



# Testing of Persons Believed to be the Source of an Occupational Exposure to HBV, HCV, or HIV

A Backgrounder

prepared by  
Theodore de Bruyn

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A Backgrounder

## Executive Summary

### Why a Backgrounder on Exposure to HBV, HCV, and HIV

In recent years in Canada there have been renewed calls for compulsory testing of persons who are believed to be the source (source persons) of an occupational exposure to hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) and who refuse to test voluntarily. Bill C-217 (formerly Bill C-244) – a private member’s bill that would authorize court-ordered testing of a source person where there are reasonable grounds to believe that a health-care worker, firefighter, volunteer, peace officer, security officer, or “good Samaritan” coming to the aid of that person may have been infected with HBV, HCV, or HIV – is currently before Parliament. Bill C-217 has received strong support from the Canadian Police Association and qualified support from the International Association of Fire Fighters – Canadian Office. It has not been supported by the Canadian Nurses Association, the Canadian Association of Nurses in AIDS Care, or the Canadian Medical Association.

What policies and procedures are currently in place to prevent and manage occupational exposures to HBV, HCV, and HIV, and how could they be improved?

### What Are the Issues?

Calls for compulsory testing raise a number of issues regarding occupational exposure to infectious diseases and the benefits and harms of compulsory testing of source persons:

1. How are HBV, HCV, and HIV transmitted in occupational settings, and what are the risks of transmission?
2. What are the consequences of an exposure for the worker, and how should the worker be supported?
3. Is post-exposure prophylaxis available and, if so, what are the risks associated with post-exposure prophylaxis?
4. What are the capabilities of existing testing technologies, and what are their limitations with regard to managing exposures?

5. How will information about the source person's serological status, risk factors, and medical history benefit the exposed worker?
6. How many source persons consent voluntarily to provide such information, and what could be done to encourage source persons to consent?
7. What are the harms of compelling source persons to be tested and of disclosing the results of the test to the exposed worker?
8. What policies and procedures are currently in place to prevent and manage occupational exposures to HBV, HCV, and HIV, and how could they be improved?

## What Does the Backgrounder Contain?

It provides information with reference to current policies, procedures, and scientific literature on:

- the risk of occupational exposure to HBV, HCV, and HIV;
- post-exposure protocols and treatment;
- testing technologies and procedures;
- benefits to the exposed worker of information about the source person's serological status, risk factors, and medical history;
- harms of compulsory testing to the source person;
- positions of professional associations or unions on the management of occupational exposure, including testing the source person;
- improved prevention and management of occupational exposure; and
- steps that could be taken to encourage voluntary informed consent to testing by source persons.

## What Does the Backgrounder Conclude?

Information about the serological status (results of tests for viral infection), risk factors, and medical history of the source person can relieve uncertainty as to whether there was in fact an exposure to HBV, HCV, or HIV, and can contribute to decisions about preventing further transmission, post-exposure prophylaxis, testing, and follow-up for the exposed worker.

(Post-exposure prophylaxis is available only for HBV and HIV, not HCV.)

Most source persons agree to be tested and permit relevant information to be provided to the exposed worker, when they are approached in a sensitive manner and the importance of the information is explained.

If the test results of the source person are negative and there are no risk factors, the exposed worker may be reasonably certain that there was not a significant exposure, be relieved of anxiety, and forego post-exposure prophylaxis (if available). This is a significant benefit in the case of exposure to HIV because, although post-exposure prophylaxis is available and is effective in preventing transmission, it is also accompanied by debilitating side effects and other risks. Side effects are one of the main reasons that exposed workers do not complete the full course of post-exposure prophylaxis for HIV.

If the test results of the source person are positive *or* if the results are negative but there are risk factors (indicating that the test may have been taken during the window period), the exposed worker would have to take steps to prevent further transmission, consider post-exposure prophylaxis (depending on the nature of the exposure), and be tested at a later time. One cannot conclude that the exposed worker was infected on the basis of a positive test result from the source person, or that the exposed worker was not infected on the basis of a negative test result from the source person when risk factors are present.

Most source persons agree to be tested and permit relevant information to be provided to the exposed worker, when they are approached in a sensitive manner and the importance of the information is explained. This has been demonstrated by studies in health-care settings as well as in other settings (eg, with police).

Compulsory testing of a source person and disclosure of the results of the test would be an infringement of personal autonomy. Respect for personal autonomy is a fundamental principle of biomedical ethics. It is the basis for ethical rules and practices that require voluntary informed consent for medical procedures, that respect the individual's right to privacy, and that protect the confidentiality of personal medical information. The person required to be tested suffers harms to bodily and psychological integrity, an infringement of personal privacy, and a loss of confidentiality.

The Canadian Medical Association, the Canadian Nurses Association, and the Canadian Association of Nurses in AIDS Care have recently published or updated policies on occupational exposure to HIV or bloodborne pathogens. They maintain that compulsory testing or testing without informed consent is unethical and unjustified. Voluntary testing with informed consent and appropriate pre- and post-test counseling continues to be the norm for source persons and exposed workers in health-care settings.

Most occupational exposures to bloodborne pathogens are not the result of deliberate acts and are not associated with suspected or demonstrated criminal activity. It is not appropriate, therefore, to have recourse to the *Criminal Code* to compel source persons to be tested in such circumstances.

More could be done to prevent occupational exposure, to support workers, and to obtain voluntary consent for testing from source persons *without* having recourse to compulsory testing of source persons. Improvements could be made by:

- implementing existing guidelines and protocols on preventing and managing occupational exposures to infectious diseases;
- conducting regular annual education and training for workers in infectious diseases, engineering safeguards, and protective practices;
- introducing engineering safeguards, such as needle-less systems, needles with safety features, high-quality latex gloves, and puncture-resistant gloves;
- designating and training personnel to respond to occupational exposures, counsel workers, and act as a liaison with source persons;
- strengthening post-exposure counseling, support, and follow-up for exposed workers, their co-workers (if necessary), and their families;
- implementing workplace programs to correct misconceptions and reduce stigma related to infectious diseases;
- improving training and expert support for health-care providers responsible for administering post-exposure prophylaxis to ensure that it is prescribed only as recommended by current guidelines; and
- introducing provisions to protect the privacy and confidentiality of source persons, such as non-nominal requisition and reporting of test results, destruction of any records related to the test, and regulations, policies, and protocols regarding confidentiality of test results.

More could be done to prevent occupational exposure, to support workers, and to obtain voluntary consent for testing from source persons without having recourse to compulsory testing of source persons.

#### For Further Information...

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## Introduction

In recent years in Canada there have been renewed calls for compulsory testing of persons believed to be the source (“source persons”) of an occupational exposure to the hepatitis B virus (HBV), the hepatitis C virus (HCV), or the human immunodeficiency virus (HIV).

The 1999 General Council of the Canadian Medical Association adopted a motion recommending “that patients undergoing any procedure where a health care worker could be accidentally exposed to the patient’s bodily fluids be required to sign a waiver that would allow appropriate testing of the patient’s serological status of HIV and hepatitis if such exposure should occur, while ensuring patient confidentiality.”<sup>1</sup> The motion was referred for study and was subsequently rescinded at the 2000 General Council.

Also in 1999, Chuck Strahl, the then Reform member of Parliament for Fraser Valley, sponsored a private member’s bill, Bill C-244 (the *Blood Samples Act*) that would authorize court-ordered testing of a source person where there are reasonable grounds to believe that a health-care worker, firefighter, volunteer, peace officer, security officer, or “good Samaritan” coming to the aid of that person may have been infected with HBV, HCV, or HIV. The bill was re-introduced in the 37<sup>th</sup> Parliament as Bill C-217, and received first reading on 5 February 2001.

Such proposals raise a number of issues regarding occupational exposure to infectious diseases and the benefits and harms of compulsory testing of source persons. This backgrounder provides further information on:

- occupational exposure to HBV, HCV, and HIV;
- post-exposure protocols;
- testing technologies and procedures;
- benefits to the exposed worker of information about the source person’s serological status, risk factors, and medical history;
- harms of compulsory testing to the source person;
- positions of professional associations or unions on the management of occupational exposure, including testing the source person;
- improved prevention and management of occupational exposure; and
- steps that could be taken to encourage voluntary informed consent to testing by source persons.



# Occupational Exposure to HBV, HCV, or HIV

## Significant Exposure

Significant exposure to HBV, HCV, or HIV occurs when a type of body fluid capable of transmitting the virus comes into contact with:<sup>2</sup>

- tissue under the skin (eg, through a needle stick or a cut), which is called a *percutaneous* exposure;
- mucous membranes (eg, through a splash to the eyes, nose, or mouth), which is called a *mucocutaneous* exposure; and
- non-intact skin (eg, when the skin is chapped, scraped, or afflicted with dermatitis).

Contact with intact skin is not a significant exposure,<sup>3</sup> but 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.<sup>4</sup> Contact with clothing is not a significant exposure.

The types of body fluids capable of transmitting HBV, HCV, or HIV include:<sup>5</sup>

- 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); and
- saliva (saliva alone transmits only HBV; if saliva is contaminated by blood, it may also transmit HCV and HIV).

HBV, HCV, and HIV are not transmitted by feces, nasal secretions, sputum, tears, urine, and vomit unless they are visibly contaminated by blood.

## Risk Factors

Several factors influence the risk of infection from a significant exposure. These include:<sup>6</sup>

- the virus involved;
- the type of exposure;
- the amount of blood involved in the exposure; and
- the amount of virus in the source person's blood at the time of exposure.

The probability of infection from an exposure varies in proportion to the prevalence of the virus in the population.

A case-control study of health-care workers with occupational percutaneous exposure to HIV-infected blood identified several risk factors associated with HIV transmission: deep injury, injury with a device that was visibly contaminated with the source patient's blood, a procedure involving a needle placed in the source patient's vein or artery, and terminal illness in the source patient.<sup>7</sup> These risk factors are probably an indirect measure of the quantity of blood involved in the exposure and the amount of HIV in the blood,<sup>8</sup> which is higher in the initial stage of HIV infection and in the final stage of AIDS.

The probability of infection from an exposure varies in proportion to the prevalence of the virus in the population. It is greater when the source person is from a population that has a higher than average prevalence of infection. The British Columbia Centre for Excellence in HIV/AIDS estimates that the probability of HIV seroconversion in British Columbia after a single percutaneous needle exposure is 0.3 percent (1 in 300) if the source person is known to be HIV-positive; 0.12 percent (1 in 800) if the source person is an injection drug user; 0.06 percent (1 in 1600) if the source person is a man who has sex with men; and lower still if the risk factors of the source person are unknown or if the source person does not have any risk factors.<sup>9</sup> However, if an HIV-positive source person is taking antiretroviral drugs, the probability of infection from a single percutaneous needle exposure is probably lower than 0.3 percent, since the drugs reduce the amount of virus in the source person's blood.<sup>10</sup>

## Estimates of Risk

### HBV

People who have received hepatitis B vaccine and have developed immunity to the virus are at virtually no risk of infection. For an unvaccinated person, the risk from a single percutaneous exposure to HBV-infected blood ranges from 6 to 30 percent and depends on the serological status of the source person.<sup>11</sup>

99.7 percent of percutaneous exposures do not lead to infection.

