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Addendum

One of the drugs in the pediatric basic HIV PEP liquid kit, Lamivudine 10mg/ml oral solution (brand: 3TC), has been discontinued by the manufacturer. An alternative product, Lamivudine 5mg/ml (brand: Heptovir), is being supplied as replacement. As a result, the **Integrated Post-exposure Protocol for HIV, HBV and HCV** (http://www.gov.mb.ca/health/publichealth/cdc/protocol/hiv_postexp.pdf) is updated as follows:

Update 1: Change in strength of supplied Lamivudine oral solution in the Pediatric HIV PEP regimen

Current statement on Page 26, Table 2:

Basic PEP	
< 50 kg	Zidovudine 10 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 100 mg capsule or 10 mg/mL oral solution AND Lamivudine 8 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 150 mg tablet or 10 mg/mL oral solution

Updated statement, effective immediately:

Basic PEP	
< 50 kg	Zidovudine 10 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 100 mg capsule or 10 mg/mL oral solution AND Lamivudine 8 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 150 mg tablet or 5 mg/mL oral solution

Update 2: Change in tradename and strength of Lamivudine included in the Pediatric HIV PEP Starter Kits

Current statement on Page 28, Table 4:

Basic LIQUID Kit	Zidovudine (Retrovir®) 10 mg/mL solution	160 mL
	Lamivudine (3TC®) 10 mg/mL solution	120 mL

Updated statement, effective immediately:

Basic LIQUID Kit	Zidovudine (Retrovir®) 10 mg/mL solution	160 mL
	Lamivudine (Heptovir®) 5 mg/mL solution	240 mL

This addendum is appended at the beginning of the protocol.

Sincerely,

(orig. sgd.)

Richard Baydack, PhD
Director

(orig. sgd.)

Joss Reimer, MD
Medical Officer of Health

Integrated Post-exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids

MARCH 2009

COMMUNICABLE DISEASE CONTROL

Manitoba

Integrated Post-exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids

Manitoba

Communicable Disease Control Branch

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1. Overview

Exposures to human blood and body fluids may transmit human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). Disease-specific management of such exposures involving medication or immunization is termed post-exposure prophylaxis (PEP). Most exposures to blood and body fluids will not require PEP, but evaluation is necessary.

This document integrates post-exposure management guidelines for HIV, HBV and HCV. PEP for HIV involves antiretroviral therapy; PEP for HBV may involve both passive and active immunization against HBV. Currently, there is no effective PEP regimen for HCV; however, post-exposure management including testing and follow-up may be indicated.

This protocol provides a list of definitions and abbreviations used in the protocol, as well as the risk assessment necessary to determine the need for PEP and risk reduction strategies to prevent exposures resulting in the need for PEP. This document details the administrative responsibilities surrounding the management of exposures including notification procedures and the completion and submission of forms.

Further information on this protocol can be obtained during regular office hours (8:30 to 4:30) by contacting your local public health office. The appropriate public health office is the one serving the place of residence of the Exposed. After hours, contact the Medical Officer of Health on-call at 788-8666.

1.1 Purpose of Post-exposure Prophylaxis

The purpose of providing PEP is to prevent infection subsequent to exposure rather than treatment of an established infection.

1.2 Scope

This protocol will cover occupational and non-occupational exposures to human blood and/or body fluids sustained through percutaneous injuries as well as those resulting from mucous membrane and non-intact skin exposures. Occupational exposures include, but are not limited to the following:

- Health care workers directly involved in patient care;
- Other health care workers not directly involved in patient care (e.g., housekeeping, laundry);
- Other occupations such as emergency responders, law enforcement, corrections and waste management where exposures to blood and body fluids are possible;
- Scientific research, diagnostic laboratory and biological production facility personnel who may be exposed to infected fluids or concentrated virus solutions;
- Rarely, patients exposed to infected health care workers.

Non-occupational exposures include but are not limited to exposures to blood and/or body fluids sustained through:

- Human bites;
- Cuts, nosebleeds, etc., as a result of physical assaults or sports injuries;
- Needle-sharing;
- Abandoned needles or sharps;
- Sexual assault;
- Consensual sex (serodiscordant partners).

The management of perinatal exposures is described in the HIV/AIDS, Hepatitis B and Hepatitis C Manitoba Health and Healthy Living (MHHL) communicable disease management protocols available at: **www.gov.mb.ca/health/publichealth/cdc/protocol/index.html**

1.3 Protocol Definitions and Abbreviations

1.31 Definitions

Exposed: Individual who comes into contact with the potentially infected blood/body fluid.

Mucous membrane exposure: When blood/body fluids come into contact with mucosal membranes (e.g., eyes, oral cavity).

Non-intact skin exposure: When blood/body

fluids come into contact with exposed skin that is chapped, abraded or non-intact because of dermatitis or an open wound.

Percutaneous injury: Puncture or laceration of the skin that penetrates into or below the dermis.

Post-exposure prophylaxis (PEP): Timely provision of medication/immunization following an exposure to potentially infected blood or body fluids in order to minimize the risk of acquiring infection (1).

Routine Practices: Guidelines for preventing the transmission of infection in health care.

Serodiscordant partners: Situation where one sexual partner is infected and the other is not.

Source: Individual from whose body the potentially infected blood/body fluid originated from.

Window period: Period of time from exposure to a virus to development of detectable antibody to the virus. Transmission of infection to others may be possible while an individual is in the window period. The window period is usually two weeks to three months for HIV, but may be longer in immunocompromised persons (see MHHL HIV/AIDS protocol). The window period for HBV is from three to six months. For HCV, it is usually three to three and a half months, but sometimes longer.

1.32 Abbreviations

HBV: Hepatitis B virus

HBsAg: Hepatitis B surface antigen

Anti-HBs: Antibody to Hepatitis B surface antigen

HBIG: Hepatitis B Immune Globulin

HCV: Hepatitis C virus

Anti-HCV: Antibody to Hepatitis C virus

HIV: Human immunodeficiency virus

Anti-HIV: Antibody to human immunodeficiency virus

HAART: Highly active antiretroviral therapy

STI: Sexually transmitted infection

MHHL: Manitoba Health and Healthy Living

2. Risk Reduction Strategies

The following risk reduction strategies are aimed at preventing occupational exposures from occurring or reducing the need for post-exposure prophylaxis should an exposure occur. Risk reduction strategies (prevention) for the community are addressed in the Manitoba Health and Healthy Living disease specific protocols for HIV, HBV and HCV, available at: **www.gov.mb.ca/health/publichealth/cdc/protocol/index.html**

- Educate all health care workers at risk of exposure to blood or blood contaminated body fluids on the epidemiology of bloodborne pathogen transmission and means of minimizing risk.
- Use engineering controls proven to reduce exposure risk such as impervious needle disposal containers, safety engineered needles and needleless connectors (2).
- Offer hepatitis B immunization to at-risk health care workers (3).
- Immunize individuals with HBV vaccine in other occupations who may be at higher risk of exposure such as police and firefighters. Currently there is no data available to quantify risk (3).
- Assess and document antibody status after hepatitis B immunization of health care workers and other occupations at higher risk of exposure (e.g., police, firefighters)(3).
- Determine the anti-HBs status of individuals in health care or other professions at higher risk of exposure to HBV (e.g., police, firefighters) who were previously immunized against HBV, but whose anti-HBs titres were not determined post-immunization.
- Employ Routine Practices (see definition above and *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care CCDR 1999; Vol. 25S4)* in the care of all patients.
- Use personal protective equipment (e.g., goggles, face shields, masks, gloves) to perform procedures for which it can reasonably be

anticipated that exposure to blood/body fluids might occur (2).

- Monitor and review exposure incidents, identify trends, and initiate changes and prevention plans to decrease risk when problems are identified.

3. Initial Non-specific Prophylactic Measures After Exposure Occurs

The following actions are recommended immediately following any exposure to blood/body fluids regardless of whether the Source is known to pose a risk of infection for HIV, HBV and/or HCV. Any additional facility specific instructions for post-exposure management should also be followed.

- Free bleeding of puncture wounds should be encouraged (4, 5); however, there is no documented evidence to support that squeezing the wound will further reduce the risk of transmission of bloodborne infection (2, 5).
- The site of exposure (e.g., wound or non-intact skin) should be immediately washed well with soap and water (2, 5) but without scrubbing (5).
- Clothing contaminated by blood/body fluids should be removed (4).
- After mucosal surface exposure, the exposed mucous membranes should be flushed well with water. Eyes should be irrigated with water (5, 6). Some sources (5) recommend washing eyes before and after removal of contact lenses. Other sources (6) recommend removing and discarding contact lenses.
- Antiseptics, bleach and skin washes should not be used (5, 7) as there is no evidence of their efficacy (2), and their effect on local defense mechanisms is unknown (5).
- Vaginal or anal douching is not recommended after sexual exposures since it may increase the transmission of HIV and other sexually transmitted infections (6).
- In sexual assault situations, the survivor (Exposed) should be discouraged from bathing, showering, washing, gargling, brushing teeth, douching, urinating or changing clothes until after evaluation by a health care provider, to preserve evidence (8).

NOTE: While not considered an exposure requiring PEP, splashes and spills of blood/body fluids onto intact skin should be washed well with soap and water. The larger the area of skin exposed and the longer the time of contact, the more important it is to verify that all of the relevant skin area is intact (4).

4. Documentation and Reporting of Exposure Incident

4.1 Occupational Exposures

Workers need to comply with any employer and/or Occupational Health and Safety requirements in their workplace. Requirements may vary depending upon the facility/organization and the occupation of the Exposed.

1) The exposure incident (for health care workers and emergency responders) must be reported immediately to the appropriate administrative personnel, usually the immediate supervisor of the unit/facility where the exposure occurred.
2) The forms and requisitions that must be completed, as well as instructions as to how and where to report incidents should be itemized or included in a directive/policy or package for potentially exposed workers.
3) The exposure report should include the following details as well as any other information requested in an exposure report form. These exposure details should also be included in the health care worker's confidential medical file.
    - Date, time and location of the exposure.
    - Job duty being performed at the time of exposure.
    - Details of exposure incident (e.g., instruments used, severity of exposure, Source).
    - Precautions taken while performing the job.
    - Witnesses.

- Factors that may have contributed to the exposure incident.
- If Exposed was previously vaccinated against HBV.
- HBsAg and anti-HBs results from previous vaccination.
- Action taken after exposure.
- Results of initial and follow-up testing of Source and Exposed.

4) The facility's Occupational Health Unit or equivalent must be notified of the exposure incident. If this service is not immediately available, if possible, leave a message indicating the name of the exposed worker and Source as well as a contact number for a return call.

5) Initial assessment of an exposure in a timely manner (within 30 minutes of the event) is necessary by an emergency room physician, an occupational medicine physician, an occupational health nurse or another health care professional educated in the assessment of exposures.

6) Complete and return MHHL's "Information Record: HIV Post-exposure Prophylaxis" form (refer to Appendix A) for all exposure situations where HIV prophylaxis (i.e., starter kit) is used. Send the form (available at: www.gov.mb.ca/health/publichealth/cdc/protocol/form12.pdf or through Materials Distribution Agency at 204-945-0570 or 204-945-3000) to the Communicable Disease Control Branch, Manitoba Health and Healthy Living (Secure Fax: 204-948-3044).

4.2 Non-occupational Exposures

1) The forms and requisitions that must be completed as well as instructions as to how and where to report incidents, should be itemized or included in a directive/policy or package for those providing the initial assessment of an exposure. The service designated to provide the initial assessment may vary among different provincial regional health authorities and First Nations Inuit Health jurisdictions.

2) Complete and return MHHL's "Information Record: HIV Post-exposure Prophylaxis" form (refer to Appendix A) for all exposure situations where HIV prophylaxis (i.e., starter kit) is used. Send the form (available at: www.gov.mb.ca/health/publichealth/cdc/protocol/form12.pdf or through Materials Distribution Agency at 204-945-0570 or 204-945-3000) to the Communicable Disease Control Branch, Manitoba Health and Healthy Living (Secure Fax: 204-948-3044).

3) Advise the Exposed to complete and file any forms that may be required for insurance coverage (e.g., Blue Cross, Autopac).

5. Risk Assessment of Exposure Incident for Consideration of PEP

If the Source is infected, the risk of transmission to the Exposed will depend upon:

- the body fluid involved;
- the type of exposure;
- status of the infected Source (e.g., if source is infected with HIV, whether they are Class I or Class II).

5.1 Body Fluid Involved (9, 10)

Blood is the most infectious body fluid for the transmission of HIV, HBV and HCV. If the exposure incident involved a body fluid capable of transmitting any of the viruses (HIV, HBV or HCV) (refer to Table 1 below), further evaluation is warranted. Table 1 has been adapted from the BC Centre for Disease Control *Blood and Body Fluid Exposure Management*, May 2005 and the Saskatchewan Health *Guidelines for the Management of Potential Exposures to Hepatitis B, Hepatitis C, HIV and Recommendations for Post-Exposure Prophylaxis*, January 2004.

Table 1. Body Fluids Presenting Risk for Bloodborne Disease Transmission

Fluid	HIV	HBV	HCV
Lab specimens/cultures containing concentrated virus	Yes	Yes	Yes
Blood, serum, plasma or other biological fluids visibly contaminated with blood	Yes	Yes	Yes
Pleural, amniotic, pericardial, peritoneal, synovial and cerebrospinal fluids	Yes	Yes	Yes
Semen, vaginal secretions	Yes	Yes	Yes
Saliva	No, unless contaminated with blood	No, unless contaminated with blood[1]	No, unless contaminated with blood
Urine, vomitus, feces, nasal secretions, sputum, sweat or tears not visibly contaminated with blood	No	No	No
Breast milk	Yes	Biologically plausible, particularly if nipples are cracked or bleeding	Biologically plausible, particularly if nipples are cracked or bleeding
Organ and tissue transplants	Yes	Yes	Yes
Screened donated blood and manufactured blood products	Minimal risk in Canada	Minimal risk in Canada	Minimal risk in Canada

NOTE: If the exposure incident did not involve a body fluid capable of transmitting HIV, HBV or HCV, further evaluation for PEP is not indicated.

5.2 Type of Exposure

Exposures of concern for possible transmission of HIV, HBV and HCV and consideration of PEP are detailed below (sections 5.21 – 5.28). Tables 2 and 3 provide average per act transmission risk information. In general, the risk of viral transmission after a percutaneous injury is highest for HBV, followed by HCV and HIV.

5.21 Percutaneous Injury

Puncture or laceration of the skin that penetrates into or below the dermis. For the purposes of this protocol, a percutaneous exposure to blood/body fluids which has one or more of the following factors present will be defined as a **more severe exposure** (11).

- Deep percutaneous injury (9, 12)
- Visible blood present on the device associated with the exposure (9, 12)
- Exposure from a procedure which involved a needle placed directly into the Source's vein or artery (9, 12)
- Large-bore hollow needle (9, 11)

A percutaneous exposure which has none of the above characteristics will be defined as a **less severe exposure** (e.g., superficial injury, no visible blood present on device associated with the exposure, procedure from which exposure resulted did not involve a needle being placed directly into the Source's vein or artery, solid needle) (11).

1 For the purposes of post-exposure management.

5.22 Mucous Membrane and Non-intact Skin Exposures

Mucous Membrane Exposure: When blood/body fluids come into contact with mucous membranes (e.g., eyes, oral cavity) (11).

Non-intact Skin Exposure: When blood/body fluids come into contact with an open wound or exposed skin that is chapped, abraded or non-intact because of dermatitis (11).

A larger volume of blood/body fluid is associated with increased transmission risk for mucous membrane and non-intact skin exposures (11). For the purposes of this protocol, a mucous membrane or non-intact skin exposure involving a major splash of blood/body fluids will be defined as a **large volume exposure** (11). Exposures involving lesser amounts (e.g., only a few drops of fluid) will be defined as a **small volume exposure** (11).

5.23 Human Bites

Human bites may occur in both occupational and non-occupational settings. The person bitten has a potential percutaneous exposure and the person who was the biter has a potential mucous membrane exposure. Therefore, an individual who bites may be both the Source and Exposed in bite incidents. As HBV is present in saliva at concentrations 1,000 to 10,000 times less than in blood (3), for the purposes of post-exposure prophylaxis, generally only exposures to saliva containing visible blood would be considered for HBV PEP (such as deep bites associated with bleeding in the mouth of the biter) (3).

The following human bites should prompt further evaluation for consideration of HIV, HBV and HCV post-exposure management (13).

- **Blood exposure to the biter (mucous membrane exposure):** when the biter inflicts a wound that breaks the skin of the person bitten and blood from the bitten person enters his/her mouth.
- **Blood exposure to the bitten person (percutaneous exposure):** when the biter has blood in his/her mouth (e.g., from bleeding gums or lesions) and inflicts a wound that breaks the skin of the person bitten. If available for examination, the mouth of the biter should be examined to determine if the person bitten was likely exposed to the biter's blood (e.g., bleeding gums or lesions) (7).
- **Blood exposure to both parties (mucous membrane and percutaneous exposures):** when the biter inflicts a wound that breaks the skin of the person bitten and blood from the bitten person enters his/her mouth AND when the biter has blood in his /her mouth (e.g., from bleeding gums or lesions) and inflicts a wound that breaks the skin of the person bitten. If available for examination, the mouth of the biter should be examined to determine if the person bitten was likely exposed to the biter's blood (e.g., bleeding gums or lesions)(7).

Exposure incidents resulting from bites should be categorized as defined above in sections 5.21 and 5.22 (e.g., more severe percutaneous or small volume mucous membrane). A bite is not considered a risk exposure to either party when the integrity of the skin and/or the biter's oral cavity is not disrupted.

Pediatric Bites:

Risk assessment is as above. Most bites by children do not result in blood exposure (14). In child care settings, immune status testing is generally not indicated for children of unknown immune status due to the low prevalence of HBV infection in this population in Canada (14).

5.24 Exposures to Blood/Body Fluids Obtained Through Cuts, Nosebleeds, Physical Assaults, Sports Injuries

See 5.21 and 5.22 above to determine whether the exposure meets the definition of percutaneous injury (less severe or more severe) or mucous membrane exposure or non-intact skin exposure (small volume or large volume).

5.25 Exposures from Needle-sharing (e.g., Injection Drug Use)

In general, there is greater likelihood of transmission when (6):

- multiple exposures occur
- sharing of injection drug paraphernalia occurs in an area of high prevalence of infection with HIV, HBV and/or HCV

PEP may be considered when an uninfected individual shares injection drug paraphernalia (e.g., syringes) with another person (6).

5.26 Exposures to Abandoned Needles and Sharps

- These exposures may occur in public locations including parks and schoolyards as well as from contact with laundry bags and waste disposal systems.
- No efficacy studies on PEP in these situations are available outside the health care setting (6).
- These injuries may pose less of a risk for HIV transmission than needlestick injuries that occur in health care settings (15).
- For factors associated with increased transmission risk, see 5.21 above.
- The prevalence of HBV, HCV and HIV in the community or facility where the exposure occurred should be taken into consideration (13).
- Discarded needles should not be tested for HBV, HCV or HIV because of low yield and risk to personnel involved in testing.
- HIV prophylaxis is generally not recommended for percutaneous injuries from abandoned needles when they are outside the health care setting or when there is no history of the use of the needle or the time of abandonment (i.e., inside health care setting) (10, 12).

5.27 Consensual Sex (Serodiscordant Partners)

HBV and/or HIV PEP should be considered for the following unprotected (e.g., condom breakage) sexual exposures where the Source is known to be positive for the respective viruses (6, 7, 16, 17).

- Receptive anal or vaginal sex
- Oral receipt of seminal or vaginal fluid or human blood

Other sexual exposures where trauma, genital ulcer disease or other STI are present in the Source or Exposed may also be considered for PEP (18) as these features will increase the risk of transmission.

NOTE: In consensual sex situations where the status of the Source is unknown (e.g., anonymous sex), manage the same as sexual assault below.

5.28 Sexual Assault

Sexual assault causes extreme emotional distress, making it more difficult for the Exposed to make informed decisions about whether to initiate post-exposure prophylaxis (19).

HBV and HIV PEP should be considered for the following sexual assault situations (6, 7, 16, 17).

- Unprotected receptive anal or vaginal sex
- Oral receipt of seminal or vaginal fluid or human blood

Other sexual exposures where trauma, genital ulcer disease or other STI are present in the Source or Exposed may also be considered for PEP (18) as these features will increase the risk of transmission.

Table 2: Average Per Act Occupational Risk of Transmission for HIV, HBV and HCV from an Infected Source Based on Exposure Route* (2, 11)

Exposure Route	HIV	HBV	HCV
Percutaneous Injury	0.3% (3 in 1,000)	6-30% (6-30 in 100)	1.8% (18 in 1,000)
Mucous Membrane Exposure	0.09% (9 in 10,000)	Not quantified	Not quantified
Non-intact Skin Exposure	Not quantified, estimated to be less than 0.09%	Not quantified	Not quantified

* average per cent per exposure event

Table 3: Average Per Act Non-occupational Risk of Transmission for HIV, HBV and HCV Based on Exposure Route* (17, 20)

Exposure Route	HIV	HBV	HCV
Blood transfusion	0.00002% (1 in 4,700,000)[2]	.00121% (1 in 82,000)[2]	.00003% (1 in 3,100,000)[2]
Percutaneous needlestick	0.30% (1 in 333)[3]	6-30%[3]	1.8%[3]
Needle-sharing injection –drug use	0.67% (1 in 149)[3]	Not quantified	Not quantified
Receptive anal intercourse	0.50% (1 in 200)[3]	Not quantified	Not quantified
Receptive penile-vaginal intercourse	0.10% (1 in 1,000)[3]	Not quantified	Not quantified
Insertive anal intercourse	0.065% (1 in 1,548)[3]	Not quantified	Not quantified
Insertive penile-vaginal intercourse	0.050% (1 in 2,000)[3]	Not quantified	Not quantified
Receptive oral intercourse (Performed on a male)	0.010% (1 in 10,000)[3]	Not quantified	Not quantified
Insertive oral intercourse (Performed on a male)	0.005% (1 in 20,000)[3]	Not quantified	Not quantified

Note: Estimates of risk for transmission from sexual exposures assume no condom use.
* average per cent per exposure event

PEP recommendations for potential exposures to HIV, HBV and HCV are specified in sections 8, 9 and 10 respectively (Tables 4, 10, 11).

5.3 Evaluation of the Source

- Source evaluation (including testing) is necessary only if **both** the type of body fluid involved (e.g., blood, refer to section 5.1) and the exposure type (e.g., more severe percutaneous, refer to section 5.2) as detailed above are of concern for consideration of PEP. Refer to "Testing" in section 6 for testing procedure including the information that should be shared with the client undergoing testing.
- If the Source has previously tested negative for HIV, re-testing the Source is still recommended (12).
- Every effort should be made to locate and determine the HIV antibody status of each Source as soon as possible as this affects the management of the Exposed (12).

2 Represents the current average per event risk of virus transmission from the receipt of donated blood or blood products in Canada. The risk is low due to donor screening.

3 When the Source is known to be infected.

- If HIV PEP is indicated based on the nature of the exposure incident, it should not be delayed:
  - While awaiting Source results; or
  - If the Source is not available for testing (6).
- The Source does not need to be tested for HBsAg if the Exposed is known to be immune to HBV (i.e., immunity demonstrated via titre testing) or if the Exposed has previously tested positive for HBsAg (12). In this case the Exposed does not require prophylaxis with HBIG or HBV vaccine.

5.31 Source is Known to be Positive for HIV, HBV and/or HCV

Complete testing (refer to section 6, "Testing" below) for viruses to which the Source status is unknown. **Source consent is required in order for the infection status and any other related health information of the Source to be released to other health professionals and the Exposed.**

The following information should be obtained (if available) in an HIV-positive Source (2).

- Most recent HIV viral load;
- Most recent CD 4 cell count;
- History of antiretroviral therapy;
- Results of previous resistance testing.

5.32 Source Identity is Known but Status of Source is Unknown

Source is available for testing: Refer to section 6, "Testing" below. Other factors in addition to test results for HIV, HBV and HCV that should be taken into consideration when evaluating the Source are (2):

- Clinical symptoms suggestive of early infection with HIV, HBV or HCV;
- History of recent (i.e., within three months) possible HIV, HBV or HCV exposures (e.g., injection-drug use or sexual contact with a known positive partner). See *Source Risk Factors* below.

Although concerns have been expressed regarding HIV negative Sources being in the window period for seroconversion, no case of HIV transmission involving an exposure Source in the window period has been reported (11).

Source is not available for testing: Evaluate the Source for the following risk factors based on available known history. Sources having one or more of the following risk factors are more likely to be infected.

Source Risk Factors for HIV (3, 12):

1. History of residence in a country or area with a high prevalence of infection
2. Sexual contact with a known case (i.e., HIV antibody positive)
3. Blood contact with a known case (i.e., HIV antibody positive)
4. History of injection drug use
5. Needle-sharing (e.g., tattoo, body piercing, other activities involving needle-sharing)
6. Sexual partner who is an injection drug user
7. History of a sexually transmitted infection, particularly ulcerative infection (e.g., herpes, syphilis)
8. History of multiple sex partners
9. Recipient of blood products prior to 1985
10. Commercial sex worker or sexual contact with a commercial sex worker
11. If male, history of sex with other male

Source Risk Factors for HBV: As above for HIV, except receipt of blood or blood products prior to 1970 (3) and the addition of:

- In close family contact with an HBV-infected person.

Source Risk Factors for HCV: As above for HIV, except receipt of blood or blood products prior to April 1992. Risk factors 2, 6, 7, 8, 10 and 11 are less applicable as HCV is not transmitted as easily as HIV and HBV by sexual routes (21).

5.33 Source is Unknown

- The evaluation should take into consideration risk factors associated with the facility or geographical area where the exposure occurred (e.g., high prevalence of injection drug use). For exposures to needles and sharps when the Source is unknown, testing of the Exposed for HIV is generally not indicated. In contrast to HBV, HIV does not survive long on exposed surfaces. In rare situations, HIV testing and HIV chemoprophylaxis might be undertaken if the Exposed requires reassurance or if there is reasonable suspicion that the abandoned needle or sharp may have been in recent contact with an HIV infected person (12).

5.34 Source is an Infant up to the Age of Six Months

- Consideration may be given to testing the biologic mother as an alternative to testing the infant as antibody testing of infant serum and maternal serum will likely yield identical results unless other risk factors are present in the infant. However, not every baby born to an HIV- and/or HCV-positive mother is positive and infectious for the virus(es), so results need to be interpreted cautiously.
- If there is strong suspicion that the infant is positive for HIV and/or HCV, nucleic acid and/or antigen testing can be performed on the infant's blood. Such situations should be evaluated on a case-by-case basis.
- Testing an infant under the age of six months for HBV (HBsAg) is generally not helpful. If the infant was born to an HBsAg positive mother and received prophylaxis at birth (HBV vaccine plus HBIG), HBsAg may be detectable without the infant being infectious. However, if there is a strong suspicion that the infant is infected with HBV, the infant can be tested for HBV DNA. Results for this test may take 72 hours or longer (see section 9.1 for management).

6. Testing

6.1 Information to be Shared with Client (Source or Exposed)

It is recommended that the following information be shared confidentially with each client, (Source or Exposed), who is undergoing testing for HIV, HBV and/or HCV:

- why the individual requires testing;
- voluntary nature of testing (refer to section 6.2, "Consent" below);
- testing options (refer to section 6.3 below);
- precautions to take to prevent transmission to others;
- when results will be ready;
- how results will be communicated and with whom the results will be shared (refer to section 6.4 "Confidentiality" below);
- what the results mean (e.g., infected, not infected, explain window period only if relevant);
- where the results are documented and stored;
- availability of referral for additional health /social services; and
- adverse reactions to medications if prescribed and immunizations if provided.

NOTE: Where the testing is being done pursuant to an order issued under *The Testing of Bodily Fluids and Disclosure Act* (refer to web2.gov.mb.ca/laws/statutes/2008/c01908e.php# for more information), it is acknowledged that there may be no opportunity for sharing the above information with the client (Source) prior to the blood being drawn. The client served with an order to submit to testing will be encouraged to seek medical advice as soon as reasonably possible after receiving the order and before attending to have the blood drawn. If that is not possible, the Source will be encouraged to seek medical advice after having blood drawn for testing.

6.2 Consent

Except where the testing is being conducted pursuant to an order issued under *The Testing of Bodily Fluids and Disclosure Act*, all testing is voluntary; informed consent must be obtained prior to all testing. Both the Source and the Exposed have the right to refuse any recommended testing for HIV, HBV and HCV. Consent may be collected verbally rather than in writing, but this should be documented. For the Source, consent should include permission to make the test results available to the Exposed. In most situations, the Exposed should not participate in obtaining consent from the Source.

6.3 Testing Options

Nominal[4] testing is the only option for HBV and HCV testing; it is the **preferred** option for HIV testing. Non-nominal[5] testing is available for HIV testing; however, it is not recommended in blood/body fluid exposure situations when provision of PEP is being considered. Anonymous[6] testing is not an option for HIV testing in blood/body fluid exposure situations when provision of PEP is being considered.

6.4 Confidentiality

In any testing situation, confidentiality must be maintained to the extent possible. Where the testing was done pursuant to an order issued under *The Testing of Bodily Fluids and Disclosure Act*, refer to the *Act* (available at: web2.gov.mb.ca/laws/statutes/2008/c01908e.php#) for more information.

6.5 Testing of the Source

When Source testing is indicated based on the nature of the exposure incident (blood/body fluid involved and type of exposure) and Source evaluation, the following testing for HIV, HBV and/or HCV should be performed on the Source.

- HIV antibody
- HBsAg
- Anti-HCV

In addition to referral to the primary health care provider:

- Any Source diagnosed with HIV infection as a result of Source testing should be referred to the Manitoba HIV Program (204-940-6089 or 1-866-449-0165) by the health professional receiving the test results for appropriate counseling and treatment.
- Any Source diagnosed with HBV or HCV as a result of Source testing should be referred to an expert in the field or the Viral Hepatitis Investigative Unit (VHIU at 204-787-3630) by the health professional receiving the test results.

See also the respective protocols for HIV, HBV and HCV in the Manitoba Health and Healthy Living *Communicable Disease Management Protocol Manual* at: www.gov.mb.ca/health/publichealth/cdc/protocol/index.html

6.6 BaselineTesting of the Exposed

Blood for HIV, HBV and/or HCV testing should be drawn before hepatitis B Immune Globulin (HBIG) or HBV immunization is given (4).

Exposed individuals who decline baseline blood testing should not be refused prophylaxis for HBV and/or HIV if the risk assessment concludes it is indicated.

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4 Nominal testing: the test is ordered using the name of the person being tested.

5 Non-nominal testing: the HIV test is ordered using an alpha-numerical code for the person being tested. Only the person ordering the test knows the identity of the person being tested and is able to link the results to that person's health care record.

6 Anonymous testing: the test is ordered using a unique non-identifying code. The person(s) ordering the test and providing the result do not know the identity of the person being tested. Only the person being tested knows the code, so the test result is not linked to that person's health care record.

In addition to referral to the primary health care provider:

- Any exposed person diagnosed with HIV infection as a result of testing should be referred to the Manitoba HIV Program (204-940-6089 or 1-866-449-0165) by the health professional receiving the test results for appropriate counseling and treatment.
- Any exposed person diagnosed with HBV or HCV as a result of testing should be referred to an expert in the field or the Viral Hepatitis Investigative Unit (VHIU at 204-787-3630) by the health professional receiving the test results.

See also the respective protocols for HIV, HBV and HCV in the Manitoba Health and Healthy Living *Communicable Disease Management Protocol Manual* at: www.gov.mb.ca/health/publichealth/cdc/protocol/index.html

6.61 Testing for HIV

When HIV testing is indicated in the Exposed (based on the risk assessment described in section 5), baseline testing for HIV antibody (anti-HIV) should be performed.

6.62 Testing for HBV

The Exposed does not require baseline testing for HBsAg and anti-HBs when (12):

- The Exposed is known to be immune to HBV (immunity must be demonstrated via titre testing).
- The Exposed has previously tested positive for HBsAg.

Baseline testing of the Exposed for HBsAg and anti-HBs is recommended when:

- Previous anti-HBs results are unknown/unavailable (e.g., those with documented 3-dose series immunization but no post-immunization testing);
- Exposed has never received HBV vaccine; or
- The HBV vaccination status is uncertain (e.g., Exposed cannot remember if they were immunized or they did not complete the full 3-dose series).

6.63 Testing for HCV

When HCV testing is indicated in the Exposed (based on the risk assessment described in section 5), baseline testing for HCV antibody (anti-HCV) should be performed.

6.7 Procedures for Laboratory Testing

In Manitoba, all diagnostic testing for human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) is performed at Cadham Provincial Laboratory (CPL) (204-945-6123).

6.71 Testing Schedule and Reporting of Results

- HIV Antibody (anti-HIV) testing: daily Monday to Friday; negative results available within 24-48 hours. Initial positive EIA tests are confirmed by a second (western blot) test. Confirmatory test results are available within seven days. To obtain initial positive EIA test results the ordering health professional must:
  - Phone for results or
  - Clearly request on the requisition that they wish to be contacted (include phone number) when initial positive test results are known
- Hepatitis B surface antigen (HBsAg) and antibody (anti-HBs) testing: daily Monday to Friday: results available within 24-48 hours.
- HCV antibody (anti-HCV) testing: daily Monday to Friday; results available within 24-48 hours.

6.72 Sample Collection

- Samples from the Source and the Exposed should be taken at the same time to facilitate timely intervention if required.
- One tube (10 cc) of blood is required for HIV/HBV/HCV testing if the nominal HIV testing option is chosen. If the non-nominal HIV testing option is chosen, two tubes (10 cc each) of blood are required; one for HIV testing and the other for HBV/HCV testing.
- Requisition numbers should be recorded for future reference. The code used on the non-nominal HIV requisition must be recorded confidentially to facilitate linking results to a specific client.

6.73 Requisitions

- If the nominal HIV testing option has been selected, complete the general CPL requisition, indicating that HIV, HBV and HCV testing is to be performed. CPL will then perform the required battery of tests.
- If the non-nominal HIV testing option has been chosen, complete the *Non-nominal HIV Antibody Laboratory Requisition* for HIV testing AND the general CPL requisition for HBV and HCV testing.
- Label all requisitions NEEDLESTICK or EXPOSURE TO BLOOD/BODY FLUIDS to ensure priority testing. A check-off list to indicate the reason for the follow-up is provided on both requisitions.
- Indicate clearly whether the sample is from the Source or the Exposed and provide the following additional information on the requisitions.
  - Name of person to whom results are to be provided. If arrangements have been made to phone results, include telephone number of person to whom results are to be phoned.
  - Time and type of exposure.
  - HBV vaccination status of Exposed on the Exposed's HBV testing requisition only. The Exposed's information should NOT be documented on the Source's requisition.
- Complete all fields on the requisition to ensure that the sample will be processed and the results reported.

NOTE: The ordering health professional must be cognizant of the need for the follow-up health professional to have access to the test results in a timely manner and should facilitate the process by which this is made possible.

6.74 Urgent or "STAT" Test Requests

- Phone the laboratory (204-945-6123) and ask for the Serology Department:
  - to inform the lab how and when the samples will arrive;
  - to provide the name of the person who is to be notified of the results;
  - to provide the name (or code) of the Source and Exposed; and
  - to ensure that the specimens will receive prompt attention.
- After hours the telephone is answered by the CPL security guard. Ask to speak to the physician on call.
- When phoning for results of urgent tests, please ensure that you provide the requisition numbers as well as the name/code of the client.

See Sections 8, 9 and 10 for follow-up testing recommendations for HIV, HBV and HCV respectively.

7. Implementation of Post-exposure Prophylaxis

The decision to implement PEP will be determined on a case-specific basis, after carefully weighing the potential risks and benefits of providing PEP based on a risk assessment of the exposure incident (section 5) and an evaluation of the Exposed. Testing recommendations for the Exposed based on the risk assessment are found in section 6.6 "Baseline Testing of the Exposed". If the Exposed is known (documented) to be HIV-, HBV- or HCV-positive prior to exposure, post-exposure management for that particular pathogen is not required.

- Occupational situations: Post-exposure prophylaxis should be initiated by the occupational health physician/designate of the institution or organization. If this individual is not available to institute therapy within two to four hours, the emergency room or urgent care facility on-call physician/designate may need to perform this function.
- Non-occupational situations (e.g., sexual assault): Post-exposure prophylaxis can be initiated by the emergency room or on-call physician/designate.
- Follow-up should be provided by the occupational health physician/designate (for health care worker exposures) and appropriate primary health care provider (i.e., primary care clinic, family physician, nurse practitioner, etc.) for community and other occupational exposures.

8. HIV Post-exposure Prophylaxis

8.1 General Considerations

HIV PEP should be initiated within two to four hours of exposure for maximal efficacy. As the time period from exposure to initiation of PEP increases, the likelihood of the virus establishing infection and spreading beyond the local site of inoculation to regional lymph nodes increases, greatly reducing the effectiveness of PEP. However, since there is limited data to indicate if there is a specific time after which PEP is ineffective, consider implementing for up to 72 hours after exposure (12).

Baseline and follow-up testing of the Exposed is recommended in situations where risk assessment of the exposure incident has concluded that HIV PEP is indicated, but a decision has been made not to initiate HIV PEP (e.g., elapsed time considered too long, patient declines).

A risk assessment (see section 5 above) should be completed in order to determine prophylaxis category. However, no laboratory evaluation (i.e., baseline testing) is required prior to initiation of HIV PEP.

To make fully informed decisions regarding HIV PEP, it is recommended that women of childbearing age who may be pregnant (e.g., those trying to become pregnant) undergo pregnancy testing prior to initiating HIV PEP.

HIV PEP recommendations based on the risk assessment are described in Table 4 below.

If HIV PEP was appropriate but not initiated for the Exposed at the time of exposure and the Source is subsequently discovered to be HIV positive, HIV PEP should be started as soon as possible if the exposure occurred less than 72[7] hours prior. In this case, HIV PEP should be initiated upon receipt of the first positive HIV antibody screening test, before confirmatory test results are available (12).

If the Exposed has begun an HIV PEP regimen and the Source is later determined to be HIV-negative, HIV PEP should be discontinued, regardless of the number of days of prophylaxis completed (11). In these situations, it should be emphasized to the Exposed that there is no benefit to completing the medications(s) in the starter kit. Continuation of chemoprophylaxis might be considered in rare instances where there is realistic concern that the Source is in the window period of infection (seroconversion phase).

Consultation with a specialist in HIV medicine or infectious diseases is recommended for the situations listed below. If expert consultation is not immediately available and risk assessment concludes that post-exposure prophylaxis is indicated, the Exposed should be started on the Basic PEP regimen. If deemed necessary upon expert consultation, the regimen can be changed to the Expanded regimen.

- Any time that an Expanded PEP regimen is being considered.
- Known or suspected pregnancy or lactation in the Exposed.
- Delayed presentation by the Exposed to a health care provider (i.e., > 72 hours) for the initial assessment.
- Exposed is immunocompromised.
- Known or suspected resistance of the Source virus to antiretroviral agents.
- Toxicity of the initial PEP regimen.

If the Exposed has had a traumatic exposure (e.g., sexual assault) and has declined HIV PEP, they should be offered the opportunity to return (i.e., within 72 hours of the exposure) for further evaluation.

Exposures in children: For exposures where HIV PEP is being considered, consultation with a pediatric infectious disease specialist (204-787-2071) is recommended. However, there should not be a delay in the administration of Basic PEP.

7 For exposures occurring greater than 72 hours prior to presentation to a health care provider, consultation with a specialist in HIV medicine or infectious diseases should be sought.

Table 4. Recommended HIV Post-exposure Prophylaxis (PEP) (4, 11, 12, 17)

Exposure Type	Condition	Recommendation based on HIV Status of Source		
		HIV Positive, Class 1[8]	HIV Positive, Class 2[9]	HIV Status Unknown or Unknown Source
Percutaneous Exposures (including human bites, i.e., person bitten)	Less Severe[10]	Basic PEP	Expanded PEP	Generally no PEP[11]
	More Severe[12]	Expanded PEP	Expanded PEP	Consider Basic PEP
Mucous membrane and Non-intact Skin Exposures (including human bites, i.e., biter)	Small Volume[13]	Consider Basic PEP	Basic PEP	Generally no PEP
	Large Volume[14]	Basic PEP	Expanded PEP	Consider Basic PEP
Needle-sharing (e.g., IDU equipment)	Refer to Percutaneous Exposures category above. An injection drug user who routinely shares IDU equipment is unlikely to present for PEP unless they are planning to change IDU practice.			
Community Exposures to Abandoned Needles/Sharps	Less Severe[10]	Not applicable	Not Applicable	Generally no PEP[11]
	More Severe[12]	Not Applicable	Not Applicable	Generally no PEP[11]
Consensual Sex (serodiscordant partners)	Receptive anal/ vaginal sex or oral receipt of semen, vaginal fluid or blood	Basic PEP	Expanded PEP	Not Applicable (see Sexual Assault)
	Other sexual exposures	Generally no PEP[15]		Not Applicable (see Sexual Assault)
Sexual Assault	Receptive anal/ vaginal sex or oral receipt of semen, vaginal fluid or blood	Basic PEP	Expanded PEP	Consider Basic PEP
	Other sexual exposures	Generally no PEP[15]		Generally no PEP

NOTE: The recommendation "consider Basic PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the Exposed and the treating clinician regarding the risks versus benefits of PEP.

8 HIV-Positive Class 1: Asymptomatic HIV infection or known low viral load (e.g., < 1,500 ribonucleic acid copies/mL)(11). Refer to section 5.31 for additional Source information to obtain (11).

9 HIV-Positive Class 2: Symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load (≥ 1,500 ribonucleic acid copies/mL) (11). Refer to section 5.31 for additional Source information to obtain.

10 A percutaneous exposure that has none of the characteristics associated with a more severe exposure (e.g., superficial injury, no visible blood present on device associated with exposure incident, needle was not placed directly into the Source's vein or artery, solid needle was used).

11 Basic PEP should be considered only if Source has risk factors (i.e., Source is known, but status unknown) or HIV prevalence in the facility/community where the exposure occurred is high (i.e., Source is unknown).

12 A percutaneous injury characterized by one or more of the following: deep percutaneous injury, visible blood present on device associated with the exposure, exposure from a procedure which involved a needle placed directly into the Source's vein or artery, large bore hollow needle.

13 Exposures involving lesser amounts (e.g., only a few drops of blood and/or body fluid)

14 A major splash of blood and/or body fluids.

15 Basic PEP should be considered only if genital/rectal trauma/bleeding have occurred.

For HIV PEP Regimens, refer to Appendix B.

8.2 HIV Post-exposure Prophylaxis Follow-up:

Follow-up testing and medical evaluation should be provided for all Exposed who are started on HIV PEP.

8.21 HIV Testing

- Follow-up testing of the Exposed for HIV (if previous tests are negative) is recommended at:
  - baseline (if not previously performed);
  - six weeks to three months post-exposure; and
  - six months post-exposure.
- Follow-up testing at 12 months may be undertaken in rare instances when it is felt that HIV seroconversion may be delayed.
- The Exposed should be referred to the Manitoba HIV Program (204-940-6089 or 1-866-449-0165) in addition to their primary health care provider if they test positive at any time.
- If the Source tests negative, follow-up HIV testing of the Exposed is generally not necessary, but might be considered if there is concern about the Source being in the window period of infection (usually two weeks to three months, but may be longer in immunocompromised persons).
- Follow-up testing of the Exposed (as detailed above) should also be considered if a Source with known HIV risk factors refused testing and risk assessment of the exposure incident indicated that transmission was possible.
- Follow-up testing of the Exposed (as detailed above) may be considered if the identity of the Source was unknown.

8.22 Medical Evaluation

- If HIV chemoprophylaxis is continued for the full 28-day course, drug toxicity monitoring at baseline and at two weeks after starting chemoprophylaxis should be performed (12).
- Monitoring should include a complete blood count and hepatic chemical function tests (i.e., total bilirubin, AST, ALT, alkaline phosphatase) and any other tests as deemed necessary (12).
- If toxicity is noted (i.e., hemoglobin < 80 mg/l, three-fold increase in liver function tests, neutropenia < 1000/mm^3), dose reduction or dose substitution should be considered, after consultation with a specialist in HIV medicine (12).

8.23 Discontinuing Post-exposure Prophylaxis

If the Exposed has begun chemoprophylaxis and the Source subsequently tests negative, chemoprophylaxis should be discontinued. In these situations, it should be emphasized to the Exposed that there is no benefit to completing the medication(s) in the starter kit. Continuation of chemoprophylaxis might be considered in rare instances where there is concern about the Source being in the window period of infection (seroconversion phase).

9. Hepatitis B Post-exposure Prophylaxis

The post-exposure prophylaxis recommendations in Tables 10A and 10B below are intended for the Exposed, when both the type of body fluid (e.g., blood) and the exposure type (e.g., more severe percutaneous) as detailed in sections 5.1 and 5.2 are of concern for consideration of HBV PEP. Recommendations for the administration of hepatitis B vaccine and hepatitis B immune globulin (HBIG) vary according to the status of both the Source and the Exposed. Expert consultation should be sought when the Exposed is immunocompromised.

9.1 General Considerations

- When anti-HBs testing of the Exposed is indicated it should be performed as soon as possible to avoid needless administration of HBIG and since HBIG efficacy is unknown if given after seven days (3). With sexual exposures, HBIG benefit has been demonstrated up to 14 days after exposure (3). If test results of the Exposed and the Source are not available within 48 hours, management of the Exposed should assume possible exposure to an HBV-positive Source (3).

- The blood for HBsAg and anti-HBs testing of the Exposed should be drawn before the first dose of HBV vaccine and/or hepatitis B Immune Globulin (HBIG) is given (4).
- Initiation or continuation of HBV immunoprophylaxis (HBIG and/or HBV vaccine) in the Exposed is not required when the following test results are received:
  - Exposed tests HBsAg positive.
  - Exposed tests anti-HBs positive.
  - Source tests HBsAg negative (unless there is reason to believe that the Source might be in the three to six month window period). Immunoprophylaxis may be initiated or continued in the Exposed if the Exposed desires protection against possible future exposures.
- Clients testing HBsAg positive (Source and/or Exposed) are infected and should be referred to an expert in the field or the Viral Hepatitis Investigative Unit (VHIU) (204-787-3630) in addition to their primary health care provider. See also Hepatitis B protocol in the Manitoba Health and Healthy Living Communicable Disease Management Protocol Manual at: www.gov.mb.ca/health/publichealth/cdc/protocol/index.html
- When indicated (refer to Tables 10A and 10B below), HBIG should be given as soon as possible, ideally within 48 hours as efficacy decreases sharply thereafter (3). HBIG and HBV vaccine may be given at the same time but at different sites (3).
- The dose of Hepatitis B vaccine is brand- and age-dependent. Refer to Appendix C for the preferred vaccine schedule as well as instructions on how to obtain HBV vaccine and HBIG.
- When HBIG is given, determination of the anti-HBs titre should be delayed for six months to allow HBIG antibodies to wane (3).
- The following definitions apply to Tables 10A and 10B below.
  - **Responder (Anti-HBs Positive):** an individual who has an anti-HBs titre of ≥ 10 IU/L. The individual is considered immune to HBV.
  - **Non-responder:** An individual who has an anti-HBs titre of < 10 IU/L. The individual is considered susceptible to HBV.
- Tables 10A and 10B have been adapted from the 2006 edition of the *Canadian Immunization Guide*.

Table 10A: Recommended Hepatitis B PEP – HBsAg-Positive Source OR Source Status Unknown with Identified Risk Factors*

Vaccination Status of the Exposed	Recommended Action for the Exposed		
Unvaccinated	Test for anti-HBs, give HBIG x 1 and first of 3-dose vaccine series.	Responder	Consider immune, no action required.
		Non-responder	1. Complete vaccine series. 2. Test for anti-HBs 1-6 months after completion of vaccine series.
Vaccinated: Responder to 3-dose series	No prophylaxis required.		
Vaccinated: Non-responder to 3 dose series	1. Give HBIG+ and 2nd 3-dose vaccine series. 2. Test for anti-HBs 1-6 months after vaccine series is completed.		
Vaccinated: Non-responder to 2 x 3-dose series	1. Give HBIG+ x 2. The 2nd dose can be given 1 month after the first.		
Vaccinated: Unknown Response to 1 dose of 3-dose series	1. Test for anti-HBs (does not change vaccine schedule but may reassure Exposed about immediate risk of becoming infected), give HBIG+& x 1 and 2nd vaccine dose. 2. Complete vaccine series. 3. Test for anti-HBs 1-6 months after series is completed.		
Vaccinated: Unknown Response to 2 doses of 3-dose series	Test for anti-HBs and give 3rd vaccine dose	Responder	Consider immune, no action required.
		Non-responder	1. Give HBIG+ x 1. 2. Test for anti-HBs 6 months later. 3. If still non-responder, complete 2nd 3-dose vaccine series. 4. Test for anti-HBs 1-6 months after completing the 2nd 3-dose vaccine series.
		Unknown anti-HBs after 48 hours	1. Give HBIG+ x 1. 2. When anti-HBs result is known; if responder, consider immune; if non-responder, test for anti-HBs 6 months later. 3. If still non-responder, complete 2nd 3-dose vaccine series and test for anti-HBs 1-6 months later.
Vaccinated: Unknown Response to 3-dose series	Test for anti-HBs.	Responder	Consider immune, no action required.
		Non-responder	1. Give 1st dose of second series and HBIG.+ 2. Test for anti-HBs 6 months later. 3. If still non-responder, complete 2nd 3-dose vaccine series and test for anti-HBs 1-6 months later.
		Unknown anti-HBs after 48 hours	1. Give 1st dose of second series. 2. When anti-HBs result known: if responder, consider immune; if negative, give HBIG+ and test for anti-HBs 6 months later. 3. If still non-responder, complete 2nd 3-dose vaccine series and test for anti-HBs 1-6 months later.

* Risk factors for the Source include: if the Source comes from a highly endemic region for HBV [Africa, Southeast Asia, China, Hong Kong, Mongolia, North and South Korea, Taiwan, South Pacific (excluding Australia, Guam and New Zealand), Middle East (Jordan and Saudi Arabia), Eastern Europe and Northern Asia, Western Europe (Malta and indigenous populations in Greenland), Alaska Natives, Amazonian areas of Bolivia, Brazil, Colombia, Peru and Venezuela, and Turks and Caicos in the Caribbean (CDC 2006)] or person of Inuit descent; has sexual relations with multiple partners; has a partner infected with HBV or at high risk of being so; is in close family contact with an infected person; uses injection drugs or received blood products prior to 1970. If the Source is unknown, background circumstances may provide some indication of degree of risk (e.g., syringe found in an area where injection drug use is prevalent).

\+ HBIG can be omitted if Source can be tested within 48 hours and is found to be HBsAg-negative; in that case follow Table 10B.

& If it is possible to quickly obtain an anti-HBs-positive titre in the Exposed, HBIG can be omitted.

Table 10B: Recommended Hepatitis B PEP – Source HBsAg Status Unknown and no Identified Risk Factors*

Vaccination Status of the Exposed	Recommended Action for the Exposed		
Unvaccinated	1. Vaccinate with 3 dose vaccine series. 2. Test for anti-HBs 1-6 months after completion.		
Vaccinated: Responder to 3-dose series	No action required.		
Vaccinated: Non-responder to 3-dose series	1. Give 2nd 3-dose vaccine series. 2. Test for anti-HBs 1-6 months after vaccine series is completed.		
Vaccinated: Non-responder to 2 x 3-dose series	No action required.		
Vaccinated: Unknown response to 1 or 2 doses of 3-dose series	1. Complete vaccination according to schedule. 2. Test for anti-HBs 1-6 months after completion of vaccine series.		
Vaccinated: Unknown response to 3-dose series	Test for anti-HBs	Responder	Consider immune, no action required.
		Non-responder	1. Give 1 vaccine booster. 2. Test for anti-HBs 1 month later. 3. If still non-responder, complete 2nd course of vaccine and test for anti-HBs 1-6 months after completion of 2nd series.

* Risk factors for the Source include: if the Source comes from a highly endemic region for HBV [(Africa, Southeast Asia, China, Hong Kong, Mongolia, North and South Korea, Taiwan, South Pacific (excluding Australia, Guam and New Zealand), Middle East (Jordan and Saudi Arabia), Eastern Europe and Northern Asia, Western Europe (Malta and indigenous populations in Greenland), Alaska Natives, Amazonian areas of Bolivia, Brazil, Colombia, Peru and Venezuela, and Turks and Caicos in the Caribbean (CDC 2006)] or person of Inuit descent; has sexual relations with multiple partners; has a partner infected with HBV or at high risk of being so; is in close family contact with an infected person; uses injection drugs or received blood products prior to 1970. If the Source is unknown, background circumstances may provide some indication of degree of risk (e.g., syringe found in an area where injection drug use is prevalent).

9.2 Follow-up Testing

Refer to Tables 10A and 10B for follow-up testing recommendations.

9.3 Pediatric Bite Recommendations

Refer to Tables 10A and 10B with the exception that: In child care settings, immune status testing is generally not indicated for children of unknown immune status due to the low prevalence of HBV infection in this population in Canada (14).

Follow-up: Follow-up should be arranged to complete HBV vaccine series as needed, and for HBV serology at six months after known HBV exposures (14).

See Appendix C for acquisition and administration of HBV vaccine and HBIG.

10. Hepatitis C Post-exposure Management

There is no known effective chemoprophylaxis or immunoprophylaxis for individuals exposed to an HCV-positive source. However, post-exposure testing, information sharing and medical follow-up may be indicated. See Table 11 below for initial and follow-up testing recommendations.

If the Exposed becomes infected with HCV, he/she should be referred to an expert in the field or the Viral Hepatitis Investigative Unit (VHIU) (204-787-3630) in addition to their primary health care provider, for further evaluation and treatment, if indicated.

Table 11: Recommended Hepatitis C Post-exposure Management (2, 4, 12)

Status of Source	Recommended Action for the Exposed
Source is HCV Antibody Negative	Generally no further action is required, unless the Source is an injection drug user and there is reason to suspect that he/she may have been infected recently, and not yet produced sufficient antibody to test positive (i.e., Source is in the 3-3 1/2 month window period). In this case, see "Source is HCV Antibody Positive".
Source is HCV Antibody Positive	1. Test Exposed for anti-HCV at time of exposure. If negative, test for HCV-RNA at 3 months post-exposure and anti-HCV at 6 months post-exposure. NOTE: The Exposed should be educated about possible symptoms of acute hepatitis C (e.g., fatigue, anorexia, nausea and vomiting, jaundice, vague abdominal discomfort). The Exposed should be advised to return to their primary health care provider for possible earlier follow-up testing and referral to the VHIU should symptoms occur. 2. If Exposed tests positive for either marker, at any time, refer to VHIU (204-787-3630) for evaluation in addition to primary health care provider.
Source Status is Unknown (i.e., unknown Source or Source not available for testing)	1. Test Exposed for anti-HCV at time of exposure. If negative, test for anti-HCV at 6 months post-exposure. 2. If the Exposed tests anti-HCV positive at any time, refer to VHIU (204-787-3630) for evaluation in addition to primary health care provider.

11. References

1. International Labour Organization and World Health Organization. Joint ILO/WHO guidelines on health services and HIV/AIDS, 2005.
2. Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR Morb Mortal Wkly Rep* 2001; 50 (RR-11): 1-52.
3. Public Health Agency of Canada. *Canadian Immunization Guide 7th ed*. 2006; 189-208.
4. Public Health Agency of Canada. An Integrated Protocol to Manage Health Care Workers Exposed to Bloodborne Pathogens. *Canada Communicable Disease Report* 1997; 23S2.
5. UK Chief Medical Officers' Expert Advisory Group on AIDS, Department of Health. HIV Post-Exposure Prophylaxis February 2004; 1-40.
6. Nonoccupational HIV PEP Task Force, Brown University AIDS program and the Rhode Island Department of Health. Nonoccupational Human Immunodeficiency Virus Postexposure Prophylaxis Guidelines for Rhode Island Healthcare Practitioners August 2002.
7. Federal Bureau of Prisons Clinical Practice Guideline. Medical Management of Exposures: HIV, HBV, HCV, Human Bites and Sexual Assaults May 2007.
8. Manitoba Health. Emergency Treatment Guidelines: Sexual Assault, May 2006.
9. Saskatchewan Subcommittee on HIV/AIDS, Saskatchewan Health. Guidelines for the Management of Potential Exposures to Hepatitis B, Hepatitis C, HIV and Recommendations for Post-Exposure Prophylaxis, January 2004.
10. Communicable Disease Control, BC Centre for Disease Control. Blood and Body Fluid Exposure Management May 2005; 1-26.
11. Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. *MMWR Morb Mortal Wkly Rep* 2005; 54 (RR-9) 1-17.

12. Manitoba Health. Integrated Post-Exposure Protocol: Guidelines for Managing Exposures to Blood/Body Fluids, November 2003.

13. New York State Department of Health AIDS Institute. HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault 2005.

14. Canadian Paediatric Society. Position Statement (ID 2008-04): A bite in the playroom: Managing human bites in child care settings. *Paediatr Child Health* 2008; 13 (6): 515-519.

15. American Academy of Pediatrics. Injuries from Discarded Needles in the Community. In: Pickering LK ed. *Redbook: 2006 Report of the Committee on Infectious Diseases 27th ed*. Elk Grove Village, IL: American Academy of Pediatrics, 2006; 188-191.

16. Wiebe Ellen R, Comay Susan E, McGregor Margaret and Ducceschi Sylvia. Offering HIV prophylaxis to people who have been sexually assaulted: 16 months' experience in a sexual assault service. *Canadian Medical Association Journal* 2000; 162 (5): 641-645.

17. Centers for Disease Control and Prevention. Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States, Recommendations from the U.S. Department of Health and Human Services. *MMWR Morb Mortal Wkly Rep* 2005; 54 (RR-2): 1-19.

18. San Francisco Department of Public Health, The California HIV PEP after Sexual Assault Task Force and The California State Office of AIDS. Offering HIV Prophylaxis Following Sexual Assault: Recommendations for the State of California, 2001.

19. Bamberger Joshua D, Waldo Craig R, Gerberding Julie Louise and Katz Mitchell H. Postexposure Prophylaxis for Human Immunodeficiency Virus (HIV) Infection following Sexual Assault. *The American Journal of Medicine* 1999; 106: 323-326.

20. Callum JL and Pinkerton PH. Bloody Easy 2, Blood Transfusions, Blood Alternatives and Transfusion Reactions: A Guide to Transfusion Medicine, Second Edition 2005, Public Health Agency of Canada.

21. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2006 with April 2007 updates. *MMWR Morb Mortal Wkly Rep* 2006; 55 No. RR-11.

Appendix A: Information Record: HIV Post-exposure Prophylaxis

Information Record:
HIV Post-exposure Prophylaxis

Manitoba Health and Healthy Living

Complete this form for EACH individual receiving Post-exposure Prophylaxis (PEP) for HIV.
PLEASE PRINT CLEARLY

Exposed Name OR HIV Non-nominal Code: _____

Provider Name: _____ Phone: _____

Health Facility: _____

RHA: _____ Date of Exposure (yyyy/mm/dd): _____

1. Describe the Exposure: _____

2. Exposure:
   - ☐ Occupational ☐ Non-occupational

3. Exposure Type:
   - ☐ Percutaneous (e.g., needlestick)
   - ☐ Mucous membrane (e.g., splash to eyes, oral cavity, etc.)
   - ☐ Non-intact skin (e.g., splash to open wound)
   - ☐ Needle-sharing (e.g., injection drug use)
   - ☐ Other: _____
   - ☐ Abandoned needle or sharp
   - ☐ Sexual assault
   - ☐ Unprotected sex
   - ☐ Human bite

4. Number of **hours** between exposure and initiation of chemoprophylaxis:
   - ☐ 0 – 2 ☐ 2 – 4 ☐ 4 – 12 ☐ 12 – 24 ☐ 24 – 48 ☐ 48 – 72
   - ☐ Other: _____days

5. HIV status of Source:
   - ☐ Positive ☐ Negative ☐ Unknown (e.g., source identity unknown or source unavailable for testing)

6. Type of kit prescribed:
   - ☐ Adult Basic
   - ☐ Adult Expanded (Basic kit + lopinavir/ritonavir (Kaletra®)
   - ☐ Pediatric Basic
   - Pediatric Expanded
     - ☐ Basic kit + lopinavir/ritonavir (Kaletra®)
     - ☐ Basic kit + nelfinavir (Viracept®)

7. If pediatric kit prescribed, was an ID specialist consulted? ☐ Yes ☐ No

8. Was the exposed referred for follow-up?
   - ☐ Yes ☐ No

9. If yes, exposed referred to:
   - ☐ Occupational health
   - ☐ ID specialist
   - ☐ Primary care
   - ☐ Family physician
   - ☐ Public health

Turn over to page 2

If person completing page 1 of this form is not going to provide follow-up care, please forward this form with the patient referral to follow-up care provider.

Completed by follow-up care provider: *PLEASE PRINT CLEARLY*

Exposed Name OR HIV Non-nominal Code: _____

Provider Name: _____ Phone: _____

Health Facility: _____

RHA: _____ Date of Visit (yyyy/mm/dd): _____

10. Exposed completed all drugs in starter kit(s)?
    - ☐ Yes
    - ☐ No
    - ☐ Unknown

    If no, number of days of therapy completed: ☐ 1 ☐ 2 ☐ 3 ☐ 4

11. If no to above, exposed stopped drugs because:
    - ☐ Source tested negative for HIV
    - ☐ Unable to tolerate medication
    - ☐ Other, please specify _____

12. Was the Exposed advised to complete the full 28 days of therapy? ☐ Yes ☐ No

    If yes, why?
    - ☐ Source HIV positive
    - ☐ Source HIV negative, but concerned about window period
    - ☐ HIV status of source unknown; source judged to be high risk for HIV

13. Exposed completed the full 28 days of prophylactic therapy? ☐ Yes ☐ No

    If no, why not:
    - ☐ Unable to tolerate meds
    - ☐ Other_____

14. If No, exposed completed ____ days of therapy

Follow-Up Care Provider – please return the completed form to:

STI/BBP Program Specialist
CDC Branch, Public Health Division
Manitoba Health and Healthy Living
4th Floor – 300 Carlton Street
Winnipeg, MB R3B 3M9

Secure Fax: 204-948-3044

Appendix B: HIV PEP Regimens

At the time of publication, the Basic and Expanded HIV PEP regimens for adults and children (Tables 1 and 2 below) consist of a 28-day course of the following highly active antiretroviral drugs. The HIV PEP regimens consist of a combination of two, three or four medications. Due to the increased prevalence of HIV resistance, antiviral monotherapy (e.g., zidovudine alone) is not recommended for HIV post-exposure prophylaxis.

Table 1: Adult PEP Regimen

Basic PEP	
Zidovudine/lamivudine (Combivir®) 1 tablet orally twice a day x 28 days	Supplied as zidovudine 300 mg plus lamivudine 150 mg tablet
Expanded PEP (Administer in addition to the Basic regimen)	
Lopinavir/ritonavir (Kaletra®) 2 tablets orally twice a day x 28 days	Supplied as lopinavir 200 mg plus ritonavir 50 mg tablet

Table 2: Pediatric PEP Regimens

Basic PEP	
< 50 kg	Zidovudine 10 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 100 mg capsule or 10 mg/mL oral solution AND Lamivudine 8 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 150 mg tablet or 10 mg/mL oral solution
≥ 50 kg Replace above with:	Zidovudine/lamivudine (Combivir®) 1 tablet orally twice a day x 28 days Supplied as zidovudine 300 mg plus lamivudine 150 mg tablet
Expanded PEP (Administer in addition to the Basic regimen)	
< 30 kg	Nelfinavir (Viracept®) 100 mg/kg/24h orally divided into 2 doses per day x 28 days Supplied as 250 mg tablet (may be split, crushed or dissolved)
30 -49 kg	Lopinavir/ritonavir (Kaletra®) 100 mg/25 mg tablet 600 mg (lopinavir)/m^2 /24h orally divided into 2 doses a day x 28 days[16] Supplied as lopinavir 100 mg plus ritonavir 25 mg tablet
≥ 50 kg	Lopinavir/ritonavir (Kaletra®) 200 mg/50 mg 2 tablets orally twice a day x 28 days Supplied as lopinavir 200 mg plus ritonavir 50 mg tablet

- The chemoprophylactic regimen chosen for HIV post-exposure prophylaxis is stratified on the basis of severity of the exposure and likelihood of a resistant virus (refer to section 5).
- For a less severe exposure and where drug resistance is unlikely, the Basic PEP regimen consisting of zidovudine/lamivudine (Combivir®) is recommended.
- For a more severe exposure and where resistance is a consideration, an Expanded regimen with a boosted protease inhibitor (lopinavir and ritonavir) (Kaletra®) is added to the Basic regimen.

16 Use nelfinavir (Viracept®) in children unable to swallow the lopinavir/ritonavir (Kaletra®) tablet intact (i.e., without chewing or crushing).

- A three or four drug highly active antiretroviral therapy (HAART) regimen may provide the best chance of preventing infection in a person who has a significant potential HIV exposure, but there is no published evidence that it is more effective than a two drug regimen. Clinicians should consider using a two drug regimen (i.e., zidovudine and lamivudine) (Combivir®) if they have concerns regarding adherence and toxicity (refer to Education section below) with using a three or four drug HAART regimen.
- For pediatric clients, there are two choices for the Expanded Regimen: the boosted protease inhibitor (lopinavir and ritonavir) (Kaletra®), or the protease inhibitor, nelfinavir (Viracept®). There is insufficient evidence to conclude that either option is superior for PEP in the pediatric population. The choice is based on the client's ability (based on age and neurologic development) to swallow and tolerate an intact, solid dosage form. The lopinavir/ritonavir (Kaletra®) tablet is large and hard. It should not be cut, crushed or broken. If the coating is broken, the taste of the medication may be intolerable. The nelfinavir (Viracept®) tablet is easily cut, crushed or dissolved, and may be mixed with non-acidic foods or beverages to facilitate administration even in infants and young children.
- In select situations where the HIV status of the Source is known and the virus is resistant to the agents in the recommended regimens specified above, alternate post-exposure prophylaxis regimens may be considered. The decision should be made in consultation with a health professional with expertise in the management of HIV infection.
- The need for compliance with the HIV PEP regimen chosen should be emphasized to the Exposed or the parent/guardian in cases where the Exposed is a minor.

Availability of HIV PEP Regimens

Five-day Basic and Expanded starter kits are provided by Manitoba Health and Healthy Living (MHHL) to depots throughout the province. Depots (primarily hospital emergency departments) refer to all facilities where HIV PEP kits may be obtained. Distribution depots refer to selected depots that are responsible for ordering the HIV PEP kits directly from the vendor and distributing them to other depots. A listing of current HIV PEP kit depots is available at: www.gov.mb.ca/health/publichealth/cdc/pepdepot.html

- The starter kits are provided to the depots at no cost (including delivery) through the MHHL pharmaceutical vendor. The current vendor is Taché Pharmacy in Winnipeg.
- The starter kit is supplied at no charge to the client.
- Distribution depots may order replacement starter kits for used or expired product from Taché Pharmacy using the MHHL HIV Post-exposure Prophylaxis Drug Order Form available at: www.gov.mb.ca/health/publichealth/cdc/protocol/pep.pdf or through Materials Distribution Agency at 204-945-0570 or 204-945-3000. Facilities requesting replacement kits must complete all information requested on the MHHL HIV Post-exposure Prophylaxis Order Form in order to obtain replacement kits.
- Once Source HIV test results are available, a decision regarding the need to continue or discontinue HIV PEP must be made. If HIV PEP is to be continued for the full 28 day course, the additional drug supply [(in addition to those provided in the starter kit(s)] shall be prescribed by a physician or other authorized health professional. The prescription can be dispensed by the community pharmacy of the Exposed's choice or the parent/guardian's choice (when the Exposed is a minor).
- MHHL will not assume the cost of the additional drugs. It will be the responsibility of the client to cover the cost of the additional drugs unless other sources of funding are available to the client (e.g., personal insurance plan). Occupational exposures may qualify for funding through the employer, through the Workers Compensation Board or possibly through a personal health insurance plan. For clients eligible for support through Manitoba Social Assistance or the First Nations Non-insured Health Benefits Plan, medication costs may be submitted to those plans. Manitoba Pharmacare coverage may be available for the additional drug costs required in non-occupational exposures and possibly in those occupational exposures where the cost is not covered by the employer or the Workers Compensation Board.

Table 3: Adult HIV PEP Starter Kits

Basic Kit	Zidovudine/lamivudine (Combivir®) tablets	10
Expanded Kit	Lopinavir/ritonavir (Kaletra®) 200 mg/50 mg tablets (dispense with ONE adult Basic kit)	20

Table 4: Pediatric HIV PEP Starter Kits

Basic LIQUID Kit	Zidovudine (Retrovir®) 10 mg/mL solution Lamivudine (3TC®) 10 mg/mL solution	160 mL 120 mL
Basic SOLID Kit	Zidovudine (Retrovir®) capsules or Apo-Zidovudine 100 mg capsules Lamivudine (3TC®) 150 mg tablets	20 10
Nelfinavir (Viracept®) Expanded Kit	Nelfinavir (Viracept®) 250 mg tablet (dispense with ONE pediatric Basic LIQUID or SOLID kit)	70
Lopinavir/ritonavir (Kaletra®) Expanded Kit	Lopinavir/ritonavir (Kaletra®) 100 mg/25 mg tablet (dispense with ONE pediatric Basic LIQUID or SOLID Kit)	40

Education for the Exposed About Compliance, Potential Adverse Effects, Cautions and Contraindications to HIV PEP Medications

The Exposed or, the parent/guardian of the Exposed (when the Exposed is a minor) should be informed of the following points.

General Points:

- In Canada, a 28 day course of antiviral drug prophylaxis is recommended in cases of potential HIV exposure.
- Information about the efficacy and toxicity of HIV chemoprophylaxis for PEP is limited, especially in the pediatric population. However, best practice is to offer chemoprophylaxis to individuals following occupational and non-occupational HIV exposure.
- Taking the multiple medications required for PEP, especially the Expanded regimen, may be difficult. Problems with tolerance, adherence, cost and other factors limit the proportion of clients who finish the PEP regimen.
- The Exposed or the parent/guardian of the Exposed (when the Exposed is a minor) should be provided with information about the potential adverse effects of the anti-retroviral therapy, and tips for improving tolerance (managing adverse effects; see below) and easing administration.

Compliance:

- The Exposed, or parent/guardian (when the Exposed is a minor), may decline or discontinue treatment at any time; however, it is recommended that the entire 28 day course of chemoprophylaxis be completed, unless otherwise directed by a physician.
- Education about compliance with the regimen must be emphasized and the health professional should provide ongoing encouragement and support for the Exposed and his/her family.

Potential Adverse Effects:

- The antiviral medications produce a number of common, non-serious adverse effects (refer to Table 5 below) that may be troubling to the Exposed and contribute to non-compliance with the HIV PEP regimen. The most common adverse effects are gastrointestinal (e.g., nausea, diarrhea, dyspepsia) or constitutional (e.g., fatigue, malaise, muscle aches). These adverse

effects may be significant. The Exposed or parent/guardian (when the Exposed is a minor) should be reassured that all of the common adverse effects will resolve when the medications are discontinued. Most of the adverse effects decrease over the initial week of therapy. These adverse effects are not a reason to discontinue the regimen. If necessary, medications to manage the adverse effects may be recommended.

- Case series and compliance studies report a higher incidence of adverse effects to the antiviral medications in PEP clients compared to clients treated for HIV infection. Some researchers attribute the difference in the reported incidence of adverse effects to anxiety associated with the fear of HIV infection.
- The use of analgesic (e.g., acetaminophen), antiemetic or anti-motility agents may improve compliance by controlling common adverse effects from the HAART medications.

TABLE 5: Antiretroviral Medication Adverse Effects

Drug	Common, Non-serious Adverse Effects	Significant Adverse Effects
zidovudine (AZT, Retrovir®, Apo-Zidovudine)	nausea, headache, muscle aches, insomnia	bone marrow suppression, anemia, neutropenia, pancreatitis (especially in children)
zidovudine/lamivudine (Combivir®)	refer to zidovudine and lamivudine	
lamivudine (3TC)	fatigue, headache, nausea, vomiting, diarrhea weakness	
lopinavir/ritonavir (Kaletra®)	diarrhea (mild to moderate), nausea, vomiting	hepatic dysfunction, elevated blood sugar, lipid abnormalities, pancreatitis
nelfinavir (Viracept®)	diarrhea (mild to moderate), nausea dyspepsia (upset stomach)	rash, leukopenia

Cautions:

- Pancreatitis
- Bone marrow suppression
- Renal dysfunction (S_{CR} > 3 x normal)
- Hepatic dysfunction
- Drug interactions – if patient takes other medications, check with a pharmacist before initiating the Expanded regimen. Caution may need to be exercised in co-administering multiple potentially hepatotoxic medications, but occasional use of acetaminophen, for example should not be problematic.
- The Expanded regimen should be prescribed with caution and additional monitoring in persons treated with other myelosuppressive, nephrotoxic or hepatotoxic drugs in the two weeks prior to initiation of PEP therapy.
- **In Pregnancy/Lactation:**
  - Assess benefit versus risk.
  - With the exception of zidovudine, information on the use of antiretroviral agents in pregnancy is limited. Zidovudine, lamivudine, lopinavir and ritonavir have been used in the first, second and third trimesters of pregnancy. Based on case reports, the prevalence of fetal malformations is not different than expected from an untreated population. There are no randomized, placebo-controlled trials of antiretroviral medications in various stages of pregnancy.
  - When the Exposed is known to be pregnant at the time of exposure, an infectious disease specialist should be consulted before

prescribing antiretroviral medications. As a caution, all women of child-bearing age should be counseled to avoid pregnancy while on the PEP regimen.

Contraindications:

- Allergy to the medication or ingredients.
- Co-administration of lopinavir/ritonavir (Kaletra®) or nelfinavir (Viracept®) with the following medications: Refer to Table 6 below.

Table 6: Co-administration of Lopinavir/ritonavir (Kaletra®) or Nelfinavir (Viracept®) with Other Medications

Medication	Reaction
Ergot derivatives (e.g., ergonovine, Cafergot®, Bellergal® Spacetabs)	acute ergot toxicity (e.g., nausea, vomiting, diarrhea, vasospastic ischemia)
fentanyl	increased sedation or respiratory depression
midazolam, triazolam	increased sedation or respiratory depression
omeprazole	decreased response to nelfinavir
pimozide (e.g., Orap®)	potential for arrhythmias
rifampin	loss of virologic response
St. John's wort	loss of virologic response
statins (HMG-CoA reductase inhibitors)	myopathy, rhabdomyolosis

Tips for Administering Antiretroviral PEP Medications:

Zidovudine, Lamivudine and Zidovudine/lamivudine (Combivir®): If the patient is unable to swallow the tablet or capsule, and (for children) does not want the liquid product:

- Empty the zidovudine capsule (wear gloves)
- Crush the zidovudine/lamivudine (Combivir®) or lamivudine tablet (avoid inhaling powder)
- Mix powder with applesauce, water or juice

Lopinavir/ritonavir (Kaletra®) (strong, foul taste especially for solution)

Tablet:

- Swallow whole, do NOT chew or crush
- If unable to swallow tablets whole, use nelfinavir (Viracept®)
- May take with food or on an empty stomach

Nelfinavir (Viracept®)

Tablet:

- May take with food or on an empty stomach
- May crush and mix with non-acidic foods or beverages (i.e., NO apple sauce, apple juice, orange juice) (acidic foods create a bitter taste with nelfinavir)

For further information about PEP regimens, consult a specialist in HIV medicine or infectious diseases.

Disposal of HIV PEP Drugs

- Health professionals should dispose of expired/damaged/unfinished HIV PEP kits in a manner consistent with the Manitoba Pharmaceutical Association (MPhA) practice guidelines and specific hazardous waste material guidelines in addition to any disposal policy developed by a specific regional health authority.
- Health professionals should instruct clients to return unfinished HIV PEP kits to a local pharmacy for appropriate disposal.

Appendix C: Acquisition and Administration of HBV Vaccine and HBIG:

Sites authorized to stock adult and pediatric formulations of HBIG and hepatitis B vaccines are listed below; specific formulations may or may not be stocked at the sites listed below. To obtain HBIG and HBV vaccine from sites other than those listed below, contact the Provincial Vaccine Warehouse (weekdays 8:30 a.m. – 5:00 p.m.) at 204-633-2621 or 800-665-7315, fax: 204-694-2380. After 5:00 p.m., call 204-781-5342. A current Biologics/Vaccine Order Form is available by calling the warehouse or at: www.gov.mb.ca/health/publichealth/cdc/protocol/index.html#forms

Assistance in determining the need for HBIG and HBV vaccine can be obtained from the local or on call Medical Officer of Health by calling (204) 788-8666. HBIG and HBV vaccine can be released to a Public Health Unit or physician.

Hospitals in Winnipeg:

Concordia Hospital

Grace Hospital

Health Sciences Centre (Children's and Adult Emergency)

Misericordia Urgent Care

Seven Oaks General Hospital

St. Boniface General Hospital

Victoria General Hospital

Hospitals and Health Centres Outside Winnipeg:

Brandon Regional Health Centre

Boundary Trails Health Centre

Churchill Health Centre Pharmacy

Dauphin Regional Health Centre

Flin Flon General Hospital

Portage District General Hospital

Swan River Health Centre

Thompson General Hospital

Immunization providers should consult the respective product monograph prior to administering HBIG and HBV vaccine for information such as storage and handling, administration schedule, injection site, dose specific to age and weight (for HBIG) etc.

- HBIG:
  - Administration is intramuscular (anterolateral thigh muscle of infants; deltoid muscle of children and adults) (3).
  - The standard HBIG dose for newborns and children ≤ 8.3 kg is 0.5 mL; the dose for children > 8.3 kg and adults is 0.06 mL/kg.
- HBV Vaccine:
  - Administration is intramuscular (anterolateral thigh muscle of infants; deltoid muscle of children and adults) (3).
  - There are various HBV vaccine schedules, formats, strengths. The pediatric preparation used in Manitoba is thimerosal-free.
  - Preferred schedule: second and third doses of HBV vaccine should be administered one and six months after the start of the immunization series unless otherwise indicated (e.g., serologic testing demonstrates HBsAg positivity).