) in the repeat testing, report HIV negative if A1 is a 2nd or 3rd generation assay; if A1 is a 4th generation assay, report the report the test result as HIV inconclusive (Indeterminate) and retest the client after 14 days
5. After doing A3, there could be total two different outcomes. If result is A1+ A2+ A3+, then report the result as positive. If the result is A1+ A2+ A3-, then consider the results as HIV inconclusive (Indeterminate) and retest the client after 14 days.

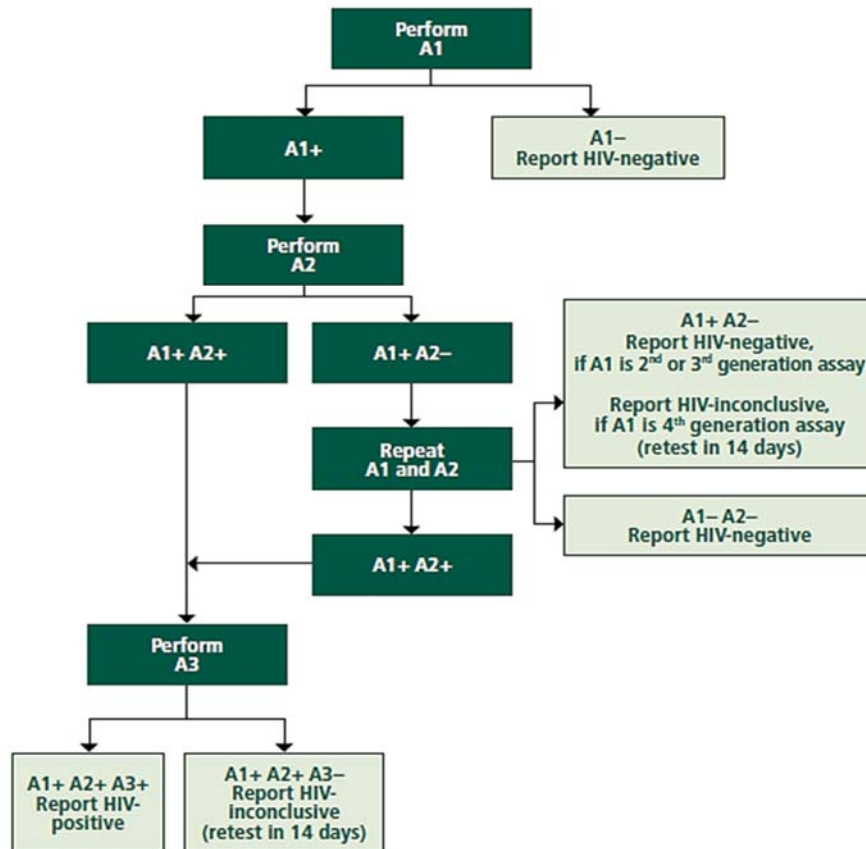


Figure 5. HIV testing algorithm

Detailed testing procedure is attached at the end of the guideline at annex.-

3.6 Understanding of HIV test results by HTS providers

HTS providers should have a good understanding of the meaning HIV antibody results in order to advise patients accurately on the interpretation of their test results.

A negative result indicates that no antibodies to HIV have been detected in the blood. This result can have one of several meanings:

1. The person is not infected with HIV.

2. The person may be infected; antibodies to the virus are yet to high up to be detected. Depending on the risk behavior and exposure (by using risk assessment tool), the person may said to be within the window period depending and advised to test after 2 weeks.

A positive result indicates that antibodies to HIV have been detected in the person's characteristics blood. This result means the person has been infected with HIV.

Indeterminate result: If the result is indeterminate, review the risk factors & test quality (including verifying reagents). If risk factors/ behaviors are present, request the client to repeat the test after 2 weeks.

False positive results: Currently available HIV antibody tests are extremely sensitive and false positive rates are appreciable, particularly in low prevalence populations. A false positive on one assay is unlikely to also test positive on the second assay. A false positive on an ELISA or rapid test in persons may occur due to several reasons as given in table below.

False negative results: A false negative result reports that the sample is not HIV infected when in fact it is infected. The most common reason for a false negative HIV antibody result is that the patient is recently infected with HIV and is currently within the window period. Therefore accurate HIV risk assessment during the period is essential. Conducting detailed risk assessment is an important aid to diagnosis as it may identify significant exposure risks that occur within the window period.

Table 4. Common causes of false results in HIV serological assays¹⁰

1.	
Biological error	
1.	Ongoing seroconversion
2.	Divergent HIV strain
3.	Inhibitory factors in specimen
Human error	
1.	No specimen or insufficient specimen added
2.	Too much buffer added
3.	Test kits stored outside of recommended storage conditions (either too hot or too cold) during transport or storage, leading to denaturation of reagents or test devices
4.	Use of expired reagents or test devices
Manufacturing error	
1.	Manufacturing defects due to lapse in quality management system
2. Potential causes of false-reactive (positive) test results, irrespective of assay format	
Biological error	
3.	Non-specific IgG binding Cross-reactive antigens Contaminating proteins in specimen
Human error	
4.	Test kits stored outside of recommended storage conditions (either too hot or too cold) during transport or storage, leading to denaturation of reagents or test devices
5.	Over-interpretation of weakly reactive test lines on visually read assays

¹⁰ WHO Consolidated HTS Guideline 2015, page-97

Manufacturing error

1. Manufacturing defects due to lapse in quality management system

Conditions/diseases that may cause false-reactive (positive) test results:

A. HLA cellular antigens cross reacting in persons with:

1. Rheumatoid arthritis
2. Multiple sclerosis
3. SLE
4. Type 1 diabetes mellitus
5. Addison's disease
6. Spondylitis
7. Chronic hepatitis
8. Malignant cancers
9. Severe kidney disease

B. and in persons who had a:

1. Flu shot within the past 30 days;
2. Gamma globulin injection
3. Recent transfusion or organ transplant

Window period of HIV infection: The window period represents the period of time between initial infection with HIV and the time when HIV antibodies can be detected in the blood stream by currently available diagnostic tests. During this period, HIV replicates in the target cells, the subject is highly infectious and may be symptomatic but the patient's blood sample will test negative for HIV antibody. The window period can last up to 12 weeks and may vary between different assays using different methodologies or due to different type of HIV.

Situations when HIV antibody assays cannot be used to diagnose HIV infection: There are recognized clinical situations in which HIV infection cannot be diagnosed by standard HIV antibody assays. Two such situations include:

1. acute HIV infection, and
2. diagnosis of HIV in the newborn (Note: For children younger than 18 months of age a positive virological test for HIV or its components (HIV-DNA or HIV-RNA or ultrasensitive HIV p24 antigen) confirmed by a second virological test obtained from a separate specimen taken between 6-8 weeks of age). (*Refer to Early Infant Diagnosis chapter in National PMTCT guideline*)

3.7 Retesting

Retesting refers to using the same testing algorithm on a second specimen from the same individual. Supplemental testing refers to further testing of the same specimens with additional assay(s) to obtain more information.

Retesting of individuals who test HIV-negative: The vast majority of individuals do not require retesting to verify an HIV-negative status, particularly in the absence of any ongoing risk. However, it

is important to accurately identify individuals who test HIV-negative and may require retesting in certain circumstances.

HIV-negative individuals with ongoing risk: Certain individuals who test HIV-negative warrant retesting:

1. People from key populations
2. People with a known HIV-positive partner
3. People with known recent HIV exposure
4. Pregnant and breastfeeding women in high incidence/prevalence settings
5. Individuals seen for a diagnosis or treatment of STIs
6. TB patients with a possible recent HIV exposure or who are at higher risk for HIV
7. exposure
8. Outpatients with clinical conditions indicative of HIV infection
9. Individuals taking PEP or PrEP (pre exposure prophylaxis)

HIV retesting is recommended preferably six monthly or at least once yearly for key populations who have ongoing risk behavior.

Retesting clients with HIV-inconclusive status: In alignment with WHO recommendation, ASP also recommends that clients with HIV-inconclusive status be retested after 14 days in order to:

1. Rule in seroconversion, if HIV reactivity evolves to concordant between A1 and A2, that is A1+; A2+
2. Rule out seroconversion, if HIV reactivity remains unchanged, with likely non-specific false-positive reaction for A1 and A3 (the negative predictive value for A2 will be very high)
3. Rule out specimen mix-up, particularly if a unique client identifier and consecutive specimen identifiers are not assigned, or
4. Rule out random error, either user/operator error or test device error.

If the HIV status is remains same upon retesting, then the individual should be considered HIV-negative. If HIV status is not the same upon retesting, the individual or the specimen may be referred for additional testing at a higher-level facility.

Retesting to verify HIV-positive diagnosis before initiating care or ART¹¹: To ensure that individuals are not needlessly placed on life-long ART (with potential side-effects, waste of resources, psychological impact of misdiagnosis), in alignment with WHO recommendation, ASP also recommends that all individuals be retested to verify their HIV status prior to enrolling in care and/or starting ART.

Key recommendation for retesting before initiating ART: Retest all clients diagnosed HIV-positive with a second specimen and a second operator using the **same testing strategy and algorithm before enrolling** the client in care and/or initiating ART, irrespective of whether or not ART initiation depends on CD4 count.

11 WHO consolidated HIV testing guideline 2015, page-111

Caution in Retesting people 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, particularly on assays using oral fluid, 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.

3.8 External Quality Assessment of HIV Rapid Testing

External quality assessment (EQA) is a way to evaluate the integrity of the entire laboratory testing process, and aims to educate and develop performance in quality assurance (QA) issues. The purpose of EQA is to assess the operations and performance of an HIV testing site by an external agency or personnel. There are three major EQA methods – a. Proficiency testing (PT) – Proficiency panel may be used during on-site visits, b. On-site evaluation, which is sometimes referred to as on-site monitoring visits or audits and c. rechecking or retesting of specimens.

In Bangladesh commonly used method is “retest of specimens” as External Quality Assessment procedure /method. Each HTS site need to send all positive samples and 3-5% of the negative samples for EQA in Government Designated National Reference Laboratory. In this process already tested samples will be randomly selected for retesting at Reference Laboratory. Samples [Dried blood spot (DBS) or serum] from each HTS site has to be preserved and sent periodically to the designated Reference Laboratory for retesting.

All positive samples and 3-5 % of negative samples will be sent to the reference laboratory for “Retesting” by ELISA and WB/LIA periodically from each HTS site.

CHAPTER FOUR: HIV PRE TEST AND POST-TEST SERVICES

1. Introduction
2. Key Components of HIV Testing Services
3. Key Attributes of an Efficient HTS Provider
4. Pre-test information in HTS
5. Counseling in HIV Testing Services
6. Post-HIV test counseling
7. Partner disclosure counseling
8. Counseling Ethics
9. Counseling Supervision and Support

Key Messages

10. The key objective of HIV Counseling includes to prevent HIV transmission by providing information about transmission risks, testing and provide psychological support to people who are infected with and affected by HIV as well as support them in treatment adherence.
11. Different types of counseling include HIV Pretest information, Post-test Counseling, Ongoing Counseling for people infected/affected by HIV and treatment adherence counseling.
12. Disclosure has a number of potential benefits for the individual including increased opportunities for social support, improved access to necessary medical care including antiretroviral treatment, increased opportunities to discuss and implement HIV risk reduction with partners, and increased opportunities to plan for the future.
13. WHO has defined five key components—the “5 Cs”—consent, confidentiality, counseling, correct test result, connection/linkage to care, prevention and treatment, must be respected and adhered to by all HIV Testing service providers.
14. Effective counseling session should include ample time, acceptance, accessibility, informed consent, consistency, accuracy and confidentiality.
15. A good counselor should have genuineness, positive regard, cultural sensitivity, believe in client and be a good listener, patient and knowledgeable.
16. Basic communication skill of a HTC counselor includes attending and listening skills, paraphrasing, reflecting emotions, using an appropriate language level, non-verbal behavior, questioning skill, using silence and immediacy.
17. A code of ethics outlines the fundamental values of counseling. HTS providers should have knowledge about these values to maintain professional relationship with their clients.
18. Counselling supervision and support is important to maintain accountability between and among those who offer services as counsellor to the beneficiaries.

4.1 Introduction

HIV information is a key component for HIV testing Services (HTS) is used to embrace the full range of services that should be provided together with HIV testing – counselling (pre-test information and post-test counselling). The rapid expansion of care and treatment services has increased the need of counseling for the people living with HIV. Different groups of population require different approaches for increasing access to available care and treatment services.

Attaining the UN 90–90–90 targets depends on the first 90 – diagnosing 90% of people with an HIV infection.¹² Worldwide an estimated 13 million people on ART but still many people needing care and treatment remain undiagnosed. Successful linkage from diagnosis to prevention, treatment and care services is also essential to reach the second and third 90s – that 90% of HIV-positive people who have been diagnosed are on ART and that 90% of people with HIV receiving ART have achieved viral suppression.

Receipt of an HIV diagnosis empowers individuals to make informed decisions about HIV prevention, treatment and care that will affect both HIV transmission and an individual’s health and survival. Therefore, linkage to appropriate services following diagnosis should be regarded as a key component of effective and comprehensive HTS. This chapter discusses essential services prior to HIV testing as well as post-test services. Post-test services are given for the individuals who have HIV-negative result, HIV-positive result and an inconclusive HIV status.

During post-test session, the importance of linkages to prevention, treatment and care is explained, and innovative approaches to improve successful linkages are explored.

4.2 Key Components of HIV Testing Services

WHO has defined five key components—the “5 Cs”—that must be respected and adhered to by all HIV Testing service providers. These components are:

¹² UNAIDS. ‘90-90-90: An ambitious treatment target to help end the AIDS epidemic’. 2014

Consent: People being tested for HIV must give informed verbal consent to be tested. They must be informed of the process for HTS, available services, and their right to refuse HIV testing. Depending upon the context, written consent could be taken. Mandatory or compulsory (coerced) testing is never appropriate, regardless of where that coercion comes from: health-care providers, partners, family members, employers, or others.

