MYANMAR NATIONAL GUIDELINES ON

HIV TESTING SERVICES

Ministry of Health and Sports, Myanmar
2018

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Contents

ABBREVIATIONS AND ACRONYMS

5 Cs	**C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and **C**onnection (link age to prevention, care and treatment)
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Anti-retroviral Therapy
eMTCT	elimination of Mother-To-Child Transmission
EQA	External Quality Assessment
FSW	Female Sex Worker
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HTS	HIV Testing Services
IPT	Isoniazid Preventive Therapy
MCH	Maternal and Child Health
MOHS	Ministry of Health and Sports
M&E	Monitoring and Evaluation
MSM	Men who have Sex with Men
NAP	National AIDS Programme
NGO	Non-Governmental Organization
NHL	National Health Laboratory
NPV	Negative Predictive Value
OST	Opioid Substitution Therapy
PEP	Post-Exposure Prophylaxis
PHC	Primary Health Care
\PITC	Provider-Initiated Testing and Counselling
PMTCT	Prevention of Mother-To-Child Transmission
PPV	Positive Predictive Value

PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
QA	Quality Assurance
QC	Quality Control
RDT	Rapid Diagnostic Test
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNODC	United Nations Office on Drugs and Crime
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

GLOSSARY

Acute infection: the period between HIV-infection and the detection of antibodies by a serological assay (1).

Early infant diagnosis: testing of infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), peripartum (during delivery), or postpartum (through breastfeeding, or via parenteral exposure (2).

Eclipse period: the period between HIV-infection and detection of virological markers such as HIV RNA/DNA, and HIV p24 antigen (1).

External quality assessment scheme: inter-laboratory comparison to determine if the HIV testing service can provide correct test results and diagnosis.

Generalized epidemic: is where HIV is firmly established in the general population. Although subpopulations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain the epidemic. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women attending antenatal clinics.

Index testing: often referred to as index-case or index patient HIV testing, a focused HTS approach in which the household and family members (including children) of people diagnosed with HIV are offered HIV testing services (3).

Indicator condition-guided HIV testing: a focused HIV testing approach to test people more likely to be infected by identified through indicator conditions, such as STI's, lymphoma, cervical/anal neoplasia, herpes zoster, hepatitis B/C and others. These occur more frequently in HIV-infected individuals, either because they share a common mode of transmission or because their occurrence is facilitated by the characteristic immune deficiency associated with HIV-infection (4).

Integration: the co-location and sharing of services and resources across different disease areas. In the context of HIV, this may include the provision of HIV testing, prevention, care and treatment services alongside other health services, such as TB, STI, viral hepatitis, antenatal care, contraceptive and other family planning services, and screening and care for other conditions, including non-communicable diseases.

In vitro diagnostic (IVD): a medical device, used alone or in combination, intended by the manufacturer for the examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. For example, IVDs can be used for the following test purposes: diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status. Examples of IVDs include reagents, calibrators, control materials, and specimen receptacles (5).

Key populations: are defined groups who due to specific higher-risk behaviours, 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; sex workers; and transgender people.

Trained Community worker: a person who performs functions related to health-care delivery and has been trained to deliver services but has received no formal professional or paraprofessional certificate or tertiary education degree (6).

Concentrated epidemic: where HIV has spread rapidly in a defined subpopulation, but is not well established in the general population. This type of epidemic suggests active networks of people with high-risk behaviours within the subpopulation. The future course of the epidemic is determined by the nature of the links between subpopulations with a high HIV prevalence and the general population. Numerical proxy: HIV prevalence is consistently over 5% in at least one defined subpopulation but is below 1% in pregnant women attending antenatal clinics. Myanmar is considered to have a low and concentrated HIV epidemic.

Negative predictive value: the probability that a person with a negative test result is not infected with HIV, i.e. "true negative" (7).

Non-reactive test result: a test result that *does not* show a reaction indicating the presence of analyte. In the context of HIV, this includes HIV p24 antigen or HIV-1/2 antibodies (8).

Nucleic acid testing (NAT): also referred to as molecular technology, for example polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA). This type of testing can detect very small quantities of viral nucleic acid i.e. RNA, DNA or TNA qualitatively and quantitatively (9).

Pre-test information: a dialogue and the provision of accurate information by trained worker or health worker before a HIV test is performed (10).

Quality assurance: a systematic and planned approach to assessing, monitoring and improving the quality of health services on a continuous basis within available resources (11).

Quality control: an assessment of product compliance with stated requirements (11).

Quality improvement: an approach to the study and improvement of the processes of providing health-care services to meet client needs (11).

Quality management system: a systematic process-oriented approach to meeting quality objectives.

Reactive test result: a test result that shows a reaction to indicate the presence of analyte. In the context of HIV, this includes HIV p24 antigen or HIV-1/2 antibodies.

Repeat testing: refers to a situation where additional testing is performed for an individual **immediately** following a first test during the same testing visit due to inconclusive or discordant test results; the same assays are used and, where possible, the same specimen (8).

Retesting: There are certain situations in which individuals should be retested after a defined period of time: (1) HIV-negative people with recent and specific risk (2) HIV-negative people with on-going risk of exposure, (3) people with an HIV-inconclusive status and (4) HIV-positive people when they enrol in care and before they initiate Anti-Retroviral Treatment (ART). Reasons for retesting before initiation of ART include ruling out laboratory or transcription error and either ruling in or ruling out seroconversion (12, 13).

Rapid diagnostic test (RDT): in vitro diagnostics of immunochromatographic or immunofiltration formats for the detection of HIV-1/2 antibodies and/or HIV p24 antigen, in the case of HIV diagnosis (7, 9).

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 (12).

Sensitivity: denotes the probability that an HIV assay/algorithm will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV p24 antigen (8).

Sentinel surveillance: a type of surveillance that is conducted through sites that provides access to populations that are of particular interest or representative of a larger population, for example antenatal clinics (7).

Seroconversion: when an individual produces a sufficient quantity of HIV antibodies to become detectable on a given HIV serology assay (8).

Serodiscordant couple: a couple in which one partner is HIV-positive and one partner is HIV-negative (13).

Serology assay: is an assay that detects the presence of antibodies in human specimens, typically serum or plasma but also capillary/venous whole blood and oral fluid. For example, RDTs, immunoassays (including EIAs, CLIAs, ECLs) and certain supplemental HIV assays are serology assays (9).

Serosurveillance: epidemiological studies or activities, in which serological testing is used to detect the presence or absence of HIV antibodies and measure HIV prevalence in a given population or geographic setting (7).

Specificity: denotes the probability of the assay/algorithm to correctly detect specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Supplemental assay: an assay that provides additional information for specimens that have been found reactive on a first-line assay previously, but may not be able to definitively confirm that reactivity.

Task sharing: the rational redistribution of tasks and the increased scope of work among different cadres of health-care providers, such as trained workers (6, 14).

Screening testing: an HIV testing approach involving trained and supported community workers conducting a single HIV RDT. The community workers then promptly link individuals with reactive test result to a provider and site certified to provide confirmation testing for further HIV testing and to an assessment for treatment. Individuals with a non-reactive test result 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 (15).

Testing algorithm: is the combination and sequence of specific assays used within HIV testing strategies(8).

Testing strategy: generically describes a testing sequence for a specific objective taking into consideration the presumed HIV prevalence in the population being tested (16).

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

FOREWORD

The Government of Myanmar recognizes that HIV is one of the priority public health issues. The country has been implementing a wide range of activities and services as national concern since 1989 with high political commitment.

Myanmar achieved major progress in expanding the coverage of HIV prevention among key populations and HIV treatment and care. Especially, antiretroviral treatment (ART) coverage doubled from 24% in 2012 to almost 50% in 2015. Part of this impressive achievement includes the shift of patients from private sector to the public sector – Government now manages nearly 56% of ART cases.

Despite the major progress, there remains a long way before accomplishing the vision of ending HIV as a public health threat by 2030. This vision is crucial in supporting Myanmar to achieve the Sustainable Development Goals (SDGs) and universal health coverage, by strengthening the leadership and enhancing public, private and community partnerships at all levels.

HIV testing service is one of critical elements of continuum of HIV prevention, care and treatment. The National Strategic Plan on HIV and AIDS 2016-2020 (NSPIII) stipulated 'maximize HIV testing and immediate initiation of ART among priority populations' as one of priority interventions. In particular, the NSPIII identified the following proposed approaches for HIV testing services;

- Outreach testing and key population service centre for key populations
- VCT for clients of female sex workers, unreached key populations and their partners in hospitals
- Co-location of confirmation HIV testing service and ART initiation in hospitals
- Provider initiated testing/counselling for sexually transmission clients, tuberculosis patients, pregnant women and prisoners
- Expanded quality assurance
- Demand raising through social network campaign, social media, FM radio
- Peer facilitated/peer navigated linkages to care and treatment

These Myanmar Guidelines on HIV Testing Services provide a series of important recommendations for implementing quality HIV testing services in public and private sectors across the country. The Ministry of Health and Sports acknowledge the contribution of experts and partners including WHO, US-CDC, ICAP at Columbia University, Japan International Cooperation Agency (JICA), National Reference Laboratory (NRL) Australia, and UNAIDS.

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EXECUTIVE SUMMARY

Purpose

Myanmar is a concentrated epidemic country with a strong history of providing HIV testing and treatment. HIV testing services (HTS) are the entry-point for HIV prevention, care and treatment. These new Guidelines for HIV testing services in Myanmar have been updated to reflect current science and evidence regarding HIV testing, the current epidemiology of HIV in Myanmar, and the need to expand coverage of HIV testing services especially for key populations and other vulnerable populations.

These guidelines aim to:

- provide comprehensive evidence-based recommendations for HTS;
- support testing by trained persons to increase access to HTS through community-based approaches;
- offer guidance on how to deliver a mix of HTS approaches appropriate to the Myanmar context, focusing HTS to groups most affected and currently undiagnosed and underserved;
- provide guidance to ensure accuracy of test results and support improvement of the quality of HTS;
- support effective HTS as a key element of the comprehensive HIV programme in Myanmar with better linkage to prevention, care and treatment to achieve reduced HIV incidence, morbidity and mortality

Key definition: HIV testing services

Throughout these guidelines the term **HIV testing services (HTS)** is used, embracing the full range of services that should be provided together with HIV testing – **counselling** (pre-test information and post-test counselling); **linkage** to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support **quality assurance** and the delivery of **correct results**. The World Health Organization 5 Cs of *consent, confidentiality, counselling, correct test results and connection to care and treatment* are principles that apply to all models of HTS and in all circumstances.

What has changed from previous HIV testing guidelines and HIV testing practice?

The Ministry of Health and Sports (MOHS), the National AIDS Programme (NAP), and the National Health Laboratory (NHL) remain committed to observing the basic WHO 5 Cs. Due to new evidence, increasing global emphasis on reaching persons not previously tested, and the

need to simplify and improve procedures, some changes from previous practice in Myanmar are recommended. These include:

1. Key populations need more attention: Persons who are at elevated risk for HIV infection, including men who have sex with men; people who inject drugs; sex workers; and transgender people are considered "key populations". Special efforts are needed to ensure that key populations have access to HIV testing services, and these services should be provided without discrimination or stigma.

2. "Window period" retesting should be reduced: It is no longer considered necessary to instruct all persons who test negative that they might be in the window period. For most people who test negative, there is no need for retesting. However, those persons who test negative but report a specific recent exposure or recent risk within the last 6 weeks, should be told to return for retesting in 4 to 6 weeks.

3. Pre-test information: A lengthy pre-test counselling session is no longer considered necessary. However, all persons should receive health information about HIV testing and should provide informed consent before being tested.

4. Post-test counselling: This is recommended primarily for persons with HIV-positive status. Persons who test negative can benefit from brief health information and the opportunity to ask questions.

5. HIV-positive diagnosis: WHO and the Myanmar MOHS, NHL, and NAP recommend that in a concentrated epidemic country such as Myanmar, three different assays should be performed before giving a patient or client confirmed HIV-positive status, and all three assays should have concordant HIV-reactive test results.

6. HIV-negative diagnosis: Persons who test non-reactive result on the first assay can be confirmed as HIV-negative.

7. HIV-inconclusive status: Persons who test reactive on the first assay and non-reactive on the second or third assay should have all 3 assays repeated immediately. If the test results remain different, this is called HIV-inconclusive and these persons should return for additional testing in 14 days or 2 weeks.

8. Community testing can provide either (a) confirmation testing with a definitive diagnosis being issued, by health care worker or (b) screening testing with only one assay being used and referral for confirmation testing for any person with a reactive test.

9. Screening testing is an approach which can be used especially where there is no trained health care worker available and/or the site does not meet the minimum criteria needed for confirmation testing but has been certified to provide screening testing.

In the screening testing approach, a trained community worker or health care worker will conduct only a single rapid test. Persons who test reactive should be referred immediately for additional confirmation testing and if confirmed HIV-positive, should be linked and enrolled on ART as promptly as possible.

10. Patients at higher risk of HIV infection in clinical setting: Patients who have tuberculosis (TB) or a sexually transmitted infection (STI) have a higher risk of being HIV-positive and should be offered HIV testing.

11. Retesting before starting ART: Starting anti-retroviral treatment (ART) is a serious medical decision, especially since ART is life-long treatment. Retesting to verify the diagnosis is recommended by the World Health Organization, and is considered "good clinical practice". This has been endorsed by the Myanmar Ministry of Health and Sports, the National AIDS Programme, and the National Health Laboratory. If ART will be provided by the same facility or health worker that did the initial testing, it is recommended that retesting should be performed using a new specimen and by a second tester, whenever feasible.

Note: All sites and programs offering HIV Testing Services should have at least one copy of these guidelines to ensure the services follow these standards. A "Brief Version" of these guidelines, (4 pages) is available at the end of this document. A copy of the Brief Version should be provided to every health worker, counselor, or other trained worker who provides HIV testing services.

Different levels of Testing

1. INTRODUCTION

1.1 Progress and challenges

Knowledge of HIV serostatus through HIV testing services (HTS) is a critical component of the HIV response. It is the gateway to HIV prevention, care, treatment and other support services. (17) The United Nations Joint 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". In Myanmar, the Ministry of Health and Sports, the National AIDS Programme, and the National Health Laboratory have worked to provide HIV testing services since 2000. Because of the serious medical, social and psychological consequences of HIV testing, all programmes and persons providing HIV testing must **strive for zero misclassifications and zero misdiagnoses.**

The overarching goals of HIV testing services are to:

- identify people with HIV through the provision of quality services for individuals, couples and families
- link individuals and their families to appropriate HIV treatment, care and support, as well as HIV prevention services, based upon their serostatus
- support the scale-up of high impact interventions in Myanmar to reduce HIV transmission, morbidity and mortality, including early access to antiretroviral therapy (ART), prevention of mother-to-child transmission (PMTCT), post-exposure prophylaxis (PEP), Pre-exposure Prophylaxis (PrEP) and other interventions as approved by the National AIDS Programme and the Ministry of Health and Sports.

The new National Strategic Plan (2016-2020) calls for 90% of female sex workers (FSW), men who have sex with men (MSM), people who inject drugs (PWID), prisoners and migrants have access to combination prevention services, 90% of people living with HIV know their status, 90% of people living with HIV who know their status receive treatment, 90% of people on treatment have achieved viral suppression and 90% of people living with, at risk of and affected by HIV report no discrimination, especially in health, education and workplace settings (18). The first "90" – knowledge of HIV serostatus – is essential for treatment initiation. In turn, early diagnosis and treatment initiation can improve patient outcomes as well as prevent HIV-1 transmission (19).

Access to and uptake of HTS has increased in Myanmar in recent years. The challenge now is to increase access to and uptake of HTS in a more focused and strategic way so as to better reach those who are currently undiagnosed and who are at greatest ongoing risk of HIV infection.

Increasing access for key populations

Key populations continue to be disproportionately affected by HIV in all countries, including

Myanmar. Adolescents (10–19 years old) and young people (15–24 years old) from key populations are at greater risk for HIV than older people from key populations and the general population (10). In Myanmar, HIV testing often takes place within ANC services and does not necessarily reach key populations. In many countries, including Myanmar, people from key populations are more likely to face barriers accessing HIV services because their behaviour is criminalized and they experience stigma and discrimination (10). Key populations often report that they avoid health services because of fear of legal consequences. Likewise, in many countries, men who have sex with men report that the experience of homophobia is the most important deterrent to accessing health services (20). To better serve key populations in Myanmar, it is important to prioritize and focus on tailored HTS approaches for key populations and deliver services free of stigma and discrimination.

