GUIDELINE

Post exposure prophylaxis following non-occupational exposure to body fluids (nPEP)

Scope (Staff):	Clinical Staff – Medical, Nursing, Pharmacy
Scope (Area):	Perth Children's Hospital (PCH)

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this disclaimer

It is recommended that ALL cases are discussed with the on-call infectious diseases (ID) consultant

Aim

The following guideline represents a stepwise approach for clinicians when managing children at risk of blood-borne infections (± sexually transmitted diseases) following non-occupational exposure to body fluids. This includes cases of **child sexual assault (CSA), human bites, and splash injuries.** nPEP is generally not required for **community-acquired needle stick injuries.** For further information about needlestick injuries, please refer to the PCH emergency department guidelines.

Occupational exposures to blood and body fluids that occur at CAHS sites including Perth Children's Hospital should be discussed with CAHS Staff Health on 0436 595 144 (Monday to Friday 8am to 4pm, excluding public holidays) and the PCH Hospital Clinical Manager outside of these hours. Further information can be found in: CAHS Exposure to Blood and Body Fluid policy (internal document) and on the Information hub: Occupational Exposure to Transmissible Disease (health.wa.gov.au) (internal link).

Background

In Australia, the seroprevalence of human immunodeficiency virus (HIV) is 0.14%; higher rates are observed in men who have sex with men (MSM) (7.3%) and injecting drug users (2.5%)[1]. MSM who also inject drugs have a HIV prevalence of 10%. The prevalence of chronic Hepatitis B is 0.9%; chronic hepatitis C approximates 1.4%.[1-3]

Non-occupational post-exposure prophylaxis (nPEP) is recommended to reduce the risk of HIV transmission immediately following significant risk exposures. Few randomised control trials of nPEP have been conducted. Recommendations are largely informed by data from animal studies, observational studies in humans, and expert opinion. Inappropriate administration of nPEP in cases where it is not required increases the risk of medication-related side-effects/adverse events, is costly, and can increase the stress experienced by an acutely traumatised child.[4-6]

Definitions

- HIV: human immunodeficiency virus
- nPEP: non-occupational post-exposure prophylaxis
- MSM: men who have sex with men
- VL: viral load
- ART: anti-retroviral therapy

Recommended management

1. First aid

- Wash wounds/skin sites with water/sodium chloride 0.9% that have been in contact with blood/body fluids
- Spit out body fluids/blood after oral exposure and rinse with water
- Do not apply disinfectants to wounds
- Do not douche the vagina/rectum

2. Child Protection Unit (CPU) referral and consideration of forensic evaluation/testing.

- Refer to CPU if acute sexual assault (<72 hours) or other child protection concerns with exposure to body fluids (e.g. shared needles and intravenous drug use). Contact the CPU Duty Social Worker (weekdays 0830-1700 hours) on 6456 4300 or CPU Dr on-call (after-hours and weekends) via switchboard.

3. Does the exposure/HIV transmission risk warrant nPEP?

The risk of HIV transmission **= Risk of HIV viraemia in the source population x Exposure risk**

- **If there is evidence to indicate that the HIV viral load of the index case has been UNDETECTABLE for ≥6 months prior to the incident, nPEP is NOT RECOMMENDED.**

Please see *Table 1* for the recommended approach to risk stratification.

Table 1: Risk stratification – adapted from UK Guideline for the use of HIV Post-Exposure Prophylaxis[7]