Confidentiality: Testing services must be confidential, meaning that the content of discussions between the person tested and the service provider as well as the test results, will not be disclosed to anyone else without the consent of the person tested.

Counseling: Testing services must be accompanied by appropriate and high-quality pre-test information or counseling, and post-test counseling. Supportive supervision and mentoring mechanisms should be in place to ensure the quality of counseling services.

Correct test results: Trained and certified HTS providers should strive to provide high-quality testing services so that correct test results are ensured. Designated health care professional will be responsible for ensuring the quality of HIV testing services at periodic interval while using prescribed tool. Certain proportion of HIV test samples will be retested as part of external quality assessment (See detail in chapter 3).

Connection/linkage to prevention, care and treatment: Connections to HIV prevention, treatment and care and support services should be supported through concrete and well-resourced patient referral, support, and/or tracking systems.

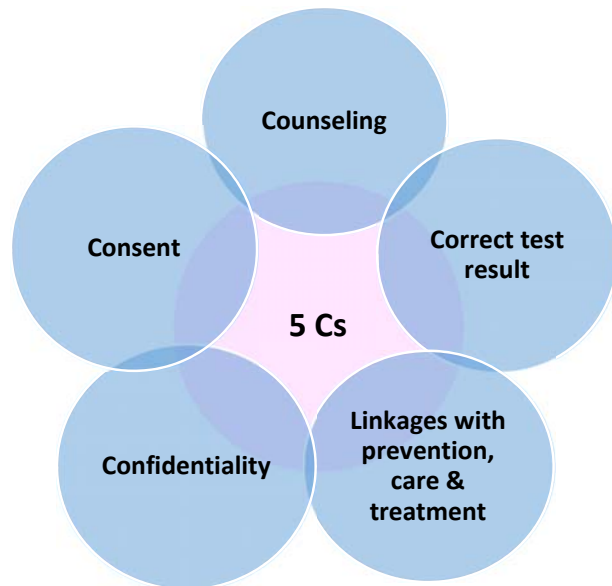


Figure 6. Five Key Components of HTS

4.3 Key Attributes of an Efficient HTS Provider

Essential attributes of an efficient HTS provider are as follows:

Maintaining confidentiality: Always respect the confidentiality of what is disclosed to HTS provider. Lack of confidentiality will make a mockery of the whole process of HTS.

Genuineness: A genuine relationship between service provider and client is the basis of successful service delivery.

Unconditional positive regard: Sensitivity, respect, friendliness and consideration are essential qualities for building an entrusted relationship. Showing personal warmth is basic in any relationship.

Listening: Listening involves attending to the client’s verbal and non-verbal messages. The way of provider’s listening, plays a big part in encouraging or discouraging a client to keep talking.

Believing the client: Provider needs to be able to communicate to the client that counselor believes him or her. As a client it is very comforting to realize that someone understands how the client is feeling.

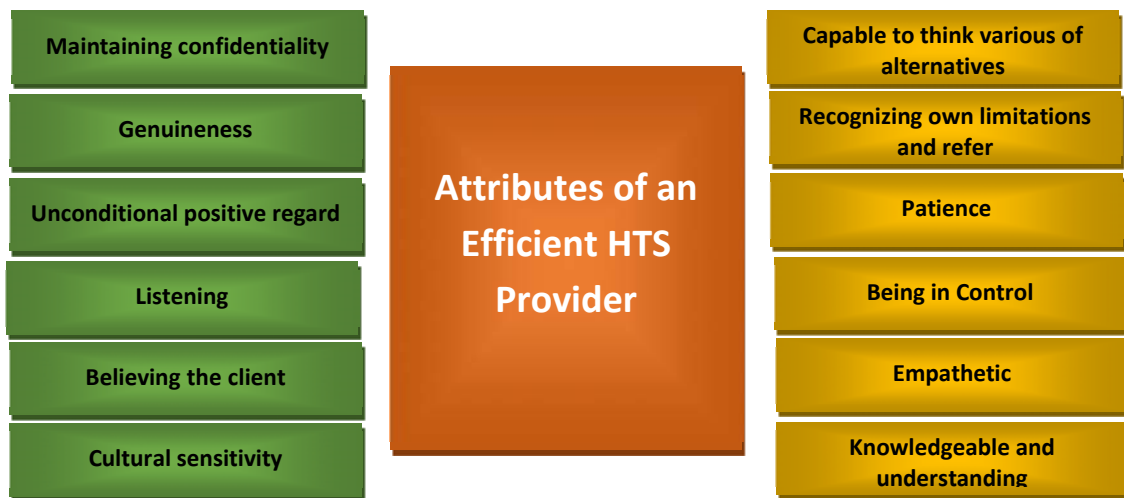


Figure 7. Attributes of an effective HTS provider

Cultural Sensitivity: HTS provider should respect the client’s culture and belief and be sensitive to cultural context and traditions. Culture shapes people in the way they do and react to things. Acknowledging differences, exploring beliefs and asking questions are important to increase understanding of cultural context.

Capable to think of various alternatives: HTS provider will assist client’s thinking for various alternatives available to them and work with them to consider the advantages, disadvantages and implications of each alternative.

Recognizing own limitations and refer: Provider needs to have self-awareness and honesty to acknowledge his/her limitations in regards to skills or ability and they should refer their clients to other experts if necessary.

Patience: Counselor must have patience to go along with client’s pace. Client may take longer to open up or discuss about some issues especially when that includes a sensitive topic or they may take time to make sure that they can trust the counselor.

Being in control: Provider need to stay focused and should not wander around many topics at the same time. Losing focus can easily happens when the counselor get stuck in the story instead of the issues of concern pertinent to a specific client.

Empathetic: This is the ability to see the problem as the client sees it yet at the same time standing back and objectively observing what is happening with the client-HTS provider relationship.

Knowledgeable and understanding: It is essential to have accurate and up-to-date knowledge. HTS provider should be well informed about the field they work within, including the services and resources available to their client group.

4.4 Pre-test information in HTS

Using HIV rapid diagnostic tests (RDTs), most people receive their confirmatory HIV test result often on the same day. Depending on type of clients, HIV testing approach, service delivery conditions and resources, pre-test information could be provided through individual or group information sessions. Individual risk assessment and individualized counselling before HIV testing is important for clients at high risk of HIV infection. When children and adolescents receive HTS, information should be presented in an age-appropriate way to ensure comprehension. Educational materials e.g. leaflet, brochures on HTS could be distributed to the clients for improving understanding about HIV transmission and prevention. Informed consent to the test either verbally or written, whatever necessary depending upon situation should always be obtained individually. Essential information provided during pretest session are captured in box below.

Offering or recommending HIV testing to a client or a group of clients includes clear and concise information on:

19. basic information on HIV transmission and prevention
20. window period related to last risk exposure
21. benefits of HIV testing including testing procedures
22. meaning of an HIV-positive and an HIV-negative result
23. the services available in case of an HIV-positive diagnosis, including availability of ART
24. a brief description on prevention options and encouragement of partner testing
25. maintenance of confidentiality of information provided by the client and test result
26. client's right to refuse testing and declining testing will not affect the client's access to HIV-related services or general medical care
27. opportunity to ask the provider additional questions
28. provision of voluntary and fully informed verbal consent for testing

29. in case of pregnant women information should be provided on syphilis, HBV and HCV and encourage testing

30.

Integration of TB screening in HTS: Tuberculosis (TB) is the most common presenting illness among people with HIV. On the other hand, the burden of TB cases is high in Bangladesh. So, it is essential to support intensified tuberculosis case finding at HIV testing facilities. It is fatal if undetected or untreated and is the leading cause of death among people with HIV, responsible for about one of every four HIV-associated deaths. Early detection of TB and prompt linkage to TB treatment along with ART can prevent these deaths. HTS provides an important opportunity for intensified TB case finding and, thus, early detection and treatment of TB.

4.5 Counseling in HIV Testing Services

HIV and AIDS Counseling is confidential communication between a client and a service provider aimed at enabling the client to take personal decisions relating to HIV and AIDS. The counseling process includes the evaluation of personal risk of HIV transmission, the facilitation of preventive behavior and evaluation of coping mechanisms when the client is confronted with a positive result. Through this confidential communication counselor also helps PLHIV for psychological, social, physical and spiritual well-being so that they live positively with hope.

Counseling can be provided through different service delivery mode:

Individual Counseling: It is one-to-one and face-to-face consultation between a counselor and a client. In this kind of arrangement, the counselor attend a client in a private set-up where the client can share his or her thought feeling and behavior in detail with assurance of confidentiality.

Couple Counseling: This type of counseling is needed in case of HIV positive couple when various psychological counseling issues are associated e.g. trauma arising from broken entrusted relationship, fear, blame, conflict, separation, impending violence etc. Couple counseling may often be integrated with individual counseling.

Family Counseling: It involves counseling regarding care and support to be provided to the family members. Usually family counseling is provided as an extension of individual or couple counseling for addressing stigma and discriminatory attitudes and practices.

Group Counseling: It involves a group of individuals with similar issues, problems, needing similar psycho-social support etc. are counselled in a group by a counselor. Group counseling help the clients to improve understanding, enhance self-esteem, bring back to normal, feel hopeful, cared, and valued.

Tele-Counseling: Tele-counseling involves a client and a counselor engaged in a therapeutic relation over telephone. Although, it is said that tele-counseling involves some sort of crippled form of communication (due to limited non-verbal cues), its importance is never questioned. Tele-Counseling help minimize the accessibility barrier (e.g. distance, stigma) and add convenience to the clients.

4.6 Post-HIV test counseling

Post-test counseling is done primarily to ensure that individuals understand the meaning and implications of their test results. If the client tests positive for HIV antibodies, post-test counseling

helps client to better understand the result, to mitigate immediate psychological reactions e.g. anger and fear, and to minimize suicidal risk as well as address perceived stigma and discrimination associated with the disease. Suicidal threat poses significant challenge to counselors. So, it is important to conduct suicidal risk assessment if it is indicated by the client.

4.6.1 Steps to follow for providing HIV-negative results

1. Cross-check result against client file. This should be done before the HTS provider meets with the client, to ensure that the client-specific result is provided.
2. Be aware of the way you call client from the waiting area. An HTS provider may unintentionally convey result to clients and others in the waiting area through verbal and non-verbal behaviour when calling client to receive result.
3. When the client is ready, provide results to the client in person to ensure that appropriate person receives the result, confidentiality is protected, client adequately understands the results and receives sufficient support.
4. Check for possible exposure in the window period. A client who has had an exposure risk that necessitates a retest.
5. Reinforce information on HIV transmission prevention strategies and personal risk reduction plan.

Key considerations for post-HIV test counseling

6. An explanation of the test result and reported HIV status;
7. Education on methods to prevent HIV acquisition and provision of male or female condoms, lubricant and guidance on their use;
8. Emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couples testing services;
9. Referral and linkage to relevant HIV prevention services, including voluntary male medical circumcision (VMMC) for HIV-negative men, PEP, PrEP for people at substantial ongoing HIV risk;
10. A recommendation on retesting based on the client's level of recent exposure and/or ongoing risk of exposure (see next section);
11. An opportunity for the client to ask questions and request counselling.

4.6.2 Retesting during the window period

In many settings post-test counselling messages recommend that all people who have a non-reactive (HIV-negative) test result should return for retesting to rule out acute infection that is too early for the test to detect – in other words, in the window period. However, for most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary unless continuous risk exposures are indicated.

4.6.3 Detailed steps to follow when providing HIV-positive results

1. Begin the post-test session by asking how the client has been feeling since he or she had the blood sample drawn. Congratulate the client for returning or waiting for the results.
2. If the client is known to have a history of drug or alcohol use, assess whether he or she is sufficiently alert and coherent to receive the result. It is not uncommon for individuals who are awaiting results to manage their anxiety by self-medicating.
3. When the client is ready, let him or her know the test results in a neutral tone of voice and wait for the client to respond before proceeding. Say, “Your test result was positive. That means you are infected with HIV.”
4. Give the client time to absorb the information before proceeding. Make sure that he or she has understood the test results and absorbed the information mentally and emotionally. A prolonged silence or no response could be due to shock, denial, or helplessness. Check to see if the client understands the result: “Can you tell me what this means for you?” You may also want to ask,
5. “I’m wondering what you’re thinking or feeling right now...” Often, however, clients will not be able to tell you what they are feeling and may instead simply react in one of the following ways mentioned in the Managing Client Emotional Responses
6. Let the client talk about his or her feelings. Then gently review with the client the exposure risks that he or she reported during Pretest Information. The client can also be reminded of the precautions taken during blood collection to ensure that the blood sample was not wrongly labeled.

4.6.4 Managing emotional responses of client

1. **Crying:** If the client breaks down and starts crying, it is important to let them cry. Give them space to ventilate the feelings. Ensure that it is okay to cry.
2. **Anger:** The client might start swearing or exhibit outbursts of anger. Do not panic, stay calm and give the client space to express their feelings. Acknowledge that their feelings are normal and let them talk about what it is making them angry.
3. **No response:** This could be due to shock or denial or helplessness etc. Check that the client understands the result. Be on the alert for suicidal thoughts.
4. **Denial:** This could be verbal or non-verbal. Counseling should acknowledge client’s difficulty in accepting the information. Let them talk about their feelings. Link back to risk assessment done in the pretest session where the client report exposure risk. This may help the Client to accept the result at cognitive level.

4.6.5 Clients who disbelieve their negative test results

Many clients find it difficult to believe an HIV test is actually negative, especially if they have engaged in high-risk behavior in activities that they feel are wrong. It is important to clarify whether the client has an undisclosed HIV risk or is continuing to engage in risky behavior. Sometimes this is why people find it hard to accept an HIV-negative result. If reassurance does not reduce anxiety and the client repeatedly asks to be retested, consider referring the client to a mental health specialist for follow-up treatment and shift the focus of counseling from a discussion of HIV and its symptoms to a discussion of the impact of worry on the client’s life.

