

**Post Exposure Prophylaxis (PEP) Guidelines for Children Exposed To Blood
Borne Viruses (HIV/Hepatitis B & Hepatitis C) - Full Clinical Paediatric
Guideline – Joint Derby and Burton**

Reference no.: CH CLIN G80/Apr 22/v003

Introduction

Please note this guideline has been extracted from the CHIVA guideline which can be found online at [CHIVA | CHIVA PEP](#).

The risk of community acquired HIV in children is extremely low. However, children and adolescents are potentially at risk of contracting HIV from a variety of exposures, including needle stick injury, sexual abuse and consensual sexual activity in adolescence, there have been no reported school-related transmissions.

The HIV status of the source is often unknown and difficult to establish. Body fluids presenting a risk of HIV transmission include blood, breast milk, semen or any body fluid if visibly blood stained. 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, mucosal trauma and the cervical ectopy and vaginal epithelial thinness found in children.

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).

More than 80% of adolescents living with perinatally acquired HIV in the UK are on suppressive ART with an undetectable plasma viral load and therefore their sexual partners would not require PEPSE following consensual unprotected sex. However, consideration for PEPSE should be given to sexual partners of those not on suppressive ART. When the index case has unknown HIV status, the only circumstance when PEPSE is strongly recommended is following unprotected receptive anal intercourse.

Main body of Guidelines

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. However, it is important to consider risk of pregnancy and sexually transmitted infections following high-risk sexual exposure, and any safeguarding concerns.

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 needle stick 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
Human bite	< 1 in 10,000

If the HIV status of the source is not known, the risk can be calculated from the following formula:

$$Risk\ of\ HIV\ transmission = Risk\ that\ source\ is\ HIV\ positive \times Risk\ of\ exposure$$

The risks of transmission of Hepatitis B (HBV) and Hepatitis C (HCV) from a community acquired needle stick injury are significantly higher than for HIV.

The probability of HIV transmission depends upon the exposure characteristics, the infectivity of the source, and host susceptibility. Where individuals have multiple exposures within 72h, a cumulative risk should be considered.

Table 2. UK seroprevalence data for blood-borne infections in people who use intravenous drugs (from 2020 report)

	Antibody positive	Detectable viraemia in those with positive antibody
HIV Prevalence	0.82%	6%
HBV Prevalence	9.5%	3.1%
HCV Prevalence	54%	42% **

*** Wide spread availability of short course curative HCV therapy is rapidly reducing HCV viraemia within the UK population and rates of detectable viraemia in those with a positive HCV antibody is likely to be significantly lower in 2021.*

The risk of acquiring HIV from a community acquired needle stick injury can therefore be assessed as

Risk that source is HIV positive with a detectable HIV viral load x Risk of exposure i.e.

$$0.82/100 \times 6/100 \times 0.03/100 = 0.00000015 \text{ i.e. less than 1 in 100,000}$$

Note that quoted risks are based on injuries from needles contaminated with fresh blood and therefore should only be used, and PEP considered if the needle is known to be freshly discarded. Old blood in a syringe and a needle found in the park is likely to carry a lower risk of transmission. In studies where a small amount of blood is retained in a syringe, viable HIV cannot be detected after 24 hours.

The risk of HBV seroconversion following a needle-stick from known high risk HBV infected source (HBe Ag +ve) is 37-62% and around 5% following needle-stick from a known low risk HBV infected source (HBe Ag –ve). The average HCV seroconversion rate following needle-stick from known HCV positive source is 1.8%. Data for risk of transmission of HBV or HCV from single sexual exposure are not robust. HCV is inefficiently transmitted. Risks from high risk HBV infected source may be as high as 50% for seroconversion (lower for clinically symptomatic HBV infection).

Mechanism of action of HIV PEP

Previously Department of Health (DOH) recommendations for PEP in adults were Truvada® (a combination of tenofovir + emtricitabine) and Kaletra® (lopinavir/ritonavir), a reflection of the rapid genital tract penetration of tenofovir and efficacy of Truvada®/Kaletra® against most current viral isolates in the UK. There are no DOH recommendations for PEP in children. However, recently adult national PEP guidelines have moved to the combination of raltegravir with Truvada® prompted by MHRA warnings against the use of antiemetics in conjunction with ritonavir containing antiretroviral regimens, due to the increased risk of cardiac events (prolonged QT interval) in adults. Raltegravir is an integrase inhibitor licensed for use as first line therapy for treatment naïve adults and in treatment experienced children. For dosing information, see table 3 below.