	INDEX HIV POSITIVE		INDEX OF UNKNOWN HIV STATUS	
	HIV viral load (VL) unknown or detectable	**HIV viral load (VL) undetectable**	**High-risk group***	**Low risk group**
SEXUAL EXPOSURES				
Receptive anal sex	Recommended	Not recommended[a]	Recommended	Not recommended
Insertive anal sex	Recommended	Not recommended[a]	Consider on a case by case basis[b]	Not recommended
Receptive vaginal sex	Recommended	Not recommended[a]	Not recommended	Not recommended
Insertive vaginal sex	Recommended	Not recommended[a]	Not recommended	Not recommended
Fellatio with ejaculation	Not recommended	Not recommended[a]	Not recommended	Not recommended
Fellatio without ejaculation	Not recommended	Not recommended[a]	Not recommended	Not recommended
Splash of semen into eye	Not recommended	Not recommended[a]	Not recommended	Not recommended
Cunnilingus	Not recommended	Not recommended[a]	Not recommended	Not recommended
Digital penetration	Not recommended	Not recommended[a]	Not recommended	Not recommended
OTHER EXPOSURES				
Sharing of injecting equipment	Recommended	Not recommended[a]	Generally not recommended	Not recommended
Sharps injury	Recommended	Not recommended[a]	Generally not recommended	Not recommended
Mucosal splash injury	Recommended	Not recommended[a]	Generally not recommended	Not recommended
Human bite	Not recommended	Not recommended[a]	Not recommended	Not recommended
Community acquired needlestick injury	Not recommended	Not recommended[a]	Not recommended	Not recommended
Recommend: the benefits of nPEP are likely to outweigh the risks, nPEP should be given unless there is a clear reason not to				
Consider on a case by case basis: the risk/benefit balance of nPEP is less clear. The risk should be assessed on a case by case basis. Factors that influence decision-making are listed in footnote b				
Generally not recommended: the risk of HIV transmission is very low, the potential toxicity and inconvenience of nPEP is likely to outweigh the benefit unless there is a clear specific extenuating factor which increases the risk (see footnote b)				
Not recommended: the risk of HIV transmission is negligible and nPEP should not be given.				
***High-risk group:** e.g. MSM, from high prevalence country & no previous screening, People Who Inject Drugs				
a: Provided on Antiretroviral therapy (ART) >6 months with undetectable HIV viral load throughout and good adherence				
b: Factors that may increase the risk of HIV acquisition (and consideration of nPEP use) include: (1) The assault: confirmation of penetrative assault (and number of episodes), whether there is evidence of mucosal injury, whether ejaculation has occurred, the timing of the assault i.e. <24 hours, 24-72 hours versus >72 hours (2) The victim: the younger the child (pre-pubertal mucosa), the higher the risk (3) The perpetrator: whether there is confidence about other high-risk behaviours e.g. People who inject drugs or MSM and (4) The context: whether follow-up will be achievable, the nature of the child's environment, whether compliance is likely to be achieved and the likelihood of drug interactions (5) Sexually transmitted infections in either person				

4. Recommended testing for blood-borne viruses and sexually transmitted infections (STIs)

Table 2: Recommended testing and follow-up for blood-borne viruses and STIs

Test	Baseline	3 months
HIV serology	X	X
Hepatitis B serology	X	X
Hepatitis C serology	X[a]	X[a]
Syphilis serology	X	X
Sexually transmitted infection screen	X[b]	
Full blood picture[c], Urea, electrolytes, creatinine, Liver function tests	X	X
Pregnancy test	X	
Consider HPV vaccine (if required)		X
[a]Hepatitis C RNA PCR may be considered as a preferable screening test if high-risk exposure		
[b]PCR for gonorrhoea and chlamydia on urine samples and PCR for gonorrhoea/chlamydia on vaginal samples (± other samples if indicated)		
[c]If commenced on regimens containing zidovudine		

5. When should nPEP be initiated?

a. As soon as possible and **≤ 72 hours** following exposure.

b. nPEP is generally NOT required following human bites, or if the source is HIV positive with an undetectable viral load.

c. Duration of nPEP is 28 days; provision of the full course at presentation is recommended, as this is associated with improved adherence.

6. What regimen should I prescribe and what are the potential side-effects?

- If the criteria for nPEP are met, the following regimens are recommended:

Table 3 Recommended nPEP regimens

Age	Recommended regimen
Children ≥ 25 kg	**PREFERRED REGIMEN ≥ 25 kg:** Biktarvy® (bictegravir 50 mg/ tenofovir alafenamide 25 mg/ emtricitabine 200 mg)*
	ALTERNATIVE REGIMEN > 35 kg: Truvada® (tenofovir disoproxyl fumarate 300 mg/ emtricitabine 200 mg) **PLUS** dolutegravir
Children < 25 kg	**PREFERRED REGIMEN** lamivudine + zidovudine **PLUS** dolutegravir *Note: zidovudine and lamivudine are also available as a combination product (Combivir® - zidovudine 300 mg/lamivudine 150 mg tablet) for patients >14 kg.*
*This recommendation is based on data extrapolated from adults and expert opinion, and is consistent with the ASHM guidelines.	

