Guidance for management of exposure events where there is a risk of transmission of blood borne viruses (HIV, Hepatitis B and Hepatitis C) in the community

SUMMARY

- Where a child is thought to have had had a significant exposure to a blood borne virus (BBV) then they should be referred urgently to the paediatric on-call team
- A risk assessment of the injured person and the source should be completed by whomever the injured person presents to (primary care, emergency department, minor injuries unit, infectious diseases, sexual health etc)
- Sexual exposure incidents presenting between 9am to 5pm except weekends and public holidays should be asked to attend Tayside Sexual and Reproductive Health Services; South Block, Level 7, Ninewells Hospital or Drumhar Health Centre, Perth (see section 7 for opening times)
- The majority of exposure events do not require onward referral for HIV post exposure prophylaxis (PEP) as following assessment they are usually found not to be of sufficiently high risk to require HIV PEP
- Where there is a significant risk and HIV PEP is recommended, this is available for non-sexual exposure and out of hours at the Emergency Departments of Ninewells Hospital, Dundee and Perth Royal Infirmary, Perth. Follow up will be arranged within the Infectious Diseases Department, Ninewells Hospital, Dundee
- HIV PEP is not recommended beyond 72 hours post exposure. Hepatitis B PEP can be given up to a week after exposure but is ideally started within 48 hours
- PEP is available against HIV and Hepatitis B. Whilst there is no PEP for hepatitis C, early diagnosis allows treatment with a high chance of cure

INTRODUCTION

Healthcare Improvement Scotland Standards for HIV Services (July 2011) state that Scottish Health Boards must have a policy in place for the 24 hour availability of HIV post-exposure prophylaxis (PEP), including for sexual exposure (PEPSE). This guidance has been produced to meet the requirements of the HIS Standards and are in accordance with the recommendations from the UK Chief Medical Officers' Expert Advisory Group on AIDS (2008) and includes the "Change to recommended regimen for post-exposure prophylaxis (PEP)" September 2014 and "Updated recommendation for HIV post-exposure prophylaxis (PEP) following occupational exposure to a source with undetectable HIV viral load" December 2013. In addition these guidelines were produced using the British Association of Sexual Health and HIV UK Guideline for the use of post-exposure prophylaxis for HIV following sexual exposure (2011) and the UK Department of Health's Green Book on Immunisation against Infectious Diseases.

This guidance is aimed at all NHS Tayside staff, including Primary Care, Sexual Health Clinics, Minor Injuries Units and the Emergency Department, where people may present who think they may have been exposed to a blood borne virus (BBV). There is separate guidance for NHS Tayside workers who sustain a contamination/needlestick injury available from Staffnet.

Preventing exposure to BBVs is not always possible but reducing the risk of transmission is possible using PEP. The management of exposure events where there is a risk of BBV transmission, including the use of PEP, is complex and members of the public can present to a number of sites for advice following an event.

The majority of exposure injuries do not require onward referral, as following careful risk assessment they are usually found not to be of sufficiently high risk to require PEP. PEP is available against HIV and Hepatitis B. HIV PEP is most likely to be effective if initiated within hours of exposure and is not recommended beyond 72 hours post exposure. Hepatitis B PEP can be initiated up to a week after exposure though ideally it should be started within 48 hours of exposure. An early diagnosis of Hepatitis C allows for treatment with a high chance of cure.

Exposure events that have a risk of BBV transmission include needlestick injuries (percutaneous), body fluids on open skin or in the eyes, nose and mouth (mucocutaneous exposure) and sexual exposure. The risk of BBV transmission and thus the management of these injuries vary based on the source patient, type of injury and the body fluid involved. For an exposure to be considered of sufficient risk of transmitting HIV, the **type of exposure**, the **body fluid** involved must be high-risk plus the **source individual** will be known to have HIV or come from a high prevalence group.

Table 1 – the risk of transmission of BBVs in an untreated source patient by different exposure events. Data is not available for all BBVs and exposure events.