- ✓ Markedly reduces vertical transmission of HIV from mother to child.
- ✓ AZT reduces the transmission rate of HIV by 79% (data from a small case controlled study).
- ✓ Most effective when started within 24 hours of exposure, although there may be benefit for PEP initiation up to 72 hours after exposure.
- ✓ PEP should be taken for 28 days, if tolerated.

HBV Vaccination

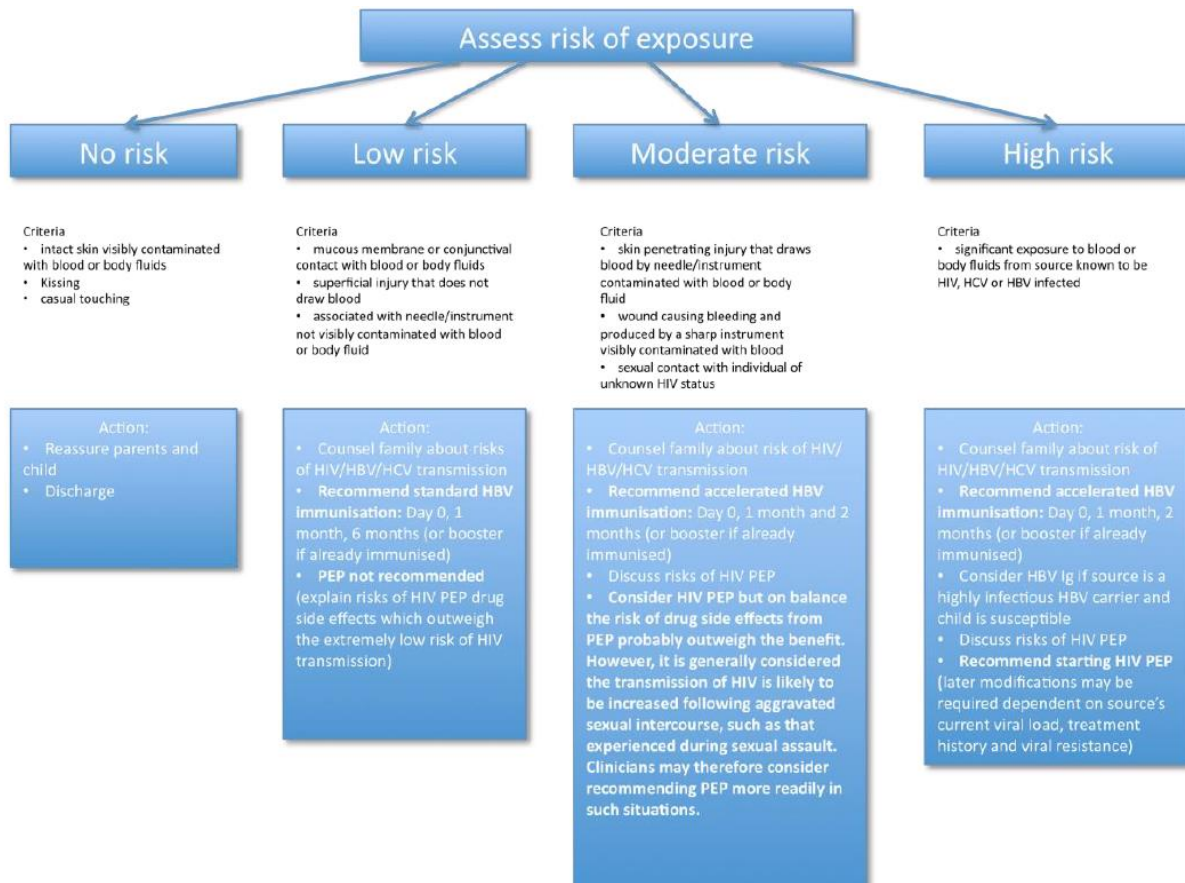
Given the safety of HBV vaccination, the risk-benefit ratio favours vaccinating all exposed children following needle stick injuries or sexual assault, unless they have a documented prior history of successful HBV immunisation. In the UK, universal neonatal HBV immunisation was added to the infant vaccination schedule in the autumn of 2017. Baseline HBV serology should be taken, an initial HBV vaccination given, with an accelerated course of HBV vaccination recommended at follow up if baseline HBsAb.

