National HIV Testing Guidelines

2019

National STD / AIDS Control Programme

National STD/AIDS Control Programme

Ministry of Health Sri Lanka

World Health Organization

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Compiled by

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Foreword

National STD/AIDS Control Programme (NSACP) of the Ministry of Health of Sri Lanka works with a broad vision of providing quality sexual health services including HIV related services for a healthier nation. Currently, Sri Lanka is experiencing a low level of HIV epidemic with a prevalence of less than 0.02% in the general population and less than 1% among most at risk population groups for HIV.

The United Nations member states have agreed to end AIDS epidemic by 2030, within Sustainable Development Goals. Achieving 90-90-90 targets by 2020, is a major milestone on the way to end AIDS by 2025 in Sri Lanka. The first 90 of 90-90-90 targets is that 90% of people living with HIV know their sero-status.

The national HIV testing guideline will be the key document that sets principles and arrangements for HIV testing in Sri Lanka and this will be helpful in expanding testing services throughout the country. I thank all contributors to this guideline which is an important source of information on HIV testing. I hope that the information available in this document will be used to further strengthen the national response to HIV epidemic in Sri Lanka.

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Acknowledgement

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal clinics
ART	Antiretroviral treatment
ARV	Antiretroviral drugs
ATV/r	Atazanavir and ritonavir
BB	Beach boys
CBO	Community based organizations
CSF	Cerebrospinal fluid
DNA	Deoxyribonucleic acid
DU	Drug user
ELISA	Enzyme linked immunosorbent assay
ETU	Emergency treatment unit
FBC	Full blood count
FSW	Female sex workers
FTC	Emtricitabine
HCW	health care workers
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
ICU	Intensive care unit
LFT	Liver function test
LPV/r	Lopinavir and ritonavir
MLT	Medical laboratory technician
MO	Medical officer
MOH	Medical officer of health
MSM	Men who have sex with men
NGO	Nongovernmental organization
NSACP	National STD/AIDS control programme
OI	Opportunistic infections
OPD	Outpatient department
PCU	Preliminary care unit
PEP	Post exposure prophylaxis
PITC	Provider initiated testing and counselling
RFT	Renal function test
RNA	Ribonucleic acid
STD	Sexually transmitted diseases
STI	Sexually transmitted infections
TB	Tuberculosis
TCP	Trained care provider
TDF	Tenofovir
VCT	Voluntary testing and counselling

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The NSACP appreciates contribution made by

Dr. Chandrika Wickramasuriya

(Consultant Venereologist)

in preparation of National HIV testing Guideline

1. HIV testing services

1.1 Background

Early detection and appropriate interventions improve survival and quality of life of people infected with Human Immunodeficiency Virus (HIV) and reduces the risk of onward transmission. However, a significant proportion of people living with HIV remain undiagnosed until they become symptomatic, therefore, presenting late for treatment. Late presentation diminishes the impact of anti-retroviral therapy (ART) on morbidity and survival and delays adoption of preventive measures by persons living with HIV and their partners.

Promotion of HIV testing services is recognized as an important strategy in both prevention and care for HIV in Sri Lanka. As the country is aiming to end AIDS by 2025, achieving 90-90-90 targets by 2020 is an important milestone. Scaling up of HV testing services is the most important step to achieve the first 90 (90% of those who are infected know their status). Despite scale-up of HIV testing services across diverse contexts, the current reach of these services (especially for key affected populations) remains low. Even though, the availability of HIV testing facilities has improved over the past years, utilization of these services in health care settings remain inadequate. Operational, logistic, and social barriers (including stigma, discrimination, and punitive laws and policies) continue to limit those accessing existing testing services. These barriers have to be overcome to make progress toward universal access to essential services including HIV testing services.

The national HIV testing guidelines is the principal document that sets out the objectives, principles and arrangements for HIV testing services in Sri Lanka. These guidelines are based on the National AIDS Policy and National HIV Strategic Plan 2018-2022. They provide guidance on HIV testing in the country. The guidelines ensure quality screening and diagnostic testing become readily accessible. They aim identifying HIV infection early for timely initiation of treatment for infected individuals. In all settings where people undergo HIV testing, steps should be taken that basic principles of HIV testing services are assured.

1.2 Objectives

1. Promote HIV testing services
2. Implement effective and appropriate use of provider initiated HIV testing services in health-care settings
3. Increase access and coverage of HIV testing services of key populations and vulnerable populations
4. Provide high-quality services and adherence to the guiding principles of 5 'C's in diverse HIV testing service delivery approaches

1.3 Guiding Principles

Mandatory or coerced testing is never permitted even when coercion comes from a health-care provider, partner or family member.

Regardless of the model of service delivery, all have to adhere to the **five 'C's.**

Counselling	testing is accompanied by counseling or pre-test information
Confidentiality	steps are taken to ensure confidentiality of all information
Consent	test with informed consent and voluntary participation
Correct results	steps are taken to provide high-quality testing services. Quality assurance mechanisms are in place to ensure the provision of correct result to the individual
Connect to Care	systems are in place to connect individual to required care, follow-up services including long-term prevention and treatment support.

> "Whenever a screening test becomes positive, confirmation test has to be arranged by the same care provider. Once a person is confirmed with HIV infection, they should be connected to HIV care settings for further management."

2. HIV Testing Service Model

2.1 Client initiated HIV testing

Clients who are already aware about HIV and their risk may come voluntarily to health care services for HIV testing. As the process of testing is initiated by the client it is known as client-initiated HIV testing.

These services are available to clients through government sector free of charge at STD clinics. They can also access HIV testing services from many other government health care settings free of charge.

In addition, clients can access HIV testing services through private sector; laboratories/hospitals and general practitioners (GPs) at a cost.

2.2 Provider Initiated HIV testing

Provider-initiated testing services denotes HIV testing services (HTS) offered in a health facility by a care provider. It includes providing pre-test information and obtaining consent for testing. However, the option for individuals to decline testing is assured.

Provider initiated HIV testing strategy helps to increase HTS coverage, to provide diagnosis earlier for those attending health facilities, to normalize HIV testing and to remove the need for personal motivation to seek HTS. It saves clients from the possible embarrassment of asking for an HIV test.

Provider initiated HIV testing should be offered to all categories mentioned below

A. HIV testing should be routinely offered in all of the following settings:

1. STD clinics
2. Antenatal services
3. TB clinics
4. Drug dependency programmes
5. Healthcare settings where hepatitis B, hepatitis C are diagnosed

B. HIV testing is recommended for the following patients:

1. Patients presenting with clinical features suggestive of primary HIV infection and HIV indicator conditions (see Tables 1 for clinical features of primary HIV infection and Table 2 for Clinical indicator diseases for adult HIV infection)

(Indicator diseases for pediatric HIV infection will be discussed in chapter 7)

2. Patients diagnosed with a sexually transmitted infection
3. Sexual partners of persons known to be HIV positive
4. Key populations [Men who have sex with men (MSM), Female Sex workers (FSW), People who inject drugs (PWID), Beach boys (BB), Prison inmates] and vulnerable groups (Youth, migrant workers, armed forces and tourism industry workers)
5. female sexual contacts of men who have sex with men
6. Persons who report sexual contact abroad or locally with individuals from countries of high HIV prevalence
7. Victims of sexual assault
8. Persons who reported to have sex with casual or multiple partners

C. HIV testing should also be routinely performed in the following situations;

1. Donor blood,
2. Donors of tissues and organs for transplant
3. In-utero insemination
4. Other situations when requested by relevant health care providers

Table 1 - Clinical features of primary HIV infection

Symptoms and findings	Percentage of patients
Fever	>80 to 90
Fatigue	>70 to 90
Rash	>40 to 80
Headache	32 to 70
Lymphadenopathy	40 to 70
Pharyngitis	50 to 70
Myalgia or arthralgia	50 to 70
Nausea, vomiting or diarrhea	30 to 60
Night sweats	50
Aseptic meningitis	24
Oral ulcers	10 to 20
Genital ulcers	5 to 15
Thrombocytopenia	45
Leukopenia	40
Elevated hepatic enzyme levels	21

Table 2 -Clinical indicator diseases for adult HIV infection

	AIDS-defining conditions	Other conditions where HIV testing should be offered
Respiratory	Tuberculosis Pneumocystis Pneumonia	Bacterial pneumonia Aspergillosis
Neurology	Cerebral toxoplasmosis Primary cerebral lymphoma Cryptococcal meningitis Progressive multifocal leucoencephalopathy	Aseptic meningitis/encephalitis Cerebral abscess Space occupying lesion of unknown cause Guillain–Barré syndrome Transverse myelitis Peripheral neuropathy Dementia
Dermatology	Kaposi's sarcoma	Severe or recalcitrant seborrhoeic dermatitis Severe or recalcitrant psoriasis Multidermatomal or recurrent herpes zoster
Gastroenterology	Persistent cryptosporidiosis	Oral candidiasis Oral hairy leukoplakia

		Chronic diarrhoea of unknown cause Weight loss of unknown cause Salmonella, shigella or campylobacter Hepatitis B infection Hepatitis C infection
Oncology	Non-Hodgkin's lymphoma	Anal cancer or anal intraepithelial dysplasia Lung cancer Seminoma Head and neck cancer Hodgkin's lymphoma Castleman's disease
Gynaecology	Cervical cancer	Vaginal intraepithelial neoplasia Cervical intraepithelial neoplasia Grade 2 or above
Haematology		Any unexplained blood dyscrasia including: • thrombocytopenia • neutropenia • lymphopenia
Ophthalmology	Cytomegalovirus retinitis	Infective retinal diseases including herpesviruses and toxoplasma Any unexplained retinopathy
ENT		Lymphadenopathy of unknown cause Chronic parotitis Lymphoepithelial parotid cysts
Other		Mononucleosis-like syndrome (primary HIV infection) Pyrexia of unknown origin Any lymphadenopathy of unknown cause Any sexually transmitted infection

3. Pre-test and post-test services

In order to achieve an increased uptake of HIV testing services in the country it is essential to have certain pre and post-test services available**.**

3.1 Pre-test services

3.1.1 Promoting HIV testing services (HTS)

National STD/AIDS control programme (NSACP) with the support of Ministry of Health (MoH) use variety of methods to promote HIV testing in the county.

