

## **GUIDELINES FOR THE MANAGEMENT AND POST EXPOSURE PROPHYLAXIS OF INDIVIDUALS WHO SUSTAIN NONOCCUPATIONAL EXPOSURE TO HIV**

These guidelines outline the management of known or suspected exposure to the human immunodeficiency virus (HIV) sustained in the non-occupational setting. Guidelines governing occupational exposure can be found in [ANCAHRD Bulletin No.29 September 2001](#).

Within the community, individuals may be exposed to HIV in the following ways:

- through sexual exposure
- whilst using injectable drugs
- as a result of injuries e.g. trauma, physical or sexual assault
- as a result of needlestick injuries and other exposures incurred whilst assisting HIV infected patients with home-based intravenous therapy e.g. antibiotics, antivirals and factor VIII therapy for people with haemophilia.

### **Section A: Immediate management of the individual with known or suspected exposure to HIV <sup>1</sup>**

- Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. The application of caustic agents (e.g. bleach) to wounds or skin sites is not recommended.
- If an individual has sustained wounds or abrasions, their tetanus vaccination status should be assessed.
- hepatitis B vaccination status should be assessed.
- Vaginal or rectal douching is not recommended following sexual exposure to HIV.
- Antiseptics may be used for wound cleaning, but the injection of antiseptic or disinfectant into the wound is not recommended.

### **Section B: Assessment of the risk of HIV transmission**

$$\text{RISK OF HIV TRANSMISSION} = \text{RISK CARRIED BY THE EXPOSURE} \times \text{RISK THAT SOURCE IS HIV POSITIVE}$$

The following factors determine the risk of an individual becoming infected with HIV following a single exposure to HIV:

- The known, estimated risk carried by a single exposure to HIV by either sexual, percutaneous or mucous membrane routes (Table 1).
- The risk that the source individual is HIV positive if the HIV serostatus of the source is unknown (Table 2).
- Cofactors associated with the exposed and source individuals.



## The risk of HIV transmission following a single exposure to a known HIV positive source

**Table 1.**

The table below outlines the probability of HIV transmission occurring per single exposure and per type of exposure (Table adapted from ASHM position paper, ASHM 1998).<sup>2</sup> These estimates of transmission risk *are not absolute*. Each episode of exposure to HIV within the community carries its own unique transmission risk depending on the nature of the exposure, the infectivity of the source and host susceptibility. Therefore, an individual community exposure to HIV may well carry HIV transmission risks that fall outside these given estimates.

Type of Exposure	Estimated risk HIV transmission per exposure
Receptive anal intercourse	≤ 3.0% (1/125 to 1/31) <sup>3</sup>
Receptive vaginal intercourse	≤ 0.1% (1/2000 to 1/667) <sup>4,5,6</sup>
Insertive vaginal or anal intercourse	≤ 0.1% (1/3333 to 1/1111) <sup>4,6</sup>
Needle stick injury	≈ 0.3% (1/313) <sup>7</sup>
Use of contaminated injecting drug equipment	≈ 0.6% (1/149) <sup>8</sup>
Mucous membrane exposure	≈ 0.1% (1/1111) <sup>9</sup>

Note: No quantitative estimate of risk is available for receptive oral sex with ejaculation, however the risk is very low.

### The risk that the source individual is HIV positive

If the exposed individual does not know whether the source individual is HIV positive then risk must be assessed by relying on the known HIV seroprevalence within the community at large and within various population groups. The table below summarises the seroprevalence of HIV in Australia.

**Table 2. HIV seroprevalence in Australia**

Community group	HIV seroprevalence
Homosexual men	3 - 15% <sup>10</sup>
Injecting drug users	
- Homosexual	17% <sup>11</sup>
- All others	1% <sup>11</sup>
Heterosexuals	
- Blood donors	0.0005% <sup>11</sup>
- STD clinic attendees	0.1% <sup>11</sup>



## Cofactors associated with the exposed and source individuals

The following cofactors may **increase** the likelihood of HIV transmission and should be taken into consideration when assessing risk.<sup>12</sup>

