London School of Hygiene & Tropical Medicine

Policy on Post-Exposure Prophylaxis for Needlestick Injuries, and other Exposures to Potentially HIV-Infectious Materials Occurring Outside of the U.K.

Background
1. The risk of someone being HIV-infected after a needlestick injury from an HIV-infected source person has been estimated at 3 per 1,000. The risk after exposure to splashes or contact with other tissues is lower than this. With post-exposure prophylaxis, this risk can be reduced by 50-95%. This risk is much lower than that for transmission of Hepatitis B & C but, given the potential severity of HIV disease, it is still very important to try to prevent it.

2. In many areas of the School’s current work, the risk that a source person is HIV-infected is possibly up to 50%.

3. This policy should be applied in overseas collaborative sites where local guidelines do not exist. Where local guidelines exist, a decision must be made by the senior LSHTM representative, with advice from LSHTM specialist advisers if necessary, as to which policy (local / LSHTM) should take precedence to ensure safe and appropriate consistency of application within the site.

4. It is of vital importance to ensure the availability of the required therapies and the practicalities of applying the policy or guidelines is established and maintained.

5. These guidelines are based on the references cited at the end of this policy and are subject to regular review by the School’s professional advisers.

Eligibility
6. Post-exposure prophylaxis (PEP) will only be offered to staff who are exposed while carrying out duties that are directly related to the work they have been assigned by one of the LSHTM or collaborative research projects. PEP will NOT be offered to staff for sexual exposures, with the exception of rape while in the field, nor for exposures while carrying out private duties or duties that have been assigned by another institution.

Prevention
7. All staff working on LSHTM or collaborative projects who handle potentially infectious materials (especially human blood) should have access to this policy document, which will be made available for reference in printed format at the site and is posted on the LSHTM intranet. All such staff should receive guidance on how to avoid needlestick injuries and contacts with body fluids or other body tissues, and the importance of receiving immediate first aid if they do have such an injury/contact. This should be incorporated into the training for the project staff on good clinical and laboratory practice.

Reporting for assessment and advice
8. All staff should report incidents in which they have been exposed to needlestick injuries or a contact with body fluids or other body tissues immediately to one of the project’s nominated PEP supervisors.

9. If none of the PEP Supervisors are available, one of the other medical officers working for the LSHTM related project should be contacted.

Assessment
10. The PEP supervisor should start to complete a PEP Report Form (Annex 1:Section A). They should assess the risk of exposure to infection and the need for prophylaxis using the following guidelines:
   - **Needlestick injury**: Recommend PEP in all confirmed cases of needlestick injury.
• **Mucosal contact** (e.g. mouth or eyes): Offer PEP if there was contact with blood or constituents of blood (e.g. serum/plasma/semen), or with untreated tissue (e.g. fresh vaginal swab material). Do not offer PEP if the contact was with other body fluids (e.g. urine).

• **Skin contact**: Only offer PEP if there is an obvious portal of entry (e.g. a wound or ulcer) on the skin of the exposed person, or there was extreme contact with the blood or other untreated tissue (e.g. a major splash with blood). Do not offer PEP if there is no obvious portal of entry and the exposure was not an extreme contact.

• **Rape**: If a staff member is raped while on field assignment for the collaborative projects, and there has been penetrative vaginal and/or anal intercourse, then they should be offered PEP. PEP should also be offered if there was any risk of oral mucosal contact with semen.

• **Time since incident**: If less than 14 days have elapsed since the exposure incident, prophylaxis should be considered. If 14 days or more have elapsed since the exposure incident, prophylaxis should not be considered. However, pre and post test counselling and baseline HIV testing and HIV testing at 6 weeks, 3 and 6 months should be performed with the consent of the exposed person.

11. The exposed person should immediately wash wounds with soap and water and/or flush mucous membranes with water.

**Prophylaxis**

12. If the results of the assessment indicate that it is needed and the exposed person accepts it, prophylaxis should be started immediately with a single dose of both zidovudine (ZDV) and lamivudine (3TC) and Kaletra:

- **Zidovudine 250mg and Lamivudine 150mg (Combivir) P.O.**
- **Kaletra® 2 tablets P.O.** (i.e. 400mg lopinavir + 100mg ritonavir)

13. Immediately after this, the need for an HIV test should be discussed, and full pre-test counselling given. The subject should be reassured that the results of the test will be strictly confidential to themselves and the PEP Supervisor who will give them post-test counselling. The test results will not affect their employment. However, prophylaxis will not be continued unless the HIV test is accepted.

