

# Guideline on the Prevention of Transmission of Bloodborne Viruses from Infected Healthcare Workers in Healthcare Settings

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH



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# EXECUTIVE SUMMARY

## Background

Healthcare workers (HCWs) have an ethical and professional duty to care for their patients in accordance with established standards of practice and care, acting in good faith, and not allowing their personal interests to conflict with their professional obligations. This responsibility includes minimizing the risk of patient exposure to bloodborne viruses (BBVs) while receiving care.

The purpose of this guideline is to provide a national framework for developing policies and procedures to prevent the transmission of bloodborne viruses (BBVs), specifically human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV) from infected HCWs to patients in the healthcare setting.

This document, *Guideline on the Prevention of Transmission of Bloodborne Viruses from Infected Healthcare Workers in Healthcare Settings* was developed by the Public Health Agency of Canada (PHAC) with technical expertise provided by a Guideline Development Task Group of the National Advisory Committee on Infection Prevention and Control in Canada. This guideline replaces Health Canada's 1998 *Proceedings of the Consensus Conference on Infected Health Care Workers: Risk for Transmission of Bloodborne Pathogens*.

Failure to adhere to infection prevention and control principles identified as Routine Practices could result in transmission of BBVs. This guideline assumes that HCWs will adhere to Routine Practices when providing care to all patients at all times and in all settings. Recommendations on these practices are provided in PHAC's guideline titled *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings*. As long as infected HCWs adhere to these practices, the risk of transmission of BBVs from infected HCWs to patients is negligible, except during exposure-prone procedures (EPPs), which may pose an increased but minimal risk. Exposure-prone procedures are invasive procedures where there is a risk that injury to the infected HCW may result in the exposure of the patient's open tissues to the blood of the HCW and depending on the nature of that exposure and host factors (e.g. immunity) transmission of the BBV may occur.

## Scope

This guideline is a key part of PHAC's work to provide evidence-based recommendations within the context of the Canadian healthcare system; thus providing national leadership as well as the underpinnings for organizational policy and a consistent pan-Canadian approach to the management of HCWs infected with a BBV.

Recommendations provided in this guideline are intended to assist those involved with the assessment and management of HCWs infected with a BBV, either individually (e.g., treating physician, members of an Expert Review Panel) or generally (e.g., regulatory authorities). This guideline applies to all HCWs with specific recommendations for HCWs infected with a BBV.

Implementation of these recommendations will increase patient safety while allowing HCWs infected with a BBV to continue to work safely.

## **Risk factors**

Although it is well documented that the risk of a BBV transmission from patient to HCW is significantly higher than the risk of transmission from HCW to patient, the focus of this guideline is to further reduce the minimal risk to patients and to provide guidance for the consistent management of HCWs infected with BBVs. Efforts to prevent HCW-to-patient transmission of BBVs involve understanding the factors that affect the HCWs' risk of occupational acquisition of a BBV and the subsequent risk of transmission of the BBV during an EPP.

With the availability of the hepatitis B vaccine, immune HCWs are protected from occupational acquisition of HBV. Therefore, ensuring HBV immunity among HCWs as early as possible and on admission into health professional training programs is paramount. Nevertheless, multiple percutaneous injuries throughout a HCW's career may place them at risk for occupational acquisition of HIV or HCV infection. Adequate training and education on the prevention and management of occupational injuries and potential exposures are fundamental to all HCWs as part of an occupational health program. In addition, ongoing awareness of their own serologic status is essential for HCWs who perform EPPs.

In defining the risk of transmission of a BBV from an infected HCW to a patient, it is necessary to consider both the actual risk informed by available evidence and the risk perceived by the public as these both inform what is considered acceptable risk. Patient safety studies show that the most frequent types of adverse events affecting hospitalized patients are adverse drug events, wound infections, and surgical complications. Some risks, such as those known to be associated with surgical procedures, are generally accepted by patients. Although a precise assessment of the real risk of HCW-to-patient transmission of BBVs has not been determined, factors described in reports involving potential patient exposure (with or without ensuing transmission) provided some evidence for the development of this guideline.

While zero risk of transmission is unattainable, the availability of a vaccine that prevents HBV infection, effective treatment for HCV resulting in a sustained virologic response, and suppression of HIV with strict adherence to antiviral therapy, could render this risk negligible.

## **Methodology**

A project protocol was developed to outline the steps and methods for conducting the systematic reviews and environmental scans to inform recommendations provided in this guideline. The project protocol was circulated for comments and refinement by the Guideline Development Task Group (Task Group) and PHAC, and retained for internal reference.



Systematic reviews were then conducted for Key Questions to inform the risk of transmission of HIV, HCV, and HBV from infected HCWs to patients. Additional systematic reviews were conducted to address Key Questions examining infectivity of each virus related to the source serum viral load at time of exposure. The literature informing the systematic reviews consisted primarily of lookback investigations and other descriptive studies. A published systematic review of randomized controlled trials (RCTs) was available and therefore used, along with other studies, to inform the effectiveness of double gloving in preventing HCW-to-patient transmission of a BBV. Evidence from all eligible studies was reviewed and qualitatively synthesized. Where applicable, the body of evidence was graded using PHAC's *Infection Prevention and Control Guidelines: Critical Appraisal Tool Kit*.

Environmental scans of relevant literature were conducted for Key Questions where the topic dealt with organizational, regulatory, and/or ethical issues not solely or directly informed by scientific research. No grade of evidence was assigned to recommendations from the environmental scans.

Summaries of published epidemiologic investigations involving HCWs infected with a BBV globally, from the late 1980s to 2018, were tabulated and are provided in the guideline appendices.

### **Key stakeholder input and expert review**

The process of developing this guideline involved consultation with relevant federal, provincial and territorial (FPT) partners and key stakeholder organizations which included clinicians with relevant expertise. A preliminary consultation with a targeted group of key stakeholders involved a needs assessment conducted prior to the development of the guideline to inform its scope and key issues. Existing guidelines developed for use in other countries and relevant provincial and territorial policies in Canada were reviewed for scope and content prior to the development of this guideline. Upon completion of a preliminary draft guideline, an extensive consultation with FPT partners and key stakeholders was done to obtain feedback. All feedback received from the consultation processes were reviewed and addressed as deemed appropriate by the Task Group prior to finalizing the guideline.

### **Limitations**

For ethical and methodological reasons, RCTs are not feasible to assess potentially harmful situations such as the transmission of BBVs. Many studies informing this guideline were weak in study design, with their overall quality ranging from mostly low and medium to a few high quality studies. In some instances, comparator interventions used in the selection criteria for the systematic reviews did not allow for substantially minimizing confounding factors. Where graded, the grade of evidence ranged from CI to BII. For items where there was a paucity of published studies, inconclusive study results, or information was obtained solely from environmental scans, expert opinion of the Task Group members informed recommendations for practice.

## **New approach and additional content: how this guideline differs from Health Canada's 1998 consensus document**

In the past 20 years there has been remarkable progress in the prevention, diagnosis tools, treatment regimens, and management of infections due to BBVs as well as major improvements in guideline development methodology. These advancements were considered in developing this guideline. As a result, there are key differences in the approach used for the development of this guideline and Health Canada's 1998 consensus document. Some key items include:

- The Task Group was selected by PHAC based on identified expertise needed for the guideline topic - infectious diseases, medical microbiology and virology, infection prevention and control, public health, occupational health, hepatology, dentistry, medical ethics, and obstetrics and gynecology. The Task Group reported to PHAC's National Advisory Body on Infection Prevention and Control.
- An evidence-based approach involving rigorous review and synthesis of the evidence with expert interpretation of the evidence was used in the development of this guideline.
- The evidence base reviewed for the development of this guideline included publications of epidemiologic investigations of potential and confirmed exposure incidents; similar guidance developed by other organizations and governments; relevant policy documents, and reports from government institutions or professional organizations outside of the indexed medical literature.
- Six systematic reviews, a narrative review, and three environmental scans of the most current and relevant literature were conducted to inform the guideline content.
- Where possible, evidence from eligible studies in the systematic reviews was graded.
- Key stakeholder consultation was conducted prior to writing the guideline and an extensive consultation followed the development of the first draft of the guideline.
- The guideline is a comprehensive document providing extensive background information on each section and summary tables where applicable.

## **Major recommendations**

Recommendations were developed by the Task Group and were based on available evidence as well as collective expert opinion (where there was limited or no published evidence).

### **Key points related to recommendations**

- This guideline provides criteria to help determine whether or not a procedure performed by a HCW is an exposure-prone procedure. It does not provide risk categories for these procedures. Refer to the section on *Exposure-prone procedures* for detailed information.
- This guideline provides a viral load cut-off level to inform an infected HCW's fitness for practice, thus increasing patient safety and optimizing the work force.

- This guideline provides detailed information for establishing Expert Review Panels to assess the risk of transmission of a BBV from an infected HCW to patients. If a HCW infected with a BBV has been reviewed by an Expert Review Panel and deemed safe to practice, this negates the need for disclosure of the HCW's serologic status to patients. Refer to the section on *Expert Review Panels* for detailed recommendations.
- This guideline provides detailed information for conducting lookback investigations if deemed necessary following the identification of an infected HCW or a HCW-to-patient transmission of a BBV. Refer to the section on *Lookback investigations related to infected healthcare workers* for detailed recommendations.
- Recommendations provided in this guideline were thought to be sufficient to prevent transmission from HCWs co-infected with two or all three of these BBVs. If a HCW who performs EPPs is co-infected, the HCW should meet the defined criteria recommended for safe practice by HCWs infected with each virus.
- This guideline made every reasonable effort to further reduce the minimal risk of HCW-to-patient transmission of BBVs, with recommendations striking a balance between the reasonable expectations of the public (protection from harm) and the reasonable expectations of individual HCWs (right to privacy).

The major recommendations supported by relevant background information and context are summarized here. Users of this guideline should refer to the appropriate section(s) for the full recommendation and the context provided in footnotes.

<b>Recommendations for healthcare worker students and trainees</b>
1. Professional schools should provide counselling to students and trainees infected with a BBV on potential implications of their BBV status to their future career, in order to facilitate making an informed decision regarding their preferred stream of study.
2. Professional schools should provide all students and trainees with training and/or education on Routine Practices, including hand hygiene and sharps safety.

<b>Recommendations for healthcare worker and patient exposures</b>
1. Every organization or jurisdiction should have a mechanism for risk assessment to determine whether a patient or HCW exposure has occurred.
2. Administrative control measures should include an obligation and mechanism for reporting

patient and HCW exposure incidents in every organization or jurisdiction, and a mechanism for assessing the risk of transmission.
3. Healthcare organizations should have written policies and procedures for post-exposure prophylaxis and management of exposed patients and HCWs.
4. All HCWs should know that a patient's possible exposure to a HCW's blood requires further management and that such events are reported in their facility/organization/jurisdiction.
5. All HCWs have an ethical and professional obligation to report and be tested (as per institutional policy) following an exposure to a patient's blood or body fluid or a patient's exposure to the HCW's blood.

<b>Recommendations for management of healthcare workers infected with HIV</b>
1. All HCWs who perform EPPs have ethical and professional obligations to know their HIV status.
2. If negative, those performing EPPs should be tested at appropriate intervals as determined by their level of risk and whenever an exposure has occurred.
3. HCWs infected with HIV should seek medical care from a physician with expertise in HIV management for optimal health maintenance and should be managed according to current recommendations with regular monitoring of HIV RNA levels.
4. HCWs infected with HIV should be restricted from performing EPPs until: <ul style="list-style-type: none"> <li>a) the HCW is under the care of a physician with expertise in HIV management; and</li> <li>b) the HCW is either on effective combination antiretroviral therapy or has been identified as an elite controller; and</li> <li>c) the HCW's viral load is undetectable.</li> </ul>
5. HCWs infected with HIV who are on effective combination antiretroviral therapy (or are elite controllers), and have an undetectable viral load, should have no restrictions on practice based on HIV status alone.
6. HCWs infected with HIV who do not perform EPPs do not need any restrictions on practice based on HIV status alone.
7. If a HCW-to-patient transmission of HIV occurs, the HCW should cease clinical practice immediately until determination for fitness to return to practice is made.

<b>Recommendations for management of healthcare workers infected with HCV</b>	
1.	All HCWs who perform EPPs have ethical and professional obligations to know their HCV status.
2.	If negative, those performing EPPs should be tested at appropriate intervals as determined by their level of risk and whenever an exposure has occurred.
3.	Confirmation of active HCV infection should be done using HCV RNA testing. HCWs infected with HCV should seek medical care from a physician with expertise in HCV management for optimal health maintenance and should be managed according to current recommendations.
4.	<p>HCWs testing positive for HCV RNA should be restricted from performing EPPs until:</p> <ul style="list-style-type: none"> <li>a) the HCW is under the care of a physician with expertise in HCV management; and</li> <li>b) the HCW has completed effective therapy; and</li> <li>c) the HCW has tested negative for HCV RNA at least 12 weeks post-treatment.</li> </ul> <p>Note: Expert Review Panels may individualize practice restrictions to allow a HCW to perform EPPs while on effective therapy provided the virus is undetectable; the HCW's practice should then be restricted post treatment until a sustained virologic response (SVR) is confirmed.</p>
5.	HCWs testing negative for HCV RNA 12 weeks post-treatment can be considered to have SVR and should have no restrictions on practice based on HCV status alone.
6.	HCWs infected with HCV who do not perform EPPs do not need any restrictions on practice based on HCV status alone.
7.	If a HCW-to-patient transmission of HCV occurs, the HCW should cease clinical practice immediately until determination for fitness to return to practice is made.

<b>Recommendations for HBV immunization for healthcare workers (pre-exposure prevention)</b>	
1.	All susceptible HCWs (including students or trainees) should be immunized with hepatitis B (HB) vaccine, unless a medical contraindication exists.
2.	Students should complete their vaccination series and demonstrate immunity prior to starting any clinical rotations.
3.	<p>If a HCW has documentation of receiving a complete HB vaccine series but does not have documentation of anti-HBs serology following immunization, or, if a HCW reports HB immunization but has incomplete or no documentation of HB immunization, serologic testing for anti-HBs should be done and then:</p> <ul style="list-style-type: none"> <li>• If an anti-HBs titre of at least 10 IU/L is confirmed, testing need not be repeated nor should further immunization be undertaken, with the exception of</li> </ul>

<p>immunocompromised persons who should be tested periodically for waning immunity, and persons with chronic renal disease or on dialysis, who should be tested yearly.</p> <ul style="list-style-type: none"> <li>• If testing for anti-HBs is done 1 to 6 months after vaccination and the anti-HBs titre is less than 10 IU/L, a primary vaccine failure has occurred and the HCW should be given a second vaccine series. The HCW should be retested 1 to 6 months after completion of the second series.</li> <li>• If the HCW is tested more than 6 months after the initial series and the anti-HBs titre is less than 10 IU/L, the cause may be either a primary vaccine failure or waning antibody. Evidence shows that, in immunocompetent people, immunity is long lasting although antibody may be non-detectable. The HCW should receive one booster dose and be retested one month later to document an anamnestic response. If the anti-HBs titre is still less than 10 IU/L, the HCW should be tested for HBsAg and anti-HBc to rule out pre-existing chronic HBV infection. If both tests are negative, then a second vaccine series is indicated followed by anti-HBs serology 1 to 6 months after completing the second series.</li> <li>• HCWs who have documented evidence of failure to respond to two series of HB vaccine (i.e., anti-HBs titre of less than 10 IU/L) are unlikely to benefit from further immunization and will need passive immunization after potential exposure to HB. Occupational health or infectious disease specialists may be consulted regarding any new strategies that may be available such as intradermal vaccination or high potency vaccine.</li> </ul>
<p>4. If an HB exposure occurs, and a HCW has had a documented anti-HBs titre of at least 10 IU/L, no further testing is needed unless the HCW is immunocompromised or has chronic renal disease or is on dialysis. These HCWs should be tested for anti-HBs after a potential HB exposure and given additional vaccine and HBIG if their anti-HBs titre is less than 10 IU/L.</p>

<b>Recommendations for management of healthcare workers infected with HBV</b>
1. All HCWs who perform EPPs have ethical and professional obligations to know their HBV status.
2. HCWs who remain susceptible to HBV should be tested at appropriate intervals as determined by their level of risk and whenever an exposure has occurred.
3. HCWs born or previously residing in high HBV endemic countries should be tested for both anti-HBc and HBsAg to fully define HBV status.
4. HCWs infected with HBV should seek medical care from a physician with expertise in HBV management for optimal health maintenance and should be managed according to

current recommendations with regular monitoring of HBV DNA level.
5. HCWs infected with HBV should be restricted from performing EPPs until <ol style="list-style-type: none"> <li>the HCW is under the care of a physician with expertise in HBV management; and</li> <li>the HCW's HBV DNA level is below <math>10^3</math> IU/ml (<math>5 \times 10^3</math> GE/ml) or equivalent and monitored regularly (every 3 to 6 months).</li> </ol>
6. HCWs infected with HBV who have HBV DNA levels less than or equal to $10^3$ IU/ml ( $5 \times 10^3$ GE/ml) or equivalent should have no restrictions on practice based on HBV status alone.
7. HCWs infected with HBV who do not perform EPPs do not need restrictions on practice based on HBV status alone.
8. If a HCW-to-patient transmission of HBV occurs, the HCW should cease clinical practice immediately until determination for fitness to return to practice is made.

Abbreviations: anti-HBc, antibody to hepatitis B core antigen; HBcAg, Hepatitis B core antigen; HBsAg, Hepatitis B surface antigen

<b>Recommendations for double gloving for infected healthcare workers</b>
There is insufficient evidence to recommend for or against double gloving to prevent HCW-to-patient transmission of a BBV.

<b>Recommendations for healthcare workers' disclosure obligations and right to privacy</b>
1. A HCW infected with a BBV who performs EPPs does not have an obligation to routinely disclose his or her serologic status to patients to obtain their informed consent provided that the HCW's health status and practice have been assessed by an Expert Review Panel and all the panel's recommendations are followed.
2. All HCWs, including those infected with a BBV, have a right to privacy and confidentiality of personal health information.
3. Regulatory authorities should have policies on the management of HCWs infected with a BBV that are transparent about and detail how the right to privacy of HCWs will be upheld.
4. When a patient has been exposed to the blood of a HCW, the HCW must seek follow-up through their organizational process and the patient must be promptly informed of the nature of the exposure and the appropriate post-exposure protocol. However, the identity and confidentiality of the HCW should be protected to the greatest extent possible.

## **Summation**

This guideline was developed with a rigorous methodology involving robust systematic reviews, a narrative review, environmental scans, summaries of published epidemiologic investigations, and grading of available evidence with consideration of collective expert opinion in the development of recommendations. Adhering to recommendations provided in this guideline will result in safer practice for HCWs infected with a bloodborne virus. As new evidence develops, it may be necessary to update the recommendations.



# 1.0 FOREWORD

## Purpose of Guideline

The Public Health Agency of Canada (PHAC) develops evidence-based infection prevention and control (IPC) guidelines. These guidelines support IPC professionals, occupational health professionals, healthcare organizations, and healthcare providers in developing, implementing and evaluating IPC policies, procedures and programs that improve the quality and safety of health care and patient outcomes. Recommendations provided in these guidelines complement provincial and territorial public health efforts in monitoring, preventing, and controlling healthcare-associated infections.

The purpose of this document, *Guideline on the Prevention of Transmission of Bloodborne Viruses from Infected Healthcare Workers in Healthcare Settings*, is to provide a national framework for developing policies and procedures to prevent the transmission of three bloodborne viruses (BBVs), namely hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) from infected healthcare workers (HCWs) to patients in the healthcare setting. These three viruses account for most cases of healthcare-associated transmission of BBVs reported worldwide<sup>(1)</sup>.

This evidence-based guideline replaces PHAC's 1998 *Proceedings of the Consensus Conference on Infected Health Care Workers: Risk for Transmission of Bloodborne Pathogens*<sup>(2)</sup>. Recommendations provided in this guideline apply to all HCWs, including student and trainee HCWs.

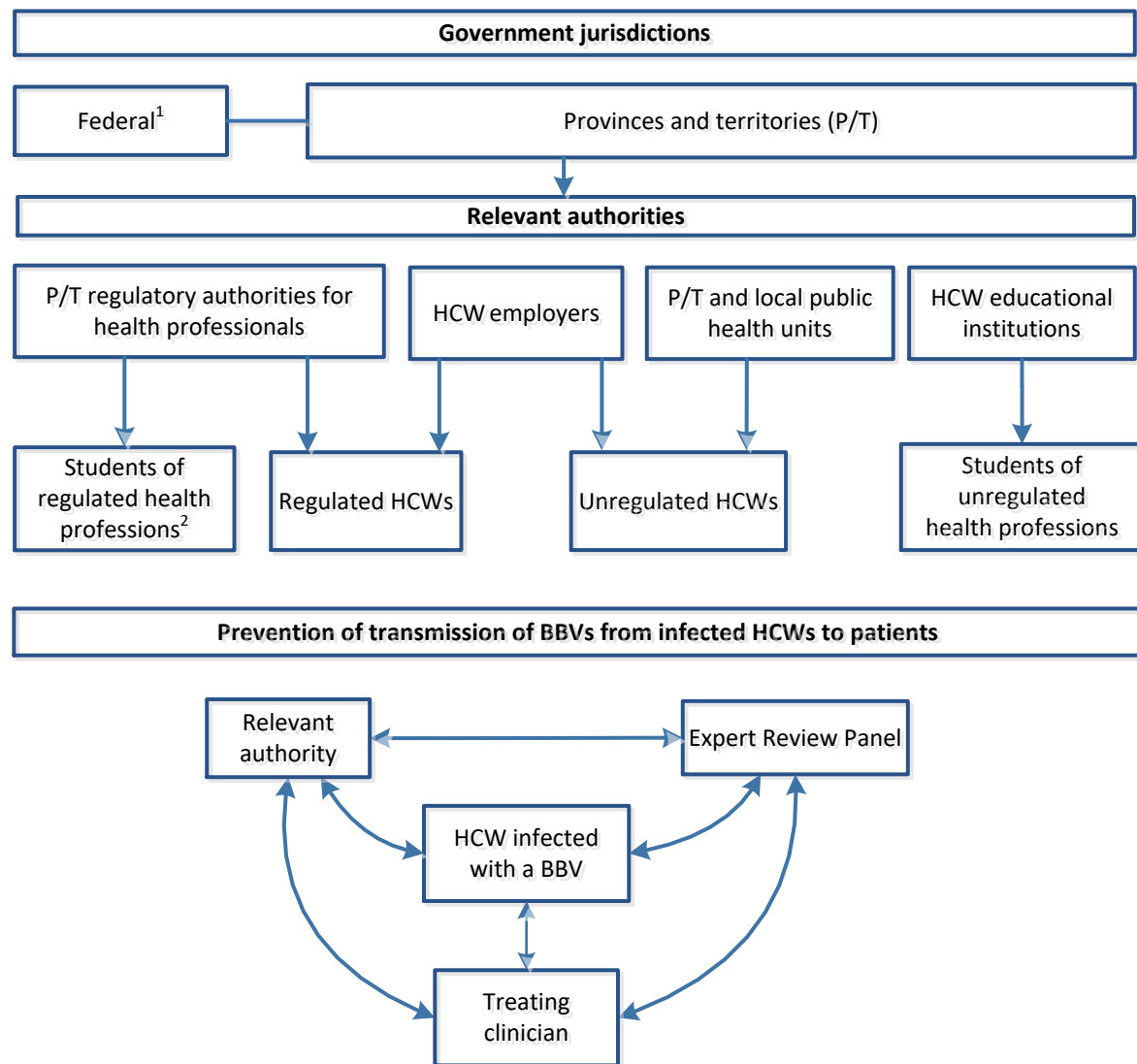
Following these recommendations will result in safer practice for HCWs infected with a BBV.

The information in this guideline was current at the time of publication. Scientific knowledge and medical technology are constantly evolving. Therefore, research and revisions to keep pace with advances in the field are necessary.

Guidelines, by definition, include principles and recommendations and should not be regarded as rigid standards. This guideline may need to be adapted to meet local, provincial and territorial requirements, or particular individual circumstances.

## Target Audience

This guideline is intended to assist those involved with the assessment and management of HCWs infected with a BBV, either individually (e.g., treating physician, members of Expert Review Panels) or generally (e.g., regulatory authorities). Key stakeholders impacted by this guideline and their inter-relationship with respect to managing the risk of transmission of BBVs from infected HCWs to patients, is shown in Figure 1.



**Legend**

<sup>1</sup> Regulated HCWs employed federally must be registered with the regulatory authority in their province or territory of work.

<sup>2</sup> In some P/T jurisdictions, students of regulated health professions are not regulated therefore responsibility for managing these HCWs lies with their educational institution.

**Abbreviations:** P/T, provinces and territories; HCWs, healthcare workers; BBVs, bloodborne viruses

**Figure 1: Stakeholders at a glance**

## 2.0 DESCRIPTION

The first section of this guideline describes the guideline development process. This is followed by a summary of the risk of transmission of BBVs, risk of injury to HCWs, student and trainee considerations, and definition of exposure-prone procedures (EPPs). The risk of HCW-to-patient transmission is discussed by type of virus, and recommendations to prevent transmission and to manage infected HCWs are provided. Finally, the roles and responsibilities of Expert Review Panels, considerations for conducting lookback investigations, and HCW's disclosure obligations and their right to privacy are discussed.

### 2.1 Guideline Development Process and Methodology

The core methods applied to the development of this guideline included identifying and reviewing existing guidelines, conducting a needs assessment, systematically reviewing evidence, grading the body of evidence, and synthesizing the evidence. A Guideline Development Task Group (Task Group) consisting of experts from across the country, developed recommendations based on available peer-reviewed evidence and collective expert opinion (where there was an absence of evidence). A broad consultation was conducted with key stakeholders to obtain feedback on the draft guideline. Relevant expert review and feedback continued throughout the development of this guideline.

#### 2.1.1 Consultation

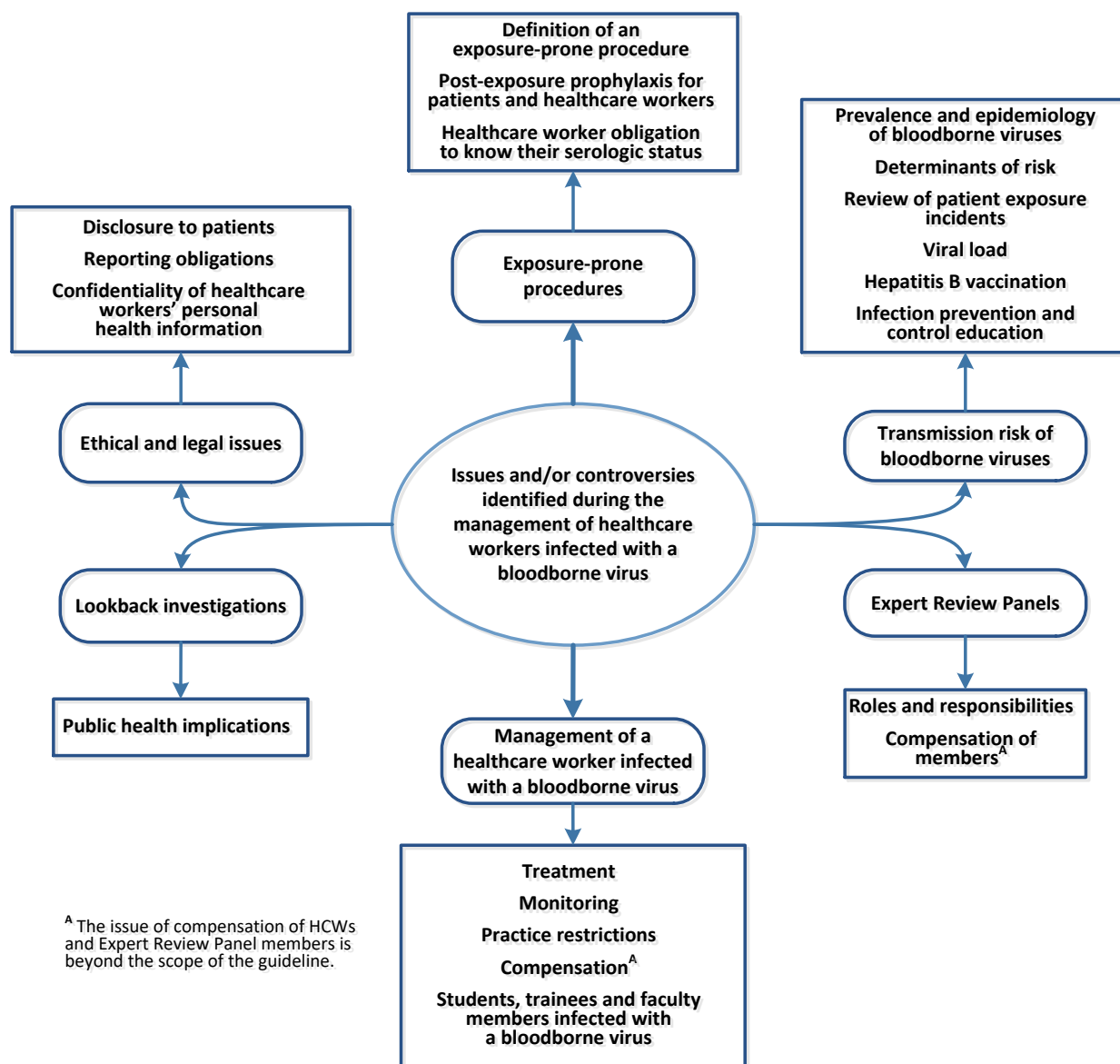
The Public Health Agency of Canada (PHAC) consulted with federal, provincial and territorial partners and key stakeholder organizations during the development of the guideline. This consultation consisted of two parts, a needs assessment conducted in 2011 and 2012 (prior to the development of the guideline), and a broad consultation conducted in 2017 and 2018 (upon completion of the first draft of the guideline).

The needs assessment was conducted to inform the scope and development of the guideline. Organizations with direct responsibilities for the assessment and management of HCWs infected with a BBV were invited to complete the *Questionnaire on the Development of a Guidance Document for the Management of Healthcare Workers Infected with Bloodborne Pathogens*. The national organizations invited to complete or share the needs assessment questionnaire with their members were identified with the assistance of the Task Group based on the following criteria: 1) national scope; 2) health professional regulatory authorities with members who might perform EPPs; 3) health professional faculties with students and trainees who might perform EPPs; 4) organizations with subject matter experts that might participate in the expert review process of HCWs infected with a BBV; and 5) upon request of another organization. The organizations invited were:

- Association of Canadian Faculties of Dentistry
- Association of Faculties of Medicine of Canada
- Association of Medical Microbiology and Infectious Disease Canada

- Canadian Association of Midwifery Educators
- Canadian Dental Regulatory Authorities Federation
- Canadian Medical Protective Association
- Canadian Midwifery Regulators Consortium
- Canadian Nurses Association
- Federation of Dental Hygiene Regulatory Authorities of Canada
- Federation of Medical Regulatory Authorities of Canada
- Occupational and Environmental Medicine Association of Canada
- Occupational Medicine Specialists of Canada
- Public Health Agency of Canada's Communicable and Infectious Diseases Steering Committee
- Resident Doctors of Canada (formerly Canadian Association of Internes and Residents)

The needs assessment was conducted using an online questionnaire that could be completed by any individual from these organizations. Each organization determined their own process to complete the questionnaire therefore it was not possible to determine individual response rates for the needs assessment. In total, 120 questionnaires were returned with 82 of these completed in full and 38 partially completed. Respondents were from all provinces and territories in Canada. The data collected was exported to an Excel spreadsheet and an analysis was performed using qualitative and basic quantitative methods. A summary of issues identified from the needs assessment is presented in Figure 2.



**Figure 2: Key issues and/or controversies identified regarding the management of a healthcare worker infected with a bloodborne virus**

A broad consultation with federal, provincial and territorial partners and key stakeholder organizations was conducted upon development of the draft guideline. This involved a thorough review of the draft guideline by individual(s) within a stakeholder organization with a goal to: 1) identify potential issues and/or concerns with any of the recommendations, including their feasibility and applicability; 2) correct erroneous information, if any; and 3) encourage broad support for the recommendations across the country. The organizations that were invited to provide feedback are summarized in Appendix III, Table 35. Each organization rolled up the individual feedback received into one organizational response and a completed feedback form was sent to PHAC. Each organization determined their own process to complete

the feedback form therefore it was not possible to determine the response rates for the broad consultation.

The feedback received from the broad consultation primarily identified the need for:

- Clarity of terminology
- Additional citations
- Minor grammatical edits
- Clear explanation of the guideline development methodology and consultation process
- Correction of erroneous background information or provision of supplemental background information with references
- Substantive edits to some technical content in the guideline
- Consideration of the applicability and feasibility of some recommendations
- Consideration of the potential impacts of some recommendations on existing organizational policies

All feedback received was tabulated and each item reviewed by the Task Group and PHAC staff to determine the appropriate action needed. Revisions were made to the draft guideline where needed and a rationale was documented where revisions were not made because the suggested edits were considered to be unnecessary, erroneous, ambiguous or not supported by current evidence.

### 2.1.2 Review of the Literature

A project protocol was developed to outline the steps and methods for reviewing relevant literature by conducting systematic reviews and environmental scans to inform recommendations provided in this guideline. The systematic review and environmental scan parameters, literature search strategy, and approach for evidence analysis were established prior to the initiation of the project. The project protocol was then circulated for internal comment and refinement by the Task Group and PHAC.

A series of Key Questions were needed to clearly address the identified issues from the needs assessment as well as the defined scope and objectives of the guideline. Ten Key Questions were drafted by the PHAC writing team and reviewed by the Task Group. Each question was structured to focus on a fundamental issue to be addressed in the guideline. A systematic review was conducted for questions where a clearly defined population, intervention, comparator and outcome (PICO) were identified and/or where it was considered necessary to review existing data for consideration in the development of recommendations. There were some limitations in identifying adequate comparator interventions and available data was qualitatively synthesized. Seven of the 10 questions developed were addressed using a systematic review process. A published systematic review of randomized controlled trials (RCTs) was available and therefore used, along with other studies, to inform one of the seven questions (i.e. clinical effectiveness of double gloving). Three questions were addressed by conducting environmental scans (refer to section 1.1.3).

Key Questions addressed by systematic reviews were:

1. What preventive or management measures can reduce the risk of transmission of HIV from infected HCWs to their patients?
2. What preventive or management measures can reduce the risk of transmission of HCV from infected HCWs to their patients?
3. What preventive or management measures can reduce the risk of transmission of HBV from infected HCWs to their patients?
4. What information exists on infectivity related to viral loads of HIV?
5. What information exists on infectivity related to viral loads of HCV?
6. What information exists on infectivity related to viral loads of HBV?
7. What is the comparative clinical effectiveness of double gloving versus single gloving in preventing transmission of bloodborne viruses from infected HCWs to patients?

Key Questions addressed by environmental scans were:

8. What are the obligations and/or recommendations for disclosure of the serologic status of HCWs infected with HIV, HCV, or HBV?
9. What are the issues that are relevant to the expert review process in Canada in the management of HCWs infected with HIV, HCV, or HBV?
10. What are the triggers, key considerations and mechanisms for conducting a lookback investigation?

## Systematic Reviews

Systematic reviews were conducted to summarize the evidence for the risk of transmission of HIV, HCV, and HBV from infected HCWs to patients. The literature search parameters were developed upon review of the project outline developed by the Task Group.

Prior to conducting the literature search, the Cochrane Collaboration Database of Systematic Reviews, the International Prospective Register of Systematic Reviews, the NIH Library of Systematic Review Protocols and Protocol Registries, the Database of Abstracts of Review of Effect, and the TRIP Database were searched for any previous systematic reviews that addressed this topic<sup>(3-7)</sup>. No published systematic review was found.

Literature search strategy concepts and keywords were selected for each topic. Four databases were reviewed: Ovid MEDLINE, EMBASE, Global Health and Scopus. Worldwide literature was searched from 1995 until the present. The literature search was conducted in 2013 and updated in 2015. Additional relevant references were obtained from supplemental sources and from manual search of reference lists of eligible studies.

The literature searches resulted in 6436 references. The references were screened for relevance and then sorted into topic-specific folders and sub-folders. All published research findings relevant to each sub-topic were reviewed. Scopus Search Alert, Global Health Search Alert, ProMED postings, Safe Injection Global Network, and the Public Health Agency of Canada Daily News were used to stay up-to-date with new studies after the formal literature searches were completed.

Relevant articles were screened for eligibility for each systematic review. For the systematic reviews informing the preventive or management measures to reduce the risk of transmission of a BBV, the criteria for selecting eligible population included infected HCWs performing or assisting with EPPs (irrespective of whether transmission occurred) and those providing direct patient care involving non-EPPs but where transmission occurred.

Critical appraisal of eligible studies was conducted using PHAC's *Critical Appraisal Tool Kit* (the Tool Kit)<sup>(8,9)</sup>. A grade was provided for the strength of the body of evidence informing each recommendation. This grade was based on a combination of strength of the individual study designs, quality of the individual studies, number of studies informing a recommendation, consistency of results from these studies, and directness of the body of evidence (i.e., assessing whether the evidence specifically researched the association of interest needed to inform the recommendation). The Tool Kit uses a grading scale that rates all levels of evidence from meta-analyses of randomized controlled trials to ecologic studies; and rates expert opinion lower than published scientific evidence. Within the hierarchy of scientific evidence, meta-analyses of RCTs are generally considered to be the best evidence available. For ethical and methodological reasons, RCTs are not feasible to assess potentially harmful situations such as the transmission of BBVs. In such situations, the best evidence becomes the evidence that exists at the highest level within the hierarchy of evidence. The body of evidence that exists to inform this guideline consists mostly of epidemiologic investigations of past exposure incidents. Although these studies are weak in design, they are nonetheless, the best available evidence informing this issue. As a result, the grade of evidence in this guideline falls within the range of CI to BII. Refer to Table 34, Appendix II, for further details on the criteria used for this rating. A grade of CII indicates where the evidence base consisted of low quality studies regardless of study design or existing studies reported contradictory results or there was a paucity of relevant studies thus the evidence was mostly based on expert opinion.

Evidence from eligible studies were reviewed and summarized. Companion articles providing additional information about eligible studies were identified in the systematic review literature database as well as from supplemental sources and/or manual search of reference list of eligible studies. Where relevant, the additional information reported in the companion articles was included in the tabular summary of the corresponding eligible study. A synthesis of evidence is provided along with the recommendations developed. Where there were insufficient published



studies or inconclusive study results, a consensus of experts in the field provided recommendations specific to practice. In addition, current practice and complex ethical and legal issues were considered and discussed in the development of final recommendations.

## Environmental Scans

An environmental scan of relevant literature (limited to English and French) was conducted for three Key Questions where the topic dealt with organizational, regulatory, and/or ethical issues not solely or directly informed by scientific research. This included the sections on disclosure of a HCW's serologic status, establishing Expert Review Panels and conducting lookback investigations.

The core methods used for conducting the environmental scans included identification and review of relevant documents obtained from a search of grey literature including policy documents, guidance from other organizations, and reports from government institutions or professional organizations outside of the indexed medical literature. These sources were used to identify the general consensus of opinion regarding these issues<sup>(10)</sup>. These sections were written as a text and/or tabular summary of the relevant literature.

The literature searches related to the disclosure of serologic status and the expert review process were limited to English and French language articles worldwide. Information obtained facilitated the development of recommendations based on relevant national and/or international guidelines, as well as regulatory authorities' and professional associations' policy statements. Relevant national guidelines on conducting lookback investigations, publications of past investigations and expert opinion informed the section on lookback investigations, with recommendations developed to fit the Canadian context.

Recommendations not informed by a systematic review of the scientific literature or where the topic deals with organizational, regulatory, and/or ethical issues not solely or directly informed by scientific research have no grade of evidence assigned.

### 2.1.3 Guideline Development Task Group (Task Group)

The *Guideline on the Prevention of Transmission of Bloodborne Viruses from Infected Healthcare Workers in Healthcare Settings* is one in a series of Infection Prevention and Control (IPC) guidelines developed by PHAC. Technical expertise for the review of the evidence and development of recommendations were provided by the Task Group. The Task Group for this guideline was composed of members with expertise in infectious diseases, medical microbiology and virology, infection prevention and control, public health, occupational health, hepatology, dentistry, medical ethics and obstetrics and gynecology. The Task Group reported to PHAC's National Advisory Committee on Infection Prevention and Control.

### **List of Guideline Development Task Group Members**

Participation in the Task Group does not constitute endorsement by affiliated organizations. The following individuals formed the Task Group (affiliations were at time of development of the guideline):

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## 3.0 INTRODUCTION

### 3.1 Background

Healthcare professionals, including physicians, dentists, nurses, physician assistants, dental hygienists and midwives, have an ethical and professional obligation to prioritize the well-being of their patients first, by providing safe, compassionate, competent and ethical care at all times<sup>(11-18)</sup>.

This responsibility includes minimizing the risk of exposure to pathogens within healthcare settings<sup>(19)</sup>. Certain surgical procedures may pose a risk of healthcare worker (HCW) injury with the possibility of exposing a patient to the blood of a HCW<sup>(20-24)</sup>. In 1998, Health Canada released recommendations from a consensus conference that was held to address the risk of transmission of bloodborne viruses (BBVs) from infected HCWs to patients<sup>(2)</sup>. This prompted key stakeholder organizations to develop policies on the issue. The policies of the professional regulatory authorities are direct and binding regulation on regulated HCWs infected with a BBV in Canada<sup>(25)</sup>. In addition, Medical Officers of Health, under their respective provincial or territorial Public Health Act, may issue an order to stop practice when an imminent risk to public health has been identified. This evidence-based guideline is intended to provide a framework for a pan-Canadian approach to the management of HCWs infected with a BBV.

