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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :LP-303 |
| **Title**  **HIV COUNSELLING AND TESTING** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

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| **Review date** | **Revision Date** | **Signature** |
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**Document History**

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| **Version number** | **Reason for change** | **Date** |
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1. **Introduction**

HIV counselling and testing (HCT) allows individuals to learn their HIV status. After learning of their status, activities for positive life changes can be initiated involving physical, emotional and social health. Making good decisions and providing support early can greatly enhance the future life of PLHIV. Post-HCT services should also reach clients who have recently learned that they are positive.

1. **Objectives**

To establish a standardized operating procedure for HIV counselling and testing.

1. **Scope**

This SOP applies to the process and procedure for all laboratory personnel who have been trained and are competent in the counselling and testing of HIV infection in the study.

1. **Responsibility**

All study personnel who have been trained and are competent in the counselling and testing of HIV infection.

1. **Standard precautions**

Wear gloves when handling participant’s specimens to protect from exposure to blood borne pathogens.

1. **Definitions**

* **Pre – HIV test counselling:** The part of HCT counselling, which is done to prepare the client for testing. It is also called pre-test counselling as it is done before testing for HIV.
* **Post- HIV test Counselling**: Also called Post-test counselling. The part of HCT counselling conducted to prepare the client to receive the results of the test. No test result should be given without appropriate counselling. At this stage clients are in a state of anxiety and stress, and proper care should be taken.
* **HIV testing**: Test conducted after pre-HIV counselling to know the HIV status of clients.

1. **Special Instruction**

HIV test results obtain from any official and approved HIV counselling and test centres within the study sites and other approved government hospital is acceptable for the study purposes. However all HIV negative test result must be reconfirmed at study site HCT centre before registering as negative.

1. **Pre – HIV test counselling**

The Counselor will:

1. Cross-check participant’s ID numbers on ALL forms.
2. Introduce and orient the client
   1. Name, designation and role

i.e. “*My name is …………. I am a counselor at this centre. My role is to discuss issues pertaining to HIV and AIDS and any other concerns that you may have.*”

* 1. Confidentiality (including discussion of sensitive issues) and anonymity.

i.e. “*Whatever we discuss will remain within this centre and is confidential. Any information that we get from you in relationship to HIV is kept in your file, with only your ID numbers on the outside. These files will be kept secured in the study office.*”

* 1. VCT process outline – sessions, duration, testing procedures.

i.e. *“Our services are for people who come to this centre voluntarily. We will talk for 20 to 30 minutes. If you decide to be tested, you will need to wait approximately 20 to 60 minutes for the results. You will need a further 15 to 60 minutes to discuss the results after that.”*

* 1. Record taking by counselor

i.e. *“At the end of the session I will take down a few notes on our discussion for record keeping purposes.”* Discuss measures you will take to keep confidentiality.

1. Provide basic information about HIV and transmission discussing briefly the key methods of infection and also briefly how you cannot contract HIV.
2. Conduct clinical risk assessment. Combine risk education and assessment of risk. Give the following explanation for discussing sensitive issues: “I need to discuss some things today that perhaps normally we wouldn’t discuss with others. I need to discuss these things in order to be able to:
   1. Give you realistic feedback about your risk of being infected – you may be worrying unnecessarily.
   2. Ensure you know how to keep yourself and partners safe in the future – different practices have different risks.
   3. See if you have other potential health problems that this test will not identify – maybe we will need to consider other types of tests.
   4. Make appropriate treatment and care suggestions. If you test HIV positive it would be important for us to know when you most likely contracted HIV or any other infections as this may determine the type of care offered.”

*“As you can see these are some good reasons for us to talk openly about these things even though it may not be comfortable”.*

Then proceed with clinical risk assessment. Provide information first followed by assessment of the client’s individual risk, when the risk occurred and whether this date falls within the three-month window period. Provide feedback to clients on their risk. Avoid saying they are very high or low risk. Talk to them in terms of having significant risks or appearing to have limited risks. Remind clients that the only way they can know if they are infected is by having an HIV test.

1. Discuss prevention related issues - condom use, including condom demonstration and safe injecting information. Exploration and problem solving of constraints to risk reduction should be offered. Such exploration may include:

* Risk reduction attempts [previous]
* Details of successful attempts
* Details of failed attempts/obstacles

For e.g. “What has been the most difficult part of reducing your HIV risk?”

