Guideline on the Management of Post Sexual exposure to HIV and other blood borne viruses.

Cardiff and Vale University Health Board 2017

Document Control

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1.0 Introduction

This document discusses the use of HIV treatment as post-exposure prophylaxis following potential sexual exposure (PEPSE) to HIV in an attempt to prevent infection with the virus.

Immediate risk assessment is crucial to establish whether the individual is at significant risk. This is dependent on the characteristics of the exposure, the infectivity of the source and host susceptibility. The longer the delay to risk assessment and administration of PEPSE, the less effective PEPSE is likely to be.

In the Emergency Department (ED), patients should be seen as soon as possible by an appropriate clinician, and not in time order, bearing in mind that PEPSE must be given within 72 hours of exposure. The assessment can be performed in all ED settings.

The need for hepatitis B vaccine (+/- immunoglobulin) and hepatitis C follow-up should also be considered. All those presenting for PEPSE should be advised about screening for other sexually transmitted infections after an appropriate time interval. This will be coordinated by the Sexual Health clinic at the time of referral.

For patients accessing the Sexual Assault Referral Centre (SARC) it is important to consider the risk of contracting Blood Borne Viruses following sexual assault. PEPSE against HIV and prophylactic Hepatitis B vaccination should be considered in all cases. (See Appendix 5)

PEPSE is not routinely recommended after any type of sex with HIV-positive source on anti-retroviral therapy with a <u>confirmed and sustained</u> (more than 6 months) undetectable viral load (less than 70 IU/ml). Neither is PEPSE recommended where there has been protected sexual intercourse, i.e. using a condom for all sexual activity. Information regarding the alleged source and type of sexual activity is therefore necessary to carry out a proper assessment.

PEPSE consists of 28 days of combination antiretrovirals (3 drugs). The treatment potentially has significant side effects. PEPSE should only be given if the potential benefits of outweigh the risks. The individual should also be provided with sufficient information with which to make an informed decision.

2.0 Objective

The guideline offers recommendations on how to assess risk following a potential exposure to HIV, and how and when to prescribe post exposure prophylaxis medication following sexual exposure.

3.0 Scope of Policy

This guideline is for clinicians in areas of first contact with individuals potentially exposed to HIV; this may include those working in the Emergency Department and the Sexual Assault Referral Centre.

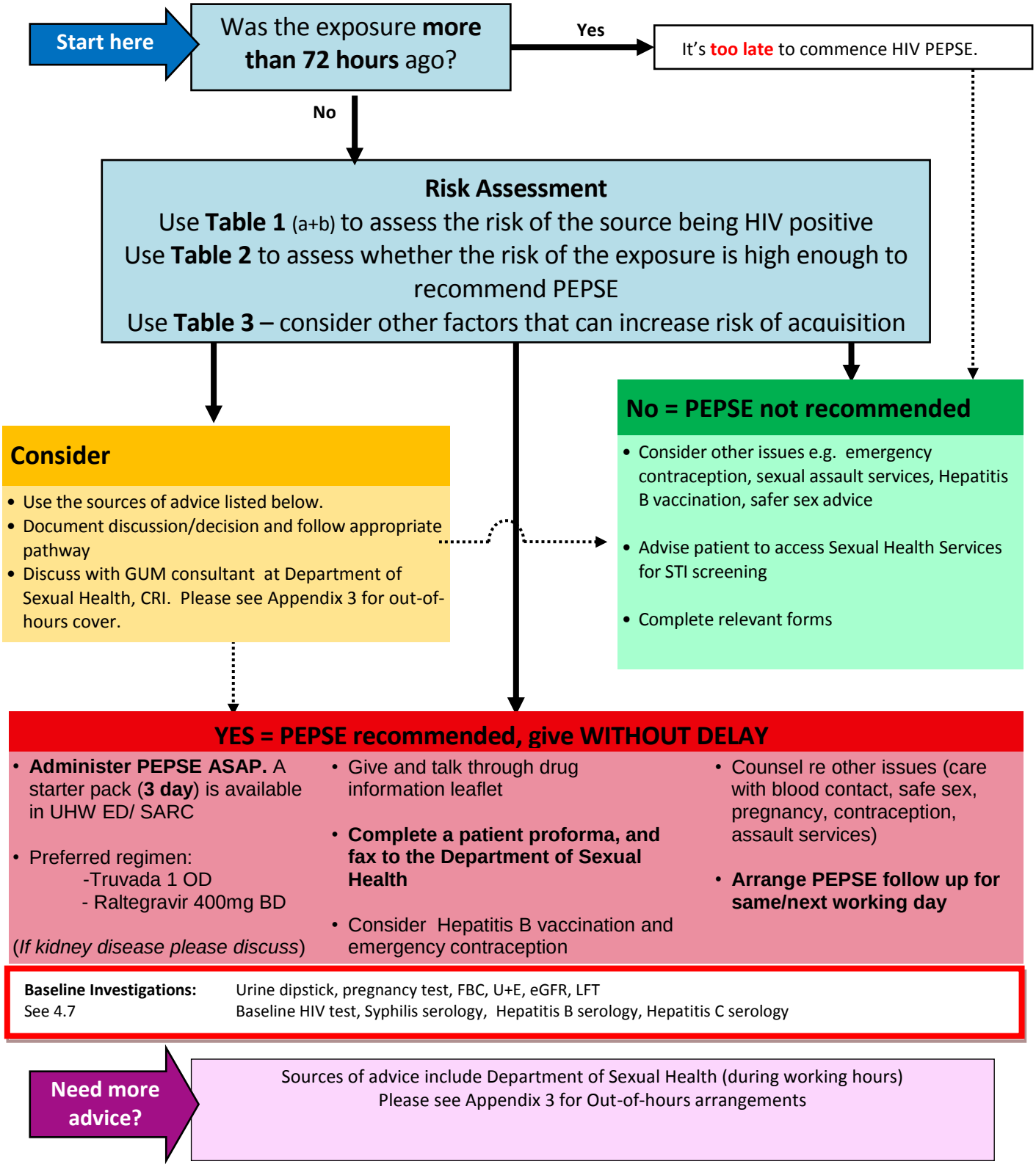
This guidance refers primarily to the issue of HIV post-exposure prophylaxis.