14. If the HIV test is accepted, prophylaxis should be continued with:

- **Zidovudine 250mg twice per day and Lamivudine 150mg twice per day P.O.**
- **Kaletra® 2 tablets twice per day P.O.** (i.e. 400mg lopinavir + 100mg ritonavir)

*Note: Kaletra is contraindicated if someone is taking the following drugs:

- Antiarrythmics – Flecanide, Propafenone, Amiodarone
- Antibiotics – Rifampacin
- Antihistamines – Astemizole, Terfenadine
- Benzodiazapines – Midazolam, Triazolam
- Ergot derivatives – Ergotamine, Ergodryal and related drugs
- GI motility agents – Cisapride
- Herbal Products – St John’s Wort
- Neuroleptics – Pimozide
- Statins – Lovastatin, Simvastatin

In this case the clinician or PEP coordinator should only give the emergency dose of Combivir and should seek advice as soon as possible from a senior doctor on the team.

15. **The full course of PEP is 4 weeks** (but see Section 7 for the rules about continuing or stopping prophylaxis depending on the HIV test result). The PEP Patient Information Sheet (Annex 2) should be read out to the patient, who should be given a copy to keep. The drugs should be taken with a light meal or snack to ensure adequate absorption.
Side effects
16. Diarrhoea. This can usually be managed conservatively with anti-diarrhoeals.
17. ZDV-associated anaemia is unlikely within 4 weeks of treatment unless the exposed person already has anaemia. If this is the case, an alternative regimen should be chosen once baseline blood tests have been checked. Increased total cholesterol and GGT are noted on laboratory testing.
18. Other possible minor side effects with Kaletra include insomnia and headache.
19. Rarely Kaletra can cause pancreatitis. This is more common in people with pre-existing liver disease.
20. Kaletra also interferes with the oral contraceptive pill and reduces its effectiveness. In any event, whether the exposed person accepts HIV-testing or not, they should be encouraged to abstain from sex or to use a condom consistently during the first six months after exposure, and thereafter unless they have had a negative HIV test at least six months after the exposure incident.

HIV Testing
21. Blood from both the source person and the exposed person should be tested for HIV as soon as possible after the incident. The source person should receive full pre-test counselling, and has the right to refuse to be tested. The importance of maintaining confidentiality for the exposed person is paramount. The source person should always sign to give their permission for the test, in the presence of an impartial witness who should counter-sign the permission. The PEP Supervisor is responsible for ensuring that the serological testing is done and reported promptly, and that the confidentiality of both the exposed person and the source person is maintained. This should be done by assigning a code to each person.
22. The decision to continue or stop prophylaxis should be based on the following:
   - Exposed person HIV-positive: Stop prophylaxis
   - Exposed person and source person are HIV-negative, where source person is from a low risk group (e.g. children): Stop prophylaxis
   - Exposed person and source person are HIV-negative but source person is from high HIV incidence risk group (e.g. barworker) where early HIV infection cannot be excluded: Continue prophylaxis for a total of 4 weeks
   - Exposed person is HIV-negative and source person is either HIV-positive or cannot be tested: Continue prophylaxis for a total of 4 weeks.

Documentation
23. The PEP Supervisor should complete a PEP Report Form and file this in a locked cabinet. They should cover the names of both the exposed person and the source person with opaque paper and photocopy the form as soon as they have completed Section A. This will create an “anonymised” PEP Report Form. As soon as possible after the incident, the PEP Supervisor should copy the anonymised PEP Report Form to:
   - The local LSHTM team leader
   - The LSHTM Safety Manager, if the exposed person is a member of staff or student of LSHTM
   - The appropriate manager, if the exposed person is employed by an institution other than LSHTM.
24. These people should discuss the incident (anonymously) with the PEP Supervisor and to make recommendations of any steps that should be taken to avoid such incidents in future.

Follow-up
25. The exposed person should be encouraged to have further counselling and HIV testing at 4 weeks, 3 months and 6 months after the incident to document any seroconversion.

