

**ALBERTA  
GUIDELINES FOR POST-  
EXPOSURE PROPHYLAXIS  
IN  
NON-OCCUPATIONAL  
SETTINGS**

**HIV, Hepatitis B, Hepatitis C and  
Sexually Transmitted Infections**

**ALBERTA nPEP PROTOCOL**

**INTERIM DOCUMENT  
CURRENTLY  
UNDER REVISION**

Minor changes made January 2010 to September 2008 protocol

-clarification of hepatitis B testing / PEP pgs19, 28

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**nPEP PROTOCOL**

**September 2008**

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## INTRODUCTION

In January 1997, the Council of Medical Officers of Health (CoMOsH) identified the need for a set of province-wide standards for post-exposure follow-up and prophylaxis of blood-borne pathogens in the community setting (non-occupational settings). The “*Alberta Health Standards for Non-Occupational Community Post-Exposure Follow-up and Prophylaxis of Bloodborne Pathogens*” was developed in 1998 in response to this request. These standards were revised in July 2006 and published as “*Alberta Health Guidelines for Post exposure Prophylaxis in the Non-occupational Setting*”. The July 2006 guidelines are now out-of-date and has been replaced by this document, “*Alberta Guidelines for Post-exposure Prophylaxis in Non-occupational Settings*” dated April 2007.

Despite the absence of national guidelines in many countries, including Canada, the use of non-occupational post-exposure prophylaxis (nPEP) is widespread. Since the initial development of this protocol in 1998, the Centers for Disease Control in the United States have issued guidelines for HIV post-exposure prophylaxis (PEP) in non-occupational settings (CDC, 2005).

There is an ongoing need for post-exposure prophylaxis to HIV, hepatitis B, hepatitis C and sexually transmitted infections in non-occupational settings in Alberta, including sexual assault/abuse in both adults and children. The medical and psychological assessment and medico-legal aspects of sexual assault are beyond the scope of this document. In addition, this document will not address PEP for perinatal exposures.

The role of public health is predominantly in follow-up of significant exposures that occur in community settings. Significant exposures that occur in occupational settings are not generally considered the responsibility of public health; however, some RHAs have policies in place that involve public health in risk assessment and follow-up of cases. In certain situations, the provision of publicly-funded PEP to individuals exposed in occupational settings (e.g. hotel cleaners) will be considered on a case-by-case basis following consultation with the Office of the Chief Medical Officer of Health (OCMOH).

This protocol applies to all permanent residents of Alberta including those living in First Nations communities.

## GENERAL CONSIDERATIONS

### Human Immunodeficiency Virus (HIV)

The most effective methods for preventing HIV infection remain those that prevent exposure to HIV. Decisions to provide antiretroviral agents to individuals after possible non-occupational exposure to prevent the establishment of HIV infection must balance the potential benefits and risks (Appendix A). Antiretroviral drugs should only be used for this indication after careful consideration of the potential risks and benefits with a full awareness of the gaps in current knowledge.

Factors influencing the potential efficacy of HIV nPEP include:

- the risk of transmission of HIV (a factor of the probability that the source is HIV-infected and the likelihood of transmission by that particular exposure)
- the interval between exposure and initiation of therapy
- the efficacy of the drug(s) used to prevent infection
- the patient's adherence to the prescribed drug(s) regimen

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

### Factors Affecting HIV Transmission

- the estimated risk of a single exposure to HIV by percutaneous, sexual or mucous membrane exposure to HIV is summarized in Appendix B, Table 1.
- the risk that the source is HIV infected, estimated based on which population group the individual belongs to (assuming HIV status unknown), is summarized in Appendix C, Tables 1 to 3. It should be noted, however, that there may be wide geographical variation within the province of prevalence of HIV in any given risk group.
- other **associated factors** may increase the likelihood of transmission:
  - high plasma viral load in the source (Lee, 1996). A very low or undetectable viral load decreases, but does not completely eliminate, the risk of transmission.
  - a deep percutaneous injury with a hollow bore needle, direct injection into a vein or artery with a needle/syringe containing HIV positive blood (Cardo, 1997)
  - viral subtype (Yang, 2003; Renjufi, 2004)

## GENERAL CONSIDERATIONS

- in sexual assault/abuse settings:
  - the presence of a sexually transmitted infection in either the source or the recipient (Mastro, 1994)
  - the presence of oral or mucosal disease of the mouth in either the source or recipient (Rothenberg, 1998)
  - degree of trauma associated with the sexual act
  - children may be at a higher risk of transmission of HIV because child sexual abuse is often associated with multiple episodes of assault and often results in mucosal trauma (CDC, 2002)

### Rationale for HIV nPEP

#### *Pathogenesis of Early HIV Infection*

Information about the initial physiologic events after HIV exposure suggests that it can take several days for infection to become established in the lymphoid and other tissues. During this time, interventions to interrupt viral replication may present an opportunity to prevent an exposure from becoming an established infection (Pinto, 1997; Saag, 1997).

#### *Studies of Antiretrovirals in Animal Models*

Many primate studies have provided evidence to support the use of reverse transcriptase inhibitors for post-exposure prophylaxis. Single agent PEP has been effective in preventing retroviral infection following both intravenous and mucosal simian immunodeficiency virus (SIV) and HIV-2 exposures (Martin, 1993; Tsai, 1995; Bottiger 1997; Black, 1997; Grob, 1997; Tsai, 1998; Van Rompay, 1998; Van Rompay, 2000; Otten, 2000).

The data from animal studies suggest that decreased PEP efficacy is associated with:

- higher inoculum size
- longer interval between exposure and treatment
- shorter duration of treatment
- lower doses of PEP agents

#### *Studies of the Efficacy of Antiretrovirals in Preventing Vertical Transmission of HIV*

The ACTG 076 trial of zidovudine administration to HIV-infected women during pregnancy and labor and to their infants post-partum reduced perinatal transmission by 67% (from 25% to 8%) among those receiving treatment as compared to those receiving placebo (Connor, 1994). The relative impact of the three components (pregnancy, intra-partum and neonatal) of zidovudine prophylaxis in reducing mother-to-child transmission has not been quantified. The rationale for the neonatal component of the prophylaxis is based on

## GENERAL CONSIDERATIONS

PEP efficacy data (Coll, 2002) and its importance has been confirmed in an observational study where the mothers did not receive the pregnancy or intra-partum components (Wade, 1998). In a trial conducted in Thailand, zidovudine prophylaxis from 36 weeks of gestation until delivery reduced perinatal transmission by 51% (CDC, 1996-1998). In addition, another study of nevirapine use in pregnant women in Uganda supports the efficacy of the neonatal component in preventing vertical transmission (Guay, 1999).

### *Studies of HIV PEP in Occupational Settings*

A retrospective case-control study using data from health care workers in France, Italy, the United Kingdom and the United States, showed that zidovudine use was associated with a 81% (95% CI 48%-94%) decrease in the risk for HIV infection after percutaneous exposure to HIV-infected blood (CDC, 1996; CDC, 1998; CDC, 1995; Cardo, 1997). Despite the limitations of the study, this remains the most convincing data to support the use of HIV PEP.

### **Choice, Number, Timing, Side Effects, and Duration of Antiretroviral Drugs used for PEP**

HIV PEP has failed in at least 21 instances where the source was known to be HIV-infected, with 16 of the cases using zidovudine as single agent PEP, 2 cases using a combination of zidovudine and didanosine, and 3 cases using  $\geq 3$  drugs in combination (Jochisem, 1997; Ippolito, 1998; Pratt, 1995; Lot, 1995; Weisburd, 1996; Perdue, 1999; Lot, 1999; Beltrami, 2000). Reasons proposed for the failures include delayed treatment, large inoculum, exposure and lower than recommended doses of drug used for shorter than recommended durations. In addition, antiretroviral resistance was considered to be a factor in the failure of PEP because 13 of the source cases had received antiretroviral therapy prior to the exposure. It would, therefore, seem prudent to use antiretroviral regimens based on the source individual's treatment history and most recent plasma viral load if available (Roland, 2001). It has also been argued that where there is no suspicion of possible zidovudine resistance, zidovudine should usually be a part of the initial PEP regimen as it is the only antiretroviral agent for which PEP efficacy data are available (CDC, 1995; Cardo, 1997).

Based on the ability of highly active antiretroviral therapy to reduce viral load and limit the development of antiviral resistance, the use of combination regimens has been advocated for PEP (Puro, 2000; Puro, 2001). The goal of preventing transmission; however, differs from that of treatment (Bassett, 2004). After a needlestick, the intent is to prevent small amounts of virus from establishing infection, a rare event even in the absence of prophylaxis (CDC, 2001). Two drug regimens have fewer side effects than three drug regimens; however, the higher incidence of side effects did not appear to influence the discontinuation of drug regimens in health care workers in some reports (Puro, 2000; Puro, 2001; Wang, 2000; National, 2003). Other investigators, however, have reported that three drug regimens carry an unacceptable risk of severe side effects as compared to two drug regimens (Laporte, 2002; Wang, 2000; Jochisem, 1999). In addition, non-adherence to treatment regimens in PEP recipients is seen more frequently than in patients receiving antiretrovirals for known HIV

## GENERAL CONSIDERATIONS

infection (Bassett, 2004). Whether two or three drug regimens are chosen for PEP should be based on the level of risk of HIV transmission represented by the exposure (CDC, 2001). Information from the US National Surveillance system for health care workers indicates that nearly 50% of health care workers experience adverse symptoms (nausea, malaise, headache, anorexia, headache) while taking PEP and that approximately 33% discontinue the medications due to adverse symptoms and signs (CDC, 2001). Nevirapine should probably not be used as part of a PEP regimen due to the high rate of serious adverse events associated with its use for PEP (CDC, 2001).

