



Ministry of Health & Population  
National AIDS Program  
Arab Republic of Egypt

# **Operating Procedures for The Central Laboratory Voluntary HIV Counseling And Testing Services**



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FHI 360 is a nonprofit human development organization dedicated to improving lives in lasting ways by advancing integrated, locally driven solutions. Our staff includes experts in health, education, nutrition, environment, economic development, civil society, gender, youth, research and technology – creating a unique mix of capabilities to address today's interrelated development challenges. FHI 360 serves more than 60 countries, all 50 U.S. states and all U.S. territories.

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Development of this document and the establishment of Voluntary Counseling and Testing (VCT) Services at the Central Laboratory were a fully collaborative effort with the Egyptian Ministry of Health and Population (MOHP), Family Health International (FHI) and the United States Agency for International Development (USAID).

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The views expressed in this document do not necessarily reflect the views of USAID.



Ministry of Health & Population  
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# Operating Procedures for The Central Laboratory Voluntary HIV Counseling And Testing Services





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The upgrading of health services offered to the Egyptian population is a major priority area for the Ministry of Health & Population (MOHP).

Due to worldwide concern regarding the spread of HIV/AIDS, preventive health services remain imperative in controlling the epidemic. Since 1986, the National AIDS Program has been working to ensure Egypt maintains its low prevalence of HIV/AIDS. To further enhance preventive HIV/AIDS activities, the Egyptian MOHP has introduced anonymous Voluntary Counseling and Testing (VCT) Services for HIV, integrated within various other health services.

I would like to take this opportunity to acknowledge the MOHP staff and all the individuals who have contributed to the development of the VCT documents and establishment of Egypt's first VCT center for HIV. This includes:

- The VCT Task Force and Technical Reviewers that adapted the VCT Operating Procedures and National Guidelines to the Egyptian context.
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- The United State Agency for International Development (USAID) and Family Health International (FHI) for their technical guidance in establishing VCT services, the National Policies for these services and in launching the first center for HIV, based on international standards for VCT.
- Ford Foundation for their support in operating the VCT Center.

Looking forward to the success of these services in maintaining the good health of all Egyptians.

Sincerely,

Dr. Magda Rakha  
First Undersecretary  
Ministry of Health and Population

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## Acronyms

<b>AIDS</b>	Acquired Immunodeficiency Syndrome
<b>ARV</b>	Antiretroviral
<b>CDC</b>	Centers for Disease Control
<b>CSW</b>	Commercial Sex Worker
<b>ELISA</b>	Enzyme-linked Immunosorbent Assay
<b>FHI</b>	Family Health International
<b>HIV</b>	Human Immunodeficiency Virus
<b>IDU</b>	Injecting Drug User
<b>IEC</b>	Information, Education and Communication
<b>IMPACT</b>	Implementing AIDS Prevention and Care
<b>M&amp;E</b>	Monitoring and Evaluation
<b>MOHP</b>	Ministry of Health and Population
<b>MOU</b>	Memorandum of Understanding
<b>MSM</b>	Men who have sex with men
<b>NAP</b>	National AIDS Program
<b>PEP</b>	Post-Exposure Prophylaxis
<b>PLHA</b>	People Living with HIV/AIDS
<b>STI</b>	Sexually Transmitted Infection
<b>TB</b>	Tuberculosis
<b>USAID</b>	United States Agency for International Development
<b>VCT</b>	Voluntary Counseling and Testing
<b>WHO</b>	World Health Organization

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## Definitions

**HIV Testing:** is the process by which blood or body fluids are analyzed for the presence of antibodies or antigens produced in response to HIV. HIV testing should be undertaken with informed consent and be voluntary.

**Voluntary HIV Testing:** is the process by which individuals seek testing based on their personal choice and free of coercion.

**HIV Counseling:** is the process by which an individual undergoes counseling enabling him or her to make an informed choice about being tested. This process is aimed at helping them to cope with stress of being tested, providing support when receiving the test result and assists individuals in making personal decisions related to HIV/AIDS.

**Voluntary Counseling and Testing:** VCT consists of pre-test counseling, testing, post-test counseling and follow-up support (as required). VCT is delivered by trained HIV/AIDS Counselors who help clients understand the experience of being tested, the choices to be made thereafter and the various support services that might be helpful.

**Informed Consent:** No one should be coerced to undergo HIV testing. In VCT, HIV tests are to be performed only if the client has given informed consent. "Informed" in this context means that the client has been made aware of the benefits and risks of knowing their HIV sero-status in a manner that he/she can understand. "Consent" means accepting to be tested for HIV in a situation devoid of coercion such that the client is equally free to grant or withhold acceptance.

**Anonymous Testing:** HIV testing in which the blood sample and test results are identified only by code, not by name, with no identifying markers to link the sample to the client. Anonymous testing is known to increase clients accessing VCT, especially amongst already marginalized individuals, who would otherwise not be tested. This type of testing prompts earlier entry into medical care.

**Confidential Testing:** HIV testing in which some identifying information may be collected, however only the client and the Counselor involved in the client's direct care know that the test was performed and have access to the results. All medical records should be managed in accordance with appropriate standards of confidentiality. Only health workers with a direct role in the management of patients should have access to medical records.

**Referral:** The process by which immediate client needs for care and support services are assessed and prioritized and clients are provided with assistance in accessing services (setting up appointments, providing transportation, etc). Referral should also include follow-up efforts necessary to facilitate initial (and sometimes ongoing) contact with care and support service providers.

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## 1. Introduction

The Ministry of Health and Population (MOHP) is committed to an effective response to HIV/AIDS in Egypt through prevention and care. It recognizes that Voluntary Counseling and Testing (VCT) is a key entry point to prevention services in populations at risk and to care and support for persons living with HIV/AIDS (PLHA), and therefore benefits those who test positive, as well as those who test negative. Determining sero-status through counseling and testing must be promoted in Egypt if HIV prevention is to be truly effective. Many people do not know if they are infected and VCT has been largely non-existent in the region. As there is no cure for HIV/AIDS, VCT remains pivotal in a strategy to control the spread of HIV and to provide care and support to those who are HIV positive.

