POLICY ON EXPOSURE TO BODY FLUIDS AND HIV POST EXPOSURE PROPHYLAXIS

December 2015
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BACKGROUND INFORMATION

This policy is an updated version and supersedes the previous Policy on HIV Post Exposure Prophylaxis issued in July 2014.

This guidance is based on the document *HIV Post-Exposure Prophylaxis: Guidance from the UK Chief Medical Officers’ Expert Advisory Group on AIDS* revised in September 2008 (http://dhsspsni.gov.uk/hss-md-34-2008-attachment-1.pdf) and updated in September 2014. However, it has also been informed in several important areas by regional expert opinion from those Genito-Urinary Medicine Consultants dealing with HIV.

The advice contained takes account of the fact that the prevalence of HIV in the local population is low. However, it is essential that clear guidance is available as to the appropriate management of an individual who has, or may have been, exposed to HIV. This document aims to provide such guidance. Whilst previous versions of the document dealt with the issue of actual or potential occupational exposure of healthcare workers (HCWs), the Committee recognised the need for more detailed guidance in relation to sexual exposure. Hence there is now a separate section specifically dealing with sexual exposure. The Committee is grateful to the authors of this section for their input.

GENERAL PRINCIPLES

It must be stated at the outset that prevention of avoidable exposure is of paramount importance. Many occupational exposures to HIV result from failure to follow established procedures, including the safe handling of sharps. It is, therefore, essential that staff are familiar with and scrupulously follow their employers’ guidance covering such areas.

The risk of acquiring HIV infection following occupational exposure to HIV infected blood is low - on average 3 per 1000 injuries involving percutaneous exposure to HIV infected blood. It must also be remembered that exposure to blood and certain other body fluids and tissues carries the risk of transmission of other viruses, such as Hepatitis B (HBV) (approximately 1:3 risk from a single needlestick) and Hepatitis C (HCV) (approximately 1:30 risk).

On those occasions where occupational exposure occurs, all incidents should be reviewed to consider how recurrence might be prevented. In the setting of the Western Health and Social Care Trust (WHSCCT), all exposures must be reported as adverse incidents and logged on the DATIX system. The reporting system facilitates investigation and learning and allows identification of trends across the organisation.

There is evidence that administration of zidovudine significantly reduces the risk of HIV infection after occupational exposure. However, because the use of combinations of antiretroviral drugs is more effective at suppressing viral replication in established HIV infection, and because of increased prevalence of zidovudine resistance, current guidance suggests combination regimens for prophylaxis.

Whilst there may be benefit in commencing PEP even up to two weeks following exposure, it is believed that to be most effective it should be given within one hour of exposure taking place. Therefore, it is clear that a member of staff who has had significant exposure to blood or other
body fluids must report the incident immediately and that the appropriate steps are taken to deal with any risk.

The following pages give guidance as to these steps.
SECTION ONE:

MANAGEMENT OF OCCUPATIONAL AND NEEDLESTICK EXPOSURE
DECISION TREE FOR HIV POST EXPOSURE PROPHYLAXIS FOLLOWING OCCUPATIONAL EXPOSURE

TIME IS CRUCIAL. WHERE PEP IS APPROPRIATE, IT SHOULD IDEALLY BE GIVEN WITHIN ONE HOUR OF EXPOSURE.

ANY EXPOSURE


Is the route of Exposure significant?

a) Percutaneous injury
b) Exposure of broken skin
c) Exposure of Mucous Membranes (including eyes)

PEP NOT INDICATED

Is the Body Fluid High Risk?

a) Blood
b) Semen
c) Vaginal Secretions
d) Amniotic fluid
e) CSF
f) Human breast milk
g) Pericardial fluid
h) Peritoneal fluid
i) Pleural fluid
j) Blood stained saliva/saliva in association with dentistry
k) Synovial fluid
l) Unfixed human tissues and organs
m) Any other body fluid if visibly blood stained
n) Exudative or other tissue fluid from burns or skin lesions

PEP NOT INDICATED

In the case of Occupational Exposure of a Trust Employee:

Risk Assessment/ Source Testing should NOT be carried out by the healthcare worker who has sustained the exposure.

It should be carried out by the Consultant caring for the source patient or by a doctor (not Foundation Year) acting on his/ her behalf.

PEP INDICATED

Ensure Consent Form for PEP is completed by recipient and that Patient Information Leaflet is given and understood.

See page 15 for regime. Also establish HBV & HCV status of source – if necessary test with consent.

If source not known, see page 12, point 5

If informed consent cannot be obtained e.g. source is an unconscious patient, see Appendix 8

If recipient is or may be pregnant, see page 18
If this is a sexual exposure see Section 2, pages 20-29
If this is a non-occupational and non-sexual exposure also see page 30

If the route of exposure is significant and the body fluid is high risk remember to send RECIPIENT’S blood for baseline triple testing (HIV, HepB, HepC).
IMMEDIATE ACTION
FOLLOWING ANY INCIDENT OF EXPOSURE TO BLOOD OR BODY FLUIDS

Following ANY exposure – whether the source is known to pose a risk of infection or not.

Stop work IMMEDIATELY.

- Wash the site of exposure liberally with soap and water. Do not scrub. Do not use antiseptics and skin washes.

- Free bleeding of puncture wounds should be encouraged gently. Do not suck wounds.

- In the case of exposed mucous membranes, including conjunctivae, irrigate copiously with water, before and after removing any contact lenses.

Report incident immediately to Line Manager or person in charge who will arrange for a risk assessment and source testing to be carried out.

During Office Hours – Report incident IMMEDIATELY by telephone to the Occupational Health Department.

Outside Office Hours and Bank Holidays – Go To Emergency Department IMMEDIATELY.

Occupational Health opening hours – Monday-Thursday 9am-5 pm, Friday 9am 4.30pm. RISK ASSESSMENT NEEDS TO BE MADE IMMEDIATELY (See next page).

An Adverse Incident Report form must be completed, but this must not delay management of the incident of exposure.
RISK ASSESSMENT

By Whom?

Someone other than the health care worker who has sustained the exposure (the recipient).

Usually the Consultant caring for the source patient, but may be deputised to another member of his/her team (not a Foundation Year Doctor). However, if the Consultant is the recipient, another Consultant should take on this responsibility. As much information as possible should be gathered from notes and the source about HIV (and other blood borne viruses) status and about risk factors. In deciding whether or not PEP should be recommended this information will be used by the doctor providing treatment. If the source is known to be HIV positive, information should be obtained about current antiretroviral treatment and any evidence of resistance (such as prolonged treatment with any antiretroviral, clinical progression of disease or persistently increasing viral load). Similarly, in the case of a laboratory-based recipient, knowledge about the source virus may be very important, particularly if a resistant virus was being handled. In these instances, specialist advice and possibly modifications to the PEP regime would be required. However, it is important to avoid delay, so usually the standard regime should be used in the first instance.

In the case of an unknown source, risk assessment should be done by an Occupational Health or Emergency Medicine Consultant, but may be deputised to another member of his/her team.