Late or delayed linkage to prevention, care, treatment and support

Globally, many people diagnosed with an HIV-infection are not promptly linked to care and treatment (3), and this remains a problem in Myanmar. Barriers that hinder or delay linkage to HIV care and treatment persist, including transportation costs and distance to the facility, stigma, fear of disclosure, staff shortages and long waiting times (21), as well as policy and legal barriers that may hinder access particularly for adolescents and key populations. In many countries including Myanmar, many people with HIV test late and start ART late, even though there is considerable evidence for the medical and prevention benefits of early ART (22). A combination of interventions is needed to strengthen linkages to prevention, care and treatment, to improve retention for specific groups at risk and to reduce loss to follow-up between HIV testing and care and treatment, especially for key populations.

Quality HIV testing challenges

In addition to strategically expanding HTS, it is equally important that all clients or patients who undergo HIV testing receive the correct HIV diagnosis and HIV status reports. Recent reports suggest that misdiagnosis of HIV status is occurring in resource-limited settings (23). Poor quality HIV testing can be the result of a number of problems, including poorly performing products, improper storage or management of test kits and supplies, clerical or transcription errors, user errors in performing or interpreting the test, lack of training and supportive supervision, improper testing strategy and/or unvalidated testing algorithm, lack of standard operating procedures (SOPs) and poor record-keeping. Thus, it is important that quality assurance systems function effectively and expand in parallel with the delivery of HTS.

1.2. Scope of these Guidelines

These guidelines aim to improve the quality of HIV testing services and expand access to HTS, especially for key populations. These guidelines are based on the WHO 2015 Consolidated Guidelines on HIV Testing Services but have been adapted to the Myanmar context. These Myanmar HTS Guidelines are intended to assist national programme managers and service

providers, including those from community-based programmes, in planning for and implementing HTS. The entire WHO 2015 Consolidated Guidelines as well as annexes are available on the WHO website.

1.3. Guiding principles of HIV Testing Services in Myanmar

All forms of HIV testing should adhere to the WHO **"5 Cs":** *Consent, Confidentiality, Counselling, Correct test results and Connection* (linkage to prevention, care and treatment services) (24). Coerced testing is never appropriate, whether that coercion comes from a health-care provider, employer, authorities, such as immigration services, or from a partner or family member.

The 5 Cs are principles that apply to all HIV Testing Services 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. Although confidentiality should be respected, it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should discuss, among other issues, whom else the person may wish to inform of their sero-status 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 if appropriate, but all persons should have the opportunity to ask questions in a private setting if they request. All HTS must be accompanied by appropriate and high-quality post-test counselling, based on HIV test results. 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 HTS 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 include support from the national reference laboratory. All people who receive a positive HIV diagnosis should be retested to verify their diagnosis before initiation on ART or engagement in HIV care.

- **Connection:** Linkage to prevention, care and treatment services should include the provision of effective and appropriate follow-up as indicated, including long-term prevention and treatment support.

2. PRE-TEST AND POST-TEST SERVICES

Key points

- The 5 Cs are essential for all HTS: **consent, confidentiality, counselling, correct** test results, and **connection** to HIV prevention, treatment and care**.**
- **HTS should be prioritised for and promoted** to those who are at high risk and have not been tested recently.
- Verbal **consent** is usually adequate, but all individuals should have a private opportunity to refuse testing. Mandatory testing is never warranted.
- HTS providers must ensure that all tests results and client information are **confidential**. Although disclosure to sexual partners, supportive family members and health workers is often beneficial, this must be done only by or with the consent of the person being tested.
- **Retesting for the window period** is not recommended except for people who report specific recent risk. For people with ongoing risk, retesting is recommended every six months (details in page 110)
- It is the ethical and professional responsibility of the person providing HIV test results to adhere to international and national guidelines to ensure **correct test results.**
- **People who test HIV-negative** will usually need only brief health information about their test result, how to prevent HIV acquisition in the future and where and how to link to HIV prevention services, as appropriate. People with significant ongoing risk may need more active support and linkage to HIV prevention services.
- **People with first test reactive should receive confirmation testing.** If confirmation testing is not available on site, prior to referral, people should receive information on the meaning of reactive result for screening test and need of confirmatory test.
- Everyone who tests **HIV-positive should receive post-test counselling.** This should include recommending HIV testing for partners and children of all people with HIV. **Couples** where one or both test HIV-positive will often benefit from being counselled together so that they can be helped to disclose and support each other to link to ART and remain in care.
- **People** whose test results are not yet verified or who receive **inconclusive test results** need follow-up services to ensure that they receive verified results.
- **Key populations** need tailored approaches and messages.
- **Connection** to prevention, care and treatment is an essential component of HTS.

2.1. Introduction

Attaining UN 90–90–90 goals depend on the first "90" – diagnosing 90% of people with HIV. Many people in Myanmar with HIV have already been diagnosed, as evidenced by achievements, such as the estimated 85,000 people on ART in Myanmar as of the end of 2014. Many people needing care and treatment, however, remain undiagnosed. Successful linkage from diagnosis to prevention, care and treatment services is also essential to reach the second "90" – that 90% of people who know their HIV-positive status are on ART (18).

2.2. Services prior to HIV testing

Promotion and advocacy

In Myanmar, awareness raising programs should be focused on increasing access to HIV testing for key populations. The use of social media has also been shown to increase uptake, especially among key populations.

In addition to outreach and targeted promotion, clear signs that direct prospective clients to testing are important. This applies to testing in health facilities, in the community and through mobile services. In certain clinic settings, where HIV testing is offered, such as ANC, STI clinics and TB services, signs, printed information and posters and group health education sessions can efficiently inform pregnant women, other clients and family members that testing is offered.

Creating an enabling environment

Critical enablers are elements outside of health sector interventions that allow health interventions and services to be provided effectively and safely. Examples range from tolerance amongst the larger population toward people from key populations to laws and policies that enable young people to be tested without parental consent. Health-care providers and organizations delivering HTS should work with community-based and advocacy organizations and legal authorities to ensure that the environment supports and enables people to learn their HIV status. Health care workers should have training to enable to deliver respectful non-judgmental services.

WHO recommendation

Initiatives should be put in place to enforce privacy protection and institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV. This can help create environments where disclosure of HIV status is easier.

Source: WHO, 2011 (26).

Ensuring a confidential setting and preserving confidentiality

All HTS providers must remain committed to preserving confidentiality, one of the 5 Cs of HTS. Confidentiality applies not only to the test results and reports but also to any personal information, such as information concerning sexual behaviour and the use of illegal drugs. HIV testing services should avoid practices that can inadvertently reveal test results to others in the waiting room or in the health facility. Such practices might include counselling all people diagnosed HIV-positive in a special room or by a specific provider or making it obvious to others who is receiving additional testing or lengthy post-test counselling. Health workers and others who provide HIV testing may need special training regarding the confidentiality of medical records, particularly where key populations are concerned.

Pre-test information

Historically, HIV counselling has been provided both before and after HIV testing. However, with the wide use of rapid tests in Myanmar, most people receive their HIV test results– at least of their first test – and often a diagnosis on the same day. Therefore, intensive pre-test counselling is no longer needed and may create barriers to service delivery (27, 28). Individual risk assessment and individualized counselling is no longer recommended during the pre-test information session. Depending on local conditions and resources, programmes may provide pre-test information through individual or group information sessions, multimedia sources such as posters, brochures, websites and short video clips shown in waiting rooms, among others.

The aim of offering or recommending HIV testing to a client or a group of clients is to provide clear and concise information that includes:

- the benefits of HIV testing
- the meaning of a first reactive rapid test and the importance of immediate referral for confirmation testing where screening testing is implemented
- the meaning of a confirmed HIV-positive and an HIV-negative diagnosis
- the meaning of an inconclusive result and the importance of retesting after 14 days
- the services available in the case of an HIV-positive diagnosis, including where ART is provided
- a brief description of prevention options
- encouragement of partner testing in particular for all persons who test positive
- the fact that the test result and any information shared by the client is confidential

- the fact that the client has the right to refuse to be tested and that declining testing will not affect the client's access to services or general medical care
- potential risks to the client in settings where there are legal implications for those who test positive and/or those whose sexual or other behaviour is stigmatized
- an opportunity to ask the provider additional questions.

Special considerations for pregnant or postpartum women

Pre-test information or health education for women who are or may become pregnant should also include:

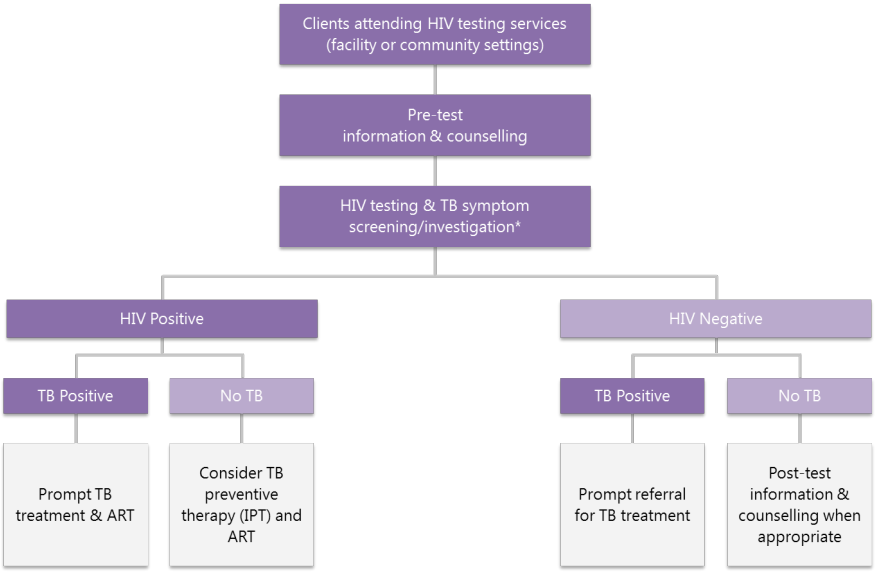
- the potential risks of transmitting HIV to the infant
- measures that can be taken to reduce mother-to-child transmission, including the provision of ART to benefit the mother and prevent HIV transmission to the infant
- counselling on infant feeding practices to reduce the risk of HIV transmission
- the benefits of early HIV diagnosis for mothers and infants
- encouragement of partner testing

Intensified TB case finding at HIV testing facilities

Tuberculosis is the most common presenting illness among people with HIV. It is fatal if undetected or untreated and is the leading cause of death among people with HIV, responsible for about one in 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.

HTS should integrate TB symptom screening into the pre-test information session before HIV testing, both at health facilities and in community-based testing. All clients with TB symptoms should be thoroughly investigated, and post-test counselling should discuss the outcome of this investigation. All clients diagnosed with TB should be promptly registered with the national TB programme and started on anti-TB treatment. HIV-positive clients diagnosed with active TB should be urgently started on ART, while those not having TB should be started on TB preventive therapy (for example, isoniazid preventive therapy) as indicated in the schema below.

Figure 1. HIV/TB testing and screening algorithm to increase TB case finding in HTS



*Per national guidelines.

Special considerations for key populations

There are many reports of discrimination and stigma against key populations in health-care settings. Health care workers may need training so that they better understand the needs of key populations and be familiar with local support and prevention services (10). Links with key population networks and community-based organizations to support or provide HTS, including services delivered by peers, may increase reach, uptake and acceptability. Such services for key populations already exist in Myanmar and expansion should be considered.

Consent by adults

Informed consent remains one of the essential 5Cs of testing services. It should always be obtained individually and in private by an HTS provider. In most settings verbal consent for HIV testing is sufficient. The provider must ensure that the client has learned enough about testing to give informed consent. HTS may provide information about testing and the need for consent in a group setting, such as group health education, but clients should give consent in an individual and private manner. In settings such as antenatal care or TB clinics, where HIV testing may be routine, health workers should carefully explain how a client can decline testing and ensure that each person has a private opportunity to opt out of testing. People who are intoxicated or otherwise mentally impaired should not be tested, as they are not able

to give informed consent. People who are seriously ill with no ability to give consent should only be tested if the health care provider believes that HIV testing could provide best benefit for individual's further medical care. HTS managers and supervisors should ensure that no one coerces clients or patients into being tested.

Consent by adolescents

Health care workers and HTS providers should assess the maturity of the adolescent prior to providing HIV testing services. WHO encourages countries to uphold adolescents' rights to make choices about their own health and well-being, with consideration for different levels of maturity and understanding.

2.3. Services after testing for those who test HIV-negative

Individuals whose HIV diagnosis is negative should be informed about their test results and be provided with brief information and an opportunity to ask questions and discuss any concerns they have. Research to date has not demonstrated that a lengthy counselling session is beneficial. (29)

The following brief information should be provided for persons who test negative:

- an explanation of the test result
- for people with ongoing HIV risk should have education on methods to prevent HIV acquisition and promotion of condom use. Note that key population clients should be provided with male and female condoms, lubricant and guidance on their use where possible.
- emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couples testing services
- referral and linkage to relevant HIV prevention services should be prioritised for people at ongoing HIV risk, particularly people from key populations, including harm reduction and other interventions such as pre-exposure prophylaxis (PrEP). PrEP has been shown to be highly effective in preventing new HIV infections among persons at risk. The National AIDS Programme is assessing the potential of PrEP in Myanmar.
- **Note that for most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary** (8). However a recommendation for retesting for HIV-negative persons, based on the client's risk of exposure should be made for the following two scenarios
    - a person with recent and specific risk that occurred in the last 6 weeks should return for retesting in 4 to 6 weeks

- an HIV-negative person with on-going risk of exposure such as key populations and persons in sero-discordant relationship (s) may benefit from testing every 6 months

Persons who do not report recent or on-going risk should be advised to return for testing only if their personal situation changes and if they are potentially exposed to HIV infection.

2.4. Services for those whose test results are inconclusive or not yet confirmed

An **HIV-inconclusive test status** means that first reactive assay result was not confirmed after additional testing, or when the two assay results are reactive but the 2nd or 3rd assay is non-reactive. All people with inconclusive status should be encouraged to **return in 14 days for retesting.**

Receiving inconclusive results may be confusing and stressful for the individual or couple and may be difficult for the provider to explain. Most inconclusive diagnoses can be resolved with retesting 14 days or 2 weeks later. For full discussion of inconclusive test status, see Chapter 5. Individuals with an HIV-inconclusive status should be informed that a confirmed diagnosis cannot be provided that day and encouraged to return for retesting 14 days or 2 weeks later. The individual can also be informed that this is not an HIV diagnosis therefore referral to HIV care or ART initiation is not appropriate.

A person with a reactive HIV test result on a first rapid test diagnosed in a screening testing service needs to be linked immediately to the nearest HIV confirmation site. The following brief information should be provided for persons prior to referral for confirmation testing.

- Meaning of reactive result (i.e. the test may have reacted to HIV, and possibility of reaction to something else in client's blood)
- Importance of confirmation testing to confirm HIV result through three different serology assays.
- Facilities where confirmation testing is available
- Education on methods to prevent HIV acquisition should be provided and condom use be promoted.

Note that key population clients should be provided with male and female condoms, lubricant and guidance on their use where possible.

All clients with inconclusive results need to be provided with a clear plan for follow-up testing. Clients with reactive test result of HIV screening test, he/she need to be informed that the screening result is not a diagnosis and needs to be confirmed.

2.5. Services for those whose status is HIV-positive

A diagnosis of HIV-infection is a very serious event. It is the professional and ethical duty of the person providing the HIV diagnosis to ensure that testing procedures follow NAP and NHL recommended testing strategies.

Once health workers, counsellors, or other trained persons are confident of adherence to all measures to ensure **correct test results,** they should prov de post-test health education along with **counselling** for those testing HIV-positive. All post-test counselling should be "**client-centred**", which means avoiding formulaic messages that are the same for everyone regardless of their personal needs and circumstances. Counselling should **always be responsive** to and tailored to the unique situation of each individual or couple. Health care workers, professional counsellors, social workers, and trained peer counsellors can provide counselling. People living with HIV and peer counsellors who are trained in counselling may be particularly understanding of the needs and concerns of those who receive an HIV diagnosis and facilitate linkage to ART and when necessary to TB and STI treatment services.

The information and counselling that health workers or others provide to those with a **confirmed HIV diagnosis** should include that listed below. Providing all of this information in one session may be very challenging, and a follow-up counselling session may be required. Indeed, the shock of learning of an HIV-positive diagnosis may make it difficult for a person to take in further information immediately.