Knowing one's HIV infection status strengthens prevention efforts by encouraging infected persons to avoid ongoing transmission to others and motivating those who are not infected to protect themselves through risk reduction strategies and behavior change. HIV counseling and testing can lead to a reduction in the number of sexual partners, increased condom use, fewer sexually transmitted infections (STIs) and safer injecting practices.

The Central Laboratory in Cairo has been providing mandatory and voluntary HIV testing services to the general public since 1986. HIV testing has included access to screening and confirmatory testing using sophisticated Enzyme-linked Immunosorbent Assay (ELISA) and Western Blot technology. In order to respond more effectively to community needs and to provide a comprehensive service, the Central Laboratory has developed a complete package of VCT services. The VCT services allow clients the opportunity to utilize pre-test and post-test counseling services when considering an HIV test, and to be linked to a range of care and support services that meet their needs. VCT services at the Central Laboratory will offer anonymous HIV counseling and testing. By not requiring any identifying information from the clients, VCT becomes attractive to high-risk groups who have previously feared being tested for HIV.

The objective of this document is to provide practical standardized guidance on the implementation of VCT practices at the Central Laboratory. This document outlines the process and services available, the roles and responsibilities of all service staff, all aspects of administrative procedures and how the VCT administration aims to ensure quality service provision to all prospective clients. All forms for conducting VCT are included in the Monitoring and Evaluation Plan for VCT.

The procedures will be reviewed and updated regularly in the context of changes in national and/or legal policies and/or Central Laboratory practices and/or situational changes that relate to HIV/AIDS in Egypt.

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## **a) Principles Underlying VCT Practices at the Central Laboratory**

For VCT to be effective, the following principles should be adhered to:

- The human rights and dignity of all people irrespective of their HIV status will be respected.
- Elimination of discrimination against and stigmatization of PLHA will be promoted in policy and in practice.
- The protection of oneself and others from HIV infection through informed responsible behavior is a requirement that should be upheld by all people.
- Comprehensive, quality HIV/AIDS services and care should be available, accessible and affordable to all citizens, particularly PLHA and their families.
- Effective referral to related services is an integral part of care provision to all who require it.
- All persons have the right to clear and accurate information, education and communication (IEC) on HIV/AIDS and STIs.
- Barrier methods (condoms) will be made available and accessible to all sexually active individuals.
- A supportive environment at every level of society will enhance the response to HIV/AIDS by individuals, families and communities.

## **b) Voluntary Counseling and Testing Goals and Objectives**

### ***Goals***

- To provide anonymous high-quality counseling and testing to persons considering an HIV test.
- To help clients make an informed decision about testing.
- To assist clients to cope effectively with their test results.
- To assist clients to reduce personal risks and to address care needs.

### ***Objectives***

- To provide clients with information on modes of HIV transmission and methods of prevention.
- To help clients to assess their risk of HIV and to develop a risk reduction plan accordingly.
- To help clients make informed decisions on issues including sexual practices, nutrition, health care, relationships with partners and families, drug and alcohol abuse.
- To provide psychological support for clients.
- To provide appropriate referrals for individual needs and support, including STIs clinics, tuberculosis (TB) programs, drug treatment services, family planning, and maternal and child health services.
- To discuss and negotiate with the client issues relating to disclosure, including notification of sexual partners and/or peers with whom injecting equipment or other high-risk behaviors have been shared (providing the client has given their consent).



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### **c) Minimum Requirements for VCT at the Central Laboratory**

- A discreet and easily accessible site.
- Clear, non-stigmatizing signs for the VCT service (to know where to go and what to expect at the site).
- 2 private rooms for counseling.
- 2 rooms for HIV testing.
- A comfortable and discreet waiting area.
- Appropriate equipment, test kits and supplies for testing.
- 2 trained Counselors on site.
- 2 health workers certified in HIV testing.
- Record keeping, monitoring and evaluation systems.
- Printed health education materials and condom stocks.

### **d) Target Group for VCT Services at the Central Laboratory**

Clients may refer themselves for VCT (walk-ins) or can be referred by other agencies, including health providers, hotline services, the National AIDS Program (NAP), non-governmental and private facilities, etc. Clients who are most likely to benefit from the service, and who will be actively targeted through service promotion and outreach include:

- Clients with known sexual or needle sharing exposure to an HIV infected person.
- Client groups who are known to be at risk of HIV infection through past or present practices or potential exposure e.g. injecting drug users (IDUs), commercial sex workers (CSWs) and men who have sex with men (MSM).
- Clients who have clinical symptoms suggesting HIV infection (e.g. fever of unknown origin, opportunistic infection including active tuberculosis without known reason for immune suppression).
- Clients who have diagnoses suggesting increased risk of HIV infection (e.g. another STI or blood borne infection).
- Clients exposed to contaminated equipment.
- Sexual partners of HIV infected persons.

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## 2. Ethical Practices for VCT at the Central Laboratory

### a) Informed Consent

All clients undertaking VCT do so only with their own informed consent. Consent will be provided verbally and a witnessed informed consent form will be completed by the Counselor. The Witnessed Consent Form which facilitates the anonymous nature of testing is located in the *Monitoring and Evaluation (M&E) Plan for Voluntary HIV Counseling and Testing*. No client will be tested under the coercion of another individual or agency.

### b) Anonymity and Confidentiality

VCT will be done in a private, anonymous setting. Anonymity must be guaranteed for all clients. Anonymity forbids any discussion of a client or a test result, except within a professional relationship that is beneficial to the client, and even then only with the consent of the client. In these cases, the client moves from receiving anonymous service, to one where confidentiality is maintained.

The following are the only circumstances under which confidentiality may be breached, and will only apply in rare cases, when all other avenues have been explored and must be made known to the individual client or couple prior to commencement of counseling:

- Where an individual is at risk of inflicting harm to him/herself (e.g. self destructive behavior, suicidal tendencies, etc.).
- Where an individual is at risk of inflicting harm on others (e.g. violent behavior, knowingly planning to infect or expose another individual to HIV, etc.).
- Where an individual is unable to make competent decisions for him or herself.

In these circumstances, the client must be informed of the Counselor's "duty of care" and intention to notify another party e.g. psychiatric services or a potential partner at risk.