Consideration must also be given to risk of exposure to Hepatitis B and Hepatitis C. Further details are given within the guideline and in Appendix 5.

The main guideline is for individuals over 16 years of age.

Please see Appendix 2 for local CVUHB Paediatric PEPSE Guidance.

4.1 HIV PEPSE Algorithm



ASSESSING RISK AND NEED FOR PEPSE

Table 1a: Probability that the source is HIV positive

High Risk	Low Risk
MSM (men who have sex with men)	UK-born heterosexuals
Commercial sex workers who are not from Western Europe	Commercial sex workers from Western Europe
Injecting drug users from London or Glasgow, and other high-risk countries	Injecting drug users from the rest of the UK
Heterosexuals born, living or who have lived in geographical areas with high HIV prevalence (table 1b) NB: This includes ALL of Sub-Saharan Africa.	Heterosexuals born, living or who have lived in geographical areas with lower HIV prevalence (not listed in table 1b)
*If the source cannot be identified further than 'African' or 'Caribbean', regard as HIGH RISK	

Table 1b: High Prevalence Countries

Africa	**Sub-Saharan Africa**
Americas	Bahamas Barbados Belize Bermuda Dominican Republic Guatemala Guyana Haiti Jamaica Trinidad & Tobago Uruguay
South-East Asia	Cambodia Thailand
Europe	Russia Ukraine

Please refer to http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport

Table 2: Is PEPSE Indicated?

KEY		
	YES	PEPSE recommended
	Consider	Discuss with specialist and review Table 3
	No	PEPSE not recommended

			HIV positive		Unknown	
			Viral load detectable (≥70 IU/ml)	Viral load undetectable (<70 IU/ml for >6 months)	High risk	Low risk
Sexual Exposure	**Receptive** - Patient received penis into their body	Anal sex	YES	No	YES	No
		Fellatio with ejaculation*	No	No	No	No
		Fellatio, no ejaculation	No	No	No	No
		Vaginal sex	YES	No	Consider*	No
	Insertive - Patient inserted his penis into another's body	Anal sex	YES	No	Consider*	No
		Fellatio	No	No	No	No
		Vaginal sex	Consider*	No	Consider*	No
	Other	Splash of semen into eye	No	No	No	No
		Cunnilingus	No	No	No	No
Other Exposure	Sharing of injecting equipment		YES	No	Consider*	No
	Human bite (a bite is assumed to constitute breakage of skin with passage of blood)≠*		No	No	No	No
	Superficial injury with blunt instrument, with no visible blood drawn in injury		No	No	No	No
	Needlestick from a discarded needle in the community		No	No	No	No
	Bodily fluid or blood on intact skin		No	No	No	No

* Review Table 3 (+/- discuss with specialist) as this may convert a "consider" or "no" into a "Yes"
≠ Consider risk to person inflicting bite as well

Table 3: Factors increasing the risk of HIV transmission

1. A high plasma HIV viral load in the source (eg HIV seroconversion)
2. Breaches in the mucosal barrier such as mouth or genital ulcer disease, or anal/vaginal trauma following sexual assault. The presence of sexual assault may convert a “consider” to a “recommended”.
3. Menstruation or other bleeding
4. Presence of another sexually transmitted infection
5. Ejaculation
6. Non-circumcision
7. Discordant HIV viral load in the genital tract (in general, genital tract viral load is undetectable when the plasma viral load is undetectable).

If in doubt, start PEPSE and ensure early follow-up to review requirement for PEPSE.

