



Aboriginal and Torres Strait Islander Health Practice	Occupational Therapy
Chinese Medicine	Optometry
Chiropractic	Osteopathy
Dental	Pharmacy
Medical	Physiotherapy
Medical Radiation Practice	Podiatry
Nursing and Midwifery	Psychology

Australian Health Practitioner Regulation Agency

Public consultation

5 September 2019

Public consultation on draft guidelines for registered dental, medical, nursing and midwifery, paramedic and podiatric practitioners and students in relation to blood-borne viruses

This consultation paper released by the Dental, Medical, Nursing and Midwifery, Paramedicine and Podiatry Boards of Australia seeks feedback on draft *Guidelines for registered health practitioners and students in relation to blood-borne viruses* (the draft guidelines).

The draft guidelines are intended to support practitioners in these professions to comply with the Communicable Diseases Network Australia *Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses* (the CDNA guidelines).

The Boards participating in this consultation all regulate practitioners whose scope of practice may include exposure-prone procedures.

The National Law¹, empowers the National Boards to develop and approve codes and guidelines to provide guidance to health practitioners. The National Law requires National Boards to ensure there is wide-ranging consultation on the content of any proposed registration standard, code or guideline.

The Dental, Medical, Nursing and Midwifery, Paramedicine and Podiatry Boards of Australia are inviting general comments on the draft guidelines for the health practitioners that they register, in relation to blood-borne viruses. There are also specific questions which you may wish to address in your response:

1. Are the draft guidelines necessary?
2. Is the content of the draft guidelines helpful, clear and relevant?
3. Is there any content that needs to be changed, added or deleted in the draft guidelines?
4. Do you agree with the proposal that the Boards expect registered health practitioners and students to comply with CDNA guidelines? That includes testing requirements set in the CDNA guidelines.
5. Do you have any other comments on the draft guidelines?

¹ Health Practitioner Regulation National Law, as in force in each state and territory

Making a submission

Please provide written submissions by email to bbvguidelines@ahpra.gov.au by close of business on **1 November 2019**

Submissions for publication on our website/s should be sent in Word format or equivalent.²

Please address any submissions by post to the Executive Officer, Medical, AHPRA, GPO Box 9958, Melbourne 3001.

Publication of submissions

The Boards publish submissions at their discretion. The Boards generally publish submissions on their websites to encourage discussion and inform the community and stakeholders. Please let us know if you do not want us to publish your submission, or want us to treat all or part of it as confidential.

We will not place on our website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the subject of the consultation.

Before publication, we may remove personally-identifying information from submissions, including contact details.

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the Boards.

The Boards accept submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982* (Cth), which has provisions designed to protect personal information and information given in confidence.

Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is requested.

² You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file. However we request that you supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx

Background

There is a risk of transmission of a blood-borne virus from practitioner to patient when health practitioners who are living with a blood-borne virus perform a class of procedures called 'exposure-prone procedures'.

When referring to blood-borne viruses, we mean hepatitis B, hepatitis C and Human immunodeficiency virus (HIV).

Exposure-prone procedures are defined as *procedures where there is a risk of injury to the healthcare worker³ resulting in exposure of the patient's open tissues to the blood of the healthcare worker. These procedures include those where the healthcare worker's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times.*⁴

Exposure-prone procedures are generally limited to the practice of dental practitioners, medical practitioners (particularly surgeons, obstetricians and gynaecologists and emergency physicians), nurses (operating room and emergency) and midwives, podiatric surgeons and paramedics.

Acupuncture, venepuncture, excision of skin lesions and other procedures where the hands are visible at all times and outside of the body are not exposure-prone procedures.

Some of the Boards have received feedback that further guidance for practitioners in relation to blood-borne viruses is necessary.

2014 consultation

You may recall that the Boards previously consulted on *Guidelines for the regulatory management of registered health practitioners and students infected with blood-borne viruses* in 2014 (the 2014 Guidelines).

The 2014 Guidelines required all registered practitioners and students to comply with the CDNA guidelines for health practitioners infected with a blood-borne virus.

There was general support for the notion that the Board guidelines align with the CDNA guidelines. However, there was a great deal of feedback that the CDNA guidelines in place at the time were outdated and not in line with current evidence and international practice. Given the feedback about the CDNA guidelines, a decision was made to wait until the CDNA guidelines had been updated before proceeding with Boards' guidelines.