* Assess condom use skills and condom demonstration
* Re-visit risk triggers for high risk behaviour
* Engage in structured problem solving with the client to resolve difficulties in engaging in transmission risk reduction strategies, and develop a personal risk reduction plan for the client.

1. Discuss testing: provide basic information about the test and how results are provided.

Some points to discuss here include:

* . Explain HIV testing procedure and possible test results
* . Discuss meaning of positive, negative and indeterminate results
* . Discuss advantages and disadvantages of having an HIV test
* . Advantages include being able to look after your health by seeking treatment
* . Discuss implications of results to self, partner and family
* . Explain about the window period

*When HIV infects a person’s body, their body realizes HIV is a virus that should not be in the body. The immune system in the body will begin to develop antibodies to try to kill the HIV and protect the person. The test used to check for HIV looks for these antibodies in the blood, and is called an antibody test.*

*It can take up to 12 weeks after infection with HIV for these antibodies to develop. This means that an HIV test can not guarantee a person’s HIV status as negative if they have had any risk for HIV in the 12 weeks immediately before the test. This time period of 12 weeks before the test is called the “window period”.*

1. Obtain informed consent to undergo HIV testing and note on counselling record form.
2. **HIV rapid test procedures**

A. **Materials and equipment**

* HIV 1/2 test kit
* Micropipette
* Timer

B. **Procedure**

1. Check the expiry date and recommended storage temperature of the kit on the kit box./ Do not use expired kits or kits stored at non recommended temperature.
2. Bring desired number of HIV 1/2 test kit to room temperature
   1. Label client ID on test kit
   2. Remove the protective kit cover from each test
   3. Using a micro pipette, apply 50 μl of whole blood, serum or plasma to the sample pad marked by the arrow symbol
   4. For whole blood sample, drop chase buffer one drop after apply the sample
   5. Wait a minimum of 15 minutes (up to 60 minutes) and read the result and record results
   6. Interpretation of test result

**Non-reactive** (One Bar): One red bar appears in the control window of the strip

and no red bar appears in the client window of the strip.

**Reactive** (Two bars): Red bars appear in both the control window and the client window of the strip. Any visible red colour in the client window should be interpreted as reactive.

**Invalid** (No Bar): If there is no bar in the control window of the strip and even if a red bar appear in the patient window of the strip, the result is invalid and should be repeated.

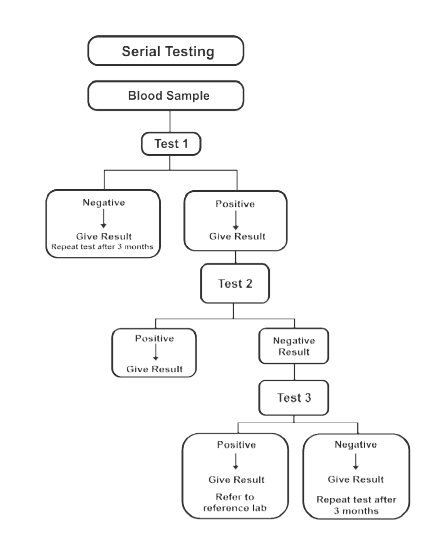
1. Testing Algorithm

The recommended algorithm for routine use is the serial HIV testing algorithm. Rapid HIV test kits currently recommended for use in Nigeria include: Determine, Unigold, Stat Pak and Double-check gold.

1. Serial testing

This refers to the use of 2 screening tests employed sequentially to test for HIV antibody. If the initial screening is negative, no further testing is required. If the initial test is positive, it is followed by one more test. The first test should be the most sensitive test and the second test should be very specific, and be based on an antigen source different from that of the first test.

Samples that produce discordant results in the two tests are subjected to further testing.



1. **Post – HIV test counselling**

The Counselor will:

Understand Results

**Negative Test Result** – A negative test result is given if the first screening test or the tiebreaker test in the serial algorithm shows non-reactive result. A negative test means that the person is either (1) not infected with HIV, or (2) so recently infected that the test could not detect the HIV antibodies (window period).

**Positive Test Result**- A positive test result is given if both first screening and second

confirmatory tests or the tie-breaker test show reactive result in the serial algorithm. A

positive test means that the person is infected with HIV, that the HIV antibodies have been detected and that the person can transmit HIV to others.