- **Explain** the testing results and diagnosis (status).
- **Give the client time** to consider the results and help the client cope with emotions arising from the diagnosis of HIV-infection.
- Discuss **immediate concerns** and help the client decide who in her or his social network may be available to provide immediate support.
- Assess the risk of **intimate partner violence** and discuss possible steps to ensure the physical safety of clients, particularly women, who are diagnosed HIV-positive.
- Assess the risk of suicide, depression, and other **mental health** consequences of a diagnosis of HIV-infection.
- Provide clear **information on ART** and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to obtain ART.
- Explain that the Care and Treatment site will retest once more for **verification** prior to enrolment.
- Arrange a specific date and time for **active referral.** The health worker or person doing the test should make an appointment for the client and if at all possible, accompany

the client or patient to the appointment and assist the client to enrol in clinical care and treatment. Discuss barriers to linkage to care, same-day enrolment and ART eligibility assessment. Arrange for follow-up of clients who are unable to enrol in HIV care on the day of diagnosis.

- Provide information on how to **prevent transmission of HIV,** including information of the reduced transmission risks when virally suppressed on ART
- Provide male or female **condoms and lubricants** and guidance on their use. Consistent use of condoms is particularly important for people with HIV infection to prevent HIV transmission to sexual partners until they are virally supressed on ART.
- Discuss possible disclosure of the result and **the risks and benefits of disclosure**, particularly among couples and partners. Offer couples counselling to support mutual disclosure.
- Encourage and offer HIV **testing for sexual partners, children and other family members** of the client. This can be done individually, through couples testing, index case testing or partner notification.
- Provide information about **PrEP for HIV-negative partners** at sites where services may become available in the future, to protect the HIV-negative partner in a sero-discordant relationship until the HIV-positive partner has successfully enrolled in ART and achieved viral suppression.
- Provide **additional referrals for prevention, counselling, support and other services** as appropriate (for example, TB screening and treatment and ITP for people screened negative for TB, HBV and HCV testing prophylaxis for opportunistic infections, STI screening and treatment, contraception, antenatal care, opioid substitution therapy and access to sterile needles and syringes).
- Encourage and provide time for the client to ask additional questions.

Special considerations concerning disclosure

People who test HIV-negative can usually disclose their test results to others, though some may need guidance on disclosure. Maintaining privacy about HIV-positive test results is a very serious concern for many who test positive, especially those from key population groups such as MSM, Transgender persons, sex workers, and people who inject drugs.

There are three forms of disclosure relevant and appropriate to HIV testing:

- **Disclosure by the individual to a sexual partner, family member or friend.** Disclosure has considerable benefits, particularly for couples and sexual partners as

this can provide support for linkage to ART, adherence to treatment and retention in care. However, many clients who learn that they are HIV-positive need time to absorb the diagnosis before they are ready to disclose and may benefit from additional counselling. Women who have experienced intimate-partner violence prior to testing may experience violence from their partner after disclosing the HIV test results. Providers and counsellors should assess the risk of intimate partner violence in the individuals they serve (31, 32) and give referrals as needed.

- **Disclosure by a health worker to other health workers** involved in the client's care. Providers need to inform people who test HIV- positive that, in order to assure appropriate medical care, the diagnosis will be shared with other medical workers as needed. This disclosure should respect the basic client right to privacy and confidentiality of all medical information.

- **Disclosure by a health worker to a sexual partner of the individual requires prior consent from the person tested positive.** Disclosure of test results to sexual or drug-injected partners can be beneficial, but must always be voluntary and with the informed consent of the person with HIV. Providers need to be aware that some clients are more susceptible to adverse outcomes of disclosure of HIV status such as discrimination, violence, abandonment or incarceration. In such cases, clients may need additional counselling to ensure informed consent before testing as well as to support appropriate disclosure after testing.

Disclosure by a health worker to the police or other legal authorities is not considered ethical in the context of HTS unless the client has consented to this disclosure.

Post-test counselling for special populations

Key populations. Intensified post-test counselling combined with follow-up counselling by health care workers or peer counsellors significantly increases the proportion of people with HIV who enrol in HIV care (33). PWID are more likely to start and stay in HIV treatment if they are participating in opioid substitution therapy (OST) programmes (34). Therefore, referral for other services such as OST should be included in post-test counselling for people from key populations. Some people from key populations who test HIV-positive may lack social networks and/or a supportive family to help them deal with their diagnosis. These people may need additional counselling as well as peer support services, including support groups to cope with this diagnosis. A peer counsellor may particularly help people understand and cope with the diagnosis and support linkage to care and treatment by serving as a "peer navigator" who assists with finding, choosing and obtaining a full range of services.

Pregnant women. Post-test counselling for pregnant women whose test result is HIV-positive should include the following, in addition to the standard messages described above for all people diagnosed with HIV-infection:

- **childbirth plans:** providers should encourage HIV-positive pregnant women to deliver in a health facility for their own well-being as well as to ensure access to PMTCT services,
- **use of ARVs for the client's health**, as well as the use of **ARVs to prevent transmission to the infant,**
- the importance of **partner testing** of sero-positive pregnant women should be emphasized and there are variety approaches to this including availability of couples testing services
- ensuring **screening for tuberculosis** and testing for other infections such as syphilis
- **counselling on adequate maternal nutrition**, including iron and folic acid, **advice on infant feeding options** and support to carry out the mother's infant feeding choice,
- Importance of regular Ante-Natal care and infant immunization at health facility
- **HIV testing for the infant** and needed follow-up for HIV-exposed infants.

Adolescents. Along with standard messages for all those diagnosed with HIV-infection, post-test counselling for adolescents whose test result is HIV-positive should include (30):

- **tailored help** with linkage to HIV care and treatment;
- counselling, referral and linkage to specific **psychosocial and mental health services** tailored to both the situation in which infection happened and the developmental age of the individual;
- information on **right to confidentiality;**
- an opportunity to ask questions and discuss **issues related to sexuality** and the challenges they may encounter in relationships, marriage and childbearing;
- individualized planning on **how, when and to whom to disclose** HIV status and engage families and peers in providing support;
- referral for **small group counselling and structured peer support groups,** which may particularly benefit for adolescents with HIV.

Children. WHO recommends that disclosure to children is a process and should be started as early as possible and full disclosure should be achieved by 12 years. http://www.who.int/hiv/pub/hiv_disclosure/en/

2.6. Linkage to care and treatment

HTS providers have a crucial responsibility to ensure prompt linkage to care and treatment or people diagnosed with HIV-infection. 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 (35). Follow-up may be needed.

Key messages about linkages and connections to prevention, care and treatment

- All people who test HIV-positive need immediate linkage to care to maximize the benefits of ART.
- Special efforts will be needed to link people who test positive in community settings to facility-based services for verification of results and assessment for ART.
- People diagnosed HIV-positive and those testing HIV-negative with ongoing HIV risk need to be linked to prevention services.

Linkage to care after receiving a HIV-positive status remains challenging in many countries, including Myanmar. Systematic reviews and observational studies describe practices, listed below, that may improve linkage to care and treatment after HIV testing.

Good practices to increase linkage to care and treatment

- **Integrated or co-located services,** where testing, confirmation, verification of test results, HIV prevention, care and treatment, TB and STI screening and treatment, harm reduction services, and other relevant services are provided together at a single facility or site (36)**;**
- **Key population friendly services,** this may include centers for sex workers, MSM, TG and PWID, private and public facilities where HCWs have been trained to provide services for key populations should be supported and expanded.
- Providing assistance with transport, such as **transportation vouchers** if the ART site is far from the HTS site (21, 37);
- **Decentralized provision** and community-based distribution of ART (38);
- Support and involvement of **trained community workers or volunteers** who are peers and act as peer navigators, expert patients and community outreach workers to provide support and to identify and reach people lost to follow-up (38-40);
- **Intensified post-test counselling** by health care workers or peer counsellors (41);
- Using communication technologies, such as **mobile phones and text messaging,** which may help with disclosure, adherence and retention (42-44), particularly for adolescents and young people (30);
- 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 (28, 45, 46);
- **Promoting partner testing** may increase rates of HIV testing and linkage to ART and adherence to treatment and retention in care. Male involvement in PMTCT settings should be encouraged. (47, 48).

3. SERVICE DELIVERY APPROACHES

Key points

- There are **many facility-based and community-based approaches to delivering HTS.** Selecting approaches strategically and applying effective programming practices is critical.
- There are **many advantages to integrating HIV testing with testing for HBV and HCV, and screening and testing for TB and STIs.**
- **Trained and supervised community workers using RDTs are authorized to perform HIV testing, provide pre-test information and post-test counselling.** This will increase access, particularly to community-based services.
- The **routine offer of HTS in clinical settings (PITC)** is being scaled up in Myanmar in antenatal, STI, hepatitis and TB clinics. Many private providers such as GPs have been trained to provide HIV testing in their offices. Expansion of testing in ANC, TB and private clinics should continue but appropriate training and supervision is needed.
- In this guidance an additional approach is proposed **screening testing,** in which a single RDT is offered with linkage to further testing to confirm the diagnosis and clinical care, when needed.

3.1. Principles and approaches to service delivery

HTS can be delivered in different ways and to different people. They can be offered in a variety of settings, both in health facilities and in the community. HTS can be offered in facilities such as primary care clinics such as ANC, specialist clinics such as STI, hepatitis and TB clinics, in district and provincial or regional hospitals and their laboratories and in private clinical services. In the community, HTS can be offered through outreach to key populations.

A strategic mix of HTS approaches facilitates diagnosis of as many people as early as possible, with linkage to prevention, care, treatment and support for those testing HIV-positive and to prevention services for those who test HIV-negative.

Task sharing of HTS: increasing the scope of trained community workers

Task sharing – that is, the rational redistribution of tasks from "higher level" cadres of health-care providers to other cadres – is a pragmatic response to health workforce shortages. (14) Task sharing may help to address the needs of key populations and other priority groups that may be reluctant or unable to access HTS in health facilities. A trained person who has not received formal professional or para-professional training in health care services but has been trained to provide HIV testing services may provide these services in Myanmar. This approach has been recommended by the World Health Organization, the Myanmar Ministry of Health and Sports, and the National AIDS Programme.

Additional considerations for trained community workers

Selection. In general, clients prefer providers they can trust; such trust is based on providers' professional conduct, knowledge, politeness, adeptness in dealing with sensitive issues and ability to listen (49). Sometimes clients prefer providers from within their own community; others prefer the privacy of receiving HTS services from a stranger or a person from another community.

Training, mentoring and ongoing support. All persons involved in HTS delivery, including health care workers, laboratory technicians, trained community workers or peer counsellors, and others need training, mentoring, and supervision. Standardized training should cover how to conduct full HTS procedures, including collecting specimens, performing RDTs following the validated national testing algorithm and testing strategy, providing counselling and issuing test results as well as record-keeping and reporting in line with the type and level of HTS services providers will be engaged in implementing. They should also have access to these guidelines, the brief version of these guidelines, up to date job aids, and standard operating procedures (SOPs).

Human rights and medical ethics: All persons providing HTS, including health care workers, laboratory technicians, and trained community workersor peer counsellors, should be trained in medical ethics and human rights issues relevant to health so that they are fully aware of their duties to obtain consent, to maintain confidentiality regarding the client and the test result, respect the human rights of all clients and patients and provide non-discriminatory and key population friendly services.

3.2. HIV testing service approaches

WHO as well as the Myanmar MOHS and NAP recommend making HTS available through a wide range of approaches, both in facilities and in the community, as appropriate to local epidemiology and context.

Facility-based HIV testing services

"Facility-based HIV testing services" refers to HTS provided in a health facility or laboratory setting for provider and client initiated (walk-in) clients.

Provider-initiated testing and counselling (PITC)

PITC denotes HTS that is routinely offered in a health facility or routinely offered by health care workers.(50) It also includes providing pre-test information and obtaining consent with the option for individuals to decline testing. In a concentrated epidemic setting such as Myanmar, routine PITC will most likely not be cost-effective outside of services mentioned below. However, HIV testing should still be made available for persons who request testing, those who exhibit clinical signs and symptoms indicative of HIV, or meet the categories below:

PITC offered routinely in ANC is now the standard policy in Myanmar. Repeat testing in pregnancy is not necessary unless the woman reports recent and specific risk.

PITC offered routinely in TB clinics, to all TB patients, is standard in Myanmar.

PITC offered in clinical settings where higher rates of HIV-infection are often observed, including STI and hepatitis clinics and services for key populations including harm reduction services for PWID (50).

PITC offered to people presenting in inpatient and outpatient hospital settings with symptoms and clinical conditions indicative or related to HIV-infection. This may also be offered by private medical practitioners. This is sometimes called "indicator condition-guided testing" where HIV testing is offered to patients with TB, STIs, viral hepatitis and other clinical conditions associated with HIV. (52)

Paediatric testing: Offering HIV testing to all children whose parents have HIV and to all children with conditions indicative of HIV and in malnutrition clinics may identify children with previously undiagnosed HIV infection.

Testing for TB through HIV services

Tuberculosis is the leading cause of death among people infected with HIV (53). However, only an estimated 48% of TB patients with HIV receive an HIV test. HIV testing in TB settings needs scaling up (53). WHO recommends intensified TB case finding among persons with HIV to facilitate early TB detection and treatment (54). HTS offer an opportunity to screen for TB and detect it early. **Systematic TB screening should be integrated into HTS and offered wherever HIV testing is carried out and to all populations receiving HIV testing, irrespective of their test result.** Intensified TB case finding in clinical and outreach settings will facilitate early detection of HIV-associated TB and linkage to treatment. Particularly in settings with a high burden of both TB and HIV, it might also contribute appreciably to the detection and treatment of TB in general (55, 56) and so reduce morbidity and mortality associated with TB.

Pre-test information for all clients willing to undergo HIV testing should include information on systematic assessment of TB. All persons with TB symptoms should be promptly referred for a TB diagnostic workup that includes investigations such as sputum smear microscopy, chest X-ray, histopathology and molecular testing, depending on country context and national guidelines (57). Return of screening findings should be prompt so that the results can be shared with the client along with post-test HIV information. If a person is found to have TB, he or she should start TB treatment promptly.

Testing for HIV and other STIs

HIV and STI co-infection is common (58). Services providing care for STIs are one of the key

entry points for HIV prevention and referral services. **WHO recommends routinely offering HIV testing for patients diagnosed with other STIs** (59). Several studies have shown that HIV testing in STI clinics is feasible and uptake of testing is high (60, 61). Treatable STIs, such as gonorrhoea and syphilis, indicate recent un-protected or sex without a condom, and this may identify people at a heightened risk of HIV acquisition. People receiving STI treatment may also have primary HIV-infection and therefore have a high HIV viral load. Thus, diagnosing individuals with co-infection is important both as a prevention strategy and to improve the quality of care for persons with HIV.

In particular, both syphilis testing and HIV testing should be routinely offered to women attending ANC (59, 62). Syphilis testing and treatment (if reactive on a treponemal RDT) are prevention activities demonstrated to be effective in pregnancy. Given their common mode of sexual transmission, HIV and syphilis co-infection is common. Syphilis infection is a recognized cofactor for HIV transmission and acquisition, and maternal syphilis infection has been associated with increased risk of mother-to-child transmission of HIV (63). In general, syphilis screening and treatment for pregnant women is one of the most cost-effective antenatal interventions, even in settings with a low prevalence of syphilis (62, 64).

WHO recommendations relevant to Myanmar:

In low-level or concentrated epidemic settings, HIV testing should be offered to patients (adults, adolescents and children) in clinical settings who present with symptoms or medical conditions that could indicate HIV-infection, including presumed and confirmed TB cases.

Regardless of epidemic type routine HIV testing should be considered for malnutrition clinics, STI, hepatitis and TB services and ANC settings and for health services for key populations.

Sources: WHO, 2004 (59); WHO, 2007(65); WHO 2013 (57).

Community-based HIV testing services

Myanmar has already introduced community-based HTS, primarily for key populations. This is an important approach to reach first-time testers and people who encounter barriers to accessing clinical services due to stigma and discriminations, such as key populations (3). Linkage to prevention and treatment service is critical and should be emphasized and actively supported in association with all community-based HTS.

