NATIONAL HIV TESTING GUIDELINES - 2016

National STD/AIDS Control Programme
SRI LANKA

Ministry of Health Sri Lanka

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Compiled by

Sexually Transmitted Infection(STI) Care, HIV testing and Counselling Unit,

National STD/AIDS Control Programme

Co - ordinated by Dr. G. Weerasinghe (Consultant Venereologist - NSACP)

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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.

Dr. Sisira Liyanage

Director

National STD/AIDS Control Programme

Acknowledgements

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UN Partners and other Stakeholders

- The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)
- Dr. N. Janakan – NPO, WHO
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- Mrs. T. Argus – Executive Director, FPA,
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- Mrs. A. M. C. Kanthi Abeykoon -Project Co-ordintor, CSDF
- Mrs. Princy Mngalika – Positive Women network

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
- ICU Intensive care unit
- 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
- LFT Liver function test
- LPV/r Lopinavir and ritonavir
- MLT Medical laboratory technician
- MSM Men who have sex with men
- MO Medical officer
- MOH Medical officer of health
- 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
- TDF Tenofovir
- TCP Trained care provider
- VCT Voluntary testing and counselling

The NSACP appreciates contribution made by

Dr. Chandrika Wickramasuriya

(Consultant Venereologist)

in preparation of National HIV testing Guideline

Contents

Chapter 1: HIV Testing services

1.1 Background

Early detection and appropriate interventions improves survival and quality of life of people infected with 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 ART on morbidity and survival and delays adoption of preventive measures by persons living with HIV and their partners.

Promotion of testing and counselling is recognized as an important strategy in both prevention and care for HIV in Sri Lanka. Despite scale-up of client- and provider-initiated HIV testing and counselling(HTC) services across diverse contexts, the current reach of these services (especially for key affected populations) remains low. In low-level epidemics, despite high levels of testing in clinical settings, populations most at risk of infection are often not reached. Structural, 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 maximize knowledge of HIV status and make progress toward universal access to essential services.

The national HIV testing guidelines is the principal document that sets out the objectives, principles and arrangements for HIV testing in Sri Lanka. These guidelines are based on the National AIDS Policy and National HIV Strategic Plan 2013-2017. They provide guidance on HIV testing in the country. This ensure quality screening and diagnostic testing become readily accessible, with the aim of identifying HIV infection early so that risk reduction and timely initiation of treatment of infected individuals will be facilitated. Aiming to address this, HIV testing is scaled up with protection from stigma and discrimination in variety of settings. In all settings under which people undergo HIV testing steps are taken to protect human rights and ethical principles.

1.2 Objectives

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

1.3 Guiding Principles

Mandatory or coerced testing is never permitted whether that 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, and quality assurance mechanisms are be in place to ensure the provision of correct result to the individual
Connect to Care	-	systems are set in place to connect individual to required care presence of effective referrals to follow-up services as indicated, 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."

Chapter 2: HIV Testing Service Model

2.1 Voluntary counselling and testing

Client-initiated HIV testing to learn HIV status is called voluntary counseling and testing (VCT). Clients can access HIV screening test at government STD Clinics free of charge or in the private sector health facility.

a. Testing in government STD clinics

When a client access for VCT, pre-test counselling is provided on an individual basis. Both HIV-negative and HIV- positive results are given to the individual with post-test counselling. Following a positive screening test result, a second sample of blood is taken to do the confirmatory test (Western Blot Test). Positive or negative confirmatory test results will be given during post-test counseling.

Negative clients are further counseled on risk reduction in future.

Positive clients are enrolled for continuum of care for HIV at the STD clinic.

b. Testing in private sector

In private sector, VCT could be accessed by clients where such services are available. Pre-test counselling is provided prior to HIV screening test. Both HIV negative and HIV positive screening test results are given to the individual following counselling. Following a positive screening test result, it is strongly recommend sending the positive individual to STD clinic. However, failing that option a second sample of blood is sent for confirmatory test. Confirmatory test will be performed at the National Reference Laboratory. Result of the confirmatory test is sent to the referring clinician or laboratory authority 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.