Continuous pre-service and in-service training programmes are being conducted by NSACP and peripheral STD clinics for healthcare providers to promote HIV testing for clients who attend health care services. Number of full time and part-time STD clinics are being increased continuously giving more access to STI and HIV services. In addition, STD clinics promote HTS tailor-made to the particular needs of the districts including training of health care workers, outreach testing and supportive supervision for peer led interventions in the district. In addition, accessibility and turnaround time of testing have improved significantly with availability and of rapid HIV testing services at STD clinics, hospitals, MOHs, GPs and in number of privet laboratories.

Print, electronic and social media are used to promote HIV testing in general as well as among risk groups and vulnerable groups.

In addition, peer led community interventions and outreach HIV testing services are in place to reach previously unreached key affected population, vulnerable populations and people in geographically difficult areas. A special internet based peer led intervention was recently being introduced to promote HIV testing among KPs.

3.1.2 Creating an enabling environment

NSACP and other relevant stakeholders are working towards creating an enabling environment for HIV testing services in the country. During training of health staff on HIV, special emphasis is given about addressing issues on human rights, stigma and discrimination and importance of non-judgmental attitudes towards KPs. Advocacy programmes are conducted for policy makers, community leaders, media and other relevant sectors to create an enabling environment for KPs. Training programmes are conducted for law enforcement officers to sensitize them on human rights and fundamental freedom for all. The legal and ethics subcommittee of the NAC is working

towards to revisit and repeal laws that criminalize KPs. Capacity building of PLHIV networks and KP groups and getting their partnership in planning and implementation of HIV testing services are other steps taken in that direction.

3.1.3 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 of HIV status but also to any personal information, such as information concerning sexual behavior and the use of illegal drugs. HTS should avoid practices that can inadvertently reveal a client's test results, or HIV status, to others in the waiting room or in the health facility.

3.1.4 Pretest information

All clients who undergo HIV test should be provided with adequate pretest information. The information could be provided through individual or group counselling, posters or leaflets. The depth of provision of pretest information depends on the setting.

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

- meaning of HIV and AIDS
- modes of transmission and brief natural history
- the benefits of HIV testing
- the meaning of an HIV-positive and an HIV-negative diagnosis
- the services available (including ART)
- the potential for incorrect results if a person already on ART is tested
- a brief description of prevention options and encouragement of partner testing
- confidentiality of results
- 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 HIV-related services or general medical care
- potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behavior is stigmatized
- availability of opportunity to ask questions from the provider

If a patient refuses a test, the reasons why they have made that choice should be explored to ensure that these are not due to incorrect beliefs about the virus or the consequences of testing

Special considerations for pregnant or postpartum women

In addition to the pre-test information mentioned above for women who are or may become pregnant or are in postpartum should also receive following additional information:

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

3.2 Post - test services

3.2.1 Post - test counselling following HIV negative screening results

Individuals who test HIV-negative should receive brief health information about their test results.

Counselling for those who test HIV-negative should include the following:

- an explanation of the test result and reported HIV status;
- education on HIV prevention methods
- emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couples testing services at STD clinic if relevant
- referral and linkage to STD clinics for people at substantial ongoing HIV risk
- a recommendation on retesting based on the client's level of recent exposure and/or ongoing risk of exposure
- opportunity for the client to ask questions and request counselling.

Retesting during window period

Retesting should be arranged for individuals who report recent or ongoing risk of exposure.

Retesting for those who remain at high risk of HIV acquisition.

People who are diagnosed HIV-negative but remain at high risk (key populations), may benefit from regular retesting. Therefore, they should be encouraged to get retested by annually.

3.2.2 Post - test counselling following HIV positive confirmatory test results

Name and other identity details of the client should always be checked before disclosing the results to clients. It should be always 'client centered' which means counselling should always be responsive to and tailored to the unique situation of each individual or couple

- Make sure the client is ready to receive results
- Explain that a positive result means the client is infected with HIV.
- Make sure that the client understands the results
- Reinforce confidentiality
- Give the client time to absorb the information before proceeding. Assess the client's ability to cope with the diagnosis and check the support available to the client immediately.
- Provide brief information on available HIV treatment and care services and refer the clients to nearest STD clinic for further counselling and HIV care
- Make an active referral to nearby STD clinic with a specific time and date. (An active referral is one in which the tester makes an appointment for the client or accompanies the client to an appointment and enrolment into HIV clinical care.)
- If the individual refuse to go to a particular clinic an alternative arrangement should be made
- Assess the risk of suicide, depression and other mental health consequences of a diagnosis of HIV infection
- Check whether the client has any questions
- Ensure client's safety in travelling home

Partner and family screening and partner disclosure is best to be discussed and arranged at STD/ HIV clinic later. Most clients will be too distressed for a detailed discussion about ways of transmission and will not be able to absorb information at this point. Thus, may need to be discussed at another counselling session/s.

If the care provider is not in a position to provide a proper post - test counselling it is always advisable to refer the client to STD clinic for further management

3.2.3 Service for Inconclusive/ Indeterminate HIV test results

Receiving an HIV-inconclusive status may be confusing and stressful for the individual or couple and may be difficult for the provider to explain. Therefore, it is always advisable to refer the patient to Venereologist for

- proper counselling to avoid unnecessary distress to the patient
- arranging appropriate testing to arrive at a diagnosis and minimize loss to follow up

In community based / outreach testing the client should be given an appointment to return in 14 days for retesting. If the patient is willing to go to STD clinic, an active appointment should be arranged for further testing.

4. Types of HIV testing services

There are two methods in routine practice for testing for HIV involving either venipuncture and a screening assay where blood is sent to a laboratory or a rapid point of care test (POCT). In all facility base HIV testing for adults, national HIV testing algorithm for adult (Figure 1) should be followed.

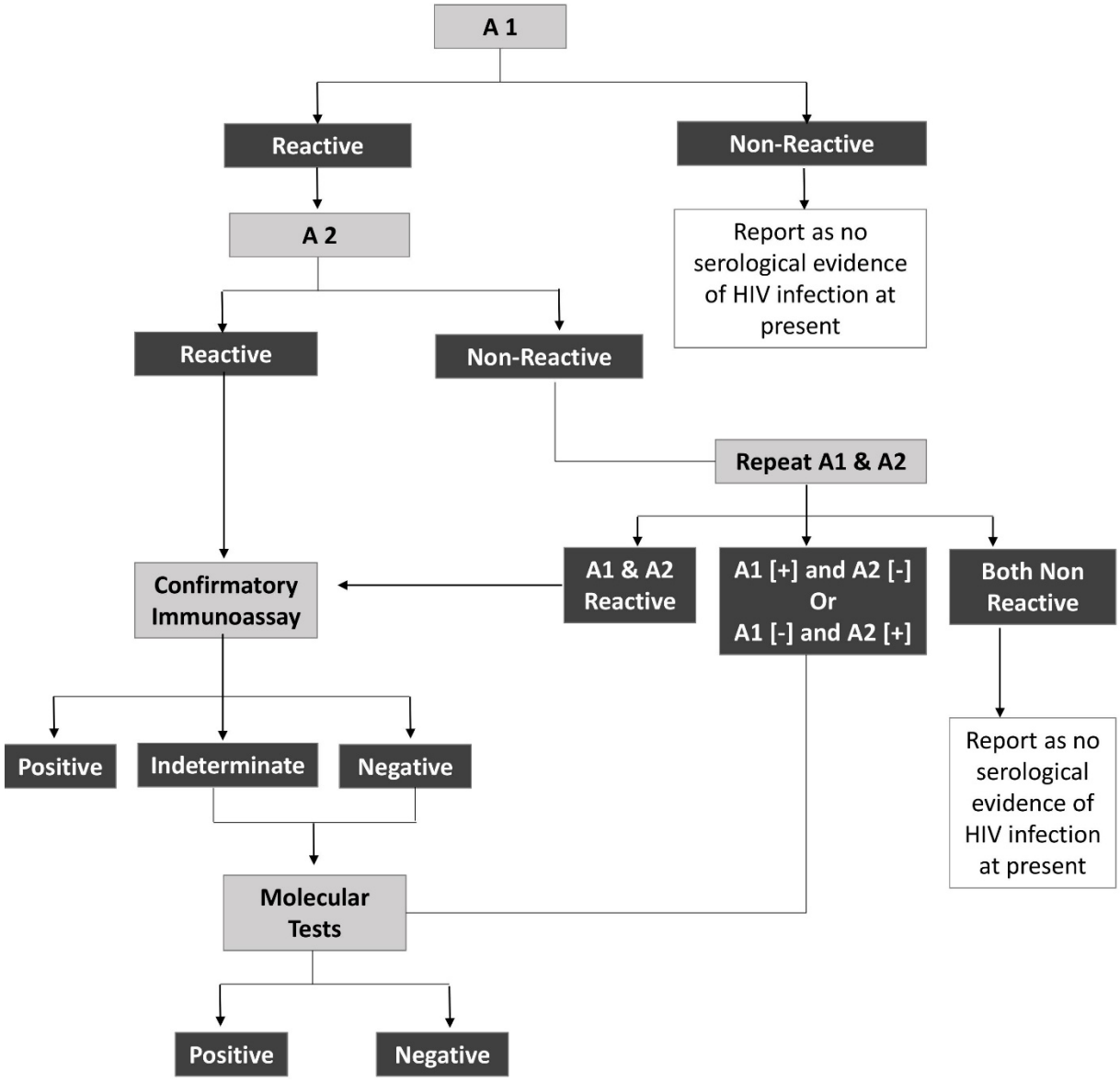
4.1 Screening tests

The recommended first-line assay detects HIV antibody AND p24 antigen simultaneously. These are termed fourth generation assays, and have the advantage of reducing the time between infection and testing HIV positive to two to three weeks. All government STD clinics screen the samples using 4th generation ELISA assays. For all private sector testing centers it is recommended to use 4th generation assays.

