

# 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

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#### 1. SUMMARY

• Where a child is thought to have had had a significant exposure to a blood borne virus (BBV) 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 <a href="http://www.sexualhealthtayside.org">www.sexualhealthtayside.org</a> for opening times or call 01382 425542)

- Post Exposure Prophylaxis (PEP) is available for HIV and Hepatitis B. Whilst PEP is not available for hepatitis C, early diagnosis allows treatment with a high chance of cure
- The majority of exposure events do not require onward referral for HIV PEP as following assessment they are usually found not to be of sufficiently high risk to require it

• Where there is a significant risk and HIV PEP is recommended, this is available for non-sexual exposure and sexual exposure incidents out of hours at the Emergency Departments in Ninewells Hospital, Dundee and Perth Royal Infirmary. Follow up will be arranged within the Infectious Diseases Department, Ninewells Hospital, Dundee or Sexual and Reproductive Health Service respectively

• HIV PEP is not recommended after 72 hours post exposure. Hepatitis B PEP can be given up to a week after exposure but is ideally started within 48 hours

#### 2. INTRODUCTION

This guidance has been produced to meet the requirements of Healthcare Improvement Scotland Standards (Sexual health 2021) and follow the recommendations of the British Association of Sexual Health and HIV and British HIV association UK Guideline for the use of HIV post-exposure (2021) and the UK Department of Health's Green Book on Immunisation against Infectious Diseases.

This guidance is for all NHS Tayside staff, including Primary Care, Sexual Health Clinics, Minor Injuries Units and the Emergency Department, where people may present who think they have been exposed to a blood borne virus (BBV). There is separate guidance for NHS Tayside workers who sustain an occupational exposure incident available on 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 24 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 and the body fluid** involved must be high-risk plus the **source individual** will be known to have HIV with a detectable viral load 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	Needlestick	Receptive	Mucocutaneous
	Anal Sex	injury	Vaginal Sex	exposure
HIV	1 in 90	1 in 333	1 in 1000	1 in 1000
Hepatitis C		1 in 30		
Hepatitis B		1 in 3		

# 3. ASSESSMENT AND MANAGEMENT OF EXPOSURE EVENTS

# 3.1. FIRST AID

- Keep calm
- Gently encourage bleeding in the puncture site
- Wash the injured area with soap and water
- Do not scrub the site or use antiseptic agents
- Cover the wound with an impermeable dressing after cleansing
- In the case of mucosal exposure, wash the exposed area copiously with water or normal saline
- If contact lenses are worn, wash the eyes with water or normal saline both before and after removing the lenses

#### 3.2. 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: <u>https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/148506/Green-Book-Chapter-30-dh\_103982.pdf</u>

# 3.3. RISK ASSESSMENT OF THE EXPOSURE

Only certain events 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 HIV positive source with a detectable viral load 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.

<ul> <li>High risk exposures</li> <li>Needle, surgical instrument or other sharp (bone spike, broken tooth) penetrating skin</li> <li>Fluid on to mucous membrane (eye, nose or mouth)</li> <li>Insertive anal sex without condom</li> <li>Insertive vaginal sex without condom</li> </ul>	<ul> <li>Low risk exposures</li> <li>Fluid onto intact skin</li> <li>Fluid onto non-intact skin (risk is considered to be negligible)</li> <li>Any other sex with or without a condom</li> </ul>
• Fluid on to mucous membrane (eve.	
Insertive anal sex without condom	
Insertive vaginal sex without condom	
Receptive anal sex without a condom	
Receptive vaginal sex without a condom	
Human bite causing bleeding	



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

\* 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.

# 3.4. RISK ASSESSMENT OF THE SOURCE INDIVIDUAL

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

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

Has the source been previously tested for BBVs and if so can you access records to confirm the results?

Blood borne virus	Unknown	Confirmed negative	Confirmed positive
Hepatitis B			
Hepatitis C *If HCV antibody positive, ensure a			
PCR test is requested to confirm active infection			
HIV *If HIV positive, does the source have an			
undetectable viral load			

If the source has HIV, understanding whether they are on treatment and their last viral load helps refine the risk assessment. PEP is no longer recommended if the source is on antiretroviral therapy for at least 6 months with a confirmed and sustained plasma HIV viral load <200 copies/ml) within the last 6 months.