### c) Disclosure of HIV Test Results to Sexual Partners

It is the role of the Counselor to encourage clients to disclose positive test results to their spouse. Partner notification by a provider or Counselor should only be considered if all other avenues have failed, and should allow clients the opportunity to address this on their own or in the presence of the Counselor.

Strategies for encouraging beneficial disclosure by the client include:

- Promote VCT of partners together so that both are informed at the same time of their HIV status.
- Encourage people with HIV infection to inform their partners of their HIV status and to use barrier methods to protect each other from infection and re-infection.
- Promote education, information and communication to change people's attitudes about disclosing their HIV status to those who have critical reasons to know.

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#### **d) Age of Consent**

Anonymous VCT is available to any client aged 16 years and above with individual consent. Parental consent is not required for those aged 16 and above.

Under the following circumstances, confidential HIV testing may be of benefit to minors:

- Children (15 years and below) with clinical indications of HIV/AIDS.
- Children at increased risk of HIV infection (e.g. street children who engage in prostitution, injecting drug use, and/or other high-risk behaviors).
- Children who have been sexually abused.

In these circumstances, the Counselor will explore with individuals and/or their parent/guardian:

- Is it in the best interest of the child to be tested for HIV.
- Whether the child and/or parent/guardian would benefit from counseling.
- Who will provide consent for the child to be tested.
- Whether the child will be informed of the result, when and how.

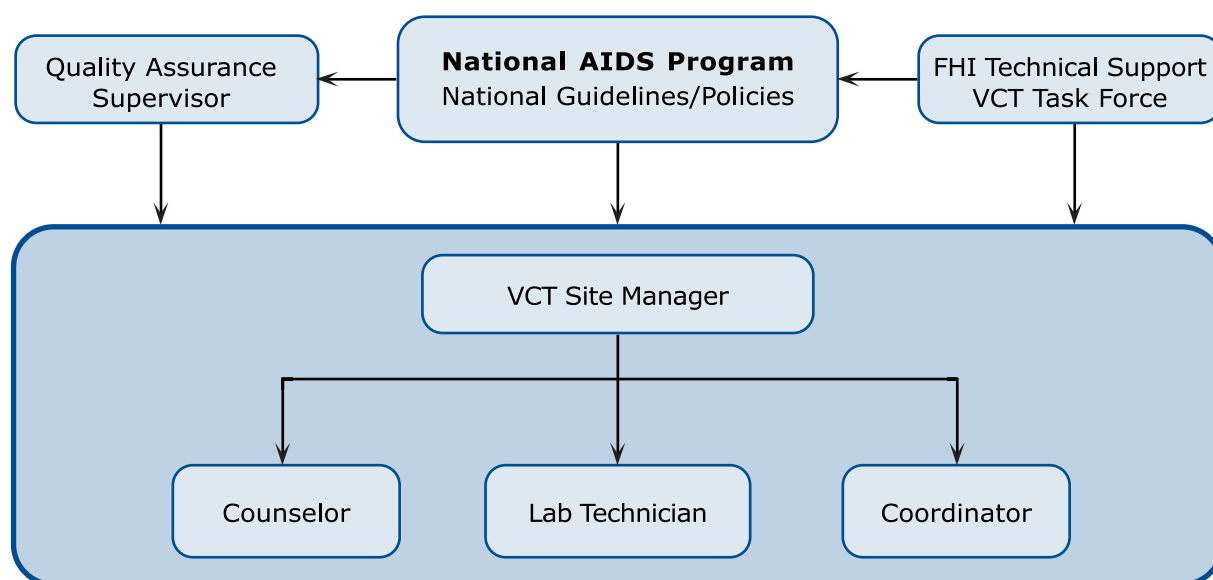
Each case will need to be assessed by the individual health professional and a decision reached on the basis of what is ultimately in the best interest of the child.

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### 3. Administrative Structures and Operational Procedures

#### a) Administrative Structure for VCT at the Central Laboratory

As depicted in the diagram below, the NAP provides the overall responsibility for the site with technical input from the VCT Task Force and FHI. The site operates under the leadership of the Site Manager, to whom all employed site staff are accountable. There are regular lines of liaison between the Site Manager and NAP and clear lines of reporting and responsibility between agencies. These are delineated in the signed Memorandum of Understanding (MOU).



#### b) Client Flow for VCT at the Central Laboratory

- Upon arrival at the Laboratory the security guards (who will be oriented with the VCT program) will direct all clients seeking VCT services to the VCT site.
- Clients will be seated in the waiting area until they are met by the Coordinator, for registration followed by pre-test counseling.
- Following pre-test counseling, consenting clients who wish to continue with the test procedures will be sent to the pay office to pay fees.
- Clients will schedule their post-test counseling visit with the VCT site Coordinator. Attempts should be made to ensure the client will receive their test result from the same Counselor that conducted the pre-test counseling session.
- The pay office will provide clients with a receipt and direct clients back to the Laboratory.
- The client, upon returning from the pay office, will have their blood drawn.
- Upon the time/day of return, the client will be seen by the same Counselor who undertook the pre-test counseling (when possible).

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### **c) Operating Hours**

Voluntary Counseling and Testing Services will be available to the general public from 9:00 am to 3:30 pm (Saturday - Wednesday). The last counseling session will be undertaken at 3:00 pm and the last HIV test sample will be drawn at 3:30 pm.

### **d) Fees**

All counseling services at the Central Laboratory will be provided free of charge, however there will be a charge for HIV testing services (includes screening and confirmatory tests).

### **e) Site Security and Confidentiality Requirements**

- All client records will be maintained in locked cabinets in the counseling rooms.
- Access to client records is restricted to Counselors, the Coordinator and the Site Manager.
- Testing supplies and consumables will be stored in the main laboratory area in which access is restricted to Laboratory Technicians and the Site Manager.
- All testing supplies and consumables will be kept within locked premises with only the Senior Laboratory Technician/s and Site Manager having access to keys.
- IEC materials and condoms will be kept in locked cupboards in counseling rooms, with only the Coordinator and the Site Manager having access to keys.