The following questions need to be asked:

1. Does the Body Fluid or Substance involved have the potential to transmit HIV?

   The following fluids and substances are considered to carry such potential.

   a) Blood
   b) Semen
   c) Vaginal secretions
   d) Amniotic fluid
   e) CSF
   f) Human breast milk
   g) Pericardial fluid
   h) Peritoneal fluid
   i) Pleural fluid
   j) Blood stained saliva or saliva in association with dentistry
   k) Synovial fluid
   l) Unfixed human tissues and organs
   m) Any other body fluid if visibly blood stained
   n) Exudative or other tissue fluid from burns or skin lesions

2. Was the route of Exposure significant?

   a) Percutaneous injury (needles, instruments, bone fragments, significant bites which break the skin – in the last instance, although non-blood stained saliva is generally regarded as low risk, a bite should be regarded as a significant injury).
   b) Exposure of broken skin (abrasions, cuts, eczema).
c) Exposure of mucous membranes, including the eye.

If the answer to either of the above is NO, there is no indication for PEP as the exposure does not have the potential for HIV transmission.

If the answer to BOTH 1 and 2 is YES, the Source needs to be considered (See next page).
SOURCE CONSIDERATIONS

The source may be known to be HIV positive. If this is the case and the exposure was significant, PEP would be recommended. Details of the source’s current treatment and any evidence of resistance should be sought and recorded. Occupational Health or the Emergency Department must be informed immediately if the source is known to be HIV, HBV or HCV positive, or if the source is considered to be high risk.

1. Unless the status of the source is definitely known for all three blood borne viruses, Trust policy is that ALL sources should be asked for informed consent for triple virus testing (HBV, HCV and HIV). One clotted blood sample is required and should be sent to the laboratory using a virology form. This form should be clearly marked as “Source Patient”.
   - This approach should NOT be made by the recipient. Normally, it will be done by the person carrying out the risk assessment.
   - The standard consent form, enclosed with this information pack should be used and should be filed in the source patient’s notes (see Appendix 4).
   - The reason for the request should be discussed with the source. The difficulties of the recipient should be pointed out. These include the importance of not missing the potential benefit of PEP where appropriate, whilst avoiding unnecessary treatment with the potential for unpleasant side effects in the short term and unknown side effects in the long term.

3. In the case of the source being unconscious, or otherwise unable to give informed consent, the guidance from the GMC must be followed (see Appendix 8).

4. The source patient must be made aware of the outcome of the test. This should be done by the Consultant responsible for the source. If the result is POSITIVE for HIV, follow up must be arranged with the GUM clinic. The patient’s GP should be informed, but only with the patient’s consent. In the case of a positive result, informing the GP should again be discussed with the patient (even though this area was previously raised when seeking consent for triple testing) and the results of this discussion documented.

5. In the situation of the source being unknown, given the low prevalence of HIV, PEP would not be justified in the vast majority of occasions. However, risk assessment should be completed on an individual basis and recorded on Datix, taking all known details into account.

6. Individuals considered to be at high risk of HIV include the following:
   - Homosexual men
   - Bisexual men
   - Intravenous drug abusers
   - Those who have lived/ travelled in areas with a high prevalence of HIV (e.g. sub-Saharan Africa)
   - Those who have had multiple sexual partners
   - Those who have had sexual relationships with any of the above.
OTHER ACTIONS (RECIPIENT BLOOD FOR TESTING/ HBV VACCINATION)

The RECIPIENT should also have a clotted sample of blood sent to the laboratory using a virology form. The form should indicate that the sample was taken following exposure to blood/body fluids. The source details should also be recorded where known (Name, DOB and Hospital Number). In light of guidance from the British Association for Sexual Health and HIV (BASHH), and to ensure uniformity of approach independent of the circumstances of the exposure, the recipient’s blood should, with consent, be sent for baseline triple testing (HIV, HBV, HCV). Results of triple testing for recipients who are referred to Occupational Health for follow up must be clearly marked to go back to a Trust Occupational Health Consultant. Follow up triple testing should be offered at three and six months after cessation of PEP (or after the incident if PEP not taken).

Action to reduce the risk of transmission of Hepatitis B should also be considered. In the context of a recipient presenting out of hours to the Emergency Department, it may be appropriate in certain circumstances to administer a dose of vaccine. In a small number of cases a dose of Hepatitis B immunoglobulin may also be indicated. Further management may be deferred to follow up at Occupational Health or the GUM Clinic. If follow up is in the latter facility and further doses of vaccine are required, then the patient would normally be referred to their General Practitioner, by the GUM Clinic, for these.

The table below gives guidance for the IMMEDIATE MANAGEMENT of recipients who present out of hours to Accident & Emergency. Where the source is known to be Hepatitis B Negative, there is no need for immediate action.

<table>
<thead>
<tr>
<th>HBV status of RECIPIENT</th>
<th>SOURCE Unknown</th>
<th>SOURCE HbsAg POSITIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>Give dose of Vaccine</td>
<td>HBIG (Hepatitis B Immunoglobulin) + dose of Vaccine</td>
</tr>
<tr>
<td>Vaccinated. Antibody titre known to be &lt;10miu/ml at time of incident</td>
<td>Give dose of Vaccine</td>
<td>HBIG + Dose of Vaccine</td>
</tr>
<tr>
<td>Vaccinated. Antibody titre known to be &gt;10 but &lt;100miu/ml at time of incident</td>
<td>Give dose of Vaccine</td>
<td>Give dose of Vaccine</td>
</tr>
<tr>
<td>Non-Responder</td>
<td>HBIG</td>
<td>HBIG</td>
</tr>
</tbody>
</table>

Note: In the event of uncertainty (for instance where the recipient has been previously vaccinated, but the antibody titres are unknown) the decision about Hepatitis B vaccination can be deferred to initial follow up.
SHOULD PEP BE RECOMMENDED?

Remember – it is recommended that for optimal efficacy, where appropriate, PEP should be commenced within ONE HOUR of exposure.

YES  If an individual has sustained a significant occupational exposure to blood or another high risk body fluid from a patient or another source known to be HIV positive, or considered to be at high risk of HIV infection where the result of HIV testing has not been, or cannot be, obtained in a timely fashion for whatever reason.

If, in the case of sexual exposure, the Risk Assessment Tool (see Section Two) indicates that PEP is recommended.

The recipient’s past history and details of current medication – including oral contraception – should be established. Females of childbearing age should be asked about the possibility of pregnancy and, if pregnancy cannot be excluded a pregnancy test should be urgently performed (see page 19).

The recipient should be given a patient information leaflet (Appendix 6), which should be explained to them and their giving or withholding of consent should be documented using the consent form (Appendix 5).

NO   After any exposure through any route with low risk materials (e.g. urine, vomit, saliva, faeces), unless visibly blood stained.

Source has tested negative for HIV.

If risk assessment has concluded that HIV infection of the source is highly unlikely.

The views of the exposed individual should be taken into account. For instance, if the exposure was significant, he/she may wish to commence PEP until further information is available. Changes can then be made to the regime, including cessation, where appropriate, when such information comes to hand.

In cases of uncertainty or where special circumstances apply, further advice should be sought.

