NHS Lothian Post-Exposure Prophylaxis (PEP) for Sexual and Non-Occupational Exposure to bloodborne viruses

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1 Scope

This guideline is for use primarily by healthcare professionals in the emergency department, primary care and GP Out of Hours (OOH), for the assessment of individuals aged over 16 presenting following a potential sexual or non-occupational exposure to blood-borne viruses (BBVs). Although assessment of BBV exposure in children and young people is not covered in this document, we have included contact details for services who can provide support in this setting.

2 Table of abbreviations

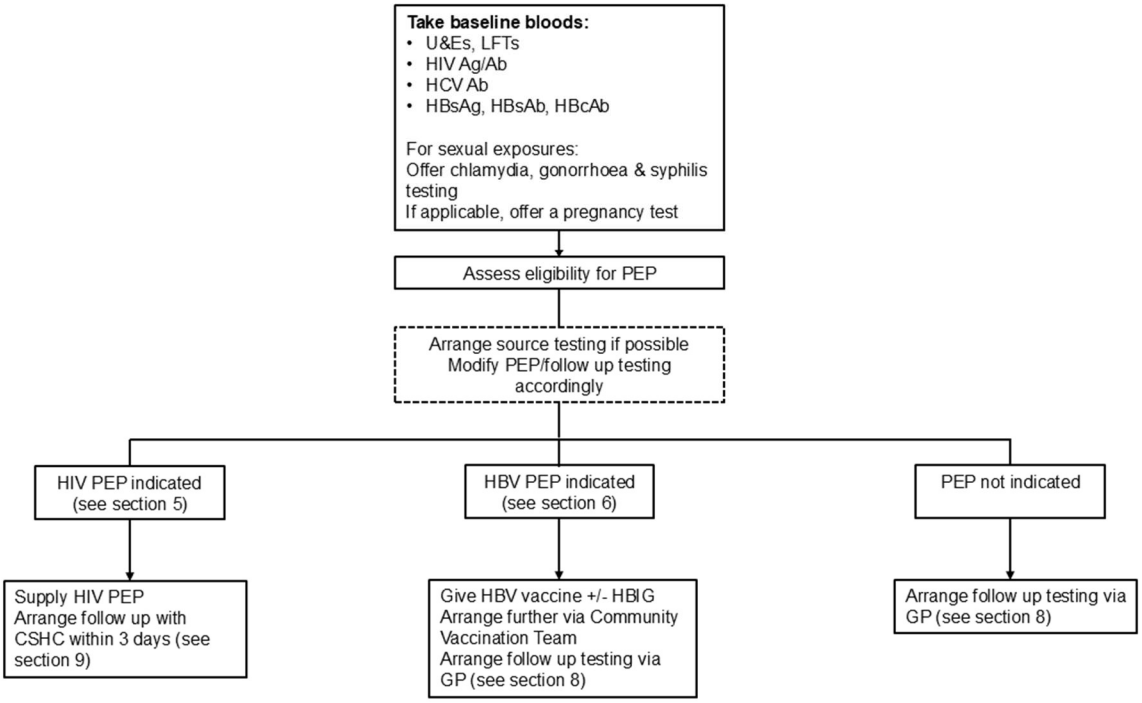
BBV	Blood-borne virus		LFTs	Liver function tests
CrCl	Creatinine clearance		MSM	Men who have sex with men
CSHC	Chalmers Sexual Health Clinic		OOH	Out of hours
ED	Emergency department		PEP	Post exposure prophylaxis
HBcAb	HBV core antibody		PLWH	Person living with HIV
HBsAb	HBV surface antibody		PrEP	Pre exposure prophylaxis
HBsAg	HBV surface antigen		PWID	People who inject drugs
HBV	Hepatitis B virus		RIDU	Regional Infectious Diseases Unit
HCV	Hepatitis C virus		U&Es	Urea & electrolytes
HCV Ab	HBV antibody		U=U	Undetectable = untransmissible
HIV	Human immunodeficiency virus		VL	Viral load
HIV Ag/Ab	Combined HIV antigen/antibody			