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## 4. Staffing

### a) Roles and Responsibilities

#### ***NAP Representative:***

- To complete the MOU between collaborating agencies (NAP, Central Laboratory, Ford Foundation and FHI).
- To sensitize all senior level stakeholders to the VCT services at the Central Laboratory.
- To coordinate VCT activities at the national level and facilitation of referral networks.
- To provide all national level policy and procedure documents relating to VCT to the Central Laboratory.
- To monitor all data received from the site for integration and application to the National AIDS Program.
- To oversee the quality assurance mechanism (with assignment of a NAP supervisor on a regular basis) to provide support to the staff of the Central Laboratory VCT service.
- To organize regular monitoring and evaluation of the services as well as an annual evaluation and review.

#### ***Central Laboratory Site Manager:***

- To oversee the effective daily operation of the VCT site including maintenance of all basic standards and requirements for staffing, space, equipment and commodities.
- To be the focal person to which VCT staff is accountable.
- To be the focal point for liaison between the VCT site and the NAP.
- To oversee internal monitoring of the site, including completion and assessment of all monthly, quarterly and annual VCT records.
- To provide internal administrative supervision to staff on a regular basis.
- To respond to training needs.
- To conduct random direct observation of counseling sessions on a weekly basis, using the forms provided in the M&E Plan.

#### ***Counselor:***

- To inform the client about VCT in the presence of a witness before completing the witnessed consent form.
- To conduct all pre/post-test and supportive counseling with clients (no more than seven clients per day).
- To complete the Client Intake Form, as well as the Laboratory Request Form and the Referral Form as necessary.
- To direct all clients wishing to be tested to the fee collector/laboratory technician.
- To ensure the coordinator has scheduled post-test counseling sessions with the clients, attempting as much as possible to have the client return to meet the same Counselor that conducted the pre-test counseling session.

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- To transfer HIV Test Results onto the Client Intake Form.
  - To provide effective referrals, educational materials and condoms for clients as necessary.
  - To follow-up on referrals with clients and service providers regarding quality of care and maintenance of confidentiality.
  - To return all forms to the Coordinator for filing, and ensure the transfer of recorded data by the Coordinator into the VCT Logbook and VCT electronic database as necessary.
  - To report to the Site Manager and discuss all emerging issues on a weekly basis.
  - To participate in all site monitoring and evaluation activities.
  - To participate in all internal and external supervision activities.
  - To undertake VCT service promotion activities as appropriate.

***Laboratory Technician/Physician:***

- To receive VCT clients in the lab anonymously using only the client code listed on the VCT Lab Request Form for identification of the client and the client blood samples.
- To review the Laboratory Request Form and ensure payment of the test fees.
- To draw blood samples and run HIV tests according to the testing protocol.
- To keep a separate laboratory record of all VCT clients test results by code.
- To report individual test results back to the VCT center by completing and signing the results portion of the VCT Lab Request Form in clear legible handwriting, and returning the forms back to the VCT Coordinator.
- To discuss all emerging issues on a weekly basis with the VCT Site Manager.
- To participate in all laboratory site monitoring and evaluation.
- To participate in all laboratory internal and external supervision activities.
- To undertake VCT service promotion activities as appropriate.
- To monitor HIV testing equipment stocks and supplies and report all requirements or issues arising to the Laboratory Manager/VCT Site Manager.

***Coordinator:***

- To welcome all clients and explain the VCT procedures.
- To register all client visits by code in the VCT Logbook on a daily basis.
- To issue a new client code and file for every presenting client who does not already have a code.
- To complete a Witnessed Consent Form for every new client accepting the conditions of providing VCT services.
- To track client progress through VCT services by recording completed steps in the VCT Logbook.
- To schedule post-test counseling sessions. Attempts should be made to ensure the client will receive their test result from the same Counselor that conducted the pre-test counseling session.



- To collect completed Laboratory Request Forms from the Laboratory Technicians/Physicians at the beginning of each day, and provide Counselors with the files of the clients whose test results have been received, to ensure the Counselor transfers the test results to the Client Intake Form.
- To distribute commodities among the waiting area and counseling rooms.
- To track commodities by completing the Inventory Form each morning and afternoon.
- To ensure there is a constant supply of commodities.
- To collect all completed client forms from the Counselors at the end of each counseling session and transfer required client data into the VCT Logbook and the VCT electronic database.
- To manage and update a secure filing system containing all client records.
- To produce the monthly report from the VCT electronic database and present it to the Site Manager for review.
- To send Monthly Reports to FHI and the NAP.
- To assist the Site Manager in regularly completing Direct Observation Sessions and Client Exit Questionnaires for the monitoring of VCT activities.

#### ***Fee Collector:***

- To collect fees from clients who have undergone pre-test counseling and wish to be tested for HIV.
- To issue a receipt for payment to all clients.
- To direct the client back to the laboratory for HIV testing.

#### ***Security Guards:***

- To direct all clients to the appropriate service (voluntary versus work-related/mandatory testing).
- To direct all VCT clients to the appropriate building and location.

#### ***NAP Supervisor/External Supervisor:*** (Contract or assigned professional, preferably with a psychology background)

- To provide supportive and educational supervision to counseling and testing staff at regular intervals.
- To observe all aspects of site operation with a focus on quality of service provision to clients.
- To monitor the quality of counseling practices through one to one supervision and direct observation (with client consent).
- To provide feedback on findings to staff, the Site Manager and the NAP, with recommendations for strategies to strengthen service provision.
- To conduct client exit questionnaires with randomly selected clients.
- To conduct random direct observation of counseling sessions on a weekly basis, using the forms provided in the M&E Plan.

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## **b) Staffing Requirements**

*All Counseling Staff at the site will meet the following requirements:*

Counselors for VCT will be recruited and selected from amongst health graduates and workers including laboratory technicians or graduates in the fields of social work, psychology and nursing. Selection criteria will also include personal attributes conducive to HIV counseling including empathy, understanding, warmth, maturity, patience, the capacity to be non judgmental and demonstrable comfort speaking about “taboo topics” explicitly – such as sexual practices, prostitution and drug use – and explaining condom use.

All recruited counseling staff will undergo a VCT counseling skills training program as approved by the National AIDS Program.

