NATIONAL GUIDELINES FOR HIV COUNSELING AND TESTING

Ministry of Health
Royal Government of Bhutan

About the guideline: The National HIV Counseling and Testing guidelines was prepared in line with the WHO and UNAIDS latest recommendations, other global and national best practices and then national field experiences to provide the practical guidance to the health workers and the trained lay-providers.

This guideline embraces the core principles of HIV counseling and testing to provide comprehensive HIV testing services to the Bhutanese populations. This guideline also contains the latest updates on the new testing approaches such as self-testing and community-based testing including the index testing for partner notification.

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FOREWORD

The Department of Public Health, Ministry of Health is pleased to publish the National Guidelines for HIV Counselling and Testing (HCT). The revision of the guideline is in line with the vision of ending AIDS as a public health threat in Bhutan and also to update the latest scientific information and strategies on HCT. The Ministry of Health has accorded high priority on HCT services since the beginning of the HIV epidemic in the country to enhance the case diagnosis on a timely basis.

This guideline provides comprehensive guidance on new HIV testing strategies to the health workers, clinicians and other relevant stakeholders for the uniform application and implementation of HCT services across the health centres and other settings. The guidelines outline differentiated HIV testing services as a core approach to intensify the HIV Counselling and Testing services. The differentiated HIV Testing services encompass facility-based testing, community-based testing and HIV Self-testing. Such approach is very important to diversify the HCT services to reach the unreached key populations like MSM, transgender person, female sex workers, Injecting Drug Users (IDUs) and other vulnerable populations who are at higher risk of HIV acquisition and transmission.

The national guidelines are based on the latest WHO and UNAIDS guidelines and other scientific evidence gathered through in-depth literature review and field experiences. We hope this guideline will benefit the users to provide prompt HCT services in the most appropriate means by following the core principles of HCT services. The HCT is the only means to end the AIDS epidemic by 2030 as envisioned by the world as it is the gateway for care, support and treatment.

(Dr, Pandup Tshering)
Secretary
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ACKNOWLEDGEMENT

The National HIV/AIDS and STIs Control Program (NACP) under the Department of Public Health would like to express our deep gratitude to WHO, UNAIDS and the National Technical Advisory Committee (TAC) for their technical support amid the COVID-19 pandemic. We also would like to thank all those who have attended the national stakeholder consultation meetings for the valuable feedback.

We also remain thankful to the Communicable Disease Division and the Department of Public Health for their unwavering support in this endeavour. The requirement of good coordination and cooperation from all the stakeholders is found to be critical to complete the development of guidelines on time.

We are optimistic that the guidelines will help all those engaged in providing the HIV Counseling and Testing Services more effectively to meet the national goal of 95-100-95 by 2025 to end the AIDS epidemic by 2030.

(Lekey Khandu)
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LIST OF ABBREVIATIONS

HCT:	HIV Counselling and Testing
PrEP:	Pre-exposure Prophylaxis
ANC:	Antenatal Care
HIV:	Human Deficiency Virus
STI:	Sexually Transmitted Infection.
TB:	Tuberculosis
NGO:	Non-Governmental Organization
HTS:	HIV Testing Services
MSM:	Men having Sex with Men ‘
FSW:	Female Sex Worker
TG:	Transgender
IDU:	Injecting Drug Use
OST:	Oral Substitution Therapy
PLHIV:	People Living with HIV
VCT:	Voluntary Counseling and Testing
HISC:	Health Information and Service Center
PIHCT:	Provider Initiated HIV Counseling and Testing
CBT:	Community-based Testing
RDT:	Rapid Diagnostic Test
HIVST:	HIV Self Testing
NRL:	National Reference Lab
EPOA:	Enhanced peer outreach approach
ART:	Antiretroviral Therapy
RCDC:	Royal Center for Disease Control
IEC:	Information Education & Communication
PEP:	Post Exposure Prophylaxis.
CD4:	Cluster of Differentiation 4
VL:	Viral Load
LFT:	Liver Function Test
RFT:	Renal Function Test
EID:	Early Infant Diagnosis
ELISA:	Enzyme-linked Immunoassay
EQAS:	External quality assessment scheme
EQA:	External quality assurance
DHIS-2:	District Health Information System 2.

BACKGROUND

Since 1993-until Dec 2020, of the estimated 1300 HIV cases, the Ministry of Health has diagnosed 741 (384 male and 357 Female) Cases. However, we still need to find 559 missing cases to bridge the current detection gap of 43%. Like many other countries in the region, the majority (70%) of the reported HIV cases in Bhutan is between the age range of 25-49 years old while 14% are between 15-24 years old and the remaining 5% below 15 years of age and then 10% above 50 years. This shows that HIV in Bhutan has primarily affected the most economically productive age group. About 93.9% of them have acquired HIV infection through the heterosexual route, 5.3% from mother to child transmission (MTCT), 0.4% each from Injecting Drug Use and blood transfusion (Outside Bhutan).

HIV Testing and Counseling is the gateway to care, support and treatment. Therefore, making high-quality HIV testing services accessible to key and vulnerable populations is critical to prevent further transmission from the source by initiating early treatment. The first voluntary and counselling guidelines were developed in 2006 and since then the guideline was not revised despite many changes that occurred in the area of HIV testing services. As a result, the revision of these guidelines was initiated to ensure that all the important recommendations of 2019 WHO consolidated guidelines and other global best practices relevant to Bhutan are well adapted.

The need to consider the recent development in HIV testing services has become crucial to overcome the current testing gap in the county. Today despite the testing facilities available in all the hospitals, primary health care centres, Health Information and Service Centers (HISC) and private diagnostic clinics many of the people are still not coming forward for testing. The ultimate reason could be because of fear and stigma associated with HIV which should not be the case in today's world because HIV/AIDS can be treated well with the best treatment options available in the county. To find those missing HIV cases innovative testing approaches like HIV Self-testing, community-based testing and index testing for partner notification has become critical for reaching the unreached populations.

1. HIV COUNSELING AND TESTING SERVICES

1.1. Overall Goal

- To identify People Living with HIV (PLHIV) at the earliest possible to link them for timely care, support and treatment.
- To facilitate behavior change and prevent the acquisition and transmission through appropriate HIV prevention services such as pre-exposure prophylaxis (PrEP), Post Exposure Prophylaxis (PEP), harm reduction services and access to condoms and lubricants.

1.2 Objectives

- To guide the implementation of the differentiated HIV Counseling and Testing Services (HCTS) across the health facilities and at the community level.
- To guide the different testing strategies and algorithms for effective diagnosis of HIV.
- To guide the implementation of the HIV/Syphilis dual testing as the first test in ANC.

1.3 Intended audience

- This guideline is meant for those engaged in providing the continuum of HIV prevention, care and treatment services at the national program, district health sectors and primary health centres.
- This guideline will also assist those working in the areas of prevention and control of STIs and viral hepatitis including TB at the national and district level in providing the comprehensive package of integrated prevention services.
- These guidelines can also be used by the community-based organizations and NGOs and private partners working in the areas of HIV prevention and control for early diagnosis and linkage to care and treatment.

1.4 Guiding principles

All HTS approaches should adhere to the WHO 5 Cs: Consent, Confidentiality, Counselling, Correct test results and Connection (linkage to prevention, care and treatment services.

- **Consent:** All those coming forward for HIV Testing Services (HTS) Clients must provide informed consent to be tested and counselled. Verbal informed consent is sufficient and no written consent is needed. They should be informed of the process, and of their right to decline to test. Mandatory testing is not recommended at all. There should be no coercion for HIV testing from a health-care provider, or a partner/family member or community counsellors and outreach workers. The community-based testing services provided by the trained lay community members to their key population networks like MSM, TG, Female Sex Workers (FSWs) and Injecting Drug Use (IDUs) should also be voluntary.
- **Confidentiality:** All the information collected should be kept confidential and should not be shared with anyone without the consent of the client. Although confidentiality always needs to be respected, it should never reinforce secrecy, fear, shame or prejudice. Counsellors should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with a partner or family member, or trusted others is often highly beneficial. All PORW, HISC staff and others who has access to HIV client information must sign an, "Confidentiality agreement with the MoH"
- **Counselling:** The good-quality pre-test information and post-test counselling can be given in group but people should have the opportunity to ask questions in a private setting if they request it. All HIV testing must be accompanied by appropriate and high-quality post-test counselling, based on the specific HIV test result and HIV status reported.
- Correct test results: Quality assurance mechanisms, supportive supervision and a mentoring system should ensure that people receive a correct diagnosis. All these services need to be in place to ensure the provision of high-quality testing and counselling services. Unless it is confirmed by quality assured laboratory, the test should not be treated or declared as a confirmed case.
- **Connection:** All HIV services should have a linkage to prevention, care and treatment services. All positive clients should be linked to treatment and care preferably within 24 hours . Partner notification and testing services should be offered to all HIV-positive clients. Those with negative results should also be connected to prevention services like behavior change counselling, and access to condoms and condom-compatible lubricants. For the PrEP, PEP, opioid substitution therapy (OST) and others it should be based on identified key population as per the community-based HIV prevention and national treatment guidelines.

1.5 National HTS standards

- In general, all HCTS must be conducted following the WHO's 5 Cs (Consent, confidentiality, Counseling, Correct test result and Connection (linkages to prevention, care and treatment)
- All the Health Care Workers engaged in providing HCT must be well trained on all aspects of HCTS including the treatment and management of PLHIV.
- All the identified laymen providers from the community must also be adequately trained on the HCTs and basics about the treatment and management of the PLHIV.
- All the testing centres should have standard operating procedures (SoPs) and an ethical code of conduct.
- Voluntary HIV partner notification should be implemented among all the positive HIV persons .
- All HIV positive diagnosis should be based on confirmation from the national reference lab based on the standard national testing algorithm of this guide book.
- All HIV positive cases and those HIV-negative and at ongoing risk also need to be tested and linked to appropriate prevention services.

2. DIFFERENTIATED HCTS DELIVERY APPROACHES

2.1 Facility-based HCT services

Voluntary Counseling and Testing (VCT) Services

The VCT is the older model of HCTS delivered in the health facilities and standalone Health Information and Service Centers (HISCs) for a key and vulnerable population and still considered an essential part in the prevention and control of HIV and other STIs. Although this model doesn't necessarily generate demand for HIV and other STIs testing as providers have to wait for the client to initiate testing by themselves. However, it should be recommended as an option for the people to know their status for timely prevention, care and treatment services.

The VCT should be provided to all those walk-in clients who initiate HIV testing by themselves irrespective of the type of testing centres (health facility, non-health facilities like community centres and outreach mobile testing) following the standard HCT principles and ethics.

