Royal United Hospital Bath NHS
NHS Trust

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Clinic no
DOB

Post Exposure Prophylaxis for HIV following Sexual Exposure (PEPSE) Assessment Proforma

PART A: FOR COMPLETION AT INITIAL PRESENTATION

The use of PEP following potential sexual exposure to HIV is only recommended where the individual presents **within 72 hours** of exposure. Within that time frame, it is recommended that PEP (if given) should be administered as early as possible.

Date and time seen_____ Seen by_____

No of hours since incident* [ ]

***If >72 hours, PEPSE NOT indicated: STOP and refer to sexual health clinic for review and STI screening.** *(walk-in clinic Mon, Weds,Fri 8.15-11am, or phone 01225 824617 for appointment)*

*If <72 hours, continue to assess for PEPSE

1. Patient details:

HIV status

Never tested/unknown [ ]
Negative [ ] if yes, date of last test_____
Positive [ ] → PEPSE NOT indicated
HIV test performed at this presentation? Yes/No

Is the patient known to have Hepatitis B?

If yes – IS NOT a contraindication to PEPSE

Relevant PMHx (particularly renal):
Caution with tenofovir in renal disease.

Current medication_____ Drug allergies_____

Female patients: Assess pregnancy risk

Current contraception_____ LMP_____

Emergency contraception required? Yes/No

2. Brief description of incident:

3. Exposure details

Type of Sex (circle all that apply) Vaginal / Anal / Oral / Other

If Anal intercourse (AI): Receptive / Active
If Receptive anal or vaginal: Ejaculation inside? Yes / No

Condoms used?: Yes / No / split condom

Sexual Assault? Yes / No

Previous PEP Use:
Previous use of PEPSE? : Yes/No If yes → Well tolerated? Yes/No
If NOT well tolerated patient may prefer NOT to take again.

Risk Assessment :
Have there been any other risks in last 3/12? Yes/No
Other unprotected AI in last 3/12? Yes/No
Intravenous drug use in last 3 months? Yes/No
May already be HIV positive but undiagnosed and PEPSE is potentially contraindicated. Risk of undiagnosed infection should be taken into account when discussing whether or not PEPSE is recommended.

4. Source (sexual partner) information

Male/female (delete as appropriate)

Source: Please circle	**Comments**
Known HIV positive, on ART* with undetectable viral load	Proceed to section 6
Known HIV positive, Not on ART* or on ART but viral load detectable or unaware if on ART* or not	Proceed to section 6
Unknown HIV status	Proceed to section 5
Known HIV negative	If HIV **negative** then PEP is **NOT** indicated and can reassure

*Antiretroviral therapy

5. HIV risk assessment of source (where HIV status is unknown)

Attempt should be made, where possible, to establish the HIV status of the source individual (according to appropriate guidance on HIV testing and consent) as early as possible. The following table may help to distinguish higher risk individuals. Those in groups with prevalence 0.8% or higher (highlighted in green) should be deemed to be high risk. Essentially this refers to all MSM and injecting drug users plus heterosexual contacts from Sub-Saharan Africa, the Caribbean, Eastern Europe and Central Asia.

Source community	HIV seroprevalence
Homosexual men	
London	8.1%
Elsewhere in UK	3.1%
Injecting drug users	
London	0.9%
Elsewhere in UK	0.4%

Source community UNAIDS 2009	HIV seroprevalence
Heterosexuals	
Sub Saharan Africa	5.0%
Caribbean	1.0%
Eastern Europe & Central Asia	0.8%
Latin America	0.5%
North America	0.5%
South and SE Asia	0.3%
Australia & New Zealand	0.3%
N. Africa and Middle East	0.2%
Western Europe	0.2%
East Asia	0.1%
UK	0.1%

6. Exposure risk and recommendation for PEPSE

In all of the exposures listed it is assumed that condoms (or other barrier methods) were not used, or breakages occurred.

Factors associated with increased risk:

- Sexual assault (especially if associated with genital injury)
- Source ill with HIV/known high viral load
- Source has acute HIV/seroconversion illness
- Source or index known to have concurrent STI
- Menstruation/bleeding
- Mouth/genital ulcer disease

Use the table below to identify those in whom PEPSE **IS** recommended. Circle the option(s) relating to this case and use highest recommendation given as guidance.