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

In instances where a client get an over the counter HIV screening test he/she has the option to attend the local STD clinic and discuss the results

2.2 Provider Initiated HIV testing

A routine offer of HIV screening test by health care providers are made to all persons seeking care in the government health care settings for sexually transmitted infections, TB, hepatitis B and C and pregnant women attending ANC services.

Adequate information that a patient need in order to be able to provide informed consent is given prior to the test.

a. HIV screening among STD attendees

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

Blood samples are tested at the STD clinic laboratory.

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.

b. 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.

In the event of a positive screening test result, either a second sample of blood or the individual with positive screening test result 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.

c. 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 (preferred option) or a second sample of blood is sent to the local STD clinic to arrange confirmatory test. Results of confirmatory test 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.

d. HIV screening for pregnant women attending ANC services (prevention of mother-to-child transmission)

All pregnant women should be offered with adequate pre-test information to be able to make an informed decision in testing prior to offering the test. Mothers have option of 'opt out' of testing.

Blood samples are drawn at the antenatal clinics and sent to local STD clinic laboratory for testing. Screening test results are sent to the obstetrician or medical officer of health (MOH) in charge of the mothers.

Pregnant mothers with the positive screening test result are sent to the local STD clinic to arrange confirmatory test. 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 obstetrician or medical officer of health (MOH) in charge of the mother will be informed.

Chapter 3: Diagnostic HIV testing

Diagnostic HIV testing is indicated whenever a person shows signs or symptoms that are consistent with HIV related disease or AIDS. However, this should be abided by the guiding principle of **five 'C's including shared confidentiality.**

At least minimum pretest information has to be given prior to diagnostic testing**.**

Rare circumstance

HIV testing without consent may be justified in the rare circumstance in which a patient is unconscious, his/her parent or guardian is absent, and knowledge of HIV status is necessary for purposes of optimal management. In these circumstances, counselling should not be a barrier for HIV testing for in-ward patients.

Chapter 4: Outreach/ Community level HIV testing using rapid HIV screening tests

Outreach/ Community level HIV Testing (using rapid HIV tests) are promoted for following groups / situations;

4.1 Key Affected Populations (FSW, MSM, DU, BB)
4.2 Vulnerable population (prisoners, migrant workers, youth, hospitality industry workers, people in disaster situations etc.)
4.3 People living in difficult geographical areas (estate sector, urban low-socioeconomic areas)
4.4 People who find it difficult to attend services during working hours (three wheeler drivers, fishermen, long distance drivers etc.)
4.5 Special events based HIV testing (World AIDS day, special exhibitions etc.)

4.1 Key Affected Populations

HIV testing is carried out by STD clinic staff/ NGOs/CBOs by outreaching to service recipients through provider initiated testing and counseling approach. Pre-test information is provided on individual or group basis. If requested, individual pre-test counseling should be provided by a trained care provider. (TCP - health staff and/or NGO staff who are other than trained medical-laboratory technicians. However, they will be trained properly to carry out rapid HIV testing prior to embark on community level HIV testing services.) People who consent for testing should be provided the services.

Rapid HIV screening test is performed. Results of HIV screening test will be given by a trained care provider.

Negative results will be given with relevant post-test information.

A person with a positive screening test result should be informed of the necessity of a second test to confirm the diagnosis. A sample of blood need to be drawn from the person with positive screening test and sent for confirmation.

Discuss whether the person is willing to come to STD clinic to get the confirmatory test result. If not, a suitable way to deliver results should be arranged through discussion. Contact details of the person to be obtained.

Confirmed HIV positive tests should be given with detailed post-test counseling by a trained care provider.

Testing frequency

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

Please refer Annexure II for the protocol for community based HIV testing.

4.2 Vulnerable populations

- **(i)** Prisoners - voluntary testing through provider initiated approach will be 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.
- **(ii)** 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.
- **(iii)** Youth and adolescents in vulnerable settings.
- **(iv)** Tourism industry worker.

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

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

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

4.4 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.

4.5 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.

Chapter 5: HIV screening of blood units / organ transplant / major invasive surgical procedures

- 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).
- 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.
- Major invasive surgical procedures.