4.6.6 Counseling after an HIV-indeterminate test result

An indeterminate HIV test result is confusing. It either means that the person is newly infected and has just begun to produce HIV antibodies, or that something else in his blood causes a partially positive test by mistake. In case of an indeterminate result, the counselor should give the client a clear explanation of what such a test result means. The period of uncertainty following an indeterminate test result may be three months or even longer. It is important for the counselor to stress the essential information related to the prevention of transmission: sexual activity, drug use, donation of body fluids or tissues, and breastfeeding.

4.6.7 Ongoing Counseling for people affected by HIV

The chronic and progressive natural history of HIV infection means that the psychosocial issues confronting both infected and affected individuals change throughout the course of the illness. In addition to issues directly related to HIV, patients may present with a range of psychosocial problems that are pre-morbid or only indirectly related to HIV. HTS provider must work with multiple clients who present a range of problems that vary across the disease continuum.

4.6.8 Treatment adherence Counseling

Patients are confronted with many difficulties when required to take medication. Those taking medication for HIV, TB, STI, or hepatitis in particular must deal with many psychological, physical, and practical barriers to treatment adherence. Non-adherence can lead to inadequate suppression of bacteria and, in the case of HIV, increased viral replication. Counseling for treatment is provided to improve the patient's knowledge of both the disease and the medications and their side-effects. Counseling helps the patient set goals, develop positive beliefs and perceptions, and increase self-efficacy in maintaining treatment.

4.7 Partner disclosure counseling

Providers should be aware of the impact that HIV can have on a client's life. When a client tells a partner about the infection, the partner's reaction can cause problems. Providers need to minimize these kinds of problems by ensuring confidentiality and by ensuring that clients agree to help with partner referral voluntarily.

4.7.1 Facilitating decision making

Counseling is not telling people what to do. Rather it is encouraging them to think through the advantages and disadvantages of options and helping them come to an informed decision. It also is about helping them overcome the barriers that they may encounter. A counselor can assist clients in considering the benefits of disclosure to them as individuals and to their relationships with others, as well as its negative consequences. Because disclosure is a very private and individual decision, all relevant personal circumstances should be considered.

The advantages and disadvantages of disclosure of HIV status is portrayed in the table below:

Table 5. Advantages vs disadvantages of disclosure or non-disclosure

Option	Advantages	Disadvantages
Disclosure of HIV/STI status	<ol style="list-style-type: none"> 1. Burden of secrecy is lifted 2. Emotional support is available 3. Health care and medications are more accessible (no need to 4. hide them) 5. Symptoms and worries can be discussed freely 6. (If disclosing to spouse or partner) Safer-sex and family-planning choices can be discussed freely 7. Reasons for specific activities (e.g., breast-feeding, replacement feeding) can be shared freely 8. Partner can be tested and treated 9. Other 	<ol style="list-style-type: none"> 10. Person is distanced or rejected outright by partner, 11. spouse, friends 12. Job loss is possible* 13. Children are shunned in school* 14. Promiscuous label is attached to person 15. Person is discounted because of fatal illness* 16. All signs or symptoms are assumed to be HIV-related* 17. Others fear for their safety around the person* 18. Person is at risk of mental or physical harm 19. Other 20. Associated with HIV 21. discrimination and stigma
Non-disclosure of HIV/STI status	<ol style="list-style-type: none"> 22. Status is kept secret 23. Status quo (“normalcy”) or current situation is maintained 24. Person is protected against stigma, isolation, rejection, loss of income, violence, blame for change in 25. social status 26. Person is not prevented from having children in the future 27. They are not forced to seek 28. medical care that they do not need 29. Other 	<ol style="list-style-type: none"> 30. Secret is a burden 31. Anxiety builds because of fear of involuntary disclosure 32. Social support is inaccessible 33. Person is isolated 34. Sexual partners are put at risk 35. Access to medical care is delayed 36. Trust of children, family is lost 37. Other

4.7.2 Steps of Disclosure

The counselor will facilitate disclosure of HIV status while ensuring non-coercive environment as follows:

Step 1: Open with an open-ended question, e.g. “Many clients I give results to feel it will be difficult or not possible to tell their partner they have HIV. What difficulties do you think you will have?”

Step 2: Listen and list. List the concerns of the client. Use reflection of feeling and paraphrase to demonstrate to the client that the counsellor understands his or her feelings and concerns.

Step 3: Challenge the client’s thinking. Review the client’s reasons gently one by one and ask a counsellor challenge question. Challenge questions are designed to assess the validity of the client’s fears, gain more information, and challenge the client to think realistically and evaluate perceived threats and negative consequences, e.g., in response to the fear of violence from the partner, “What has happened in the past to make you believe your partner will be violent?”

Step 4: Role Play. Role-play rehearsal is again important if the client will be making the disclosure himself or herself. All of the planning discussed for self-disclosure should be discussed before the session with the client.

As the partner may have questions for the counsellor during the session, it is important that you clearly plan with the client in advance what can and cannot be disclosed during the session. It may be a good idea to document the permissible and non-permissible disclosure items in the Counseling record form agreement.

4.7.3 Disclosure options

Another powerful way to support decision making around disclosure is to offer the client a variety of disclosure options (see box). Often clients feel that they cannot make the disclosure themselves; while others feel it would only upset their partner to hear the news from someone other than themselves.

Box.....: Partner disclosure options	
38.	Client discloses to partner
39.	Client brings partner/family to clinic and discloses with counselor present
40.	Client brings partner/family to clinic and counselor discloses in front of client
41.	Client authorizes counselor to disclose without the client
42.	Client discloses to a key trusted family or community member who discloses to partner
43.	Client hands out referral cards to sexual contacts

4.8 Counseling Ethics

HIV/AIDS is a highly emotive and sensitive subject for both individuals and societies and pose complex ethical issues for counselors/ HTS providers and other health care workers. The ethical responsibility

of counselors/ HTS providers is to provide care to their clients, but they also have obligations (often reflected in legislation and policies) towards others. Often ethical dilemmas will arise when there are conflicts between the interests of the client and those of the community.

Code of Ethics for HTS providers: A code of ethics outlines the fundamental values of counseling. HTS providers should have knowledge of these values to help maintain a professional relationship with their clients. There are standards for HTS providers and clients to follow so that this is achieved and at the same time integrity, impartiality and respect for the two parties is maintained.

4.8.1 Purpose and responsibility for code of ethics

1. Purpose of counseling code of ethics

The code of ethics outlines the fundamental values of counseling, namely, integrity, impartiality and respect. The purpose of the counseling code of ethics is to:

1. establish and maintain standards for HTS providers; and
2. Inform and protect members of the public who seek and use their services.

3. HTS provider's responsibilities to the client

1. **Client safety:** HTS providers should take all reasonable steps to ensure that the client suffers neither physical nor psychological harm during counseling.
2. **Client autonomy:** HTS providers are responsible for working in ways that promote the client's control over his or her own life and respects the client's ability to make decisions and change in the light of his or her own beliefs and values.
3. **Contracting:** HTS providers are responsible for communicating the terms on which counseling is being offered, including availability, the degree of confidentiality offered, and their expectations of clients.
4. **Competence:** HTS providers should monitor actively the limitations of their own competence through counseling supervision or consultative support, and by seeking the views of their clients. It is an indication of the competence of HTS providers when they recognize their inability to counsel a client and make appropriate referrals.

5. Responsibility to self as a HTS provider

Counselor/HTS providers have a responsibility to themselves and their clients to maintain their own effectiveness, resilience, and ability to help clients. They are expected to monitor their own functioning and to seek help or withdraw from counseling, whether temporarily or permanently, when their personal resources are sufficiently depleted. HTS providers should receive basic counseling training before starting counseling, and should maintain ongoing professional development.

6. Responsibility to other HTS providers

A HTS provider who suspects misconduct by another HTS provider that cannot be resolved or remedied after discussion with the HTS provider concerned should implement a complaints procedure (if there is any) without unnecessary breaches of confidentiality.

7. Responsibility to colleagues, members of the caring professions, and the community

HTS providers should be accountable for their services to colleagues, employers, and funding bodies as appropriate. This should be achieved with respect to the client's needs. No colleague or member of the caring professions should be led to believe that a service is being offered by the HTS provider.

8. Informed Consent

All people taking an HIV test must give informed consent prior to being tested. Consent can be taken in verbally or written form. The key defining characteristics of informed consent are:

1. The client should be told sufficient details about what is being agreed to and any risks or implications involved.
2. The client should be capable of understanding what he or she is told (capacity is often defined in terms of age, intellectual capacity or psychiatric state).
3. In case of orphan or street children under 18 years with no legal guardian, the HTS provider can contact a child protection institute to take the custody of the child and thereby have that institute provide the consent.
1. The client should not be coerced in any way into giving consent that is they should not be forcefully persuaded or pressured by the HTS provider even though the HTS provider believes it is in their best interests to have an HIV test. When conducting research in a service setup, separate consent should be taken and the client should be clearly informed that non-consent for research would not affect their reception of service.

2. Medical Consent

Medical Consent can be given by the physician when a medical procedure is being performed on a person legally incapable of giving consent. And the physician reasonably believes that a medical procedure should be undertaken immediately and that there is insufficient time to obtain the informed consent of a person authorized to give such consent for the client.

3. Confidentiality

Consent to disclose an individual's HIV status to a third person e.g. referral agency, a health worker planned to be involved in a client's care, or the sexual partner of the infected person, should always be obtained. This is best to be written and should be noted on the medical/counseling record. Confidentiality should be upheld and no information or/and material heard, obtained or provided in the counseling relationship, concerning the client, should be given away without the permission of the client.

Shared confidentiality, which refers to confidentiality that is shared with others, is encouraged but it should also be based on client's consent). These others might include family members, loved ones, caregivers, trusted friends; referral to other services. This shared confidentiality is at the discretion of the person who will be tested.

If client confidentiality is breached, there can be ramifications in terms of psychosocial effects for the client and legal ramifications for the client and HTS provider. Stigma and

discrimination is a major concern, and can result in denial of access to medical care, breakdown of family and personal relationships, and even loss of employment.

4. Problem Solving Ethical Dilemmas

HTS providers need to be well informed about the Ethical and legal frameworks within which they conduct HTC. They also need to be equipped with the in confidence and skills to effectively deal with ethical dilemmas. Health care workers must be perceived as competent professionals, capable of discussing issues openly and confidently, while maintaining client confidentiality, and of acting fairly and compassionately.

4.8.2 Disciplinary Measures

All HTS providers and associated personnel should sign an oath of ethical conduct before they are allowed to work in HIV Testing Services. Disciplinary measure should be taken in cases of any violation of ethics in services. Measure to identify such violation should be in place (e.g. a system of confidential client feedback or report). When a violation of ethics is reported, the respected organization should discuss the matter in a small committee of unbiased and non-associated members. Such committee may include members from the same organization along with outside organizational member.

4.9 Counseling Supervision and Support

Counseling supervision is the working between a supervisor and a supervisee (HTS Provider). The objective of this alliance is to enable the supervisee to gain ethical competence. Therefore, supervision is for the protection of the client and for on-going accountability and professional development of the supervisee. It also includes troubleshooting support for the HTS service provider who does counseling for the client.

It is essential that all the HTS Providers should undergo a supervision process to ensure quality service to their clients. Supervision can be provided in a one to one individual form or in a group setting. Both forms have their own strength.

1. **Individual Supervision:** This is a one to one working alliance between a HTS Provider and a supervisor where the two meet together for some specified period of time to discuss practical and skill related issues encountered by the HTS Provider in his/her counseling practice. The supervisor devises an individualized strategy for ensuring troubleshooting and professional development of the individual HTS Provider.
2. **Group Supervision:** Group supervision is a working alliance between a supervisor and several HTS Providers in which each HTS Provider can regularly offer an account or recording of his/her work on it and receive feedback and where appropriate guidance from his/her supervisor and colleagues. Group supervision should enable each HTS Provider to gain in ethical competence; confidence and creativity so as to give his/her best possible service to clients.

Counselor Burnout: It is important to acknowledge that HIV Counseling can be stressful and entails giving a lot of oneself, not just in time and energy, but emotional in compassion, understanding and

hope. HIV prevention counselors, as well as other human service providers, encounter many life and death issues in attending to their clients that can affect them physically, mentally and spiritually.

Stress management and preventing burnout: Stress management refers to efforts to control or reduce the tension felt when a situation is perceived to be especially difficult or beyond one's resources. Heavy demand and high performance is expected of HTC.

Counselors should think about their network of colleagues, friends, family, and supervisor etc. to see how they can meet the following needs:

1. Sharing your work issues in a confidential manner
1. Obtaining feedback/guidance
2. Use supervision or peer support to discuss their concerns about the work
3. Developing professional skills, ideas, information
4. Venting emotions if you are angry, fed up, discouraged
5. Acknowledging feelings of distress, pleasure, failures.
6. Feeling valued by those you count as colleagues
7. Increasing your physical, emotional or spiritual wellbeing

Support groups for HTS service providers should be instituted and HTS service providers should also be given adequate time off when needed.