If the source has not been previously tested for these viruses, is there a factor that may increase the risk?

Risk factor	Yes (High Risk)	No (Low Risk)
Source from country of HIV prevalence (sub-		
Saharan Africa, Thailand, Caribbean)		
Source had a sexual partner from or had		
condomless sex in a country of HIV prevalence		
Injecting drug user (ever)		
Man who has sex with other men		
Clinical illness compatible with HIV/AIDS		
Sexual partner of known HIV-infected person		
with a detectable viral load		

If the source patient is not known to have HIV, or have risk factors, HIV post-exposure prophylaxis is not indicated.

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)

- An injury has occurred that has been assessed as having the potential of transmitting infections to the exposed individual
- To allow a full risk assessment some information needs to be gathered from the source including whether they have or are at risk of having infections such as HIV and viral hepatitis
- Their information will be dealt with confidentially but test results will be shared with the doctor treating the exposed individual
- Questions will be asked in a non-judgemental and sensitive way. Their health record will be checked to see if they have been previously tested for these viruses
- 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 be able to access treatment and care
- 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

Does the patier	nt consent to BBV testing?
Yes	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 clinical details "Contamination injury. Source patient. Urgent HIV, Hepatitis B and Hepatitis C testing". The request should give the name and contact details for the responsible staff member to whom the results should be communicated. Offer information leaflet.
No	Offer information leaflet (LINK)



# **3.5. INDICATIONS FOR HIV PEP**

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-s	tatus
	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 provided viral load last checked less than 6 months ago and person on ART for >6months with good adherence	Generally not Recommended	Not recommended
High risk fluid on to mucous membrane (eye, nose or mouth)	Recommend	Not recommended	Generally not Recommended	Not recommended
Human Bite *	Generally not Recommended	Not recommended	Not recommended	Not recommended
Receptive anal sex without a condom	Recommend	Not recommended Provided viral load last checked less than 6 months ago and person on ART for >6 months with good adherence	Recommend	Not recommended
Insertive anal sex without a condom	Recommend	Not recommended	Consider **	Not recommended
Receptive vaginal sex without a condom	Recommend	Not recommended	Generally not Recommended **	Not recommended
Insertive vaginal sex without a condom	Consider**	Not recommended	Not Recommended	Not recommended
Fellatio with ejaculation without a condom	Not Recommended	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Not recommended	Not recommended	Not recommended	Not recommended
Fellatio without ejaculation 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 with a suspected HIV viral load of >3.0 log copies/ml, 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

\*\* Factors that may influence decision making in sexual exposures include: Breaches in the mucosal barrier such as genital ulcer disease or anal/vaginal trauma, multiple episodes of exposure e.g. group sex or STI in either partner. These patients require a specialist assessment by 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, a country of high HIV prevalence (>1%) (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 with a detectable viral load

<sup>++</sup> 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



# **3.6. INDICATIONS FOR HEPATITIS B PEP**

#### Significant exposure is defined as:

- Percutaneous exposure (needlestick or other contaminated sharp object injury, a bite which causes bleeding or other visible skin puncture)
- Sexual exposure (unprotected sexual intercourse)

	Significant exposure			Non-significant exposure	
HBV status of person prior to exposure	HBsAg positive source	Unknown sourc <del>e</del>	HBsAg negative source	Continued risk	No further risk
Unvaccinated	Accelerated course of HepB vaccine plus HBIG with first dose	Accelerated course of HepB vaccine	Consider course of HepB vaccine	Initiate course of HepB vaccine	No HBV prophylaxis Reassure
Partially vaccinated	One dose of HepB vaccine and finish course	One dose of HepB vaccine and finish course	Complete course of HepB vaccine	Complete course of HepB vaccine	Complete course of HepB vaccine
Fully vaccinated with primary course	Booster dose of HepB vaccine if last dose ≥ 1year ago	Consider booster dose of HepB vaccine if last dose ≥ 1year ago	No HBV prophylaxis. Reassure	No HBV prophylaxis Reassure	No HBV prophylaxis Reassure
Known non-responder to HepB vaccine (anti-HBs < 10mIU/ml 1-2 months post-immunisation)	HBIG Booster dose of HepB vaccine A second dose of HBIG should be given at one month	HBIG Consider booster dose of HepB vaccine A second dose of HBIG should be given at one month	No HBIG Consider booster dose of HepB vaccine	No HBIG Consider booster dose of HepB vaccine	No HBV prophylaxis Reassure

Adapted from: PHLS Hepatitis Subcommittee (1992).