26. The exposed person should be seen by the PEP Supervisor and assessed clinically at 2 weeks and at 4 weeks if they are receiving PEP to assess their clinical and mental state, with particular assessment of potential drug-related side effects. Common drug-related side effects are: nausea, vomiting, diarrhoea, tiredness and headache. At baseline and at 2 weeks, blood should be taken for full blood count and for renal and liver function tests (if possible) to monitor for drug toxicity. The exposed person should be encouraged to abstain from acting as a blood donor and to abstain from sex or to use a condom consistently during the first six months after exposure, and thereafter unless they have had a negative HIV test at least six months after the exposure incident. Condoms should be provided by the PEP supervisor.

**Staff working away from the project base**

27. Field Teams working away from base that include a medically-trained person should always carry this policy document, PEP Report Forms, and 3 days supply of PEP. One clinician should act as the Field PEP clinician. They must account for all PEP drugs they have used on the PEP Report Forms, and should restock their supply of PEP drugs as soon as possible from the PEP supervisors. They should complete Section A of the PEP Report Form.

28. Staff in such a team must report any incident to their Team Leader and the Field PEP clinician. If it is possible for this clinician to consult one of the PEP supervisors within 2 hours of the incident to seek advice (e.g. by phone), they should do so. If this is not feasible, the Field PEP clinician should make the assessment and recommend or offer prophylaxis if this is indicated (see above). They should open one of the PEP starter packs and immediately give the exposed person a starting dose of:
   - Zidovudine 250mg and Lamivudine 150mg (Combivir) P.O.
   - Kaletra 2 tablets P.O. (i.e.400mg lopinavir + 100mg ritonavir)

29. The Field PEP clinician and Team Leader should instruct the affected staff member to return to base immediately to seek further advice and treatment (if needed) from one of the PEP supervisors, and should make arrangements for this (e.g. by providing a project car). While they are making these arrangements, the exposed person should be continued on:
   - Zidovudine 250mg and Lamivudine 150mg twice daily P.O.
   - Kaletra 2 tablets P.O. twice per day (i.e.400mg lopinavir + 100mg ritonavir b.d.) swallowed whole

30. The exposed person should be sent to base with the blood specimen of the source person (if obtained), the blood specimen of the exposed person, and the PEP Report Form in a sealed envelope addressed to the PEP Supervisor by name. The envelope should be clearly marked URGENT, and both the exposed person and the driver must be told that the envelope must be delivered immediately on arrival (even if this is in the middle of the night).

31. Staff members must NEVER act as their own clinician (unless there is no other clinician available).

32. If the incident happens away from the project base and the staff member is not part of a team with a clinician, they must return to base immediately to report to one of the PEP supervisors.

**Other regimens**

33. In the event that the PEP packs provided by LSHTM have been used and it is necessary to purchase PEP locally, alternative 28 day regimens are either:
   - Zidovudine 250mg and Lamivudine 150mg twice daily P.O.
   - Indinavir (IDV) 800mg three times daily P.O.
34. EFV is currently listed as the first-line protease inhibitor for the management of HIV-infection. The most common side effects with this regimen are EFV-associated CNS effects. For this reason EFV should be taken at night before going to sleep. EFV should NOT be given in 1st trimester of pregnancy because of potential teratogenic side effects.

PEP in pregnancy

35. The regimens for exposed pregnant staff members should be either a 28 day course of:

- Zidovudine 250mg and Lamivudine 150mg twice daily P.O.
- Kaletra 2 tablets P.O. (i.e. 400mg lopinavir + 100mg ritonavir)

Or:

- Zidovudine 250mg and Lamivudine 150mg twice daily P.O.
- Nevirapine (NVP) 200mg once daily for 14 days, then 200mg twice daily for 14 days P.O.

36. All female staff aged less than 50 years should be assumed to be pregnant unless they are menstruating or have a negative pregnancy test.

37. The most common side effect with this regimen is NVP-associated rash. If mild/moderate continue tablets. If severe, stop NVP.

References

- U.K. Guidelines for the use of Post Exposure Prophylaxis for HIV following sexual exposure. BASHH. April 2004
- CDC 2005, MMWR 54 1-20
Summary

Immediately:
- Assess exposure* and administer first aid**
- Ask what other drugs the exposed person is taking***
- Give first dose of PEP
- Encourage counselling and HIV testing (unless the exposed person agrees to testing, prophylaxis cannot be continued)
- Take blood from both the source person and the exposed person for HIV testing, with a witnessed, signed agreement.
- If off base: Send the exposed person with their own blood specimen and that of the source person (in vacutainers) and the PEP Incident Form to the PEP Supervisor.
- Ensure the HIV testing is done as quickly as possible.