CHAPTER FIVE - TARGETED HIV TESTING SERVICES

1. Introduction
2. HTS for pregnant women
3. HTS for Female Sex Workers
4. HTS for People who inject Drugs
5. HTS for Men who have sex with Men
6. HTS for Couples and partners
7. HTS for Infant & Children
8. HTS for Adolescents
9. Vulnerabilities of Migrant Workers
10. HTS for other vulnerable population

Key Messages

8. All pregnant women should receive essential HIV and AIDS information at the first antenatal care contact and test facility to be available. If the woman is considered to be at high-risk of HIV transmission, she should be retested in third trimester.
9. According to WHO recommendation for developing countries mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should be counseled to exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life.
10. The key Behavior-Change Messages for sex workers include: condom use with their clients and other sex partners; Explain of the need for periodic HIV testing; Inform about PMTCT if any FSW is pregnant; Referrals to other service such as STI, RTI
11. It is important that service providers should recognize the complexity of behavior change in drug use context and recognize that simply providing information on the dangers of unsafe injection, information on how to avoid HIV is not enough.
12. HIV testing services for infants and children is very significant in order to enable more children to benefit from antiretroviral treatment, care, and support, and thus a better quality of life.
13. Couples and partners in antenatal care settings should be offered HIV testing services with support for mutual disclosure; couples and partners of HIV positive people and key population should be offered HIV testing services with support for mutual disclosure
14. HIV testing services should be routinely offered to all key populations in the community, closed settings such as prisons, and clinical settings
15. Community-based HIV testing services for key populations, with linkage to prevention, treatment and care services, is recommended in addition to provider-initiated testing and counselling

5.1 Introduction

During HIV Testing services, key population needs some special attention. They often engage in behaviors that are criminalized and stigmatized, creating barriers to accessing HIV prevention, care, and treatment services. The ability of HTS programs to make a real and lasting impact in preventing the spread of HIV and STIs will largely be determined by the service delivery environment.

5.2 Intervention for pregnant women

HIV infection used to be considered a disease that affects both men and women, in developing countries more than half of new infections are found in women. However, in Bangladesh, women share 28% of total reported HIV positive cases in 2018.¹³ Women are also the ones who are more affected by the disease from the social point of view, as they stay at home to care for family members, have less education and fewer involvements in productive work. HIV can be transmitted from mother to child during pregnancy, delivery or during breast-feeding.

Reducing HIV transmission from HIV-infected pregnant women to their infants requires a range of interventions beginning with HIV testing and counseling and including ART initiation and ARV prophylaxis for newborns, safer obstetric practices, counseling support for safer infant feeding, etc.

It is recommended to provide essential information about HIV infection and AIDS at the first antenatal care contact, to be sure that as many women as possible receive the information and are routinely offered HIV testing. This can be done through pre-test information session in groups/individual. Retesting will be done in 3rd trimester of pregnancy who turned out HIV negative at first ANC visit¹⁴. Retesting will also be done for pregnant women who tested HIV negative in 1st ANC but remained in window period.

Managing women who decline to test: If a woman refuses to get tested, service provider should explore the reasons of her refusal and support her in resolving any problems that kept her away from accepting testing. Some women may be afraid to get an HIV test, do not want to know their HIV status, or do not want to discuss results with their partner. Stigma and discrimination against pregnant or breast-feeding women who are known to be infected with HIV is a critical problem in many communities; Bangladesh is not an exception. Counseling women about the benefits to themselves and to their infant of knowing their HIV status can usually help to overcome fear of stigma and discrimination, and other barriers.

Counseling pregnant women who test positive for HIV: If a pregnant woman tests positive for HIV, service provider should discuss the following:

¹³ AIDS/STD Programme, Key note presentation, WAD 2018

¹⁴ National guidelines for the prevention of vertical transmission of HIV and congenital syphilis, 2013

1. the risk of mother-to-child transmission of HIV
2. the risk of being re infected and of transmitting infection to others (partner)
3. measures for the prevention of MTCT including infant feeding options (Ref.- National guidelines for the prevention of vertical transmission of HIV and congenital syphilis)
4. ART initiation and adherence

Counseling male partners: Men need information on how to prevent transmission of HIV to their female partners, particularly during pregnancy and breast-feeding. In all counseling contexts, especially when men present for HIV tests, counsellors should take the opportunity to ask if they have female partners and address HIV prevention strategies to reduce MTCT. Male partners of pregnant women should be explicitly warned about the risk posed to both his wife and child for their risk behaviors to get HIV infections.

5.3 Intervention for Female Sex Workers

Sex workers encompass a diverse group of people, so it is therefore difficult to generalize their behaviors and attitudes towards HIV prevention and care services. For example, they may be drug users, married women or men, transgender, students, unattached minors and may be of all genders (i.e. male, female or transgender). They may work temporarily as sex workers or full time. Effective HTC interventions need to recognize sex workers not only as sex workers, but also the other dimension of their lives as partners, wives or husbands. It is important for service provider to remain nonjudgmental while working with clients who are involved in sex work. While providing HIV prevention knowledge, condom skill and other risk reduction strategies. Adolescent sex workers in residence, hotels and brothels are usually under the control of pimps/older sex workers (Mashi) or hotel authorities and they are often not allowed to make HIV testing or using condoms for themselves.

1. According to National size estimation of key populations (2016), in Bangladesh the estimated population size of FSW is 92,572 (ranges between 82,884 and 102,260) where 36,593 SBFSW, 15,960 HBFSW, 36539 RBFSW and 3,479 BBFSW.
2. Behavioural data on FSWs have shown their high risk behaviours and vulnerability to HIV but relatively low rates of infection HIV prevalence was <1% and active syphilis rates were <5% among FSWs (IBBS 2017)

Counseling to prevent transmission can cover a range of strategies and activities to convey information and behavior-change messages. The objective is to provide knowledge about HIV transmission and ways to reduce risk of transmission (e.g.- safer sex practices, the use of condoms and lubricants, symptoms of STIs, and unsafe traditional practices or beliefs). Furthermore, counseling can play an important role in developing the communication and negotiation skills to enable them to negotiate safer sex practices successfully.

Assuring anonymity is important to encourage them to access the service in an environment where they can feel reassured of their activities. Satellite sessions can be organized for them who are unable to access the HIV testing and other sexual health services. In some settings, it can be helpful to integrate services with other health care and community services.

HIV prevention Counseling for sex workers

Things to remember during counseling for sex workers

1. Sex workers may need money urgently for pressing needs, leading them to neglect sexual health considerations (not using condoms, group sex, etc).
2. Clients of sex workers may be drunk or may not care about their own sexual health or that of others. Service providers should assess the sex workers' drug and alcohol use and consider them during counsel them
3. Clients may offer more money for unprotected sex, or pimps/Mashi/hotel authorities may encourage unprotected sex for more profit
4. Non-penetrative sex or other safe practices may be taboo
5. Condoms and lubricant may not be available, or too expensive or of poor quality.
6. Some sex workers may work informally or alone who have limited information
7. Sex workers cannot keep adequate supplies of condoms and lubricant because they might be viewed as evidence of illegal activities, or because there is nowhere to store them
8. Some sex workers negotiate from a disadvantaged position (e.g.- negotiations at street or in a place controlled by client, limiting the ability of the sex worker, etc)

The service provider should emphasize on the need of HIV testing for the sex workers during their discussion with them. Key issues are-

1. feedback on the risks associated with potential exposure in the window period
2. emphasis on safer sex and practice avoid sharing injecting equipment
3. encourage to undergo screening for HIV at least once a year.
4. providing emotional support and transmission reduction strategies and linkages to continuum of care for the clients newly identified with HIV

5.4 Intervention for People Who Inject Drugs (PWID)

PWID (People who inject drugs) are one of the key population group who inject drugs into their veins, muscle or under the skin. They usually do it in a group where a common practice is to use the same needle and syringe for injecting. Sometimes, they are not sharing needle/syringe but are sharing drugs by pulling drugs from the same ampoule or sharing other injection materials. If one member of the group has HIV infection, the infection would readily enter the other member/s. The chances of infection through the injecting route are much higher than sexual route. This one HIV enters into the circuit of PWID; the spread within the PWID community is rapid.

5. According to National size estimation of key populations (2016), in Bangladesh the estimated population size of PWID 29,626 (male- 28,670, female- 957) ranges between 26,186 and 33,067
6. Behavioural data on PWID have shown their high-risk behaviors and vulnerability to HIV, rate of HIV is highest among all key populations. As per IBBS 2017, HIV prevalence remains about 3.9% among the key population mostly in PWID; the prevalence is concentrated mainly in Dhaka city, among male PWID in A1 (old Dhaka) with 27.3% being HIV positive. This was a significant and steep rise compared to earlier years. Furthermore, HIV was not restricted to A1 but had spread to A2 (other part of Dhaka) where the HIV prevalence in male PWID was 8.9%. Taken together the HIV prevalence in this population group was 22% in all of Dhaka.

Counseling for PWID

1. Service providers working with PWIDs should have orientation of the different types of drugs, method of use, effects of drug use, intoxication, process of dependency, withdrawal and the pathways to recovery from drug dependency and issues related to relapse
2. They should have an understanding of signs and symptoms of pre-existing or drug induce psychological disorders
3. When assessing clients for drug use, service provider should pay close attention not only to signs of dependence but also to the harm arising from drug use
4. When assessing clients, only appropriately qualified service providers should make a diagnosis of dependence.
5. Service providers should avoid counseling when client is intoxicated.
6. PWID clients may have impairment in attention, concentration, memory, judgment and other cognitive functions. Therefore, service provider should avoid long sentences, should use simple language.
7. To get a clear idea of a client's drug use service provider needs to determine the following:
 1. what drugs a client currently uses;
 2. what drugs the client has used in the past;
 3. how the client has used these drugs, including the pattern of drug use (i.e. frequency of drug use, cocktail);
 4. what are the route of drug administration (i.e. intravenous, intramuscular)?
 5. whether the client is dependent on these drugs;
 6. how the client feels about his/her drug use and whether or not he/she wants to change his or her drug-use behavior.
8. To overcome reluctance to disclose drug or alcohol use the service provider should:
 1. maintain a non-judgmental attitude;
 2. acknowledge to the client that drug use can be difficult to talk about;
 3. assure the client that the consultation is confidential; and
9. Consider referral options, such as
 1. Drug and alcohol counseling
 2. Detoxification services
 3. Post-withdrawal interventions
 4. Opioid substitution therapy programmes
 5. Family therapy
 6. Positive peer support group
 7. PMTCT services

Access to HIV testing and Counseling: HTC programs have sought to affect changes in HIV and AIDS-related risk behavior among PWID. BCC approaches have a key role to play in increasing awareness of, and access to clinics and testing sites where HIV testing can be obtained. However, illiteracy level of PWID in Bangladesh is low and most of the time limited to primary level of education. Thus, outreach worker or peer educator can play a major role on HIV awareness and access to HTS. HIV testing services can also be provided in PWID hotspots through satellite session conducted by lay providers.

5.5 Interventions for Males having sex with males (MSM)

The term males having sex with males (MSM) was developed as an overarching term to cover all the different groups and sub groups of men who have sex with men.

Male-to-male sex puts men and their male or female partners at high risk for HIV infection due to transmission during unprotected insertive or receptive anal sex. Some MSM may be at higher risk due to multiple and concurrent partners, or overlapping risks such as drug and alcohol use which can impair judgement or reduce one's ability to negotiate and effectively practice safe sex.

MSM in Bangladesh

10. According to National size estimation of key populations (2016), in Bangladesh the estimated population size of MSM ranges between 85,569 and 101,695, MSW 22,698 and 29,777 (ASP 2016)
11. Behavioural data on MSM have shown their high risk behaviours and vulnerability to HIV but relatively low rates of infection with 0.3% HIV among MSM, 0.7% among MSW (ASP 2017)
12. MSM in Bangladesh are at increased risk for HIV infection due to sexual behavior, including low condom use, association with PWID, multiple sex partners etc.

MSM can include the following groups:

'Kothi' are feminized males who play the role of 'female' in their emotional, sexual and social interactions with other males. Kothi prefer to be sexually penetrated; some cross dress and/or use feminine make-up.

'Panthi', the name given by kothi, are the sex partners of kothi and are usually insertive partners in anal or oral sex. Most panthi will identify themselves as a "man" rather than panthi.

'Parik' are the male lovers of kothi, therefore, all parik are panthi, but not all panthi are parik of kothi.

'Do-parata' is MSM who practice insertive sex with kothi, as well as receptive sex with other panthi or even with kothi.

'Gays' identify themselves as westernized homosexuals, engaging in emotional and sexual relationships with other men; they are generally from an educated urban class.

'Bisexual' is someone who has sex with both men and women.

Transgender/hijra: Transgender is a broad term that designates somebody who does not fit clearly into "male and female" descriptions. The individual rejects the gender assigned to him or her at birth. Transgender is sometimes referred to as gender variant. The term transsexual refers to an individual who feels that his or her gender identity does not match the biological body he or she was born with or the gender he or she was assigned by society. Transsexuals can be referred to as male-to-female

(MTF) or female-to-male (FTM). And a variety of conditions that lead to atypical development of physical sex characteristics are collectively referred to as intersex conditions.

In Bangladesh, the transgender are known as “*hijra*”. “*hijra*” are those who identify themselves as belonging to a traditional *hijra* sub-culture and follow the guru-chela *hijra* hierarchy (Khan, S. I., et al., 2009).

MSM Risk of HIV Infection: The HTS service provider should explore the following factors during risk assessment of MSM clients:

1. Multiple sex partners
2. Unprotected anal sex
3. Hidden nature of MSM sexual relations
4. Unprotected vaginal sex with female partners
5. Unprotected oral sex with or without ejaculation
6. Use of psychoactive Drug

5.6 Couple and partners¹⁵

Participating in couples and partner HTS has a number of benefits. These include adoption of prevention strategies by the couple (for example, condom use, immediate ART, PrEP), safer conception, improved uptake of and adherence to practices for PMTCT as well as to one’s own ART (thus reducing transmission risk as well as morbidity and mortality). Partner testing is an efficient and effective way of identifying additional people with HIV, who also can benefit from treatment. Couples and partner HTS for the partners of women attending ANC.

Couples and partner HTS can be conducted in various settings, including ANC and community-based TB services, through home-based HTS, during premarital health visits and in couples’ HIVST (169, 195–197). People attending ART services can be encouraged to bring their partners to be tested. Couple and partner testing should also be a priority for people in key populations, including men who have sex with men. Programmes that particularly serve key populations should provide and encourage partner testing.