Table 4: Key points to discuss with patients

PEP is not 100% effective

Possible risks and benefits

Adherence

Side effects

Emergency contact details

Safer sex/risk reduction

4.2 How to Prescribe PEPSE

The recommended starter pack regimen comprises 3 days of:

TRUVADA	RALTEGRAVIR
245mg tenofovir (TDF) 200mg emtricitabine (FTC)	400mg raltegravir tablet
(1 tablet once a day)	(1 tablet, twice daily)
Coformulated nucleoside/tide reverse transcriptase inhibitors	Integrase inhibitor

The full course is for 28 days which will be prescribed by DOSH after their assessment. It is important to take the medication at the same time every day. However, if the initial dose is given at an antisocial time, the time can be switched to aid adherence.

4.3 Key Contraindications to PEPSE

- **Renal failure**
  - Truvada is relatively contraindicated in renal failure.
  - If the patient's eGFR is <50 ml/min or there is significant proteinuria on urinalysis, seek specialist advice.
  - If specialist advice is not available, Combivir (zidovudine+lamivudine, 1 tablet BD) is preferred to Truvada.

- **Pregnancy/risk of pregnancy is <u>not</u> a contraindication to standard PEPSE as above.**

4.4 Interactions with PEPSE

A medication history should be taken from the PEPSE recipient including over the counter drugs, vitamins and minerals, herbal remedies and recreational drugs. If the patient is taking other drugs the check the University of Liverpool website for drug-drug interactions. http://www.hiv-druginteractions.org/

Key interactions include:

- **Nephrotoxins:** Check patient isn't taking nephrotoxins alongside Truvada.
- **Rifampicin:** Avoid prescribing rifampicin, as this induces the liver enzyme UGT1A1, which metabolises raltegravir and reduces plasma levels.
- **Antacids:** Avoid prescribing antacids containing aluminium / magnesium (e.g. Rennies). These reduce absorption of raltegravir from the gut by chelation. If needed, prescribe calcium carbonate antacids or leave a 6 hour period between administration.

For further advice regarding interactions, please contact the HIV Specialist Pharmacist during working hours.
For out of hours advice, please see Appendix 3

4.5 Side effects from PEPSE

Side effects are common however they are usually mild to moderate rather than severe. This has to be balanced against the risk of acquiring the infection. Many can be managed symptomatically, for example by the use of antiemetics.

Common side effects to counsel patients about include:

- **Truvada**: Nausea, vomiting, headaches, muscle pain, lack of energy, skin rash, insomnia and anaemia.
- **Raltegravir**: decreased appetite, abnormal dreams, insomnia, nightmares, dizziness, headache, GI upset, rash, fatigue, pyrexia.

4.6 Cases of known resistance

If the source is known to have a current or past history of **treatment failure** or **resistance to antiretroviral therapy**, PEPSE should be modified in relation to the source's drug history and/or resistance testing. It would be helpful to ascertain under whose care the source patient is, and to seek his/her advice.

Please seek advice from a Consultant in Department of Sexual Health, CRI, or the HIV pharmacist Fiona Clark during working hours.
For out of hours advice, please see **Appendix 3**

If no further information/advice is available at the time of presentation, <u>prescribe routine PEPSE and refer immediately to DOSH who will adjust the medication as required.</u>

Information on contraindications, interactions, and sides effects change rapidly - please also consult up-to-date sources of information	
• http://i-base.info/guides/ or http://aidsinfo.nih.gov/ • Summary of product characteristics (SPCs) (http://www.medicines.org.uk/)	• British National Formulary • http://www.hiv-druginteractions.org/: from the Liverpool HIV Pharmacology Group

4.7 Baseline Investigations

If prescribing PEPSE, ensure the following baseline investigations are sent and processed :

Urine dipstick	**Biochemistry/Haematology**: U+E, LFT, eGFR (2 x yellow SST) FBC (1 x small purple EDTA)
Pregnancy test [Pregnancy is NOT a contraindication to PEPSE]	**Serology**: Baseline HIV test Syphilis Hepatitis B and C serology (2 x yellow SST)

(Do not send HIV/hepatitis samples for storage only)

4.8 Follow up

- Patients should be referred to DOSH immediately and be advised to attend as soon as possible, and certainly **within 3 days**. Patients walking-in for PEPSE will always be seen on the same day.

- Patients can also phone the main appointment line **02920 335208** and must advise the telephonist that they require PEPSE follow-up to ensure an appropriate appointment slot.

- The patient and their drug regimen will be reviewed in DOSH and, if appropriate, the rest of the 28 day course will be supplied.

- Close monitoring and follow up of individuals receiving PEPSE is recommended. This is to manage side effects and ensure the four week course of PEPSE is completed, undertake appropriate serological follow up, exclude other blood borne infections, encourage risk reduction strategies and provide appropriate support.

- Individuals not commenced on PEPSE are likely to benefit from sexual health follow-up for STI screening and health promotion.

4.9 Hepatitis B and C

Any individual exposed to HIV is also likely to be at risk of hepatitis B and C and should therefore undergo baseline serology. They should also be offered Hepatitis B vaccination, and in some cases Hepatitis B immunoglobulin. Please see **Appendix 5** for details of regimens.