Baseline:
- HIV ELISA x 2, Clinical assessment and blood for full blood count, urea & electrolytes, and liver function tests

After 2 weeks:
- Clinical assessment and blood for full blood count, urea & electrolytes, and liver function tests

After 4 weeks:
- Clinical assessment and stop PEP
- Counselling and HIV testing

After 3 months:
- Counselling and HIV testing

After 6 months:
- Counselling and HIV testing

* Classifying the Exposure

Exposure to the following body fluids may constitute a risk:
- blood, CSF, amniotic, pericardial, peritoneal, synovial or pleural fluid, human breast milk, saliva, vaginal secretions, semen, exudative fluid from burns or abrasions and any other body fluid if visibly blood stained.

Non-significant Injuries
- 1 - Negligible risk
  - Intact skin is contaminated with blood or body fluids.
  - PEP is not normally indicated.

Significant Injuries
- 2 - Low risk
  - Blood or body fluids contaminate broken skin, mucous membranes or conjunctivae.
  - Intradermal injury with contaminated instrument.
- 3 - Moderate risk
  - A skin penetrating injury caused by a needle or other instrument that is visibly contaminated with blood or body fluid.
- 4 - High risk
  - A significant exposure (2 or 3 above) to blood or body fluids from sources known to be infected with HIV, HBV or HCV.
  - Risk is highest for deep or penetrating injuries involving a hollow needle that has been introduced into source artery or vein.
- HIV -VE - PEP not indicated
- Source Unknown - Decide on case-by-case basis.
- HIV +VE - LOW RISK / LOW TITRE HIV - Risk very low. PEP may not be warranted. Decide on case-by-case basis.
- PEP SHOULD BE RECOMMENDED FOR ALL HIGHER RISK EXPOSURES.
Classifying the Source

**First Aid**

1) Wash the wound liberally with soap and water, without scrubbing.
2) Free bleeding of puncture wounds should be encouraged, but the wound should not be sucked.
3) Exposed mucous membranes should be liberally irrigated with water.

**Assess recipient**

1) Does recipient know his/her status for HIV / HBV?
2) Is (or could) the recipient (be) pregnant or breast feeding?
3) Does the recipient have any other medical conditions that may alter management (e.g., renal or hepatic impairment)?
4) Is the recipient on any medications that may alter management?
In order to interpret events following such injuries, a base line blood sample should be taken. On discussion with the recipient options include urgently testing for HIV or storing for future testing if indicated.

Notes

Hepatitis B:
All staff with SIGNIFICANT EXPOSURES should be vaccinated as follows:
- If fully immunised, give booster unless known non-responder
- If known non-responder or un-immunised give accelerated primary course (0, 1 and 2 months).
- Un-immunised recipients significantly exposed to HBV should ideally receive hepatitis B immune globulin.

Risk of HIV transmission:
- Data are limited. The following are guidelines based on large US studies:
  - Percutaneous exposure: 0.3% (95% CI 0.2-0.5%)
  - Mucous membrane: <0.1% (0.006-0.5%)
- Risk on exposure to other body fluids not known but probably lower.
- Risk thought to increase with severity and titre.

Symptoms and Incubation:
- Unpublished data from CDC show that about 80% of recipients who seroconverted developed symptoms consistent with a seroconversion illness (fever, rash, myalgia, lymphademopathy). The mean onset was 25 days after exposure.

Where PEP is indicated:
- Efficacy of PEP not well known.
- Efficacy data limited to ZDV. No data to show that adding other drugs provides additional benefit.
- Recommendations largely based on theoretical considerations.
- Optimum timing of PEP not known; however, animal studies suggest it should be started within hours.
- On this basis, if PEP appears to be indicated and significant delay would be introduced by testing etc, PEP should be started immediately then the situation re-assessed in light of full information.
- If risk is significant, PEP should still be started even after longer delays although efficacy is likely to be lower.
- Optimum duration of PEP is unknown. 4 weeks empirical.
- Animal models suggest that PEP can work in a number of ways including delayed onset of antigenaemia, drug-facilitated vaccine-like response (inhibition sufficient to allow the development of long-lasting protective cellular immunity) and definitive prevention of infection.
- Starting / stopping PEP without good reason may lead to drug resistant infection. Once decision is made to start PEP, it should only be discontinued if source is later found to be HIV negative or due to side effects.