4.2 Confirmatory assays

Laboratories undertaking screening tests should be able to send samples to NRL for confirmation by immuno assay (western blot) or molecular assays (RNA or DNA PCR). Currently confirmatory immuno assay is only available at NRL. All new HIV diagnoses should be made following appropriate confirmatory assays with a second sample.

Figure 1 - Testing Strategy for HIV diagnosis in Adults in Sri Lanka



A1 - A 4th Generation Immunoassay in laboratory settings
A2 – A 2nd Immunoassay Test with different method

4.3 Rapid HIV tests / Point of care testing (POCT)

Point of care tests offer the advantage of a result from finger prick sample within minutes. They have advantages of ease of use when venipuncture is not possible, e.g. outside conventional healthcare settings and where a delay in obtaining a result is a disadvantage. Since these tests can be carried out outside healthcare settings, they are useful to increase access as well as coverage of HIV testing. It is recommended to use 4th generation POCT for screening.

In outreach testing using POCT, if the screening test becomes positive it is recommended to use two different POCT using different platforms for the diagnosis. The second and 3dr assay should be antibody bases assays. (please refer Figure 2; testing strategy for HIV diagnosis for outreach programmes in Sri Lanka)

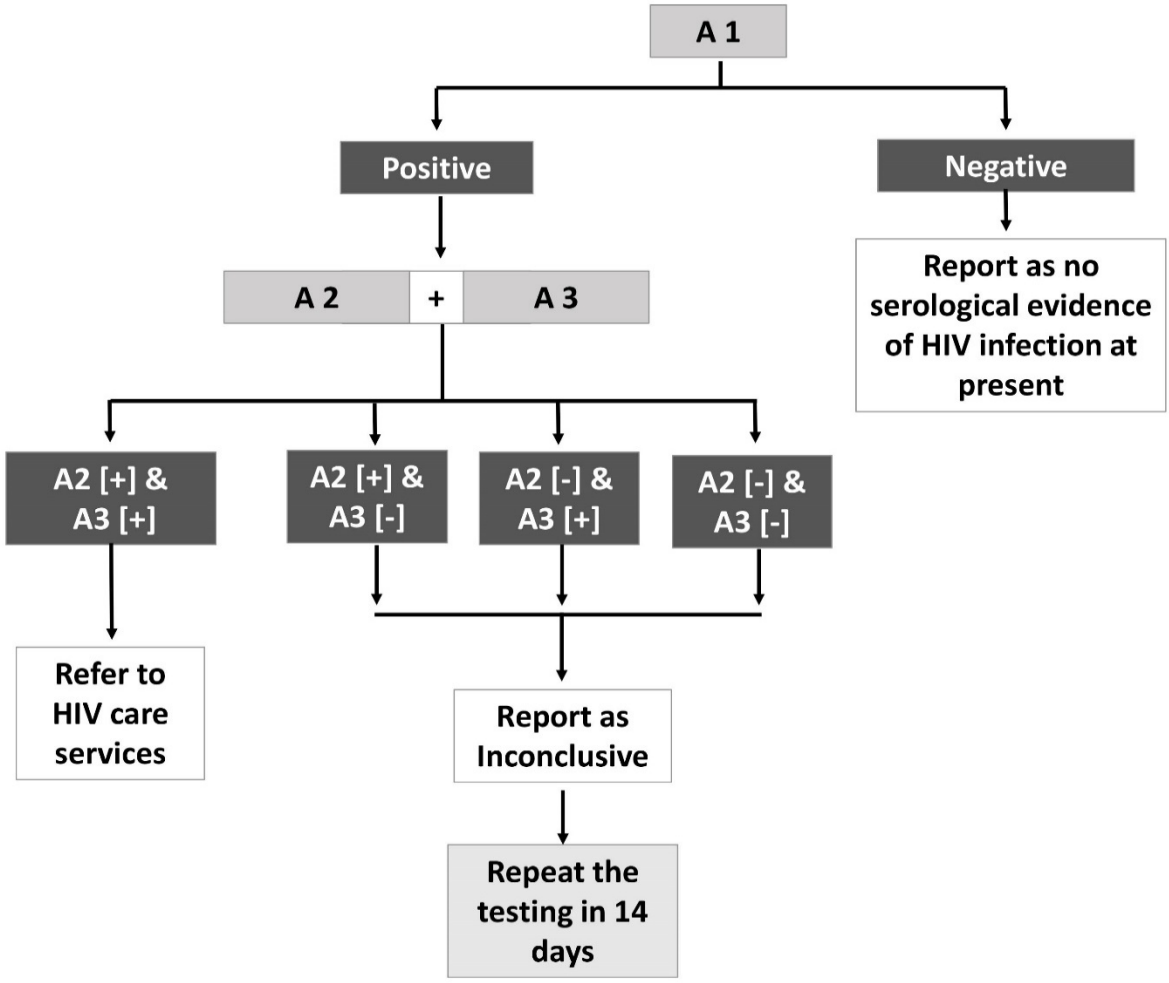
However, facility base POCT positive results are confirmed by following normal adult algorithm (Figure 1)

WHO /FDA recommended POCT kits should be used and quality assurance of the testing process should always be followed.

POCT is recommended in the following contexts:

1. Clinical settings where a rapid turnaround of test results is desirable
2. Community based testing sites
3. Outreach testing programmes
4. Urgent source testing in cases of exposure incidents (PEP services)
5. Circumstances in which venipuncture is refused.

Figure 2 - Testing strategy for HIV diagnosis for outreach programmes in Sri Lanka



A1 - 4th Generation RDT assay

A2 - Ab RDT assay

A3 - Ab RDT assay

5. HIV testing in different setting

5.1 HIV testing in government setting

HIV testing services are provided to clients free of charge through various government sector institutions.

5.1.1 HIV screening services for STD clinic attendees

HIV screening is offered to all clients who attend STI services during the first consultation following pre-test counselling/information.

Blood samples are tested at the STD clinic laboratory. All positive and negative screening test results are given with post - test counselling.

In the event of a positive screening test, a second sample of blood is taken to be sent to the National Reference Laboratory for the confirmatory test. Result of the confirmatory test is given to the client with post-test counseling.

In the event of a confirmed positive test result, the person is enrolled for further management of HIV at the STD clinic.

5.1.2 HIV screening among patients diagnosed with tuberculosis (TB)

HIV screening is offered to all persons diagnosed with TB with pre-test information. Blood samples are drawn at the TB clinics and sent to local STD clinic laboratory for testing. Screening test results are sent to the referring physician.

HIV rapid tests kits are available at some chest clinics and HIV testing is offered and done at those chest clinics.

In the event of a positive screening test result, either the client or a second sample of blood is sent to the local STD clinic to arrange confirmatory test. In case a sample has been sent for confirmatory test, result is sent to the referring TB physician. He/she will refer the patient to local STD clinic for further management where HIV is confirmed.

When patients are sent to STD clinic for confirmatory tests, results will be given during post-test counseling. In the event of a confirmed positive test result, the patient is enrolled for further management of HIV at the STD clinic.

5.1.3 HIV screening among patients diagnosed with hepatitis B/C:

HIV screening should be offered to all patients diagnosed with hepatitis B/C after providing pre-test information. Blood samples are drawn in the wards/clinics and sent to local STD clinic laboratory for testing. Screening test results are sent to the referring physicians.

In the event of a positive screening test result, the positive individual or a second sample of blood is sent to the local STD clinic to arrange confirmatory test. Results of confirmatory tests are sent to the referring physician. He/she will refer the patient to local STD clinic for further management.

When patients are received at STD clinic with positive confirmatory test, detailed post-test counseling will be done and the patient is enrolled for further management of HIV at the STD clinic.

5.1.4 HIV screening for pregnant women attending ANC services.

All pregnant women are offered HIV testing following pretest information, with the option to 'opt out'.

Blood samples are drawn at the antenatal clinics and sent to local STD clinic laboratory for testing. Screening test results are sent to the relevant obstetrician or Medical Officer of Health (MOH).

Pregnant mothers with the positive screening test result are referred to the local STD clinic to arrange confirmatory test. It is always advisable to arrange a date and time with Venereologist before sending the pregnant mother to assure proper linkage to care. Both positive and negative confirmatory test results will be given during post- test counseling at the STD clinic. In the event of a confirmed positive test result, the mother is enrolled at the STD clinic for management of HIV and relevant obstetrician or medical officer of health (MOH) will be informed.

It is recommended to offer a repeat HIV test during third trimester to pregnant women who are at risk of acquiring HIV.

5.1.5. HIV testing in government hospitals

When the government sector doctors come across any patient (inward, OPD, ETU or clinic patients) with HIV seroconversion like symptoms, HIV indicator conditions or any other indications as mentioned above, it is strongly recommended to offer HIV testing (Provider initiated HIV testing). In addition, patients themselves can request HIV test at OPD, clinic or ward consultation (client initiated HIV testing)

In both these instances patient need to be given pre - test information. After obtaining consent (verbal consent), blood samples can either be sent to nearest STD clinics with a duly filled request form or they can order rapid HIV test which is available in government hospitals. It is the responsibility of the ordering doctor to give the positive or negative results to the client with post - test counselling.

Doctors can also refer the patient to STD clinic for HIV testing and pre - test information is provided to client by medical officer at STD clinic and arrange HIV testing.

When screening test is reactive, either patient or second sample should be send to nearest STD clinic for confirmatory test. Results are provided to clients by MO/STD or Consultant Venereologist, with post - test counselling.

All confirmed positive patients are linked to nearest STD clinic for HIV care services. Maximum efforts need to be taken to link positive clients to HIV care services as soon as possible to minimize lost to follow up.

5.2 HIV testing in private sector

HIV testing facilities are available in major private hospitals/laboratories and the cost of testing need to be borne by the patient.