To minimize the risk of BBV transmission from HCWs to patients, all HCWs should adhere to Routine Practices (synonymous with Standard Precautions, refer to Glossary)<sup>(19,26)</sup>, including performing hand hygiene as required, using personal protective equipment as appropriate, and taking care in the use and disposal of needles and other sharp instruments<sup>(27)</sup>. This guideline assumes that HCWs will adhere to Routine Practices when providing care to all patients at all times and in all settings<sup>(19)</sup>. As long as infected HCWs adhere to these practices, the risk of transmission of BBVs from infected HCWs to patients is negligible except during exposure-prone procedures (EPPs), which may pose minimal risk<sup>(28)</sup>. Efforts to prevent BBV transmission involve understanding the factors that increase or decrease the risk of transmission during an EPP, thus providing a framework for developing recommendations for the management of HCWs infected with a BBV who perform or assist with EPPs<sup>(29)</sup>. There are published reports of HCW-to-patient BBV transmission solely due to IPC breaches, with some cases involving egregious breaches such as the illicit diversion of patient medication involving reuse of needles for self-injection by a HCW<sup>(30)</sup>. Illicit diversion of injectable patient medication by a HCW is considered malpractice and is not within the scope of this document.

A review of the literature to inform this guideline revealed primarily lookback investigations and other descriptive studies. Inherent limitations with these study designs make it difficult to conclusively discern the contribution of various risk factors to the transmission of a BBV from an infected HCW to a patient. Information relating to exposure incidents and history of injection

drug use or other personal risk factors reported in lookback investigations is generally obtained from interviews. Such reports do not allow for assessing the extent of recall bias (bias due to differences in accuracy of recollection of past events), interviewer bias (bias in how information is solicited, recorded, and interpreted), or social desirability bias (providing responses that are considered to be socially or politically desirable). The retrospective nature of lookback investigations limits the information obtained from the report to the data the authors had access to or chose to report. Moreover, incidences of transmission where no EPP was involved and IPC breaches were not reported pose additional questions and thus require careful review<sup>(31,32)</sup>. It is possible that an infected HCW who has very poor IPC practices could infect patients without doing exposure-prone procedures. Therefore, the situation of every infected HCW should be reviewed. This does not necessarily require a formal review by a panel, but at least a review of what procedures the HCW performs, how they follow IPC practices, and whether they are on treatment. It is also an opportunity to reinforce appropriate IPC practices.

### 3.2 Determinants of Risk of Transmission of Bloodborne Viruses

Three determinants of risk influencing the likelihood of transmission of BBVs from infected HCWs to patients during an EPP have been previously outlined<sup>(2)</sup>. These include the risk of percutaneous injury for the HCW; risk of the contaminated instrument or HCW's blood contacting the patient's open tissues; and susceptibility of the patient. Although the HCW with high levels of circulating BBV may pose some risk if their blood contacts a patient, the risk approaches zero if that HCW is treated and eradicates (HCV) or decreases (HIV and HBV) circulating virus in their blood.

For each BBV, reported exposure incidents, regardless of whether transmission occurred, have been assessed to provide a comprehensive context for the development of this guideline. The extent of reporting bias for HCWs infected with a BBV and not implicated in transmission to patients via EPPs or non-EPPs is unknown. As a result, the risk of transmission of BBVs from HCWs to patients may be overestimated in the literature. A series of BBV transmission incidents have involved a chain of patient-to-HCW-to-patient transmissions<sup>(33)</sup>. The risk of transmission of BBVs from patients to HCWs during clinical activities is influenced by the prevalence of BBVs in the population, frequency of contact with infected patients, communicability of the BBV, immunologic status of the HCW, and years of experience with tasks that include blood exposure risk<sup>(34-37)</sup>. An increased prevalence of BBVs in a population served by HCWs who perform EPPs increases the risk of occupational exposure of HCWs to BBVs<sup>(38)</sup>. One urban academic hospital in the US reported that up to 38% of all surgical procedures conducted there involved exposure to HBV, HCV, and HIV<sup>(39)</sup>.

Despite the perceived risk, a 2007 systematic review investigating a total of 6,956 HCW injuries with HCV-contaminated needles, found no cases of HCV seroconversion<sup>(40)</sup>. In one study, a total of 99 injuries occurred during 1,382 (7.1%) surgical procedures with 89% of these sustained by residents or attending surgeons. In 29 of the 99 injuries (32%) sustained by surgeons, the sharp

instrument that caused the HCW injury contacted the patient after it had penetrated the HCW's skin<sup>(21)</sup>. Another study estimated that patients may be exposed to the blood of at least one HCW in as many as one in six cardiothoracic surgery procedures that carry a high exposure risk<sup>(41)</sup>. Many changes have occurred in the operating room environment since these studies were conducted, nonetheless, ongoing improvement to protect HCWs from sharps injuries will also protect patients from possible exposure to BBVs. Seroconversion of HCWs may not be recognized in a timely manner or prior to a patient exposure incident. In addition, published lookback investigations of patient exposure incidents show that very rarely is the exposure recognized during or immediately following the incident. If exposure is recognized, timely reporting of the exposure would allow for prompt initiation of post-exposure prophylaxis for the patient (for HIV and HBV)<sup>(42)</sup>.

From a review of cases of BBV transmission from infected HCWs to patients worldwide, the factors that influence the risk of percutaneous injury and/or the risk of transmission of BBVs given HCW injury have been identified. These factors include<sup>(29,38,43-48)</sup>:

- Risk of injury
  - type and duration of procedure performed
  - surgical techniques and expertise
  - compliance with IPC practices
- Risk of transmission
  - nature of the injury and exposure
  - frequency of injury
  - size of inoculum or volume of blood present in an exposure incident
  - viral load and clinical status of the source
  - Susceptibility of the exposed individual

Reports of potential patient exposure to HCWs infected with a BBV have identified dermatitis on the HCW's hands as one factor that may amplify the risk of transmission<sup>(49-51)</sup>. In one of these incidents, atopic eczema lesions prevented the HCW from wearing gloves systematically<sup>(50)</sup>. Another incident reported severe dermatitis on the HCW's hand with episodes of serous or bloody drainage from nodular lesions during the exposure period<sup>(49)</sup>. Adherence to Routine Practices should prevent transmission of BBVs via dermatitis<sup>(19)</sup>.

### 3.3 Perception and Comparison of Risk

Along with the actual risks of transmission of BBVs, the risk perceived by the public has to be considered in determining acceptable risk<sup>(52)</sup>. Generally, people are more fearful of things that are extremely unlikely but considered beyond their control<sup>(53)</sup>. While zero risk is unattainable, every reasonable effort should be made to reduce the risk to a minimum with recommendations striking a balance between the rights and reasonable expectations of the public (informed consent and protection from harm) and the rights and reasonable expectations of individual HCWs (privacy and freedom from discrimination)<sup>(54)</sup>.

Patient safety studies show that the most frequent types of adverse events affecting hospitalized patients are adverse drug events, wound infections, and surgical complications<sup>(55,56)</sup>. Risks associated with surgical procedures have been estimated and generally appear to have been accepted by patients<sup>(57)</sup>. Examples include the mortality risk of anesthesia for surgical inpatients, which is estimated at 0.82 in 100,000<sup>(58)</sup> and the risk for surgical site infections, which is estimated to be between 2 to 5%<sup>(59,60)</sup>. The risk of transmission of BBVs from an infected HCW to a patient via an EPP is lower than the risk of acquiring a healthcare-associated infection while receiving health care or the risk of acquiring BBVs via other mechanisms such as sexual activity with infected partners<sup>(61,62)</sup>. In the 2004 report published by the UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses (UKAP), the risk of HCW-to-patient transmission of a BBV was presented in comparison to the risk of patient-to-HCW transmission of a BBV based on modelling studies (refer to Table 1)<sup>(63-65)</sup>. These studies collectively show that the risk of a BBV transmission from patient to HCW is significantly higher than the risk of transmission from HCW to patient.

**Table 1: Risk of transmission of BBVs, HCW-to-patient and patient-to-HCW<sup>A</sup>**

BBV	Risk of transmission	
	HCW-to-patient	Patient-to-HCW
HIV	1 in 42,000 to 1 in 420,000 <sup>B</sup>	1 in 300
HCV	1 in 1,750 to 1 in 16,000 <sup>C</sup>	1 in 30
HBV	1 in 420 to 1 in 4,200 <sup>B,D</sup>	1 in 3 <sup>D</sup>

Abbreviations: BBV, bloodborne virus; HCW, healthcare worker; HIV, human immunodeficiency virus; HCV, hepatitis C virus; HBV, hepatitis B virus; EPP, exposure-prone procedure

<sup>A</sup> Adapted from the *United Kingdom Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses' Annual Report, 1<sup>st</sup> April 2003 to 31<sup>st</sup> March 2004*<sup>(63)</sup>.

<sup>B</sup> Based on risk of transmission from HCW to patient in a single procedure following a single injury incident to the HCW, in a model exercise.

<sup>C</sup> Based on risk of single injury incident in a single EPP with risk of transmission based on the risk of transmitting HCV to a HCW following a needlestick injury, ranging from 2.2% to 9.2%.

<sup>D</sup> It's not clear if this risk was calculated based on non-immune persons only. Risk varies depending on the e-antigen status of source person. If source person is e-antigen positive, the risk is up to 30%; if e-antigen negative, the risk is 1-6%<sup>(66,67)</sup>.

Considering HCW's access to both effective treatment for HCV and effective vaccine against HBV, and the minimal risk of HCW-to-patient transmission of HIV, it is reasonable to expect that measures taken to address the risk of a BBV transmission from HCW to patient should avoid triggering public fears, unduly restricting individual freedom, or violating human rights<sup>(68)</sup>.

It has been reported that the risk of physicians transmitting BBVs to patients will continue to fall as more effective methods of prevention and treatment are identified<sup>(69)</sup>. To date, there are no documented cases of transmission of any BBV from Canadian dentists to patients, and also no documented transmissions of either HIV or HCV from Canadian physicians to patients. There is only one report of a Canadian physician (an orthopedic surgeon) implicated in transmitting HBV to four patients; the surgeon was compliant with universal precautions (refer to Glossary) with no

obvious breaks in technique<sup>(70)</sup> . This incident occurred prior to the availability of modern antiviral therapy for HBV<sup>(71)</sup> . In addition, there have been numerous investigations of infected HCWs that did not identify transmission of a BBV.

### 3.4 Risk of Injury to a Healthcare Worker

With the introduction of routine hepatitis B (HB) vaccination, most HCWs are protected from infection with this BBV, virtually eliminating the risk of HCW-to-patient transmission. On the other hand, multiple percutaneous injuries throughout a HCW's career may place them at risk for occupational acquisition of HIV or HCV infection that may go unnoticed and therefore not treated. This in turn may pose minimal risk of transmission to patients in the event of a HCW injury while performing an EPP<sup>(72-78)</sup> .

Surveillance of HCW occupational exposures indicates that percutaneous injuries are the most commonly reported route of HCW exposure to blood or bodily fluid<sup>(79,80)</sup> . A modelling study conducted within the framework of the World Health Organization's Global Burden of Disease project in 2002 estimated the global burden of occupational infections with HIV, HCV and HBV attributable to sharps and injuries among HCWs<sup>(81)</sup> . Bloodborne infections and injuries occurring in the year 2000 in 14 geographical regions and four age groups were assessed. Overall, it was estimated that 1,000 HIV, 16,000 HCV, and 66,000 HBV infections may have occurred among HCWs worldwide due to occupational exposure through percutaneous injuries<sup>(33,81)</sup> . This amounted to 4.4%, 39%, and 37% of all HCW injuries resulting in HIV, HCV, and HBV infections respectively. The true incidence of occupational exposure to BBVs due to a HCW injury is unknown but likely to be higher than currently available publications due to late reporting and unreported cases<sup>(80,82)</sup> . Of all HCWs, nurses report percutaneous injuries most often while doctors report them least often<sup>(83)</sup> .

Risk of injury, and by extrapolation risk of BBV transmission to HCWs who perform EPPs, is dependent on the types of procedures they do. Certain HCWs such as laboratory technologists, phlebotomists, and surgeons perform procedures that have an increased incidence of injury and occupational exposure. Sharps and needlestick injuries are reported to be about six times more common among surgical personnel compared with nonsurgical personnel<sup>(82,84)</sup> . The frequency of HCW injury also varies among surgical specialties. Based on reports, the most at-risk procedures for HCW injury have been identified during major vascular, intra-abdominal, gynecologic, and orthopedic surgeries<sup>(85,86)</sup> . A study investigating the numbers and circumstances of percutaneous injuries among surgical personnel found that the procedure injury rate ranged from 4% (orthopedic) to 10% (gynecologic) and was significantly related to procedure duration<sup>(21)</sup> . The American College of Surgeons reported that patients' blood makes contact with the skin or mucous membranes of operating room personnel in as many as 50% of operations, with cuts or needlestick injuries occurring in up to 15% of operations<sup>(87)</sup> . Surgeons and first assistants were found to be at highest risk of injury, sustaining up to 59% of injuries in the operating room<sup>(87)</sup> . At



one institution, needlestick injury prevalence increased from medical students to residents and fellows (100%) and 11% of these needlestick injuries involved patients infected with a BBV<sup>(88)</sup>. Although sharps injury rates among surgical residents have been shown to decrease with increasing surgical experience, non-compliance with sharps injury reporting protocols is most common among senior surgeons with about 50% or more of these injuries not reported<sup>(36,84,89,90)</sup>. At one institution, lack of time and fear of potential embarrassment or consequence were reported to be the two critical components of underreporting of needlestick injuries<sup>(82)</sup>.

It has been reported that most dental HCWs (dentists, hygienists, assistants and oral surgeons) experience approximately three injuries per year<sup>(91)</sup>. A survey of a random sample of 300 dentists found that all respondents had protocols in place for managing and reporting sharp injuries to dental team members but only 48% of respondents had protocols for reporting patient exposures to the blood of a member of the dental team<sup>(35)</sup>. Dental HCWs were previously reported to have a low risk for occupationally acquired HIV but a higher risk for acquiring HBV than the average citizen<sup>(92)</sup>. With the development of a vaccine against HBV, the risk for acquiring HBV has been mostly mitigated for HCWs.

Adequate training and education on the prevention and management of occupational exposures is fundamental for HCWs as part of an occupational health program for sharps safety and prevention of exposure to BBVs<sup>(19,80)</sup>. Healthcare worker injuries can be reduced by use of blunt suture needles, improved instruments, reinforced gloves, changes in surgical technique and use of less invasive procedures<sup>(29,93,94)</sup>. Safety-engineered sharp devices should be used wherever possible for the safety of patients and HCWs<sup>(19)</sup>. Further information and recommendations on sharps safety, prevention of HCW exposure to blood or body fluids, and first aid when there has been a HCW exposure can be found in PHAC's *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings*<sup>(19)</sup>.

## 4.0 HEALTHCARE WORKER STUDENT AND TRAINEE SPECIFIC ISSUES

Key issues that have been identified for the health and safety of HCW students and trainees include necessary training in IPC, reducing the risk of occupational injury, assessment of immunization status, and confirming immunity to vaccine-preventable diseases (e.g., HBV) as early as possible on admission into health professional training programs<sup>(19,95-98)</sup>.

A prospective cohort study showed that medical students had a high risk for needlestick injuries, which most commonly occurred in the operating room<sup>(99)</sup>. A more recent study reported that 28% of medical students, 83% of residents and/or fellows and 100% of faculty had been exposed to a sharp injury at some point in their career<sup>(45)</sup>. By the final year of training, 99% of surgical residents have had a needlestick injury, with 53% of these injuries involving a high risk patient (patient with a history of a BBV infection or injection drug use)<sup>(84)</sup>. Occupational injuries among HCWs in dentistry show the highest rate of exposure occurs among dental students and assistants, with needlestick injuries predominating<sup>(46,100)</sup>. Nursing students have also been reported to be at increased risk of occupational needlestick injury due to limited clinical experience<sup>(101)</sup>.

The increased risk of injury among medical, dental and nursing students and trainees, if not mitigated, could pose a concern for students, trainees and patients. Education of student and trainee HCWs on risks and precautions, immunizations, use of less invasive procedures, protection strategies to minimize risk of injuries (e.g., use of safety engineered devices), and procedures to manage exposures will improve student and trainee knowledge and reduce their exposure risk<sup>(34,36,81,90,99,102,103)</sup>.

Despite increased rates of occupational sharp injuries to students and trainees, the risk for this group of HCWs to acquire a BBV, followed by secondary transmission to patients is still considered to be minimal. Professional schools should provide education to all students and trainees regarding the implications of infection with a BBV. Medical students are very unlikely to be performing exposure-prone procedures and transmission in dental school has not been reported in the literature. Strategies to reduce student and trainee injuries are primarily for their health and safety.

### 4.1 Recommendations Specific to Healthcare Worker Students and Trainees<sup>A</sup>

Recommendations
1. Professional schools should provide counselling to students and trainees infected with a BBV on potential implications of their BBV status to their future career, in order to facilitate making an informed decision regarding their preferred stream of study.
2. Professional schools should provide all students and trainees with training and/or education on Routine Practices, including hand hygiene and sharps safety.

<sup>A</sup>Refer to section 8.8 *Recommendations for HBV Immunization for HCWs (Pre-exposure Prevention)* for additional recommendations.

## 5.0 EXPOSURE-PRONE PROCEDURES

Exposure-prone procedures (EPPs) are invasive procedures where there is a risk that injury to the HCW may result in the exposure of the patient's open tissues to the blood of the HCW. For transmission of a BBV from an infected HCW to patient to occur during an EPP, three conditions are necessary<sup>(104)</sup>:

1. HCW must sustain an injury or have a condition that allows for exposure
2. HCW's blood must come in contact with a patient's wound, traumatized tissue, mucous membranes, or similar portal of entry
3. HCW must be sufficiently viremic

EPPs with risk of transmission include<sup>(105)</sup>:

- a. Digital palpation of a needle tip in a body cavity (a hollow space within the body or one of its organs); or the simultaneous presence of the HCW's fingers and a needle or other sharp instrument or object (such as bone splinters, sternal wires etc.) in a blind or highly confined anatomic site, e.g., as may occur during major abdominal, cardiothoracic, vaginal, pelvic and/or orthopedic operations
- b. Repair of major traumatic injuries
- c. Cutting or removal of any oral or perioral tissue, during which the patient's open tissues may be exposed to the blood of an injured infected HCW.

Transmission has been documented with several surgical and dental procedures, most of which meet the above definition of an EPP. There is insufficient evidence to accurately categorize most surgical, dental and medical procedures in terms of transmission risk<sup>(106)</sup>. As a result, risk categories developed so far have been based on expert consensus on the risk of contact between the HCW's blood and that of the patient<sup>(106,107)</sup>.

This guideline does not provide risk categories for EPPs. The approach taken involves providing criteria to help experts determine whether or not a procedure is an EPP. When assessing the procedures performed by an infected HCW, experts in the appropriate specialties should be engaged in determining which procedures fit the criteria for an EPP<sup>(108)</sup>.

Failure to adhere to IPC principles identified as Routine Practices could result in transmission of BBVs during a procedure. For reference purposes only, a list of procedures reported to date which involved documented transmission of a BBV, is presented in Table 2. Documented transmissions via non-EPPs have to be assessed on a case-by-case basis in order to rule out IPC breaches, illicit diversion of patient medication involving reuse of needles for self-injection by a HCW, and determine the possible mechanism(s) of transmission.

**Table 2: Procedures during which transmission of a BBV from an infected HCW to a patient was reported<sup>A</sup>**

Specialty	Procedures
Cardiothoracic surgery	Valve replacement surgery <sup>(41,76,109-111)</sup> Coronary artery bypass graft surgery <sup>(41,76,110-114)</sup> Pulmonary surgery <sup>(76)</sup> Other bypass surgery <sup>(110)</sup> Valve and coronary artery replacement <sup>(41)</sup> Thymectomy <sup>(111)</sup> Open-lung biopsy <sup>(111)</sup> Repair of congenital heart defects <sup>(111)</sup> Orthotopic heart transplantation <sup>(111)</sup>
Orthopedic surgery	Placement of a total hip prosthesis with bone graft <sup>(72)</sup> Thompson's hip hemiarthroplasty <sup>(115)</sup> Hip replacement <sup>(75,116)</sup> Revision of total knee replacement <sup>(70)</sup> Total knee replacement <sup>(70,116)</sup>
Obstetrics and gynecology	Caesarian section <sup>(117-119)</sup> Hysterectomy <sup>(120)</sup> Hysterectomy and removal of ovarian cyst <sup>(119)</sup> Uterus/adnexa extirpation <sup>(121)</sup>
General surgery	Repair of inguinal hernia <sup>(121-123)</sup> Cholecystectomy <sup>(119)</sup> Cholecystectomy and nephrectomy <sup>(119)</sup> Sigmoid resection <sup>(121)</sup> Ileocecal resection <sup>(121)</sup> Creation or removal of intestinal stoma <sup>(121)</sup> Transanal drainage <sup>(121)</sup> Excision of ganglion <sup>(121)</sup> Hernia repair and bladder neck resection <sup>(124)</sup>
Vascular surgery	Abdominal aortic aneurysm surgery <sup>(76)</sup> Aorta bifurcation prosthesis <sup>(121)</sup> Ligation and stripping of varicose veins <sup>(121)</sup>

Specialty	Procedures
Dentistry and oral surgery	<p>Extraction of two maxillary third molars under local anaesthesia; prophylaxis, and cosmetic bonding<sup>(125,126)</sup></p> <p>Extractions, prophylaxis, periodontal scaling and root planing, and fixed and removable prosthodontics<sup>(126)</sup></p> <p>Extractions, prophylaxis, periodontal scaling and root planing, and restorative fillings<sup>(126)</sup></p> <p>Examination, prophylaxis, fluoride treatment, restorative fillings and crowns, and root canal therapy under local anaesthesia<sup>(127)</sup></p> <p>Examination and radiographs, prophylaxis, extraction, restorative fillings and root canal therapy<sup>(127)</sup></p> <p>Root canal therapy and restorative filling under local anaesthesia<sup>(127)</sup></p> <p>Examinations, radiographs, prophylaxes and restorative fillings under local anaesthesia<sup>(128)</sup></p> <p>Dental extraction<sup>(129)</sup></p> <p>Reduction of fractured mandible<sup>(129)</sup></p> <p>Enucleation of maxillary cyst<sup>(129)</sup></p> <p>Root canal and cyst enucleation<sup>(129)</sup></p> <p>Surgery and dental extraction<sup>(130)</sup></p> <p>Crown<sup>(130)</sup></p>
Miscellaneous	<p>Acupuncture<sup>(131)</sup></p> <p>Electroencephalogram with reusable subdermal electrodes<sup>(132)</sup></p> <p>Administration of intravenous antibiotics<sup>(133)</sup></p> <p>Monitoring of patient and administration of two subcutaneous injections of heparin with a non-safety injection device<sup>(32)</sup></p> <p>Care of an implanted venous port and administration of intravenous antibiotics<sup>(134)</sup></p> <p>Venepuncture and cannulation<sup>(135)</sup></p> <p>Administration of anesthesia<sup>(31,136-139)</sup></p> <p>Hemodialysis<sup>(140)</sup></p>

Abbreviations: BBV, bloodborne virus; HCW, healthcare worker

<sup>A</sup> Procedures reported in the literature which involved transmission of HIV, HCV or HBV. Only procedures that are named in the investigations are included and where multiple procedures were done on a patient, it was not indicated which procedure was involved in transmission. All procedures done on a single patient are listed as a single line item. Where more than one patient had identical procedures, it was listed only once.

## 5.1 Recommendations for Healthcare Worker and Patient Exposures<sup>A</sup>

<b>Recommendations</b>	
1.	Every organization or jurisdiction should have a mechanism for risk assessment to determine whether a patient or HCW exposure has occurred.
2.	Administrative control measures should include an obligation and mechanism for reporting patient and HCW exposure incidents in every organization or jurisdiction, and a mechanism for assessing the risk of transmission.
3.	Healthcare organizations should have written policies and procedures for post-exposure prophylaxis and management of exposed patients and HCWs.
4.	All HCWs should know that a patient's possible exposure to a HCW's blood requires further management and that such events are reported in their facility/organization/jurisdiction.
5.	All HCWs have an ethical and professional obligation to report and be tested (as per institutional policy) following an exposure to a patient's blood or body fluid or a patient's exposure to the HCW's blood.

<sup>A</sup>The term 'HCWs' in this document includes students and trainees.

## 6.0 RISK OF TRANSMISSION OF HIV

There is a lack of consistency in the body of evidence relating to viral load units of measurement for BBVs. In this document, HIV viral load is reported as copies/mL as this is the current reporting practice for Canadian laboratories.

### 6.1 Incidence and Prevalence of HIV

The prevalence of HIV infection in the general Canadian population rose steadily during the 1980s, corresponding to the initial rise of HIV incidence in the Canadian population<sup>(141)</sup>. In 2016, PHAC reported an estimated 2,165 new HIV infections in Canada<sup>(142)</sup>. Approximately 63,110 people were living with HIV (including AIDS) by the end of 2016, representing a 5% increase from the estimate at the end of 2014<sup>(142)</sup>. The number and rate (per 100,000) of reported cases of HIV infection in Canada from 2000 to 2016 based on data from the CNDSS can be found on PHAC's Notifiable Diseases Online page here: <http://diseases.canada.ca/notifiable/charts?c=pl>

Although surveillance data are limited by underreporting, an increase in numbers of people living with HIV has been observed since the late 1990s. This may largely be related to the development of more effective, less toxic and better-tolerated therapies. These developments delayed the progression of HIV to acquired immune deficiency syndrome (AIDS), resulting in reduced mortality<sup>(79,143)</sup>.

In addition to the potential risk for occupational exposure, HCWs can have the same risk factors for acquiring HIV as the general population (e.g., injection drug use, sexual contact). There are currently no published HIV prevalence data among HCWs in Canada. The total number of reported AIDS cases among adults in Canada (15 or older) due to occupational exposure from 1979 to 2012 is 9, with 7 of these cases occurring before 2006<sup>(144)</sup>. The setting for these occupational transmissions was not reported.

### 6.2 Estimated Risk of HIV Transmission

Studies have estimated the risk of HIV transmission from patients to HCWs after percutaneous injury to range from about 0% to 3%<sup>(27,145,146)</sup>. Several risk factors may collectively increase seroconversion risk by as much as 50 times<sup>(145)</sup>. A case-control study of 33 HCWs who acquired HIV from occupational percutaneous exposure, compared with 665 controls who were similarly exposed to HIV-infected blood but not infected, found that the significant risk factors for seroconversion were<sup>(146)</sup>:

- deep injury,
- injury with a device that was visibly contaminated with the source's blood (larger volume of blood),
- exposures involving a needle placed in the source's artery or vein,
- exposure to a source who died of AIDS within two months after the exposure (possibly due to higher titre of HIV in the blood), and
- lack of post-exposure prophylaxis.

It is reasonable to assume that the same risk factors for seroconversion apply to transmission of HIV from HCWs to patients. There is very limited evidence of transmission of HIV from an infected HCW to a patient during an EPP. Nonetheless, the few transmission incidents reported globally confirm that the risk is not zero nor should it be considered hypothetical (refer to Table 3). The development of effective antiretroviral therapies, and their use by HCWs or patients infected with HIV will minimize the risk of transmission in the event of an exposure during an EPP<sup>(69,147)</sup>.

The HIV transmission rates calculated from two of four reported incidents involving HCW-to-patient transmission of HIV were 0.1% and 0.4% (refer to Table 20, Appendix I)<sup>(72,117)</sup>.

Transmission rates from the other two reported incidents are not helpful in assessing risk from EPPs as one incident involved a non-EPP<sup>(32)</sup>, and another incident reported IPC breaches, although it was unclear if this was applicable to all infected patients<sup>(148)</sup>.

To determine the observed rate of transmission of HIV from infected HCWs to patients in previous HIV exposure incidents, a meta-analysis of eligible exposure incidents was conducted [manuscript in development]. A total of 17 incidents were eligible for the meta-analysis including 14 with no transmission of HIV. The pooled transmission rate for HIV using the random effects DerSimonian-Laird model was 0.0056% (95% CI: 0-0.026%). This corresponds to a chance of 5.6 per 100,000 individuals (95% CI: 0 to 26.2 per 100,000 individuals) becoming infected in the absence of IPC breaches and illicit diversion of intravenous patient medication. The range of the observed transmission rate from this meta-analysis is similar to calculations from previous modelling studies<sup>(53,64)</sup>.

### 6.3 Review of Patient Exposure Incidents with Transmission of HIV

In the worldwide literature search conducted for this systematic review, published investigations reported HIV transmission from five infected HCWs to patients. For four of the infected HCWs, the exposure incidents involved an EPP.

In the early 1990s, a number of publications documented epidemiologic investigations involving patients of a dentist infected with HIV in the USA<sup>(125,126,128,148)</sup>. The dentist was symptomatic in late 1986 and diagnosed in 1987. The dentist practised while symptomatic with advanced HIV infection; therefore the viral load, although not reported at time of exposure, was most likely very high. The dentist continued to practise for a period of time prior to beginning antiretroviral therapy with Zidovudine (a less effective regimen than currently available therapy); but was not adherent to treatment while practising. A lookback investigation was conducted and involved testing 43% of potentially exposed patients. Phylogenetic analysis confirmed transmission of HIV from the infected dentist to six patients. Breaches in IPC were reported but attempts to determine the mechanism of transmission were inconclusive<sup>(126)</sup>.



The second transmission event was published in 1999 with a probable transmission of HIV from an orthopedic surgeon to a patient in France<sup>(72)</sup>. About 33% of his patients were tested, and one was found to be infected with HIV. This patient was operated on three times by the infected surgeon with prolonged duration of potential exposure during one difficult procedure that lasted over 10 hours<sup>(149)</sup>.

The third HIV transmission event was published in 2002 and involved a nurse in France<sup>(32)</sup>. The nurse was co-infected with HCV and had advanced cirrhosis. The nurse monitored the patient and gave two subcutaneous injections of heparin calcium with a non-safety injection device. The nurse denied having a history of injection drug use. The mechanism of transmission, although clearly not via an EPP, remains unknown.

The fourth HIV transmission event was published in 2003<sup>(117,150)</sup>. An obstetrician/gynecologist in Spain transmitted HIV to a patient during a caesarean section. The HCW admitted to having sustained a percutaneous injury during the procedure. The patient and family were reported to have seen the injury during the procedure although it was not promptly reported by the HCW at the time of injury<sup>(151)</sup>.

The fifth incident of HCW-to-patient transmission of HIV was published in France in 2005<sup>(149,152)</sup>. A thoracic surgeon was identified as HIV positive during an investigation of a newly acquired HIV infection in a patient who had undergone coronary artery bypass surgery. The patient had no other recognized risk factors and no percutaneous injuries to the surgeon were reported. The surgeon had tested negative for HIV two years earlier and had a viral load of 12,000 copies/mL at time of diagnosis. Details of the investigation of this event have not been published and are therefore not included in the tables provided in this guideline.

It is possible that other HIV transmission incidents from HCW to patient have occurred but have not been published. The published lookback investigations involving patients exposed to HCWs infected with HIV with documented transmission are summarized by HCW specialty in Table 3. A total of 12,550 patients were reported to be exposed to 4 HCWs infected with HIV. Of these patients, a total of 4,261 (34%) had their HIV status examined. Transmission of HIV from HCWs to patients occurred in 9 of these patients with 6 of these transmissions possibly involving IPC breaches. A detailed summary of the individual exposure incidents is presented in Table 20, Appendix I.

**Table 3: Summary of epidemiologic investigations reporting transmission of HIV from infected HCW to patient<sup>A</sup>**

Specialty	Number of infected HCWs	Number of patients potentially exposed	Number of patients tested (%)	Number of patients infected
Dentistry <sup>(128,148)</sup>	1	1691	735 (43)	6
Orthopedic surgery <sup>(72)</sup>	1	3004	983 (33)	1
Nursing <sup>(32)</sup>	1	7580	2293 (30)	1
Obstetrics and gynecology <sup>(117)</sup>	1	275	250 (91)	1
<b>Total</b>	<b>4</b>	<b>12,550</b>	<b>4261 (34)</b>	<b>9</b>

Abbreviations: HIV, human immunodeficiency virus; HCW, healthcare worker

<sup>A</sup> The details of individual investigations are provided in *Table 20: Epidemiologic investigations reporting transmission of HIV from infected HCW to patient* (Appendix I).

For purposes of informing the systematic review question (*What preventive or management measures can reduce the risk of transmission of HIV from infected HCWs to their patients?*), data were extracted from all eligible epidemiologic investigations where HCW-to-patient transmission was reported. Epidemiologic investigations of all four published investigations were eligible for inclusion in the systematic review. Three of the four investigations involved EPPs. Findings on key preventive measures and risk factors for transmission are summarized in Table 4.

**Table 4: Preventive measures and/or risk factors reported for HIV epidemiologic investigations involving transmission<sup>A</sup>**

Author, publication year	EPP/non-EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	Percutaneous injury <sup>H</sup>	Patient PEP <sup>I</sup>	Diversion ruled out <sup>J</sup>
Ciesielski, 1992 <sup>(148)</sup>	EPP	Yes	No	Yes	Yes <sup>K</sup>	No	NR	NR	NR
Lot, 1999 <sup>(72)</sup>	EPP	No	Yes	Yes	No	No	NR <sup>L</sup>	NR	Yes
Mallolas, 2006 <sup>(117)</sup>	EPP	No	NR	No	No	NR	Yes	NR	NR
Astagneau, 2002 <sup>(32)</sup>	non-EPP	Yes <sup>M</sup>	NR	Yes	No	No	No	NR	Yes
Total Yes EPP (non-EPP)		1 (1)	1 (0)	2 (1)	1 (0)	0 (0)	1 (0)	0 (0)	1 (1)
Total No EPP (non-EPP)		2 (0)	1 (0)	1 (0)	2 (1)	2 (1)	0 (1)	0 (0)	0 (0)
Total NR EPP (non-EPP)		0 (0)	1 (1)	0 (0)	0 (0)	1 (0)	2 (0)	3 (1)	2 (0)

Abbreviations: HIV, human immunodeficiency virus; EPP, exposure-prone procedure; IPC: infection prevention and control; PEP, post-exposure prophylaxis; NR, not reported; HCW, healthcare worker

<sup>A</sup> N=4 for total number of infected HCWs from all reported investigations.

<sup>B</sup> If EPPs and non-EPPs performed by a HCW (e.g., dentistry), data from article was pooled under EPP.

<sup>C</sup> Aware of status: HCW was aware of serologic status prior to exposure incident(s).

<sup>D</sup> IPC compliance: HCW was compliant with current IPC standards.

<sup>E</sup> Symptomatic: HCW was symptomatic during screening period.

<sup>F</sup> Treatment: HCW was previously treated or was on treatment during screening period.

<sup>G</sup> Practice review: HCW's practice was previously reviewed by independent expert(s) and recommendations made.

<sup>H</sup> Percutaneous injury: Percutaneous injury potentially exposing patient to HCW's blood was reported.

<sup>I</sup> Patient PEP: Post-exposure prophylaxis was offered to exposed patient(s).

<sup>J</sup> Diversion ruled out: Illicit diversion of patient medication by HCW was ruled out.

<sup>K</sup> The HCW was on and off treatment while practising (non-adherent).

<sup>L</sup> Although no percutaneous injury potentially exposing the infected patient was recorded, the HCW reported frequent injuries and noted blood under his gloves more than once a week.

<sup>M</sup> The HCW was unaware of their serologic status at the time of the index patient's exposure incident but was aware after being hospitalized and diagnosed in 1996<sup>(32,153)</sup>.

## 6.4 Review of Patient Exposure Incidents with No Transmission of HIV

In 1995, a summary of all published and unpublished investigations from the CDC database showed that among 22,171 patients who were treated by 51 HCWs infected with HIV (29 dentists and dental students, 8 physicians and medical students, 13 surgeons or obstetricians, and 1 podiatrist), a total of 113 patients with HIV were reported<sup>(154)</sup>. Results from epidemiologic and laboratory testing did not indicate that a HCW was the source of any of these infections.

The only publicly available HIV lookback investigation conducted in Canada was done in 2004 and involved 2,560 patients operated on by an infected HCW at a pediatric hospital<sup>(155)</sup>. In this report, a total of 2175 patients (85%) were tested and no HIV infections were identified.

A review of all investigations of potential exposure to BBVs in healthcare settings in Ireland was conducted between 2007 and 2011<sup>(156)</sup>. This study identified one lookback investigation that involved testing 66 potentially exposed patients for HIV; no case of transmission from the infected HCW was identified.

Published lookback investigations, from 1985 to 2014, involving 36 incidents of patients exposed to HCWs infected with HIV with no documented transmission are summarized by HCW specialty in Table 5. A total of 41,939 patients were reported to be exposed to 36 HCWs infected with HIV in a variety of healthcare settings. Of these patients, a total of 18,391 (44%) had their HIV status examined and no transmission was found. A detailed summary of the individual exposure incidents is presented in Table 21, Appendix I.

**Table 5: Summary of epidemiologic investigations reporting no transmission of HIV from infected HCW to patient<sup>A</sup>**

Specialty	Number of infected HCWs	Number of patients potentially exposed	Number of patients tested (%)
General surgery <sup>B (155,157-159)</sup>	4	7,655	3,279 (43)
Dentistry <sup>B (74,160-168)</sup>	12	18,822	8,777 (47)
Obstetrics and gynecology <sup>B (169-173)</sup>	8	8,706	3,772 (43)
Surgery <sup>B, C (173-176)</sup>	5	951	242 (25)
Cardiothoracic surgery <sup>(177,178)</sup>	2	2,281	734 (32)
Orthopedic surgery <sup>(73)</sup>	1	2,317	1,174 (51)
Ear, nose, throat surgery <sup>(175)</sup>	1	677	18 (3)
Theatre scrub nursing <sup>(173)</sup>	1	20	9 (45)
Family practice <sup>(49)</sup>	1	336	325 (97)
Community Services <sup>(156)</sup>	1	66	61 (92)
<b>Total</b>	<b>36</b>	<b>41,939</b>	<b>18,391 (44)</b>

Abbreviations: HIV, human immunodeficiency virus; HCW, healthcare worker

<sup>A</sup> This table excludes data from studies that did not report both the number of patients potentially exposed and the number of patients tested. The details of individual investigations are provided in *Table 21: Epidemiologic investigations reporting no transmission of HIV from infected HCW to patient* (Appendix I).

<sup>B</sup> Includes students and/or trainees.

<sup>C</sup> Multiple surgical specialties or surgical specialty not reported.

For purposes of informing the systematic review question (*What preventive or management measures can reduce the risk of transmission of HIV from infected HCWs to their patients?*), data were extracted from all eligible epidemiologic investigations where no transmission was reported. Of the 44 epidemiologic investigations with no documented transmission of HIV, 15 investigations (all involving EPPs) were eligible for inclusion in the systematic review. Findings on key preventive measures and risk factors for transmission are summarized in Table 6.

**Table 6: Preventive measures and/or risk factors reported for HIV epidemiologic investigations involving no transmission<sup>A</sup>**

Author, publication year	EPP/non-EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	Percutaneous injury <sup>H</sup>	Patient PEP <sup>I</sup>	Diversion ruled out <sup>J</sup>
Mishu, 1990 <sup>(158)</sup>	EPP	No	NR	Yes	NR	NR	No	NR	NR
Porter, 1990 <sup>(174)</sup>	EPP	No	NR	Yes	NR	NR	NR	NR	NR
Dickinson, 1993 <sup>(74)</sup>	EPP	No	Yes	Yes	NR	No	No	NR	Yes
Rogers, 1993 <sup>(159)</sup>	EPP	Yes	Yes	Yes	NR	No	NR	NR	NR
von Reyn, 1993 <sup>(73)</sup>	EPP	No	Yes	Yes	No	No	No	NR	NR
Babinchak, 1994 <sup>(177)</sup>	EPP	NR	NR	NR	NR	NR	No	NR	NR
Crawshaw, 1994 <sup>(169)</sup>	EPP	No	NR	NR	No	No	NR	NR	NR
Jaffe, 1994 <sup>(166)</sup>	EPP	Yes	No	Yes	Yes	No	NR	NR	NR
Hochuli, 1995 <sup>(171)</sup>	EPP	NR	NR	Yes	NR	NR	NR	NR	NR
Pell, 1996 (HCW 1) <sup>(175)</sup>	EPP	NR	NR	Yes	NR	NR	NR	NR	NR
Pell, 1996 (HCW 2) <sup>(175)</sup>	EPP	NR	NR	Yes	NR	NR	NR	NR	NR
Donnelly, 1999 <sup>(172)</sup>	EPP	No	NR	No	No	NR	NR	NR	NR
CHU Ste-Justine, 2004 <sup>(155)</sup>	EPP	Yes	NR	NR	NR	Yes	NR	NR	NR
CDC, 2009 <sup>(178)</sup>	EPP	No	Yes	Yes	No	No	No	NR	NR
Lam, 2014 <sup>(176)</sup>	EPP	NR	Yes	Yes	NR	NR	No	NR	NR
Total Yes EPP (non-EPP)		3 (0)	5 (0)	11 (0)	1 (0)	1 (0)	0 (0)	0 (0)	1 (0)
Total No EPP (non-EPP)		7 (0)	1 (0)	1 (0)	4 (0)	6 (0)	6 (0)	0 (0)	0 (0)
Total NR EPP (non-EPP)		5 (0)	9 (0)	3 (0)	10 (0)	8 (0)	9 (0)	15 (0)	14 (0)

Abbreviations: HIV, human immunodeficiency virus; EPP, exposure-prone procedure; IPC: infection prevention and control; PEP, post-exposure prophylaxis; NR, not reported; HCW, healthcare worker

<sup>A</sup> N=15 for total number of infected HCWs from all reported investigations.

<sup>B</sup> If EPPs and non-EPPs performed by a HCW (e.g., dentistry), data from article was pooled under EPP.

<sup>C</sup> Aware of status: HCW was aware of serologic status prior to exposure incident(s).

<sup>D</sup> IPC compliance: HCW was compliant with current IPC standards.

<sup>E</sup> Symptomatic: HCW was symptomatic during screening period.

<sup>F</sup> Treatment: HCW was previously treated or was on treatment during screening period.

<sup>G</sup> Practice review: HCW's practice was previously reviewed by independent expert(s) and recommendations made.

<sup>H</sup> Percutaneous injury: Percutaneous injury potentially exposing patient to HCW's blood was reported.

<sup>I</sup> Patient PEP: Post-exposure prophylaxis was offered to exposed patient(s).