In the event of HIV PEP being prescribed, pending follow up and in the absence of seroconversion, healthcare workers need not be subject to any modification of their working practices, for example in connection with exposure prone procedures. However, advice regarding “safer sex” and avoiding blood donation during the follow up period should be given.

If a Trust employee becomes ill due to the side effects of PEP, any leave due to this illness will be treated as Special Leave and will not contribute to that employee’s sickness absence record.
PEP – WHAT’S IN THE PACK

In line with the guidance from the Expert Advisory Group on AIDS (updated guidance September 2014), the packs contain the following drugs, to be taken as shown:

<table>
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<tr>
<th>Drug</th>
<th>Dose</th>
<th>Supply</th>
</tr>
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<tbody>
<tr>
<td>TRUVADA (Tenofovir disoproxil 245mg/Emtricitabine 200mg)</td>
<td>One tablet, once daily</td>
<td>1 x 30</td>
</tr>
<tr>
<td>RALTEGRAVIR 400mg</td>
<td>One tablet, twice daily</td>
<td>1 x 60</td>
</tr>
<tr>
<td>LOPERAMIDE 2mg Capsules</td>
<td>2 stat at onset of diarrhoea and then 1 after each loose motion, max. 8 capsules in 24 hours</td>
<td>1 x 30</td>
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The tablets should be taken with food. The PEP pack can be stored at room temperature.

This regimen may alter from time to time in line with national recommendations.

The antiretroviral drugs will be prepared in packs with a full thirty days’ supply. Follow-up should, however, be arranged for as soon as possible (see next page), at which point a further decision will be made regarding continuing or modifying the regimen.

All of the above have been associated with side effects. Loperamide is included in the pack to provide relief from diarrhoea, if these symptoms occur. Instructions for its use are included in the Patient Information Leaflet.

These drugs may have potentially serious interactions with other prescribed drugs and this possibility should be checked in the British National Formulary at http://www.hiv-druginteractions.org/ (go to “Drug interaction charts” then choose the relevant options at “View interaction charts”). Further information can also be obtained at www.medicines.org.uk (to check SPCs – Summary of Product Characteristics).

They have also been associated with new onset of and exacerbation of existing diabetes mellitus.

Patients should be made aware of the potential side effects of these drugs.

It should be borne in mind that no antiretroviral drug has been licensed for PEP. Therefore, these drugs can be prescribed for PEP only on an “off-label” basis (see Appendix 10).
If the source patient is known to be HIV positive, as much information as possible about current antiretroviral medication and known or suspected drug resistance should be gathered. Expert advice should be sought as the above regime may require alteration.

**FOLLOW UP**

After any significant exposure, the recipient must be given clear guidance about follow up (whether or not PEP is indicated). A copy of notes and the Emergency Department Doctor pro forma (*Appendix 7*) should be sent with the patient.

1. WHSCT employees who have sustained an occupational exposure (includes outside contractors who, *in the course of their work in WHSCT*, sustain a significant exposure) : *Occupational Health Department* WHSCT. (WHSCT employees who sustain an exposure outside their work in WHSCT should be followed up in the GUM Clinic).

2. Medical and Nursing students in WHSCT: *Occupational Health Department* WHSCT (who may subsequently arrange referral to the appropriate University Student Health Service).

3. GPs, Most Dentists (those within the NHS) and their employees, Ambulance personnel: *Occupational Health Department* WHSCT.

4. Self-employed healthcare workers and those employed in the private sector who have sustained an occupational exposure:
   - *GUM Clinic*

5. Others who have suffered a significant occupational exposure:
   - *Own employer’s Occupational Health Department, where available* (e.g. P.S.N.I.)
   - or where such a facility is not present
   - *GUM Clinic*

6. Members of the public *aged over 13 years* who have sustained a non-occupational significant exposure:
   - *GUM Clinic*

7. Members of the public *aged 13 years or under* should be followed up in the *Paediatric Day Hospital*. In the event of a decision being made to commence PEP, this follow up should be arranged by contacting a senior paediatrician (SpR or above).
   - Note: A decision to commence PEP should not be taken without senior advice – see page 32. If PEP is not indicated, follow up should be arranged at the Paediatric Day Hospital by sending a copy of the notes to the Nurse-in-Charge of that facility.

Follow up should be at the earliest opportunity at the appropriate facility.

Note: The Infection Prevention & Control Team have NO ROLE in following up these patients.

PEP should normally be continued for 4 weeks. Every effort should be made to facilitate adherence to a full 4-week regimen. This time course, or the drugs used, may need to be modified if problems of tolerance and/or toxicity occur. For instance nausea may require the
use of antiemetics or antimotility drugs may be needed if diarrhoea develops. Therefore, a supply of Loperamide is included in the pack. If such symptoms persist the person taking PEP could return to the Emergency Department (out of hours) or to the department in which they are being followed up (during office hours). At follow up counselling about the option of Post Exposure viral testing of the recipient will be undertaken.
SPECIAL CONSIDERATIONS

Pregnancy

Pregnancy does not preclude the use of HIV PEP, although expert advice should be sought if, after risk assessment, PEP is indicated (page 32).

If a female recipient cannot exclude the possibility of pregnancy, urgent pregnancy testing should be arranged.

The following information has been obtained by the manufacturers of the drugs in the recommended regime:

**Truvada**

A moderate amount of data on pregnant women (between 300-1,000 pregnancy outcomes) indicate no malformations or foetal/neonatal toxicity associated with Emtricitabine and Tenofovir disoproxil fumarate. Animal studies on Emtricitabine and Tenofovir disoproxil fumarate do not indicate reproductive toxicity. Therefore, the use of Truvada may be considered during pregnancy, if necessary.

**Raltegravir**

Manufacturer’s advice is that there are no adequate data from the use of raltegravir in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. The manufacturer advises that ISENTRESS (Raltegravir) should not be used during pregnancy. However, “A Reference Guide to Fetal and Neonatal risk – Drugs in Pregnancy and Lactation” 9th Edition (2011); Briggs G, Freeman R and Yaffe S (pages 1257 and 8) states that “if indicated, the drug should not be withheld because of pregnancy.” Therefore specialist advice should be sought.

A pregnant healthcare worker who has experienced an occupational HIV exposure should be counselled about the risks of HIV infection, about the risks of transmission to her baby (see also the section on breast-feeding below), and about everything that is known - and not known - about the potential benefits and risks of antiretroviral therapy for her and her baby, to help her reach an informed decision about the use of PEP.

Decisions on the use of specific drugs in pregnancy may be influenced by their individual adverse effects. For example, drugs which may cause nausea may exacerbate pregnancy-associated nausea.

**Breast Feeding Mothers**

Manufacturer’s advice is that breastfeeding is not recommended while taking Raltegravir.

Therefore specialist advice should be sought.

Although there is no evidence specifically about the use of PEP in breast feeding women, the following information is available. In a developed country a pregnant HIV positive woman who does not breast feed or take anti HIV treatment has a 15-20% chance of transmitting the virus to her baby. Among women who breast feed the transmission rate is 22-30%. A number of short antiretroviral courses have proved effective in reducing transmission in women in developing countries, including where women have breast fed their children (HIV & AIDS
Treatments Directory). Where a recipient who would normally be recommended to commence PEP is breast feeding, specialist advice should be sought (see page 32).

