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HIV counseling and testing is the first step for responding to the HIV and AIDS epidemics. This intervention serves as the entry point for prevention, care, treatment and support services. HIV testing, when done in combination with appropriate counseling, is one of the core interventions that are being implemented by the health sector in responding to the HIV and AIDS pandemic.

Since the first introduction of the Client Voluntary Counselling (VCT) and Testing services in Tanzania in 1989, the services have been expanded to all regions in the country. The services are currently being provided by the government, private sector, Non Governmental Organizations (NGO) and Faith Based Organizations (FBO) through health facilities, stand-alone sites, as well as mobile and outreach services.

In responding to a strong need for national guidance in the delivery of VCT services, the National Guidelines for VCT services were developed and disseminated by the Ministry of Health and Social Welfare (MOHSW) through the National AIDS Control Programme (NACP) in 2005. To date in Tanzania Mainland there are 1,643 VCT sites with more than 2,700 trained VCT counsellors.

The introduction of Antiretroviral Therapy (ART) services in Tanzania since 2004 created the need for other counselling and testing approaches such as Provider-Initiated Testing and Counselling (PITC) to complement VCT service as a recruiting ground for patients to be enrolled on HIV and AIDS care and treatment services. PITC has been introduced in inpatient and outpatient settings to reach all individuals attending healthcare facilities. The aim of this approach is twofold. First, it is intended to foster early detection of HIV infection and link or refer those found HIV positive to existing care, treatment and support services. The other purpose is to refer those found HIV negative for further counselling to enable them maintain low risk behaviour and to remain HIV negative. The National Guidelines for this new approach have been developed and disseminated to all Regional Health Management Teams and the dissemination process will continue to cover all Council Health Management Teams.

With the nationwide expansion of HIV Testing and Counselling (HTC) services, it is crucial for the MOHSW to ensure that the provided services meet the national and international quality standards. In order to facilitate providers’ consistency and conformance to quality standards, best practice and procedures, Standard Operating Procedures (SOPs) have been developed to guide the provision of HTC services at all levels of the health system.
It is expected that this manual will serve as key tool for service providers and their supervisors in delivering quality HTC services to their clients. Furthermore, with this manual in place, it is anticipated that the roll out of quality HTC services throughout the country will increase significantly. The publication of this manual is yet another clear signal of the firm commitment of the Government of Tanzania to make all core HIV and AIDS interventions and services universally accessible to all Tanzanians.

Blandina S. J. Nyoni
Permanent Secretary
Ministry of Health and Social Welfare
Dar es Salaam
The Ministry of Health and Social Welfare wishes to acknowledge, with sincere gratitude, the contribution of all experts who worked towards the production of this Standard Operating Procedure Manual for HIV Testing and counseling (HTC) services. It is not possible to mention by names all those who contributed, but we would like to mention the lead Consultant Dr Jessie Mbwambo of Muhimbili University of Health and Allied Sciences and her assistants Ms Lucy Silas and MS Methodia Simbeye for their distinguished and invaluable input. Their contribution in preparing the initial drafts and their guidance to the Technical Working Group Teams was very useful.

We would also like to express special thanks to the different stake holders who provided technical and financial support for the production of this manual. This includes:

- The World Health Organization (WHO)
- Muhimbili University of Health and Allied Sciences (MUHAS)
- Muhimbili University Health Information Centre (MUHIC)
- Project AFIKI - Kisarawe
- African Medical and Research Foundation (AMREF)
- Japan International Cooperation Agency (JICA)

The Ministry of Health and Social Welfare acknowledges with appreciation, the efforts of the Client Initiated Voluntary Counselling and Testing (VCT) and Provider Initiated Testing and Counselling (PITC) service providers and supervisors who participated in the pre-testing of this document. Without their input the production of this manual would not have been possible.

The preparation of this manual was guided by a Technical Working Group whose contribution enriched the document and made it much more user friendly. The Technical Working Group Team comprised of experts from the following organizations (in alphabetical order).

- African Medical and Research Foundation (AMREF)
- Centers for Disease Control and Prevention(CDC)
- Family Health International (FHI)
- International Training and Education Centre on HIV (I-TECH)
- Intra-health
- Ilala Municipal Council
Japan International Cooperation Agency (JICA)

JHPIEGO an affiliate of Johns Hopkins University

Ministry of Health and Social Welfare (MOHSW)
  ♦ National AIDS Control Programme (NACP)

Temeke Municipal Hospital

Muhimbili University of Health and Allied Science (MUHAS)

Muhimbili University Health Information Centre (MUHIC)

Pathfinder International

World Health Organization (WHO)

Based on the experience of using this manual in the field by health care providers, the Ministry of Health and Social Welfare will appreciate receiving any advice and recommendation that might be used to improve future its editions. This is very important to ensure that the manual is sensitive to local circumstances and its content remains demand driven all the time.

Dr. Deo M. Mtasiwa
Chief Medical Officer
Ministry of Health and Social Welfare
Dar es Salaam
<table>
<thead>
<tr>
<th>ACRONYMS</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ANC</td>
<td>Ante Natal Care</td>
</tr>
<tr>
<td>ARVs/ART</td>
<td>Antiretroviral Drugs/Antiretroviral Treatment</td>
</tr>
<tr>
<td>CHCT</td>
<td>Couple HIV Counselling and Testing</td>
</tr>
<tr>
<td>CTC</td>
<td>Care and Treatment Center</td>
</tr>
<tr>
<td>EQA</td>
<td>External Quality Assessment</td>
</tr>
<tr>
<td>FP</td>
<td>Family Planning</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>HTC</td>
<td>HIV Testing and Counselling</td>
</tr>
<tr>
<td>IEC</td>
<td>Information, Education and Communication</td>
</tr>
<tr>
<td>IQA</td>
<td>Internal Quality Assessment</td>
</tr>
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<td>MOHSW</td>
<td>Ministry of Health and Social Welfare</td>
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<tr>
<td>PEP</td>
<td>Post-Exposure Prophylaxis</td>
</tr>
<tr>
<td>PITC</td>
<td>Provider Initiated Testing and Counselling</td>
</tr>
<tr>
<td>PLHA</td>
<td>People Living With HIV and AIDS</td>
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<tr>
<td>PMTCT</td>
<td>Prevention of Mother-to-Child Transmission</td>
</tr>
<tr>
<td>PTSS</td>
<td>Post Test Support Services</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
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<tr>
<td>SOP</td>
<td>Standard Operational Procedure</td>
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<tr>
<td>STI</td>
<td>Sexually Transmitted Infections</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>VCT</td>
<td>Voluntary Counselling and Testing</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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A.1. Introduction of the manual

The purpose of this manual is to provide conformity to common standards and procedures. All staff providing HIV testing and counselling services should adhere to the standard operating procedures when delivering services to meet the set standards of quality.

A.2. Overview of HIV testing and counseling, policy statement

An important bottleneck in access to prevention, treatment and care for HIV and AIDS is knowing one’s status. HIV testing and counselling has evidence of success in increasing access to care and treatment.

The Tanzania HIV/AIDS and Malaria Indicator Survey (2007-2008) estimated that 5.7% of adults aged 15-49 years are infected with HIV. In the year 2002, the National AIDS Control Programme (NACP) estimated that 2.2 million people were living with HIV and AIDS, and about 20% of them were in need of Anti Retroviral Drugs (ARVs). A five-year National Care and Treatment Plan for 2003-2008 was developed and approved in October 2003. The plan advocates for care, treatment and support services to improve the quality of life for People Living with HIV and AIDS (PLHA), aiming at providing ARVs to 440,000 patients in need of treatment by the end of 2008. In order to achieve this goal, access to HIV testing and counselling services must be expanded as a clinical and core intervention in the comprehensive national response to the epidemic. This includes scaling up both client-initiated Voluntary Counselling and Testing (VCT) and Provider- Initiated HIV Testing and Counselling (PITC) services.