**PEP should be started as soon as possible.** The optimal interval from time of exposure to initiation of PEP is not known but efficacy probably declines with time. Pathogenesis studies have indicated that for the first 1 to 3 days following mucosal SIV exposure in primates, virus remains concentrated at the site of infection and regional lymph nodes (Spira, 1996). It is unlikely that PEP started after 72 hours will be effective. **PEP should ideally be started within 1 to 4 hours of the exposure, if possible, and no longer than 72 hours after the exposure.** The recommended duration of PEP based on animal data (Tsai, 1998) and efficacy in occupational studies (Cardo, 1997) is 28 days.

### Sexually Transmitted Infections (STI)

Uninfected persons may or may not acquire sexually transmitted infections when exposed to an infected sex partner (Aral, 2001). Transmission probabilities and duration of infectiousness for several STI are listed in Appendix B, Table 2. Many factors increase the probability of transmission, including:

- the virulence of the pathogen (syphilis > gonorrhea > chlamydia)
- high concentration of the pathogen in semen or other genital fluids
- presence of another STI in either the infected or susceptible person
- type of sexual act (anal intercourse > vaginal intercourse > oral)
- absence of male circumcision
- cervical ectopy
- no condom use with sexual act
- use of microbicides
- trauma associated with the sexual act

PEP for STI prophylaxis should be considered in sexual assault/abuse cases. Gonorrhea, chlamydia and trichomoniasis are the most frequent infections identified in women who give a history of sexual assault (Estreich, 1990; Lacey, 1990; Jenny, 1990). The peak age incidence of sexual assault victims is similar to that of many STI and as such the presence of an STI does not necessarily indicate acquisition as a result of the assault (Jenny, 1990). Although no

## GENERAL CONSIDERATIONS

direct data exist to support the use of STI prophylaxis, it is recommended by many national guidelines including Canada, the United Kingdom and the United States (CDC, 2002; Public Health Agency of Canada, 2006; Lacey, 2001).

### Hepatitis B Virus (HBV)

For percutaneous and mucosal exposures to blood, several factors should be considered when making a decision to provide prophylaxis, including how infectious the source is (if known) and the hepatitis B immunization status and vaccine response in the recipient. Provincial immunization programs should result in an ever declining number of persons at risk of acquiring HBV. The risk of transmission is summarized in Appendix B, Table 3.

Although gay men have historically been at high risk of HBV infection through sexual exposure, recent trends have shown a rise among heterosexual persons (Lemon, 1999). HBV is reported to be transmitted 8.6-fold more efficiently than HIV (Kingsley, 1990).

Similar to STI, several factors increase the risk of transmission of HBV including:

- increasing number of sexual partners
- type of sexual act (anal intercourse > vaginal intercourse > oral-anal); oral-genital and/or oral-oral contact do not appear to influence the risk of becoming infected with HBV (Schreeder, 1982)
- the presence of proctitis
- high HBV DNA levels or HBe antigen positivity in the source

The effectiveness of PEP for HBV including hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine in various post-exposure settings has been evaluated by prospective studies. For perinatal exposure to HBV, HBIG and hepatitis B vaccine administered to the infant commencing at birth is 85-95% effective in preventing HBV infection (Beasley, 1983; Stevens, 1985). HBIG initiated within one week following percutaneous exposure to HB surface antigen positive blood provides an estimated 75% protection from HBV infection (Grady, 1978; Seeff, 1977; Prince, 1975).

### Hepatitis C Virus (HCV)

While HCV is transmitted more efficiently by the parenteral route than HIV, it is transmitted by sexual contact much less efficiently than either HBV or HIV. Transmission probabilities for HCV are summarized in Appendix B, Table 4.

Persons in long-term monogamous partnerships are at lower risk of acquisition (0 to 0.6% per year) as compared to persons with multiple partners or those at risk for sexually transmitted diseases (0.4 to 1.8% per year) (Terreault, 2002). This difference may reflect differences in sexual risk behaviour or differences in exposure to non-sexual sources of HCV, such as injection drug use or razor/toothbrush sharing. HIV co-infection appears to

## GENERAL CONSIDERATIONS

increase the rate of HCV transmission, while individuals without detectable HCV RNA appear to be at extremely low or near zero risk of transmitting HCV (Terreault, 2002; Rooney, 1998).

There is currently no effective post-exposure prophylaxis against HCV. Immune globulin has been ineffective and trials have not been conducted to assess post-exposure prophylaxis using antiviral drugs (CDC, 2001). In the absence of PEP for HCV, recommendations are to identify infection early and, if present, refer for evaluation for treatment options.

The first study reporting benefit of treatment of acute HCV was reported in 2001 (Jaeckel, 2001). In patients treated with interferon monotherapy for an average of 89 days from time of infection [defined as diagnosis of acute HCV infection, positive HCV RNA, and increased serum alanine aminotransferase (ALT)] 98% had undetectable levels of HCV RNA in serum and normal levels of serum ALT at 24 weeks after infection. Subsequently, there have been other reports of the benefits of early treatment with either interferon or pegylated interferon with or without ribavirin (Gerlach, 2003; Krycka, 2003; Kamal, 2004; Nomura, 2004). None of these studies, however, randomized patients to early versus delayed therapy. Approximately 40 to 50% of symptomatic patients (e.g. jaundice, nausea, vomiting, right upper quadrant discomfort, flu-like symptoms) will clear the virus spontaneously by three months after infection (Gerlach, 2003); therefore, treatment for individuals newly infected with HCV should probably wait until 3 to 4 months following presentation to see if persistent HCV RNA positivity is demonstrated (Sherman, 2004). Asymptomatic persons are less likely to clear infection spontaneously; therefore, earlier treatment may be considered in these individuals due to the lower rate of spontaneous viral clearance and high rates of successful treatment when administered early (Jaeckel, 2001; Sherman, 2004).

**RECOMMENDATIONS FOR TESTING AND nPEP  
(EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)**

**GENERAL COMMENTS REGARDING POST-EXPOSURE PROPHYLAXIS**

The management of potential percutaneous or mucosal exposure to HIV, hepatitis B and hepatitis C should be based on the antibody and/or immunization (in the case of hepatitis B) status of the injured person (the recipient) and the infectious status, if known, of the source. Whenever possible, in significant exposures deemed to require further follow up, every attempt should be made to test the source.

**Human Immunodeficiency Virus (HIV)**

<b>HIV Post-exposure Testing</b>	
<p><b>Source (if possible):</b> HIV antibody. Generally, if source tests negative, no further testing is required in the source or recipient. However, if the source is believed to be in the “window period” for HIV, and is at high-risk* for HIV, additional testing may be performed after consultation with an infectious diseases specialist.</p> <p>* high risk includes: known intravenous drug user; known HCV positive; history of incarceration; shared needles or other drug paraphernalia for drug use in preceding six months; multiple sexual partners or sex with sex trade workers in preceding six months; presence of symptoms consistent with an acute seroconversion illness with HIV.</p>	
<b>Recipient:</b>	
<b>Intervals</b>	<b>Specific tests</b>
Baseline	HIV antibody
6 weeks	<i>If recipient develops illness consistent with acute seroconversion to HIV (e.g. fever, headache, rash, lymphadenopathy) within 4 to 6 weeks of exposure, further testing may be considered after consultation with an infectious disease specialist.</i>
12 weeks	
24 weeks	

**RECOMMENDATIONS FOR TESTING AND nPEP  
(EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)**

<b>HIV Non-occupational Post-exposure Prophylaxis</b> (See Appendix D for drug dosages and side effects)	
<b>Source:</b> known HIV positive	
<b>Recipient:</b>	
Type of exposure	HIV nPEP
Percutaneous injury (any) OR Mucous membrane exposure to blood or visible blood stained bodily fluids OR Non-intact skin exposure to blood or visible blood stained bodily fluid	<b>Recommended*</b> <b>Three drug regimen:</b> Combivir <sup>®</sup> (zidovudine/lamivudine) + Kaletra <sup>®</sup> (lopinavir/ritonavir)  <i>*An infectious disease specialist should be consulted within 24 to 48 hours for advice on the continuing regimen with a view to altering the prophylactic regimen based on the source's treatment history for HIV, CD4 lymphocyte count and plasma HIV RNA level.</i>
Mucous membrane exposure to non-blood containing bodily fluids OR Intact skin exposure to blood or visible blood stained bodily fluid	<b>Not recommended</b>

**(EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)**

**HIV Non-occupational Post-exposure Prophylaxis**

(See Appendix D for drug dosages and side effects)

**Source:** HIV status unknown, however, high risk\* for HIV

\* high risk includes: known intravenous drug user; known HCV positive; history of incarceration; shared needles or other drug paraphernalia for drug use in preceding six months; multiple sexual partners or sex with sex trade workers in preceding six months; presence of symptoms consistent with an acute seroconversion illness with HIV.