Provider Initiated HIV Counseling and Testing Services (PIHCT)

The PIHCT is one of the important entry points for HCT services and is routinely offered at clinical sites initiated and recommended by the service providers. Under this model, HCT is recommended to all adults and adolescents seen in all health facilities. This should be initiated after health workers explain to the clients on the importance of HIV testing and clients voluntarily provide verbal informed consent.

This applies to medical and surgical services, standalone HISCs, inpatient and outpatients' settings, mobile or outreach medical services including the private diagnostic clinics. The PIHCT services are offered to the following priority populations;

a. Medical inpatients, outpatients and emergency services in the hospitals.
b. ANC Attendees (ANC-first and last trimester and also during the PNC)
c. STIs, Viral Hepatitis and TB patients
d. Patients undergoing invasive surgical procedures
e. Patients undergoing endoscopy
f. Patients with unexplained symptoms
g. Blood donors
h. Sero-discordant couples
i. Key and vulnerable population screening based on individual willingness (VCT) through mobile outreach medical camps, surveillance and community-based testing.

2.2 Community-based HCT Service

The community-based testing (CBT) services is a new model where health workers and trained laymen/women from the defined communities belonging to the specific high-risk key populations like female sex workers, MSM, TG and IDUs performs the HCTS outside the health centres. The CBT services are provided through mobile outreach and in-reached services at the venue based (entertainment centres like Drayang, karaoke, discos, bars and other mapped hotspots including the key population events). Under the CBT the trained lay providers will implement the community-led testing following the "test for triage" strategy (Figure 1) among the defined high-risk key populations. For a detailed CBT process, refer to the Comprehensive Service Package Guidance document, Annexure: SOP for CBT.

a. As Bhutan is in low burden settings, community-based HIV testing services are recommended for key populations, with linkage to prevention, treatment and care services, in addition to routine facility-based testing.
b. Combine community-based HTS with testing of other STIs based testing to achieve high testing uptake.
c. For the greatest impact, community-based HTS needs to be focused on populations and settings with the greatest unmet testing need

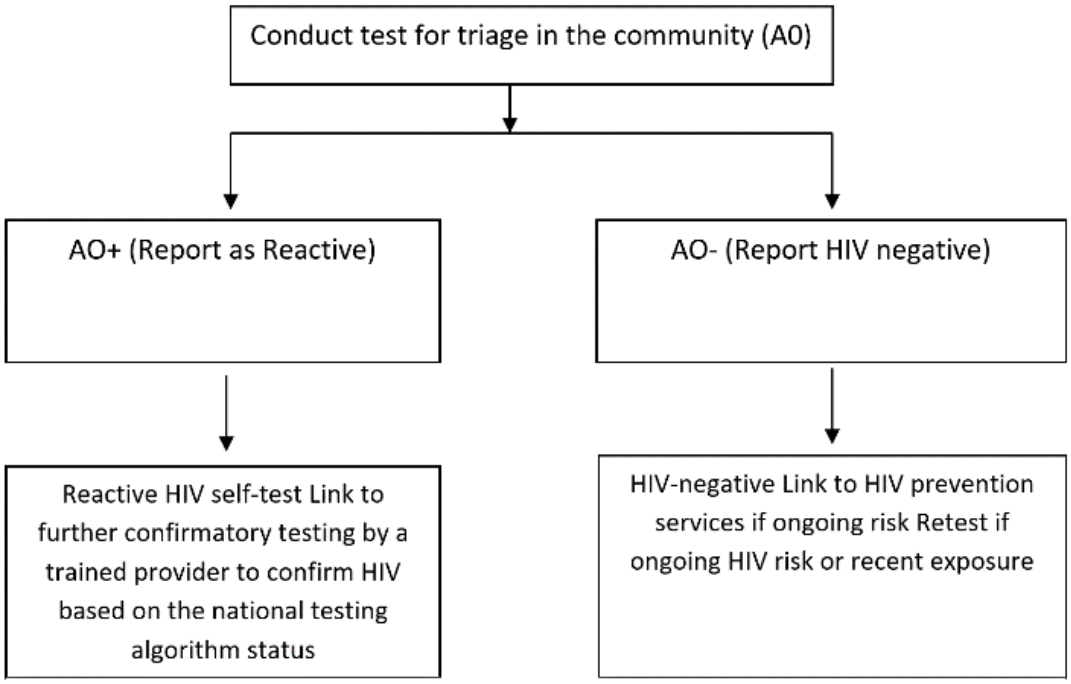


Figure 1. Test for triage-community-based HIV testing

Procedure

- Health workers conduct a single HIV rapid diagnostic test (RDT) referred to as A0 (assay 0) using the blood-based or oral-fluid-based testing kits.
- Trained lay provider conduct a single HIV rapid diagnostic test (RDT) referred to as A0 (assay 0) using the oral-fluid-based testing kits but under certain condition, blood-based will be allowed using defined rapid test kits (e.g., rapid finger prick test kit) by the NACP.
- In the case of laymen/women providers, the clients with reactive test results (A0+) should be referred and accompanied to HISCs/nearest health facilities for confirmatory testing by trained HISC Counselors or laboratory personnel as per the national testing algorithm.
- Clients with non-reactive test results (A0-) should be recommended for re-testing based on the risk factors identified including the window period and then subsequently referred to prevention services.
- All sites providing community testing services (CBT/CLT) should participate in the quality assurance (QA) mechanism conducted by the national reference laboratory.

2.3 HIV self-Testing

HIVST is a process in which a person collects their specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets their results, when and where they want. [1] However, In Bhutan's context, HIVST result interpretation will always be assisted by the trained HIV Counselors from the HISCs or other health centers with complete assurance of the client's confidentiality using the appropriate protocol. The HIVST can be implemented either of the following means based on the standard national HIVST algorithm (Figure 2). There is a separate SoP for community based-testing and reference to it is highly recommended.

a. **Assisted HIVST**: Refers to where CBT counselors and designated staff at HISCs will be trained to provide HIVST. Staff will provide KPs an in-person demonstration before or during HIVST on how to perform the test and interpret the test result. This approach can be used to support self-testers who consent to allow assisted services.
b. **Unassisted HIVST** refers to when a client self-tests for HIV and uses an HIVST kit with instructions for use provided by the manufacturer/ national program without the help of CBT counselor or staff designated at HISCs. Depending upon the preferences of the HIVST, the ORW will deliver or decide the venue, time and schedule of delivery or testing and referral systems and contact points. The client should get in touch with the HISC Counselors for result interpretation after the conduct of the self-test in a private setting.

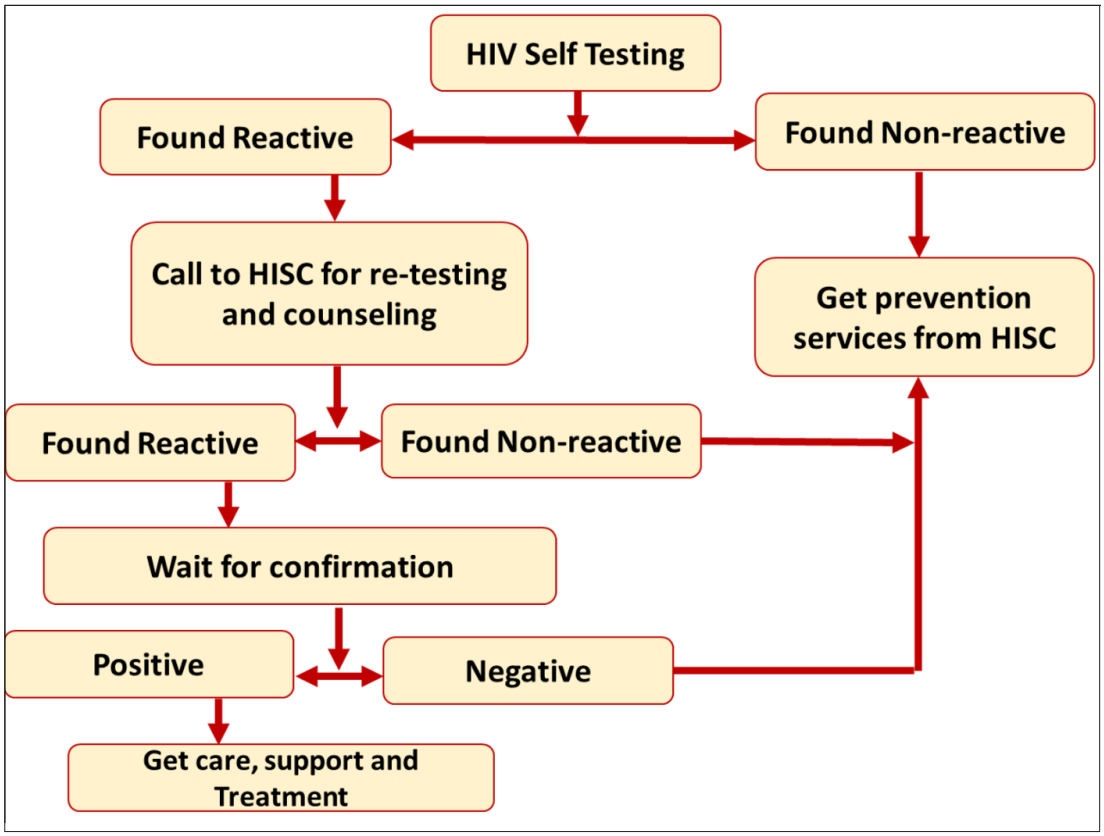


Figure 2. HIV Self testing algorithm, NACP, Ministry of Health

Procedure

- Provide pre-test information and let clients decide on assisted or unassisted HIVST.
- For unassisted HIVST, demonstrate on how to use Oraquick® and also show a video on how to use and also provide relevant contact details of HISC or PORW.
- For assisted HIVST, Health workers and trained POWR providers conduct a single HIV rapid diagnostic test (RDT) referred to as A0 (assay 0) using oral-fluid-based testing kits. Oraquick® is currently registered with the Drug Regulatory Authority of Bhutan and is being approved.
- The clients with reactive test results (A0+) should call HISC/Health Centers for re-testing and counselling. If possible, PORW can accompany the client for support and testing. The re-testing to be initiated using the blood-based rapid HIV test kit by the HISC/VCT or trained health workers.
- If the re-testing is found reactive (A1+) then refer for confirmation at the national reference lab.