In private sector, either client initiated or provider initiated HIV testing can be arranged following provision of pre - test information. Both positive and negative screening test results are given to the individual with post - test counselling. Following a positive screening test result, it is strongly recommending to send the positive individual to nearest government STD clinic for confirmatory tests. However, failing that option a second sample of blood could be sent to NRL for confirmatory test. Confirmatory test is done at the National Reference Laboratory. Result of the confirmatory test is sent to the referring clinician or laboratory in case where a sample has been sent for confirmation. It is recommended that confirmatory test result is provided to client with post - test counseling as mentioned above.

When patients are referred to STD clinics for confirmatory tests, both positive and negative confirmatory test results are given during post - test counselling at STD clinic.

In addition, any general practitioners can also arrange HIV testing for clients. It could be either client initiated or provider initiated testing. Results should be given to patient with post - test counselling.

5.2.1. HIV testing services through General Practitioners in Colombo and Gampaha districts

The NSACP / FHI 360 – linkages project in collaboration with College of General Practitioners and Independent Medical Practitioners Association introduced HIV testing services to the General Practice in Colombo and Gampaha districts. The testing services commenced in 2018 adding another feature to HIV services in Sri Lanka. The strategy used in GP HIV testing services is "Rapid HIV testing".

Currently, there are nearly 100 GPs in both districts who provide rapid HIV testing services within their practices either free of charge or for a nominal fee. The test is done using a fingerpick blood sample and the result is available to patient within 20 minutes.

The logistics such as test kits, information material etc., are provided by the nearest STD clinic and the detected reactive individuals are referred to STD clinic for further follow up. The reporting system is electronic through "Pulse App".

The list of general practitioners who provide HIV rapid testing in the relevant district can be obtained through the district STD clinics.

5.3 Outreach / Community based HIV Testing

Outreaching with HIV testing services is carried out by STD clinics as well as through peer led interventions. It is done either with serology or using rapid HIV tests. In addition to MLTs, selected health staff and NGO staff (trained care providers - TCP) are trained to perform rapid HIV testing in field level. Outreach testing is promoted for following groups / situations;

5.3.1 Key Affected Populations (FSW, MSM, TG, PWID/PWUD, BB, prison inmates)

5.3.2 Vulnerable population: armed forces and police, Returnee migrant workers, youth, tourist industry workers, people in disaster situations etc.)

5.3.3 People living in difficult geographical areas (estate sector, urban low-socioeconomic areas)

5.3.4 People who find it difficult to attend services during working hours (three wheeler drivers, fishermen, long distance drivers etc.)

5.3.5 Special events based HIV testing (World AIDS day, special Exhibitions etc.)

5.3.6 Community based HIV testing

5.3.1 Key Affected Populations

Peer-led targeted intervention programme in collaboration with STD clinics provide outreach HIV testing services for key populations on regular basis. HIV testing services are provided through outreaching to key populations by STD clinic staff on their own initiative. FSW, MSM, beach boys PWID, PWUD and prisoners are the identified KPs in Sri Lanka.

During outreach testing, pre-test information is provided on individual or group basis. If requested, individual pre-test counseling should be provided by a trained care provider. People who consent for testing should be provided with HIV rapid screening test by a trained care provider.

Testing frequency;

Optimum – once in 6 months for FSW, MSM, DU and Beach Boys

Minimum–annual

Please refer Figure 2, page 18 for the protocol for community-based HIV testing.

5.3.2 HIV testing for Vulnerable populations

I. Migrant workers – HIV testing is included in a general health screening package for external migrant workers who have returned. The services will be provided through provider initiated approach in collaboration with other relevant stakeholders. They need to be tested within one year of their return.
II. Youth and adolescents in vulnerable settings
III. Tourism industry worker
IV. Inbound health assessment for foreign labor migrant workers

Annual testing is recommended for the members of these population groups.

5.3.3 People living in difficult geographical and urban low-socioeconomic areas

The testing services are promoted among estate sector workers and people living in urban low-socioeconomic areas through provider initiated approach. However, the accessibility for HIV testing services is limited in these groups. Therefore, outreaching for them with relevant services is recommended.

5.3.4 People who find it difficult to attend services during working hours

This guideline recommends that the members of population groups such as three wheeler drivers, fishermen, and long distance drivers etc. to be provided with HIV testing services through provider initiated approach.

5.3.5 Special events based HIV testing (World AIDS day, special exhibitions etc.)

HIV testing promotional campaigns could be integrated to other related events such as World AIDS day or other health promotion exhibitions etc.

5.3.6 Community based HIV testing

Community based HIV testing is provided in the communities, by members of the communities for fellow members of their own communities (key populations). Basically this type of testing services is provided within drop-in centers run by communities. Community members visit the centers voluntarily or they are promoted to attend services by the community organizations. With pre-test information, they are offered HIV testing services (using rapid HIV tests) by train care providers within drop-in centers.

Protocol for outreach / community-based HIV testing

- Individual or group education should be provided on HIV/AIDS/STIs. Lecture / discussion should address the specific target group (FSW, MSM, DU, Beach boys, TG and other vulnerable groups as relevant).
- During the lecture / discussion, pre-test information regarding HIV testing should be provided emphasizing the importance of testing and knowing the HIV status. The benefits of early detection of HIV infection should be emphasized.
- At the end of the lecture / discussion the participants should be informed that facilities are available for onsite HIV testing and those who are willing, could undergo HIV testing.
- If anyone needs more information, a trained health care provider should discuss further regarding HIV testing.
- leaflet carrying pre-test information should be given, to reinforce the information given during the lecture.
- A rapid HIV screening test should be performed and results should be given individually by a trained care provider.

- If rapid screening test is negative – results should be given with relevant post-test information including window period and basic facts for risk reduction (leaflet should be given).
- Follow up testing for those with negative test results need to be arranged when required. It can be arranged either by referring them to the local STD clinic or in a similar out-reach activity in 3- 6 months.
- If the initial rapid test is reactive the individual should be informed about the results and a second and third rapid test using different platforms are done to confirm the results.
- Individuals who had all three screening tests positive should be linked to HIV care for further assessment. It is the responsibility of the TCP to arrange individualized appointment and accompany the positive client to HIV care services
- Those who had two screening tests positives should be retested according to national algorithm for outreach testing and follow up should be arranged accordingly.
- During subsequent visits to the same venue attempts should be made to check whether they have tested within last three months. If not, they should be encouraged to get tested 3 months after the date of possible last risky exposure/ last testing.

- During the outreach visit in addition to HIV testing following important points should be addressed;
    - Promotion and provision of condoms.
    - Referral of symptomatic people to STD clinic for treatment and care.
    - motivation and promotion of asymptomatic people to attend STD clinics for STI screening
    - promotion of clients to send their partners to STI services

Check list for Community based HIV testing

General requirement

- Covered area with adequate privacy
- Minimum of two tables and four chairs
- Waste bag and a bin
- Sharp bin
- Labels and bottle of gum
- Registration book
- Cotton wool
- 70% Alcohol

- Gloves
- Test kits

Instructions prior to do HIV testing

- Trained Care Provider / s (TCP) are responsible for providing services according to ethical and quality standards.
- Always follow the manufacturer's instructions for storage and transport of test kits. Quality assurance of test kits should always be followed.
- Pre-Test information should be provided either verbally, displaying a poster or providing leaflets.
- Guiding principles of 5 "C"s should always be followed. (Counseling, Confidentiality, Consent, Correct report and Connect to care)
- All clients should be registered in a registry with contact address and a telephone numbers if possible.
- Check the expiry date of the test kits prior to use .

Procedure of testing

- Follow the manufacture guidance
- Wear gloves prior to pricking.
- Correctly label the test strip.
- Perform the test according to the manufacturer's instructions.
- Read the result after 20 minutes.

Both positive and negative results should be given following post - test counselling

Positive results:	Inform the positive results to the client and carry out additional two different rapid tests as mentioned in the algorithm. Interpretation of results should be done according to the algorithm. All positive clients should be linked to nearest STD clinic for HIV care.
Negative results:	State as non-reactive. Provide measures for risk reduction (leaflet). Encourage re-testing in 6 monthly.
Invalid results:	Need to repeat the test.

Storage of test kits

Keep in the room temperature. Keep test kits packed in boxes and avoid exposure to direct sun light.

Management of waste

- Sharp needles or lancets: Should be discarded to sharp bin
- Cotton wool swabs and used test kits: Waste bag
- Sharp bin and waste bags should be brought back to the clinic to discard them properly.

Figure 3 - Conditions to consider HIV testing

CONDITIONS TO CONSIDER FOR HIV TESTING

Dermatological

- Kaposi's sarcoma
- Popular pruritic eruptions
- Severe or recalcitrant seborrheic dermatitis
- Severe or recalcitrant psoriasis
- Multi-dermatomal or recurrent herpes zoster
- Severe/atypical skin conditions not responding to standard treatment

Gastro-intestinal

- Persistent cryptosporidiosis
- Oral oesophageal candidiasis
- Oral hairy leucoplakia
- Chronic diarrhoea of unknown cause
- Weight loss of unknown cause
- Salmonella, shigella or campylobacter diarrhoea
- Hepatitis B infection
- Hepatitis C infection
- Necrotising gingivitis or periodontitis

Gynaecological

- Cervical cancer
- Vaginal intraepithelial neoplasia
- Cervical intraepithelial neoplasia grade 2 or above

Haematological

- Any unexplained blood dyscrasia
  - Thrombocytopenia
  - Neutropenia/Lymphopenia
- Unexplained anaemia
- Unexplained high ESR

Respiratory

- Tuberculosis
- Pneumocystis pneumonia
- Recurrent severe bacterial pneumonia
- Aspergillosis

Neurological

- Cerebral toxoplasmosis
- Primary cerebral lymphoma
- Cryptococcal leukoencephalopathy
- Aseptic meningitis/encephalitis
- Space occupying lesion of unknown cause/Guillain – barre syndrome
- Transverse myelitis
- Peripheral neuropathy
- Dementia
- Cerebral abscess

Oncological

- Non-Hodgkin's lymphoma
- Anal cancer or anal intraepithelial dysplasia
- Hodgkin's lymphoma
- Castleman's disease

Ophthalmological

- Cytomegalovirus retinitis
- Infective retinal diseases including herpes viruses and toxoplasma infections
- Any unexplained retinopathy

Risky behaviours

- History of unprotected sex and sharing of needles/syringes

Other considerations

- Pyrexia of unknown origin
- Recurrent or severe sinusitis
- Recurrent bacterial infections
- Systemic fungal infections
- Unexplained proteinuria
- Extra pulmonary tuberculosis
- Other mycobacterial infections
- Persistent generalized lymphadenopathy

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Figure 4 - 5 C of HIV Screening

5.4 HIV testing in prisons

Voluntary testing through provider initiated approach is offered to inmates while they are in prison. If the prisoner has got tested within preceding three months he/she need not be offered testing. Peer educator training programmes for prison inmate on HIV/STI are been carried out by the prison welfare officers who are trained by NSACP. The peer educators conduct both formal and informal education for prison inmates. This is followed by group discussions and one to one discussions when required. During these sessions group pre-test information / counseling is given and HIV testing is promoted. Monthly outreach HIV testing is conducted by the staff attached to Central and District STD clinics of the National STD/AIDS Control programme for prison with the support of prison staff covering HIV testing in 30 prisons island wide.