	Receptive Anal Sex	Needlestick injury	Receptive Vaginal Sex	Mucocutaneous exposure
HIV	1 in 50	1 in 300	1 in 500	1 in 1000
Hepatitis C		1 in 30		
Hepatitis B		1 in 3		

ASSESSMENT AND MANAGEMENT OF EXPOSURE EVENTS

1. First aid
2. Document timing and nature of exposure
3. Risk assessment of the injury and body fluids involved
4. Risk assessment of the source individual
5. Indications for HIV PEP
6. Indications for Hepatitis B PEP
7. Referral for PEP (if required)
8. Use of HIV post exposure prophylaxis in the Emergency Department (if required)
9. Onward referral and appropriate follow up and testing

1. FIRST AID

- If the skin is punctured gently encourage the wound to bleed
- Thoroughly wash the wound with soap and warm water. Do not scrub
- Cover with a waterproof plaster
- For splashes to mucous membranes or broken skin, irrigate with lots of water

2. DOCUMENT TIMING AND NATURE OF EXPOSURE

To make a thorough assessment of the injury a clear history including the timing of the exposure should be documented. The history should include any on-going risk of BBV acquisition. As Hepatitis B can be prevented by the use of a vaccine plus immunoglobulin post-exposure, documenting the person's vaccination history is vital to optimise use of PEP.

For tetanus prophylaxis please refer to the Department of Health Green Book:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148506/Green-Book-Chapter-30-dh_103982.pdf

3. RISK ASSESSMENT OF THE EXPOSURE

Only certain events are thought to carry significant risk of transmitting BBVs. Therefore both the injury and the body fluid involved need to be considered. The tables below outline what exposures and body fluids are considered high or low risk for HIV transmission. Only a high risk exposure involving a high risk fluid with a known and untreated HIV positive source or a source from a high prevalence group would warrant the use of HIV PEP. Please note that there are differences in the way the risk is assessed for HIV and Hepatitis B and the assessments for PEP should be made separately.

High risk exposures	**Low risk exposures**
• Needle, surgical instrument or other sharp (bone spike, broken tooth) penetrating skin • Fluid onto broken skin • Fluid on to mucous membrane (eye, nose or mouth) • Insertive anal sex without condom • Insertive vaginal sex without condom • Receptive anal sex without a condom • Receptive vaginal sex without a condom • Human bite • Receptive oral sex *	• Fluid onto intact skin • Any other sex with or without a condom

* Penis inserted into presenting/injured person's oral cavity

High risk body fluids	**Low risk body fluids**
• Amniotic fluid • Blood • Cerebrospinal fluid • Exudative or other tissue fluid from burns or skin lesions • Human breast milk • Pericardial fluid • Peritoneal fluid • Pleural fluid • Saliva in association with dentistry • Semen • Synovial fluid • Unfixed human tissues and organs • Vaginal secretions • Any other body fluid if visibly blood-stained	• Faeces • Saliva* (in absence of dentistry) • Sputum/phlegm • Tears • Urine • Vomit • Non-blood-stained or no fresh/wet blood on discarded needle

***** Spitting, even if in contact with mucosal surfaces is low risk and does not require PEP

In the case of an injury sustained with a discarded needle, where the source cannot be identified, HIV PEP is not indicated. There may be a need for Hepatitis B PEP.

If EITHER the exposure OR the body fluid/materials are low risk, HIV PEP is not indicated. There may be a need for Hepatitis B PEP.

Even when the assessment of the exposure indicates that HIV or Hepatitis B PEP is not indicated there is an opportunity to provide advice (including information leaflets) on risk and harm reduction. Specialist services are available and should be appropriately signposted to such as Tayside Sexual and Reproductive Health Service for risk reduction advice and the Harm Reduction Service for advice on safer injecting.

4. RISK ASSESSMENT OF THE SOURCE

If the exposure AND the body fluid is high risk and the source individual is known to have HIV or is from a HIV high prevalence group then HIV PEP may be indicated.

The source individual should be asked the questions below or when unavailable or unknown the exposed individual should be asked to answer to the best of their knowledge:

- Is the source known to have HIV? If the source has HIV, understanding whether they are on treatment and their last viral load helps refine the risk assessment.

If any of the questions below are answered "Yes" then the source is from a HIV high prevalence group:

- Is the source known to have Hepatitis B or Hepatitis C?
- Does the source come from an endemic region (sub-Saharan Africa, Caribbean, Thailand)?
- Has the source had a sexual partner from or had sex in an endemic region (sub-Saharan Africa, Caribbean, Thailand)?
- If the source is not from the UK, have they ever injected drugs?
- If the source is male – have they had sex with other men?
- Does the source have a sexual partner known to have HIV with a detectable viral load?
- Does the source have a current illness compatible with HIV/AIDS?