**The SOURCE is a Child**

Informed consent for triple testing must be from a person with parental responsibility.

**The RECIPIENT is a Child**

If the exposure was significant, and the source is, or is strongly suspected to be, HIV positive, specialist paediatric advice should be sought (see page 32).
SECTION TWO:

MANAGEMENT OF SEXUAL EXPOSURE
(Adapted from a policy authored by: Anne McVey, Jonathan Fyfe, Dr E. McCarty)
(Amended to take account of EAGA’s updated guidance, September 2014)
PURPOSE

To provide guidance for the Emergency Department, GP Out of Hours and GUM staff in deciding if PEPSE should be commenced. This document will also highlight potential situations where patients may be deemed to be high risk.

SCOPE

This procedure is applicable to the Emergency Department, GP Out of Hours and Genitourinary Medicine Departments of the WHSCT.

OBJECTIVES

1. To provide safe and effective care to patients in a timely manner.
2. To ensure decisions made by clinical staff are based on best evidence and that patients who require PEPSE receive it in a timely manner in accordance with recommended guidance.
3. To ensure this procedure links with guidance outlined in other Trust policies.

ROLES AND RESPONSIBILITIES

1. Clinical staff working in the Emergency Department, GP Out of Hours or GUM Clinic, must prioritise patients who potentially require administration of PEPSE.
2. The senior nurse/doctor on duty in the Emergency Department, GP Out of Hours or GUM Clinic should be informed of all patients who may fulfil the criteria for PEPSE administration as soon as possible following triage.
3. Advice will be available if required from GUM (during opening hours) or through the on call HIV Consultant (out of hours) at RVH, for staff in situations where there is ambiguity as to whether or not PEPSE should be commenced.
4. It is the responsibility of the clinician carrying out the Risk Assessment to ensure that a copy of the completed form is posted to the GUM Clinic in a sealed envelope marked “CONFIDENTIAL” so that appropriate follow up can be carried out without delay. This should be backed up by a telephone call to the GUM Clinic to alert them to the referral.
5. “It is the responsibility of the service taking specimens to ensure that the service user gets their results. A method of contact, and correct contact details, should be agreed in advance” (BASHH 2010). In the event of a positive baseline HIV test, the assessing department should be responsible for delivering this result; however advice from GUM should be sought.
6. It is the responsibility of the patient to ensure they attend for follow-up at GUM after referral from the assessing department.
PROCEDURE DESCRIPTION

A patient may attend requesting PEPSE following:
- Serious sexual assault
- Unprotected sexual intercourse, in a high risk situation.

1. Any patient who attends with either of these should be considered to be potential candidates for PEPSE and therefore treated as a medical priority.

2. Although PEPSE can be administered up to 72 hours post exposure to hazardous bodily fluid, it should be administered as soon as possible, ideally within 1 hour.

3. Consideration should also be given to whether or not the patient may require prophylaxis for Hepatitis B.

4. A risk assessment must be carried out by medical/ nursing staff in conjunction with the patient attending for treatment (see page 28). The following should be considered:
   - Type of body fluid involved in exposure;
   - Route and severity of exposure;
   - If source person is known to be HIV positive, men who have sex with men, a user of IV Drugs or from a country of high endemnicity (i.e. >3% HIV prevalence) e.g. Sub-Saharan Africa. [http://www.unaids.org/en/dataanalysis/epidemiology/](http://www.unaids.org/en/dataanalysis/epidemiology/)

5. If staff are uncertain as to whether or not to administer PEPSE, advice should be sought in the first instance from those listed on page 31 or (on a Consultant-to-Consultant basis) the regional on call GUM Consultant at Royal Victoria Hospital, Belfast, via their main switchboard (out of clinic hours).

6. A baseline HIV test must be taken prior to PEPSE being commenced. If indicated, a pregnancy test should be conducted. The responsibility for these results lies with the requesting team; however advice may be sought from GUM if necessary.
   - Patients MUST have a HIV test prior to commencing PEPSE. If the availability of this result is likely to delay the initiation of PEPSE beyond 72 hours of exposure, it is recommended to commence with result pending. If the HIV test returns positive, advice should be sought from GUM department prior to contacting the patient with their result.
   - Contact Virology, Royal Victoria Hospital on telephone number 02890635242 or 02890632662, or the Virology MLSO on-call via Royal Victoria Hospital switchboard (02890420503) to request an urgent HIV test for high risk attendee at the Emergency Department. A clotted blood sample should be sent along with a completed Virology form.

7. Patients must sign their consent on the risk assessment form prior to administration of PEPSE.

8. If PEPSE is commenced outside of GUM, a copy of the Risk Assessment tool must be sent to GUM so that they can arrange follow up with the patient. GUM can also be contacted during working hours on 02871611269 to ensure the referral has been received.
9. If PEPSE is not commenced referral on to their local GUM Clinic for further assessment of STIs is recommended. The completed Risk Assessment Tool must still be sent for audit and monitoring.

10. **Victims of Serious Sexual Assault**

Patients who present following serious sexual assault may self-present or be referred by the Forensic Medical Officer (FMO) from the Rape Crime Suite.

**Administration of PEPSE may be necessary prior to the patient being transferred to the Rape Crime Unit to undergo forensic examination.**

Patients who fulfil the following criteria may be deemed to be at risk of contracting HIV following sexual assault:

- Male sexual assault – anal penetration by someone known or unknown to the patient;
- Heterosexual sexual assault where the perpetrator is known to the victim and is HIV positive;
- Heterosexual sexual assault where the perpetrator is known to the victim and is an IV drug user but HIV status is unknown.
- Heterosexual assault where the perpetrator is unknown to the victim but may be from a high risk endemic area, i.e. >3% HIV prevalence (e.g. Sub-Saharan Africa). Prevalence data is available from UNAIDS [http://www.unaids.org/en/dataanalysis/epidemiology](http://www.unaids.org/en/dataanalysis/epidemiology)

11. **Unprotected Sexual Intercourse in ‘High Risk’ Situations**

**Male Patients:**

- Any male having unprotected sexual intercourse with another male, whether the HIV status is known or unknown would be deemed to be ‘High Risk’.
- Any male having unprotected sexual intercourse with another male or female who is a user of IV drugs and/ or is a member of an endemic population, i.e. >3% HIV prevalence (e.g. Sub-Saharan Africa). Prevalence data is available from UNAIDS [http://www.unaids.org/en/dataanalysis/epidemiology](http://www.unaids.org/en/dataanalysis/epidemiology)

**Female Patients:**

- Intercourse where the male is known to be HIV positive, bi-sexual, a user of IV drugs and/ or is a member of an endemic population, i.e. >3% HIV prevalence (e.g. Sub-Saharan Africa). Prevalence data is available from UNAIDS [http://www.unaids.org/en/dataanalysis/epidemiology](http://www.unaids.org/en/dataanalysis/epidemiology)

12. **Administration of PEPSE**

The patient should ideally have a confirmed negative HIV test prior to the administration of PEPSE if indicated. Discussion prior to PEPSE to enable the patient to give informed consent should include:

- Rationale of PEPSE (*BASHH Guidance*)
Pathogenesis studies indicate that there may be a window of opportunity to abort HIV infection by inhibiting viral replication following exposure. Once HIV crosses a mucosal barrier it may take up to 48-72 hours before HIV can be detected within regional lymph nodes and up to five days before HIV can be detected in blood. Initiation of antiretroviral therapy (ART) has been shown to reduce dissemination and replication of virus in all tissues if initiated early after inoculation in an animal model.