Chapter 6: HIV testing in special situation

6.1 Testing infants and other children for HIV

a. When a mother is known HIV positive, baby will be tested for HIV as given below;
   - HIV type 1 RNA testing at birth
   - HIV type 1 pro-viral DNA testing at 6 weeks and12 weeks
   - HIV Ag/Ab type 1 & 2 ELISA at 9 and 18 months
   - Additional HIV molecular and serology testing could be considered on individual basis according to the circumstances.

b. When a mother is known HIV positive and insist on breast feeding;
   - HIV type 1 RNA should be done at birth and once in three months
   - HIV type 1 pro-viral DNA testing at 6 and 12weeks of age and also 6 weeks after stopping breastfeeding
   - Additional HIV molecular and serology testing could be considered on individual basis according to the circumstances.

- If any of the above virological tests is positive, repeat and confirm.
- Infants whose serological assays are reactive at 9 months should undergo virological test to rule out the infection.
- Infants whose serological test is negative at 9 months should undergo repeat serological test to rule out the infection.

c. Babies of unknown mothers (when mother is not available for testing) can be tested only for HIV serology for exclusion of HIV infection, but need molecular assays for confirmation of positive HIV serology status.
d. For the purpose of diagnosis in a child who is ill (e.g. presenting with an HIV associated illness, such as tuberculosis or malnutrition, or other recurrent common childhood illnesses such as pneumonia or diarrhea).
e. For the purpose of individual diagnosis where another sibling or parent has been diagnosed with HIV or where there is a history that the parents have died as a result of AIDS or other undiagnosed debilitating illness in the family.
f. In cases where a child has been exposed or potentially exposed to HIV
- through sexual abuse
- through contaminated needle sticks or receipt of potentially infectious blood or blood products (or through other routes, e.g. wet nursing).

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

Children of 18 months of age or older with suspected HIV infection or HIV exposure will have 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 C s". Mandatory testing of children should be avoided in all cases. 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, healthcare 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. Testing frequency of negative partner/s should be once in 6 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 refugees

HIV testing and counselling should be considered among refugees attending sexually transmitted infections services, antenatal clinics, and TB treatment.

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

6.6 Surveillances Purposes

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

6.7 Victims of sexual assault and non-occupational injuries

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

Chapter 7: Protocol for outreach HIV Screening

1. Carry out individual or group education on HIV/AIDS/STIs. Lecture / discussion should address the specific target group (FSW, MSM, DU, Beach boys, other vulnerable groups as relevant).

2. During the lecture / discussion give pre-test information regarding HIV testing and emphasize the importance of testing and knowing the HIV status. Stress the benefits of early detection of HIV infection.

3. At the end of the lecture / discussion inform the participants that facilities are available for onsite HIV testing and those who are willing, can be tested.

4. If someone needs more information a trained person should discuss further regarding HIV testing.

5. Give the leaflet carrying pre-test information which will reinforce the information given during the lecture.

6. When rapid screening test is performed results will be given by a trained care provider

7. 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).

8. 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.

9. If rapid screening test is positive, results will be given to the person by a trained care provider (TCP) with adequate counseling.

10. Inform that another test is needed to confirm the diagnosis. Confirmatory test need to be arranged in the STD clinic.

11. During subsequent visits to the same venue – check whether they have tested within last three months. If so advice to get tested 3 months after the date of possible last risky exposure/ last testing.

12. During the outreach visit in addition to HIV testing;

- Promote and provide condoms.
- Refer symptomatic people to STD clinic for treatment and care.
- Encourage and motivate asymptomatic people to attend STD clinics for STI screening
- Encourage them to send their partners to STI services.

Chapter 8: Protocol for prison HIV testing

Introduction

Peer educator training programmes for prison inmate on HIV/STI are been carried out by the welfare officers within the prison. The peer educators conduct both formal and informal education to 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 programmes will be conducted by the staff attached to Central and District STD clinics of the National STD/AIDS Control programme. This activity is supported by the prison staff. HIV testing is carried out by 30 STD clinics island wide.

