CMA POLICY SUMMARY

PREVENTION OF TRANSMISSION OF HEPATITIS B

The CMA is publishing this policy to provide guidance to physicians, health care institutions and health authorities concerning measures that should be taken to prevent the transmission of hepatitis B. It replaces existing CMA policy on hepatitis B.

Background

The prevention of transmission of hepatitis B is an important public health goal. Hepatitis B virus (HBV) is transmitted in a variety of contexts in which the body fluids of one person intermingle with those of another, including sexual activity, needle-sharing and certain medical procedures. For most of the population, the potential adverse effects of exposure to HBV can be countered through vaccination. However, vaccination programs that have been put in place to date do not target the population at large, they have not achieved desired vaccination levels in the groups at greatest risk, and desirable levels of immunity have not been reached in those vaccinated.

Principles

Policy to prevent the transmission of disease, and in particular transmission that occurs as a result of the intermingling of blood or body fluids, should ground its recommendations in the best available scientific evidence and should adjudicate value issues by making explicit the principles that underlie the recommendations. Explicitness about underlying principles and about how those principles are balanced when in conflict helps to ensure that relevant considerations are given their due and that the reasoning informing the policy is transparent and open to scrutiny. Explicitness about principles is especially important when coercive means are used to prevent the transmission of disease.

The following principles should govern the development and implementation of policies relating to the transmission of disease and have been considered and weighed in the development of this policy:

- The prevention of disease is an important societal good.
- Institutions that provide health care services have a duty to implement reasonable measures to ensure that patients and health care providers are not subject to unacceptable risks in the delivery of health care services.
- Health care providers have a moral duty not to subject their patients to unacceptable risks.
- · Health care providers who perform procedures in which

- there is a risk of HBV transmission have a moral duty to know their serological status.
- Individuals have fundamental human rights that limit the choice of measures to reduce the risk of disease transmission, including rights of privacy and rights of autonomy.
- The protection of fundamental human rights is a societal good.
- Fundamental human rights may justifiably be infringed by measures to reduce the risk of disease transmission when
 - the risk of transmission is above an acceptable level;
 - there is good reason to believe that the proposed measures will be effective in reducing the risk to acceptable levels, and that they will be effectively implemented; and
 - the level of risk cannot be reduced to acceptable levels by measures that do not infringe fundamental human rights.
- The estimation and assessment of risk must be founded on the best scientific evidence available.
- The determination of whether a given risk of transmission is acceptable is a value judgement that should explicitly include consideration of
 - the magnitude or severity and the probability of the harm;
 - the threshold of acceptable risk in other areas of health care;
 - any adverse impact of risk reduction measures on fundamental human rights;
 - the costs of measures to reduce risk; and
 - the interests and values of the public.
- In the limited circumstances where fundamental human rights may justifiably be infringed, the following conditions must also be met:
 - fundamental human rights must be infringed to the most limited degree possible;
 - all reasonable efforts must be made to accommodate individuals so that they will not be burdened by the measures adopted; and
 - if accommodation cannot be achieved, individuals burdened by the measures adopted must be fairly compensated.
- Individuals have a right to know the general risks to

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- which they may be subjected in the course of the delivery of health care services. The standard of disclosure should be consistent with that for informed consent.
- Information about the serological status of individuals must be treated in strict confidence.
- Individuals must not be subject to discrimination on the basis of their known or supposed serological status.

Universal vaccination

Provincial governments are to be commended for implementing universal childhood vaccination and vaccination of high-risk groups as recommended by the National Advisory Committee on Immunization (NACI). However, universal childhood vaccination leaves most of the current adult population unprotected; programs targeted to adults in certain high-risk groups are likewise limited in the protection they afford. Significant gains in prevention and protection would come from a one-time effort to vaccinate the population of Canada against HBV. The feasibility of such an initiative, including cost and implementation issues, should therefore be investigated. The implementation of universal vaccination would immediately reduce the transmission of HBV in all contexts and reduce the risk of transmissions in higher-risk contexts.

Vaccination and serological testing in health care contexts

Despite implementation of universal vaccination, some people would elect not to be vaccinated, and some who were vaccinated would not achieve immunity. Moreover, such implementation would require the investment of resources and would take time. Given that the risk of transmission of HBV among persons receiving and providing health care services is greater than in the general population, greater efforts must be made to vaccinate those at risk of contracting HBV infection in the health care context. Vaccination should be administered in accordance with the NACI guidelines.

Mandatory vaccination or serological testing of patients or health care providers is not warranted because acceptable risk can be achieved by less intrusive measures if properly implemented. The following recommendations concerning vaccination and serological testing should be adopted to reduce the transmission of HBV in health care contexts.

- All patients awaiting elective surgical procedures who do not have immunity against HBV should be offered vaccination as part of their standard preparation for surgery. To the extent possible, the vaccination schedule should be modified to achieve the highest probability of immunity within the time frame available before the procedure.
- All health care providers and students who work or will
 work in a situation in which patients could be exposed to
 their body fluids have a moral duty to and are strongly encouraged to be vaccinated against HBV, unless a medical
 contraindication exists.
- All health care providers and students who work or will work in a situation in which they could be exposed to the body fluids of patients are strongly encouraged for their