### HCV

The risk of infection from a single percutaneous exposure to HCV-infected blood is estimated to be 1.8 percent. The risk of infection from an exposure to mucous membranes or non-intact skin is unknown, but is believed to be very small.<sup>12</sup>

### HIV

The risk of infection from a single percutaneous exposure to HIV-infected blood is estimated to be 0.3 percent (1 in 300). In other words, 99.7 percent of percutaneous exposures do not lead to infection. The rate of transmission from a mucocutaneous exposure is estimated to be, on average, 0.1 percent (1 in 1000). The rate of transmission from an exposure to the skin is estimated to be less than 0.1 percent. There have been no documented cases of HIV infection due to an exposure involving a small amount of blood on intact skin.<sup>13</sup>

## Surveillance of Occupational Exposure

### Health-care settings

There are a number of surveillance programs of occupational exposure among health-care workers in Canada and the United States. The surveillance programs record only reported cases of occupational exposure. Because of failure to report cases, surveillance programs capture only a portion of actual cases of occupational exposure.

A Québec surveillance network (SISES) for exposures to blood and body fluids in acute-care hospitals was established in 1996. As of January 1999, 21 hospitals were participating.<sup>14</sup> An analysis of data from ten hospitals participating in the network for at least six months from May 1995 to September 1997 found that 2380 significant exposures to blood and body fluids were reported. Of these 72.9 percent were needle sticks, 8.9 percent were scratches, 1.2 percent were bites, 9.9 percent were mucocutaneous exposures, and 3.1 percent were exposures to non-intact skin. Nurses sustained 61.5 percent of the exposures, physicians 9.2 percent, nursing aides 5.8 percent, and lab technicians 5.2 percent. Of the 2380 exposures, 1890 (79.4 percent) were to identified source patients, and of these 1401 (74.1 percent) were tested for HIV. Eighty-seven patients (6.2 percent) were infected with HIV.<sup>15</sup>

Health Canada has recently established the Canadian Needle Stick Surveillance Network. The initial phase of the Network includes twelve sites in nine provinces or territories. From April to September 2000, 599 exposures were reported. Of these, 514 (85.8 percent) were percutaneous exposures and 85 (14 percent) were mucocutaneous exposures. The percutaneous exposures included 406 needle sticks, 42 other sticks, 44 cuts, 15 scratches, and seven bites that broke the skin. Eighty-three percent of the known source persons agreed to be tested. Forty-three source persons tested positive for one or more virus. There were seven positive tests for HBV, 31 positive tests for HCV, and 10 positive tests for HIV. One source person was co-infected with all three viruses; three were co-infected with HCV and HIV.<sup>16</sup>

There are two surveillance programs of occupational exposure among health-care workers in the United States: the National Surveillance System for Hospital Health Care Workers maintained by the Centers for Disease Control and Prevention,<sup>17</sup> and the Exposure Prevention Information Network (EPINet) coordinated by the International Health Care Worker Safety Center at the University of Virginia.<sup>18</sup>

### Public service settings

There is limited information on occupational exposures among firefighters, ambulance attendants, police, and correctional staff.

A summary of five studies of HCV infection among emergency responders (firefighters, emergency medical technicians, and paramedics) in selected locations in the United States, conducted between 1991 and 2000, found that the rate of infection was not greater among first responders than in the general population. HCV infection among emergency responders was associated not with occupational factors (such as occupational exposures or duration of employment) but rather with non-occupational factors. The studies could not, however, exclude the possibility that some first responders had acquired HCV infection from job-related exposures.<sup>19</sup>

In a study of occupational exposure to HIV among police officers in Denver, Colorado, conducted between December 1989 and March 1991, 137 officers reported an exposure to

Health Canada has recently established the Canadian Needle Stick Surveillance Network.

There is limited information on occupational exposures among firefighters, ambulance attendants, police, and correctional staff.

blood or saliva. Forty-two of these (one-third of reported incidents) met the study's definition of a significant exposure. These occurred in the following ways: 24 were exposures of blood to non-intact skin, six were exposures of blood to mucous membranes, four were from needle sticks, and two involved lacerations by objects with blood on the surface of the object. Two-thirds of the exposures occurred in circumstances in which (1) there was little or no time for the officer to put on protective gloves and clothing because the officer was restraining or being assaulted by a suspect or (2) gloves would not have been protective because of penetration by needles. Thirty-nine of the 42 exposures were from 34 identified source persons. Thirty-two source persons (94 percent) consented voluntarily to HIV testing, and five were found to be HIV-positive. None of the officers followed for six months seroconverted. The authors of the study concluded that while the police officers rarely had percutaneous or mucocutaneous exposures to blood, when they did, the risk of exposure to HIV-infected blood was quite high.<sup>20</sup>

There have been two probable cases of occupational transmission of HIV in Canada, and one definite case.

## Occupational Transmission of HIV

The accuracy of information on occupational transmission of HIV depends on the adequacy of systems for reporting and verifying cases of transmission. Ninety-two percent of definite or probable cases of occupational transmission have been reported by countries in Europe and North America with well-developed surveillance systems. Even with these systems, however, it is likely that the incidence of occupational transmission is greater than reported cases. The incidence of occupational transmission in Africa and Asia, where the prevalence of HIV is much higher than in Europe or North America, is unknown.<sup>21</sup>

There have been two probable cases of occupational transmission of HIV in Canada, and one definite case.<sup>22</sup> The two probable cases involved laboratory workers. The first was that of a biochemist in Ontario who was diagnosed with AIDS in 1990 and whose only risk factor for HIV was work in the early 1980s with blood that was probably contaminated with HIV, while the second was that of a laboratory technician in Québec diagnosed with HIV infection in the early 1990s and whose only known risk factor was possible exposure to cultured virus during research activities. Although in both cases there were numerous instances where transmission could have occurred, in neither case was a specific incident identified.<sup>23</sup> The first definite case was reported in 1995. A health-care worker who was not wearing gloves sustained a shallow puncture wound from a small-gauge needle. The worker believed the injury to be minor and did not seek antiretroviral treatment. The source person was in the late stage of AIDS, when body fluids have elevated concentrations of HIV, presenting a higher risk of occupational transmission.<sup>24</sup>

In the United States there have been 56 documented cases of occupational transmission of HIV to a health-care worker and 138 possible cases of occupational transmission, reported through June 2000.<sup>25</sup> Of the 56 documented cases, 48 had percutaneous exposure, five had mucocutaneous exposure, two had both percutaneous and mucocutaneous exposure, and one had an unknown route of exposure. Forty-nine were exposed to blood from an HIV-positive person, one to visibly bloody fluid, three to an unspecified fluid, and three to concentrated virus in a laboratory. Twenty-three (41 percent) of documented cases were nurses; 16 (28.5 percent) were clinical laboratory technicians.

In Europe there have been 35 documented cases of occupational transmission of HIV to a health-care worker and 68 possible cases of occupational transmission, reported through June 1999.<sup>26</sup>



## A Backgrounder

# Post-exposure Protocols

In 1995 Health Canada convened a national conference that established a consensus on guidelines for a protocol to notify emergency responders (firefighters, ambulance attendants, and police) when they may have been exposed to an infectious disease (airborne or bloodborne).<sup>27</sup> The protocol provides for a Designated Officer to assess the exposure, treat the exposure, and act as a liaison with public health authorities. It also includes procedures that will facilitate the voluntary testing of source persons with informed consent and appropriate counseling. The protocol has been adopted in British Columbia, Alberta, Saskatchewan, and Ontario.<sup>28</sup>

In 1996 Health Canada convened a meeting that established a protocol to manage exposure to HBV, HCV, and HIV among health-care workers.<sup>29</sup> The protocol sets out provisions for:

- immediate post-exposure activities;
- evaluating a significant exposure;
- counseling the health-care worker;
- testing the source person and the health-care worker;
- post-exposure treatment to prevent seroconversion (post-exposure prophylaxis); and
- post-exposure counseling for the health-care worker on precautions to prevent further transmission of the virus.

Similar protocols have been developed by several provinces.<sup>30</sup> The United States Centers for Disease Control and Prevention, the United Kingdom Department of Health, and the British Columbia Centre for Excellence in HIV/AIDS have also published specific protocols for post-exposure prophylaxis for occupational exposure to HIV.<sup>31</sup>

Information about the source person's serological status can be helpful in determining how to manage an occupational exposure to HBV, HCV, and HIV.

## Obtaining Information about the Source Person's Serological Status

Information about the source person's serological status can be helpful in determining how to manage an occupational exposure to HBV, HCV, and HIV (see below). In some cases, such as when a health-care worker is exposed in a health-care institution while caring for a patient with HIV/AIDS, the source person's serological status may be known. In these circumstances, provision may be made under the confidentiality guidelines of the health-care institution to disclose the source person's serological status to the exposed worker.<sup>32</sup> In other cases, the source person's serological status may be unknown and information may need to be obtained.

"Obtaining informed consent from the source is an integral part of all post-exposure testing procedures, as is maintaining confidentiality of all information."

The 1995 national conference on guidelines for establishing a notification protocol for emergency responders considered how to obtain information about the source person's serological status and provide that information to the exposed worker. The guidelines include the following stipulations:<sup>33</sup>

- personal information about the source person cannot be released without that person's consent;
- if testing the source person is recommended, the source person's informed consent must be obtained;
- the process of obtaining informed consent and testing the source person must include appropriate pre- and post-test counseling;
- the request for testing should be made to the source person by a person designated to perform this function by the health-care facility, public health authority, or other policy-makers, not by the exposed worker;
- the type of information that may be provided to the exposed worker should be specified in a way that addresses the source person's right to privacy and confidentiality with respect to health information (eg, the exposed worker will be informed of the serological status, but not the identity, of the source person).

The 1996 meeting on an integrated protocol for managing health-care workers exposed to bloodborne pathogens made similar recommendations:

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 [HBV, HCV, and HIV], the appropriate pre- and post-test counselling for all three bloodborne pathogens should be done.<sup>34</sup>

These recommendations are consistent with guidelines in the United States and the United Kingdom.<sup>35</sup> However, testing without consent or compulsory testing is permitted by law in many jurisdictions in the United States. At least 21 states do not require informed consent to test persons who may have exposed a health-care worker, emergency services provider, or law enforcement officer to HIV. At least 17 states require or allow a court order if consent has not been given, and bills that would allow a court order to require testing are pending in at least 30 states.<sup>36</sup>

## Post-exposure Prophylaxis

If the source person tests positive for HBV, HCV, or HIV *or* if the source person tests negative for HBV, HCV, or HIV but has one or more of the risk factors, post-exposure prophylaxis (if available) may be required for the exposed worker.