- If the confirmatory test result from the national reference laboratory is positive then interpret the result as true positive and link the HIV diagnosed person to appropriate care, support and treatment.
- A non-reactive or negative result should link them to prevention services and re-testing is recommended for those at ongoing risks, such as people from key populations and those reporting potential HIV exposure in the preceding 12 weeks/three months (window period).
- All sites providing HIVST should participate in the quality assurance (QA) mechanism conducted by the National Reference Lab (NRL)

2.4 Quality Logistics Management

Effective Procurement and logistics management cycle is a key to success of extended HCT services in the country. Hence constant monitoring of the stock's availability, realistic forecasting and timely indenting of the test kits and other laboratory consumables are crucial in terms of delivering effective and timely HCT services.

Quality logistics Management refers to the adoption of uniform brand of test kits (as recommended by the technical evaluation committee) and following the same test principles as indicated in this guideline. The Private Diagnostic clinics can avail the test kits supplies from the same supplier (as with government) or may be different (but supplying the same test kits) based on their convenience. The Private Diagnostic Clinics can seek information about the supplier from the Medical Supplies and Procurement Division (MSPD) under Department DoMSHI.

3. INNOVATIVE HIV COUNSELING AND TESTING SERVICES

3.1 Index Testing for partner notification

The index testing for partner notification, or disclosure or contact tracing, is an approach to elicit only contacts of index case about their sexual partners and/or drug-injecting partners, biological children, or biological parents (if the child is index client) and, if the HIV-positive client consents, offers these partners HIV testing services.

Only these types of contacts can be counted as index testing and any other contacts who are referred should be counted as the standard HIV testing services. The evidence from current reported HIV cases in Bhutan shows that contact tracing stands the second highest mode of HIV case diagnosis. There are two types of partner notification as described below;

a) **Passive HIV/AIDS partner notification services:** Under this method, the HIV-positive clients are encouraged by a trained HIV Counselor to disclose their status to their sexual and/or drug-injecting partners by themselves, and to also suggest HTS to the partner(s) who are exposed to the index case.
b) **Assisted HIV partner notification service:** This is an approach where consenting HIV-positive clients are assisted by a trained HIV Counselor to disclose their status or to anonymously notify their sexual and/or drug-injecting partner(s) of their potential exposure to HIV infection. The HIV Counselor then offers HIV testing to these partner(s) through the following three different approaches;

- Contract referral: HIV-positive clients enter into a “contract” with a trained HIV Counselor and agree to disclose their status and the potential HIV exposure to their partner(s) by themselves and to refer their partner(s) to HTS within a specific period.
- Provider referral: With the consent of the HIV-positive client, an HIV Counselor confidentiality contacts the person’s partner(s) directly and offers the partner(s) voluntary HCTS.
- Dual referral: A trained HIV Counselor accompanies and provides support to HIV positive clients (Index case) when they disclose their status and the potential exposure to HIV infection to their partner(s). The provider also offers voluntary HTS to the partner(s).

Note: If the index case failed to notify their contacts within 30 days then the counselors will initiate contact tracing without involving index case

- If clients don’t disclose their partner at all excluding the spouses……
- Clients threatening the counselors….

3.2 Steps for Index Partner Testing Services

Step 1: Introduce Index Partner Testing Services to Index Patients/ Clients

- The trained HIV/AIDS Counselors need to schedule a good time with his or her HIV positive client to prepare for care and treatment services at the time of post-test counselling. Stress on the importance of ensuring that all partners get tested for HIV.
    - HIV-positive partners can start on HIV treatment to keep them healthy and reduce the risk that they will pass HIV to other sex partners and/or children.
    - HIV-negative partners can access HIV prevention services to help them remain HIV-negative, including condoms, pre-exposure prophylaxis (PrEP).
- If HIV positive client is ready for registering into the care and treatment then introduce case-based surveillance after the post-test counselling to carry out the detailed risk assessment of the client.
- Inform the index client that all information will be kept confidential and the provider need to ensure the following;
    - Partners will NOT be told the index client's name or test results.
    - The index client will NOT be told the HIV test result of their partner(s) or whether or not their partner (s) tested for HIV.
    - The counsellor will not contact the partner(s) without the permission of the index clients before 30 days.
    - If the contacts of the index case insist the HIV/AIDS Counselors to reveal the information as to how they are being traced for HIV testing, then the counsellors should mention that such interventions are based on the government policy.
    - The HIV/AIDS Counselor should know that revealing such information is not necessary as it is not going to benefit the contacts under any circumstances rather it should be considered a critical service for them.

Use Tool 1. Talking points for introducing partner testing services to index clients or patients. (Annexure-1). Tool 2. Index patient information form (Annexure 2).

Step 2: **Obtain a List of Sex/Needle Sharing Partners**

- Carry out the detailed risk assessment using the standard guidelines of the case-based surveillance and list out the names and contact information following by asking the index case;

- All the sexual partners in the last 3 months and above
- All the injecting drug use partner(s) in the last 3 months and above.
- All the biological children.

- Use the partner elicitation form (Annexure 3) to record all the partner(s) names.
- For each named partner, complete a partner information form (Annexure 4) to record the partner's contact information, to Screen for Intimate Partner Violence (IPV), and to establish a plan for how each partner will be contacted.

Step 3: Screen for Intimate Partner Violence

- To protect the safety of the index client, partners who pose a risk of IPV may need to be excluded from partner notification services.
- Each named partner should be screened for IPV using the 3 screening questions on the Partner Information Form (Annexure 5). These questions include:
  - Has [partner's name] ever hit, kicked, slapped, or otherwise physically hurt you?
  - Has [partner's name] ever threatened to hurt you?
  - Has [partner's name] ever forced you to do something sexually that made you feel uncomfortable?

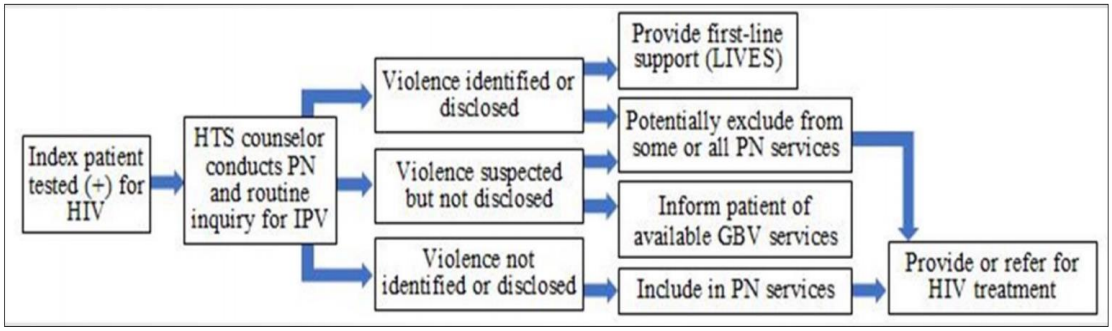


Figure 3. Steps for index testing (Adapted from partner notification: a handbok for designing and implementing programs and services of the JSI research & training institute, inc.

Step 4 & 5: Determine Partner Testing Plan and Begin Contacting Partner(s)

- Review the options for partner notification using the "Options for Notifying Your Partner about HIV Testing" card (Annexure 6).
- Document the chosen referral method for each listed partner on the Partner Information Form (Annexure 4)

Step 6: Record Outcome of Partner Testing Services

- Document the outcome of all partner testing attempts on the Outcome of Partner Testing Services Form (Annexure 5)
- If a partner was contacted, document who notified the partner, and the outcome of the partner testing service (e.g., whether or not the partner tested for HIV).
    - If the partner received an HIV test, document his or her HIV test result.
    - If the partner tested HIV-positive, record whether he or she has been initiated on ART.
- The HIV/AIDS Counselors should consider the window period of the contacts and follow up if necessary, for re-testing.

3.3 Summary of the index testing steps

(Adapted from (Adapted from partner notification: a handbook for designing and implementing programs and services of the JSI research & training institute, inc)

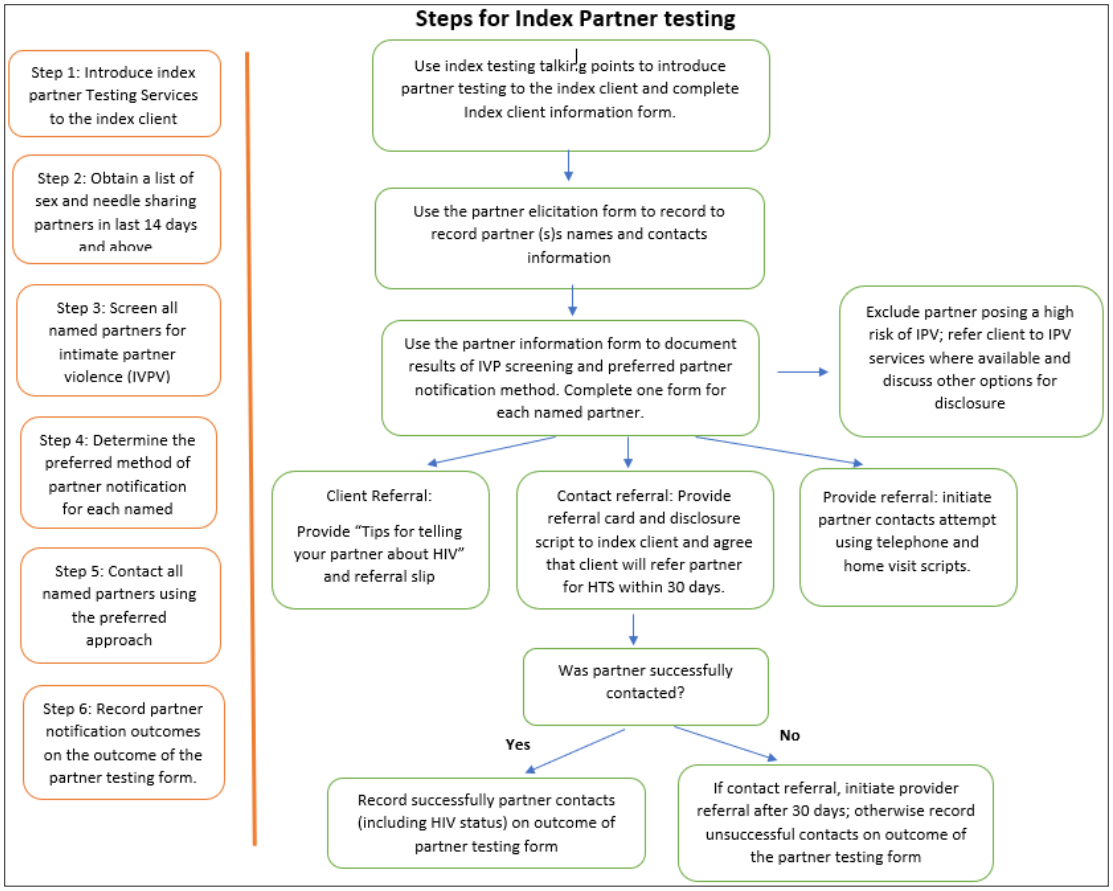


Figure 4. Steps for Index Testing for partner notification

4. ONLINE HIV COUNSELING AND TESTING

This is a new approach of reaching the key and vulnerable populations that are not able to come forward for discussion about HIV Testing and other STIs including sex, sexuality and gender in person. Social and self-stigma remains one of the strong reasons why many affected people refuse to show up for face-to-face consultation and registration. The web and mobile-based applications will reach those unaccounted HIV/AIDS population to gain access to services through virtual registration for online risk assessment, HIV counselling and ultimately to book the HIV testing online.