3 What's new since the 2019 guidance?

- Raltegravir should be given 1200mg od except in pregnancy.
- In sources with unknown HIV status, the prevalence of HIV in the source population is no longer used to determine risk; instead, the presence of detectable viraemia in the source population is used, given that the majority of people living with HIV (PLWH) in the UK are aware of their status and on effective antiretroviral therapy.
- A new category '*generally not recommended'* has been introduced which is for exposures where the risk is extremely low and where post exposure prophylaxis (PEP) should not be given unless **specific** extenuating circumstances exist.
- Changes to PEP prescribing indications include:
    - Receptive vaginal sex with a partner of unknown HIV status from high-risk group – PEP is now 'generally not recommended'.
    - Insertive vaginal sex with a partner of unknown HIV status from high-risk group – PEP is now 'generally not recommended'.
    - Sharing of injecting equipment with a partner of unknown HIV status from high-risk group – PEP is now 'generally not recommended' but prevalence in risk group must be considered.
    - Human bite – PEP is now 'generally not recommended'.
- Final HIV testing should be conducted >45 days post PEP completion (in practice, this will often be done at 12 weeks from exposure).
- A section has been included on injecting given ongoing sexualised drug use ('chemsex')
- Indications for PEP in patients taking Pre-Exposure Prophylaxis (PrEP) discussed and some other specific scenarios

4 Assessing Sexual/Non-Occupational Exposures to BBV

Figure 1:



4.1 What to do at initial visit

- Baseline investigations – sexual health screen including syphilis, U&Es, LFTs, HIV Ag/Ab, HBcAb, HBsAg, HBsAb, HCV Ab
    - If there has been a documented HBsAb > 10 IU/mL, HBV testing and vaccination is not required
- Pregnancy test and assess need for emergency contraception
- Discuss transmission risk of individual encounter (risk tables in section 5.2 often reassuring for patient as likely they will have overestimated risk)
- Source risk assessment (for guidance on source testing see Appendix B)
    - BBV status if known, as this will affect whether PEP should be given (do not delay initial prescription whilst results of source testing are awaited if PEP is indicated)
    - If known to be living with HIV:
        - Details of antiretroviral medication (if taking)
        - Where they go for follow up (Chalmers Sexual Health Clinic (CSHC) or Regional Infectious Diseases Unit (RIDU))
        - Plasma HIV viral load (VL)
- Discuss rationale for PEP – estimated transmission reduction of 80% but lack of conclusive evidence, most evidence from animal studies.
- Check past medical history & allergies
- Check medications and over-the-counter (OTC) treatments (including vitamins) using HIV drug interactions website - Liverpool HIV Drug Interactions. Raltegravir interacts with various OTC supplements, and these will need usually be stopped or taken > 4 hours apart from PEP.
- Discuss importance of adherence and what to do if missed doses

- To re-attend urgently if develops sero-conversion symptoms
- Need for HIV test > 45 days after PEP complete and for protected sex until then; this can all be done at CSHC if patient agrees.
- Discuss PrEP if likely to have ongoing risk, access via CSHC
- Assess HBV vaccine status; if fully vaccinated and documented HBsAb >10 no further vaccine required. If not see section 6.2 for management.
    - If HBV vaccine required an accelerated course at 0,1,2 and 12 months can be given
- Discuss arranging follow up at CSHC

5 HIV

- PLWH with an undetectable viral load **cannot transmit HIV sexually** – this is known as undetectable = untransmissible (U=U)
- PEP is estimated to reduce the risk of transmission of HIV by >80%.
- Timing:
  - Most effective if given within 24h of exposure
  - **Beyond 72h, PEP is not effective and should not be given.**
- Current antiretroviral recommendations for HIV PEP are detailed in Appendix A

5.1 Summary of PEP recommendations

PEP recommendations have been separated into 4 categories, informed by risk threshold:

- Recommended: the benefits of PEP are likely to outweigh the risks and PEP should be given unless there is a clear reason not to
- Consider: the risk of transmission is low and the risk/benefit balance of PEP is less clear. The risk should be assessed on a case by case basis (see section 5.4)
- Generally not recommended: the risk of HIV transmission is very low, and the risk/inconvenience of PEP is likely to outweigh benefit unless there are clear extenuating factors which increase risk of transmission (section 5.4)
- Not recommended: the risk of transmission is negligible and PEP should not be given

Table 1:

	Index living with HIV		**Index HIV status unknown**	
	HIV VL detectable or unknown	HIV VL undetectable (<200) on ART for >6 months AND reported good adherence	High prevalence (>1%) country/ risk group*	Low-prevalence country or risk group
Receptive anal sex	Recommended	Not recommended	Recommended	Not recommended
Insertive anal sex - patient inserts into index	Recommended	Not recommended	Consider	Not recommended
Receptive vaginal sex	Recommended	Not recommended	Generally not recommended**	Not recommended
Insertive vaginal sex	Consider	Not recommended	Generally not recommended**	Not recommended
Fellatio with or without ejaculation	Not recommended	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Not recommended	Not recommended	Not recommended	Not recommended

Other exposures				
Sharing injecting equipment including chem-sex	Recommended	Not recommended ***	Generally not recommended**	Not recommended
Human Bite	Generally not recommended	Not recommended ***	Not recommended	Not recommended
Needlestick from discarded needle in community	N/A	N/A	Not recommended	Not recommended

If HIV PEP is recommended, consult appendix A.

*See section 5.3
** In some circumstances, the prevalence in the source risk group may alter this recommendation and local data for the specific patient population must be considered. See section 5.4, table 4.
*** The same evidence base for U=U does not exist for non-sexual exposures although it remains unlikely that PEP would be indicated.

Please note:

- For cumulative sexual exposures risk increases, but would not alter PEP recommendations
- In sexual assault the threshold for giving PEP should be lower; however, if the perpetrator is from low prevalence group in UK in general PEP is unlikely to be indicated.
- Anxiety is not a reason to administer PEP

5.2 Risk of HIV transmission

Risk of HIV transmission through condom-less sexual exposures depends on

- Type of sexual exposure (see table)
- HIV VL of index – If this is undetectable there is no risk
    - If unknown HIV status the risk calculation is no longer based on overall prevalence of HIV in that population but on the prevalence of detectable viraemia
- Susceptibility of recipient if index has a detectable VL

Risk of HIV transmission = risk that source is HIV positive with a detectable viral load x risk per exposure

Factors increasing risk of HIV transmission

- High VL – each log increase associated with a 2.9 fold increased risk per act (high VL seen in primary or advanced infection)
- Breaches in mucosal barrier – ulcers, trauma, assault, first intercourse
- Menstruation/ bleeding (theoretical)
- Pregnancy relative risk (RR) 2.82 /post-partum RR 3.97
- Other sexually transmitted infections in either partner

Table 2:

Type of exposure	Estimated risk of HIV transmission per exposure from PLWH not on antiretroviral therapy
Receptive anal intercourse • with ejaculation • without ejaculation	1/90, 1.11% 1/65, 1.54% 1/170, 0.69%
Insertive anal intercourse • not circumcised • circumcised	1/666, 0.15% 1/161, 0.62% 1/909, 0.11%
Receptive vaginal intercourse	1/1000, 0.1%
Insertive vaginal intercourse	1/1219, 0.08%
Semen splash to eye Receptive/ insertive oral sex Human bite	< 1/10,000, <0.01% < 1/10,000, <0.01% < 1/10,000, <0.01%
Mucocutaneous	1/1000, 0.1%
Needlestick	1/333, 0.3%
Sharing injecting equipment (chemsex)	1/149, 0.67%

5.3 Definition of high-prevalence countries/risk groups

- High prevalence countries/groups are those with an undiagnosed/untreated prevalence > 1% (highlighted in red)
- Within the UK at present, this is likely to be MSM (men who have sex with men), people who inject drugs from certain groups and individuals who have immigrated to the UK from areas of high HIV prevalence, particularly sub-Saharan Africa.