## HBV and HCV

Post-exposure prophylaxis for exposure to HBV consists of treatment with hepatitis B immune globulin (HBIG) and hepatitis B vaccine, depending on the exposed worker's susceptibility or immunity to HBV infection.<sup>37</sup> If indicated, HBIG should be administered within 48 hours (United States guidelines recommend preferably within 24 hours).<sup>38</sup> The efficacy of HBIG as post-exposure prophylaxis decreases with time and is unknown after seven days.

There is no post-exposure prophylaxis for exposure to HCV.<sup>39</sup>

## HIV

Post-exposure prophylaxis for exposure to HIV consists of treatment with two or three antiretroviral drugs. Zidovudine (AZT) and lamivudine (3TC) (both nucleoside reverse transcriptase inhibitors) are often prescribed. It is now increasingly common to add a third drug (a protease inhibitor or non-nucleoside reverse transcriptase inhibitor), particularly when the risk of transmission is high, because in principle a combination of three drugs has greater antiretroviral activity and is less likely to result in drug resistance. However, it is sometimes necessary to reduce the number of drugs taken or to replace one drug with another because of side effects, adverse events, and drug resistance.<sup>40</sup>

The decision to recommend or offer prophylaxis, and the number of drugs in the treatment, depends on the assessment of the risk incurred in the exposure:<sup>41</sup>

There is no post-exposure prophylaxis for exposure to HCV.

- *higher risk of transmission:* Treatment with three drugs (eg, two nucleoside analogue reverse transcriptase inhibitors and one protease inhibitor) is recommended strongly when the exposure involves an infectious body fluid, a source person who is HIV-positive or has recently engaged in high-risk behaviours, a percutaneous exposure, or a major mucocutaneous or non-intact skin exposure (ie, more than a few drops of blood and/or duration of exposure of several minutes or more).
- *moderate risk of transmission:* Treatment with two drugs (eg, two nucleoside reverse transcriptase inhibitors) is recommended when the exposure involves an infectious body fluid; a source person who is HIV-positive or has recently engaged in high-risk behaviours, but when the injury is unlikely to result in transmission, such as a minor mucocutaneous or non-intact skin exposure (ie, less than three drops for a duration of a minute or two); or bites where there is blood in the mouth of the biter and a bleeding wound in the skin of the person bitten. (This category is being reconsidered by the British Columbia Centre for Excellence in HIV/AIDS and may be eliminated.<sup>42</sup>)
- *negligible risk of transmission:* Treatment with drugs is not recommended but counseling is offered to explain the negligible risk of transmission and to reassure the worker when the exposure involves a source person known or presumed to be HIV negative or when an injury is not known to transmit HIV or a body fluid is not known to transmit HIV.

It is virtually impossible to obtain evidence of the effectiveness of post-exposure prophylaxis in humans through a randomized controlled clinical trial, since the rate of transmission is low and it would be difficult to obtain a sufficient sample of workers with documented occupational HIV exposure. However, there is strong *indirect* evidence of effectiveness. An international case-control study of health-care workers exposed to HIV found that the odds of HIV infection among those who took zidovudine was reduced by approximately 81 percent.<sup>43</sup> In addition, a substantial number of studies have demonstrated that antiretroviral

treatment is effective in preventing HIV transmission from infected mothers to their children.<sup>44</sup>

According to the current standard of care, post-exposure prophylaxis with antiretroviral drugs should begin as soon as possible after the exposure, preferably within one to two hours of the exposure.<sup>45</sup> Treatment may still be considered at later intervals because of the potential benefits of early treatment of acute HIV infection, should seroconversion occur.<sup>46</sup> The traditional duration of treatment is 28 days or four weeks. Studies of post-exposure prophylaxis in animals have found that treatment administered within 24 to 36 hours of infection was effective in preventing transmission, whereas infection occurred in some animals when treatment was administered within 48 to 72 hours.<sup>47</sup> The evidence for a preferred duration of

Post-exposure prophylaxis with antiretroviral drugs should begin as soon as possible after the exposure.

treatment is ambiguous. Some studies in animals have also found that infection occurred when post-exposure prophylaxis was given for less than 28 days (10 days and under).<sup>48</sup> But other studies have found that shorter courses of treatment have been effective in preventing transmission, both in animals and from mother to child in humans.<sup>49</sup>

Under certain conditions, antiretroviral drugs should not be used or should be used only with extreme caution.<sup>50</sup> Protease inhibitors may have potentially serious drug interactions when used with certain other drugs, and have been associated with a variety of toxicities.<sup>51</sup> Serious concerns have recently been raised about the safety of nevirapine (a non-nucleoside reverse transcriptase inhibitor) in post-exposure prophylaxis.<sup>52</sup> It may be that risks that are acceptable when treating a person with HIV infection are not acceptable when treating a person who has only possibly been exposed to HIV. When the risk of HIV infection is low, there is reason to be conservative in prescribing antiretroviral drugs.<sup>53</sup> As noted above, the British Columbia Centre for Excellence in HIV/AIDS is reconsidering its post-exposure prophylaxis recommendations for cases of moderate risk.<sup>54</sup>

Special care is required in offering and administering post-exposure prophylaxis to pregnant women.<sup>55</sup> Information about the risks of administering antiretroviral drugs to pregnant women is extremely limited. There is evidence that zidovudine is safe and well tolerated in pregnant women and infants. It appears from limited data that lamivudine is also safe. There are no data on protease inhibitors in pregnant women.<sup>56</sup>

There are side effects and adverse events associated with post-exposure prophylaxis. A United States registry of health-care workers receiving post-exposure prophylaxis from October 1996 to March 1999 found that among those for whom data was available at six weeks, 76 percent reported some symptoms or adverse events. The most frequently cited symptoms were nausea (57 percent), malaise or fatigue (38 percent), headache (18 percent), vomiting (16 percent), diarrhea (14 percent), and myalgias or arthralgias (6 percent). Most side effects and adverse events resolved when treatment was stopped.<sup>57</sup> A recent review of 1835 cases of post-exposure prophylaxis for *non*-occupational exposures in France found 13 severe adverse events. They included nephrolithiasis (6), severe rash (2), toxic hepatitis (2), cholecystitis (1), hemolysis (1) and epidermolysis bullosa (1). All the events were reversible.<sup>58</sup>

Side effects and adverse events due to post-exposure prophylaxis result in significant time off work. The Worker's Compensation Board of British Columbia reports that 60 percent of workers receiving post-exposure prophylaxis lose time at work, and that the average time lost is 19 days.<sup>59</sup> Side effects and adverse events are also one of the main reasons for not completing the full course of post-exposure prophylaxis (the other reason being finding out that

the source person tested negative for HIV).<sup>60</sup> The United States registry of health-care workers receiving post-exposure prophylaxis found among those who discontinued all drugs or did not complete the regimen, half cited symptoms or adverse events as a reason for discontinuation.<sup>61</sup> Similarly, surveillance of health-care workers in the United Kingdom who received post-exposure prophylaxis between July 1997 and June 2000 found that, of the 100 workers who were treated, 57 discontinued treatment early, mainly because of side effects.<sup>62</sup>

Counseling is an essential component of care for a worker following an exposure.

There have been 28 reported cases worldwide of failure of post-exposure prophylaxis to prevent HIV seroconversion.<sup>63</sup> However, investigations of two such cases in the United States found that in fact seroconversion was not a result of the occupational exposure but of some other exposure, indicating that confirmation of failure may be required.<sup>64</sup>

## Counseling and Follow-up

Counseling is an essential component of care for a worker following an exposure. It helps to reduce anxiety, ensure adequate treatment and follow-up, promote adherence to post-exposure prophylaxis, and reduce the risk of transmission of the virus to others. For an exposed worker, dealing with anxiety about the possibility of infection and taking precautions to prevent transmission to others are, along with the side effects and adverse effects of post-exposure prophylaxis, the main burdens of coping with an occupational exposure. They have an impact not only on the worker, but on the families or intimates of the worker.

### Preventing further transmission

Workers exposed to HBV, HCV, or HIV should not donate blood, semen, organs, or tissues for six months, and should not share toothbrushes, razors, needles, or other implements which may be contaminated with blood or body fluids.<sup>65</sup>

For workers exposed to HBV and receiving hepatitis B immune globulin and/or the hepatitis B vaccine series, no clear guidance can be given on safer sex practices and notifying sexual partners.<sup>66</sup>

Workers exposed to HCV should be counseled about safer sex practices and about advising their sexual partners of the potential risk of transmission, which is low but not absent for HCV-positive persons with one long-term steady sexual partner.<sup>67</sup> Counseling should also be provided about other activities, such as sharing needles, that involve a risk of transmission. Women should be informed about the current state of data on transmission from mother to infant (approximately five of every 100 infants born to HCV-infected women become infected).<sup>68</sup>

Workers exposed to HIV should be counseled about safer sex practices and about advising their sexual partners of the potential risk of transmission. Counseling should also be provided about other activities, such as sharing injecting needles, that involve a risk of transmission. Women should avoid becoming pregnant until they are reasonably sure that they are not infected (three to six months). Women who are breast-feeding a child should be counseled about the risk of transmission through breast milk, particularly during the period when seroconversion may occur, and advised of alternatives while awaiting information on the source person's or their own serostatus.<sup>69</sup>

### Testing the exposed worker

When exposure to HBV, HCV, or HIV cannot be ruled out, testing the worker is necessary to determine if the worker has been infected. Testing is voluntary and must be accompanied

by appropriate counseling. Because of the window period associated with viral infections (see below), testing at time of exposure and at three and six months is recommended after exposure to HBV or HCV; and at time of exposure, six weeks, three months, and six months after exposure to HIV.<sup>70</sup>

When exposure to HBV, HCV, or HIV cannot be ruled out, testing the worker is necessary to determine if the worker has been infected.