**Recipient:**

Type of exposure	HIV nPEP
<p>Percutaneous injury</p> <ul style="list-style-type: none"> <li>• large bore needle</li> <li>• deep puncture</li> <li>• visible blood (fresh) on device/syringe</li> </ul>	<p><b>Recommended 2 or 3 drug regimen</b></p> <p><b>Two drug regimen:</b> Combivir<sup>®</sup> (zidovudine/lamivudine)</p> <p><b>Three drug regimen*:</b></p> <p>Combivir<sup>®</sup> (zidovudine/lamivudine) + Kaletra<sup>®</sup> (lopinavir/ritonavir)</p> <p><i>*An infectious disease specialist should be consulted within 24 to 48 hours for advice on the continuing regimen with a view to altering the prophylactic regimen based on the source's treatment history for HIV, CD4 lymphocyte count and plasma HIV RNA level.</i></p>
<p>Percutaneous injury</p> <ul style="list-style-type: none"> <li>• solid bore needle</li> <li>• superficial injury</li> </ul> <p style="text-align: center;">OR</p> <p>Mucous membrane exposure to blood or visible blood stained bodily fluids</p> <p style="text-align: center;">OR</p> <p>Non-intact skin exposure to blood or visible blood stained bodily fluid</p>	<p><b>Not generally recommended; but may be considered in exceptional circumstances (e.g. deep injury, extensive mucosal/non-intact skin exposure to blood)</b></p>
<p>Mucous membrane exposure to non-blood containing bodily fluids</p> <p style="text-align: center;">OR</p> <p>Intact skin exposure to blood or visible blood stained bodily fluid</p>	<p><b>Not recommended</b></p>

**RECOMMENDATIONS FOR TESTING AND nPEP  
(EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)**

**HIV Non-occupational Post-exposure Prophylaxis**

(See Appendix D for drug dosages and side effects)

**Source:** unknown, or unknown HIV status, or unknown risk factors for HIV

**Recipient:**

Type of exposure	HIV nPEP
<p>Percutaneous injury with hollow bore needle, including “cold” needle (i.e. discarded or “found” needle)</p> <p style="text-align: center;">OR</p> <p>Mucous membrane exposure to blood or visible blood stained bodily fluids</p> <p style="text-align: center;">OR</p> <p>Non-intact skin exposure to blood or visible blood stained bodily fluid</p>	<p><b>Not generally recommended; but may be considered in exceptional circumstances</b> (e.g. fresh blood on device or in syringe, deep puncture/injury, extensive mucosal/non-intact skin exposure to blood)</p>
<p>Percutaneous injury</p> <ul style="list-style-type: none"> <li>• solid bore needle</li> <li>• superficial injury</li> </ul> <p style="text-align: center;">OR</p> <p>Mucous membrane exposure to non-blood containing bodily fluids</p> <p style="text-align: center;">OR</p> <p>Intact skin exposure to blood or visible blood stained bodily fluid</p>	<p><b>Not recommended</b></p>

**RECOMMENDATIONS FOR TESTING AND nPEP  
(EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)**

**Hepatitis B Virus (HBV)**

<b>HBV Post-exposure Testing</b>	
<b>Source (if possible):</b> hepatitis B surface antigen (HBsAg)*; if source tests negative, no further testing required in recipient	
<b>Recipient*:</b>	
<b>Interval</b>	<b>Specific tests</b>
Baseline	hepatitis B surface antibody (anti-HBs) hepatitis B surface antigen (HBsAg)  <i>*if recipient is known to be immune to HBV (anti-HBs ≥ 10 IU/L) or HBsAg positive, source and recipient testing is unnecessary.</i>

# RECOMMENDATIONS FOR TESTING AND nPEP (EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)

<b>HBV Non-occupational Post-exposure Prophylaxis</b>				
(Adapted from: <i>Canadian Immunization Guide</i> , 7 <sup>th</sup> edition, 2006; Alberta Immunization Manual, 2007 draft)				
<b>RECIPIENT*</b> Immunization & baseline antibody response (anti-HBs) status		<b>SOURCE</b> HBsAg Positive	<b>SOURCE</b> HBsAg negative	<b>SOURCE</b> Unknown or not available for testing
<i>Unimmunized</i>		HBIG§ and initiate vaccine series‡ anti-HBs 1-6 months after series complete	Initiate vaccine series‡ anti-HBs 1-6 months after series complete	HBIG§ and initiate vaccine series‡ anti-HBs 1-6 months after series complete
<i>Previously immunized with complete series</i>	Responder**	No treatment	No treatment	No treatment
	Non-responder† after 3 doses of vaccine	HBIG and complete second course of vaccine series‡ anti-HBs 1-6 months after series complete	Complete second course of vaccine series‡ anti-HBs 1-6 months after series complete	HBIG and complete second course of vaccine series‡ anti-HBs 1-6 months after series complete
	Non-responder† after 2 series of 3 doses of vaccine	HBIG x 2 administered one month apart	No treatment	HBIG x 2 administered one month apart
<i>Previously immunized with incomplete series</i>	Received 1 dose of vaccine	HBIG and complete vaccine series‡ anti-HBs 1-6 months after series complete	Complete vaccine series‡ anti-HBs 1-6 months after series complete	HBIG and complete vaccine series‡ anti-HBs 1-6 months after series complete
	Received 2 doses of vaccine	Give 3 <sup>rd</sup> dose of vaccine  If baseline anti-HBs is adequate, no further treatment is required.  If baseline anti-HBs inadequate†, administer HBIG.  Test anti-HBs 6 months after HBIG. If inadequate, complete second course of vaccine series.	Give 3 <sup>rd</sup> dose of vaccine‡  anti-HBs 1-6 months after series complete	Give 3 <sup>rd</sup> dose of vaccine  If baseline anti-HBs is adequate, no further treatment is required.  If baseline anti-HBs inadequate†, administer HBIG.  Test anti-HBs 6 months after HBIG. If inadequate, complete second course of vaccine series.

\* Persons who have previously been infected with HBV are immune to re-infection and do not require post-exposure prophylaxis.

§ Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly. **Dose should be administered as soon as possible** after exposure and **within 7 days of exposure**.

‡ Hepatitis B vaccine (See current *Alberta Immunization Manual*, for details)

\*\* A responder is a person with adequate levels of serum antibody to hepatitis B (i.e. anti-HBs ≥ 10 IU/L)

† A non-responder is a person with inadequate response to vaccination (i.e. anti-HBs <10 IU/L)

## RECOMMENDATIONS FOR TESTING AND nPEP (EXCLUDING PERINATAL AND SEXUAL ASSAULT/ABUSE)

### Hepatitis C Virus (HCV)

HCV Post-exposure Testing	
<b>Source (if possible):</b> hepatitis C antibody; if source tests negative, no further testing routinely required in recipient.	
<b>Recipient:</b> testing in the recipient should only be considered in cases where the source is known to be HCV positive; and/or is at high risk for HCV (e.g. known intravenous drug user); and/or the assault involves significant trauma.	
Intervals	Specific tests
Baseline	hepatitis C antibody
12 weeks	<i>If recipient develops illness consistent with acute seroconversion (e.g. nausea, vomiting, abdominal pain, jaundice) to HCV within 4 to 10 weeks of exposure, further testing may be considered after consultation with an infectious disease specialist or hepatologist.</i>
24 weeks	

### HCV Non-occupational Post-exposure Prophylaxis

Currently, prophylaxis of HCV is neither available nor recommended although early identification of infection following exposure should be accompanied by referral to an infectious diseases or gastroenterology/hepatology specialist for further assessment. This referral should be carried out on a semi-urgent basis with assessment occurring within 1 to 3 months of new diagnosis.

# RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

## BACKGROUND

The recommendations contained in this document pertain primarily to the clinical management of the patient who is the victim of non-consensual sexual assault/abuse. The forensic requirements are beyond the scope of this document but careful attention should be paid to the documentation of course of events (history) and observed injuries and reference made to other existing guidelines.

For the purpose of this guideline, pre-pubertal refers to ages < 11 years of age, peri-pubertal refers to individuals aged 11-13, and post-pubertal to ≥14 years.

## GENERAL COMMENTS REGARDING POST-EXPOSURE PROPHYLAXIS

The management of potential percutaneous or mucosal exposure to HIV, hepatitis B and hepatitis C should be based on the antibody and/or immunization (in the case of hepatitis B) status of the injured person (the recipient) and the infectious status, if known, of the source. Whenever possible in significant exposures deemed to require further follow up, every attempt should be made to test the source.