- An online risk assessment and reservation through a web application provides the most convenient means of assessing HIV, STI related risk, and locating services at a convenient date and time.
- The link of the web application can be shared with high-risk individuals and peers/partners/spouses of PLHIV through SMS or mobile applications (messenger, Viber, Imo, etc).
- Those reached online can be linked to offline programmes for HIV testing.
- Individuals reached online can also be linked to various testing strategies such as HIVST and test for triage.
- Social media platforms such as Facebook, Instagram, WhatsApp and Twitter can also be used for demand generation, education and counselling for testing through one-on-one chat.

5. ENHANCED PEER OUTREACH APPROACH (EPOA)

- The primary actors of the EPOA are community-based workers. These lay providers identify and recruit peer mobilizers (PMs) within their network in the community as seeds.
- Like the respondent-driven sampling (RDS) method or Peer Driven Sampling (PDS) used in research and surveillance and now used in outreach, PMs recruit peers exclusively from their hidden/hard-to-reach social networks.
- PLHIV are also offered and recruited as PMs/seeds to reach out to their partners/ spouses, and within their peer networks.
- Once a PM has exhausted the potential recruits in his social network, he/she will be replaced with a new PM, and in this manner, the EPOA continually refreshes the pool from which clients are drawn

Note: Cross reference to the comprehensive service package guidance manual, 2021 and CBT SoP, 2021 is recommended for more detail information.

6. PRE-TEST INFORMATION

Before it is called pre-test, counselling and was aimed at encouraging clients to return for their test results, providing risk-reduction counselling and preparing clients to cope with a potential HIV-positive diagnosis in the absence of treatment. However, with the availability of highly effective prevention and treatment options the detailed pre-test counselling is not required instead it will create a barrier to service delivery. Therefore, WHO recommends providing concise pre-test information to people testing for HIV. This communication should provide general information, answer clients' questions and offer an opt-out and opt-in option to test.

The pretest information can be provided to an individual or in the group and it may include the following key messages;

- the benefits of HIV testing and the implications of undiagnosed HIV.
- the meaning of an HIV-positive diagnosis and an HIV-negative diagnosis.
- benefits of early ART and the fact that people with HIV who achieve and maintain an undetectable viral load cannot transmit HIV sexually to their partners.
- the importance of telling the provider if one was previously diagnosed with HIV.
- the potential for incorrect results if a person already on ART is tested and the services available if those taking ART want further testing.
- the services available to those who test HIV-positive, including where ART is provided.
- the importance of disclosure and encouragement for partner testing.
- prevention options, including risk and harm-reduction information, that are relevant and available, focused on those at high ongoing risk.
- the confidentiality of the test result and any information shared by the client.
- the client's right to refuse testing and that declining testing will not affect the client's access to HIV-related services or general medical care.
- potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behaviour is stigmatized.

7. POST TEST COUNSELING

- Diagnosing individuals with HIV and facilitating their engagement in care and early ART initiation is the professional and ethical responsibility of testers and a primary goal of all testing services. Therefore, the counsellor should provide concise messages and effective supportive interventions tailored to specific populations and their situations based on their test result (Negative, reactive, indeterminate, positive) as highlighted below;

  Key points to remember
  - Check result, records on the HCT register
  - Provide results to the client in person.
  - Be aware of how you call the client for the result.
  - Be calm when you call the client in for the result
  - Be direct in giving the result
  - Explain the results (reactive, positive indeterminate, and negative)
  - Provision of the written test result is not advised

7.1 Post-test counselling for the rapid reactive result

- Explain adequately what does the rapid reactive result mean to the client to avoid any misunderstanding.
- If a test is done at the sites, then give reactive post-test counselling in a private place.
- If only samples were collected at the sites and the test is performed at identified centers and found reactive then provide reactive post-test counseling through the call if the client insists the test result otherwise follow with RCDC for confirmatory result and provide the post-test counselling at a go for either negative or positive result.

7.2 Post-test counselling for a negative result

- Re-check for possible exposure in the window period including any risks which may have occurred since pre-test counselling.
- Reinforce information about the HIV transmission, personal risk reduction plan and safer sex practices.
- Review and explore any constraints to the practice of safer sex, infant feeding issues if breast-feeding, and where appropriate safer injecting practices.
- If the client is unduly anxious and is not convinced with an explanation of the test result refer to a psychiatrist or appropriate specialist.
- Provide IEC material e.g., leaflet, booklet etc.

7.3 Post-test counselling for confirmed HIV positive cases .

- Confirm if the client is ready to collect the test result (in a good frame of mind)
- Allow enough time for results to sink in
- Let the client acknowledge their fear
- Manage their emotional responses (crying, anger, denial, or no response)
- Never drive yourself by a client's emotions instead be calm and listen to what clients say without any interruption.
- Encourage the client to ask any questions
- Clarify any misinformation about the meaning of the result and its implications
- Assess support available for clients
- Assess client ability to cope with test results.
- Discuss short term arrangement for leaving the centre and getting back home.
- Reinforce information on disclosing status to the partner.
- Reinforce information on health, rest, diet, safer sex, and exercise and infection control issues.
- Assess for any possible self-harm ideation and provide necessary interventions
- Ask the client if they have any questions
- Offer follow up session
- Reinforce the importance of care and treatment

8. LINKAGE TO HIV PREVENTION, CARE AND TREATMENT

Any individual entering into the HIV Counseling and Testing (HCT) is subject to overcome three key test results such as reactive, negative, and positive. Irrespective of these test results and their HIV status appropriate linkage to prevention, care and treatment are very important in the overall continuum of care.[1] Without ensuring proper linkage to onward services being tested and learning one's HIV status have limited value. Therefore, linking to onward services is one of the crucial roles of the counsellors and community outreach workers for greater program impact.

8.1 Linkage to Prevention

- All those who are tested non-reactive/negative and are at continuing risk needs to be provided with HIV prevention services such as re-testing for confirmation of one's HIV status, the importance of using lubricants and condom and other preventive measures like PrEP and PEP for those high-risk populations.
- The provision of the PrEP and PEP should be as per the national HIV treatment guidelines.

8.2. Linkage to care

- Those whose reactive test result during the mobile and community-based testing also need to be linked to further HIV testing to confirm their HIV status and accordingly connect to appropriate services.
- All those diagnosed with HIV should be provided with comprehensive post-test counselling services.
- Implement the case-based surveillance to determine their risk behaviour through risk profiling to understand the source of infection and their sexual and injecting drug use partners including biological children, or biological parents (if the child is index client).
- Based on the result of the case-based surveillance conduct the index testing as per the index testing guidelines prescribed in this guideline.
- At the time of the case-based surveillance all the care services such as CD4 and VL testing including other basic laboratory examinations like LFT and RFT etc. needs to be completed as per the national treatment guidelines.

8.3. Linkage to Treatment

- The ART treatment needs to be initiated immediately alongside the other care services highlighted under linkage to care irrespective of the CD4 count of the client.

- Any diagnosed PLHIV who is not ready for linking to care and treatment must be supported to relink to ART services at the earliest possible within 30 days or earlier through proper counselling. Following are the likely people who may need re-linking to ART services.
- People diagnosed with HIV before the “treat all” era who never started treatment;
- People who were offered ART but who were not yet ready to start; and
- People who started ART but later discontinued.
- Counsellors need to assess the need of these people for re-testing and other laboratory investigations based on the CD4 count and VL test result for advance disease management.
- Those whose CD4 count is equal to or less than 200 cells/ml then the client requires advanced disease management which needs to be carried out as per the **national treatment guidelines**.

9. LABORATORY DIAGNOSIS OF HIV INFECTION (HIV TESTING)

HIV testing is one of the most important activities associated with HCT services because it is the gateway to prevention, care, support and treatment services. It is proven that people's knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of the HIV response.[4]

9.1 The benefit of early diagnosis and treatment

- To know HIV status on time and can help to reduce their risk behaviors for acquisition and transmission of HIV and STIs.
- For those diagnosed with HIV and STIs will get timely care, support and treatment.
- Appropriate treatment and timely intake of drugs will give good treatment outcome:
    - Reduce HIV in your body
    - Improve your body immune system
    - Prolong your life
    - Prevent further transmission

9.2 Risk of non-compliance to treatment

- Poor treatment outcome
- Increased onwards transmission of HIV from the source
- High chances of drug resistance
- Second-line drugs are very expensive and have more side effects compared to first-line drugs.

9.3 Types of HIV viruses

There are two main types of Human Immunodeficiency Virus (HIV)– HIV-1 and HIV-2.

- HIV-1 is most common and infectious while HIV-2 relatively uncommon and less infectious but both have the potential to cause AIDS if left untreated.[5,6] The HIV-2 virus is concentrated in West Africa but has been seen in other countries with links to West Africa.
- There are tests widely available and sensitive to both types of viruses but only one antibody test currently available can specifically distinguish between antibodies to HIV-1 or HIV-2.
- Both HIV-1 and HIV-2 have multiple groups within them. Those groups branch out even further into subtypes or strains.
- The strains of HIV-1 can be classified into four groups.[7] Of these, M is the 'major' group and is responsible for the majority of the global HIV epidemic.[8]

9.4 Types of HIV Tests

- There are two main types of HIV tests: antibody/antigen tests and virologic tests. Antibody/antigen tests look for antigens or antibodies against HIV; they do not detect the virus itself.
- When HIV enters the body, it infects white blood cells known as T4 lymphocytes or CD4 cells. The infected person's immune system responds by producing antibodies to fight the new HIV infection the presence of the antibodies is used to determine the presence of HIV infection.
- The most recent fourth generation Immunoassays are capable of detecting both HIV viral antigens and antibodies to HIV virus unlike earlier generations of assays that could only detect antibodies developed against the virus. Virologic tests determine HIV infection by detecting the virus itself. Enzyme-linked immunoassay (ELISA) for 18 months and above and then PCR-RNA test for Early Infant Diagnosis (EID).