5.4.1 Protocol for prison HIV testing

1. Prison Welfare officers facilitate HIV testing services for prison inmates with assistance of peer educators
2. Before offering HIV test, pre-test information is provided to inmates as group or individual counselling.
3. HIV testing is carried out among prisoners who are willing to get tested.
4. Blood is drawn by the STD clinic staff and laboratory testing performed at STD clinic laboratory. The blood is tested for both syphilis and HIV.
5. The contact information (phone numbers) and address of the prison inmate should be obtained to contact them by STD clinic staff to get down inmates who are released from the prison before getting the results.
6. HIV screening test results are issued to the medical officer in-charge of the prison by the medical officers at respective STD clinics.
7. Prison medical officer will reveal the negative test results with relevant information to the individual prison inmates.
8. Reactive results are indicated in the report as “need to retest” and prison medical officer send the inmates to STD clinics for detailed pre-test counseling and confirmatory testing.
9. Once confirmed, positive result is given at the STD clinics with post- test counseling by the MO/STD. Prison Medical Officer will have to share this information with the superintendent of prison / other relevant officer while maintaining confidentiality for the purpose of arranging necessary follow up and care for the HIV infected prison inmates.
10. MO/Prison make arrangements to transfer HIV positive inmates to Colombo prison for initial management (medical assessments, investigations, OI prophylaxis, initiation of ART) in

situations where there is no venereologist at local STD clinics. Otherwise are managed at the local STD clinic with consultation of the Venereologist.

11. Once initial management is done at the central STD clinic, Colombo, prison inmate could be transferred back and can be followed at the local STD clinic.
12. Before discharge from the prison HIV infected prison inmates should be referred to the local STD clinic and appropriate follow up should be established.
13. HIV rapid test is available for prisoners in Magazine prion in Colombo where there is high turnover of inmates during a short period and for peripheral prisons where local STD clinic find practical difficulties to visit the prison monthly to collect blood. Selected members of prison staff are rained on rapid HIV test by the NSACP. Pretest information and management of positive and negative results are done in the same way as described above (outreach HIV testing services using rapid HIV tests).

5.5 Internet based outreach testing

A special internet -based outreach testing programme is in place in Colombo and Gampaha districts. This programme is mainly targeting KPs who find partners through social media. Internet peer-educators encourage them through social media to carry out a HIV risk assessment and give facilities to book an appointment for HIV testing via a special app called “Know for sure”.

5.6 HIV screening of donor blood / organ transplant / major invasive surgical procedures

5.6.1 HIV screening for donor blood

Blood collected for transfusion or for manufacture of blood products are screened for HIV and other blood borne viruses. (All donors are informed during donor counseling that a sample of the given blood is tested for HIV and other blood borne viruses)

All confirmed HIV positive blood donors are traced and referred to district STD clinics for HIV care after a post- test counselling while maintaining confidentiality.

5.6.2 HIV screening in organ donors

Donors involving in transfer of bodily fluids or body parts, such as artificial insemination, corneal grafts and organ transplant are screened for HIV prior to procedures.

- Antigen and antibody combo test/Fourth generation Eliza is recommended prior to organ transplant.
- Pre-donation NAT testing may help reduce the residual risk of infection during the serological window period and may be done on an individual basis.

If the donors are found to be HIV positive they should be referred to STD clinics for further evaluation and HIV care.

5.6.3 HIV screening before major invasive surgical procedures

HIV screening is done before major surgical procedures and the HIV positives should have referred to nearest STD clinic for HIV care.

6. HIV testing in special situation

6.1 Testing infants and other children for HIV

Any infant/child/young person thought to be at significant risk of HIV infection, including all those with parents or siblings who are HIV-infected, should be tested. It is in the best interest of the infant/child/young person to be tested in these circumstances although this only needs to be undertaken urgently in infants who are at risk of rapid disease progression.

6.1.1 Indications for HIV testing among children

- infants and children whatever their age where the mother has HIV, or may have died of an HIV-associated condition
- infants born to mothers known to have HIV in pregnancy
- infants born to mothers who have refused an HIV test in pregnancy
- infants and children with signs and symptoms consistent with an HIV diagnosis (See Table 3 for indicator conditions among infant and children)
- infants and children being screened for a congenital immunodeficiency
- infants and children in circumstances of post-exposure prophylaxis
- infants and children in cases where there has been sexual abuse

6.1.2 Obtaining consent for HIV testing from children <10 years old:

As the child is unable to give consent, consent is taken from one parent or caregiver following provision of pretest information is sufficient. However, in the circumstances where a caregiver or parent is not available, the caring doctor should seek advice from Venereologist and venereologist can consider ordering HIV test for the best interest of the infant or child.

Table 3 - Clinical indicator diseases for pediatric HIV infection

	AIDS-defining conditions	**Other conditions where HIV testing should be offered**
ENT		Chronic parotitis Recurrent and/or troublesome ear infections
Oral		Recurrent oral candidiasis Poor dental hygiene
Respiratory	Pneumocystis CMV pneumonitis Tuberculosis	Recurrent bacterial pneumonia Lymphoid interstitial pneumonitis Bronchiectasis
Neurology	HIV encephalopathy meningitis/encephalitis	Developmental delay Childhood stroke
Dermatology	Kaposi's sarcoma	Severe or recalcitrant dermatitis Multi dermatomal or recurrent herpes zoster Recurrent fungal infections Extensive warts or molluscum contagiosum
Gastroenterology	Wasting syndrome Persistent cryptosporidiosis	Unexplained persistent hepatosplenomegaly Hepatitis B infection Hepatitis C infection
Oncology	Lymphoma Kaposi's sarcoma	
Haematology		Any unexplained blood dyscrasia including: • thrombocytopenia • neutropenia • lymphopenia
Ophthalmology	Cytomegalovirus retinitis	Any unexplained retinopathy
Other	Recurrent bacterial infections (e.g. meningitis, sepsis, osteomyelitis, pneumonia etc.) Pyrexia of unknown origin	

6.1.3 Testing of children of known HIV-positive parents

Testing should be offered in all cases at risk of vertical transmission. Increasing evidence shows that children infected vertically can survive into teenage years without being diagnosed. Therefore, it can't be assumed that older children of mothers with HIV do not require testing. This raises difficult issues of informed consent for these young people, particularly if they are unaware of the mother's diagnosis. Testing of neonates, children and young people where the mother refuses consent and/or disclosure of her HIV status is a complex area. The overriding consideration must be the best interests of the child, and multidisciplinary decision-making and expert advice should be sought, including legal advice where appropriate. It is not acceptable to simply accept a mother's refusal. Referral to NSACP with experience of management of HIV-infected children is strongly recommended. Parents may need to be supported in making the decision to go ahead to test their children

What do children need to know about having an HIV test?

One of the main reasons that parents do not want to test their children for HIV is because they are afraid to share the diagnosis with them. It should be explained to parents that a developmentally and age-appropriate explanation of the test should be given to children and that this does not necessarily mean using the term HIV.

1) Older children (usually those older than 11) should be asked to give consent for an HIV test.
2) Younger children (usually five to ten years of age) can be told they are being tested for a 'bug' in the blood.
3) Pre-school children and infants do not need any formal explanation of why they are having a blood test.

Appropriate HIV tests for infants and children

Children older than 18 months of age: HIV antigen antibody assays, same as for adults. Please follow the adult HIV testing algorithm.

Infants younger than 18 months of age: infants born to mothers with HIV receive trans placental maternal HIV antibodies which can usually be detected in the infant blood until about 18 months of age. Therefore, molecular diagnostics (HIV DNA/ RNA nucleic acid tests) are the investigation of choice for diagnosis of HIV in infants and children younger than 18 months.

6.1.3 A. When a mother is known HIV positive and the baby is formula fed, it is recommended to test the baby as mentioned below;

Molecular diagnostics (DNA or RNA nucleic acid tests)

- at birth (with in 48 hours)
- at 8 weeks
- at 4-6 months – Babies who have negative nucleic acid test at 8 weeks and 4-6 months are considered as HIV negative.

HIV Ag/Ab type 1 & 2 ELISA

This test is performed at 9 and 18 months to confirm sero reversion of maternal antibodies .

If HIV ELISA is negative at 9 months, it should be repeated immediately with a repeat blood sample to confirm sero reversion.

Children with perinatal HIV exposure aged 18-24 months may rarely have residuals maternal antibodies. In such cases, confirmation should be bases on nucleic acid test.

Definitive exclusion of HIV infection in non-breast fed infants

Definitive exclusion of HIV infection in non-breast fed infants is based on two or more negative virologic tests, with one obtained at age ⩾1 month and one at age ⩾4 month or two negative antibody tests from separate specimens obtained at age ⩾6 month.