<sup>J</sup> Diversion ruled out: Illicit diversion of patient medication by HCW was ruled out.

An obvious limitation in all lookback investigations is that only a percentage of potentially exposed patients are tested. Although it is not clear what the minimal criteria are to reliably conclude that there was no evidence of transmission in an exposure episode (e.g., magnitude of the lookback investigation or minimum percentage of exposed patients that should be tested), it has been indicated that available studies collectively provide evidence that the overall risk of transmission from HCWs infected with HIV to patients is “likely to be very low”<sup>(172)</sup>. Although this risk is not zero, it can be rendered negligible if HCWs infected with HIV who perform EPPs adhere to recommendations that have addressed the identified risk factors from previous exposure incidents.

Recommendations provided for minimizing risk of HCW-to-patient transmission of HIV have taken into consideration preventive measures and risk factors reported in exposure incidents to date.

## 6.5 HIV Viral Load

Deciding on a viral load cut-off level to determine an infected HCW’s fitness for practice increases patient safety and optimizes the work force. High viral load is associated with both the acute phase of the infection (which may go unnoticed) and with late-stage AIDS at which time the HCW is more likely to be symptomatic<sup>(179)</sup>. Currently, there is a paucity of empirical data relating viral load and occupational transmissibility of HIV in a quantitative manner. Instances of HIV transmission during an EPP without documented IPC breaches have not provided robust data to inform a viral load cut off. This is primarily because the HCW’s viral load at time of patient exposure, although expected to be high was most often not reported or unknown<sup>(72,117,150,180)</sup>.

Although viral load at the time of an exposure incident is usually not available, studies discussed thus far indicate that regardless of viral load, the risk of HIV transmission through an EPP is minimal. A 10-year lookback investigation involving 545 of 1,669 patients operated on by a cardiothoracic surgeon infected with HIV found no transmission occurred despite a viral load over 100,000 copies/mL at time of diagnosis<sup>(178)</sup>.

In conducting the systematic review to inform HIV infectivity or transmissibility related to viral load, the selection criteria allowed for inclusion of studies with blood-to-blood exposure and the reported time between potential exposure and source viral load determination. As a result, data informing this section includes data from patient-to-HCW exposure via percutaneous or other sharps injury. This allows for an analysis of HIV transmission (or absence thereof) from one person to another with different viral loads reported during exposure. Table 7 shows the relevant information from eligible studies of this systematic review. Overall, the studies did not show a consistent trend between high viral load and increased infectivity or transmissibility. In one study involving a HCW exposed to a high viral load of  $5.3 \times 10^7$  copies/mL (via a deep needlestick injury), HIV transmission did not occur<sup>(181)</sup>. The lowest viral load at which HIV transmission occurred from one individual to another via a definite blood-to-blood exposure was 1500 copies/mL<sup>(117)</sup>.

The demand for accurate, reproducible, and cost-effective viral load assays is recognized at a global level<sup>(182)</sup>. Studies have shown that certain assays are less reliable for accurate viral load measurements. Genetic variation in HIV subtypes or extreme divergence within HIV subtypes may also significantly affect the ability to detect and quantify the viral RNA in clinical specimens<sup>(182)</sup>. Due to the different assays used for viral load measurements or incomplete information reported on the assay used, it is not possible to accurately compare the viral loads across studies presented in Table 7. Standardizing assays and units for measuring BBV viral load will allow for more accurate comparison across studies.

Most individuals initiating antiretroviral therapy (ART) experience effective and prolonged control of viral replication in the plasma<sup>(183-186)</sup>. The impact of time of initiation of therapy on viral suppression and optimization of treatment outcome has been discussed in several studies<sup>(79,183,186-189)</sup>. In a study investigating HCW's exposure risk during surgical procedures on patients infected with HIV, the patients' viral load was reduced prior to surgery. This was done in an effort to ensure the safety of the operating team and best possible conditions for patients<sup>(147)</sup>. Collectively, these studies suggest that antiretroviral therapy lowers viral load thus minimizing the risk of HCW-to-patient or patient-to-HCW transmission. To date, there has not been a single reported case of HCW-to-patient transmission of HIV from an infected HCW receiving and adhering to antiretroviral therapy<sup>(71)</sup>. The reported transmission incidents involved untreated or treatment non-adherent HCWs. This suggests that recommendations to minimize risk of transmission should focus on treatment of infected HCWs as a means to maintain a low viral load. Strict adherence to therapy is essential for sustained HIV suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased risk of HIV transmission.



## **Elite Controllers**

Elite controllers are defined as individuals infected with HIV who are not receiving therapy and have maintained undetectable viral load in the blood (HIV RNA < 50 copies/mL) for at least one year, based on three separate viral load assessments<sup>(190-193)</sup>. This spontaneous control of viral replication in the absence of therapy is estimated to occur in approximately 1 in 300 individuals infected with HIV<sup>(191,192)</sup>.

Although elite controllers have undetectable viremia by standard clinical assays, when using more sensitive assays for RNA detection in the plasma, studies have reported that almost all elite controllers have detectable levels of plasma viremia and viral ‘blips’ of > 50 copies/mL occur<sup>(192,194-196)</sup>. This shows that virus from elite controllers is replication-competent and has no substantial genetic defect. Additional studies involving elite controllers show that despite undetectable plasma RNA levels, residual viral replication occurs in the absence of therapy and contributes to a chronic inflammation state<sup>(192,197,198)</sup>. As a result, elite controllers (including HCWs who perform EPPs) should be followed closely, as some may experience CD4<sup>+</sup> cell decline, loss of viral control, or complications related to HIV infection.

**Table 7: Viral load and other risk factors influencing risk of transmission of HIV<sup>A</sup>**

Author (publication year) Source of exposure	Type of exposure	Symptomatic	VL (copies/mL) <sup>B</sup>	On treatment	Time between exposure and source VL test	Exposed person(s) received PEP	Transmission
Pratt (1995) <sup>(199)</sup> Patient	Needlestick injury	Yes	4,261.20 x 10 <sup>2</sup>	Yes <sup>C</sup>	34 days	No <sup>D</sup>	Yes
Lot (1999) <sup>(200)</sup> Patient	Needlestick injury	No	250.00 x 10 <sup>2</sup>	No	At time of exposure	Yes	Yes
Astagneau (2002) <sup>E (32)</sup> HCW	Subcutaneous injections	Yes	838.00 x 10 <sup>2 F</sup>	No	15 or 16 days	No	Yes
French (2003) <sup>(201)</sup> Case 1 Other	Intrafamilial (sharing razors)	Yes <sup>G</sup>	820.64 x 10 <sup>2</sup>	No	Up to two years	No	Yes
French (2003) <sup>(201)</sup> Case 2 Other	Intrafamilial (caregiving <sup>H</sup> )	No	404.75 x 10 <sup>2</sup>	No	Up to six months	No	Yes <sup>I</sup>
Mallolas (2006) <sup>E (117)</sup> (HCW)	Caesarean section	No	15.00 x 10 <sup>2</sup>	No	7 months	No	Yes
Brumme (2007) <sup>(202)</sup> Other	Intrafamilial (caregiving)	Yes	3,300.00 x 10 <sup>2</sup> to 19,400.00 x 10 <sup>2</sup>	On and off <sup>J</sup>	2 to 9 months <sup>J</sup>	No	Yes
Emerson (2008) <sup>(203)</sup> Other	Intrafamilial (fist fight)	NR	48.00 x 10 <sup>2</sup>	Yes	At time of exposure	No	Yes <sup>K</sup>
Deshpande (2011) <sup>(204)</sup> Other	Intrafamilial (bite)	No	171.63 x 10 <sup>2</sup>	No	43 days	No	Yes
Sulkowski (2002) <sup>E (205)</sup> Patient	Needlestick injury	Yes	<1.93 x 10 <sup>2</sup>	NR	At time of exposure	Yes	No <sup>L</sup>
Giulieri (2007) <sup>(181)</sup> Case 1 Patient	Deep hand injury	Yes	240,000.00 x 10 <sup>2</sup>	No	At time of exposure	Yes	No
Giulieri (2007) <sup>(181)</sup> Case 2 Patient	Deep needlestick injury	Unclear <sup>M</sup>	530,000.00 x 10 <sup>2</sup>	No	At time of exposure	Yes	No
Boillat (2008) <sup>(206)</sup> Patient	Needlestick injury	Yes	>1,000.00 x 10 <sup>2</sup>	No	<24 hours	Yes	No
Kao (2011) <sup>(207)</sup> Other	Stabbing injury	NR	577.00 x 10 <sup>2</sup>	No	7.5 months	No	Yes
Upjohn (2012) <sup>(208)</sup> Case 1 Patient	Needlestick injury	Yes	>1,000.00 x 10 <sup>2</sup>	No	At time of exposure	Yes	No
Upjohn (2012) <sup>(208)</sup> Case 2 Patient	Needlestick injury	Yes	2,120.00 x 10 <sup>2</sup>	No	Approx. 3 days	Yes <sup>N</sup>	No
Upjohn (2012) <sup>(208)</sup> Case 3	Needlestick injury	Unclear <sup>O</sup>	>1,000 x 10 <sup>2</sup>	No	At time of exposure	Yes	No

Author (publication year) Source of exposure	Type of exposure	Symptomatic	VL (copies/mL) <sup>B</sup>	On treatment	Time between exposure and source VL test	Exposed person(s) received PEP	Transmission
Patient							

Abbreviations: HIV, human immunodeficiency virus; VL, viral load; PEP, post-exposure prophylaxis; HCW, healthcare worker; NR: not reported; HCV, hepatitis C virus; HBV, hepatitis B virus

<sup>A</sup> Articles reporting transmission linked to sexual, blood transfusion and perinatal routes have been excluded.

<sup>B</sup> Different assays may yield different values in copies/mL.

<sup>C</sup> Zidovudine for 4 years before the transmission.

<sup>D</sup> Initiated PEP (zidovudine 1000 mg per day) within one hour of exposure but stopped after 5 days due to side effects.

<sup>E</sup> Article identified during the systematic review for risk of transmission of HIV or viral load and infectivity for HCV or HBV.

<sup>F</sup> Goujon *et al* (2000) report that the HCW's viral load was  $1,800 \times 10^2$  copies/mL<sup>(153)</sup>.

<sup>G</sup> Source asymptomatic at time of diagnosis however, had had 'severe glandular fever' two years before (and one month after likely exposure event).

<sup>H</sup> Application of topical therapy to active psoriasis lesions without gloves.

<sup>I</sup> Source with HIV-HCV co-infection.

<sup>J</sup> Source had measurement of two plasma VL samples while being cared for by the exposed person. The exposed person was likely infected in 1999 with possible seroconversion illness seven months prior to source's death. During the exposure period, the source was not on treatment from February to July 1999.

<sup>K</sup> The source individual was on highly active antiretroviral therapy at the time of the fight.

<sup>L</sup> The source patient was HIV-HCV co-infected. The exposed person received an expanded 3-drug HIV PEP. There was no HIV transmission however, HCV was transmitted.

<sup>M</sup> Coma in injection drug user.

<sup>N</sup> The HCW delayed in reporting the injury so commencement of PEP was delayed for 84 hours.

<sup>O</sup> Patient admitted with a diagnosis of dementia.

## 6.6 Recommendations for Management of Healthcare Workers Infected with HIV

<b>Recommendations<sup>A</sup></b>	
1. All HCWs who perform EPPs have ethical and professional obligations to know their HIV status <sup>B</sup> .	
2. If negative, those performing EPPs should be tested at appropriate intervals as determined by their level of risk and whenever an exposure has occurred.	Grade of evidence: Not applicable
3. HCWs infected with HIV should seek medical care from a physician with expertise in HIV management for optimal health maintenance and should be managed according to current recommendations with regular monitoring of HIV RNA levels.	Grade of evidence: Not applicable
4. HCWs infected with HIV should be restricted from performing EPPs until: <ul style="list-style-type: none"> <li>a) the HCW is under the care of a physician with expertise in HIV management; and</li> <li>b) the HCW is either on effective combination antiretroviral therapy or has been identified as an elite controller; and</li> <li>c) the HCW's viral load is undetectable<sup>C</sup>.</li> </ul>	Grade of evidence: BII
5. HCWs infected with HIV who are on effective combination antiretroviral therapy (or are elite controllers), and have an undetectable viral load should have no restrictions on practice based on HIV status alone.	Grade of evidence: CI
6. HCWs infected with HIV who do not perform EPPs do not need any restrictions on practice based on HIV status alone.	Grade of evidence: CI
7. If a HCW-to-patient transmission of HIV occurs, the HCW should cease clinical practice immediately until determination for fitness to return to practice is made <sup>D</sup> .	Grade of evidence: CI

<sup>A</sup> The grade of the body of evidence upon which a recommendation is based is shown here (refer to Table 34, Appendix II for the grading scale). The full critical appraisal tool informing this scale can be found in PHAC's Critical Appraisal Tool Kit<sup>(8)</sup>.

<sup>B</sup> Ethical obligation may be traced to principles of non-maleficence (the duty to intentionally refrain from actions that cause harm), which includes an obligation for HCWs not to impose risks of harm to patients and creates a standard of due care<sup>(12-14,209)</sup>.

<sup>C</sup> There are variations in minimum detectable viral load thresholds for different assays. In addition, there may be situations where very low viral loads and/or transient blips (up to 400 copies/mL) may occur. These blips may not be clinically relevant and thus do not indicate treatment failure and will not necessarily trigger practice restrictions or lookback investigations. However, some jurisdictions may manage transient blips by maintaining stricter or more conservative thresholds<sup>(210)</sup>.

<sup>D</sup> Refer to the section on Expert Review Panels.

## 7.0 RISK OF TRANSMISSION OF HCV

There is a lack of consistency in the body of evidence relating to viral load units of measurement for BBVs. In this document, HCV viral load is reported as IU/mL (copies/mL) as this is the current reporting practice for Canadian laboratories and the WHO<sup>(211)</sup>.

### 7.1 Incidence and Prevalence of HCV

The first Canadian study to report seroprevalence of HCV infection based on a nationally representative household sample was the Canadian Health Measures Survey (CHMS) conducted from 2007 to 2011<sup>(212)</sup>. Estimates in this study are based on data collected from 8,434 survey respondents. Although the number of new cases of HCV in Canada has decreased in recent years, the number of prevalent cases remains high. Data from the CHMS, showed that an estimated 0.5% (95% CI: 0.3–0.9) of the population, representing a total of approximately 138,600 (95% CI: 55,800–221,300) people (aged 14–79 years) had laboratory evidence of an HCV infection as identified by HCV antibody<sup>(212)</sup>. Hepatitis C infection was more common in the 50–79 year old group compared to the 14–49 year old group and in individuals living in lower income households. A modelling study estimated that between 0.64 and 0.71% of the overall Canadian population was living with chronic HCV infection in 2011 and 44% of these individuals were undiagnosed<sup>(213)</sup>.

The number and rate (per 100,000) of reported cases of HCV infection in Canada from 1991 to 2016 based on data from the CNDSS can be found on PHAC's Notifiable Diseases Online page here: <http://diseases.canada.ca/notifiable/charts?c=pl>

The prevalence of anti-HCV positivity in HCWs worldwide ranges from 0% to 9.7% in different studies<sup>(48)</sup>. Several studies in western countries have concluded that the seroprevalence of HCV among HCWs is low and comparable to that of the general population<sup>(27,214–217)</sup>. On the other hand, a systematic review and meta-analysis of data from studies conducted internationally, generated different findings for the estimated prevalence of HCV among HCWs compared to the general population<sup>(218)</sup>. The study population was limited to HCWs in direct contact with patients or with blood. Results showed that the prevalence of HCV infection was significantly higher in HCWs than in the control general population. Stratification by occupational groups showed the highest prevalence was among medical and laboratory personnel, and HCWs who had a high risk of blood contact (surgeons, midwives, microbiologists, pathologists, blood bank and dialysis staff). Although a higher prevalence was also reported for dental HCWs (dentists and dental hygienists) than for the control group, the stratification for this group of HCWs was limited due to a paucity of published studies. Stratification by nursing staff did not show a significant increase in prevalence although results may have been confounded by blood exposure misclassification for this group of HCWs<sup>(218)</sup>. The study authors noted the need for prospective studies focusing on HCW-specific activity and personal risk factors for HCV infection.

In addition to the potential risk for occupational exposure, HCWs are subject to the same non-occupational risk factors for HCV as the general population. It is not known if the prevalence of HCV among Canadian HCWs is similar to that reported for the general public. This information as well as a Canadian estimate of the rate of transmission from infected HCWs to patients is needed to determine the true risk of transmission in Canada.

## 7.2 Estimated Risk of HCV Transmission

The risk of transmission of HCV through contaminated blood exposure, as estimated from modelling studies and lookback investigations has been found to be higher than that for transmission of HIV<sup>(65)</sup>.

Table 22, Appendix I, shows that the rate of transmission to patients estimated from epidemiologic lookback investigations following exposure episodes via an EPP varied, ranging from 0.04 to 3.7%. Generalizations regarding risk cannot be made from these transmission studies as the rates vary according to circumstances unique to each incident, such as viral load of infected HCW, sample size of the lookback investigation, and possible IPC breaches. As a result, mathematical modelling studies are also used to estimate the risk of transmission of HCV. One modelling study concluded that the risk of transmission of HCV from an infected surgeon to patient(s) is about 0.0062 to 0.057%, corresponding to 1 chance in 1,750 to 1 in 16,000 procedures<sup>(65)</sup>. When the surgeon's serologic status was unknown, the risk of transmission during a single operation was about 0.00008 to 0.000074%, corresponding to 1 chance in 135,000 to 1 in 1.2 million. This risk is comparable to the chance of acquiring HCV by receiving a blood transfusion from first-time donors who have previously screened negative for HCV antibodies<sup>(65)</sup>. Literature reviews show that the risk of HCW-to-patient HCV transmission (in incidents where illicit diversion of injectable patient medication by HCWs was considered unlikely) was less than 0.6%<sup>(30,33,219)</sup>.

To estimate the rate of transmission of HCV from infected HCWs to patients from reported HCV exposure incidents, a meta-analysis of eligible exposure incidents was conducted [manuscript in development]. A total of 9 incidents were eligible for the meta-analysis with 2 of them involving no transmission of HCV. The pooled transmission rate for HCV using the random effects DerSimonian-Laird model was 0.46% (95% CI: 0.07-1.17%). This corresponds to a chance of 460 per 100,000 individuals (95% CI: 70 to 1170 per 100,000 individuals) becoming infected in the absence of IPC breaches and illicit diversion of patient medication.

## 7.3 Review of Patient Exposure Incidents with Transmission of HCV

There have been over 20 epidemiologic investigations of HCV transmission from infected HCWs to patients conducted between 1996 and 2016 (refer to Table 22, Appendix I). It is likely that other transmission incidents have occurred but were either not published or not reported as exposures are often unrecognized and the asymptomatic phase of HCV infection can last many years, so transmission is not easily detected. The majority of investigations were triggered by

patients showing symptoms of acute hepatitis C or testing positive for HCV following surgical procedures. According to the reports from these investigations, a total of at least 13,494 patients were considered to be exposed to HCV during EPPs and in a few cases non-EPPs performed by HCWs infected with HCV. In most cases, the HCWs were either unaware of their HCV status or the study did not report on their awareness. As a result, the infected HCWs continued to perform EPPs without seeking medical attention for their infection. Of the exposed patients, a total of 8,652 (64%) were tested for HCV. Transmission of HCV from HCWs to patients occurred in 30 of these patients. Table 8 provides a breakdown of the number of patients exposed and the number of patients tested, grouped by HCW specialty. A detailed summary of the individual exposure incidents is presented in Table 22, Appendix I.

In comparison to HIV and HBV transmissions, cases of HCW-to-patient HCV transmission were disproportionately attributed to confirmed or suspected HCW illicit diversion of patient medications involving reuse of needles for self-injection by the HCW. These situations often involved infected anesthesiologists or nurse anesthetists. A recent systematic review of HCV infections from healthcare-associated outbreaks between 1999 to 2012 showed that up to 50% were attributable to HCW tampering (diversion, self-injection, and substitution) of anesthetic opioids<sup>(220)</sup>. Transmission risk from tampering was substantially higher than from surgery. Investigations reporting confirmed illicit diversion of patient medication by an infected HCW do not inform recommendations for risk of transmission during an EPP, and are therefore not included in the detailed summary of exposure investigations presented in Table 22, Appendix I<sup>(221-223)</sup>.

Some investigations revealed possible or known breaches in IPC practices as the mechanism of transmission, and therefore, may not inform recommendations for risk of transmission during an EPP<sup>(50,134,136-138)</sup>. However, these studies may provide insight into possible mechanism(s) of HCV transmission during a non-EPP. In Canada, the only reported outbreak of HCV in a tertiary-care hospital involved IPC breaches by HCWs participating in and performing procedures on each other as part of a research study, which resulted in HCV transmission from one infected healthcare technologist to 4 other HCWs. A subsequent lookback investigation to assess for HCW-to-patient transmission did not identify any patients infected<sup>(51)</sup>.

A case report of HCV transmission from an infected anesthetist to a patient without EPPs was reported in 2005<sup>(31)</sup>. This was the first case of transmission where the anesthetist was known to be HCV-RNA positive prior to the procedure and adhered to existing IPC protocols to minimize the risk of transmission. The anesthetist's HCV-RNA level was not available at the time of the exposure incident, but was found to be 11 million copies/mL when tested several years later. The anesthetist inserted a cuffed oral endotracheal tube and also inserted a peripheral cannula. The HCW denied any possibility of injection drug use, reported no open wounds, IPC breaches, or injuries during the procedure. The study authors postulated that transmission may have occurred by HCV shed from abrasions to the anesthetist and then inoculated to the patient via microabrasions. The study did not report on whether the anesthetist had undergone treatment for

HCV infection. Another report of HCW-to-patient transmission of HCV during a non-EPP involved an infected home care nurse. This incident draws attention to the risk of transmission in home care settings and the challenges of confirming direction of transmission<sup>(134)</sup>. Identification of the mechanism and implications of transmission of HCV from an infected HCW to a patient in the absence of EPP and no reported IPC breach may require a closer review of these incidents<sup>(135)</sup>. Among patients with acute HCV infection in Italy and Spain, a documented risk factor was hospitalization without any invasive procedure in some patients<sup>(224,225)</sup>. Although it was very difficult to determine the exact mechanism of HCV transmission, the mechanisms reported included patient-to-patient transmission, an outbreak due to the use of multidose drug vials, or poor IPC practices. The prolonged viability of HCV in fomites and on hospital equipment has been hypothesized to contribute significantly to healthcare-associated transmission in the absence of invasive procedures<sup>(226)</sup>.

Several studies show that EPPs were the sole or major mechanism of transmission and are therefore the basis upon which risk of transmission of HCV from an infected HCW to a patient and recommendations for prevention are based<sup>(75,76,109,112,113,118,120,219,227-231)</sup>.

The summary of epidemiologic investigations reporting HCW-to-patient transmission of HCV excludes studies that did not report the number of patients exposed and the number of patients tested (refer to Table 8). Most of the infected patients (21 out of 30) acquired their infection from either infected cardiothoracic surgeons or obstetrician/gynecologists.

A transmission incident that was recognized in 2012, involved a retired obstetrician / gynecologist who had practised for over 30 years and was unaware of an HCV infection until after retirement<sup>(78)</sup>. In an extensive lookback investigation spanning over 18 years, four out of 5500 patients (0.07%) were found to be infected (to date of writing this guideline)<sup>(78)</sup>. In another episode, an infected midwife who worked on the post-natal unit transmitted HCV to one patient<sup>(135)</sup>.

In the two transmission incidents involving anesthetists, no IPC breach was reported although drug diversion could not be ruled out in one investigation<sup>(31,137)</sup>.



**Table 8: Summary of epidemiologic investigations reporting transmission of HCV from infected HCW to patient<sup>A</sup>**

Specialty	Number of infected HCWs	Number of patients potentially exposed	Number of patients tested (%)	Number of patients infected
Cardiothoracic surgery <sup>(76,109,112)</sup>	3	1,265	769 (61)	16
Anesthesiology <sup>(137,138)</sup>	2	2,043	824 (40)	4
Obstetrics and gynecology <sup>(78,118)</sup>	2	8,407	5,596 (67)	5
General surgery <sup>(231)</sup>	1	1,461	1,193 (82)	1
Orthopedics <sup>(75)</sup>	1	229	207 (90)	1
Hemodialysis <sup>(140)</sup>	1	48	44 (92)	2
Midwifery <sup>(135)</sup>	1	41	19 (46)	1
<b>Total</b>	<b>11<sup>B</sup></b>	<b>13,494</b>	<b>8,652 (64)</b>	<b>30<sup>B</sup></b>

Abbreviations: HCV, hepatitis C virus; HCW, healthcare worker

<sup>A</sup> Excludes data from studies that did not report both the number of patients exposed and the number of patients tested. The details of individual investigations are provided in *Table 22: Epidemiologic investigations reporting transmission of HCV from infected HCW to patient* (Appendix I).

<sup>B</sup> Information on an additional 13 HCWs infected with HCV who infected 38 patients is not included due to missing data on the number of potentially exposed and tested patients.

In 2016, a lookback investigation was conducted on a HCW infected with HCV in the UK<sup>(232)</sup>. When the HCW was initially found to be seropositive, the UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses (UKAP) advised that patients did not need to be notified as the risk of transmission was thought to be low. However, following the emergence of two infected patients, further investigations found it was "probable" the HCW transmitted the virus during a surgical procedure. In total, 8,383 patients across the UK received letters informing them of the situation and urging them to arrange a blood test.

For purposes of informing the systematic review question (*What preventive or management measures can reduce the risk of transmission of HCV from infected HCWs to their patients?*), data were extracted from all eligible epidemiologic investigations where HCW-to-patient transmission was reported. Seventeen such investigations were eligible for inclusion in the systematic review. Nine of the 17 investigations involved an EPP. Findings on key preventive measures and risk factors for transmission are summarized in Table 9.

**Table 9: Preventive measures and/or risk factors reported for HCV epidemiologic investigations involving transmission<sup>A</sup>**

Author, publication year	EPP/non-EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	Percutaneous injury <sup>H</sup>	Diversion ruled out <sup>I</sup>
Esteban, 1996 <sup>(109)</sup>	EPP	Yes	Yes	No	Yes	NR	No <sup>J</sup>	NR
PHLS, 1999 <sup>(227)</sup>	EPP	No	NR	NR	NR	NR	NR	NR
Duckworth, 1999 <sup>(112)</sup>	EPP	No	NR	No	No	NR	NR	NR
PHLS, 2000 <sup>(228)</sup>	EPP	NR	NR	No	NR	NR	NR	NR
Ross, 2002 <sup>(118)</sup>	EPP	Yes	Yes	NR	NR	NR	No <sup>J</sup>	NR
Ross, 2002 <sup>(75)</sup>	EPP	NR	Yes	NR	NR	NR	No <sup>J</sup>	NR
Cardell, 2008 <sup>(113)</sup>	EPP	No	NR	No	No	NR	NR	Yes
Ross, 2008 <sup>(231)</sup>	EPP	Yes	NR	NR	NR	Yes	NR	NR
Olsen, 2010 <sup>(76)</sup>	EPP	Yes	Yes	No	No	Yes	No	Yes
Ross, 2000 <sup>(136)</sup>	non-EPP	Yes	No	Yes	NR	No	NR	Yes
Cody, 2002 <sup>(137)</sup>	non-EPP	Yes	No	Yes	No	NR	No	No <sup>K</sup>
Mawdsley, 2005 <sup>(31)</sup>	non-EPP	Yes	Yes	NR	NR	NR	No	Yes
Stark, 2006 <sup>(138)</sup>	non-EPP	No	No	No	No	No	No	Yes
Lot, 2007 <sup>(50)</sup>	non-EPP <sup>L</sup>	No	No	NR	NR	NR	No	Yes
Bourigault, 2011 <sup>(134)</sup>	non-EPP	No	NR	NR	No	No	NR	NR
Roy, 2012 <sup>(140)</sup>	non-EPP	No	No	NR	NR	NR	NR	NR
Muir, 2013 <sup>(135)</sup>	non-EPP	Yes	NR	NR	NR	NR	No	NR
Total Yes EPP (non-EPP)		4 (4)	4 (1)	0 (2)	1 (0)	2 (0)	0 (0)	2 (4)
Total No EPP (non-EPP)		3 (4)	0 (5)	5 (1)	3 (3)	0 (3)	4 (5)	0 (1)
Total NR EPP (non-EPP)		2 (0)	5 (2)	4 (5)	5 (5)	7 (5)	5 (3)	7 (3)

Abbreviations: HCV, hepatitis C virus; EPP, exposure-prone procedure; IPC, infection prevention and control; NR, not reported; HCW, healthcare worker

<sup>A</sup> N=17 for total number of infected HCWs from all reported investigations.

<sup>B</sup> If EPPs and non-EPPs performed by a HCW (e.g., dentistry), data from article was pooled under EPP.

<sup>C</sup> Aware of status: HCW was aware of serologic status prior to exposure incident(s).

<sup>D</sup> IPC compliance: HCW was compliant with current IPC standards.

<sup>E</sup> Symptomatic: HCW was symptomatic during screening period.

<sup>F</sup> Treatment: HCW was previously treated or was on treatment during screening period.

<sup>G</sup> Practice review: HCW's practice was previously reviewed by independent expert(s) and recommendations made.

<sup>H</sup> Percutaneous injury: Percutaneous injury potentially exposing patient to HCW's blood was reported.

<sup>I</sup> Diversion ruled out: Illicit diversion of patient medication by HCW was ruled out.

<sup>J</sup> Several articles indicate that although a percutaneous injury during an EPP on a specific patient was not described, injuries were reported to occur during certain procedures. The HCWs could not recall ever bleeding into a patient's wound<sup>(75,109,118)</sup>.

<sup>K</sup> The HCW denied drug abuse but the authors could not rule this out as an explanation for transmission<sup>(137)</sup>.

<sup>L</sup> Several members of the care team were tested, including surgeons, anesthesiologists, and nurses<sup>(50)</sup>. The specialty of the infected HCW was not reported, however, as it was reported that the infected HCW did not wear gloves systematically, the data have been pooled in the non-EPP column.

## 7.4 Review of Patient Exposure Incidents with No Transmission of HCV

Published epidemiologic investigations for HCV transmission from eleven infected HCWs to patients did not find any cases of transmission. Of these investigations, the nine incidents that reported the number of patients exposed and tested are summarized by HCW specialty in Table 10. Exposure incidents due to five of the infected HCWs are documented in a single report<sup>(63)</sup>. A total of 9,837 patients were reported to be exposed to the nine HCWs infected with HCV. Of these patients, a total of 5,738 (58%) had their HCV status examined and no transmission was found. A detailed summary of the 11 individual exposure incidents is presented in Table 23, Appendix I. Infection prevention and control breaches were reported in three of the investigations<sup>(173,233,234)</sup>. One investigation was conducted in Canada to determine possible HCV transmission from a general surgeon to patients who underwent high risk procedures in the three years before the surgeon was found to be seropositive<sup>(77)</sup>.

**Table 10: Summary of epidemiologic investigations reporting no transmission of HCV from infected HCW to patient<sup>A</sup>**

Specialty	Number of infected HCWs	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)
Healthcare technology <sup>(51)</sup>	1	498	215 (43)
Orthopedic surgery <sup>(235)</sup>	1	1,513	1,068 (71)
Obstetrics and gynecology <sup>(63)</sup>	5	2,500	1,562 <sup>B</sup> (62)
Dental surgery <sup>(233)</sup>	1	5,054	2,665 (53)
General surgery <sup>(77)</sup>	1	272	228 (84)
<b>Total</b>	<b>9<sup>C</sup></b>	<b>9,837</b>	<b>5,738 (58)</b>

Abbreviations: HCV, hepatitis C virus; HCW, healthcare worker; UKAP, UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses; EPP, exposure-prone procedure

<sup>A</sup> This table excludes data from investigations that did not report both the number of patients exposed and the number of patients tested. The details of individual investigations are provided in Table 23, *Epidemiologic investigations reporting no transmission of HCV from infected HCW to patient* (Appendix I).

<sup>B</sup> Staged lookback investigations related to the practices of 5 infected HCWs were recommended by the UKAP. These involved the last 500 patients (of each HCW) who had undergone higher risk EPPs. Upon extension of the lookback investigation related to one of the five infected HCWs, potentially exposed patients from 1987 onwards were tested for HCV and HCW-to-patient transmission was identified<sup>(234)</sup>. This information is captured in Table 22, *Epidemiologic investigations reporting transmission of HCV from infected HCW to patient* (Appendix I).

<sup>C</sup> Information on two additional HCWs infected with HCV is not included due to missing data on the number of potentially exposed and tested patients.

For purposes of informing the systematic review question (*What preventive or management measures can reduce the risk of transmission of HCV from infected HCWs to their patients?*), data were extracted from all eligible epidemiologic investigations where no transmission was reported. Three such investigations were eligible for inclusion in the systematic review. Two of the three investigations involved an EPP. Findings on key preventive measures and risk factors for transmission are summarized in Table 11.

**Table 11: Preventive measures and/or risk factors reported for HCV epidemiologic investigations involving no transmission<sup>A</sup>**

Author, publication year	EPP/non-EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	Percutaneous injury <sup>H</sup>	Diversion ruled out <sup>I</sup>
Mason, 2008 <sup>(233)</sup>	EPP	No	No	NR	NR	NR	NR	NR
Dawar, 2010 <sup>(77)</sup>	EPP <sup>J</sup>	No	NR	No	No	NR	Yes	NR
Saginur, 2011 <sup>(51)</sup>	non-EPP	No	NR	NR	No	NR	NR	NR
Total Yes EPP (non-EPP)		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0)	0 (0)
Total No EPP (non-EPP)		2 (1)	1 (0)	1 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Total NR EPP (non-EPP)		0 (0)	1 (1)	1 (1)	1 (0)	2 (1)	1 (1)	2 (1)

Abbreviations: HCV, hepatitis C virus; EPP, exposure-prone procedure; IPC: infection prevention and control; NR, not reported; HCW, healthcare worker

<sup>A</sup> N=3 for total number of infected HCWs from all reported investigations.

<sup>B</sup> If EPPs and non-EPPs performed by a HCW (e.g., dentistry), data from article was pooled under EPP.

<sup>C</sup> Aware of status: HCW was aware of serologic status prior to exposure incident(s).

<sup>D</sup> IPC compliance: HCW was compliant with current IPC standards.

<sup>E</sup> Symptomatic: HCW was symptomatic during screening period.

<sup>F</sup> Treatment: HCW was previously treated or was on treatment during screening period.

<sup>G</sup> Practice review: HCW's practice was previously reviewed by independent expert(s) and recommendations made.

<sup>H</sup> Percutaneous injury: Percutaneous injury potentially exposing patient to HCW's blood was reported.

<sup>I</sup> Diversion ruled out: Illicit diversion of patient medication by HCW was ruled out.

<sup>J</sup> Two patients who did not have EPPs were included in the investigation as the HCW reported a percutaneous injury during their procedures.

Recommendations provided for minimizing risk of HCW-to-patient transmission of HCV have taken into consideration preventive measures and risk factors reported in exposure incidents to date.

## 7.5 HCV Viral Load

Acute HCV infection is often asymptomatic, therefore detection and diagnosis can be difficult. Studies show that intermittent low level HCV viremia can occur up to two months before the period of exponential increase in viral load and the high titre plateau-phase viremia that usually precede seroconversion<sup>(236)</sup>. In general, 50 to 85% of people infected with HCV develop chronic infections with some variability based on certain factors<sup>(212,237)</sup>. In the chronic phase of HCV infection, infected persons can transmit infection via blood and other infected body secretions<sup>(33)</sup>. High viral load appears to be a major determinant influencing an infected individual's efficiency in transmitting HCV<sup>(238)</sup>. Most of the viral load testing conducted in lookback investigations of patients exposed to an infected HCW was done months after the exposure episode, perhaps making this information unreliable for determining infectivity based on viral load at the time of exposure.

Complete spontaneous or therapy-induced resolution of HCV infection can occur<sup>(239)</sup>. Spontaneous clearance of HCV is found to occur more frequently among those who experience symptomatic HCV with high viral titres, and occurs during the first 3 to 6 months of infection<sup>(240,241)</sup>. In a prospective cohort study, the spontaneous viral clearance rate after six months of infection was 18%; another study reported a 20 to 50% chance of spontaneous resolution of infection<sup>(242,243)</sup>.

Hepatitis C viremia is unusual after successful treatment, which is defined as sustained virologic response (SVR) or undetectable HCV RNA 8-12 weeks after therapy is completed<sup>(244-247)</sup>. A meta-analysis reported that SVR appears durable in the majority of patients at 5 years post-treatment with a summary 5-year recurrence risk of 0.95% among HCV mono-infected "low-risk" patients<sup>(248)</sup>. Notably, the higher pooled estimates of recurrence observed in high-risk and coinfecting cohorts were driven by an increase in reinfection rather than late relapse. Sustained virologic response with undetectable HCV-RNA following completion of current HCV therapy is considered a durable and clinically significant endpoint<sup>(244,246,247,249)</sup>. Treatment for HCV continues to improve and published data shows success rates in treatment should be over 90%<sup>(212,248,250-257)</sup>.

There is not much variability reported in viral loads of HCWs infected with HCV involved in transmission incidents (between  $10^5$  to  $10^7$  IU/mL) and there is no viral load that is considered non-infective. In conducting the systematic review to inform HCV infectivity or transmissibility related to viral load, the selection criteria allowed for inclusion of studies with blood-to-blood exposure and the reported time between potential exposure and source viral load determination. As a result, data informing this section includes data from patient-to-HCW exposure via percutaneous or other sharps injury. This allows for an analysis of HCV transmission (or absence thereof) from one person to another with different viral loads reported during exposure. Table 12 shows the relevant information from eligible studies of this systematic review.

The risk of transmission of HCV can be eliminated with treatment of the infected HCW resulting in no detectable HCV RNA in the blood. As a result, recommendations provided for managing HCWs infected with HCV are focused on treatment rather than identifying a viral load cut-off level for fitness-for-work.

**Table 12: Viral load and other risk factors influencing risk of transmission of HCV<sup>A</sup>**

Author (publication year) Source of exposure	Type of exposure	Symptomatic	VL (copies or genome equivalents/mL) <sup>B</sup>	VL (international units/mL) <sup>B</sup>	On treatment	Time between exposure and source VL test	Transmission
Esteban (1996) <sup>(109)</sup> HCW	Cardiothoracic surgery	No	22 x 10 <sup>6</sup> (R)	NR	Yes <sup>C</sup>	1 day to 2 years	Yes, to 5 patients
Bronowicki (1997) <sup>(258)</sup> Patient	Colonoscopy with biopsies or polypectomy <sup>D</sup>	NR	3.5 x 10 <sup>6</sup> (R) <sup>E</sup>	NR	No	8 months	Yes, to 2 patients
Duckworth (1999) <sup>(112)</sup> HCW	Cardiothoracic surgery	No	10 <sup>6</sup> (R)	NR	No	10 months	Yes, to 1 patient
Hasan (1999) <sup>(259)</sup> Patients	Needlestick injuries	NR	0.4 to 5.2 x 10 <sup>6</sup> (R) <sup>F</sup>	NR	NR	At time of exposure	No (24 HCWs exposed)
Ross (2000) <sup>(136)</sup> HCW	Anesthesia	Yes	10 <sup>6</sup> (R)	NR	No	4-6 months	Yes, to 5 patients
Wang (2002) <sup>(260)</sup> Patient	Needlestick injury	NR	>50 x 10 <sup>4</sup> <sup>G</sup> (R)	>1.85 x 10 <sup>5</sup> (C)	NR	At time of exposure	Yes, to 1 HCW
Wang (2002) <sup>(260)</sup> 11 patients	Needlestick injuries	NR	<50 x 10 <sup>4</sup> <sup>G</sup> (R)	<1.85 x 10 <sup>5</sup> (C)	NR	At time of exposure	No (11 HCWs exposed)
Ross (2002a) <sup>(118)</sup> HCW	Caesarian section	NR	13.8 x 10 <sup>5</sup> (C)	2.66 x 10 <sup>5</sup> <sup>H</sup> (R)	NR	3 months	Yes, to 1 patient
Ross (2002b) <sup>(75)</sup> HCW	Total hip arthroplasty	NR	NR	1.3 x 10 <sup>6</sup> (R)	NR	4 months	Yes, to 1 patient
Cody (2002) <sup>(137)</sup> HCW	Anesthesia	No <sup>I</sup>	37.92 x 10 <sup>6</sup> (R) <sup>F</sup>	NR	No	6 weeks	Yes, to 1 patient
Mawdsley (2005) <sup>(31)</sup> HCW	Anesthesia	NR	11 x 10 <sup>6</sup> (R)	NR	NR	Several years	Yes, to 1 patient
Orlando (2007) <sup>(261)</sup> Other	Needlestick injury <sup>J</sup>	NR	14 x 10 <sup>6</sup> (R)	NR	No	At time of exposure	Yes, to spouse
Shemer-Avni (2007) <sup>(223)</sup> HCW	Drug diversion	NR	10 <sup>5</sup> (R)	NR	NR	4 months to 2 years	Yes, to 33 patients
Kubitschke (2007) <sup>(262)</sup> Patients	Needlestick injuries	NR	NR	0.5 to 4.8 x 10 <sup>5</sup> (R) <sup>K</sup>	NR	At time of exposure	No (7 HCWs exposed)
Olsen (2010) <sup>(76)</sup> HCW	Cardiothoracic surgery	No	> 10 <sup>6</sup> (R)	NR	No	1 to 17 months	Yes, to 10 patients

Author (publication year) Source of exposure	Type of exposure	Symptomatic	VL (copies or genome equivalents/mL) <sup>B</sup>	VL (international units/mL) <sup>B</sup>	On treatment	Time between exposure and source VL test	Transmission
Bourigault (2011) <sup>(134)</sup> Companion <sup>L</sup> : <sup>(263)</sup> HCW	Rinsing of implantable venous port and intravenous antibiotic injections	NR	NR	$2.5 \times 10^7$ (7.4 log <sub>10</sub> ) (R)	No	10 to 15 months	Yes, to 1 patient <sup>M</sup>
Saludes (2013) <sup>(264)</sup> Patient	Anesthesia <sup>N</sup>	NR	NR	$7.1 \times 10^6$ (R) <sup>O</sup>	No	3 months	Yes, to 1 patient
Scaggiante (2013) <sup>(265)</sup> Patient	Needlestick injury	NR	NR	$1.4 \times 10^7$ (R) <sup>P</sup>	No	At time of exposure	Yes, to 1 HCW
Muir (2013) <sup>(135)</sup> HCW	Venepuncture and cannulation	NR	NR	$3.9 \times 10^6$ (R)	NR	> 8 weeks	Yes, to 1 patient

Abbreviations: HCV, hepatitis C virus; VL, viral load; NR, not reported; R, reported; C, calculated; HCW, healthcare worker; IPC, infection prevention and control.

