Protocol for assessment of risk for blood borne viruses (BBV) after acute sexual assault in children and young people

Scant information exists on the risk of acquisition of blood-borne viruses following acute sexual assault of children. Careful history and examination are required to assess the risk of exposure to blood-borne viruses:

- where the assailant is a family member, or known to the family, the risk is likely to be lower unless he is KNOWN to belong to a specific high risk group;
- The risk of transmission of any BBV is higher if there is significant physical trauma to the child/young person.

Each case should be considered on an individual basis.
In all cases, serum should be sent for storage to microbiology at the time of presentation.

Whatever the perceived risk, it may be helpful for concerned parents and the young person to offer serological testing for syphilis and HIV at 3 months and Hepatitis B and C at 6 months. Negative results will help them all to attain 'closure' on the incident.

HBV

For a significant exposure to an unknown source an accelerated course of HBV immunisation should be offered. **Refer to BNFc current up to date version Hep B vaccination.**

The use of intramuscular hepatitis B immunoglobulin is recommended only if the source is **known** to be HBV infected, although most would agree to its use with an unknown source if compelling circumstances existed.

It is still appropriate to give protection against HBV when a decision not to give HIV PEP has been made.

NHS Fife	Hepatitis B vaccine/Hep B immunoglobulin available via pharmacy for first dose, course completed by GP. Ulipristal & Levonelle is kept in the locked cupboard at PACU next door to the examination room.
NHS Borders	Ulipristal available in Emergency Department and BECS. Levonelle 2 via pharmacy and kept in emergency cupboard OOH accessed by nurse in charge. Hep B immunoglobulin via pharmacy and kept in emergency cupboard OOH accessed by nurse in charge Hepatitis B vaccine available in A&E.
NHS Lothian RHSC	Hepatitis B vaccine, Hep B immunoglobulin Levonelle and Ulipristal OOH in emergency drug cupboard access via clinical coordinator bleep 9278. Examining doctor is responsible for ensuring Hep B vaccine administered /baseline bloods taken , could be either via GP or A&E
NHS Lothian SJH	Hepatitis B vaccine, Hep B immunoglobulin, Levonelle and Ulipristal OOH available in children's ward accessed by nurse in charge. Complete drug administration kardex for each patient.

HCV

There is no recognised post exposure prophylaxis (PEP) for HCV. Families may be counselled that, in the event of HCV seroconversion, treatment is increasingly successful and it is worth testing for this virus.

HIV

The risk of HIV transmission varies according to type of exposure and risk category of assailant.

PEP is available but has significant side-effects and its efficacy in this context is not proven.

- Take baseline serology
- Contact ID consultant via RHSC switchboard

Incident	Risk for HIV	Action
Kissing; casual touching. Intact skin visibly contaminated with blood or body fluids.	Negligible	Reassure parents and child.

Mucous membrane or conjunctival contact with blood or body fluids from an assailant of unknown BBV status.	Very low	Counsel family about risks of HIV/HBV/HCV transmission. Consider HBV immunisation or booster if already immunised. HIV PEP **not** indicated. Offer follow-up serology at 3 and 6 months
Vaginal penetration by an assailant of unknown BBV status and not from a group or area of high (>10%) prevalence for HIV.	Low	Counsel family about risks of HIV/HBV/HCV transmission. Give accelerated HBV immunisation or booster if already immunised. HIV PEP **not** indicated Offer follow-up serology at 3 and 6 months
Anal penetration by an assailant of unknown BBV status and not from a group or area of high (>10%) prevalence for HIV. Vaginal penetration or oral penetration with ejaculation by assailant from a group or area of high (>10%) prevalence for HIV. Oral penetration with ejaculation or splash of semen into eye from assailant known to be infected with HIV	Moderate	Counsel family about risks of HIV/HBV/HCV transmission. Give accelerated HBV immunisation or booster if already immunised. **Consider** HIV PEP – discuss with on-call GUM/ID Consultant.
Anal penetration by assailant from a group or area of high (>10%) prevalence for HIV. Anal or vaginal penetration by assailant known to be infected with HIV	High	Counsel family about high risk of HIV/HBV/HCV transmission. Give accelerated HBV immunisation or booster if already immunised. HIV PEP **recommended**. If in doubt, discuss with on-call GUM Consultant.