As part of the move towards the acceleration of HIV prevention, treatment, care and support, the Ministry of Health and Social Welfare (MOHSW) has approved the introduction and scaling up of PITC services. Both VCT and PITC will be provided so that they complement each other in addressing prevention, treatment, care and support needs of the population.

In Tanzania an increasing number of PLHA are becoming ill and need treatment, care and support services. There are important benefits of knowledge of HIV status at the individual, community and population levels as follows:

A.2.1. At the individual level there is enhanced ability to reduce the risk of acquiring or transmitting HIV, coping with HIV status, planning for the future, accessing HIV prevention, treatment, care, and support services and protecting unborn children from acquiring HIV.

A.2.2. At the community level, a wider knowledge of HIV status and its links to interventions can lead to a reduction in stigma and discrimination.
A.2.3. At the population level, knowledge of HIV status trends can influence the policy environment, normalize HIV and AIDS and reduce stigma and discrimination.

A.3. HIV testing and counselling approaches in Tanzania

Different approaches to HIV testing and counselling exist in Tanzania as follows:

A.3.1. **Client-Initiated Voluntary Counselling and Testing (VCT):** In this approach the client voluntarily makes the decision to learn his or her HIV status and seeks for counselling and testing services out of his or her own will for the purpose of prevention of HIV infection and personal life decision making.

A.3.2. **Provider-Initiated HIV Testing and Counselling (PITC):** PITC refers to HIV testing and counselling which is recommended by health care providers to persons attending health care facilities as a standard component of medical care. The major purpose of such testing and counselling is to enable specific clinical decisions to be made and/or specific medical services to be offered that will not be possible without knowing of the person’s HIV status. The following are considered priorities for the implementation of PITC in Tanzania.

- **A.3.2.1.** Children and adults seeking In-patient and Out-patient services
- **A.3.2.1.** TB and STI patients
- **A.3.2.2.** Reproductive and child health services, including family planning services for adolescents

A.3.3. **HIV testing for medical research and surveillance:** In Tanzania this is performed according to specific guidelines and regulations approved by the appropriate scientific and ethical review boards.

A.3.4. **Mandatory HIV screening:** This refers to routine screening for HIV and other blood borne viruses of all blood that is destined for transfusion or for manufacture of blood products.

Routine screening of donors is required prior to any procedure involving transfer of bodily fluids or parts, such as artificial insemination, corneal grafts and organ transplant.

In addition, mandatory testing is sometimes used for immigration purposes on a mandatory basis or for pre-recruitment and periodic medical assessment of military personnel for the purposes of establishing fitness. Mandatory testing can also be ordered by court order.

A.3.5. **Home based/family testing and counselling:** Provision of testing and counselling services to patients and family member in the household level. This can be done
through using index patients or door to door testing. The approach focuses to community localities especially underserved areas.

A.4. **Policy statement and guiding principles for expanded HIV testing and counselling**

HIV testing must be provided when consented to, or indicated in accordance with the “3Cs” principles of confidentiality, counselling and informed consent which include voluntarism. WHO recommends that the following guiding principles be observed in the provision of all HIV testing and counselling services.

A.4.1. **Testing and counselling must now be scaled up:** Offering HIV testing and counselling should become standard practice wherever they are likely to enhance the health and well-being of the individual and recommended to all persons in health care facilities. The objective is to enable the greatest possible number of people to benefit from the ever-improving treatment, care and prevention options and realize their right to the highest attainable standard of health care.

A.4.2. **HIV testing should be voluntary:** Mandatory HIV testing is neither effective for public health purposes nor ethical, as it denies individuals choice and violates principles such as the right to health, including the right to privacy and the ethical duties to obtain informed consent and maintain confidentiality. Although the process of obtaining informed consent will vary according to different settings, all those offered the test should receive sufficient information and should be helped to an adequate understanding of the testing process and possible consequences of being tested.

A.4.3. **Post-test support and services are crucial:** The result of HIV testing should always be offered to the person being tested. It is the person’s decision to share this result with others. Along with the result, appropriate post-test information, counselling or referral should be offered according to the result. People who receive positive test results should receive counselling and referral to care, support and treatment.

A.4.5. **Confidentiality must be protected:** All medical records, whether or not they involve HIV-related information, should be managed in accordance with appropriate standards of confidentiality. Only health care professionals with a direct role in the management of patients or clients should have access to such records or the information they contain, and only on a “need to know” basis.
B. ETHICAL AND LEGAL CONSIDERATIONS

B.1. Eligibility
Individuals may participate in testing for HIV if they meet the following criteria:

B.1.1. Those who are 18 years of age, able and willing to provide verbal informed consent;
B.1.2. Children below 18 years if there are parents or legal guardians to provide consent;
B.1.3. Mature minors, i.e. adolescents who are married, have children, or sexually active irrespective of their age.

B.2. Client Recruitment
The counsellor will perform the following list of procedures:

B.2.1. Pull out a packet with intervention forms and documents (consent document etc.)
B.2.2. Administer verbal informed consent in the clients’ choice of language (Swahili or English).
B.2.3. Explain to the client the advantages and disadvantages of taking an HIV test and give him/her an opportunity to ask questions.
B.2.4. Ensure that the individual meets the client eligibility requirements outlined above.
B.2.5. Assign a unique personal code to one individual who agrees to undergo testing and has given informed consent.
B.2.6. Provide pretest counselling to client.

To verify that verbal informed consent has been given, the counsellor will record the counsellor’s name, the date of consent and other client information on the Counselling and Testing Register. These documents will all be stored in the lockable cabinet and will be available for review by quality assurance team/monitors or supervisors.

B.3. Informed consent
The term “informed consent” refers to a person being given an opportunity to consider the benefits and potential implications associated with having access to information regarding his HIV sero-status, an understanding of the testing procedure, and then making the decision to be tested for HIV. A person should be able to consider the implications of a negative or positive HIV test result on their personal and professional lives.
All clients in HTC should receive sufficient information and should be helped to reach an adequate understanding of what is involved. The three crucial elements in obtaining informed consent of HIV testing are: providing pre-test information or counselling on the purpose of testing and availability of care, treatment and support services; and ensuring the person’s understanding of these messages and respecting the person’s autonomy. Only when these elements are in place will clients be able to make a fully informed decision on whether or not to be tested.

The HIV test administered at the testing facility will be voluntary and will take place only after the client has provided his/her verbal informed consent.

However, a parents/guardian consent form must be filled before testing is done to the following individuals:

a. Children below 18 years except mature minors;

b. Client with communication disability.

The client will be provided with the parents/guardian consent form in Swahili or English to read and signs if opts to be tested. The counsellor will also sign as a witness.

B.4. Client confidentiality
Confidentiality is one of the guiding principles for provision of HIV testing and counselling services and must be protected. HIV test results shall be confidential, provided only to the person who has been tested. Disclosure of the results to a third person shall only be done with a written consent from the person tested.

All clients’ information will be kept confidential and private. Clients will be reassured repeatedly that all information that they provide about themselves will be kept in the strictest confidence.

Counselling will be conducted in private where the conversation between the client and the counsellor cannot be overheard.