<sup>A</sup> Articles reporting transmission linked to sexual, blood transfusion, and maternal-child routes have been excluded.

<sup>B</sup> Viral load as reported in study (R) or calculated using an assay-specific conversion factor (C). If the assay for quantification was not reported in the study or if unable to determine the conversion factor, 'NR' was included in the relevant cell. One copy is equal to 1 genome equivalent<sup>(266)</sup>.

<sup>C</sup> Treatment failed.

<sup>D</sup> The source patient underwent a colonoscopy with multiple biopsies on the same morning and prior to the two exposed patients who also underwent colonoscopies with either multiple biopsies or a polypectomy. Serious IPC breaches were identified related to the endoscope cleaning and disinfection procedures (between all patients) and for the administration of anesthesia (between the two exposed patients).

<sup>E</sup> Quantiplex bDNA 2.00, Chiron Diagnostics Europe, Cergy Pontoise, France.

<sup>F</sup> Quantiplex HCV RNA Assay [bDNA]; Chiron Corp, Emeryville, Calif.

<sup>G</sup> Amplicor HCV Monitor Test and Quanti-Path Kit, Roche Diagnostics (one IU/mL is equal to 0.9 copy/mL therefore 1 copy/mL is equivalent 1.1 IU/mL).

<sup>H</sup> Versant 3.0 b-DNA Assay (one IU/mL is equal to 5.2 copies/mL).

<sup>I</sup> The HCW became symptomatic 3 days after the exposed patient's procedure.

<sup>J</sup> Injury with tip of needle used to monitor capillary blood glucose in spouse with diabetes and known chronic hepatitis C infection.

<sup>K</sup> In-house real-time (rt)-PCR (detection limit 600 IU/mL).

<sup>L</sup> Articles identified as companion articles provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.

<sup>M</sup> The authors report as a possible case of HCW-to-patient transmission during home care as they were not able to determine the direction of transmission as the serologic status of the HCW was not known prior to the investigation<sup>(134)</sup>. In 2010, the authors report that an audit of the HCW's IPC practices is ongoing<sup>(263)</sup>; in 2011, they emphasize the importance of HCWs wearing gloves if exposed to blood, in addition to other routine IPC practices<sup>(134)</sup>.

<sup>N</sup> Transmission during the colonoscopy was determined to be less likely as a biopsy was not performed.

<sup>O</sup> Abbott RealTime HCV, Abbott Molecular.

<sup>P</sup> COBAS TaqMan, Roche, Basel.



## 7.6 Recommendations for Management of Healthcare Workers Infected with HCV

<b>Recommendations<sup>A</sup></b>	
1. All HCWs who perform EPPs have ethical and professional obligations to know their HCV status <sup>B</sup> .	
2. If negative, those performing EPPs should be tested at appropriate intervals as determined by their level of risk and whenever an exposure has occurred.	Grade of evidence: Not applicable
3. Confirmation of active HCV infection should be done using HCV RNA testing. HCWs infected with HCV should seek medical care from a physician with expertise in HCV management for optimal health maintenance and should be managed according to current recommendations.	Grade of evidence: Not applicable
4. HCWs testing positive for HCV RNA should be restricted from performing EPPs until: <ul style="list-style-type: none"> <li>a) the HCW is under the care of a physician with expertise in HCV management; and</li> <li>b) the HCW has completed effective therapy<sup>C,D</sup>; and</li> <li>c) the HCW has tested negative for HCV RNA at least 12 weeks post-treatment<sup>D</sup>.</li> </ul> Note: Expert Review Panels may individualize practice restrictions to allow a HCW to perform EPPs while on effective therapy provided the virus is undetectable; the HCW's practice should then be restricted post treatment until a sustained virologic response (SVR) is confirmed.	Grade of evidence: BII
5. HCWs testing negative for HCV RNA 12 weeks post-treatment can be considered to have SVR and should have no restrictions on practice based on HCV status alone.	Grade of evidence: CI
6. HCWs infected with HCV who do not perform EPPs do not need any restrictions on practice based on HCV status alone.	Grade of evidence: CI
7. If a HCW-to-patient transmission of HCV occurs, the HCW should cease clinical practice immediately until determination for fitness to return to practice is made <sup>E</sup> .	Grade of evidence: CI

<sup>A</sup> The grade of the body of evidence upon which a recommendation is based is shown here (refer to Table 34, Appendix II for the grading scale). The full critical appraisal tool informing this scale can be found in PHAC's *Critical Appraisal Tool Kit*<sup>(8)</sup>.

<sup>B</sup> Ethical obligation may be traced to principles of non-maleficence (the duty to intentionally refrain from actions that cause harm), which includes an obligation for HCWs not to impose risks of harm to patients and creates a standard of due care<sup>(12-14,209)</sup>.

<sup>C</sup> Due to the availability of effective therapy for HCV with sustained virologic response, this guideline does not recommend a serum HCV RNA cut off level for practice restrictions as recommended in other guidelines.

<sup>D</sup> The overarching principle for management of HCWs infected with HCV who perform EPPs is to restrict practice while the virus is detectable<sup>(267)</sup>.

<sup>E</sup> Refer to the [section on Expert Review Panels](#).

## 8.0 RISK OF TRANSMISSION OF HBV

There is a lack of consistency in the body of evidence relating to viral load units of measurement for BBVs. In this document, HBV viral load is reported as IU/mL (GE/mL) as this is the current reporting practice for Canadian laboratories and WHO<sup>(268)</sup>.

### 8.1 Incidence and Prevalence of HBV

Approximately two billion people worldwide have serologic evidence of past or present HBV infection and approximately 350 million people are currently chronically infected<sup>(269,270)</sup>. Canada is considered a country of low HBV endemicity; however, there are substantially more reported cases within the foreign-born population, Indigenous peoples of Canada, people who inject drugs and men who have sex with men<sup>(212)</sup>. In Canada, the rates of reported acute HBV infections declined from 1.0 to 0.6 per 100,000 between 2005 and 2012<sup>(237)</sup>. Primary HBV infection can be self-limited, with elimination of the virus from blood and subsequent lasting immunity against reinfection, or it can progress to chronic infection<sup>(270)</sup>. The risk for progression to chronic infection is inversely related to age at the time of infection<sup>(270)</sup>. Persons with chronic HBV infection are the major source of new infections<sup>(270)</sup>. Chronic HBV is likely to occur in <5% of infected older children and adults, approximately 25 to 50% of infected children aged 1 to 5 years old, and >90% of infants infected at birth<sup>(212,237,270,271)</sup>. Reporting of chronic HBV infection was variable across provinces and territories until 2009, making interpretation of earlier trends difficult. The number and rate (per 100,000) of reported cases of HBV infection in Canada from 1969 to 2016 based on data from the CNDSS can be found on PHAC's Notifiable Diseases Online page here: <http://diseases.canada.ca/notifiable/charts?c=pl>

Approximately half of all HBV cases are asymptomatic and approximately half of individuals infected with HBV are unaware of their status. As a result, the true incidence of HBV infection is most likely significantly underestimated<sup>(212,269)</sup>.

The introduction of the HBV vaccine in 1982, followed by the implementation of routine childhood immunization programs in Canada in the 1990s and screening during pregnancy have all contributed to decreasing rates of HBV<sup>(95,212,237)</sup>. Results from the Canadian Health Measures Survey conducted from 2007 to 2011, showed that 72.6% (95% CI: 69.6–75.4) of children aged 14–19 years had vaccine-induced immunity, and this rate decreased with increasing age but natural immunity increased with age<sup>(212)</sup>. Overall, the incidence of hepatitis B infection has decreased in all age groups in recent years, and has virtually disappeared in the cohorts that have benefited from routine immunization programs<sup>(95)</sup>.

Several seroprevalence surveys conducted before the availability of the HBV vaccine showed that HCWs had prevalence rates of past or present HBV infection that were three to fivefold higher than the general US population<sup>(272)</sup>. Following the implementation of preventive measures including HB vaccine and universal precautions (refer to Glossary), there was a significant decline in the incidence rates among HCWs<sup>(270,273)</sup>.

In addition to potential risk of occupational exposure, HCWs who have not been vaccinated or who are nonimmune following vaccination are subject to the same risk factors for HBV infection as the general population. The rates of HBsAg and anti-HBc positivity in HCWs worldwide published in several studies over the last three decades range from 0.1% to 8.1% and 6.2% to 73.4% respectively<sup>(48)</sup>. It is not known if the seroprevalence of HBV among Canadian HCWs is similar to that reported for the general public.

## 8.2 HBV Serologic Markers

HBV is a DNA virus with a core protein surrounded by a coat containing surface antigen (HBsAg). The serologic markers of chronic HBV infection are varied and complex. Antigens and antibodies associated with HBV infection include HBsAg and antibody to HBsAg (anti-HBs), antibody to HBcAg (anti-HBc), and hepatitis B e antigen (HBeAg) and antibody to HBeAg (anti-HBe). At least one serologic marker is present during each of the different phases of HBV infection<sup>(270)</sup>. The serologic markers are briefly described in Table 26, Appendix I<sup>(62,270,274-276)</sup>. Some individuals infected with HBV carry a viral strain with a nucleotide substitution in the precore region of the viral genome. This mutation prevents transcription of the precore region and therefore, the release of HBeAg from the hepatocyte which results in a negative serum test for HBeAg.

The serologic markers currently used to identify a person's HBV status are HBsAg, anti-HBc IgG, and anti-HBs<sup>(270)</sup>. The only way to definitively differentiate acute from chronic infection is if HBsAg persists for more than 6 months. Table 27, Appendix I describes the typical serologic patterns used to interpret HBV serologic status. HCWs infected with HBV have transmitted infection to patients while in the incubation period of infection, during acute hepatitis, a few months following acute hepatitis, and during the chronic phase of infection.

## 8.3 Estimated Risk of HBV Transmission

HBV is highly infectious, can be transmitted in the absence of visible blood, and has been reported to remain infectious on environmental surfaces for at least 7 days<sup>(66,270,277,278)</sup>. Hepatitis B virus is approximately 100 times and 10 times more infectious than HIV and HCV respectively. Several instances of healthcare-associated transmission were documented in the 1980s and summarized in several articles<sup>(64,269,279)</sup>.

In a study involving 405 reported cases of acute HBV infection, 262 cases were interviewed for risk factors. A total of 1.9% reported percutaneous injury and 3.1% reported healthcare-associated risk factors<sup>(269)</sup>. In studies of HCWs who sustained injuries from needles contaminated with HBV, the risk of developing acute hepatitis if the blood was both HBsAg positive and HBeAg positive was 22–31%; and the risk for developing serologic evidence of HBV infection was 37–62%. By comparison, if the blood was HBsAg positive and HBeAg-negative, the risks decreased to 1–6% and 23–37% respectively<sup>(277)</sup>. It is reasonable to assume that the same risk for seroconversion, following patient exposure to an HBV-contaminated needle, apply to HBV transmission from HCWs to patients.

Results from prospective studies showed that the estimated risk of transmission during exposure of two groups of 1,000 patients each to HBsAg positive HCWs and to HBsAg negative HCWs were both estimated to be less than 1%<sup>(280)</sup>. Transmission rates ranging from 0.06–11.11% have been reported from retrospective lookback investigations (refer to Table 24, Appendix I). This highlights the limitation of retrospective studies (triggered by reported transmission events) in obtaining data on transmission rates. When an infected patient is the trigger for an investigation seeking to identify other potentially exposed patients, the study design will result in documented transmission (the index patient)<sup>(280)</sup>. On the other hand, if an infected HCW is the trigger for an investigation (lookback), results will indicate either transmission or no transmission to patients. Although prospective studies provide an opportunity for appropriate controls, the infected HCWs' knowledge that they are being followed may influence them to follow more stringent precautions to prevent transmission<sup>(280)</sup>. Data informing the risk of transmission of HBV is mostly informed by published lookback investigations thus providing more incidents of transmission than no transmission of HBV.

Table 24 (Appendix I) shows the rates of transmission estimated from epidemiologic investigations following a transmission or exposure event. The risk of infection was positively associated with the invasiveness of the procedures<sup>(121,281)</sup>. Generalizations cannot be made from the transmission rates in these studies due to circumstances specific to each incident, including the viral load of the infected HCW, level of risk posed by the procedure(s) associated with transmission, sample size (which was very small in most studies), and possible IPC breaches<sup>(132,133,139,282,283)</sup>. As a result, mathematical modelling studies are also used to estimate the risk of transmission of HBV. A modelling study concluded that the risk of transmission of HBV from an infected surgeon is about 0.24–0.024%, corresponding to 1 chance in 420 to 1 in 4,200 per procedure<sup>(64)</sup>. The probability of transmission during a single procedure by an HBeAg positive surgeon is 0.24%. In one transmission incident, the risk of acquiring HBV from an infected surgeon did not significantly exceed the risk of acquiring HBV from other sources<sup>(284)</sup>.

To determine the observed rate of transmission of HBV from infected HCWs to patients in previous HBV exposure incidents, a meta-analysis of eligible exposure incidents was conducted [manuscript in development]. A total of 20 incidents were eligible for the meta-analysis

including 3 with no transmission of HBV. The pooled transmission rate for HBV using the random effects DerSimonian-Laird model was 1.45% (95% CI: 0.601–2.658%). This corresponds to a chance of 1,450 per 100,000 individuals (95% CI: 601 to 2658 per 100,000 individuals) becoming infected in the absence of IPC breaches and illicit diversion of patient medication.

#### 8.4 Review of Patient Exposure Incidents with Transmission of HBV

Since the introduction of serologic testing in the 1970s, there have been over 45 reported incidents of HCW-to-patient transmission of HBV<sup>(273)</sup>. Published investigations (from 1986 to date) have been summarized in Table 24, Appendix I. A summary of these transmission incidents by HCW specialty is provided in Table 13. All levels of experience including trainees, clinical assistants and senior surgeons are represented; technical expertise or competence was not usually identified as a contributing factor in transmission incidents<sup>(285)</sup>. No dentist-to-patient transmission of HBV has been reported since the late 1980s. Two published incidents of HCW-to-patient HBV transmission occurred in Canada. One involved transmission by an infected electroencephalogram technician due to IPC breaches during a non-EPP<sup>(132)</sup> and the other involved transmission by an infected orthopedic surgeon during an EPP<sup>(284)</sup> (refer to Table 24).

A review of reported HCW-to-patient HBV transmission incidents in medical and dental settings, suggests that HCWs infected with HBV who are not involved in EPPs do not transmit infection unless there are IPC breaches<sup>(285)</sup>.

A total of 35,665 patients were exposed to 21 HCWs infected with HBV from a variety of healthcare specialties. Out of this exposed group of patients, a total of 22,191 (62%) were tested and 216 of them were confirmed to be infected with HBV (refer to Table 13). The number of infected patients could be higher if one includes the additional 38 infected patients that were considered by the study authors to be probable or possible transmission from a HCW or were cases of undetermined origin where transmission during a procedure could not be ruled out.

Eight of the investigation reports did not address the hepatitis B (HB) immunization status of the HCWs who were infected. The remaining studies provided some information about whether the HCWs completed a full or partial vaccination series and whether they had documented serological confirmation of immune status as a result. Two HCWs had been vaccinated but most likely acquired their infection before vaccination. Of the incidents that reported immunization data, none of the infected HCWs implicated in transmission of HBV to their patients had completed a full HB vaccination series with documented serological confirmation of their immunity or there was inadequate investigation of nonresponder status after vaccination<sup>(116,121,123,124)</sup>.

**Table 13: Summary of epidemiologic investigations reporting transmission of HBV from infected HCW to patient<sup>A</sup>**

Specialty	Number of infected HCWs	Number of patients potentially exposed	Number of patients tested (%)	Number of patients infected
Obstetrics and gynecology <sup>(119,281,286,287)</sup>	5	1,537	717 (47)	33
Cardiothoracic surgery <sup>(41,110,111,114)</sup>	4	1,100	880 (80)	58
Orthopedics <sup>(70,115,116)</sup>	3	2,271	1,952 (86)	7
General surgery <sup>B (119,121,122)</sup>	3	1,883	1,643 (87)	12
Surgery <sup>(123)</sup>	1	583	538 (92)	1
Dentistry <sup>(130)</sup>	1	1,413	1,123 (80)	24
Acupuncture <sup>(131)</sup>	1	890	290 (33)	3
Surgery house officer <sup>C (133)</sup>	1	4,948	3,150 (64)	2
Healthcare technology <sup>D (132)</sup>	1	18,567	10,244 (55)	75
Anesthesia nursing <sup>(139)</sup>	1	2,473	1,654 (67)	1
<b>Total</b>	<b>21</b>	<b>35,665</b>	<b>22,191 (62)</b>	<b>216</b>

Abbreviations: HBV, hepatitis B virus; HCW, healthcare worker

<sup>A</sup> This table excludes data from studies that did not report both the number of patients exposed and the number of patients tested. It includes articles published in 1992 or later as well as articles identified as part of the systematic review of the literature for risk of transmission of HBV from infected HCWs to patients. The details of individual incidents are provided in Table 24, *Epidemiologic investigations reporting transmission of HBV from infected HCW to patient* (Appendix I).

<sup>B</sup> One HCW performed both general surgery and urologic procedures<sup>(119)</sup>.

<sup>C</sup> Performed venepuncture, inserted intravenous lines and prepared and administered intravenous antibiotics.

<sup>D</sup> HCW performed electroencephalograms with reusable needle electrodes.

For purposes of informing the systematic review question (*What preventive or management measures can reduce the risk of transmission of HBV from infected HCWs to their patients?*), data were extracted from all eligible epidemiologic investigations where HCW-to-patient transmission was reported. Twenty-eight such investigations were eligible for inclusion in the systematic review. Twenty-three of the 28 investigations involved an EPP. Findings on key preventive measures and risk factors for transmission are summarized in Table 14.

**Table 14: Preventive measures and/or risk factors reported for HBV epidemiologic investigations involving transmission<sup>A</sup>**

Author, publication year	EPP/non EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	HB vaccine <sup>H</sup>	Percutaneous injury <sup>I</sup>	Patient PEP <sup>J</sup>	Diversion ruled out <sup>K</sup>
Lettau, 1986 <sup>(286)</sup>	EPP	Yes	NR	Yes	NR	Yes	NR	NR	NR	NR
Polakoff, 1986 <sup>(288)</sup> (HCW2)	EPP	No	NR	Yes	No	No	NR	NR	NR	NR
Shaw, 1986 <sup>(130)</sup>	EPP	No	No	No	No	No	Yes <sup>L</sup>	No	NR	NR
Welch, 1989 <sup>(281)</sup>	EPP	No	NR	NR	No	No	NR	NR	NR	NR
Prendergast, 1991 <sup>(289)</sup>	EPP	Yes	NR	NR	NR	NR	NR	No	NR	NR
Johnston, 1992 <sup>(70)</sup>	EPP	Yes	Yes	No	NR	Yes	NR	No	NR	NR
Prentice, 1992 <sup>(110)</sup>	EPP	No	NR	No	No	No	Yes <sup>L</sup>	NR	NR	NR
Harpaz, 1996 <sup>(111)</sup>	EPP	Yes	Yes	Yes	NR	NR	No	Yes	NR	NR
The Incident Control Team and Others, 1996 <sup>(41)</sup>	EPP	Yes	NR	NR	NR	NR	NR	No	Yes	NR
Mukerjee 1996 <sup>(122)</sup>	EPP	No	NR	NR	No	No	Yes <sup>L</sup>	No	No	NR
The Incident Investigation Teams and Others 1997 <sup>(119)</sup> (HCW1)	EPP	No	Yes	No	No	No	No	No	NR	NR
The Incident Investigation Teams and Others, 1997 <sup>(119)</sup> (HCW2)	EPP	No	Yes	No	No	No	Yes	No	NR	NR
The Incident Investigation Teams and Others, 1997 <sup>(119)</sup> (HCW3)	EPP	Yes	Yes	No	NR	NR	No	No	NR	NR
The Incident Investigation Teams and Others, 1997 <sup>(119)</sup> (HCW4)	EPP	No	Yes	No	No	No	Yes	No	NR	NR
Sundkvist, 1998 <sup>(115)</sup>	EPP	Yes	NR	NR	NR	Yes	Yes <sup>M</sup>	NR	Yes	NR
Oliver, 1999 <sup>(123)</sup> (HCW1)	EPP	No	NR	NR	No	NR	Yes <sup>N</sup>	NR	Yes	NR
Oliver, 1999 <sup>(123)</sup> (HCW2)	EPP	No	NR	NR	No	NR	Yes <sup>O</sup>	NR	Yes	NR
Oliver, 1999 <sup>(123)</sup> (HCW3)	EPP	No	NR	NR	No	NR	Yes	NR	Yes	NR
Molyneaux 2000 <sup>(114)</sup>	EPP	Yes	NR	NR	NR	Yes	No	NR	NR	NR
Spijkerman, 2002 <sup>(121)</sup>	EPP	No	Yes	No	No	No	Yes <sup>N</sup>	Yes	NR	NR
Laurenson, 2007 <sup>(124)</sup>	EPP	No	NR	NR	No	No	Yes <sup>N</sup>	NR	NR	NR
Enfield, 2013 <sup>(116)</sup>	EPP	No	Yes	No	No	No	Yes <sup>N</sup>	No	NR	NR

Author, publication year	EPP/non EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	HB vaccine <sup>H</sup>	Percutaneous injury <sup>I</sup>	Patient PEP <sup>J</sup>	Diversion ruled out <sup>K</sup>
Sugimoto, 2013 <sup>(287)</sup>	EPP	No	Yes	No	No	No	NR	No	NR	NR
Polakoff, 1986 <sup>(288)</sup> (HCW1)	non-EPP	Yes	No	Yes	NR	Yes	NR	NR	NR	NR
Walsh, 1999 <sup>(131)</sup>	non-EPP	Yes	No	NR	NR	NR	NR	No	NR	NR
Hepatitis B Outbreak Investigation Team, 2000 <sup>(132)</sup>	non-EPP	No	No	No	NR	NR	NR	NR	NR	NR
Smellie, 2006 <sup>(133)</sup>	non-EPP	No	No	No	No	No	Yes <sup>L</sup>	Yes <sup>P</sup>	NR	NR
Poujol, 2008 <sup>(139)</sup>	non-EPP	Yes	No	NR	NR	NR	Yes <sup>Q</sup>	Yes <sup>R</sup>	NR	NR
Total Yes EPP (non-EPP)		8 (3)	9 (0)	3 (1)	0 (0)	4 (1)	12 (2)	2 (2)	5 (0)	0 (0)
Total No EPP (non-EPP)		15 (2)	1 (5)	10 (2)	15 (1)	12 (1)	4 (0)	11 (1)	1 (0)	0 (0)
Total NR EPP (non-EPP)		0 (0)	13 (0)	10 (2)	8 (4)	7 (3)	7 (3)	10 (2)	17 (5)	23 (5)

Abbreviations: HBV, hepatitis B virus; EPP, exposure-prone procedure; IPC: infection prevention and control; PEP, post-exposure prophylaxis; NR, not reported; HCW, healthcare worker

<sup>A</sup> N=28 for total number of infected HCWs from reported investigations.

<sup>B</sup> If EPPs and non-EPPs performed by a HCW (e.g., dentistry), data from article was pooled under EPP.

<sup>C</sup> Aware of status: HCW was aware of serologic status prior to exposure incident(s).

<sup>D</sup> IPC compliance: HCW was compliant with current IPC standards.

<sup>E</sup> Symptomatic: HCW was symptomatic during screening period.

<sup>F</sup> Treatment: HCW was previously treated or was on treatment during screening period.

<sup>G</sup> Practice review: HCW's practice was previously reviewed by independent expert(s) and recommendations made.

<sup>H</sup> HB vaccine: HCW had previous HBV vaccine.

<sup>I</sup> Percutaneous injury: Percutaneous injury potentially exposing patient to HCW's blood was reported.

<sup>J</sup> Patient PEP: Post-exposure prophylaxis was offered to exposed patient(s).

<sup>K</sup> Diversion ruled out: Illicit diversion of patient medication by HCW was ruled out.

<sup>L</sup> Response to HB vaccine not assessed post-vaccination for five HCWs<sup>(110,122,123,130,133)</sup>.

<sup>M</sup> HCW was a known non-responder. Since the HCW was hepatitis B e antigen negative with hepatitis B e antibodies and there was no report of transmission, the HCW was allowed to practice as per existing guidelines<sup>(115)</sup>.

<sup>N</sup> Evaluation of lack of response to vaccine not performed for four HCWs<sup>(116,121,123,124)</sup>.

<sup>O</sup> One HCW was allowed to perform surgical procedures prior to confirmation of response to HB vaccine<sup>(123)</sup>.

<sup>P</sup> Two incidents during a 6-month period when HCW cut hand while breaking a glass vial with frank bleeding on one occasion<sup>(133)</sup>.

<sup>Q</sup> HCW was vaccinated in 1990 without prior serologic testing; testing in 1992 revealed chronic carrier status that did not require further follow up<sup>(139)</sup>.

<sup>R</sup> HCW recalled several needlestick injuries but never reported them and did not recall an injury when providing care to the index case<sup>(290)</sup>.



## 8.5 Review of Patient Exposure Incidents with No Transmission of HBV

There are very few reported HBV patient exposure incidents that describe a lack of transmission from the infected HCW. Three incidents reported in the literature are presented in Table 25, Appendix I. Only one study provided information on numbers of patients potentially exposed and tested related to a HCW infected with HBV (refer to Table 15). One study compared the risk factors for two infected surgeons, one who performed uncomplicated or low risk procedures and the other who performed higher risk procedures<sup>(122)</sup>. All patients who were seropositive for HBV infection were operated on by the surgeon who performed lower risk procedures, wore single gloves for operations and did not have post-exposure vaccination offered to his patients (refer to Table 16). An accelerated course of HB vaccine was offered to patients of the surgeon who performed higher risk procedures, under the premise that even if infection had already occurred, severe illness and the development of a chronic state may be prevented (refer to Table 16).

A second study was conducted prospectively to investigate possible transmission of HBV from nine infected HCWs to 246 patients<sup>(280)</sup>. Patients were exposed a total of 483 times and no transmission was documented. Two of the nine infected HCWs who were HBeAg positive and had circulating HBV DNA accounted for a total of two-thirds of patient contacts. This study reported aggregate data for number of patients exposed to all nine HCWs therefore could not be included in Table 15.

**Table 15: Summary of epidemiologic investigation reporting no transmission of HBV from infected HCW to patient<sup>A, B</sup>**

Specialty	Number of infected HCWs	Number of patients potentially exposed	Number of patients tested (%)
Orthopedic surgery <sup>(122)</sup>	1	17	17 (100)
<b>Total</b>	<b>1</b>	<b>17</b>	<b>17 (100)</b>

Abbreviations: HBV, hepatitis B virus; HCW, healthcare worker; ICU, intensive care unit

<sup>A</sup> This table excludes data from studies that did not report both the number of patients exposed and the number of patients tested. It includes articles published in 1992 or later as well as articles identified as part of the systematic review of the literature for risk of transmission of HBV from infected HCWs to patients. The details of individual incidents are provided in Table 25, *Epidemiologic investigations reporting no transmission of HBV from infected HCW to patient* (Appendix I).

<sup>B</sup> Labrecque *et al.* (1986) report on a prospective study of patients of 9 HCWs infected with HBV, 6 with chronic infection (2 surgeons, 1 dialysis nurse, 1 pediatric ICU nurse, 1 pharmacist and 1 orderly) and 3 with acute infection (1 dental technician, 1 ICU nurse and 1 medical student) over a 30-month period. The results of the study were pooled for all patients of all HCWs (n=246) and for all exposures (n=483) with no evidence of transmission identified<sup>(280)</sup>.

For purposes of informing the systematic review question (*What preventive or management measures can reduce the risk of transmission of HBV from infected HCWs to their patients?*), data were extracted from all eligible epidemiologic investigations where no transmission was reported. Three such investigations were eligible for inclusion in the systematic review, all involving an EPP. Findings on key preventive measures and risk factors for transmission are summarized in Table 16.

**Table 16: Preventive measures and/or risk factors reported for HBV epidemiologic investigations involving no transmission<sup>A</sup>**

Author, publication year	EPP/non-EPP <sup>B</sup>	Aware of status <sup>C</sup>	IPC compliance <sup>D</sup>	Symptomatic <sup>E</sup>	Treatment <sup>F</sup>	Practice review <sup>G</sup>	HB vaccine <sup>H</sup>	Percutaneous injury <sup>I</sup>	Patient PEP <sup>J</sup>	Diversion ruled out <sup>K</sup>
Labrecque, 1986 (HCW 1) <sup>(280)</sup>	EPP	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Labrecque, 1986 (HCW 2) <sup>(280)</sup>	EPP	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Mukerjee, 1996 <sup>(122)</sup>	EPP	No	NR	NR	No	No	NR	NR	Yes	NR
Total Yes EPP (non-EPP)		2 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0)	0 (0)
Total No EPP (non-EPP)		1 (0)	0 (0)	0 (0)	1 (0)	1 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total NR EPP (non-EPP)		0 (0)	3 (0)	3 (0)	2 (0)	2 (0)	3 (0)	3 (0)	2 (0)	3 (0)

Abbreviations: HBV, hepatitis B (HB) virus; EPP, exposure-prone procedure; IPC: infection prevention and control; PEP, post-exposure prophylaxis; NR, not reported; HCW, healthcare worker

<sup>A</sup> N=3 for total number of infected HCWs from all reported investigations.

<sup>B</sup> If EPPs and non-EPPs performed by a HCW (e.g., dentistry), data from article was pooled under EPP.

<sup>C</sup> Aware of status: HCW was aware of serologic status prior to exposure incident(s).

<sup>D</sup> IPC compliance: HCW was compliant with current IPC standards.

<sup>E</sup> Symptomatic: HCW was symptomatic during screening period.

<sup>F</sup> Treatment: HCW was previously treated or was on treatment during screening period.

<sup>G</sup> Practice review: HCW's practice was previously reviewed by independent expert(s) and recommendations made.

<sup>H</sup> HB vaccine: HCW had previous HBV vaccine

<sup>I</sup> Percutaneous injury: Percutaneous injury potentially exposing patient to HCW's blood was reported.

<sup>J</sup> Patient PEP: Post-exposure prophylaxis was offered to exposed patient(s).

<sup>K</sup> Diversion ruled out: Illicit diversion of patient medication by HCW was ruled out.

Recommendations provided for minimizing risk of HCW-to-patient transmission of HBV have taken into consideration preventive measures and risk factors reported in exposure incidents to date.

## 8.6 HBV Viral Load

There was no clinical test for HBV viral load until the late 1990s. In general, the presence of e-antigen is associated with high HBV viral load and was therefore used as a surrogate measure for infectivity in earlier recommendations<sup>(124,291)</sup>. However, a small subset of persons who are HBeAg negative may still have a high viral load<sup>(105,292)</sup>. Following reported transmission incidents from HBeAg negative HCWs<sup>(114,115,119,121,293)</sup>, and detection of HBV DNA in 64.5% of HBeAg-negative carriers<sup>(294)</sup>, the focus for assessing infectivity and risk of transmission has changed from HBeAg status to HBV DNA levels. Viral load and volume of blood determine the transmission risk of HBV and as a result, recent guidelines have indicated that viral loads are a more accurate measure on which to base recommendations for practice restrictions of HCWs infected with HBV who perform EPPs<sup>(105,190,273,295)</sup>. A comparison of various guidelines on this topic show a lack of consensus for the threshold above which practice restrictions are recommended for HCWs infected with HBV<sup>(44,105,273,296-298)</sup>. This is likely the result of a very limited evidence base available to inform an optimal threshold<sup>(299,300)</sup>.

Several lookback investigations predate the availability of viral load testing. Information on viral load provided in some lookback investigations is limited by the inability to link HCW viral load at time of transmission with rate of transmission. The viral load is usually tested weeks or months after transmission has occurred. This has led to concerns that data on HBV DNA levels to inform a cut-off level for HCWs who perform EPPs is not sufficiently robust<sup>(47)</sup>.

There are considerable differences in results obtained from various HBV DNA quantitative assays for individual sera<sup>(301)</sup>. In addition, various publications use slightly different conversion factors for the unit(s) used to report HBV DNA, largely based on the assay used. For purposes of this guideline, HBV DNA is expressed in terms of IU/mL as recommended by the World Health Organization (WHO). The unit copies/mL is considered equivalent to genome equivalent (GE/mL) and one IU/mL is considered approximately equivalent to 5 GE/mL or copies/mL<sup>(105,266,302)</sup>.

Results from transmission incidents indicate that risk of transmission was higher with HBV DNA levels above  $1.8 \times 10^5$  IU/mL ( $10^6$  GE/mL)<sup>(292)</sup>. Analysis of HBV DNA levels in surgeons who transmitted HBV to their patients helped identify an HBV DNA level above which transmission of HBV during an EPP could not be excluded. The identified HBV DNA level was  $6.9 \times 10^3$  IU/mL ( $4 \times 10^4$  GE/ml) (refer to Table 17)<sup>(294)</sup>. The study authors noted that assays for HBV DNA based on polymerase chain reaction (PCR) have a  $\frac{1}{2} \log_{10}$  variance. In addition, fluctuations in HBV DNA levels up to  $2 \log_{10}$  have been reported in individuals infected with HBV who were HBeAg-negative and even higher fluctuations in individuals infected with HBV

who are not on treatment. This necessitates allowing for *in vitro* variation in test results and *in vivo* fluctuations in HBV DNA levels (as demonstrated in HBeAg-negative individuals) before defining a cut-off HBV DNA level<sup>(294,303)</sup>. A review of available data showed that a minimal risk strategy would be to set a cut off level well below levels documented in transmission incidents to allow for fluctuations and a 3 log<sub>10</sub> safety margin was considered sufficient to account for this<sup>(47)</sup>. A viral load cut-off level of 2,000 IU/mL (10<sup>4</sup> GE/mL) is recommended in Europe<sup>(273)</sup>, and 1,000 IU / ml (5x10<sup>3</sup> GE / mL) in the US<sup>(105)</sup>. The thresholds provided are thought to increase patient safety as well as optimize the workforce by preventing loss of HCWs who are safe to practice<sup>(273)</sup>.

Treatment with current antivirals reduces HBV DNA levels to undetectable or almost undetectable levels in most persons<sup>(105,268,304-308)</sup>. Virtually all persons infected with HBV under treatment can expect reduction in HBV DNA viral loads within weeks or months of initiating therapy<sup>(105,306)</sup>. In a study involving 18 surgeons with chronic HBV infection monitored every three to six months for a median period of 5.6 years, antiviral therapy was offered if HBV DNA was above 10<sup>5</sup> copies/ml<sup>(57)</sup>. Sustained viral suppression was achieved in both HBeAg-negative and HBeAg- positive surgeons<sup>(57,300)</sup>. The provision of regular expert monitoring, including quantification of HBV DNA was considered a necessary aspect of successfully managing infected surgeons using antiviral therapy. A small proportion of untreated individuals infected with HBV who are HBeAg negative with low HBV DNA are at risk for having fluctuating HBV DNA levels. Regular monitoring of HBV DNA will assess for these fluctuations making it unnecessary to have a very high safety margin in setting a viral load cut off level for HBV infection<sup>(47)</sup>. If a HCW performing EPPs elects not to go on therapy, they would need to have their viral load checked frequently and would not be able to do EPPs if they go above the threshold. In addition, with a safety margin of 3 log<sub>10</sub>, there is no real difference between a HBV DNA cut-off level of 1000 IU/mL and 2000 IU/mL. HBV treatment is very effective at suppressing the viral load and HBV blips while on treatment would not go beyond 1000 IU/mL.

The availability of safe and effective antiviral agents to treat chronic HB infection provides a greater imperative to identify persons who might benefit from medical evaluation, management, and treatment<sup>(270)</sup>.

**Table 17: Viral load and other risk factors influencing risk of transmission of HBV<sup>A</sup>**

Author (publication year) Source of exposure	Type of exposure	Symptomatic	VL (genome equivalents/mL) <sup>B</sup>	VL (international units/mL) <sup>C</sup>	On treatment	Time between exposure and source VL test	Exposed person(s) received PEP	Transmission
Harpaz (1996) <sup>(111)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Thoracic surgery	Yes	1.0x10 <sup>9</sup> (C) 15ng/mL <sup>E</sup> (R)	2.00x10 <sup>8</sup> (C)	NR	4 months	No	Yes
Incident Investigation Team and Others (1997) <sup>(119)</sup> Companions <sup>D</sup> : <sup>(105,293)</sup> HCW	General surgery	No	1x10 <sup>7</sup> <sup>F</sup> (R)	2.00x10 <sup>6</sup> (C)	NR	12 weeks	NR	Yes
Incident Investigation Team and Others (1997) <sup>(119)</sup> Companions <sup>D</sup> : <sup>(105) (293)</sup> HCW	General surgery	No	2.5x10 <sup>5</sup> <sup>F</sup> (R)	5.0x10 <sup>4</sup> (C)	NR	12 weeks	NR	Yes
Molyneaux (2000) <sup>(114)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	1.03x10 <sup>6</sup> <sup>G</sup> (R)	2.06x10 <sup>5</sup> (C)	NR	Up to 9 months	No	Yes
Ngui (2000) <sup>(293)</sup> Companions <sup>D</sup> : <sup>(105) (122)</sup> HCW	Cardiothoracic surgery	NR	10 <sup>8</sup> <sup>H</sup> (R)	2.00x10 <sup>7</sup> (C)	NR	6 months	NR	Yes
Ngui (2000) <sup>(293)</sup> Companions <sup>D</sup> : <sup>(105) (41)</sup> HCW	General surgery	NR	10 <sup>9</sup> <sup>H</sup> (R)	2.00x10 <sup>8</sup> (C)	NR	>8 weeks	No	Yes
Spijkerman (2002) <sup>(121)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	General surgery	No	5x10 <sup>9</sup> <sup>I</sup> (R)	1.00x10 <sup>9</sup> (C)	No	1 year	No	Yes
Corden (2003) <sup>(294)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	3.60x10 <sup>7</sup> <sup>J</sup> (R)	6.19x10 <sup>6</sup> (C)	NR	At least 3 months	NR	Yes
Corden (2003) <sup>(294)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	3.30 x10 <sup>5</sup> <sup>J</sup> (R)	5.67x10 <sup>4</sup> (C)	NR	At least 3 months	NR	Yes
Corden (2003) <sup>(294)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	9.40x10 <sup>5</sup> <sup>J</sup> (R)	1.62x10 <sup>5</sup> (C)	NR	At least 3 months	NR	Yes

Author (publication year) Source of exposure	Type of exposure	Symptomatic	VL (genome equivalents/mL) <sup>B</sup>	VL (international units/mL) <sup>C</sup>	On treatment	Time between exposure and source VL test	Exposed person(s) received PEP	Transmission
Corden (2003) <sup>(294)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	4.00x10 <sup>4</sup> <sup>J</sup> (R)	6.87x10 <sup>3</sup> (C)	NR	At least 3 months	NR	Yes
Corden (2003) <sup>(294)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	≥4.00x10 <sup>7</sup> <sup>J</sup> (R)	6.87x10 <sup>6</sup> (C)	NR	At least 3 months	NR	Yes
Corden (2003) <sup>(294)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Surgery	NR	2.20x10 <sup>8</sup> <sup>J</sup> (R)	3.78x10 <sup>7</sup> (C)	NR	At least 3 months	NR	Yes
Enfield (2013) <sup>(116)</sup> Companion <sup>D</sup> : <sup>(105)</sup> HCW	Orthopedic surgery	No	1.00x10 <sup>8</sup> (C)	>1.79x10 <sup>7</sup> <sup>K</sup> (R)	No	14 weeks	No	Yes
Sugimoto (2013) <sup>(287)</sup> HCW	Gynecologic surgery	No	>1.6x10 <sup>9</sup> <sup>L</sup> (R)	3.20x10 <sup>8</sup> (C)	NR	Approximately 4 months	NR	Yes

Abbreviations: HBV, hepatitis B virus; VL, viral load; PEP, post-exposure prophylaxis; HCW, healthcare worker; C, calculated; R, reported; NR, not reported

<sup>A</sup> Articles reporting transmission linked to sexual, blood transfusion and perinatal routes have been excluded.

<sup>B</sup> Viral load as reported in each study. One copy is equal to 1 genome equivalent<sup>(266)</sup>.

<sup>C</sup> One IU/mL is considered equivalent to 5 copies/mL<sup>(302)</sup> (therefore 1 copy/mL is equivalent to 0.2 IU/mL) except for studies described in Corden (2003)<sup>(294)</sup> where an assay-specific conversion factor of 5.82 was used as indicated by Roche.

<sup>D</sup> Companion: Articles that provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.

<sup>E</sup> Semi-quantitative PCR dot-blot hybridization, with comparison serum containing 108 chimpanzee-infectious material<sup>(105)</sup>.

<sup>F</sup> Liquid hybridization and enzyme-linked oligonucleotide assay<sup>(105)</sup>.

<sup>G</sup> Lightcycler PCR<sup>(105)</sup>.

<sup>H</sup> Semi-quantification by end-point dilution<sup>(105)</sup>.

<sup>I</sup> Limited dilution PCR<sup>(105)</sup>.

<sup>J</sup> Chiron Quantiplex Branched DNA assay and Roche Amplicor HBV DNA monitor<sup>(105)</sup>.