6.1.3 B. When a mother is known HIV positive and breast feeding;

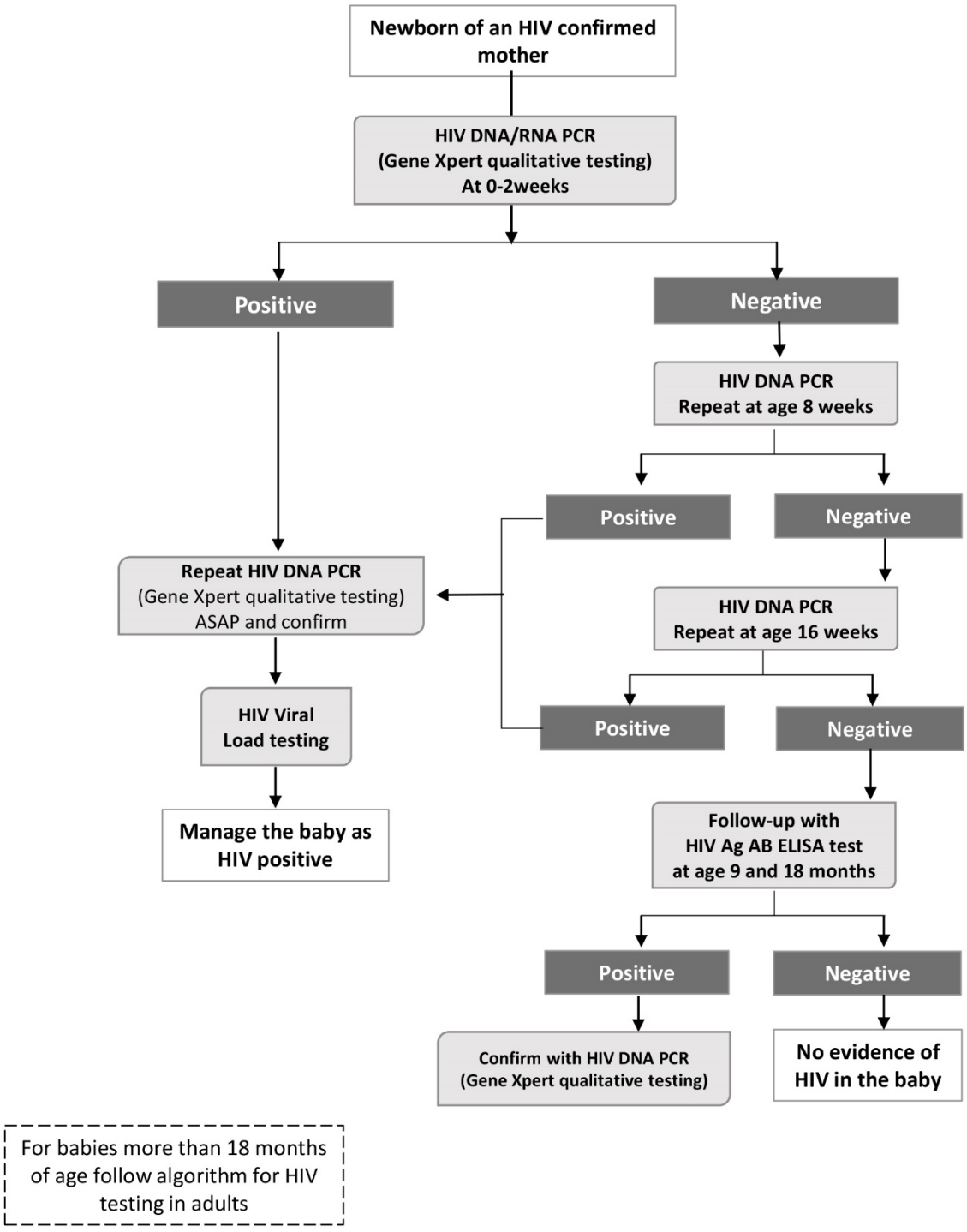
In addition to the testing mentioned for non-breast fed infants, monthly molecular testing is recommended until cassation of breast feeding and the last test 6 weeks after stopping breast feeding.

Confirmation of HIV positive results

If any of the above molecular tests becomes positive, it is recommended to repeat testing using a separate sample immediately and confirm the diagnosis.

Infants whose serological assays are reactive at 9 months should undergo virological test to rule out the infection.

Figure 5 - HIV testing algorithm for early infant diagnosis



Source: Adopted from Anteretroviral therapy for HIV infection in infants and children: towards universal access. Recommendations for a public health approach. 2010 revision. Geneva, WHO 2010

6.1.4 HIV testing in babies whose mother's HIV status is unknown

Babies of unknown mothers (when mother is not available for testing) can be tested with serological tests for exclusion of HIV infection, but if they become positive it should always be confirmed by molecular assays.

Children less than 18 months of age with a reactive screening test should undergo molecular assays for confirmation.

On the other hand definitive exclusion of prenatally acquired HIV infection in children whose mothers HIV status is unknown and mother is not available for testing is only possible by two negative antibody tests from separate specimens obtained at age ⩾6 month, provided that they are not breastfed during last 6 weeks.

Children of 18 months of age or older with suspected HIV infection or HIV exposure should undergo HIV serological testing performed according to the validated national testing algorithm used in adults.

6.2 Adolescents (10-19 years)

Two groups of adolescents need HIV testing:

- Adolescents who had the risk of perinatal transmission of HIV and who were not diagnosed in infancy
- Adolescents who are vulnerable to HIV through early sex or injecting drug use, particularly adolescents from key populations and those with other vulnerabilities.

Age of consent in children less than 16 years

HIV testing in children is conducted case by case basis, in consultation with relevant authorities within health system. It has to be done adhering to the principles of "five Cs". Consent of the parent or legal guardian following counseling should be sought prior to testing children below the age of 16 years. If a parent or caregiver refuses HIV testing, the health-care provider should offer additional Counselling on the rationale for testing and the potential benefits to the child. When counseling of a child below 16 years is required, preferably it should be done with parent's consent.

When all efforts to obtain parental consent have failed, health care provider has an ethical responsibility to act in the best interests of the child as the treatment available is lifesaving. In the given context, the provider should test the child and initiate treatment.

In situations that child presents the services alone, health care provider can perform the HIV test, whenever he/she satisfied with competency of child understanding about the test.

Parents and guardians also have the right to maintenance of confidentiality and privacy within the context of HIV testing. Additionally, HIV testing and the status of the child tested must not be used to deny other rights to a child.

In instances where there is no parent or legal guardian to give consent (eg: orphans, abandon children, street children) decision to test should be made by the health care provider and it should be done in the best interest of the child.

6.3 Partners of HIV infected people

Partner HIV testing services with support for mutual disclosure is offered to all individuals who are diagnosed with HIV. Uptake of HIV test by the partner has to be voluntary.

When a sero-discordant couple is under care, health care provider has to explain the positive person about healthcare provider's responsibility towards the health of negative partner and by doing so to persuade for regular HIV testing services for negative partner. Negative partners should be tested every six months

6.4 HIV testing related to post exposure prophylaxis PEP

Testing both healthcare provider and source person for HIV is required during management of healthcare workers following occupational exposure to blood and other body fluids.

PEP circular is attached as an annex (1).

6.5 International migrant workers

HIV testing and counselling should be considered among international migrant workers who come from countries with high HIV prevalence.

HIV testing services should adhere to the "Five Cs".

6.6 Surveillance Purposes

In situations of various surveillances / researches where HIV testing is required, voluntary participation is essential and need to be in conformity with National HIV testing guideline. Sri Lanka being a country with low level HIV epidemic, regular HIV biological surveillance is confined to key population groups. It is recommended to use linked testing approach during HIV sero-surveillance

6.7 Victims of sexual assault and non-occupational injuries

Testing victims of child sexual abuse - Testing of victims of child sexual abuse should be considered in every case according to risk factors. Testing should always be performed if post-exposure prophylaxis is to be given.

In situations of sexual assaults and non-occupational injuries HIV testing services should be offered on case by case basis.

7. Collection and transport of blood samples for HIV testing

Blood samples for HIV screening can be send to National reference laboratory (NRL) at National STD AIDS Control Programme, De Saram Place, Colombo 10, or to other STD clinic laboratories which are located in the peripheral STD clinics island wide.

The NRL is the only laboratory which provide HIV confirmatory testing facility for the whole country.

Service hours for the Laboratories

NRL

- Week days - from 8.00 am to 4.00 pm
- Saturday - From 8.00 am to 12. 00 noon

District Laboratories

- Week days - from 8.00 am to 4.00 pm
- Saturday - From 8.00 am to 12. 00 noon

Closed on public holidays.

7.1 Sample acceptance time

Table 4 Sample Acceptance time

Investigation	Sample acceptance time	
	Week days	Saturday
HIV Ag+Ab ELISA Test	8.00am - 3.30 pm	8.00 am-11.30 am
Partical agglutination test		
Western blot		
Ag+Ab rapid test	8.00am - 4.00 pm	8.00 am-12.00 noon
RNA PCR- Viral load	8.00am – 2.30 pm	Not accepted
PCR- GeneXpert for VL		
PCR for EID		

7.2 Sample collection and dispatch

It is essential to follow Standard precautions at all times during specimen collection, storage, testing, transportation and disposal of bio-hazardous waste. Standard precautions are meant to reduce the risk of transmission of blood borne and other pathogens from both recognized and unrecognized sources.