Because HIV and AIDS are highly sensitive and emotionally charged issues, information about the clients’ HIV sero-status and his/her sexual partners must be considered the most confidential information and must be protected at all times. Discussions between counsellors or health care providers and supervisors, including case discussions in supervision, shall protect the privacy of clients. Individuals’ confidentiality will be protected in conversations between counsellors and other staff members.

Any staff member who breaches confidentiality is acting contrary to the professional code of conduct and may be subjected to legal action.
B.5. Confidential record keeping
All client registers as well as informed consent records must be managed in accordance with the stipulated standards of confidentiality in the centre. Only persons with a direct role in the management of the client should have access to these records.

B.6. Shared confidentiality
Shared confidentiality is when a person utilizing VCT and PITC service wishes to involve significant others in the HIV testing and counselling process, including receiving the HIV test result. Shared confidentiality can be also applied to the disclosure of information from an individual to family member and friends. Counsellors should educate clients on the importance of disclosure of their HIV status and encourage them to do so.

B.7. Beneficial disclosure
All clients, both HIV positive and HIV negative, should be encouraged to inform their partner(s) about their HIV test results. HIV positive persons who are reluctant or fearful to disclose their results to their partner(s) must be referred for additional, ongoing more in-depth counselling to help them to do so.

Women potentially face gender-related negative consequences following disclosure of HIV status. There will be special pre-test counselling component designed for all female clients. It outlines physical risks that may be associated with disclosure with reliable questions to determine whether or not women are subject to intimate partner violence. In addition, given that a history of prior domestic violence is the best predictor of future violence, counsellors will be equipped with tools to identify women with such a history so that these women may assess their potential risks before testing and be counselled about referrals to minimize these risks.

B.8. Oath of confidentiality
Counsellors will sign the oath of confidentiality after being trained. Signing of the oath indicates that the staff member agrees to uphold the confidentiality specific to their work, that all clients’ information is confidential and shall not be divulged or made known to unauthorized persons, and that a breach of confidentiality may be grounds for disciplinary action or termination of employment. The signed oath is kept in personnel files.

B.9. Negative life events and incidents
Negative life events are detrimental social interactions experienced by clients. During counselling, clients, particularly women, may report negative events associated with testing for HIV. These may include breakup of their marriage or sexual relationship, physical abuse by their sexual partner, neglect or disownment by their family, rejection by peers, and discrimination by health care providers or employers.

Clients will be provided with a “Palm Card” containing information on how to contact the health care provider/counsellor to report such events so that necessary referrals can be made to mitigate potential harm. Primarily women who may be subject to negative adverse events will go to referral sites where services are offered.
Information cards will not include identifying information about the services or references to HIV or HIV testing, so that the cards will not have the potential to jeopardize the confidentiality of clients.

**B.9.1. Adverse Events and Incidents**

Adverse Events, Serious Adverse Events, and Incidents are categories of occurrences that can occur during the HTC. Broadly defined as follow:

**B.9.1.1.** An adverse Event (AE) is any undesirable, unintended reaction or event (whether expected or unexpected) that results from procedures or interventions.

**B.9.1.2.** A Serious Adverse Event (SAEs) will be defined as a subset of AEs that are fatal, life threatening, require hospitalization or prolong existing hospitalization, or result in persistent or significant disability.

**B.9.1.3.** Incidents are defined as a problem involving the conduct of the trial. Examples of incidents would include protocol violations, e.g. enrolling a client who did not meet eligibility criteria and other events such as harassment of staff that do not qualify as AEs.

The following steps are important when adverse events or incidents, errors, and problems occur:

**B.9.1.4.** Investigate the event to determine cause.

**B.9.1.5.** Take action to address the cause of the event.

**B.9.1.6.** Communicate appropriately with all those affected by the event, for example testing staff, counselling staff, physician, and/or client.

**B.9.1.7.** Keep a record of all circumstances related to the event. Also keep a record of corrective action taken and any communications with affected persons.

**B.9.1.8.** Adverse events log book will be available to administer all the occurrences.

**B.9.1.9.** Take actions correctively in the centre.
C. HIV TESTING AND COUNSELING SET-UP

C.1. Client Initiated Counselling and Testing (i.e VCT) services

C.1.1. VCT Site – Set up
VCT sites are organized in a manner that is convenient to clients. All measures are taken to assure client comfortability from the point of entry to the point of exit as per the national guidelines of the MOHSW:

C.1.2. Reception area set up

C.1.2.1. The reception area shall meet all conditions of privacy and confidentiality. It shall be furnished with two chairs and a table with lockable drawers for safekeeping of clients’ records.

C.1.2.2. For outreach services, mats or stools may be used and the counseling session can be held in a secluded open area that allows for privacy.

C.1.3. Waiting area set up

C.1.3.1. The waiting room shall be adequately spaced, well furnished and have a comfortable seating arrangement.

C.1.3.2. Health education materials including those with information on HIV and AIDS shall be displayed and distributed liberally. Where available, audio and audio-visual equipment can also be used to relay and disseminate health information.

C.1.3.3. Information, Education, and Communication (IEC) materials in waiting area can be:
   a. Site information leaflet
   b. General HIV and HTC brochure
   c. Male and female condoms
   d. Pamphlets on male and female condom use
   e. Others including those that relate to positive living and where to get access post test services like Care and Treatment Centre (CTC), Prevention of Mother to Child Transmission (PMTCT), Sexually Transmitted Infections (STI) and Tuberculosis (TB) treatment

C.1.4. Counselling room set up
The counselling room shall be clean, well ventilated, well lighted and assure privacy. It shall be furnished with the following important equipment and furniture:
C.1.4.1. A table with lockable drawers

C.1.4.2. At least three (comfortable) chairs to allow for couple/group counselling

C.1.4.3. Lockable cupboard for client records

C.1.4.4. Disposal bin for sharps as stipulated in the Injection Safety Guidelines by the MOHSW and foot-operated buckets for other waste

C.1.4.5. Running water, wash basin, soap and disposal towels.

C.1.4.6. Counselling area materials and supplies:
   a. VCT guidelines, SOPs for HTC services and VCT cue cards
   b. Informed Consent Information Sheet
   c. Staff schedule
   d. Laboratory/test request form, where applicable
   e. Male and female condoms
   f. Pamphlets on male and female condom use
   g. Envelopes to carry condoms and information
   h. Penile model
   i. Model pelvis/vagina
   j. Box of tissues, pens, pencils, paper
   k. Referral Materials:
      - Information sheets about Post Test Support Services (PTSS)
      - VCT-PTSS referral cards
      - Negative Life Events Card (Palm Card)

C.1.5. Testing room set up
A separate room or curtained-off space shall be set aside for testing. The testing room shall offer privacy and have the following equipment:

C.1.5.1. Two chairs

C.1.5.2. A table

C.1.5.3. Lockable cupboard

C.1.5.4. Running water, wash-basin, soap and disposal towels
C.1.5.6. Disinfectant and antiseptics
C.1.5.7. Disposal bin for sharps and foot-operated buckets for other waste
C.1.5.8. Refrigerator or cooler box with ice
C.1.5.9. Enough supplies including gloves, vacutainer syringe ad tube, syringes with a self retracting needles, lancers, tourniquet, cotton wool, stamp and stamp pad
C.1.5.10. Testing kits according to approved algorithm
C.1.5.11. Functional First Aid box
C.1.5.12. PEP procedures
C.1.5.13. Testing SOPs and algorithm

C.2. Provider Initiated Testing and Counselling Services

C.2.1. Consultation room
PITC will often be delivered where other health care is provided therefore there is a need to ensure an area where consent and test result can be given in confidence and with privacy. The PITC sites are organized in a manner that is convenient to patients and health care providers. All measures are taken to assure patient comfortability from the point of entry to the point of exit as per the guidelines from the MOHSW:

C.2.2. Reception area set up
C.2.2.1. The reception area shall be furnished with comfortable chairs and a table with IEC materials that the patient can take way at the conclusion of their hospital visit.