Taken from

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/628602/Greenbook\_cha pter\_\_\_\_18.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 as an accelerated schedule with a dose of vaccine given at zero, one and two months. 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.

# 3.7. REFERRAL FOR PEP (IF REQUIRED)

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.



# 3.8. USE OF HIV PEP IN THE EMERGENCY DEPARTMENT (IF REQUIRED)

#### **Baseline bloods**

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

#### **HIV PEP Prescription**

Prescription: This is available in Emergency Departments as a 7 day starter pack.

<u>Emtricitabine</u> 200mg/<u>Tenofovir Disoproxil</u> 245mg ONE tablet immediately then ONE tablet every 24 hours

Raltegravir 400mg tablets ONE tablet immediately then ONE every 12 hours

- [ ] Follow prescribers guidance sheet (See Appendix 4)
- [] Provide patient information leaflet (See Appendix 6) (copy also included in 7 day pack)
- [] Patient should be advised to use condoms until definitive bloods at 3 months. 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 (<u>tay.id@nhs.scot</u>)
- [] 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)

[] Photocopy this proforma for your records.

[] Sign prescription and send to Pharmacy department as detailed at the top of the form (See Appendix 5)

# 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 eGFR 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.



- 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

UK guideline for the use of HIV post-exposure prophylaxis following sexual exposure (2021)

https://www.bashhguidelines.org/media/1258/pep-2021.pdf

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

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	Initiated (follow up with	Not indicated	Indicated	and
prophylaxis	ID arranged)		declined	
Hepatitis B vaccine (single	Given	Not indicated	Indicated	and
dose)			declined	
Hepatitis B	Given	Not indicated	Indicated	and
Immunoglobulin			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:

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	Contact telephone number
CHI Address	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 People 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	YES/NO
Hep B vaccination given?	
Date and Time of Baseline Blood	
Tests	
Other Relevant Info i.e. PMH of	
note	
Renal impairment with	YES/NO
eGFR<50ml/min?	
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: <u>tay.id@nhs.scot</u> To arrange follow up with Sexual Health Services please email this form to: <u>tay.tsrh@nhs.scot</u>



# 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 British HIV association (BHIVA) and the British Association for Sexual Health and HIV (BASHH)
- Treatment should be started **as soon as possible** after exposure, ideally within 24 hours of the incident, but can be considered up to 72 hours. Initiation after 72 hours is not recommended.
- 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 <u>www.hiv-druginteractions.org</u>
- Ensure the patient reads the information leaflet (copy also included in pack)
- 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
- Doses should not be missed and dosage intervals should be followed strictly. 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
- Ensure the patient has been given details of follow up and any contact numbers required



### 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: 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 – **STOP while taking PEP** Proton pump inhibitors and H<sub>2</sub> 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

# **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  $\Box$ 

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 tablets immediately, then ONE every 12 hours

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

PRINT NAME:.....

Please specify which hospital department <u>supplied</u> medication:

NW A&E 🗆 PRI A&E

#### Appendix 6 HIV POST EXPOSURE PROPHYLAXIS (PEP)

#### INFORMATION FOR PATIENTS - 7 DAY PACK (OF A 28 DAY COURSE)

READ THE INFORMATION IN THIS LEAFLET CAREFULLY BEFORE TAKING ANY MEDICATION IN THIS PACK. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT ANYTHING PLEASE ASK THE PRESCRIBER.

