Post-Exposure Prophylaxis (PEP) Guidelines for children and adolescents potentially exposed to blood-borne viruses

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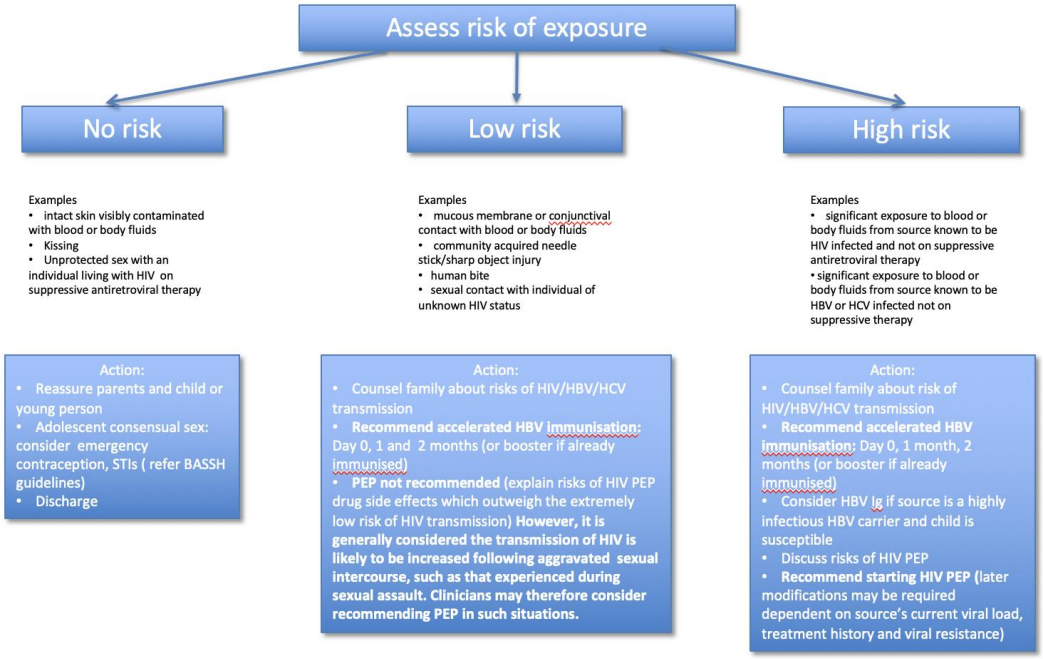
Scope of Guideline: Following exposure to blood-borne viruses, it should be remembered that the risk of transmission is highest for Hepatitis B, then Hepatitis C and then HIV. As this document has been prepared for the CHIVA website its focus is on HIV. However, it is important to consider risk of pregnancy and sexually transmitted infections following high-risk sexual exposure, and any safeguarding concerns.

Guidelines for the prevention of transmission of HIV in pregnancy (https://www.bhiva.org/pregnancy-guidelines) and British Association of Sexual Health guideline for the use of Post-Exposure Prophylaxis for HIV following sexual exposure (https://www.bashhguidelines.org/media/1269/pep-2021.pdf.), particularly for sexually active adolescents, should be used alongside this guidance.

New in Guideline 2021 update:

1. Switch from Kaletra® to dolutegravir-based regimens for younger children due to improved tolerability and once daily dosing. Kaletra® and raltegravir based regimens remain as alternatives.
2. Recommendations for older children (12 years and 40kg) are in line with BASHH guidance for adults (raltegravir 1200mg once daily with emtricitabine/tenofovir disoproxil)[1]. Dolutegravir with emtricitabine/tenofovir alafenamide is an alternative once daily regimen.
3. Risk of HIV transmission where the source is unknown is calculated by the prevalence of detectable HIV viraemia within the source population, rather than the HIV prevalence and reflects the changing UK epidemiology where most individuals living with HIV are aware of their diagnosis, linked to care and on suppressive antiretroviral therapy (ART)[2]. People living with HIV on suppressive ART (HIV plasma viral load <200 copies/ml) for 6 months or longer cannot transmit HIV to others[3].