Table 3:

Risk group		Prevalence PLWH with detectable VL (per 100 population)
Gay and bisexual men	England	2.3
	London	3.21
	Elsewhere	2.09
Heterosexual men	Black African	0.58
	Non-black African	0.02
Heterosexual women	Black African	0.87
	Non-black African	0.01
Persons Who Inject Drugs (PWID)	All	0.67
	Men	0.53
	Women	1.15
	PWIDs in Glasgow	4.8
	PWIDs in Lothian	0.6

- High prevalence countries: includes most of sub-Saharan Africa. Country specific HIV prevalence can be found at https://aidsinfo.unaids.org**.** Cases can be discussed with CSHC or RIDU if there is uncertainty. If in doubt, PEP should not be delayed.

For example, if a man presents for PEP following an episode of condomless receptive anal intercourse with ejaculation with a Scottish male partner of unknown HIV status:

Risk of HIV transmission = risk that source is PLWH with detectable VL (2.09/100) x risk per exposure (1/65) = 2.09/6500 = 0.03% → PEP should be discussed

5.4 Further information: 'Consider' or 'generally not recommended' exposures

In exposures where PEP is to be *considered* or *generally not recommended,* other risks that would increase HIV transmission as detailed in section 5.2 should be considered. **In cases where the prevalence of HIV with viraemia in the source risk population is very high, this may also change the recommendation and local data must be considered** (see table 4).

If the source patient is living with HIV and known to have an undetectable VL, but for less than 6 months, PEP is generally not required but can be discussed with CSHC/RIDU.

Table 4: Risk of HIV transmission through sexual exposures with source living with HIV with detectable viraemia in comparison to risk of transmission from PWID with unknown HIV status in Lothian and Glasgow.

	Source		
	PLWH with detectable VL	PWID in Lothian	PWID in Glasgow
Insertive anal sex	1/666, 0.15%	1/111,000, 0.0009%	1/13,875, 0.0072%
Receptive vaginal sex	1/1000, 0.1%	1/166,667, 0.0006%	1/20,833, 0.0048%
Insertive vaginal sex	1/1219, 0.08%	1/203,166, 0.0005%	1/25,395, 0.0038%
Sexualised injecting drug use	1/149, 0.67%	1/24,833, 0.0040%	1/3,104, 0.0322%*

*Note that in this case the risk is >1/10,000 (0.01%) and PEP should be considered.

5.5 Patients taking PrEP

- Patients taking PrEP in the UK are normally taking emtricitabine/tenofovir disoproxil (Truvada) or emtricitabine/tenofovir alafenamide (Descovy), either daily ('Daily PrEP') or either side of anticipated sexual encounters (called 'Event Based PrEP').
- PrEP is highly effective at preventing HIV and there is no indication for PEP if the exposed individual is on PrEP and taking it appropriately.
- For patients on 'Event Based PrEP', who did not take PrEP as recommended, treat significant exposures **as if they were not taking PrEP**.
- For patients taking daily PrEP, PEP does not need to be started, as long as adherence is adequate (see table 5):

Table 5:

Site of exposure	Last tablet	Number of tablets in past 7 days
Anal	Within last 7d	4 or more
Vaginal, Frontal (Trans male), Neovaginal (Trans female)	Within last 48h	6 or more

5.6 Other scenarios

5.6.1 Pregnancy / breastfeeding

- A pregnancy test should be undertaken in women of childbearing age but does not exclude very early pregnancy (within the preceding 3 weeks).
- Pregnancy or breastfeeding should not alter decision to provide PEP
- Pregnancy increases risk of transmission and primary HIV infection would increase risk of intra-uterine infection
- Counsel that PEP is unlicensed in pregnancy
- In women that are breastfeeding, discuss that PEP can be transferred to the baby via the breast milk
- Use twice daily raltegravir

5.6.2 Sexual assault

- Possibility of higher risk of transmission given trauma (not evidence based), and if assailant from a group with higher prevalence of HIV viraemia, then PEP may be recommended more readily.
- If assailant from low prevalence group, it is likely PEP will not be indicated as sexual assault alone is not an indication for PEP.