#### You must tell the prescriber if you:

- Have diabetes
- Have a history of anaemia
- Have kidney disease
- Have liver disease
- Have any history of pancreatitis
- Are pregnant or breastfeeding
- Have any allergies to medication
- Are taking any other medication for example:

Prescribed medication from GP or hospital	Including inhalers and nasal sprays	
Over the counter medication from pharmacy,	E.g. vitamins, indigestion remedies and herbal	
supermarket or health food shops	supplements	
Medication and supplements bought online	E.g. gym supplements	
Recreational drugs	E.g. cannabis or cocaine	

#### What is post exposure prophylaxis (PEP)?

PEP is a course of medicines taken to reduce the risk of a person becoming infected with HIV after they may have come into contact with the virus.

#### What is HIV?

HIV stands for Human Immunodeficiency Virus. It is a virus which attacks the body's immune system.

#### Is PEP effective?

- It is important to remember that in most circumstances the risk of actually catching HIV from either a single needle stick injury or sexual act is small.
- Taking the 28 day course of anti-HIV medication should make that risk even smaller.
- PEP should be started as soon as possible after risk of contact with the virus and always within 72 hours of contact.
- All the tablets should be taken as prescribed at regular intervals.



#### How will I know PEP has worked?

You will have follow up appointments during your treatment and HIV tests after treatment. These appointments are important as PEP does not reduce risk of transmission to zero. Please make sure you know where to attend for follow up.

#### How do I take the medication?

This pack contains a **7** day supply of two anti-HIV medications which need to be taken together as prescribed. *The full course of PEP is 28 days therefore you need to be assessed by a specialist before this 7 day pack is finished to decide if you need to be prescribed a full 28 day course.* 

Tenofovir disoproxil 245mg/Emtricitabine 200mg Tablets x 7

Raltegravir 400mg Tablets x 14

Tenofovir disoproxil 245mg/Emtricitabine 200mg	Take ONE tablet immediately then ONCE daily at the same time each day	Take with food or light snack if possible	Most common side effects include diarrhoea, vomiting, nausea, dizziness, headache, rash, weakness, difficulty sleeping, abnormal dreams stomach discomfort, bloating
			and flatulence
Raltegravir 400mg Tablets	Take ONE tablet immediately then take ONE tablets every 12 hours	Swallow whole do not crush or chew. Can be taken with or without food	Most common side effects include Decreased appetite, trouble sleeping, dizziness, headache, bloating, diarrhoea, nausea, vomiting, rash, weakness, fever and change in mood.

- If you have a rash or any sign of allergy seek medical advice
- Further information on side effects can be found in the medication packaging but most side effects during PEP should be mild and improve as the course continues. However if you feel you are experiencing severe side effects please contact your follow up clinic.

#### What do I do if I forget to take a tablet or I am sick?

It is important to try not to miss any doses as taking these medications regularly will improve the chance of them working. If you do miss a dose take it as soon as you remember then continue with normal dose times. If it is nearly time for the next dose when you remember then don't take the forgotten dose and continue as usual, do not take double doses to make up for a missed dose.



If it is more than 48 hours since you have last taken a dose then please contact your follow up clinic to discuss. Depending on the reason for missing doses then PEP medicines may need to be changed or stopped.

If you vomit within 2 hours of taking your medication then take the dose again.

#### Can I take other medicines?

The health professional reviewing you for PEP will check that there are no problems with other medicines or supplements you are taking and the medicines in this pack.

Calcium, iron, zinc, magnesium and aluminium which can be found in indigestion remedies, some medicines, vitamins and mineral tablets can stop you from absorbing raltegravir properly. Ideally these should not be taken while you are taking post exposure prophylaxis treatment. If they cannot be stopped then please check with a pharmacist about timing of doses.

Always check with a doctor, pharmacist or nurse before starting any new medicines during the treatment.

#### What else do I need to know?

- Make sure you know how your follow up will be arranged for you
- Do not donate blood and use condoms with all sexual partners while you are being treated and until you have your results of your final HIV test.

Adapted from HIVPA/BHIVA/BASHH PEP leaflet and NHS Board leaflets for NHS Scotland Drafted by: Scottish HIV Pharmacists Group Approved by: HIV and SH Lead Clinicians Date: 05/2021 Review Date: 05/2024

#### **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 community exposure:* You will be referred to and contacted by an Infectious Diseases doctor within 3-5 days.