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)

This document should be read in conjunction with this DISCLAIMER

In ALL cases, contact the infectious diseases team (including after hours) to discuss the need for nPEP and to organise follow-up.

Aim

The following guideline represents a stepwise approach for the clinician when managing children at risk of blood-borne infections (± sexually transmitted diseases) following non-occupational exposure to body fluids. This includes cases of sexual assault and community-acquired needle stick injury.

Background

In Australia, the seroprevalence of HIV is 0.1%; higher rates are observed in men who have sex with men (~10%) and injecting drug users (~1%). The prevalence of chronic Hepatitis B is 1%; chronic hepatitis C approximates 1.4%.

Non-occupational post-exposure prophylaxis (nPEP) is recommended to reduce the risk of HIV transmission immediately following significant risk exposures. No randomised, placebo controlled trials of nPEP have been conducted. Recommendations are 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 adverse events due to medication.

Process/Procedure

1. First aid

- Wash wounds/skin sites with water/saline that have been in contact with blood/body fluids
- Spit out body fluids/blood after oral exposure and rinse with water
- Don't apply disinfectants to wounds
- Don't douche the vagina/rectum

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

- The **HIV post-exposure prophylaxis checklist form** (see final page) should be completed for all children being considered for nPEP (see useful resources).

- **The risk of HIV transmission= Exposure risk x Source risk**

		SOURCE RISK		
		HIV-INFECTED	**HIGH-RISK** (MSM[a] OR MSM-IVDU[b] OR HPC[c])	**LOW-RISK** (Heterosexual OR IVDU OR Non-HPC)
EXPOSURE RISK	**TRANSMISSION RISK**	1	1/10	1/100
Receptive intercourse (anal/vaginal)	1/100			
Use of shared needle	1/100			
Insertive intercourse (anal/vaginal)	1/1000			
Oral sex – non-intact mucosa	1/1000			
Oral sex – intact mucosa	Very low risk			
Digital anal/vaginal penetration – intact mucosa	Very low risk			
Community acquired needlestick[d]	Very low risk			

PEP **recommended;** risk ≥ 1:10 000

PEP **NOT recommended;** risk < 1:10 000

[a]MSM: Men who have sex with men; HIV prevalence ≈ 10% in Australia (4.5% Perth)

[b]IVDU: Intravenous drug user; HIV prevalence 1%. If MSM *and* IVDU; HIV prevalence 30%

[c]HPC: High prevalence country = HIV prevalence ≥1%

[d]HIV virus in dried blood becomes non-viable after a couple of hours. In studies where small amounts of blood remain in a syringe, viable HIV cannot be detected at 24 hours

3. Laboratory tests and follow-up?

Test	Baseline[a]	1-2 weeks	4-6 weeks	3 months
HIV serology[b]	✓		✓	✓[c]
Hepatitis B serology	✓			✓
Hepatitis C antibody	✓		✓	✓
Syphilis Serology[d]	✓		✓	✓
Chlamydia/Gonorrhoea[e]	✓		✓[f]	✓[g]
FBC, UEC, LFT + Ck[h]	✓	Clinical review; consider bloodwork if symptoms dictate		
Pregnancy Test[i]	✓		✓	

[a]Conduct baseline tests on the source if possible.
[b]If HIV positive on confirmatory testing, perform viral load and genotypic resistance testing.
[c]Note delayed HIV seroconversion has been reported in the setting of co-acquisition of HCV relating to the same exposure incident
[d]Re-test 6 months after treatment (if positive serology) to confirm response to treatment
[e]Testing depends of nature of sexual assault. Consider chlamydia/gonorrhoea PCR on urine, vaginal/endocervical swab ±oropharyngeal swab (gonorrhoea only) ±anal swab
[f]Only if not treated at baseline
[g]Re-test 3 months following treatment for chlamydia/gonorrhoea
[h]Consider these tests at baseline or other time-points depending on previous medical history and symptomatology
[i]For female patient of child-bearing age following vaginal receptive assault

4. When should nPEP be initiated?

a. Ideally within **1 hour,** and **≤ 72 hours** following exposure.

b. If the source is HIV positive (except in the instance of insertive/receptive oral intercourse with intact membranes) and in some circumstances when the source HIV status is unknown, institute nPEP.

c. nPEP is NOT required following community-acquired needlestick injury.

d. Duration of nPEP is 28 days; provision of the full course at presentation should occur, as this is associated with improved compliance.