CDNA guidelines

The Australian Health Ministers' Advisory Council (AHMAC) have now endorsed the CDNA's *Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses*.

The revised CDNA guidelines provide information and recommendations for all healthcare workers (HCWs) but they are particularly relevant to:

- healthcare workers who perform exposure prone procedures
- healthcare workers living with a blood-borne virus and
- doctors treating healthcare workers with a blood-borne virus

The CDNA also provide information and recommendations for public health authorities.

³ The CDNA refers to healthcare workers while the Boards refer to practitioners

⁴ This is the definition adopted by the CDNA

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Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

The CDNA guidelines provide guidance on testing for blood-borne viruses and the circumstances when practitioners living with a blood-borne virus can resume performing exposure-prone procedures. This is based on current evidence and international practice.

The Boards' guidelines

The Dental, Medical, Nursing and Midwifery, Paramedic and Podiatry Boards are now proposing guidelines that are complementary to the CDNA guidelines. The guidelines:

- inform all practitioners registered by the Dental, Medical, Nursing and Midwifery, Paramedic and Podiatry Boards of Australia that they must comply with the CDNA guidelines, as current and as revised in the future. That includes testing for blood-borne viruses
- explain the circumstances in which a practitioner treating a registered health practitioner or student may have a responsibility to notify AHPRA that their patient is living with a blood-borne virus, and
- provide information on the range of actions that a Board may take if it receives a notification that a registered health practitioner or student is infected with a blood-borne virus and may be impaired or otherwise poses a risk to the public.

Options

The Boards have considered the following options in developing this proposal.

Option 1 – Maintain the status quo

Option 1 is to not publish guidelines.

While Option 1 has been the approach taken to date, practitioners, employers and internal decision-makers have provided feedback that additional guidance would be helpful, particularly as the CDNA guidelines are explicit that practitioners living with a blood-borne virus can practise their profession in the circumstances described.

Option 2 – Proposed guideline

Option 2 is to consult on proposed guidelines that require practitioners to comply with the AHMAC endorsed CDNA guidelines. The guidelines contain general guidance for all practitioners and provide additional guidance for practitioners who are treating a practitioner or student with a blood-borne virus.

Option 3 – Develop clinical guidelines that reproduce elements of the CDNA guidelines

Option 3 is to develop more detailed guidelines that include clinical elements, including aspects that are already contained in the CDNA guidelines.

Option 3 introduces a risk that the CDNA and Board guidelines may not be completely aligned resulting in confusion and additional and unnecessary complexity for practitioners.

If Option 3 is adopted, there will be a period of time (months) when the Boards' guidelines will be out of date when the CDNA guidelines are updated, given the consultation requirements for Board guidelines.

Preferred option

The Boards prefer Option 2. It achieves the outcome of providing guidance to practitioners with the minimum regulatory burden.

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

Questions for consideration

The Boards are inviting general comments on the draft revised guideline as well as feedback on the following questions.

1. Are the draft guidelines necessary?
2. Is the content of the draft guidelines helpful, clear and relevant?
3. Is there any content that needs to be changed, added or deleted in the draft guidelines?
4. Do you agree with the proposal that the Boards expect registered health practitioners and students to comply with CDNA guidelines? That includes testing requirements set in the CDNA guidelines.
5. Do you have any other comments on the draft guidelines?

Attachments

1. Draft *Guidelines for registered health practitioners and students in relation to blood-borne viruses*
2. The Boards' statement of assessment against AHPRA's Procedures for the development of registration standards, codes and guidelines and Council of Australian Governments (COAG) principles for best practice regulation.

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Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

Draft Guidelines

September 2019

Registered health practitioners and students in relation to blood-borne viruses

1. About the Podiatry Board of Australia and AHPRA

The Podiatry Board of Australia regulates registered podiatrists and podiatric surgeons practitioners in Australia. It is responsible for registering podiatrists and podiatric surgeons and podiatry students, setting the standards that practitioners must meet, and managing notifications (complaints) about the health, conduct or performance of practitioners.