If the source is available and agrees to testing, the exposed individual can often have post-exposure prophylaxis stopped preventing side effects, worry and cost. When a high risk injury, with a high risk fluid, has been sustained all available source individuals with unknown blood borne virus status should be asked to consent to HIV, Hepatitis B and Hepatitis C testing. This could be through the source's own GP; by Tayside Sexual and Reproductive Health if related to a sexual exposure; or if the exposed individual is referred for PEP, testing of a known source can be arranged via the Infectious Diseases Department. If the source is unavailable, but known to the injured person, information on how the source can be tested for HIV, Hepatitis B and C should be offered (LINK).

What to tell the source (gaining consent for BBV testing)

1. An injury/incident has occurred that has been assessed as having the potential of transmitting infections to the exposed individual
2. We can test you (the source) for HIV, Hepatitis B and Hepatitis C to understand what the best treatment is for the exposed individual. By having the tests you will also understand whether there is a risk you could pass on an infection in the future and also you would be able to access treatment and care
3. Your test results will be shared with the doctor treating the exposed individual
4. If any of the tests are positive you will be informed and referred to a specialist for assessment and care (referrals to Infectious Disease, Ninewells Hospital, Dundee)

Testing the source

Should the source consent to BBV testing, obtain blood in gold-topped Vacutainer. On ICE the 3 tests required are described as "HIV screening test", "Hepatitis B (HBsAg) infection screen" and "Hepatitis C antibody screen" indicate in the clinical details **"Contamination injury. Source individual. Urgent HIV, Hepatitis B and Hepatitis C testing".** The request should include the name and contact details for the responsible staff member to whom the results should be communicated. Offer an information leaflet to the source whether they consent to testing or not (LINK).

5. INDICATIONS FOR HIV POST EXPOSURE PROPHYLAXIS

Using the information gathered the table below outlines when HIV PEP is indicated. This combines the injury, body fluid and the initial assessment of the source's risk.

	Source HIV status			
	HIV positive		**Unknown HIV-status**	
	Viral load detectable or unknown	**Viral load undetectable ++**	**High prevalence group +**	**Low prevalence group**
Needle, or other sharp item contaminated with fresh, wet blood penetrating skin	Recommend	Not recommended unless viral load last checked more than 6 months ago or result not immediately available	Recommend	Not recommended
High risk fluid onto broken skin	Recommend	Not recommended	Recommend	Not recommended
High risk fluid on to mucous membrane (eye, nose or mouth)	Recommend	Not recommended	Recommend	Not recommended
Human Bite *	Recommend	Not recommended	Not recommended	Not recommended
Receptive anal sex without a condom	Recommend	Not recommended unless viral load last checked more than 6 months ago or result not immediately available.	Recommend	Not recommended
Insertive anal sex without a condom	Recommend	Not recommended	Recommend **	Not recommended
Receptive vaginal sex without a condom	Recommend	Not recommended **	Recommend **	Not recommended
Insertive vaginal sex without a condom	Recommend**	Not recommended	Recommend **	Not recommended
Fellatio (giving) with ejaculation without a condom	Recommend **	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Not recommended	Not recommended	Not recommended	Not recommended
Fellatio (giving) without ejaculation without a condom	Not recommended	Not recommended	Not recommended	Not recommended
Fellatio (receiving) without a condom	Not recommended	Not recommended	Not recommended	Not recommended
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended

** Recent guidance has indicated that a human bite is unlikely to transmit HIV. In the context of a source individual with known HIV infection, especially with blood in the mouth prior to the bite (for example in association with dentistry) or where there is significant tissue trauma the risk may be greater and PEP should be prescribed*

*** These patients require a specialist assessment within Tayside Sexual and Reproductive Health at*

the earliest opportunity. With further assessment, continuation of HIV PEP may not be required and this will be discussed with the patient

[+] *High prevalence groups include – Having sex in, or a partner from, or coming from, an endemic region (sub-Saharan Africa, Caribbean, Thailand); A person who injects or has injected drugs; A man who has sex with other men; A current clinical illness compatible with HIV/AIDS; A sexual partner of known HIV infected person*