Mobile and outreach HTS includes community-based HTS service provision at sites such as bars and clubs, cruising sites, mines and factories. Mobile HTS can be provided through mobile vans or tents, or take place in sites temporarily used for the purposes of delivery of HTS service delivery. Such services may be offered continuously, on a regular schedule or as a one-time or occasional promoted event. Outreach services may be designed to serve key populations, such as "moonlight HTS", in which services are offered at night.

Implementing confirmation HIV testing can be successfully done in community settings. In some settings with human resources or other constraints, WHO recommends screening testing as an additional option, described below.

Screening testing: a strategy to support expanding HTS

screening testing is an approach to support HTS provided by trained community workers or health care workers(15). In this approach trained community workers or health care workers conduct a single HIV RDT for a client. Individuals with a non-reactive test result are informed of their HIV-negative status, referred for appropriate HIV prevention services, and advised to re-test if they have had recent or have on-going HIV risk. Retesting to rule out recent infection should follow procedures described in Chapter 2.

If the single RDT test result is *reactive*, individuals should be linked immediately to the nearest HIV confirmation site and provider certified to provide HTS following the validated national testing algorithm, beginning with A1 (see Chapter 5). Clients with one reactive test result should not be told they are HIV-positive until their status is confirmed (see 2.4 for details). When the reactive test result is confirmed by additional testing, the individual is diagnosed HIV-positive, the result issued to the client, and the client should be linked for clinical assessment and prompt enrolment in treatment.

Key advantages of the screening testing approach are that it:

- simplifies the scope of work for trained community workers and permits task sharing;
- reduces logistics, supply chain and training constraints, as a single RDT is used;
- improves access for those at highest risk and not currently testing for HIV;
- takes a first step toward linking a person with a first reactive test to confirmation testing, where a definitive diagnosis using the complete testing algorithm can be made;
- facilitates quick scale-up of HTS in settings and among populations where HIV prevalence is high.

Potential challenges of the screening testing approach are that it:

- may have an initial false reactive tests recognizing the need for prompt confirmation;
- trained community workers may not correctly communicate the meaning of a reactive screening testing result, and clients may mistake a reactive test result as a HIV-positive diagnosis;
- may result in poor linkage to additional testing to confirm the HIV diagnosis;

- may be difficult to track and monitor for those who test reactive on a first test to confirmation testing and, if confirmed HIV-positive, to HIV care and treatment if delivered at a different site.

Special emphasis on offering and supporting testing for all partners of people with HIV

Ways to increase offer and uptake of testing for sexual and drug injecting partners of people with HIV should be developed and supported. **Voluntary partner notification should be strongly encouraged for any person diagnosed as HIV-positive. Partner notification should only occur with the express consent of the HIV-positive client, and be made to their partners(s) alone, no one else.** Partner and couple testing should also be a priority for people in key populations, including MSM and transgender persons and for the regular/ intimate partner of sex workers. Programmes that particularly serve key populations should encourage and provide partner testing.

Partner testing and couples counselling promotes mutual disclosure of HIV status and increases adoption of prevention measures, especially in the case of discordant couples. The pre-test information session for couples should not ask about past sexual behaviour or risks, as this is unnecessary and may create problems for the couple. The person conducting a pre-test information session should make clear that both testing and post-test counselling can be provided individually if either partner prefers, and that disclosure of HIV status to the other person is not required.

Special attention and support needs to be offered to sero-discordant couples and should include provision of condoms, prompt enrolment in care and provision of ART for the HIV-positive partner and where available Pre-Exposure Prophylaxis (PrEP) can be offered to the sero-negative partner.

Providers may require training in how to non-judgementally engage in a discussion about sexual and drug injecting partner(s), facilitate mutual disclosure for couples, and effectively locate partners.

HIV self-testing

Over the decades, HIV testing using RDTs has been a gateway to prevention, treatment and care in Myanmar, and in turn, this testing strategy has created a demand for new policies and technologies that can potentially increase access to and uptake by the community. HIV self-testing (HIV-ST) is a new strategy introduced globally, and WHO recommends HIV-ST as an additional (HIV screening) approach to existing HIV testing services. However, in-country policy to demonstrate the effectiveness of this new approach has not been developed yet. This new guideline recommends to demonstrate ***HIV testing approach in Myanmar using WHO pre-qualified 100% sensitive (to ensure quality) RDT, either oral fluid or blood based.***

With the HIV-ST approach, the result of a single rapid diagnostic test (RDT) is not sufficient to make an HIV-positive diagnosis. The interpretation of HIV-ST reactive result needs further confirmation (see HIV-ST testing algorithm on Page 28) using the validated Myanmar National HIV testing algorithm. All self-testers with a non-reactive test result should retest if they might have been exposed to HIV in the preceding six weeks or are at high ongoing HIV risk. Individuals receiving an HIV-ST must receive adequate information on how to use the HIV-ST and information on where to go for further HIV testing services (confirmation) and/or other prevention services. The organization/providers/sites that support and provide HIV-ST will be responsible for effective communication (e.g. a helpline, website, etc.) to address the use of HIV-ST, provide information on where to access further confirmatory HIV testing and or any other information regarding the HIV-ST. Global updates and new emerging recommendations will inform introduction and implementation of HIV-ST in-country.

4. PRIORITY POPULATIONS IN MYANMAR

This chapter considers HIV testing service issues relating to key populations and other vulnerable populations.

- **Key populations.** HIV testing services for key populations are inadequate, and access to HIV prevention, care and treatment services remains low. Acceptable services for key populations must be expanded. Social, legal and health systems barriers must be reduced to encourage access to HTS for key populations.
- **Pregnant women.** Offering HIV testing in ANC as part of PMTCT has been highly successful in many countries. It has resulted in significant decreases in new paediatric HIV-infections and increased ART coverage for women.
- **Adolescents.** Adolescents who request HIV testing, especially those from key populations, need special attention, and health care workers need to be sensitive to the need for confidentiality when testing of young people.
- **Infants and children:** Diagnosing HIV-exposed infants as early as possible through virological testing is critical to starting ART as soon as possible and thus preventing early morbidity and mortality.

4.1. Key populations

Key populations – Men who have sex with men (MSM), people who inject drugs (PWID), sex workers (SW) and transgender people (TG) – continue to have limited access to health services, including HTS, in many countries In many settings these groups experience high HIV incidence (10). Stigma, discrimination, lack of confidentiality, coercion and fear of negative outcomes, as well as lack of appropriate health services, prevent people from testing and, if HIV-positive, linking to care (66, 67). Like all HTS, programmes for key populations need to emphasize WHO's "5 Cs" – particularly consent, confidentiality and connection to comprehensive prevention, care and treatment.

Community-based HTS is a critical approach for reaching people from key populations some of whom may face barriers to accessing services at facility level. To improve access to and uptake of HIV testing, community-based HTS should be made available in settings acceptable and convenient to people from key populations (68).

HTS in the context of medical care among key populations is recommended, so long as it is not compulsory or coercive and it is linked to treatment and care (10). In addition to HTS, testing and screening for STIs, TB and viral hepatitis should be offered to key populations (10). Intensified TB case finding, along with HTS, is also desirable among key populations as they are highly vulnerable to TB.

Retesting every six months is recommended for all people from key populations in Myanmar.

WHO recommendations related to HTS for key populations

- HIV testing services should be routinely offered to all key populations in the community, closed settings such as prisons, and clinical settings.
- Community-based HIV testing services for key populations, with linkage to prevention, care and treatment services is recommended, in addition to provider-initiated testing and counselling.
- Couples and partners should be offered HIV testing services with support for mutual disclosure. This applies also to couples and partners from key populations.

Source: WHO, 2014 *(10)*.

4.2. Other vulnerable populations

In prisons and other closed settings offering voluntary HIV testing as part of a package of care is a critical approach. HIV testing using RDTs could improve uptake of HTS and speed the receipt of test results. Particular attention should go to providing accurate information, obtaining informed consent and maintaining confidentiality and linkage to ART for those who test HIV-positive. Also, there are often major challenges to continuity of care within closed settings and between prisons and the community (69), so careful planning is needed.

Special considerations for people in prisons and other closed settings

- It is important to guard against negative consequences of testing in prisons – for example, segregation of prisoners – and to respect confidentiality. It is also important that people who test positive have access and are linked to HIV care and treatment services.
- HTS should be voluntary in all settings.
- The use of "on-site" HIV testing using RDTs can increase the likelihood that prisoners will receive their results.
- Testing in conjunction with other risk-reduction services can increase the benefits of HIV testing. Such services include provision of condoms with lubricants; STI, TB and viral hepatitis screening and treatment; provision of sterile injection equipment and opioid substitution therapy, and ART for those with HIV-positive status.

Source: WHO, 2014 (10).

Depending on context there are a number of other groups, which may be vulnerable to HIV-infection. These may include miners, migrant workers, long distance truck drivers, refugees and other displaced populations. Migrant workers, refugees and displaced persons have difficulty

accessing health-care services because of stigma, language differences, lack of necessary documentation, lack of transportation and long distances to services, discrimination and legal barriers. Displacement of key populations and others through human trafficking may further complicate the provision of HTS (76).

4.3. Pregnant women

The Myanmar MOHS and the NAP have endorsed HTS as early as possible during pregnancy so that pregnant women with HIV benefit from prevention, treatment and care and to reduce the risk of HIV transmission to their infants. (70) HIV testing is now offered in many ante-natal clinics (ANC) to eliminate mother-to-child transmission of HIV (eMTCT). (62) HIV testing in ANC settings has considerable public health benefits. HTS should also be routinely offered to the partners of all pregnant women who test HIV positive, and may also be provided to the partners of pregnant women who request HTS.

Pregnant women testing HIV-positive must be linked to ART for PMTCT and HIV services for their own health. Particularly for women from migrant or key populations, HIV testing may also be a point of entry to a broad range of pregnancy care services. The package of care for pregnant women with HIV should include systematic screening for TB and STI symptoms and referral and treatment as necessary. The presence of undetected TB among HIV-positive pregnant women doubles the rate of vertical HIV transmission (71).

Retesting in pregnancy

Pregnant women who report risk of HIV infection during pregnancy should be offered retesting later in the pregnancy. However, for most women in Myanmar, one test during pregnancy is adequate. Retesting all pregnant women in ANC or in the breastfeeding period is not warranted, as the incidence of seroconversion will be extremely low.

4.4. Adolescents

HTS for adolescents should be based on a human rights and public health approach (30). As with all HTS, HTS for adolescents should offer protection from stigma and discrimination related to HIV-positive status and risk behaviours and should also be confidential, respectful, inclusive and non-judgemental. It should provide strong referrals and linkages to HIV prevention, treatment, care and support services. When appropriate, and only with the adolescent's specific permission, health-care personnel should engage the support of adults – family members, care givers, teachers, and community members – as adolescents learn to manage living with HIV. In Myanmar efforts to support testing of adolescent and young people should focus on those from key population groups.

Age of consent: In general, adolescents should be assessed for their levels of maturity and understanding as well as their family situation and allowed to consent for testing as needed. In particular, HTS should be accessible to adolescents from key population groups, including

children who have been sexually abused or exploited and children who inject drugs. Authorities also should consider the role of other decision-makers in HTS for adolescents without parents or for those unwilling to involve parents.

4.5. 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. Diagnosing HIV-exposed infants as early as possible through virological testing is critical to starting ART and thus preventing early morbidity and mortality. (2) All babies and infants known to be HIV exposed should be tested as early as possible. If the mother's HIV status is unknown, infants with HIV related diseases or if the clinician suspects HIV infection should be tested.

- **For infants and children under 18 months,** HIV infection can be diagnosed only by virological testing because maternal HIV antibodies remain in the infants' bloodstream until 18 months of age, making test results from serological assays ambiguous. Virological testing using nucleic acid testing technologies (NAT) should be conducted using dried blood spot (DBS) specimens collected at health facilities. These specimens should be sent to the NHL and PHL for testing.

Regarding early infant diagnosis (EID), it is recommended that:

  - All HIV exposed infant should have HIV virological testing at 4-6 weeks of age or at the earliest opportunity thereafter.
  - If resources are available, addition of nucleic acid testing (NAT) at birth to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants.
  - In infants and children undergoing virological testing, the following NAT assays are strongly recommended for use: HIV DNA on DBS; HIV RNA on plasma or DBS.

- For children 18 months of age and older (who are not breastfeeding or who have stopped breastfeeding at least 3 months earlier), standard HIV serological assays such as RDTs and EIAs can reliably determine HIV status. However, a non-reactive test result on a serological assay does not exclude HIV infection particularly when RDTs are used between 4 and 18 months and infants are exposed to HIV postpartum through the breast milk of an HIV-infected mother.

5. DIAGNOSTICS FOR HIV DIAGNOSIS

Key points

- **Rapid diagnostic tests** (RDTs) are a critical tool for scaling up HIV testing. They can be performed by health-care workers, laboratory professionals, and other trained community workers. Such testing can be done in health facilities, clinics, and community settings, as these tests do not require specialized equipment or venepuncture specimen collection.
- **Retesting** is recommended:
    - for **all** individuals with HIV-inconclusive results
    - for **all** individuals with a confirmed HIV-positive status prior to ART initiation
    - for HIV-negative individuals with **ongoing risk** (i.e. key populations and people in serodiscordant relationships) every six months
    - for HIV-negative individuals who report a specific recent HIV exposure in the last 6 weeks, offering retesting after 4-6 weeks
- **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, non-reactive testing results should be interpreted with caution.

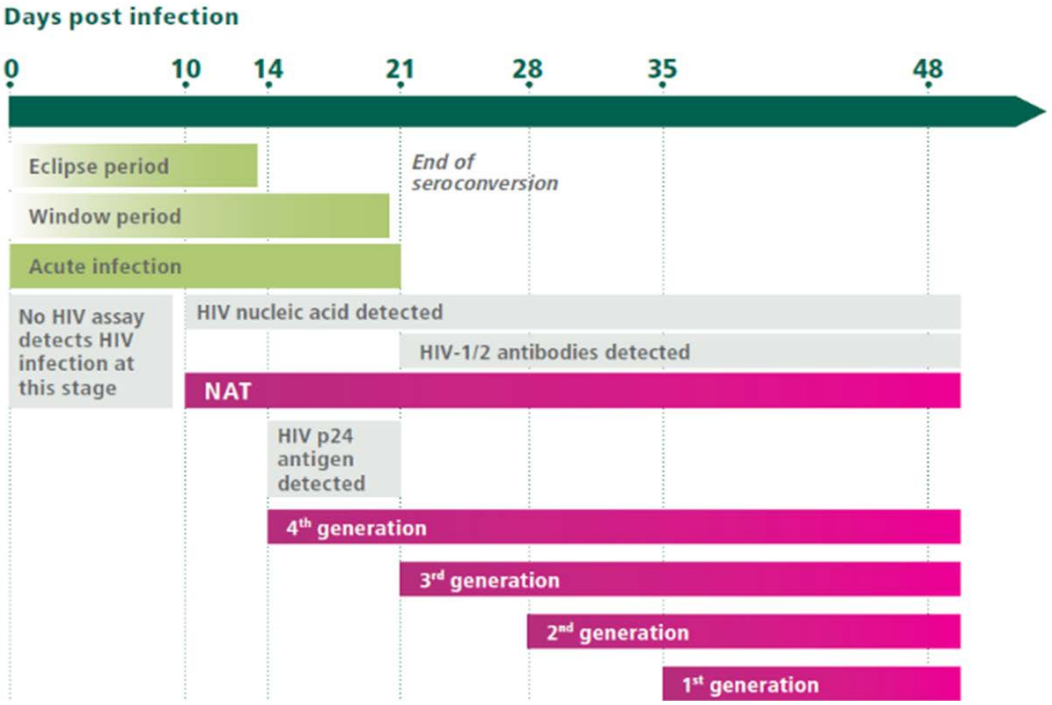
5.1. Overview of HIV diagnosis

HIV testing may take place at any level of the health-care system, and a diagnosis can be established for many individuals on the same day. Some people will access HIV testing in their community or at the primary care level; others will be tested in hospitals or special testing sites. Rapid diagnostic tests (RDTs) are a critical tool for scaling up HIV testing. They can be performed by trained community workers, health-care workers and laboratory professionals in various settings.

Number of assays for a confirmed diagnosis: For Myanmar, with a concentrated HIV epidemic, the recommended WHO HIV testing strategy states that any reactive HIV test result be confirmed with a second and a third assay that are more specific than the first assay (three reactive test results are required for a HIV-positive status to be issued). Additional testing may be needed to resolve cases of false reactivity (rule out false positives) and to verify reactivity (rule in true positives).

