Canadian Association of General Surgeons position statement: recommendations for surgeons with blood-borne communicable diseases

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SUMMARY

The potential for transmission of hematogenously transmitted pathogens during exposure-prone procedures is a clinically important concern to both patients and surgeons. There is inconsistency among regulatory bodies in Canada regarding the management of infection risk among surgeons, particularly with regard to screening and the postexposure management of infected surgeons. The Canadian Association of General Surgeons commissioned a task force to review the evidence regarding the management of blood-borne pathogens and transmission risk during surgical procedures. The results of this review indicate a need for several jurisdictions to update their guidelines to reflect current evidence-based practices.

xposure-prone procedures (EPPs) are those in which the surgeon is exposed to the tissues in a patient's body cavity and there is a possibility of blood contamination via sharp objects/instruments or sharp tissues (e.g., bone).¹ An overwhelming concern during EPPs is the potential for transmission of hematogenously transmitted pathogens between patients and surgeons. The guidelines adopted by provincial regulatory authorities with regard to EPPs are relevant and of great importance to general surgeons in Canada, who routinely perform these procedures. While surgeons consider it their professional and moral obligation to provide medical care to patients regardless of the risk for infection, there is an equal obligation to protect patients from the risk of transmission of blood-borne viruses (BBVs) from surgeons. In developing this position statement, the primary consideration of CAGS and its members was the protection and minimization of risk to patients.

In 1991 the Centers for Disease Control (CDC) published recommendations to prevent the transmission of BBVs from infected health care providers to patients during the performance of EPPs.² These recommendations advocated that there be no restrictions for BBV-positive physicians who do not perform EPPs; that providers who perform EPPs should be aware of their hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) status; that BBV-positive providers should have their activities guided by expert panels; and that BBVpositive providers who perform EPPs should notify patients in advance of their seropositivity. Based on the CDC and the Public Health Agency of Canada (PHAC) guidelines and the desire for regulatory bodies to adopt a "zero-risk" model, several provincial colleges advocated mandatory testing for BBVs as well as restrictive and punitive measures for physicians who tested positive for BBVs, including mandatory disclosure to patients and restriction of practice.3 Regulatory bodies also selected thresholds of viral activity (i.e., HBeAg positivity or viral DNA/RNA levels) for EPP restrictions without appropriate evidence.

In recent years, the CDC and the Society for Healthcare Epidemiology of America (SHEA)⁴ have issued up-to-date evidence-based guidelines for

the management of health care workers infected with BBVs, including HBV, HCV and HIV. These have been recognized and adopted by some licensing bodies, including the College of Physicians and Surgeons of Ontario.⁵ However, the PHAC³ and many other provincial regulatory bodies have failed to update their policies on this matter.

In Canada there is a lack of synchronization and transparency regarding the issue of BBV-infected health care workers across provinces and territories. Not all jurisdictions have published guidelines, and in some provinces it is the regulatory colleges that have addressed this issue, while in others it is individual institutions and/ or organizations that have addressed it. As the Canadian Association of General Surgeons (CAGS) represents surgeons who routinely perform EPPs, the elimination of transmission of BBVs between general surgeons and their patients and the management of BBV-infected surgeons has been identified as a relevant concern of the association. The recommendations provided by CAGS are informed by previous publications on the topic, including those recently published by the Canadian Medical Protective Association (CMPA).⁶ CAGS calls on all provincial Colleges to update their guidelines and policies on this matter to reflect the current evidence and understanding of the risk of transmission.

RECOMMENDATIONS

There is currently a lack of consistency across Canada in the management of surgeons found to be infected with BBVs, with many jurisdictions publishing guidelines that are not based on evidence. The primary concern must be the protection of patients; however, policies that are not evidence-based and too restrictive can have negative implications for surgeons and the public. CAGS proposes the following principles in the management of surgeons who perform EPPs and are infected with BBVs, and provides specific suggestions for HBV, HCV and HIV based on the current evidence of risk of transmission.

Recommendations for the management of risk of BBV infection in surgeons who perform EPPs

- 1. All surgeons performing EPPs should be vaccinated against BBVs when effective vaccines exist.
- 2. All surgeons performing EPPs (including abdominal, thoracic, breast, head and neck surgery) should be aware of their BBV status.
- 3. Screening of surgeons for BBVs should occur after potential or presumed exposure. Recommendations on routine screening for surgeons should be evidence-based. There is currently no evidence to support the mandatory or regular, intensive (i.e.,

yearly) screening advocated by some jurisdictions.

- 4. Surgeons should at all times observe standard universal precautions when performing an EPP in any patient.
- 5. Endoscopy and robotic surgery are considered minimalrisk procedures and should not be classified as EPPs.
- 6. Surgeons should consult with an infectious disease expert and/or their hospital/regional workplace health and safety (WHS) department if they have been exposed to blood or body fluids by percutaneous (e.g., needle stick) or mucosal routes for the purpose of testing and potential prophylaxis. Unless there is clear evidence of risk to patients, surgeons should be permitted to perform EPPs until definitive postexposure testing is performed.
- 7. Following exposure to potential infection, surgeons should consult with the appropriate hospital and infectious disease resources and comply with prophylaxis treatment, where available.