- Wear appropriate personal protective equipment (PPE) and follow only the recommended practices when collecting and handling specimens
- Collect adequate volume of the specimen in the appropriate collection container(s). Ensure the specimen collection kits are not expired.
- Label each specimen container with the patient's unique identifiers, the source of the specimen, date and time of collection.
- All specimens should accompany a complete and correctly filled request form signed by the medical officer who attend to the patient
- Once the sample is collected, it should be delivered to the laboratory in leak proof container. All measures should be taken to avoid the undue delays
- All the information pertaining to sample collection and dispatch has to be recorded in a register
- Disposal of collecting devices and contaminated material should be according to the waste management procedures of the institution

Table 5 - Instructions for containers and volume of specimen

Investigation	**Container**	**Volume**	**Specimen**
HIV Ag+Ab ELISA Test	Plain tube Size 10 cc	3 cc	Blood/Serum
Particle agglutination test	Plain tube Size 10 cc	3 cc	Blood/Serum
Western Blot	Plain tube Size 10 cc	3 cc	Blood/Serum
Ag/Ab rapid test	Plain tube Size 10 cc	3 cc	Blood/Serum
RNA PCR - Viral load	K3EDTA Tube	3 cc	Blood/Plasma
RNA PCR - GeneXpert	K3EDTA Tube	3 cc	Blood/Plasma
PCR for EID	K3EDTA Tube	3 cc	Blood

Figure 6 - Specimen collection containers

10cc

4cc

Plain tube(Red cap)

For serological testing

EDTA Tube (Purple cap)

for molecular testing

Table 6 - Request forms for HIV testing

Investigation	Name of the request form	Number of the request form	Annexure Number
Ag + Ab ELISA Test	Request for Special Tests NSACP	Health 407	Annex 01
	Request form of Department of Health Services	Health 350	Annex 07
Western Blot	Request for confirmatory HIV testing from the Reference laboratory of the National STD/AIDS Control Programme		Annex 08
Ag/Ab rapid test	Request for Special Tests NSACP	Health 407	Annex 01
RNA PCR - GeneXpert	Request form for HIV Viral Load Assay	NRL/RQ/8/HIV/VL	Annex 04
DNA PCR	Request for Early infant diagnosis of HIV DNA	NRL/RQ/6/HIV/GX	Annex 13

7.2.1 Collection of Blood specimens for Serological Investigation

Sample Collection

- Collect 3-5ml of blood (adults) in to a dry, sterile plain tube.
- Allow blood to clot at room temperature for a minimum of 20-25 minutes in vertical position before dispatching to laboratory.

Storage and Transportation

- Keep the blood tubes in a rack in refrigerator at 4^0C.
- Transport within 24 hours to the laboratory at 40C.
- If any delay in transport, centrifuge at 2500 rpm for 10-15 minutes.
- Pipette the supernatant serum into another sterile tube; label it.
- Separated serum should reac the laboratory within 5 days.

7.2.2 Collection of blood for Gene X pert and EID

Sample collection

- Collect 3ml of venous blood under aseptic conditions into K3EDTA tube.
- Note: Fill the tube exactly up to the marked level of EDTA tube. Excess EDTA, as well as insufficient EDTA will cause coagulation problems in the sample which can affect the accuracy of results.
- Mix the tube gently by inverting 10 times.

7.3 Storage and transportation of specimens

7.3.1 Storage of specimens

- Store at room temperature if the sample is dispatched to the laboratory within 8hrs.
- If there is a delay of more than 8 hours to reach the laboratory the blood sample should be stored 2-8^{0}C
- The blood can be stored at this temperature up to 72 hours.
- Transport the specimen in 2-80C.

7.3.2 Transport of specimens

Transport of specimens should always ensure the safety of all individuals handling the specimen and should meet the specific criteria involved in receiving a good sample to perform the test. Therefore, packaging and transportation of specimens should be done appropriately to obtain accurate results.

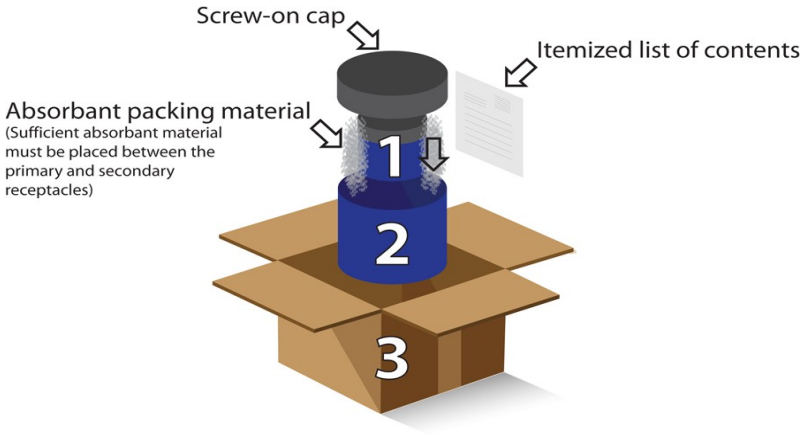
Packing of specimens

For Blood and blood products it is recommended to use "Three-layer packing" to ensure safety of the specimen and the handling individuals

The three layers involve

1. Primary receptacle
2. Secondary receptacle
3. Outer package

Figure 7 - Three-layer packing for transport of Specimens



7.4 Sample reception

All the samples are collected at sample reception counter of NRL or of peripheral STD clinic laboratory. A medical laboratory technologist (MLT) and/or a lab orderly are available at all times in the sample reception counter.

Sample reception procedure

- The specimen should correctly be paired with the appropriate request form.
- Check following information on the label.
    - Patient number
    - Hospital/clinic/institution
    - Type of test
    - Date and time of collection
- Specimen is registered in the sample reception register.

Urgent samples should immediately be sent to the relevant section.

7.5 Sample rejection

Any specimen not meeting the required conditions are rejected as per policy. The requests of rejected specimen are be given to medical staff without a delay. The medical officers inform the originating location/collector of the need to re-collect or re-order, if a specimen is rejected. All the rejected samples are entered in a special register.

Reasons for potential specimen rejection may include the following:

- Samples without labels/ Inadequately written labels
- Samples without accompanying request forms
- Incomplete request forms - Request forms are incomplete without the following information.
    - BHT number/Clinic number for patient identity
    - Ward /Clinic
    - Type of the sample (Eg: blood, CSF, urine)
    - Tests requested
    - Date &Time of sample collection
    - Short, relevant clinical history of the patient
    - Any relevant detail which specifically requested in request form

- If the details on the label of the sample and the request form are not identical.
- Specimens showing gross evidence of decomposition
- Inadequate/over collected volume of the specimen for the tests requested.
- Samples in inappropriate containers/ wrong container type.
- Specimens which were not transported properly and were not stored properly Clotted/partially clotted specimens Eg: FBC, ESR, fasting plasma glucose
- Specimens that have leaked or have specimen material on the outside of the container
- Delay in receipt of sample as specified against test (Eg: Sample for CD4 testing should reach the NRL before 12 noon on Friday)
- Duplicate samples
- Visible contamination of sample
- Delayed transport

8. Annexures

General Circular Letter No: 01-19/2017

My No…….
Department of Health services
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Colombo 10.
…… ……2017.

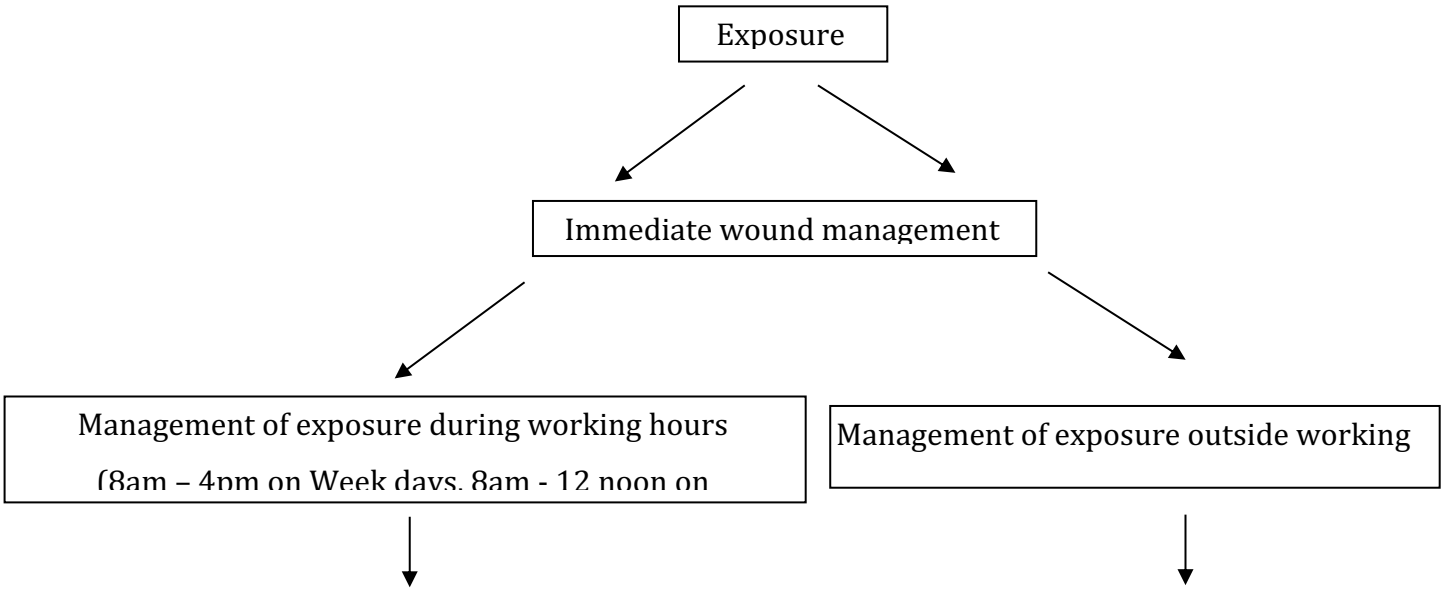
Provincial directors of health services
Deputy Provincial directors of health services
Directors of teaching hospitals
Heads of specialized campaigns
Heads of government Medical Institutions

Management of healthcare workers following occupational exposure to blood and other body fluids and post exposure prophylaxis for HIV

The General Circular letter reference No -36/2001 dated 12th March 2001 on "Management of Health-Care Worker Exposures to HIV and Recommendations for Post Exposure Prophylaxis" is hereby cancelled.
This circular outlines recommendation for the management of health care workers who experience occupational exposures to blood and other body fluids that might contain Human Immunodeficiency Virus (HIV).
Although preventing exposures to blood and other body fluids that might contain HIV is the primary means of preventing occupationally acquired HIV infection, appropriate post-exposure management is an important element of workplace safety. Department of Health has considered information available worldwide and recommends that the following procedure for post exposure prophylaxis (PEP) be followed in an accidental exposure.
This circular recommends all health care workers with occupational exposures to HIV to attend to a STD clinic with the source blood sample as early as possible for management and follow up.
It is the responsibility of the head of the institution to make sure;

- That there is a functional system of management of healthcare workers following occupational exposure to blood and other body fluids.
- That antiretroviral drugs (ARV) are available for PEP.

