Who must comply with this procedure?

Emergency Department (ED) Medical Officers, Paediatric and Adult Infectious Diseases (ID) Medical Officers, Victorian Institute of Forensic Medicine (VIFM) Medical Officers, Victorian Forensic Paediatric Medical Services (VFPMS), Occupational Exposure Co-ordinator, Pharmacists, Nurses, Midwives

This procedure applies in the following setting:

Any adult, child or adolescent patient who experiences a possible exposure to Human Immunodeficiency Virus (HIV) or any individual (including Monash Health (MH) staff member) who experiences a possible exposure to HIV during the course of their work. A possible exposure to HIV may require post exposure prophylaxis (PEP) with antiretroviral medicines.

Requests for HIV PEP at Kingston Centre and Moorabbin Hospital must be referred to a Monash Health site which has an ED (Clayton, Dandenong or Casey Hospitals).

Precautions and Contraindications

Previous adverse reaction to antiretroviral medications- consult relevant ID unit for advice.

Patient exposed to a source with known HIV resistance- an alternative PEP regimen may be required. Consult ID unit for advice

Renal impairment-

Tenofovir (including Truvada® (tenofovir/emtricitabine)) requires dose modification if <u>Creatinine</u> <u>Clearance</u> (CrCl) < 50 mL/min. Contact ID for an alternative recommendation.

Lamivudine requires dose modification if CrCl < 50 mL/min. Contact ID for an alternative recommendation.

Chronic or active hepatitis B (HBV)- check HBV viral load in these patients upon completion of their PEP course if they have received a lamivudine, tenofovir or emtricitabine containing regimen. Advice from a specialist in the management of viral hepatitis must be sought when the PEP course is completed.

Concurrent medicines – some medicines can interact with antiretroviral therapy. If the patient is taking concurrent medicines check for potential interactions with a pharmacist.

Pregnancy- some antiretroviral medicines may be harmful to the fetus. Specialist consultation is required. Contact ID for advice.

Breastfeeding – not recommended due to the risk of HIV transmission via breast milk. HIV status remains unclear until the final HIV blood test is completed.

Equipment

- Monash Health hospital prescription form or electronic prescribing software (MerlinMap)
- HIV Post Exposure Prophylaxis (PEP) Patient Information Leaflet

For any patient who has a non-occupational exposure, also:

- <u>Participant Information Form</u> for the Victorian Non-Occupational Post Exposure Prophylaxis (NPEP) Service Database
- <u>Victorian NPEP Service Initial Consultation Form</u>
- <u>Victorian NPEP Service Follow up Consultation Form</u>

These forms are located in the after-hours Emergency Department cupboard or Monash Health Pharmacy intranet.

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1. Investigations

- 1.1. Establish whether exposure occurred within the last 72 hours. Give PEP as soon as possible after exposure. Do not offer PEP more than 72 hours after exposure without consulting with an Infectious Diseases physician.
- 1.2. Identify whether the exposure to HIV occurred in an occupational or non-occupational setting.
- 1.3. Document details of the exposure:
 - Time of exposure
 - Details of source (HIV status, other relevant demographic features, plasma viral load and CD4 count if source is positive).
 - Exact mode and details of exposure (including contributory factors), blood or body fluid involved, trauma, first aid measures applied.
- 1.4. Order appropriate blood tests:
 - 1.4.1 For management of Monash Health staff members with an occupational exposure: contact the Occupational Exposure Site Co-ordinator (available 7 days, 24 hours a day) by paging site pager numbers: Clayton 4411, Moorabbin 8811, Casey 3311, Dandenong 7711, and Kingston 5511.
 - Manage exposure in accordance with the <u>Occupational exposure to blood and body</u> <u>fluids management procedure.</u>