In fact, many exposed workers do not follow through with testing. The SISES surveillance network for blood and body fluid exposures in acute care hospitals in Québec found that of health-care workers exposed to fluids from a person with HIV, 44.3 percent had an HIV test at the time of the exposure, 24.8 percent had a test at six weeks, 22.4 percent had a test at three months, and 20.2 percent had a test at six months. Follow-up testing among

workers for whom the source person of an exposure was not identified was even lower.<sup>71</sup> Similar loss to follow-up has been observed elsewhere.<sup>72</sup>



# Testing Technologies and Procedures

## Types of Tests

Several types of tests are used to determine whether a person has been exposed to or infected by HBV, HCV, or HIV. There are tests that detect the presence of antibodies to the virus or antibodies to a particle of the virus (antigens). These include:

- tests for antibodies to the hepatitis B surface antigen (anti-HBs), hepatitis B core antigen (anti-HBc), and hepatitis B e antigen (anti-HBe). (The presence of anti-HBs at levels  $\geq 10$  IU/L or the presence of anti-HBc is a sign of immunity to hepatitis B.<sup>73</sup>)
- tests for antibodies to hepatitis C (anti-HCV).
- tests for antibodies to HIV (anti-HIV).

There are tests that detect the presence of particles of the virus in the blood. These include:

- tests for hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg). (The presence of HBsAg is a sign of immunity to hepatitis B; blood containing HBsAg is considered infectious. The presence of HBeAg is a sign of viral replication and high infectivity, while the presence of anti-HBe indicates reduced viral replication and lower infectivity.<sup>74</sup>)
- tests for the HIV p24 core antigen (p24 antigen).

There are tests, called nucleic acid tests (NAT), that detect the presence of genetic material (RNA or DNA) of HBV, HCV, and HIV in the blood. Various technologies are used: polymerase chain reaction (PCR)-based tests, transcription-mediated amplification tests, and branched DNA signal amplification tests.

In addition, in the case of HBV and HCV, there are tests that measure the levels of alanine aminotransferase (ALS) and aspartate aminotransferase (AST), which are liver enzymes. Higher-than-normal levels of these enzymes can be a sign of changes in liver function.

## The Window Period

All viral infections begin with a window period in which the virus is present in the body but antibodies to the virus are not present in blood or cannot be detected with confidence by current antibody tests. There are two phases to the window period. In the first phase virus is not present in blood or cannot be detected by existing testing technologies. In the second phase virus is present in blood and can be detected by nucleic acid tests or antigen tests. According to current models of early infection:<sup>75</sup>

- HBV DNA can be detected up to 23 days before HBsAg, HBsAg can be detected 56 days after infection, and HBV antibodies can be detected 60 days after infection;
- HCV RNA can be detected 12 days after infection, and HCV antibodies can be detected 70 days after infection; and
- HIV RNA can be detected 11 days after infection, HIV p24 antigen can be detected 16 days after infection, and HIV antibodies can be detected 22 days after infection.

It is not possible to rule out infection until the window period is over (when antibodies to the virus are present in the blood). The length of the window period varies from person to person. In most people, seroconversion to HCV and HIV occurs within six months. In some people, it occurs later, nine months after exposure to HCV and up to a year after exposure to HIV. (Approximately five percent of persons infected with HIV develop antibodies after six months).<sup>76</sup> Therefore, to be sure that they are not infected, workers exposed to HBV should be re-tested at six months; workers exposed to HCV should be re-tested at three months and six months; and workers exposed to HIV should be re-tested at six weeks, three months, and six months (some protocols recommend testing for HIV after one year).<sup>77</sup>

## Screening Tests and Supplemental/Confirmatory Tests for HCV and HIV

The standard diagnostic testing process for HCV and HIV consists of a screening test (an enzyme immunoassay or EIA) and a supplemental or confirmatory test for antibodies to the virus. Although nucleic acid tests and antigen tests can detect infection earlier than antibody tests, they are not used as standard diagnostic tests. The reasons for this include cost, the complexity of the technique, problems in assuring reliable and standard results, and problems associated with false negative and false positive results.<sup>78</sup> All diagnostic testing must be accompanied by appropriate pre- and post-test counseling, including information about, among other things, the window period and the possibility of false test results.

### HCV

Screening tests for HCV detect anti-HCV in 97 percent or more of infected people, but do not distinguish between acute, chronic, and resolved infection. The tests yield a high proportion of false positive results when used in populations with low prevalence of HCV infection. A person is considered positive for anti-HCV if the result of the screening EIA and the supplemental test are positive. Persons with a negative EIA result or a positive EIA and a negative supplemental test are considered uninfected, unless other evidence exists to indicate HCV infection.<sup>79</sup>

The steps in HCV testing are as follows:<sup>80</sup>

- apply an EIA to a blood specimen;
- if the result is negative, test again as required by the window period (at three and six months);

- if the result is positive, repeat the EIA in duplicate on the same blood specimen;
- if the results of the second two EIAs are negative, test again as required by the window period;
- if the results of the second two EIAs are positive/negative or positive/positive, apply a supplemental test (another EIA or an immunoblot);
- if the result of the supplemental test is negative, test again as required by the window period; if positive, evaluate clinically; if indeterminate, consider applying a nucleic acid test.

## HIV

The EIA for HIV is highly sensitive. As a result, the likelihood of missing antibody is low, and the probability that a negative result is a true result is very high. However, a positive reaction to the EIA may be caused not by antibodies to HIV but by factors acting like antibodies to HIV (a false positive result). Therefore a more specific confirmatory test is required. While repeatedly positive EIA results are considered highly suggestive of infection, a positive confirmatory test (Western blot or other approved test) is required for a definite diagnosis of HIV infection.<sup>81</sup>

HIV p24 antigen and HIV RNA tests have been used to provide an early indication, prior to detection of HIV antibodies, of HIV infection in a health-care worker after an occupational exposure.<sup>82</sup> However, these tests cannot be relied on for a definite diagnosis of HIV infection. A study of persons in the early stage of HIV infection who tested negative for HIV antibodies found that p24 antigen tests detected approximately 90 percent of infections before HIV antibodies were detected. (There were some false negative results but no false positive results with the p24 antigen tests.) HIV RNA tests detected 100 percent of infections (there were no false negative results), but included some false positive results.<sup>83</sup> It is important to note that these findings cannot be applied to later stages of HIV disease, since the level of virus in the blood drops after the initial stage of infection, and tests that detect virus in the blood may produce false negative results.<sup>84</sup> This is particularly likely in persons receiving antiretroviral drugs, which can reduce the amount of virus in the blood to undetectable levels.

The steps in testing for antibodies to HIV are as follows:<sup>85</sup>

- apply an enzyme immunoassay (EIA) to a blood specimen;
- if the result is negative, test again as required by the window period (at six weeks, three months, and six months);
- if the result is positive, repeat the EIA in duplicate on the same blood specimen;
- if the result of the second two EIAs is negative, test again as required by the window period;
- if the result of the second two EIAs is positive, apply a Western blot or other approved confirmatory test;
- if the test is negative, test again as required by the window period; if positive, provide appropriate counseling, care, and treatment.

## Expedited Testing and Rapid HIV Tests

Standard screening and confirmatory HIV tests take time to complete, partly because samples are batched to reduce the costs of testing. Some jurisdictions in Canada provide for expedited laboratory processing of tests (24 to 48 hours) in the event of an occupational

exposure. It is usually recommended that the laboratory be notified in advance by telephone to ensure that the processing is expedited, particularly on weekends.<sup>86</sup>

Rapid point-of-care HIV tests can reduce the time required to obtain results. These tests are approved for use by health-care providers at the point of care. The tests use an EIA that is an equivalent of the EIAs used in laboratories to test blood specimens, but they can produce a result in less time (from a few minutes to two hours). If the result is negative, no further testing is required. If the result is positive or equivocal, a blood sample for further testing is obtained (with appropriate counseling), an EIA is applied in a laboratory and, if the result is positive, a confirmatory test is applied.<sup>87</sup>

The United States guidelines for managing occupational exposures among health-care workers recommend that an approved rapid HIV test should be considered for use in testing the source person, particularly if an EIA cannot be completed by a laboratory within 24 to 48 hours:

Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary for making initial decisions about post-exposure management but should be done to complete the testing process.<sup>88</sup>



A Backgrounder

## Benefits to the Exposed Worker of Information about the Source Person

Information about the serostatus, risk factors, and medical history of the source person may be useful when managing an occupational exposure to HBV, HCV, and HIV. But there are important qualifications as to how useful or timely the information may be.

### Information about the Source Person's Serological Status and Risk Factors

If the source person is known not to have HBV, HCV, or HIV and has no risk factors, the exposed worker will not have to take precautions to prevent further transmission, receive post-exposure prophylaxis, or be tested for infection. However, counseling should be provided to explain the negligible risk of infection and to alleviate anxiety.

If the source person tests positive for HBV, HCV, or HIV *or* if the source person tests negative for HBV, HCV, or HIV but has one or more risk factors, the exposed worker should receive counseling, consider post-exposure prophylaxis (if available), take precautions to prevent further transmission, and be tested for infection. (When risk factors are present, the possibility remains that the source person is infected despite a negative test result, because of the window period.)

Risk factors for HBV within the past three months include:<sup>89</sup>

- high-risk sexual behaviour (ie, men who have sex with men, sexual partner who is an injection drug user, multiple sexual partners);
- sexually transmitted disease(s);
- sexual or blood contact with a person known to be infected with HBV; and
- injection drug use or tattoo/body piercing.

Risk factors for HCV over a lifetime include:<sup>90</sup>

- high-risk sexual behaviour (ie, sexual partner who is an injection drug user, multiple sexual partners);
- sexual or blood contact with a person known to be infected with HCV;
- injection drug use 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; and
- dialysis.

Risk factors for HIV within the past six months include:<sup>91</sup>

- high-risk sexual behaviour (ie, men who have sex with men, sexual partner who is an injection drug user, multiple sexual partners);
- sexually transmitted disease(s);
- sexual or blood contact with a person known to be infected with HIV; and
- injection drug use or tattoo/body piercing.

As noted above, rapid point-of-care HIV tests can provide results relatively quickly, and a negative result may contribute to a decision not to begin post-exposure prophylaxis for HIV infection.<sup>92</sup> However, since treatment should ideally begin within two hours, it is not advisable to wait for the results of the test of the source person before starting post-exposure prophylaxis and taking preventative precautions.<sup>93</sup> If the result of the source person's test is found to be negative, the exposed worker can then decide to discontinue post-exposure prophylaxis and preventative precautions. In fact, the British Columbia Centre for Excellence in HIV/AIDS has found that the most common reason for discontinuing treatment is that the source person tested negative.<sup>94</sup> Similarly, the United States registry of health-care workers receiving post-exposure prophylaxis from October 1996 to March 1999 found that among those for whom data were available, at week six 48 percent of those who discontinued post-exposure prophylaxis did so because the source person tested negative.<sup>95</sup>

## Information about the Source Person's HIV Disease and Treatment

If the source person is known to be HIV positive and is receiving medical care, information about the source person's disease status and treatment may be useful in designing or modifying post-exposure prophylaxis for the exposed worker. This information includes the source person's stage of infection (ie, asymptomatic or AIDS), CD4+ T-cell count, results of viral load testing (tests that measure the quantity of virus in the blood), and current and previous antiretroviral therapy.<sup>96</sup> It is important to determine whether the source person has developed resistance to any antiretroviral drugs, since these drugs may then be excluded from the post-exposure prophylaxis for the exposed worker or may be complemented with drugs to which the source person has no known resistance.<sup>97</sup>



A Backgrounder

## Harms to the Source Person from Compulsory Testing and Disclosure

Most source persons agree to be tested and permit relevant information to be provided to the exposed worker when they are approached in a sensitive manner and the importance of the information is explained.<sup>98</sup> A survey of 38 hospitals in Maryland, where an HIV test cannot be done unless the person consents, found that, of 1350 requests for HIV testing, 92 percent of patients agreed to be tested (two percent already knew their HIV status and six percent refused testing).<sup>99</sup> Likewise, in the first six months of the Canadian Needle Stick Surveillance Network, 83 percent of known source persons agreed to be tested.<sup>100</sup> So too, the study of occupational exposure among police officers in Denver, Colorado, reports that, of 34 identified source persons, 32 (or 94 percent) agreed to be tested for HIV.<sup>101</sup>

However, some source persons do not agree to be tested or to disclose confidential medical information. What harms will such persons incur if testing and disclosure are compulsory?