All Counselors will be in possession of:

- National VCT Guidelines
- Operating Procedures for the Central Laboratory Voluntary HIV Counseling and Testing Services
- VCT Reference Guide for Counselors
- Monitoring and Evaluation Plan for VCT

*Laboratory Technicians for the site will meet the following requirements:*

- Be selected and recruited from existing Central Laboratory staff
- Be trained in the use of all current HIV endorsed testing technology
- Be trained in how to procure and monitor all necessary testing supplies and equipment
- Be trained in how to undertake quality assurance on test samples

All laboratory technicians will be in possession of:

- National VCT Guidelines
- Operating Procedures for the Central Laboratory Voluntary HIV Counseling and Testing Services

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### c) Oath of Confidentiality

After receiving training in VCT, all VCT staff are required to read and sign an oath of confidentiality. The signed oaths are maintained in the staff personnel files.

*I understand that, in the course of my duties in this service, I will come in contact with sensitive, personal information about clients attending VCT. I understand that this information is confidential and pledge to protect the anonymity/confidentiality of all clients attending the service by not disclosing or discussing any information about them to an unauthorized person, including the fact that they attended this service. Unauthorized persons may include but are not limited to, my family, friends, co-workers, and community leaders. I understand that test results are also confidential documents. I understand the potential harm that may come to clients whose test results are disclosed to unauthorized persons. I understand that willful disclosure of any information about any client to unauthorized persons could result in termination of my employment and/or result in legal action against me.*

Name: .....

Position: .....

Signature: .....

Witness: .....

Date: .....

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## 5. The VCT Process

VCT consists of pre-test, testing, post-test and follow-up counseling/support. Counseling should be adapted to the needs of the client.

### a) Client Registration

- All clients will be registered by the Coordinator.
- Each client is allocated a code number and a code name (unique identifier picked by the client); this serves the purpose of enhancing the client's awareness regarding the anonymity of the service provided by the VCT site.
- The code number and code name are recorded on the Client Intake Form, and the code number is recorded on the Laboratory Request Form/test result form and the VCT Logbook.
- The clients are given cards with their unique code number and identifier which they will provide when they return for their results or for an additional visit.
- Each client will have a file. The client code number is placed on the outside of a blank file and on all forms placed in the file:
  - Client Intake Form
  - Witnessed Consent Form for HIV Testing
  - Laboratory Request Form

Throughout the registration process, steps must be taken to ensure the anonymity of each client is maintained and that the nature of the service provided is kept confidential.

Each new client's file is used by the Counselor during the first session and then filed in a first visit folder in the lockable cabinet at the end of each day.

Files will be categorized into active files (current clients and those still to collect results or plan a return visit) and inactive files (those who have received all services, including test results and referrals completed with no current ongoing contact with the service).

Files can be organized in numerical order or by time frames.

All files will be retained for 5 years. After this time they will be archived.

### b) Pre-Test Counseling Protocol

Pre-test counseling is a prerequisite for all clients who present for VCT.

Basic points to be covered in Pre-test counseling

- The client's reason/motivation for testing.
- The client's understanding of HIV transmission and the meaning of an HIV test.
- The client's individual risk assessment and a personalized risk reduction plan.
- The client's understanding of the benefits and challenges associated with knowing his/her HIV sero-status.

- The meaning of the test results (positive, negative, indeterminate), including the window period. Clients who have potentially been exposed or have engaged in a risk practice within three months of presenting for HIV testing will need to be advised to return for a repeat test after the three month period following the potential exposure has elapsed. In the interim they must be encouraged to practice safer sex and reduce other high-risk practices and not to donate blood.
- The client's capacity to cope with the result (if positive or negative).
- The support systems and resources available to the client.
- Disclosure issues (whom the client might tell about their test result e.g. spouse/relative).
- The client's familiarity with condom use. Conduct a condom demonstration as appropriate.
- The signing of the Witnessed Consent Forms used in VCT.
- Any other questions the clients may have.
- The scheduling of follow-up appointments for post-test counseling, receipt of test results, or other issues as required.

<b>Pre-Test Counseling Introduction Protocol</b>	<b>Duration (5 minutes approximately)</b>
Introduce self to client	<i>Hello. My name is _____. I am a Counselor here at the Central Laboratory VCT service. I'll be talking with you today about what has brought you to the center and any related concerns you may have.</i>
Describe your role as Counselor	<i>My role as your Counselor is to assist you in exploring your HIV risks, the process of VCT and issues related to your HIV risks.</i>
Explain confidentiality and anonymous testing	<i>I want you to know that what we are going to talk about today will be kept private. That means that your personal information will be absolutely confidential and will not be discussed with anyone. The testing process and your result are anonymous. Only your code number, which remains anonymous, will link your test and results to you.</i>
Review the test process: <ul style="list-style-type: none"> <li>• If negative, not infected as of three months earlier</li> <li>• If positive, infected with HIV</li> <li>• Results available within next few days</li> <li>• Results are highly accurate</li> </ul>	<i>If you decide to be tested, the test is an HIV test that detects if you are infected with the virus that causes AIDS. If the test is negative, it means you are not infected with HIV. However, if you were exposed within the last three months this exposure may not have been detected yet.</i>

<b>Pre-Test Counseling Introduction Protocol (cont.)</b>	<b>Duration (5 minutes approximately)</b>
	<p><i>If the test is positive, it means you are infected with HIV. It does not mean you are sick or will soon become ill.</i></p> <p><i>Your test results would be available to you in the coming few days. The test is very accurate and all positive test results samples are reconfirmed using a confirmatory test.</i></p>
<p>Outline content of session:</p> <ul style="list-style-type: none"> <li>• Exploration of HIV risk</li> <li>• Discuss test and meaning of results</li> <li>• Options for risk reduction</li> <li>• Risk reduction planning and referral</li> </ul>	<p><i>We will talk about your risk for HIV and how you have tried to reduce your risk. We will talk about changes you could make to further reduce risks and make a plan for how to do this. I may also be able to assist with referrals for specific needs.</i></p>
Outline process for VCT	<p><i>We will chat for about 25 minutes here and then if you decide to test you will pay the HIV testing fee at the pay office downstairs and then go to the second floor to have your blood drawn. You can then return in the next few days and we will look at your results and discuss them. Is this clear?</i></p>
Address immediate questions and concerns	<p><i>Before we go further do you have any concerns or questions?</i></p>