Preventing secondary transmission
- Although the risks of HIV transmission are thought to be low in most circumstances, the recipient should still be advised to take steps to prevent secondary transmission.
**Annex 1: LSHTM PEP Report Form**

This form is STRICTLY CONFIDENTIAL and should only be seen by the clinician(s) responsible for the persons involved in the incident (usually only the PEP Supervisor). The form should be anonymised by covering the names in Section A: Q2.1 and Q3.1 and photocopying the form, before the photocopied version can be shown to anyone else.

**Section A. To be completed immediately**

1. **Basic information**
   1.1 Clinician’s Staff code (Initials of their name)  
   1.2 Date of consultation  
   1.3 Time of consultation  
   1.4 Place:

2. **Exposed Person**
   2.1 Name of Exposed Person  
   2.2 Anonymous Code assigned to exposed person (eg. 01E)  
   2.3 Sex  
   2.4 Pregnant?  
   2.5 Date of incident  
   2.6 Time of incident  
   2.7 Interval between time of incident and time of consultation  
   2.8 Nature of exposure: 1=Needlestick; 2=Splash; 3=Other (specify)  
   2.9 Description of exposure:  
   2.10 Did you consult anyone else before making the assessment decision?  
   2.11 Staff codes of others consulted:  
   2.12 Assessment: 1=Prophylaxis needed; 2=Prophylaxis not needed  
   2.13 Initial prophylaxis accepted?  
   2.14 First dose of Combivir (Zidovudine & Lamivudine) given?  
   2.15 First dose of Nelfinavir given?  
   2.16 If no, other drug given (name)  
   2.17 Pre-test HIV counselling given?  
   2.18 HIV test accepted?  
   If no, terminate the PEP procedures & cross out the remainder of this form  
   If yes, complete a Request for HIV Test Result Form  
   2.19 Request for HIV Test Result Form completed?  
   2.20 Full Blood Count Results:  
   2.21 U&E Results:
2.22 Liver Function Test Results:

2.23 Number of additional doses of PEP given:

2.24 Referred to PEP Supervisor? 1=Yes; 8=NA, I am a PEP Supervisor

Ask them to come to see the PEP Supervisor again at 2 weeks post-exposure

3. Source Person

3.1 Name of Source Person

3.2 Anonymous Code assigned to source person (eg. 01S)

   **Number should be the same as for the exposed person**

3.3 Pre-test HIV counselling given? 1=Yes; 2=No

3.4 HIV test accepted? 1=Yes; 2=No

   **If No, terminate the HIV test procedures for the Source Person only.**

   If Yes, complete a Request for HIV Test Result Form, an HIV VCT Linking Form, and a VT Slip for the Source Person

Section B. To be completed by the PEP Supervisor

4. HIV Test Results

4.1 Clinician’s Staff code

4.2 Date

4.3 Source Person’s HIV Test Result: 1=Positive; 2=Negative; 8=NA (Test was not accepted)

4.4 Clinician’s Staff code

4.5 Date

4.6 Exposed Person’s HIV Test Result: 1=Positive; 2=Negative; 8=NA (Test was not accepted)

4.7 PEP continued? 1=Yes; 2=No

4.8 If no, Give Reason:

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5. Two Week Check-up

5.1 Clinician’s Staff code

5.2 Date

5.3 Exposed Person Attended? 1=Yes; 2=No

5.4 Clinical details:

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5.5 Full Blood Count Results:

5.6 U&E Results:

5.7 Liver Function Test Results:

5.8 PEP continued? 1=Yes; 2=No

5.9 If No, Give Reason:
6. Four Week Check-up & HIV Test

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If no, ask them to come to see you again at 3 months If yes, complete a Request for HIV Test Result Form & arrange a date for them to come for their HIV test result

7. Four week HIV Test Post-Test Counselling

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If HIV-negative or decline testing or result, ask them to come to see you again at 3 months post-exposure If HIV-positive, this is the end of the PEP procedures, but you should offer further post-test counselling

8. Three Months Check-up & HIV Test

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9. Post-Three Month HIV Test Post-Test Counselling