HIV Post-Exposure Prophylaxis

https://www.chiva.org.uk/files/1215/4454/3739/CHIVA_PEP_2017.pdf

2015 UK guidelines for children regarding HIV PEP has recommended a switch from Kaletra®-based PEP to raltegravir-based regimens for older children who are able to swallow tablets and inclusion of chewable raltegravir as an option in younger children in centres where chewable raltegravir is available. The switch is in line with the change in adult guidelines prompted by MHRA warnings against the use of antiemetics in conjunction with ritonavir-containing regimens, due to the increased risk of cardiac events (prolonged QT interval) in adults. Raltegravir based ART was recommended by the Public Health England Expert Advisory Group on AIDS as it has been extensively tested in HIV infected adults with no significant safety issues and is better tolerated than Kaletra® so switching is likely to improve adherence and hence the efficacy of PEP.

Counselling and support

Before initiating HIV PEP discuss with the on-call GUM/ID consultant. HIV PEP is most effective if started within 1 hour of exposure, but may be beneficial up to 72 hours. The family should be given 5 days of PEP, a full 4 weeks should **NOT** be prescribed at the first appointment. . An appointment should be made for the patient to see GUM/ID specialist within 72 hours of starting treatment.

A further prescription for **a total of 4 weeks** should be given at consultant review if PEP is to be continued. They should be counselled about likely side-effects (see Table) and given contact phone numbers in case of concerns during or after the treatment period

Regimen

The table below shows the preferred regimes in accordance with changes in the adult guidance, however the start of PEP should not be delayed while obtaining paediatric formulations of newer agents.

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Age (years)	PEP - preferred	PEP - alternative	Notes
10 +	Raltegravir + Truvada® (emtricitabine 200mg/tenofovir disoproxil fumarate 300mg) NB if under 35kg, in centres where TDF paediatric formulations are immediately available, we would recommend age and weight appropriate dosing of raltegravir + TDF + lamivudine	1. Raltegravir + lamivudine 150mg/zidovudine 300mg combined tablet 2. Kaletra® + lamivudine 150mg/zidovudine 300mg combined tablet	As per adult guideline with an alternative for tenofovir in those with renal insufficiency.
6-9	Raltegravir + lamivudine + zidovudine	1.Kaletra® + lamivudine + zidovudine 2.Raltegravir or Kaletra® + paediatric tenofovir + lamivudine	Adult dose raltegravir for children above 25kg. Note that the chewable formulation of raltegravir is not bioequivalent to the tablets (see table 4)

2- <6	Kaletra® + lamivudine + zidovudine	1. Raltegravir+ lamivudine + zidovudine 2. Raltegravir or Kaletra® + paediatric tenofovir + lamivudine	Alternative option for centres with access to chewable raltegravir
<2		Kaletra® + lamivudine + zidovudine	Liquid formulations

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 + a fixed dose combination of lamivudine 150mg/zidovudine 300mg 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. Although raltegravir is currently licensed in children younger than 6 years, experience of use in children in this age group is very limited and chewable formulation is rarely immediately available even in specialist centres. For these reasons Kaletra® remains first line recommendation in children under 6 years of age with chewable raltegravir as an alternative