5.0 Roles and Responsibilities

The guideline is for clinicians in areas of first contact with individuals potentially exposed to HIV; this may include those working in ED, Infectious Diseases, Occupational Health, Sexual Assault Referral Centre and Sexual Health clinics. The responsibility for the implementation and audit of these guidelines lies with the Clinical Leads of those respective departments at each site.

6.0 Associated documentation and references

These guidelines reflect recommendations from the Expert Advisory Group on AIDS. The preferred first-line regimen is now Raltegravir/Truvada for 28 days. For ease of assessment by non-specialists, there is now one unified algorithm for occupational and sexual exposure. Sources for developing this guideline also include:

- The Department of Health document on HIV Post Exposure Prophylaxis that has been developed by the UK Chief Medical Officers' Expert Advisory Group on AIDS (EAGA).
  https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/351633/Change_to_recommended_regimen_for_PEPSE_starter_pack_final.pdf

- The clinical effectiveness group (CEG) national guidelines of the British Association of Sexual Health and HIV (BASHH)
  https://www.bashhguidelines.org/media/1027/PEPSE-2015.pdf

7.0 Training & Resources

Clinicians in areas of first contact with individuals potentially exposed to HIV should be directed towards the Guidelines for Post Exposure Prophylaxis at Induction. Members of the Infectious Diseases/Department of Sexual Health team provide outreach teaching regarding HIV on a rotational basis. They will also provide planned training sessions when required.

Copies of the guideline and the case record forms will be available in the accident and emergency department and SARC.

8.0 Monitoring and Audit

Services providing PEPSE should undertake routine clinical audit to ensure quality of service. The Department of Sexual Health will continue to audit referrals and management of patients seen for PEPSE.

Appendix 1: Glossary of Terms used within Policy

DOSH = Department of Sexual Health, Cardiff Royal Infirmary
MSM = Men who have sex with men
PEPSE = Post Exposure Prophylaxis after sexual exposure
SARC = Sexual Assault Referral Centre
BBV = Blood Borne Viruses

Appendix 2: Post-Exposure Prophylaxis (PEP) Guidelines for children and adolescents under the age of 16 years potentially exposed to blood-borne viruses

This guideline is adapted from the CHIVA guideline updated in June 2015
www.chiva.org.uk/files/2814/3575/6995/CHIVA_PEP_2015_final.pdf

New in 2015 guideline update

1. Switch from Kaletra®-based PEP to raltegravir-based regimens for children older than 6 years. Raltegravir is better tolerated than Kaletra® so switching is likely to improve adherence and hence the efficacy of PEP.
2. Reduction in the window period for repeat HIV testing from 12 weeks to 8 weeks post completion of PEP.

Background

The risk of community acquired HIV in children is extremely low. Following exposure to blood-borne viruses, it should be remembered that the risk of transmission is highest for Hepatitis B, then Hepatitis C and then HIV. The HIV status of the source is often unknown and difficult to establish.
The risks of HIV being transmitted from a variety of exposures are shown in
Table 1.
HIV-infected fluids cannot penetrate intact skin. Sexual abuse represents a particular risk because of possible multiple exposures and trauma.

Table 1. Estimated risks of HIV transmission according to type of exposure from a known HIV positive individual with detectable HIV viral load

Type of HIV exposure	**Risk of transmission**
Occupational needlestick injury that punctures skin	0.3% or 1 in 333
Unprotected receptive anal sex	1.11% or 1 in 90
Unprotected receptive vaginal intercourse	0.1% or 1 in 1000

Up to 40% of 15 year olds in the UK are sexually active. Following the widespread use of HAART (Highly Active Antiretroviral Therapy) children with perinatally acquired HIV-1 infection are surviving into adolescence and entering sexual relationships with their HIV negative peers who may present for PEPSE (Post Exposure Prophylaxis following Sexual Exposure). Please refer to BASHH Guidelines http://www.bashh.org/documents/4076.pdf. However it should be noted that following consensual unprotected vaginal sex PEPSE is no longer recommended where the HIV positive partner is known to be on effective antiretroviral therapy with an undetectable plasma HIV viral load.

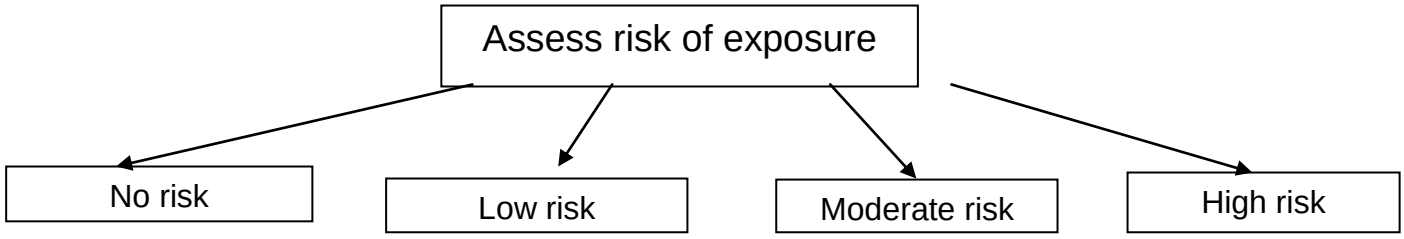
Mechanism of action of HIV PEP
The presumed mechanism for HIV PEP is that shortly after an exposure to HIV a window period exists of 72 hours during which antiretroviral therapy may help to diminish or end viral replication.
It may not completely prevent transmission but can significantly reduce the risk.