[++] *Viral load undetectable is where the source is known to have HIV, has had a viral load below 200 copies per ml for at least 6 months and this has been checked within the last 6 months, and is adherent to medication*

6. INDICATIONS FOR HEPATITIS B POST EXPOSURE PROPHYLAXIS

Significant exposure is defined as:

(i) percutaneous exposure (needlestick or other contaminated sharp object injury, a bite which causes bleeding or other visible skin puncture)

(ii) mucocutaneous exposure to blood (contamination of non-intact skin, conjunctiva or mucous membrane)

(iii) sexual exposure (unprotected sexual intercourse)

	Significant exposure			Non-significant exposure	
HBV status of person exposed	**HBsAg positive source**	**Unknown source**	**HBsAg negative source**	**Continued risk**	**No further risk**
≤ 1 dose HB vaccine pre-exposure	Accelerated course of HB vaccine* HBIG × 1	Accelerated course of HB vaccine*	Initiate course of HB vaccine	Initiate course of HB vaccine	No HBV prophylaxis. Reassure
≥ 2 doses HB vaccine pre-exposure (anti-HBs not known)	One dose of HB vaccine followed by second dose one month later	One dose of HB vaccine	Finish course of HB vaccine	Finish course of HB vaccine	No HBV prophylaxis. Reassure
Known responder to HB vaccine (anti-HBs >10mIU/ml)	Consider booster dose of HB vaccine	Consider booster dose of HB vaccine	Consider booster dose of HB vaccine	Consider booster dose of HB vaccine	No HBV prophylaxis. Reassure
Known non-responder to HB vaccine (anti-HBs < 10mIU/ml 2–4 months post-immunisation)	HBIG × 1 Consider booster dose of HB vaccine A second dose of HBIG should be given at one month	HBIG × 1 Consider booster dose of HB vaccine A second dose of HBIG should be given at one month	No HBIG Consider booster dose of HB vaccine	No HBIG Consider booster dose of HB vaccine	No prophylaxis. Reassure

*An accelerated course of vaccine consists of doses spaced at zero, one and two months.
A booster dose may be given at 12 months to those at continuing risk of exposure to HBV.
Source: PHLS Hepatitis Subcommittee (1992).

Taken from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/503768/2905115_Green_Book_Chapter_18_v3_0W.PDF

HBIG is used after exposure to give rapid protection until hepatitis B vaccine, which should be given at the same time, becomes effective. The use of HBIG in addition to vaccine is recommended only in high-risk situations or in a known non-responder to vaccine. Whenever immediate protection is required, immunisation with the vaccine should be given. When appropriate, this should be combined with simultaneous administration of HBIG at a different site. HBIG should be given as soon as possible, ideally within 48 hours, although it should still be considered up to a week after exposure.

7. REFERRAL FOR PEP

If a child has had a significant exposure they should be referred urgently to the paediatric team.

All sexual exposure incidents presenting between 9am to 5pm except weekends and public holidays should be asked to phone Tayside Sexual and Reproductive Health Services (01382 425542; select option 4) and state they are seeking HIV PEP.

Where HIV PEP is indicated out of hours please contact the closest Emergency Department and arrange for the injured person to attend with all information documented at the earliest opportunity. HIV PEP is most likely to be effective when initiated as soon as possible, within hours, allowing for careful risk assessment. HIV PEP is not recommended beyond 72 hours post exposure.

8. USE OF HIV PEP IN THE EMERGENCY DEPARTMENT

HIV PEP PRESCRIPTION

- HIV PEP is available in the Emergency Department at PRI and Ninewells Hospital as a 7 day starter pack of Emtricitabine 200mg/Tenofovir disoproxil 245mg ONE every 24 hours and Raltegravir 400mg ONE tablet every 12 hours
- There is a prescriber's guidance sheet in Appendix 4 that should be followed and the injured person should also be given the information leaflet in Appendix 5
- Sign prescription and send to Pharmacy department as detailed at the top of the form in Appendix 6
- There are no significant drug interactions with contraceptives
- HIV PEP follow up for non-sexual exposure should be arranged with the Infectious Diseases team. Complete the referral in appendix 3 and email (tay.id@nhs.scot)
- HIV PEP follow up for sexual exposure should be arranged with Tayside Sexual Health Service. Complete the referral in appendix 3 and email (tay.tsrh@nhs.scot)