Mandatory testing of a source person and disclosure of the results of the test would be an infringement of that person's personal autonomy. Respect for personal autonomy is a fundamental principle of biomedical ethics. It is the basis for ethical rules and practices that require voluntary informed consent for medical procedures, that respect the individual's right to privacy, and that protect the confidentiality of personal medical information.<sup>102</sup> The right to autonomy, and the rules and practices based on it, are not absolute; they may be infringed, if there is sufficient justification based on other ethical principles, such as the principle of beneficence or the principle of justice. However, the justification must be substantial and the terms of the infringement must be carefully circumscribed.

A recent Canadian study of the experience of being tested for HIV confirms the importance of respect for personal autonomy, privacy, and confidentiality in the testing process. People being tested expected those providing the test to acknowledge the test recipient as an

Some source persons do not agree to be tested or to disclose confidential medical information. What harms will such persons incur if testing and disclosure are compulsory?

individual and include the recipient in decision-making. Test recipients universally valued confidentiality and preferred anonymity, although this was not often their experience. They valued a testing environment where privacy and anonymity would be respected, and where individuals feel accepted and acknowledged.<sup>103</sup>

The Supreme Court of Canada and appellate courts have repeatedly affirmed that a person cannot be subjected to medical procedures without his or her consent.

Out of respect for personal autonomy, the Supreme Court of Canada and appellate courts have repeatedly affirmed that a person cannot be subjected to medical procedures without his or her consent.<sup>104</sup> Bill C-217 violates this legal doctrine, as well as the principle of personal autonomy, by mandating serological testing of the source person; by permitting disclosure of the results of the test to the medical practitioner who took the blood sample, to the peace officer executing the warrant authorizing the blood sample to be taken, and to the exposed worker; and by requiring that the source person be informed of the results of the test.

Bill C-217 also arguably infringes several rights and freedoms guaranteed by the *Canadian Charter of Rights and Freedoms*.<sup>105</sup>

These include the right to “life, liberty and security of the person and the right not to be deprived thereof except in accordance with principles of fundamental justice” (section 7), and the right to be “secure against unreasonable search or seizure” (section 8).

According to Canadian courts, the fundamental purpose of section 8 is “to protect individuals from unjustified state intrusions upon their privacy.”<sup>106</sup> The Supreme Court of Canada has ruled that

the use of a person’s body without his consent to obtain information about him, invades an area of personal privacy essential to the maintenance of his human dignity. . . . [T]he protection of the *Charter* extends to prevent a police officer, an agent of the state, from taking a substance as intimately personal as a person’s blood from a person who holds it subject to a duty to respect the dignity and privacy of that person.<sup>107</sup>

The Supreme Court has also repeatedly affirmed the importance of protecting the privacy of personal information, ruling that the Charter protects “the right of the individual to determine for himself when, how, and to what extent he will release personal information about himself.”<sup>108</sup>

Where a law is found to limit a Charter right, it is open to the courts to uphold the law under section 1 of the Charter. Section 1 guarantees the rights and freedoms set out in the Charter “subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.” The Supreme Court of Canada has set out the requirements for justifying legislation that infringes Charter rights:<sup>109</sup>

- the objective to be served by the measures that limit a Charter right must be sufficiently important to warrant overriding a constitutionally protected right or freedom, in that it must at least relate to societal concerns that are “pressing and substantial” in a “free and democratic society”;
- the measures must be fair and not arbitrary, carefully designed to achieve the objective in question, and rationally connected to that objective;
- the measures should impair the Charter right as little as possible; and
- there must be proportionality between the effects of the limiting measure and the objective – the more severe the infringement of the right, the more important the objective

must be if the measure is to be reasonable and demonstrably justified in a free and democratic society.

At present, the *Criminal Code* allows bodily samples to be taken without consent in two carefully limited circumstances: testing for alcohol when there are reasonable grounds to believe an offence of impaired driving has been committed, and taking samples for the purpose of DNA analysis relating to a prosecution for certain designated serious offences. In both cases the infringement of privacy has been deemed justified in the interests of law enforcement once reasonable grounds exist for believing a person has engaged in criminal wrongdoing. Bill C-217 proposes to take bodily samples without this precondition.<sup>110</sup>

Requiring a person to be tested for HBV, HCV, and HIV is more than a minimal impairment of Charter rights, and the seriousness of the impairment is compounded by possible imprisonment for refusal to be tested and the lack of any confidentiality protections for those subjected to compulsory testing.<sup>111</sup> Bill C-217 does not require anyone receiving the test results to keep those results confidential (nor is such an obligation clearly established elsewhere in law). The bill does not prescribe a criminal penalty for a breach of confidentiality or create a civil cause of action against anyone who breaches confidentiality. Nor does the bill require a ban on publishing the source person's identity, to prevent widespread disclosure of personal health information through, for example, media reporting on a court application for a warrant authorizing testing.<sup>112</sup>

The stated objective of the bill is to provide for the taking of blood samples for the benefit of persons who are exposed while performing a designated function, that is, a function performed by a firefighter, health-care provider, peace officer, security officer, or "good Samaritan." This benefit presumably consists of information that may contribute to decisions about post-exposure prophylaxis and relieve uncertainty as to whether there was in fact an exposure to HBV, HCV, or HIV. If the test results of the source person are negative and there are no risk factors (information that Bill C-217 does not require to be gathered), the exposed person may be reasonably certain that there was not a significant exposure, be relieved of anxiety, and forego post-exposure prophylaxis (if available). If the test results of the source person are positive or if the results are negative but there are risk factors (indicating that the test may have been taken during the window period), the exposed person would have to take steps to prevent further transmission, consider post-exposure prophylaxis (depending on the nature of the exposure), and re-test at a later time. It is not possible to deduce from such results that the exposed person was infected. Post-exposure prophylaxis should not be necessary for occupational exposure to HBV (preventative vaccination is available), and is not available for exposure to HCV. It is available for exposure to HIV, but should ideally be started within two hours of the exposure. It is highly unlikely that a compulsory testing procedure, which involves obtaining a judicial warrant, would produce information in time to contribute to decisions to start HIV post-exposure prophylaxis. The information would only be used in decisions to stop prophylaxis should the results of the test be negative and no risk factors be present.

These benefits to the exposed worker must be weighed against the harms of compulsory testing. The person required to be tested suffers harms to bodily and psychological integrity, an infringement of personal privacy, and a loss of confidentiality.<sup>113</sup> If the results of the tests

It is highly unlikely that a compulsory testing procedure, which involves obtaining a judicial warrant, would produce information in time to contribute to decisions to start HIV post-exposure prophylaxis.

are positive, the person may experience further harms, which in the case of HIV infection include feeling stigmatized, anticipating being stigmatized, fear of the course of the illness, fear of infecting others, fear of leaving loved ones, and suicidal thoughts.<sup>114</sup> These harms may come at a time when the person is already having to deal with the circumstances in which the occupational exposure occurred, such as an accident or a medical crisis. Compulsory testing in such circumstances may cause the person tested to distrust those whose role it is to assist, damaging, for instance, the therapeutic relationship that is necessary for good health care.<sup>115</sup>

Whatever justification there may be for these harms is weakened by the relatively low risk of occupational transmission of HBV, HCV, and HIV, as well as the relatively high potential to prevent occupational exposure and transmission by using routine precautions in health-care settings and public service settings (see below).



A Backgrounder

# Positions of Professional Associations and Unions on Management of Occupational Exposure

## Canadian Nurses Association

In November 2000 the Canadian Nurses Association published a revised position statement on bloodborne pathogens.<sup>116</sup> The revised statement, which replaces a 1993 statement, endorses the use of routine precautions (also called “standard precautions”):<sup>117</sup>

The Canadian Nurses Association endorses the necessity for implementation of policies and procedures requiring the use of Standard Precautions (previously called Universal Precautions). Adherence to Standard Precautions is the appropriate and effective means to protect nurses, clients and others from the spread of blood-borne pathogens. Adherence to Standard Precautions is ethically acceptable as it precludes the need to know the blood-borne pathogen status of clients or nurses, and safeguards the rights of individuals for privacy and confidentiality of information.

The statement specifically addresses the issue of testing:

Compulsory testing for blood-borne pathogens either before or after significant exposure is not warranted because current technology cannot always identify persons infected with blood-borne pathogens. In caring for all clients, whether their status regarding blood-borne pathogens is known, the nurse is guided by the values of the *Code of Ethics for Registered Nurses*.<sup>118</sup> The nurse has an ethical responsibility to provide care that includes bringing good to the client, minimizing harm, and respecting the right of the client to accept or to refuse treatment.

The statement concludes by noting the responsibilities that nurses and their employers have to remain up-to-date in policies and practices related to bloodborne pathogens:

Nurses have the professional responsibility to regularly update their knowledge of blood-borne pathogen practices. Practices related to prevention, immediate exposure, testing, reporting, use and disposal of equipment are of particular importance. Nurses participate with experts and other health professionals to develop clear policies and procedures based on current knowledge. Employers share in this responsibility by promoting a safe, quality practice environment including access to relevant educational resources.

## Canadian Association of Nurses in AIDS Care

In April 2000 the Canadian Association of Nurses in AIDS Care/Association Canadienne des Infirmières et Infirmiers en Sidologie (CANAC/ACIIS) published a position statement on the prevention and management of occupational exposure.<sup>119</sup> According to this statement, exposures are linked to procedures, the organization of care, and human factors such as burnout

Employers should be made aware that the risk of occupational exposures is increased by unrealistic workloads and by the use of less-skilled workers replacing highly skilled workers in the performance of high-risk procedures.

and stress. It is difficult to assess the number and severity of occupational exposures to bloodborne pathogens because many incidents in health-care settings are not reported. Not all health-care facilities have implemented employee safety programs or guidelines on post-exposure management, and access to appropriate post-exposure management is inconsistent from one location to the next.