Procedure for Children and Adolescents presenting with possible exposure to HIV

1. Risk Assess

-  Take a careful history and examination to assess the risk of exposure to HIV.
-  Establish whether exposure occurred within the last 72 hours.

Detailed plan in Immediate Action Algorithm Figure 1 below.



2. Investigation

Source

In rare situations the source may be known and if the individual gives consent HIV, HBV and HCV serology may be tested. If the source is already known to be HIV positive, 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. Most virologists now do NOT recommend testing of source materials such as needles found in public places, since the test results are of low sensitivity and should not be used to guide management.

Child/Adolescent

Obtain baseline HCV, HBV and HIV antibody status (HCV IgG +/- HCV PCR/antigen, HBcAb, HBsAg, HBsAb, HIV1&2 Ag/Ab). If antiretroviral therapy is to be started also request FBC, U&E and LFTs.

Ascertainment that the child / adolescent is not already HIV infected is important, as treatment with PEP in that circumstance would be inappropriate (although awaiting this result should not delay PEP as it can be started and subsequently stopped or switched if necessary).

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). Baseline Point of Care testing (POCT) is not recommended in this situation.

A pregnancy test should be performed for post pubertal girls.

3. Management

The following threshold can be used to determine if PEPSE is indicated:

- **Transmission risk is greater than 1 in 1000** - PEPSE is recommended.
- **Transmission risk is between 1 in 1000 and 1 in 10,000** - PEPSE may be considered. When the exposure is classified as 'consider', PEPSE should only be prescribed if there are additional factors that may increase the likelihood of transmission.
- **Transmission risk is less than 1 in 10,000** PEPSE is not recommended.

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 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 5 days of PEP should be prescribed. A full 4 weeks should **NOT** be prescribed at the first appointment for children. Whilst adult guidance has moved to providing a full 28 day course at baseline for those with no clinical or adherence concerns, for children a review of adherence, tolerability and toxicity within 5 days of starting PEP remains a recommendation.
- For adolescents (>40kg) an adult PEP pack may be prescribed but follow up should occur within 3-5 days to discuss baseline results and assess adherence and tolerability.

- For children a further prescription for a **total of 4 weeks** should be given at consultant review if PEP is to be continued.
- PEP regimens may sometimes need modification if the index case is known to or likely to harbour drug resistant virus. Seek expert help but do not delay starting PEP.

Regimens

PEP should be prescribed as triple therapy; a combination of a dual nucleoside backbone (NRTI) with a 3rd agent (see Table 3). PEP regimens for UK adults recommend the integrase inhibitor (INSTI) raltegravir with the fixed dose NRTI tablet of tenofovir and emtricitabine, based on rapid genital tract tissue penetration, efficacy against most circulating UK variants, tolerability, safety and cost.

Raltegravir continues to be recommended as the preferred INSTI due to “1) concern about neural tube defects in women at risk of pregnancy which would complicate the counselling process for PEP providers 2) cost and 3) good tolerability data from a UK observational study”.

The regimens below are based on age bandings; however accurate weight and height measurements should be used to calculate individual drug doses as per Table 3 or the CHIVA antiretroviral dosing table (<http://www.chiva.org.uk/>).

Preferred regimens reflect changes in adult PEP guidance, however **the start of PEP should not be delayed whilst obtaining paediatric formulations of newer agents and hence alternative regimens are provided.**

In centres where dispersible dolutegravir is not available, for children requiring liquid formulations raltegravir or Kaletra® with zidovudine and lamivudine are acceptable alternatives.