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

- When a decision is made to institute nPEP, a **3-drug regimen** is recommended in all cases to ensure maximum suppression of viral replication and better protection against acquiring resistant virus.
- The following regimens are recommended at our institution:
- Please see the following link for consumer information: Medications you have been recommended for post-exposure prophylaxis

Age	Recommended 3-drug regimen
Adolescents ≥13 years/adults (or if >35kg) (with normal renal function)	**Tenofovir** disoproxil fumarate with **Emtricitabine** PLUS **Raltegravir**
Children 4 weeks to 12 years	**Zidovudine** PLUS **Lamivudine** PLUS **Raltegravir** *Note: Zidovudine and Lamivudine are also available as a combination product (Combivir®) for patients >14kg.*

Medication[1,2,3]	Dose	Available preparations	Adverse effects	Comments
Zidovudine	180mg/m^2/dose BD (max dose 250mg BD) **OR** **8-14kg:** 100mg BD **15-23kg:** 100mg morning and 200mg night **24-34kg:** 200mg BD **>35kg:** 250mg BD	100mg or 250mg capsule 10mg/mL liquid	Granulocytopenia, anaemia, nausea, headache, myopathy, hepatitis, nail pigmentations, neuropathy	Can be taken with or without food. The capsules can be opened and the contents dissolved in water.

Medication[1,2,3]	Dose	Available preparations	Adverse effects	Comments
Lamivudine	4mg/kg/dose BD (max dose 150mg BD) **OR** **14-21kg:** 75mg BD **>21-30kg:** 75mg morning and 150mg night **>30kg:** 150mg BD	150mg tablet 10mg/mL liquid	Nausea, diarrhoea, headache, fatigue	Can be taken with or without food. Tablets can be crushed and mixed with food or water.

Medication[1,2,3]	Dose	Available preparations	Adverse effects	Comments
Raltegravir	**Chewable tablets:** **<11kg:** 6mg/kg BD **11-14kg:** 75mg BD **14-20kg:** 100mg BD **20-25kg**: 150mg BD **25-28kg:**150mg BD* **28-40kg:** 200mg BD* **>40kg:** 300mg BD* **Standard tablets:** >25kg and > 6years: 400mg BD ***Patients ≥25kg may use either weight based dosing (chewable tablet) or adult dosing (standard tablet).**	**Chewable tablets:** 25mg tablet 100mg tablet **Standard tablets:**400mg tablet **Note: 400mg tablets and the chewable tablets are NOT bioequivalent**	Nausea, dizziness, insomnia, rash, pancreatitis, elevated alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT) and creatine kinase (CK)	Both tablets and the chewable tablets can be cut or crushed. Can be taken with or without food. Avoid calcium, magnesium, iron, aluminium, zinc and multivitamins 4 hours before and after the dose.
Tenofovir disoproxil fumarate with emtricitabine >35kg	**>35kg:** 1 tablet daily	Tablet: tenofovir 300mg/ emtricitabine 200mg	Headache, diarrhoea, nausea, vomiting, renal tubular dysfunction	Take with food. Tablets can be cut or dispersed in water or juice, but has a bitter taste.
Combivir® (zidovudine with lamivudine) >14kg	**14-21kg:** Half a tablet BD **>21-30kg:** Half a tablet morning and 1 tablet at night **>30kg:** 1 tablet BD	Tablet: zidovudine 300mg/ lamivudine 150mg	As above for individual agents	Can be cut or crushed prior to administration. Can be taken with or without food.