- own protection to be vaccinated against HBV, unless a medical contraindication exists.
- Public health authorities, health care institutions and educational facilities should expedite and support efforts to vaccinate health care providers by providing vaccination and serological testing to health care providers and students free of charge and as conveniently as possible.
- Public health authorities, health care institutions, educational
 facilities, professional associations and licensing authorities
 should inform health care providers and students about the
 risks of contracting HBV infection or transmitting the virus in
 the health care setting, the benefits to themselves and others
 of being vaccinated and their moral duty to know their serological status and not to subject patients to unacceptable risks.
- As part of the vaccination protocol, serological testing should be offered to all those vaccinated. Health care providers who do not respond to the vaccine (those who remain negative for antibodies to hepatitis B surface antigen [HBsAg]) have a moral duty to and are strongly encouraged to be tested for HBsAg and, if negative, to seek additional or higher doses of vaccine or a different vaccine in order to make every effort to achieve seroconversion.
- Health care providers for whom vaccination is contraindicated or who elect not to be vaccinated and who work or will work in a situation in which patients could be exposed to their fluids have a moral duty to and are strongly encouraged to be tested for antibodies to HBsAg, and, if seronegative, to be tested for HBsAg.
- Health care providers who are seronegative for both HBsAg and its antibodies and the few who remain seronegative for both despite concerted efforts to achieve seroconversion through vaccination have a moral duty to and are strongly encouraged to have periodic serological tests for potential conversion to HBsAg-positive status and not to expose their patients to unacceptable risks.

Professional self-regulation

Professional self-regulation is part of a social contract whereby society grants certain privileges to professions in the expectation and trust that societal needs will best be met if the professions are given autonomy in determining how to train, organize, monitor and discipline their members. As such, professional self-regulation is a societal good. Health care providers who are members of self-regulating professions are subject to ethical codes of conduct and to the scrutiny and sanction of their licensing authorities. Risk reduction measures directed to health care professionals should draw support from the ethic of professionalism under which health care professionals practise and should be consistent with the principles of self-regulation.

Given that different kinds of health care providers are regulated differently in the accountability provisions under which they practise, any recommendations in this policy that specifically address physicians might not be applicable to other health care professionals or health care providers. Professional associations, licensing authorities and employers of non-physician health care providers should consider adopting recommendations similar to those defined herein but altered to fit their circumstances and mandates.

Case management of physicians who test positive for HBsAg

- Physicians who test positive for HBsAg and who could expose patients to their body fluids have a moral duty to and are strongly encouraged to seek appropriate treatment for their condition and inform their licensing authority about their serological status.
- Physicians who test positive for HBsAg have a moral duty to and are strongly encouraged to cease those activities of their practice that could expose patients to their body fluids until their practice has been reviewed by an expert committee.
- Medical licensing authorities should establish expert committees to review the cases of physicians who test positive for HBsAg and who could expose patients to their body fluids. Medical licensing authorities should determine acceptable levels of risk in accordance with the principles articulated in this policy, instruct expert committees of this determination and make this determination public. The expert committees should include a public health expert, an expert in HBV, a non-physician, a public member of the board of the licensing authority, a physician with practice expertise suitable for providing advice on the potential for altering the practice of the subject physician and a person skilled in ethical analysis. The composition of the committees should ensure competence to carry out the functions listed below.
- The expert committees should carry out the following functions:
 - provide advice and direction to the physician regarding his or her case:
 - recommend treatments to lower, if possible, the HBV infectiousness to acceptable levels;
 - if the HBV infectiousness cannot be reduced to acceptable levels or until it can be, to restrict the physician's practice by directing the physician
 - to practise only on immune or infected patients when his or her body fluids could come into contact with those of the patient; and
 - in the event the patient's immune status is unknown, not to practise specified procedures during which his or her body fluids could intermingle with those of the patient;
 - determine the appropriate range of practice and possible alternative scopes of practice of the subject physician, temporarily or permanently, in order not to subject patients to unacceptable risks;
 - provide ongoing evaluation, advice and direction to the infected physician;
 - recommend to public health authorities whether or not the physician's patients should be contacted for HBV testing; and
 - recommend to the licensing authority whether any conditions or restrictions should be placed on the physician's practice.

- The committee should meet within 7 days of the licensing authority being notified of the case.
- If the infected physician wishes, he or she may attend and
 participate at committee hearings to observe and to ask
 and answer questions, or may have his or her personal
 physician attend on his or her behalf. Unless the infected
 physician elects to appear, the committee members should
 operate without knowing his or her identity.

Support for infected physicians

Counselling, adequate support and retraining services for all physicians whose practices are restricted because they have tested positive for HBsAg should be publicly funded and readily available. Disability insurance offered to physicians by physician organizations should explicitly cover loss of income due to practice restrictions imposed to prevent transmission of HBV to patients.

Universal precautions and other preventions

In addition to vaccination programs, measures such as the observance of universal precautions and the development and implementation of new surgical techniques and technologies are important for reducing the risk of transmission of disease from health care providers to patients and from patients to health care providers. Health care institutions should ensure that health care providers are properly educated about universal precautions and have the resources to observe them. The development of new surgical techniques and technologies to reduce the risk of transmission should be supported.

Exposure incidents

All needle-stick and sharps injuries involving potential exchange of body fluids between patients and health care providers should be reported to a designated committee or individual in an institutional setting or recorded in a log book in a non-institutional health care setting. The committee or individual recording the injury should be responsible for ensuring that currently recommended protocols are followed to limit the transmission of bloodborne diseases after a needlestick or sharps injury. The same post-injury protocol should be used for patients and health care providers.

Research and epidemiology

Public health authorities should determine if individuals with acute HBV infection who do not have other recognized risk factors have undergone any medical or dental procedures within the incubation period of their infection. If so, the health care providers involved in these procedures should be contacted and their consent sought to investigate their HBV serological status. This would have the potential to contribute considerably to the evidence on which the expert committees could base their deliberations as to which practices of infected health care providers represent an unacceptable risk to patients.