

# ALBERTA GUIDELINES FOR MANDATORY TESTING AND DISCLOSURE ACT POST-EXPOSURE PROPHYLAXIS

HIV, Hepatitis B, Hepatitis C

## ALBERTA MTDA PEP PROTOCOL

Revision 1. September, 2007

– deletion of nelfinavir as an alternate drug due to a Health Canada Advisory.

[http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2007/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2007/index_e.html)

Revision 2, January 2009

- Change in reference to the Office of the Chief Medical Officer of Health

Revision 3, October 2010

- Change in fax numbers

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## INTRODUCTION

The *Mandatory Testing and Disclosure Act* (MTDA) provides a mechanism for certain individuals exposed to the risk of communicable disease infection through contact with another individual (the source) to compel the source individual to provide a bodily substance for testing. An order for testing may be issued if the Court is satisfied that the information that may be obtained under the proposed testing order cannot reasonably be obtained in any other manner. The Alberta Guidelines for Mandatory Testing and Disclosure Act Post-exposure Prophylaxis Protocol is intended to provide guidance to physicians regarding assessment and management of a patient who wishes to make an application under the MTDA.

The MTDA in no way affects the routine clinical management of a patient exposed to a bodily substance of another individual (source). The Act and the MTDA assessment and reporting processes only apply in specific emergency situations as outlined in the legislation and at the patient's request. (See Mandatory Testing and Disclosure Act Backgrounder for details)

It is important that the patient be treated and the Physician Report completed by a physician knowledgeable in assessing and managing blood and bodily fluid exposure. The assessment and reporting processes as outlined in this document are important for all applications under the MTDA.

## 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 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 post-exposure prophylaxis (PEP) 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

### Rationale for HIV PEP

#### *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 labour 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 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).

## GENERAL CONSIDERATIONS

### *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 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).

## GENERAL CONSIDERATIONS

**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.

### 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 2.

HBV is reported to be transmitted 8.6-fold more efficiently than HIV (Kingsley, 1990) and high HBV DNA levels or HBe antigen positivity in the source is associated with a higher risk of transmission.

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 HBsAg 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 3.

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 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).

## GENERAL CONSIDERATIONS

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).

### 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. Under the MTDA, determination of source serostatus for HIV, HCV, and HBV becomes possible either through a search of existing databases or through testing of the source.

Clinical management of the exposed individual should not be delayed while awaiting the results of testing of the source. Particularly in the case of HIV PEP, **prophylaxis should be initiated as soon as possible after the exposure (ideally within one to four hours and up to a maximum of 72 hours after exposure).**

Determination of source serostatus may be beneficial to the recipient through:

- determining whether HIV PEP should be discontinued
- allaying anxiety
- discontinuing recommendations made regarding measures to prevent transmission of HIV/HBV (e.g. need to practice safer sex, sharing of razors/toothbrushes, donations, etc)

Although the MTDA allows for an application to be made for source testing within 30 days of the exposure, the incubation periods of the viruses need to be taken into consideration. The incubation period or “window period” (period of time from exposure to time that presence of infection is determined) will depend on a number of factors including type of exposure, serostatus or risk status of the source, and the type of test used to determine the presence of infection.

## RECOMMENDATIONS FOR MTDA TESTING AND PEP

### Human Immunodeficiency Virus (HIV)

#### HIV Post-exposure Testing

**Source:** 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.

\* 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:

Intervals	Specific tests
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 MTDA TESTING AND PEP

<b>HIV 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 PEP
Percutaneous injury (any) OR Mucous membrane exposure to blood or visibly blood stained bodily fluids OR Non-intact skin exposure to blood or visibly 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 bodily fluids not containing blood OR Intact skin exposure to blood or visibly blood stained bodily fluid	<b>Not recommended</b>

## RECOMMENDATIONS FOR MTDA TESTING AND PEP

### 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
Percutaneous injury <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>
Percutaneous injury <ul style="list-style-type: none"> <li>• solid bore needle</li> <li>• superficial injury</li> </ul> <p style="text-align: center;">OR</p> Mucous membrane exposure to blood or visibly blood stained bodily fluids <p style="text-align: center;">OR</p> Non-intact skin exposure to blood or visibly blood stained bodily fluid	<p><b>Not generally recommended; but may be considered in exceptional circumstances</b> (e.g. deep injury, extensive mucosal/non-intact skin exposure to blood)</p>
Mucous membrane exposure to bodily fluids not containing blood <p style="text-align: center;">OR</p> Intact skin exposure to blood or visibly blood stained bodily fluid	<p><b>Not recommended</b></p>

## RECOMMENDATIONS FOR MTDA TESTING AND PEP

<b>HIV Post-exposure Prophylaxis</b> (See Appendix D for drug dosages and side effects)	
<b>Source:</b> unknown HIV status or unknown risk factors for HIV	
<b>Recipient:</b>	
Type of exposure	HIV PEP
Percutaneous injury with hollow bore needle, including “cold” needle (i.e. discarded or “found” needle)  OR  Mucous membrane exposure to blood or visibly blood stained bodily fluids  OR  Non-intact skin exposure to blood or visibly blood stained bodily fluid	<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)
Percutaneous injury <ul style="list-style-type: none"> <li>• solid bore needle</li> <li>• superficial injury</li> </ul> OR  Mucous membrane exposure to bodily fluids not containing blood  OR  Intact skin exposure to blood or visibly blood stained bodily fluid	<b>Not recommended</b>

## RECOMMENDATIONS FOR MTDA TESTING AND PEP

### Hepatitis B Virus (HBV)

HBV Post-exposure Testing	
<b>Source:</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 <math>\geq</math> 10 IU/L) or HBsAg positive, source and recipient testing is unnecessary.</i>

## RECOMMENDATIONS FOR MTDA TESTING AND PEP

<b>HBV 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 and complete second course of vaccine series  anti-HBs 1-6 months after series complete	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 and complete second course of vaccine series  anti-HBs 1-6 months after series complete

\* 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 MTDA TESTING AND PEP

### Hepatitis C Virus (HCV)

HCV Post-exposure Testing	
<p><b>Source:</b> hepatitis C antibody. Generally, if source tests negative, no further testing routinely required in the source or recipient. Even if the source is believed to be in the “window period” for HCV, and is at high risk* for HCV, there is generally no need for additional testing as there is no PEP for HCV. Additional testing (e.g. HCV RNA) may be helpful in rare instances as it may alter the follow-up testing in the recipient. Additional testing may be performed after consultation with an infectious diseases or gastroenterology specialist.</p> <p>* high risk includes: shared needles for intravenous drug use within preceding six months</p>	
<b>Recipient:</b>	
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 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.

## 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. If contraindications to use of lopinavir/ritonavir exist or if side effects occur, alternate agents should be used after consultation with an HIV expert.

Appropriate referral should be made as necessary and available (e.g. to local police/RCMP, psychologist support, 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 PEP**



**RISKS**

- Uncertain efficacy of HIV PEP in exposures to blood-borne pathogens
- Adverse effects of drugs
- Cost of drugs
- Potential negative behaviour change as a result of availability of HIV PEP

**BENEFITS**

Reduced risk of acquiring HIV if PEP 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, and HCV

<b>Exposure</b>	<b>Per episode probability of transmission</b>
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)

<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>Table 3: Transmission probabilities of HCV</b>	
<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)

**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%
TOTAL	3350	2700 - 4000	100%

**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%
Total – Canada	47,000	0.30%	8,000	0.07%

## 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

Drug	Dose	Supplied	Possible side effects	Additional information
<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, pimozide, 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)	<p><b>Adult or adolescent (≥ 13 years):</b> 150 mg po BID</p> <p><b>Children (1 month to 12 years):</b> &lt; 37.5 kg: 4 mg/kg/dose po BID &gt; 37.5 kg: 150 mg po BID</p>	<p><b>Tablets:</b> 150 mg and 300 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>Oral solution:</b> 10 mg/mL (240 mL bottle)</p>	<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>)

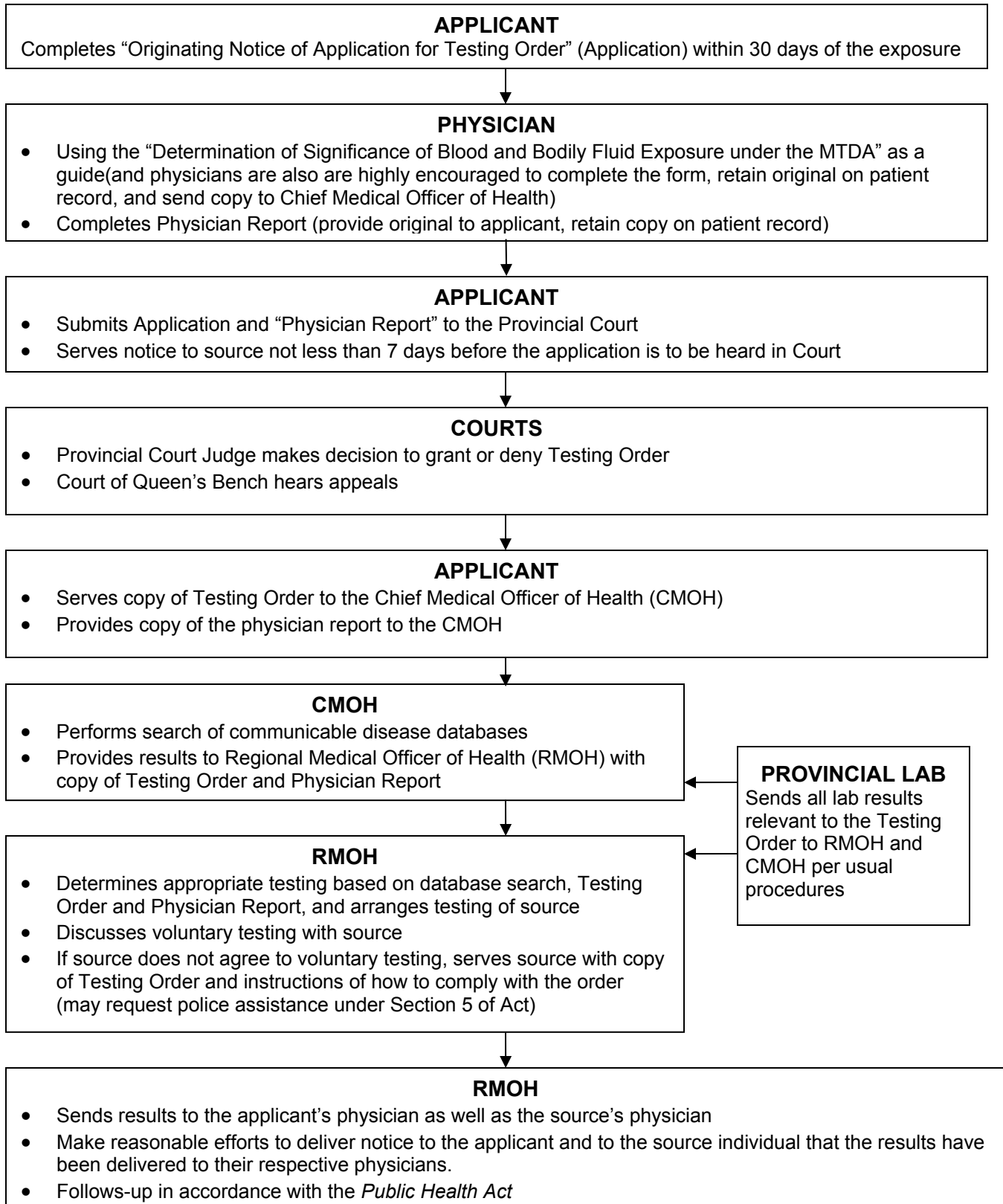
Havens PL and the Committee on Pediatric AIDS. Post-exposure prophylaxis in children and adolescents for non-occupational exposure to human immunodeficiency virus. Pediatrics 2003; 111:1475-89

### SUMMARY OF PROCESS UNDER MTDA

- The MTDA creates a procedure for the compulsory taking of bodily samples and the disclosure of personal information derived from the analysis of those bodily samples.
- This procedure is initiated by application to the Provincial Court by an exposed individual (applicant) or someone acting on that individual's behalf. This application must occur not more than 30 days after the exposure.
- The "source individual" (source) must be served with notice not less than seven days before the application is to be heard in court.
- The Provincial Court considers the application and may order that the source be tested (Testing Order).
- The applicant must serve a copy of the Testing Order and a copy of the Physician's Report to the Chief Medical Officer of Health.
- The applicant's physician, uses the Determination of Significance of Blood and/or Bodily Fluid Exposure Form as a tool in making the assessment required in the Physician Form, and is encouraged to complete the form, keep original on file and fax a copy to the Chief Medical Officer of Health.
- The Chief Medical Officer of Health (CMOH) provides a copy of the Testing Order and Physician's Report together with the results of any database search ordered by the Court to the Regional Medical Officer of Health (RMOH) for the health region where the source individual resides.
- The RMOH then designates a health professional and analyst to collect and test a sample/samples and serves notice to the source individual with directions on how to comply with the order. (Both the RMOH and the health professional can request police assistance under Section 5 of the Act.)
- The RMOH provides a copy of the test results to the applicant's physician and the source individual's physician.

## APPENDIX E

### Process under the Mandatory Testing and Disclosure Act



### DEFINITIONS AND INTERPRETATIONS UNDER MTDA AND ACCOMPANYING REGULATIONS

#### **Applicant**

- Under the MTDA, an “applicant” is an individual who applies for a Testing Order or in respect of whom an application for a Testing Order is made.
- The applicant can be anyone who has come into contact with a “bodily substance” of a “source individual” under given situations.
  - While providing emergency assistance to a source individual who is ill, injured or unconscious as a result of an accident or other emergency.
  - While performing duties as a firefighter, paramedic or peace officer.
- The application may be made by the recipient of the exposure or a “guardian” on their behalf.

**Bodily substance** means a natural bodily fluid or secretion.

**Communicable diseases** referred to under this Section 18(1)(a) MTDA include:

- HIV
- Hepatitis B
- Hepatitis C

**Communicable disease databases** as prescribed by regulation include: Northern and Southern Alberta HIV Program databases; Alberta Health and Wellness Communicable Disease Reporting System database; and the Provincial Laboratory for Public Health (Microbiology) database.

#### **Determination of significance of blood and bodily fluid exposure under the MTDA form**

- Form to be completed during physician assessment of exposure
- Form will help to guide decision-making process regarding significance of exposure and recommendations for testing order

**Guardian** means a guardian as defined in the *Dependent Adults Act* or a guardian within the meaning of Part 2 of the *Family Law Act*.

**Physician Report under the MTDA** means a report required for the purposes of an application made under section 3 of MTDA.

- Qualifications of physician for the purpose of preparing a Physician Report are: a member in good standing with the College of Physicians and Surgeons of Alberta.
- Form to be signed by the physician who completes the Determination of Significance of Blood and Bodily Fluid Exposure under the MTDA form.
- Form to be provided to the applicant who will submit to the Provincial Court together with the application for Testing Order. The Judge will determine whether a Testing Order will be issued requiring the source to be tested.

## APPENDIX F

**Qualified health professionals** means:

- Medical laboratory technologists
- Physicians
- Registered nurses
- Licensed Practical Nurses
- Certified combined laboratory and x-ray technicians

**Qualified analyst** means a registered medical laboratory technologist who performs analytic services in a laboratory approved by the College of Physicians and Surgeons of Alberta.

**Source individual** means an individual from whom a sample of bodily substance is sought for the purpose of testing.

# FAX – Medical Confidential



Office of the Chief Medical Officer of Health

## Determination of Significance of Blood and/or Bodily Fluid Exposure under the Mandatory Testing and Disclosure Act

**Instructions: Reporting physician**– please complete and fax this form to Alberta Health and Wellness for applications under the Mandatory Testing and Disclosure Act. Please keep original of the completed form on applicant’s chart.

Date of fax: _____ <div style="text-align: center; margin-top: 5px;"> <span style="margin: 0 10px;">/</span> <span style="margin: 0 10px;">/</span> </div> <div style="text-align: center; margin-top: 5px;"> <span style="margin: 0 10px;">YYYY</span> <span style="margin: 0 10px;">MM</span> <span style="margin: 0 10px;">DD</span> </div>	Re: <b>Mandatory Testing and Disclosure Act – Determination of Significance</b>
To: <b>Alberta Health and Wellness</b>  <b>Office of the Chief Medical Officer of Health</b>	From: _____ <i>Name of Reporting Physician</i>  _____ <i>RHA</i>
Fax: (780) 427-7683	Phone: _____  _____ <i>Physician phone number</i>
Phone: (780)427-5263	
	Pages: (including cover)

*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*

**Please keep original on applicant’s chart**

**Determination of Significance of Blood and/or Bodily Fluid Exposure under the Mandatory Testing and Disclosure Act**

**A. Applicant (recipient of exposure) information**

				Alberta personal health number	
<b>Name</b>		<b>Last</b>	<b>First</b>	<b>Middle</b>	
<b>Address</b>		City/town	Province	Postal code	
<b>Phone number</b>	Alternate phone number	<b>Date of birth</b>		<b>Age</b>	<input type="checkbox"/> Female <input type="checkbox"/> Male

<b>Family physician's name</b> (if different from Reporting Physician)			
<b>Office address</b>	City/town	Province	Postal code
<b>Office phone number</b>	<b>Office fax number</b>		

**B. History of exposure**

**Date of exposure** \_\_\_\_\_ **Time of exposure** \_\_\_\_\_ (24 hour)

**Type of exposure** (check all that apply)

- Percutaneous injury (specify) →
  - needlestick-hollow bore needle
  - needlestick-solid needle
- cut by sharp object
- other (specify) \_\_\_\_\_
- Bite which breaks the skin
- Other (specify) \_\_\_\_\_
- Contact with applicant's non-intact skin (specify) →
  - cut skin
  - chapped/abraded skin
- Contact with applicant's mucous membranes (specify) →

**Type of bodily fluid/substance contacted by the applicant** (check all that apply)

- Blood/serum/plasma
- Other bodily fluid/substance (specify) \_\_\_\_\_
- Biologic fluid/substance visibly contaminated with blood (specify) →
  - tears
  - urine
  - nasal secretions
  - feces
  - sputum
  - saliva
  - vomitus
  - other (specify) \_\_\_\_\_

Description of circumstances surrounding the exposure **(as provided by applicant)**

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**C. Examination of applicant**

Findings related to the exposure including assessment of injuries, if any (e.g. depth/type of injury)

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**D. History of immunization and serostatus of applicant**

<b>Immunization history of applicant</b>	<b>Unknown</b>	<b>No</b>	<b>Yes</b>	<b>Date (if applicable)</b>
Received hepatitis B vaccine – dose 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Received hepatitis B vaccine – dose 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Received hepatitis B vaccine – dose 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

<b>Serostatus history of applicant</b>	<b>Unknown</b>	<b>No</b>	<b>Yes</b>	<b>Serostatus result (if applicable)</b>	<b>Date (if applicable)</b>
Hepatitis B carrier (HBsAg positive)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Hepatitis B immune (anti-HBs positive)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
HCV positive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
HIV positive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

**E. Information on source of blood and/or bodily fluid (check all that apply)**

injection drug user                     
  Source risk factors unknown                     
  History of incarceration  
 Other risk factors (specify) \_\_\_\_\_

**F. Baseline testing of applicant**

- **mandatory for application to proceed unless applicant known to be positive**
- mark baseline testing requisition "STAT"
- copy of baseline testing results must be sent to applicant's family physician named in Section A.

	<b>Refused by applicant</b>	<b>Serostatus result</b>	<b>Date</b>
Hepatitis B surface antigen (HBsAg)	<input type="checkbox"/>	_____	_____
Hepatitis B surface antibody (anti-HBs)	<input type="checkbox"/>	_____	_____
Hepatitis C antibody	<input type="checkbox"/>	_____	_____
HIV antibody	<input type="checkbox"/>	_____	_____

**G. Post-exposure prophylaxis of applicant**

	<b>Refused by applicant</b>	<b>Not applicable</b>	<b>Date initiated/administered</b>
Hepatitis B vaccine	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hepatitis B immune globulin (HBIG)	<input type="checkbox"/>	<input type="checkbox"/>	_____
HIV post-exposure prophylaxis	<input type="checkbox"/>	<input type="checkbox"/>	_____

**H. Counselling**

Applicant has been counselled as outlined in MDTA protocol  
 Yes                     
  No (specify reason) \_\_\_\_\_                     
  Refused by applicant

**I. Referral of applicant for follow-up**

<b>Follow-up physician's name</b>			
<b>Office address</b>	<b>City/town</b>	<b>Province</b>	<b>Postal code</b>
<b>Office phone number</b>	<b>Office fax number</b>		

**J. Assessment of significance of exposure (as defined in MTDA protocol)**

- Significant exposure                     
  Non-significant exposure

Comments:

\_\_\_\_\_

\_\_\_\_\_

Reporting physician's name (please PRINT)

Signature of reporting physician

Date

**Please keep original on applicant's chart**

***What is the Mandatory Testing and Disclosure Act?***

The *Mandatory Testing and Disclosure Act* provides a mechanism for certain individuals exposed to the risk of communicable disease infection through contact with another individual (the source) to compel the source individual to provide a bodily substance for testing. An order for testing may issue if the Court is satisfied that the information that may be obtained under the proposed testing order cannot reasonably be obtained in any other manner.

The Provincial Court may issue a testing order to compel the source individual to provide a bodily substance for testing.

The Act requires that an application to the Provincial Court for a testing order include a Physician's Report.

***What is the required Physician's Report?***

- The Physician Report provides the Court with information relevant to the court application from a physician knowledgeable in blood and body fluid exposures.
- In completing a Physician Report, a physician must assess the risk to the health of the applicant resulting from the applicant's contact with a bodily substance of the source individual. To make this determination, a physician may require the applicant to submit to an examination, testing or treatment.
- The information provided in the Physician Report will assist the Court in determining if a testing order is required and what should be included in the testing order. The original signed copy must be provided to the Court.
- A copy of the Physician Report must also be provided to the Chief Medical Officer of Health.

***What is required to complete the Physician's Report?***

- It is important that the patient be treated and the Physician Report completed by a physician knowledgeable in assessing and managing blood and body fluid exposures.
- Clinical guidelines are set out in the *MTDA Post Exposure Prophylaxis Protocol*.
- The *MTDA Post Exposure Prophylaxis Protocol* and the *Determination of Significance of Blood and Body Fluid Exposure Form* have been distributed to physicians and are also available online at [www.health.ab.ca](http://www.health.ab.ca).
- A copy of any supporting form completed by a physician in regard to an application must also be sent to the Chief Medical Officer of Health upon request.

**Mandatory Testing and Disclosure Act**

In the matter of the application of \_\_\_\_\_, for a testing order under  
(applicant's name)

section 3 of the *Mandatory Testing and Disclosure Act*, I Dr. \_\_\_\_\_  
(physician's name)

as a member in good standing with the College of Physicians and Surgeons of Alberta, report the following:

a) I am knowledgeable in assessing and managing blood and body fluid exposures.  Yes  No

b) A history of the applicant's account of contact with a bodily substance of the source individual has been obtained by me.  Yes  No

c) The applicant has been examined by me.  Yes  No

d) It has been determined that the applicant is not immune to or has not tested positive for:

Hepatitis B  Yes  No

Hepatitis C  Yes  No

HIV  Yes  No

e) Post Exposure Prophylaxis for Hepatitis B has been prescribed for the applicant.  Yes  No

I have confirmed that the applicant has commenced this prophylaxis if prescribed.  Yes  No

f) Post Exposure Prophylaxis for HIV has been prescribed for the applicant.  Yes  No

I have confirmed the applicant has commenced this prophylaxis.  Yes  No

If No in (e) and/or (f), why?

1. Patient Refused

2. Not medically required

3. Other (please explain)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

g) Additional physician comments:

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Based on the information provided by the applicant, the examination and testing performed, and the incubation periods for pathogens in the human body, it is my opinion that:

1. There are reasonable grounds to believe that the applicant might have become infected with a pathogen that causes a communicable disease resulting from the applicant's contact with a bodily substance of the source individual.  Yes  No
2. An examination and tests on the applicant can not accurately determine, in a timely manner, whether the applicant has, as a result of the contact with a bodily substance from the source individual, become infected with a pathogen that causes a communicable disease.  Yes  No
3. A testing order is necessary to treat or manage the health of the applicant.  Yes  No
4. This testing order should include the following instructions:

A serum sample should be obtained from the source individual for the following tests:

- HIV Antibody
- Hepatitis C Antibody
- Hepatitis B Surface Antigen
- Other (*please list tests which should be conducted on the sample(s) obtained*)

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Signature of physician <b>X</b>	Business phone number Area code ( )	Fax number Area code ( )
Business address	City	Postal code