Principles for the management of surgeons who perform EPPs and are infected with BBVs

- 1. Surgeons infected with BBVs (HBV, HCV, HIV) should receive support, their privacy should be respected, and they should be encouraged to seek expert advice and treatment.
- 2. Evidence-based policies should require "reasonable measures" to minimize the risk of transmission to patients during EPPs. Procedures should be stratified according to perceived risk of transmission according to SHEA guidelines.⁴
- 3. Surgeons infected with BBVs should not be restricted from performing category 1 and 2 EPPs as long as the risk of transmission is considered to be negligible.
- 4. Restrictions should be placed on BBV-infected surgeons performing category 3 EPPs if their viral activity is above a threshold that indicates a risk for transmission. The threshold at which surgeons should be restricted depends on the specific infection (see the sections that follow) and should be based on evidence of risk for transmission to patients.
- 5. The degree of restrictions depends on accurate and expert assessment of the surgeons' infectivity and the surgical procedures performed.
- 6. Surgeons should be allowed to resume performing category 3 EPPs once their viral load falls or once it is maintained below an approved threshold with appropriate antiviral therapy, where the risk for transmission is considered to be minimal.
- 7. Programs should be in place to retrain surgeons who cannot control their infection below the risk threshold with treatment or to assist them to refocus their practices on non-EPP activities (e.g., endoscopy). Surgeons should not be required to disclose their infection status to patients in advance except in

circumstances where documented transmission from that surgeon to a patient has occurred.

HEPATITIS B

There are approximately 350 million people with chronic HBV infection worldwide; however, the prevalence in Canada is quite low, with HBV infection rates estimated at 0.1%–0.5% of the general population.⁴ Since 1990 the rate of new HBV infection has decreased 5-fold owing to initiatives to prevent person to person and perinatal transmission and owing to vaccination programs. None-theless, the prevalence of HBV infection in Canada has been increasing owing to immigration from areas of endemic HBV infection. Physicians may acquire HBV through occupational exposure, or physicians born in endemic regions may have acquired the virus through vertical or early horizontal childhood transmission.

There have been substantial developments in understanding the risk of transmission to patients from HBVinfected health care providers. In addition, the general adoption of universal precautions, the declining prevalence of HBV, and the development of effective antiviral therapy have significantly altered our understanding of the HBV transmission risk. Furthermore, there is an enhanced understanding that non–evidence based punitive measures by regulatory bodies may lead surgeons to avoid HBV testing, conceal positive tests and delay or decline HBV treatment, which places both patients and physicians at increased risk.

The risk of transmission from an HBV-infected surgeon to a patient has been estimated by PHAC at between 24 and 2400 transmissions per 1 million procedures. Since 1992 there has been only 1 reported case in Canada and 1 case in the United States of transmission of HBV from an infected surgeon to patients. Transmission has occurred from both HBeAg-positive and negative physicians and most implicated health care workers had high viral DNA levels (i.e., above 1×10^5 general equivalents [GE] or 20 000 IU/mL). Disclosure of a physician's HBV serology has never been demonstrated to reduce the risk of transmission. Despite its rare occurrence, the infection of a patient with HBV from an infected surgeon is a devastating occurrence and should be avoided at all costs.

Principles for the management of surgeons exposed to or infected with HBV

- 1. All surgeons should be vaccinated against HBV and have postvacination serology performed to document immunity.
- 2. Surgeons known to be infected with HBV should be encouraged to seek antiviral therapy to reduce the risk of transmission and for personal health reasons.

- 3. The monitoring of treatment response and thresholds to perform EPPs should be based on HBV DNA levels obtained using the current standard sensitive polymerase chain reaction assay.
- Surgeons with HBV DNA levels < 1 × 10⁴ GE/mL (2000 IU/mL) should not be subjected to any restrictions on their practice of EPPs.
- 5. Surgeons with HBV DNA levels $< 1 \times 10^5$ GE/mL (20 000 IU/mL) but $> 1 \times 10^4$ GE/mL (2000 IU/mL) should be allowed to perform lower-risk (category 2) procedures, including laparoscopic, thyroid/parathyroid, thoracoscopic, minor vascular and cutaneous procedures.
- 6. HBV DNA levels should be checked every 6 months in surgeons with known chronic HBV infection. Transient elevations in HBV DNA can represent spontaneous fluctuations and may not represent increased infectivity in those not undergoing therapy. In those who are receiving therapy, this may represent virologic breakthrough due to nonadherance. A single reading above threshold (> 1 × 10⁴ GE/mL or 2000 IU/mL) should prompt more frequent follow-up of HBV DNA levels until levels fall below threshold or until therapy is altered or introduced.

HEPATITIS C VIRUS

HCV infection is a global health concern. The primary means of exposure is parenteral; although historically infection was most commonly due to blood products transfused before 1990, now the most common causes are intravenous drug use and, in the developing world, percutaneous health care–associated exposure. Therapy for HCV continues to improve rapidly. The newest antiviral agents (sustained viral response) can achieve cure rates of 90%–100% (i.e., HCV viremia undetectable in plasma).⁷ The risk of transmission of HCV from an infected physician to a patient is extremely low (< 0.0025%).