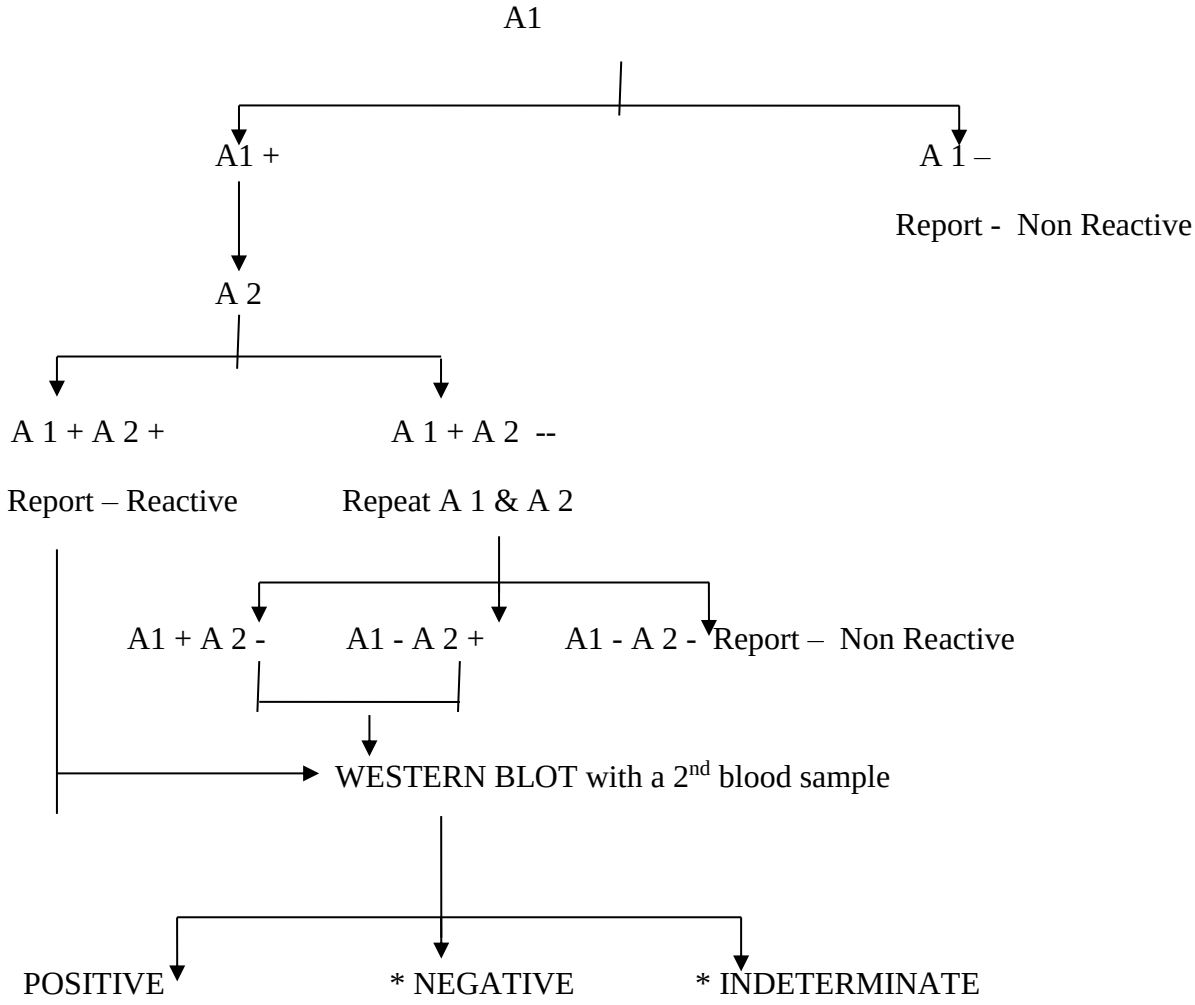
HIV testing procedure

1. Prison Welfare officers facilitate HIV testing services for prison inmates with assistance of peer educators.
2. Before the offer of HIV test, pre-test information is provided by STD care providing staff which will include window period consideration, importance of receiving the results and need for retesting in certain situations.
3. HIV testing is carried out among prisoners who are willing to get tested.
4. Blood is drawn by the STD clinic staff and test will be performed at STD clinic laboratory.
5. The contact information (phone numbers) of the prison inmate should be obtained to contact them by STD clinic staff to deliver results of persons who are released from the prison before getting the results.
6. HIV screening test results will be 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. Screening positive results will be indicated in the report as “need to retest” and prison medical officers are requested to send the inmates to STD clinics for detailed pre-test counseling and confirmatory testing.
