

SCOPE OF PRACTICE

TARGET POPULATION

- Clients at risk of acquiring HIV sexually, within 72 hours of a significant exposure
- Clients at risk of acquiring HIV parenterally, within 72 hours of a significant exposure which includes the sharing of syringes and needles (not other injecting equipment) with a known HIV positive source by injecting drug use
- Clients who present for routine follow up after commencing non- occupational post exposure prophylaxis (NPEP) and who have experienced no significant adverse reactions to NPEP

EXCLUSION CRITERIA

- Clients who present requesting NPEP >72 hours post exposure
- Clients who present for NPEP after an occupational exposure or post sexual assault
- Clients who are pregnant or breastfeeding
- Clients who present with significant adverse reactions following commencement of NPEP
- Clients with known renal and hepatic disease or other chronic illnesses
- Clients on other medications

GUIDELINE OBJECTIVES AND ANTICIPATED OUTCOMES

- Identify risk of acquisition of HIV and determine appropriateness for NPEP as per the Victorian NPEP Service Guidelines¹
- Identification of individual STI risk and provision of appropriate screening
- Follow up of clients at appropriate intervals following commencement of NPEP
- Identify public health risks to control infections by:
 - Provision of STI education and information
 - Identification and exploration of sexual risk taking behaviours
 - Testing for HIV post exposure at the appropriate window period
 - Counselling and other appropriate referral
 - Monitoring adverse events of NPEP

BACKGROUND

NPEP

The rationale behind NPEP is to reduce the risk of HIV transmission to the recipient following a significant sexual or percutaneous exposure.^{1, 2} The goal of combined antiretroviral therapy (ARV) is to prematurely terminate viral replication and thus prevent or reduce infection of new target cells.² NPEP is recommended as soon as possible, within 72 hours of a significant exposure to HIV. Significant exposure includes unprotected anal sex with a source known to be HIV positive or source of unknown HIV status. NPEP consists of 28 days of highly active anti-retroviral (HAART) drugs.²

Definitions of significant exposure:^{1,2}

- High risk exposure includes **unprotected receptive** anal / vaginal intercourse with a known HIV positive source, including epidemiologically linked to high prevalence HIV groups (MSM, sex in sex-on-site venues, beats) with or without the following;
 - The presence of an STI in either the recipient or source
 - HIV positive source has known or suspected anti-retroviral (ARV) resistance
- Direct sharing of injecting equipment with a source known to be HIV positive
- Open wound exposure to HIV infected blood

Where the recipient is the **insertive partner** and the source is of unknown HIV status, the following factors are relevant when deciding on NPEP prescription^{1,2} If none of the cofactors are present, then NPEP should not be prescribed

- The presence of an STI in either the exposed person or the source
- Mucosal integrity
- Presence of blood

The Victorian NPEP Service Guidelines provides a detailed summary of the efficacy of NPEP and clearly defines the definition of HIV risk and assessment in fulfilling the criteria for prescribing NPEP.¹

HIGH RISK EXPOSURE	LOW RISK EXPOSURE
<ul style="list-style-type: none"> • Unprotected receptive vaginal or anal sex 	<ul style="list-style-type: none"> • Unprotected insertive anal or vaginal sex
<ul style="list-style-type: none"> • Direct sharing of injecting equipment 	<ul style="list-style-type: none"> • Superficial percutaneous needle stick injuries
<ul style="list-style-type: none"> • Open wound exposure to HIV infected blood 	<ul style="list-style-type: none"> • Mucous membrane exposure brief, low volume
<ul style="list-style-type: none"> • Source has known or suspected ARV resistance 	

Table N1.1: Classification of risk exposure

INVESTIGATIONS AND DIAGNOSIS

Clients attending for NPEP are a clinical priority and require immediate review. Assessment of the source, recipient and details of the exposure are essential for risk assessment and NPEP recommendation.