Previously, Department of Health recommendation for PEP in adults was Truvada® (a combination of tenofovir +emtricitabine) and Kaletra® (lopinavir/ritonavir). Recently, however, adult
national PEP guidelines have moved to the combination of Raltegravir with Truvada, which has fewer side effects.

Raltegravir dose for children 25kg or more is the full adult dose of 400mg (single pink film coated tablet) twice daily. Alternative chewable formulations of raltegravir are available for children over 11kg.
It should be noted that the film coated tablet and the chewable preparations are not bioequivalent. (See dose tables below).

Procedure for Children and Adolescents presenting with possible exposure to HIV

Risk assessment
Careful history and examination to assess the risk of exposure to HIV. Establish whether exposure occurred within the last 72 hours.



No risk	Low risk	Moderate risk	High risk
• Intact skin visibly contaminated with blood or bodily fluids • kissing • Casual touching	• Mucous membrane or conjunctival contact with blood or bodily fluids • Superficial injury that doe not draw blood • Associated with needle / instrument not visibly contaminated with blood bodily fluids	• Skin penetrating injury that draws blood by needle / instrument contaminated with blood / bodily fluid • Sexual contact with individual of unknown HIV status	• Significant exposure to blood or bodily fluids from source known to be HIV,HBV or HCV infected
Action Reassure parents and child discharge	**Action** Counsel family about risks of HIV/HBV/HCV transmission Standard HBV immunisation (0,1 & 6 months) or booster if already immunised PEP not recommended. Explain risks of PEP side effects outweigh extremely low risk of HIV transmission	**Action** Counsel family about risks of HIV/HBV/HCV transmission Accelerated HBV immunisation (0,1 & 2 months) or booster if already immunised Discuss risks of HIV PEP. Consider HIV PEP but on balance the risks of PEP probably outweigh the benefit. BUT the likelihood of transmission is likely to be increased during aggravated sexual intercourse so in the case of sexual assault clinicians should consider recommending PEP more readily.	**Action** Counsel family about risks of HIV/HBV/HCV transmission Accelerated HBV immunisation (0,1 & 2 months) or booster if already immunised Consider HBV Ig if source is highly infectious HBV carrier Discuss risks of HIV PEP. Recommend starting PEP

Investigations

Source
In rare situations the source may be known and, if that individual gives consent HIV, HBV and HCV serology may be tested. If the source is already known to be HIV positive, where possible obtain details of present and past antiretroviral medications, known previous resistance mutations and
consider further resistance testing (if viral load detectable), although the latter should not delay commencement of PEP.

Child/Adolescent
Obtain a medical history paying particular attention to renal disease, as this would exclude the use of tenofovir (component of Truvada). Check that the child / adolescent is not already HIV infected.
Obtain baseline syphilis, HCV, HBV and HIV antibody status.
If antiretroviral therapy is to be started also request FBC, U&E and LFTs.
The baseline HIV test result on the child/adolescent should be available at the first follow up visit, within 24-72 hours of PEP initiation.

HIV PEP
HIV PEP is most effective if started within 1 hour of exposure, but may be beneficial up to 72 hours after.
The child and their family should be counselled about likely side effects and given contact phone numbers in case of concerns during or after the treatment period.
An appointment to see a paediatrician/HIV physician ideally within 24-72 hours of starting HIV PEP should be made.

Initially 3 days of PEP should be prescribed, (on a bank holiday give 2 packs).
A full 4 weeks should **NOT** be prescribed at the first appointment. A further prescription for **a total of 4 weeks** will be given at consultant review if PEP is to be continued.

PEP Drug Regimens
The regimens below are based on age bandings; however accurate weight and height measurements should be used to calculate individual drug doses as below or the CHIVA antiretroviral dosing table (http://www.chiva.org.uk/). Formula for surface area below.
The choice of PEP depends on whether the child can take or chew tablets or whether they need liquid formulations

Age >10 years >35kg

Preferred PEP	**Raltegravir BD + Truvada® OD**
Alternative PEP *Do not use Truvada (tenofovir) if known renal impairment*	**Raltegravir BD + Combivir BD**

Doses and formulations

Raltegravir	**Tablet (400mg)**	**Chewable tablet (25mg & 100mg)**
*It should be noted that the film coated tablet and the chewable preparations are **not** bioequivalent*	**From 25kg 400mg bd**	11-14kg – 75 mg BD 14-20kg – 100mg BD 20-28kg – 150mg BD 28-40kg – 200mg BD >40kg – 300mg BD
Truvada	**Combined tablet of tenofovir 300mg/ Emtricitabine 200mg**	>35kg **one tablet once daily**
Combivir	**Combined tablet of lamivudine 150mg / zidovudine 300mg**	>30kg **one tablet twice daily**