Fig 1. Immediate Action Algorithm



Background

The risk of community acquired HIV in children is extremely low and continues to fall as the majority of people living with HIV are on suppressive ART and therefore cannot transmit HIV to others.[2,3] In the UK in 2019, 94% of those living with HIV were aware of their HIV status, 98% of those were accessing ART with 97% achieving viral suppression.[2] However, children and adolescents remain potentially at risk of contracting HIV from a variety of exposures, including sexual abuse and consensual sexual activity in adolescence.[4] There have been no reported school-related transmissions. The risk of HIV acquisition from biting and from community acquired needle stick injuries is extremely low unless the source is known to be HIV infected and not on suppressive ART. [5,6]

The HIV status of the source is often unknown and difficult to establish. Body fluids presenting a potential risk of HIV transmission include blood, breast milk, semen or any body fluid if visibly bloodstained. The risks of HIV being transmitted from a variety of exposures where the index case is NOT on suppressive ART 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.[7]

Up to 40% of 15 year olds in the UK are sexually active. Following the widespread use of ART, 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.[8,9] Please refer to BASHH Guidelines.[1] When the index case has unknown HIV status, the only circumstance when PEPSE is strongly recommended is following unprotected receptive anal intercourse .[1]

Table 1. Estimated risks of HIV transmission according to type of exposure from a known HIV positive individual with detectable HIV viral load [1,5,10]

Type of HIV exposure	**Risk of transmission per exposure from HIV positive source NOT on suppressive ART**
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
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 with a detectable HIV viral load x Risk of exposure

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

Table 2. UK seroprevalence data for blood-borne infections in people who use intravenous drugs (from 2020 report)[11]

	Antibody positive	**Detectable viraemia in those with positive antibody**
HIV Prevalence	0.82%	6%[2]
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 ie
0.82/100 x 6/100 x 0.03/100 = 0.00000015 ie 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.[12]

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).[13] The average HCV seroconversion rate following needle-stick from **known** HCV positive source is 1.8%.[13] 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

The presumed mechanism for HIV PEP is that shortly after an exposure to HIV a window period exists during which antiretroviral therapy may help to diminish or end viral replication. In a small case controlled study, AZT reduced the transmission rate of HIV by 79%.[14] In addition, combination antiretroviral therapy has been shown to markedly reduce vertical transmission of HIV from mother-to-child.[15] PEP is 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.[16]

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 <10 IU/L. Baseline HCV IgG and HCV PCR/antigen if high risk exposure, and HBsAg, HBsAb and HBcAb are recommended, with follow up HBV and HCV serology at 3 months post exposure.

Procedure for Children and Adolescents presenting with possible exposure to HIV

1. Risk assessment

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 (Fig 1).

2. Investigations

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 latest plasma HIV viral load, present and past antiretroviral medications, known previous resistance mutations and consider repeat viral load, although the latter should not delay commencement of PEP. Testing of source materials such as needles found in public places is not recommended, 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

HIV PEP

The child and family should be counselled about likely side effects (Table 4) 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.

ART 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.[1] 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 3) good tolerability data from a UK observational study".*[1] For pragmatic reasons preferred regimens for those ≥40kg and 12 years, (age/weight banding for licensed use of once daily

raltegravir (≥40kg) and tenofovir DF/emtricitabine FDC [≥12 years and 35kg]) reflect changes in adult PEP guidance**.** However regimens based around the INSTI dolutegravir are acceptable alternatives. Dolutegravir is licensed at adult dosing (50mg tablet once daily) from ≥6 years and ≥20kg with dispersible tablet formulation licensed from ≥4 weeks of age and ≥3kg and is the preferred first line agent for the treatment of children living with HIV. Initial concerns regarding a possible increase in neural tube defects in infants exposed to DTG in pregnancy have reduced, with DTG based regimens now recommended WHO first line therapy for all those living with HIV including women of children bearing potential.[17,18] Emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®) is licensed from ≥12 years and ≥35kg, although when included in fixed dose combination therapy for the treatment of HIV from ≥6 years and ≥25kg. In combination with dolutegravir it has the advantage offering a once daily, low toxicity, 2 small pill regimen and may be considered for children from ≥6 years and ≥25kg who struggle with the larger pill size/burden of other regimens.