Test	Baseline	Week 1	Week 4-6	Week 12	Comments
HIV antibody	\checkmark			\checkmark	
Hepatitis A serology	\checkmark				MSM [#] who have negative hepatitis A serology must be immunised
Hepatitis B serology	\checkmark				Individuals screened for hepatitis B may be: immune (require no further follow up), non- immune (require follow up), chronically infected (require appropriate management)
Hepatitis C serology	\checkmark			\checkmark	Test for hepatitis C up to 6 months where the exposure was high risk for hepatitis C (e.g. involved injecting drug use or sexual exposure which may have involved mucosal trauma)
Sexually transmitted infection (STI) screen (syphilis, gonorrhoea, chlamydia)	\checkmark	\checkmark	V		Perform STI screen at baseline if exposed individual has symptoms of an STI. Repeat syphilis serology 4-6 weeks after sexual exposure.
Urea, electrolytes, creatinine	\checkmark				
Creatinine Kinase	\checkmark				If raltegravir is prescribed. Caution patient about rhabdomyolysis & clinically monitor for myalgia
Pregnancy test	\checkmark				Perform in women of reproductive age & wherever clinically indicated during the follow up period

1.4.2 For all other patients:

Table 1: Recommended laboratory evaluations for exposed individuals

MSM = men w ho have sex with men

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- 1.4.3 Order other blood tests as clinically indicated if the patient becomes symptomatic during the PEP course. Routine full blood examination and liver function tests are no longer recommended at baseline.
- 1.5. Assess the patient's estimated risk of HIV transmission by either referring to an ID medical officer (contact via switch board) or using the appropriate <u>HIV Post exposure prophylaxis risk</u> <u>assessment (Adult) implementation tool</u> or <u>HIV Post Exposure Prophylaxis Risk Assessment:</u> <u>Children or Adolescent Patients implementation tool</u>.
 - 1.5.1. Document in the health record the estimated risk of HIV transmission and whether HIV PEP is indicated.

Arrange a follow up consultation for the patient with ID within 7 days without delay if no PEP medicines are required.

- 1.5.2. Complete the '<u>Victorian NPEP Service Initial Consultation Form</u>' for all patients with <u>non- occupational exposures</u> regardless of whether PEP medicines are required.
- 1.5.3. Give non-occupational exposure patients the '<u>Participant Information Form</u> for the Victorian NPEP Service Database' and ask them to read this document.
- 1.5.4. Fax the completed Victorian NPEP Service Initial Consultation Form to the ID Pharmacist at Clayton on: 9594 6283.
- 1.5.5. Place the completed form (with the prescription) in the after-hours cupboard for collection by the ED Pharmacist on the following day.
- 1.6. Obtain height and weight for paediatric and adolescent patients requiring PEP treatment and calculate the <u>body surface area</u>. For the purpose of dosing in post exposure prophylaxis, consider adolescent to be 15 years and younger.

Body Surface Area (m^2) =



2. Initiating PEP Treatment

Prescribing

2.1. Contact ID Medical Officer (via switch-board) for prescribing advice. PEP cannot be prescribed unless authorised by ID.

Inform ID if the contact source is known to be HIV positive, if the patient has renal impairment with a CrCI < 50 mL/min or has chronic HBV.

- 2.2. Refer to relevant (adult or paediatric) HIV Post Exposure Prophylaxis Risk Assessment Tool for clinical guidance.
- 2.3. If PEP is indicated, prescribe appropriate PEP regimen (7 days of therapy) on a MH hospital prescription form or using electronic prescribing software. (Note: the medicines used for post exposure prophylaxis are not covered by the Pharmaceutical Benefit Scheme (PBS). Please select non-PBS supply if using ePrescribing software.)

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4. Occupational Exposure				
Adults				
Medicine & Form	Dose, Route, Frequency	Quantity to prescribe		
Tenofovir 300 mg tablet	ONE tablet orally daily	7 tablets		
PLUS Lamivudine 300 mg tablet	ONE tablet orally daily	7 tablets		
PLUS Raltegravir 400 mg tablet	ONE tablet orally TWICE a day	14 tablets		

Non-Occupational Exposure

The Victorian NPEP Service now recommends that where PEP is indicated, a 2-medicine regimen be used unless the source is HIV positive and is not on treatment, or is on treatment with a detectable viral load. If the source is unknown, seroprevalence data will assist in determining the risk of transmission. Refer to <u>HIV Post exposure prophylaxis risk</u> <u>assessment (Adult)</u> Tool for estimates on risk of transmission.) Adults or Children/Adolescents > 40kg & able to swallow tablets

Medicine & Form	Dose, Route, Frequency	Quantity to prescribe
Tenofovir 300 mg tablets	ONE tablet orally daily	7 tablets
PLUS Lamivudine 300 mg tablets	ONE tablet orally daily	7 tablets
ADD (if risk of transmission is high) ∞ Raltegravir 400 mg tablets	ONE tablet orally TWICE a day	14 tablets

∞ Refer to HIV Post Exposure Prophylaxis Risk Assessment Tool: Adult Patients for estimates on risk of transmission.