### **Counselor proceeds to pre-test protocol**

<b>Pre-Test Counseling Protocol Component</b>	<b>Duration (25 – 35 minutes)</b>
Situational Assessment	<p><i>Motivating reasons for testing and current understanding of HIV/AIDS.</i></p> <p><i>5 minutes</i></p>
Risk Assessment ( <i>see table below</i> )	<p><i>5-10 minutes</i></p>
Risk Reduction: includes condom demonstration	<p><i>Modes of transmission which apply. How to reduce their risk.</i></p> <p><i>5-10 minutes</i></p>
Test Decision Counseling: includes intentions after learning sero-status, coping with results (if negative or positive), support systems and disclosure. Obtain informed consent	<p><i>5-10 minutes</i></p>

### Examples of Risk Assessment Screening Questions

"What are you doing now or what have you done in the past that you think may put you at risk for HIV infection?"

"Since your last HIV test (if previously tested) have you ever:

- Injected drugs and shared equipment (needles, syringes, cotton) with others?"
- Had unprotected intercourse with someone that you think might be infected (e.g. a partner who injected drugs, has been diagnosed or treated for a sexually transmitted disease or hepatitis, has had multiple or anonymous sex partners, or has exchanged sex for drugs, money or gifts?"
- Had unprotected vaginal or anal intercourse with more than one sexual partner?"
- Been diagnosed or treated for STIs, hepatitis or tuberculosis?"
- Had a fever or illness of unknown cause?"
- Been told you have an infection related to a weak immune system?"

**\*\*** *Clients who respond affirmatively to one or more of these questions should be considered at increased risk for HIV.*

If the client wishes to proceed, the Counselor does the following:

- Completes the Client Intake Form and obtains Witnessed Informed Consent.
- Directs the client to the pay office for fee payment.
- Completes the Laboratory Request Form (including writing in the client code number) and organizes the blood draw.
- Informs the client of the day/time to return for results.
- Informs the client to retain their client code number and code identifier for receipt of test results as well as for any future visits to the center.

Completed Laboratory Request Forms must be kept in a central file until being filed in each client's individual folder.

Once test results are completed, all test results are matched back by code to the client's individual file. The test results are then transcribed by the Counselor on to the Client Intake Form (and to the Electronic Database by the Coordinator).

### c) Condom Demonstration and Availability

- Condom demonstrations to clients are an integral part of pre-test and sometimes post-test counseling. All counselors should provide condom demonstrations to VCT clients as appropriate and with the clients' permission.
- Condoms should be available at all times.
- Information on where to purchase condoms can also be given to clients as appropriate.



### Additional Procedures for VCT with Couples

- Ensure that both individuals are accessing VCT truly voluntarily and there is informed consent from each individual.
- Each individual is made aware that they will be expected to disclose their test results to their partner during VCT.
- In the pre-test session each member of the couple are given the opportunity to assess their risk behaviors individually with the Counselor (without the spouse present).
- In the post-test session results may be given either together or individually with the Counselor facilitating sharing of disclosure depending on couple preference.
- After disclosure of test results, post-test counseling proceeds with both partners present.

### d) Post-Test Counseling Protocol

The main goal of this session is to inform the client of their test result and to help clients understand and cope with the results.

<b>Post-Test Counseling Protocol (Is exactly the same regardless of the test result)</b>	<b>Duration (25- 50 minutes)</b>
Test result counseling: <ul style="list-style-type: none"><li>• Assess client's readiness to receive the result</li><li>• Provide the test result and remind the client of the meaning of the test result</li><li>• Ensure the client understands what the results mean and address immediate emotional concerns</li></ul>	<i>5-10 minutes</i>
Negotiate risk reduction	<i>5-10 minutes</i>
Disclosure to partner/plans for disclosure	<i>5-10 minutes</i>
Identify clients needs and make appropriate referral/s	<i>5-10 minutes</i>
Provide time to ask questions, address concerns and make a follow-up appointment	<i>5-10 minutes</i>

*Once the client has left:*

Complete additional details on the Client Intake Form and VCT Logbook.

File under inactive files (if follow-up is not required) or place in follow-up folder (if client is in a high-risk category and/or identified additional support or referral needs that require follow-up).

*For additional subsequent client visits:*

The client will be asked by the Coordinator for the code number and/or code name, as their client folder will be pulled from the files. The file remains with the Counselor until completion of the session when it is either returned to the follow-up folder or filed with inactive files.

## e) Strategies for Risk Reduction During Post-Test Counseling

Global Risk Reduction steps which are unlikely to be effective in changing behavior	Specific Risk Reduction steps which are likely to be more effective in changing behavior
Always use condoms	<ul style="list-style-type: none"><li>* Buy a condom tomorrow and try it on</li><li>* Carry a condom next time you go out</li><li>* Starting today put condoms beside the bed</li><li>* Starting tonight request your partner/s to use a condom or tell them you will not have (vaginal/anal) sex</li></ul>
Have fewer or less risky partners	<ul style="list-style-type: none"><li>* Stop seeing (specific partner) who is seeing other people</li><li>* Break up with (specific partner) before getting together with someone new</li></ul>
Have safer sex	<ul style="list-style-type: none"><li>* Talk honestly about your HIV status with (specific partner) and ask about his/her HIV status</li><li>* Next time you are out with friends and may have sex, avoid getting "high" on drugs or alcohol</li><li>* Only kissing, etc. with (specific partner)</li><li>* Tomorrow, ask (specific partner) if he/she has had a recent HIV test and has been tested for other sexually transmitted diseases</li></ul>
Stop injecting drugs	<ul style="list-style-type: none"><li>* Contact a drug treatment center and make an appointment</li><li>* Obtain clean equipment tomorrow so you can use it next time</li><li>* Make sure each time you "use" it is with clean equipment and do not share your equipment (needles, syringes, cotton, etc.)</li></ul>

When exploring risk-reduction strategies with a client, time must be taken to address potential barriers to implementing such strategies and to develop personalized ways of overcoming such barriers.