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

### Sexually Transmitted Infections (STI)

(Public Health Agency of Canada, 2006)

STI Post-exposure Testing	
<b>Source:</b> it is assumed that the source will not be available for testing in most instances.	
<b>Recipient:</b> post-pubertal <b>adolescents or adults</b>	
STI	Recommended specimen type
<b>Gonorrhea</b>	<ul style="list-style-type: none"> <li>Gram stain (for gram negative intracellular diplococci) if available</li> <li>Culture from all penetrated (partially or fully) orifice(s) and urethra in males and females</li> <li>A molecular diagnostic test, preferably a nucleic acid amplification test (NAAT) should also be collected from urethra (males), endocervix/urethra (females), urine (males and females), as appropriate. This test is generally more sensitive than culture but may not be acceptable for medico-legal purposes unless confirmed by a second set of primers or in some cases a second test sent to another laboratory for testing. NAAT should not be performed on pharyngeal specimens, and referral to the manufacturer's guidelines is recommended for testing of rectal specimens.</li> <li>Culture tests collected &lt; 48 hours after exposure may be falsely negative, they should be repeated 1 to 2 weeks after exposure if prophylaxis is not offered; post-exposure NAAT testing can be taken at the time of presentation.</li> </ul>
<b>Chlamydia</b>	<ul style="list-style-type: none"> <li>Molecular diagnostic tests, especially NAAT are more sensitive and specific than culture and should be performed whenever possible for urine (males and females), urethral (males) or cervical (females) specimens. Urine testing, although it has a lower sensitivity for detection, is acceptable and may make testing more acceptable to some individuals.</li> <li>Cultures have been the preferred method for medico-legal purposes, but NAAT may be acceptable if the positive results are confirmed by a second set of NAAT primers or in some cases a second test sent to another laboratory for testing. NAAT has not been adequately evaluated for throat and rectal specimens.</li> <li>If available, both tests (culture and NAAT) should be performed.</li> <li>Culture tests collected &lt; 48 hours after exposure may be falsely negative, they should be repeated 1 to 2 weeks after exposure if prophylaxis is not offered; post-exposure NAAT testing can be taken at the time of presentation.</li> </ul>
<b>Trichomonas</b>	<ul style="list-style-type: none"> <li>If available, wet mount and/or culture for <i>T. vaginalis</i></li> </ul>
<b>Syphilis</b>	<ul style="list-style-type: none"> <li>A non-treponemal test (e.g. RPR) and a treponemal test (e.g. TP-PA) should be performed</li> <li>Both the treponemal and non-treponemal tests should be repeated at 12 and 24 weeks after exposure. In some instances (e.g. high risk assailant or in areas experiencing outbreaks of syphilis) it may be appropriate to repeat tests 2 to 4 weeks post-assault.</li> </ul>

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

<b>STI Post-exposure Testing</b>	
<b>Source:</b> it is assumed that the source will not be available for testing in most instances.	
<b>Recipient:</b> pre-pubertal or peri-pubertal <b>children</b>	
<b>Specimen* type by gender</b>	<b>Condition or organism to be detected</b>
Urine: males and females <ul style="list-style-type: none"> <li>• First void urine (10-20 mL) or after not voiding for 2 hours</li> </ul>	<ul style="list-style-type: none"> <li>• Molecular diagnostic test, preferably a nucleic acid amplification test (NAAT) for gonorrhea and chlamydia. This test is generally more sensitive than genital culture and may be acceptable for medico-legal purposes if confirmed by a second set of primers or in some cases, a second test sent to another laboratory.</li> <li>• Post-exposure NAAT can be taken at the time of presentation.</li> </ul>
Vagina [vestibule or discharge (if present)] and urethra: females <ul style="list-style-type: none"> <li>• 1 urethral swab, pre-moistened with sterile water to minimize discomfort</li> <li>• vaginal wash technique preferred to multiple vaginal swabs if NAAT used for <i>C. trachomatis</i> and <i>N. gonorrhoeae</i></li> </ul>	<ul style="list-style-type: none"> <li>• Gram stain for abnormal bacterial flora, bacterial vaginosis, candida, gonorrhea</li> <li>• Molecular diagnostic tests, especially NAAT, are more sensitive than culture for <i>C. trachomatis</i> and <i>N. gonorrhoeae</i></li> <li>• Cultures have been the preferred method for medico-legal purposes, but NAAT may be acceptable if the positive results are confirmed by a second set of NAAT primers or in some cases, a second test sent to another laboratory for testing.</li> <li>• If available, culture tests <i>and</i> NAAT should be performed</li> <li>• If available, wet mount and/or culture for <i>T. vaginalis</i></li> <li>• Since culture tests collected &lt; 48 hours after exposure may be falsely negative, they should be repeated 1 to 2 weeks after exposure if prophylaxis is not offered; post-exposure NAAT testing can be taken at the time of presentation.</li> </ul>
Urethra: males <ul style="list-style-type: none"> <li>• 1 urethral swab, pre-moistened in sterile water to minimize discomfort</li> </ul>	<ul style="list-style-type: none"> <li>• Gram stain for urethritis, gonorrhea</li> <li>• Molecular diagnostic tests, especially NAAT, are more sensitive than culture for <i>C. trachomatis</i> and <i>N. gonorrhoeae</i></li> <li>• Cultures have been the preferred method for medico-legal purposes, but NAAT may be acceptable if the positive results are confirmed by a second set of NAAT primers or in some cases, a second test sent to another laboratory for testing.</li> <li>• If available, culture tests <i>and</i> NAAT should be performed</li> <li>• If available, wet mount and/or culture for <i>T. vaginalis</i></li> <li>• Since culture tests collected &lt; 48 hours after exposure may be falsely negative, they should be repeated 1 to 2 weeks after exposure if prophylaxis is not offered; post-exposure NAAT testing can be taken at the time of presentation.</li> </ul>

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## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

<b>STI Post-exposure Testing</b> (continued)	
<b>Source:</b> it is assumed that the source will not be available for testing in most instances.	
<b>Recipient:</b> pre-pubertal or peri-pubertal <b>children</b>	
<b>Specimen* type by gender</b>	<b>Condition or organism to be detected</b>
Pharynx: males and females <ul style="list-style-type: none"> <li>• 1 swab</li> </ul>	<ul style="list-style-type: none"> <li>• <i>N. gonorrhoeae</i> culture</li> <li>• Test for <i>C. trachomatis</i>: culture +/- NAAT, if available; organisms can be detected in oropharynx from perinatal transmission for up to six months following birth.</li> <li>• No approved NAAT for throat specimens</li> </ul>
Rectum: males and females <ul style="list-style-type: none"> <li>• 1-2 swabs</li> </ul>	<ul style="list-style-type: none"> <li>• <i>N. gonorrhoeae</i> and <i>C. trachomatis</i> culture; no approved NAAT tests at present</li> <li>• HSV culture (if inflammation present)</li> </ul>
Genital ulcers: males and females <ul style="list-style-type: none"> <li>• 1 swab</li> </ul>	<ul style="list-style-type: none"> <li>• HSV culture</li> <li>• Direct test (e.g. FA for <i>T. pallidum</i>)</li> </ul>
Serology: males and females	<ul style="list-style-type: none"> <li>• A non-treponemal test (e.g. RPR) and a treponemal test (e.g. TP-PA) for syphilis should be performed</li> <li>• Both the treponemal and non-treponemal tests should be repeated at 12 and 24 weeks after exposure. In some instances (e.g. high risk assailant or in areas experiencing outbreaks of syphilis) it may be appropriate to repeat tests 2 to 4 weeks post-assault.</li> </ul>

\* In an acute assault, collection of specimens for forensic evidence should follow established sexual assault protocols. At a minimum, specimens should be collected for chlamydia and gonorrhea.

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

### Considerations for STI Post-exposure Prophylaxis

Offer prophylaxis if:

- it is likely that the patient will not return for follow up
- it is known that the assailant is infected or at high risk for an STI
- requested by the patient/parent/guardian
- the patient has signs or symptoms of an STI
- in addition, it may be appropriate to offer prophylaxis in situations where vaginal, oral or anal penetration has occurred because most sexual assault victims do not return for follow up visits

The efficacy of antibiotic prophylaxis has not been studied in sexual assault. Prophylaxis should be as recommended for treatment of specific diseases in the *Alberta Treatment Guidelines for STI in Adolescents and Adults, 2002* and *Canadian STI Guidelines, 2006*.