5.6.3 Chronic HBV

- If patient is on daily tenofovir as HBV treatment PEP unlikely to be required but discuss with RIDU/CSHC
- If HBV diagnosed at assessment arrange assessment with Hepatology/RIDU; if this has not occurred when PEP course is complete continue tenofovir/emtricitabine until assessed.

5.6.4 Shared use of injecting equipment/chemsex)

- Seroprevalence of HIV in PWID is low outside localised outbreaks (Glasgow has ongoing outbreak)
- Consider PrEP if sexualised drug use is an ongoing risk
- PEP recommended if any contact is living with HIV with a detectable/unknown VL

6 Hepatitis B virus

6.1 Assessment

- Obtain vaccination status of patient (including HBsAb titre if known), HBV status of source if possible, and consult table.
- Please note:
  - Those with previous HBV infection cannot be reinfected and require no prophylaxis.
  - Known vaccine responders with a HBsAb ≥10 require no follow up testing

Table 6:

	Significant exposure		
HBV status of person	**HBsAg positive source**	**Unknown source**	**HBsAg negative source**
Unvaccinated	HBIG plus accelerated course of HBV vaccine*	Accelerated course of HBV vaccine*	Consider course of HBV vaccine
Partially vaccinated	One dose of HBV vaccine and finish course	One dose of HBV vaccine and complete course	Complete course of HBV vaccine
Fully vaccinated; HBsAb unknown	Booster dose of HBV vaccine if last dose > 1 year ago	Consider booster dose of HBV vaccine if last dose > 1 year ago	Reassure
Fully vaccinated; HBsAb > 10 mIU/mL	Reassure	Reassure	Reassure
Known non-responder to HBV vaccine (HBsAb < 10 mIU/mL	HBIG, with repeat dose at 1 month Booster dose of HBV vaccine	HBIG, with repeat dose at 1 month Consider booster dose of HBV vaccine	No HBIG Consider booster dose of HBV vaccine

*See section 6.2

6.2 Giving HBV PEP

6.2.1 HBV vaccination

Indications	• All cases of condomless sexual exposure (unless known to be immune with HBsAb ≥10) • Other indications as per section 6.1
Administration Window	Can be beneficial up to 6 weeks post exposure
Dosage	• Booster: stat dose of any HBV vaccine • Accelerated schedule*: give HBV vaccine at 0, 1, 2 and 12-months (Give initial dose in ED, then arrange further doses via community vaccination team) • Consider boosters as per section 6.1
Notes on admin	Do not co-administer HBIG and HBV vaccine at the same site Consider initiating a course of HBV vaccine if there is ongoing risk, for completion in primary care

*A super accelerated/very rapid schedule is also available (0, 7, 21 days +/- 12 months) but not usually recommended for post-exposure prophylaxis. It may be considered if there is concern that the exposed person cannot commit to the timings of the accelerated schedule but its use should be discussed with Virology or Infectious Diseases.

6.2.2 Hepatitis B Immunoglobulin (HBIG)

HBIG is indicated if the index case is known HBsAg positive, unless the patient's HBsAb is known to be ≥10 IU/ml.

Indications	• Unvaccinated injured party; HBV positive index case • Vaccine non-responder; source is HBV positive or status unknown
Administration Window	Ideally within 48h; can be given up to 7d postexposure
Dosage	• Adult and child >10yrs: 500 IU IM injection stat. • Children <10yrs: contact the paediatric ID consultant at RHCYP.
Notes on admin	Do not co-administer HBIG and HBV vaccine at the same site

7 Hepatitis C virus

- There is no PEPSE available for Hepatitis C.
- Hepatitis C is extremely rarely transmitted through penile-vaginal intercourse or oral sex
- Baseline & follow-up HCV testing **is indicated in MSM who have had condomless anal sex, or anyone who has injected/inhaled drugs or shared injecting equipment**.