As with all HTS approaches, couples and partner HTS should be voluntary. Informed consent should be obtained from all individuals receiving HIV testing. Providers must be aware of the potential for intimate partner violence and should support people’s decisions not to test with their partners.

There are many potential benefits to supporting couples to test together for HIV infection and to mutually disclose their HIV status—most importantly, that together they can then make informed decisions about HIV prevention and reproductive health, including contraception and conception.

¹⁵ WHO Consolidated Guideline on HTS 2015

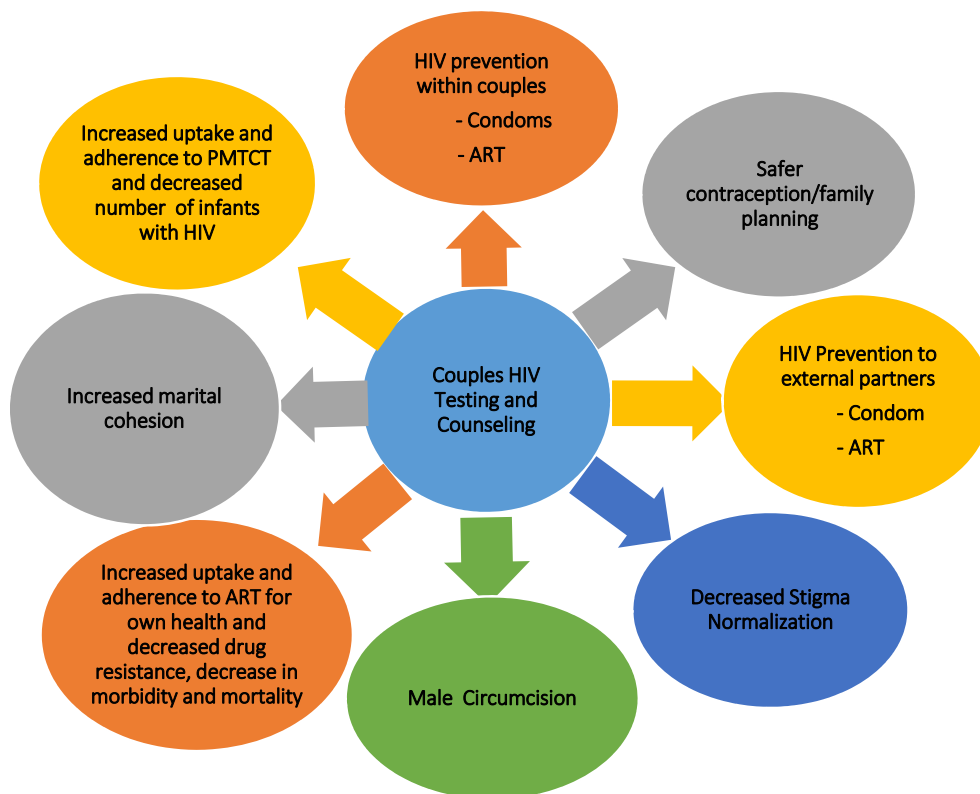


Figure 8. Potential benefits of couples HIV testing and Counseling¹⁶

5.7 Infants and children

Mortality is very high in the first year of life among infants infected with HIV who go untreated. In this period early HIV testing, prompt return of results and rapid initiation of treatment are vital. HIV testing for infants should be implemented with the aim of identifying as many HIV-infected infants as possible as early as possible.

For infants and children under 18 months, HIV infection can be diagnosed only by virological testing; maternal HIV antibodies remain in the infant’s bloodstream until 18 months of age, making test results from serological assays ambiguous. Virological testing using nucleic acid testing (NAT) technologies can be conducted using dried blood spot (DBS) specimens, which are collected at local sites and sent to centralized laboratories for testing. Several approaches can increase infant testing. Scaling up early infant diagnosis (EID) through task sharing with lay providers is one promising approach. HIV testing at the time of birth may improve linkage to treatment and reduce loss to follow-up; however, it is likely to be an effective public health strategy only in settings with a high proportion of

¹⁶ *Guidance On Couples HIV Testing And Counseling Including Antiretroviral Therapy For Treatment And Prevention In Serodiscordant Couples: Recommendations For A Public Health Approach, 2012*

deliveries taking place in facilities. In any case, this approach would miss infant infections that take place during breastfeeding.

For children 18 months of age and older (who were not breastfed or who have stopped breastfeeding at least six weeks earlier), standard HIV serological assays such as RDTs and EIAs can reliably determine HIV status. A negative serological test result for an infant does not completely exclude HIV exposure and infection, particularly when certain RDTs are used to test infants between four and 18 months of age, due to imperfect sensitivity during seroconversion for infection acquired postpartum through breastfeeding. During this time virological tests may be used to determine HIV infection.

There is a need for significant scaling-up of access to HIV testing services for infants and children in order to enable more children to benefit from antiretroviral treatment, care, and support, and thus a better quality of life. Most-at-risk young children and adolescents are unlikely to seek HIV testing and are more likely to be counseled and tested as a result of provider-initiated or caretaker-initiated testing. Given this context, issues of informed consent* and rights-based approach are of particular importance.

In general, the testing of infants and children occurs in a number of specific circumstances, including:

1. children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection including tuberculosis (if HIV prevalence in TB patients is low, HIV testing and Counseling would not be a priority);
2. HIV-exposed children or children born to HIV-positive women;
3. after birth, for early diagnosis of HIV;
4. diagnosis of an ill infant or child; or
5. upon admission to an orphanage, drug rehabilitation centre, or other similar institution

In cases where the child has been, or could have been, exposed to HIV through:

6. mother-to-child transmission;
7. sexual activity;
8. injecting drug use;
9. sexual abuse or rape;
10. exposure within a health-care setting (e.g., contaminated needle stick injury or receipt of potentially infectious blood); or

Early diagnosis of infants and young children has the following potential advantages:

11. early identification, and access of, HIV-infected infants and children to timely and optimal treatment, care, and support;
12. access to information and services to prolong life, for example, by improving nutrition and taking exercise;
13. easier decision-making regarding infant feeding;
14. elimination of anxiety and stress of parents of HIV-negative infants, and among HIV-positive children relief of knowing the truth rather than being worried about the unknown;
15. reduction of potential stigma, discrimination, and psychological distress among those diagnosed HIV-negative;
16. easier life-planning for parents and children who are HIV-infected; and

17. among older children who are HIV-positive, a better understanding of the importance of preventing further transmission, including the practice of safe behaviours to avoid infecting others.

Counseling children in association with HIV testing: Counseling must be available for any child undergoing HIV testing, including post-test Counseling for the child and the parent(s) or caretaker(s). Counseling children infected or affected by HIV and AIDS requires the following skills:

18. assessing maturity for understanding the benefits and risks of testing and for providing consent;
19. age-appropriate communication;
20. disclosure;
21. the process of informing a child of his or her HIV status;
22. Counseling for adherence to HIV medication;
23. ability to talk to children about death;
24. assessment of sexual abuse and rape;
25. parent or caretaker Counseling; and
26. ongoing psychosocial Counseling.

The foundation for a relationship between a counsellor and a child is good communication. Children should never be forced to tell their “story”—there may be good reasons when children cannot communicate about something. To help children to communicate freely, a counsellor can use one or more of the following creative and non-threatening tools such as:

1. drawing;
2. storytelling;
3. drama and role-plays; or
4. plays.

5.8 Intervention for Adolescents¹⁷

Engaging adolescents in HIV testing, as well as in prevention, treatment and care, requires specific strategies. All HTS for adolescents, either in health services or in the community, should be based on

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adolescent-friendly principles to ensure that psychological as well as physical needs are addressed. Adolescents may need support particularly with issues of disclosure – when and to whom to disclose HIV-positive status.

Involving adolescents in the design, delivery and evaluation of HIV services is necessary to ensure that these programmes address their needs (54). Services need to be convenient and available, through flexible opening hours and/or walk-in or same-day appointments. Separate hours and special events exclusively for adolescents may help overcome adolescents’ concerns that older relatives, neighbours or family friends will see them attending HIV services, including HTS.

The national strategic plan identified especially vulnerable adolescents as an emerging risk groups and stressed the need for implementing specifically targeted interventions for averting the possible spread of HIV infection among them. We have a considerable number of street children, under aged sex worker who falls under this vulnerable group and because of consent issue, providing HTC service to these groups become very challenging.

5.9 Vulnerabilities of Migrant Workers

Increasing and improving access to HTC is particularly important for the populations that are most at risk and most vulnerable including migrant and seasonal workers. They are susceptible to human immunodeficiency virus (HIV) due to poverty, inadequate knowledge of preventive strategies, and lack of access to health care. This is due to the impact of socio-cultural patterns of the migrant situation on health, their economic transactions, reduced availability and accessibility of health services.

5.10 Other Vulnerable Populations¹⁸

Depending on context, there are a number of other groups, in addition to key populations, that are particularly vulnerable to HIV infection. These include, in high prevalence settings, migrant workers, refugees and other displaced populations, and other country-specific populations that may be at increased risk, for example, fisher folk and long-distance truck drivers, all of whom can be hard to reach and, typically, seldom use HIV services. Migrant workers, refugees and people who are displaced have difficulty accessing health-care services because of stigma, language differences, lack of required documentation, lack of transportation and long distances to services, discrimination and legal barriers. Some jurisdictions mandate HIV testing of immigrants; this requirement is not justified and can exacerbate the challenges of providing voluntary health services, including voluntary HIV testing. Displacement of key populations and others through human trafficking may further complicate the provision of HTS.

To address the needs of vulnerable populations, countries need to evaluate their epidemic and its social context and identify the groups, in addition to key populations, that are at highest risk and in need of services. Based on these assessments, programmes can adapt HTS approaches and deploy

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them so as to increase access to testing and uptake. Special policies and practices to protect vulnerable populations from mandatory or compulsory testing may be needed.



CHAPTER SIX - REFERRALS AND LINKAGES AND CONNECTION TO PREVENTION, TREATMENT AND CARE

1. Referral and Linkage to treatment and care
2. Typical referral and linkage needs

Key Messages	
3.	Sero-positive clients should be immediately referred to care and support, to maximize the benefits of ART which is an integral part of ongoing care and support services.
4.	Special efforts will be needed to link people who have a reactive test result in a community setting to facility-based services for additional testing and an HIV diagnosis.
5.	For those diagnosed HIV-positive, retesting to verify diagnosis is critical before care or treatment is initiated.
6.	Sero-negative clients should also be referred to care and support counseling, especially if their family or friends have HIV/AIDS.
7.	Referral to a TB clinic is of critical importance in the prevention and management of TB infection among people living with HIV (PLHIV).
8.	Following HTS, service providers/counsellors should refer pregnant women to reproductive health services for appropriate antenatal care and PMTCT.
9.	Many clients who are HIV-infected or are at increased risk for HIV are also at increased risk for acquiring STI including viral hepatitis (B and C). MSM and PWID should be vaccinated against hepatitis B following HBV and HCV screening and all KPs at risk of HIV should be screened for STIs.

HIV Testing services (HTS) has been shown to be more effective when developed in conjunction with support services such as medical, social, emotional, legal, family planning, STI, and ante-natal services, as well as in conjunction with support groups for PLHIV, community groups, NGOs and CBOs.

6.1 Referral and Linkage to Treatment and Care¹⁹

Linkage 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. For people with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment.

A referral and linkage system should be developed in consultation with NGOs, community-based organizations, hospital directors, and other service managers, as well as with networks of PLHIV. Regular meetings among service providers should be held to review and improve the referral system.

¹⁹ WHO Consolidated Guideline on HTS 2015

Good practices to increase linkage²⁰: Providers of HTS have a crucial role in ensuring linkage to care for people diagnosed with an HIV infection, whether that linkage is quick or delayed. Prompt linkage to HIV care and treatment is ideal and should be encouraged. However, many people do not link to care and treatment immediately. Often, people need time to accept the diagnosis and seek support from partners and families before linking to care, and others cycle in and out of care.

Good practices include:

1. **Integrated services**, where HIV testing, HIV prevention, treatment and care, TB and STI screening and other relevant services are provided together at a single facility or site;
2. Providing **on-site or immediate CD4 testing with same-day results**
3. Providing assistance with transport, such as **transportation vouchers**, if the ART site is far from the HTS site;
4. **Decentralized ART provision** and community-based distribution of ART;
5. Support and involvement of **trained lay providers** who are peers and act as peer navigators, expert patients/clients and community outreach workers to provide support and to identify and reach people lost to follow-up;
6. **Intensified post-test counselling** by community health workers;
7. Using communication technologies, such as **mobile phones and text messaging**, which may help with disclosure, adherence and retention, particularly for adolescents and young people;
8. Providing **brief strengths-based case management**, which emphasizes people's self-determination and strengths, is client-led and focuses on future outcomes, helps clients set and accomplish goals, establishes good working relationships among the client, the health worker and other sources of support in the community, and provides services outside of office settings;
9. **Promoting partner testing** may increase rates of HIV testing and linkage to care, as may approaches in PMTCT settings that encourage male involvement.
10. **Intimate partner notification** by the provider, with permission, is feasible in some settings; it identifies more HIV-positive people and promotes their early referral to care.

6.2 Typical Referral and Linkage needs

HIV Counseling, care and support: After HIV counseling clients need to be referred for follow-up counseling, irrespective of their HIV status. Sero-positive clients should be referred to care and support for counseling, ART, OIs management, and other support and treatment. Seronegative clients should also be referred to care and support for counseling, especially if their family or friends have HIV/AIDS.

Medical care and treatment: HIV-infected clients should be referred to medical services for further clinical evaluation and management. Screening and prophylaxis of opportunistic infections is important for HIV-infected persons. In addition, the co-infection of HIV and other communicable diseases (e.g. TB, STDs, and hepatitis) can, if untreated, pose a risk to susceptible community members. Therefore, the providers of HTS should be familiar with the appropriate screening tests (e.g.