- If baseline renal impairment is present, please seek subspecialty ID advice.
- For patients on other medications, check interactions on the HIV interaction checker

Table 4 Medications and side-effects[8-11]

Medication	Dose		Potential side-effects	Comments
Biktarvy® Bictegravir 50 mg/ tenofovir alafenamide 25 mg/ emtricitabine 200 mg tablet	**≥ 25 kg:** 1 tablet daily		Nausea, diarrhoea, fatigue, headache, rash, mood changes	DO NOT crush. Take with or without food. Avoid antacids/multivitamins. Tablet may be dispersed in 20 mL of orange juice.
Tivicay® *Dolutegravir* 50 mg **standard** tablet	**≥ 20 kg:** 50 mg daily		Insomnia, mood changes, headache, hepatitis, rash, weight gain	Take with food. Avoid antacids/multivitamins. Tablet may be cut or crushed and mixed with a small amount of water or food.
Tivicay PD® *Dolutegravir* 5 mg **dispersible** tablets	Dolutegravir 5 mg dispersible tablets are only available via the Special Access Scheme. ALL patients require a category A approval to be completed at the time of prescription via the TGA SAS Online System			
	≥ 3 to < 6kg	5 mg once daily	Insomnia, mood changes, headache, hepatitis, rash, weight gain	The **dispersible** tablet and the **standard** tablet are not bioequivalent and are not directly interchangeable. Take with food. Avoid antacids/multivitamins. Dissolve doses ≤ 15 mg in 5 mL of water and doses of 20 mg or 25 mg in 10 mL of water (tablets will take 1-2 minutes to dissolve). The full dose should be given within 30 minutes of dissolving.
	≥ 6 kg to < 10 kg and < 6 months	10 mg once daily		
	≥ 6 kg to < 10 kg and ≥ 6 months	15 mg once daily		
	≥ 10 kg to < 14 kg	20 mg once daily		
	≥ 14 kg to < 20 kg	25 mg once daily		
	≥ 20 kg	Refer to standard tablet dosing		
Truvada® Tenofovir disoproxyl fumarate 300 mg/ emtricitabine 200 mg tablet	**> 35 kg:** 1 tablet daily		Headache, nausea/vomiting, renal or hepatic impairment, bone problems, myalgia, neutropenia, anaemia	Take with food. Tablet may be crushed, chewed, dispersed in 10 mL of water or mixed with food to aid in administration.
Lamivudine 150 mg tablet or 10 mg/mL liquid	**≥ 3 months old:** 5 mg/kg BD **14 - 19 kg:** 75 mg BD **> 20 - 24 kg:** 75 mg mane and 150 mg nocte **> 25 kg:** 150 mg BD		Nausea, diarrhoea, headache, fatigue	Take with or after food, tablets may be crushed and mixed with a small amount of water or food

Medication	Dose		Potential side-effects	Comments
Zidovudine 100 mg or 250 mg capsule or 10 mg/mL liquid	liq	**≥ 4 - 9 kg:** 12 mg/kg BD **> 9 kg - 30 kg:** 9 mg/kg BD (maximum of 300 mg BD)	Granulocytopenia, anaemia, nausea, headache, myopathy, hepatitis, nail pigmentation, neuropathy	Take with/without food. Capsules can be opened, and contents can be mixed with a small amount of food or dispersed in water. Pregnant parents or carers should not open the capsule for administration.
	cap	**≥ 8 - 13 kg:** 100 mg BD **14 - 21 kg:** 100 mg mane and 200 mg nocte **22 - 27 kg:** 200 mg BD **≥ 28 kg:** 250 mg BD		
Combivir® Zidovudine 300 mg/lamivudine 150 mg tablet	**14 - 21 kg:** HALF a tablet BD **21 - 30 kg:** HALF a tablet mane and 1 tablet nocte **> 30 kg:** 1 tablet BD		As per individual agents	Take with/without food. Tablets can be cut/crushed and mixed with a small amount of water or food.

7. How do I access these medications?

- The above medications (except liquid formulations) are kept in the automated dispensing machines (CPU-specific ADM) and in the Emergency Department (ED) at Perth Children's Hospital. Imprest locations can be found via Formulary One.
- Dolutegravir 5 mg dispersible tablets are only available via the Special Access Scheme. ALL patients require a category A approval to be completed at the time of prescription via the TGA SAS Online System.
- As dolutegravir is supplied to PCH via a Medicine Access Program, each patient or their parent/ carer must sign a patient consent form – see Appendix A.

Pharmacy Hours		
Mon-Fri	0800 - 1630	Contact ChAMP pharmacist via Vocera or Pharmacy on 6456 0190. If the patient is admitted, contact the ward pharmacist via Vocera.
Sat-Sun & public holidays	0800 - 1600	Contact Pharmacy on 6456 3569.
After hours	Contact the on-call pharmacist via switchboard.	

Please note, many regional hospitals in Western Australia keep the above medications, please contact the specific hospital for more information.