The Australian Health Practitioner Regulation Agency (AHPRA) works in partnership with the National Boards to implement the National Registration and Accreditation Scheme, under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

The core role of the Podiatry Board of Australia and AHPRA is to protect the public.

2. About these guidelines

These guidelines have been developed under section 39 of the National Law. They are aimed at:

- health practitioners registered under the National Law who perform exposure-prone procedures or are living with a blood-borne virus
- students registered under the National Law who perform exposure-prone procedures or are living with a blood-borne virus and
- registered health practitioners who are treating registered health practitioners or students who are living with a blood-borne virus.

Education providers and employers of registered health practitioners may also bring these guidelines to the attention of their students and employees respectively.

In brief, these guidelines:

- inform all practitioners that they must comply with the Communicable Diseases Network Australia (CDNA) guidelines *Australian national guidelines for the management of healthcare workers living with blood-borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses*, as current and as revised in the future. The current CDNA guidelines are attached to these guidelines
- explain when a practitioner treating a registered health practitioner or student may have a responsibility to notify AHPRA that their patient is living with a blood-borne virus, and
- provide information on the range of actions that a Board may take if it receives a notification that a registered health practitioner or student is infected with a blood-borne virus and may be impaired or otherwise poses a risk to the public.

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

3. What is not covered in these guidelines?

- 3.1 These guidelines are about health practitioners and students in relation to blood-borne viruses. They do not include guidance for registered health practitioners and students in relation to other infectious diseases who should refer to, and comply with, relevant current infection control guidelines.

4. General guidance for all registered health practitioners and students

- 4.1 Registered health practitioners and students have a responsibility to prevent the transmission of blood-borne viruses from themselves to their patients and their co-workers.
- 4.2 Registered health practitioners and students have a right to protect themselves from transmission of blood-borne viruses.
- 4.3 All registered health practitioners and students must comply with the CDNA guidelines. The guidelines are particularly relevant to health practitioners and students living with a blood-borne virus, health practitioners and students who perform exposure-prone procedures and medical practitioners treating healthcare workers and students with a blood-borne virus.

5. Guidance for registered health practitioners and students living with blood-borne viruses

- 5.1 Registered health practitioners living with a blood-borne virus can continue to practise their profession if they comply with the CDNA guidelines.
- 5.2 Registered students living with a blood-borne virus can continue in their course of study if they comply with the CDNA guidelines.
- 5.3 Registered health practitioners and students who are living with a blood-borne virus must remain under regular medical supervision. They must seek and accept their treating practitioner's advice on the safe limits of practice. If the practitioner or student who is living with a blood-borne virus does not comply with the treating practitioner's advice, the treating practitioner may have to report their practitioner or student patient to AHPRA.
- 5.4 Registered health practitioners and students living with blood-borne viruses do not need to notify AHPRA about their infection if they are following their treating practitioner's advice and have complied with, and are continuing to comply with, the CDNA guidelines.

6. Guidance for treating practitioners

Note: In most instances, treating practitioners will be registered medical practitioners.

- 6.1 Treating practitioners who are treating a registered health practitioner or student living with a blood-borne virus do not have an obligation to report their patient to AHPRA if the practitioner or student is complying with the CDNA guidelines.
- 6.2 Treating practitioners can seek advice on individual health practitioners or students living with a blood-borne virus from their jurisdictional public health authority.
- 6.3 If a registered health practitioner or student living with a blood-borne virus is not complying with the CDNA guidelines, they may be putting the public at risk. Therefore, treating practitioners may have an obligation to notify AHPRA. Treating practitioners must inform AHPRA if their patient:
- does not attend their appointments or fails to be tested with the prescribed timeframe without prior notification and adequate justification to their doctor
 - refuses to have their viral load tested, or
 - continues to perform exposure-prone procedures when excluded by the CDNA guidelines.
- 6.4 Treating practitioners who are treating a registered health practitioner or student with a blood-borne virus should refer to the National Law and the Boards' guidelines on mandatory reporting notifications to help them decide whether it is necessary to make a mandatory notification.