CONTRAINDICATIONS TO HIV PEP

The only absolute contraindication for use of HIV post-exposure prophylaxis is if the injured person is already known to have HIV. Pregnancy and known chronic kidney disease are relative contraindications and a pregnancy test should be performed if there is doubt. Where there is a relative contraindication to PEP, the benefits of PEP may still outweigh the risks. The first dose of PEP should be taken and the 7 day pack issued. Individuals with renal impairment may need dose reduction based on creatinine clearance. Follow up should be ensured within 72 hours if creatinine clearance is <50ml/min or in pregnancy. If HIV PEP is declined or indicated but not prescribed the rationale should be clearly documented.

Pregnancy is not a contraindication to PEP. Indeed seroconversion during pregnancy will lead to a higher than normal risk of intrauterine infection. However, it should be noted that the medicines used for PEP will be off license in this case and follow up with infectious diseases or GUM should happen as soon as possible. Please indicate this in the referral form in appendix 3.

BASELINE TESTS

All individuals started on HIV PEP should have baseline blood tests: U+E, LFT, and a full BBV screen requested (gold top tube to microbiology). A urinalysis should be documented and a pregnancy test completed for female patients.

9. ONWARD REFERRAL AND APPROPRIATE FOLLOW UP AND TESTING

- All individuals prescribed HIV PEP will be offered support whilst they are on treatment
- Infectious Diseases team will offer all individuals started on HIV PEP for non-sexual exposure an initial meeting to discuss continuing HIV PEP and will communicate this to primary care. The Infectious Diseases team will perform a review of the injured person's risk for BBVs and arrange testing if required
- If HIV PEP is continued ID will arrange the remaining 21 days to be collected from the hospital pharmacy and will arrange any follow up blood testing required depending on baseline results
- Infectious Diseases will outline the routine blood screening that is required to be completed in primary care. (Testing for Hepatitis B, Hepatitis C and HIV at 12 weeks after exposure event or if known chronic Hepatitis C positive source, HCV PCR should also be requested 6 and 12 weeks after exposure. Hepatitis B and Hepatitis C serology should be repeated again at 6 months. Hepatitis B serology not required in Hepatitis B vaccine responder)
- Infectious Diseases will also advise on whether any additional action is required after the initial assessment with regard to Hepatitis B vaccination
- For all HIV PEP started for sexual exposure, Tayside Sexual and Reproductive Health Service will follow up

For immediate advice or early follow up please contact the ID Consultant on Call (Page 5075) or the Sexual and Reproductive Health Service on 01382 425542 or 07805 762 572.

References

HIV post-exposure prophylaxis *Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS* 2008 http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089997.pdf

UK guideline for the use of HIV post-exposure prophylaxis following sexual exposure (2015) http://www.bashh.org/documents/PEPSE%202015.pdf

The Green Book – Immunisation against infectious diseases – Department of Health http://immunisation.dh.gov.uk/green-book-chapters/

Exposure to hepatitis B virus: guidance on post-exposure prophylaxis. CDR Review Volume 2, Review Number 9, 14 August 1992.

Appendix 1
CONFIDENTIAL - Letter template for communication to primary care from the Emergency Department following a needlestick injury or other exposure to body fluid in the community

Dear Doctor,
Your patient attended the Emergency Department after a needlestick/exposure to body fluids.

Name :

CHI: Date attended:

Your patient's exposure was deemed to be significant / non-significant.
(Circle as appropriate)

Summary of Blood Borne Virus Status of Source *(Circle appropriate box)*			
Hepatitis B Status of Source	HBsAg positive	HBsAg negative	Unknown
Hepatitis C Status of Source	Antibody positive	Antibody negative	Unknown
HIV Status of Source	Antibody positive	Antibody Negative	Unknown

Action taken *(circle appropriate box)*			
HIV post exposure prophylaxis	Initiated (follow up with ID arranged)	Not indicated	Indicated and declined
Hepatitis B vaccine (single dose)	Given	Not indicated	Indicated and declined
Hepatitis B Immunoglobulin	Given	Not indicated	Indicated and declined

Your patient will require to complete a Hepatitis B vaccine course in the following circumstances:
□□□He or she has had a significant injury and not completed a course of Hepatitis B vaccination;
□□□He or she is at risk of future exposure.
Further guidance can be obtained from the Green Book: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/503768/2905115_Green_Book_Chapter_18_v3_0W.PDF
We would recommend after a significant exposure the following tests:
□□□Hepatitis B, Hepatitis C and HIV serology at 12 weeks post exposure.
Hepatitis B and Hepatitis C serology should be repeated 6 months post exposure.