²⁰ WHO Consolidated Guideline on HTS 2015

TB), vaccines (e.g. hepatitis B and C), prophylactic STI and TB treatment, and the clinical evaluation of active TB to ensure that these communicable diseases are identified early and that appropriate clinical referrals are made, even if clients forego outpatient HIV treatment.

Couple and partner counseling, disclosure and referral services: HIV-positive clients should receive adequate information, or be referred to proper services, in order to help them disclose their condition to their spouses, sex partners or the people with whom they share their injecting drug equipment. The clients should let these people know that they have been exposed to HIV and how they can access HTS.

Family planning: Women who choose to avoid pregnancy in the future, because of their HIV infection should be referred to family planning services. Women who opt for two years of replacement feeding should also receive advice on contraception. If they choose to bear more children, they should be encouraged to delay a new pregnancy for at least two years.

PMTCT and reproductive health services: Much has been learnt in recent years about the prevention of mother-to-child transmission (PMTCT) through antiretroviral therapy and other interventions. These interventions rely substantially on the identification of those pregnant women who are infected with HIV. Following HTS, counsellors should refer pregnant women to reproductive health services for appropriate antenatal care and PMTCT.

Infant and children: Diagnosing HIV-exposed infants as early as possible through virological testing (<18 months: nucleic acid testing (NAT) technologies can be conducted using dried blood spot (DBS) specimens; >18 months: HIV Rapid test) is critical to starting ART as soon as possible and thus preventing early morbidity and mortality.

Adolescent: In high prevalence settings there are two groups of adolescents (that is, people 10–19 years of age) who need access to HIV testing: (1) perinatally HIV-infected adolescents who were not diagnosed in infancy and (2) adolescents who acquire HIV through early sex or injecting drug use, particularly adolescents from key populations. Engaging adolescents in HIV testing, as well as in prevention, treatment and care, requires specific strategies. All HTS for adolescents, either in health services or in the community, should be based on adolescent-friendly principles to ensure that psychological as well as physical needs are addressed. Adolescents may need support particularly with issues of disclosure – when and to whom to disclose HIV-positive status.

TB clinics: Tuberculosis is the most common opportunistic infection and the leading cause of death among HIV-infected persons in Bangladesh. TB is so common in the country that often people get exposed to it in early childhood and become susceptible to the disease. If a person like this gets an HIV infection later in life, also TB is reactivated. Research has shown that with Isoniazide-preventive therapy (IPT), usually Isoniazid 300 mg daily for 6 months, the incidence of clinical TB in people with HIV can be halved. It is, however, important to screen the patients for active TB before IPT is given. Therefore, referral to a TB clinic is of critical importance in the prevention and management of TB infection among PLHIV.

Prevention and treatment of drug or alcohol use: Clients who use drugs should receive appropriate information or be referred to substance abuse prevention and treatment services and/or needle exchange programmes/OST programme. All PWID must be referred to harm reduction programmes during post-test Counseling, irrespective of their HIV status.

Support Groups for socio-economic support: Assistance for HIV positive individuals and their family is very much required. Some PLHIV may need help to make plans for their future and for the future of their dependents. HIV counsellors should be knowledgeable about social services that help people with these decisions. Material and financial support is sometimes requested, and counsellors need to be aware of any available services, although these are often limited.

Psychiatric and Psychological help services: Clients who have a mental illness, developmental disability, or difficulty coping with their HIV diagnosis should receive psychiatric help or be referred to appropriate mental health services.

Rape and sexual abuse victims: Young people are often particularly vulnerable to sexual abuse, especially from people close to their families. However, young people are often reluctant to report rape or sexual abuse or to seek Counseling and HTS following a sexual assault. There are some NGOs in the country who are specifically working on rape and sexual abuse. Development of referral services with these organizations may prove helpful to these young people.

STI clinics: Clients who are at an increased risk for HIV are also prone to contract other STIs. All clients who suffer from any STI should be referred to STI clinics for STI management and HTS.

Screening and treatment for viral hepatitis: Many clients who are HIV-infected or are at increased risk for HIV are also at increased risk for acquiring viral hepatitis (B and C). MSM and PWID should be vaccinated against hepatitis B following HBV and HCV screening. Those who are found to be infected by either virus may be referred to gastroenterologists for further clinical evaluation and management.

CHAPTER SEVEN: MONITORING AND EVALUATION

1. Introduction
2. Monitoring
3. Evaluation
4. Record Keeping

Key Messages

M&E plays an important role in the effective and efficient management of health programmes by ensuring that:

5. resources devoted to a programme are used appropriately;
6. services provided are accessed by the target population;
7. programme activities happen in a timely manner;
8. expected results are achieved.

M&E will help programme managers assess the effectiveness and linkages between services along the cascade of testing, treatment and care for HIV and associated conditions. Such information is essential to detect and respond to bottlenecks or gaps in HTS programme performance

Selection of HTS indicators should be based on factors such as level of the epidemic, national HTS goals and objectives, scale of the programme and resources available to collect and analyse data.

ASP is responsible for coordination, monitoring and evaluation (M&E) of the national HTS response under the overall guidance of a Line Director. An entire system for strategic information needs to be put in place and information gathered, analysed and disseminated in a systematic manner.

7.1 Introduction

A key principle of the Bangladesh HIV National Strategy is that decision-making should be evidence based (4th NSP). A monitoring and evaluation system should be established from the onset of HTS. HTS protocol may vary from one programme to another, as it should be based on the goals and objectives of the programme. But whatever the approach taken is, HTS must be regularly evaluated to determine whether it satisfies client needs and is provided in accordance with the pre-determined protocol as well as position against respective SDG.

7.2 Monitoring

Monitoring is the routine tracking of service and programme performance using information collected on an ongoing basis. Monitoring is used to assess the extent to which a policy or programme is achieving its intended activity outputs and targets as planned. (WHO,2011)

7.3 Evaluation

Evaluation is the episodic assessment of changes in results that can be attributed to programme activities. It uses monitoring data as well as additional indicators and information that are not collected through routine information systems. Evaluation explores the causes of failure to achieve the expected results as planned and allows for mid-course corrections that may be necessary. Evaluation is concerned with measuring both the progress in programme implementation and the outcomes and impact of programme activities on target populations. (WHO,2011). Both monitoring and evaluation are critical components of national HIV/AIDS monitoring and evaluation plan.

As recommended by WHO to assess different types of achievements of HTS, defining a set of standard indicators is essential. An indicator is a quantitative or qualitative measure that helps to determine how well a system or programme performs and progresses towards meeting its objectives.

The indicators defined in this guide are for use at the national programme level. However, the progress of a national programme is based on the performance of individual sites providing HTS services. Therefore, programme-level data from individual HTS sites form the backbone of the M&E system used to manage a national programme.

Types of indicators: As mentioned by UNAIDS in 2008, indicators are often grouped according to the different aspects of implementation that they measure:

Inputs	The various types of resources invested in a programme, including the guidelines and strategy document for implementation.
Activities/Processes	The actions that cover all parts of implementation, making use of the available resources. Outputs – refer to the immediate results (i.e. services provided) of the activities and processes of implementation.
Outcomes	The downstream changes (usually in behaviours) that may result from provision of services.
Impact	The achievement of the programme’s goals, often in terms of biological or epidemiological changes.

The use of indicators at the global, national and site levels: In 2011 WHO recommended to use these following broad categories of indicators

Global indicator	A global indicator provides standard measures of achievement in a given programme area, which can be used to assess progress towards an HTS target. for example, it can be used to measure the “scale up” over time or coverage of a service, or allow a comparison to be drawn across different countries or regions with similar epidemics. for providing a global assessment, it is necessary for as many countries as possible to report against a standard set of indicators.
National-level indicator	A national-level indicator is used to measure an expected level of programmatic achievement in priority areas of a national strategy. A national HIV and AIDS strategy should have a manageable number of core indicators, so any specific programme area (such as HTS) may have a small number of national-level core indicators. National-level indicators should prompt action from a national manager if performance falls below the expected level. This requires all reporting units to use standard definitions and methods for reporting data on national-level indicators.
Site-level indicator	To operate a service delivery site efficiently and effectively, site managers must monitor a range of inputs and outputs of their programme. The M&E data collected and analysed locally should lead to action at the site level, and much of the data may not need to be reported to higher levels of management. Different sites may require different indicators to account for variations in models of service delivery, local targets and priority populations.

The monitoring of HTS quality starts with the review of national testing policies and standards, the quality of test kits and testing strategies/testing algorithms being used, the accuracy of diagnoses and the quality of counselling and referrals provided. Also, the laboratory-based aspects of HTS need to demonstrate quality, as measured through documentation, SOPs, QC results, and the results of external quality assessments (such as proficiency testing). As HIV testing is the gateway to the HIV services cascade, the strength of linkages to prevention and care services should be measured. Finally, monitoring should assess the alignment of HTS policies, programmes and practices with human rights norms and standards, especially in HTS services for key populations.

Why Monitoring and Evaluation are important?: Up-to-date monitoring of HTS allows for prompt identification and resolution of the challenges (and successes) of an HTS programme. M&E allows for observation of a programme trend, which can guide priority setting and resource allocation at the local, district/divisional and national level. M&E data can also be used to answer critical questions about Bangladesh HIV epidemic at the service delivery, divisional, national, or international context. This data also forms a basis for research hence it is critical that the quality of data is assured at all levels.

Monitoring and evaluation involve:

1. Routine HTS data including linkage to care and treatment

2. Periodic surveillance data tools
3. National M&E tools should be used for HTS data collection and reporting at all levels; HTS Lab registers, client referral forms, reporting/summary forms, DHIS.

It is the responsibility of the government to ensure continuous availability of the national M & E tools at all service delivery points.

Human rights protection in the context of HTS: Monitoring human rights protection in an HTS programme is implicit in any basic assessment of the quality and effectiveness of services. All aspects of HTS programming should ensure the protection of human rights of those with HIV and of key populations who are vulnerable to acquiring infection. in the context of HTS,

Human rights issues are particularly relevant in terms of:

4. ensuring that all testing is voluntary;
5. ensuring that informed consent of patients is obtained before testing;
6. ensuring the confidentiality of test results and establishing mechanisms to minimize harms or provide redress for wrongful disclosure of results;
7. minimizing stigma and discrimination or other forms of harassment/abuse against those who test and those who test positive;
8. supporting effective counseling;
9. monitoring the uptake/acceptability of models of testing by those being tested (e.g. piTC);
10. linking those tested to prevention, care and treatment services.

Data sources

M&E data on HTS can be collected by three main methods:

11. Routine monitoring is carried out through programme monitoring and is usually conducted quarterly and reported on annually, so that progress and trends can be measured.
12. Periodic assessment of particular aspects of the HTS, such as site assessments for quality assurance (QA) and quality improvement purposes, can be used to monitor and improve performance.
13. Population-based survey data from international data collection programmes such as the Demographic and Health Survey (DHS) and Multiple indicator Cluster Surveys (MICS). (UNICEF,2010)

These national surveys are carried out periodically, usually every three to five years. It is useful to have data from both routine monitoring and population-based survey sources for triangulation purposes.

Table 6. Indicators to be considered for national HTS programmes

SL	Indicator	Frequency of collection	Primary data source
1	Number of public health and other facilities that provide HIV testing services in the past 12 months	Monthly/Annually	HMIS/Program data
2	Number and percentage of people received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
2.1	Number and percentage of MSM received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
2.2	Number and percentage of MSW received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
2.3	Number and percentage of transgender received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
2.4	Number and percentage of PWID received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
2.5	Number and percentage of FSW received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
3	Number of migrants received HIV test in the past 12 months who know their test results	Monthly/Quarterly	HMIS/Program data
4	Numbers and percentage of pregnant women who received an HIV test in the past 12 months and know the result	Monthly/Quarterly	HMIS/PMTCT
4.1	Number and percentage of infants who received an HIV test within two months of birth (in the past 12 months)	Monthly/Quarterly	HMIS/PMTCT
4.2	Number and percentage of children who received an HIV test and identified HIV positive from mother-to-child transmission in the past 12 months	Monthly/Quarterly	HMIS/PMTCT
5	Number and percentage of newly diagnosed HIV-Positive enrolled to TCS	Monthly/Quarterly	HMIS/Program data
5.1	Number and percentage of newly diagnosed HIV-Positive KPs (MSM, MSW, TG, FSW, PWID) enrolled to TCS	Monthly/Quarterly	HMIS/Program data
5.2	Number and percentage of newly diagnosed HIV-Positive adults and children enrolled to TCS	Monthly/Quarterly	HMIS/Program data

6	Number and percentage of HIV Positive patients with documented TB status in the past 12 months	Monthly/Quarterly	Program data
7	Number and percentage of TB patients with documented HIV status in the past 12 months	Monthly/Quarterly	Program data

Collection systems for routine monitoring purposes: According to WHO’s HTS related M&E guideline, the following data collection systems will be in placed-

1. A national inventory of HTS sites
2. A site-level client/patient register to record basic information
3. A laboratory log
4. Standard data collation tools and reporting formats

Data demand and information use: It is the responsibility of HTS providers to understand and use HTS data to improve the services. Further, it is the responsibility of managers at facility, district, division and national structures to analyze and use this data to monitor quality of services, trends and allocate resources. Respective authorities have the responsibility to build capacity for data analysis and use for health service providers and managers. Data sharing forums are encouraged at all levels.

Training and orientation to service providers: All service providers should be trained / oriented on data collection, reporting and analysis. Service providers should be oriented on tools and indicators to enhance their understanding and correct use.