Window period retesting: The length of the window period is determined primarily by the type of serology assay used and also by individual's immune response. For a period of about 10 days following HIV-infection, known as the **eclipse period,** no serological or virological markers can be detected by any currently available assay. The end of the eclipse period is marked by the appearance of HIV RNA detectable by nucleic acid testing (NAT) and then HIV p24 antigen by immunoassay. The period prior to antibody detection is often referred to as "**acute infection**" (1, 19). 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, levels of HIV p24 antigen decrease as it binds to the binding sites available. Detection of HIV-1/2 antibodies by serology assays signals the end of the diagnostic window period and the end of seroconversion. Figure 7.2 from the WHO *"Consolidated guidelines on HIV testing services."* 2015 illustrates the eclipse and window period.

Figure 2. Detecting HIV infection with various formats and generations in vitro diagnostics over the natural history of infection



The National Health Laboratory of Myanmar will assess RDTs available and will recommend appropriate RDTs that can be used as the first, second, and third assay for use in Myanmar. The National Health Laboratory indicates which RDTs should be used in each of the testing strategies described below.

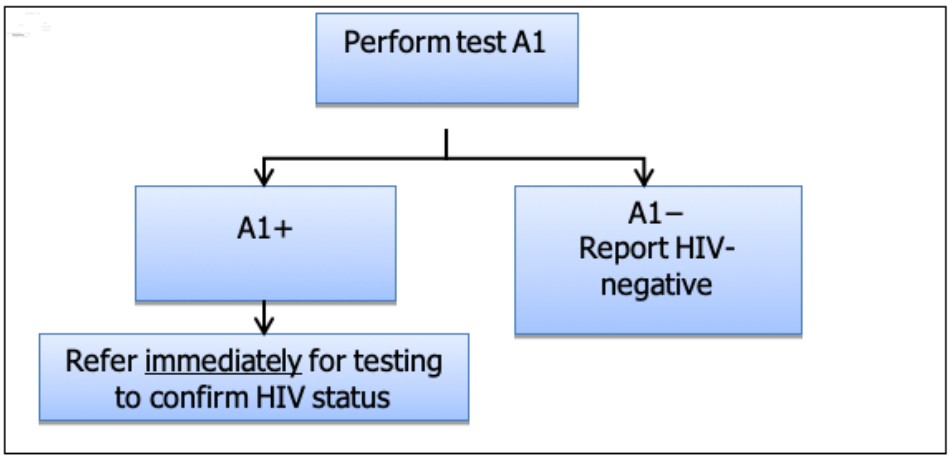
5.2. HIV testing strategies for diagnosis (18 months of age and older)

The following testing strategies are to be followed in Myanmar.

Screening testing

This strategy is recommended in settings (e.g. community outreach, community based sites, health facilities, and general practitioners) where the provider and/or the site does not meet the minimum standards needed for confirmation testing but has been certified to provide screening testing. In this strategy, a trained community worker or health care worker will conduct only a single RDT. Figure 1 below shows the testing algorithm for HIV screening.

Figure 3. Testing algorithm for HIV screening

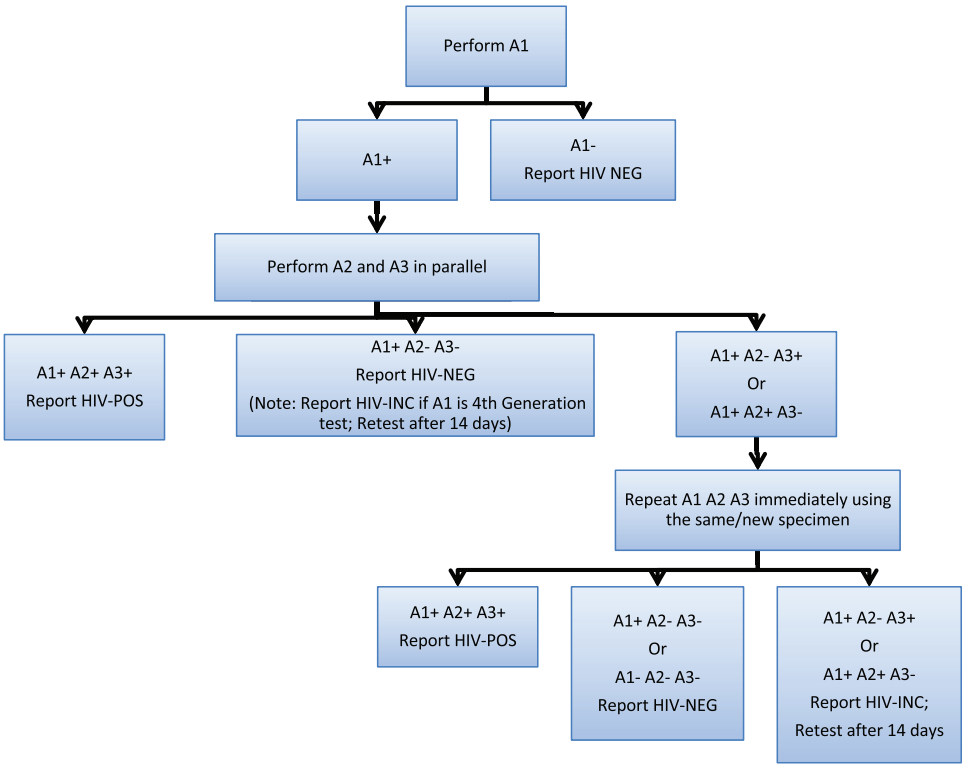


The assay (labelled A1 in Figure 1 above) must be a RDT that is **highly** sensitive.

Individuals who test HIV reactive should be referred immediately to the nearest site and provider approved for to provide testing to confirm their HIV status as per the national HIV testing algorithm. Approved sites for testing to confirm HIV status can be a community site, or health facility, or a certified laboratory, or a health facility which provides ART. The provider who performed the first assay **must take an active role to ensure that all persons who screen reactive actually receive testing to confirm their HIV status.**

At sites that meet the minimum standards to perform testing to confirm HIV status, a 3-assay testing strategy (adopted from WHO guidelines) will be used (see figure 2 below).

Figure 2. Testing algorithm for HIV confirmation



All specimens are first tested with a highly sensitive assay (A1), and specimens that are non-reactive (A1-) are considered HIV-negative and reported as such. These RDTs are the most sensitive assays currently available in Myanmar and take into account diagnostic sensitivity, and seroconversion sensitivity.

Any person with a reactive result on the first-line assay (A1+) should be retested using a separate and distinct second and third assay (A2 and A3) comprised of a different antigen preparation to avoid false cross-reactivity with A1. A2 and A3 which are required for HIV-positive diagnosis can be run in parallel. Assays A2 and A3 must have a higher specificity than A1.

For specimens that are reactive on the first, second and third assays (**A1+ A2+A3+**), the diagnosis is reported as **HIV-positive** and the individual needs to be referred for prompt enrollment in ART. Note: retesting to verify the HIV diagnosis should be performed prior to ART initiation. Please see chapter 2 for further information about counseling and services for HIV-positive clients.

If the results of the second and third assays are non-reactive (**A1+ A2- A3 -**), the diagnosis is reported as **HIV-negative.** Brief information and prevention services for HIV-negative clients are described in chapter 2. If the A1 assay is **4th generation**, this should be considered HIV-inconclusive and the individual should be retested in 14 days as 4th generation serology assays incorporate detection of both HIV-1/2 antibodies and HIV p24 antigen. It should be noted that 4th generation assays are not widely used in Myanmar.

For specimens that are reactive on the first-line assay but non-reactive on the second-line or third-line assay (A1+ A2- A3+ or A1+A2+A3-) testing should be repeated using a same/new specimen with the same three assays.

Any specimens that remain reactive on retesting with the first assay but are non-reactive on the second or third assay (**A1+ A2- A3+ or A1+A2+A3-**) **should be reported HIV-inconclusive and retesting in 14 days be recommended.** See Chapter 2 for counselling messages for persons with HIV-inconclusive results.

Recommended rapid test kits for 3-assay HIV Testing Strategy are:

A1 = Alere Determine HIV-1/2 (manufactured by Alere Medical Co., Ltd., Japan) (D) ICT (sensitivity 100% and specificity 99.75%)

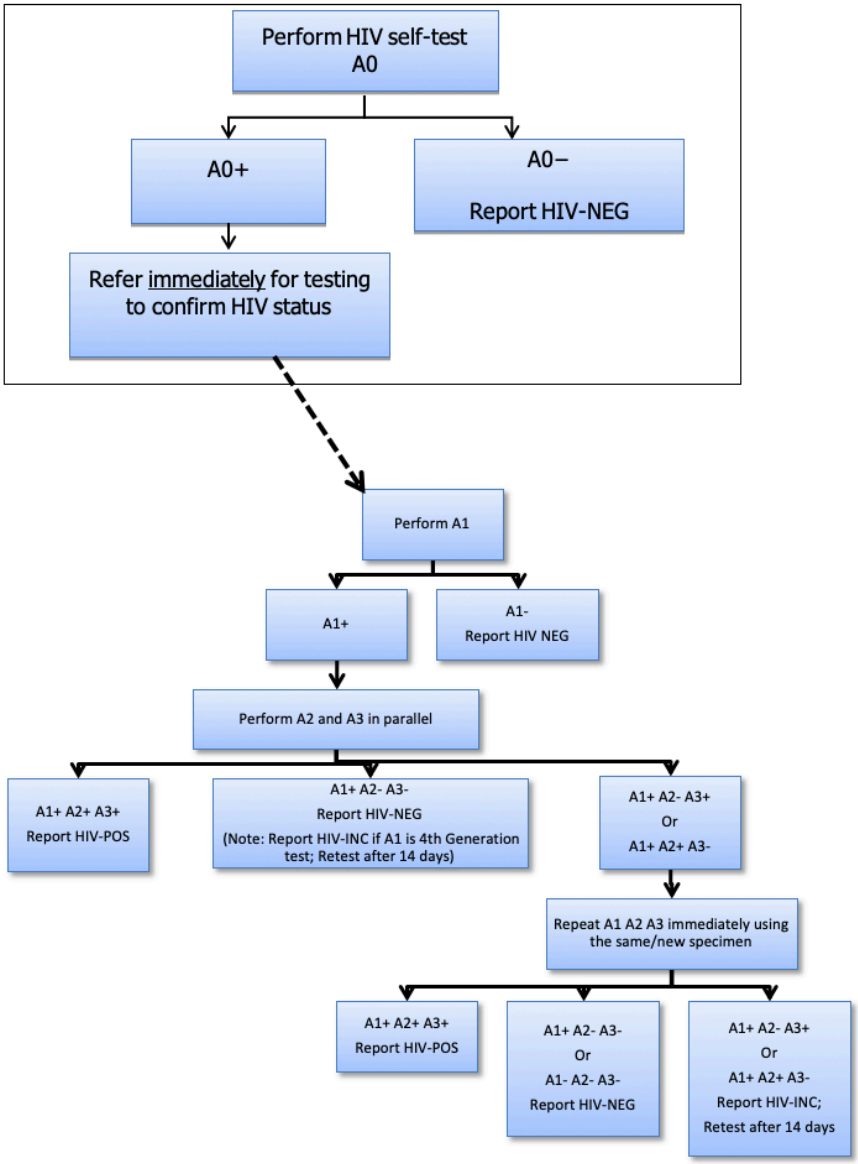
If not available, WHO pre-qualified RDT with 100% sensitivity and specificity similar to Determine.

A2 = Uni-Gold HIV (manufactured by Trinity Biotech Manufacturing Ltd., Ireland) (UG) ICT (sensitivity 100% and specificity 100%)

A3 = HIV 1/2 STAT-PAK (manufactured by Chembio Diagnostic Systems Ltd., USA) (SP) ICT (sensitivity 99% and specificity 100%)

For children of 18 months of age or older, who are not on breastfeeding anymore, or who have stopped breastfeeding at least six weeks earlier), can be diagnosed with standard HIV serological tests.

HIV-ST and HIV confirmation testing



HIV diagnosis in infant and children

Because of high mortality in the first year of life among untreated HIV-infected infant, early HIV testing, prompt return of results and rapid initiation of treatment are essential. Regarding early infant diagnosis (EID), it is recommended that:

- All HIV exposed infant should have HIV virological testing at 4-6 weeks of age or at the earliest opportunity thereafter.

- If resources are available, nucleic acid testing (NAT) at birth in addition to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants.
- In infants and children undergoing virological testing, the following NAT assays are strongly recommended for use: HIV DNA on DBS; HIV RNA on plasma or DBS.

HIV virological assays used for the purpose of clinical diagnostic testing (usually at or after 6 weeks of age) have a sensitivity of at least 95% and ideally greater than 98%, and specificity of 98% or more under quality assured, standardized and validated laboratory conditions.

HIV testing algorithm for infants born to HIV infected mother is shown in Figure 5.

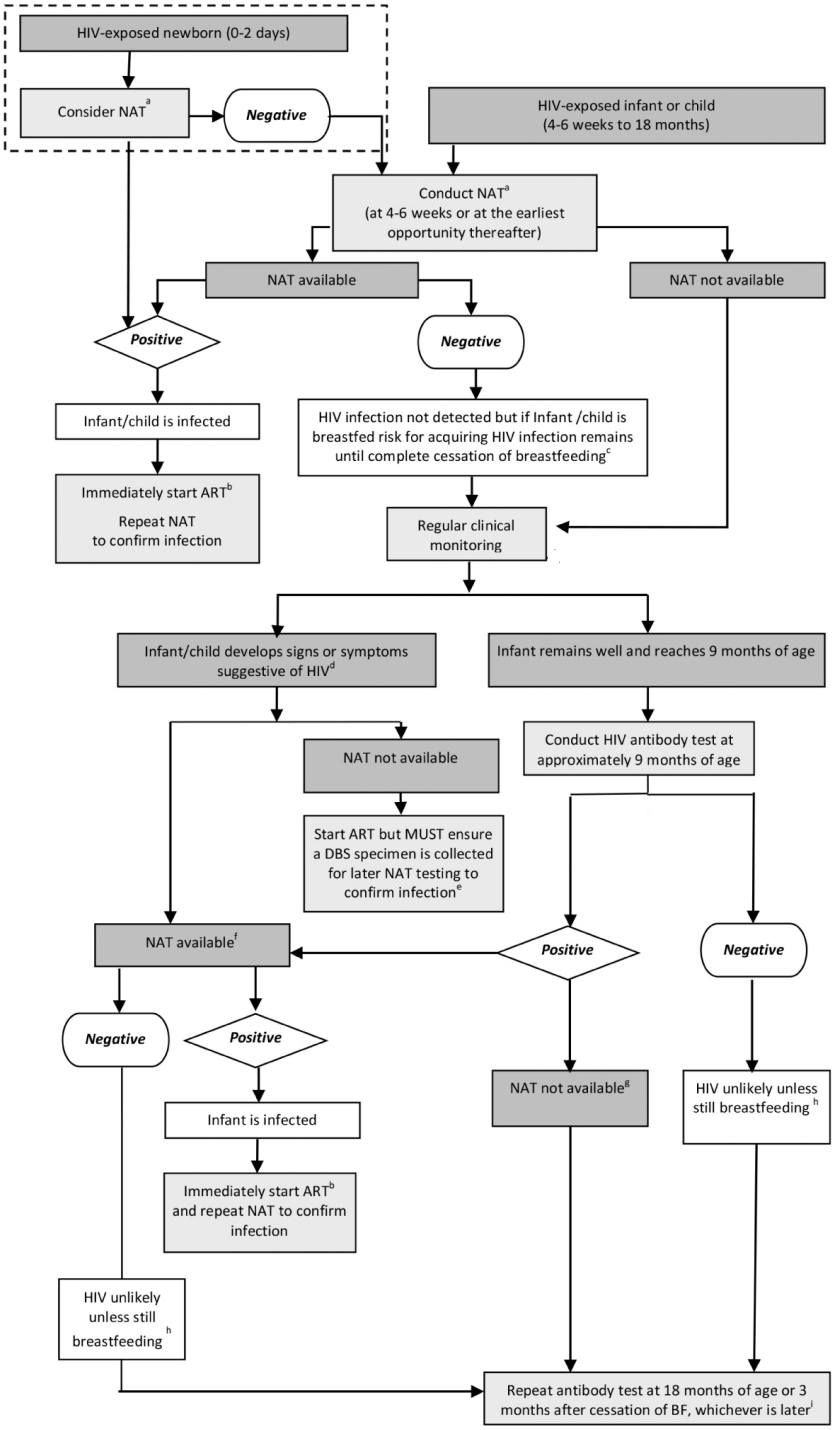
In infants with an initial positive virological test result, ART should be started without delay and, at the same time, a second specimen is collected to confirm the initial positive virological test result. ART should not be delayed while waiting for the result of the confirmatory testing.