8. Follow-up

- Medication-related side-effects are common; this can lead to non-compliance.
- Follow-up for children following CSA can be arranged through the combined Child Protection Unit (CPU)/Infectious Diseases (ID) clinic at Perth Children's Hospital, as follows:

Acute presentation with CSA and nPEP prescribed

At presentation (CPU)

- CPU to discuss with on-call ID Doctor (Dr) regarding the prescribing of nPEP
- CPU to submit an e-Referral to ID (including information on which CPU Doctor (Dr) and Social Worker (SW) are arranging the follow-up appointment)

1–2-week review (CPU and ID)

- CPU and SW to decide on suitable time/date for the follow-up (avoid Tuesday other than 1230-1330, Thursday pm and Friday 0800-0930)
- CPU SW to contact the ID Outpatient Registrar via switchboard. If unable to contact the ID Outpatient Registrar, then call the ID Consultant on-call and advise them of the time/date of review clinic
- Review clinic to occur in CPU – initially CPU Dr and SW followed by ID Dr and CPU SW

3-month-review (can be CPU alone or CPU and ID)

- CPU Dr and SW to organise a 3-month blood test for serology. This may be done at PCH or at an external Pathwest collection centre. It is the duty of the CPU Dr to ensure that the blood test request is done, to follow up the result and to inform the family of the result.

- If the results are positive or it is considered beneficial to have an ID Dr at this appointment, then follow the same procedure as for the 1–2-week appointment above. Otherwise, this can be done face-to-face or by telephone by the CPU Dr/SW.

Acute presentation with CSA and nPEP not prescribed

- CPU Dr and SW to consider whether a 1–2-week review clinic is required and if so, to organise with the family
- CPU Dr and SW to consider whether 3-month serology is required and if so, to organise as above.

Non-acute presentation with CSA

- CPU Dr and SW to consider whether a follow-up is required and if so, to organise as needed.

Other presentations (non-CPU)

- Follow-up for children following exposures other than CSA can be arranged with the Infectious Diseases team or through the local health care provider (e.g. GP or alternative health service provider).

  To facilitate follow-up at PCH, please contact the Infectious Diseases fellow or consultant on-call AND ensure an *e-referral* has been sent to the Infectious Diseases team via: eRefferals.

9. Other important aspects of management to consider:

a) Ensure the microbiology laboratory is contacted (Microbiology registrar during normal work hours, after hours on – call Microbiology consultant) to ensure that Hepatitis B serology is performed URGENTLY, **within 24 hours of collection (this is the responsibility of the ordering physician).** If the source is known to be Hepatitis B positive, or if the child is unvaccinated/incompletely vaccinated against Hepatitis B, the child should receive:

Hepatitis B vaccination (Engerix B® Paediatric; 10 microgram/0.5 mL IM **OR** H-B-Vax II® Paediatric; 5 microgram/0.5 mL IM)

AND

Hepatitis B immunoglobulin

<30 kg: 100 units IM

>30 kg: 400 units IM

If children are vaccinated but do not demonstrate sufficient levels of protective antibody on baseline bloods (Hepatitis B surface antibody - HBsAb <10 iu/mL), the child should be recalled for **Hepatitis B vaccination and Hepatitis B immunoglobulin (IVIG);** while administration of IVIG should preferably occur **within 72 hours of exposure,** there is some evidence for efficacy if given within **14 days of exposure.**[12]

b) For children following *penetrative* CSA, if testing in a timely manner and/or follow up is not guaranteed, the following empiric treatment for potential sexually transmitted infection (STI) is recommended to protect against Chlamydia and Gonorrhoea:[13]

Azithromycin: 20 mg/kg (maximum 1 g) PO STAT
PLUS
Ceftriaxone: 50 mg/kg (maximum 500 mg) IV/IM STAT

c) If the exposure event is alleged child sexual abuse, have other important aspects of care such as emergency contraception been considered? Please refer to the Sexual Assault Management guideline for further information.

d) If indicated, has a mandatory report been made?

https://mandatoryreportingweb.communities.wa.gov.au/ or via phone1800 708 704

e) If indicated, has a referral to the Child Protection Unit (CPU) occurred?

Mon-Fri 0830-1700: phone extension 64300 or via switchboard after-hours.

10. After-hours: CPU Doctor on call Information for parents

- Ensure parents are given the number of PCH switchboard (08) 6456 2222 and instruct them to contact the on-call Infectious Diseases specialist via the hospital if their child refuses/spits out/is non-compliant with medication, or if suspected side-effects occur.
- Please provide the nPEP information sheet, available here

11. Sexual Assault Referral Centre (SARC)

- Adolescents between 13 and less than 16 years of age may be seen initially at SARC (located in Subiaco, adjacent to King Edward Memorial Hospital) and referred for a follow-up with the Infectious Diseases team at Perth Children's Hospital or their local health care provider.
- SARC also have counsellors who can be accessed by anyone who has experienced a sexual assault. Details about this service can be found at King Edward Memorial Hospital - SARC for health professionals or call 6548 1828.