9.5 Phases of HIV infection

The detection of HIV infection depends on the presence of antibodies and virus component, which depends on the days since the initial infection. The following are different phases of HIV infections;

a. **Eclipse period.** This period refers to the period of about 7–10 days following HIV infection, during which currently available assays cannot detect any marker of HIV infection. The end of the eclipse period is marked by the appearance of HIV RNA or DNA, detectable by nucleic acid testing (NAT) or then HIV p24 antigen, detectable by immunoassay. After a week of detection of HIV antigen in the blood, HIV antibodies appear in the blood and antibody-based assays can detect HIV infection.
b. **Acute HIV infection**. Acute HIV-1 infection is the phase of HIV-1 disease immediately after infection, which is characterized by an initial burst of viraemia; HIV-1 RNA or p24 antigen is present.
c. **Window period**. The period between HIV infection and the detection of HIV ½ antibodies using immunological assays is the window period. This signals the end of seroconversion period. The window period for a 4th generation antigen/antibody test is about four weeks. By this time 95% of infections will be detected. There is a three months window period after exposure, for the confirmatory result to detect more than 99.9% of infections. Revise/validate the test kit and window period (21 to 3 months).
d. **Recent infection.** Any infection detected within six months of exposure is considered a recent infection.

9.6 Selection of HIV Testing Strategies

The selection of testing strategies takes into account the scientific validity (accuracy) of the test. The two measures used are sensitivity and specificity.

Sensitivity: is the probability that a test will be positive when the infection is present. For example, if a test is 99 percent sensitive, 99 of 100 HIV positive people will correctly test positive, and one person will falsely test negative.

Specificity: is the probability that a test will be negative when the infection is not present. In other words, if a test is 99 percent specific, 99 of 100 people who are not infected will correctly test negative, and one person will falsely test positive.

An antibody test is rarely 100 per cent sensitive and 100 per cent specific. Therefore, UNAIDS, WHO and the CDC recommend that all positive tests results be confirmed by retesting, preferably by a different testing method.

9.7 Type of test kits

Table 1. Test/diagnostic kits used in the national algorithm

Test stages	Test kits	Level of facility
Assay 1	Rapid blood based	Primary testing center
	Rapid Oral Swap (OraQuick)	Community-based testing centers.
Assay 2	Gelatin particle agglutination test (GPA)	Confirmatory testing centre
Assay 3	4th Gen.ELISA (HIV 1/2 Ab/Ag)	Confirmatory test centre.

9.8 Sample Collection and Transportation

There are two sample collection procedures based on the current rapid test kits supplied in the health centres, standalone HISCs and other community-based testing centers.

a. **Whole blood through venipuncture**
   - Clean the skin area with a spirit cotton swab
   - Collect 3-4 ml of venipuncture blood
   - Keep the whole blood sample at room temperature for overnight to get clear serum if there is no centrifuge.

- If the centrifuge is available at the site keep the whole blood sample at room temperature for about 20-30 mins to clot and then carry out the serum separation without having to wait for a day to deliver an instant result.

b. Whole blood through finger pricking

- Choose the fingertip of the ring finger
- Clean fingertip with alcohol cotton swab
- Use a new lancet and press the lancet against the finger and puncture the skin
- Apply pressure gently
- Touched the EDTA capillary pipette to draw 50 ul of blood each for HIV, Syphilis and HBsAg.
-

9.9 Testing procedure

- All samples are tested for HIV antibodies using rapid diagnostic (determine HIV 1/2 test) kits as a first-line test (screening test).
- All non-reactive (negative) samples are reported as negative.
- All reactive samples coming from the private diagnostic clinic and onsite community-based testing should be re-tested at the HISC/health centers and if found reactive then refer the sample to the national reference lab for a confirmatory test. Follow the national testing algorithm.
- All reactive samples at the primary health centers and hospitals should follow the national testing algorithm.

9.10 Test results interpretation

Test results	Meaning of test result
Negative Results	HIV antibodies were not detected in the person's sample, either because the person is not infected or because the person is still in the window period.
Positive Results	Antibodies to HIV were detected in the person's blood. It means the person is infected with HIV and he or she can transmit the virus to others if he or she engages in risky behaviors. It does not necessarily mean that the person has AIDS.
Indeterminate Results	The presence or absence of HIV antibodies could not be confirmed. This could be because the person is in the process of sero-converting; the person may have a prior medical condition that is affecting the test. In this case, the person is always asked to come back after six weeks for retesting.

9.11 The place to conduct HIV testing and counselling services

The table depicts the HIV testing services and level of health facilities including human resource needed.

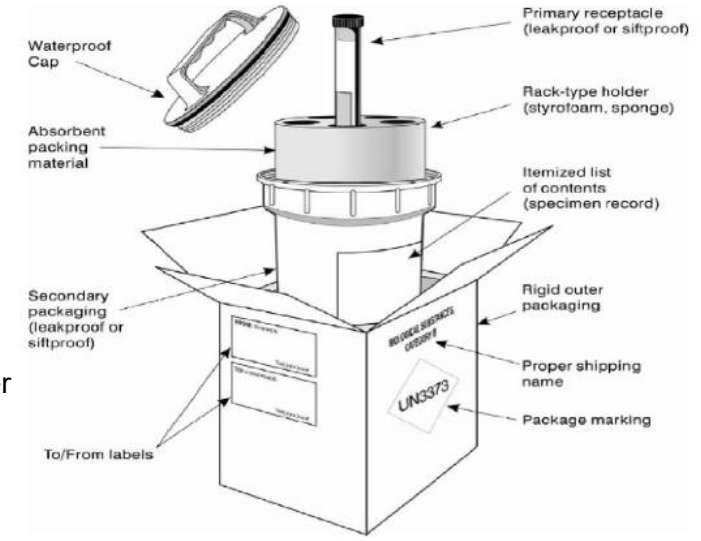
Health Facility Level	HIV Testing Services	Human Resource	Remarks
Royal Centre for Disease Control (RCDC)	• Rapid diagnostic test • Enzyme-linked immunoassay (ELISA) (4th Gen. Ag-Ab/ latest Assays). • PCR-RNA test for Early Infant Diagnosis (EID) • CD4 count • PCR-DNA for viral load estimation.	Laboratory Specialists, Laboratory Technologists, Laboratory Technicians	HIV confirmation is done at the National Reference Laboratory (PHL)
National/ Regional Referral Hospital	• Rapid diagnostic test • Enzyme-linked Immunoassay (ELISA) • CD4 count • HIV Viral Load Testing by Gene Xpert	Laboratory Technologists, Laboratory Technicians	
District/General Hospital	• Rapid diagnostic test • Enzyme-linked immunoassay (ELISA)	Laboratory Technologists, Laboratory Technicians	ELISA and CD4 count testing available hospitals located in strategic areas.
Hospital	• Rapid diagnostic test	Laboratory Technicians	
Primary Health Care	• Rapid diagnostic test	Trained Health Assistants, Basic Health Workers	
Health Information and Service Center (HISC)	• Rapid diagnostic test (Blood and Oral-based)	Trained counsellor (Health Assistant/ Basic Health Worker)	Includes mobile van, home-based, onsite and at the community centers. .
Community testing centers	• Oral-based	Trained CBT Counselors/laymen tester.	
Private Diagnostic Lab	• Rapid diagnostic test oral-based.	Laboratory Technicians	

9.12 Sample packaging and transportation

To ensure maximum accuracy of results on a timely basis the proper specimen collection, packing, handling and appropriate transportation system are necessary.

a. Materials used for packaging and transportation

- The triple layer packaging (ideal material) should be followed as far as possible while transporting the samples from one health canter to another or from the field to the national reference lab (Figure …)



  - **<u>Advantage</u>**Triple-layer container (WHO & UN recommended)
    - Durable
    - Efficient
    - Light
    - Safety
  - **<u>Disadvantage</u>**
    - Not readily available
    - Expensive
    - Need dry ice (not feasible)
- Cold box is also used for transporting heat-sensitive vaccines that ensures a predetermined temperature range (+2 to + 8˚ C) for a particular period.
- Considering the temperature range, availability and convenience cold box are also used for the shipment of biological samples in our system although not recommended by WHO and the UN for shipping biological substances.

b. Sample packaging

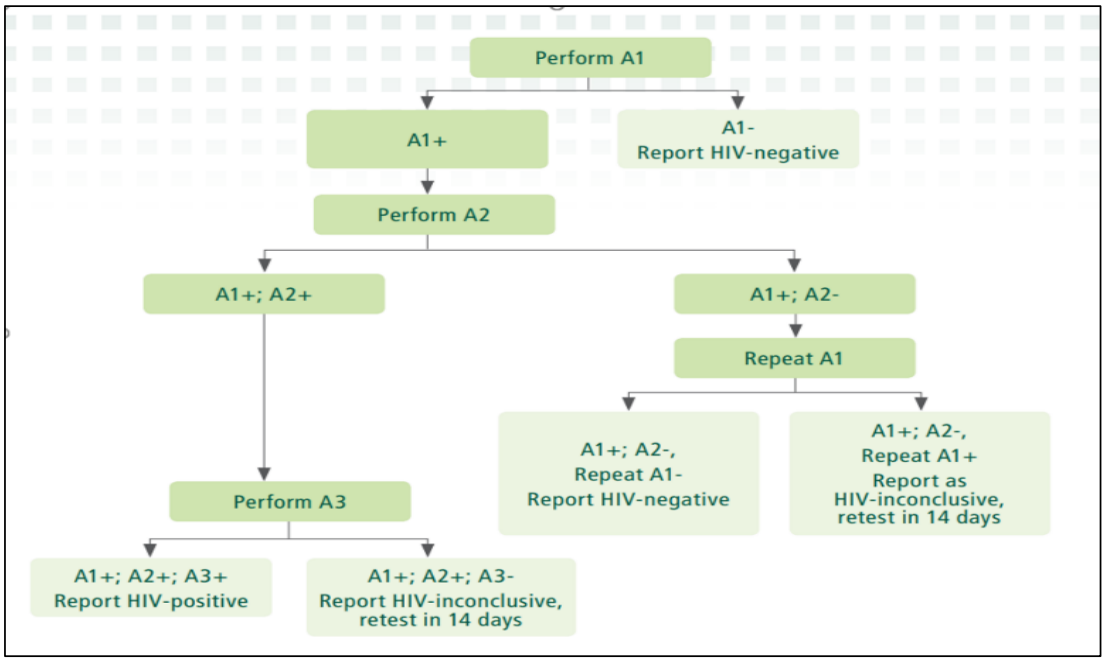
- Sample must be packed carefully to avoid sample breakage and leaks. Keep paperwork dry and separate from specimens.
    - The tube containing samples should be wrapped around with the tissue (absorbent).