- Risks and side effects

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Estimated Risk of HIV Transmission per Exposure %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion (one unit)</td>
<td>90 – 100</td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>0.01 – 3</td>
</tr>
<tr>
<td>Receptive vaginal intercourse</td>
<td>0.001 – 0.3</td>
</tr>
<tr>
<td>Insertive vaginal intercourse</td>
<td>0.001 – 0.38</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>0.01 – 0.06</td>
</tr>
<tr>
<td>Receptive oral sex (fellatio)</td>
<td>0 – 0.04</td>
</tr>
<tr>
<td>Needlestick injury</td>
<td>0.3 (95% CI 0.2 - 0.5%)</td>
</tr>
<tr>
<td>Sharing injecting equipment</td>
<td>0.67</td>
</tr>
<tr>
<td>Mucous membrane exposure</td>
<td>0.63 (95% CI 0.018 – 3.47%)</td>
</tr>
</tbody>
</table>

Side effects:
Mainly gastrointestinal side effects with Raltegravir medication, especially diarrhoea, hence co-administration of Loperamide. A rash is also a common side effect of raltegravir. If this is severe or if accompanied by fever, malaise, arthralgia, myalgia, blistering, mouth ulceration, conjunctivitis, angioedema, hepatitis or eosinophilia, normal advice would be to discontinue. Specialist advice should be sought.

- Arrangement for follow-up

With the Trust GUM Clinic, Anderson House, Altnagelvin.
• Drug regime

30 day supply of medication to be given.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUVADA (Tenofovir disoproxil 245mg/ Emtricitabine 200mg)</td>
<td>One tablet, once daily</td>
<td>1 x 30</td>
</tr>
<tr>
<td>RALTEGRAVIR 400mg</td>
<td>One tablet, twice daily</td>
<td>1 x 60</td>
</tr>
<tr>
<td>LOPERAMIDE 2mg Capsules</td>
<td>2 stat at onset of diarrhoea and then 1 after each loose motion, max. 8 capsules in 24 hours</td>
<td>1 x 30</td>
</tr>
</tbody>
</table>

13. **Follow-Up of Patients Prescribed PEPSE**

Any person prescribed PEPSE will be followed up at the GUM clinic at Anderson House. During working hours an urgent appointment may be secured for the patient by contacting the clinic on 02871611269 and completed Risk Assessment Tool should be sent to GUM.

**SOURCES OF ADVICE AND FURTHER INFORMATION**

Staff must take cognisance of relevant legislations and guidance relating to this protocol including:

**Legislation**

- Data Protection Act 1998
- Disability Discrimination Act (1995)
- Equality/Good relations :section 75 of the N I Act (1998)
- The Human Rights Act (1998)
- The Health and Safety at Work (Northern Ireland) Order 1978
- The Management of Health and Safety at Work Regulations (Northern Ireland) 2000

**Codes of Practice**

- Nursing and Midwifery Council (2008), The Code Standards of conduct, performance and ethics for nurse and midwives.
- Nursing and Midwifery Council (2004), Midwives Rules and Standards.
- General Medical Council Code of practice
- Society of Sexual Health Advisers, Code of Professional Conduct.
Further Guidance for HIV Testing and Management

  www.bhiva.org/documents/Guidelines/Testing/GlinesHIVTest08.pdf

- British Association of Sexual Health and HIV (BASHH) (2006) UK Guideline for the use of post exposure prophylaxis for HIV following sexual exposure


- DOH -Expert Advisory Group on Aids (EAGA) 2008 HIV Post-exposure Prophylaxis, guidance from Chief Medical officers EAGA.


HIV PEPSE Risk Assessment Tool
(Post Exposure Prophylaxis for Sexual Exposure)

Date: / /  Time:  Location:  Clinician:

<table>
<thead>
<tr>
<th>Patient Details</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>Mr ☐ Mrs ☐ Ms ☐ Miss ☐</td>
<td>Address:</td>
<td>Mobile No:</td>
</tr>
<tr>
<td>Surname:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forename:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Birth:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex:</td>
<td>Male ☐ Female ☐</td>
<td>Postcode:</td>
<td>Clinic ID No:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Risk:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approximate Time of Risk:</td>
<td>If &gt;72 hours PEPSE NOT Recommended</td>
<td>Contact Persons Details (If Known):</td>
<td></td>
</tr>
<tr>
<td>Location of exposure to Risk:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Person:</td>
<td>Known ☐ Unknown ☐</td>
<td>Contact No:</td>
<td></td>
</tr>
<tr>
<td>Contact Gender:</td>
<td>Male ☐ Female ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Ethnicity:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Person HIV Risk/ Status</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative ☐</td>
<td>PEPSE NOT Recommended</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown ☐</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive ☐</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral Load (if known)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Treatment (if Known)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Resistance (if Known)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Attempts should be made, where possible, to establish the HIV status of the Contact individual as early as possible. If the contact person is also attending with the patient HIV testing is recommended. If the contact person is not present then efforts should be made to encourage the patient to notify their partner where possible to arrange urgent HIV testing as early as possible. If the contact person is known to be HIV positive attempts should be made at the earliest possible stage to determine their viral load, resistance profile and treatment history. Where the viral load is undetectable it is assumed that the risk of transmission will be significantly reduced. If there is evidence that the contact person has current or past history of treatment failure, the PEP antiretroviral therapy should be modified in relation to the drug history. Expert advice should be sought. BASHH 2011.
**Sexual Contact**

Consensual Sex:  Yes  ☐ No  ☐  It is believed that transmission of HIV is likely to be increased following aggravated sexual intercourse (anal or vaginal), such as that experienced during sexual assault. BASHH 2011.