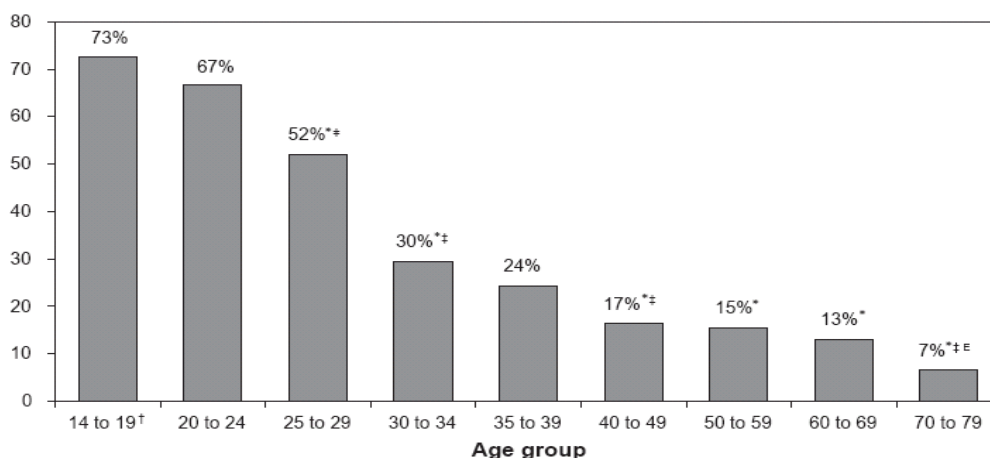
<sup>K</sup> Versant HBV bDNA 3.0 assay.

<sup>L</sup> Detection assay based on TaqMan technology.

## 8.7 HBV Vaccination

Prior to the introduction of a vaccine in the 1980s, HBV was a major occupational risk to HCW with exposure to blood, blood products, and other body fluids. HBV infection is currently preventable by vaccination, and Canada has had high risk and universal childhood HBV immunization programs in place, in all provinces and territories, since the mid-1990s<sup>(62)</sup>. A survey conducted over a decade after the introduction of vaccines showed that 90% of dentists in Canada had completed an immunization series and an additional 3% had natural immunity<sup>(309,310)</sup>. A study to identify the proportion of transplant surgeons in the US who were adequately vaccinated against HBV was conducted in 2006<sup>(311)</sup>. Out of 94 surgeons (27.3% of participants) who reported at least one needlestick exposure while operating on a patient infected with HBV, 14 (14.9%) were inadequately vaccinated. The authors concluded that the surgeons underestimated both the risk of percutaneous exposure while operating, and the risk of becoming infected with HBV if exposed. An inadequate vaccination series is likely to lead to antibody loss during long-term follow up of HCWs<sup>(312)</sup>.

Evidence-based strategies to improve compliance with HB immunization recommendations in the Canadian Immunization Guide have been successful<sup>(313)</sup>. Although the success of HB vaccination programs is well documented among the younger population (Figure 3), there may be many HCWs who remain at risk of acquiring HBV. The risk of HBV transmission to a HCW who has been fully immunized and has developed an immune response after vaccination is virtually zero<sup>(314,315)</sup>. Therefore, increasing the emphasis on universal HB vaccination programs among HCWs in Canada will reduce the future risk of HBV transmission from HCWs to patients and from patients to HCWs.



**Figure 3: Prevalence of hepatitis B vaccine-induced immunity, by age group, household population aged 14 to 79, Canada, 2007 to 2011**

(Data from Statistics Canada. *Seroprevalence of hepatitis B and C virus infections: Results from the 2007 to 2009 and 2009 to 2011 Canadian Health Measures Survey*<sup>(212)</sup>.)

Strategies applied by a university postgraduate medical school to improve medical trainee compliance with immunization standards led to very high compliance with statistically significant increases in compliance over a 3-year period<sup>(313)</sup>. Canada's National Advisory Committee on Immunization (NACI), recommends immunization with HB vaccine and post-immunization serologic testing within 1 to 6 months of completion of the vaccine series for people who are at increased risk of infection through occupational exposure to blood, blood products and bodily fluids that may contain HBV<sup>(95)</sup>. This group includes all HCWs exposed to blood and other body fluids. Detailed recommendations on HB vaccination can be found in the *Canadian Immunization Guide*<sup>(95)</sup>.

Response to HB vaccine after a 3-dose series is generally greater than 95% in young healthy people<sup>(95,316)</sup>. For cases of nonresponse, revaccination with  $\geq 1$  dose of HB vaccine subsequent to the primary series increases the proportion of persons achieving vaccine-induced seroprotection and a cumulative response rates of 69% has been reported among initial nonresponders after three revaccination doses<sup>(277)</sup>. The vaccine response decreases with age and several factors have been used to predict risk of nonresponse or vaccine failure<sup>(317)</sup>. Although typical anti-HBs levels in the 100s to 1000s IU/L are achieved following vaccination, levels of anti-HBs above 10 IU/L have been documented to provide virtually complete protection against HBV<sup>(310)</sup>. HCWs who perform EPPs and do not have a protective level of antibody titre against HBsAg (anti-HBs  $\geq 10$  IU/L) after vaccination require further investigation<sup>(95,116,119)</sup>. A potential cause of vaccine non-response is established chronic HBV infection. Other common causes include immune suppression (steroid therapy), chronic illness (hepatitis C infection, dialysis, rheumatoid inflammatory diseases), smoking and older age<sup>(318,319)</sup>.

Once there is a record of a complete vaccination series and seroconversion has been documented for a HCW, i.e., anti-HBs titre  $\geq 10$  IU/L, he/she can be considered immune and no further testing is required, even if an exposure occurs. HCWs who have not responded to appropriate vaccination should be counseled on their ongoing risk of infection as well as the use of measures to reduce the risk of transmission. They should also be regularly assessed for infection (e.g., annually and after exposure)<sup>(95)</sup>.

People who develop an anti-HBs titre of at least 10 IU/L (adequate anti-HBs titre) following the completion of a recommended vaccination schedule are considered protected for life<sup>(95)</sup>.

Exceptions are some immunocompromised persons and people with chronic renal disease or on dialysis, who may require periodic booster doses if their anti-HBs titre falls below 10 IU/L. In immunocompetent individuals, although anti-HBs titres may become non-detectable over time, immune memory persists<sup>(95)</sup>. An assessment of evidence on long-term efficacy and effectiveness of HB vaccines in immunocompetent individuals, with particular focus on individuals immunized as infants and HCWs has been conducted<sup>(320,321)</sup>. NACI currently recommends that, following immunization of immunocompromised individuals, initial annual monitoring of HB antibody levels may be considered<sup>(322)</sup>.



## 8.8 Recommendations for HBV Immunization for Healthcare Workers (Pre-exposure Prevention)

Recommendations <sup>A</sup>
1. All susceptible HCWs (including students or trainees) should be immunized with hepatitis B (HB) vaccine, unless a medical contraindication exists.
2. Students should complete their vaccination series and demonstrate immunity prior to starting any clinical rotations.
<p>3. If a HCW has documentation of receiving a complete HB vaccine series but does not have documentation of anti-HBs serology following immunization, or, if a HCW reports HB immunization but has incomplete or no documentation of HB immunization, serologic testing for anti-HBs should be done and then:</p> <ul style="list-style-type: none"> <li>• If an anti-HBs titre of at least 10 IU/L is confirmed<sup>B</sup>, testing need not be repeated nor should further immunization be undertaken, with the exception of immunocompromised persons who should be tested periodically for waning immunity, and persons with chronic renal disease or on dialysis, who should be tested yearly.</li> <li>• If testing for anti-HBs is done 1 to 6 months after vaccination and the anti-HBs titre is less than 10 IU/L<sup>B</sup>, a primary vaccine failure has occurred and the HCW should be given a second vaccine series. The HCW should be retested 1 to 6 months after completion of the second series.</li> <li>• If the HCW is tested more than 6 months after the initial series and the anti-HBs titre is less than 10 IU/L<sup>B</sup>, the cause may be either a primary vaccine failure or waning antibody. Evidence shows that, in immunocompetent people, immunity is long lasting although antibody may be non-detectable. The HCW should receive one booster dose and be retested one month later to document an anamnestic response (defined as anti-HBs titre <math>\geq 10</math> IU/L one to four weeks post booster vaccination). If the anti-HBs titre is still less than 10 IU/L<sup>B</sup>, the HCW should be tested for HBsAg and anti-HBc to rule out pre-existing chronic HBV infection. If both tests are negative, then a second vaccine series is indicated followed by anti-HBs serology 1 to 6 months after completing the second series<sup>B</sup>.</li> <li>• HCWs who have documented evidence of failure to respond to two series of HB vaccine (i.e., anti-HBs titre of less than 10 IU/L) are unlikely to benefit from further immunization and will need passive immunization after potential exposure to HB<sup>B, C</sup>. Occupational health or infectious disease specialists may be consulted regarding any new strategies that may be available such as intradermal vaccination or high potency vaccine.</li> </ul>
4. If an HB exposure occurs, and a HCW has had a documented anti-HBs titre of at least 10 IU/L, no further testing is needed unless the HCW is immunocompromised or has chronic renal disease or is on dialysis. These HCWs should be tested for anti-HBs after a potential HB exposure and given additional vaccine and HBIG if their anti-HBs titre is less than 10 IU/L <sup>B</sup> .

Abbreviations: HB, hepatitis B; anti-HBs, antibody to surface antigen; HBIG, hepatitis B immune globulin

<sup>A</sup> Recommendations 3 (adapted) and 4 are excerpted from the *Canadian Immunization Guide*<sup>(95)</sup>. Additional information is provided in the 1993 NACI Hepatitis B statement<sup>(323)</sup>. This statement was published prior to the development of the NACI methodology for grading of recommendations<sup>(324)</sup>. As a result, these recommendations are not graded.

<sup>B</sup> Anti-HBs titre less than 10 IU/L is the international standard utilized by most laboratories but may vary by jurisdiction. Check with your local laboratory for the standard used locally.

<sup>C</sup> The HCW should be referred to a specialist in immunization.

## 8.9 Recommendations for Management of Healthcare Workers Infected with HBV

Recommendations <sup>A</sup>	
1. All HCWs who perform EPPs have ethical and professional obligations to know their HBV status <sup>B</sup> .	Grade of evidence: Not applicable
2. HCWs who remain susceptible to HBV should be tested at appropriate intervals as determined by their level of risk and whenever an exposure has occurred.	Grade of evidence: Not applicable
3. HCWs born or previously residing in high HBV endemic countries should be tested for both anti-HBc and HBsAg to fully define HBV status <sup>C,D</sup> .	Grade of evidence: Refer to referenced documents
4. HCWs infected with HBV should seek medical care from a physician with expertise in HBV management for optimal health maintenance and should be managed according to current recommendations with regular monitoring of HBV DNA level <sup>E</sup> .	Grade of evidence: Not applicable
5. HCWs infected with HBV should be restricted from performing EPPs until <ul style="list-style-type: none"> <li>a) the HCW is under the care of a physician with expertise in HBV management; and</li> <li>b) the HCW's HBV DNA level is below 10<sup>3</sup> IU/mL (5 x 10<sup>3</sup> GE/mL)<sup>F</sup> or equivalent and monitored regularly (every 3 to 6 months)<sup>G</sup>.</li> </ul>	Grade of evidence: BII
6. HCWs infected with HBV who have HBV DNA levels less than or equal to 10 <sup>3</sup> IU/mL (5 x 10 <sup>3</sup> GE/mL) <sup>E</sup> or equivalent should have no restrictions on practice based on HBV status alone.	Grade of evidence: CI
7. HCWs infected with HBV who do not perform EPPs do not need restrictions on practice based on HBV status alone.	Grade of evidence: CI
8. If a HCW-to-patient transmission of HBV occurs, the HCW should cease clinical practice immediately until determination for fitness to return to practice is made <sup>H</sup> .	Grade of evidence: CI

Abbreviations: anti-HBc, antibody to hepatitis B core antigen; HBcAg, hepatitis B core antigen; HBsAg, hepatitis B surface antigen

<sup>A</sup> The grade of the body of evidence upon which a recommendation is based is shown here (refer to Table 34, Appendix II for the grading scale). The full critical appraisal tool informing this scale can be found in PHAC's *Critical Appraisal Tool Kit*<sup>(8)</sup>.

<sup>B</sup> Ethical obligation may be traced to principles of non-maleficence (the duty to intentionally refrain from actions that cause harm), which includes an obligation for HCWs not to impose risks of harm to patients and creates a standard of due care<sup>(12-14,209)</sup>

<sup>C</sup> Countries or areas with moderate to high risk of HBV are identified by the World Health Organization<sup>(325)</sup>.

<sup>D</sup> Refer to the *Canadian Immunization Guide* for immunization of persons new to Canada<sup>(95)</sup>.

<sup>E</sup> HBV antiviral therapy may be required to allow HCWs infected with HBV to perform EPPs.

<sup>F</sup> One IU/mL is considered equivalent to 5 copies/mL (i.e., 1 copy/mL is equivalent to 0.2 IU/mL)<sup>(302)</sup>.

<sup>G</sup> Because the focus is on patient safety, HCWs who perform EPPs should be treated at this serum level regardless of recommendations in current treatment guidelines. With adherence to treatment as part of the threshold for infected HCWs to perform EPPs, HBV DNA levels are reduced to almost undetectable in most people. As a result, several known inconsistencies (e.g., differences in recommended HBV DNA threshold in various international guidelines, in-vivo fluctuations in a person's HBV DNA levels without treatment, variation in HBV DNA test results based on different assays used, or variations in results from repeated test of the same blood sample using the same assay) will likely have minimal impact on decisions regarding practice restrictions.

<sup>H</sup> Refer to the section on Expert Review Panels.

## 9.0 CO-INFECTION WITH BLOODBORNE VIRUSES

Due to similar routes of infection, co-infection with any combination of HIV, HCV or HBV is not uncommon, especially among individuals with high risk of blood exposure such as hemophiliacs and people who use injection drugs<sup>(32,184,326-329)</sup>. A review of published literature on co-infection involving any two or all three of these BBVs was conducted in order to summarize considerations or challenges associated with management of HCWs with a BBV co-infection related to the risk of BBV transmission to patients.

Reports of co-infection with HIV-HBV and HBV-HCV are limited<sup>(328,330)</sup>, while reports of co-infection with HIV-HCV are more extensive<sup>(326,327,327,331-339)</sup>. There is limited published data on co-infection by all three viruses<sup>(340-343)</sup>.

Overall, studies on BBV co-infection focus more on disease progression and prognosis and not much is reported on the effect of co-infection on infectivity or transmissibility of these viruses. Following the review of currently available publications on BBV co-infection, recommendations provided in this guideline for the management of individual BBVs were thought to be sufficient to prevent transmission from co-infected HCWs. This is because these recommendations primarily focus on treatment for the infections and setting viral load thresholds for safely performing EPPs. The effect of co-infection on disease progression and treatment is relevant primarily for the treating physician responsible for the clinical management of the infected HCW<sup>(184,344)</sup>.

If a HCW who performs EPPs is co-infected with any combination of these BBVs, the HCW should meet the defined criteria recommended for safe practice by HCWs infected with each virus<sup>(296)</sup>.

## 10.0 DOUBLE GLOVING

Several studies investigating IPC practices of surgeons implicated in transmission of a BBV to patient(s) assessed the gloving practices of the infected HCW<sup>(116,118,122,345)</sup>. Glove failure due to perforations and/or HCW injury can result in exposure to blood and body fluids and therefore increased risk of transmission of a BBV. It is unclear if glove failure carries the same risk for both HCWs and patients when either is infected. The practice of double gloving (wearing two pairs of gloves) as an effort to mitigate this risk has been well documented and is discussed below.

Studies attempting to assess potential benefits of double gloving are mainly focused on protecting HCWs as data show they have a higher risk of acquiring a BBV from patients than vice versa<sup>(63)</sup>. Some studies report that due to paucity of evidence, no conclusions can be drawn regarding the comparative effectiveness of double versus single gloving for minimizing the risk of transmission of BBVs<sup>(346)</sup>. Other studies have drawn conclusions from the limited available evidence<sup>(347-349)</sup>. The different conclusions reached in these studies likely reflect differences in interpretation of the evidence as it relates to risk of BBV transmission.

Most relevant studies on gloving practices compared glove perforation rates by assessing for body fluid contact or leaks in gloves<sup>(20,347,348,350-355)</sup>. Glove perforation is particularly high during certain types of procedures. Healthcare workers performing orthopedic, cardiothoracic, gynecologic and trauma surgeries are more frequently involved in procedures with higher risk of glove perforations and percutaneous injury than other HCWs<sup>(20-24,86,356)</sup>.

When two pairs of gloves are worn, the number of perforations to the inner glove and consequently potential HCW exposure to patient blood, is significantly reduced (70–87%) compared to when a single pair of gloves is used<sup>(87,348,355-357)</sup>. As a result, some literature and lookback investigations postulated that there would be a similar reduction in the risk of BBV transmission from HCW to patient, with double gloving more protective than a single pair of gloves<sup>(49,350,351)</sup>.

A systematic review of RCTs investigated whether double gloving reduced the incidence of infections including surgical site infections, and bloodborne infections in surgical patients and in the surgical team<sup>(356)</sup>. The secondary study objective was to determine if additional glove protection reduced the number of perforations to the innermost pair of surgical gloves. Eligible RCTs involving two or more types of gloving including single gloving, double gloving, triple gloving, glove liners, knitted outer gloves, steel weave outer gloves, and perforation indicator systems were compared. A total of 61 RCTs informed the authors' conclusions on the various outcomes measured. A meta-analysis of 14 of these trials which included 8,885 surgeries, demonstrated that the addition of a second pair of gloves significantly reduced perforations to the innermost gloves (odds ratio 4.10, 95% confidence interval 3.30–5.09)<sup>(356)</sup>. Collectively, these studies may indicate that double gloving is indeed important for procedures with high risk of

glove perforations and may therefore be a relevant preventive measure for transmission of bloodborne infections.

Deterrents against the wide adoption of double gloving by HCWs who perform EPPs include the need to change a habit, decreased manual dexterity and tactile sensation, constriction of the hands and digits leading to discomfort, paucity of evidence, and low perceived personal risk by HCWs<sup>(20,349,350,353,358-360)</sup>. In many cases, a period of adaptation and “retraining” seems to be required before practitioners feel comfortable with double gloving<sup>(87,361)</sup>. A prospective randomized controlled trial involving 53 surgeons concluded that double gloving did not have a substantial impact on manual dexterity or tactile sensitivity when compared to single gloves or no gloves<sup>(358)</sup>. Results from a survey of 155 surgeons and residents affiliated with two Canadian universities showed that 43% of them routinely double gloved in 75% or more of procedures<sup>(361)</sup>.

Some professional organizations recommend double gloving as a standard of practice for invasive procedures in order to reduce body fluid exposure caused by glove tears and sharps injuries in surgeons and scrub personnel<sup>(87,362-365)</sup>. In a Canadian survey of 170 surgeons, 87% of orthopedic surgeons double gloved while none of the urologists surveyed did<sup>(349)</sup>. In certain types of surgery (such as neurosurgery), where delicate manipulation of instruments and tissues is required, double gloving may impair the surgeon’s ability to safely perform the procedures. Thus, the surgeon may decide to forego double gloving. Although it is clear that double gloving reduces the risk of exposure to blood and body fluids due to glove perforations, the evidence is insufficient to determine how it affects the risk for BBV transmission from HCW to patient and vice versa<sup>(347,356)</sup>. As a result, it is not possible to conclusively state that double gloving is a critical element for preventing transmission of BBVs between HCWs and patients.

Double gloving by HCWs, to protect themselves and their patients, may best be addressed as a matter of preference until further studies are conducted. Factors to consider in making a decision whether or not to double glove based on identified risk factors for glove perforations are summarized below<sup>(24,351,353)</sup>:

- The addition of a second pair of surgical gloves significantly reduces perforations to innermost gloves<sup>(355,356,361)</sup>.
- Sensitivity and manual dexterity may be improved by choosing a suitable combination of inner- and outer-glove size<sup>(358)</sup>.
- Wearing two pairs of gloves does not substantially impact tactile sensitivity or manual dexterity to the point of resulting in more perforations<sup>(356,358)</sup>.
- Wearing one pair of orthopedic gloves (thicker than standard latex) is as effective as wearing two pairs of standard latex gloves in reducing the number of perforations to innermost gloves<sup>(366)</sup>.
- Risk of glove perforation has been reported to increase with the length and complexity of the procedure as well as HCW expertise and risk of injury associated with the procedure<sup>(24,84)</sup>. Deep procedures carry a significantly higher risk of glove failure (up to sevenfold) compared with superficial procedures<sup>(348,359)</sup>.

- The frequency of glove changes depends on length of procedure, amount of blood loss, and HCW injury<sup>(347,351,367)</sup>.
- Glove perforations are significantly higher for emergency procedures than they are for scheduled procedures<sup>(24,353,367)</sup>.
- If double gloving, wearing glove perforation indicator systems results in significantly more inner glove perforations being detected during surgery than when wearing standard double latex gloves<sup>(348,368)</sup>.
- If HCWs choose to double glove, they should do so routinely and not based on the risk status of a patient. Occasional double gloving would not provide the opportunity for the HCW to adapt to it thereby potentially posing a risk to both the HCW and the patient<sup>(87)</sup>.

### 10.1 Recommendation for Double Gloving for Infected Healthcare Workers

Recommendation
<p>1. There is insufficient evidence to recommend for or against double gloving to prevent HCW-to-patient transmission of a BBV.</p> <p>Grade of evidence: Not applicable due to insufficient data specific to BBV transmission</p>

# 11.0 INFECTION PREVENTION AND CONTROL MANAGEMENT OF INFECTED HEALTHCARE WORKERS

## 11.1 Reporting Obligations

In all provinces and territories, certain HCWs are obligated by law to report patients infected with specified communicable diseases including HIV, HBV and HCV to public health<sup>(369)</sup>. There may be additional ethical, legal or regulatory reporting requirements related to patients infected with a BBV, who are also HCWs. As a result, all treating clinicians should be familiar with the reporting obligations in effect within their province or territory of practice<sup>(369)</sup>.

## 11.2 Expert Review Panels

Within the context of this guideline, Expert Review Panels (ERPs) are advisory committees to the relevant jurisdictional authority (e.g., public health, regulatory authority) whose primary role is to assess the risk of transmission of a BBV from an infected HCW to patients and assess whether practice modifications or restrictions are needed if the infected HCW performs EPPs.

A review of existing guidelines from Canada, the United States, the United Kingdom, Europe, France, Ireland, Australia, and the Netherlands shows differences in approach to convening and/or implementing an expert review process<sup>(2,44,105,190,273,298,300,370,371)</sup>. The UK has a national-level ERP called *The UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses* (UKAP), which has been in place since 1991<sup>(234)</sup>. In 2011, France recommended a similar approach for the creation of an ERP at a national level<sup>(44)</sup>.

### 11.2.1 Canadian Approach

The approach taken for the establishment of ERPs in Canada varies across provinces and territories (P/Ts). Table 36 (Appendix III) describes key elements of the expert review process in two provinces that have a centralized approach for all HCWs. ERPs have been convened by P/T ministries of health or public health agencies, as well as by university faculties (e.g., medicine) or regulatory authorities for HCW professional groups<sup>(274,372-380)</sup>. Health Canada's 1998 consensus document recommended the creation of an ERP<sup>(2)</sup>. At the time of developing this guideline, not all HCWs infected with a BBV in Canada had access to an ERP. Where ERPs exist, the process for implementation and monitoring for compliance with recommendations provided by the panel also varies across P/Ts. The inconsistencies in establishing an ERP and developing a framework for their decision-making have led to inconsistent practices across Canada. This could result in movement of an infected HCW between provinces and territories, a situation where an infected HCW is not being managed, or management of an infected HCW using advice that is not based on available evidence regarding risk of transmission. A consistent evidence-based approach across the country will improve patient safety and support the effective

and equal treatment of HCWs infected with a BBV irrespective of where they work in Canada. This guideline is intended to support consistency in availability of ERPs and their practices nationally.

For purposes of developing this guideline, an environmental scan of relevant literature was conducted to address the key question, *What issues are relevant to the expert review process in Canada for the management of HCWs infected with HIV / HCV / HBV?* Characteristics of ERPs in Canada were identified through an environmental scan of publicly available documents and personal communication where necessary. Upon review of relevant documents, current practice, and stakeholder engagement, essential components were identified to inform recommendations for establishment of effective ERPs by provincial and territorial health authorities. These recommendations prioritize patient safety using a consistent and evidence-based approach to decision-making regarding the management of infected HCWs while ensuring that each HCW's right to privacy and the confidentiality of their personal medical information are maintained.

### 11.2.2 Recommendations for Expert Review Panels

Recommendations for the governance, authority, responsibility and processes for ERPs are provided below. These issues should be clearly defined for each P/T such that all HCWs (including students) who may be affected by the policies are afforded the opportunity to receive expert guidance related to their BBV infection.

Expert Review Panels should refer to Sections 6.6, 7.6 and 8.9 for *Recommendations for Management of HCWs infected with HIV, HCV and HBV* respectively.

<b>Accountability, Governance and Membership</b>
<ul style="list-style-type: none"> <li>• The P/T Ministries of Health and regulatory authorities have a shared responsibility to protect the health and well-being of the population. The P/T Ministries of Health have the responsibility to ensure that all HCWs, including students, have access to an ERP. <ul style="list-style-type: none"> <li>○ The ERP can be at various levels e.g., faculty, regulatory authority, or ministry.</li> <li>○ The composition of the panel and who it reports to should be publicly available.</li> </ul> </li> <li>• P/Ts and regulatory authorities without the necessary resources and expertise to establish an ERP, should partner with another P/T to ensure that all HCWs infected with a BBV have access to an ERP.</li> <li>• Expert Review Panels should engage relevant stakeholders such as public health, health faculties and healthcare institutions.</li> <li>• Indemnification should be provided for all ERP members.</li> <li>• The ERP should be adequately resourced to complete its mandate. The governing authority for an ERP is responsible for addressing the remuneration of the ERP members.</li> <li>• The ERP should be convened in a timely manner when an infected HCW is identified for review.</li> </ul>



- There should be sufficient members on the ERP to provide the breadth of expertise required to assess the risk posed by a HCW infected with a BBV, and offer recommendations to mitigate the risk. Membership on an ERP should include an infectious disease physician and a public health professional. Other members may include: a hepatologist, surgeon, medical/clinical microbiologist, infection prevention and control professional, occupational health physician, bioethicist, member of the public, and peer HCW (in the same area of practice as the HCW infected with a BBV).

### **Roles and Responsibilities**

- An ERP should assess the risk that the HCW may pose to patients and make recommendations on fitness for practice based on the HCWs' health status and practice.
- The HCW or their delegate should have an opportunity to present information during the assessment for fitness to practice.
- The HCW or their delegate should have an opportunity to discuss the recommendations prior to implementation and have an opportunity for clarification or a re-evaluation.
- The ERP processes should be conducted in a manner that protects the HCW's privacy and maintains confidentiality.
- The ERP or regulatory authority should sign a written agreement with the HCW that identifies the recommendations and specifies any practice modifications or restrictions, with whom the agreement will be shared with (regulatory authority, program director, etc.), who will be monitoring the HCW's compliance, and who will be responsible for monitoring the HCW's health status. Ensuring that the HCW is under the care of a clinician with expertise in management of the BBV(s) is an important aspect of care for the HCW; this care provider may have an ongoing role in receiving test results and communicating status updates with the regulatory authority at defined intervals.
- Recommendations of the ERP including the signed agreement should be in the possession of the regulatory authority that is responsible for monitoring the HCW's compliance with the recommendations.
- The relevant authority should have a process in place in the event a HCW wishes to request a re-evaluation of any ERP recommendation(s). Acceptable reasons for a re-evaluation should be outlined and may include concerns with the process, availability of new treatment regimens, or new information about the HCW's health status or practice.

### Referral to an ERP

There are several mechanisms for initiating a referral to an ERP. The options provided here are not exhaustive.

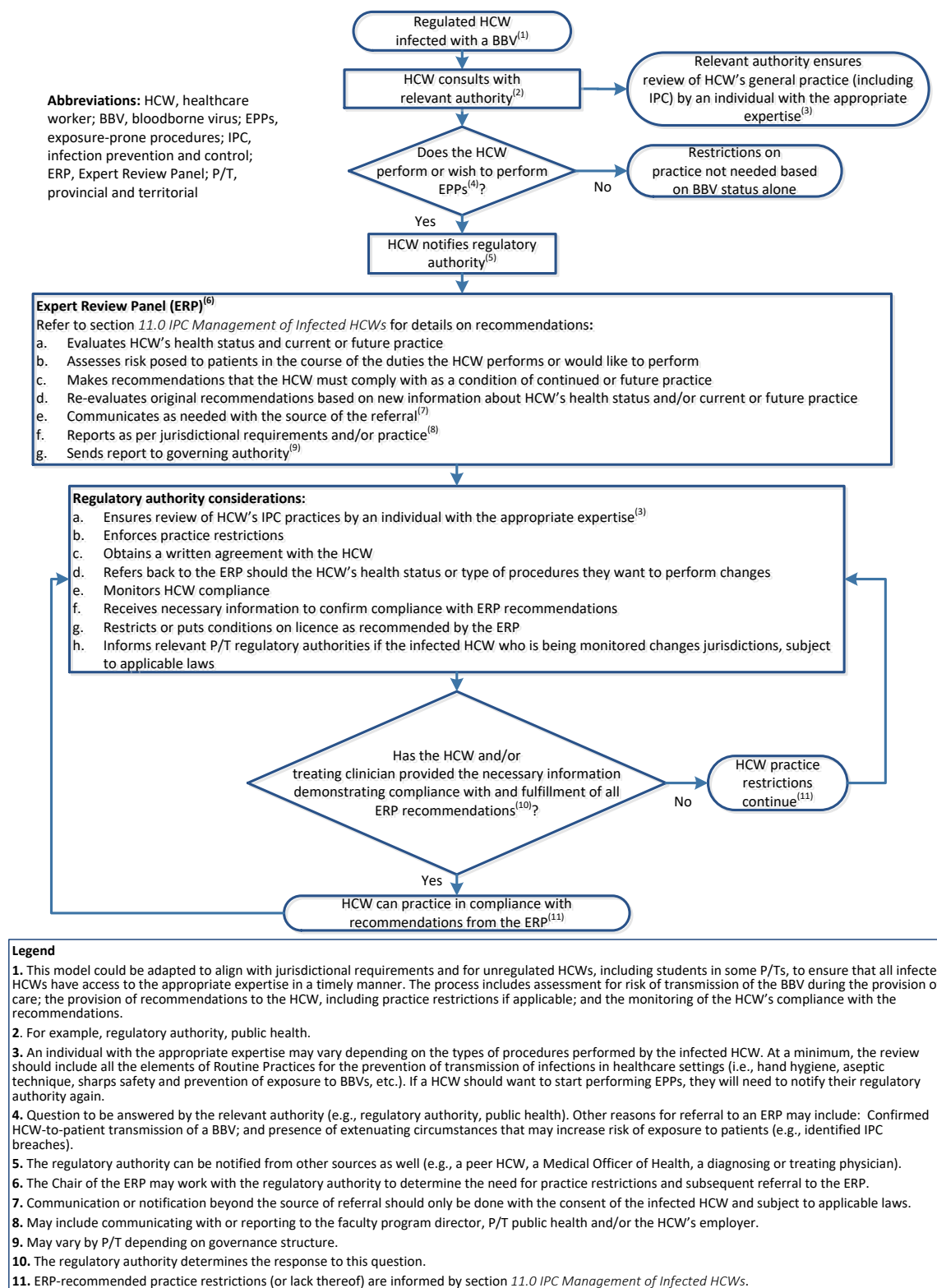
- All HCWs, including students and trainees, may self-refer to an ERP.
- The referral to the ERP may be initiated by the Medical Officer of Health or the regulatory authority; with appropriate information communicated in writing, in person, or by phone. If initiated by the regulatory authority, their monitoring department may send a list of HCWs infected with BBVs to an ERP for review.
- The referral to the ERP may be initiated by the HCW and done via telephone contact to maintain anonymity. Alternatively, the HCW may choose to initiate the referral via an advocate, surrogate, or legal representative. Most often the advocate is the treating physician.
- In the case of students and trainees, the referral may be initiated through the undergraduate or post-graduate office of the faculty.
- If the HCW is a student or trainee, a person in charge of the program or a faculty member may provide procedural advice and assistance to the student or trainee.

### Implementation, Monitoring and Compliance with ERP Recommendations

- The ERP should provide recommendations informed by Sections 6.6, 7.6 and 8.9 *Recommendations for Management of HCWs infected with HIV, HCV and HBV* respectively.
- The HCW and treating clinician should provide the relevant authority with the necessary information to confirm compliance with the recommendations.
- The relevant regulatory authority may remove the HCW's licence if the HCW is non-compliant with practice restrictions.
- In the event that a HCW who is being monitored changes jurisdictions or institutions, the regulatory authority or faculty should inform the appropriate jurisdictional authorities subject to applicable laws.

A sample flow chart providing an overview of the interactions and responsibilities of regulated HCWs infected with a BBV, an ERP, and relevant authorities is shown in Figure 4. Although local jurisdictions can adapt the referral and implementation processes within the context of the relevant authorities and available resources, specific guidelines and recommendations are provided above for each key step. Table 37 (Appendix III) lists select regulated and unregulated HCWs in Canada by P/T.

Policies regarding the management of HCWs infected with BBVs must comply, as appropriate, with applicable jurisdictional health and privacy legislation, employment law, Human Rights codes and the Canadian Charter of Rights and Freedoms.



**Figure 4: Model Expert Review Panel process for a regulated HCW infected with a bloodborne virus**

## 12.0 DISCLOSURE OBLIGATIONS AND RIGHT TO PRIVACY

This section addresses the HCW's disclosure obligations to their patients and the HCW's right to privacy. Few Canadian guidelines and policies address the issue of disclosure obligations to patients. None of those reviewed regard routine disclosure of HCW serologic status to patients as a necessary requirement for the provision of care. When a HCW infected with a BBV has been reviewed by an ERP and deemed safe to practice, the issue of disclosure is not applicable.

### 12.1 International Approach

The United States Centers for Disease Control and Prevention (CDC) previously required that HCWs infected with HBV or HIV who perform EPPs disclose their serologic status to their patients<sup>(291)</sup>. However, this is no longer a requirement in the CDC's updated recommendations for the management of HCWs infected with HBV<sup>(105)</sup>. These recommendations state that routine mandatory disclosure might be counterproductive to public health, as it might lead to avoidance of testing, vaccination, treatment and/or management, and may result in non-compliance with practice oversight from an ERP. The risk of transmission of a BBV is greater from unknown infections than from known infections. Mandatory disclosure was "accepted to be an insurmountable barrier to practice, and might limit patient and community access to quality medical care"<sup>(105)</sup>.

Internationally, none of the reviewed policy documents regard disclosure of a HCW's serologic status to patients as a necessary requirement for the provision of care<sup>(44,105,190,370,371)</sup>. The HCW right to privacy is comprehensively addressed, but the practical steps to ensure that this right is upheld are not included in most policies.

A harmonized, evidence-based approach to addressing HCW disclosure obligations and right to privacy is warranted, and stands to benefit HCWs, patients, and society. Ensuring safe medical care and protecting HCW privacy rights should be achieved in a consistent and transparent manner in all healthcare settings across Canada. An essential precursor for safe patient care is the ethical and professional obligations of the HCW performing EPPs to know their serologic status, and seek and receive necessary guidance accordingly (refer to section *11.0 Infection Prevention and Control Management of Infected Healthcare Workers*)<sup>(11-18)</sup>. This obligation of HCWs in Canada, whether ethical or professional, is increasingly recognized. Concurrently, policies are being developed to address issues related to HCW rights to privacy, and attenuate risks to patients in healthcare settings. This trend does not, however, extend to a disclosure obligation of serologic status from HCW to patient.

## 12.2 Disclosure Obligations

Many of the current guidelines and policies that address HCWs and BBV infections do not contain explicit recommendations regarding disclosure obligations of HCWs to patients. None of the reviewed guidelines and policies recommends mandatory routine disclosure of HCW serologic status to patients, regardless of whether or not the HCW performs EPPs<sup>(13,54,71,274,377,381-384)</sup>.

Some publications suggest that mandatory disclosure of a HCW's serologic status to patients be restricted to cases arising when: (1) exposure from a HCW infected with a BBV to a patient has occurred; (2) the HCW has been non-compliant with an ERP's recommendations or (3) viral load in the infected HCW constitutes a material risk to the patient. If the ERP has deemed the HCW safe to practice, this negates both material risk and a need for disclosure.

## 12.3 Right to Privacy

The right to privacy of a HCW infected with a BBV is addressed in most relevant Canadian and international guidelines and policies. While the wording to describe this right varies, the guidelines and policies uniformly recognize the importance of maintaining HCW privacy without specifying mechanisms to achieve this.

## 12.4 Ethical Aspects

There is an inherent ethical dilemma in considering disclosure. The risk of transmission of a BBV from HCW to patient is non-zero (i.e. the risk exists, even if minimal). Therefore patients have an interest in knowing about the risk, while HCWs have an interest in protecting their privacy; given the impact that disclosing to patients might have on their practice and personal lives.

Ethically, the interests of the patient and HCW must also be balanced against other competing rights and interests which, in this case, may include denying patients the services of HCWs without improving the safety of care, creating unfair hardship for HCWs, and creating an economic burden on the health system.

HCWs performing EPPs have ethical and professional obligations to know their serologic status, and to seek guidance and follow expert advice if infected (refer to section *11.0 Infection Prevention and Control Management of Infected Healthcare Workers*). These obligations may be traced to principles of non-maleficence (the duty to intentionally refrain from actions that cause harm), respect for autonomy (the responsibility to obtain informed consent from patients for treatment, and provide all information material to their decision making), and the right to privacy (the obligation to minimize the extent to which HCWs may experience stigmatization, discrimination and/or reduced professional prospects as a result of disclosing their serologic status)<sup>(209)</sup>. It is expected that HCWs follow all the elements of code of practice of which informed consent and fitness to practice are included.

## 12.5 Legal Context

In accordance with the Canadian legal system, policies regarding the management of HCWs infected with BBVs must comply, as appropriate, with applicable jurisdictional health and privacy legislation, employment law, Human Rights codes and the Canadian Charter of Rights and Freedoms<sup>(385)</sup>. Provincial Human Rights codes prohibit discrimination on several grounds, including “disability”, a term that, under antidiscrimination law in Canada, includes infection with HBV, HIV and/or HCV.

In all provinces and territories in Canada, HIV (or AIDS), HBV and HCV are reportable diseases under public health legislation<sup>(386-388)</sup>. It has not been established, however, whether an obligation to disclose serologic status to patients exists under common law. Such an obligation would likely infringe upon the HCWs’ rights to privacy and freedom from discrimination under the Charter and Human Rights codes. When such conflicts arise between the Charter, Human Rights Codes and common law, the courts recognize that rights are non-absolute and have limits, and evaluate the case on consideration of matters such as the balance between the provision of safe health care to patients and respect for the rights of HCWs<sup>(54)</sup>. Fiduciary duties may require HCWs to disclose their serologic status when performing EPPs. However, if the HCW takes reasonable steps to reduce the risk of transmission to acceptable levels, fiduciary duty obligations may be satisfied without having to disclose serologic status<sup>(54)</sup>.

A HCW infected with HBV, HCV and/or HIV could in theory face legal liability for failure to obtain informed consent if the HCW does not disclose their serologic status. To give informed consent, a patient must be provided with all information material to the proposed treatment plan, including all ‘material, and special or unusual risks’<sup>(389,390)</sup>. The likelihood of risk and the consequences of the risk (impacts of the HIV, HBV or HCV infections) would be factors considered by the Courts to determine whether the HCW serologic status constitutes a material risk to be disclosed to the patient. In the context of EPPs, the risk could therefore be considered material for the purpose of informed consent. In previous cases, courts have affirmed that physicians did not have to routinely disclose their medical information to patients<sup>(391)</sup>, and that the informed consent requirement is to be judged by the “reasonable patient” standard, i.e., what a reasonable patient in that position would have expected to hear before consenting<sup>(390)</sup>. It has been suggested that the disclosure obligations may be better managed by regulatory authorities. It is possible the courts may also take into account the public policy consequences of disclosure, and the special nature of the relationship between HCWs and patients, in determining whether and to what extent an obligation exists<sup>(392)</sup>.

The following recommendations are based on a review of existing Canadian and international guidelines and policies, taking into consideration the ethical and legal contexts.

## 12.6 Recommendations for HCW Disclosure Obligations and Right to Privacy

Recommendations
1. A HCW infected with a BBV who performs EPPs does not have an obligation to routinely disclose his or her serologic status to patients to obtain their informed consent provided that the HCW's health status and practice have been assessed by an Expert Review Panel and all the panel's recommendations are followed.
2. All HCWs, including those infected with a BBV, have a right to privacy and confidentiality of personal health information.
3. Regulatory authorities should have policies on the management of HCWs infected with a BBV that are transparent about and detail how the right to privacy of HCWs will be upheld.
4. When a patient has been exposed to the blood of a HCW, the HCW must seek follow-up through their organizational process and the patient must be promptly informed of the nature of the exposure and the appropriate post-exposure protocol. However, the identity and confidentiality of the HCW should be protected to the greatest extent possible.

## 13.0 LOOKBACK INVESTIGATIONS RELATED TO INFECTED HEALTHCARE WORKERS

### 13.1 Overview of Lookback Investigations

This section addresses the principles and considerations for lookback investigations, which may be performed following the identification of a HCW-to-patient transmission or identification of an infected HCW with no known transmission to patients.

Complete reports on lookback investigations are rarely published in peer-reviewed journals<sup>(168)</sup>. There have been five Canadian lookback investigations involving infected HCWs published to date. These involved two HCWs infected with HBV<sup>(70,132)</sup>, two HCWs infected with HCV<sup>(51,77)</sup>, and one HCW infected with HIV<sup>(155)</sup>. Key aspects from these investigations are summarized in Table 18. Although the majority of lookback investigations are initiated as a result of transmission of a BBV infection through exposure-prone procedures (EPPs), one significant Canadian lookback investigation identified transmission during non-EPPs due to IPC breaches<sup>(132)</sup>. Detailed information on relevant lookback investigations published internationally between 1985 and 2016 can be found in summary tables for each BBV in *Appendix 1: Epidemiologic investigations summary tables*.