Data quality audit (DQA)/Routine data quality assessment (RDQA): The importance of quality data cannot be overemphasized as it is critical for correct interpretation of data. It is the responsibility of all levels; service providers and managers at all levels to ensure accurate documentation and reporting as per data management guidelines. DQA/RDQA should be conducted at all levels with emphasis on completeness, accuracy, consistency and timeliness in reporting:

1. At service delivery level health care workers should use available instructions to complete tools daily
2. HTS implementing organizations should conduct quarterly DQA/RDQA on random basis
3. National level DQA/RDQA should be conducted quarterly/annually on random basis

HTS data analysis and use: When analysed and interpreted, M&E data can answer important questions about an HTS programme. Are the services provided achieving a minimum level of quality? Are the highest priority populations being served? What level of coverage does the programme provide? in addition to being used for calculating specific core indicators, developing figures and graphs that can be used routinely to review the core indicators can be helpful. Graphical formats often help to more easily identify potential weaknesses in programme performance than viewing the data in tables of numbers. for example, graphs or figures can:

1. incorporate aspects of trends over time;
2. compare different subgroups (by geography, target population, implementing agency or type of service);
2. mark targets or thresholds of minimum performance standards for clear comparison with actual

3. achievements;
4. indicate major events (e.g. policy change, scale up of services or change in technology),
5. Which could have had an underlying effect on the quality, accessibility or utilization of services.

Once standard formats are developed for such figures and graphs, these can be easily generated with updated data for use on a regular basis by managers at different levels. It is important to consider issues related to data reliability or completeness when analyzing, interpreting and presenting M&E data. For example, is an increase in service utilization in a region the effect of recent expansion of the number of HTS sites, or does it reflect effective promotion of services? Is a sudden drop in coverage due to a missing routine report, or a recalculation of the size of the population (i.e. the denominator), or a real decline in the uptake of services?

Data sharing and feedback: Broader sharing and discussion of HTS programmatic data at all levels is intended:

6. to lead to improved service provision and delivery;
7. to identify target populations in need of strengthened HTS efforts;
8. to motivate programme staff and stimulate programme performance;
9. to address issues in data quality;
10. to ensure that HTS sites, as well as district and national offices, realize the benefits of dedicating resources to the M&E process.

Confidentiality of medical records: Information from HTS service delivery points should be treated with the same level of confidentiality that all medical records are given. Only authorized officers should be permitted to handle client-level data. Results of all HIV tests should be systematically recorded as well as the details of all the test kits used. Records must be kept confidential and in lockable storage location that is only accessible to authorized persons.

Data flow: Data should flow from the service delivery points up to DHIS2 from where all stakeholders will access it as illustrated in the flow diagram below. Service providers will complete data collection tools, from which they will generate service delivery point monthly reporting. These reports will be forwarded to the district health service centers or designated person to aggregate and forward to the respective Principal Recipients (PRs) or designated person. The PRs or assigned officials will enter the data into DHIS2. The PRs or assigned officials should ensure the data is validated before entry into the DHIS2.

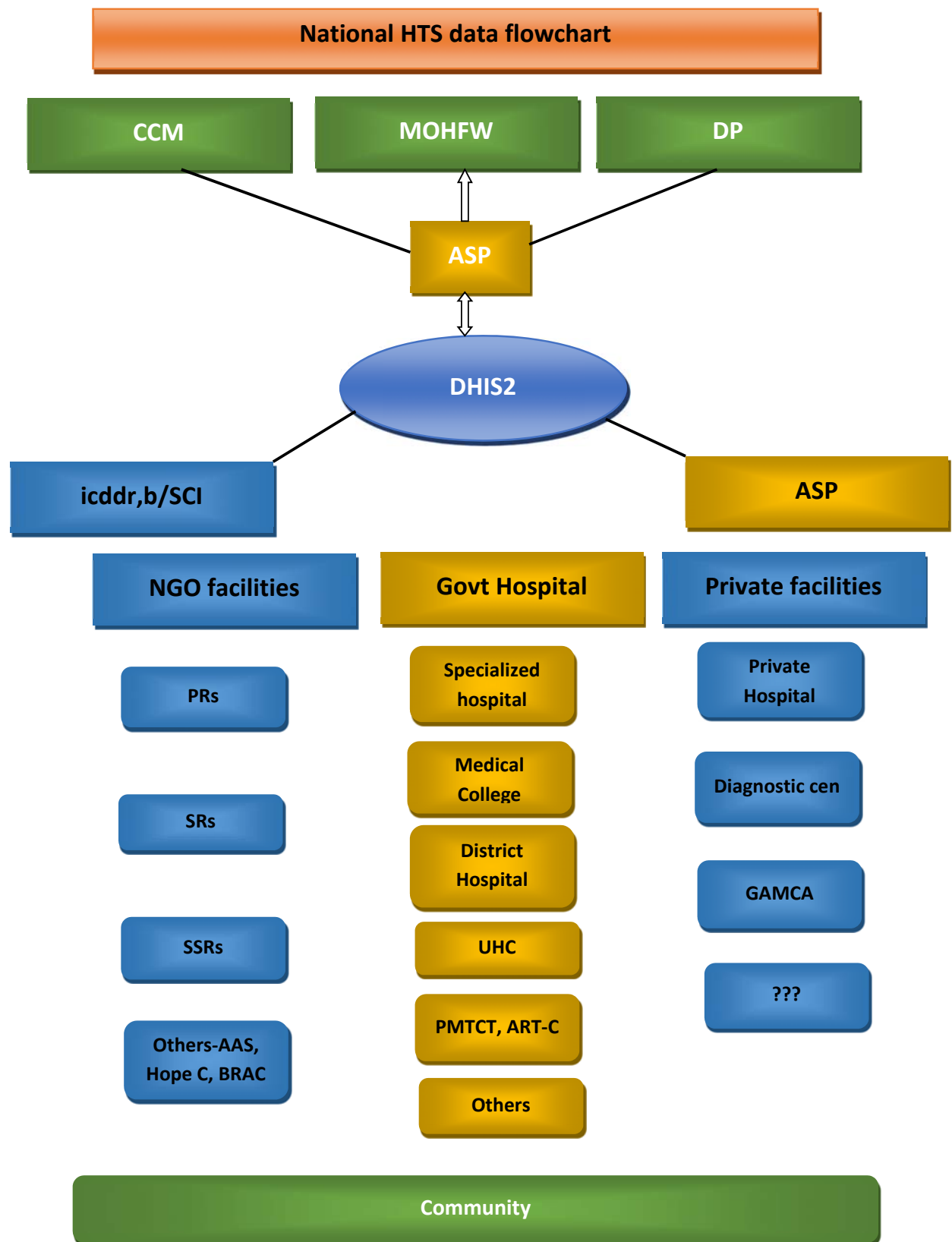


Figure 9. National HTS data flow

REFERENCES

ANNEXURE

Annexure 1. List of Logistics and consumables

Necessary Logistics and Consumables Required for HIV Rapid Testing

i. Test Kits

1. Test-1: Determine HIV-1/2 test kits (100 kits/box, with Buffer, capillary tube & lancet)
2. Test-2: Uni-Gold HIV-1/2 test kits (20 kits/box, with Buffer & capillary tube)
3. Test-3: First Response HIV-1/2 test kits with Buffer (30 kits/box, with Buffer, capillary tube & lancet)

ii. Consumables

1. Timer/Stop watch
2. Fine point cryomarker (for labeling of test kis)
3. Single use gloves (2 pair for each test)
4. Alcohol pad (2 pieces for each test)
5. Cotton role
6. Chlorohexidine
7. Tourniquet (*for test 2 &3, to collect blood for venipuncture*)
8. Syringe 3 cc (*for test 2 &3, to collect blood for venipuncture*)
9. Vacutainer 5 cc (*for test 2 &3, to preserve blood from venipuncture*)
10. Liquid soap (for hand washing)
11. Sharp container
12. Medical waste container

iii. Documents/Guidelines/SOPs

13. Job aids/SOP on testing procedure
14. Form/Formats
1. Counseling & test result forms
2. HTS registers
1. Monitoring tools and formats

Annexure 2. Testing procedures

HIV Rapid Test-1: Determine™ HIV Rapid Test

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit to room temperature prior to use.
- Always use universal precautions during testing procedure. Keep work areas clean and organized.

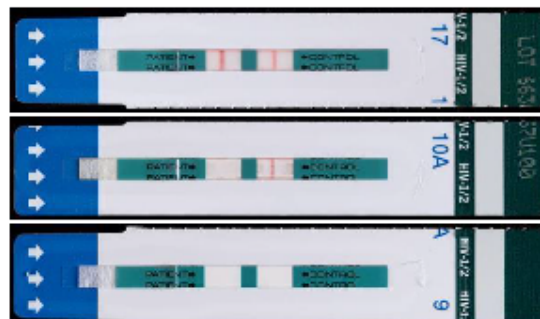
 <p>1. Use one strip per test & preserve lot number</p>	 <p>2. Label test strip with lab client identification number</p>	 <p>3. Pull off the protective foil cover</p>	 <p>4. Tell patient to hold hands in downward position & rub both hands to make warm</p>
 <p>5. Choose tip of ring/middle finger of left hand, clean the site with alcohol pad and dry the site</p>	 <p>6. Hold the finger in an upward position, press the finger firmly and lance palm-side surface</p>	 <p>7. Wipe out the first drop of blood</p>	 <p>8. Collect blood into capillary tube up to black mark (50 µl)</p>
 <p>9. Lightly touch the absorbent pad & apply blood on the strip</p>	 <p>10. Add one drop of buffer solution one minute after pouring blood</p>	 <p>11. Wait 15 minutes before reading the result</p>	 <p>12. Read & record result and other pertinent info on lab result form & lab register</p>

Determine™ HIV Rapid Test Results

Reactive
2 lines of any intensity appear in both the control and patient areas.

Non-reactive
1 line appears in the control area and no line in the patient area.

Invalid
No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the patient area.



HIV Rapid Test-2: Uni-Gold™ HIV Rapid Test

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

 <p>1. Collect test items and other necessary lab supplies</p>	 <p>2. Remove device from package and label device with client identification number</p>	 <p>3. Tell patient to hold hands in downward position & rub both hands to make warm</p>	 <p>4. Choose tip of ring/middle finger of left hand, clean the site with alcohol pad & dry</p>
 <p>5. Hold finger in an upward position, press finger firmly & lance palm-side surface</p>	 <p>6. Wipe out the first drop of blood</p>	 <p>7. Collect blood into disposable Uni-gold supplied dropper</p>	 <p>8. Hold dropper vertically over the sample port & discharge 2 drops (60 µl) whole blood</p>
 <p>9. Add 2 drops (approx. 60 µl) of appropriate wash reagent to sample port immediately</p>	 <p>10. Wait 10 minutes before reading the result</p>	 <p>12. Read & record result and other pertinent information on lab result form & lab register</p>	

Uni-Gold™ HIV Rapid Test Results

Reactive

2 lines of any intensity appear in both the control and test area.

Non-reactive

1 line appears in the control area and no line in the test area.

Invalid

No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.



HIV Rapid Test-3: FIRST RESPONSE HIV 1-2.0 CARD Test

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

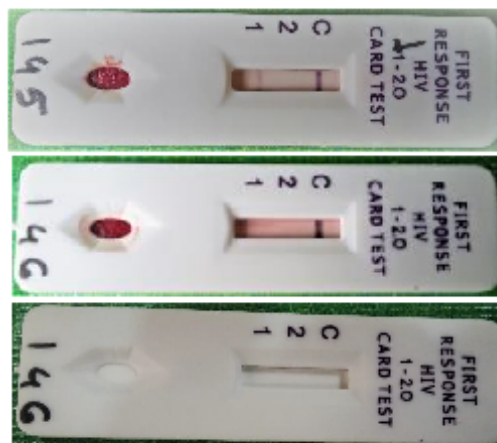
 <p>1. Collect test items and other necessary lab supplies</p>	 <p>2. Remove device from package and label device with client identification number</p>	 <p>3. Tell patient to hold hands in downward position & rub both hands to make warm</p>	 <p>4. Choose tip of ring/middle finger of left hand, clean the site with alcohol pad & dry</p>
 <p>5. Hold finger in an upward position, press finger firmly & lance palm-side surface</p>	 <p>6. Wipe out the first drop of blood</p>	 <p>7. Collect 20 µl (2 drops) whole blood using sample pipette</p>	 <p>8. Hold pipette vertically over the sample well & slowly discharge the blood</p>
 <p>9. Add 1 drop (approx. 35 µl) of Assay Diluent to the sample well</p>	 <p>10. Wait 15 minutes before reading the result</p>	 <p>11. Read & record result and other pertinent info on lab result form and lab register</p>	

FIRST RESPONSE HIV 1-2.0 CARD TEST RESULT













Reactive
 Color bands of any intensity appear in the control 'C' and test areas in HIV-1 '1' (as specified in the figure) or at HIV-2 '2' or both.

Non-reactive
 1 line appears in the control 'C' area and no line in the patient area as shown as '1' and '2'.

Invalid
 No line appears in the control 'C' area. Do not report invalid results. Repeat test with a new test device even if a line appears in the patient area.