<table>
<thead>
<tr>
<th>Oral sex</th>
<th>Insertive ☐</th>
<th>Receptive ☐</th>
<th>Protected ☐</th>
<th>Unprotected ☐</th>
<th>With ejaculation ☐</th>
<th>Without ejaculation ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal Penetration</td>
<td>Insertive ☐</td>
<td>Receptive ☐</td>
<td>Protected ☐</td>
<td>Unprotected ☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Anal Penetration</td>
<td>Insertive ☐</td>
<td>Receptive ☐</td>
<td>Protected ☐</td>
<td>Unprotected ☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Semen into eye</td>
<td>Yes  ☐ No  ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other information:

---

### SEXUAL ACTIVITY

<table>
<thead>
<tr>
<th>HIV Positive</th>
<th>CONTACT PERSON’S HIV STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral Load Detectable</td>
<td>Unknown High Risk Group/Area</td>
</tr>
<tr>
<td>HIV Positive</td>
<td>Viral Load Undetectable</td>
</tr>
</tbody>
</table>

| Receptive Anal Sex | Recommended | Not Recommended | Consider* | Not Recommended |
| Insertive Anal Sex | Recommended | Not Recommended | Consider* | Not Recommended |
| Receptive Vaginal Sex | Recommended | Not Recommended | Consider* | Not Recommended |
| Insertive Vaginal Sex | Recommended | Not Recommended | Consider* | Not Recommended |
| Receptive oral with Ejaculation | Consider | Not Recommended | Not Recommended | Not Recommended |
| Oral sex without Ejaculation | Not Recommended | Not Recommended | Not Recommended | Not Recommended |
| Splash of semen into eyes | Consider | Not Recommended | Not Recommended | Not Recommended |

* High prevalence groups within this recommendation are those where there is a significant likelihood of the source individual being HIV positive. Within the UK at present, this is likely to be MSM and individuals who have immigrated to the UK from areas of high HIV prevalence.

---

- Consent patient for Baseline Tests (HIV, U&L, LFT, uPCR)
- Check Medical History, Risk of Pregnancy & Drug interactions for suitability of PEPSE
- Commence 1 month PEPSE Pack
- Refer to GUM for follow-up

- Refer to BASHH Guidelines for further information on risk at http://www.bashh.org/guidelines
- Seek further advice from Regional HIV Consultant on Call at RVH

- Reassure Patient re. Risk
- Refer Patient to GUM for further Assessment, Advice & Testing

---

Policy on Exposure to Body Fluids and HIV Post Exposure Prophylaxis  
Page 28 of 45
When prescribing PEP it is essential to ensure that the potential for drug-drug interactions are considered. Clinicians are advised to liaise with an HIV specialist pharmacist and/or use online tools such as [http://www.hivdruginteractions.org/](http://www.hivdruginteractions.org/) for this purpose.

### Medical History

<table>
<thead>
<tr>
<th>Drug Allergies</th>
<th>PEPSE Commenced:</th>
<th>Yes</th>
<th>No</th>
<th>HIV Test Taken</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### Current Medications

<table>
<thead>
<tr>
<th>Drugs Prescribed:</th>
</tr>
</thead>
</table>

At presentation, and prior to administration of PEPSE, the following issues must be discussed with the individual:

- The rationale for PEPSE
- The lack of conclusive data for the efficacy of PEPSE
- The potential risks and side-effects of PEPSE
- The arrangement for early follow-up with GUM to arrange monitoring.

### Additional Information/ Actions:

### Consent to PEPSE

<table>
<thead>
<tr>
<th>Patient Signature:</th>
<th>Clinician Contact No/ Bleep:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: / /</td>
<td>Clinician Signature:</td>
</tr>
<tr>
<td></td>
<td>Date: / /</td>
</tr>
</tbody>
</table>
OTHER SITUATIONS

A variety of situations may arise where potential or actual exposure may occur outside either the healthcare or sexual exposure setting. These may include sharing of drug injecting equipment or accidental (or intentional) needlestick injuries.

In such situations further advice should generally be sought.

Even in the rare situation where the source is known to be HIV positive, it is unlikely that all details will be available in terms of current antiretroviral therapy or evidence of resistance. Therefore, the risk of infection with a drug resistant strain HIV in the event of failure of PEP is increased. This outcome is all the more likely if adherence to the PEP regimen is suboptimal. Additionally, it is unlikely that presentation will be within the one hour window during which commencement of PEP is thought to be most beneficial (although longer periods from exposure are not considered an absolute contraindication to PEP).

Bearing the above in mind and given the fact that the source will often be unknown, it seems likely that in the majority of cases of non-occupational/sexual exposure (except where the source is known or strongly suspected to be HIV positive), PEP would not be appropriate. Nevertheless a risk assessment needs to be performed on each occasion with as much information as possible being gathered about the incident and the source. Remember the possibility of HBV and/or HCV transmission and treat accordingly.

If PEP has the potential to be effective after non-occupational/sexual exposure, benefits are more likely in situations where:

- The risk of HIV transmission is considered to be high
- Such exposure is considered unlikely to be repeated
- PEP can be started promptly
- Good adherence to the regimen is considered likely

Informed consent should be obtained from the exposed person prior to prescribing PEP. This should include the following information:

- The need to start/resume relevant measures to reduce risk of exposure to HIV
- The lack of evidence of efficacy of PEP in these circumstances and the differing views of experts about its use in this context
- Known side effects and unknown toxicity of the drugs to be prescribed
- The importance of close adherence to the regimen
- Arrangements for follow up (usually the next available GUM Clinic except children)
- Symptoms and signs of HIV seroconversion (e.g. fever, rash, myalgia, fatigue, malaise, lymphadenopathy).

In the case of any doubt, further advice should be sought in these cases (see page 32).
FURTHER ADVICE

If further advice is required, the following may be contacted:

Emergency Medicine Consultant on-call for Northern and Southern Sectors respectively (in the event of an Emergency Medicine doctor dealing with a recipient of an exposure) via Switchboard

Dr R. Gamble, Consultant in Occupational Health via Switchboard

Dr G. Glynn, Consultant Microbiologist via Switchboard

Dr C. Armstrong, Consultant Microbiologist via Switchboard

If further specialist advice is required the duty Consultant in Communicable Disease Control is available via Switchboard. Additionally, help is obtainable from a Consultant in Genito-Urinary Medicine via Royal Victoria Hospital Switchboard. In both situations such advice should only be sought by a CONSULTANT in WHSCT.
Appendix 1

MEMBERSHIP OF COMMITTEE

Dr James Steele (Chairman) - Consultant in Emergency Medicine
Dr C. Armstrong - Consultant Microbiologist
Ms K. Boles - Head of Public Health
Dr Campbell Brown - Consultant in Emergency Medicine
Mr Alan Convery - Charge Nurse, GUM Clinic
Dr Wallace Dinsmore - Consultant in Genito-Urinary Medicine
Dr Rodney Gamble - Consultant Occupational Health
Dr Gerard Glynn - Consultant Microbiologist
Mrs Fiona Hughes - Head of Infection Prevention & Control
Ms A. McCauley - Sexual Health Co-Ordinator
Mrs K. McDaid - Assistant Director of Health Care, Woman & Children’s Directorate
Mrs L. Mullan - Principal Pharmacist
Dr. Say Quah - Consultant in Genito-Urinary Medicine
Appendix 2

AVAILABILITY OF PEP

Packs of PEP are available in the following sites:

- Emergency Department, Altnagelvin: 2 packs
- Emergency Department, SWAH: 1 pack
- Minor Injuries Unit, TCH: 1 pack
- GUM Clinic, Altnagelvin: 1 pack

Remember, to be most effective, PEP should be commenced within ONE HOUR of exposure. However, it may be worth considering PEP even up to two weeks after exposure.
INTERACTIONS OF PEP DRUGS WITH OTHER MEDICATIONS

N.B. Many other drug interactions exist and information may change. Therefore you are advised to check prescribing information in BNF. Full details of interactions are available at http://www.hiv-druginteractions.org/ (go to “Drug interaction charts” then choose the relevant options at “View interaction charts”).