9. Confirmatory testing is carried out and test results are given at the STD clinics with post- test counseling by the MO/STD. During counseling advantages of informing the test results to the prison medical officer will be discussed with the prisoners and will be done with consent.

10. Prison Medical Officer will have to share this information with the superintendent of prison / other relevant officer who is involved in arranging necessary follow up and care for the HIV infected prison inmates.
11. In peripheral prisons, MO/Prison should 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 are no venereologists at local STD clinics. If not, they should be managed at the local STD clinic with consultation of the venereologist in the center.
12. 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.
13. Attention should be given to arrange follow up visits at the STD clinic as indicated.
14. HIV infected prison inmates should be referred to the local STD clinic and appropriate follow up should be established before discharge from the prison.

Chapter 9: Algorithm for HIV diagnosis

9.1 National Protocol



Test specimen – serum

* -repeat testing in 2 months

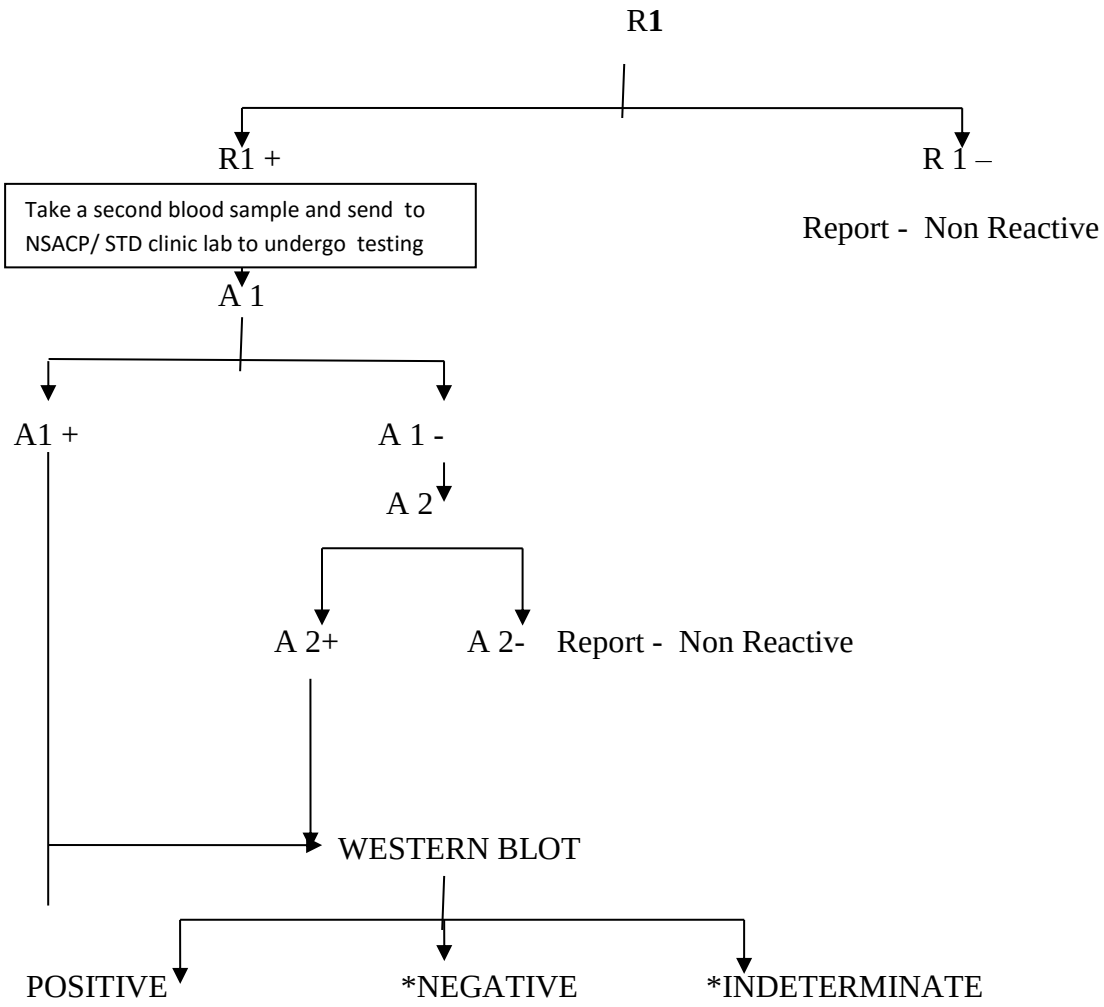
A1 – Screening Assay 1 - 4th Generation Ag – Ab ELISA Test