Test results from virological testing in infants should be returned to the clinic and mother/ caregiver as soon as possible, preferably within four weeks of specimen collection.

HIV RDTs for use in infants and children

Many settings use HIV-1/2 RDTs to assess HIV exposure in infants and children younger than 18 months and to diagnose HIV-infection in children older than 18 months. The performance of these assays is acceptable for infants younger than 4 months. Concerns have been raised, however, concerning the reliability of certain serological assays between 4 and 18 months, most notably for second generation RDTs that may not include detection of IgM (77-79). For this reason HIV testing of the mother is preferable, whenever possible, to rule out HIV exposure of the infant and to diagnose the mother. Where possible, use of virological testing should be considered if HIV-infection is suspected. Serological testing of the child should be repeated after 18 months of age to assess final status, with the caveat that exposure to ART may lead to false-negative results with certain serology assays. For children over 18 months of age, the above HIV testing algorithm should be applied.

Figure 5. Algorithm for early infant diagnosis



Important Notes:

[a] Based on these revised Guidelines addition of NAT at birth to the existing testing algorithm can be considered.

[b] Start ART, without delay. At the same time, it needs retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase and re-testing after a first positive NAT is important to avoid unnecessarily treatment, particularly in settings with lower transmission rates. If the second test is negative, a third NAT should be done before interrupting ART.

[c] For children who were never breastfed additional testing following a negative NAT at 4-6 weeks is included in this algorithm to account for potential false-negative NAT results.

[d] Signs and symptoms suggestive of HIV (oral thrush, recurrent or severe bacterial infections such as pneumonia or sepsis, FTT/wasting or AIDS indicator condition http://www.who.int/hiv/pub paediatric/infants2010/en/).

[e] If infant presents with signs and symptoms of HIV disease (see footnote d above) but NAT is unavailable, consider starting ART, especially if an antibody test is conducted and result positive at 9 months or later. A DBS specimen must be collected prior to starting treatment for later NAT testing to confirm HIV diagnosis, because subsequent diagnostic testing while already on ART might be difficult to interpret.

[f] If infant presents with signs and symptoms of HIV disease (see footnote d above) consider starting ART while waiting for NAT result. However, another DBS specimen should be collected prior to starting treatment for later NAT testing to confirm HIV diagnosis.

[g] Regular and periodic monitoring should be ensured while waiting for NAT to be available or for antibody testing to be conducted at 18 months. If infant presents with signs and symptoms of HIV disease, he/she should be managed as described previously (see footnote e).

[h] The risk of HIV transmission remains as long as breastfeeding continues. If the 9 months antibody testing is conducted earlier than 3 months after cessation of breastfeeding, infections acquired in the last days of breastfeeding may be missed so retesting at 18 months should be ensured for final assessment of HIV status.

[i] If breastfeeding beyond 18 months, final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants < 18 months of age positive antibody testing requires NAT to confirm infection. If infant is > 18 months, negative antibody testing confirms infant is uninfected; positive antibody testing confirms infant is infected

5.3. HIV testing algorithms

The National Health Laboratory of Myanmar will select and validate the specific assays to be used as A1, A2, and A3. First-line assays should have the ability to identify any potential HIV-positive specimens and, thus, should have superior diagnostic sensitivity. These assays are likely to detect all true positive specimens as well as some specimens that are in fact HIV false-reactive. Second-line and third-line assays are used to validate the initial reactivity observed in the first-line assay, and so they should have superior diagnostic specificity, to rule out false reactivity.

It is essential to minimize the potential for shared false reactivity through careful selection of the combination of HIV assays used through the validation of testing algorithms**.** Where possible, assays based on different antigen preparations should be used in combination. Assays from different manufacturers are more likely to be made of different antigen preparations. Increasingly, however, WHO has noted that manufacturers sell finalized or semi-finalized products to other manufacturers under re-branding or re-labelling arrangements, making it difficult to determine the antigen preparation used. In the absence of information about the antigen source, a validation study to determine the optimal testing algorithm should be conducted. If the validation panel is chosen carefully, this study provides data on the degree of cross-reactivity.

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 recent or ongoing risk. However, it is important to accurately identify individuals who test HIV-negative and may require retesting (8).

HIV-negative individuals with recent and specific risk

Individuals who test HIV-negative but have had a recent exposure or risk event occurring in the last 2weeks prior to initial testing may be in the window period and should be invited to return for testing after 4 to 6 weeks.

HIV-negative individuals with ongoing risk

Individuals who test HIV-negative but warrant special attention and more frequent retesting than the general population in the Myanmar context include:

- people from key populations
- persons with a known HIV-positive partner

Persons with ongoing risk should be offered HIV testing every six months.

Special attention should be paid also to:

- individuals seen for a diagnosis or treatment of STIs
- TB patients with a possible recent HIV exposure or who are at higher risk for HIV exposure
- outpatients with clinical conditions indicative of HIV-infection
- individuals taking PEP or PrEP

Health care providers should offer HIV testing to individuals from the above groups even if they had an HIV-negative test on a prior occasion.

Retesting of individuals with HIV-inconclusive results

Retesting 14 days after an HIV-inconclusive test result is recommended to:

- rule in seroconversion, if HIV reactivity evolves to concordant test results for the three assays;
- rule out seroconversion, if HIV reactivity remains unchanged, with likely non-specific false-positive reaction
- rule out specimen mix-up, particularly if unique patient ID and consecutively assigned specimen IDs are not assigned; or
- rule out random error, either user/operator error or test device error.

Specimens from individuals with clinical signs meeting the WHO criteria for stage III or IV may show HIV-inconclusive status due to a decrease of HIV antibodies with advanced disease progression and/or impaired or reduced immune response.

If the testing results are the same upon retesting (still discordant), then the individual should be considered as HIV-inconclusive and referred to a higher level laboratory for DNA PCR. If the testing results are not the same upon retesting, the individual may be assigned as HIV-negative or HIV-positive, depending on the results.

Retesting to verify HIV-positive status prior to ART and/or care initiation

To ensure that individuals are not needlessly placed on life-long ART (with potential side-effects, waste of resources, psychological impact of misdiagnosis), **the Myanmar Ministry of Health and Sports and the National AIDS Program recommend that all individuals be retested to verify their HIV status prior to enrolling in care and starting of ART.**

Misclassification, irrespective of its scale, is of critical importance. Any incorrect diagnosis whether a false-positive or a false-negative has deleterious personal and public health consequences, often with severe repercussions.

As noted above, "retesting" refers to the testing of a new specimen for each newly diagnosed individual, conducted by a different provider using the same testing algorithm, prior to initiation of ART. Retesting can be conducted at a different site, ideally the site where the decision about ART initiation will be made. Retesting according to this procedure aims to rule out possible technical or clerical errors, including specimen mix-up through mislabelling and transcription errors, as well as random error either by the testing provider or one of the tests used in initial testing.

Certain testing services are programmatically organized to conduct HIV testing for diagnosis with immediate initiation of ART irrespective of CD4 count. In these programmes it may not always be feasible to retest at a different site, although it should usually be feasible for a different provider to conduct retesting on a new specimen.

If the HIV status is the same upon retesting, the individual's HIV-positive status should be considered as verified. If the test status is not the same upon retesting, the individual or their specimen should be referred for additional testing at a higher-level facility using a specific testing strategy for this objective.

WHO recommendation

Retest all newly diagnosed HIV-positive individuals with a second specimen and a second tester using the same testing strategy and testing algorithm before initiating ART, irrespective of whether or not ART initiation depends on CD4, preferable at a different site.

Source: WHO, 2014 (80).

Retesting people on ART

All individuals receiving HIV testing should be asked if they have been tested previously and told they are HIV-infected, and if they have ever received ART or are now receiving ART. ART may suppress antibody production and lead to "false-negative" results. Individuals undergoing HIV testing must be made aware of the risk of incorrect diagnosis, if they do not disclose that they are on ART.

6. ENSURING QUALITY OF HIV TESTING SERVICES

Key Points

- Quality management systems are essential for any testing service, ranging from HIV testing conducted in laboratories and health facilities to community-based settings, including rapid diagnostic tests (RDTs) performed by trained community workers.
- It is the ethical responsibility of all people conducting HIV testing (including health workers, private providers, and any other trained person) and all programmes or facilities offering HTS to participate in routine and standardized quality management systems to ensure the highest level of quality and accuracy.
- The Myanmar National Health Laboratory has had a quality assurance program in place since 2005 and carefully implements external assessment through on-site visits and proficiency testing.
- In vitro diagnostics (IVDs) should meet regulatory standards according to national guidelines. In addition, WHO conducts an independent prequalification assessment of IVDs, with particular emphasis on HIV IVDs including RDTs intended for use at or near to the point of care in resource-limited settings.
- In certain situations providers may refer individuals to another site for additional testing to verify their HIV status. Consistent, clear, confidential and accurate record-keeping and communication are critical at both the initial testing site and the referral centre.

Definitions
Quality management system: a system that controls, assures and manages the quality of testing services and ensures that quality objectives are met. These can be described as the building blocks of quality.
Quality assurance (QA): planned and systematic activities to provide confidence that a testing service fulfils requirements for quality.
External quality assessment (including proficiency testing) (EQA): inter-laboratory comparison to determine if the HIV testing service can provide correct test status.
Quality control/process control (QC): within a laboratory, procedures to determine if the test itself works. It cannot assure that the correct test status will be given.

Quality improvement (QI): the study and improvement of the processes of providing HIV testing services that respond to client needs.

Source: WHO, 2010 (11)

6.1. Assuring the quality of HIV testing results

Assuring correct HIV test results is a priority, and a crucial component of WHO's 5 Cs for HTS (24). Misclassification of HIV status – both false-positive and false-negative results – has been reported in some countries (23, 81-85). It is a priority for the Ministry of Health and Sports, the National AIDS Program, and the National Health Laboratory to implement robust quality assurance systems that deliver high-quality and accurate reporting of HIV test results (86).

In Myanmar, the National Health Laboratory, with mandate from the MOHS, plans and implements a variety of quality assurance activities to monitor and improve the quality of testing. The National Health Laboratory has conducted this quality assurance plan since 2005, and has published the results of these activities.(86) These activities may be decentralized at the provincial or district level depending on the scope of the activities. These activities include promoting the use of standardized logbooks, or registers, provision of EQA schemes with analysis of EQA data, and implementation of corrective actions.

Any programme considering the expansion of HTS, including facility-based testing (laboratories, clinical facilities), community-based testing and testing conducted at point of care, such as those performed by health workers or other trained persons, should:

1. Follow the national **HIV testing policy that is regularly updated** and linked to the National Health Laboratory policy and strategic plan;

2. **Implement a quality management systems** for all HIV testing, irrespective of where testing takes place, based on standards issued by the National Health Laboratory;

3. Ensure adequate **training and supportive supervision** of all HIV testing providers, with requirement for certification;

4. Conduct accurate **forecasting** and, therefore, quantification, with **procurement systems** in place to avoid stock-outs of test kits and critical consumables

All health workers and other trained persons who conduct HIV testing should have adequate hands-on training on the Standard Operating Procedures for testing in order to perform individual assays and follow national testing algorithms. Training should also include:

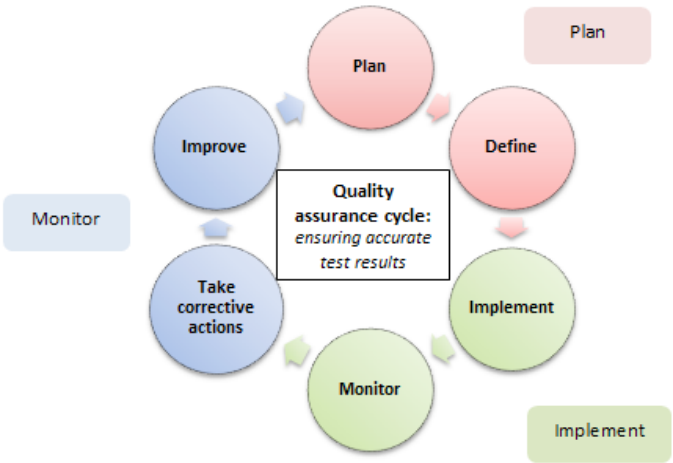
1) ethical and legal consideration

2) how to keep testing records as standardized logbooks

3) the EQA scheme provided by the National Health Laboratory (proficiency testing programme) and importance of QC specimens

4) site supervisory visits and corrective actions

Figure 6. Quality assurance cycle: a continuous quality assurance and improvement process



Source: WHO, 2015 (87).

Planning: focuses on planning for QA through engaging leadership, establishing a national QA coordination team, defining roles and responsibilities, reviewing and developing policies, and financing and staffing for QA.

Implementing: focuses on implementing QA through training of HIV testing providers and their certification, site accreditation (may also be called site registration or certification), supportive supervision, adequate process control, documentation and record-keeping and ensuring a robust supply chain.

Monitoring: focuses on evaluating quality through post-market surveillance, EQA, using data for decision-making, making improvements, advocacy and communication and increasing country ownership. For information on how to implement a quality system, particularly for HIV testing at the point of care, please see WHO/CDC guidance on this topic, *Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results (87).*

The responsibility for ensuring the quality of testing should be seen as a continuum throughout each tier of the health system. These roles and responsibilities are detailed in Table 6.1.

Table 1. Roles and responsibilities for all staff to ensure the quality of HIV testing

Level	Where	Counselling	Testing	Records	Supplies
Community	Outside of facilities (key population outreach, mobile, outreach)	Monitor own performance Conduct client exit interviews	Adhere to SOPs Run QC Participate in EQAS	Keep accurate testing records	Ensure sufficient test kits and supplies
Primary	Facility-based (stand-alone, clinical, private providers, laboratories)				
District	Clinical facilities, district laboratories	Monitor own performance Conduct client exit interviews Provide supportive supervision of counselling in levels 0, 1, 2 Suggest corrective actions	Adhere to SOP Run QC Participate in EQAS Supportive supervision of testing processes in levels 0, 1, 2 Suggest corrective actions	Aggregate data (EQAS, NCs) on a monthly basis	Order test kits/supplies from national level Distribute QC specimens & EQAS panels
Provincial	Clinical facilities, provincial laboratories				
Level	**Where**	**General roles/ responsibilities**			
National	National Health Laboratory	Validate national testing algorithms Perform lot verification testing for post-market surveillance Produce QC specimens and EQA scheme panels Evaluate data (EQAS, NC) from all states/regions on biannual basis, suggest corrective actions Develop site SOPs and job aids Conduct Training of Trainers using standardized hands-on curriculum			
	Ministry of Health and Sports	Ensure testing sites' readiness for accreditation (laboratories, clinical facilities) or site registration (stand-alone sites, community programmes) Establish national HIV testing policy that includes QA Establish national QA coordination team Allocate resources for QA Procure, store and distribute test kits/supplies		

	Regulatory bodies	Set national regulatory standards for IVDs Set standards for accreditation/certification of testing sites Respond to field safety notices arising from post-market surveillance

SOP: standard operating procedure; EQAS: external quality assessment scheme; NC: non-conformance; IVDs: in vitro diagnostics.

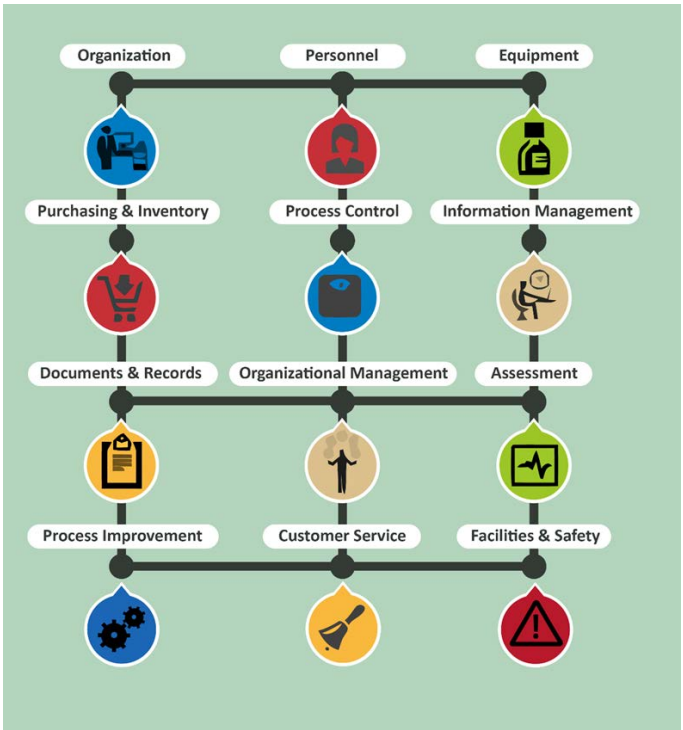
Sources: Taegtmeyer M et al., 2003 (88); WHO, 2010 (11); WHO, 2015 (87).