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

7. The Board's response to notifications involving a practitioner living with a blood-borne virus

- 7.1 If the Board receives a notification about a registered health practitioner or student with a blood-borne virus, it will manage the notification in accordance with the provisions in the National Law¹. The Board may obtain additional information to assess whether the practitioner's practice or student's participation in clinical training poses a risk to the public. While each notification is considered on its individual merits, the Board can decide whether to:
- request the practitioner or student to ask their treating medical practitioner to provide a report to the Board. The Board would seek information to help it assess whether the registered health practitioner or student poses a risk to the public, given their infective status and their scope of practice and/or
 - require the practitioner or student to undergo a health assessment with an independent practitioner who is a specialist in the treatment of blood-borne viruses, who will report to the Board.
- 7.2 After assessing the risk posed by the practitioner or student the Board:
- will not take regulatory action if a registered health practitioner or student is complying with the CDNA guidelines and is therefore not placing the public at risk
 - will take the necessary action under the National Law to protect the health and safety of the public if a registered health practitioner or student is not complying with the CDNA guidelines and is therefore placing the public at risk. This action could include taking immediate action (suspension, imposition of conditions or accepting undertakings), investigating further, referring to a panel hearing or referring to a tribunal.
- 7.3 If the Board suspends a practitioner's registration, imposes conditions or accepts undertakings, it will publish relevant information on the Register of practitioners, as required by the National Law. The Board will not publish information on the Register of practitioners that states that a practitioner has a blood-borne virus. However, it will publish that the registration is subject to conditions which are not publicly available due to privacy obligations.
- 7.4 The Board must inform the student's education provider if it suspends a student's registration, imposes conditions or accepts undertakings. The education provider must as soon as practicable give notice to any entity with whom the person is undertaking training as part of the program of study that the Board has suspended the student's registration, imposed conditions or accepted undertakings.²
- 7.5 As provided for in the National Law³, the Board may inform the relevant health department or other entity of the Commonwealth or a State or Territory, if a practitioner or student with a blood-borne virus has not complied with the CDNA guidelines to allow the department to decide whether further action is necessary.

8. Other relevant regulatory aspects

- 8.1 When applying for registration and for renewal of registration, all practitioners are required to declare that they do not have an impairment. A blood-borne virus in itself does not constitute an impairment. However, a registered health practitioner with a blood-borne virus who is not complying with the CDNA guidelines has an impairment because they have a condition that 'detrimentally affects their capacity to practise the profession'. Therefore, they must declare that they are impaired.

¹ The Health Practitioner Regulation National Law, as in force in each state and territory

² S. 92 of the National Law

³ S. 219 of the National Law

- 8.2 The Board will assess positive declarations, initially by seeking additional information and will take necessary action under the National Law to protect the public.
- 8.3 The Board can take action under the National Law if a practitioner makes a false declaration.
- 8.4 At **initial registration**, the Board will ask practitioners who may perform exposure-prone procedures to commit that they will comply with the CDNA guidelines, including the testing requirements.
- 8.5 At **renewal of registration**, the Board will ask practitioners who perform exposure prone procedures to declare that have complied with the CDNA guidelines in the previous registration period and to commit that they will comply with the CDNA guidelines in the upcoming registration period. This includes testing requirements.
- 8.6 While practitioners are expected to have the testing prescribed in the CDNA guidelines, the Board will not ask for test results for the purpose of registration or renewal of registration processes.

Definitions

Blood-borne viruses for the purposes of this guideline are HIV (Human immunodeficiency virus), HBV (hepatitis B virus) and HCV (hepatitis C virus)

CDNA is the Communicable Diseases Network Australia

CDNA guidelines are the Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses that are endorsed by AHMAC and published by the CDNA

Exposure prone procedure - The definition in the CDNA guidelines is *procedures where there is a risk of injury to the healthcare worker resulting in exposure of the patient's open tissues to the blood of the healthcare worker. These procedures include those where the healthcare worker's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times.*

Health assessment means an assessment of a person to determine whether the person has an impairment and includes a medical, physical, psychiatric or psychological examination or test of the person.

Registered health practitioner means a person who is registered by one of the health practitioner boards under the Health Practitioner Regulation National Law, as in force in each state and territory. In the case of this guideline, it also includes registered students.