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## **f) Quality Assurance Measures for Counseling**

All VCT sites and counseling services must ensure that the counseling provided to clients is of high quality. The following strategies should be applied at all VCT sites to maintain quality assurance:

- Foundation training, refresher training and training updates for counseling staff.
- Regular formalized supervision and support for counseling staff (by a psychologist or social worker). Supervision may include case presentations, observation of counseling sessions (with client consent), taped counseling sessions (with client consent), application of quality assurance tools (checklists and reflection forms), etc.
- Peer support between Counselors as required.
- Feedback from clients on their levels of satisfaction, via one page anonymous surveys to random clients or brief interviews of clients after receiving services (conducted by site managers or supervisors).

## **g) Procedures at the End of Each Day**

The Coordinator ensures all files are completed in full and filed appropriately and confidentially. The Coordinator also tallies the data in the VCT Logbook and electronic database. The data for the monthly reports will be obtained from the VCT Logbook and the Client Intake Form.

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## 6. Referral

Clients will be referred to available services that are responsive to their priority needs. A referral directory for such services will be developed. Hence, clients will be moving from an anonymous structure, to one where confidentiality is maintained.

Potential services to be included:

- **Partner counseling:** to address risk reduction issues (with sexual and/or injecting partners) or to assist clients to facilitate beneficial disclosure.
- **Psychological/Mental health services:** Clients who have mental illness, developmental disability or ongoing difficulty coping with HIV diagnosis or conditions should be referred to appropriate mental health services.
- **Support groups:** assistance for HIV positive individuals, their spouses and families where appropriate and available.
- **Reproductive health services:** Female clients who are pregnant or of childbearing age should be referred to reproductive health services.
- **Drug or alcohol prevention and treatment:** Clients who abuse drugs or alcohol should be referred to substance abuse services.
- **Medical care and treatment:** e.g. screening, diagnosis and/or treatment of opportunistic infections (including TB), sexually transmitted diseases, hepatitis, assistance for nutritional guidance, home care, etc.

Facilitation of referral will be documented on the Client Intake Form and the VCT Logbook. Facilitation of the referral will be done verbally, by phone, or in writing by a referral letter that the client carries with him/her to the referral agency (subject to the client's preference).

All Counselors will maintain and update a comprehensive standard list of referral agencies and contact details. Where possible, Counselors will follow-up on referrals to ensure high-quality client care and service provision.

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## 7. Record Keeping

Client records are confidential and are stored in secured locked cabinets. Data collection instruments used by the Central Laboratory include:

- VCT Logbook (this register is also used when compiling statistical information for the site and NAP, along with the Client Intake Form)
- Witnessed Consent Form for HIV Testing
- Client Intake Form (more in depth record of client details, needs and services provided)
- HIV Laboratory Request Form
- Inventory Form
- VCT Service Request for Referral (to be used when written referrals are required)
- Client Exit Questionnaire
- Checklist For Direct Observation of Counseling Sessions
- Central Lab VCT Center Monthly Report
- Medical care and treatment: e.g. screening, diagnosis and/or treatment of opportunistic infections (including TB), sexually transmitted diseases, hepatitis, assistance for nutritional guidance, home care, etc

All of the above data collection instruments can be found in the *Monitoring and Evaluation Plan for Voluntary HIV Counseling and Testing*.

## 8. Notification of HIV Positive Case Statistics to the National AIDS Program

The Central Laboratory VCT site is required to submit available demographic data on all new HIV positive cases (that have not previously tested positive) to the NAP. It is the role of the Site Manager to provide the NAP with this data (see Monthly Report Form in the M&E Plan).

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## 9. HIV Testing

The Central Laboratory undertakes HIV testing for VCT as well as for the following purposes:

- Testing of samples received for diagnostic purposes from health facilities
- Testing of anonymous sera for surveillance purposes amongst sub populations
- Certification for work/study purposes
- Verification of HIV/AIDS related legal claims

### a) HIV Testing for Certification Purposes

The Central Laboratory is the accredited facility to carry out certification for all HIV testing. Due to the large numbers of clients presenting for this purpose on a daily basis and the differential motivation for testing, it is not feasible to offer pre- and post-test counseling to all such clients. However the following steps will be followed:

- All offsite certification clients (work/study abroad clients) who test positive should be directly referred to the VCT site for post-test counseling.
- All certification clients should have an opportunity to receive written materials on HIV/AIDS, STIs, and prevention strategies to take with them.

### b) Issuing of HIV Test Results

- Test results are to be provided during post-test counseling. As much as possible, this should be done by the same Counselor who provided the pre-test counseling.
- Face to face issuing of test results through post-test counseling is strongly encouraged.
- All clients are provided with the opportunity of viewing their test result documents.
- To avoid misuse of test results, test results documentation remain the property of the testing site and certified copies are not issued unless the client specifically presents for certification and is willing to produce valid personal identification. In these cases, the client must be advised that they are forgoing their anonymous status.

### c) When should a person who tests negative have a subsequent test?

Because of the window period, a person who is HIV infected will require up to three months in many cases until sero-conversion takes place. This will be communicated during pre-test counseling to assist in test decision making. Persons exposed to potential risk practices (e.g. unsafe sex or contaminated blood) recently will be encouraged to test and/or re-test after three months of the most recent risk exposure to ensure an accurate test result. This message should be repeated during post-test counseling for clients who test negative. Clients with exposure to ongoing risk practice may also benefit from referral to other services because their current risk practices might be reinforced by repeated negative HIV tests or they might view HIV testing as “protective”.