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

<b>STI Non-occupational Post-exposure Prophylaxis</b>	
<b>STI</b>	<b>nPEP</b>
<b>Gonorrhea</b>	<p><b>All adults (including pregnant or breast-feeding women)</b> cefixime 400 mg po single dose</p> <p><b>Children</b> &lt; 45 kg: cefixime 8 mg/kg (max 400 mg) po single dose &gt; 45 kg: cefixime 400 mg po single dose <i>or</i> ciprofloxacin 500 mg po single dose</p>
<b>Chlamydia</b>	<p><b>Non-pregnant adults</b> azithromycin 1 gm po single dose <i>or</i> doxycycline 100 mg po BID x 7 days</p> <p><b>Pregnant adults</b> amoxicillin 500 mg po TID x 7 days <i>or</i> azithromycin* 1 gm po single dose *Discuss unknown long term effects of azithromycin to fetus while emphasizing benefits of treatment of chlamydia and the fact that use of azithromycin to date has not been associated with any harm to fetus.</p> <p><b>Children</b> &lt; 45 kg: azithromycin 15 mg/kg (max 1 gm) po single dose &gt; 45 kg: azithromycin 1 gm po single dose</p>
<b>Trichomoniasis</b>	<p><b>Treat only if positive test for trichomonas: all adults</b> &lt; 45 kg: metronidazole 30 mg/kg/day divided q 6 to q 12 hourly x 7 days &gt; 45 kg: metronidazole 2 gm po single dose</p>
<b>Syphilis</b>	<p>Prophylaxis with azithromycin (given for prophylaxis against chlamydia) is no longer considered to be effective against incubating syphilis in light of recent emergence of syphilis resistant to azithromycin.</p> <p>If recipient subsequently has reactive syphilis serology, re-treatment with benzathine penicillin should be carried out in conjunction with regional or provincial STD services</p>

# RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

## Hepatitis B Virus (HBV)

HBV Post-exposure Testing	
<b>Source (if possible):</b> hepatitis B surface antigen (HBsAg)*; if source tests negative, no further testing required in recipient.	
<b>Recipient*:</b>	
Interval	Specific tests
Baseline	hepatitis B surface antibody (anti-HBs) hepatitis B surface antigen (HBsAg)  <i>*if recipient is known to be immune to HBV (anti-HBs ≥ 10 IU/L) or HBsAg positive, source and recipient testing is unnecessary.</i>

### HBV Non-occupational Post-exposure Prophylaxis

Prophylaxis for hepatitis B should be considered in all cases of sexual assault/abuse, where the sexual acts have included anal or vaginal penetration or oral-anal contact without a condom or condom status is unknown. Oral-genital and oral-oral contact do not appear to be significant modes of transmission.

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

<b>HBV Non-occupational Post-exposure Prophylaxis</b>				
(Adapted from: <i>Canadian Immunization Guide</i> , 7 <sup>th</sup> edition, 2006; Alberta Immunization Manual, 2007 draft)				
<b>RECIPIENT*</b> Immunization & baseline antibody response (antiHBs) status	<b>SOURCE</b> HBsAg Positive	<b>SOURCE</b> HBsAg negative	<b>SOURCE</b> Unknown or not available for testing	
<i>Unimmunized</i>	HBIG§ and initiate vaccine series‡  anti-HBs 1-6 months after series complete	Initiate vaccine series‡  anti-HBs 1-6 months after series complete	HBIG§ and initiate vaccine series‡  anti-HBs 1-6 months after series complete	
<i>Previously immunized with complete series</i>	Responder**	No treatment	No treatment	No treatment
	Non-responder† after 3 doses of vaccine	HBIG and complete second course of vaccine series‡  anti-HBs 1-6 months after series complete	Complete second course of vaccine series‡  anti-HBs 1-6 months after series complete	HBIG and complete second course of vaccine series‡  anti-HBs 1-6 months after series complete
	Non-responder† after 2 series of 3 doses of vaccine	HBIG x 2 administered one month apart	No treatment	HBIG x 2 administered one month apart
<i>Previously immunized with incomplete series</i>	Received 1 dose of vaccine	HBIG and complete vaccine series‡  anti-HBs 1-6 months after series complete	Complete vaccine series‡  anti-HBs 1-6 months after series complete	HBIG and complete vaccine series‡  anti-HBs 1-6 months after series complete
	Received 2 doses of vaccine	Give 3 <sup>rd</sup> dose of vaccine  If baseline anti-HBs is adequate, no further treatment is required  If baseline anti-HBs inadequate†, administer HBIG  Test anti-HBs 6 months after HBIG. If inadequate, complete second course of vaccine series	Give 3 <sup>rd</sup> dose of vaccine‡  anti-HBs 1-6 months after series complete	Give 3 <sup>rd</sup> dose of vaccine  If baseline anti-HBs is adequate, no further treatment is required  If baseline anti-HBs inadequate†, administer HBIG  Test anti-HBs 6 months after HBIG. If inadequate, complete second course of vaccine series

\* Persons who have previously been infected with HBV are immune to re-infection and do not require post-exposure prophylaxis.

§ Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly. **Dose should be administered as soon as possible** after exposure and **within 14 days of exposure**.

‡ Hepatitis B vaccine (See *Alberta Immunization Manual, January 2001 for details*)

\*\* A responder is a person with adequate levels of serum antibody to hepatitis B (i.e. anti-HBs ≥ 10 IU/L)

† A non-responder is a person with inadequate response to vaccination (i.e. anti-HBs <10 IU/L)

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

### Hepatitis C (HCV)

HCV Post-exposure Testing	
<b>Source (if possible):</b> hepatitis C antibody; if source tests negative, no further testing routinely required in recipient.	
<b>Recipient:</b> testing in the recipient should only be considered in cases where the source is known to be HCV positive; and/or is at high risk for HCV (e.g. known intravenous drug user); and/or the assault involves significant trauma because of the extremely low likelihood of transmission through sexual acts.	
Intervals	Specific tests
Baseline 12 weeks 24 weeks	hepatitis C antibody  <i>If recipient develops illness consistent with acute seroconversion (e.g. nausea, vomiting, abdominal pain, jaundice) to HCV within 4 to 10 weeks of exposure, further testing may be considered after consultation with an infectious disease specialist or hepatologist.</i>

### HCV Non-occupational Post-exposure Prophylaxis

Currently, prophylaxis of HCV is neither available nor recommended although early identification of infection following exposure should be accompanied by referral to an infectious diseases or gastroenterology/hepatology specialist for further assessment. This referral should be carried out on a semi-urgent basis with assessment occurring within 1 to 3 months of new diagnosis.

# RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

## Human Immunodeficiency Virus (HIV)

HIV Post-exposure Testing	
<p><b>Source (if possible):</b> HIV antibody. Generally, if source tests negative, no further testing required in the source or recipient. However, if the source is believed to be in the “window period” for HIV, and is at high-risk* for HIV, additional testing may be performed after consultation with an infectious diseases specialist.</p> <p>* high risk includes: known intravenous drug user; known HCV positive; history of incarceration; shared needles or other drug paraphernalia for drug use in preceding six months; multiple sexual partners or sex with sex trade workers in preceding six months; presence of symptoms consistent with an acute seroconversion illness with HIV.</p>	
<b>Recipient:</b>	
Intervals	Specific tests
Baseline	HIV antibody
6 weeks	<p><i>If recipient develops illness consistent with acute seroconversion to HIV (e.g. fever, headache, rash, lymphadenopathy) within 4 to 6 weeks of exposure, further testing may be considered after consultation with an infectious disease specialist.</i></p>
12 weeks	
24 weeks	

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

<b>HIV Non-occupational Post-exposure Prophylaxis</b> (See Appendix D for drug dosages and side effects)	
<b>Source:</b> known HIV positive assailant	
<b>Recipient:</b>	
Type of exposure	HIV nPEP
Anal or vaginal or oral penetration* without condom or condom broke or condom status unknown  <i>*Partial or complete insertion of penis (with or without ejaculation) into mouth, vagina or anus</i>	<b>Recommended*</b>  <b>Three drug regimen:</b>  Combivir <sup>®</sup> (zidovudine/lamivudine) + Kaletra <sup>®</sup> (lopinavir/ritonavir)  <i>*An infectious disease specialist should be consulted within 24 to 48 hours for advice on the continuing regimen with a view to altering the prophylactic regimen based on the source's treatment history for HIV, CD4 lymphocyte count and plasma HIV RNA level.</i>
No anal or vaginal or oral penetration  OR  Anal or vaginal or oral penetration with intact condom	<b>Not recommended</b>

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

### HIV Non-occupational Post-exposure Prophylaxis

(See Appendix D for drug dosages and side effects)

**Source:** assailant with high risk\* factors for HIV

\* high risk includes: known intravenous drug user; known HCV positive; history of incarceration; shared needles or other drug paraphernalia for drug use in preceding six months; multiple sexual partners or sex with sex trade workers in preceding six months; presence of symptoms consistent with an acute seroconversion illness with HIV.

**Recipient:**

Type of exposure	HIV nPEP
<p>Anal or vaginal or oral penetration* without condom or condom broke or condom status unknown</p> <p><i>*Partial or complete insertion of penis (with or without ejaculation) into mouth, vagina or anus</i></p> <p style="text-align: center;">OR</p> <p>Unknown exposure (e.g. victim under influence of drugs/alcohol)</p>	<p><b>Recommended 2 or 3 drug regimen</b></p> <p><b>Two drug regimen:</b> Combivir<sup>®</sup> (zidovudine/lamivudine)</p> <p><b>Three drug regimen*:</b></p> <p>Combivir<sup>®</sup> (zidovudine/lamivudine) + Kaletra<sup>®</sup> (lopinavir/ritonavir)</p> <p><i>*An infectious disease specialist should be consulted within 24 to 48 hours for advice on the continuing regimen with a view to altering the prophylactic regimen based on the source's treatment history for HIV, CD4 lymphocyte count and plasma HIV RNA level.</i></p>
<p>No anal or vaginal or oral penetration</p> <p style="text-align: center;">OR</p> <p>Anal or vaginal or oral penetration with intact condom</p>	<p><b>Not recommended</b></p>

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

<b>HIV Post-exposure Prophylaxis</b> (See Appendix D for drug dosages and side effects)	
<b>Source:</b> unknown assailant or assailant with low risk factors for HIV	
<b>Recipient:</b>	
Type of exposure	HIV nPEP
Anal or vaginal or oral penetration* without condom or condom broke or condom status unknown  <i>*Partial or complete insertion of penis (with or without ejaculation) into mouth, vagina or anus</i>  OR  Unknown exposure (e.g. victim under influence of drugs/alcohol)	<b>Not generally recommended; but may be considered in exceptional circumstances</b> (e.g. significant injuries, multiple assailants, male victim of male sexual assault, etc)
No anal or vaginal or oral penetration  OR  Anal or vaginal or oral penetration with intact condom	<b>Not recommended</b>

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

### Other Management Issues

#### Referrals

Appropriate referral should be made as necessary and available, e.g. to Sexual Assault teams, local police/RCMP, psychological support, local victim support organizations, etc.