6.2. Quality management systems for HIV testing services

A quality management system can be implemented in varying degrees, but the basic principles still apply to any service providing HIV testing results. Any site conducting HIV testing should implement a quality management system that incorporates the elements detailed in the following pages.

The WHO *Laboratory quality management system: handbook* (89) provides further guidance.

Figure 7. The 12 components of quality management systems



(1) Organization

Irrespective of their location, both facility testing services (laboratories and clinical facilities) and community-based testing services should have a commitment to assure quality. All testing services should have a quality policy that specifies the following aspects of the quality of HTS:

- ensuring that competent and trained staff (including community workers) are employed (see point 2 below)
- ensuring purchase of quality-assured test kits, equipment and consumables (see points 3 and 4)
- ensuring QC of daily testing processes (see point 5)
- creating and managing documents (see point 7)
- Keeping records confidential (see point 7)
- recording and following up on complaints (see point 8)
- evaluating and following up on results of EQA schemes/proficiency testing and on-site supervision (see point 9).

Generic quality policy may be developed nationally for all types of testing sites that are similar on the basis of, for example, test formats used, infrastructure available and type of testing providers. These policies may require adaption, based on input from management and other staff and volunteers, to ensure they are appropriate to the specific site.

How to implement:

- Ensure **policies, processes and procedures** are relevant for the specific type of testing service.
- Ensure **professional commitment** to the quality of HTS, with regular management review of the quality policy.
- Assign one staff member in each HIV testing service as the quality representative, who **champions the quality** of all aspects of the HIV testing service.

(2) Personnel

All testing services must employ the number of trained, certified and supported personnel to conduct each of the elements of HIV testing adequate for the expected number of tests conducted and the number of people being served. To assess and manage human resource planning, tools such as the WHO Workload Indicator for Staffing Need (WISN) (http://www.who.int/hrh/resources/wisn_user_manual/en/) can be useful to calculate the number of

health workers and trained community workers needed to provide adequate HTS.

All personnel, including those taking specimens, conducting testing, providing test results, compiling HTS reports, and data clerks and other auxiliary staff, must be trained adequately. All staff should have appropriate qualifications, such as certifications according to national guidelines, and demonstrated proficiency in performing the tasks within their scope of work.

Both pre-service and **in-service training,** including periodic refresher trainings, should be part of the training requirements for all testing services. This is particularly important for sites with very low specimen throughput or where HIV testing is performed occasionally. In addition, regular **supportive supervision** and ongoing **mentoring** of all staff are essential. Ensuring the psychological and physical well-being of HIV testing providers is critical. In particular, good vision is required for reading subjective assays.

How to implement:

- Develop a site **organogram** that describes the roles and responsibilities of all staff members, including trained community workers in the testing service, that outlines who may mobilize clients, who may collect specimens, who may provide counselling, who may perform testing, who may issue results, and who may double-check test results and reports.
- Maintain **training checklists** for all staff.
- Encourage a yearly **bidirectional performance appraisal** to discuss any issues that may affect a provider's ability to perform his or her assigned tasks.

Furthermore, at a national level, it is critical to have:

- national human resources planning and management systems, including human resource information systems
- strong pre-service education institutions
- standardized and coordinated in-service training (with hands-on practicum and competency-based assessment)
- an inclusive national policy that supports task sharing, with scope for trained community workers to conduct testing and issue test reports
- recruitment and retention strategies, especially for underserved and stigmatized populations
- advancement of health worker regulation and policy, including capacity-building of regulatory bodies and professional associations.

(3) Equipment

Regardless of where testing takes place and whether it is performed using HIV RDTs or laboratory-based diagnostics, it is critical to have appropriate equipment available and fully functional.

For testing services using primarily RDTs, it is important to have **timers** and access to **refrigerators** if ambient temperatures will exceed the manufacturer's recommended storage temperatures.

For HTS that rely on laboratory-based techniques, **calibration and maintenance of equipment** is paramount for providing accurate testing results.

How to implement:

- Maintain an **inventory** of all equipment.
- Ensure that all equipment in the inventory is subject to **preventive and corrective maintenance** on an appropriate cycle, depending on throughput.
- Ensure that equipment that is not working is prominently labelled as such and, therefore, not used in any process to provide testing results.
- Ensure that **SOPs** exist for all equipment, for example, with instructions how to turn on and off, how to clean and any calibration that the user must make.

(4) Purchasing and inventory

Purchasing refers to activities that must be undertaken at the programmatic level to ensure that adequate supplies of test kits and other items required for the testing process are available on-site.

Stock-outs of HIV test kits or any essential consumables, such as lancets, alcohol swabs or specimen transfer devices are one of the biggest sources of poor quality and client dissatisfaction with HTS. Lack of the first-line assay (A1) may lead to use of a less sensitive assay instead (A2 or A3 instead of A1). The lack of single-use specimen transfer device will lead to an incorrect specimen volume added, likely resulting in an inaccurate test result.

It is necessary to ensure that an adequate system is in place at the testing service site to **track procurement of test kits, reagents and consumables** (venous or finger-stick blood collection supplies) when they are ordered and when received. Each HIV testing service should then track consumption of all test kits and consumables so that they can inform the central medical stores (or other purchasing body) when they need to replenish stock. As stocks are received, it is critical to take special note of expiry dates and to order ahead, allowing adequate time for the next delivery.

How to implement:

- Maintain a **list of inventory requirements,** for example, assays, consumables or additional supplies such as gloves, lancets, alcohol swabs and disposal containers.
- Ensure adequate physical **space to store test kits** (including refrigeration if room temperature is above manufacturer's recommended storage conditions) and record storage temperatures.
- Do not split larger test kits into smaller quantities.

It is critical at the national level to have regulatory processes and procedures that support the procurement of quality-assured diagnostics, equipment and other items required for providing HTS.

(5) Quality control

Quality control (QC), also known as process control refers to processes and activities to ensure that **testing procedures** are performed correctly, that **environmental conditions** are suitable and that the **assay** works as expected. QC intends to detect, evaluate and correct errors due to assay failure, environmental conditions or operator performance, before results are reported. Hence, QC is a multi-step process with certain checkpoints throughout the testing process.

- Before testing (pre-analytical):
    - Check that the temperature of the testing area is within the manufacturer's recommendations and record the temperatures.
    - Check that stocks of test kits and required consumables are on hand.
- While testing (analytical):
    - Ensure that any QC specimens have been run (for example, test kit controls and/or external QC specimen) and that the results are within QC acceptance criteria.
    - Ensure that a second reader will double-check all visually read assays.
- After testing (post-analytical):
    - Double-check report of test status to client.

Ideally, a **second reader** should make a blinded reading of any visually read assay. This is standard practice for visually read assays, both for HIV and for other conditions. The second reader needs to be trained only on how to read the assay, not necessarily on the test procedure itself. If the two readers interpret test results the same way, the test report is issued as is. If the two readers do not agree, HIV testing should be repeated using a new specimen and a new test device. Inter-reader disagreement for RDTs ranges from 0 to 1.6% (9, 90).

Internal QC refers to processes within the assay that check whether the test procedure is working; the appearance of a control line for HIV RDTs is an example of internal QC.

Only a few RDTs contain a control line that indicates that the specimen has been added. Instead, most RDTs contain a control line that indicates only the flow of liquid, rather than that specimen has been added or that the correct volume of specimen has been added.

Test kit controls (known as positive and negative controls) may be supplied by the manufacturer. They are standard for most assay formats; with the exception of RDTs. Few HIV RDTs have accompanying test kit controls, making QC problematic.

As an addition to the test kit controls, **external quality control specimens** may be produced. These are prepared and validated by the specimen provider, usually the national reference laboratory or commercial entity, for the assay separately from the manufacturer. The dried tube specimen methodology is useful in this regard.

Any test kit controls should be run according to the manufacturer's instructions, and external QC specimens should be run:

- once weekly, preferably at the beginning of the week
- for any new operator (including trained staff who have not conducted testing for some time)
- for each new lot of test kits
- for each new shipment of test kits
- when any environmental conditions (for example, temperature and humidity) fall outside the range recommended by the manufacturer.

How to implement:

- Establish criteria for **specimen acceptance or rejection,** and specimen storage, retention, disposal and referral of the specimen to another site for testing.
- Establish criteria for **QC of qualitative and quantitative assays** with established limits of acceptability.

(6) Information management

Information management consists of the **paper-based and electronic systems** for storing records and documents, including emails or text messages that provide testing results or reminders to clients. It is closely linked to documentation and record-keeping.

To assure the quality and integrity of the test status given to a client, HTS must minimize the risk of transcription errors. Assigning patient identification numbers and specimen identification numbers to each subsequent specimen received from the same individual will serve to reduce the possibility of transcription errors. It will also protect the confidentiality of people undergoing HIV testing. Linking a series of HIV test results also is critical when retesting to validate HIV-positive results and for clients with HIV-inconclusive results.

It is critical that all information be kept **confidential,** with access restricted to qualified staff.

Automated electronic RDT readers that can accommodate one or many brands of RDTs are increasingly becoming available. Many of these RDT readers can connect to 3G or 4G wireless networks. Such connectivity also can be useful for quality assurance, for procurement and for data management.

(7) Documents and records

Documentation is critical to ensure that a correct test result goes back to the correct person undergoing testing. **Documents** are policy, process and procedural documentation for all aspects of the testing service and its quality management system. It is critical that document forms are approved prior to use, revised when necessary and removed from circulation when obsolete.

Job aids are useful tools for HTS. These are short, concise documents that describe each test procedure, how to interpret test results according to the validated testing algorithm and how to refer for retesting. Annex 7.4 presents an example of a generic job aid for an HIV RDT.

Records are generated as a result of performing testing activities. It is critical that these are filled correctly and stored for up to five years. Records are particularly useful for retesting referrals to rule in or rule out HIV-infection and community-based testing services where the results may be verified at another testing facility.

The types of records required for a quality system are:

- specimen request forms
- testing/laboratory logbook
    - This should record details to identify the person undergoing testing (patient ID, name [optional], date of birth [optional]), the assays used, with lot numbers

and expiry dates, the test results (preferably, band intensity when using RDTs), both readers' results (when using RDTs), date of test run, name of operator and QC results.

- overall test status reports as given to the individual
- referral slips for retesting or other post-test services
- staff training records and other personnel records
- internal and external audit reports
- non-conformance and complaint records, with action taken
- equipment maintenance records and inventory charts.

How to implement:

- Ensure that SOPs exist for all procedures, including specimen collection and processing requirements, testing algorithms and all test procedures, with QC and final reporting (in accordance with a validated testing algorithm).
- Keep equipment maintenance records and temperature records for refrigerators, freezers and the testing room.
- Keep laboratory notebooks and forms used to record testing results.

For an example of a standardized testing register, or logbook, see *Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results (87)*

(8) Occurrence management

"Occurrence management" refers to processes for detecting and documenting non-conformances and then implementing any necessary corrections. A **non-conformance is something that went wrong** – a problem has occurred and needs to be addressed. A non-conformance might be a lack of documented processes or procedures or when documented processes or procedures are not followed. For occurrence management to have a meaningful effect it must be investigated and the problem corrected.

The following sources of data may be used to check if there are problems or potential mistakes made:

- internal audit reports
- supervisory reports

- QC data, including higher than expected rates of invalid results (for example, when using RDTs, if no control line appears or a high background on the test strip obscures the reading window)
- results of EQA schemes (proficiency testing)
- a higher than expected rate of discrepant test results for clients who return for retesting.

How to implement:

- Establish a system to immediately capture quality issues or problems, then identify the root cause and implement corrective action.
- To identify non-conformance, routinely monitor indicators, such as turnaround times for each assay, turnaround time for an overall testing report, rate of discrepant results, rate of invalid results, rate of specimen rejection, rate of test kit stock-outs, rate of supplies stock-outs and frequency of expiration of test kits.

(9) Assessment

Testing services should undertake both internal and external assessment to assure the quality of testing. Internal assessment usually takes the form of an **internal audit**, by either a site supervisor or relevant health authorities, which observes testing practices at least annually but preferably every six months. For certain tasks an internal audit may be performed by another staff member who does not usually perform the task but has enough familiarity with the process to conduct an audit.

External quality assessment assures that assays are performed accurately, results are reproducible and errors are detected and corrected to avoid misclassification or incorrect diagnosis. EQA usually takes the form of participation in EQA **schemes** (also called proficiency testing), which include following up any unacceptable EQA results with corrective actions.

The objectives of participating in EQA schemes are to:

- evaluate testing competence
- assess performance of specific testing providers
- evaluate the reliability of HIV testing procedure
- establish the accuracy of reports of HIV status
- provide information for self-evaluation.

Rechecking samples of specimens using dried blood spots (DBS) as an EQA mechanism is no longer recommended given the recommendation to retest all seropositive individuals prior to starting ART.

Another form of external assessment is **accreditation** of testing sites (may be referred to as registration or certification) by an external certification body.

How to implement:

- All testing sites (facility and community-based) should participate in EQA schemes.
- All testing sites (facility and community-based) should receive support through on-site supervision.
- All testing sites (facility and community-based) should be registered, certified or accredited, according to national guidelines.

(10) Process improvement

Testing services need to identify areas requiring improvement, plan and undertake improvements and evaluate their effect. Depending on the improvement suggested, programmes can improve processes at the site-level or at the district or national level. Local factors, which may not be predicted at the national level, may define site-level improvements such as changes to opening hours or changes to the flow of clients through the testing site. Programmes may use data from internal audits, participation in EQA schemes and on-site supportive supervision to improve testing processes.

A **corrective action** is an action taken to address a problem, removing its root cause or reducing or eliminating its recurrence. A **preventive action** is an action taken to avoid a possible problem or reduce the likelihood that it will happen. Data from EQA activities and process control can guide corrective and preventive actions in the framework of continued process improvement.

How to implement:

- Site supervisors should proactively identify opportunities for improvement of services, and then relay these to a higher level of management for implementation of better working practices.

(11) Client service assessment

Programmes need to ensure client (customer) satisfaction with the testing service. This includes both so-called internal clients, such as doctors, nurses, counsellors, other health-care workers, and external clients, such as individuals undergoing testing, including clients from key populations and other vulnerable populations as well as professional associations and

regulatory agencies. Ensuring client satisfaction means meeting their expectations of quality, for example, delivering **accurate results in a timely manner.**

How to implement:

- Seek feedback from clients through, for example, periodic exit interviews as well as regular meetings with community and KP representatives. Feedback may focus such on aspects as flexibility of opening hours, friendliness of the testing providers and the staff at the site, friendliness of the testing environment, confidentiality and satisfaction with services.
- Establish a client suggestion box for anonymous reporting, including complaints.

(12) Facilities and safety

It is critical that testing facilities are well-designed and maintained. The testing site, including where counselling takes place, where specimens are taken and where the test is performed, should be clean and comfortable, with adequate lighting (for reading visually read assays) and free of any potential hazards.

It is imperative to follow the assay manufacturer's recommendation for the ambient temperature of areas where testing is performed. Where possible, testing should take place in climate-controlled areas. There must be proper **waste disposal** for biological (infectious and non-infectious), chemical and paper waste and sharps according to Medical Laboratory Waste Management Instruction provided by the National Health Laboratory.

It is critical to guard against harm to any client, HIV testing provider or other person at the testing site. This means that a **safe working environment** must be maintained by and for all staff, with necessary procedures in place. These procedures include universal precautions (assume that all specimens are potentially infectious), prevention of and/or response to needle-stick injuries or other occupational exposures, chemical and biological safety, spill containment, waste disposal and use of personal protective equipment.