Signed _____
Name _____
Designation _____
Date _____

Appendix 2
Needlestick/Body Fluid Exposure Assessment Summary Form for Community Use

Name of exposed individual CHI Address	Contact telephone number Date and time of exposure (24 hour clock) HH:MM DD/MM/YY Date and time of assessment HH:MM DD/MM/YY

- If the exposed individual is a child please refer to the paediatric registrar on-call
- In the case of an injury sustained with a discarded needle, where the source cannot be identified, HIV PEP is not indicated. There may be a need for Hepatitis B PEP
- HIV PEP is only indicated within 72 hours of exposure, Hepatitis B PEP may be used up to one week after exposure

HIV PEP Assessment Was the injury, body fluid and source individual high risk? Yes / No Is HIV PEP recommended based on above guidance? Yes / No If Yes – ask the patient to attend, for sexual exposure, the closest TSRH department or, for non-sexual exposure or out of hours, the closest Emergency Department
Hepatitis B PEP Assessment Was the exposure significant i.e. percutaneous, mucocutaneous with blood, or sexual exposure? Is Hepatitis B Immunoglobulin (HBIG) indicated? Yes / No Is Hepatitis B Vaccination indicated? Yes / No
Recommend testing for HIV, Hepatitis B and Hepatitis C to all available source individuals

After a significant exposure testing for HIV, Hepatitis B and Hepatitis C three and six months after the event is recommended.

Advice available from:

- Infectious Diseases On-call Doctor available via Ninewells Hospital Switchboard 01382 660111 bleep 5075
- Tayside Sexual and Reproductive Health Service on 01382 425542 or 07805 762 572

Appendix 3
Referral to Infectious Diseases or Sexual and Reproductive Health Service for Patients Commenced on PEP(SE)

Injured Person Details

Name	
Date of Birth	
Phone Number	
Best Time to Call	

Detail of Injury

Date and Time of Injury/sexual contact	
Nature of Injury/sexual contact (vaginal, anal, oral penetration)	
Date and Time Started on PEP	
Hepatitis B Status including requirement for HBIG	
If not vaccinated, was first dose Hep B vaccination given?	YES / NO
Date and Time of Baseline Blood Tests	
Other Relevant Info i.e. PMH of note	
Renal impairment with creatinine clearance <50ml/min?	YES / NO
Is the injured person pregnant?	YES / NO

Details of Source Patient

Does Patient Consent to Testing?	YES / NO
Patient Tested?	YES / NO
Patient Known BBV? If so which	
Source Patient CHI & Contact Details (occupational injury only)	

Details of Referring Doctor

Name	
Grade	
Contact Details	

To arrange follow up with Infectious Diseases please email this form to: tay.id@nhs.scot
To arrange follow up with Sexual Health Services please email this form to: tay.tsrh@nhs.scot

Appendix 4

HIV POST EXPOSURE PROPHYLAXIS (PEP) and POST EXPOSURE PROPHYLAXIS following SEXUAL EXPOSURE (PEPSE)

Starter Pack Prescriber's Guidance

What you need to know

- No antiretrovirals are licensed for PEP so these drugs are prescribed 'off label' however their use is recommended by the UK Department for Health, British HIV association (BHIVA) and the British Association for Sexual Health and HIV (BASHH)
- Treatment should be started **as soon as possible**, ideally within 1 hour of the incident
- The starter pack contains a 7 day supply of 3 antiretroviral drugs:
  Emtricitabine 200mg/Tenofovir disoproxil 245mg x 7 tablets
  Raltegravir 400mg x 14 tablets
  Brief details of each drug are given in the appendix along with links to further information
- The list of side effects in the appendix is not exhaustive, consult current edition of the BNF (www.bnf.org) or Summary of Product Characteristics (www.medicines.org.uk), for further information
- These drugs have been chosen as they have less significant drug-drug interactions than previous nationally recommended regimes