C.2.3. Waiting area set up
C.2.3.1. The waiting room shall be adequately spaced, well furnished and have a comfortable seating arrangement.
C.2.3.2. Health education materials including those with information on HIV and AIDS shall be displayed and distributed liberally. Where available, audio and audio-visual equipment can also be used to relay and disseminate health information.
C.2.3.3. IEC materials in waiting area can be:
   a. Facility information leaflet
   b. General HIV and PITC brochure
   c. Male and female condoms
d. Pamphlets on male and female condom use

e. Others including those that relate to positive living and where to get access post test services like Care and Treatment Centre (CTC), Prevention of Mother to Child Transmission (PMTCT), Sexually Transmitted Infections (STI) and Tuberculosis (TB) treatment

C.2.4. Consultation room set up
The consultation room shall be clean, well ventilated, well lighted and assure privacy. It shall be furnished with the following important equipment and furniture:

C.2.4.1. A table with lockable drawers

C.2.4.2. At least three (comfortable) chairs to allow for relative to escort couple counselling

C.2.4.3. Lockable cupboard for client records

C.2.4.4. Disposal bin for sharps as stipulated in the Injection Safety guidelines by the MOHSW and foot-operated buckets for other waste

C.2.4.5. Running water, wash basin, soap and disposal towels.

C.2.4.6. Counselling area materials and supplies:

a. PITC guidelines, SOPs for HTC services and PITC cue cards

b. Informed Consent Information Sheet

c. Staff schedule

d. Laboratory/test request form.

e. Male and female condoms

f. Pamphlets on male and female condom use

g. Envelopes to carry condoms and information

h. Penile model

i. Model pelvis/vagina

j. Box of tissues, pens, pencils, paper

k. Referral Materials:

- Information sheets about post test support services (PTSS)
- Referral cards
- Negative Life Events Card (Information Card)
C.2.5. Testing room set up
Testing can be carried out in the consulting room. A separate room or curtained-off space shall be set aside for testing. The testing room shall offer privacy and have the following equipment:

C.2.5.1. Two chairs

C.2.5.2. A table

C.2.5.3. Lockable cupboard

C.2.5.4. Running water, wash-basin, soap and disposal towels

C.2.5.6. Disinfectant and antiseptics

C.2.5.7. Disposal bin for sharps and foot-operated buckets for other waste

C.2.5.8. Refrigerator or cooler box with ice

C.2.5.9. Enough supplies including gloves, syringes, needles, lancers, tourniquet, cotton wool, stamp and stamp pad

C.2.5.10. Testing kits according to approved algorithm

C.2.5.11. Functional First Aid box

C.2.5.12. PEP procedures

C.2.5.13. Laboratory testing SOP and algorithm
D. CONTENTS OF COUNSELLING INTERVENTION

D.1. Client Initiated Counselling and Testing
The counselling and testing intervention includes at least one pre-test counselling session and one post-test counselling session. It is anticipated that counselling sessions will last at least 30 minutes each, depending on the individual client’s situation. Pre- and post-test counselling is separated by the length of time required to generate test results (approximately 20 minutes). If there are many clients consider having group information sessions.

D.1.1. Pre-test counseling
Counselling is a relationship. Connect with the client, answer questions and make sure that the client understands the information you are providing.

D.1.1.1. Review client knowledge on HIV and AIDS and correct any misperceptions about the HIV and AIDS and transmission of HIV.

D.1.1.2. Then engage the client in assessment of his or her own HIV-related risk behavior and negotiating a realistic, personalized risk reduction plan.

D.1.1.3. Form an alliance with the client to undertake the risk assessment, including gathering information about the client’s sexual and other risk behavior as well as his or her interpersonal, social, and resource situation.

D.1.1.4. Work with the client to develop strategies to reduce his or her risk. For each risk reduction behavior, assess internal and external barriers to change, perceived efficacy to enact the new behavior, readiness to change, and the availability of resources to change.

D.1.1.5. Acknowledge and support the client’s strengths and his or her enactment of the personalized risk reduction plan, work with the client to solve problems regarding anticipated difficulty in enacting the plan.

D.1.1.6. When appropriate, the risk reduction plan may be written and given to the client to remind and reinforce behavior change.

D.1.1.7. Assess clients’ knowledge on proper use of condoms and do a condom demonstration.

D.1.1.8. Confirm that the informed consent has been obtained and assure client confidentiality.

D.1.1.9. Inform client that they can withdraw consent at any stage of the HTC process.
D.1.2. **Preparation for testing**  
This is done during pre-test counselling. The counselor should:

D.1.2.1. Solicit the client’s knowledge about the HIV antibody test and any previous testing experiences.

D.1.2.2. Provide information about the test as needed and correct any misconceptions about testing and/or test results.

D.1.2.3. State the meaning of a negative test result and a positive test result.

D.1.2.4. Discuss with a client on action plan in case of a negative test result or a positive test result.

D.1.2.5. Provide contact information for crisis management in the case of negative HIV-related life events.

D.1.2.6. Ensure sufficient time is given to think through the issues.

D.1.2.7. At the end of pre-test counselling, ask the client if he or she would like to proceed with HIV testing.

D.1.2.8. If the answer is no, thank the client, plan for next counselling session and let him/her go.

D.1.2.9. If the answer is yes, fill out the laboratory form with the client’s unique personal code. Refer the client to a testing staff for taking the sample and testing or proceed with the testing if you are doing it yourself.

D.1.2.10. The testing staff will then prepare for the test according to Laboratory SOPs. The testing procedures will run for about 15 to 20 minutes during which the client is asked to rest in a waiting room or space.

D.1.3. **Disclosure of results**

D.1.3.1. The test result will be given to the counsellor by the testing staff or will be available to the counsellor if she/he does the test by themselves.

D.1.3.2. The counsellor will then invite the client to return to the counselling room and will check with the client to determine if he or she is prepared to receive the test result and post-test counselling.

D.1.3.3. For continuity purposes, it is recommended that the same counselor offer both pre- and post-test counselling to the client.

D.1.3.4. The results will only be disclosed to the client during post-testing counselling.
D.1.4. **Post-test counseling**
Post-test counseling will begin with the disclosure of test results.

D.1.4.1. **Giving negative results**

a. Make sure you have the test results ready.

b. Greet the client. Establish rapport.

c. Give the client time. Ask the client: “Are you ready to receive your HIV test result?”

d. If the client is ready, state in a neutral tone: “Your test result is negative meaning you have not been infected with HIV.”

e. Pause and wait for the client to respond before continuing. Give the client time to express any emotions.

f. Client should be shown the result slip if they so wish.

g. Discuss and support the client’s feelings and emotions.

h. Check the client’s understanding of the meaning of the results.

i. Discuss the following questions:
   - Do you remember the differences between HIV and AIDS?
   - How is the knowledge of your status going to help you?
   - How can you protect yourself further from HIV infection?
   - Who else will be affected by this result?
   - Inform the client to consider having another test in three months and/or encourage his/her partner to go for testing.

j. If there was a recent risk exposure, discuss the need to retest. For persons with ongoing risk of exposure, recommend follow up testing at least annually.

k. Discuss ways to remain negative and assist the client in exploring future risk reduction so that her or his status remains negative, in view of the high risk associated with new infections.

l. Discuss disclosure support and subsequent counselling sessions.

m. Discuss some basic risk-reduction strategies with the client:
• Good clinic attendance;
• Good nutrition status;
• Avoidance of alcohol and drug abuse;
• Use of condoms;
• Limiting the number of sexual partners.

n. Encourage the client about partner testing.
o. Inform the client that counselling is available for couples.
p. Encourage client to join post test support groups:
   • Post Test Support Services (PTSS) club.
q. Ask whether the client has questions or concerns. Explain to the client how to contact the VCT facility in case any new concerns arise.
r. Remind pregnant mothers and families that counselling will be available throughout pregnancy in order to help them to plan for the future and to obtain the services they need.
s. Refer the client for screening and treatment of STIs when necessary.