Age >10 years <35kg

Preferred PEP	**Raltegravir BD + Lamivudine BD + Tenofovir OD**
Alternative PEP *Do not use tenofovir if known renal impairment*	**Raltegravir BD + Lamivudine BD + Zidovudine BD**

Doses and formulations

Raltegravir	**As above**	
Lamivudine	**Tablet:** 100mg, 150mg **Liquid:** 10mg/ml	**Tablet or liquid:** 4mg/kg/dose BD to a maximum dose of 150mg BD
Tenofovir	**Paed tab:** 150mg,200mg 250mg	**Paed tab:** 17-22kg – 150mg OD 23-28mg – 200mg OD 28-34kg – 250mg OD
Zidovudine	**Capsule**: 100mg, 250mg **Liquid**: 10mg/ml	**Capsule or liquid:** 180mg/m2/dose BD to a maximum dose of 250mg BD

Age 2 – 9 years

Preferred PEP	**Raltegravir BD + Lamivudine BD + Zidovudine BD**
Alternative PEP (if unable to swallow or chew tablets and would prefer liquid)	**Kaletra BD + Lamivudine BD + Zidovudine BD**

Doses and formulations

Raltegravir	**As above**	
Lamivudine	**As above**	
Zidovudine	**As above**	
Kaletra (lopinavir (LPV)/ ritonavir RTV) Use if unable to swallow or chew Raltegravir tablets **All doses based on lopinavir**	**Liquid:** LPV 80mg/RTV 20mg / ml	**Liquid:** 300mg/m²/dose BD Dose in mls = (300 x SA)/80

Calculation of SA

$$\mathrm{BSA}(m^2) = \sqrt{\frac{\mathrm{height(cm)} \times \mathrm{weight(kg)}}{3600}}$$

Age <2 years

Use liquid formulations

Preferred PEP	**Kaletra BD + Lamivudine BD + Zidovudine BD**

Drug doses see above

Notes:

1. Young people from 10 years of age and over 35 kg who are able to swallow tablets should receive PEP as for adults:- raltegravir 400mg (1 tablet) bd + Truvada® 1 tablet od

2. Young people 10 years of age or older with renal insufficiency should not receive tenofovir and should therefore be given:- raltegravir 400mg (1 tablet) bd + Combivir (a fixed dose combination of lamivudine/zidovudine 1 tablet bd).

3. Tenofovir should be avoided in the context of renal impairment at any age if at all possible (seek expert advice)

4. Drug interactions that may reduce the effectiveness of raltegravir:
- Rifampicin within the preceding 2 weeks
- Aluminium/ magnesium containing antacids

Antiemetics:
Antiemetics are not routinely prescribed. However gastrointestinal side effects are more likely to occur with regimens that contain Kaletra® when compared to Raltegravir. For those with nausea and vomiting on Kaletra® based PEP a switch to paediatric Raltegravir should be considered.

Alternatively the addition of an anti-emetic to a Kaletra® based regimen requires a risk benefit discussion with the family
(including discussion regarding the unknown risk of prolonged QT in the paediatric population inferred from adult data) and specialist advice from a tertiary centre and/or HIV pharmacist is recommended. **(JE to discuss with Fiona)**

HBV
For a significant exposure to an unknown source an accelerated course of HBV immunisation (Day 0, 1 month and 2 months with a booster at 12 months) should be offered. The HPA recommends the use of intramuscular hepatitis B immunoglobulin only if the source is known to be HBV infected,
although would agree to its use with an unknown source if compelling circumstances existed.

HCV
There is no recognised PEP for HCV. Families may be counselled that, in the event of HCV seroconversion, therapy is increasingly successful.

Tetanus
The need for tetanus injection/booster should be assessed per usual practice.

Emergency contraception and screening for sexually transmitted infections
Following sexual exposure it is important to consider emergency contraception in girls of reproductive age and the need for screening/prophylaxis for other sexually transmitted infections.
See SARC and BASHH Guidelines.

Follow-up
Prior to discharge families embarking on HIV PEP should have the following:
 Arrangements for an outpatient appointment, within the next 72 hours to see a named clinician with experience in prescribing antiretroviral drugs.
 Contact telephone numbers in case of concerns about any aspect of the HIV PEP including out-of-hours number.
 3 days of antiretroviral therapy
 A letter for their GP, with patients/parents consent.

A minimum of 4 weeks AFTER PEP completion (8 weeks from high risk exposure):
Follow-up HIV testing should be undertaken. Antibody screening for Hepatitis B and C and syphilis is also recommended.
Optimally this should be performed 4-8 weeks after completing the 3 doses of HBV vaccine, so that infection can be excluded (HBsAg and HBcAb) and to ascertain that the vaccine response was satisfactory (HBsAb >10mIU/ml).

Appendix 3 – Out-of-Hours Advice for PEPSE

There is no dedicated out-of-hours support for PEPSE advice.