A2 – Screening Assay 2 - particle Agglutination Test

This protocol should be adhered to until informed otherwise by NSACP

(*Protocol Reviewed and approved by Dr. Jayanthi .P. Elwitigala , Consultant Microbiologist /NSACP on 20.04.2013)*

9.2 Algorithm for Diagnosis (Outreach Programmes)



Specimen - serum/whole blood * - repeat testing in 2 months

R1 – Rapid test for screening
A1 – Screening Assay 1 - 4th Generation Ag – Ab Test
A2 – Screening Assay 2 - particle Agglutination Test
This protocol should be adhered to until informed otherwise by NSACP

(Protocol preparation – Dr J.P. Elwitigala - Consultant Microbiologist / NSACP & Mrs D. Dombawela (MLT/HIV /NSACP)

This protocol was discussed &agreed upon with HIV& STD care coordinators -11.03.2015)

Annex 1

General Circular Letter No……

My
No…….
Department of Health services
385,Baddegama Wimalawansa Mw,
Colombo 10.
…… ……2016.

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 recommendations for the management of health care workers who experience occupational exposures to blood and other body fluids that might contain Human Immunodeficiency Virus (HIV).

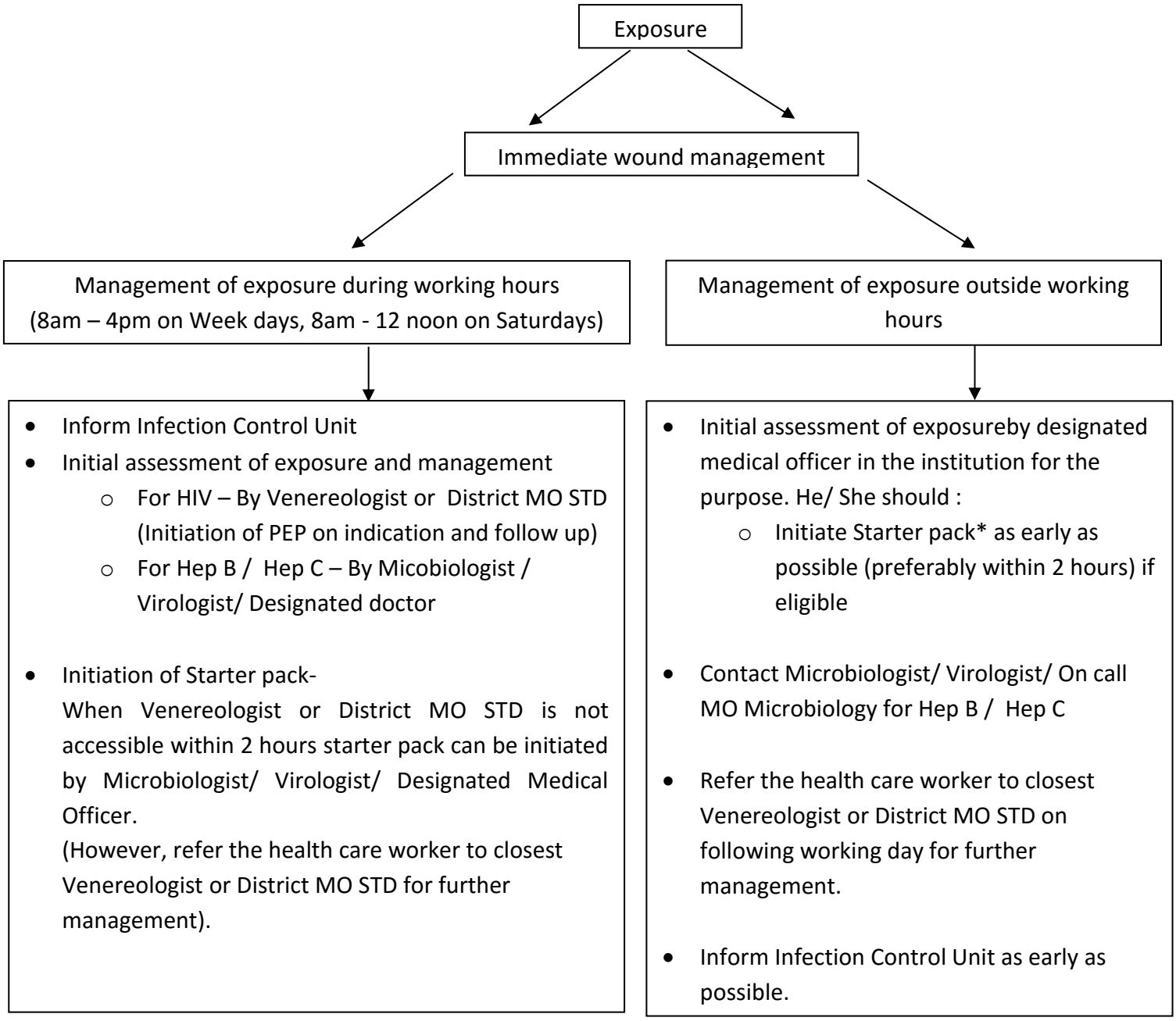
Although preventing exposures to blood and other body fluids that might contain HIV is the primary means of preventing occupationally acquired HIV infection, appropriate post-exposure management is an important element of workplace safety. Department of Health has considered information available worldwide 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



*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**

<u>When source patient is available</u>
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).

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4. World Health Organization. Guidelines on post exposure prophylaxis for HIV and the use of co-trimoxazole prophylaxis for HIV related infections among adults, adolescents and children: recommendations for public health approach. December 2014 supplement to the 2013 guidelines.
5. UK guidelines for the use of HIV post-exposure prophylaxis following sexual exposure. 2015.
6. AIDS EAGO. HIV post-exposure prophylaxis: guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS (2008) 2008.