The regimens below are based on age and weight bandings, and dosing is correct based on date of publication (August 2021); however accurate weight measurements should be used to calculate individual drug doses as per Table 4 or the CHIVA antiretroviral dosing table (http://www.chiva.org.uk/). **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.

Table 3. Suggested PEP regimens (see dose table below)

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

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 ≥40kg weight with tenofovir/emtricitabine licensed from ≥35kg and ≥12 years of age.

Table 4 HIV PEP Drugs, Doses and Side effects

Dosing is correct as per date of guideline publication (August 2021) but for updated dosing please see CHIVA ART dosing table http://www.chiva.org.uk/

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

Drug	Formulation	Dose	Side Effects*
Raltegravir (RAL) NOTE: different formulations are **not** bioequivalent. Must specify formulation when prescribing; use chewable tabs for children ≥11kg 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:** **≥40kg 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 ≥40kg 300mg BD **Sachets:** ≥3kg 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
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 (**≥4 weeks**):** 3-5kg 5mg OD 6-9kg 15mg OD 10-13kg 20mg OD 14-19kg 25mg OD ≥20kg 30mg OD	Nausea, rash, sleep disturbance
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	Granulocytopenia and/or anaemia, nausea, headache, myopathy, hepatitis, neuropathy.

		≥28kg 250mg BD	
Lamivudine (3TC)	**Tablet:** 100mg, 150mg **Liquid:** 10mg/ml	**Liquid**: ≥3months 5 mg/kg BD or 10mg/kg OD Max dose 300mg/day **Tablet**: 14-19kg 75mg BD *or* 150mg OD 20-24kg 75mg AM & 150mg PM *or* 225mg OD ≥25kg 300mg OD	Peripheral neuropathy, nausea, diarrhoea, headache.
Tenofovir Disoproxil /emtricitabine (TD+FTC) **Do not use if known renal impairment**	**Combined tablet:** TD 245mg/FTC 200mg	**Combined tablet:** ≥35kg – 1 tablet OD	Headache, diarrhoea, nausea, vomiting, renal tubular dysfunction, bone demineralization
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
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	**Tablet:** >35kg – 245mg OD **Paed tab:** 17-22kg – 123mg OD 23-28mg – 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**
Lamivudine 150mg/zidovudine 300mg (Combivir® or generic equivalent)	**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****	**Adult tablet:** LPV 200mg/RTV 50mg **Paed tablet:** LPV 100mg/RTV 25mg **Liquid:** LPV 80mg/RTV 20mg per mL	**Adult tablet:** ≥35kg 2 tabs BD **Paed tablet**: 10-13kg 2 tabs AM & 1 tab PM 14-24kg 2 tabs BD 25-34kg 3 tabs BD ≥35kg 4 tabs BD **Liquid:** 3-5 kg 1ml BD 6-9kg 1.5ml BD 10-13kg 2ml BD 14-19kg 2.5ml BD 20-24kg 3ml BD	Diarrhoea, abdominal pain, nausea, vomiting, headache.

*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.

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.[1]

NB: Children under 18 presenting with non-consensual sexual activity should be referred to the local Safeguarding team. 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 out-of-hours number.
- At least 5 days of antiretroviral therapy
- A letter for their GP, with patient's/parent(s)' 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).

Outpatient Follow up

Within 72hrs: Review in clinic, assess adherence and toxicity, 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 only 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 ongoing 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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