Impairment means:

in relation to a person, means the person has a physical or mental impairment, disability, condition or disorder (including substance abuse or dependence) that detrimentally affects or is likely to detrimentally affect—

- (a) for a registered health practitioner or an applicant for registration in a health profession, the person's capacity to practise the profession; or
- (b) for a student, the student's capacity to undertake clinical training—
 - (i) as part of the approved program of study in which the student is enrolled; or
 - (ii) arranged by an education provider.

Attachment

Communicable Diseases Network Australia: *Australian National Guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses*

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses



**AUSTRALIAN NATIONAL GUIDELINES
FOR THE MANAGEMENT OF
HEALTHCARE WORKERS LIVING WITH
BLOOD BORNE VIRUSES AND
HEALTHCARE WORKERS WHO PERFORM
EXPOSURE PRONE PROCEDURES
AT RISK OF
EXPOSURE TO BLOOD BORNE VIRUSES**

These *Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses*, endorsed by the Australian Health Ministers' Advisory Council (AHMAC) on 26 June 2018, supersede the 2012 version of these Guidelines.

Acronyms

ACEM	Australasian College for Emergency Medicine
AHMAC	Australian Health Ministers' Advisory Council
AHPPC	Australian Health Protection Principal Committee
AHPRA	Australian Health Practitioner Regulation Agency
ASHM	Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
ASID	Australian Society for Infectious Diseases
BBV	Blood borne virus
BBVSS	Blood Borne Viruses and Sexually Transmissible Infection Subcommittee
cART	Combination antiretroviral therapy
CDC	Centers for Disease Control and Prevention
CDNA	Communicable Diseases Network Australia
DAA	Direct Acting Antiviral
DNA	Deoxyribonucleic acid
EAC	Expert Advisory Committee
EPP	Exposure prone procedure
GEQ	Genome equivalents
HBeAg	Hepatitis B e antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCW	Healthcare worker: persons, including students and voluntary workers who undertake procedures in public and/or private healthcare settings, that normally involve patient care and/or contact with blood or other body fluids
HIV	Human immunodeficiency virus
IDU	Injecting drug user
IU	International units
NATA	National Association of Testing Authorities, Australia
NERP	National Expert Reference Panel
NSI	Needle-stick injury
PBS	Pharmaceutical Benefits Scheme
PCR	Polymerase chain reaction

PHA	Public Health Authorities
RACDS	Royal Australasian College of Dental Surgeons
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCPA	Royal College of Pathologists of Australasia
RNA	Ribonucleic acid
SVR	Sustained virological response
UK	United Kingdom

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Who are these Guidelines^I for?

These Guidelines are presented in two parts to provide succinct information for two different audiences:

- Part A provides information and recommendations for all healthcare workers (HCWs), in particular:
 - HCWs who perform exposure prone procedures (EPPs)
 - HCWs living with a blood borne virus (BBV)^{II}, and
 - doctors treating HCWs with a BBV.
- Part B provides information and recommendations for public health authorities including, but not limited to, hospitals and jurisdictional health departments, when managing or investigating a situation where a HCW with a BBV was not compliant with these Guidelines and/or may have placed a patient(s) at risk of infection.

^I Throughout this document, the term 'the Guidelines' refers to the Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses.

^{II} For ease of reading throughout this document, the term 'HCW living with a BBV' indicates a HCW with a confirmed infection of one or more BBV.

Executive Summary

These national Guidelines articulate the current expert consensus on the evidence in relation to healthcare workers (HCWs)^{III} and their blood borne virus (BBV) status. The recommendations in these Guidelines include measures related to the prevention of transmission from, and the management and treatment of HCWs with hepatitis B virus (HBV), hepatitis C virus (HCV) and/or human immunodeficiency virus (HIV). The foundations of these Guidelines rest upon the *primum non nocere* (first, do no harm) principle and that the HCW has a professional and ethical responsibility to take reasonable steps to know their BBV status.

There is a very low, but real, risk of transmission from a HCW with a BBV to a patient, despite best practice infection control practices, in Australian healthcare settings. There are certain types of procedures, known as exposure prone procedures (EPPs), where it is possible that injury to the HCW could result in the worker's blood coming into contact with the patient's open tissues. Therefore, there is an increased risk of BBV transmission from either the HCW or the patient during EPPs. The published evidence to date of infected HCW to patient and infected patient to HCW risk of BBV transmission has been reviewed, and is presented in Table 1.