D.1.4.2. Giving positive results
Counselling is a relationship. Connect with the client, answer questions and make sure that the client understands the information you are providing.

a. Make sure you have the test results.
b. Greet the client. Establish rapport.
c. Ask whether the client has any questions that have arisen since testing was performed. Answer the questions and tell the client that counselling will continue to be available in order to help the client to make important decisions.
d. Give the client time. Ask the client: “Are you ready to receive your HIV test result?”
e. State in a neutral tone: “Your test result is positive meaning you have been infected with HIV”.
f. Pause and wait for the client to respond before continuing. Give the client time to express any emotions.
g. Client should be shown the result slip if they so wish.
h. Check the client’s understanding of the meaning of the result.

i. Explain that the client’s feelings and emotions may change frequently at this time.

j. Go over what was said during the pre-test counselling session. Tell the client that you are doing this to make sure he or she can recall the information that was given.

k. Ask the following questions:
   - Do you remember the differences between HIV and AIDS?
   - How is the knowledge of your status going to help you?
   - How can you protect yourself from further infection?
   - Who else will be affected by this result?

l. Discuss positive living including:
   - adequate nutrition;
   - prompt medical attention, prophylaxis and treatment of opportunistic infections;
   - ways to stay healthy including exercises;
   - treatment and support systems;
   - reducing the risk of infecting others and re-infecting yourself;
   - screening and treatment for sexually transmitted infections and TB.

m. Where appropriate, revisit PMTCT issues such as:
   - infant feeding options;
   - childbirth plans including contraceptive use;
   - antiretroviral prophylaxis if required ARV medication for the mother;
   - condom use;
   - partner testing.

n. Identify sources of hope for the client, such as family, friends, community based services, spiritual supports and treatment options. Make referrals when appropriate.
Discuss disclosure and support issues and subsequent counselling sessions.

Ask whether the client has questions or concerns. Explain to the client how to contact the clinic in case any concerns arise.

Remind mothers and families that supportive counselling will be available throughout pregnancy in order to help them to plan for the future and obtain the services they need.

If the client already has children, discuss and plan their testing.

Refer for psychosocial support, medical assessment and treatment and follow-up.

**D.2. Provider Initiated Testing and Counselling**

**D.2.1. Introduction**

This refers to HIV testing and counselling recommended during treatment by health care providers to enable specific clinical decisions to be made and/or specific medical services to be offered that would not be possible without knowledge of the person’s HIV status.

A brief counselling or pre-test education/information should always accompany testing even for diagnostic purposes and clients/patients should never be forced to undergo testing against their will.

In clients/patients presenting with symptoms or signs of illness possibly attributable to HIV, it is a basic responsibility of health care providers to recommend HIV testing and counselling as part of routine clinical management. PITC also aims to identify unrecognized or unsuspected HIV infection in clients/patients attending health facilities. Providers may therefore recommend HIV testing and counselling to clients/patients who do not exhibit obvious HIV-related symptoms and signs. Such HIV testing and counselling is recommended by the health care provider as part of a package of services provided to all clients/patients during all clinical interactions in the facility.

PITC encompasses both the “opt-in” or “opt-out” strategies used in HTC, “opt-in” generally refers to counselling and testing where a client/patient explicitly consents to the test. With the “opt-out” approach, individuals may specifically decline the HIV test having received pre-test information, without this decision affecting their clinical care.

UNAIDS suggests in resource and capacity constraints areas the following scenarios should be considered as priorities for the phasing of implementation of PITC in generalized epidemic settings: (1) Medical inpatient and outpatient facilities, including tuberculosis clinics; (2) Antenatal, childbirth and postpartum health services; (3) Health services for most-at-risk populations; (4) Services for younger children (under 10 years
of age); (4) Surgical services; (5) Services for adolescents; and (6) Reproductive health services, including family planning.

D.2.2. Pre-test information

D.2.2.1. Create rapport with the client/patient.

D.2.2.2. Discuss the need for HIV testing, highlighting the benefits of accessing the service.

D.2.2.3. Ascertain interest in being tested for HIV.

D.2.2.4. Move on to preparing for HIV testing if client/patient is agreeable to the test.

D.2.2.5. Client/patient declining the test should be offered assistance to access either client initiated (VCT) or provider initiated (PITC) HIV testing and counselling in the future.

D.2.3. Prepare for HIV testing

D.2.3.1. Solicit the client/patient’s knowledge about the HIV antibody test and any previous testing experiences.

D.2.3.2. Provide information about the test as needed and correct any misconceptions about testing and/or test results.

D.2.3.3. State the meaning of a negative test result and a positive test result.

D.2.3.4. Discuss with the client/patient on action plan in case of a negative test result or a positive test result.

D.2.3.5. Ensure sufficient time is given to think through the issues.

D.2.3.6. At the end of the preparation for testing, ask the client/patient if he or she would like to proceed with HIV testing.

D.2.3.7. If the answer is no, thank the client/patient, plan to refer to VCT counselor and inform him or her that not testing for HIV will in no way interfere with their access to the other services offered by the health facility.

D.2.3.8. If the answer is yes, fill out the laboratory form or register with the client/patient’s name and hospital registration number.

D.2.3.10. Refer the client/patient to testing staff for taking the sample and testing or proceed with the testing if you are doing it yourself.

D.2.3.11. The testing staff will then prepare for the test according to laboratory SOPs. The testing procedure will run for about 15 to 20 minutes during which
the patient may be asked to rest in a waiting room or space. If testing is done elsewhere, it is an opportunity for the health provider to see another patient.

D.2.4. Prepare for providing client/patient with their HIV test result

D.2.4.1. The test result will be given to the health provider by the testing staff or will be available to the provider if he or she does the test by himself/herself.

D.2.4.2. The provider will then invite the client/patient to return to the counselling process and will check with the client/patient to determine if he or she is prepared to receive the test result and post-test counselling.

D.2.4.3. For continuity purposes, it is recommended that the same provider offers both pre-test information, prepares for testing and does post-test counselling to the patient. If further counselling is needed referral to a counsellor will be provided.

D.2.4.4. The results will be given to the client/patient during post-testing counselling.

D.2.5. Post-test counselling

Post-test counselling will begin with the disclosure of test results. Counselling is a relationship. Connect with the patient, answer questions and make sure that the client/patient understands the information you are providing.