Several countries have national regulations and/or policies that frame and guide decisions and risk assessments surrounding lookback investigations<sup>(2,190,370,393,394)</sup>.

Healthcare organizations have an obligation to inform patients of an exposure incident where there is a risk of transmission of a BBV<sup>(231,233,395)</sup>. Neglecting this patient right prevents them from obtaining an early diagnosis and treatment and minimizing risk of secondary transmission<sup>(165)</sup>. In a survey of patients involved in a large lookback investigation, the majority of patients stated that they wished to know about an exposure despite the anxiety that the knowledge caused them<sup>(395)</sup>.

A HCW's right to privacy and confidentiality of his or her personal health information must be respected during a lookback investigation<sup>(165)</sup>. It is feasible to conduct the investigation and publish a report without infringing on the rights of the affected HCW<sup>(155,393)</sup>. This is important to reassure and encourage potentially infected HCWs to come forward in the future<sup>(168)</sup>.



**Table 18: Published Canadian lookback investigations**

Author (publication year) Province	Virus	Trigger for LB	HCW performed EPPs	Lead authority for LB	Patient population for LB	Factors amplifying risk of potential exposure	Infected patients identified during LB	Cost of LB
Johnston (1992) <sup>(70)</sup> Companion <sup>A</sup> : <sup>(284)</sup> Nova Scotia	HBV	Infected patients	Yes	Hospital	All who underwent surgery after HCW's last negative HBV serology from 1986 to 1991	None	Yes <sup>B</sup>	NR
Hepatitis B Outbreak Investigation Team (2000) <sup>(132)</sup> Ontario	HBV	Infected patients	No	Public health	All attending clinics operated by same neurologist from 1990 to 1996	IPC breaches	Yes <sup>B</sup>	NR
Saginur (2001) <sup>(51)</sup> Ontario	HCV	Infected HCW	No	Hospital	All who had arterial puncture performed by HCW between June 1992 and October 1993	Dermatitis of hands	No	NR
CHU Sainte-Justine (2004) <sup>(155)</sup> Quebec	HIV	Infected HCW	Yes	Hospital	All who underwent a surgical procedure while the HCW was infected from 1990 to 2003	None	No	\$250,000 <sup>C</sup>
Dawar (2010) <sup>(77)</sup> Prince Edward Island	HCV	Infected HCW	Yes	Public health	All who underwent EPPs or non-EPPs with a reported percutaneous injury to the HCW from 2004 to 2007 <sup>D</sup>	None	No	NR <sup>E</sup>

Abbreviations: LB, lookback investigation; HCW, healthcare worker; EPP, exposure-prone procedure; HBV, hepatitis B virus; NR, not reported; IPC, infection prevention and control; HCV, hepatitis C virus; HIV, human immunodeficiency virus

<sup>A</sup> Articles that provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.

<sup>B</sup> In addition to patients identified prior to the lookback investigation.

<sup>C</sup> The report states that approximately 40 full-time equivalent positions were required in the first week alone. In addition, external expertise was obtained from the provincial ministry of health, public health, medical regulatory authority, legal counsel, and a communications consultant.

<sup>D</sup> A phased approach by greatest risk of transmission and exposure was used. The parameters for the screening period were determined based on the HCW's abnormal laboratory findings and HCV mutation over time.

<sup>E</sup> As there was no transmission identified in the first phase, the investigators decided not to pursue screening of patients with a lower risk of exposure thus permitting an efficient use of public health resources.

### 13.2 Key Considerations and Objectives of a Lookback Investigation

Lookback investigations require resources to identify, notify, counsel and test all the potentially exposed patients<sup>(165)</sup>. These investigations often involve collaboration between a healthcare organization or facility where an infected HCW practiced and public health authorities. Although such collaborations may potentially pose a challenge for conducting the investigation, the process is generally coordinated by an Investigation Management Team with the expertise needed to successfully and efficiently manage the investigation<sup>(122,156,171,370)</sup>.

Lookback investigations are both time consuming and costly activities requiring significant financial and human resources<sup>(115)</sup>. Direct and indirect costs are associated with salaries for personnel, honoraria for expert advice, counseling and testing of patients, courier services and support services such as information technology, telephone services, security, and media relations. These resources can come at the expense of other institutional or public health activities<sup>(114)</sup>. One report stated that the cost of a lookback investigation was equivalent to a third of the state's entire annual budget for HIV and AIDS surveillance (excluding the costs to other organizations involved in the investigation)<sup>(49)</sup>. Investigations conducted in the early 1990s cost over US \$100,000<sup>(49,159)</sup>, with the cost for lab testing alone in one investigation estimated at US \$76,000<sup>(32)</sup>. In the UK, the total cost for lookback investigations, where reported, exceeded well over £200,000<sup>(168,172)</sup>. Canadian healthcare organizations or facilities may not have sufficient resources, either human, laboratory or financial, to conduct a lookback investigation without support from public health authorities. Poor quality patient information retention by a health organization or facility<sup>(148)</sup>, or the lack of computerized information systems to assist with information retrieval, can also hinder an investigation.

Lookback investigations related to an infected HCW may be undertaken to:

- a. notify patients of their potential exposure
- b. identify infected patients and provide appropriate advice and treatment recommendations
- c. prevent secondary transmission
- d. reassure the public
- e. maintain the public's trust and confidence in the healthcare system
- f. contribute to the evidence base on risk of transmission.

### 13.3 Recommendations for Conducting Lookback Investigations

Recommendations provided in this section are expert opinion informed by published lookback investigations and existing guidelines<sup>(2,190,298,393,394,396)</sup> as well as current practice.

Prior to initiating a lookback investigation, a risk assessment is conducted by a team with the expertise needed to determine the requirement for an investigation and if applicable, define its scope. Recommendations for conducting the risk assessment are provided below including supporting tools to facilitate decision making.

### **Risk assessment to determine requirement for a lookback investigation**

- If a HCW who performs EPPs is found to be infected with a BBV, a team should be assembled to perform a risk assessment. Some organizations may have a standing risk assessment panel or process that could be utilized.
- The HCW should cease performing EPPs immediately and be referred to an ERP for practice evaluation while the risk assessment is underway.
- Although there is a necessary link between the tasks done by both groups, the team responsible for performing the risk assessment should be different from the Expert Review Panel (ERP).
- Members of the risk assessment team should be familiar with the legal obligations in effect within their jurisdiction that may impact the decision-making process related to lookback investigations.
- The risk assessment team should include individuals with sufficient expertise to assess both the risk of potential exposure and transmission and to identify the process required to address these risks (e.g., infectious disease physician with expertise in relevant BBV, infection control professional, public health physician, peer HCW, medical microbiologist, bioethics expert, facility senior management, and legal counsel).
- Processes should be in place to ensure there is no conflict of interest or bias with regards to conducting the lookback investigation.
- For a consistent and thorough approach to risk assessment, pre-developed tools should be used to perform the assessment. Refer to the following tools below:
  - A checklist to record relevant information (Table 19).
  - An algorithm and legend for guidance on the risk assessment (Figure 5).

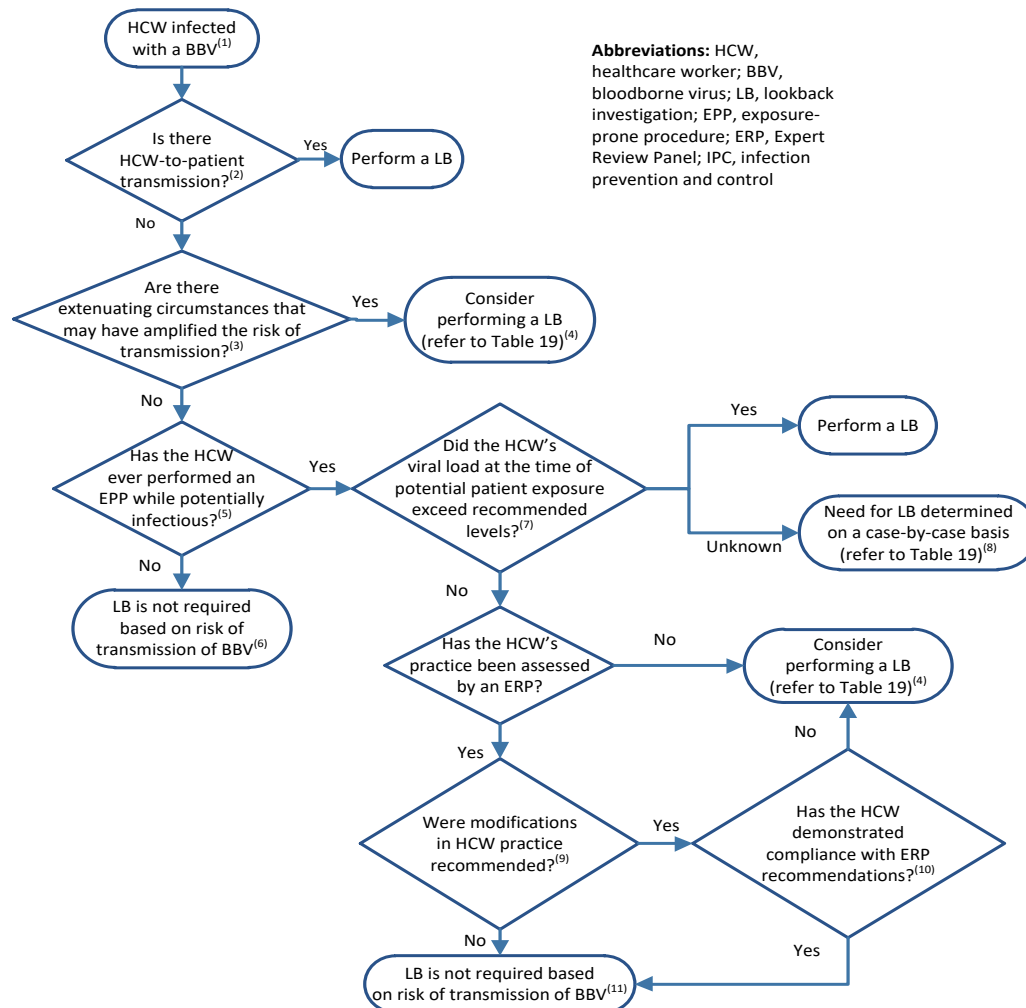
Data collected in Table 19 will facilitate use of the risk assessment algorithm (Figure 5). The risk assessment team will need to consider the information compiled in Table 19 as well as any additional details unique to each event in order to make a decision regarding whether or not there was a risk of patient exposure and a lookback investigation is required.

**Table 19: Checklist for risk assessment and lookback investigation related to a HCW infected with a BBV<sup>A</sup>**

	Questions to consider related to transmission
1	Has HCW-to-patient transmission been identified? Note: If the answer is yes, perform a lookback investigation. In addition, the HCW should cease practice immediately pending the outcome of the investigation and be referred to an ERP with knowledge that transmission has occurred.
2	How was the HCW's BBV infection identified (e.g., disclosure by the HCW; traceback investigation of an acute BBV infection in a patient; routine medical assessment; post-exposure follow-up screening; assessment of HBV vaccine non-response; other)?
	Questions to consider related to the HCW's health status
3	Which BBV infection is the HCW diagnosed with?
4	What are the dates and results of serum viral loads (if available)?
5	Is there evidence of any physical, neurological or psychological impairment?
6	Is the HCW receiving treatment for the BBV infection?
7	Since when has the HCW been considered infectious and potentially exposing patients?
	Questions to consider related to the HCW's scope of practice
8	In what specialty/ies has the HCW been employed?
9	What type of procedures (EPP and/or non-EPPs) did the HCW perform?
10	If the HCW was involved with performing EPPs, what was the HCW's role?
11	Has the HCW ceased undertaking EPPs?
12	Has the HCW's practice ever been reviewed by an ERP? Note: If yes, identify the ERP recommendations and whether the HCW was compliant with them.
	Questions to consider related to extenuating circumstances
13	Has the HCW complied with current infection prevention and control standards (i.e., Routine Practices)?
14	Does the HCW use technique(s) (e.g., surgical) that may increase his/her risk of percutaneous injuries during procedures that can put patients at risk of exposure to the HCW's blood?
15	Has the HCW had percutaneous injuries that exposed a patient to the HCW's blood (both reported and unreported)?
16	Has the HCW ever noted blood on his/her hands after removal of surgical gloves following procedures performed on patients?
17	Has the HCW ever had evidence of a skin condition on his/her hands that potentially created an exit portal for BBVs (e.g., dermatitis)?

Abbreviations: HCW, healthcare worker; BBV, bloodborne virus; ERP, Expert Review Panel; EPP, exposure-prone procedure

<sup>A</sup> Adapted from UKAP (2004) enquiry pro forma<sup>(63)</sup>.



#### Legend

1. Identification of a HCW infected with a BBV may trigger a risk assessment to determine if a lookback investigation is required. In addition, the HCW should be referred to an ERP as soon as possible to have their health status and practice reviewed (if not previously done).
2. As determined by a traceback investigation. Refer to *Appendix V, Glossary* for a definition of traceback investigation.
3. Extenuating circumstances include IPC breaches by the HCW that put patients at risk of exposure during the provision of care or illicit diversion of patient medication.
4. Refer to *Table 19: Checklist for risk assessment and lookback investigations related to a HCW infected with a BBV* for questions to consider to assist the decision-making process.
5. Refer to section 5.0 *Exposure-prone procedures*.
6. A lookback investigation may not be required based solely on risk of transmission of BBV however, a risk assessment team may determine that a lookback investigation is necessary based on other considerations (e.g., contribute to evidence base, alleviate public anxiety).
7. HCW who, at the time of potential patient exposure, had: i) HBV viral load greater or equal to  $10^3$  IU/ml ( $5 \times 10^3$  GE/ml); ii) detectable HIV viremia; or iii) circulating HCV RNA.
8. The risk assessment team should determine the need for a LB on a case-by-case basis considering all relevant information.
9. Refer to relevant sections: 6.0 *Risk of Transmission for HIV*, 7.0 *Risk of Transmission for HCV*, 8.0 *Risk of Transmission for HBV* and 11.2 *Expert Review Panels*.
10. Refer to section 11.2 *Expert Review Panels*.
11. Although the risk of transmission is not zero, it can be rendered negligible if HCWs infected with a BBV who perform EPPs adhere to recommendations which have addressed the identified risk factors from previous exposure incidents.

**Figure 5: Risk assessment to determine requirement for a lookback investigation related to a HCW infected with a BBV**

### **Lookback investigation: scope, roles and functions**

- A LB investigation management team with an identified lead should be assembled to coordinate the investigation. This may be the same group as the risk assessment team.
- The investigation management team should include individuals with expertise in infectious disease, infection prevention and control, public health, medical microbiology, bioethics, laboratory services, the relevant BBV and the types of procedures performed by the infected HCW. In addition, representatives from the facility's senior management, communications department, risk management, and legal counsel should be included. Members of the investigation management team should be familiar with the legal obligations in effect within their jurisdiction that may impact the decision-making process related to lookback investigations.
- Members of the investigation management team should sign a pledge of confidentiality.
- The lookback investigation should be undertaken in a reasonable amount of time.
- The lookback investigation should be a collaborative process between the healthcare organization or facility where the infected HCW practices and public health authorities.
- The healthcare settings and organizations or local public health could be the lead authority depending on:
  - whether the HCW has practiced in more than one healthcare organization or facility within the jurisdiction of the local public health authority
  - whether the HCW has practiced outside of a healthcare organization or facility (e.g., private practice)
  - whether the healthcare organization or facility has sufficient resources to conduct the lookback investigation.
- The local public health authority may request assistance from their provincial or territorial counterparts, who may also request federal assistance if the investigation goes beyond their jurisdiction.

### **Access to resources**

- Lookback investigations can be resource intensive and impact on laboratory resources should be considered. The public health laboratory should be involved with the investigation, whenever possible, to ensure appropriate testing, reporting and accountability.
- Detailed molecular analysis of samples in the investigation should be done to confirm or exclude HCW-to-patient transmission.
- Members of the risk assessment and investigation management teams should have access to appropriate patient information to support the decision-making process as per relevant provincial and territorial legislation.
- Provincial or territorial public health authorities may request the assistance of their federal counterparts.
- Lookback investigations should be conducted in a manner that facilitates efficient and effective use of public health and institutional resources.

### **Risk communications**

- A well-developed and coordinated communication strategy should be in place prior to patient notification.
  - Consideration should be given to setting up a call centre with a telephone hotline for public inquiries with personnel trained to provide accurate information while managing the anxiety that may be generated.
  - A list of potentially exposed patients to be notified should be assembled such that all patients are notified simultaneously and prior to public announcements.
  - All information necessary to inform the advice and counselling provided to potentially exposed individuals and their families should be compiled prior to patient notification.
  - All reasonable steps should be taken to identify and contact potentially exposed patients and encourage them to be tested for their own benefit.
  - Communication via traditional news media (press releases and conferences) as well as use of social media should be well coordinated.
  - Communication strategies should consider the following stakeholders: facility or organization personnel, the media, healthcare providers in the community, political representatives of the district and the general public.
- Reports on lookback investigations should be published to contribute to the evidence base on risk of transmission from HCW to patients, inform future policy development, estimate cost associated with these investigations and improve patient safety.
- A national repository to document all lookback investigations, including those where no transmission was found, should be created.

### HCW confidentiality and right to privacy<sup>A</sup>

- Every effort should be made to avoid revealing the identity or information that would allow deductive disclosure of the HCW infected with a BBV. However, there may be instances where patient safety precludes this.
- Members of the investigation management team have an obligation to keep the information they receive confidential and respect the HCW's right to privacy.
- The right to privacy still applies if the infected HCW has died, or has already been identified publicly.
- The number of individuals who know the identity of the infected HCW should be kept to a minimum at all stages. It may not be necessary for all members of the team(s) to be aware of the identity of the infected HCW.

<sup>A</sup> Adapted from the UK's *HIV Infected Health Care Workers: Guidance on Management and Patient Notification*, 2005<sup>(393)</sup>



# APPENDIX I: EPIDEMIOLOGIC INVESTIGATIONS SUMMARY TABLES

**Table 20: Epidemiologic investigations reporting transmission of HIV from infected HCW to patient**

Author (publication year) Country	Specialty	EPPs	Year diagnosed	Index cases (n)	Screening period <sup>A</sup>	Number of patients potentially exposed <sup>B</sup>	Number of patients tested <sup>B</sup> (% of potentially exposed)	Number of patients infected <sup>C</sup>	Transmission rate (%) <sup>D</sup>	HCW risk factors <sup>E</sup>
Ciesielski (1992) <sup>F (148)</sup> Companions <sup>G: (125-128)</sup> US	Dentistry	Yes	1986	1	1981–1989	1691	735 (44) <sup>H</sup>	6	0.82 C	Symptomatic <sup>I</sup> : Yes Aware of status <sup>J</sup> : Yes IPC breaches <sup>K</sup> : Yes
Lot (1999) <sup>F (72)</sup> Companion <sup>G: (180)</sup> France	Orthopedic surgery	Yes	1994	0	1983–1993	3004	983 (33)	1	0.10 C	Symptomatic <sup>I</sup> : Yes Aware of status <sup>J</sup> : No IPC breaches <sup>K</sup> : No
Astagneau (2002) <sup>F (32)</sup> Companion <sup>G: (153)</sup> France	General duty nursing	No	1996	1	1990–1997	7580	2293 (30)	1	0.04 C	Symptomatic <sup>I</sup> : Yes Aware of status <sup>J</sup> : Yes <sup>L</sup> IPC breaches <sup>K</sup> : NR
Mallolas (2006) <sup>F (117)</sup> Companions <sup>G: (150,151)</sup> Spain	Obstetrics	Yes	2001	1	NR	275	250 (91)	1	0.40 C	Symptomatic <sup>I</sup> : No Aware of status <sup>J</sup> : No IPC breaches <sup>K</sup> : NR

Abbreviations: HIV, human immunodeficiency virus; HCW, healthcare worker; EPP, exposure-prone procedures; C, calculated; IPC, infection prevention and control; NR, not reported

<sup>A</sup> Screening period: Time span selected by the investigators to screen patients.

<sup>B</sup> Number excludes index case(s).

<sup>C</sup> Includes index case(s); confirmation test for transmission include phylogenetic analysis, genotyping, or other.

<sup>D</sup> Transmission rate as reported (R) in the study or calculated (C) by reviewers; formula for calculated transmission rate = [number of infected/(number of tested + index case)]\*100

<sup>E</sup> HCW risk factors reported to be present at any point during the screening period.

<sup>F</sup> Article met the eligibility criteria for data extraction to inform the systematic review on the risk for transmission of HIV from infected HCWs to patients.

<sup>G</sup> Articles identified as companion articles provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.

<sup>H</sup> Total number of patients tested consisted of: 519 patients initially tested (which identified the second and third cases); plus three patients later tested (who were identified by cross-matching the patient list with the state's AIDS surveillance records, self-identification, and routine testing for application to the military); plus an additional 141 patients tested with no evidence of transmission amongst them<sup>(126,128)</sup>.

<sup>I</sup> Indicates whether the HCW was symptomatic at any point during the screening period. Where the article described the HCW's clinical symptoms but did not clearly state that they were linked to the HIV infection, experts reviewed the information provided to determine whether the HCW's symptoms were compatible with an HIV infection. If so, a response of "Compatible with HIV" was recorded.

<sup>J</sup> Indicates whether the HCW was aware of their HIV-positive serologic status at any time during the screening period. If the article stated that the HCW was aware of their serologic status but it was unclear when they became aware of it, a response of "NR" was recorded.

<sup>K</sup> Indicates whether IPC breaches were identified. A response of "Yes" indicates any of the following: 1) there was a lack of adherence to standard IPC practices and protocols; or 2) the Guideline Development Task Group determined that by current standards, an IPC breach was present. A response of "No" indicates that an independent review of the HCW's practice was undertaken with no IPC breaches noted.

<sup>L</sup> The HCW was unaware of their serologic status at the time of the index patient's exposure incident but was aware after being hospitalized and diagnosed in 1996<sup>(32,153)</sup>.

**Table 21: Epidemiologic investigations reporting no transmission of HIV from infected HCW to patient**

Author (publication year) Country	Specialty	Year diagnosed	Screening period <sup>A</sup>	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)	HCW risk factors <sup>B</sup>
Sacks (1985) <sup>(397)</sup> US	Surgery	NR	1978–1983	400	NR	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Armstrong (1987) <sup>(157)</sup> US	General surgery	1985	1982–1985	1804	75 (4)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : No
Porter (1990) <sup>F, (174)</sup> UK	Surgery	1988	1987–1988	339	76 (22)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
Mishu (1990) <sup>F (158)</sup> US	General surgery	1989	1982–1988	2160	616 (29)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
Danila (1991) <sup>(49)</sup> US	Family practice	1990	1990–1991	336	325 (97)	Symptomatic <sup>C</sup> : Yes <sup>G</sup> Aware of status <sup>D</sup> : Yes IPC breaches <sup>E</sup> : Yes
Comer (1992) <sup>(161)</sup> Companion <sup>H</sup> : (398) US	Dentistry (student)	NR	NR	163	154 (94)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Heuer (1992) <sup>(162)</sup> US	Dentistry (student)	1991	1990–1991	125	85 (68)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : Yes IPC breaches <sup>E</sup> : NR
Taylor (1992) <sup>(399)</sup> US	Dentistry (student)	1991	1991	47	NR	Symptomatic <sup>C</sup> : NR <sup>I</sup> Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Cottone (1992) <sup>(163)</sup> US	Dentistry (student)	1991	1991	26	26 (100)	Symptomatic <sup>C</sup> : No Aware of status <sup>D</sup> : Yes IPC breaches <sup>E</sup> : No
York (1993) <sup>(160)</sup> US	Dentistry	NR	NR	1339	854 (64)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
York (1993) <sup>(160)</sup> US	Dentistry	NR	NR	603	495 (82)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
York (1993) <sup>(160)</sup> US	Dentistry	NR	NR	945	690 (73)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
Rogers (1993) <sup>F (159)</sup> Companion <sup>H</sup> : (400) US	Surgery	NR	1984–1990	1131	413 (37)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : Yes IPC breaches <sup>E</sup> : No
Arnow (1993) <sup>(164)</sup>	Dentistry	1990	1988–1990	88	41 (47)	Symptomatic <sup>C</sup> : NR

Author (publication year) Country	Specialty	Year diagnosed	Screening period <sup>A</sup>	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)	HCW risk factors <sup>B</sup>
US						Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : No
Dickinson (1993) <sup>F (74)</sup> US	Dentistry	1991	1985–1991	1192	900 (76)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : No
von Reyn (1993) <sup>F (73)</sup> US	Orthopedic surgery	1991	1978–1991	2317	1174 (51)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : No
Longfield (1994) <sup>(165)</sup> US	Pediatric dentistry	1991	1988–1991	1489	966 (65)	Symptomatic <sup>C</sup> : No Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : No
Babinchak (1994) <sup>F (177)</sup> US	Cardiothoracic surgery	NR	1984–1986	612	189 (31)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Crawshaw (1994) <sup>F (169)</sup> UK	Obstetrics and gynecology (trainee)	1990	NR	1217	520 (43)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
Jaffe (1994) <sup>F (166)</sup> US	Dentistry	1988	1986–1991	6474	1279 (20)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : Yes IPC breaches <sup>E</sup> : Yes
Bek (1994) <sup>(170)</sup> Australia	Obstetrics and gynecology	1994	1992–1994	149	134 (90)	Symptomatic <sup>C</sup> : No Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
Hochuli (1995) <sup>F (171)</sup> UK	Obstetrics and gynecology	1993	1983–1993	4594	1206 (26)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Pell (1996) <sup>F (175)</sup> Scotland	Multiple specialties 'junior doctor'	1993	NR	441	15 (3)	Symptomatic <sup>C</sup> : Yes <sup>J</sup> Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Pell (1996) <sup>F (175)</sup> Scotland	Ear, nose and throat surgery	1994	1984–1994	677	18 (3)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHLS (1997) <sup>(401)</sup> UK	Emergency Obstetrics and gynecology	NR	1996–1997	38	NR	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Donnelly (1999) <sup>F (172)</sup> UK	Obstetrics and gynecology 'junior doctor'	1997	1991–1997	1852	1180 (64)	Symptomatic <sup>C</sup> : No Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR
Robinson (2000) <sup>(167)</sup> UK	Dentistry	NR	NR	449	191 (43)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Irwin (2002) <sup>(168)</sup>	Dentistry	2000	1988–2000	5929	3096 (52)	Symptomatic <sup>C</sup> : NR

Author (publication year) Country	Specialty	Year diagnosed	Screening period <sup>A</sup>	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)	HCW risk factors <sup>B</sup>
UK						Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
CHU Ste-Justine (2004) <sup>F (155)</sup> Companion <sup>H</sup> : (402) Canada	Pediatric general surgery	NR	1990–2003	2668	2175 (82)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : Yes IPC breaches <sup>E</sup> : NR
PHE (2004) <sup>K (63)</sup> UK	Dentistry	NR	NR	NR	NR	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2006) <sup>K (234)</sup> UK	Dentistry	NR	NR	NR	NR	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2006) <sup>K (234)</sup> UK	Ear, nose, and throat surgery	NR	NR	NR	NR	Symptomatic <sup>C</sup> : Compatible with HIV Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2006) <sup>K (234)</sup> UK	Orthopedic surgery	NR	NR	NR	NR	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2006) <sup>K (234)</sup> UK	Orthopedic surgery	NR	NR	NR	NR	Symptomatic <sup>C</sup> : No <sup>L</sup> Aware of status <sup>D</sup> : No <sup>L</sup> IPC breaches <sup>E</sup> : NR
CDC (2009) <sup>F (178)</sup> Israel	Cardiothoracic surgery	2007	1997–2007	1669	545 (33)	Symptomatic <sup>C</sup> : Yes Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : No
PHE (2010) <sup>K (173)</sup> UK	Obstetrics and gynecology	NR	NR	292	253 (87)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2010) <sup>K (173)</sup> UK	Obstetrics and gynecology	NR	NR	2	2 (100)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2010) <sup>K (173)</sup> UK	Theatre scrub nursing	NR	NR	20	9 (45)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2010) <sup>K (173)</sup> UK	Obstetrics and gynecology	NR	NR	552	451 (82)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2010) <sup>K (173)</sup> UK	Surgery (trainee)	NR	NR	27	19 (70)	Symptomatic : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR

Author (publication year) Country	Specialty	Year diagnosed	Screening period <sup>A</sup>	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)	HCW risk factors <sup>B</sup>
PHE (2010) <sup>K (173)</sup> UK	Surgery (trainee)	NR	NR	1	0 (0)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
PHE (2010) <sup>K (173)</sup> UK	Obstetrics and gynecology	NR	NR	48	26 (54)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Donohue (2012) <sup>(156)</sup> Ireland	Community services	NR	2003–2006	66	61 (92)	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : NR
Lam (2014) <sup>F (176)</sup> Hong Kong	Surgery	2012	2010–2012	143	132 (92)	Symptomatic <sup>C</sup> : Compatible with HIV Aware of status <sup>D</sup> : NR IPC breaches <sup>E</sup> : No
Bodkin (2017) <sup>(403)</sup> Companions <sup>H</sup> : (404–406) UK	Orthopedic surgery and Emergency	NR	2010–2015	400	NR	Symptomatic <sup>C</sup> : NR Aware of status <sup>D</sup> : No IPC breaches <sup>E</sup> : NR

Abbreviations: HIV, human immunodeficiency virus; HCW, healthcare worker; NR, not reported; IPC, infection prevention and control; HBV, hepatitis B virus; PHE, Public Health England

<sup>A</sup> Screening period: Time span selected by the investigators to screen patients.

<sup>B</sup> HCW risk factors reported to be present at any point during the screening period.

<sup>C</sup> Indicates whether the HCW was symptomatic at any point during the screening period. Where the article described the HCW's clinical symptoms but did not clearly state that they were linked to the HIV infection, experts reviewed the information provided to determine whether the HCW's symptoms were compatible with an HIV infection. If so, a response of "Compatible with HIV" was recorded.

<sup>D</sup> Indicates whether the HCW was aware of their HIV-positive serologic status at any time during the screening period. If the article stated that the HCW was aware of their serologic status but it was unclear when they became aware of it, a response of "NR" was recorded.

<sup>E</sup> Indicates whether IPC breaches were identified. A response of "Yes" may also indicate any of the following: 1) there was a lack of adherence to standard IPC practices and protocols; or 2) the Guideline Development Task Group determined that by current standards, an IPC breach was present. A response of "No" indicates that an independent review of the HCW's practice was undertaken with no IPC breaches noted.

<sup>F</sup> Article met the eligibility criteria for data extraction to inform the systematic review on the risk for transmission of HIV from infected HCWs to patients.

<sup>G</sup> The severe dermatitis on the HCW's hands contributed to the decision to investigate potential transmission of HIV to his patients.

<sup>H</sup> Articles identified as companion articles provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.

<sup>I</sup> HCW with HIV-HBV co-infection.

<sup>J</sup> Article reported on this HCW risk factor but did not report on the screening period. As a result, it is unclear if the HCW risk factor existed during the time span selected for screening potentially exposed patients.

<sup>K</sup> Investigations providing information on HCW risk factors and/or data on number of exposed and tested patients are included in this table. In the UK, HCWs infected with HIV were restricted from performing any exposure-prone procedures until 2014<sup>(190,393)</sup>. Public Health England reports that there were 39 investigations related to HCWs infected with HIV between 1998 and 2008 in the UK with no evidence of transmission<sup>(190)</sup>. Higher-risk exposure-prone procedures, where theatre scrub nurses infected with HIV had acted as first assistants, were a part of these investigations but were excluded from this table as no relevant information was reported<sup>(63,173,234)</sup>.

<sup>L</sup> HCW with HIV-HBV co-infection identified as a result of screening.

**Table 22: Epidemiologic investigations reporting transmission of HCV from infected HCW to patient<sup>A</sup>**

Author (publication year) Country	Specialty	EPPs	Year diagnosed	Index cases (n)	Screening period <sup>B</sup>	Number of patients potentially exposed <sup>C</sup>	Number of patients tested <sup>C</sup> (% of potentially exposed)	Number of patients infected <sup>D</sup>	Transmission rate (%) <sup>E</sup>	HCW risk factors <sup>F</sup>
Esteban (1996) <sup>G (109)</sup> Spain	Cardiothoracic surgery	Yes	1991	2	1988–1994	643	222 (35)	5	2.23 (C)	Symptomatic <sup>H</sup> : No Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : No
Duckworth (1999) <sup>G (112)</sup> Companion <sup>K</sup> : (407) UK	Cardiothoracic surgery	Yes	1993	1	1993–1995	352	277 (79)	1	0.36 (R) 0.36 (C)	Symptomatic <sup>H</sup> : No Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : NR
PHLS (1999) <sup>G (227)</sup> Companions <sup>K</sup> : (120,408) UK	Obstetrics and gynecology	Yes	1997	1	1978–1999	1500	NR	3	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : NR
PHLS (2000) <sup>(120)</sup> UK	Surgery	Yes	NR	2	1995–1999	2000	NR	2	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : NR
PHLS (2000) <sup>(228)</sup> UK	Surgery	Yes	NR	1	1995–1999	723	NR	1	NR	Symptomatic <sup>H</sup> : No Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : NR
Ross (2000a) <sup>G, (136)</sup> Companion <sup>K</sup> : (409) Germany	Anesthesiology (nurse assistant)	No	1998	4	1998	39	NR	5	NR	Symptomatic <sup>H</sup> : Yes Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : Yes <sup>L</sup>
PHLS (2001) <sup>(229)</sup> UK	Surgery	Yes	2001	1	NR	228	NR	1	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : NR
Cody (2002) <sup>G (137)</sup> Companion <sup>K</sup> : (410) US	Anesthesiology	No	1996	1	1995–1997 <sup>M</sup>	782	348 (45)	1	0.29% (C)	Symptomatic <sup>H</sup> : Yes <sup>M</sup> Aware of status <sup>I</sup> : Yes <sup>M</sup> IPC breaches <sup>J</sup> : Yes
Ross (2002a) <sup>G (118)</sup> Germany	Obstetrics and gynecology	Yes	1997	1	1993–2000	2907	2285 (79)	1	0.04 (R) 0.04 (C)	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : No
Ross (2002b) <sup>G (75)</sup> Germany	Orthopedic surgery	Yes	NR	0	1999–2000	229	207 (90)	1	0.48 (R) 0.48 (C)	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : No
Williams (2004) <sup>(219)</sup> US	Cardiac surgery	Yes	NR	NR	NR	NR	937	14	1.49 (C)	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : NR
PHE (2004) <sup>N (63)</sup> Companion <sup>K</sup> : (234) UK	Obstetrics and gynecology	Yes	NR	1	1987–NR	NR	NR	3	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : NR
PHLS (2005) <sup>(230)</sup> England and Scotland	NR	Yes	NR	1	NR	2851	NR	1	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : NR

Author (publication year) Country	Specialty	EPPs	Year diagnosed	Index cases (n)	Screening period <sup>B</sup>	Number of patients potentially exposed <sup>C</sup>	Number of patients tested <sup>C</sup> (% of potentially exposed)	Number of patients infected <sup>D</sup>	Transmission rate (%) <sup>E</sup>	HCW risk factors <sup>F</sup>
Mawdsley (2005) <sup>G (31)</sup> Companion <sup>K</sup> : (345) England	Anesthesiology	No	NR	1	None	NA	NA	1	NA	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : No
PHE (2006) <sup>N (234)</sup> UK	Obstetrics and gynecology	Yes	NR	0	1981–NR	NR	NR	3	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : NR IPC breaches <sup>J</sup> : NR
Stark (2006) <sup>G (138)</sup> Germany	Anesthesiology	No	2001	3	NR	1261	476 (38)	3	0.63 (C)	Symptomatic <sup>H</sup> : No Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : Yes
Lot(2007) <sup>G (50)</sup> France	NR	No <sup>O</sup>	NR	1	1978–1997	2700	NR	1	NR	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : Yes
Cardell (2008) <sup>G (113)</sup> Sweden	Thoracic surgery	Yes	1993	2	None	NA	NA	2	NA	Symptomatic <sup>H</sup> : No Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : NR
Ross (2008) <sup>G (231)</sup> Germany	General surgery	Yes	2002	1	2002–2005	1461	1193 (82)	1	0.08 (C)	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : NR
Olsen (2010) <sup>G (76)</sup> Norway	Cardiothoracic surgery	Yes	2007	0	2004–2007	270	270 (100)	10	3.7 (R) 3.7 (C)	Symptomatic <sup>H</sup> : No Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : No
Bourigault (2011) <sup>G (134)</sup> France	Home care nursing	No	2009	1	None	NA	NA	1	NA	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : NR
Roy (2012) <sup>G (140)</sup> Spain	Hemodialysis	No	2010 <sup>P</sup>	2	Aug.-Nov. 2010	48	44 <sup>O</sup> (92)	2	4.4 (C)	Symptomatic : NR Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : Yes
Rutherford (2013) <sup>(78)</sup> Wales and other UK	Obstetrics/ gynecology	NR	NR	2	1984–2003	>5500	3311 (~60)	4	0.12 (C)	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : No IPC breaches <sup>J</sup> : NR
Muir (2013) <sup>G (135)</sup> England	Midwifery	No	NR	1	NR	41	19 (46)	1	5.0 (C)	Symptomatic <sup>H</sup> : NR Aware of status <sup>I</sup> : Yes IPC breaches <sup>J</sup> : NR

Abbreviations: HCV, hepatitis C virus; HCW, healthcare worker; EPP, exposure-prone procedure; C, calculated; IPC, infection prevention and control; R, reported; NR, not reported; PHE, Public Health England; UKAP, United Kingdom Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses; NA, not applicable

<sup>A</sup> Epidemiologic investigations that reported illicit diversion of patient medication by a HCW infected with HCV have been excluded from this table.

<sup>B</sup> Screening period: Time span selected by the investigators to screen patients.

<sup>C</sup> Number excludes index case(s).

<sup>D</sup> Includes index case(s); confirmation tests for transmission include phylogenetic analysis, genotyping, or other epidemiologic evidence of transmission during surgery.

<sup>E</sup> Transmission rate as reported in the study (R) or calculated by reviewer (C); formula for calculated transmission rate= [number of infected/(number of tested + index case)]\*100.

<sup>F</sup> HCW risk factors reported to be present at any point during the screening period.

<sup>G</sup> Article met the eligibility criteria for data extraction to inform the systematic review of HCV exposure incidents with HCW to patient transmission.

<sup>H</sup> Indicates whether the HCW was symptomatic at any point during the screening period. Where the article described the HCW's clinical symptoms but did not clearly state that they were linked to the HCV infection, experts reviewed the information provided to determine whether the HCW's symptoms were compatible with an HCV infection. If so, a response of "Compatible with HCV" was recorded.

<sup>I</sup> Indicates whether the HCW was aware of their HCV-positive serologic status at any time during the screening period. If the article stated that the HCW was aware of their serologic status but it was unclear when they became aware of it, a response of "NR" was recorded.

<sup>J</sup> Indicates whether IPC breaches were identified. A response of "Yes" may also indicate any of the following: 1) there was a lack of adherence to standard IPC practices and protocols; or 2) the Guideline Development Team and/or the Task Group determined that by current standards, an IPC breach was present. A response of "No" indicates that an independent review of the HCW's practice was undertaken with no IPC breaches noted.

<sup>K</sup> Articles identified as companion articles provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.

<sup>L</sup> Ross *et al.* (2000a) reported that the HCW did not wear gloves and had a weeping wound on a finger of his right hand which bled repeatedly and was not covered during the provision of care to patients<sup>(136)</sup>.

<sup>M</sup> Two separate lookback investigations for the same infected HCW have been combined. The first investigation involved testing of potentially exposed patients in the 6 months before the HCW's acute illness. The HCW was not aware of their serologic status and was symptomatic during the screening period (1995). The second investigation involved testing of potentially exposed patients in the 18 months following unsuccessful treatment for hepatitis C infection (1996 to 1997).

<sup>N</sup> Investigations providing information on HCW risk factors and/or data on number of exposed and/or tested patients are included in this table. In the United Kingdom, HCV RNA positive HCWs are restricted from performing EPPs unless they have been successfully treated<sup>(411)</sup>. Since 2005, if no evidence of transmission of HCV or other risk factor increasing risk of transmission from an HCV-infected HCW is present, the UKAP does not recommend that patients be notified or tested<sup>(173)</sup>.

<sup>O</sup> The infected HCW's specialty is not described however it is reported that his atopic eczema prevented him from wearing gloves systematically. Based on this information, it was determined that cardiothoracic surgery was not the procedure where transmission occurred. Note that several HCWs were tested including a surgeon, 4 nurses, 2 cardiopulmonary bypass technicians, 2 surgical assistants and 4 anesthesiologists.

<sup>P</sup> HCW was diagnosed as HCV positive in 2006 but had a subsequent negative PCR result. In 2010, the HCW's viral load was  $2.4 \times 10^6$  IU/mL.

<sup>Q</sup> Four of the 48 potentially exposed patients were known to be infected with HCV.