Principles for the management of surgeons exposed or infected with HCV

- 1. There is currently no good evidence that mandatory testing of surgeons for HCV infection reduces risks to patients. If testing is performed, HCV antibody negativity is adequate to exclude HCV infection. Conversely, both HCV antibody and HCV RNA positivity should be used to indicate infection.
- 2. Surgeons in whom HCV infection is confirmed should be encouraged to seek medical assistance and should strongly consider undergoing antiviral therapy.
- 3. Surgeons infected with HCV who have measurable levels of HCV RNA above a threshold of 1×10^4 GE or virus copies/mL should be restricted from performing category 3 EPPs, but should be permitted to resume

performing category 3 EPPs while undergoing anti-HCV therapy when HCV RNA is either undetectable or below the threshold of 1×10^4 GE/mL.

- 4. Once anti-HCV is completed a 12-week window exists during which surgeons should refrain from performing category 3 EPPs. At 12 weeks posttreatment HCV RNA levels should be rechecked. If HCV RNA is confirmed to be negative (i.e., $< 1 \times 10^4$ GE/mL), then the surgeon may resume performing category 3 EPPs.
- 5. There is currently no good evidence on which to base recommendations regarding repeat testing. Although late relapse is exceedingly rare, confirmation of HCV RNA negativity may be considered at 6 and 12 months.

HUMAN IMMUNODEFICIENCY VIRUS

Since its original detection there have been great strides made in the detection and treatment of HIV. Combination antiretroviral therapies can suppress the viral levels of HIV to below what is currently detectable in virtually all patients. There have been only 2 cases of surgeon to patient transmission of HIV; both surgeons were not aware of their infections and consequently were not undergoing any therapy. The estimated risk of transmission to a patient is between 1 in 2.69 million and 1 in 26.88 million.

Principles for the management of surgeons exposed to or infected with HIV

- 1. Surgeons infected with HIV with viral levels above a threshold of 5×10^2 GE/mL should be restricted from performing category 3 EPPs, but should be permitted to resume performing category 3 EPPs while undergoing antiretroviral therapy when their HIV RNA levels fall below 5×10^2 GE/mL.
- 2. Regular testing (every 4–6 mo) to ensure that viral load remains below the acceptable threshold should be considered under the supervision of a qualified physician.

CONCLUSION

Transmission of BBV between patients and physicians is an important concern. Policies regarding BBV testing and the management of BBV-infected surgeons by provincial regulatory bodies are inconsistent and often are not evidence-based. Surgeons should at all times observe universal precautions to reduce the risk of transmission of BBVs through exposure to infective tissues/fluid during surgery or other duties in the provision of medical care. At the same time, every effort should be made to prevent transmission of BBVs from infected surgeons to their patients, and concerns for public safety must be paramount. Surgeons should be vaccinated against BBVs when effective vaccines exist, and they should be encouraged to report and seek out medical assistance following potential exposure to BBVs so that prophylactic measures can be taken. There is currently no evidence to support routine (i.e., annual) BBV testing for physicians. Surgeons known to be infected with BBVs should be encouraged to disclose their status without fear of reprisals and should be provided with appropriate medical care and support. BBVinfected surgeons with high viral activity that indicates a risk for transmission to patients should be restricted from performing category 3 invasive procedures but should be allowed to perform category 1 and 2 procedures. Restrictions in scope of practice for BBVinfected surgeons should be guided by evidence-based risk for transmission based on viral activity levels and response to therapy. Surgeons should be allowed to resume a full scope of practice once viral levels have fallen below an evidence-based threshold on appropriate antiviral therapy.

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References

- 1. Health Canada. Proceedings of the Consensus Conference on Infected Health Care Workers: risk for transmission of blood-borne pathogens. CCDR, 1998; 24S4.
- CDC. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. [No. RR-8]. MMWR 1991:40.
- 3. Public Health Agency of Canada. Hepatitis B infection in Canada. Available: www.phac-aspc.gc.ca/id-mi/hepatitisBCan-hepatiteBCan -eng.php (accessed 2015 Dec. 14).
- Henderson DK, Dembry L, Fishman NO, et al. SHEA guideline for management of healthcare workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* 2010;31:203-32.
- College of Physicians and Surgeons of Ontario. Policy statement # 3-12. Blood borne pathogens. Available: www.cpso.on.ca /uploadedFiles/policies/policyitems/Blood-Borne-Pathogens _Policy.pdf (accessed 2015 Dec. 14).
- Canadian Medical Protective Association. Physicians with blood borne viral infections: understanding and managing the risks. Available: https://oplfrpd5.cmpa-acpm.ca/-/physicians-with-blood-borne -viral-infections-understanding-and-managing-the-risks (accessed 2015 Dec. 14).
- Afdhal N, Reddy KR, Nelson DR, et al. Ledipasvir and sofosbuvir for previously treated HCV genotype 1 infection. N Engl J Med 2014;370:1483-93.