D.2.5.1 Giving negative results

a. Make sure you have the test results ready.

b. Greet the client/patient when they enter the consultation room. Establish rapport.

c. Give the client/patient time. Ask the patient: “Are you ready to receive your HIV test result?”

d. If the client is ready, state in a neutral tone: “Your test result is negative meaning you are not infected with HIV”

e. Pause and wait for the client to respond before continuing. Give the client/patient time to express any emotions.

f. Client/patient should be shown the result slip if they so wish

g. Check the client/patient’s understanding of the meaning of the results

h. Discuss about and support patients feelings and emotions.

i. If there was a recent risk exposure, discuss the need to retest.
j. Discuss ways to remain negative and assist the client/patient in exploring future risk reduction so that her or his status remains negative, in view of the high risk associated with new infections.

k. Ask whether the client/patient has questions or concerns. Explain to the client how to contact a VCT clinic or counsellor in case any new concerns arise as well as for retesting for HIV in three months.

l. Remind pregnant mothers and families that counselling will be available throughout pregnancy in PMTCT in order to help them to plan for the future and to obtain the services they need.

m. Refer the client for screening and treatment of STIs when necessary.

n. Continue treating patient for initial medical problem.

D.2.5.2. Giving positive results

a. Make sure you have the test results.

b. Greet the patient. Re-Establish rapport.

c. Ask whether the client/patient has any questions that have arisen since testing was performed. Answer questions and tell the client/patient that counselling will continue to be available in order to help with important decisions.

d. Give the client/patient time. Ask the patient: “Are you ready to receive your HIV test result?”

e. State in a neutral tone: “Your test result is positive meaning you have been infected with HIV”.

f. Pause and wait for the patient to respond before continuing. Give the client time to express any emotions.

g. Client should be shown the result slip if they so wish.

h. Check the client/patient’s understanding of the meaning of the result.

i. Explain to the patient that feelings and emotions may change frequently at this time.

j. Go over what was said during the pre-test information session. Tell the patient that you are doing this to make sure he or she can recall the information that was given.

k. Additionally ask the following questions.
Do you know the differences between HIV and AIDS?

- How is the knowledge of your status going to help you?
- How can you protect yourself from further infection?
- Who else will be affected by this result?
- Discuss disclosure and support issues and subsequent counselling sessions.
  - Establish who the patient would like to tell about their positive status, focus on when and how they will disclose; the reactions they anticipate from these people (this could best be done through role play).
  - Emphasize the importance of disclosure to current and future partner or partners, children and other family members.

**D.2.6. Discuss Positive Living**

**D.2.6.1.** When the client/patient is emotionally stable, tell him/her what “positive living” is. Enquire whether the client/patient knows that “Positive living means taking care of his/her health and emotional wellbeing in order to enhance the quality of your life”:

- a. Ways to stay healthy and encourage active lifestyle
- b. Adequate and proper nutrition;
- c. Prompt medical attention including referral to Care and Treatment Center, prophylaxis and treatment of opportunistic infections;
- d. Reducing the risk of infecting others;
- e. Screening and treatment for sexually transmitted infections and TB in some settings and for certain high risk populations which have capacity and treatment, referral for viral hepatitis screening may be appropriate
- f. Where appropriate, revisit PMTCT issues such as:
  - infant feeding;
  - childbirth plans including contraceptive use;
  - antiretroviral prophylaxis;
  - condom use;
  - Partner testing.
D.2.6.2. Identify sources of support for the client, such as family, friends, and community based services, spiritual, paralegal and psychosocial support and treatment options. Make referrals when appropriate.

D.2.6.3. Ask whether the client has questions or concerns. Explain to the client how to contact the clinic in case any concerns arise.

D.2.6.4. Discuss the importance of testing for other family members including children with consent from parent or guardian.

D.2.6.5. Continue treating patient for initial medical problem.

D.3. Couple HIV Counselling and Testing

D.3.1. Introduction to Couple HIV Counselling and Testing (CHCT)

Couple HIV Counselling and testing is emerging as one of the most important interventions aiming at preventing transmission of HIV between sex partners and those living together (cohabiting or married). Couple counselling aims at: (1) providing accurate information and behavioural change messages that make them to seek HTC; (2) removing tension and reducing blame as to the possible cause of infection; (3) reducing myths about HIV transmission; (4) creating safe environment for disclosing HIV sero-status; and (5) finding options to be used for disclosure of HIV sero-status to their children and helping them in the decisions of testing the children when felt to be necessary.

When a counsellor deals with a couple they should ensure that they demonstrate non-biased concern for both pairs of the couple; show respect in the couple’s relationship and facilitate equal participation during the counselling session by both partners. The counsellor should also allow the couple to speak between them and raise difficult issues that the couple will need to address.

During the counselling encounter with the couple the counsellor should try to look at the future rather than the past; where any discussion or potential hostility is anticipated, the counsellor need to redirect and reframe questions and discussions at the same time addressing any underlying hostile feelings. In doing so, the counsellor and the couple do not spend time in looking for the source of infection but look into the expressed ability of the couple in dealing with HIV related issues.

For couples to get couple counselling they should agree to discuss their HIV related risks and receive test results together; commit to shared confidentiality and the need to make mutual disclosure decisions.
D.3.2. Initial couple counselling session

D.3.2.1. Introduce yourself and describe your role.

D.3.2.2. Discuss the benefits of CHCT.

D.3.2.3. Describe the conditions of receiving CHTC.

D.3.2.4. Obtain concurrence to get CHTC.

D.3.2.5. Look into expectations, roles and responsibilities of the couples in the session.

D.3.2.6. Give the session overview including timing and contents:
   a. Review the couple’s situation;
   b. Discuss HIV risk issues and concerns (not risk assessment);
   c. Preparation for rapid HIV testing, the testing process and possible results;
      - Discuss couples about getting same results all negative (discuss meaning of HIV negative results);
      - Discuss couples about getting same results all positive (discuss meaning of HIV positive results);
      - Discuss that the couple may get different results, one HIV negative and another HIV positive (discuss meaning of discordant results);
   d. Conduct the rapid HIV test to each individual;
   e. Disclosure of the results and post-test counselling.

D.3.3. Post-test counselling

D.3.3.1 Giving concordant HIV negative results
   a. Make sure you have the test results.
   b. Greet the couple. Establish rapport.
   c. Ask whether the couple has any questions that have arisen since testing was performed. Answer the questions and tell the couple that counselling will continue to be available in order to help them make important decisions.
   d. Inform the couple that their results are available.
   e. Give the couple time. Ask the couple: “Are you ready to receive your HIV test result?”
   f. If they are ready, state in a neutral tone: “Both your test results are negative.”
g. Pause and wait for the couple to respond before continuing. Give the couple time to express their emotions.

h. If the couple wishes to see the results, provide them.

i. Check the couple’s understanding of the meaning of the HIV test result.

j. Explain that the couple’s feelings and emotions may change frequently at this time.

k. Discuss the result within the context of recent risks outside their relationship:
   - Encourage a mutual faithfulness relationship;
   - Remind them their status is not a reflection of past relationships;
   - Problem solving obstacles to being mutually faithful.

l. Discuss the couple’s HIV specific concerns.

m. Emphasize use of condoms outside their permanent relationship

n. Explore what is needed to reduce risks.

o. Encourage the couple’s communication.

p. Build confidence between the partners in completing risk reduction plan and protecting each other.

q. Encourage the couple to become advocates of CHCT.

r. Provide the couple with referrals to STI and FP clinics, ANC care or any other support where indicated

D.3.3.2 Giving concordant HIV positive results

a. Make sure you have the test results.

b. Greet the couple. Establish rapport.

c. Ask whether the couple has any questions that have arisen since testing was performed. Answer the questions and tell the couple that counselling will continue to be available in order to help them with important decisions.

d. Inform the couple that their HIV test results are available.

e. Give the couple time. Ask the couple: “Are you ready to receive your HIV test result?”

f. State in a neutral tone: “Both your test results are positive.”
g. Pause and wait for the couple to respond before continuing. Give the couple time to express their emotions.

h. If the couple wishes to see the results, provide them.

i. Check the couple’s understanding of the meaning of the HIV test result.

j. Encourage mutual support and diffuse blame.

k. Invite each pair of the couple to express their feelings and concerns.

l. Promote acceptance of the HIV test results and normalize the couple’s feelings as well as dealing with HIV positive test results.

m. Ask the couple how best they can support each other.

n. Recall on the couple’s strengths and convey hope that they will be able to cope and adjust themselves with living with HIV.

o. Let the couple address immediate concerns.

p. Discuss positive living (refer D.27 for discussion on positive living) and HIV care and treatment.

q. Discuss risk reduction strategies.

r. Discuss children, family planning and PMTCT options.

s. Discuss disclosure and getting support.