**Table 23: Epidemiologic investigations reporting no transmission of HCV from infected HCW to patient<sup>A</sup>**

Author (publication year) Country	Specialty	Year diagnosed	Screening period <sup>B</sup>	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)	HCW risk factors <sup>C</sup>
Saginur (2001) <sup>D (51)</sup> Canada	Healthcare technology	1993 <sup>E</sup>	1992–1993	498	215 (43)	Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : No IPC breaches <sup>H</sup> : NR <sup>I</sup>
Ross (2003) <sup>(235)</sup> Germany	Orthopedic surgery	NR	1996–2001	1513	1068 (71)	Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : NR IPC breaches <sup>H</sup> : NR
PHE (2004) <sup>J (63)</sup> UK	Obstetrics and gynecology and other	NR	NR	2500 <sup>K</sup>	1562 <sup>K</sup>	Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : NR IPC breaches <sup>H</sup> : NR
PHE (2006) <sup>J (234)</sup> UK	Dentistry	NR	NR	NR	NR	Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : NR IPC breaches <sup>H</sup> : Yes
PHE (2010) <sup>J (173)</sup> UK	Acupuncture	NR	NR	NR	5	Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : NR IPC breaches <sup>H</sup> : Yes
Mason (2008) <sup>D (233)</sup> Companion <sup>L</sup> : (412) Wales	Dental surgery	2005 <sup>M</sup>	1969–2005	5054 <sup>M</sup>	2665 (53)	Symptomatic <sup>F</sup> : NR <sup>M</sup> Aware of status <sup>G</sup> : No IPC breaches <sup>H</sup> : Yes
Dawar (2010) <sup>D (77)</sup> Canada	General surgery	2007	2004–2007	272	228 (84)	Symptomatic <sup>F</sup> : No Aware of status <sup>G</sup> : No IPC breaches <sup>H</sup> : NR

Abbreviations: HCV, hepatitis C virus; HCW, healthcare worker; NR, not reported; IPC, infection prevention and control; PHE, Public Health England; UKAP, United Kingdom Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses

<sup>A</sup> Epidemiologic investigations that reported illicit drug use by an HCV-infected HCW have been excluded from this table. The HCV component of the epidemiologic investigation reported in Astagneau *et al.* (2002)<sup>(32)</sup> has also been excluded from this table as no viral sequencing and analysis of risk factors was undertaken for the 43 HCV-positive patients that were identified.

<sup>B</sup> Screening period: Time span selected by the investigators to screen patients.

<sup>C</sup> HCW risk factors reported to be present at any point during the screening period.

<sup>D</sup> Article met the eligibility criteria for data extraction to inform the systematic review on the risk for transmission of HCV from infected HCWs to patients.

<sup>E</sup> Although diagnosed in 2003, a stored sample of blood from April 1991, when the HCW was first denied for blood donation, was seropositive for HCV.

<sup>F</sup> Indicates whether the HCW was symptomatic at any point during the screening period. Where the article described the HCW's clinical symptoms but did not clearly state that they were linked to the HCV infection, experts reviewed the information provided to determine whether the HCW's symptoms were compatible with an HCV infection. If so, a response of 'Compatible with HCV' was recorded.

<sup>G</sup> Indicates whether the HCW was aware of their HCV-positive serologic status at any point during the screening period. If the article stated that the HCW was aware of their serologic status but it was unclear when they became aware of it, a response of 'NR' was recorded.

<sup>H</sup> Indicates whether IPC breaches were identified. A response of 'Yes' may also indicate any of the following: 1) there was a lack of adherence to standard IPC practices and protocols; or 2) the Guideline Development Team and/or the Task Group determined that by current standards, an IPC breach was present. A response of 'No' indicates that an independent review of the HCW's practice was undertaken with no IPC breaches noted.

<sup>I</sup> IPC breaches were reported during the research project which led to transmission however there was no report of IPC breach related to the HCW's practice during patient care.

<sup>J</sup> Investigations providing information on HCW risk factors and/or data on number of exposed and/or tested patients are included in this table. In the United Kingdom, HCV RNA positive HCWs are restricted from performing exposure-prone procedures unless they have been successfully treated<sup>(411)</sup>. Since 2005, if no evidence of transmission of HCV or other risk factor increasing risk of transmission from a HCW infected with HCV is present, the UKAP does not recommend that patients be notified or tested<sup>(173)</sup>.

<sup>K</sup> Staged lookback investigations related to the practices of 5 infected HCWs were recommended by the UKAP. These involved the last 500 patients who had undergone higher risk exposure-prone procedures. One of the investigations identified infected patients after the 2004 report was published. The numbers of patients potentially exposed and tested, prior to the identification of an infected patient, are included in this table. This investigation has also been included in Table 22, Epidemiologic investigations reporting transmission of HCV from infected HCW to patient with the numbers of potentially exposed and tested patients indicated as 'NR'.

<sup>L</sup> Companion articles provide supplementary information about the specific epidemiologic investigation. Where such articles exist, the additional information is included in the table.

<sup>M</sup> Information obtained from Charles *et al.* (2007)<sup>(412)</sup>. In October 2005, the HCW was being investigated for 'unspecified ill health' and stopped work immediately.

**Table 24: Epidemiologic investigations reporting transmission of HBV from infected HCW to patient<sup>A</sup>**

Author (publication year) Country	Specialty	EPPs	Year diagnosed	Index cases (n)	Screening period <sup>B</sup>	Number of patients potentially exposed <sup>C</sup>	Number of patients tested <sup>C</sup> (% of potentially exposed)	Number of patients infected <sup>D</sup>	Transmission rate (%) <sup>E</sup>	HCW risk factors <sup>F</sup>
Shaw (1986) <sup>G (130)</sup> US	Dentistry	Yes	1984	4	1983– 1984	1,413	1,123 (80)	Confirmed <sup>H</sup> : 24 Undetermined <sup>I</sup> : NR	2.12 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : Yes
Polakoff (1986) <sup>G (288)</sup> UK	Perfusion technology	No	NR	0	1980– 1983	NR	NR	Confirmed <sup>H</sup> : 6 Undetermined <sup>I</sup> : NR	NA	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : Yes
Polakoff (1986) <sup>G (288)</sup> UK	Cardiac surgery	Yes	NR	0	1980– 1983	NR	NR	Confirmed <sup>H</sup> : 5 Undetermined <sup>I</sup> : NR	NA	HBeAg: NR Symptomatic <sup>J</sup> : Yes Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
Lettau (1986) <sup>G (286)</sup> US	Obstetrics and gynecology	Yes	1983	2	1983– 1984	274	207 (76)	Confirmed <sup>H</sup> : 6 Undetermined <sup>I</sup> : 5	2.87 C	HBeAg: Positive Symptomatic <sup>J</sup> : Yes Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : NR
Welch (1989) <sup>G (281)</sup> UK	Gynecology	Yes	1987	3	1985– 1987	268	247 (92)	Confirmed <sup>H</sup> : 22 Undetermined <sup>I</sup> : 14	8.8 C	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
Prendergast (1991) <sup>G (289)</sup> US	Surgery	Yes	NR	2	None	NA	NA	Confirmed <sup>H</sup> : 5 Undetermined <sup>I</sup> : NR	NA	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : No
Johnston (1992) <sup>G (70)</sup> Companion <sup>M (284)</sup> Canada	Orthopedic surgery	Yes	1986	2	1986– 1991	1,691	1,532 (91)	Confirmed <sup>H</sup> : 4 Undetermined <sup>I</sup> : NR	0.26 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : No
Prentice (1992) <sup>G (110)</sup> UK	Cardiothoracic surgery	Yes	1988	2	1987– 1988	361	280 (78)	Confirmed <sup>H</sup> : 17 Undetermined <sup>I</sup> : NR	6.03 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
Zuckerman (1995) <sup>(413)</sup> UK	Surgery	NR	1975	1	None	NA	NA	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : NR	NA	HBeAg: Not detected Symptomatic <sup>J</sup> : Yes Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
The Incident Control Teams and Others (1996) <sup>G (41)</sup> UK	Cardiothoracic surgery	Yes	NR	3 <sup>N</sup>	1992– 1993	374 <sup>O</sup>	307 (82)	Confirmed <sup>H</sup> : 20 <sup>N</sup> Undetermined <sup>I</sup> : NR	6.45 C	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : Yes <sup>P</sup> IPC breaches <sup>L</sup> : NR

Author (publication year) Country	Specialty	EPPs	Year diagnosed	Index cases (n)	Screening period <sup>B</sup>	Number of patients potentially exposed <sup>C</sup>	Number of patients tested <sup>C</sup> (% of potentially exposed)	Number of patients infected <sup>D</sup>	Transmission rate (%) <sup>E</sup>	HCW risk factors <sup>F</sup>
Mukerjee (1996) <sup>G</sup> (122) UK	General surgery	Yes	NR	0	NR	59	59 (100)	Confirmed <sup>H</sup> : 2 Undetermined <sup>I</sup> : NR	3.39 C	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
Harpaz (1996) <sup>G</sup> (111) US	Thoracic surgery	Yes	1992	1	1991– 1992	239	170 (71)	Confirmed <sup>H</sup> : 19 Undetermined <sup>I</sup> : NR	11.11 C	HBeAg: Positive Symptomatic <sup>J</sup> : Yes Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : No
The Incident Investigation Teams and Others (1997) <sup>G</sup> (119) UK	General surgery (HCW 1)	Yes	1988	1	None	NA	NA	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : NR	NA	HBeAg: Negative <sup>Q</sup> Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : No
	Obstetrics and gynecology (HCW 2)	Yes	1993	1	NR	104	91 (88)	Confirmed <sup>H</sup> : 3 Undetermined <sup>I</sup> : 0	3.26 C	HBeAg: Negative <sup>Q</sup> Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : No
	Obstetrics and gynecology (HCW 3)	Yes	1989	1	NR	114	110 (96)	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : 4	0.90 C	HBeAg: Negative <sup>R</sup> Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : No
	General surgery and urology (HCW 4)	Yes	1995	1	NR	21	20 (95)	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : 0	4.76 C	HBeAg: Negative <sup>Q</sup> Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : No
Sundkvist (1998) <sup>G</sup> (115) Companion <sup>M</sup> (414) UK	Orthopedic surgery	Yes	1995	1	1995– 1996	252	188 (75)	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : 0	0.53 C	HBeAg: Negative <sup>Q</sup> Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : NR
Walsh (1999) <sup>G</sup> (131) UK	Acupuncture	No	1989	3	1989– 1992	890	290 (33)	Confirmed <sup>H</sup> : 3 Undetermined <sup>I</sup> : 9	1.02 C	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : Yes
Oliver (1999) <sup>G</sup> (123) UK	Surgery (HCW 1)	Yes	1994	1	1993– 1994	583 <sup>S</sup>	538 (92)	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : 10	0.19 C	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
	Surgery (HCW 2)	Yes	1994	0	1993– 1994	133 <sup>T</sup>	112 (84)	Confirmed <sup>H</sup> : 0 Undetermined <sup>I</sup> : 2	NA	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
	Urology (HCW 3)	Yes	1994	0	1994	61 <sup>U</sup>	48 (79)	Confirmed <sup>H</sup> : 0 Undetermined <sup>I</sup> : 1	NA	HBeAg: Positive Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR

Author (publication year) Country	Specialty	EPPs	Year diagnosed	Index cases (n)	Screening period <sup>B</sup>	Number of patients potentially exposed <sup>C</sup>	Number of patients tested <sup>C</sup> (% of potentially exposed)	Number of patients infected <sup>D</sup>	Transmission rate (%) <sup>E</sup>	HCW risk factors <sup>F</sup>
Hepatitis B Outbreak Investigation Team (2000) <sup>G</sup> (132) Canada	Healthcare technology	No	1996	1	1990– 1996	18,567	10,244 (55)	Confirmed <sup>H</sup> : 75 Undetermined <sup>I</sup> : NR	0.73 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : Yes
Molyneaux (2000) <sup>G</sup> (114) Scotland	Cardiothoracic surgery	Yes	NR	1	1998– 1999	126	123 (98)	Confirmed <sup>H</sup> : 2 Undetermined <sup>I</sup> : 0	1.61 C	HBeAg: Negative <sup>Q</sup> Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : NR
Spijkerman (2002) <sup>G</sup> (121) Netherlands	General surgery	Yes	1999	3	1995– 1999	1,803	1,564 (87)	Confirmed <sup>H</sup> : 9 Undetermined <sup>I</sup> : 18	0.57 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : No
Smellie (2006) <sup>G</sup> (133) UK	Surgery house officer	No	1998	2	1997	4,948	3,150 (64)	Confirmed <sup>H</sup> : 2 Undetermined <sup>I</sup> : 0	0.06 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : Yes
Laurenson (2007) <sup>G</sup> (124) UK	General surgery	Yes	2001	2	NR	NR	NR	Confirmed <sup>H</sup> : 3 Undetermined <sup>I</sup> : 0	NA	HBeAg: Negative Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : NR
Poujol (2008) <sup>G</sup> (139) Companion <sup>M</sup> (290) France	Anesthesia nursing	No	1992	1	NR	2,473	1,654 (67)	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : 0	0.06 C	HBeAg: Negative <sup>V</sup> Symptomatic <sup>J</sup> : NR Aware of status <sup>K</sup> : Yes IPC breaches <sup>L</sup> : Yes
Enfield (2013) <sup>G</sup> (116) US	Orthopedic surgery	Yes	2009	0	NR	328	232 (71)	Confirmed <sup>H</sup> : 2 Undetermined <sup>I</sup> : 6	0.86 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : No
Sugimoto (2013) <sup>G</sup> (287) Japan	Gynecologic surgery	Yes	2010	1	2006– 2010	777	62 (8)	Confirmed <sup>H</sup> : 1 Undetermined <sup>I</sup> : NR	0.18 C	HBeAg: Positive Symptomatic <sup>J</sup> : No Aware of status <sup>K</sup> : No IPC breaches <sup>L</sup> : No

Abbreviations: HBV, hepatitis B virus; HCW, healthcare worker; EPP, exposure-prone procedure; HBeAg, hepatitis B e-antigen; IPC, infection prevention and control; NR, not reported; C, calculated; NA, not applicable; PEP, post-exposure prophylaxis

<sup>A</sup> Only articles published in 1992 or later are included as well as articles identified as part of the systematic review of the literature for risk of transmission of HBV from infected HCWs to patients.

<sup>B</sup> Screening period: Time span selected by the investigators to screen patients.

<sup>C</sup> Number excludes index case(s).

<sup>D</sup> Includes index case(s); confirmation test for transmission include phylogenetic analysis, genotyping, or other epidemiologic evidence of transmission during surgery.

<sup>E</sup> Transmission rate as reported in the study (R) or calculated by reviewer (C); formula for calculated transmission rate= [number of confirmed infected/(number of tested + index case)]\*100

<sup>F</sup> HCW risk factors reported to be present at any point during the screening period.

<sup>G</sup> Article met the eligibility criteria for data extraction to inform the systematic review of HBV exposure incidents with HCW to patient transmission.

<sup>H</sup> Confirmed cases are: 1) Patients with a temporally-related active HBV infection that is genetically linked to the HBV-infected HCW; or 2) Patients with a serologic evidence of a previous infection consistent with timing of exposure or evidence of pre-exposure seronegative status; or 3) Reported as confirmed transmission cases by the authors.

- <sup>I</sup> Undetermined cases: 1) Reported as undetermined by the authors; 2) serologic evidence of a previous infection with no evidence of pre-exposure seronegative status or no lifetime risk factors; or 3) no lookback investigation for sub-clinical infection was performed.
- <sup>J</sup> Indicates whether the HCW was symptomatic at any point during the screening period. Where the article described the HCW's clinical symptoms but did not clearly state that they were linked to the HBV infection, experts reviewed the information provided to determine whether the HCW's symptoms were compatible with an HBV infection. If so, a response of "Compatible with HBV" was recorded.
- <sup>K</sup> Indicates whether the HCW was aware of their HBV-positive serologic status at any time during the screening period. If the article stated that the HCW was aware of their serologic status but it was unclear when they became aware of it, a response of "Not reported" (NR) was recorded.
- <sup>L</sup> Indicates whether IPC breaches were identified. A response of 'Yes' may also indicate any of the following: 1) there was a lack of adherence to standard IPC practices and protocols; or 2) the Guideline Development Team and/or the Task Group determined that by current standards, an IPC breach was present. A response of 'No' indicates that an independent review of the HCW's practice was undertaken with no IPC breaches noted.
- <sup>M</sup> Articles identified as companion articles provide supplementary information about the specific epidemiologic investigation included in the systematic review. Where such articles exist, the additional information is included in the table.
- <sup>N</sup> Includes the cases related to both clusters but excludes one case of secondary transmission identified in the first cluster.
- <sup>O</sup> Number applies to investigation of second cluster only.
- <sup>P</sup> The HCW was linked to both the first and second cluster when it was determined (during the second investigation) that the HCW had provided a blood sample taken from another person during the investigation for the first cluster. The HCW served a custodial sentence and was removed from the Medical Register.
- <sup>Q</sup> Positive for hepatitis Be antibodies.
- <sup>R</sup> Negative for hepatitis Be antibodies.
- <sup>S</sup> Ninety-nine potentially exposed patients received PEP.
- <sup>T</sup> Eleven potentially exposed patients received PEP.
- <sup>U</sup> Eighteen potentially exposed patients received PEP.
- <sup>V</sup> Hepatitis B e-antibody status was not reported.

**Table 25: Epidemiologic investigations reporting no transmission of HBV from infected HCW to patient<sup>A</sup>**

Author (publication year) Country	Specialty	Year diagnosed	Screening period <sup>B</sup>	Number of patients potentially exposed	Number of patients tested (% of potentially exposed)	HCW risk factors <sup>C</sup>
Labrecque (1986) <sup>D, E (280)</sup> US	Surgery (HCW 1)	NR	NR	NR	NR	HBeAg: Positive Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : Yes IPC breaches <sup>H</sup> : NR
Labrecque (1986) <sup>D, E (280)</sup> US	Surgery (HCW 2)	NR	NR	NR	NR	HBeAg: Negative Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : Yes IPC breaches <sup>H</sup> : NR
Mukerjee (1996) <sup>D (122)</sup> UK	Orthopedic surgery	NR	NR	17 <sup>I</sup>	17 (100)	HBeAg: Positive Symptomatic <sup>F</sup> : NR Aware of status <sup>G</sup> : No IPC breaches <sup>H</sup> : NR

Abbreviations: HBV, hepatitis B virus; HCW, healthcare worker; NR, not reported; HBeAg, hepatitis B e-antigen; IPC, infection prevention and control; ICU, intensive care unit

<sup>A</sup> Only articles published in 1992 or later are included as well as articles identified as part of the systematic review of the literature for risk of transmission of HBV from infected HCWs to patients.

<sup>B</sup> Time span selected by the investigators to screen patients.

<sup>C</sup> HCW risk factors reported to be present at any point during the screening period.

<sup>D</sup> Article met the eligibility criteria for data extraction to inform the systematic review on the risk for transmission of HBV from infected HCWs to patients.

<sup>E</sup> Prospective study of patients of 9 HBV-infected HCWs, 6 with chronic infection (2 surgeons, 1 dialysis nurse, 1 pediatric ICU nurse, 1 pharmacist and 1 orderly) and 3 with acute infection (1 dental technician, 1 ICU nurse and 1 medical student) over a 30-month period. Only the information related to the two surgeons is contained in this table. The results of the study were pooled for all patients (n=246) and for all exposures (n=483) with no evidence of transmission identified.

<sup>F</sup> Indicates whether the HCW was symptomatic at any point during the screening period.

<sup>G</sup> Indicates whether the HCW was aware of their HBV-positive serologic status at any point during the screening period.

<sup>H</sup> Indicates whether IPC breaches were identified.

<sup>I</sup> Potentially exposed patients were offered post-exposure prophylaxis if the time since potential exposure was within the incubation period for HBV infection.

**Table 26: Descriptions for HBV serologic markers**

<b>Serologic Marker</b>	<b>Description</b>
<b>HBsAg</b>	This is detected during the first 3 to 5 weeks after infection, but may take up to 9 weeks to be detectable <sup>(270)</sup> . The presence of HBsAg indicates that the person is infected but does not indicate level of infectivity. Persistence of HBsAg for 6 months or more indicates chronic infection <sup>(415)</sup> . Spontaneous resolution of the infection with clearance of HBsAg occurs in 0.1 to 0.8% of chronic carriers annually <sup>(416-421)</sup> . Those with resolving acute HBV will clear HBsAg several months after initial infection <sup>(212)</sup> .
<b>Anti-HBs</b>	The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B <sup>(270)</sup> .
<b>Anti-HBc total</b>	The presence of anti-HBc (IgG or IgM and IgG) indicates previous or ongoing infection with HBV <sup>(270)</sup> .
<b>Anti-HBc IgM</b>	Anti-HBc IgM appears early in acute HBV infection and persists for about 6 months <sup>(270)</sup> . It may also be seen in chronic infection during flares of activity, so clinical / epidemiological correlation is required for interpretation <sup>(62,270)</sup> .
<b>Anti-HBc IgG</b>	Anti-HBc IgG appears shortly after infection and usually persists for life in the majority of persons, sometimes showing up as the antibodies to all other proteins fade <sup>(62)</sup> .
<b>HBeAg</b>	This is a secreted product of the nucleocapsid gene of HBV that is found in the serum during acute and chronic HBV infection <sup>(270)</sup> . It is a marker of active viral replication and its presence indicates high infectivity <sup>(62,237,270)</sup> . Some individuals infected with HBV, carry a viral strain with a nucleotide substitution in the precore region of the viral genome. This mutation prevents transcription of the precore region and therefore, the release of HBeAg from the hepatocyte which results in a negative serum test for HBeAg. This mutation is important because infections caused by these viruses are difficult to treat, can cause prolonged infections, and are associated with a higher risk of liver cirrhosis.
<b>Anti-HBe</b>	Appears with recovery from acute infection, but may disappear over time. In chronic infection, the presence of anti-HBe is generally a marker of reduced viral replication, indicating a less infectious state <sup>(62)</sup> . For individuals carrying the viral strain with a mutation preventing transcription of the precore region and therefore, the release of HBeAg from the hepatocyte, this allows anti-HBe to be detected but HBV DNA is still high.
<b>HBV DNA</b>	Used to measure level of infectivity and response to treatment <sup>(270)</sup> .

Abbreviations: HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; anti-HBs, hepatitis B surface antibody; anti-HBc, hepatitis B core antibody; IgG, immunoglobulin G; IgM, immunoglobulin M; HBeAg, hepatitis B e-antigen; anti-HBe, hepatitis B e-antibody; HBV DNA, hepatitis B DNA



**Table 27: Typical serologic patterns used to interpret HBV infection status<sup>A</sup>**

Serologic marker				Interpretation
HBsAg	Anti-HBs	Anti-HBc total	Anti-HBc IgM	
Negative	Negative	Negative	Negative	Susceptible <sup>B</sup>
Positive	Negative <sup>C</sup>	Positive	Negative <sup>C</sup>	Chronic infection <sup>D</sup>
Positive <sup>E</sup>	Negative <sup>C</sup>	Positive	Positive	Acute infection
Negative	Positive <sup>E,F</sup>	Positive	Negative	Immune – due to recovery from past infection
Negative	Positive <sup>E</sup>	Negative	Negative	Immune - due to immunization <sup>B</sup>
Negative	Negative	Positive	Negative	Resolved infection (isolated anti-HBc total) <sup>G</sup>

Abbreviations: HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; anti-HBs, hepatitis B surface antibody; anti-HBc, hepatitis B core antibody; IgM, immunoglobulin M

<sup>A</sup> This table was developed from information obtained from published studies<sup>(270,415,421-425)</sup>.

<sup>B</sup> About 5%–10% of people will not respond to the vaccine or do not produce protective levels of antibody post-vaccination<sup>(62)</sup>.

<sup>C</sup> This marker is most often negative but may be positive in some individuals.

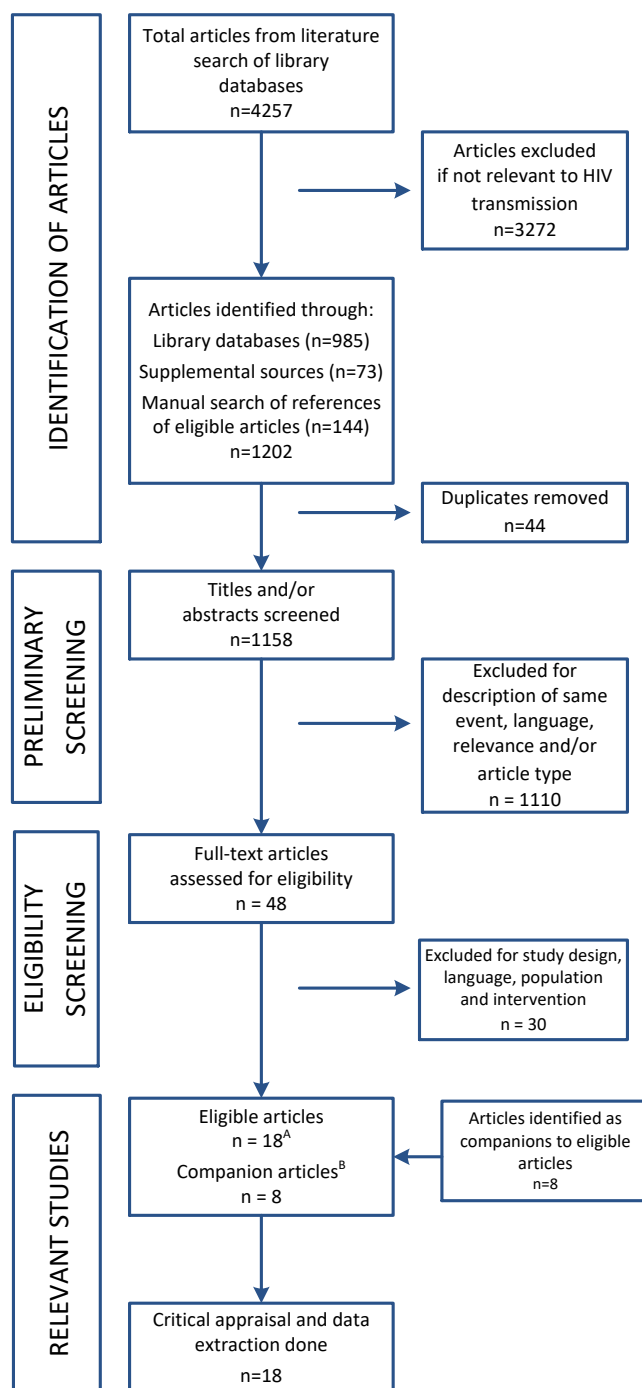
<sup>D</sup> To ensure that this is not a false positive test, samples with repeatedly reactive HBsAg results should be tested with a licensed neutralizing confirmatory test<sup>(270)</sup>. A small percentage of people with chronic infection will have both HBsAg and anti-HBs markers present<sup>(62)</sup>.

<sup>E</sup> This marker is most often positive but may be negative in some individuals.

<sup>F</sup> Levels of anti-HBs may decline over time and become undetectable<sup>(212)</sup>.

<sup>G</sup> Isolated anti HBc total is commonly the only serum marker detected indicating resolved infection. The reason for this test result is that anti-HBs titres fall with time and can become negative. Some earlier studies erroneously interpreted isolated anti HBc total as 1) a false positive result (based on an incorrect belief that hepatitis B was not that common); 2) "low level" chronic infection (if so, this would be HBsAg positive); 3) resolving acute infection (if so, this would be anti-HBc IgM positive or HBsAg positive or anti-HBs positive).

## APPENDIX II: SYSTEMATIC REVIEW AND EVIDENCE GRADING



<sup>A</sup> One of the 18 articles reports on two HCWs infected with HIV, for a total of 19 investigations. Sixteen out of 18 articles were eligible for the meta-analysis. One of the 16 articles reported two exposure incidents, therefore a total of 17 exposure incidents were included in the meta-analysis.

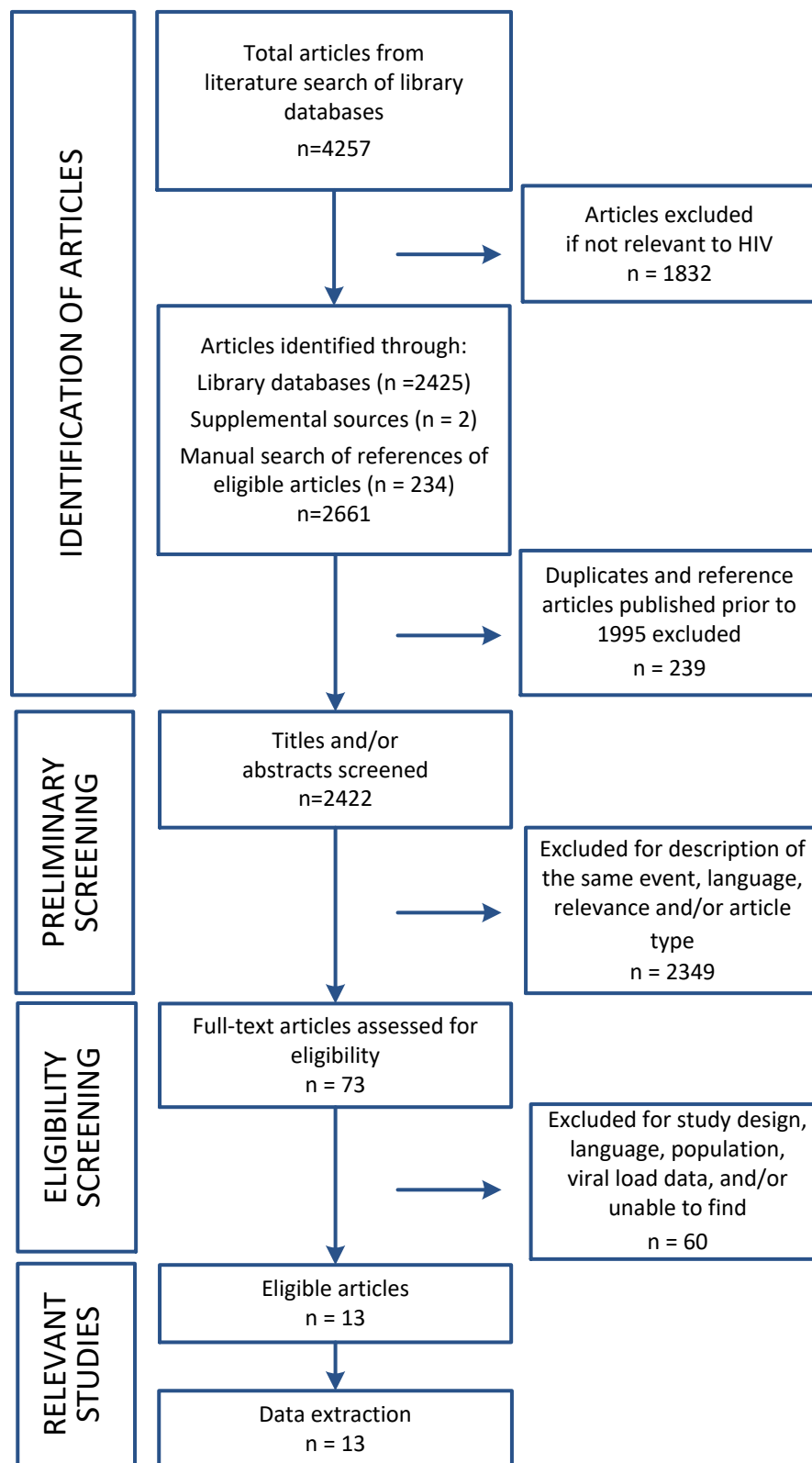
<sup>B</sup> Companion articles provide supplementary information about specific epidemiologic investigations.

**Figure 6: Risk of HIV transmission—study selection flow chart**

**Table 28: Studies excluded from the systematic review on the risk of transmission of HIV from infected HCWs to patients**

Reason study excluded	Author, publication year n=30
<b>Study design</b> Not an analytic study (including trials and observational studies) or a descriptive study	Chamberland, 1992 <sup>(426)</sup> ; AIDS Committee SHEA, 1992 <sup>(427)</sup> ; Debry, 1993 <sup>(428)</sup> ; Robert, 1995 <sup>(154)</sup> ; Anonymous, 1995 <sup>(429)</sup> ; Schaffner, 1995 <sup>(93)</sup> ; Hansen, 1996 <sup>(53)</sup> ; PHLS, 1997 <sup>(430)</sup> ; PHLS, 1997 <sup>(401)</sup> ; Bartlett, 2000 <sup>(431)</sup> ; Puro, 2001 <sup>(238)</sup> ; McCarthy, 2002 <sup>(432)</sup> ; Tansley, 2004 <sup>(433)</sup> ; Department of Health and Children, 2005 <sup>(370)</sup> ; Société française d'hygiène hospitalière, 2006 <sup>(434)</sup> ; Rogowska-Szadkowska, 2006 <sup>(435)</sup> ; Flint, 2011 <sup>(436)</sup> ; PHE, 2012 <sup>(107)</sup> ; PHE, 2014 <sup>(190)</sup>
<b>Language</b> Not English or French	Hasselhorn, 2000 <sup>(28)</sup> ; Puro, 2003 <sup>(29)</sup> ; Stulhofer, 2006 <sup>(437)</sup> ; Ross, 2007 <sup>(438)</sup>
<b>Population</b> Did not report on HCWs infected with HIV who either: 1) performed EPPs; or 2) provided direct patient care not involving EPPs where transmission was reported	Delwart, 1995 <sup>(439)</sup> ; Smith, 2002 <sup>(440)</sup> ; Bredell, 2003 <sup>(441)</sup> ; Roy, 2005 <sup>(442)</sup> ; Negut, 2007 <sup>(443)</sup> ; Jones, 2009 <sup>(444)</sup>
<b>Intervention</b> Did not report on any preventive or management intervention or measure for HCWs that may affect risk of transmission	Irwin, 2002 <sup>(168)</sup>
<b>Outcome</b> Did not report on indicators of transmission	Nil

Abbreviations: HIV, human immunodeficiency virus; HCWs, healthcare workers; SHEA, Society for Healthcare Epidemiology of America; PHLS, Public Health Laboratory Services; PHE, Public Health England

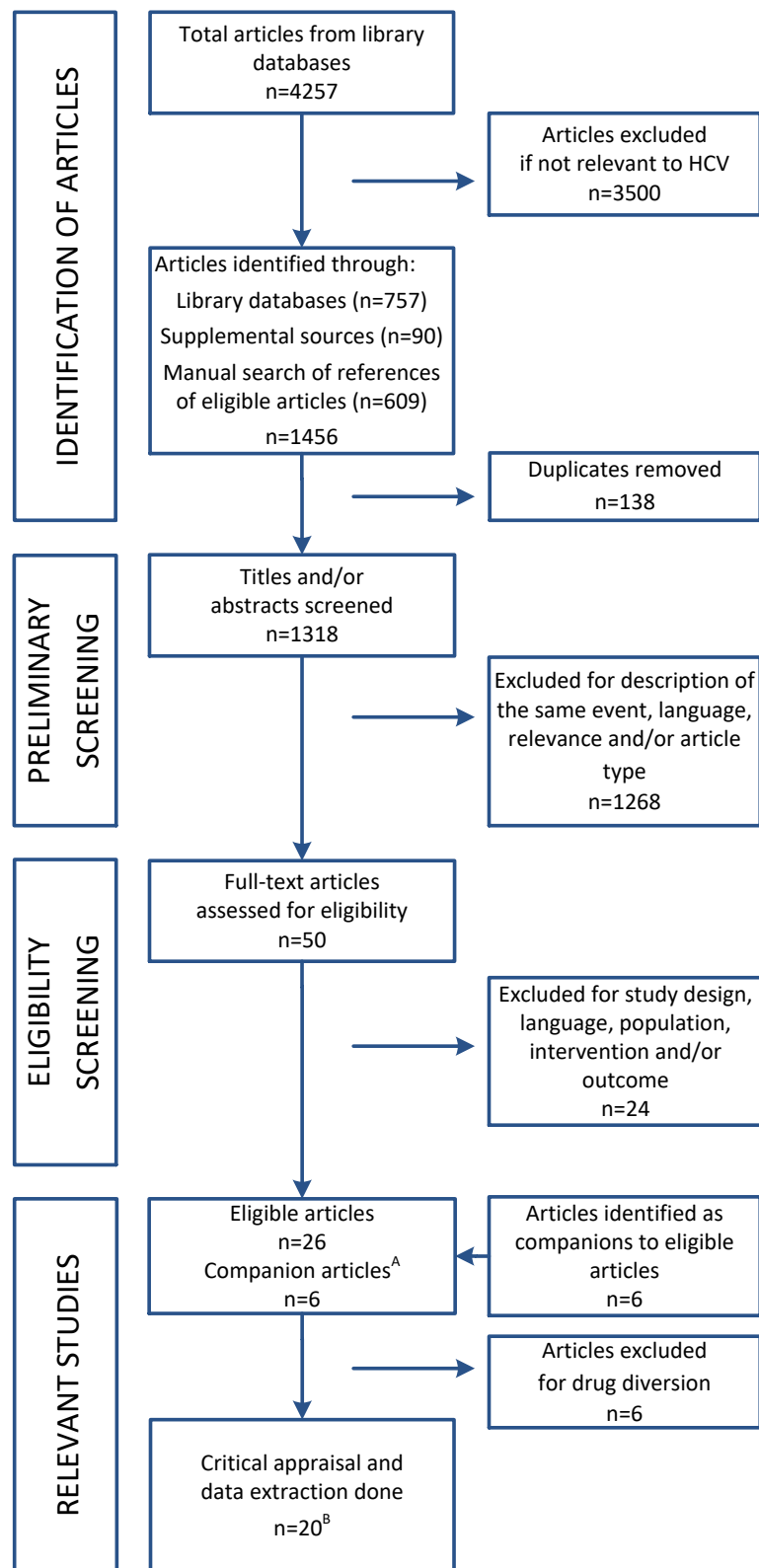


**Figure 7: HIV viral load and infectivity—study selection flow chart**

**Table 29: Studies excluded from the systematic review on HIV viral load and infectivity**

Reason study excluded	Author, publication year n=60
<b>Study design</b> Not an analytic study (including trials and observational studies) or a descriptive study	PHLS, 1997 <sup>(445)</sup> ; Aboulafia, 1998 <sup>(446)</sup> ; Bartlett, 2000 <sup>(431)</sup> ; PHE, 2005 <sup>(80)</sup> ; Criscione, 2012 <sup>(447)</sup> ; Herbeck, 2014 <sup>(448)</sup> ; Institut National de Santé Publique du Québec, 2015 <sup>(449)</sup>
<b>Language</b> Not English or French	Anonymous, 1997 <sup>(450)</sup> ; Trenning-Himmelsbach, 1997 <sup>(451)</sup> ; Blazquez, 2001 <sup>(452)</sup> ; Resino, 2007 <sup>(453)</sup> ; Lucena, 2011 <sup>(454)</sup>
<b>Population</b> Did not report on blood-to-blood exposure and/or reported on sexual, perinatal, transfusion or transplantation-related exposures	Belec, 1998 <sup>(455)</sup> ; Donnelly, 1999 <sup>(172)</sup> ; Kallenborn, 2001 <sup>(456)</sup> ; Blick, 2007 <sup>(457)</sup> ; CDC, 2009 <sup>(178)</sup> ; Ding, 2009 <sup>(458)</sup> ; Hecht, 2010 <sup>(459)</sup> ; Miller, 2013 <sup>(460)</sup>
<b>Viral load data</b> Did not report the time between a person's exposure and viral load testing of the source individual	Robert, 1995 <sup>(154)</sup> ; Romea, 1995 <sup>(461)</sup> ; CDC, 1995 <sup>(462)</sup> ; Lot, 1995 <sup>(463)</sup> ; Bell, 1996 <sup>(464)</sup> ; Tereskerz, 1996 <sup>(465)</sup> ; Vidmar, 1996 <sup>(466)</sup> ; Cardo, 1997 <sup>(467)</sup> ; CDC, 1997 <sup>(468)</sup> ; Dorozynski, 1997 <sup>(469)</sup> ; Lancaster, 1997 <sup>(470)</sup> ; Lymer, 1997 <sup>(471)</sup> ; PHLS, 1997 <sup>(430)</sup> ; PHLS, 1997 <sup>(401)</sup> ; Pugliese, 1997 <sup>(472)</sup> ; Anonymous, 1998 <sup>(473)</sup> ; Blanchard, 1998 <sup>(180)</sup> ; Gilbert, 1998 <sup>(474)</sup> ; Ippolito, 1998 <sup>(475)</sup> ; Nielsen, 1998 <sup>(476)</sup> ; Amirat-Combralier, 1999 <sup>(477)</sup> ; Lot, 1999 <sup>(72)</sup> ; Guimet, 2001 <sup>(478)</sup> ; King, 2001 <sup>(479)</sup> ; Lohiya, 2001 <sup>(480)</sup> ; Nguyen, 2001 <sup>(43)</sup> ; Baldo, 2002 <sup>(481)</sup> ; Irwin, 2002 <sup>(168)</sup> ; Metzker, 2002 <sup>(482)</sup> ; Seabra Santos, 2002 <sup>(483)</sup> ; Beltrami, 2003 <sup>(484)</sup> ; Bosch, 2003 <sup>(150)</sup> ; Do, 2003 <sup>(485)</sup> ; Keiserman, 2003 <sup>(486)</sup> ; Andreo, 2004 <sup>(487)</sup> ; Bartholomew, 2006 <sup>(488)</sup> ; Gisselquist, 2006 <sup>(145)</sup> ; Lam, 2014 <sup>(176)</sup>
<b>Unable to find</b>	PHLS, 1997 <sup>(489)</sup> ; Donnelly, 1998 <sup>(490)</sup>

Abbreviations: HIV, human immunodeficiency virus; PHLS, Public Health Laboratory Service; PHE, Public Health England; CDC, Centers for Disease Control and Prevention



<sup>A</sup> Companion articles provide supplementary information about specific epidemiologic investigations.