CANAC/ACIIS emphasizes that there is an urgent need to collect and analyze data on needle sticks and other occupational injuries in Canada to identify the extent of occupational injuries. It sets out numerous steps that could be taken to prevent occupational exposures and respond to them in a timely manner, such as:

- health-care facilities should examine current practices for invasive procedures, and design and implement protocols and programs to eliminate registered nurses' unnecessary exposure to bloodborne pathogens;
- employers should be made aware that the risk of occupational exposures is increased by unrealistic workloads and by the use of less-skilled workers replacing highly skilled workers in the performance of high-risk procedures;
- health-care facilities should implement work-practice measures, such as new safety devices, to minimize or eliminate the risk of occupational exposure to bloodborne pathogens;
- manufacturers should develop affordable safety devices for preventing needlestick injuries and collaborate with professional nursing associations to find realistic economic solutions;
- comprehensive educational and training programs that address prevention measures and post-exposure management should be included in nursing curricula, employee training programs, and continuing education programs;
- registered nurses should take steps to ameliorate any current inadequacies by, for example, requesting training programs, becoming knowledgeable about the risks and

management of occupational exposure, ensuring that HIV post-exposure kits are available in less than two hours, collaborating with employers and/or facilities in developing policies and procedures, reporting every occupational exposure, and adhering to policies and procedures to minimize the risk of seroconversion; and

- employers should implement structures or create links with existing structures to make available pre- and post-test counseling and support for registered nurses, respecting the human rights of the registered nurse and the patient.

CANAC/ACIIS maintains that testing a patient without informed consent is unethical.

## Canadian Medical Association

The Canadian Medical Association (CMA) revised its policies on Acquired Immunodeficiency Syndrome and HIV Infection in the Workplace in 2000. These revisions ended a process that began when the 1999 General Council of the CMA adopted a motion recommending compulsory serologic testing of a patient after a health-care worker has been exposed to the patient's body fluids.<sup>120</sup> This motion, along with an accompanying motion recommending compulsory serologic testing of the health-care worker if a patient has been exposed to the worker's body fluids, was referred for study. During the following year, the CMA commissioned an epidemiological review and two legal opinions. The motions were rescinded by the 2000 General Council.

The CMA policy on HIV infection in the workplace addresses HIV infection and AIDS in the general workplace and in the health-care workplace, and discusses testing for HIV antibody. It notes that

[a]ny policy in this area should be based on scientific, epidemiologic and ethical principles. The primary purpose is the promotion of effective action to control infection among health care workers and the public and the safeguarding of human rights.<sup>121</sup>

The policy discusses the risk of HIV transmission in the general workplace and in the health-care workplace. Regarding the general workplace, the policy states:

Some occupations may place the worker at potential risk of exposure to HIV. For example, police work, firefighting or garbage collection may place a worker in contact with the body fluids of people who may be HIV-positive. In such circumstances the risk of transmission is extremely low. However, as a general measure to minimize the risk of infection from HIV or other pathogens, workers should take reasonable precautions when at work. Such precautions include the use of gloves when possible to reduce contact with body fluids and the use of bleach solution for cleaning up spilled blood.

Regarding the health-care workplace, the policy states:

The nature of the health care workplace carries with it a greater risk of occupational exposure to HIV than the general workplace. A health care worker may be directly exposed to the blood or body fluid of an HIV-positive patient during routine work or through a work-related accident such as a needle-stick injury. Nevertheless, the occupational risk of HIV infection for health care workers, although not absent, is very low. The risk of transmission from an infected health care worker to a patient is also very low.

Risk of infection does not warrant refusal of services. The policy states:

Traditionally health care services have been provided even when they might pose a risk to the health care worker. In the case of HIV infection this risk, although low, can be further reduced by the rigorous application of infection-control guidelines. Health care workers have an ethical responsibility to provide appropriate services to patients who are HIV positive or whose serological status is unknown.

The policy discusses both health-care workers with HIV infection and health-care workers who may have been exposed to HIV. With regard to the latter, the policy states:

Any occupational injury of a health care worker that may have exposed the worker to HIV should be reported confidentially to the physician responsible for occupational employee health in the institution where the injury occurred or to a physician not involved in the injury or the care of the infected patient. The patient should be asked to undergo voluntary HIV antibody testing and to consent to communication of the results to the injured worker, unless it is already known that the patient is HIV positive. Such testing should always be accompanied by pretest and post-test counselling. Compulsory testing is unjustified.

This policy is consistent with the CMA's policy on HIV testing for diagnostic purposes. The CMA maintains that "[b]ecause of the potential psychologic, social and economic conse-

quences attached to a positive HIV test result, informed consent must, with rare exceptions, be obtained from a patient before testing." The CMA also "stresses the need to respect the confidentiality of patients with HIV infection and consequently recommends that legal and regulatory safeguards to protect such confidentiality be established and maintained."<sup>122</sup>

Prevention of exposure to HIV-infected blood or body fluids can best be achieved by the routine application of infection-control guidelines for all patients.

The CMA policy on occupational exposure of health-care workers to HIV also recommends that counseling and voluntary HIV-antibody testing be made available to the health-care worker and that the results remain confidential. However, neither the patient's refusal to be tested nor the injured worker's refusal to be tested should jeopardize the outcome of a compensation claim of the worker. Workers' compensation boards must be urged to develop and implement criteria for determining eligibility for compensation while nevertheless recognizing workers' and patients' rights to refuse testing without prejudice.

Finally, the CMA policy observes that "prevention of exposure to HIV-infected blood or body fluids can best be achieved by the routine application of infection-control guidelines for all patients." Accordingly, the CMA recommends that

[h]ealth care facilities and workers should follow current guidelines for universal precautions and infection control in the handling of blood and body fluids.... Educational programs in infection control should be made available to all health care workers. They should be required in prelicensure training and feature strongly in continuing education programs.

The CMA urges funding agencies "to assess the costs of infection-control measures, such as the use of high-quality gloves and containers for sharp objects, and ensure that additional funds are provided to cover these costs."

## Canadian Union of Public Employees

The Canadian Union of Public Employees (CUPE) represents members in a number of health-care or health-related occupations at risk of occupational exposure: ambulance attendants, housekeeping staff, waste handlers, laundry workers, materials handlers, nurses' aides, and laboratory technicians and technologists. CUPE does not support compulsory testing of source persons in the event of an occupational exposure to an infectious disease.<sup>123</sup> CUPE participated in the 1995 conference that established guidelines on infectious disease notification for emergency responders, and continues to support the guidelines.<sup>124</sup>

CUPE has adopted an AIDS/HIV Policy Statement; published fact sheets on hepatitis B, HIV and AIDS, and preventing needlestick injuries; and prepared an information kit on AIDS/HIV in the Workplace (currently in the process of being updated). The information kit affirms the right to privacy and the importance of confidentiality of medical information as it applies to employees.

It also affirms the right of employees to safe and healthy working conditions, and requires that “[i]n occupations where exposure to blood and body fluids is likely to occur, employers should institute infection control programs, including the provision of necessary clothing and devices.”<sup>125</sup>

The fact sheet on preventing needlestick injuries discusses the importance of engineering controls (such as sharps disposal containers, needles with safety features, or needle-less systems), personal protective equipment, training in bloodborne pathogens and protective equipment and practices, and exposure management. It also states the fundamental rights of every Canadian worker: the right to know any dangers present in the workplace; the right to participate, through the joint health and safety committee, in the day-to-day detection and elimination of workplace hazards; and the right to refuse to work in conditions workers believe to be dangerous to their health and safety, without repercussions or fear of reprisals.<sup>126</sup> However, CUPE notes that provincial legislation may restrict police, firefighters, correctional officers, and health-care workers from using the right to refuse work if their refusal places the life, health, or safety of people in their care in danger.<sup>127</sup>

In occupations where exposure to blood and body fluids is likely to occur, employers should institute infection-control programs, including the provision of necessary clothing and devices.

## International Association of Fire Fighters

The International Association of Fire Fighters (IAFF) has approximately 17,000 members in Canada, drawn from all provinces and territories except Québec. The IAFF has published a fact sheet on the management of occupational exposure to infectious diseases and Bill C-217.<sup>128</sup>

The IAFF “strongly supports a fire fighter’s right to know the infectious disease status of a person with whom they have come in contact in the line of duty.” Because the health status of persons with whom firefighters come into contact is almost never known, there is a strong need for a mechanism that allows firefighters to find out quickly if they have been exposed to an infectious disease, so that treatment, if available, can begin as soon as possible and so that the stress of not knowing, which affects the firefighter and his or her family, can be alleviated. The IAFF holds that an infectious diseases notification protocol, such as the one established by Health Canada in 1995,<sup>129</sup> is an effective way to address these concerns. However, the IAFF seeks further action on the protocol. First, the IAFF urges that it be implemented in every jurisdiction in Canada, so that there will be “a nation-wide system

of equivalent provincially-adopted protocols that address a mechanism under which the infectious disease status of an individual can be ascertained in those cases where a blood sample is available from a medical facility or where an individual voluntarily provides a sample.” Currently, only British Columbia, Alberta, Saskatchewan, and Ontario have adopted the protocol. Second, the IAFF supports “modifying and strengthening the ... protocol to deal with those scenarios where the bloodwork information is not available and the individual refuses to provide a sample.” The IAFF does not explain what modifications are required or how they might be implemented.

The IAFF supports compulsory testing of source persons who do not agree to be tested, but recommends changes to Bill C-217 “so that it reflects and is an extension of the [1995]

The Canadian Police Association (CPA) supports compulsory testing of source persons who may have exposed police, firefighters, other emergency response personnel, and “good Samaritans” to an infectious disease.

notification protocol.” First, “any process for obtaining a warrant should only arise where bloodwork information is not available from a medical facility and the individual in question refuses to provide a sample.” As with the 1995 protocol, “the application for processing the warrant for a blood sample must be initiated by the employer, through a designated officer, and not the exposed individual.” The employer should bear all costs associated with processing the warrant and obtaining the sample.

Second, the IAFF advocates that “exposure” as defined by the 1995 protocol – through the skin, through the mucous membranes (eye, nose, or mouth), or airborne – be used, rather than “contact.” The IAFF also suggests that the list of designated diseases in the 1995 protocol is more appropriate than the term “designated virus,” defined by the bill as meaning HBV, HCV, and HIV.