#### Suspected Sexual Abuse in Children

Under the *Alberta Child, Youth and Family Enhancement Act (CYFEA)*, all persons under 18 years of age are considered “children.” In all cases where a person under 18 is found to have an STI, an assessment should be carried out by the clinician to determine whether the child is “a child in need of intervention”.

Under s.4(1) of the CYFEA, a child is “in need of intervention” if there are reasonable and probable grounds to believe that the survival, security or development of the child is endangered because of any of the following:

- the child is neglected by the guardian
- the child has been or there is substantial risk that the child will be physically injured or sexually abused by the guardian of the child
- the guardian of the child is unable or unwilling to protect the child from physical injury or sexual abuse

Sexual abuse is further defined under CYFEA s.1(3)(c) as occurring if the child is inappropriately exposed or subjected to sexual contact, or behaviour including prostitution related activities.

Canadian law is fairly nuanced in respect to defining the points at which sexual activities involving persons under the age of 18 become criminal offences (*Canada Criminal Code, R.S.C. 1985, c. C-46, s.150.1 - 153.1*). Depending on the circumstances, any form of touching for a sexual purpose can constitute an offence. Consent is the key factor in determining whether any form of sexual activity is a criminal offence. The law recognizes some minors as having the ability to consent, in some situations. Generally speaking, persons over 14 are recognized as being able to give consent to participate in sexual activities, unless the activities are taking place in a relationship where one participant has some authority over or is in a position of trust in relation to the other person, where there is dependency, or where there is exploitation of one participant by the other. The Criminal Code provides a “close in age” exception: a 12 or 13 year old can consent to engage in sexual activity with another person who is less than two years older and with whom there is no relationship of trust, authority, dependency, or exploitation. Children under 12 do not have the legal capacity to consent to any form of sexual activity.

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

On June 22, 2006 the federal government introduced a bill in the House of Commons that proposes to raise the age of consent in Canada. If Bill C-22 becomes law, the age of consent will rise from 14 to 16 years of age.

### Recommendations in Suspected Child Abuse

In any person under 18 years of age, where there is concern about the child's safety or welfare as described above, contact Child Welfare Services. For contact numbers see: <http://www.child.gov.ab.ca/cfsa/page.cfm?pg=index> or the Child Abuse Hot Line (1-800-387-5437).

It is recommended that all pre-pubertal and peri-pubertal children be managed in consultation with a referral centre in either:

- **Edmonton:** Child and Adolescent Protection Centre, Stollery Children's Hospital, 1C4.24 Mackenzie Health Sciences Centre, 8440 - 112 Street, Edmonton. T6G 2B7, Tel: 780-407-1240
- **Calgary:** Child Abuse Program, Alberta Children's Hospital, 1820 Richmond Road SW, Calgary, Alberta. T2T 6C7, Tel: 403-943-7886

### Prevention of Further Transmission of STI or Blood-borne Pathogens

Advise potentially exposed individual of the need to practice safe sex or abstain from sexual intercourse until infection has been ruled out and/or prophylaxis is complete.

### Tetanus Prophylaxis

Immunizing agents (vaccine and/or tetanus immune globulin) are recommended for post-exposure prevention of tetanus in the context of wound management (e.g. dirty wounds/abrasions sustained outdoors). It is important to ascertain the number of doses of tetanus toxoid previously given and the interval since the last dose. See the current *Canadian Immunization Guide* (<http://www.phac-aspc.gc.ca/publicat/cig-gci/index.html>) and *Alberta Immunization Manual* for detailed recommendations. When a tetanus booster dose is required, the combined preparation of tetanus and diphtheria toxoid (Td) is used for adults. For adolescents who have not already received a pertussis booster vaccine dose, the combined preparation of diphtheria, tetanus and acellular pertussis (dTap) is preferred.

### Pregnancy

- if pregnancy is a possible result of the assault, the Emergency Contraceptive Pill (ECP) should be considered (Dunn, 2003)
  - preferred: Plan B: levonorgestrel 1.5 mg orally as a single dose *or*

## RECOMMENDATIONS FOR TESTING AND nPEP IN SEXUAL ASSAULT/ABUSE

- levonorgestrel 0.75 mg po BID x 2 doses if single dose not likely to be tolerated [Gravol<sup>®</sup> (dimenhydrinate) 50 mg given 30 minutes before the second dose of levonorgestrel may prevent vomiting of medication]
- treatment should be taken as soon as possible, up to a maximum of 12 hours after exposure
- more effective and better tolerated than the Yuzpe method (WHO, 1998)
- contraindicated if there is evidence of an established pregnancy as confirmed by a positive pregnancy test

## COUNSELING

The following recommendations are intended as a guide and are not intended to replace expert consultation where appropriate or individualized case management depending on specific circumstances.

Refer to other existing guidelines for detailed recommendations.

### **Prevention of further transmission of blood borne pathogens**

Advise potentially exposed individual of the need to practice safer sex (i.e. use condoms) or abstain from sexual intercourse until infection has been ruled out (typically until 6 month serology for HIV and HCV can be performed).

Also advise potentially exposed individual not to donate blood, tissues, organs or semen until infection has been ruled out.

## FOLLOW-UP

Ideally a physician experienced in prescribing antiretroviral agents should follow patients continuing on HIV nPEP. All patients prescribed a protease inhibitor (e.g. lopinavir/ritonavir) should be ideally followed by or in conjunction with an infectious diseases/HIV specialist.

Appropriate referral should be made as necessary and available (e.g. to sexual assault teams, local police/RCMP, psychologist support, local victim support organizations, etc).

Suggested frequency of clinic visits/laboratory tests and reasons for follow-up for individual receiving:

### **Combivir® only**

1. Baseline visit
  - CBCD, AST
  - review possible side effects of medications (most common – nausea, vomiting; anemia, neutropenia)
  - review need for 100% compliance with medications and need to complete full course
2. Two week follow-up
  - CBCD, AST
  - assess compliance with medications
  - review for side effects (most common – nausea, vomiting, anemia, neutropenia)
3. Other serologic follow-up as recommended for HIV/HCV and HBV in previous tables

### **Combivir® plus Kaletra®**

1. Baseline visit
  - CBCD, AST
  - review past medical history and concurrent medications for potential drug interactions with Kaletra® (See Appendix D)
  - review possible side effects of medications (most common – nausea, vomiting; anemia; neutropenia; elevated transaminases)
  - review need for 100% compliance with medications and need to complete full course
2. Two week follow-up
  - CBCD, AST
  - assess compliance with medications
  - review for side effects (most common – nausea, vomiting, anemia, neutropenia, elevated transaminases, diarrhea)
3. Other serologic follow-up as recommended for HIV/HCV and HBV in previous tables

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**RISKS AND BENEFITS OF HIV nPEP**



**RISKS**

- Uncertain efficacy of HIV PEP in exposures in non-occupational settings
- Adverse effects of drugs
- Cost of drugs
- Potential negative behaviour change as a result of availability of HIV nPEP

**BENEFITS**

Reduced risk of acquiring HIV if nPEP is started as soon as possible after exposure and the individual is compliant with the drug regimen

## APPENDIX B

### PROBABILITY OF TRANSMISSION OF HIV, HBV, HCV and STI

Exposure	Per episode probability of transmission
Blood transfusions (single unit of whole blood)	95%
Intravenous needle or syringe exposure	0.67% (Kaplan, 1992)
Needlestick	0.3% (95% CI = 0.2 to 0.5%) (Bell, 1997) <i>There have been no reported instances of transmission of HIV from improperly discarded needles outside of the health care setting in either the USA or UK (MG Fowler, CDC, June 15, 2002 cited in Havens, 2003; Robertson, 2001)</i>
Receptive penile anal sexual exposure	0.1 to 3% (Mastro, 1996)
Receptive vaginal exposure	0.1 to 0.2% (Mastro, 1996)
Receptive oral exposure	Described but not quantified; presumed to be less than other routes of sexual transmission (Schacker, 1996; Berrey, 1997)
Mucous membrane exposure to blood or bodily fluids contaminated with blood	0.1% (ANCHARD,2001)