Table 1: Risk of BBV transmission per exposure episode from untreated infected HCW to patient and untreated infected patient to HCW (in the absence of additional risk management).

Blood Borne Virus	Risk of infected HCW to patient transmission	Risk of infected patient to HCW transmission
Hepatitis B virus	0.2% - 13.19%	1% - 62%*
Hepatitis C virus	0.04% - 4.35%	0% - 7%
Human immunodeficiency virus	0.0000024% - 0.000024%	0.3%

* There is a wide variability in infectiousness of people with hepatitis B reported in the literature and this depends on their hepatitis B e-antigen status.

To mitigate this risk, HCWs with a BBV must not perform EPPs unless complying with these Guidelines. In addition, all HCWs who undertake EPPs must take reasonable steps to know their BBV status and should be tested^{IV} for BBVs at least once every three years. HCWs must also be tested for BBVs after the occurrence of any potential occupational exposure incident. In addition, HCWs who are exposed to risks for BBV transmission in non-occupational settings should be aware of national recommendations for testing frequencies that sit outside of these Guidelines. All registered HCWs who perform EPPs must confirm when applying for renewal of registration that they comply with these Guidelines.

Part A of these Guidelines provides key recommendations for all HCWs, particularly those who perform EPPs. Information and recommendations for the management of HCWs living

^{III} For the purposes of these guidelines HCW includes student HCWs.

^{IV} All laboratory tests referred to throughout this guideline are to be conducted in a National Association of Testing Authorities, Australia (NATA)/Royal College of Pathologists of Australasia (RCPA) accredited laboratory.

with a specific BBV can be found in separate sections within Part A of these Guidelines, which must be read in conjunction with the remainder of Part A. These recommendations operate on the understanding that HCWs diagnosed with a BBV follow their professional obligation to seek advice about personal care and work practices.

Part B of these Guidelines provides recommendations for public health authorities about the management of patients following exposure to the blood and/or bodily fluid of a HCW with a BBV. Indications for when a lookback is required are detailed for potential iatrogenic transmission of a BBV, and for when a HCW who performs EPPs is newly diagnosed with a BBV. All states and territories should have implementation procedures that are consistent with these Guidelines.

Key recommendations for all HCWs

All HCWs should be encouraged to undertake regular testing for BBVs.
All HCWs have the right to access confidential testing, counselling, support and treatment.
All HCWs should be vaccinated against HBV.

Key recommendations for HCWs who perform EPPs

HCWs who undertake EPPs must take reasonable steps to know their BBV status and should be tested for BBVs at least once every three years.
All registered HCWs who undertake EPPs must declare when applying for renewal of registration that they are complying with, and have been tested in accordance with these Guidelines.
All HCWs who undertake EPPs should understand their obligation to report their BBVs status, if required, under jurisdictional legislation and/or policies.
HCWs should understand their obligation to report all sharps injuries, whether or not there was a risk of patient exposure.