PLEASE CHECK!!
WESTERN HEALTH & SOCIAL CARE TRUST

PATIENT CONSENT TO BLOOD SAMPLE BEING TAKEN FOLLOWING ACCIDENTAL EXPOSURE OF STAFF MEMBER

NOTES TO PATIENT
You have been informed that a member of staff accidentally came in contact with your blood or other body fluids. You will also know that, so we can protect our staff member, we now need to take a blood sample from you to check your blood for three important viruses – Hepatitis B, Hepatitis C and Human Immunodeficiency (HIV).

Please be assured that there is a very small risk of any of these viruses being present in your blood. We will tell you the results of the tests and if a virus is present, we will fully discuss with you how best to treat that virus. With your agreement, we will give your GP the test results.

The doctor will have told you that this is part of our normal routine in these cases. You will also have been told that you have a right to refuse to give us a blood sample. We hope, however, that you will agree so that we can decide how best to treat our member of staff.

People often worry that if they have an HIV test, this will affect any future application for life or other insurance cover. We have been informed by the Association of British Insurers that it is only necessary to advise insurance companies if a test has shown that you have HIV. They do not need to know if you have had a negative test. We hope this reassures you on this point.

If you have any more questions about this request for a blood sample, please feel free to ask the doctor. Once you are satisfied with the information you have been given, please complete this form. The completed form will be held in your confidential hospital record.

Thank you.

NAME …………………………………………………….. DOB………………………………………………..

CONSULTANT NAME………………………………….. HOSPITAL NO. ……………………………..

I consent to a blood sample being taken and tested for Hepatitis B, Hepatitis C, and Human Immunodeficiency (HIV).

I have read the notes above and have had any questions answered to my satisfaction.

I understand that I have a right to refuse consent and that such refusal will have no bearing on my future care and treatment.

I agree/ do not agree (please clearly indicate) to the results of the test being made known to my GP.

Signed ___________________________________        Date  ___________________________

Patient’s signature
What Happens Now?

If you have been exposed to someone else’s blood or body fluid, you may be worried about the risks of contracting a blood borne virus, such as HIV.

It is important to realise that the incidence of these viruses is low. Additionally, even when the “source” is definitely HIV positive, the risk of transmission after a needlestick injury is about 1 in 300.

To try to further reduce this small risk it is possible to receive a course of several anti-HIV drugs. However the available evidence only relates to occupational exposure in the health care setting. After looking at all the information available about the incident which has occurred to you, the doctor caring for you believes that there may be a benefit to you in commencing such a course.

It is important that you realise that these drugs can have unpleasant side effects in the short term (such as vomiting and diarrhoea) and that the long term effects are not known. Also taking these drugs does NOT guarantee that there is no chance of transmission of HIV. The drugs do not affect the risk of transmission of other blood borne viruses.

Normally the course lasts for 4 weeks, but it may be that as further information becomes available about the incident the drugs may need to be changed or may no longer be necessary. However it is important that you take the tablets you have been given exactly as prescribed unless you are advised otherwise at review. It is also extremely important that you attend for review as advised.

• I have read the leaflet “Post Exposure Prophylaxis (PEP)” and understand that it has been recommended that I commence a course of HIV post exposure prophylaxis drugs.
• I realise that the aim of these drugs is to try to reduce the risk of transmission of HIV. However, it cannot be guaranteed that taking this medication will completely exclude the possibility of this occurring.
• I realise that evidence for the benefit of these drugs in reducing the risk of HIV transmission relates only to occupational exposure in the health care setting.
• I have read the Patient Information Leaflet on HIV PEP and am aware that the drugs involved can cause unpleasant short term side effects and that their long term effects are not known.
• I appreciate the importance of attending for review as arranged.

• I AGREE to commencing a course of HIV Post Exposure Prophylaxis OR
• I DO NOT AGREE to commencing a course of HIV Post Exposure Prophylaxis (delete whichever of the above does not apply)

Name: ____________________________
Health & Care No: ______________________
Signature: ___________________________
Date: ____________________________

This section should be separated from the leaflet “Post Exposure Prophylaxis” and placed in the RECIPIENT’S notes.
Patient Information Leaflet on HIV Post-Exposure Prophylaxis

You have been prescribed a course of drugs, which have been shown to be helpful in preventing HIV infection following exposure. They are not currently licensed for this use.

The full course must be taken for FOUR weeks. At your follow up appointment a decision will be made about continuing treatment.

**IT IS VERY IMPORTANT TO TAKE THE MEDICINES EXACTLY AS PRESCRIBED**

Treatment must be started as soon as possible after exposure. Take the first dose of all the medication as soon as possible.

**PREVENTION TREATMENT INCLUDES**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE</th>
<th>HOW TO TAKE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Truvada &amp; Emtricitabine</td>
<td>245mg/200mg</td>
<td>Once daily. Take with or just after food or a meal</td>
</tr>
<tr>
<td>Tablets</td>
<td>One tablet in the morning</td>
<td></td>
</tr>
<tr>
<td>Raltegravir 400mg</td>
<td>One tablet, twice daily</td>
<td>Swallow whole, do not crush or chew</td>
</tr>
</tbody>
</table>

**SIDE EFFECTS OF PREVENTION TREATMENT**

Like all medicines, these drugs have some side effects. The most important ones are: Nausea, Vomiting, Diarrhoea, Abdominal Pain, and Tiredness

Inside the pack you will find a pack of Loperamide used to treat diarrhoea (take two to start, and then one after each loose stool, up to a maximum of eight per day). These should only be used if diarrhoea actually occurs.

If you experience nausea or vomiting, please consult your doctor.

The drugs can also cause some more serious side-effects like anaemia and pancreatitis. These are rare and you will be closely monitored throughout treatment in case these problems occur. If you would like further information, please contact the department where your follow up is being arranged (Genito-Urinary Medicine Clinic or Occupational Health Department, WHSCT).

If you experience any of these side effects or any other problems, tell the doctor. In the case of side effects being severe, you should contact the department where you are attending for follow up (Genito Urinary Medicine Clinic or Occupational Health Department, WHSCT) during
office hours or Accident and Emergency out of hours. Obviously, if you can continue treatment it would be best for you.

**OTHER POINTS**

- It would be advisable to use a barrier form of contraception e.g. condoms, until HIV infection has been excluded.

- Similarly, do not donate blood during this period.

**Please Note:** Unused drugs from the starter pack should be returned to Pharmacy Department, Altnagelvin Hospital, SWAH or TCH.

These tablets may INTERACT with other MEDICINES. This includes some medicines which can be bought over the counter in pharmacies, or herbal remedies. It is very important to advise the doctor treating you or following you up if you are taking any other medication.

Always CHECK with your doctor or pharmacist BEFORE STARTING any new medication whilst taking these tablets.

JUNE 2014
Appendix 7

Management of Significant Exposure to Blood or Other Body Fluids

Emergency Department Pro Forma

Please complete this document together with the usual notes. The patient should be advised to bring this document with them at follow up.