RECIPIENT ASSESSMENT
<p>Sexual Health history with emphasis on HIV exposure^{1,2}</p> <ul style="list-style-type: none"> • Last HIV test of recipient • Any risk of HIV since last negative HIV test <p>Any symptoms indicative of a STI including:</p> <ul style="list-style-type: none"> • Urethral discharge, dysuria, urethral itch or irritation • Proctitis, rectal pain, anal bleeding and or discharge • Genital ulceration or skin conditions • HIV seroconversion type illness • History of genital herpes <p>Medical history</p> <ul style="list-style-type: none"> • Allergies, history of adverse drug reactions and current medications (including complementary or herbal medicines)

- Co-morbidities – assess liver and renal function including hepatitis B and C; blood dyscrasias (anaemia and neutropaenia),
- Mental health history
- Alcohol and other drug use

Other History

- Exclude pregnancy
- Previous history of NPEP

Table N1.2: Recipient Assessment

SOURCE ASSESSMENT

HIV status of source (if contactable)

If HIV negative

- Last HIV test
- Any recent at-risk sexual contact in the window period
- Arrange HIV testing of source
- Symptoms of an STI

If unknown HIV status

- Contact and discuss testing
- Ascertain last HIV negative test
- Symptoms of an STI

If HIV positive

- Last HIV RNA level (viral load);
- Current or past history of HAART
- Drug resistance
- Symptoms of an STI

Table N1.3: Source Assessment

EXPOSURE ASSESSMENT

Time and date of exposure

Sexual exposure

- Gender of recipient and gender of source
- Type of exposure (Receptive anal, insertive anal, receptive vaginal, receptive vaginal, receptive oral, insertive oral)
- Condom use
- Presence of ejaculate
- None consensual sex
- Drug use

Mucous membrane or non intact skin exposure

- Site of exposure
- Type of body fluid

Sharps or injecting exposure

- Shared needles, syringe, tourniquet
- Accidental needle stick injury
- Community needle stick injury
- Type of injury (superficial / deep)
- Blood visualized on needle

Table N1.4: Exposure Assessment

FACTORS INFLUENCING NPEP PRESCRIPTION

- Risk of HIV following a single sexual exposure
- Risk transmission per exposure; dependent on type of sexual encounter
- Time of exposure to time of prescribing NPEP
- Client factors;
 - choice
 - likelihood of compliance
 - client's risk assessment
 - psychological factors
 - previous NPEP treatment
- Referral to counselling services as required

INVESTIGATIONS AT INITIAL CONSULTATION FOR ASYMPTOMATIC CLIENT

Baseline STI / HIV Screen should be completed on initial visit, other investigations are dependant on presentation, history and symptoms. See appropriate CPG for management.

SEROLOGY, MICROSCOPY AND CULTURE

- HIV antibody test (baseline)
- Syphilis serology
- Hepatitis B (If not previously immune – offer vaccination)
- Hepatitis A (if not previously immune, refer to local GP for vaccination)
- Hepatitis C (where risk indicated)
- Gonorrhoea
- Chlamydia

If client not suitable for NPEP according to Victorian NPEP Guidelines the following should be completed on initial visit.

- Pre-HIV test discussion
- Reassurance – ensure adequate support post-discharge
- Return for HIV re-test post window period at 6 weeks post exposure
- Baseline STI / HIV test if indicated
- Safe sex practices re-enforced
- Consider referral to counselling where indicated

TREATMENT AND MANAGEMENT

NPEP PRESCRIPTION

The most suitable PEP regimen for the client is based on the above assessment. The NP will refer to an MO in cases where the need to prescribe is less clear.

TREATMENT OPTION 1: 28 DAY 2-DRUG REGIME: SOURCE HIV UNKNOWN

TREATMENT OPTION 1

COMBIVIR	Lamivudine 150 mg + zidovudine 300 mg One tablet orally bd for 28 days
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RECOMMENDED

- Intravenous drug user (IDU) with a MSM source
- Receptive anal sex with MSM

CONSIDERED

- Heterosexual IDU
- Insertive anal sex with MSM if trauma or blood was present, presence of STI
- Insertive or receptive vaginal sex with a source from a high prevalence country
- MSM source exposure where large volume mucous membrane / non-intact skin exposure

GENERAL MANAGEMENT

- Adherence is a critical component to the success of HAART. Lack of adherence causes suboptimal viral suppression and promotes development of drug resistance
- There are many common adverse events with ARVs including drug interactions³
- The initial amount of medication given to clients is for 7 days after which they will have to return to clinic for a review
- Review is recommended at completion of course at Day 28
- A follow up blood test should be conducted at 16 weeks as the duration of the 'window period' may alter with NPEP²
- It is important to advise clients not to re-expose themselves to potential HIV risks (i.e. safer sex practices and safer IDU) while on NPEP
- STI information and safe sex counselling
- Informational counselling, medication regimen information
- Review compliance, adverse effects and side effects of prescribed medication

PUBLIC HEALTH CONSIDERATIONS - FOLLOW UP AND REVIEW

Initially clients will be provided with 7 days of NPEP. They will be followed up through an appointment 7 days post NPEP to determine side effects. Where the source case is able to be identified, support will be offered for client to be tested at baseline and re-offered test at the 6 week window period.