Finally, the IAFF holds that the process for obtaining a warrant and a blood sample should respect the provisions for confidentiality in the 1995 protocol:

specifically that the infectious disease status, as obtained through a sampling process for the designated infectious diseases, must only be given to the designated officer, who in turn must provide it to the exposed emergency responder. The information should also be given to the person from whom the sample was taken. There is no reason for this information to be given to anyone else, including the peace officer who executed the warrant. For the purposes of assuring compliance, the peace officer should only be informed that the infection sampling was fulfilled.

## Canadian Police Association

The Canadian Police Association (CPA) supports compulsory testing of source persons who may have exposed police, firefighters, other emergency response personnel, and “good Samaritans” to an infectious disease. The 2000 Annual General Meeting of the CPA adopted a resolution that Parliament “pass legislation that will permit access to information for police and emergency services personnel concerning verification of exposure to infectious diseases” and that the CPA “actively support Private Member’s Bill C-244.”<sup>130</sup> The CPA and a number of its member associations wrote letters in support of Bill C-244, and a delegation from the CPA appeared before the Standing Committee on Justice and Human Rights on 14 June 2000 during hearings on Bill C-244.<sup>131</sup>

The CPA's position is that police, firefighters, emergency response personnel, and good Samaritans "should be entitled to reasonable information, protection, and peace of mind, in order that they can make informed decisions with respect to precaution and treatment, to protect themselves and their loved ones."<sup>132</sup> The CPA believes that Bill C-244 "could be tailored to meet the concerns of good Samaritans and emergency responders, while satisfying privacy and security concerns arising out of Charter protections."<sup>133</sup> While the CPA acknowledges that the bill in its present form is not perfect, it does not suggest what might be done to improve it.<sup>134</sup>

The CPA believes that needle sticks, attacks, and other exposures will increasingly place its members at risk of infectious diseases because of higher-than-national rates of infection among populations that police frequently interact with, such as injection drug users, prostitutes, and prisoners. While the CPA recognizes the importance of universal precautions and exposure protocols, these do not, in its view, solve the problem. The CPA believes that exposed officers need more information than is currently available to make informed medical decisions, avoid unnecessary post-exposure prophylaxis with its side effects and adverse events, and relieve anxiety.

The CPA believes that an amendment to the *Criminal Code* is an appropriate means to provide for compulsory testing. Police are most often exposed to blood and body fluids when they are trying to arrest or detain an individual and in such circumstances are often justified in using physical force to perform their duties. Therefore, according to the CPA, when police officers are exposed, there will usually be a clear nexus with the criminal law. An amendment to the *Criminal Code* would also provide a measure that would be enforceable in all jurisdictions, unlike provincial public health statutes or federal health legislation.<sup>135</sup>



# Improved Prevention and Management of Occupational Exposure

A comprehensive program to manage occupational exposure to infectious diseases should include:<sup>136</sup>

- policies and procedures developed for a specific sector (eg, various health-care settings, emergency responders, police);
  - appropriate personal protective equipment, engineering controls, protective practices, and disinfectants;
  - ongoing education and training of workers and of staff responsible for acting in the event of an occupational exposure (eg, a designated officer to assess the exposure and act as an intermediary with public health);
  - a pre-exposure program;
  - a post-exposure program; and
  - partnership with public health.

Pre-exposure programs are key to the prevention of occupational exposures and to the readiness to respond to exposures.

Pre-exposure programs are key to the prevention of occupational exposures and to the readiness to respond to exposures. They should include:

- standards, education, and training related to information on infectious diseases, methods of transmission, assessment of risk of exposure, definition of significant exposures, disinfection and decontamination procedures, and the use of personal protective equipment, engineering controls, and protective practices;
- an immunization program;
- screening for airborne infections such as tuberculosis if there is a risk of exposure;
- protocols for managing bloodborne pathogens;

- employee input in testing protective equipment and developing protective practices;
- respect for confidentiality of individuals as required by law; and
- respect for the right to work in compliance with occupational health and safety legislation.

Post-exposure programs are key to the timely and effective response to an occupational exposure. They should include:

- standards and protocols for responding to exposures, including provisions for immediate post-exposure activities (first aid, disinfection, reporting, and referral), assessing the exposure, counseling the exposed worker, referral for medical care and post-exposure prophylaxis, testing and follow-up for the exposed worker, and obtaining information from the source person;
- selection of designated personnel and training in their roles (first point of referral for exposed worker, assessment of exposure, administration of post-exposure prophylaxis, liaison with source person, liaison with public health);
- established systems for timely and knowledgeable delivery of medical care, counseling, and follow-up; and
- education and training of staff in the protocols, personnel, and systems involved in responding to exposures.

Research studies and anecdotal reports suggest that the prevention and management of occupational exposure could be improved, both in health-care settings and in public service settings. Studies in Canada, the United States, and Europe have found evidence of unsafe practices in disposing of needles, failure to use routine precautions, continuing rates of injury, delays in administering post-exposure prophylaxis, and insufficient expertise in assessing exposures and recommending post-exposure prophylaxis:

- A 1992 study in five Montréal hospitals found that many health-care workers still re-capped needles or left them loose. This unsafe practice resulted in the majority of injuries. Over six percent of exposures were related to the disposal of needles in sharps containers, indicating a need for improvement in the design and use of sharps containers.<sup>137</sup>
- A 1995 survey of Canadian dentists found that those who had percutaneous exposures were significantly less likely to use puncture-proof containers for sharps disposal and to comply with post-exposure protocols. It also found that those who experienced mucocutaneous exposures were significantly less likely to use eye protection and masks.<sup>138</sup>
- A seven-year study among medical students at the University of California in San Francisco found that students did not report all exposures and that the rate of follow-up testing among exposed students was poor. The authors suggest that “[t]he fact that exposures continued to be underreported may have more to do with role models among faculty and housestaff than with the system provided for education and counseling. Students report that they are discouraged from leaving the operating room after an accident except to rescrub and change gloves. They also report being left to perform procedures on very sick patients in the emergency department, where they are the least well-trained provider.” When exposures are not reported promptly, the health-care worker is deprived of risk assessment, medical care, counseling, and follow-up, and the institution is

The prevention and management of occupational exposure could be improved, both in health-care settings and in public service settings.

deprived of information that might identify high-risk activities and improve prevention.<sup>139</sup>

- A 1996 study of needlestick injuries in the San Diego Police Department found a greater rate of injury in the first five years of police work. Nearly two-thirds of those who had experienced a needle stick incurred their first injury during the first five years. Only 40 percent of those who had experienced a needle stick sought medical attention at the time of the injury.<sup>140</sup>
- A 1998 survey of 38 teaching hospitals in London, England, found many deficiencies in the administration of Department of Health guidelines on post-exposure prophylaxis for occupational exposure to HIV among health-care workers. Occupational health nurses who made the initial assessment were not knowledgeable about drugs used in post-exposure prophylaxis starter kits, injured workers were required to go to another hospital for assessment and prophylaxis, and junior doctors on call (particularly at night) did not know whom to contact in the event of an injury.<sup>141</sup>
- A recent study by the British Columbia Centre for Excellence in HIV/AIDS of the province's HIV post-exposure prophylaxis program found that 30 percent of people who received three drugs should not have, 30 percent of people who received two drugs should not have, and 50 percent of people who received post-exposure prophylaxis should not have. The actual cost of the program was about \$540,000. If the drugs had been dispensed according to existing guidelines, the expected cost would have been about \$240,000 to \$300,000 less than the actual cost.<sup>142</sup> In a related study the British Columbia Centre for Excellence in HIV/AIDS found that the likelihood of receiving triple-drug HIV post-exposure prophylaxis did not correspond to what one would expect according to existing guidelines.<sup>143</sup> The authors suggest that more education is needed among health-care providers, particularly in rural areas, to ensure that issues related to the transmission of HIV, the risks and benefits of post-exposure prophylaxis, and the content of post-exposure prophylaxis guidelines are more thoroughly understood.<sup>144</sup>

Anecdotal reports identify numerous factors that contribute to occupational exposures, particularly needle sticks, in health-care settings: unsafe procedures in re-capping needles or in placing needles in sharps containers; sharps containers being out of easy and safe reach from the point of care; needles left in bedding or on surfaces; inadequate training in safe practices, especially among students; fatigue due to long shifts and burnout; an organizational environment and system that does not encourage and foster occupational safety; and a lack of a sense of personal or professional worth.<sup>145</sup>

Prevention of occupational exposures requires an integrated system of personal protective equipment, engineering controls, workplace practices, education and training, surveillance, and risk-reduction programs. It also includes addressing occupational factors (eg, insufficient staff, long shifts, worker fatigue) that contribute to the risk of occupational exposure. The importance of engaging management and staff in consultation, review, training, and support cannot be over-emphasized. Workers need to be involved in assessing accidents or near-accidents, suggesting solutions, implementing and evaluating solutions, and fostering ongoing training in engineering controls and routine practices.

Health Canada has made a series of recommendations about reducing the risks of occupational exposure to bloodborne pathogens in the workplace.<sup>146</sup> They include recommendations on risk reduction in the workplace, immunization, engineering safeguards, personal protective equipment, hygiene and sanitation, education of workers, quality assurance and improvement, firefighters and emergency medical services, and law enforcement and

correctional facility officers. It is incumbent on employers and employees to review these recommendations, determine if they are being implemented in a *regular and sustained* fashion, and remedy any lapses in policy, practice, or training.

In health-care settings particular attention should be given to reducing the incidence of needle sticks. These account for the majority of percutaneous exposures. Needle-less systems and needles with safety features are currently available, and could contribute to reducing the incidence of needle sticks. In November 2000 the federal Needlestick Safety and Prevention Act was signed into law in the United States. The new law requires health-care facilities under the federal Occupational Safety and Health Administration to use safer medical devices. Specifically, it requires health-care employers to provide safety-engineered sharps devices and needle-less systems; expands the definition of “engineering controls” to include devices with engineered sharps injury protection; requires that exposure control plans (to be reviewed and updated at least annually) document consideration and implementation of safer medical devices designed to eliminate or minimize occupational exposure; requires each health-care facility to maintain a sharps injury log with detailed information on percutaneous injuries; and requires employers to solicit input from non-managerial health-care workers when identifying, evaluating, and selecting safety-engineered sharps devices and to document this in the exposure control plan.<sup>147</sup> Seventeen states in the United States have passed similar legislation.<sup>148</sup>



## Encouraging Voluntary Consent to Testing

As already noted, most source persons consent to being tested and to disclosing the results to the exposed worker.<sup>149</sup> A number of steps could be taken to encourage such consent.

Most source persons consent to being tested and to disclosing the results to the exposed worker. A number of steps could be taken to encourage such consent.