Weight/Age	PEP recommendation	PEP - alternative
≥40kg and 12 years	Raltegravir 1200mg once daily + emtricitabine 200mg/ tenofovir disoproxil ¹ 245mg	3 rd agent: dolutegravir 50mg od, raltegravir 400mg bd NRTI: emtricitabine 200mg/tenofovir alafenamide 25mg ³ lamivudine 150mg/zidovudine 300mg
≥6 years and ≥25 to <40kg	Dolutegravir + lamivudine + zidovudine	3 rd agent: raltegravir or Kaletra® (lopinavir/ritonavir) NRTI: lamivudine + tenofovir disoproxil ¹ emtricitabine 200mg/tenofovir alafenamide 25mg ³
<6 years and <25kg	Dolutegravir + lamivudine + zidovudine	3 rd agent: raltegravir or Kaletra® (lopinavir/ritonavir) NRTI: lamivudine + tenofovir disoproxil ¹
< 3kg or <4 weeks	Seek expert advice	

Table 3. Suggested PEP regimens

Notes:

1. Tenofovir disoproxil should not be used in the presence of renal impairment so an alternative backbone of lamivudine with zidovudine or emtricitabine/tenofovir alafenamide should be used (seek expert advice)
2. Although paediatric formulations of dolutegravir and raltegravir are licensed from infancy, preparations are rarely immediately available. For these reasons Kaletra® (lopinavir/ritonavir) liquid remains an alternative recommendation in children unable to swallow tablets.
3. Emtricitabine/tenofovir alafenamide (Descovy) is licensed from ≥12 years and ≥35kg although within fixed dose combination therapy for the treatment of HIV from ≥6 years and ≥25kg.

4. Standard adult PEP; once daily raltegravir is licensed from ≥ 40 kg weight with tenofovir/emtricitabine licensed from ≥ 35 kg and ≥ 12 years of age.

Table 4 (below) HIV PEP Drugs, Doses and Side effects *Please note, some doses in table below deviate from CHIVA guidelines, but has been aligned with BNFC.

Dosing is correct as per date of guideline publication but for updated dosing please see CHIVA ART dosing table <http://www.chiva.org.uk> and refer to this alongside the BNFC.

An accurate medication history should be obtained, including use of over the counter medications, vitamins/minerals, herbal remedies, and recreational drugs before PEPSE is prescribed.

It is recommended that a pregnancy test is offered in women considering PEPSE, but that the result should not affect the decision to start PEPSE. Women must be counselled that antiretroviral agents used for PEPSE are unlicensed in pregnancy and risks/benefits must be carefully discussed.

***N.B film coated tablet and the chewable preparations are not bioequivalent.**

Dose frequency abbreviations: OD = once daily, BD = twice a day, AM = morning, PM = evening

Drug	Formulation	Dose	Side Effects**	Stocked at UHDB (check with pharmacy)
Raltegravir (RAL) NOTE: different formulations are not bioequivalent. Must specify formulation when prescribing; use chewable tabs for children ≥ 11 kg who cannot swallow tablets	Tablet: 400mg, 600mg Chewable tablet: 25mg, 100mg (can be chewed or swallowed) 100mg granules for oral suspension: Recommended dilution 10mg/ml	Tablet: ≥ 40 kg 1200mg OD (2x 600mg) or 400mg BD Chewable tablet: 11-13kg 75 mg BD 14-19kg 100mg BD 20-27kg 150mg BD 28-39kg 200mg BD ≥ 40 kg 300mg BD Sachets: ≥ 3 kg 25mg BD 4-5kg 30mg BD 6-7kg 40mg BD 8-10kg 60mg BD 11-13kg 80mg BD 14-19kg 100mg BD	Rash, Nausea, hepatitis	400mg Tablets Contact pharmacy for most up to date availability
Dolutegravir (DTG) NOTE: different formulations are not bioequivalent. Must specify formulation when prescribing	Tablet: 50mg, 25mg, 10mg Dispersible tablets for oral suspension: 5mg tabs	Tablet: >20kg 50mg OD 14-19kg 40 mg OD Dispersible tablet: Age 1-5 months: 3-5kg 5mg OD 6-9kg 10mg OD Child 6-9kg 15mg OD 10-13kg 20mg OD 14-19kg 25mg OD ≥ 20 kg 30mg OD	Nausea, Rash, Sleep disturbance	50mg tablets Contact pharmacy for most up to date availability
Zidovudine (AZT, ZDV)	Capsule: 100mg, 250mg Liquid: 10mg/ml	Liquid: 4-8kg 12mg/kg BD ≥ 9 -30kg 9mg/kg BD Max dose 300mg BD Capsule: 8-13kg 100mg BD 14-21kg 100mg am & 200mg pm 22-27kg 200mg BD ≥ 28 kg 250mg BD	Granulocytopenia and/or anaemia, nausea, headache, myopathy, hepatitis, neuropathy.	250mg capsules, 50mg/5mL oral syrup Contact pharmacy for most up to date availability