Accurate weight and height measurements should be used to calculate doses

Drug	Formulation	Dose	Side Effects*
Raltegravir (RAL) NOTE: formulations are **not** bioequivalent; use chewable tabs for children 11-25kg and children >25kg who cannot swallow tablets	**Tablet:** 400mg **Chewable tablet:** 25mg, 100mg (can be chewed or swallowed)	**Tablet:** From 25kg: 400mg BD **Chewable tablet:** 11-14kg – 75 mg BD 14-20kg – 100mg BD 20-28kg – 150mg BD 28-40kg – 200mg BD >40kg – 300mg BD	Rash, nausea, hepatitis
Zidovudine (AZT, ZDV)	**Capsule**: 100mg, 250mg **Liquid**: 10mg/ml	**Capsule or liquid:** 180mg/m^2/dose BD to a maximum dose of 250mg BD (max. 300mg BD when used in combination products)	Granulocytopenia and/or anaemia, nausea, headache, myopathy, hepatitis, neuropathy.
Lamivudine (3TC)	**Tablet:** 100mg, 150mg **Liquid:** 10mg/ml	**Tablet or liquid:** 4mg/kg/dose BD to a maximum dose of 150mg BD	Peripheral neuropathy, nausea, diarrhoea, headache.
Truvada® (TDF+FTC) **Do not use if known renal impairment**	**Combined tablet:** TDF 300mg/FTC 200mg	**Combined tablet:** >35kg – 1 tablet OD	Headache, diarrhoea, nausea, vomiting, renal tubular dysfunction, bone demineralization
Tenofovir (TDF) Note: 300mg tenofovir disoproxil fumarate (TDF) = 245mg tenofovir disoproxil (TD) All doses expressed as TDF	**Tablet TDF (TD):** **300mg (245mg)** **Paed tab TDF (TD):** **150mg (123mg) 200mg (163mg) 250mg (204mg)** **Powder TDF (TD):** **40mg (33mg) per 1g scoop**	**Tablet:** **>35kg – 300mg OD** **Paed tab:** **17-22kg – 150mg OD** **23-28mg – 200mg OD** **28-34kg – 250mg OD** **Powder:** **2-12 yrs** **10-12kg – 2 scoops** **12-14kg – 2.5 scoops** **14-17kg – 3 scoops**	Do not use if known renal impairment

		17-19kg – 3.5 scoops **19-22kg – 4 scoops** **22-24kg – 4.5 scoops** **24-27kg – 5 scoops** **27-29kg – 5.5 scoops** **29-32kg – 6 scoops** **32-34kg – 6.5 scoops** **34-35kg – 7 scoops** **≥35kg – 7.5 scoops**	
Lamivudine 150mg/zidovudine 300mg (Combivir® or generic equiv)	**Combined tablet: 3TC 150mg/ZDV 300mg**	**Combined tablet:** **>30kg – 1 tablet BD**	As for ZDV and 3TC
Kaletra® (LPV/RTV) 2 adult tabs = 4 paed tabs = 5ml of liquid **All doses based on LPV**	**Liquid:** **LPV 80mg/RTV 20mg per mL** **Paed tablet: LPV 100mg/RTV 25mg (yellow)** **Adult tablet: LPV 200mg/RTV 50mg (orange)**	**Liquid:** **300mg/m2/dose BD** **Dose in mls = (300 □ SA)/80** **Paed tablet:** **15-25kg – 2 tabs BD** **25-35kg – 3 tabs BD** **>35kg – 4 tabs BD** **Adult tablet:** **>35kg – 2 tabs BD**	Diarrhoea, abdominal pain, nausea, vomiting, headache.

Antiemetics: 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.

Follow-up

Children and young people at risk of infection will need repeat blood sampling: as a minimum they should have serum sent for HBV, HCV and HIV antibodies at 3 and 6 months after exposure.

If they have started and completed PEP then they should have a repeat sample at 8 weeks.

- Discuss with GP by phone on the next working day
- GP to complete Hep B vaccination. Accelerated course is recommended – **Refer to BNFc current up to date version Hep B vaccination**
- Refer to ID/GUM specialist for counselling and ongoing assessment.

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References

Post-Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to blood-borne viruses
https://www.chiva.org.uk/files/1215/4454/3739/CHIVA_PEP_2017.pdf

UK Guideline for the use of HIV Post-Exposure Prophylaxis Following Sexual Exposure (PEPSE) 2015 Guideline

https://www.bashh.org/documents/PEPSE%202015%20guideline%20final_NICE.pdf

HPS website with link to DoH guidelines and Scottish HIV statistics:
http://www.hps.scot.nhs.uk/bbvsti/index.aspx

National guideline for the management of suspected sexually transmitted infections in children and young people. *Arch Dis Child* 2003; 88:303-11

http://www.bashh.org/guidelines

Immunisation against Infectious Disease. Department of Health, Welsh Office, Scottish Office Department of Health, DHSS (Northern Ireland), 1996

The Physical Signs of Child Sexual Abuse. An evidence-based review and guidance for best practice. Royal College of Paediatrics and Child Health (March 2008), Interim Statement July 2011.