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……

2Institution ……
……..

3 Name/designation of HCW
……

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

5Details 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

7Details 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
……..

9Follow upHIV test on HCW

6/10 weeks : Positive / Negative

12/16 weeks: Positive / Negative

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

Annex 2

Protocol 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) will be responsible for providing services according to ethical and quality standards.

Pre-Test information should be provided either displaying a poster or providing leaflets.

Guiding principles of 5 “C”s should be followed strictly. (Counseling, Confidentiality, Consent, Correct report and Connect to care)

All clients should be registered in a registry with contact numbers if possible.

Check 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.

After 20 minutes, read the result.

Reporting to the client

Positive results : State as reactive. Link him to nearest STD clinic where necessary tests will be carried out.

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 : 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 it properly.

Do not leave behind any material at the site.

References

1. Consolidated Guidelines on HIV Testing Services , WHO July 2015
2. Comprehensive list of HTS approaches and considerations by epidemic setting WHO/HIV/2015.31
3. Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people. Recommendations for a public health approach WHO2011
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5. Guidance on provider initiated HIV Testing and counselling in health facilities, WHO 2007
6. Service delivery approaches to HIV testing and Counselling: A strategic HTC programme frame work, WHO 2012
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8. Guidance on couple HIV testing and counselling, WHO 2012
9. Policy requirements for HIV testing and counselling of infants and young children in healthcare settings, WHO/UNICEF 2010
10. Policy Statement on HIV Testing and Counselling for Refugees and other persons of concern to UNHCR, UNHCR 2014
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