Antimicrobial drug dosing in renal impairment can be guided by eTG recommendations

6. How do I access these medications?

Pharmacy Hours		
Mon-Fri	0830 - 1800	Contact ChAMP pharmacist via Vocera or Pharmacy on 6456 0190
Sat-Sun (including public hols)	0800 - 1600	Contact Pharmacy on 6456 0190
After hours	Contact the on-call pharmacist via switchboard	

The above medications (except liquid formulations) are kept in the automatic dispensing machines (ADM's) in ED.

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

7. How should I organise follow-up?

- Contact the Infectious Diseases fellow or consultant on-call AND ensure the HIV post-exposure checklist (attached; acts as a referral) has been faxed to the Paediatric Infectious Diseases (ID) Team via (08) 6456 2322.
- The ID team are happy to review all cases at risk of blood borne illness following a risk exposure, even in instances when nPEP is not prescribed, to facilitate appropriate follow-up.

8. Other important aspects of care 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/HIV testing is performed URGENTLY, within 24 hours of collection.

b) *It is the responsibility of the ordering physician to ensure this result is performed/acted on within 24 hours of blood collection.*

> All persons not known to be previously vaccinated against Hepatitis B should receive Hepatitis B vaccination. (Engerix B®; 0.5mL IM)
>
> For children who are non-immune to hepatitis B as determined by baseline serology, the child should be recalled for hepatitis B immunoglobulin as below, in addition to Hepatitis B vaccination if not already administered;
>
> Hepatitis B immunoglobulin 100 units if <30kg and 400 units if >30kg
>
> Whilst administration should preferably occur within **72 hours** of exposure, there is some evidence for efficacy if given within **14 days of exposure.**

c) Has empiric treatment for potential sexually transmitted infection (STI) been administered where appropriate? This includes:

> **Azithromycin: 20mg/kg (maximum 1g) PO STAT AND**
>
> **Ceftriaxone: 50mg/kg (maximum 500mg/dose) IV/IM STAT**

Ceftriaxone is not indicated in all cases due to the low prevalence of Gonorrhoea in our population. Ceftriaxone is indicated if the child is symptomatic, comes from a high risk area, is unlikely to return for follow up or the perpetrator is considered high risk for STI. It is not indicated for asymptomatic low risk children.

d) Is tetanus immunisation required?

e) Has emergency contraception been offered, where appropriate?

Consider levonorgesterol 1.5mg PO as a single dose within 72 hours of unprotected vaginal intercourse

f) If indicated, has a mandatory report been made?
http://mandatoryreporting.dcp.wa.gov.au or via phone 1800 708 704

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

Mon-Fri 0830-1700: phone extension 63089

Mon-Fri 1700-2200: CPU Doctor on call for acute forensic assessments

Weekends/Public Holidays 0830-2200: CPU Doctor on call for acute forensic assessments

9. 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.

10. Sexual Assault Referral Centre (SARC)

- Adolescents between 13 and less than16 years of age may be seen initially at SARC (located in Subiaco, adjacent to King Edward Memorial Hospital) and referred for follow up with the Infectious Diseases team at Perth Children's Hospital (see item 7 for details on arranging follow up).
- SARC will dispense 28 days of the 3 drug regimen to these adolescents prior to referral to ID for follow up.
- SARC also have counsellors who can be accessed by anyone who has experienced a sexual assault. Details about this service can be found at http://www.kemh.health.wa.gov.au/services/sarc/ or call 6548 1828.

11. Useful information for clinicians: see resource table below:

Useful resources (including related forms)
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
HIV post-exposure prophylaxis checklist form
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

References

1. Centers for Disease Control. Updated guidelines for antiretroviral prophylaxis post-exposure after sexual assault, IVDU or other non-occupational exposure to HIV- United States. 2010. Available at: https://stacks.cdc.gov/view/cdc/38856
2. ASHM. National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV. 2016; 2nd Edition. Available from: http://www.ashm.org.au/products/product/978-1-920773-47-2
3. ANZPID. ANZPID Guidelines for Post-exposure prophylaxis (PEP) after non-occupational exposure to blood borne viruses in children.
4. Cardo et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. NEJM. 1997;337(21):1485-1490.

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