Children/Adolescents < 40kg** OR Children/Adolescents > 40kg & unable to swallow tablets		
Medicine & Form	Dose, Route, Frequency	Quantity to prescribe
Zidovudine[≭] 50 mg/5 mL oral liquid <i>OR</i> 250 mg or 100 mg capsule	180 mg per m ² each dose TWICE a day (max. dose of 250 mg TWICE a day)	200 mL to 600 mL liquid OR 7 days supply of capsules
PLUS Lamivudine 10 mg/mL oral liquid <i>OR</i> 100 mg or 150 mg tablets	4 mg/kg per dose TWICE a day (max dose of 150 mg TWICE a day)	240 mL liquid OR 7 days supply of tablets
PLUS Kaletra ^{®≠} lopinavir 400 mg and ritonavir 100 mg/5 mL	230 mg per m ² (lopinavir component) per dose TWICE a day with food. Dose in mL = $230 \times body \ surface \ area \ 80$	60 mL to 120 mL liquid
	(maximum dose 5 mL TWICE a day)	

** Children weighing < 40 kg who can swallow tablets can be offered capsules/tablets where available.

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Organise supply of PEP medicines

- 2.5. Within normal working hours: Contact Emergency Department Pharmacist (for patients presenting to Emergency Department) or the ID Pharmacist (for patients presenting to Crisis Care Unit) to dispense PEP prescription.
 - Emergency Department Pharmacist Clayton pager: 4225. Available Monday to Friday from 8:00 17:15 and 9:00-17:00 on weekends and public holidays.
 - Emergency Department Pharmacist Dandenong pager: 7192 or extension 49950. Available Monday to Friday from 8:00- 17:15 and 9:00-17:00 on weekends and public holidays.
 - Emergency Department Pharmacist Casey pager: 2723. Available Monday to Friday from 8:00 16:30 and from 09:30 11:30 on weekends and public holidays.
 - ID Pharmacist pager: 4325 (Clayton site only). Available Monday to Friday from 8:45-17:15.
- 2.6. Outside normal working hours

For adult patients or children/adolescents prescribed tablets:

- 2.6.1. Supply the relevant HIV Post Exposure Prophylaxis Starter Kit (occupational or nonoccupational kit) (located in the After Hours ED Cupboard (AHEDC) (at Clayton, Dandenong and Casey) or in the Crisis Care Unit office (Clayton only).
 - Consider the risk of HIV exposure and supply either two or three antiretroviral agents according to this risk. Refer to <u>HIV Post exposure prophylaxis risk assessment (Adult)</u> or to <u>HIV Post Exposure Prophylaxis Risk Assessment: Children or Adolescent Patients</u> <u>implementation tools.</u>
- 2.6.2. Complete the patient name, date and prescriber name on the external label and individual medication containers.
- 2.6.3. Endorse 'PEP starter pack dispensed' on the prescription and leave the prescription along with the completed NPEP initial consultation form (if it is a non-occupational presentation) in the pharmacy tray in the Emergency Department: after-hours cupboard or in the Crisis Care Unit medication cupboard.
- 2.6.4. VIFM/VFPMS: Notify the ID Pharmacist on the next working day.

Emergency Department: notify the Emergency Department: Pharmacist on the next working day.

For patients prescribed liquids:

- 2.6.5. Page the On-call Pharmacist via the nursing supervisor for supply of PEP medicines.
- 2.7. Provide PEP information leaflet and PEP medication information leaflet and counsel the patient on the following:
 - Possible short term side effects of PEP medicines including nausea and vomiting. Raltegravir[®] may also cause myalgia. If the patient is prescribed raltegravir, document the use of statin medicines which are also associated with rhabdomyolyisis and caution patients who engage in heavy gym work about the increased risk of rhabdomyolysis.
 - Take the medicines with food to minimise any nausea and prescribe anti-emetics if appropriate and required.
 - Emphasise the need for adherence.