What you need to do

- Check with the list of interactions on the next page and current edition of the BNF or SPC or HIV drug interactions website www.hiv-druginteractions.org
- Ensure the patient reads the information leaflet
- Complete the prescription sheet in Appendix 6 and send it to the Pharmacy Department as indicated
- Check the expiry date on the pack
- A qualified prescriber must write the patient's name and date of dispensing on the outside of each pack and on the 2 containers of tablets inside the pack where indicated and have it checked by another practitioner

What you need to tell the patient

- They are being supplied with a 7 day starter pack ONLY and appropriate follow up will be arranged as per the assessment form
- No antiretroviral drugs are licensed for this indication however the choice of antiretrovirals is based on UK national guidance
- The dosage intervals should be followed strictly (i.e. for twice daily every 10 - 12 hours) and doses should not be missed. This will ensure maximum benefit and reduce the emergence of resistant strains.
- The most frequently occurring minor side effects include: diarrhoea, nausea, vomiting, flatulence, dizziness, insomnia, sleep disturbances, fatigue and headache. These usually improve.
- If a rash develops the patient should contact the department issuing PEP pack
- If there is a history of pancreatitis they should stop PEP immediately if they develop abdominal pain and contact specialist staff

THIS INFORMATION IS INTENDED AS A QUICK REFERENCE GUIDE ONLY

1. EMTRICITABINE 200mg + TENOFOVIR DISOPROXIL 245mg tablets

MODE OF ACTION:	Nucleotide/nucleoside reverse transcriptase inhibitors
DOSE:	ONE tablet immediately then ONE tablet every 24 hours with food or a light snack to improve absorption (this is not critical and should not delay first dose).
CAUTIONS:	Pregnancy, breast feeding, hepatic disease, chronic hepatitis B or C, elderly, pancreatitis Renal impairment (eGFR <50ml/min). However, it is safe to give the first few doses and contact an ID specialist for advice within 72 hours.
SIDE EFFECTS: (Very common or common listed in SPC)	Nausea, vomiting, diarrhoea, abdominal pain, flatulence, renal impairment, neutropenia, hypophosphataemia, insomnia, abnormal dreams, headache, dizziness, raised LFTs, raised CK, rash, pruritis, urticaria, raised amylase, raised glucose, raised triglycerides, pain, asthenia
POTENTIAL INTERACTIONS:	Concomitant use of nephrotoxic agents – monitor renal function closely Potential for CYP450 mediated interactions is low.

2. RALTEGRAVIR 400mg tablets

MODE OF ACTION:	Integrase inhibitor
DOSE:	ONE tablet immediately then ONE tablet every 12 hours with or without food
CAUTIONS:	Severe hepatic impairment, risk factors for myopathy or rhabdomyolysis, chronic hepatitis B or C (increased risk of side effects), psychiatric illness (may exacerbate underlying illness including depression) , pregnancy. None of these cautions prevent initial prescription of PEP starter pack.
SIDE EFFECTS: (Very common or common listed in SPC)	Decreased appetite, abnormal dreams, insomnia, nightmares, abnormal behaviour, depression, vertigo, abdominal distension, abdominal pain, diarrhoea, flatulence, nausea, vomiting, dyspepsia, rash, asthenia, fatigue, pyrexia, alanine aminotransferase increased, atypical lymphocytes, aspartate aminotransferase increased, blood triglycerides increased, lipase increased, blood pancreatic amylase increased
POTENTIAL INTERACTIONS:	Antacids or calcium supplements **– should be avoided while on PEP** Proton pump inhibitors and H_2 antagonists increase levels of raltegravir but no dose adjustment is required Rifampicin – decreases raltegravir levels Orlistat – may prevent absorption of raltegravir **This list is not exhaustive so check patient's medication on HIV drug interaction site:** www.hiv-druginteractions.org

Appendix 5

ANTIRETROVIRAL POST EXPOSURE PROPHYLAXIS STARTER PACK

PATIENT INFORMATION LEAFLET

This is only a ***starter pack*** of medication for 7 days. You will need to be assessed by a specialist before the medicine in this pack is finished, to decide whether you need to continue treatment for a ***full 28 day course***. This follow up will be arranged for you.