	Source HIV status			
	HIV positive Viral load detectable/unknown	HIV positive Viral load undetectable	Unknown high prevalence group/area	Unknown low prevalence group/area
Receptive anal sex	Recommended	Recommended	Recommended	Not recommended
Insertive anal sex	Recommended	Not recommended	Consider	Not recommended
Receptive vaginal sex	Recommended	Not recommended	Consider	Not recommended
Insertive vaginal sex	Recommended	Not recommended	Consider	Not recommended
Giving fellatio with ejaculation ¥	Consider	Not recommended	Not recommended	Not recommended
Giving fellatio without ejaculation ¥	Not recommended	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Consider	Not recommended	Not recommended	Not recommended
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended

¥ PEPSE is not recommended for individuals receiving fellatio i.e. inserting their penis into another's oral cavity

Does the exposed person need HIV Post-Exposure Prophylaxis?
If the answer to all questions is yes please give PEPSE as soon as possible
If the answer is no to any question and uncertainty remains – discuss with senior doctor.

	Yes	No
Less than 72 hours since exposure		
PEPSE recommended or considered (as above)		
Safe to give PEPSE (no contraindications)		
Discussed potential side effects		
Patient wishes to take PEPSE		

Recommended PEPSE regimen

Kaletra (Lopinavir 200mg + Ritonavir 50mg)	2 Tablets BD
Truvada (Tenofovir 245mg + Emtricitabine 200mg)	1 Tablet OD
plus	
Domperidone 10mg (for nausea)	1-2 Tablets TDS
Loperamide 2mg (for diarrhoea)	2 Tablets stat then 1 qds

A 3 day starter pack should be prescribed in the first instance (x 2 packs if Bank Holiday weekend) with follow up at sexual health and HIV medicine within this time frame. Please phone and leave a message on x 4558

Ensure patient is aware of:

1. Rationale for PEPSE Y/N
2. Lack of evidence base Y/N
3. Potential side effects Y/N
4. Follow up and support Y/N → follow up appointment _____

_____ _____
Signature Date

_____
Print Name & Designation

Explanatory notes re Post Exposure Prophylaxis (PEP) for HIV following Sexual Exposure assessment document

Rationale

The risk of acquiring HIV through sexual exposure varies according to source and exposure type. The use of antiviral drugs has been shown to reduce the risk of infection fivefold when used in an occupational setting (for needle stick injuries etc.). Data from studies looking at sexual exposure is limited but have shown a reduction in transmission of HIV.

Risks and side effects of treatment

The frequency, severity, duration and reversibility of side effects and potential for as yet unknown long-term complications must be compared with the potential benefit of post-exposure prophylaxis. It is well reported that health care workers have experienced significant toxicities from PEP. The potential (and significance) for four-week course of antiretroviral agents, such as protease inhibitors, to cause toxicities such as metabolic disturbances, as seen in chronic infection remains unknown.

If the exposed person is already HIV positive but unaware of their status then there is the potential that a course of antiretrovirals may not be appropriate for their stage of infection. It is recommended that all exposed persons undergo an HIV test to ascertain status as soon as possible.

Drug information

The starter packs contain information on when and how the drugs should be taken and known interactions. Information for patients is also on final page of assessment sheet (read through with patient).

Common Side effects of Anti-retrovirals

Kaletra (lopinivir/ritonavir)	• Frequently causes diarrhoea & other gastro-intestinal disturbances • Patients may benefit from pro-active management of side-effects by the inclusion of anti-diarrhoeal and anti-emetic medication
Truvada (tenofovir/FTC)	• Proximal renal tubular dysfunction and fanconi's syndrome well reported in patients receiving long-term Truvada but not yet reported in the setting of PEP

Key drug interactions

Drug	Common Interactions
Truvada (Tenofovir/emtricitabine)	Few significant interactions
Kaletra (lopinavir/ritonavir)	Anti-arrhythmics Aripiprazole Sertindole Carbamazepine Chlorphenamine Some calcium channel blockers Dexamethasone Methadone Ethinyl oestradiol (the pill) Lidocaine Midazolam/Triazolam Quinidine Pimozide Primidone Quinine Clarithromycin Phenytoin Rifampicin/ Rifabutin Terfinadine St Johns Wort Sildenafil Warfarin Erythormycin

HIV POST-EXPOSURE PROPHYLAXIS (PEP)
PATIENT INFORMATION

- You have been prescribed post-exposure prophylaxis (PEP) because you may have been exposed to the HIV virus. The risk of developing HIV after exposure to HIV positive blood or body fluid is relatively small, depending on the nature of sexual activity. There is some evidence that taking PEP can reduce this risk further.