**D.3.3.3 Giving discordant HIV positive and negative results**

a. Make sure you have the test results.

b. Greet the couple. Establish rapport.

c. Ask whether the couple have any questions that have arisen since testing was performed. Answer questions and tell the couple that counselling will continue to be available in order to help them with important decisions.

d. Inform the couple their results are available.

e. Give the couple time. Ask the couple: “Are you ready to receive your HIV test result?”

f. State that test results are different, “**xx** your results are positive, while **xxx** your test results are negative”. Pause for a short time to ensure there is understanding of what the results mean.

g. Show the couple the result slip, if they so wish.
h. Review the explanation of the couple’s different HIV test results.

i. Invite each pair of the couple to share their feelings and concerns.

j. Facilitate acceptance of the HIV test results and normalize the couples feelings as well as dealing with discordant HIV test results.

k. Ask un-infected partner how best he or she can support partner.

l. Recall the couple’s strengths and convey hope that they will be able to cope and adjust themselves to the situation.

m. Let the couples address immediate concerns.

n. Discuss positive living and HIV care and treatment.

o. Discuss healthy living (refer D.27 for discussion on positive living).

p. Discuss protecting the HIV negative partner from HIV infection.

q. Discuss child(ren), family planning and PMTCT options for discordant partners.

r. Discuss disclosure and getting support.
E. TEST PERFORMANCE PROCEDURES

E.1. The testing staff must ensure that the testing procedures are correctly performed, the environment is suitable for reliable testing, and that the test kit work as expected to produce accurate and reliable results.

- Supervision should be conducted by laboratory technicians especially where no technicians are performing the test.

E.2. Steps in the testing process follow the path of workflow, and begin with tasks done before testing (pre-analytic), followed by tasks done during (analytic) and after testing (post-analytic). When using HIV rapid test kits, there are a number of steps in these three parts of the path of workflow that are essential in order to assure accurate and reliable test results.

E.3. A laboratory standard operating procedure (SOP) is developed to provide detailed instructions on all aspects of the testing, to include transport of specimens, storage and inventory information, test requesting, environmental requirements, specimen collection and management, test performance, quality control instructions, test interpretation, reporting and recording results, appropriate use of the testing algorithm, and any external quality assessment requirements.

E.4. Each testing product (SD Bio-line, Determine™, and Uni-Gold) needs its own written SOP and should be available at testing site, and should always be followed when conducting tests.

E.5. The testing staff should perform the following procedures while conducting tests:

E.5.1. Pre-analytic
   E.5.1.1. Check storage and room temperatures daily.
   E.5.1.2. Check inventory and test kit lots as needed.
   E.5.1.3. Receive requests for testing. Ensure client lab. Request form is duly filled (Appendix A shows example of Test Request Form)
   E.5.1.4. Set up test area.
   E.5.1.5. Record all needed data, such as kit lot number, operator identity.

E.5.2. Analytic
   E.5.2.1. Follow the biohazardous safety precaution as is shown in the laboratory safety procedures and disposal.
   E.5.2.2. Perform external quality control according to instructions.
a. Run a negative and a positive control (and weekly positive when possible) at the following times:
   ● At least once weekly, preferably at the beginning of the week;
   ● When a new operator (a trained staff member who has not been doing testing for awhile or a newly trained operator) is performing testing;
   ● When beginning the use of HIV rapid test kits with a new lot number;
   ● Whenever a new shipment of test kits is received;
   ● If rapid test kits are exposed to environmental conditions that fall outside the range needed for stability as defined by the manufacturer.

b. Correctly identify person to be tested. Invite into the testing room.

c. Greet the client/patient and establish rapport. Ensure client confidentiality, reassure and alleviate his or her fear of needles or sight of blood.

d. Collect the specimen, including specimen for External Quality Assessment (EQA).

e. Perform the test as directed by the manufacturer (follow Laboratory SOP for each test product).

f. Interpret the test results. The serial testing with a tie breaker is recommended by the MoHSW guidelines (see the algorithm below).

E.5.3. Post-analytic

E.5.3.1. Re-check patient identifier and report results.

E.5.3.2. Clean up and dispose bio-hazardous waste.

E.5.3.3. Package and transport EQA re-test specimens to referral laboratory, or appropriately store until next shipment to referral laboratory, if needed.
Figure 1: National HIV Testing Algorithm

Test sample using SD Bio-line

Negative test results

NEGATIVE

Positive test results

Retest with Determine™

Negative test results

Retest with Uni-Gold

Negative test results

NEGATIVE

Positive test results

Positive test results

POSITIVE

POSITIVE
Quality Assurance activities in an HTC setting are essential to ensure the provision of quality counselling and accurate and reliable HIV testing. The quality of counselling has an implication on the outcome of a client’s decision to test or not to test as well as how the client handles and copes with the test results. Also, regardless of whether a test result is positive or negative, it has major implications on a client’s life. In this regard, HIV testing must be done properly using reliable tests, reagents and correct procedures. Quality Assurance Protocols are developed and made available to all persons working in and managing VCT services. Clear Standard Operating Procedures manual and protocols are established for service delivery. The areas covered include:

a. client registration and intake;

b. obtaining informed consent;

c. maintaining confidentiality;

d. pre-test counselling or pretest information in PITC;

e. delivery of HIV testing, PEP; laboratory protocols;

f. post-test counselling, care and support;

g. beneficial disclosure;

h. ensuring non-discrimination in service provision;

i. existing referral mechanisms.

Quality improvement processes are required for auditing adherence to policies, protocols and procedures. It is important to use these processes to assess issues such as staff competency/proficiency, counsellor skills, counselling protocols, the adequacy of laboratory testing and the perspective of clients on the accessibility and acceptability of testing and counselling services.

F.1. Quality assurance of counselling services

F.1.1. Quality assurance is a way of monitoring and evaluating the quality of counselling services provided in accordance with established guidelines, policies and standards.

F.1.2. Approaches for assessing quality of counselling include regular training, supportive supervision, counsellor self assessment and stress management sessions, client exit interviews and suggestions to measure client satisfaction, and regular monitoring of all activities along the workflow.
The cue cards that will support counsellor during the counselling process is included as a separate document to be used together with the SOPs. These cue cards aim to standardize the language and the foundation for continued learning. The cue cards are one tool that will be use by counsellors and providers to sustaining the skills of quality HTC.

F.1.3. Quality control procedures consist of regular supervision of all staff, weekly staff meetings, regular feedback to individuals by project coordinator, and bi-annual evaluation of staff performing counselling.