First, the approach to the source person should be undertaken by a trained health professional who was not involved in the exposure and is not providing care to either the source person or the exposed worker. While this should be the norm in all situations, it may be particularly important when the occupational exposure is the result of a conflict, as in arrest or restraint by police. The source person may regard the trained professional with more trust, especially if the professional's approach is sensitive and considerate.<sup>150</sup>

Second, the approach should be made in a setting that affords privacy and protects confidentiality. As noted above, a recent Ontario study found that people being tested for HIV universally valued confidentiality and preferred anonymity, but that in fact this was not often their experience.<sup>151</sup>

Third, the person making the approach should be non-judgmental, non-abusive, skillful, knowledgeable, and informative. The person should recognize the needs of the source person, and include the source person in decision-making. The person should be able to answer specific questions, provide an opportunity for the source person to disclose concerns, and help alleviate anxiety around testing. These are qualities that people coming for HIV testing expect of the test provider.<sup>152</sup>

Fourth, the source person should have the right to refuse to be informed of the results of the test. If public health legislation requires that, in the event of a positive result, the source person's sexual or injecting partners are to be informed that they may have been exposed to an infectious disease, the source person should be advised of this before deciding to take the test.<sup>153</sup>

Fifth, the requisition for the test and the recording of the result should be made in a way that does not disclose the identity of the source person (eg, a non-nominal identifier). Numerous studies suggest that availability of protections of identity (as in anonymous testing) encourages people to come forward to be tested, particularly those who are at greatest risk for HIV infection.<sup>154</sup>

Sixth, regulations, policies, and protocols should set out in specific terms who will have information about the source person, the test, and the result of the test, and what information they will have. Regulations, policies, and protocols should also set out in specific terms the requirements of confidentiality on the part of persons receiving information, and stipulate penalties for any breaches of confidentiality. Although such provisions may, practically speaking, be of little value to the source person in the event of a breach, they nevertheless establish a basis for recourse against anyone breaching confidentiality.

Seventh, provision may be made to destroy any record of the results of the test, so that the source person may be assured that the results may not be used in any future considerations with regard to employment, insurance, disability, etc.



## Discussion

Workers who have been exposed to HBV, HCV, or HIV must cope with the consequences of exposure, which are not insignificant. These include anxiety and stress arising from uncertainty as to whether they have been infected, the impact on their private lives of measures to prevent further transmission, and (in the case of exposure to HIV) side effects and risks associated with post-exposure prophylaxis.

Information about the serological status (results of tests for viral infection), risk factors, and medical history of the source person can relieve uncertainty as to whether there was in fact an exposure to HBV, HCV, or HIV, and can contribute to decisions about preventing further transmission, post-exposure prophylaxis, testing, and follow-up for the exposed worker. (Post-exposure prophylaxis is available only for HBV and HIV, not HCV.)

If the test results of the source person are negative and there are no risk factors, the exposed worker may be reasonably certain that there was not a significant exposure, be relieved of anxiety, and forego post-exposure prophylaxis (if available). This is a significant benefit in the case of exposure to HIV, since, although post-exposure prophylaxis is available and is effective in preventing transmission, it is also accompanied by debilitating side effects and other risks. Side effects are one of the main reasons that exposed workers do not complete the full course of post-exposure prophylaxis for HIV.

If the test results of the source person are positive *or* if the results are negative but there are risk factors (indicating that the test may have been taken during the window period), the exposed worker would have to take steps to prevent further transmission, consider post-exposure prophylaxis (depending on the nature of the exposure), and be tested at a later time. One cannot conclude that the exposed worker was infected on the basis of a positive test result from the source person, or that the exposed worker was not infected on the basis of a negative test result from the source person when risk factors are present.

Because post-exposure prophylaxis for HIV should ideally be started within two hours of exposure, the exposed worker should not wait to find out about the source person's serolog-

How necessary, feasible, and appropriate is compulsory testing?

ical status before starting treatment, if treatment is recommended. If it is later established that the source person was not infected and had no risk factors, the exposed worker can then discontinue post-exposure prophylaxis.

In 1995 Health Canada convened a national conference that reached a consensus on guidelines for a protocol to notify emergency responders (firefighters, ambulance attendants, and police) when they may have been exposed to an infectious disease (airborne or bloodborne). The protocol includes procedures that facilitate the voluntary testing of source persons with informed consent and appropriate counseling.

How necessary, feasible, and appropriate, then, is compulsory testing?

Most source persons agree to be tested and permit relevant information to be provided to the exposed worker, when they are approached in a sensitive manner and the importance of the information is explained. This has been demonstrated by studies in health-care settings as well as in other settings (eg, with police).

A compulsory testing procedure, which involves obtaining a judicial warrant, would probably not produce information in time to contribute to decisions to start HIV post-exposure prophylaxis. The information would only be used in decisions to stop prophylaxis, should the results of the test be negative and no risk factors be present.

Compulsory testing of a source person and disclosure of the results of the test would be an infringement of that person's personal autonomy. Respect for personal autonomy is a fundamental principle of biomedical ethics. It is the basis for ethical rules and practices that require voluntary informed consent for medical procedures, that respect the individual's right to privacy, and that protect the confidentiality of personal medical information. The person required to be tested suffers harms to bodily and psychological integrity, an infringement of personal privacy, and a loss of confidentiality.

The Canadian Medical Association, the Canadian Nurses Association, and the Canadian Association of Nurses in AIDS Care have recently published or updated policies on occupational exposure to HIV or bloodborne pathogens. They maintain that compulsory testing or testing without informed consent is unethical and unjustified. Voluntary testing with informed consent and appropriate pre- and post-test counseling continues to be the norm for source persons and exposed workers in health-care settings.

Most occupational exposures to bloodborne pathogens are not the result of deliberate acts and are not associated with suspected or demonstrated criminal activity. It is not appropriate, therefore, to have recourse to the *Criminal Code* to compel source persons to be tested in such circumstances. If, in order to address occupational exposures that are the result of deliberate acts or are associated with suspected or demonstrated criminal activity, an exception is to be made to the existing ethical and legal consensus regarding an individual's right to voluntary informed consent to medical procedures, the exception should be based on detailed medical, ethical, and legal argumentation justifying the exception. In addition, the exception should be strictly circumscribed so as to prevent unnecessary and undue harms to persons who may be compelled or may be likely to be compelled to be tested.

Voluntary testing with informed consent and appropriate pre- and post-test counseling continues to be the norm for source persons and exposed workers in health-care settings.

More could be done to prevent occupational exposure, support workers, and obtain voluntary consent for testing from source persons without having recourse to compulsory testing of source persons.

More could be done to prevent occupational exposure, support workers, and obtain voluntary consent for testing from source persons *without* having recourse to compulsory testing of source persons. Studies in Canada, the United States, and Europe have found evidence of unsafe practices in disposing of needles, failure to use routine precautions, continuing rates of injury, delays in administering post-exposure prophylaxis, and insufficient expertise in assessing exposures and recommending post-exposure prophylaxis. Improvements could be made by:

- implementing existing guidelines and protocols on preventing and managing occupational exposures to infectious diseases;
- conducting regular annual education and training for workers in infectious diseases, engineering safeguards, and protective practices;
- introducing engineering safeguards, such as needle-less systems, needles with safety features, high-quality latex gloves, and puncture-resistant gloves;
- designating and training personnel to respond to occupational exposures, counsel workers, and act as a liaison with source persons;
- strengthening post-exposure counseling, support, and follow-up for exposed workers, their co-workers (if necessary), and their families;
- implementing workplace programs to correct misconceptions and reduce stigma related to infectious diseases;
- improving training and expert support for health-care providers responsible for administering post-exposure prophylaxis to ensure that it is prescribed only as recommended by current guidelines; and
- introducing provisions to protect the privacy and confidentiality of source persons, such as non-nominal requisition and reporting of test results, destruction of any records related to the test, and regulations, policies, and protocols regarding confidentiality of test results.



## A Backgrounder

# Notes

- <sup>1</sup> Personal communication, Dr J Williams, Director of Ethics, Canadian Medical Association, 20 April 2000.
- <sup>2</sup> Health Canada. An integrated protocol to manage health care workers exposed to bloodborne pathogens. *Canada Communicable Disease Report* 1997; 23(Suppl 23S2): 1-14 at 3. See also Health Canada. Preventing the transmission of bloodborne pathogens in health care and public service settings. *Canada Communicable Disease Report* 1997; 23(Suppl 23S3): Centers for Disease Control and Prevention. Public health service guidelines for the management of health-care worker exposures to HIV and recommendations for postexposure prophylaxis. *Morbidity and Mortality Weekly Report* 1998; 47(RR-7): 1-33; JL Gerberding. Management of occupational exposures to blood-borne viruses. *New England Journal of Medicine* 1995; 332(7): 444-451.
- <sup>3</sup> Health Canada. Preventing the transmission of bloodborne pathogens, supra, note 2.
- <sup>4</sup> Health Canada. An integrated protocol, supra, note 2 at 3.
- <sup>5</sup> Ibid. See also Gerberding, supra, note 2.
- <sup>6</sup> Centers for Disease Control and Prevention. Exposure to Blood: What Health-Care Workers Need to Know, 1999, available at [www.cdc.gov/ncidod/hip/blood/hiv.htm](http://www.cdc.gov/ncidod/hip/blood/hiv.htm).
- <sup>7</sup> DM Cardo et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *New England Journal of Medicine* 1997; 337(21): 1485-1490 at 1487; an earlier report of this study was published as: Case-control study of HIV seroconversion in health-care workers after percutaneous exposure to HIV-infected blood – France, United Kingdom, and United States, January 1988-August 1994. *Morbidity and Mortality Weekly Report* 1995; 44(50): 929-933.
- <sup>8</sup> Centers for Disease Control and Prevention. Public health service guidelines, supra, note 2 at 4.
- <sup>9</sup> British Columbia Centre for Excellence in HIV/AIDS. Therapeutic Guidelines. Section 7: Management of Accidental Exposure to HIV, Appendix S7-2a, available at <http://cfeweb.hivnet.ubc.ca/guide>.
- <sup>10</sup> Personal communication, Dr A McLeod, 22 May 2001.
- <sup>11</sup> Centers for Disease Control and Prevention. Exposure to Blood, supra, note 6; for different estimates of the rate of transmission of HBV, see Health Canada. Preventing the transmission of bloodborne pathogens, supra, note 2; PHLS AIDS and STD Centre at the Communicable Disease Surveillance Centre & Collaborators. *Occupational Transmission of HIV: Summary of Published Reports*. December 1999, available at [www.phls.co.uk/facts/HIV/hivoc99.pdf](http://www.phls.co.uk/facts/HIV/hivoc99.pdf).
- <sup>12</sup> Centers for Disease Control and Prevention. Exposure to Blood, supra, note 6; see also Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *Morbidity and Mortality Weekly Report* 1998; 47(RR-19): 1-39 at 7.
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A Backgrounder

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