Infectious agent	Disease	Transmission probability (per partnership)	Mean duration of infectiousness (untreated) in years
<i>Neisseria gonorrhoeae</i>	Gonorrhea	0.5	0.5
<i>Chlamydia trachomatis</i>	Urethritis/salpingitis	0.2	1.0
<i>Treponema pallidum</i>	Syphilis	0.6	0.5
<i>Haemophilus ducreyi</i>	Chancroid	0.8	0.008

## APPENDIX B

<b>Exposure</b>	<b>Per episode probability of transmission</b>
Sexual exposure	<ul style="list-style-type: none"> <li>not quantified; however, receptive anal intercourse &gt; insertive anal intercourse &gt; vaginal intercourse &gt; oral-anal contact</li> <li>oral-genital and oral-oral contact do not appear to be significant modes of transmission</li> <li>estimated to be transmitted 8.6 fold more efficiently than HIV</li> <li>increased risk of transmission if source more infectious (i.e. higher HBV DNA and/or HBeAg positive)</li> </ul>
Needlestick Source: HBsAg positive & HBeAg positive	37-62% (Mast, 1993)
Needlestick Source: HBsAg positive & HBeAg negative	23-27%

<b>Exposure</b>	<b>Per episode probability of transmission</b>
Sexual exposure	<p>Not quantified; however:</p> <ul style="list-style-type: none"> <li>long-term discordant monogamous partnerships are at lower risk of acquisition (0 to 0.6% per year) as compared to persons with multiple partners or those at risk for sexually transmitted diseases (0.4 to 1.8% per year)</li> <li>risk of transmission increased if source HIV co-infected</li> </ul>
Needlestick	1.8% (range 0 to 7%) (Alter, 1997; Lanphear, 1994; Puro, 1995; Mitsui, 1992)

## APPENDIX C

### PREVALENCE OF HIV/AIDS

**Table 1: Estimated prevalence of HIV in Alberta by exposure category, 2005**

(Source: C. Archibald on behalf of the Centre for Infectious Disease Prevention and Control, Population and Public Health Branch, Public Health Agency of Canada)

Exposure category	Estimated prevalence		% of total
	Number of cases	Range	
MSM (men who have sex with men)	1140	900 - 1380	34%
MSM-IDU	60	40 - 80	2%
IDU	1060	830 - 1300	32%
Heterosexual/non-endemic	760	570 - 950	23%
Heterosexual/endemic	280	200 - 360	8%
Other	50	30 - 70	2%
<b>TOTAL</b>	<b>3350</b>	<b>2700 - 4000</b>	<b>100%</b>

**Table 2: Number and prevalence of HIV-positive residents 18 years and older in Canada by province and sex, 2002\***

[Source: Robert Remis, Department of Public Health Sciences, University of Toronto; HIV Laboratory, Public Health Branch, Ontario Ministry of Health and Long-Term Care; Ontario Registrar-general office and Health Canada (Table used with permission from Dr. M. Loutfy on behalf of Centre for Research in Women's Health, Toronto, Ontario)] \*2005 figures not available

Region	Male		Female	
	HIV number	HIV prevalence	HIV number	HIV prevalence
British Columbia	8,418	0.54%	1,012	0.06%
Alberta	2,899	0.25%	362	0.03%
Saskatchewan	426	0.11%	157	0.04%
Manitoba	522	0.12%	84	0.02%
Ontario	18,684	0.42%	2,471	0.05%
Quebec	14,713	0.53%	3,651	0.13%
New Brunswick	376	0.13%	73	0.02%
Nova Scotia & PEI	701	0.19%	95	0.02%
Newfoundland	771	0.10%	94	0.05%
<b>Total – Canada</b>	<b>47,000</b>	<b>0.30%</b>	<b>8,000</b>	<b>0.07%</b>

## APPENDIX C

**Table 3: Estimated prevalence of HIV positive adults aged 15 to 49, by country globally (end 2003)**

[Source: Table of country-specific HIV and AIDS estimates and data, end 2003 (July 2004)]

Available at: [http://www.unaids.org/bangkok2004/GAR2004\\_pdf/GAR2004\\_table\\_countryestimates\\_en.pdf](http://www.unaids.org/bangkok2004/GAR2004_pdf/GAR2004_table_countryestimates_en.pdf)  
(Accessed July 12, 2006)]

Country	HIV prevalence
Australia	0.1%
Brazil	0.7%
Canada	0.3%
Congo	4.9%
Dominican Republic	1.7%
Ethiopia	4.4%
Germany	0.1%
India	0.9%
Kenya	6.7%
Mexico	0.3%
Russian Federation	1.1%
Rwanda	5.1%
South Africa	21.5%
Spain	0.7%
Thailand	1.5%
United Kingdom	0.2%
United States	0.6%

**ANTIRETROVIRAL DRUGS USED FOR HIV POST-EXPOSURE PROPHYLAXIS**

<b>Drug</b>	<b>Dose</b>	<b>Supplied</b>	<b>Possible side effects</b>	<b>Additional information</b>
<b>Kaletra<sup>®</sup></b> (lopinavir/ ritonavir)	<p><b>Adult or adolescent (&gt; 12 years):</b> 400 lopinavir/100 ritonavir po BID (2 tabs po BID)</p> <p><b>Children (6 months to 12 years):</b> 7 to &lt; 15 kg: 12 mg/kg lopinavir/3 mg/kg ritonavir po BID 15 to 40 kg: 10 mg/kg lopinavir/2.5 mg/kg ritonavir po BID &gt; 40 kg: use adult dosing</p>	<p><b>Tablets:</b> (use the tablet formulation) 200 mg lopinavir + 50 mg ritonavir</p> <p><b>Capsules:</b> 133 mg lopinavir + 33 mg ritonavir</p> <p><b>Pediatric oral solution:</b> 80 mg lopinavir + 20 mg ritonavir per mL. Contains 42.4% alcohol.</p>	<ul style="list-style-type: none"> <li>diarrhea, nausea, perioral tingling, headache, rash, elevated cholesterol &amp; triglycerides, hyperglycemia (long-term use)</li> </ul>	<ul style="list-style-type: none"> <li>the tablets may be taken with or without food and can be stored at room temperature.</li> <li>the capsules and oral solution must be taken with food and require refrigeration if &gt; 42 days at room temperature.</li> </ul> <p><b>Numerous drug interactions</b> (potent CYP3A4 inhibitor):</p> <ul style="list-style-type: none"> <li>avoid concurrent use with: fluticasone (i.e. Advair<sup>®</sup>, Flovent<sup>®</sup>), simvastatin, lovastatin, rifampin, astemizole, terfenadine, cisapride, midazolam, triazolam, pimozone, ergot derivatives, St. John's wort</li> <li>caution with oral contraceptives and phenytoin, phenobarbital and carbamazepine</li> </ul>
<b>Retrovir<sup>®</sup></b> (zidovudine)	<p><b>Adult or adolescent (≥ 13 years):</b> 300 mg po BID</p> <p><b>Children (1 month to 12 years):</b> 180 to 240 mg/m<sup>2</sup>/dose po BID (max 300 mg)</p>	<p><b>Capsules:</b> 100 mg</p> <p><b>Combination tablet:</b> Combivir<sup>®</sup> zidovudine 300 mg + lamivudine 150 mg in a single tablet. The dose is 1 tablet po BID.</p> <p><b>Syrup:</b> 10 mg/mL (240 mL bottle)</p>	<ul style="list-style-type: none"> <li>nausea, headaches, malaise, anorexia, anemia, neutropenia, myopathy</li> <li>rare: hepatotoxicity, lactic acidosis</li> </ul>	<ul style="list-style-type: none"> <li>may take with or without food</li> <li>caution when used with other bone marrow suppressing drugs</li> </ul>

Drug	Dose	Supplied	Possible side effects	Additional information
<b>3TC<sup>®</sup></b> (lamivudine)	<b>Adult or adolescent (≥ 13 years):</b> 150 mg po BID  <b>Children (1 month to 12 years):</b> < 37.5 kg: 4 mg/kg/dose po BID > 37.5 kg: 150 mg po BID	<b>Tablets:</b> 150 mg and 300 mg  <b>Combination tablet:</b> Combivir <sup>®</sup> zidovudine 300 mg + lamivudine 150 mg in a single tablet. The dose is 1 tablet po BID.  <b>Oral solution:</b> 10 mg/mL (240 mL bottle)	<ul style="list-style-type: none"> <li>• well tolerated</li> <li>• headache, nausea, diarrhea, abdominal pain and insomnia</li> <li>• rare: rash, pancreatitis, lactic acidosis</li> </ul>	<ul style="list-style-type: none"> <li>• may take with or without food</li> </ul>

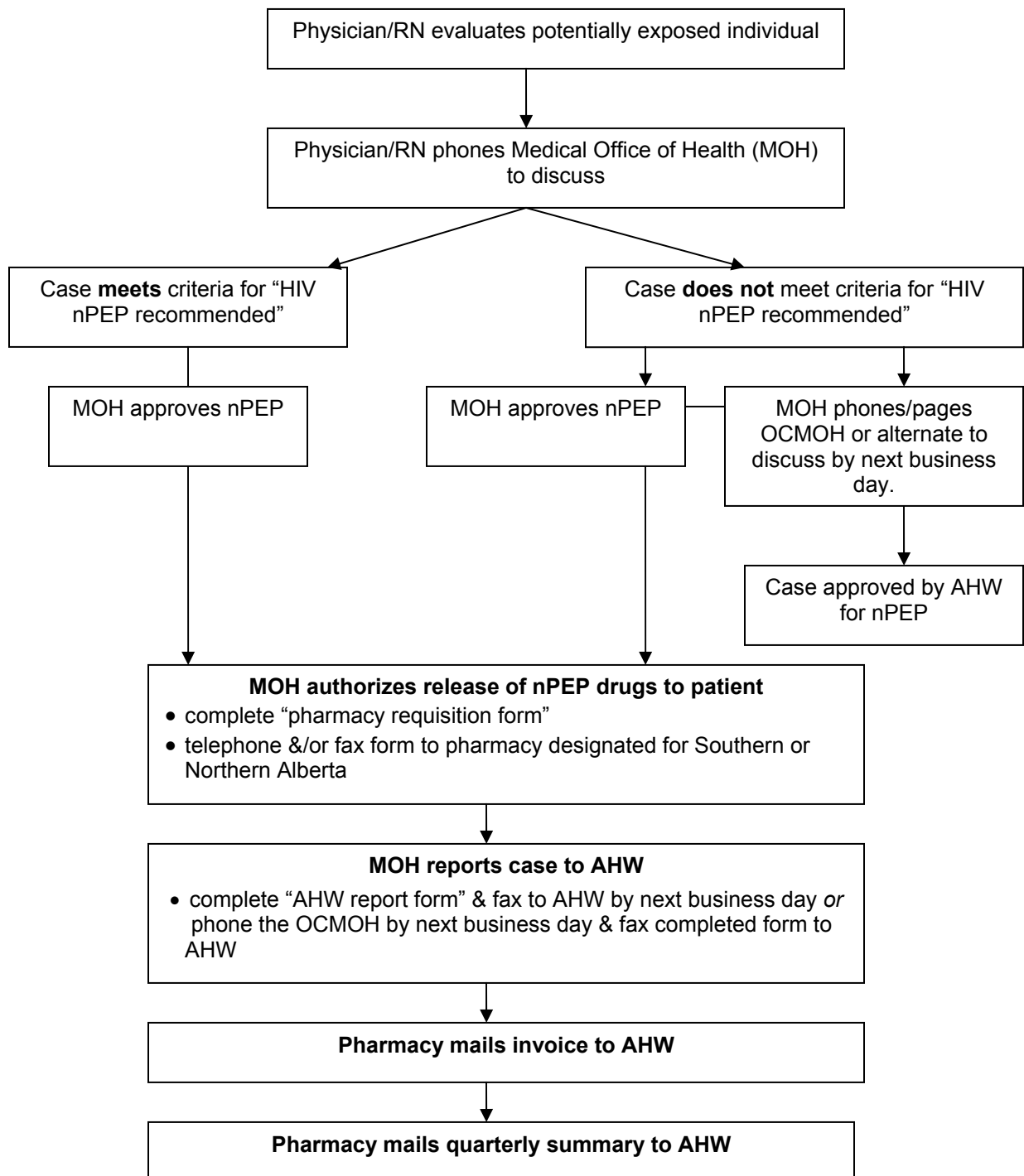
Additional information on drug interactions available at: <http://hivinsite.ucsf.edu/InSite.jsp?page=ar-00-02> (accessed July 12, 2006)

**References:**

DHHS. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. May 4, 2006 (Updated guidelines available at <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>)

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**REQUISITION AND REPORTING PROCESS FOR ALBERTA nPEP PROTOCOL**



### REQUISITION AND REPORTING PROCESS FOR ALBERTA nPEP PROTOCOL

#### Introduction

This protocol applies to all permanent residents of Alberta including those living on First Nations communities.

#### Sexually Transmitted Infections (STI) PEP

A Notification of Sexually Transmitted Disease form should be completed and submitted to Alberta Health and Wellness STD Services.

#### Hepatitis B nPEP

HBIG and hepatitis B vaccine should be obtained as per current provincial/AHS procedures.

#### Hepatitis C nPEP

No nPEP available.

#### Human Immunodeficiency Virus (HIV) nPEP (see process chart-previous page)

1. Physician/RN evaluating individual potentially exposed to HIV (see protocol for criteria) phones Medical Officer of Health (MOH) to discuss situation.
2. MOH approves HIV nPEP

For cases meeting HIV nPEP **recommended** criteria as outlined in the protocol: MOH forwards the following information (see AHW report form Appendix E) to Alberta Health and Wellness by secure fax 780-415-9609 by next business day:

- name of individual providing information
- name, date of birth, Alberta Personal Health Care number of exposed individual
- type, date and time of exposure
- date and time HIV nPEP started
- type of HIV nPEP (please specify drugs)
- what is known about source (e.g., gender, known IDU, history of incarceration)

For cases **not** meeting the HIV nPEP recommended criteria as outlined in the protocol:

- phone Alberta Health and Wellness, OCMOH, at 780-427-5263 or pager 780-638-3630 by next business day and forward completed AHW report form to Alberta Health and Wellness by secure fax 780-415-9609 by next business day.

## APPENDIX E

3. In addition, the MOH should contact (see pharmacy requisition form) by the next business day one of the following pharmacies to indicate that the drugs have been approved by AHW; the **name and date of birth of the exposed individual** should be provided:

- Southern Alberta: Safeway Pharmacy  
Phone: 403-210-0224  
Fax: 403-210-0279
- Northern Alberta: University of Alberta Hospital Rexall Pharmacy  
Phone: 780-407-6990 (Mon-Fri 08:00-18:00, Sat 08:00-13:00, closed stat holidays)  
Fax: 780-407-1090

### Follow up of patients prescribed HIV nPEP

- initial nPEP will most often be started in ER departments with dispensing of starter kits to cover the patient until a physician who will provide ongoing care can assess the patient. Arrangements for follow-up care will vary by region.
- ideally, a physician experienced in prescribing antiretroviral agents should follow patients continuing on HIV nPEP.
- all patients prescribed a protease inhibitor (e.g. lopinavir/ritonavir) should ideally be followed by or in conjunction with an infectious diseases/HIV specialist.

### Dispensing of HIV nPEP

- HIV nPEP should be dispensed for a **maximum of one week at a time** unless unusual circumstances exist (e.g. patient living in remote community, etc.)
- starter kits for HIV nPEP should be available for use within hours of potential exposure to HIV and continued until a prescription can be filled at one of the above listed out-patient pharmacies

### Information for pharmacies

- invoices with the exposed individual's name and date of birth and name of prescribing physician **must** be submitted by mail to Alberta Health and Wellness, Communicable Disease Control at
  - Alberta Health and Wellness  
23<sup>d</sup> floor, Telus Plaza North Tower  
10025 Jasper Avenue NW  
Edmonton, AB. T5J 1S6
- quarterly summaries (dispensary log/summary) of HIV nPEP dispensed **must** be mailed to the above address.

### Auditable outcomes

Collection of the information described above will achieve the following objectives:

- verification of approval of HIV nPEP for reimbursement
- determination of the proportion of individuals approved HIV nPEP who meet the *recommended, generally not recommended* and *not recommended* criteria
- determination of the types of exposures for which HIV nPEP is being approved
- determination of the duration of HIV nPEP dispensed per approved individual
- in the future, it is hoped that the following additional information will be obtained:
  - proportion of individuals experiencing adverse events
  - adverse events which result in discontinuation of nPEP,
  - proportion of individuals who complete the 28 days of nPEP,
  - proportion of individuals who have follow up serology at 6 weeks, 3 and 6 months





<b>To:</b>	<b>Alberta Health and Wellness – MEDICAL CONFIDENTIAL Communicable Disease Control Fax: 780-415-9609 Phone: 780-427-5263</b>	
Name of exposed person:	_____ Surname First name	
Date of birth of exposed person:	____/____/____ DD MMM YYYY	
Alberta Personal Health Number:	____ - ____	
Gender of exposed person: (circle one)	Male/Female	
Type of exposure: (please provide details – e.g. sexual assault with or without barrier contraception; needlesticks-hollow bore or solid bore, depth of injury, etc)		
Date and time of exposure:	____/____/____ : ____ DD MMM YYYY (24:00 clock)	
Gender of source: (circle one)	Male/Female	
Other source information: (e.g. history of incarceration, known injection drug user, MSM, etc)		
Type of HIV PEP: (circle as appropriate)	<ul style="list-style-type: none"> <li>• Combivir®</li> <li>• Combivir® + Kaletra®</li> <li>• Other – specify: _____</li> </ul>	
Date and time HIV PEP started:	____/____/____ : ____ MM DD YYYY (24:00 clock)	
Other comments: (e.g. recipient or source intoxicated, etc)		
Name of Medical Officer of Health (designate):		Contact number:
Alberta Health Services Zone / Region:		Date:
<p><i>The contents of this transmission are intended for the use of the addressee only and may contain information that is privileged and confidential. If you are not the intended recipient, please be advised that any dissemination, distribution or copying of the content of this fax is strictly prohibited. If you have received this fax in error, or if you have trouble receiving this fax, please notify us immediately by calling the number noted above.</i></p>		