For HIV testing that takes place outside of a facility, programmes must ensure that the provider can conduct the testing without hazard to themselves or to the client. Thus, providers must observe universal precautions and appropriate waste disposal procedures.

In addition, providers must make all efforts to protect clients' confidentiality and privacy.

How to implement:

- All staff should be trained on biological and chemical safety measures.
- One staff member at each testing site should act as a safety champion.

- Staff responsible for timely ordering and issuing of adequate quantity and quality bio-safety supplies (e.g. gloves, single use lancets, sharps containers etc.) should be assigned and trained for each site including community-based sites and mobile teams.

6.3. Quality improvement for HIV testing, monitoring, and evaluation

Quality assurance is not a one-time event. Testing providers and managers must continually monitor and evaluate their programme and improve the quality of services. To maintain a coherent, functioning quality management system that addresses national, subnational, facility and community concerns, all stakeholders must be involved at every level to monitor quality and make improvements. More guidance on monitoring, evaluation, and use of HIV testing in the context of surveillance and surveys is available in a number of WHO documents.

ADDITIONAL SUGGESTED GUIDELINES

Consolidated Guidelines on HIV Testing Services. Geneva: World Health Organization; 2015

(http://www.who.int/hiv/pub/vct/en/)

Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV-infection: recommendations for a public health approach. Geneva: World Health Organization; 2013 (http://www.who.int/hiv/pub/guidelines/arv2013/en/).

Service Delivery Issues:

HTS in health facilities:

Guidance on provider-initiated HIV testing and counselling in health facilities. Geneva: World Health Organization; 2007 http://www.who.int/hiv/pub/guidelines/9789241595568_en.pdf.

HIV/TB:

WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders. Geneva: World Health Organization; 2012. (http://www.who.int/tb/publications/2012/tb_hiv_policy_9789241503006/en/).

Couples testing:

Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples (http://apps.who.int/iris/bitstream/10665/44646/1/9789241501972_eng.pdf)

Retesting:

Delivering HIV test results and messages for retesting and counselling in adults. Geneva: World Health Organization; 2010

(http://www.who.int/hiv/pub/vct/hiv_re_testing/en/)

Quality of Testing:

Laboratory quality management system: handbook. Geneva: World Health Organization; 2011 (http://www.who.int/hiv/pub/lqms/en/)

The quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results. Geneva: World Health Organization; in press.

Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results (http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf).

Handbook for improving quality of HIV testing and counselling. Geneva: World Health Organization; 2010 (http://www.who.int/hiv/pub/vct/9789241500463/en/).

WHO manual for procurement of diagnostics and related laboratory items and equipment (http://www.who.int/diagnostics_laboratory/procurement/en/).

HTS and Specific Populations

Pregnant Women:

Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV-infection: recommendations for a public health approach. Geneva: World Health Organization; 2013 (http://www.who.int/hiv/pub/guidelines/arv2013/en/).

Key Populations:

Consolidated guidelines on diagnosis, prevention, care and treatment for key populations Geneva: WHO 2014

(http://www.who.int/hiv/pub/guidelines/keypopulations/en/)

Refugees:

Policy statement on HIV testing and counselling for refugees and other persons of concern to UNHCR. Geneva: UNHCR, WHO, UNAIDS; 2014 http://www.unhcr.org/53a816729.pdf.

Adolescents:

HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV (http://www.who.int/hiv/pub/guidelines/adolescents/en/)

Adolescent HIV testing, counselling and care: implementation for health providers and planners (http://www.who.int/adolescent/hiv-testing-treatment/en)

Infants and Children:

Diagnosis of HIV infection in infants and children: WHO recommendations. Geneva: World Health Organization; 2010 (http://www.who.int/entity/hiv/pub/paediatric/diagnosis/en/)

Guidance on HIV disclosure counselling for children 12 years of age and younger (http://www.who.int/hiv/pub/hiv_disclosure/en/)

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Brief Summary: Myanmar HIV Testing Services Guidelines

HIV Testing Services refer to the full range of services that should be provided together with HIV testing – **counselling** (pre-test information and post-test counselling); **linkage** to appropriate HIV prevention, care and treatment 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 of *consent, confidentiality, counselling, correct test results and connection to care and treatment* are principles that apply to all models of HTS and in all circumstances.

Pre-test information: All persons receiving HIV testing should receive clear information about:

- the benefits of HIV testing
- the meaning of a first reactive rapid test and the importance of immediate referral for confirmation testing where screening testing is implemented
- the meaning of a confirmed HIV-positive and an HIV-negative diagnosis
- the meaning of an inconclusive result and the importance of retesting after 14 days
- the services available in the case of an HIV-positive diagnosis, including where ART is provided
- a brief description of prevention options
- encouragement of partner testing in particular for all persons who test positive
- the fact that the test result and any information shared by the client is confidential
- the fact that the client has the right to refuse to be tested and that declining testing will not affect the client's access to services or general medical care
- potential risks to the client in settings where there are legal implications for those who test positive and/or those whose sexual or other behaviour is stigmatized
- an opportunity to ask the provider additional questions
- provision of informed consent for testing

Post-test brief information for persons who test negative:

- an explanation of the test result
- for people with ongoing HIV risk should have education on methods to prevent HIV acquisition and promotion of condom use. Note that key population clients should be

provided with male and female condoms, lubricant and guidance on their use where possible.

- emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couples testing services
- referral and linkage to relevant HIV prevention services should be prioritised for people at ongoing HIV risk, particularly people from key populations, including harm reduction and other interventions such as pre-exposure prophylaxis (PrEP). PrEP has been shown to be highly effective in preventing new HIV infections among persons at risk. The National AIDS Programme is assessing the potential of PrEP in Myanmar.

- **Note that for most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary** (8). However a recommendation for retesting for HIV-negative persons, based on the client's risk of exposure should be made for the following two scenarios
    - a person with recent and specific risk that occurred in the last 6 weeks should return for retesting in 4 to 6 weeks
    - an HIV-negative person with on-going risk of exposure such as key populations and persons in sero-discordant relationship (s) may benefit from testing every 6 months

Persons who do not report recent or on-going risk should be advised to return for testing only if their personal situation changes and if they are potentially exposed to HIV infection.

Post-test counselling for persons who test positive:

- **Explain** the test results and diagnosis (status).
- **Give the client time** to consider the results and help the client cope with emotions arising from the diagnosis.
- Discuss **immediate concerns** and help the client decide who in her or his social network may be available to provide immediate support.
- Assess the risk of **intimate partner violence** and discuss possible steps to ensure the physical safety of clients, particularly women, who are diagnosed HIV-positive.
- Assess the risk of suicide, depression, and other **mental health** consequences of a diagnosis of HIV-infection.
- Explain that the Care and Treatment site will repeat HIV testing once more for **verification** prior to enrolment.

- Provide clear **information on ART** and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to obtain ART.
- Arrange a specific date and time for **active referral.** The health worker or person doing the test should make an appointment for the client and if at all possible, accompany the client or patient to the appointment and assist the client to enrol in clinical care and treatment. Discuss barriers to linkage to care, same-day enrolment and ART eligibility assessment. Arrange for follow-up of clients who are unable to enrol in HIV care on the day of diagnosis.
- Provide information on how to **prevent transmission of HIV,** including information of the reduced transmission risks when virally suppressed on ART
- Provide male or female **condoms and lubricants** and guidance on their use. Consistent use of condoms is particularly important for people with HIV infection to prevent HIV transmission to sexual partners until they are virally supressed on ART.
- Discuss possible disclosure of the result and **the risks and benefits of disclosure,** particularly among couples and partners. Offer couples counselling to support mutual disclosure.
- Encourage and offer HIV **testing for sexual partners, children and other family members** of the client. This can be done individually, through couples testing, index case testing or partner notification.
- Provide information about **PrEP for HIV-negative partners** at sites where services may become available in the future, to protect the HIV-negative partner in a sero-discordant relationship until the HIV-positive partner has successfully enrolled in ART and achieved viral suppression.
- Provide **additional referrals for prevention, counselling, support and other services** as appropriate (for example, TB screening and treatment and ITP for people screened negative for TB, HBV and HCV testing prophylaxis for opportunistic infections, STI screening and treatment, contraception, antenatal care, opioid substitution therapy and access to sterile needles and syringes).Encourage and provide time for the client to ask additional questions.

Pregnant women. Post-test counselling for pregnant women whose test result is HIV-positive should include the following, in addition to the standard messages described above for all people diagnosed with HIV-infection:

- **childbirth plans:** providers should encourage HIV-positive pregnant women to deliver in a health facility for their own well-being as well as to ensure access to PMTCT services

- **use of ARVs for the client's health,** as well as the use of **ARVs to prevent transmission to the infant**
- the importance of **partner testing** of sero-positive pregnant women should be emphasized and there are variety approaches to this including availability of couples testing services
- ensuring **screening for tuberculosis** and testing for other infections such as syphilis
- **counselling on adequate maternal nutrition,** including iron and folic acid, **advice on infant feeding options** and support to carry out the mother's infant feeding choice
- Importance of regular Ante-Natal care and infant immunization at health facility
- **HIV testing for the infant** and needed follow-up for HIV-exposed infants

Post-test counselling for persons with inconclusive results:

An **HIV-inconclusive test status** means that first reactive assay result was not confirmed after additional testing, or when the first two assay results are reactive but the third assay is non-reactive. All people with inconclusive status should be encouraged to **return in 14 days for retesting.** Receiving inconclusive results may be confusing and stressful for the individual or couple and may be difficult for the provider to explain. Most inconclusive diagnoses can be resolved with retesting 14 days or 2 weeks later. Individuals with an HIV-inconclusive status should be informed that a confirmed diagnosis cannot be provided that day and encouraged to return for retesting 14 days or 2 weeks later. The individual can also be informed that this is not an HIV diagnosis therefore referral to HIV care or ART initiation is not appropriate.

Key populations need tailored approaches and messages. Links with key population networks and community-based organizations to support or provide HTS, including services delivered by peers, may increase reach, uptake and acceptability. Such services for key populations already exist in Myanmar and expansion should be considered.

For key populations who test HIV positive: Intensified post-test counselling combined with follow-up counselling by health care workers or peer counsellors significantly increases the proportion of people with HIV who enrol in HIV care. PWID are more likely to start and stay in HIV treatment if they are participating in opioid substitution therapy (OST) programmes. Therefore, referral for other services such as OST should be included in post-test counselling for people from key populations. Some people from key populations may lack social networks and/or a supportive family to help them deal with their diagnosis. These people may need additional counselling as well as peer support services, including support groups to cope with this diagnosis. A peer counsellor may particularly help people understand and cope with the diagnosis and support linkage to care and treatment by serving as a "peer navigator" who assists with finding, choosing and obtaining a full range of services.

Adolescents. Along with standard messages for all those diagnosed with HIV-infection, post-test counselling for adolescents whose test result is HIV-positive should include:

- **tailored help** with linkage to HIV care and treatment
- counselling, referral and linkage to specific **psychosocial and mental health services** tailored to both the situation in which infection happened and the developmental age of the individual
- information on **right to confidentiality**
- an opportunity to ask questions and discuss **issues related to sexuality** and the challenges they may encounter in relationships, marriage and childbearing;
- individualized planning on **how, when and to whom to disclose** HIV status and engage families and peers in providing support;
- referral for **small group counselling and structured peer support groups** which may particularly benefit for adolescents with HIV.

Infants and Children. WHO recommends that disclosure to children is a process and should be started as early as possible and full disclosure should be achieved by 12 years. http://www.who.int/hiv/pub/hiv_disclosure/en/

Community based testing: Community testing can provide either (a) confirmation testing with a definitive diagnosis being issued, by health care worker or (b) screening testing with only one assay being used and referral for confirmation testing for any person with a reactive test.

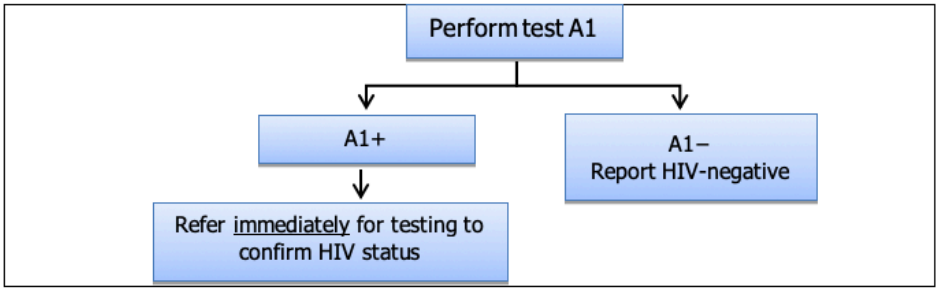
Screening testing is an approach which can be used especially where there is no trained health care worker available and/or the site does not meet the minimum s needed for confirmation testing but has been certified to provide screening testing. In the screening testing approach, a trained community worker or health care worker will conduct only a single rapid test. Persons who test reactive should be referred immediately for additional confirmation testing and if confirmed HIV-positive, should be linked and enrolled on ART as promptly as possible. Persons testing negative may be given the test results immediately, referred for appropriate HIV prevention services, and advised to re-test if they have had recent or have on-going HIV risk.

Adherence to quality assurance measures: All testing services and all persons providing HIV testing must participate in quality assurance programs to ensure that a correct diagnosis is provided. The full guidance on HIV testing services provides thorough information on quality assurance.

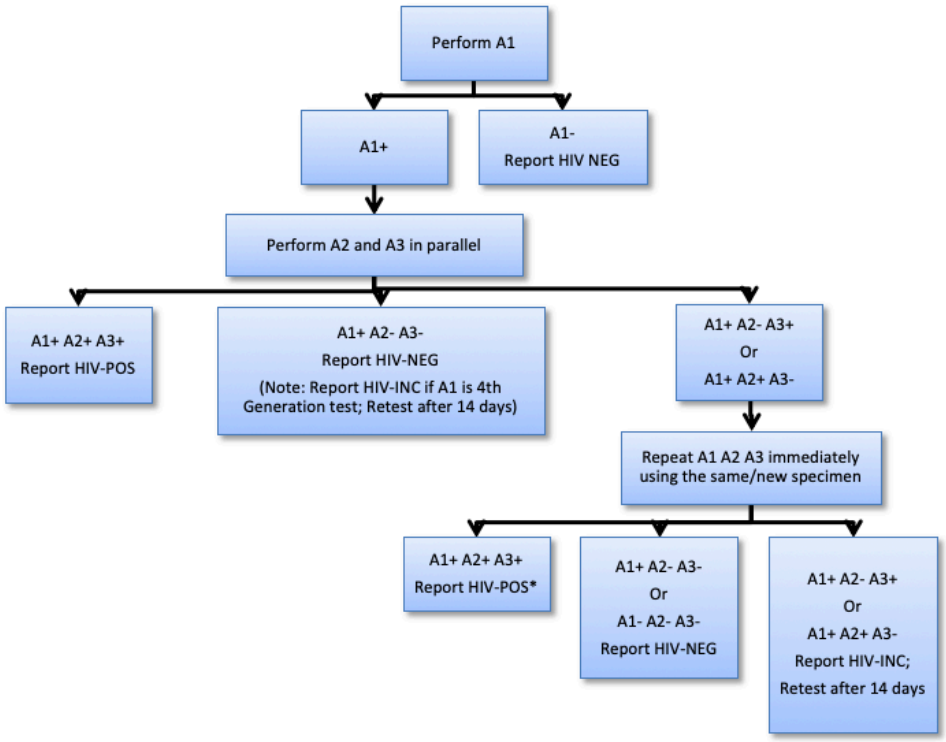
Testing algorithm for HIV screening:

Testing algorithm for HIV confirmation:

*All HIV positive diagnosed patients have to be retested to verify the HIV status with a new specimen using the same testing algorithm, conducted preferably by a different provider, prior to initiation of ART.



Testing algorithm for HIV confirmation:



Recommended rapid test kits for 3-assay HIV Testing Strategy are:

A1 = Alere Determine HIV-1/2 (manufactured by Alere Medical Co., Ltd., Japan) (D) ICT (sensitivity 100% and specificity 99.75%)

If not available, WHO pre-qualified RDT with 100% sensitivity and specificity similar to Determine.

A2 = Uni-Gold HIV (manufactured by Trinity Biotech Manufacturing Ltd., Ireland) (UG) ICT (sensitivity 100% and specificity 100%)

A3 = HIV 1/2 STAT-PAK (manufactured by Chembio Diagnostic Systems Ltd., USA) (SP) ICT (sensitivity 99% and specificity 100%)