- Paper, then tied with a rubber band. This is the primary container.
- It should then be placed in a zip lock bag which serves as the secondary container.
- In another zip lock bag enclose a completed “Sample ID Form” with each sample shipment, and/or include a packing list of samples (describing samples in-full, and matching tube labels) that specifies tests to be performed, as well as a brief current medical-history of the patient for records.
- The secondary container along with the Ziplock is then placed in the tertiary container (a cool-box/vaccine carrier with ice-packs). A set of four ice packs maintains refrigeration for up to 48 hours.

c. Sample transportation

- Before shipment, the package must be marked or labelled “**Biological Substance Category B**” on the outer package including the name, address and telephone number of a responsible person.
- Serum samples can be stored in the refrigerator (+2 – + 8°C) for up to one week only. Therefore, packed samples should be transported as quickly as possible in cold conditionsto the testing laboratory.
- Fresh frozen cold packs must be used at all times.

9.13 National HIV Testing algorithm for above 18 months.



- As per the recommendation of the WHO, Bhutan adheres to the three consecutive reactive test results to provide an HIV-positive diagnosis. Therefore, HIV testing and confirmation procedures will be as per the national testing algorithm of this guideline.
- All testing centres will use the standard operating procedures (SOP) for initial screening (A1) at their facilities using the rapid test kits or ELISA wherever feasible. The test will be repeated for all the initial reactive (IR) tests.
- If the repeat test is reactive the samples will be sent to the national reference laboratory for a confirmatory test (A2 and A3).
- All individuals are tested on Assay 1 (A1). Anyone with a non-reactive test result (A1−) is reported HIV negative.
- Individuals who are reactive on Assay 1 (A1+) should then be tested on a separate and distinct Assay 2 (A2).
- Individuals who are reactive on both Assay 1 and Assay 2 (A1+; A2+) should then be tested on a separate and distinct Assay 3 (A3).
    - Report HIV-positive if Assay 3 is reactive (A1+; A2+; A3+)
    - Report HIV-inconclusive if Assay 3 is non-reactive (A1+; A2+; A3−). The individual should be asked to return in 14 days for additional testing.
- Individuals who are reactive on Assay 1 but non-reactive on Assay 2 (A1+; A2−) should be repeated on Assay 1.
- If repeat Assay 1 is non-reactive (A1+; A2−; repeat A1–), the status should be reported as HIV negative.
- If repeat Assay 1 is reactive (A1+; A2–; repeat A1+), the status should be reported as HIV-inconclusive, and the individual asked to return in 14 days for additional testing.

9.14 Viral load testing and EID

It is strongly recommended that all HIV exposed infants, and all infants with unknown or uncertain HIV status should have an HIV virological test performed at 4 -6 weeks of age or the earliest opportunity thereafter. All infants with an initial positive virological test result should be started on ART without delay and, at the same time, a second specimen should be collected to confirm the initial positive virological test result.

To reduce the cost of virological testing, a serological test should be done for HIV-exposed infants and children aged 9 to 18 months. Only those with reactive serological assays should have a virological test to confirm HIV infection and determine who needs ART.

Table 2. The frequency for viral load and EID

Target population	Time of EID/VLT & Frequency
1. Exposed Children	Antibody screening at 18 months & EID as early as possible after the delivery
2. Pregnant Women	Baseline within 6 months and yearly thereafter
3. WHO clinical stage1-4	Baseline within at 6 months and yearly thereafter

Note: VL count >1000copies/mm^3 but CD4 count within the normal range without OIs.

Table 3. Summary of testing approaches for infants

Category	Test Provided	Testing Period/ Frequency	Service Availability	Action
Healthy, HIV exposed baby	Virological testing (EID)	• As early as possible after birth • Repeat after 4 weeks if negative	JDWNRH	Start ART immediately if positive but confirm with a second sample
Healthy, HIV exposed infant	Serological test (Rapid/ ELISA)	9 months and above	All health facilities	Repeat at 18 months if positive If negative, repeat once after one month and then only declare Negative
Healthy, HIV exposed baby	Serological test (Rapid/ ELISA)	18 months	All health facilities	For confirmation of HIV status

9.15 HIV-Syphilis Dual Testing

Much has been done to eliminate mother-to-child transmitted HIV but efforts are still needed for preventing congenital syphilis which leads to birth complications, stillbirths and neonatal deaths. To close the gap, the WHO recommends a single finger-prick rapid diagnostic test that screens for HIV and syphilis simultaneously. A dual test can be performed as Assay 1 for pregnant women at the antenatal clinic.

These simple tests can detect antibodies to both Treponema pallidum (the cause of syphilis infection) and HIV, using a single rapid test device and can be carried out in community health facilities. Dual testing could maximize its benefits, such as the

need to provide the service in community settings to reach pregnant women from key populations who are at heightened risk for both HIV and syphilis.

Advantages of dual testing;

- Rapid result
- Early treatment
- Cost effective
- Avoids repeat sampling
- Reduce storage and transportation costs, wastes.

Dis-advantages of dual testing;

Does not differentiate between active or past syphilis infection, a past syphilis infection may still produce a positive result. Any positive test result for Syphilis would require confirmation if the infection was recent and look for any evidence of **prior treatment** for the same.

The WHO recommends that any woman testing positive for syphilis be prescribed benzathine penicillin after a final, confirmatory diagnosis.

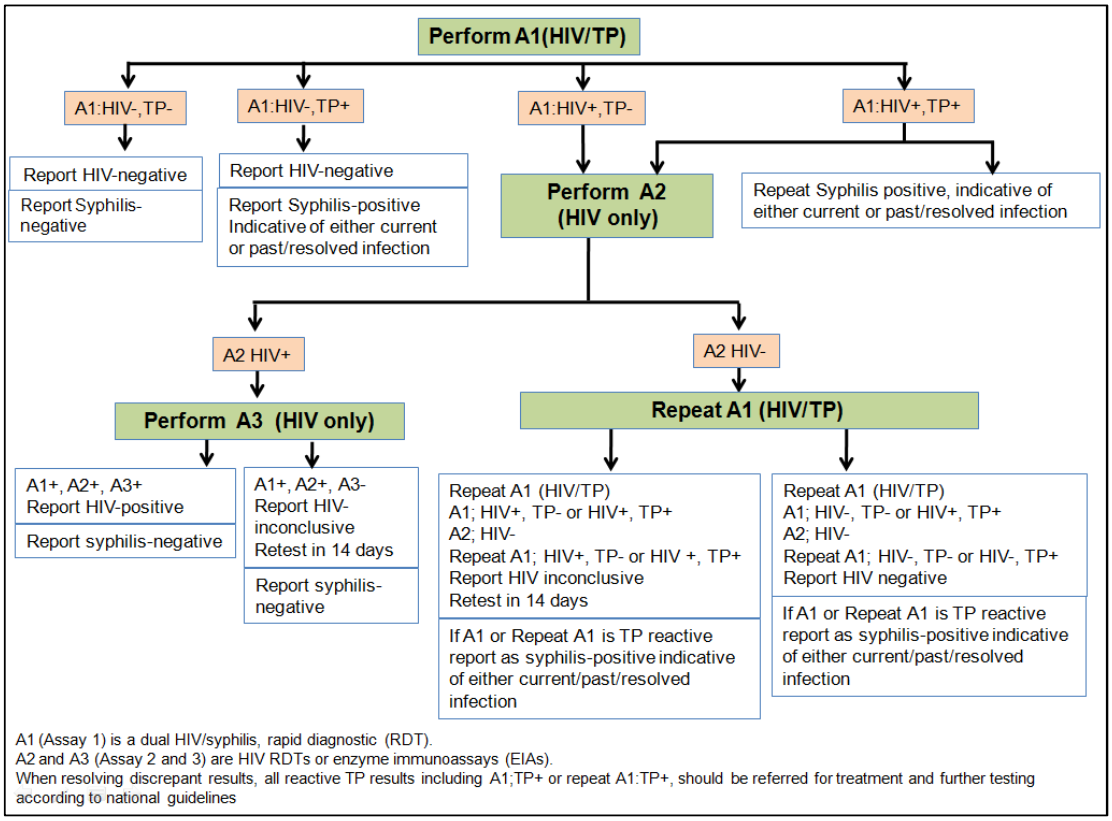
However, it is important to note that the dual test is not necessary for;

- Women living with HIV who are already on antiretroviral treatment
- Those with an existing syphilis infection which is being treated
- For testing for HIV

Sample collection and test procedure

Sample for the dual testing can be blood collected through venipuncture or a finger prick performed in the same way for screening HIV, following standard procedures for blood samples collection. However, it is recommended that manufacturer's instructions are adhered to in order to ensure reliable test result.

Dual testing Algorithm



Figure

9.16 Dual test result interpretation

Table 4: Test result interpretation

Test results	Interpretation
HIV Negative, Syphilis Negative	Antibodies/Antigen to HIV and Treponema pallidum not detected in the blood specimen, either because the person is not infected, is still in the window period for HIV.
HIV positive, Syphilis Negative	Antibodies/Antigen to HIV are detected but no antibodies to Treponema pallidum detected. Probably negative for Syphilis.
HIV Negative, Syphilis Positive	No Antibodies/Antigen to HIV detected, cannot rule out window period. Syphilis positive (indicative of current/past/resolved infection.
HIV Positive, Syphilis Positive	Antibodies/Antigen to both HIV and Treponema are detected in the blood (indicative of current/past/resolved syphilis infection).

- Positive HIV tests need further confirmation through Assay 2 and Assay 3.
- Positive Syphilis cases should be investigated and treated at the earliest.

9.17 Laboratory quality assurance

The QA system is a part of overall quality management that aims to ensure consistency, reproducibility, traceability, reliability and efficiency of products or services. Laboratories that conduct HIV testing should have functional internal quality control system in place and participate in an HIV external quality assessment scheme (EQAS).

- Internal quality control includes procedures undertaken by laboratory staff at the institution to ensure quality from the collection of specimens, the performance of the test up to analytical results, and the procedure is planned, ordered and followed up by the staff itself.
- External quality assurance (EQA) is the assessment of the quality of the laboratory by a reference laboratory, higher authorities or independent agency. EQA leads to correction and improvement of laboratory quality. EQA can be done through proficiency panel testing, retesting or on-site monitoring.