- A high plasma viral load is associated with an increased risk of HIV transmission.<sup>13</sup> (Note: a very low, or undetectable plasma HIV viral load is likely to decrease the risk of transmission but does not exclude the possibility that transmission may occur).<sup>1</sup>
- The presence of a sexually transmitted disease including gonorrhoea, syphilis, chlamydial infections and ulcerative genital disease in either the exposed individual or the source individual.<sup>14</sup>
- The presence of mucosal disease of the mouth, mouth ulcers or gum disease in the exposed individual who has had unprotected, receptive oral sex with ejaculation. Similarly, the recipient may be at increased risk of HIV transmission if the source individual has these mouth diseases and performs oral sex on the recipient.<sup>15</sup>
- A deep percutaneous injury with a hollow bore needle, or direct injection into the vein, or artery with a needle/syringe containing HIV positive blood.<sup>16</sup>

## Calculating the risk of HIV transmission

The following table provides estimates of an individual's risk of HIV transmission if the source is known to be HIV positive **or** if the HIV status of the source is not known.

It also provides the approximate risk associated with a variety of exposure categories.

Risk is calculated using the formula *Risk of HIV transmission = risk carried per single exposure x risk of source being HIV positive*.

**Table 4**

Population group and Type of Exposure	Status of source UNKNOWN	Source KNOWN to be HIV positive
<b>Homosexual men</b> Unprotected receptive anal intercourse	$3\% \times 15\% \approx 0.45$	$\approx 3.0\%$
<b>Homosexual men</b> Unprotected insertive anal intercourse	$0.1\% \times 15\% \approx 0.015\%$	$\approx 0.1\%$
<b>Homosexual men</b> Sharing injecting drug equipment	$0.6\% \times 15\% \approx 0.09\%$	$\approx 0.6\%$
<b>Homosexual men</b> Non-intact skin or wounds exposed to blood	$0.6\% \times 15\% \approx 0.09\%$	$\approx 0.6\%$
<b>Homosexual men</b> Mucous membranes exposed to blood	$0.1\% \times 15\% \approx 0.015\%$	$\approx 0.1\%$
<b>Heterosexual#</b> Receptive vaginal intercourse	$0.1\% \times 0.1\% \approx 0.0001\%$	$\approx 0.1\%$



Population group and Type of Exposure	Status of source UNKNOWN	Source KNOWN
<b>Heterosexual</b> Insertive vaginal intercourse	$0.1\% \times 0.1\% \approx 0.0001\%$	$\approx 0.1\%$
<b>Heterosexual</b> Sharing injecting drug equipment	$0.6\% \times 0.1\% \approx 0.0006\%$	$\approx 0.6\%$
<b>Heterosexual</b> Non-intact skin or wounds exposed to blood	$0.6\% \times 0.1\% \approx 0.0006\%$	$\approx 0.6\%$
<b>Heterosexual</b> Mucous membranes exposed to blood	$0.1\% \times 0.1\% \approx 0.0001\%$	$\approx 0.1\%$

# Assumes a high risk partner with a prevalence of HIV similar to that seen in heterosexuals presenting to a sexually transmissible infection clinic <sup>11</sup>

## Section C: Clinical and laboratory assessment that should be performed when an individual presents for Post Exposure Prophylaxis

The following aspects of the exposure should be carefully documented in the patient's records (adapted from the ASHM position paper 1998). <sup>2</sup>

Factors	Need to be assessed
<b>Associated with the exposure</b>	Time since the exposure
	Exact mode and details of exposure
	Amount of blood or body fluid involved
<b>Associated with the exposed individual</b>	Date and result of most recent HIV antibody test
	Previous courses of PEP
	Evidence of concurrent sexually transmitted diseases (gonorrhoea, syphilis, herpes)
	Pregnancy risk and contraception methods; intercurrent breast feeding



	Psychiatric history: past history suicide attempts, depression, psychosis
	Intercurrent major medical illness
	Current medications
	Drug allergies
	Prior hepatitis B vaccine
	Factors that may have contributed to the exposure e.g. alcohol, other drugs
	Understanding of risks and benefits of PEP

<b>Associated with the source individual if source is known to be HIV positive</b>	Clinical stage of HIV infection
	Recent CD4 cell count
	Recent plasma HIV RNA viral load
	Current and prior antiretroviral use
	Recent HIV resistance genotyping results
	Evidence of concurrent sexually transmitted diseases (gonorrhoea, syphilis, herpes)
	Past history of hepatitis B or C
<b>Baseline blood tests to be performed upon all exposed individuals</b>	Baseline HIV antibody test Baseline hepatitis B and C serology Pregnancy test where indicated
<b>Additional baseline blood tests if exposed individual has consented to PEP therapy</b>	Baseline full blood count, liver function and renal function tests and serum amylase