- You have been given a 3 day starter pack however you will need to continue the treatment for four weeks. Follow up arrangements should have been made for you to be seen in the Department of Sexual Health Medicine at the RUH. If you do not have an appointment, please telephone 01225 824558 to arrange this.

- The treatment consists of a combination of two tablets:

  Truvada (tenofovir 245mg & emtricitabine 200mg) – **one tablet once a day.**

  Kaletra (lopinavir 200mg and ritonavir 50mg) – **two tablets twice a day.**

- Truvada (one tablet) should be taken together with Kaletra (two tablets). A further dose of Kaletra (two tablets) should be taken 12 hours. The two doses should be taken 12 hours apart, at the same times each day (e.g. 8am and 8pm). If you have difficulty remembering to take them, use an alarm on your watch or mobile phone.

- The tablets should be taken with a meal or snack. Swallow the tablets whole with plenty of water. It is important they are not chewed or crushed.

- The most common side effects of the medicines are rash, nausea (feeling sick), diarrhoea, headache, tiredness, weakness and muscle aches. Speak with a doctor if you get any of these side effects and you are finding them difficult to cope with. Do not stop the medication unless asked to by a doctor.

- You must tell the doctor about any medical problems you have and whether you are taking any other medications including herbal remedies e.g. St John's wort.

- The medication will reduce the effectiveness of some hormonal contraceptive methods. These methods should not be relied on while you are taking the medication, and you should use a barrier method in addition. If you are pregnant or suspect you could be pregnant please inform the doctor.

- It is important to attend the clinic for an HIV test 3 months after completing the PEP medication.

RUH logo here

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PART B: FOR COMPLETION AT FOLLOW UP

Date and time seen_____ Seen by_____

Date PEPSE commenced_____

Adherence?

Side effects?

Further information available re source?

Further information about this patient:
HIV test at presentation NOT DONE/AWAITED/POSITIVE/NEGATIVE
Hepatitis B status

Never tested/unknown	[ ]	→	test today
Naturally immune	[ ]		
Active infection	[ ]		
Vaccinated	[ ]	if yes,	date of last dose_____ HepBsAb result_____

Previous PEPSE use:
Last PEPSE Access Date: _____ Clinic:_____

How many previous PEPSE episodes? 1 / 2 / 3 / more

Current partner?

Any sexual contact since risk incident?

STI screen Accepted/declined

STI tests performed (circle all that apply)

NAATs	Urine /vagina /cervix /rectum /throat
Culture	Urethra /vagina /cervix /rectum /throat
Bloods	HIV /STS /Hep B / Hep C / Hep A

Should PEPSE be continued?

	Yes	No
PEPSE still recommended or considered (recommendation unchanged by any new information)		
Safe to give PEPSE (no contraindications)		
Discussed potential side effects		
Patient wishes to continue PEPSE		

If "YES" to all above, prescribe PEPSE for a further 28 days.

Recommended PEPSE regimen

Kaletra (Lopinavir 200mg + Ritonavir 50mg)	2 Tablets BD
Truvada (Tenofovir 245mg + Emtricitabine 200mg)	1 Tablet OD
plus	
Domperidone 10mg (for nausea)	1-2 Tablets TDS
Loperamide 2mg (for diarrhoea)	2 Tablets stat then 1 qds

Ensure patient is aware of:

1. Rationale for PEPSE Y/N
2. Lack of evidence base Y/N
3. Potential side effects Y/N
4. Follow up and support Y/N
5. Need for repeat HIV test 3/12 after completion of PEPSE Y/N

Check contact details and preferred method of contact Y/N

Consent to write to GP? Y/N

Copy letter to self? Y/N

_____ _____

Signature Date

_____

Print Name & Designation