10. OPERATIONAL GUIDELINES FOR HIV COUNSELING AND TESTING SERVICES

10.1 Location

All VCT and HISCs should have standard signboards, symbols and logo directing clients to the centers and to each unit. A free-standing HISCs may be located in a busy part of the town where there is easy access for clients.

Integrated VCT Centers will be located in the existing Hospital setting. A separate unit is created to provide privacy and client anonymity. For instance, a VCT centre could be located near the blood bank or the ANC in the Hospital setting.

10.2 Infrastructure

Adequate space is needed for service provision, especially because these clients are not sick. Therefore, clients would like to have an environment that is welcoming and relaxing. The ideal space requirements are as following proposes:

a) Reception and waiting Rooms –

A part of the waiting room may be used for the reception. The reception area will be welcoming. Two waiting areas are recommended for clients of feasible for the following proposes:

i. To sit and relax while waiting for VCT services.
ii. For clients who are waiting for test results or counselling

b) Counselling rooms –

A minimum of two rooms is required so that clients are not kept waiting if one of the counseling rooms is in use.

c) Laboratory-

A separate room is required for sample collection, testing of blood and storage of testing kits as per the laboratory protocol.

d) Examination room –

A doctor or a health worker could examine patients here and recommend further treatment and referrals wherever and whenever necessary.

e) Medical Records Storage room –

In this room, the clients records and registers will be kept under lock and key so that client files are kept safely and thus confidentiality is maintained. This can also be used as a data entry room where there is access to a computer and internet facility.

f) Restroom-

Ideally, two rooms are preferred, each for the staffs and the clients.

10.3 Staffing

A trained counselor appointed as the person in charge will manage the HISC and VCT Center. The overall management of the HISC and VCT will be through a team approach. The HISCs will have the following category of staff and the number will depend upon the workload of each HISC.

1) Receptionist
2) Counsellors
3) Laboratory technician
4) Outreach Workers
5) Doctors/clinicians
6) Support staff

However, VCT Centers will work very closely with the existing staff under the Hospital administration.

Description of roles for VCT Centers

- **Receptionist:** This is a critical position as the receptionist is the first person that the client meets and can therefore have a positive or negative impact on how the service is viewed by the potential users. A receptionist will receive clients and ensure that the VCT service is explained to them and prepare them for counselling sessions with the counsellor.
- **Counsellor:** Counselors will provide counselling services and referrals.

- **Laboratory technician:** A trained laboratory technician will be identified as a focal person for the VCT and will be responsible for testing and providing the test result to the counsellor.
- **Support Staff:** this cadre will be responsible to keep the site clean and also do miscellaneous activities like going to the post office, filling documents, accompanying the client etc.
- **Doctor/clinicians**: the placement of a medical doctor or clinicians will depend on the uptake and the need of the clients. The appointment may not be a feasible option at this point, but outreach visits may be required depending on the uptake of the services.

10.4 Equipment

The equipping of all the rooms is aimed at coming up with a non-medical atmosphere, which is both, relaxing for the clients and counsellors. The seating arrangement will be comfortable. There will be minimum standards for such specialized areas as mentioned below.

i. The office utilities and stationery like television, computer, telephone, sofa set and other furniture.
ii. The laboratory such as refrigerator, test kits, reagents etc
iii. Information materials like books, posters and IEC material on STI/HIV and other related health issues.
iv. Miscellaneous equipment like BP apparatus, weighing scale etc

10.5 Operating hours and Days

Free-standing HISCs will have a flexible time to suit its clients. The clients may adjust the operating hours after an evaluation of the service utilization. For the initial period, recommended timing for the free-standing HISC will be from 10 am to 7 pm. Free-standing HISCs will function on the above time from Monday to Friday. On Saturday, VCT will operate from 10 am to 1 pm. On Sunday and other public holidays, the free-standing HISCs will be closed. Whereas VCT centers located under the umbrella of the hospital administration, the timing will be based on the routine timing of the hospital.

11. RECORDING AND REPORTING

The quality routine recording and reporting of HIV testing, care and treatment are critical at all levels of health facility to make informed programmatic and clinical decisions to enhance the case diagnosis and improve the quality of the life of the PLHIV. Moreover, such information is very important at the national program level for the development of the overall evidence-based strategies. Therefore, the concerned health workers should take the following action;

- All the information related to HIV Counseling and Testing should be entered into the DHIS-2 system on a timely basis and will be validated by the M & E Officer of the NACP every month.
- All those diagnosed with PLHIV should be registered for chronic care and treatment management into the DHIS-2 system using the case-based surveillance form and should be followed up as per the national treatment guidelines.
- The concerned health workers should follow the DHIS-2 system SoP for correct operation and management of the DHIS-2 system.

12. INFECTION CONTROL PROTOCOL

Performing HIV tests poses a potential health hazard to the tester. Coming in contact with human blood or blood products is potentially hazardous. Safety involves taking precautions to protect you and the client against infection. All specimens should be treated as though potentially hazardous.[9]

Who need to be protected from cross infection?

- ⇒ Besides tester and client, we need to protect other people from infection.
- ⇒ Never leave blood spills that could infect others.
- ⇒ Never leave used lancets lying around for anyone else to pick up – they could prick themselves with HIV contaminated lancets.
- ⇒ Always seal contaminated waste – you don't want to risk infecting the person who removes contaminated waste from the rapid testing site.
- ⇒ In addition, it is important to protect the integrity of test products. Shield unused tests from any contamination. If a new or unused test is contaminated by a drop of blood from a previous client, the test may not yield accurate result when used on the next client.
- ⇒ It is also important to protect the environment from hazardous material. Avoid transferring contaminated materials into areas outside of the testing area.

Universal or Standard Precautions

- ⇒ Before testing, specimens shall be transported in a manner to prevent contamination of workers, patients, and environment. This includes using appropriate packing containers, and following national and international postal and transport regulations.
- ⇒ During testing, follow the safety rules when performing finger-prick and actual testing of the client's blood.
- ⇒ After testing, remember to clean up working area and properly dispose of contaminated waste.
- ⇒ Develop Personal Safe Work Habits. It is important that you:
    - o Wash hands before and after testing each patient.
    - o Wear a fresh pair of gloves with each patient.
    - o Wear lab coat or apron
    - o Dispose of contaminated sharps and waste immediately after testing
    - o Never pipette by mouth.
    - o Never eat, drink or smoke at the test site
    - o Keep food out of the laboratory/testing site refrigerator

- Remember, never let your mouth touch anything from work, such as pens, pencils, etc.
- Maintain Clean & Orderly Work Space
- It is important to:
- Keep work areas uncluttered and clean
- Disinfect work surfaces daily ("disinfect" means kill any harmful germs/ pathogens)
- Restrict or limit access when working
- Keep supplies locked in a safe and secure area
- Keep emergency eye wash units in working order and within expiry date.
- The eye wash unit is used to clean one's eyes when they are accidentally splashed with any type of specimen (for example, from patients, controls, reagents, etc.). If an eye wash unit is not available, please consult your local infection control personnel for alternate procedures to follow in the event of an accidental splash.

Take Precautions to avoid Needle Stick Injury

⇒ Needle-stick injury can be dangerous because infected blood containing pathogens can be transferred to the person and cause infection.

⇒ Needle stick injury may occur due to lack of concentration, inexperience, lack of concern for others, or improper disposal of sharps. To prevent needle stick injury, you should focus on where the needle is, as well as where your hand and your client's hand are. Don't let yourself be distracted. Only people who have received appropriate training should perform the finger-stick procedure.

⇒ Always follow proper procedures to dispose of used needles and sharps. For example,

⇒ Place used lancets in the sharp's disposal container.

⇒ Do not leave used needles or lancets lying around.

⇒ Clean up after each client.

⇒ Any needle stick injury should be reported to NACP and initiate PEP as per protocol

Drop Used Sharps in Special Containers

There are many makes, shapes and sizes of sharp bins. However, all sharp containers should have:

⇒ lid

⇒ Puncture-proof or thick walls

⇒ large enough hole for lancets and needles

⇒ Leakproof sides and bottom
⇒ label or color code indicating bio-hazard material
⇒ And should be available in Sufficient quantity at each testing site

Note: Not all sharp containers need be purchased commercially. An empty bleach container will suffice such as seen on the right. This type container meets all previously mentioned specification. Additionally, the opening is small so that you cannot insert your hand.

Do's and Don'ts-Sharps and Waste Containers

⇒ Do not break, bend, re-sheath or reuse lancets, syringes or needles. You could injure yourself if you try to bend needles or lancets.
⇒ Never shake sharps containers to create space because this leads to formation of aerosols. Aerosols are tiny invisible droplets in the air that can also carry infectious agents/pathogens.
⇒ Never Place Needles or Sharps in Office Waste Containers
⇒ Plastic bag must be securely tied once filled. This is appropriate for disposing of contaminated waste such as used gauze. This type of container is NOT appropriate for disposal of sharps.
⇒ Contaminated waste should be kept separate for office waste. It is the tester's responsibility not to put any other persons at risk of infection.

Sharp container: The sharps containers must be:

⇒ Placed near workspace
⇒ Closed when not in use
⇒ Sealed when ¾ full

HIV testing related incineration of waste

Incineration is the burning of contaminated waste to destroy and kill micro-organisms. Contaminated waste should be burned to completion (that is, beyond re-use). It protects environment and must be supervised. Care should be taken in transporting waste from one site to another for incineration.

Disinfect work areas with bleach

In order to keep a clean and orderly work area, disinfect your work surface on a daily basis. It is part of the general safe practice that you need to follow. Remember, disinfection to;

⇒ Kills germs and pathogens
⇒ Keeps work surface clean

⇒ Prevents cross-contamination
⇒ Reduces risks of infection

In case of an accident

There are three types of accidents that may happen:

⇒ Potential Injury, i.e., needle pricks, falls
⇒ Environmental, i.e., splashes or spills
⇒ Equipment damage

Note: In case of an accident, you should report to your supervisor immediately. Assess the situation and take action accordingly. Record the accident using appropriate forms, and continue to monitor the situation. For more detail, refer to the national HIV testing and treatment guidelines for Post Exposure Prophylaxis.

13. ANNEXURES

Annexure 1: TALKING POINTS FOR INTRODUCING PARTNER

TESTING SERVICES TO INDEX CLIENTS OR PATIENTS

DURING PRETEST INFORMATION/COUNSELING, PROVIDERS SHOULD:

= **Explain the importance of ensuring that all partners get tested for HIV.**

- HIV-positive partners can start on HIV treatment to keep them healthy and reduce risk that they will pass HIV to other sex partners and/or children.
- HIV-negative partners can access HIV prevention services to help them remain HIV negative, including condoms, pre-exposure prophylaxis, and male circumcision.