- If there are no medical contraindications to antiretroviral therapy, and there is a potential risk of HIV exposure, start the patient on PEPSE as per this guidance and refer urgently to the Department of Sexual Health to be seen as soon as possible.

- If there are concerns specifically related to the medication (e.g. drug interactions, renal dysfunction, contraindications) the case may be discussed with the on-call pharmacist.

- There may sometimes be an Infectious Diseases physician on call as per the microbiology out-of-hours rota but not always.

If in doubt, start PEPSE and ensure early follow-up to review requirement for PEPSE.

Appendix 4 – Useful Contact Details

DOSH Consultants (CRI)	02920 335169 (sec)
Dr Darren Cousins	(or via switch - mobile)
Dr Laura Cunningham	
Dr Rachel Drayton	
Dr Nicola Lomax	
ID Consultants (UHW)	
Dr Andrew Freedman	02920 746516
Dr Richard Evans	02920 746516
Dr Brendan Healy	02920 744515
Dr Harriet Hughes	02920 744515
Dr Matthijs Backx	02920 744515
SPR in Infectious Diseases (UHW)	Bleep 5402 /via switchboard
HIV Specialist Pharmacist	
Fiona Clark	Bleep 5991/via switchboard
Paediatric ID Consultant	
Dr Jennifer Evans (UHW)	029 20742198/via switchboard

If Dr Jennifer Evans not available, please contact the On-call Paediatric Infectious Disease Consultant at St Mary's Hospital, London – 0207 8866349

Sexual Assault Referral Centre (CRI)

Dr Alison Mott – Clinical Lead	02920 536789
Ruth Nash – SARC Manager	029 20 335795
SARC Reception	02920335795 in hours
	02920 335533 Emergency

Appendix 5 – ADULT Hepatitis B Vaccination Schedules

- Patients who may have been exposed to Hepatitis B should be offered the first dose of the monovalent hepatitis B vaccination at their first presentation if they have not previously had a full and successful vaccination course.

- This can be given using either the ultra-rapid or rapid vaccination schedule, as below. The course can be completed in DOSH or at their GP surgery.

Vaccine Schedule	Advantages	Disadvantages
Ultra rapid 0,1,3 weeks, 12 months	- Rapid immunity, - Short duration, - High antibody titres at 12 and 13 months - Better uptake	- Less evidence on HIV or other immune-compromised patients - Low antibody titres in the first year (but current evidence suggests that protection is still adequate in the immune-competent)
Rapid 0,1,2,12 months	- Shorter time to early immunity than the 0,1,6 course - High antibody titres at 12 and 13 months	- Antibody titres lower than the 0,1,6 regimen in the first year

BASHH Guidelines 2015

For further information about HBV prophylaxis, please also refer to the Green Book table as below, remembering that an ultra rapid schedule may also be used in addition to the rapid schedule.

Table 18.5 HBV prophylaxis for reported exposure incidents

	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).

Immunisations against infectious diseases (The Green Book); Public Health England, September 2013, updated September 2014.
https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18 (accessed February 2017)

Cardiff and Vale University Health Board (CVUHB) HIV Post Exposure Prophylaxis following sexual exposure (PEPSE)

Patient Proforma/Referral Form

To be completed for all patients attending CVUHB requesting, or being considered for, post-exposure prophylaxis for HIV.

Date: ..... Time: ..... Seen by: .....

A Details of exposure

Date and time of potential HIV exposure .....Hours since potential HIV exposure .....

NB - If > 72 hours since last exposure PEPSE is NOT indicated

B. Details of source:

1. Is source **known** to be HIV positive Yes / No (if No, go to Q2)

If yes:

Are they known to be on treatment Yes/ No

If so, what.....

Do they **definitely** have an undetectable viral load for > 6months, and have been adherent to their regimen? Yes / No

Are they known to have a resistant strain of HIV? Yes / No

Where do they receive their care .....

PEPSE is not routinely recommended after any type of sex where the HIV positive source has a confirmed and sustained (> 6 months) undetectable HIV viral load (<70 IU/ml). Where there is any doubt, PEPSE should be given.

2. If not known to be HIV positive, are they in a high risk category for HIV? Yes / No

If yes, please specify:

MSM Yes / No

Born, living or have lived in high prevalence area for HIV Yes/No

If known, please specify where .....

Commercial sex worker, not from Western Europe Yes/No

Injecting drug user from London, Glasgow or other high risk countries Yes/No

3. Has the patient been sexually assaulted Yes / No

If yes, are there clinical signs of anal or vaginal trauma Yes / No

Other relevant information about source .....

.....