<table>
<thead>
<tr>
<th>Recipient</th>
<th>Source (if known)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname</td>
<td>Surname</td>
</tr>
<tr>
<td>Forename</td>
<td>Forename</td>
</tr>
<tr>
<td>D.O.B.</td>
<td>D.O.B.</td>
</tr>
<tr>
<td>Job Title (Trust Employees)</td>
<td>Hospital Number (where applicable)</td>
</tr>
<tr>
<td>Ward/ Area of work (Trust Employees)</td>
<td>Ward (where applicable)</td>
</tr>
</tbody>
</table>

- Record incident in Clinical Notes
- Ensure source blood sent for triple testing (with consent)
- Ensure recipient blood sent for triple testing (with consent)
- Give as much information about source and about recipient’s previous history of HBV vaccination (if any) as possible:

  ____________________________
  ____________________________

- Tick if dose of Hepatitis B vaccine given:
- Tick if dose of anti-HBs globulin given
- Any other action taken (e.g. commencing HIV PEP )

  ____________________________
  ____________________________

- Recipient referred to __________ When? __________

Name: ________________________

Signed: ________________________ Date: ________________________

A copy of this document should be filed in the Emergency Department (secretary’s office)

Effective from January 2013
PROBLEMS WITH CONSENT
(including the unconscious patient)

Following the introduction of the Human Tissue Act 2004, which came into force in England, Wales and Northern Ireland on 1 September 2006, the GMC’s advice [paragraphs 8 to 11 of the GMC’s guidance booklet Serious Communicable Diseases (1997)] on testing blood or bodily fluids from a patient who lacks capacity after a doctor has sustained a needlestick injury, has been superseded.

The following statement has been accessed from the GMC’s website:

“Current GMC advice on consent to testing can be found in Consent: patients and doctors making decisions together. Our advice on disclosure of confidential patient information to third parties (such as a person’s infection status) can be found in Confidentiality: protecting and providing information.

Decisions about testing the infection status of incapacitated patients, after a needle-stick or other injury to a healthcare worker, must take account of the current legal framework governing capacity issues and the use of human tissue. In England, Wales and Northern Ireland this area is covered by the Human Tissue Act 2004 and the Mental Capacity Act 2005 (E&W only). In Scotland this area is covered by the Adults with Incapacity (Scotland) Act 2000 and the Human Tissue (Scotland) Act 2006. As we understand it, current law does not permit testing the infection status of an incapacitated patient solely for the benefit of a healthcare worker involved in the patient’s care. Concerns about how best to care for healthcare workers who may have had high risk exposure to a serious communicable disease, where the patient’s infection status is not known, should be raised with local occupational health advisers, and legal advice should be sought where necessary.”

Whilst the GMC point this out on their website, they have not yet issued new guidance.


Given that this is an area fraught with difficulty, any decision to test a source without consent can only be made after extremely careful consideration. Those who encounter such a situation should consider involving the Trust’s legal advisers as well as their medical defence organisation. Advice should also be sought from senior clinical colleagues.
HEALTH CARE WORKERS SECONDED/ WORKING OVERSEAS

The situation may arise where a HCW employed by the WHSCT Trust undertakes temporary clinical work overseas in an area where HIV is a particular problem. Such a HCW should attend the Occupational Health department before travelling for advice about reducing the risk of occupational exposure to HIV and other blood borne viruses. Limitation of future career choices in the event of HIV infection of a HCW (depending on their discipline) should be carefully explained. It may be the case that in some countries access to PEP may be difficult. If this is the case, the HCW may wish to take this into account when making a decision whether or not to undertake such work. On return, the HCW should attend the Occupational Health Department for debriefing prior to commencing exposure prone procedures.
GUIDANCE CONCERNING THE UNLICENSED USE OF MEDICINES

As has been stated in the preceding guidance, whilst the drugs involved are licensed for the treatment of established HIV, they are not licensed for PEP.

Professional guidance is available in the Trust Policy for the Purchase and Supply of Unlicensed Medicinal Products, November 2008.

A brief extract is reproduced below relating to the area of unlicensed use of medicines with a Product Licence.

When a licensed medicine is prescribed for an unlicensed indication (i.e. in breach of the terms of its product license), the prescriber is professionally accountable for his/her judgment in so doing, and may be called upon to justify his/her actions. The manufacturer is unlikely to be found liable for any harm caused by that medicine, unless the harm is directly attributable to a defect in it, rather than the way in which it was prescribed.

The onus of responsibility falls back on the prescriber.

Recognising that the use of an unlicensed medicine is sometimes necessary in order to provide the optimum treatment, the Trust will accept liability on behalf of the prescriber and/ or pharmacist provided that the principles outlined in the Trust policy have been followed.

Given that the guidance is based on the recommendations of the UK Chief Medical Officers’ Expert Advisory Group and regional expert opinion from those Genito-Urinary Medicine Consultants dealing with HIV, it would have to be proven that the Trust had acted negligently in following this guidance.
TRAINING

The issues surrounding PEP are complex and, at least until the present, the occasions when PEP is actually indicated are rare. There is also the potential for severe anxiety in the person who has sustained the exposure. It is, therefore, important that anyone assessing risk and deciding whether or not PEP is indicated is adequately trained. This is likely to be particularly true of Emergency Department junior doctors who will be the first point of contact in a large proportion of instances.

Therefore, a training session for Emergency Department staff will be included in both Departmental training programmes. This training will highlight the urgency of cases of potential or actual exposure to blood borne viruses, the principles involved in risk assessment and the indications for PEP. It will also reinforce the importance of seeking further advice where appropriate.
ABI STATEMENT OF BEST PRACTICE FOR HIV AND INSURANCE (JULY 2008)

This is a comprehensive document dealing with all aspects of this issue. However, the most relevant section (in relation to patients’ fears about the possible consequences of being tested for HIV) is on page 6 and is quoted below:

“**Asking about the applicant’s HIV status and risk**

3.6 Since publication of the ABI Statement of Best Practice on Underwriting Life Insurance for HIV in July 1994, insurers have not asked whether an applicant had undergone counselling about HIV, or had taken a HIV test. Instead, insurers ask whether the applicant had tested positive for HIV, or was awaiting the results of an HIV test.

3.7 Insurers that use “short” application forms (which have a minimum of medical questions) may choose to incorporate these questions in a separate questionnaire. ABI members should use the following questions (in bold type):

(A) **HIV, hepatitis B or hepatitis C status**

Have you ever tested positive for HIV, hepatitis B, or hepatitis C, or are you awaiting the results of such a test?

**Note:** If the result is negative, the fact of having a HIV test will not, of itself, have any effect on your acceptance terms for insurance”

Clearly a positive test would have to be declared.
REFERENCES


Policy for the purchase and supply of unlicensed medicinal products, November 2008.

SIGNATORIES

Signed for and on behalf of the Western Health & Social Care Trust:

______________________________  ________________________
Dr James Steele  
Consultant in Emergency Medicine  Date

______________________________  ________________________
Fiona Hughes  
Head of Infection Prevention and Control  Date