## Section D: Prescribing HIV Post Exposure Prophylaxis

Based upon the estimates of risk following possible or definite exposure to HIV, as outlined in Table 4, postexposure prophylaxis should be considered in the following situations if the following conditions are met (adapted from the San Francisco General Hospital Guidelines, 1997).<sup>17</sup>

### Condition 1. One of the following exposures has occurred:

#### Higher risk

- Unprotected receptive anal intercourse
- Sharing needles or syringes
- Unprotected receptive vaginal intercourse
- Unprotected insertive anal intercourse
- Unprotected insertive vaginal intercourse
- Mucous membranes, or non-intact skin or wounds exposed to HIV positive blood

#### Lower risk

- Unprotected receptive fellatio with ejaculation if the source individual is known to be HIV positive and if the exposed individual has any disease of the oropharynx
- Mucous membranes, or non-intact skin or wounds exposed to HIV positive secretions including blood-stained fluid, vaginal secretions, semen and other bodily fluids

### Condition 2.

- (1) The source individual is known to be HIV positive  
OR  
(2) The source individual reports HIV risk behaviour  
OR  
(3) The exposure occurred in a setting where the local HIV seroprevalence is high

### Condition 3.

The patient presents within 72 hours of the exposure.

This recommendation is not absolute: if an individual presents after 72 hours following a significant exposure to HIV, PEP should still be offered to them with the understanding that PEP may offer some benefit, but less benefit than if they had received PEP within 72 hours.

### Key points to remember when prescribing PEP so that the potential efficacy of PEP therapy is maximised for the exposed individual:

- **PEP must be commenced as soon as possible following the exposure**
- **Patients must be triaged as a priority in the clinical and hospital setting: delay in commencing PEP decreases the benefit of PEP.**<sup>1</sup>
- **All PEP regimens should be prescribed for 28 days**

It is recommended that the clinician carefully document the following:

- Whether they recommended PEP or not to the patient.
- The patient's decision on whether to commence PEP or not.



- Their discussion with the patient regarding the potential risk and benefits of PEP including the risk of potentially dangerous side effects and drug toxicities. Patient information and contraindications should be stored with the guidelines.

## Section E. Prescribing two antiretroviral drugs for post exposure prophylaxis

### **If it is unknown whether the source is HIV positive:**

If the clinician and individual decide that PEP should be prescribed it is recommended, unless specified in section F below, that the patient should be prescribed only two HIV antiretroviral drugs in combination for HIV postexposure prophylaxis. This usually comprises two nucleoside reverse transcriptase inhibitors (NRTI's).

It should be noted that the risk of side-effects is considerable with antiretroviral drugs. Consultation with an HIV specialist is strongly recommended.

### **If the source is known to be HIV positive:**

If the clinician and individual decide that PEP should be prescribed it is recommended, unless specified in section F below, that the patient should be prescribed only two HIV antiretroviral drugs in combination for HIV postexposure prophylaxis.

However, in this setting, the choice of dual therapy should be based upon the available current drug treatment, the drug history of the source and drug resistance test results (see section F). It is recommended that the clinician consult with an HIV specialist in all circumstances.

## Section F. When to use three drugs for HIV postexposure prophylaxis

**Three drugs should only be used in PEP regimens when it is known that the source is HIV positive. If it is unknown whether the source is HIV positive, it is not recommended to add a third drug to the PEP regimen.**

If the source is known to be HIV positive, the addition of a third drug is warranted in the following situations:

- If a higher risk exposure has occurred e.g. unprotected receptive anal/vaginal intercourse, unprotected insertive anal/vaginal intercourse, sharing injecting drug equipment, or mucous membrane, or non-intact skin exposure (see section D).