12. Useful information for clinicians

- See resource table below

References and related external legislation, policies, and guidelines
1. Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2021. Sydney: Kirby Institute, UNSW; 2021. 2. Romero N MK, Allard N, MacLachlan JH, Cowie BC,. National Surveillance for Hepatitis B Indicators: Measuring the progress towards the targets of the National Hepatitis B Strategy – Annual Report 2019. Melbourne: WHO Collaborating Centre for Viral Hepatitis, The Doherty Institute; 2020. 3. Hepatitis C. Australian Journal for General Practitioners. 2013;42:452-6. 4. Seña AC, Hsu KK, Kellogg N, Girardet R, Christian CW, Linden J, et al. Sexual Assault and Sexually Transmitted Infections in Adults, Adolescents, and Children. Clin Infect Dis. 2015;61 Suppl 8:S856-64. 5. Crawford-Jakubiak JE, Alderman EM, Leventhal JM. Care of the Adolescent After an Acute Sexual Assault. Pediatrics. 2017;139(3). 6. Cardo DM, Culver DH, Ciesielski CA, Srivastava PU, Marcus R, Abiteboul D, et al. A Case–Control Study of HIV Seroconversion in Health Care Workers after Percutaneous Exposure. New England Journal of Medicine. 1997;337(21):1485-90.

7. Cresswell F. UK Guideline for the use of HIV Post-Exposure Prophylaxis available from https://www.bashhguidelines.org/media/1289/pep-2021.pdf. British Association for Sexual Health and HIV; 2021.
8. Foster C, Lyall H, Tudor-Williams G, Tickner N. Antiretroviral / HIV Drug Dosing for Children and Adolescents 2021-22. Imperial College Healthcare NHS Trust2021.
9. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2022.
10. Symons K, Emer J (editors). Australian Don't Rush to Crush Handboook. 4th edition ed. Collingwood: The Society of Hospital Pharmacists of Australia; 2021.
11. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2023 [cited 2024 May 14th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.
12. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au.
13. Sexual Health and Blood-borne virus program. Silver book - A guide for managing sexually transmitted infections. Department of Health - Western Australia; 2020.

Useful resources (including related forms)
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
Children's HIV Associates (CHIVA)
Centers for Disease Control and Prevention – Post exposure prophylaxis (PEP)
British Association for Sexual Health and HIV
The Kirby Institute for infection and immunity in society
Sexual Assault Resource Centre
Medications you have been recommended for post-exposure prophylaxis

This document can be made available in alternative formats on request.

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Appendix A: Medicines Access Program, Patient Consent Form

WA.TAG WESTERN AUSTRALIAN THERAPEUTIC ADVISORY GROUP

Medicines Access Programs
Form B: Patient Consent Form

I, _____, hereby agree to treatment with
(name of patient or agent)

_____ under the specified Medicines Access Program:
(name of medicine)

Name of program: _____

Start Date: _____ Stop Date: _____

Please tick the following boxes:

- ☐ I have been given clear information by my doctor about the reasons for using this medicine, its known effects and possible risks.
- ☐ I have had an opportunity to ask questions relating to the treatment and discussed alternative treatments.
- ☐ My doctor has advised me of any conflicts of interest he/she has in relation to this Medicines Access Program.

I understand that:

- ☐ The medicine is supplied under a Medicines Access Program and that in order to provide this medicine the doctor/hospital may be required to give information about my response to this medicine to the pharmaceutical company supporting the Program.
- ☐ The hospital is not expected to subsidise the cost of the medicine for me at the end of the Medicines Access Program.
- ☐ The medicine is not currently subsidised under the Pharmaceutical Benefits Scheme (PBS) and may not be subsidised for me when the Medicines Access Program ends.
- ☐ If the medicine is not subsidised by the PBS for me, the cost of the medicine may be high.
- ☐ If the medicine is not subsidised by the PBS or included on the Hospital Formulary at the end of the Program, I may need to change to a suitable alternative medicine that is subsidised.
- ☐ The usual hospital medication charges will apply to all items supplied under the Medicines Access Program.

Based on the information given to me (tick box if applicable):

- ☐ If the Program or my treatment is terminated for safety or clinical reasons and I want to continue with this medicine, I am prepared to pay the cost of ongoing treatment, which I will obtain from my local pharmacy.

Patient: _____ _____ _____
(Patient signature) (Print patient name) (Date)

Witness: _____ _____ _____
(Witness signature) (Print witness name) (Date)

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