C. Is PEPSE recommended? (please circle relevant option)

			HIV positive		Unknown	
			Viral load detectable (≥70 IU/ml)	Viral load undetectable (<70 IU/ml for >6 months)	High risk	Low risk
Sexual Exposure	**Receptive** - Patient received penis into their body	Anal sex	**YES**	No	**YES**	No
		Fellatio with ejaculation*	No	No	No	No
		Fellatio, no ejaculation	No	No	No	No
		Vaginal sex	**YES**	No	Consider*	No
	Insertive - Patient inserted his penis into another's body	Anal sex	**YES**	No	Consider*	No
		Fellatio	No	No	No	No
		Vaginal sex	Consider*	No	Consider*	No
	Other	Splash of semen into eye	No	No	No	No
		Cunnilingus	No	No	No	No
Other Exposure	Sharing of injecting equipment		**YES**	No	Consider*	No
	Human bite (a bite is assumed to constitute breakage of skin with passage of blood)**		No	No	No	No
	Superficial injury with blunt instrument, with no visible blood drawn in injury		No	No	No	No
	Needlestick from a discarded needle in the community		No	No	No	No
	Bodily fluid or blood on intact skin		No	No	No	No

If "consider", discuss with DOSH or prescribe to be reviewed in DOSH at follow-up.

If recommendation is to consider PEP, has it been given? Accepted / declined / not offered
Decision discussed with (if applicable).....

D. To be completed in all patients

NB – All patients should be considered for a full STI screen including HIV, syphilis and hepatitis serology, hepatitis B vaccination and emergency contraception on the day of presentation if indicated, regardless of whether PEPSE is given or not (use relevant proformas)

Previous hepatitis B vaccination Yes / No
Is the patient commencing hepatitis B vaccination today? Accepted / declined / not indicated

Women only:
LMP ..... Contraception ..... Pregnancy test *(if relevant)*: Pos/Neg
Emergency contraception discussed Yes/No.
Details of any Emergency contraception prescribed: .....

E. To be completed if PEP given

Past medical history .....

Drug history ..... Allergies .....

The standard PEPSE pack contains 3 days of Truvada x1 OD plus Raltegravir 400mg BD

If the patient has significant renal impairment please replace Truvada with Combivir 1 tablet twice a day.

Please advise patient not to take antacids containing Magnesium or Aluminium within 2 hours of the Raltegravir dose.

To check for any potential drugs-drugs interaction, please refer to the website http://www.hiv-druginteractions.org/

3 day PEP pack prescribed e.g. Truvada 1 od/Raltegravir 400mg bd ☐
(if bank holiday, give 2 packs)

Other regimen prescribed (please specify and give reasons) .....
.....

Patient counselled regarding:
Uncertain effectiveness of PEPSE ☐
Importance of taking at same time every day ☐
Possible side effects and their management ☐

Check list:

Hepatitis B vaccination given ☐

Emergency contraception given & if so what?

..... ☐

Baseline bloods taken and **marked as URGENT** ☐

Patient information leaflet given ☐

Patient advised to attend DOSH ASAP ☐

Proforma completed and faxed to DOSH☐

Test	Taken	Results seen
Urine dipstick		
Pregnancy test		
FBC		
U&E and eGFR		
LFT		
HIV antibody		
Syphilis serology		
Hep B cAb		
Hep B sAg		
Hep B sAb		
Hep C Ab		

Signed.....

Print name .....

Designation..... Date.....

APPENDIX 1

Table 4. Recommended combinations for PEP

	NRTI Backbone (2 medications)	Third agent
Recommended combination	**Truvada[&] one tablet once daily** (tenofovir disoproxil fumarate 245mg, emtricitabine 200mg)	**Raltegravir 400mg every 12 hours***
Alternative 1[#]	Combivir (Zidovudine 250mg twice daily plus lamivudine 150mg twice daily)	Protease inhibitor Kaletra (lopinavir 200mg, ritonavir 50mg**) Two tablets twice daily OR Darunavir 800mg once daily + ritonavir 100mg** once daily OR Atazanavir 300mg once daily + ritonavir 100mg** once daily OR Dolutegravir 50mg once daily[$]

[&] Truvada is the preferred agent in chronic hepatitis B virus infection

* Antacids and multivitamins (products containing metal cations e.g. magnesium / aluminium, which can chelate and reduce the absorption of raltegravir) should be avoided where possible during PEP, see appendix A. An alternative non-interacting medication may be considered. See appendix A about co-administration of rifampicin

[#] Combivir may be preferred to Truvada in patients with abnormal renal function at baseline. Lamivudine may require dose-adjustment depending on renal function.

**Significant drug-drug interactions can occur with boosted protease inhibitors, seek expert advice from a HIV specialist pharmacist, local medicines and poisons information centre or use the website www.hiv-druginteractions.org

[$] At the time of publication there are no data on the use of dolutegravir as PEP but it is anticipated to be well-tolerated

Swallowing difficulty - Truvada can be disintegrated in 100 ml of water or orange juice and taken immediately. Kaletra can be used as an alternative to raltegravir and is commercially available as an oral solution; the recommended dosage is 5ml twice daily with food.

APPENDIX 2

High Prevalence Countries			
Africa	Sub-Saharan Africa	**South-East Asia**	Cambodia Thailand
Americas	Bahamas Barbados Belize Bermuda Dominican Republic Guatemala Guyana Haiti Jamaica Trinidad & Tobago Uruguay	**Europe**	Russia Ukraine

Please refer to http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport