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AN INTEGRATED PROTOCOL TO MANAGE HEALTH CARE WORKERS EXPOSED TO BLOODBORNE PATHOGENS

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Preface

The current document presents integrated recommendations for the management and follow-up of the health care worker with a potential occupational exposure to HBV, HCV, or HIV.

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Introduction

In March 1996, the Division of Nosocomial and Occupational Infections, Bureau of Infectious Diseases, and the Division of HIV Epidemiology Research, Bureau of HIV/AIDS and STDs, of the Laboratory Centre for Disease Control (LCDC) hosted a meeting to develop integrated recommendations for the management and follow-up of the health care worker (HCW) with a potential occupational exposure to bloodborne pathogens[†]. When implemented, this protocol will enable health care facilities, public health agencies, laboratories, and emergency response organizations to manage a significant occupational exposure to hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

LCDC has published recommendations to help minimize the HWC's risk of exposure to fluids capable of transmitting bloodborne pathogens (i.e. HBV, HCV, and HIV) in health care and other workplace situations[1-5]. These recommendations focus on preventing exposure through administrative controls, improved instrument design, safer workplace practices, and the appropriate use of personal protective equipment. Compliance with these key preventive measures is essential in the overall management of exposure to bloodborne pathogens.

Preventive measures also include hepatitis B vaccination which is recommended for persons at increased risk of exposure to blood (including increased risk of injury from a sharp) and other body fluids capable of transmitting infection. HCW students should complete their vaccine series before possible occupational exposure to blood or body fluids capable of transmitting infection. Health care facilities may choose to make HBV immunization a condition of employment and/or a prerequisite for physician admitting privileges.

The Canadian National Advisory Committee on Immunization (NACI) regularly reviews and revises recommendations for vaccine-preventable diseases. Hepatitis B vaccination recommendations date from 1979 and were revised in 1984, 1989, and 1993[6].

Prior work on post-exposure management for HBV, HCV, and HIV has also been done. In 1984, NACI issued recommendations for effective follow-up after a significant exposure to HBV[7]. In 1990, LCDC issued guidelines for post-exposure management of the HCW exposed to HIV, including testing and possible treatment[8]. In 1995, LCDC endorsed the development of a national post-exposure protocol for HCV[9]. The present document replaces and updates these guidelines and recommendations.

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† A videotape of the opening session of the meeting may be borrowed; fax (613) 952-6668, to the attention of the Division of Nosocomial and Occupational Infections.

Recommendations for an Integrated Protocol

1. Immediate Post-Exposure Activities

1.1 First aid

- Remove the contaminated clothes.
- Allow immediate bleeding of the wound.
- Wash the injured area well with soap and water, and apply an antiseptic (if available).
- If the eyes, nose, or mouth are involved, flush them well with large amounts of water[10].

1.2 Reporting and assessment

The exposed HCW should report the injury to a designated person. Details of the accident should be documented and the significance of the exposure assessed. In light of revised chemoprophylaxis recommendations for HIV (*see Appendix*), it is urgent for the HCW to be assessed as soon as possible after exposure. If post-exposure chemoprophylaxis is to be implemented, it should begin as soon as possible — preferably within 1 to 2 hours after exposure.

2. Evaluating a Significant Exposure

The type of body fluid and the type of injury must be investigated to determine if the exposure of the HCW to a bloodborne pathogen is significant. A combination of one of the types of body fluids and one of the injuries listed below constitutes a significant exposure.

2.1 Types of body fluids

Body fluids capable of transmitting HBV, HCV, and HIV from an infected individual include:

- blood, serum, plasma, and all biologic fluids visibly contaminated with blood
- laboratory specimens, samples, or cultures that contain concentrated HBV, HCV, and HIV
- organ and tissue transplants
- pleural, amniotic, pericardial, peritoneal, synovial, and cerebrospinal fluids
- uterine/vaginal secretions or semen (unlikely to transmit HCV)
- saliva (for HBV only, unless contaminated with blood).

Feces, nasal secretions, sputum, tears, urine, and vomitus are not implicated in the transmission of HBV, HCV, and HIV unless visibly contaminated with blood. The risk of transmission from screened, donated blood, and manufactured blood products is negligible in Canada.

2.2 Types of injuries

Injuries in which one of the infected fluids listed in 2.1 comes into contact with the HCW's:

- tissue under the skin (e.g. percutaneous or following a bite when the skin is broken)
- non-intact skin (e.g. cut, chapped or abraded skin†)
- mucous membrane (e.g. eyes, nose, or mouth).

In summary, further investigation is warranted if the type of body fluid and the type of injury indicates that a significant exposure has occurred.

3. Counselling the HCW Following a Significant Exposure

The HCW may be more likely to report injuries and comply with the follow-up if the post-exposure protocol for bloodborne pathogens integrates all relevant viruses. Compensation for an occupational infection may depend on documented test results from the source and the HCW.

Obtaining informed consent from the HCW and maintaining strict confidentiality of all information are integral parts of the post-exposure management program. When consent is obtained, consider drawing blood from the HCW for testing for all three pathogens immediately following injury, since the infection status of the source may not be known at that time.

Counselling the HCW must be done prior to the blood specimen being tested.

4. Testing the Source and the HCW

It is in the interest of the HCW to determine if the blood from the source is infected with HBV, HCV, or HIV. In addition to secondary prevention measures and counselling of the HCW, potential compensation for an occupational infection must be considered.

Every reasonable effort should be made to obtain permission to test the source for HBV, HCV, and HIV. Obtaining informed consent from the source is an integral part of all post-exposure testing procedures, as is maintaining confidentiality of all information. Testing the source without consent is unethical. When consent is given to draw blood for all three viruses, the appropriate pre- and post-test counselling for all three bloodborne pathogens should be done.

Information from the source's test result will be used to determine which tests will be done for the HCW.

Different testing procedures are required for the HCW if the source agrees to testing and is positive for HBV, HCV, or HIV; if the status of the source is unknown; or if the source is negative but has risk factors for bloodborne pathogens. If the source is negative for HBV, HCV, or HIV and has no risk factors, testing the HCW is not necessary.

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† The larger the area of skin exposed and the longer the time of contact, the more important it is to verify that all the relevant skin area is intact.

4.1 Testing the source (Table 1)

Table 1 Testing the source, upon consent	
Bloodborne Pathogens	**TEST THE SOURCE**
HBV	• Do not test the source if the HCW is known to be *immune*† to HBV. (**This is presently under review by NACI.**) • Test for hepatitis B surface antigen (HBsAg) at the time of injury if the HCW is known to be *susceptible*† to HBV, a *non-responder*†, or has an *unknown*† HBV status.
HCV	• Test for HCV antibodies (anti-HCV) at the time of injury.
HIV	• Test for HIV antibodies at the time of injury.
† See section 7.	

4.2 Testing the HCW (Tables 2 and 3)

If the results of testing indicate the source is positive for anti-HCV, HBsAg, or HIV antibodies, or if the status of the source is unknown, further investigation of the HCW is warranted (Table 2).

Table 2
Testing the HCW, if the source is positive or the status of the source is unknown

Bloodborne Pathogens	TEST THE HCW
HBV	• Do not test the HCW if known to be *immune*† to HBV. (**This is presently under review by NACI.**) • Test for HBsAg, anti-hepatitis B surface antigen (anti-HBs), and anti-hepatitis B core antigen (anti-HBc) at the time of injury, if the HWC is known to be *susceptible*† to HBV, a *non-responder*†, or has an *unknown*† HBV status. If tests are negative, retest at 6 months after exposure. • Some experts suggest a medical assessment 3 months after exposure to assess the clinical evidence for hepatitis.
HCV	• Test for HCV antibodies (anti-HCV) at the time of injury. If the test is negative, retest for anti-HCV at 3 months and 6 months after exposure. • Test for liver function using serum alanine aminotransferase (ALT) at the time of injury and 6 months after exposure.
HIV	• Test for HIV antibodies at the time of injury. If tests are negative, retest at 6 weeks, 3 months, and 6 months (if subsequent tests continue to be negative). Virtually all seroconversions occur within 6 months of exposure[11,12], although there have been rare reports of seroconversions after 6 months[13]. • Given the very low probability of seroconversion after 6 months and the unnecessary anxiety that would be caused by extending the testing period beyond 6 months, testing at 12 months is not recommended, but may be considered on a case-by-case basis. • When the status of the source is unknown, the risk of infection should be assumed to be present unless local epidemiology or the clinical setting strongly suggests otherwise.

† See section 7.

If the source is negative but has risk factors for bloodborne pathogens, testing and following up the HCW may still need to be done (Table 3).

Table 3
Testing the HCW, if the source is negative but has risk factors for bloodborne pathogens

Bloodborne Pathogens	TEST THE HCW
HBV	• Test for HBsAg, anti-HBs, and anti-HBc if the HCW is known to be *susceptible*† to HBV, a *non-responder*†, or has an *unknown*† HBV status and the possibility exists that the source is in the window period (up to 3 months after exposure). • Risk factors within the last 3 months include: - high-risk sexual behaviour [i.e. men who have sex with men, sexual partner who is an injection drug user (IDU), multiple sexual partners] - sexually transmitted disease(s) - sexual or blood contact with a known case of HBV infection - IDU or tattoo/body piercing.
HCV	• Test for anti-HCV at the time of injury if the source has one or more lifetime risk factors. Retest at 3 months and 6 months after exposure. • Lifetime risk factors include: - high-risk sexual behaviour (i.e. a sexual partner who is an IDU, multiple sexual partners) - sexual or blood contact with a known case of HCV infection - IDU or tattoo/body piercing - receipt of blood or blood products before 1990 - receipt of blood-derived coagulation products before 1985 - origin in a developing country - dialysis.
HIV	• Test for HIV antibodies at the time of injury if the source has one or more risk factors and the possibility exists that the source is in the window period (up to 6 months after exposure). Retest at 6 weeks, 3 months, and 6 months if the previous test is negative. • Risk factors within the last 6 months include: - high-risk sexual behaviour (i.e. men who have sex with men, sexual partner who is an IDU, multiple sexual partners) - sexually transmitted disease(s) - sexual or blood contact with a known case of HIV infection - IDU or tattoo/body piercing.

† See section 7.

5. Post-Exposure Prophylaxis for the HCW (Table 4)

Table 4
Post-exposure prophylaxis for the HCW, if the source is positive or status is unknown or is negative but has risk factors

Bloodborne Pathogens	PROPHYLAXIS FOR THE HCW
HBV	• No further action is needed if the HCW is *immune*† to HBV (**This is presently under review by NACI.**) • Give hepatitis B immune globulin (HBIG), preferably within 48 hours of exposure (efficacy decreases with time and is unknown after 7 days[14]) if the HCW is *susceptible*† to HBV or has an *unknown*† status. In addition, start HB vaccine for HCWs who are *susceptible*† to HBV and have not received HB vaccine. Provide a single dose of vaccine for HCWs who have an *unknown*† status after HB vaccine††. • Give one dose of HBIG, preferably within 48 hours and another in 1 month if the HCW is a known *non-responder*† to the HB immunization series. • Draw blood for testing before HBIG or immunization is given.
HCV	• Effective post-exposure prophylaxis is not available at this time. Immunoglobulin is not effective[9].
HIV	• Consider immediate post-exposure chemoprophylaxis (*see Appendix*).

† See Section 7.

†† Note: Testing an exposed HCW (of "*unknown*† HBV status" at the time of exposure but who has received a complete series of HB vaccine or who has a history of unspecified clinical hepatitis) for HBV markers on an urgent basis may clarify the status of such a HCW regarding HBV and this may, in some cases, alter the post-exposure prophylaxis used. While not necessary in this protocol, individual agencies could consider such testing for these specific HCWs if they are able to know the test results and provide applicable post-exposure prophylaxis within 48 hours of exposure. Otherwise, post-exposure prophylaxis will need to be based on information about the HCW's status available at the time of exposure.

6. Post-Exposure Counselling Recommendations for the HCW (Table 5)

If the HCW is exposed to a bloodborne pathogen, the HCW should not donate blood, semen, organs or tissues for 6 months, and should not share razors or toothbrushes. The HCW should be followed medically.

Table 5
Post-exposure counselling recommendations for the HCW with a potential risk for bloodborne pathogens

Bloodborne Pathogens	COUNSELLING RECOMMENDATIONS
HBV	• No further precautions are necessary if the HCW is *immune*† to HBV. • No clear guidance can be given on issues related to safer sex practices and notifying sexual partner(s) for HCWs who are receiving HBIG and/or the HB vaccine series.
HCV	• The HCW exposed to HCV should advise their sexual partner(s) of the potential risk[9], although the risk of sexual transmission appears to be lower than that of HIV or HBV. The HCW should be provided with information on safer sex practices[15]. • Current data indicate that transmission from mother to infant is rare. Specific recommendations for or against pregnancy and breast feeding cannot be made[9].
HIV	• The HCW should practice safer sex[15] for a 6-month period and notify sexual partner(s) of the potential exposure to HIV. • Pregnancy should be avoided for 6 months[8]. • Breast feeding should be stopped, unless an HIV antibody test in a known low risk source is expected to be available in the next few days. In this case, breast milk can be temporarily expressed or pumped and breast feeding resumed if the result is negative.

† See Section 7.

7. Definitions

Immune to HBV — a HCW who has known documentation of an anti-HBs level ≥ 10 IU/L when tested following the complete HB immunization series, or has an anti-HBs level ≥ 10 IU/L, or is anti-HBc+, or is HBsAg+ from hepatitis B infection.

Susceptible to HBV — a HCW who, after HBV immunization, has an inadequate anti-HBs level (< 10 IU/L) when done 4 to 8 weeks after completing the immunization series, or when there is no history of HB immunization and tests for anti-HBs, anti-HBc, and HBsAg are all negative.

Non-responder — a HCW who has had two complete series of HB vaccine and has tested anti-HBs negative (< 10 IU/L) post HB immunization after each of the series.

Unknown HBV status — when there are no results available from previous testing for suitable HBV serologic markers (anti-HBs for post-vaccination response, anti-HBc for natural infection) regardless of whether the HCW has received HB immunization or has a clinical history of hepatitis.

Appendix

Post-Exposure Chemoprophylaxis Guidelines for Occupational Exposure to HIV

Background

Until recently, the information available on the post-exposure use of chemoprophylactic agents such as zidovudine (ZDV) has not been sufficient to either recommend or discourage their use as part of the exposure protocol in Canada[8] or the United States[16]. The decision to use ZDV has been left to the discretion of the patient and the treating physician, taking into consideration the details of the exposure, side effects, and uncertain efficacy of ZDV. A number of centres with extensive experience in the area of occupational exposure, for example the San Francisco General Hospital, have encouraged the use of ZDV for massive exposures and definite parenteral exposures, and also for probable parenteral exposures especially if the source patient has AIDS[17,18].

A recent case-control study identified three categories of factors associated with seroconversion among occupational exposures to HIV: a group of variables related to volume of blood injected (deep injury, procedure involving a needle placed directly into source patient's vein or artery, and visible contamination of sharp with patient's blood); terminal HIV illness in source patient; and non-use of ZDV post-exposure prophylaxis[19]. This study illustrates the importance of the specific circumstances of the exposure in determining the risk of transmission and supports the efficacy of ZDV for post-exposure prophylaxis. Although transmission has been known to occur despite ZDV post-exposure prophylaxis (PEP)[20], the case-control study suggests that ZDV PEP reduces the risk of HIV seroconversion, following percutaneous exposure, by about 80%. ZDV has also been shown to reduce the rate of transmission from mother to infant by 67% when given to HIV-infected pregnant women and their infants[21], although it is not clear how much of this effect is due to a direct PEP-like effect on the infant. Some animal studies also show that PEP with ZDV or other nucleosides can prevent retroviral infection[22,23].

There are no data on the effectiveness or side effects of other anti-retroviral agents or combined therapy for PEP. However, it is tempting to make an analogy with the treatment of HIV-infected patients where data show that combination therapies are more effective than ZDV alone in reducing viral load[24,25]. Combination therapy could also be useful in situations where drug resistance is present. The use of combination therapy for PEP therefore has some biologic plausibility. However, it is not known if the side-effects of these drugs seen in HIV-infected patients will be the same in HIV-uninfected patients. The potential benefits and risks of PEP must be carefully considered. The appeal of implementing post-exposure treatment immediately, i.e. to err on the side of caution, must be tempered by the facts that the toxicities of these new drugs in the post-exposure setting are not yet well understood and that most exposures

do not result in the transmission of HIV (average risk of infection after percutaneous exposure to HIV-infected blood is 0.3%)[20].

The provisional recommendations noted below for PEP are fairly general and will need to be updated periodically as new data become available. Their general nature will allow needed flexibility in their implementation since regions of the country differ in the availability and use of the various antiretroviral agents. These guidelines should be implemented in consultation with local or regional experts in the care and treatment of HIV disease.

Provisional Recommendations for HIV Post-Exposure Chemoprophylaxis

The use of PEP for occupational exposure to HIV is either recommended, offered, or not offered depending on the circumstances of the exposure and the characteristics of the source.

PEP is **recommended** for the following exposures that carry an increased risk for transmission of HIV:

- percutaneous, mucous membrane, or non-intact skin (*see Section 2.2*) exposure to concentrated virus in a research laboratory or similar facility; or
- percutaneous exposures to potentially infectious blood or body fluids *(see Section 2.1)* which involve deep injury, injection of source patient's blood or body fluid, a needle placed directly in source patient's blood vessel, or source patient with high viral titre (as in acute retroviral illness or terminal HIV disease).

PEP is **offered** (not actively recommended) to the HCW, with appropriate counselling for situations that involve less risk of transmission of HIV, for the following categories of exposures to potentially infectious blood or body fluids *(see Section 2.1)*:

- percutaneous exposures that do not involve deep injury, injection of source patient's blood or body fluid, a needle placed directly in source patient's blood vessel, or source patient with high viral titre as in acute retroviral or terminal illness. (An example would be a superficial injury from a solid suture needle used in a source patient with asymptomatic HIV infection.); or
- mucous membrane or non-intact skin exposures. (The larger the area of skin exposed and the longer the duration time of exposure, the more important it is to verify that all the relevant skin area is intact).

PEP is **not offered** at all for exposures to body fluids that are not potentially infectious for HIV, such as non-bloody urine or feces *(see Section 2.1)*. In situations where the HIV status of the source is not immediately known, the decision to initiate PEP should be made on a case-by-case basis and it may be modified if and when additional information becomes available. These provisional recommendations are summarized in Table 6.

Table 6
Provisional recommendations for chemoprophylaxis after occupational exposure to HIV by exposure type and source material

Type of Exposure	Source Material	Antiretroviral Prophylaxis
Any percutaneous, mucous membrane, or non-intact skin† exposure in research laboratory or similar facility	• Concentrated virus	Recommend
Percutaneous	• Blood and other infectious body fluids‡ - higher risk§ - lower risk††	 Recommend Offer
	• Other body fluids‡‡	Not offer
Mucous membrane or non-intact skin†	• Blood and other infectious body fluids‡	Offer
	• Other body fluids‡‡	Not offer

† The larger the area of skin exposed and the longer the contact time, the more important it is to verify that all the relevant skin area is intact.

‡ Serum, plasma, any fluid containing blood, organ and tissue transplants, vaginal/uterine fluids, semen, and pleural, amniotic, pericardial, peritoneal, synovial, and cerebrospinal fluid.

§ Higher risk percutaneous exposures include exposures involving deep injury, injection of source person's blood or body fluid, a needle placed directly in a source person's blood vessel, or a source person with high viral titre (as in acute retroviral illness or terminal HIV disease).

†† Lower risk percutaneous exposures do not involve any of the features noted in §.

‡‡ Body fluids not mentioned in ‡ (such as non-bloody urine or feces).

If PEP is to be implemented, it should be started as soon as possible, preferably within 1 to 2 hours after exposure. It is thought to be less effective if delayed, but there are no data to indicate if there is a specific time after which it is ineffective.

The optimal regimen for PEP is controversial and may vary with local circumstances and the changing availability and use of antiretroviral drugs. However, ZDV should be included in all PEP regimens because there are data to support its efficacy and its side effects are well known. The suggested ZDV regimen is 200 mg three times a day for 4 weeks. At least one other agent should be added to the PEP regimen to take advantage of the possibly greater antiretroviral activity of drug combinations and to address the possibility of a ZDV-resistant strain of HIV in the source patient.

The specific drug to be added to ZDV will depend on local availability and expert clinical advice. Possibilities include another nucleoside reverse transcriptase inhibitor, such as lamivudine (3TC) or zalcitibine (ddC); non-nucleoside reverse transcriptase inhibitors, such as nevirapine or delavirdine; or protease inhibitors, such as indinavir

or saquinavir. For example, the United States Centers for Disease Control and Prevention (CDC) recommends lamivudine as the second drug to be added (150 mg two times a day for 4 weeks) due to the demonstrated effect of this combination on viral load and the relatively few side effects in HIV-infected patients[26]. The addition of a third drug may be considered for certain exposure situations, such as very high-risk exposure or cases where the patient has been on multiple, long-term therapy and multi-drug resistance is considered likely. For example, CDC recommends adding indinavir (800 mg three times a day for 4 weeks) as the third drug for percutaneous exposures that involve both a large volume of blood and a source patient with high HIV viral titre[26]. The International AIDS Society suggests the use of two drugs that have not been used in the source patient[25].

It is recognized, however, that PEP guidelines cannot be rigid at this time of rapidly evolving information; flexibility must be maintained on a case-by-case basis, regionally, and over time. These guidelines for post-exposure prophylaxis for HIV will be modified and updated as new information becomes available. At present, combination therapy with at least two drugs is recommended for PEP, but local expert advice should be sought regarding the potential risks and benefit of a two-drug versus a three-drug regimen and the specific drug choices. Expert advice should also be sought regarding frequency of medical follow-up for cases using PEP to monitor for drug tolerances and toxicities.

It is recommended that each institution give consideration to establishing a specific regimen based on local drug availability and resistance patterns. Since maximum benefit is likely to be obtained when prophylaxis is started immediately, it is further recommended that institutions consider making standard prophylaxis kits readily available for use in occupational HIV exposures.

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