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<td>9.4</td>
<td>HIV Test Result:</td>
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<td>9.5</td>
<td>Post-test counselling given:</td>
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<td>9.6</td>
<td>Result given:</td>
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9.7 If No, Give Reason:  

If HIV-negative or decline testing or result, ask them to come to see you again at 3 months post-exposure  
If HIV-positive, this is the end of the PEP procedures, but you should offer further post-test counselling  

10. Six Months Check-up & HIV Test  

10.1 Clinician’s Staff code:  
10.2 Date:  
10.3 Exposed Person Attended?:  
1=Yes; 2=No  
10.4 Clinical details:  

10.5 Pre-test HIV counselling given?:  
1=Yes; 2=No  
10.6 HIV test accepted?:  
1=Yes; 2=No  
**If no, this is the end of the PEP Procedures**  
If yes, complete a Request for HIV Test Result Form & arrange a date for them to come for their HIV test result  

10.7 Request for HIV Test Result Form completed?:  
1=Yes; 2=No  

11. Post-Six Month HIV Test Post-Test Counselling  

11.1 Clinician’s Staff code:  
11.2 Date:  
11.3 Exposed Person Attended?:  
1=Yes; 2=No  
11.4 HIV Test Result:  
1=Positive; 2=Negative; 8=NA (Test was not accepted)  
11.5 Post-test counselling given:  
1=Yes; 2=No; 8=NA (Test was not accepted)  
11.6 Result given:  
1=Yes; 2=No; 8=NA (Test was not accepted)  
11.7 If No, Give Reason:  

If HIV-negative or decline testing or result, this is the end of the PEP procedures  
If HIV-positive, this is the end of the PEP procedures, but you should offer further post-test counselling
Annex 2: Patient’s Information Sheet

You have sustained an injury that may have exposed you to HIV infection. We are giving you medicines that will help to reduce your chances of getting HIV infection by more than 80%. It is important that you read and understand the following information.

The full course of treatment is 4 weeks. The treatment may need to be taken 2 times a day. The doctor will explain when you should take the tablets and whether you should take them with food. **IT IS ESSENTIAL THAT YOU COMPLETE THE FULL 4 WEEK COURSE OF TREATMENT** unless we ask you to stop taking the tablets.

Please tell the doctor if you are taking any other medicines. Some of these may not work when you are taking the medicine we give you, so it is important that we know what drugs you are taking. Do not stop them unless we tell you to. You should not take any other medicines unless you discuss them with the doctor first so that we can check that they do not interfere with the medicine we are giving you.

If you have any problems while taking the medicine we give you, please come back and see the doctor. These problems may include diarrhoea, rashes, vomiting, abdominal pain or tiredness.

**IMPORTANT**
You must use condoms or abstain from sexual intercourse until we have checked you for HIV infection after you have finished the medicines. This is because:

- You may be infectious to your partner
- You may catch HIV from a partner
- You may have been given medicine that may harm a baby if you get pregnant
- You may have been given a medicine can interfere with the oral contraceptive pill so that it no longer works to prevent pregnancy. The oral contraceptive pill will work again once you have finished the medicine we have given you. The doctor will advise you about this.

If you have any questions or concerns, please ask us about them now.

If you have any problems on the medication, you should contact one of the doctors treating you.
Annex 3: REQUEST HIV TEST RESULT FORM

*Please give patient the following information about the voluntary HIV testing service.*

“As you were told earlier, all the information and the results of the test on blood you have given us will be kept secret. If you decide you would like to know your HIV result, I will take a sample of blood from you. This sample will be tested for HIV. Your name will not be on this sample. No one except you and myself will see whose result this is. I will give you an appointment to come back to collect the result. At that time I will also give you further advice and information”

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<tr>
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<th>Requests Voluntary HIV test</th>
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<td>1</td>
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<tr>
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<th>Have you given the pre-test counselling?</th>
<th>1=Yes; 2=No</th>
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<td>2</td>
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<td>VTCouns</td>
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<tr>
<th></th>
<th>Have you taken and labelled the blood?</th>
<th>1=Yes; 2=No</th>
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<td>VTBlood</td>
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<th>Date for participant to return for results</th>
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<th>Signature of person requesting VCT</th>
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<th>Signature of doctor providing pre-test counselling</th>
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