Lamivudine (3TC)	Tablet: 100mg, 150mg Liquid: 10mg/ml	Liquid: ≥3months 4 mg/kg BD or 8mg/kg OD Max dose 300mg/day Tablet: 14-20kg 75mg BD or 150mg OD 21-29kg 75mg AM & 150mg PM or 225mg OD ≥30kg 150mg BD or 300mg OD Child 12-17 years: 150mg BD or 300mg OD	Peripheral neuropathy, nausea, diarrhoea, headache.	100mg tablets, 150mg tablets, 50mg/5ml oral solution Contact pharmacy for most up to date availability
Tenofovir Disoproxil /emtricitabine (TD+FTC) Do not use if known renal impairment	Combined tablet: TD 245mg/FTC 200mg	Combined tablet: Child 12-17 years: ≥35kg – 1 tablet OD	Headache, diarrhoea, nausea, vomiting, renal tubular dysfunction, bone demineralization	Contact pharmacy for most up to date availability
Tenofovir alafenamide fumarate /emtricitabine (Descovy®) (FTC/TAF)	Tab: FTC 200mg/ TAF 10mg FTC 200mg/ TAF 25mg	Licensed ≥12 years or ≥35kg (trial evidence from ≥6yrs & ≥25kg) Use 200mg/25mg tab OD with RAL or DTG Use 200mg/10mg with Kaletra®	Nausea	Contact pharmacy for most up to date availability
Tenofovir Disoproxil (TD) Note: 300mg tenofovir disoproxil fumarate (TDF) = 245mg tenofovir disoproxil (TD) All doses expressed as TD	Tablet TD: 245mg Paed tab TD: 123mg 163mg 204mg Powder TD: 33mg per 1g scoop 7.5 scoops of granules contains approx. 245 mg tenofovir disoproxil (as fumarate).	>35kg – 245mg OD Paed tab: Child age 6-17 years 17-21kg – 123mg OD 23-27kg – 163mg OD 28-34kg – 204mg OD Powder: 10-11kg – 2 scoops OD 12-13kg – 2.5 scoops OD 14-16kg – 3 scoops OD 17-18kg – 3.5 scoops OD 19-21kg – 4 scoops OD 22-23kg – 4.5 scoops OD 24-26kg – 5 scoops OD 27-28kg – 5.5 scoops OD 29-31kg – 6 scoops OD 32-33kg – 6.5 scoops OD 34kg – 7 scoops OD ≥35kg – 7.5 scoops OD	Do not use if known renal impairment	Contact pharmacy for most up to date availability

*This list of side effects is not exhaustive – refer to product datasheet for detailed information on side effects, interactions with other medicines and other cautions for use.

Table 4 Cont. (Above/Below) HIV PEP Drugs, Doses and Side effects

Lamivudine 150mg/zidovudine 300mg (Combivir® or generic equivalent)	Combined tablet: 3TC 150mg/ZDV 300mg	Combined tablet: Child: 14-20kg: 0.5 tablets BD 21-29kg: 0.5 tablets in the morning and 1 tablet in the evening ≥30kg: 1 tablet BD	As for ZDV and 3TC	See Lamivudine/Zi dovudine Contact pharmacy for most up to date availability
Kaletra® (LPV/RTV) 2 adult tabs = 4 paed tabs = 5ml of liquid **All doses based on LPV**	Adult tablet: LPV 200mg/RTV 50mg Paed tablet: LPV 100mg/RTV 25mg Liquid: LPV 80mg/RTV 20mg per mL	Adult tablet: ≥40kg and BSA >1.2m ² 2 tabs BD Paed tablet: Body weight up to 40kg and:- BSA 0.5-0.7m ² 2 tablets BD BSA 0.8-0.1.1m ² 3 tablets BD Liquid: Child 14 days–5 months 3.75 mL/m ² twice daily For Child 6 months–17 years 2.9 mL/m ² twice daily (max. per dose 5 mL).	Diarrhoea, abdominal pain, nausea, vomiting, headache.	200mg/50mg tablet, 400mg/100mg per 5mL oral solution Contact pharmacy for most up to date availability