8 Baseline & Follow Up Testing

- Take baseline bloods including BBV and sexual health screen at presentation
- Follow up testing should be offered in all cases but recommended in high-risk scenarios.
- The information leaflet Testing for Blood Borne viruses can be given to patients prior to testing; this contains basic information on BBVs and issues to consider prior to being tested.
- If HIV PEP prescribed or if PrEP is being considered, follow up is through CSHC. Otherwise, BBV follow up testing is performed in primary care.

Table 7:

BBV	Testing schedule			
	Baseline	**2-6 weeks**	**12 weeks**	**6 months**
	U+E, LFT, pregnancy test, STI screen)	Repeat if appropriate		
HIV	HIV Ag/Ab		HIV Ag/Ab	
HBV	HBsAg HBsAb HBcAb		HBsAg (Only if HBsAb <10 at baseline)	HBsAg HbcAb (Only if HBsAb < 10 at baseline)
HCV	HCV Ab	HCV PCR*	HCV Ab HCV PCR*	HCV Ab

*Only if the source is **known** to have HCV

9 Contact Details for Advice & Follow Up

Not given PEP	GP (follow up blood testing only) If any difficulties arranging follow up bloods in primary care then can be referred to CSHC per guidance below.
Given PEP, or PEP/PrEP being considered	The patient should be advised to contact CSHC as soon as possible (within 3 days) so follow up can be arranged regarding follow up testing and consideration of future PrEP. CSHC • Telephone: 0131 536 1068 • Web: https://www.lothiansexualhealth.scot/book-an-appointment/ • Email (health professionals only): loth.chalmersclinicaladv@nhs.scot Clinical advice can be obtained 0900-1700 if required for complex cases. OOH, advice can be obtained from the Infectious Diseases registrar 1700-1900 (#8161) or the consultant 1900-0900 (via switchboard)
Child	On-call paediatric ID consultant at RHCYP (0131 536 0000), or alternatively the on-call consultant in Glasgow (0141 201 0000).

10 Further information

- Drug interactions: www.hiv-druginteractions.org
- BHIVA/BASHH UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021

APPENDIX A: Giving HIV PEP

Indications	• PEP recommended in table in section 5.1. • PEP 'Generally not recommended', or 'consider', but additional risk factors are present (see section 5.4)
Current recommended PEP	*If index case has known resistance or renal impairment discuss with CSHC/RIDU* Non-pregnant adults: supply **30 days** of: • Emtricitabine/tenofovir disoproxil 200/245mg one tablet daily **AND** • Raltegravir 1200mg once daily. PLUS a patient information leaflet. A full course is 28-30 days. It is best practice to issue a 30-day pack as it has been shown this improves adherence, however if unclear if PEP appropriate and unable to access support from CSHC or Infectious Diseases a starter pack can be used and follow up at CSHC advised. Pregnant adults: supply 7 day starter pack of: • Emtricitabine/Tenofovir 200/245mg one tablet daily **AND** • Raltegravir 400mg twice daily. There is limited experience of using PEP in pregnant patients, but nominally it appears to be well-tolerated and safe. These patients must be followed up within 3-7 days (see section 8).
Location of PEP	• CSHC • RIE/SJH: Emergency department • WGH: RIDU (ward 74) • Royal Hospital for Children and Young People (RHCYP) Ward 6 (emergency cupboard) • Roodlands Hospital Ward 1 (back up cupboard) Patients started on PEP should be subsequently be assessed within 3 days at CSHC (adults) or RHCYP (children).
Discuss before administering PEP	• The rationale for PEP • The lack of conclusive data for the efficacy of PEP • The need to start PEP as soon as possible and importance of adherence to optimise efficacy • The potential side-effects of PEP • Drug interactions, including over the counter drugs such as multivitamins/antacids/iron (iron should not be used with once daily raltegravir or if an essential medication, iron should be spaced at least 4 hours apart from raltegravir dosing) • Emergency contraception (if appropriate) • The need to seek urgent medical attention if they develop symptoms of possible seroconversion (e.g. flu-like illness, fever, rash, adenopathy) • The need to arrange early follow-up • The need for baseline HIV testing • The need to continue PEP for a minimum of 28 days if the baseline result is negative • The need to have a follow-up HIV test a minimum of 45 days after completion of the PEP course