Clients will be followed up at 6 weeks post exposure as well as at Week 12-16 post exposure. A clinical pathway for NPEP will allow monitoring of progress and follow-up.

Where clients are diagnosed with HIV or any other STI, routine partner notification procedures and protocols will be adhered to.

MEDICATION FORMULARY ^{4,5,6,7}

DRUG	INDICATIONS	ROUTE	DOSE	FREQUENCY	THERAPEUTIC CLASS/ Poisons Schedule	CONTRAINDICATIONS/ INTERACTIONS	PRECAUTIONS/ ADVERSE EFFECTS
Combivir [Zidovudine 300 mg / lamivudine 150 mg]	NPEP	Oral	One tablet	B.D for 28 days	S4 B3	Pts with abnormally low neutrophil counts or low haemoglobin levels Hypersensitivity to zidovudine or lamivudine	Haematological toxicity including granulocytopenia and severe anaemia Use of Paracetamol (duration of use) correlated with granulocytopenia; opportunistic infections; renal, hepatic impairment; elderly; pregnancy; lactation
						Paracetamol; trimethoprim; nephrotoxic, cytotoxic or drugs with haematological effects; phenytoin; ribavirin; zalcitabine; stavudine	Anaemia, neutropaenia and leucopaenia Malaise; fatigue

DRUG	INDICATIONS	ROUTE	DOSE	FREQUENCY	THERAPEUTIC CLASS/ Poisons Schedule	CONTRAINDICATIONS/ INTERACTIONS	PRECAUTIONS/ ADVERSE EFFECTS
Metoclopramide	Antiemetic	Oral	10 mg	TDS pc	S4 A	GI haemorrhage, mechanical obstruction or perforation Severe renal insufficiency Known hypersensitivity to the drug	Extrapyramidal symptoms incl. dystonic reactions including tardive dyskinesia. Neuroleptic malignant syndrome
						Anticholinergic drugs and narcotic analgesics antagonizes GI motility Additive sedative effects when taken with alcohol, sedatives, hypnotics, narcotics or tranquilizers Paracetamol, tetracycline. L-dopa may accelerate absorption of drugs Digoxin diminish absorption of drug	Restlessness; anxiety or agitation Drowsiness Fatigue and lassitude Insomnia, headache, dizziness, nausea and bowel disturbances
Prochlorperazine	Antiemetic	Oral	5 mg	Bd-tds	S4 C	Avoid in clients with renal dysfunction, Parkinson's disease, hypothyroidism, myasthenia gravis, CNS depression (incl drug intoxication); sensitivity to phenothiazines.	Tardive dyskinesia Neuroleptic malignant syndrome QT interval prolongation Cerebrovascular events
						Enhanced CNS effect if taken with alcohol or other depressant drugs Potentiate anticholinergic effects	Constipation, dry mouth, drowsiness, akathisia, parkinsonism, blurred vision; urinary retention, inhibition of ejaculation

REFERENCE

1. Wright E, Pierce A, Cockroft E, et.al Victorian NPEP Service Guidelines, July 2007
2. Vujovic O. Post-exposure prophylaxis. In: Hoy J and Lewin S (Eds) HIV Management in Australasia; a guide for clinical care. Sydney, ASHM, 2004
3. Pierce A. Antiretroviral therapy. In: Hoy J and Lewin S (Eds) HIV Management in Australasia; a guide for clinical care. Sydney, ASHM, 2004
4. GlaxoSmithKline Australia P/L Product Information – Combivir
5. Abbott Australasia. Product Information – Kaletra
6. Valeant Pharmaceuticals Australasia P/L. Product Information – Metoclopramide hydrochloride
7. Aventis Pharma P/L. Product Information – Prochlorperazine mesylate
8. Gilead Sciences P/L. Product Information – Truvada