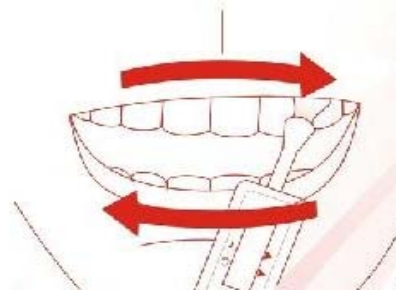
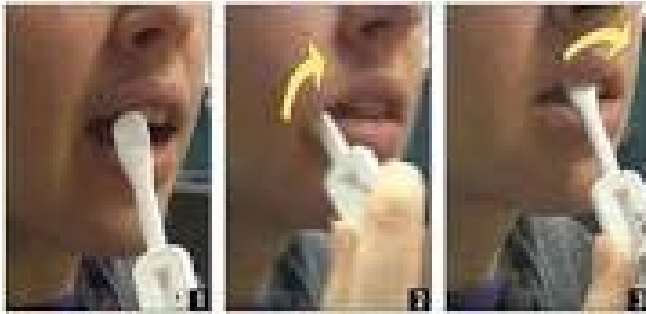


DBS SAMPLE PREPARATION FOR EQA

		
<p>1. Cut the DBS card keeping three holes in one side and two holes on the other side</p>	<p>2. Write down patient identification number and date of sample collection on the zip sticker</p>	<p>3. Paste the sticker on the cover leaf of DBS card</p>
		
<p>4. Put scotch tape over the sticker for fixing it.</p>	<p>5. Clean the finger-tip of left hand (ring/middle) with alcohol pad & dry</p>	<p>6. Hold finger in an upward position, press finger firmly & lance palm-side surface</p>
		
<p>7. Wipe out the first drop of blood, first collect blood for Determine™ HIV rapid test, then collect blood onto DBS card</p>	<p>8. Allow blood drop to fall directly from pricked finger onto circle of DBS card. Ensure finger-tip does not touch circle.</p>	<p>9. Fill-out three holes with drops of whole blood. Ensure blood does not spread outside the circle</p>
		
<p>10. Keep the DBS card horizontally. Ensure one does not touch the other and allow air drying for at least 3 hours at room temperature.</p>	<p>11. Keep desiccant pack & dried DBS card inside ziplock bag</p> <p>Then remove air by pressing ziplock bag and seal it.</p>	<p>12. Clearly label the contents on the bag.</p>

HIV Testing Procedure with Oral Fluids (OraQuick ADVANCE rapid test kit)

1. Steps of oral fluid collection



1. Ensure prior to test that the subject has not had anything to eat or drink at least 15 minutes before
2. Subject have used any oral care product must be wait for 30 minutes prior to testing.
3. Do not allow the person to touch the flat pad.
4. Ensure that the descant is in the packet.
5. Direct the person to place the flat pad above the teeth against the outer gum.
6. Direct the person to gently swab completely around the outer gum (upper and lower)

B. Testing Procedure:

1. Insert the flat pad of the device all the way into the vial
2. Make sure that the flat pad touched the bottom of the vial
3. The result window on the device should be facing toward you
4. Start timing the test (20 minutes).
5. Do not remove the device from the vial while the test is running
6. Pink fluid will appear and travel up the result window and will gradually disappear as the test develops
7. Read the result after 20 minutes but not more than 40 minutes



Developer Solution vial



Result window in test device

Annexure 3. M&E tools/forms and formats



1. HTS register

Format no. 01

AIDS/STD Programme-ASP
National AIDS/STD Control-NASC
Directorate General of Health Services
Ministry of Health and Family Welfare
HIV Testing services (HTS) Register

SC Name: _____ SC Code: _____

Month/Year: _____

Sl	Date (dd/mm/yyyy)	Client's ID				Name of Client	NID & Phone No.	Father's Name (if married give Spouse name)	Mother's Name	District (Detail Address)	Demographic Information				History of Migration		Visit Type		How client learnt about this service? Self-motivated =1, others=2	Counseling and Testing						Remarks	Signature of Counselor		
		SC Code (xxx)	Target Group Code (zz)	Registration Year (yyyy)	Registration # (uuuu)						Age	Sex (Male=1, Female=2 & Hijra=3)	Marital Status	Education	Occupation	External Migrant (Current/Previous)	Partner External Migrant (Current/Previous)	New HTS Client		Follow-up	Pre-test Information (yes/no)?	Lab Result Negative=1, Positive=2, Indeterminate=3	Post-test Counseling provided (yes/no)?	Result Provided (yes=1, No=2)	Referred for Care, Support & Treatment (yes/no)?			If referred then when and where?	ART ID
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
1																													
2																													
3																													
4																													
5																													

2. HTS Counseling formats

এইডস/এসটিডি প্রোগ্রাম
 RvZxq GBWm/GmUwW KfUij
 তথ্য আবেদন
 তথ্য I cmi evi Kj vY gš/vj q

di tgU bs:02



GBPAvBwf cixqv ceEzPKvDfYij s/Z_ mel qK dg©

(tmev cã vbKvix GB dgU tmev-MnxZvi mrf_ Avtj vPbvi ciciB ciY Ki tãb Ges tmev-MnxZvi e"MZ dvBtj msi qY Ki tãb)

GAvi uJ/GBPm tmUvti i bvg

ev f evqbkvix msã vi bvg

tmev-MnxZvi

AvBwT

mWk vtb uK

SC Code		TG Code		Registration Year				Registration #				

(v) mPy m b A_ev

mWk vtb wj Lp

- 1| Avtj vPbvi Zwi Lt ____/____/____
- 2| tmev-MnxZvi eZgub eqmt _____ (eQi); 3| wj ½t cj æl/gwj v/inRov; 4| SãKcY(†Kic):-----
- 5| mkyMZ thvM Zvt
- 6| tckvt
- 7| †Rj vi bvg (wR †Rj vmn w e f wi Z mKvbt) t

- 8| eZgub gwmK Avqt _____ (UvKv)
- 9| tmev MnxZvi tgevbj baf I RvZxq cmi Pq c f baf
- 10| eZgub wevniK Ae vt AvevniZ/wevniZ/weaev/wecZwK/Zvj vKcuv/wevniZ mKs' Avj v v emevm Kti b/wevni e mZti †K GK f emevm Kti b
- 11| eZgub tckvt _____
- 12| cteKlBl GBPAvBwf cixqv Kti tQb? -----, DEi nv ntj ..
 (K) GLb chS KZevi GBPAvBwf cixqv Kti tQb? ____ evi; meKl GBPAvBwf cixqv Zwi Lt ____/____/____ I dj v dj t _____

- 13.1| tmev-MnxZvi SãKi gv v cwi gcbt
 (K) bvK/Kvb tãvovtãv ev ki tãi t Kv_vl /Dwé AvKvãbv ntãtQ: n wlv (L) i ³ ev A½ ms vcb Kiv ntãtQ: n wlv /bv
 (M) tmev-MnxZvi tckvMZ SãK AvtQ; - n wlv / bv / Rvrv bvB; (N) m½x SãKcYAvPi tã Af f f ; n wlv / bv / Rvrv bvB;
 (O) mB- vmi A f vMvM Kti e envi Kti: n wlv /bv (P) m½x A_ev gv/evvi tKE mK GBPAvBwfZ Avmã f t n wlv/Rvrv bvB
 (Q) thSb m½xi msL vt GK/GKwaK /bvB; (R) m½xi ai Yt wãqgZ /AwãqgZ/cãhr bq;
 (S) KbWãgi e envi t Kti bv / wãqgZ / AwãqgZ / cãhr bq; (T) thSb KvãRi ai Yt thvãct_/cvãct_/gãL/Ab v b ____;

- 13.2 meKl SãKcYAvPi tã mte Zwi Lt ____/____/____ (cãhr tã fã); A_ev cãhr bq
- 13.3 tmev MnxZv DBtUv wci qãW_vKtj , GBPAvBwf cãtãcixqv Zwi Lt ____/____/____; A_ev cãhr bq

13.4 eZgub / AZãZ wãR /m½x/ Dfãq thSbtãvM Avmã f /Avmã f ntãtQ tã b;

13.5 eZgub / AZãZ wãR /m½x/ Dfãq h²v tiãM Avmã f /Avmã f ntãtQ tã b |

- 14| tmev MnxZv I Zvi wãqgZ thSb(?) m½x mãcãKZ Z_:

 - tmev MnxZv eZgub/AZãZ tãv tã tã wãtãtãQb/AvfãwãZ (Migration) ntãtQb mKbãt
 niã bv , niã ntã tãv tã tãt , KZã b aã tgm/eQi
 - tmev MnxZv wãqgZ thSb m½x eZgub/AZãZ tãv tã tã AvfãwãZ (Migration) ntãtQb mKbãt
 niã bv , niã ntã tãv tã tãt , KZã b aã tgm/eQi

15 | tmev MnxZv wbtR /m/x MfēZx ntj, Mfē³vi eZg³vb chēqt 1-3 gym; 3-6 gym; >6 gym; A_{er} cthvR³ bq

16 | tmev MnxZvi mvt_{er} AvtjvPbvq KvD³tYj i th mKj KivR Kti³tQb [cthvR³ t³q³t³ Ōv Ō w³b]

- cwi³vPZ nI qv I KvE³tYj t³i i fngKv,
- e³w³MZ tMvcbxqZv I b³msi q³Y³ w³l t³q AvtjvPbv Kiv Ges m³g³Z t³bl qv ntq³tQ
- tmev MnxZvi GBPAvBv³f mn Ab³v³ thšbtiv³tMi Av³ms³š³ nI qvi S³ak I Zvi gv³tv w³bi/cY Kiv ntq³tQ
- S³pkcY³Av³PIY cwi eZ³ Ges m³w³K w³bq³t³g KbWg/m³β-w³mi Ä e³en³t³i i w³l t³q AvtjvPbv Kiv/c³k³ Kiv ntq³tQ
- GBPAvBv³f I Ab³v³ thšbtiv³tMi m³sp³gY I Zv c³w³Z³tiv³tai t³Kškj Ges m³br³KiY cix³q³v I Zvi djvdj m³u³t³K³AvtjvPbv

Kiv ntq³tQ

- tmev MnxZvi GBPAvBv³f cix³q³vi c³w³Z³ Ges djvdj t³kv³vi I t³gtb t³bl qvi ³oZv hvPvB Kiv ntq³tQ
- cwi³evi, e³ÜyI c³w³Z³tek³mn Ab³ Kv³tiv KvQ t³tk m³vqZv c³w³Bi m³e³te³Zv hvPvB Kiv ntq³tQ

17 | tmev MnxZvi m³g³Zt GBPAvBv³f mn Ab³v³ thšbtiv³tMi m³sp³gY I Zv c³w³Z³tiv³tai t³Kškj Ges m³br³KiY cix³q³v I Zvi djvdj m³u³t³K³ Avgt³K w³l³ w³i Z Rvbt³bv ntq³tQ Ges e³w³MZ tMvcbxqZv i q³vi w³b³qZvi cwi t³c³w³q³tZ, Awg (big) _____ GBPAvBv³f cix³q³vi m³g³Z c³v³ KivQ | GKbmv³t_{er}, w³pk³rmvi c³t³qvR³t³b Ab³ t³Kv³ c³w³Z³vb/tmev t³K³ e³w³i w³bKU Avgt³K t³c³iY A_{er} Avgvi t³i³w³ m³sp³š³ hveZiq (tMvcbxq) Z_{er} t³merc³vbKvi³t³ i Rvbt³bv m³g³Z c³v³ KivQ |

_____ tmev MnxZv GBPAvBv³f cix³q³vi Rb³ c³er Z Ges m³g³Z c³v³ Kti³tQb |

tmev MnxZvi t³q³i/w³c mB

tmev c³v³Kivi³xi Zwi Lmn t³q³i

oe t³ w³bq³Z m³x ntZ c³ti t³gv³ t³q³t³ /t³q³t³ eÜyA_{er} Lt³i i hvi m³t_{er} w³bq³Z thšb m³u³K³Av³tQ ev w³Qj | Kv³tiv Kv³tiv GKwaK w³bq³Z m³x v³K³tZ c³ti |



7 | tmev cã vbKvixi gSÍ e't

Avti K` dv Avtj vPbvi Ges/ev GBPAvBwf ci x¶¶vi ctqvRb AvtQ cieZP Avtj vPbvi Ges/ev ci x¶¶vi Zwi L ____/____/____		
_____ tmev cã vbKvixi big	_____ ¶¶¶i	_____ Zwi L

7. GBPAvBwf Gi j`veti Uwi ci x¶¶vi djvdj Avgvi KvtQ e'vL`v Kiv ntqtQ | G djvdttj i GK Kwc Awg MnY Kijvg |

_____ tmev-MnxZvi big	_____ ¶¶¶i / wJc mB	_____ Zwi L
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4. Referral format

di tGU bs:04

রেফারেল ফর্ম

নিবন্ধন নং: _____ তারিখ: ____/____/____

রোগীর নাম: _____ বয়স: _____ বছর

যে সকল সেবা সমূহের জন্য পাঠানো হলো (সঠিক স্থানে “√” চিহ্ন দিন)	অনুরোধক্রমে
<input type="checkbox"/> ল্যাবরেটরি পরীক্ষা	
<input type="checkbox"/> চিকিৎসা বা চিকিৎসা পুনঃমূল্যায়ন	
<input type="checkbox"/> কাউন্সেলিং	
<input type="checkbox"/> অন্যান্য	
সেবার বিস্তারিত	যে প্রতিষ্ঠানে সেবা গ্রহীতাকে পাঠানো হলো, তার বিস্তারিত
	প্রাপ্তিবীকার

5. Lab register

Format no. 05

National AIDS/STD (Control) Programme-NASP
 Directorate General of Health Services
 Ministry of Health and Family Welfare

Laboratory Register

SL	Lab ID			Client's ID							Sex	Sample Location box	HIV Test						HIV Final Results Neg/Pos/ Indeterminate	Syphilis Test							Retested at BSMMU	Remarks									
	SC	Reg. M	Reg. Y	Serial #	SP Code	SC Code	TG Code	Reg.M	Reg. Y	Serial #	M/F/T		HIV Testing date	Lot number of HIV test kits			Expiry date of HIV test kits			HIV Test Results			Date of Syphilis test	Lot number of Syphilis test kits		Expiry number of Syphilis test kits			Syphilis Test Results								
														T-1	T-2	T-3	T-1	T-2		T-3	T-1 (+/-)	T-2 (+/-)		T-3 (+/-)	RPR	TPPA			RPR	TPPA	RPR		TPPA	Syphilis Final Results			
																															Qualitative (+/-)	Semi-Qualitative (Titer)			Positive/Negative		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36		