### **AND**

1. If all that is known about the source individual is that s/he has advanced HIV disease

### **OR**

2. If the source individual is known to have recently had an HIV plasma viral load greater than 10,000 copies/ml bDNA (>20,000 copies/ml RT-PCR)

### **OR**

3. If it is known, as a result of HIV antiretroviral drug resistance testing, that the source individual has evidence of drug resistance involving primary mutations to drugs from at least 2 drug classes

**Examples of three drug regimens or triple therapy would include the following combinations:**

- Two nucleoside reverse transcriptase inhibitors (NRTI's) and a protease inhibitor
- One NRTI, one non-nucleoside reverse transcriptase inhibitor (NNRTI) and one protease inhibitor
- Two (NRTI's) and an NNRTI



It should be noted that cases of severe, life threatening side effects have been reported with the use of 4 weeks of the NNRTI nevirapine in the HIV postexposure setting.<sup>18,19</sup> Nevirapine is not recommended as part of an HIV postexposure prophylaxis treatment regimen.

It should be noted that the risk of side-effects is considerable with all antiretroviral drugs. Consultation with an HIV specialist is strongly recommended.

If the clinician is unsure about prescribing a third drug, or which drug to prescribe, or feels under pressure against their better judgement to add a third drug then a second opinion from an HIV specialist should be sought.

## Section G: If the source has a low or undetectable plasma viral load

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It is recommended that the clinician urgently consult with an HIV specialist in this circumstance. A low viral load in the source does not mean that HIV infection cannot be transmitted,<sup>1</sup> and PEP should still be considered in this situation.

## Section H: Interpreting drug resistance testing results

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It is recommended that the clinician urgently consult with an HIV specialist in this circumstance.

## Section I. How to manage the patient who demands PEP following a possible exposure to HIV despite the clinician's assessment that PEP is not warranted.

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This is a difficult situation. The individual needs support and unambiguous information to help clarify why PEP is not warranted.

It is recommended in this situation:

- that the clinician seek a second opinion from an HIV specialist to further explore the clinician's initial assessment.
- that the risk of side effects to the individual, including severe side effects, be clearly explained.
- that the individual be offered further counselling within the next 24-48 hours to have the opportunity to have the decision to withhold PEP explained again and to allow the individual to outline any ongoing anxieties about not receiving prophylaxis.
- that GP HIV prescribers and hospitals be cognisant of the medicolegal ramifications of withholding HIV PEP if the exposed individual is requesting HIV PEP, or prescribing HIV PEP in circumstances where PEP is not deemed to be warranted by the prescribing clinician.

## Section J: How to manage individuals who re-present for PEP

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This may be a very difficult counselling situation, but the most positive approach is to view the repeat presentation as an opportunity to further intensify counselling, education and support strategies for the individual. Re-presentation for PEP probably signifies that the individual is at high risk for future HIV infection transmission unless clear interventions are made at the time of re-presentation.

Repeat prescriptions of PEP **should not be withheld** if the individual's exposure is deemed significant according to these guidelines.



## Section K: Counselling and management of the HIV exposed individual who receives PEP or who warrants PEP but declines drug therapy

If PEP is to be considered or offered, a detailed appraisal of the individual followed by comprehensive counselling regarding the risks and benefits of PEP must be undertaken. This counselling should include:

- A discussion surrounding the fact that HIV PEP in humans has only been shown to be effective using zidovudine monotherapy in the health care occupational setting. There is no evidence to show that the use of 2 or 3 drugs for HIV PEP is superior to monotherapy in either the occupational, or non-occupational setting.
- A discussion of that fact there is limited knowledge regarding the efficacy of PEP for non-occupational HIV exposures.
- A discussion surrounding the importance of the need to take and complete the medication as prescribed to help reduce the likelihood of HIV transmission.
- Information that there have been several reports of PEP failing in the setting of occupational exposure to HIV <sup>1</sup>.
- Information about the known, potential side effects from the individual drugs used in HIV PEP regimens. These side effects include kidney stones <sup>1</sup>, bone marrow suppression <sup>1</sup>, rash <sup>19</sup>, hepatitis <sup>1</sup> and, in one case, hepatic failure requiring liver transplantation. <sup>18</sup>
- A discussion of the fact there is limited knowledge regarding any long-term toxicity of PEP e.g. bone marrow, or reproductive tract toxicities.
- A discussion surrounding the potential toxicity of PEP to a foetus if a woman is pregnant, or may become pregnant as a result of their HIV exposure, or to an infant if a woman is breastfeeding.
- Education about the symptoms of the HIV seroconversion and the need for the individual to report these symptoms immediately.
- A discussion of the theoretical concern that if PEP fails the individual may develop antiretroviral resistant HIV as a consequence of PEP therapy.
- Recommendations that during the 6 month follow-up period and until it has been confirmed that the individual is NOT HIV positive, that the individual should adopt safer sex practices, should not (at any time) share injection equipment, should use contraception where necessary, should be careful with disposal of any blood products, should refrain from sharing sharps e.g. razors, and should not donate blood, body tissues, semen or breast milk.
- An assessment should be made of the individual's immediate family and social supports and an assessment of any intercurrent or past psychiatric illness should be made to ascertain any short-term suicide risk.
- Depending on the type of exposure involved, education about safe practices whilst assisting in home-based therapy, injecting drug use, or education about the relative risks of different types of sexual activities and the need for and appropriate use of condoms and water based lubricants may be required.
- Long term HIV negative partners of HIV positive people may be at risk of HIV transmission through sexual activity, injecting drug use, or home-based therapy practice. Education about HIV risk reduction pertaining to all of these at-risk activities needs to be given to these individuals to try and prevent recurrent exposure to HIV.
- Education about the disinhibitory effects of alcohol, and illicit drugs sedatives, opiates, "ice", amphetamines, ecstasy, cocaine etc needs to be discussed, where relevant, with the individual.



## Section L. Laboratory follow-up

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For individuals who have received PEP, HIV antibody testing should be repeated at 3-6 weeks, 3 months and 6 months.

For individuals who may have sustained dual exposure to HIV and hepatitis C, consideration should be given to performing HIV antibody testing out to 12 months as there are some case reports of delayed HIV seroconversion in health care workers who initially seroconverted to hepatitis C.<sup>1</sup>

A full blood count, liver function test, electrolytes, amylase and urinalysis (if indinavir is used) should be performed at 2 weeks and at 4 weeks.

## Section M. Clinical follow-up

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If the individual is found to be HIV antibody positive at baseline testing then the individual needs to receive counselling and immediate clinical assessment to ascertain if the individual is seroconverting to HIV, or has established HIV infection that antedates the exposure. If the individual is seroconverting to HIV they should be referred to an HIV specialist.

If the individual does seroconvert to HIV during the follow-up period despite PEP therapy, the individual needs to have a plasma HIV viral load and HIV genotyping performed and should be referred to an HIV specialist as soon as possible.

Any adverse events associated with the drugs prescribed for HIV PEP should be referred to the Adverse Drug Reactions Advisory Committee.

### Contact Details:

#### **Adverse Drug Reactions Advisory Committee**

PO Box 100  
WODEN ACT 2606

#### **Australian National Council on AIDS, Hepatitis C and Related Diseases - Clinical Trials and Research Committee (CTARC)**

c/o Flinders Institute for Health Research  
Level 3B, Mark Oliphant Building  
Laffer Drive  
BEDFORD PARK SA 5042

## Section N: Research and HIV postexposure prophylaxis

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During 2001, the National Centre for HIV Epidemiology and Clinical Research (NCHECR) is conducting a national monitoring study of prescription of non-occupational PEP. This study involves the collection of routinely collected data at baseline, at the end of therapy and six months after the exposure. The study aims to characterise the use of PEP in Australia and to document compliance and the frequency of side effects. Participating doctors are re-imbursed \$50 for each patient that they enrol. For enrolment forms, or to check the current status of the study, contact Dr Andrew Grulich at the NCHECR on 02 9332 4648.



## Section O: Management of possible exposure to hepatitis B

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It is recommended that the individual be assessed for the possibility of exposure to hepatitis B and that the guidelines from the Australian Immunisation Handbook 7th edition for management of exposure to hepatitis B be followed.

## Section P: Management of possible exposures to hepatitis C

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It is recommended that the individual be assessed for the possibility of exposure to hepatitis C and that the NSW Health Department Guidelines should be followed.<sup>20</sup>

## Section Q: Management of possible exposures to sexually transmitted diseases

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It is recommended that the individual be assessed for the possibility of exposure to sexually transmitted diseases and that the NSW Health Department Guidelines be followed.<sup>20</sup>

Last edited  
June 24th 2001



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