<table>
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The need to use condoms until the follow-up HIV testing is negative
Coping strategies, assessment of vulnerabilities and social support
Signposting to Harm Reduction Services if exposure was through drug use/shared injecting equipment

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<tr><td>Common Adverse effects</td><td>

Nausea, vomiting, diarrhoea
Headache
Dizziness
Rash
Feeling weak

Drug-specific concerns:

Emtricitabine/tenofovir disoproxil & renal impairment: If baseline CrCl <50 mL/min (eGFR <50), consider if the benefits outweigh the risks or use alternative (discuss with CSHC or ID if alternative is required)
Raltegravir:

Avoid cytochrome P450 enzyme inducing medication (e.g. Rifampicin)
Do not take multivitamins/antacids containing calcium, iron, magnesium or aluminium at the same time as Raltegravir (limits absorption; leave 4h either side)

Drug interactions can be checked using the Liverpool HIV drug interaction checker.
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<tr><td>Missed Doses</td><td>
<table>
<tr><th>Time since last dose</th><th>Recommendation</th><th>Comment</th></tr>
<tr><td><24h</td><td>Take missed dose immediately; take subsequent doses at usual time</td><td rowspan="2">Reinforce importance of adherence; re-evaluate motivation to continue PEP</td></tr>
<tr><td>24-48h</td><td>Do not take any additional or missed dose; Continue PEP</td></tr>
<tr><td>>48h</td><td>Recommend stopping PEP</td><td></td></tr>
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<tr><td>Patient Information Leaflets</td><td>A PIL is included with every PEP pack. The leaflet Testing for blood borne viruses can also be issued</td></tr>
<tr><td>Extending PEP</td><td>
If high-risk sex occurs during the last 2 days of PEP, extend the course:

48h after anal sex
7 days after vaginal/frontal sex

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Follow up assessment if PEP started

This is done at CSHC. The patient should be told to telephone CSHC to make an appointment within 3 days of being prescribed PEP.

Patients who decline PEP should be offered follow up testing as normal.

APPENDIX B: Source Testing

Who should speak to source patient	• Community source patients: Usually no tracing can be done • If the source presents to ED alongside the patient; consent can be obtained by reviewing clinician.

Pre-test consent	Can be performed by any competent healthcare worker:
	• Inform them about the incident and reason for the request.
	• Discuss the injured party's situation, noting:
	  ○ The benefits of PEP, and
	  ○ If testing is negative, that there are considerable savings in terms of cost, repeat testing and reduced anxiety for the injured person.
	• Explain that treatment is available for all 3 BBVs
	Consent to BBV virus testing is rarely withheld in these circumstances, when the approach is made in a sensitive manner.

If consent withheld	Testing cannot occur
If source patient cannot consent	If the source patient is unable to give informed consent (e.g. unconscious, altered mental status) then testing can be performed if the primary purpose is in THEIR best interests. It is deemed sensible to use the result to guide decisions for the secondary purpose of whether to provide PEP to the injured party.
Source testing panel	• HIV antigen / antibody • HBV surface antigen / core antibody • HCV PCR / HCV antibody
Informing source patient of test results	• Test results should be conveyed to the source patient, even if negative. • Any source patient newly diagnosed with blood borne viral infection will need early access to specialist post-test counselling (see NHS Lothian BBV Testing in Adults Guideline 2025)