Key recommendations for HCWs living with a BBV*

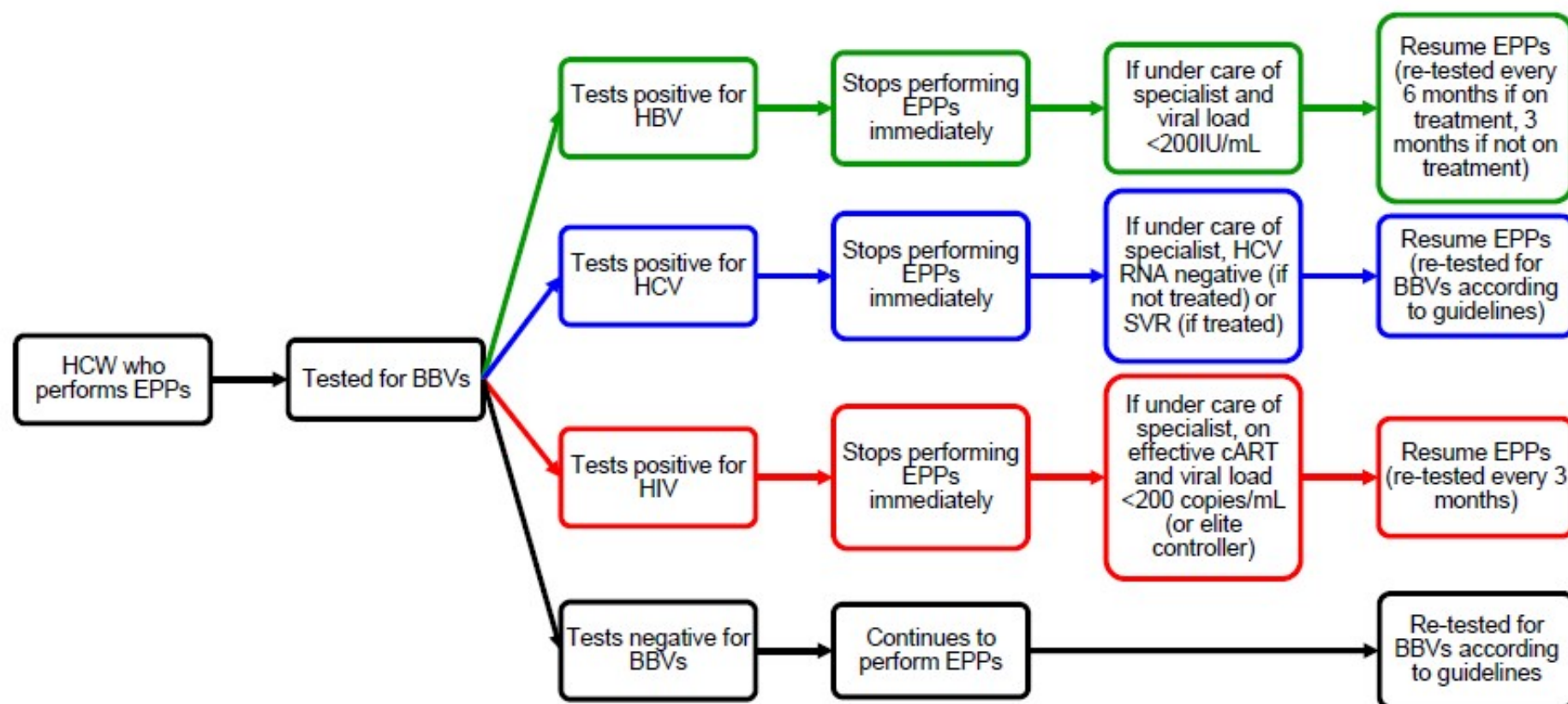
When diagnosed with a BBV, HCWs must cease performing EPPs immediately and seek appropriate medical care. HCWs with a BBV may return to performing EPPs once they meet the criteria set out within these Guidelines. A summary of the key steps and recommendations are provided in Figure 1: BBV testing requirements for HCWs who perform EPPs.

All HCWs with a BBV must have appropriate and ongoing medical care.
All HCWs living with one or more BBVs must be tested for the respective BBV viral load levels, as well as for other BBVs, in accordance with the Guidelines
HCWs who are HBV deoxyribonucleic acid (DNA) positive are permitted to perform EPPs if they have a viral load below 200 International Units (IU)/mL and meet the criteria set out in detail within these Guidelines.
HCWs must not perform EPPs while they are HCV ribonucleic acid (RNA) positive, but may be permitted to return to EPPs after successful treatment or following spontaneous clearance of HCV RNA.
HCWs who are HIV positive are permitted to perform EPPs if they have a viral load

below 200 copies/mL and meet the criteria set out in detail within these Guidelines.

*Detailed information and recommendations are provided in the sections for each BBV.

Figure 1: BBV testing requirements for HCWs who perform EPPs



SVR: Sustained virological response, cART: combination antiretroviral therapy

Part A

Guidelines for Healthcare Workers and Treating Doctors

1. Introduction

These Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses (the Guidelines) were endorsed by the Australian Health Ministers' Advisory Council (AHMAC) on 26 June 2018. The previous Guidelines, endorsed in 2012, were reviewed on the basis of new evidence and significant changes in recommendations made in other countries, including the United Kingdom (UK), specifically on the management of HCWs with HIV. In addition, there have been advances in the treatment of HCV and improved sensitivity of virological tests for BBVs, which triggered the revision of the remainder of the Guidelines. A number of Communicable Diseases Network Australia (CDNA) working groups and an advisory group have been involved in the development and revision of the Guidelines (Appendix 4: Technical working group members). A wide range of stakeholders were consulted during their preparation, and the Guidelines were subsequently endorsed by CDNA, the Australian Health Protection Principal Committee (AHPPC) and ultimately AHMAC.