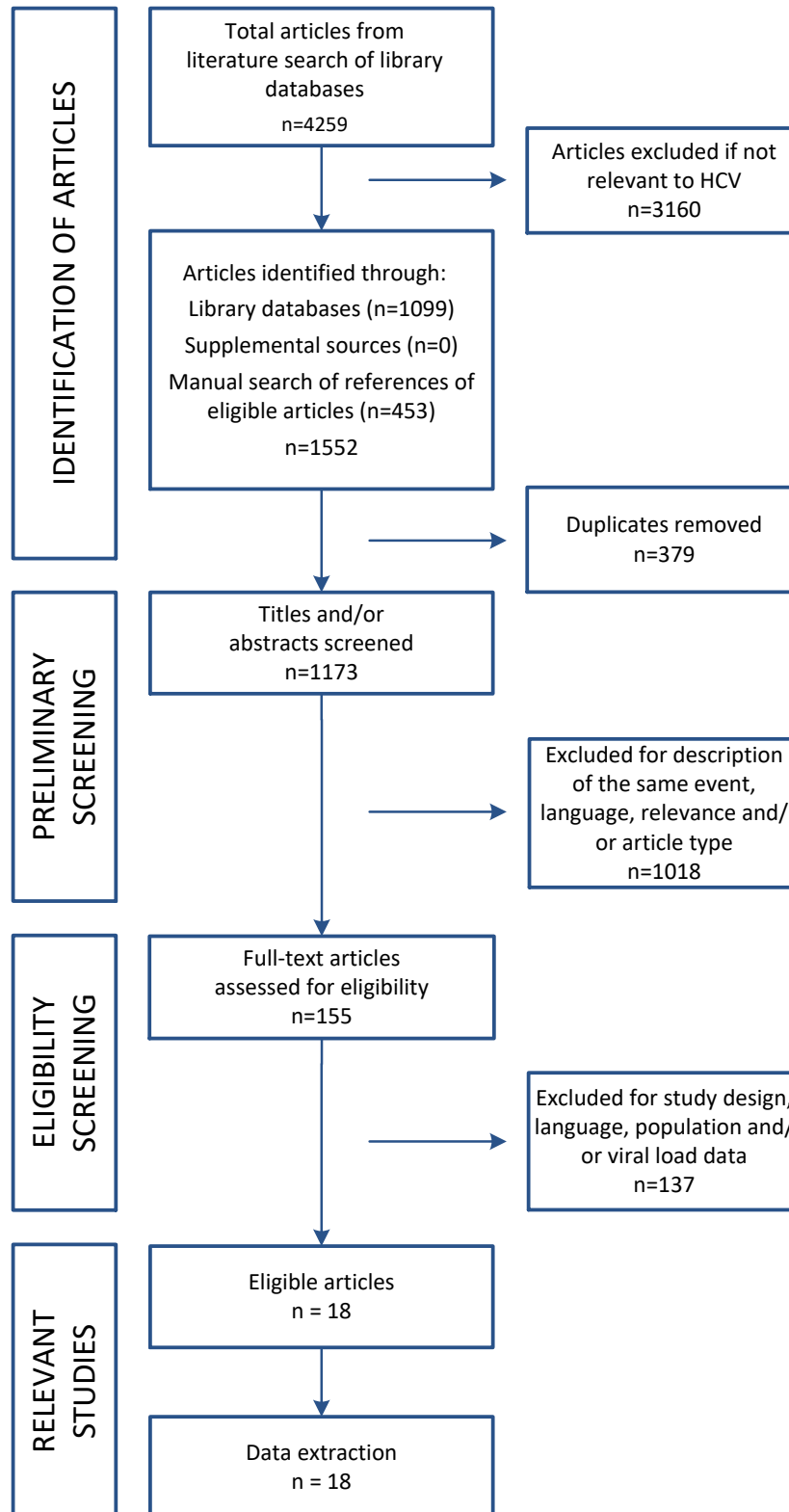
<sup>B</sup> Nine out of 20 articles were eligible for the meta-analysis.

**Figure 8: Risk of HCV transmission—study selection flow chart**

**Table 30: Studies excluded from the systematic review on the risk of transmission of HCV from infected HCWs to patients**

<b>Reason study excluded</b>	<b>Author, publication year n=30</b>
<b>Study design</b> Not an analytic study (including trials and observational studies) or a descriptive study	Schaffner, 1995 <sup>(93)</sup> ; Roudot-Thoraval, 2000 <sup>(491)</sup> ; Bartlett 2000 <sup>(431)</sup> ; Ross, 2000 <sup>(65)</sup> ; Heptonstall, 2000 <sup>(492)</sup> ; Carbonne, 2006 <sup>(394)</sup> ; Roche, 2008 <sup>(493)</sup> ; Carlson, 2010 <sup>(33)</sup> ; Ramer, 2013 <sup>(494)</sup> ; Chen, 2016 <sup>(495)</sup> ; De Peyer, 2016 <sup>(232)</sup>
<b>Language</b> Not English or French	Hasselhorn, 2000 <sup>(28)</sup> ; Puro, 2003 <sup>(29)</sup> ; Gerlich, 2004 <sup>(496)</sup>
<b>Population</b> Did not report on HCWs infected with HIV who either: 1) performed EPPs; or 2) provided direct patient care not involving EPPs where transmission was reported	Hohne, 1994 <sup>(497)</sup> ; Dumpis, 2003 <sup>(498)</sup> ; PHLS, 2005 <sup>(230)</sup> ; Bonnal, 2010 <sup>(499)</sup>
<b>Intervention</b> Did not report on any preventive or management intervention or measure for HCWs that may affect risk of transmission	PHLS, 2001 <sup>(229)</sup> ; Januszkiewicz-Lewandowska, 2003 <sup>(500)</sup> ; Ross, 2003 <sup>(235)</sup> ; Wrobel, 2006 <sup>(501)</sup>
<b>Outcome</b> Did not report on indicators of transmission	Smith, 2002 <sup>(440)</sup> ; PHE, 2013 <sup>(502)</sup>
<b>Drug diversion</b> Reported drug diversion by the HCW	Sehulster, 1997 <sup>(503)</sup> ; Akehurst, 1998 <sup>(504)</sup> ; Petruccielli 2005 <sup>(505)</sup> ; Shemer-Avni, 2007 <sup>(223)</sup> ; Hellinger, 2012 <sup>(506)</sup> ; Gonzalez-Candelas, 2013 <sup>(507)</sup>

Abbreviations: HCV, human immunodeficiency virus; HCW, healthcare workers; PHLS, Public Health Laboratory Service; PHE, Public Health England



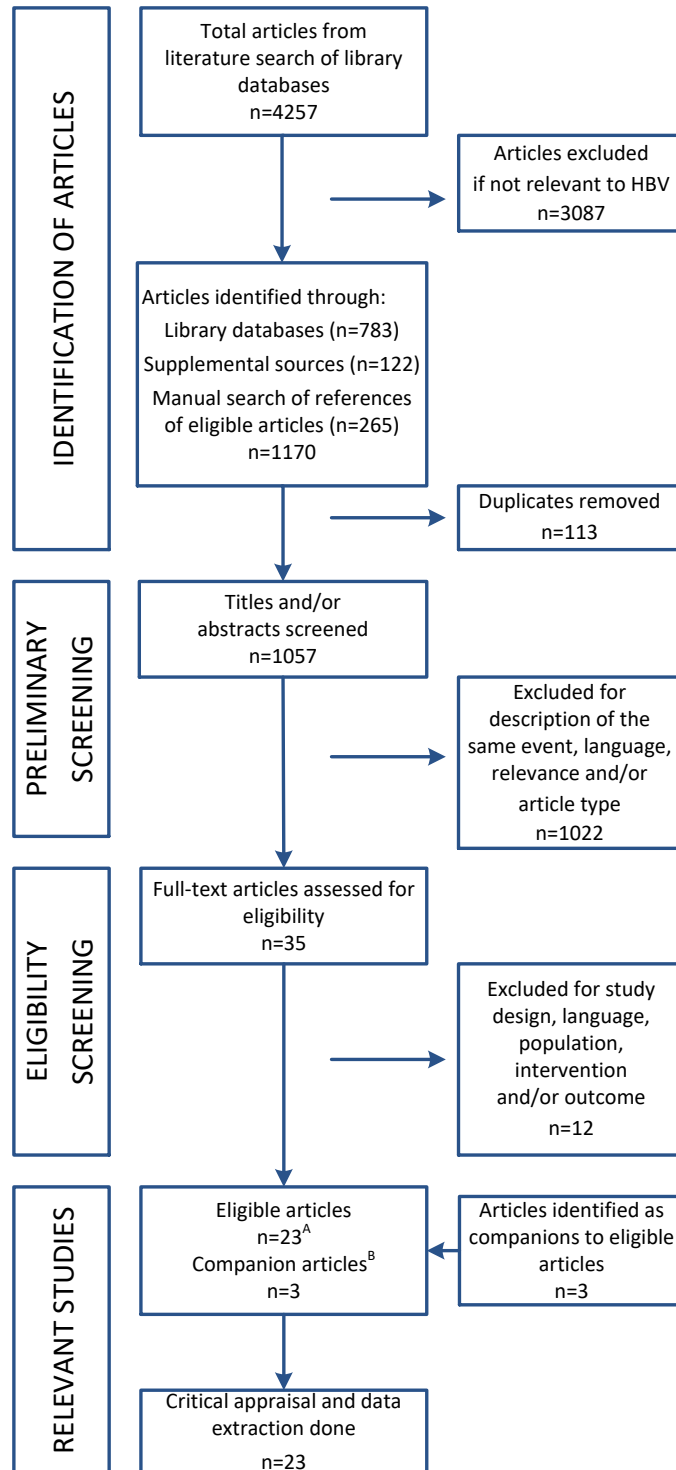
**Figure 9: HCV viral load and infectivity—study selection flow chart**



**Table 31: Studies excluded from the systematic review on HCV viral load and infectivity**

Reason study excluded	Author, publication year n=137
<b>Study design</b> Not an analytic study (including trials and observational studies) or a descriptive study	Seeff, 1991 <sup>(508)</sup> ; Anonymous, 1996 <sup>(509)</sup> ; Canadian Medical Association, 2010 <sup>(381)</sup> ; CADTH, 2012 <sup>(510)</sup> ; American Society of Anesthesiologist, 2014 <sup>(511)</sup> ; GOV.UK, 2014 <sup>(512)</sup>
<b>Language</b> Not English or French	Berger, 1998 <sup>(513)</sup> ; Laufs, 1998 <sup>(514)</sup> ; Olaso, 1999 <sup>(515)</sup> ; Cordoba, 2000 <sup>(516)</sup> ; Del Poggio, 2000 <sup>(517)</sup> ; Hasselhorn, 2000 <sup>(28)</sup> ; Blázquez, 2001 <sup>(452)</sup> ; De Figueiredo, 2003 <sup>(518)</sup> ; Velasco, 2003 <sup>(519)</sup> ; Beran, 2004 <sup>(520)</sup> ; Castro Ferreiro, 2004 <sup>(521)</sup> ; Gerlich, 2004 <sup>(496)</sup> ; Husa, 2004 <sup>(522)</sup> ; Bilski, 2005 <sup>(523)</sup> ; Guglielmi, 2005 <sup>(524)</sup> ; Bilski, 2006 <sup>(525)</sup> ; Campins Martí, 2006 <sup>(526)</sup> ; Warley, 2006 <sup>(527)</sup> ; Anonymous, 2007 <sup>(528)</sup> ; Kubitschke, 2007 <sup>(40)</sup>
<b>Population</b> Did not report on blood-to-blood exposure and/or reported on sexual, perinatal, transfusion or transplantation-related exposures	Caporaso, 1998 <sup>(529)</sup> ; Anonymous, 2000 <sup>(530)</sup> ; File, 2003 <sup>(531)</sup> ; Keiserman, 2003 <sup>(486)</sup> ; Nikolopoulou, 2005 <sup>(532)</sup> ; Patel, 2006 <sup>(533)</sup> ; CDC, 2009 <sup>(534)</sup> ; Dawar, 2010 <sup>(77)</sup>
<b>Viral load data</b> Did not report the time between a person's exposure and viral load testing of the source individual	Al-Sohaibani, 1995 <sup>(535)</sup> ; Petrosillo, 1995 <sup>(536)</sup> ; PHLS, 1995 <sup>(407)</sup> ; Roth, 1995 <sup>(537)</sup> ; Carrillo, 1996 <sup>(538)</sup> ; Dibenedetto, 1996 <sup>(539)</sup> ; Djordjevic, 1996 <sup>(540)</sup> ; Garces, 1996 <sup>(541)</sup> ; Bouvet, 1997 <sup>(542)</sup> ; Dimache, 1997 <sup>(543)</sup> ; Guyader, 1997 <sup>(544)</sup> ; Lymer, 1997 <sup>(471)</sup> ; Bouvet, 1998 <sup>(545)</sup> ; Öge, 1998 <sup>(546)</sup> ; Brown, 1999 <sup>(408)</sup> ; Goob, 1999 <sup>(547)</sup> ; Hamid, 1999 <sup>(548)</sup> ; Oketani, 1999 <sup>(549)</sup> ; PHLS, 1999 <sup>(227)</sup> ; Alfurayh, 2000 <sup>(550)</sup> ; Burgard, 2000 <sup>(551)</sup> ; Garfein, 2000 <sup>(410)</sup> ; Kato-Maeda, 2000 <sup>(552)</sup> ; Krajden, 2000 <sup>(553)</sup> ; Guimet, 2001 <sup>(478)</sup> ; Lohiya, 2001 <sup>(480)</sup> ; Puro, 2001 <sup>(238)</sup> ; Ross, 2001 <sup>(409)</sup> ; Saginur, 2001 <sup>(51)</sup> ; Baldo, 2002 <sup>(481)</sup> ; Sulkowski, 2002 <sup>(205)</sup> ; Baffoy-Fayard, 2003 <sup>(554)</sup> ; Beltrami, 2003b <sup>(484)</sup> ; De Carli, 2003 <sup>(555)</sup> ; Dumpis, 2003 <sup>(498)</sup> ; Allam, 2003 <sup>(556)</sup> ; Hosoglu, 2003 <sup>(557)</sup> ; Januszkiewicz-Lewandowska, 2003 <sup>(500)</sup> ; Nguyen, 2003 <sup>(558)</sup> ; Raghuraman, 2003 <sup>(559)</sup> ; Siegel-Itzkovich, 2003 <sup>(560)</sup> ; Tarantola, 2003 <sup>(561)</sup> ; Thompson, 2003 <sup>(562)</sup> ; Akhtar, 2004 <sup>(563)</sup> ; Comstock, 2004 <sup>(564)</sup> ; Mérat, 2004 <sup>(565)</sup> ; Spada, 2004 <sup>(566)</sup> ; Bernstein, 2005 <sup>(567)</sup> ; Finelli, 2005 <sup>(568)</sup> ; Forns, 2005 <sup>(569)</sup> ; Glynn, 2005 <sup>(236)</sup> ; Kopka, 2005 <sup>(345)</sup> ; Mehta, 2005 <sup>(570)</sup> ; Sonder, 2005 <sup>(571)</sup> ; Yazdanpanah, 2005 <sup>(572)</sup> ; Yildirim, 2005 <sup>(573)</sup> ; Hutchinson, 2006 <sup>(574)</sup> ; Kogure, 2006 <sup>(575)</sup> ; Stark, 2006 <sup>(138)</sup> ; Tarantola, 2006 <sup>(576)</sup> ; Yazdanpanah, 2006 <sup>(577)</sup> ; Bruguera, 2007 <sup>(578)</sup> ; Haber, 2007 <sup>(579)</sup> ; Kamili, 2007 <sup>(580)</sup> ; Lot, 2007 <sup>(50)</sup> ; Tosti, 2007 <sup>(581)</sup> ; Wang, 2007 <sup>(242)</sup> ; Brouard, 2008 <sup>(582)</sup> ; Cardell, 2008 <sup>(113)</sup> ; Mason, 2008 <sup>(233)</sup> ; Papenburg, 2008 <sup>(583)</sup> ; Quer, 2008 <sup>(584)</sup> ; Ross, 2008 <sup>(231)</sup> ; Sikuler, 2008 <sup>(585)</sup> ; Corey, 2009 <sup>(586)</sup> ; Nightingale, 2009 <sup>(587)</sup> ; Antono, 2010 <sup>(588)</sup> ; Lanini, 2010 <sup>(589)</sup> ; Sanderson, 2010 <sup>(590)</sup> ; Wu, 2010 <sup>(591)</sup> ; Doerrbecker, 2011 <sup>(592)</sup> ; Gatserelia, 2011 <sup>(241)</sup> ; Kim, 2011 <sup>(593)</sup> ; Butsashvili, 2012 <sup>(594)</sup> ; El Tayeb, 2012 <sup>(595)</sup> ; Hellinger, 2012 <sup>(506)</sup> ; Holodniy, 2012 <sup>(596)</sup> ; Moini, 2012 <sup>(597)</sup> ; Peric, 2012 <sup>(598)</sup> ; Roy, 2012 <sup>(140)</sup> ; Ryoo, 2012 <sup>(599)</sup> ; Shriyan, 2012 <sup>(600)</sup> ; Tomkins, 2012 <sup>(601)</sup> ; Zaijer, 2012 <sup>(602)</sup> ; Gonzalez-Candelas, 2013 <sup>(507)</sup> ; Heller, 2013 <sup>(603)</sup> ; Okulicz, 2013 <sup>(604)</sup> ; Said, 2013 <sup>(605)</sup> ; De Carli, 2014 <sup>(606)</sup> ; Eskandarani, 2014 <sup>(607)</sup> ; Piao, 2014 <sup>(608)</sup> ; Schaefer, 2014 <sup>(609)</sup> ; Hawks, 2015 <sup>(610)</sup>

Abbreviations: HCV, hepatitis C virus; CADTH: Canadian Agency for Drugs and Technologies in Health; CDC, Centers for Disease Control and Prevention; PHLS, Public Health Laboratory Service



<sup>A</sup> Fifteen out of 23 articles were eligible for meta-analysis. Two articles included 3 incidents each and 1 article included 2 incidents, for a total of 20 incidents. Three articles were excluded for IPC breaches.

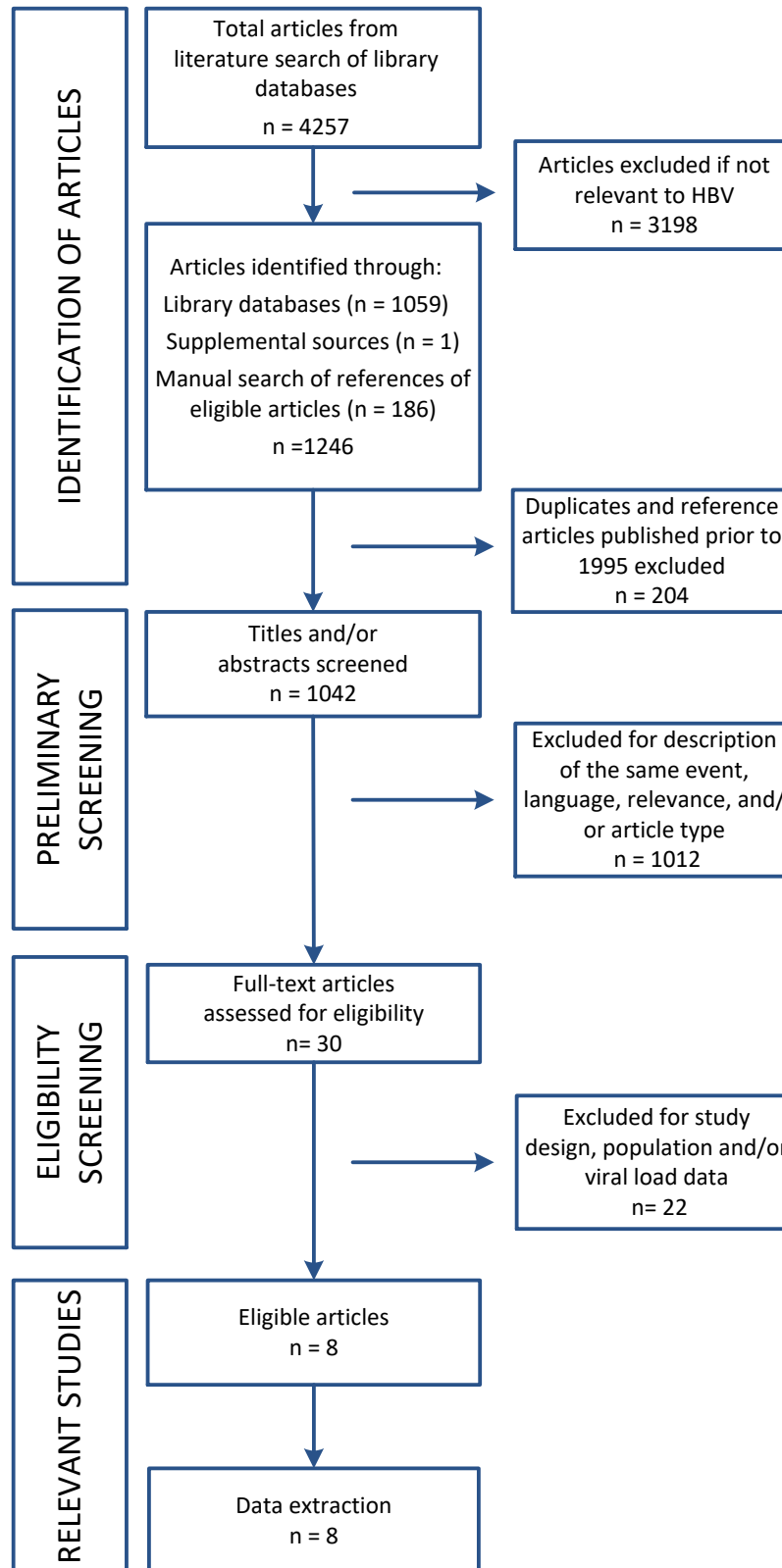
<sup>B</sup> Companion articles provide supplementary information about specific epidemiologic investigations.

**Figure 10: Risk of HBV transmission—study selection flow chart**

**Table 32: Studies excluded from the systematic review on the risk of transmission of HBV from infected HCWs to patients**

<b>Reason study excluded</b>	<b>Author, publication year n=12</b>
<b>Study design</b> Not an analytic study (including trials and observational studies) or a descriptive study	Bartlett, 2000 <sup>(431)</sup> ; Carbonne, 2006 <sup>(394)</sup> ; Danzmann, 2013 <sup>(611)</sup>
<b>Language</b> Not English or French	Zaaijer, 1999 <sup>(612)</sup> ; Puro, 2003 <sup>(29)</sup> ; Bilski, 2005 <sup>(523)</sup>
<b>Population</b> Did not report on HCWs infected with HIV who either: 1) performed EPPs; or 2) provided direct patient care not involving EPPs where transmission was reported	Zuckerman, 1995 <sup>(413)</sup> ; Curran, 2000 <sup>(613)</sup> ; Corden, 2003 <sup>(294)</sup> ; Buster, 2004 <sup>(614)</sup>
<b>Intervention</b> Did not report on any preventive or management intervention or measure for HCWs that may affect risk of transmission	Ngui, 2000 <sup>(293)</sup> ; Carlson, 2010 <sup>(33)</sup>
<b>Outcome</b> Did not report on indicators of transmission	Nil

Abbreviations: HBV, hepatitis B virus; HCWs, healthcare workers



**Figure 11: HBV viral load and infectivity—study selection flow chart**

**Table 33: Studies excluded from the systematic review on HBV viral load and infectivity**

<b>Reason study excluded</b>	<b>Author, publication year n=22</b>
<b>Study design</b> Not an analytic study (including trials and observational studies) or a descriptive study	Sikora, 2010 <sup>(615)</sup>
<b>Language</b> Not English or French	Nil
<b>Population</b> Did not report on blood-to-blood exposure and/or reported on sexual, perinatal, transfusion or transplantation-related exposures	Zeuzem, 1997 <sup>(616)</sup> ; Datta, 2006 <sup>(617)</sup> ; Criscione, 2012 <sup>(618)</sup> ; Buchner, 2015 <sup>(619)</sup>
<b>Viral load data</b> Did not report the time between a person's exposure and viral load testing of the source individual	Tedder, 1995 <sup>(620)</sup> ; Zucherman, 1995 <sup>(413)</sup> ; The incident control teams and others, 1996 <sup>(41)</sup> ; Mukerjee, 1996 <sup>(122)</sup> ; Sundkvist, 1998 <sup>(115)</sup> ; Oliver, 1999 <sup>(123)</sup> ; Nguyen, 2001 <sup>(43)</sup> ; Spijkerman, 2002 <sup>(121)</sup> ; Nguyen, 2003 <sup>(558)</sup> ; Kidd-Ljunggren, 2006 <sup>(621)</sup> ; Smellie, 2006 <sup>(133)</sup> ; Harling, 2007 <sup>(622)</sup> ; Laurenson, 2007 <sup>(124)</sup> ; Poujol, 2008 <sup>(139)</sup> ; Demirturk, 2014 <sup>(623)</sup> ; Du Plessis, 2014 <sup>(624)</sup> ; Dwibedi, 2014 <sup>(625)</sup>

Abbreviation: HBV, hepatitis B virus

**Table 34: Criteria for rating evidence on which recommendations are based<sup>A</sup>**

Grade of Evidence		
Strength of Evidence	Grades	Criteria
<b>Strong</b>	<b>AI</b>	Direct evidence from meta-analysis or multiple strong design studies of high quality, with consistency of results
	<b>AII</b>	Direct evidence from multiple strong design studies of medium quality with consistency of results OR At least one strong design study with support from multiple moderate design studies of high quality, with consistency of results OR At least one strong design study of medium quality with support from extrapolation from multiple strong-design studies of high quality, with consistency of results
<b>Moderate</b>	<b>BI</b>	Direct evidence from multiple moderate design studies of high quality with consistency of results OR Extrapolation from multiple strong design studies of high quality, with consistency of results
	<b>BII</b>	Direct evidence from any combination of strong or moderate design studies of high/medium quality, with a clear trend but some inconsistency of results OR Extrapolation from multiple strong design studies of medium quality or moderate design studies of high/medium quality, with consistency of results OR One strong design study with support from multiple weak design studies of high/medium quality with consistency of results
<b>Weak</b>	<b>CI</b>	Direct evidence from multiple weak design studies of high/medium quality, with consistency of results OR Extrapolation from any combination of strong/moderate design studies of high/medium quality, with inconsistency of results
	<b>CII</b>	Studies of low quality regardless of study design OR Contradictory results regardless of study design OR Case series/case reports OR Expert opinion

<sup>A</sup> Excerpt from the Public Health Agency of Canada's *Infection Prevention and Control Guidelines: Critical Appraisal Tool Kit*<sup>(8)</sup>.

## APPENDIX III: SUPPLEMENTARY BACKGROUND INFORMATION

**Table 35: Organizations invited to provide comment on the draft Guideline on the Prevention of Transmission of Bloodborne Viruses from Infected Healthcare Workers in Healthcare Settings<sup>A</sup>**

Federal, Provincial and Territorial Partners	
Pan-Canadian Public Health Network's Communicable and Infectious Disease Steering Committee	National Defence and the Canadian Armed Forces
Health Canada's First Nations and Inuit Health Branch	Correctional Service Canada
Health Professional Regulatory Authorities	
Federation of Medical Regulatory Authorities of Canada	Department of Health and Social Services, Government of NWT
College of Family Physicians of Canada	College of Dental Hygienists of Nova Scotia
Canadian Dental Regulatory Authorities Federation	Department of Health and Social Services, Government of Nunavut
Federation of Dental Hygiene Regulatory Authorities	College of Dental Hygienists of Ontario
Canadian Nurses Association	Dental Council Prince Edward Island
Ordre des infirmières et des infirmiers du Québec	Ordre des hygiénistes dentaire du Québec
College of Nurses of Ontario	Saskatchewan Dental Hygienists Association
Registered Nurses Association of the NWT and Nunavut	Department of Community Services, Community Services, Government of Yukon
Canadian Midwifery Regulators Consortium	Manitoba Dental Assistant Association
College of Registered Dental Hygienists of Alberta	Association des Assistant(e)s Dentaires du Québec
College of Dental Hygienists of British Columbia	New Brunswick Dental Assistant Association
College of Dental Hygienists of Manitoba	Nova Scotia Dental Assistant Association
New Brunswick College of Dental Hygienists	Newfoundland Dental Assistant Association
Newfoundland and Labrador Council of Health Professionals	Association of Alberta Dental Assistants
Specialties	
Medicine	
Canadian Medical Association	The Canadian Neurosurgical Society
Canadian Medical Protective Association	The Canadian Orthopaedic Association
Occupational and Environmental Medicine Association of Canada	The Canadian Society for Vascular Surgery
Occupational Medicine Specialists of Canada	The Society of Obstetricians and Gynaecologists of Canada
Association of Medical Microbiology and Infectious Disease	Canadian Fertility and Andrology Society
Royal College of Physicians and Surgeons of Canada	Canadian Society of Internal Medicine
Canadian Society of Cardiac Surgeons	National Specialty Society for Community Medicine
The Canadian Orthopaedic Association	The Canadian Critical Care Society
Canadian Anesthesiologists' Society	The Society of Gynecologic Oncology of Canada
Canadian Association of Emergency Physicians	Canadian Society of Palliative Care Physicians
Canadian Association of Gastroenterology	Doctors of BC
Canadian Association of Paediatric Surgeons	Alberta Medical Association
Canadian Association of Thoracic Surgeons	Saskatchewan Medical Association
Canadian Cardiovascular Society	Doctors Manitoba
Canadian Society of Colon and Rectal Surgeons	Ontario Medical Association

Canadian Society of Otolaryngology — Head & Neck Surgery	Quebec Medical Association
Canadian Society of Plastic Surgeons	New Brunswick Medical Society
Canadian Society of Surgical Oncology	Doctors Nova Scotia
Canadian Thoracic Society	Medical Society of Prince Edward Island
Canadian Urological Association	Newfoundland and Labrador Medical Association
The Canadian Association of General Surgeons	Northwest Territories Medical Association
The Canadian Association of Radiologists	Yukon Medical Association
<b>Dentistry and Allied Dental Professionals</b>	
Canadian Dental Association	Canadian Dental Hygienists Association
Canadian Dental Assistants Association	
<b>Nursing</b>	
Canadian Occupational Health Nurses Association	Canadian Nurses Protective Society
Nurse Practitioner Association of Canada	
<b>Midwifery</b>	
Canadian Association of Midwives	
<b>Faculty and Student/Trainee Associations</b>	
Canadian Association of Schools of Nursing	Canadian Federation of Medical Students
Association of Canadian Faculties of Dentistry	Canadian Nursing Students' Association
Association of Faculties of Medicine of Canada	Fédération des médecins résidents du Québec
Resident Doctors of Canada (RDoC)	Fédération des médecins étudiants du Québec
<b>Podiatry</b>	
Canadian Federation of Podiatric Medicine	Canadian Podiatric Medical Association
<b>Other</b>	
Canadian Association of Physician Assistants	Canadian Association of Naturopathic Doctors
<b>Patient Safety</b>	
Canadian Patient Safety Institute	Patients for Patient Safety Canada
<b>Miscellaneous</b>	
Infection Prevention and Control Canada	Canadian Association for the Study of the Liver
Association des infirmières en prévention des infections du Québec	Canadian Public Health Association
HealthCareCan	
<b>International Organizations and Subject Matter Experts</b>	
David Henderson, MD, Deputy Director for Clinical Care, Associate Director for Hospital Epidemiology and Quality Improvement, National Institutes of Health, Department of Health and Human Services U.S. Federal Government <sup>B</sup>	John T. Brooks, MD, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of HIV/AIDS Prevention-Surveillance & Epidemiology, Office of the Director U.S. Centers for Disease Control and Prevention <sup>C</sup>
David Kuhar, MD, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Prevention and Response Branch U.S. Centers for Disease Control and Prevention <sup>C</sup>	Anne C. Mooreman, MPH, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of Viral Hepatitis, Epidemiology and Surveillance Branch U.S. Centers for Disease Control and Prevention <sup>C</sup>
Society for Healthcare Epidemiology of America	Société française d'hygiène hospitalière
HIV Medicine Association	

<sup>A</sup> Stakeholder organizations and international subject matter experts were identified with the assistance of the Guideline Development Task Group and key international guidelines or reports.

<sup>B</sup> Feedback provided as a subject matter expert and does not necessarily represent the official position of the U.S. Federal Government or the Society for Healthcare Epidemiology of America.

<sup>C</sup> Feedback provided as a subject matter expert does not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.



**Table 36: Expert review process in two Canadian provinces with a centralized approach for all HCWs**

Key elements	Alberta <sup>A</sup>	Quebec <sup>B</sup>
<b>Name</b>	Expert Review Panel for Blood Borne Viral Infections in Health Care Workers	<u>Blood-Borne Infection Risk Assessment Unit</u>
<b>Governance</b>	Administered by the CPSA for the Chief Medical Officer of Health <sup>A</sup>	Ministerial mandate to the provincial public health department, the INSPQ <sup>C</sup>
<b>Mandate</b>	Provide advice to referring authority (e.g., Medical Officer of Health, regulatory authority).	To provide an assessment of risk of transmission of BBVs to patients from infected HCWs who perform EPPs (including students) <sup>D</sup>
<b>Panel composition</b>	Medical Officer of Health, infectious disease specialist, infection prevention and control professional, public health nurse, occupational health professional, dentist. Others as required (e.g., treating physician, peer HCW)	Infectious disease specialist, public health specialist, peer HCW (or program representative if a student) <sup>E</sup>
<b>Review process</b>	Anonymous (i.e., anonymized reports, treating physician as surrogate) or in person by HCW	Anonymous <sup>E</sup>
<b>Appeal process</b>	No formal appeal process, however, the Panel's recommendations can be reconsidered via the Physician Health Monitoring Program if required.	No formal appeal process, however, a re-evaluation based upon a founded request is always possible
<b>Remuneration</b>	Member expenses related to a review are covered by the relevant regulatory authority. Per diem rate also paid to members whose employment is not paid for by government.	Remuneration of the ERP members is based on provincial Treasury Board policies
<b>Indemnification</b>	Through the CPSA's usual mechanism for its committees	Possible for the ERP, by the Ministry of Health and Social Services <sup>F</sup>

Abbreviations: HCW, healthcare worker, BBIRAU, Blood-Borne Infection Risk Assessment Unit; ERP, Expert Review Panel; CPSA, College of Physicians & Surgeons of Alberta; INSPQ, Institut national de santé publique du Québec; BBV, bloodborne viruses; EPPs, exposure-prone procedures

<sup>A</sup> Content confirmed via personal communication (conversation with Dr. J Beach, Assistant Registrar, College of Physicians & Surgeons of Alberta, on June 5, 2018; unreferenced).

<sup>B</sup> Content confirmed via personal communication (email discussion with A Kimpton, Head of the Scientific Unit, The Institut national de santé publique du Québec, on June 29, 2018; unreferenced).

<sup>C</sup> Supported by a Steering Committee whose members include the Ministry of Health and Social Services, the relevant regulatory authorities and a legal ethicist. If the infected HCW performs EPPs and no previously formulated recommendations can be applied, an ad hoc panel is assembled to assess the risk of transmission and make recommendations on practice or training and medical follow-up needed for the HCW to practice EPPs (follow-up is done by the BBIRAU for students and by the relevant authority for HCWs).

<sup>D</sup> The Steering Committee's mandate is to "define the BBIRAU's orientations and responsibilities as well as to approve its operational procedures, promotional tools and evaluation framework. This committee can address recommendations to the Minister of Health and Social Services regarding the prevention of transmission of bloodborne infection transmission by infected caregivers during health care delivery."

<sup>E</sup> The BBIRAU's team performs an anonymous preliminary screening of the HCW and determines if there is a need to convene the ERP. If so, the HCW completes a consent form and arrangements are made for the HCW's medical records to be transmitted from their attending physician.

<sup>F</sup> In case of litigation against the panel or any of its experts, the INSPQ notifies the Ministry of Health and Social Services who takes the necessary steps to guarantee the legal protection of the ERP members. The INSPQ does not divulge the identity of the ERP members to the HCW or the relevant regulatory authority.

**Table 37: Regulated and Unregulated Health Professions in Canada<sup>A</sup>**

Profession	Province/Territory												
	NL	PE	NS	NB	QC	ON	MB	SK	AB	BC	YT	NT	NU
<b><u>Acupuncturist</u></b>	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	No	No	No
<b><u>Chiropodist/Podiatrist</u></b>	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
<b><u>Dental Assistant</u></b>	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No
<b><u>Dental Hygienist</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b><u>Dental Therapist</u></b>	No	No	No	No	No	No	No	Yes	No	Yes	Yes	Yes	Yes
<b><u>Dentist</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b><u>Licensed Practical Nurse</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b><u>Midwife</u></b>	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
<b><u>Naturopathic Physician</u></b>	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No	No
<b><u>Nurse Practitioner</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b><u>Paramedic</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
<b><u>Physician</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b><u>Physician Assistant</u></b>	No	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No
<b><u>Registered Nurse</u></b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b><u>Registered Psychiatric Nurse</u></b>	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No
<b><u>Respiratory Therapist</u></b>	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No

Abbreviations: NL, Newfoundland and Labrador; PE, Prince Edward Island; NS, Nova Scotia; NB, New Brunswick; QC, Quebec; ON, Ontario; MB, Manitoba; SK, Saskatchewan; AB, Alberta; BC, British Columbia; YT, Yukon Territories; NT, Northwest Territories; NU, Nunavut

<sup>A</sup> The format for this table was adopted from a report by the Canadian Institute for Health Information. (CIHI)<sup>(626)</sup>; data for each profession and P/T was either obtained from CIHI documents or other reliable source (refer to hyperlinks in each cell). Yes - Profession is regulated in Province/Territory; No - Profession is not regulated in Province/Territory.

## APPENDIX IV: ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immune deficiency syndrome
Anti-HBc	Antibody to hepatitis B core antigen
Anti-HBe	Antibody to hepatitis B e antigen
Anti-HBs	Antibody to hepatitis B surface antigen
ART	Antiretroviral therapy
BBV	Bloodborne virus
CDC	Centers for Disease Control and Prevention
CHMS	Canadian Health Measures Survey
CNDSS	Canadian Notifiable Disease Surveillance System
EPP	Exposure-prone procedure
ERP	Expert Review Panel
HB	Hepatitis B
HBcAg	Hepatitis B core antigen
HBeAg	Hepatitis B e antigen
HBIG	Hepatitis B immune globulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HBV DNA	Hepatitis B DNA
HCV	Hepatitis C virus
HCW	Healthcare worker
HIV	Human immunodeficiency virus
IPC	Infection prevention and control
LB	Lookback investigation
NACI	National Advisory Committee on Immunization
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PHAC	Public Health Agency of Canada
PHLS	Public Health Laboratory Services
P/T	Provinces and territories
RCT	Randomized controlled trial
RNA	Ribonucleic acid
UKAP	United Kingdom Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses
VL	Viral load
WHO	World Health Organization

## APPENDIX V: GLOSSARY

**Expert Review Panel (ERP):** Within the context of this guideline, an ERP is an advisory committee whose primary role is to assess the risk of transmission of a BBV from an infected HCW to patients and assess whether practice restrictions are needed if the infected HCW performs EPPs.

**Exposure-prone procedure (EPP):** An invasive procedure where there is a higher-than-average risk that injury to the HCW may result in the exposure of the patient's open tissues to the blood of the HCW.

**Healthcare facility:** Includes but is not limited to acute-care hospitals, emergency departments, rehabilitation hospitals, mental health hospitals, and long-term care facilities<sup>(19)</sup>.

**Healthcare organization:** The organizational entity that is responsible for establishing and maintaining healthcare services provided by HCWs and other staff in one or more healthcare settings throughout the healthcare continuum<sup>(19)</sup>.

**Healthcare setting:** Any location where health care is provided, including emergency care, prehospital care, hospital, long-term care, home care, ambulatory care and facilities and locations in the community where care is provided (e.g., infirmaries in schools, residential or correctional facilities)<sup>(19)</sup>.

**Healthcare worker (HCW):** Individuals who provide health care or support services, such as nurses, physicians, dentists, dental hygienists, physician assistants, nurse practitioners, paramedics and sometimes emergency first responders, allied health professionals, unregulated healthcare providers, clinical instructors and students, volunteers and housekeeping staff. Healthcare workers have varying degrees of responsibility related to the health care *and support services* they provide, depending on their level of education and their specific job and/or responsibilities<sup>(19)</sup>.

**Lead authority:** Within the context of this guideline, it is the healthcare organization, facility, public health unit or agency that coordinates a lookback investigation related to a HCW infected with a BBV.

**Lookback investigation (LB):** If a HCW has been identified as infected with HBV, HCV or HIV and has performed exposure-prone procedures that could have put patients at risk of exposure to an infection, then the organization employing the HCW or the local public health unit contacts patients at risk to give advice about testing and potential treatment and to discuss methods of preventing further transmission with those found to be infected<sup>(2)</sup>.

**Outcome:** A term used to refer to results of interest in a study such as infections, diseases, behaviours, effects or conditions<sup>(8)</sup>.

**Peer healthcare worker (HCW):** A HCW from the same area of practice as the infected HCW who assists: 1) the expert review panel to determine the need for practice restrictions or modifications; 2) the risk assessment team to determine if a lookback investigation is required; and 3) the investigation management team to assist with the coordination of the investigation. The peer HCW provides information on the procedures performed by the infected HCW and whether there is a risk of patients being potentially exposed to the HCW's blood.

**Regulated HCW:** Within the context of this guideline, refers to any HCW whose work or practice is regulated by a provincial or territorial regulatory authority (legislation may vary by province and territory).

**Regulatory authorities:** Within the context of this guideline, refers to any agency established by provincial or territorial legislation to regulate the practice of health professionals (e.g., medicine, dentistry, nursing, etc.) (Adapted from the Federation of Medical Regulatory Authorities of Canada definition for Medical Regulatory Authority)<sup>(627)</sup>.

**Routine Practices** (synonymous with Standard Precautions<sup>(26)</sup>): A comprehensive set of infection prevention and control measures that has been developed for use in the routine care of all patients at all times in all healthcare settings. Routine Practices aim to minimize or prevent healthcare-associated infections in all individuals in the healthcare setting, including patients, HCWs, other staff, visitors and contractors<sup>(19)</sup>.

**Traceback investigation:** If a patient has been identified as infected with a HBV, HCV or HIV and has no identifiable risk of infection from that virus, as assessed by the physician or local public health unit, but has undergone an exposure-prone procedure within the appropriate incubation period, then the local public health unit seeks to identify the HCW who has performed exposure-prone procedures and other infected or potentially infected patients in order to provide treatment and counselling on preventing further transmission<sup>(2)</sup>.

**Universal precautions:** A set of infection prevention and control measures that was developed with the primary purpose of protecting the HCW from exposure to bloodborne viruses, and was based on the principle that it was not possible to know which patients harboured bloodborne viruses<sup>(19)</sup>. Universal precautions were used in conjunction with category - or disease-specific isolation systems for patients with specific symptoms or infections<sup>(628,629)</sup>.

**Unregulated HCW:** Within the context of this guideline, refers to any HCW whose work is not regulated by a provincial or territorial regulatory authority (legislation may vary by province and territory).

**Viral load:** Refers to the number of circulating viruses in a unit of blood.

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