Counselors will consider the following factors when recommending timing and frequency for follow-up testing:

- Timing of the last potential exposure

- Probability of HIV infection given type of exposure
- Presence or potential of ongoing risk behavior
- Likelihood of returning for follow-up VCT
- Client anxiety
- Provider and client relationship

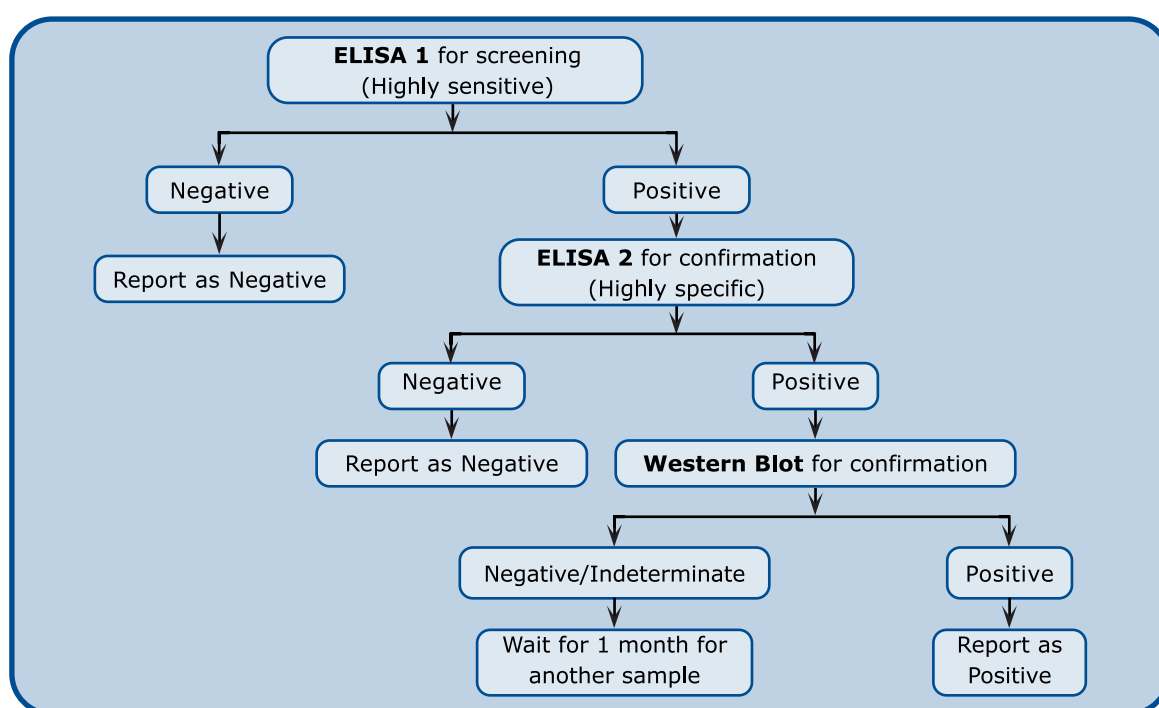
#### d) HIV Testing Algorithm

At present ELISA testing is the screening method used at the Central Laboratory. The MOHP recommends the use of a second different ELISA test for those blood samples that test positive. Western Blot is used as the confirmatory test. The VCT site uses identified test kits endorsed by the MOHP and World Health Organization (WHO). Test kits will be procured via standard application to the MOHP.

Below is an explanation of how the test algorithm should be interpreted.

1. All specimens are first tested with one assay ELISA 1 which is highly sensitive.
2. Specimens that are negative are reported to be negative.
3. Any specimen found positive on ELISA 1 is retested with a second highly specific ELISA 2.
4. Specimens that are negative on ELISA 2 are reported to be negative.
5. Specimens that are positive on ELISA 1 and ELISA 2 will require a Western Blot test for confirmation.
6. A specimen that is negative or indeterminate on Western Blot is reported as negative/indeterminate. In this case, the client should be advised to return for a re-test in one month.
7. Specimens that are positive on Western Blot are reported to be positive.

#### *Interpreting the Test Algorithm*





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## **e) Quality Assurance of Testing**

The following measures will be followed:

- All positive samples tested during screening will be retested for confirmation using a test kit with different antigens and principles.
- Internal quality control of all HIV test samples maintained onsite will be conducted on daily basis.
- Test kits will be stored properly and used prior to expiration.

### ***Guidelines for Quality Assurance Among Health Workers Performing Testing***

- Welcome the client and explain that a small amount of blood will be drawn.
- Draw a blood sample from the client.
- Ensure that the sample is marked with the client's code number corresponding to the Laboratory Request Form and clients VCT card. Show this to the client so that they are reassured that the blood sample matches their code.
- Ensure the client has made an appointment with the VCT site coordinator on when to return for their test results and that the result will be given during post-test counseling.
- Do not draw blood from another client until you have completed testing procedures and documentation for the current client.
- When results are available, record additional documentation on client records and return it to the coordinator.
- Report if there are any test kits that have expired or are almost expired.

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## 10. Infection Control Measures and Post-Exposure Prophylaxis (PEP)

Infection Control Procedures will follow the Guidelines of the National Infection Control Program.

### Post-Exposure Prophylaxis

At present, no antiretroviral (ARV) drugs are available at the VCT site. Provision of antiretroviral drugs for post-exposure prophylaxis (PEP) for all phlebotomy staff is important in case of any potential exposures, such as needle stick injuries.

Immediately following any exposure – whether or not the source is known to pose a risk of infection – the site of exposure (e.g. wound or intact skin) should be washed liberally with soap and water, but without scrubbing. Free bleeding of puncture wounds should be encouraged gently, but wounds should not be sucked. Exposed mucous membranes, including conjunctivae, should be irrigated copiously with water, before and after removing any contact lenses.

The issuing of PEP should be considered after an exposure with the potential to transmit HIV, and hepatitis, based on the type of body fluid or substance involved, and the route and severity of exposure.

PEP should be started as soon as possible after potential exposure to HIV. The medications used in PEP depend on certain aspects of the exposure to HIV.

The following situations are considered serious exposure:

- Exposure to a large amount of blood
- Blood coming in contact with cuts or open sores on the skin
- Blood visible on a needle that stuck someone
- Exposure to blood from someone who is HIV positive

For serious exposures it is recommended to use a drug combination of more than two approved ARV drugs for four weeks.

For less serious exposure, four weeks of treatment with two ARV drugs is recommended.

### Side Effects of ARV

The most common side effects from PEP medications are nausea and generally not feeling well. Other possible side effects include headaches, fatigue, vomiting and diarrhea. Thus, health care workers taking PEP medications do require support due to the side effects of ARVs, as many health care workers do not complete the treatment.

NOTES