** Individuals experiencing a skin rash or flu-like illness while or after taking PEPSE should be advised to attend for urgent review to exclude an HIV seroconversion**

Drug interactions that may reduce the effectiveness of dolutegravir/raltegravir:

- Divalent cations: iron, calcium, magnesium, aluminium (seek pharmacy advice re drug spacing)
- Rifampicin within the preceding 2 weeks

Avoid co-administration of ritonavir with steroids including nasal/inhaled preparations of fluticasone and budesonide due to the interaction with ritonavir producing extremely high steroid levels impacting on bone metabolism.

Further information on drug interactions with antiretrovirals can be obtained at <http://www.hiv-druginteractions.org/> or discuss with a pharmacist.

Antiemetics

Gastrointestinal side effects are more likely to occur with regimens that contain Kaletra® when compared to dolutegravir/raltegravir. For those with nausea and vomiting on Kaletra® based PEP, a switch to paediatric dolutegravir/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.

HBV

For a significant exposure to an unknown source an accelerated course of HBV immunisation (Day 0, 1 month and 2 months) should be offered.

PHE 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, curative therapy (8-12 weeks single tablet regimen) is available for children from 6 years of age.

Tetanus

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

4. Emergency contraception and screening for sexually transmitted infections

In cases of sexual assault refer to BASHH guidelines on management of adult and adolescent complainants of sexual assault www.bashh.org/documents/4450.pdf.

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 BASHH Guidelines.

NB: Children under 18 presenting with non-consensual sexual activity should be referred to the Child Protection Co-ordinator. For those cases where sexual trauma has occurred in a child with a risk of HIV transmission, those carrying out testing and PEP care need to be sensitive to reducing possibility of creating extra trauma or exacerbating distress. E.g. blood tests/investigations should be in a paediatric setting if younger child.

5. Follow-up

Prior to discharge from A&E families embarking on HIV PEP should have the following:

- An outpatient appointment, preferably 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 an out-of-hours number
- Minimum of 5 days of antiretroviral therapy
- A letter for their GP, with patients/parents' consent.

Clear guidance should be provided for family/child as well as involved services about what details will be communicated between services (those dealing with original abuse/rape or other incident and those managing the PEP).

6. Outpatients Visits

Within 72hrs:

Review in clinic, assess adherence and toxicity, and decide whether PEP should continue for the full four-week course. Document and give baseline HIV, HBV, HCV Ab results. Arrange psychological support as necessary.

Newly diagnosed Hepatitis B infection If the exposed patient is HBsAg positive there is a risk of flare of hepatitis after tenofovir and/or lamivudine/emtricitabine are stopped and specialist advice should be sought prior to the cessation of PEP

Day 14: Review in clinic, assess adherence and toxicity, check FBC, U&E, LFTs.

Day 28: Review in clinic, assess adherence and toxicity, check FBC, U&E, LFTs (if abnormalities on previous blood tests or clinically indicated).

A minimum of 4-6 weeks AFTER PEP completion (8 -10 weeks from exposure):

Follow-up HIV testing should be undertaken with a fourth generation combined HIV antibody/antigen assay. Antibody screening for Hepatitis B and C 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). If on-going risk of exposure to HBV, then a 4th dose of HBV vaccine should be given at 12 months. If further HBV vaccination required arrange appropriate follow up (either clinic or GP based).

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[Guidelines for children and adolescents exposed to blood-borne viruses \(chiva.org.uk\)](https://www.chiva.org.uk) accessed 22.04.22

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