READ THIS LEAFLET CAREFULLY BEFORE YOU TAKE ANY MEDICATION FROM THIS PACK

You must tell the prescriber if you:

- Have diabetes
- Have any history of anaemia
- Are pregnant or breastfeeding
- Are allergic to any medication
- Have any kidney or liver disease
- Have any history of pancreatitis
- Are taking any other prescribed medication including contraceptives, inhalers or nasal sprays or any medication bought at a pharmacy e.g. antacids, health food store or supermarket or any recreational drugs

When taking medication from this pack you should:

- **Start, if at all possible, within one hour of the incident or as soon as possible after that.**
- Take the tablets at regular intervals as directed on the labels on the medicines and detailed on the next page. If the drugs are not taken regularly, they may not work as effectively.
- If you miss a dose, take the missed dose as soon as possible, and then continue with your normal dose at the regular time. If it is nearly time for your next dose, forget about the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.
- If you vomit less than 2 hours after taking the tablets you will need to take another dose.
- Store the medication in a cool, dry place.
- Keep out of reach and sight of children.
- Use condoms to prevent the potential spread of HIV virus and other sexually transmitted infections.
- Emtricitabine/tenofovir disoproxil and raltegravir tablets, like all other medicines, have some side effects. The most common are listed on the next page.
- Tell the hospital department/clinic if you get a rash or have any very bad side effects. Serious side effects are unlikely to appear during this starter pack.

This pack contains a 7day supply of:

- Emtricitabine 200mg/Tenofovir disoproxil 245mg x 7 tablets
- Raltegravir 400mg tablets x 14

EMTRICITABINE 200MG/TENOFOVIR DISOPROXIL 245MG tablets

Dose:	Take ONE tablet immediately, then ONE tablet every 24 hours
Note:	Take with food or a light snack if possible. Can be dispersed in half a glass of orange juice or water. There is a desicant in the bottle to protect the tablets from moisture.
Most common side effects:	Diarrhoea, vomiting, nausea, dizziness, headache, rash, difficulty sleeping, abnormal dreams, feeling weak, stomach pain/discomfort, feeling bloated, flatulence,

RALTEGRAVIR 400mg tablets

Dose:	Take ONE tablet immediately, then ONE tablet every 12 hours with or without food.
Note:	Swallow the tablets whole with or without food. They should not be chewed, broken or crushed. There is a desicant in the bottle to protect the tablets from moisture.
Most common side effects:	Decreased appetite, trouble sleeping, feeling dizzy, headache, feeling bloated, diarrhoea, nausea, vomiting, rash, weakness, change in mood, fever

FOLLOW UP

Ensure that you are informed about follow up.

*If you are taking this pack following **sexual exposure**:*
You will be referred to a Sexual Health Clinic.
If you have not been contacted by the clinic within 5 days please phone the triage line: **01382 425542 between 9:00am - 12:00pm**

*If you are taking this pack following **occupational exposure**:*
You will be referred to and contacted by an Infectious Diseases doctor within 3-5 days.
You must also inform the Occupational Health Service of your injury on 01382 346030 or email tay.occhealth@nhs.scot

Appendix 6

ANTIRETROVIRAL POST EXPOSURE PROPHYLAXIS STARTER PACK

PRESCRIPTION FORM

This form must be completed and signed by a prescriber.

The completed form should be returned to Antimicrobial Pharmacy Team, Pharmacy Department, Level 5, Ninewells Hospital, Dundee.

Tick as applicable: PEP for NHS Tayside staff ☐

PEP for Non NHS workers/Community injuries ☐

PEP following sexual exposure (PEPSE) ☐

NAME: ……

DATE OF BIRTH/CHI: ……

ADDRESS: ……..……..

……..

……..

If given to a member of NHS Tayside staff:

Hospital and Ward where incident occurred: ……..

Designation of Staff member injured:…….

The following medication was supplied to the person named above:

Emtricitabine 200mg/Tenofovir disoproxil 245mg tablets x 7
Take ONE tablet immediately, then ONE every 24 hours

Raltegravir 400mg tablets x 14
Take ONE immediately, then ONE every 12 hours

PRESCRIBER'S SIGNATURE: ……..…… DATE: ……..……..

PRINT NAME:……

Please specify which hospital department supplied medication:

NW A&E ☐ PRI A&E ☐