**Indeterminate/Inconclusive Test Results**- In the national serial testing algorithm there is no provision for indeterminate test result. All reactive with the first screening test are tested with the second confirmatory test and if both give different result, then the third tie-breaker test is used. The result of the tie-breaker test is taken as final. An indeterminate/inconclusive test result may either represent:

* A biologic false positive test result, or
* A truly positive test from a recent infection in which antibodies have not yet fully developed.

Clients must take the same risk reduction precautions as persons testing HIV positive until the indeterminate finding is resolved.

Need for repeat test:

A repeat test is recommended 12 weeks after the date of the inconclusive test result (or sooner if desired by the client; however the result may not be accurate before 6 weeks).

Provide Results:

Key Principles

The result giving session addresses following main areas:

* Giving test results, which includes dealing with emotional reactions and re-visiting risk reduction plans
* Repeat counselling sessions

Show the result in person on an individual basis:

* + Not on the phone
* . Not in the mail
* . Not to other people – staff, friends or family
* . NOT in groups ( even if negative)

Check the details of client medical record with test results – make sure the results are in the correct medical record.

Check the details of client medical record with the client – make sure you are giving the results to the correct client.

Providing HIV Negative Test Results

1. After seating the client and confirming that they are ready for their results simply explain the result is HIV negative.
2. Explain that the test has shown that the client is not infected however explain that if a risk occurred within the last three month period before the test was taken it will mean that there is still a chance that they may be infected and that this has not yet shown up in the test result that they have received today.
3. Check for any window period exposure that the client may not have disclosed at the time of pre-test counselling. If the client has not received a same day test result also discuss if their have been risks since the test was taken.
4. Advise the client with “window period” exposure of the need to practise safer sex throughout the life until a further test has been conducted. Advise them of the importance of this, emphasizing that people may be highly infectious when they first come into contact with HIV, even though the first test may have indicated that they are not infected.
5. Inform the client who has had “window period” exposure that they require a further retest and based on the last risk behaviour advise them when to present for that re-test (give a date for re-testing).
6. Review the common means of how HIV infection is transmitted and how transmission can be prevented. Review the clients decisions about a personal risk reduction plan.

Providing HIV Positive Test Results

After seating the client and confirming that they are ready for their results simply explain the result is HIV positive. The results should be given promptly and then allow time for the news to sink in. The counselor should help the client to regain a sense of control by helping them to:

* Freely express their anxiety and fears.
* Feel more secure by being warm and maintaining a calm presence.
* Explore exactly what it is that seems overwhelming.
* Break down the problems into manageable aspects and set priorities.
* Help client to develop an action plan for coping.

The steps to follow are:

1. Be aware of non-verbal communications when calling client to the counselling room from the waiting room.
2. Check client details.
3. Be direct e.g. *“I need to tell you that your result has come back positive and that means the HIV virus has been detected in your blood, which means you are infected with the virus”*
4. Provide some silence and time for the client to absorb the news.
5. Make a gentle enquiry *“I’m wondering what you’re thinking or feeling right now…”*
6. Encourage ventilation of emotion (normalize).
7. Check the client’s ability to cope emotionally, assess for possible self-harm (suicide) or of the client threatening harm to others.
8. Provide brief information about
   1. Follow-up and support available
   2. Provide contact number of the C-M VCT center, hotline telephone number if available in the area
   3. Incase of emergency go to the nearest hospital
   4. Provide a back-up to verbal information about diagnosis with written information. E.g. IEC materials.
9. Assist client with concrete planning
   1. Planning to reduce HIV transmission to others
   2. Address issues related to disclosure (who, what, when and why).
   3. Leaving the clinic e.g. consider how will a distressed client get home?
   4. Planning for the next 48 hours. This should include a follow up counselling visit if possible.
10. Offer all clients testing positive an appointment for Essential Package of Care services.
    1. If these are available the same day, this is best.
    2. Some clients may not be ready and may need some time before this step, but an appointment date should always be given.
    3. It is extremely important to emphasize that there are things that the client can do to live a longer, healthier and normal life. Getting regular check-ups by a provider with knowledge in HIV is one of them. There are preventative medicines that can extend life and in most parts of the country ART is available, which can treat, although not cure, HIV.
11. Remember to ask if the client has any further questions.
12. Ask clients to write future questions down that arise between visits.
13. Provide referrals as required

**This SOP has been read and understood by:**

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