F.2. Quality Assurance of HIV testing

Quality Assurance (QA) is defined as the overall programme that ensures that the final HIV test results reported are correct. A false result may irrevocably damage the reputation of the VCT service and the consequences to the client may result in social, psychological and stigmatization problems. Two levels of Quality Assurance are recognized:

F.2.1. Internal Quality Assessment (IQA)/Quality control procedures

These are essential to ensure that the testing process has been carried out properly and that the kit reagents are performing as intended. These are activities conducted during testing in order to quickly identify and correct deviations from protocol as well as identify “less than optimal performance”. The quality control procedures are designed to maintain the integrity of the components by assessing adherence and assisting staff in meeting goals IQA involves the following:

F.2.1.1. Good laboratory practices with set standards for performing HIV testing;
F.2.1.2. Systems for management of HIV test results;
F.2.1.3. Tracking records on available test kits, batch numbers and expiry dates;
F.2.1.4. Periodic inclusion of previously characterized samples in order to identify problems with competency of the personnel performing the HIV tests, and also identifying problems with new lots of test kits;
F.2.1.5. All quality control data are well recorded for easy review and analysis.

F.2.2. External Quality Assessment (EQA)

This involves objective assessment of a test site’s operations and performance by an external agency or personnel. Laboratory practitioners have a vital role to play in the supervision of activities at the HIV rapid testing sites. EQA involves the following:

F.2.2.1. Proficiency Testing: All personnel providing HIV testing services will receive HIV proficiency samples from the reference or consultant hospital laboratories at least twice a year. All personnel failing the proficiency tests need to receive additional technical supervision and support.
F.2.2.2. **On-site Monitoring and Evaluation:** This involves periodic site visits to assess practices at the HIV testing sites. The supervision role should be undertaken by the laboratory practitioners in Charge. On-site assessment will also be done by the Consultant Hospital and National Reference Laboratories when deemed necessary. In order to make the assessment objective, a standardized on-site evaluation checklist is established for use during the supervision. On-site monitoring and evaluation at VCT site shall be done at least twice yearly.

F.2.2.3. **Re-test of specimens:** Retest specimens are randomly selected from all tested clients daily. Both positive and negative samples are taken for retest. Depending on the volume of bloods tested in the facility, every fifth positive and twentieth negative samples are collected and transferred to reference laboratory weekly for retesting.
G. REFERENCES

1. CBVCT Standard Operating Procedures manual, NIMH Project Accept, November, 2005

2. Counseling Skills, Ethical Codes and Supervision of Counseling Practice for HIV and AIDS Voluntary Counseling and Testing, Module 8, MoHSW, NACP, Tanzania, February 2008


10. Operational Plan for the National Laboratory System To Support HIV/AIDS Care and Treatment, MoHSW, November 2004


APPENDIX A: RAPID HIV TEST REQUEST FORM

Site Code: ___________ VCT Number: ___________ Age: ___________ Sex M/F

Code name of counsellor/person collecting blood ________________

Origin of sample (hospital department – please tick)

- Antenatal clinic
- General VCT
- Counselling Area
- TB Ward
- Outpatients
- Paediatric Ward
- Medical Ward

Purpose of testing (reason for test - please circle)

- A = Pregnant woman/ANC attendee
- B = male partner
- C = VCT general client
- D = clinical care/medical diagnosis
- E = TB patient
- F = Child given Nevirapine/other ARV at birth

Laboratory/Test Site Report

Date ________/_________/_________ Lab/Test Site No..............................................

RESULTS:

FIRST TEST: _______________ Lot No._____________ Expiry Date____________
SECOND TEST: _______________ Lot No. ___________ Expiry Date____________

REPEAT TEST:

1. _______________ Lot No._____________ Expiry Date____________
2. _______________ Lot No. ___________ Expiry Date____________

TIEBREAKER:

EXPIRY DATE: _______________ Lot No.____________________________

FINAL RESULT: ______________________________________________________

TESTS PERFORMED BY: _____________________________________________

(PRINT NAME AND SIGN)
Client Result Sheet

Site Code: ___________________  VCT Number: ___________________  Lab Test

Site no: ______________________

Code name of counsellor/person collecting blood: ________________________________

Origin of sample (hospital department – please tick)

- Antenatal clinic
- General VCT
- Counselling Area
- TB Ward
- Outpatients
- Paediatric Ward
- Medical Ward

Result:

HIV Antibody Test Result ...........................................  Signed.........................................................
HTC client will be provided a "Palm Card" which contains information on how to contact the health care provider/counsellor or further assistance.

Palm Card

Palm Card

NOTE: Palm Card can be customised by counsellor according to service availability and necessary information for the each client.
APPENDIX C: HELPFUL TIPS FOR USING CUE CARDS

- Cue cards serve as shared language, the shared foundation for continued learning. The cue cards are one tool we will use together to sustaining the skills of HTC. **The cue cards are your most important tool in operations for HTC.**

- Counsellors all over the world have used them. At the beginning using these cards may feel awkward. **Trust the learning process and use the cards.**

- **Be patient with yourself when learning to use these cards.** Anything we learn takes time and practice before it becomes comfortable. Add some spice to your regular way of counselling. Accept the challenge.

- The cue cards will help you remain focused on your client’s or patients risk and successfully deliver the intervention. Remember you are the deliverer following a map (cue cards) ensuring that your passenger (client or patient) gets to his/her destination (risk reduction) **Give it a try.**

- If you commit to using the cards, you can be assured that you will deliver a consistent and effective prevention intervention. **Every client or patient deserves to receive the same benefits of HTC.** Using the cue cards will make a difference.

- Remember the questions have been developed to help you achieve the objective of each component of the intervention. The questions build on each other. **Take one step at a time, one question at a time.**

- Having the questions helps you to elicit important information from your client and the scripted questions allow you to really listen to your client rather than trying to think of the next question. **Take advantage of having the questions.**

- In using the cue card, try using the questions provided. It is alright to skip a question if the client or patient already gave you the information or if it is not relevant to your client’s or patient’s situation. **Keep a balance between listening and asking the cue card questions.** Then purposefully select your next question. Role-playing will provide you with opportunities to practice.

- If the client or patient is silent after you have asked a question, he/she may need a moment to think, process, reflect and/or digest what has been asked or discussed. If you need to organize your thoughts or to decide on the next appropriate and relevant question take a moment of silence to do this. **The use of silence is an effective counseling skill.**
• At your site you might meet as a group and decide if you should modify some questions to reflect your culture and issues specific to your site. You may need to translate questions into local languages and the vernacular of your site. Confirm with others that the questions you develop are asking what you are attempting to elicit from the client or patient.

• Developing questions that elicit the appropriate information from the client is challenging. Crafting effective questions requires a thoughtful and meticulous process.

• Remember some questions are intended to help the client or patient gain insight, reflect on alternative choices, or recognize conflicts. Understand the purpose of each question.

• When revising the questions, be careful to ensure that each question follows the previous one and assists in accomplishing the goals and objectives of the relevant component. Only revise a question if another question might better to enhance your ability to reach the objectives of the component.

• Remember most of the cue card questions are carefully developed, counsellor tested and proven to elicit important information from the client or patient. There is no need to re-invent the wheel. If questions already work for you, keep them.

• We strongly recommend that if you revise or translate the questions from the cue cards into another language, that you also develop a complete new set of cue cards for each counsellor. You should use the cue cards in your HTC sessions for at least the first three months following the HTC training. After that time, your supervisor may approve the use of the session guide alone if you’ve demonstrated consistent competence in achieving each of the intervention components in your HTC sessions.