Management of occupational exposures



- Inform Infection Control Unit
- Initial assessment of exposure and management
  - For HIV – By Venereologist or District MO STD
    (Initiation of PEP on indication and follow up)
  - For Hep B / Hep C – By Micobiologist / Virologist/ Designated doctor

- Initiation of Starter pack-
  When Venereologist or District MO STD is not accessible within 2 hours starter pack can be initiated by Microbiologist/ Virologist/ Designated Medical Officer.
  (However refer the health care worker to closest Venereologist or District MO STD for further management).

- Initial assessment of exposure by designated medical officer in the institution for the purpose. He/ She should:
  - Initiate Starter pack* as early as possible (preferably within 2 hours) if eligible

- Contact Microbiologist/ Virologist/ On call MO Microbiology for Hep B / HepC

- Refer the health care worker to closest Venereologist or District MO STD on following working day for further management.

- Inform Infection Control Unit as early as possible.

*Antiretroviral medication for the post exposure prophylaxis for 5 days. We recommend keeping this starter pack in a readily accessible place / places such as OPD/ETU/ICU/PCU/Pharmacy

Definition of a Health Care Worker (HCW) for the purpose of this circular

The term HCW refers to all persons working in the health care setting who has the potential for exposures to infectious materials, including body substances (e.g. blood, tissue and specific body fluids), contaminated medical supplies and equipment, and contaminated environmental surfaces (1).

Definition of Exposure

An "exposure" that may place a health care worker at risk for HIV infection and requires consideration of PEP is defined as follows:

1. Percutaneous injury- Needle stick or cut with a sharp object.
2. Contact of mucous membranes
3. Non-intact skin- chapped, abraded or afflicted with dermatitis

With blood, tissue or other body fluids that are potentially infected.

(Semen, vaginal secretions, breast milk, cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid are considered potentially infectious)(2).

Saliva, urine, nasal secretions, vomitus and faecies bear no risk of HIV infection In the absence of visible blood. Exposure to tears and sweat does not require post exposure prophylaxis (2)(3).

Risk of Occupational Transmission of HIV to HCWs from HIV infected blood

• Percutaneous injury	0.30%	95% CI = 0.2% - 0.5%.(1)(3)(5)
• Mucous membrane	0.09%	95% CI = 0.006% - 0.5%.(1)(3)

Management of the Exposed Site

Exposed sites should be cleansed of contaminated fluid as soon as possible after exposure. Wounds and skin sites are best cleansed with soap and water, avoiding irritation of the skin. Exposed mucous membranes should be flushed with water. Alcohol, hydrogen peroxide, betadine or other chemical cleansers are best avoided. HCWs should be made aware to avoid "milking" or squeezing out needle-stick injuries or wounds (AII)(2)(3).

Evaluating the Exposure

Prompt initiation of PEP is recommended for exposure to blood, visibly bloody fluids or other potentially infectious material from HIV-infected or HIV-unknown sources in any of the significant exposure situations outlined in Table 1(AII).

Whenever a worker has been exposed to potentially HIV-infected blood, visibly bloody fluids or other potentially infectious material through the percutaneous or mucocutaneous routes or through non-intact skin, PEP is indicated. For these exposures, prompt initiation of PEP followed by telephone or in-person consultation with a clinician experienced in HIV PEP is recommended.

Table 1 : Exposures requiring initiation of a starter pack
• Break in the skin by a sharp object (including hollow-bore, solid-bore, and cutting needles or broken glassware) that is contaminated with blood, visibly bloody fluid, or other potentially infectious material, or that has been in the source patient's blood vessel. • Bitten by a person with visible bleeding in the mouth that causes break in the skin or mucosa the exposed worker. • Splash of blood, visibly bloody fluid or other potentially infectious material to a mucosal surface (mouth, nose, or eyes). • A non-intact skin (e.g: dermatitis, chapped skin, abrasion or open wound) exposure to blood, visibly bloody fluid or other potentially infectious material.

Determine the HIV status of the source patient and initiation of PEP

1. Known Positive patient

Start PEP immediately with available three drug regimen.
Contact Consultant Venereologist (STD clinic) as early as possible.

2. Sero - status is unknown

When source patient is available

Consent for HIV testing of the source patient should be sought (AII)(2). If facilities are available, rapid HIV test on source sample should be carried out. This can be done at closest STD clinic or any other lab where rapid test is available.

- Consent for HIV testing

When the source patient has the capacity to consent to HIV testing, informed consent is required.
When the source person does not have the capacity to consent, consent may be obtained from a surrogate, or anonymous testing may be done if a surrogate is not immediately available (2).

If the result from testing source patient is not immediately available, considering severity of exposure and epidemiological likelihood of HIV status of the source, starter pack can be initiated (preferably within 2 hours of the exposure) while source testing and further evaluation are underway (2).

When source patient is not available (e.g. needles in sharp bins and laundry)

Considering severity of exposure and epidemiologic likelihood of HIV exposure, starter pack can be initiated. Decision regarding continuation of PEP where source patient is not available should be made on a case by case basis by Venereologist / MO-STD.

Timing of the Initiation of PEP

When a potential occupational exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, ideally within 2 hours (AII). A first dose of PEP should be offered to the exposed worker while the evaluation is underway (2).

Decisions regarding initiation of PEP beyond 72 hours post exposure should be made on a case-by-case basis with the understanding of diminished efficacy when timing of initiation is prolonged (AIII)(2).

Recommended PEP regimen

Three drug regimen

TDF 300mg daily

FTC 200mg daily

LPV/r 400/100mg 12 hourly or ATV/r 300/100mg daily

Venereologist could decide on alternative regimens according to circumstances.

Duration of PEP Regimen

PEP need to be considered for 28 days (1)(2)(3).
When the source patient is confirmed to be HIV-negative, PEP could be discontinued (1)(3).

Baseline testing for the exposed health care worker and Follow up

Confidential baseline HIV testing of the exposed worker should be obtained at the time the occupational exposure is reported or within 3 days of the exposure (AIII).

All exposed workers receiving PEP should be re-evaluated within 3 days of the exposure. This allows for further clarification of the nature of the exposure, review of available source patient data and evaluation of adherence to and toxicities associated with the PEP regimen (1)(3).

The exposed worker should be evaluated weekly while receiving PEP to assess treatment adherence, side effects of treatment, interval physical complaints and emotional status.

Clinicians should provide risk-reduction counseling to HIV-exposed workers to prevent secondary transmission during the 12-week follow-up period. HIV-exposed workers should be educated and counseled on:

- Use of condoms to prevent potential sexual transmission
- Avoiding pregnancy and breastfeeding (2)
- Avoiding needle-sharing
- Refraining from donating blood, plasma, organs, tissue or semen
- Identifying symptoms of primary HIV infection and report as soon as possible

Investigations recommended for the healthcare worker who are on PEP							
	Baseline	*Week 1*	*Week 2*	*Week 3*	*Week 4*	*Week 10*	*Week 16*
Clinic visit	√	√Or by telephone	√	√Or by telephone	√		
Pregnancy test	√						
FBC*,LFT & RFT	√		√		√		
HIV test	√					√	√
**Follow-up FBC is indicated only for those receiving a zidovudine-containing regime.* *Week 10 , 16 HIV testing should be done by using ELISA*							
HIV testing recommended for the healthcare worker who are not on PEP at baseline , week 6 and 12 from the exposure date.							

Exposed workers who are pregnant and breast feeding

Pregnancy and breast feeding are not contraindications for PEP and recommended regimens can be used (2).

Before administering PEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus (2)(3).

Clinicians should counsel women who may have been exposed to HIV through occupational exposure to avoid breastfeeding for 3 months after the exposure (AII). If HIV infection is definitively excluded in the source patient at any time prior to 3 months post-exposure, the woman may resume breastfeeding.

Exposure Report

If an occupational exposure occurs, the circumstances and post exposure management should be recorded in the HCW's confidential exposure report (Annex I).

Level of evidence

A – High quality evidence
B – Moderate quality evidence
C – Low quality evidence
D – Very low quality evidence

Annex I

Exposure Report

1 Date ……../……../20……

2 Institution ……
……..

3 Name/designation of HCW
……..

4 Date/Time of exposure
……./……./20…….
……./……. am/pm

5 Details of the procedure
i Laboratory / theatre / ward / clinic / labour room / others
ii How the exposure occurred

6 Details of the exposure

Type of body fluid …….. Amount – small/large

i Percutaneous injury – Yes/No
If Yes, type of the device – Hollow bore needle / solid needle / Other sharp devices / blunt devices

ii Mucosal exposure – Yes/No
If yes, site of exposure - ……..

iii Non intact skin – Yes/No

7 Details of the source
Source identified – Yes/No
If Yes, HIV sero status of the source – Positive/Negative/Weakly reactive
(According to Rapid test / HIV Elisa)

If HIV positive - Stage of the disease ……..
Recent Viral load ……..
CD4 count ……..
On ART - Yes/No if yes, regimen ……..
Resistance details ……..

If HIV Negative - Possibility of acute infection / High risk behaviour : Yes/No

Other blood-borne pathogens ……

8 Management of post exposures

PEP recommended Yes/No
PEP accepted by HCW Yes/No
If yes, Regimen

……..

9 Follow up HIV test on HCW

6/10 weeks : Positive /Negative

12/16weeks: Positive /Negative

10Name, Signature and Designation of counselor
……..
……..

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