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2.8. Notify the on-call ID doctor via switch of the exposure and arrange a follow up ID consultation with the doctor for the patient. Patients are not to return to Emergency Department for follow up supply. The follow up **must** occur within 7 days without delay. The remaining 21 days of therapy will be supplied during the follow up consultation if required.

3. Follow up consultation : ID Medical Officer

- 3.1. Assess the patient's adherence and tolerance to the PEP regimen.
- 3.2. Complete the <u>Victorian NPEP Service Follow Up Consultation Form</u> (for non-occupational exposures) and return it to the ID Pharmacist.
- 3.3. Repeat the HIV antibody test at week 4 to 6 and week 12. There is no need to repeat the HIV blood test at the 7 day follow up.
- 3.4. Write a MH hospital prescription form for the antiretroviral agents the patient was initially prescribed for a further 21 days (to complete a 28 day treatment course).
- 3.5. Arrange for the patient to return for follow up visits at 4 weeks and 3 months.
- 3.6. Page the ID Pharmacist (pager 4325) and advise the patient to take the prescription to the Monash Health Pharmacy Department to be dispensed.

4. Dispensing: Initial Consultation

- 4.1 Emergency Department/ID Pharmacist: collect the prescription (if the prescription was in the after-hours cupboard, collect on the next day).
- 4.2 Check the prescription is in accord with this procedure.
 - 4.2.1 For children/adolescents check the prescription against the patient's weight and/or body surface area.
- 4.3 Enter the prescription into Merlin[®]
 - 4.3.1 Enter the 'Patient Category' (i.e. E1 for Clayton Emergency, E2 for Dandenong Emergency, E3 for Casey Emergency, O for Clayton Outpatient Clinic)
 - 4.3.2 Enter the 'Clinic Code' (i.e. CAS for Clayton, DCAS for Dandenong, BCAS for Casey, ID for Clayton Outpatient Clinic)
 - 4.3.3 Enter directions. If dispensed from the after-hours cupboard, include "RSO" (replacement stock only).
 - 4.3.4 Emergency Department Pharmacist: replace the HIV PEP Starter Kit in Emergency Department. ID Pharmacist: replace the kit in Crisis Care Unit (with stock from Clayton Pharmacy)
 - 4.4 Do not charge for PEP medicines (zero the cost).
 - 4.4.1 **Exception**: Occupational exposure of non-MH staff (e.g. community health care workers, ambulance officers and police officers) generate an invoice for PEP medicines and forward to ID pharmacist. Refer to Merlin® restrictions for pricing.

Dispensing: Follow up Consultation

4.5 Dispense the prescription in accord with this procedure and the Medication Dispensing Procedure. Ensure there is 21 days' supply of antiretroviral medicines to complete a 28 day course.

4.6 Refer to 4.4 for invoicing instructions.

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- 4.7 Supply items on the prescription using stock available in the pharmacy.
- 4.8 Page ID Pharmacist to provide additional medication counselling to the patient.
- 4.9 ID pharmacist: file a copy of the prescription and the consultation form in the NPEP folder (located in QUM office).
- 4.10 ID Pharmacist: Forward the Victorian NPEP Service Initial and Follow Up Consultation Forms to the Victorian NPEP Service and arrange for reimbursement of antiretroviral medicines used for NPEP.

List of implementation tools

- HIV Post exposure prophylaxis risk assessment (Adult)
- HIV Post Exposure Prophylaxis Risk Assessment: Children or Adolescent Patients.

Useful resources

- <u>Victorian guidelines for post-exposure prophylaxis following non-occupational exposure to HIV</u> (Alfred)
- <u>Children's CHIVA HIV Association Post-Exposure Prophylaxis (PEP) guidelines for children and adolescents exposed to blood-borne viruses</u>
- HIV Guidelines
- <u>Centre for Disease control and prevention</u>

Keywords or tags

HAART, needle, stick injury, NPEP

Document Management

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