= **Inform the index client that:**

- The clinic is offering partner testing services to assist the client to contact their partners so that these partners can learn their HIV status.
- The service is offered because we know disclosure of HIV status to partners can be difficult.
- You will be asking the client to list the names of all persons they have had sex with, including people, they may have only had sex with once. Also ask for their names of the people that the client has shared needles with.
- You will also be asking for the names of any child(ren) who may need an HIV test.

DURING POST-TEST COUNSELING AND/OR COUNSELING IN THE HIV CLINIC:

= Remind the client of the importance of partner testing using information from above.

- Inform the client that there are three options for contacting their partners
    - Client can contact them to let them know they should be tested for HIV
    - Client can contact them within a certain time period, after which the provider will offer assistance if the partner hasn't been tested
    - The health care providers can contact the partners directly, without telling them the client's name (this will be done anonymously).

= Options for approaches such as use of "love letters" or couples counseling should be mentioned if offered.

= If the client chooses option two, they will have four weeks to bring in or refer their partner for HTS.

- If the partner does not come in for HTS after four weeks, then the provider will contact the index client for permission to contact the partner.

= Inform the index client that:

- All information will be kept confidential. This means that:
  - Partners will NOT be told the index client's name or test results.
- The index client will NOT be told the HIV test results of their partner(s) or whether them partner(s) actually tested for HIV.
- You will NOT contact the partner without first contacting them to get their permission.
- They will continue to receive the same level of care at this health facility regardless of whether they choose to participate in PN services.
- Answer any questions that the index client might have and obtain verbal consent to continue.

= Use the Tool 2: Index Patient Information Form to record contact information for the index client.

Annexure 2: INDEX PATIENT INFORMATION FORM

Instructions: Complete this form while interviewing the HIV-positive index client who has verbally agreed to receive index partner testing or partner notification services.

***Complete one form per index client.**

Date form completed (dd/mm/yyyy: _____/ _____ / _____

Name of person completing form: _____

Name of health facility or HIV testing site: _____

INFORMATION ABOUT THE INDEX CLIENT OR PATIENT Index client's name (last, first, middle): _____DOB: (dd/mm/yyyy): _____Age: _____yrs.

Sex/Gender: ♦ Male ♦ Female ♦ Transgender (Male to Female) ♦ Transgender (Female to Male)

Marital status: ♦ Single ♦ Engaged to be married ♦ Married/cohabitating-monogamous ♦ Divorced ♦ Widow/er ♦ Married-polygamous: # wives _____

Client's personal mobile number: _____

Alternate contact number (if available): _____

Address (including any landmarks, e.g., "next to the church"): _____

_____

_____

Date of HIV diagnosis: (dd/mm/yyyy): _____ Is the index client currently enrolled in an HIV treatment program? ♦ Yes ♦ No

If yes, name of health facility _____

If yes, list the index client's ART enrollment number: _____

For women: How many children age 12 or under does the index client have? _____ _____ # children age 12 and under.

Annexure 3. PARTNER ELICITATION OR IDENTIFICATION FORM

*Complete one form for each index client instructions:

Ask the index client to tell you the names of all the people they have had sex with in the past 12 months, including both main/married partners and casual/unmarried partners. If the client injects drugs, ask them to also tell you the names of their injecting drug use partners, or you may wish to start by asking about the most recent partner and working backward in time.

LIST NAME(S) OF PARTNERS (TICK IF NAME IS UNKNOWN)	PHONE NUMBER	ALTERNATIVE PHONE NUMBER
1. ♦	_____ ♦ Unknown	_____ ♦ Unknown
2. ♦	_____ ♦ Unknown	_____ ♦ Unknown
3. ♦	_____ ♦ Unknown	_____ ♦ Unknown
4. ♦	_____ ♦ Unknown	_____ ♦ Unknown
5. ♦	_____ ♦ Unknown	_____ ♦ Unknown
6. ♦	_____ ♦ Unknown	_____ ♦ Unknown
7. ♦	_____ ♦ Unknown	_____ ♦ Unknown
8. ♦	_____ ♦ Unknown	_____ ♦ Unknown

Annexure 4: PARTNER INFORMATION FORM

*Complete one form for each partner named by the index client.

Instructions: Ask the client to give you as much information as they can about each of the partners, they named on the partner elicitation form. Write "N/A" for any information not available. After completing a separate form for each contact, file all completed forms in the client's folder or medical chart. Be sure to observe measures to maintain confidentiality of this information. Partner's name (last, first, middle): _____Partner's nickname: _____
Partner's DOB (dd/mm/yyyy): _____ Partner's age: _____ yrs.

Partner's Sex/Gender: ♦ Male ♦ Female ♦ Transgender (Male to Female) ♦ Transgender (Female to Male)

Partner's physical description: _____
_____
_____
_____

Partner's address (including any landmarks, e.g., "next to the church"): _____
_____ _____
_____
_____

How would you describe your relationship to this partner?

♦ My wife/husband/fiancée ♦ We live together but are not married

♦ My girlfriend/boyfriend ♦ Someone I had sex with for fun

♦ Someone who pays me or gives me things to have sex with her/him

♦ Someone I paid to have sex with

Do you currently live with this partner?

♦ Yes ♦ No ♦ Declines to answer

As far as you know, has this partner ever tested positive for HIV?

♦Yes ♦ No ♦ Don't know ♦ Declines to answer

If known HIV-positive partner: is this partner currently taking medications for HIV?

♦ Yes ♦ No ♦ Don't know ♦ Declines to answer

Annexure 5. INTIMATE PARTNER VIOLENCE SCREENING TOOL

SCREENING TOOL FOR INTIMATE PARTNER VIOLENCE

Use this screening tool for all clients or patients who participate in PN services. Use one form for each partner identified by the client or patient. If the client or patient responds “yes” to any of these questions, consider options for partner notification that the index patient or client feels safe to use. Figure 5 on page 25 of this document illustrates a method to decide on PN methods based on the response to the intimate partner violence screening tool. Please state to the client or patient: Because your safety is very important to us, we ask all clients the following questions:

1. Has [partner’s name] ever hit, kicked, slapped, or otherwise physically hurt you?

♦ Yes ♦ No

2. Has [partner’s name] ever threatened to hurt you?

♦ Yes ♦ No

3. Has [partner’s name] ever forced you to do something sexually that made you feel uncomfortable?

♦ Yes ♦ No

4. Has [partner’s name] ever threatened you in other ways, such as divorce, desertion, lack of support, taking away access to your children, or other threats?

♦ Yes ♦ No

Annexure 6. OPTIONS AND PLAN FOR PARTNER TESTING

DECIDE ON A PLAN FOR PARTNER TESTING

Instructions: Show the "Options for Getting Your Partner Tested" card to the index client or read this to them if there are any challenges with literacy. Review the three options. Ask the client which option they would prefer and record their chosen option below. If the client chooses "contract referral," record the date (30 days from today's date) by which the partner should come for HIV testing services. s INDEX

CLIENT'S PLAN FOR NOTIFYING THIS PARTNER:

- ♦ Client Referral: Index client will notify partner.
- ♦ Provider Referral: Health care providers will notify the partner.
- ♦ Contract Referral: Both the index client and health care provider will notify the partner.

The index client will first try notifying the partner no later than _____/ _____ / _____. After which the provider will contact the partner (with permission from the index client).

- ♦ No partner testing needed; partner is known positive.
- ♦ Partner testing is not recommended at this time due to safety concerns.

Annexure 7: OUTCOMES OF PARTNER TESTING SERVICES FORM

INDEX CLIENT INFORMATION

Name: _____

HTS/ART Clinic Number: _____

Gender: ♦ Male ♦ Female ♦Transgender Date of Birth:_____/_____/_____

*Complete additional forms if index client has more than three partners.

PARTNER 1

Gender:
♦Male ♦Female ♦Transgender Date of Birth: _____/_____/_____

Type of Partner Testing:
♦Male ♦Female ♦Transgender Date:

Date/method of 1st Contact Attempt:
_____/_____/____Phone/Home

Date/method of 2nd Contact Attempt:
_____/_____/____Phone/Home

Date/method of 3rd Contact Attempt:
_____/_____/____Phone/Home

Was partner contacted?
♦ Yes ♦ No
If yes, who contacted partner?
♦ Client ♦ Provider
♦Client + Provider

Outcome of Partner Testing Services:
♦ Partner received an HIV test
♦ Partner refused an HIV test
♦ Partner known to be HIV-positive
♦ Other: _____

Partner's HIV status (if tested):
♦ HIV-positive ♦ HIV-negative

Is the partner on ART (if HIV positive)?
♦ Yes ♦ No

PARTNER 2

Gender:
♦Male ♦Female ♦Transgender Date of Birth: _____/_____/_____

Type of Partner Testing:
♦Male ♦Female ♦Transgender Date:

Date/method of 1st Contact Attempt:
_____/_____/____Phone/Home

Date/method of 2nd Contact Attempt:
_____/_____/____Phone/Home

Date/method of 3rd Contact Attempt:
_____/_____/____Phone/Home

Was partner contacted?
♦ Yes ♦ No
If yes, who contacted partner?
♦ Client ♦ Provider
♦Client + Provider

Outcome of Partner Testing Services:
♦ Partner received an HIV test
♦ Partner refused an HIV test
♦ Partner known to be HIV-positive
♦ Other: _____

Partner's HIV status (if tested):
♦ HIV-positive ♦ HIV-negative

Is the partner on ART (if HIV positive)?
♦ Yes ♦ No

PARTNER 3

Gender:
♦Male ♦Female ♦Transgender Date of Birth: _____/_____/_____

Type of Partner Testing:
♦Male ♦Female ♦Transgender Date:

Date/method of 1st Contact Attempt:
_____/_____/____Phone/Home

Date/method of 2nd Contact Attempt:
_____/_____/____Phone/Home

Date/method of 3rd Contact Attempt:
_____/_____/____Phone/Home

Was partner contacted?
♦ Yes ♦ No
If yes, who contacted partner?
♦ Client ♦ Provider
♦Client + Provider

Outcome of Partner Testing Services:
♦ Partner received an HIV test
♦ Partner refused an HIV test
♦ Partner known to be HIV-positive
♦ Other: _____

Partner's HIV status (if tested):
♦ HIV-positive ♦ HIV-negative

Is the partner on ART (if HIV positive)?
♦ Yes ♦ No

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