The majority of procedures in the healthcare setting pose minimal risk of transmission from a HCW with a BBV to a patient, provided that appropriate routine infection prevention and control precautions are practised. However, there are certain procedures performed by HCWs during which BBVs may be more likely to be transmitted which are referred to as EPPs. An EPP is a procedure where there is a risk of injury to the HCW resulting in exposure of the patient's open tissues to the blood of the HCW. These procedures include those where the HCW's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times.

During EPPs, it is possible that injury to the HCW could result in the worker's blood coming into direct contact with the patient's open tissues. Under these circumstances transmission of BBVs is possible. For this reason HCWs with BBVs, who are considered to pose such a risk, must not perform EPPs unless complying with these Guidelines.

These Guidelines provide advice on best practice. It should be noted that the current evidence-base is limited and these Guidelines are based upon the best available evidence at the time of completion, placing scientific knowledge about transmission into a risk management approach. This area will be monitored by CDNA and changes will be made to these Guidelines, if indicated, as new evidence becomes available.

2. Guiding principles

HCWs have the same right to access confidential testing, counselling and treatment as the general population.

All patients and HCWs have the right to protection from healthcare acquired infections, in accordance with workplace health and safety, including exposure to BBVs via nosocomial

sharps injuries and/or exposure to body fluids and secretions. All HCWs must have access to timely testing, counselling and treatment if such an event occurs.

While the protection of public health is paramount, employers of HCWs must also consider relevant anti-discrimination, privacy, industrial relations and equal employment opportunity legislation in discharging their duty of care to both clients and staff. Employers must ensure that the status and rights of HCWs with a BBV as employees are safeguarded.

3. Recommendations for all HCWs

All HCWs are expected to protect the health and safety of their patients. This obligation includes taking all reasonable measures to prevent transmission of BBVs from themselves to their patients. All HCWs should be aware of their BBV status, and if they have non-occupational risk factors associated with the acquisition of BBVs, they should be encouraged to have regular BBV testing according to standard guidelines [1-3].

All HCWs, including student HCWs, should be vaccinated against HBV prior to the commencement of employment, studies or clinical placements if they have no documented evidence of pre-existing immunity (from resolved infection or prior vaccination). All HCWs should be assessed for immunity post-vaccination.

In the case of non-responders to the hepatitis B vaccine, treating doctors should refer to *The Australian Immunisation Handbook* [4] for further vaccination requirements and management after potential exposures to HBV.

4. Recommendations for HCWs who perform EPPs

4.1 Diagnosis and frequency of BBV testing

HCWs who perform EPPs must take reasonable steps to know their BBV status and should be tested for BBVs at least once every three years.

HCWs who perform EPPs and assess their risk of exposure to be high should consider more frequent BBV testing. HCWs who perform EPPs should be tested for HIV and HCV^V. They should also be tested for HBV unless immunity to HBV, through vaccination or resolved infection, has been demonstrated. HBV vaccine non-responders, who do not have HBV infection, can perform EPPs but should be tested for HBV at least once every three years, and receive advice on measures to minimise the risk of infection at work and of avoiding non-occupational risks of infection.

Any testing performed should be with the knowledge that appropriate support is available to those who test positive for a BBV, through health professional training organisations and/or employers, where applicable.

^V HCWs with previous HCV infection, who have undergone successful treatment, must be tested for HCV RNA not HCV antibodies.

Due to the nature of EPPs, HCWs who perform these procedures are at higher risk of acquiring a BBV from a patient and also of transmitting a BBV to a patient.

HCWs performing EPPs must have appropriate timely testing and follow-up care after a potential occupational or non-occupational exposure associated with a risk of BBV acquisition. HCWs have the option of arranging testing with a practitioner of their choice. Post exposure prophylaxis should be offered where appropriate.

Registered HCWs who perform EPPs must declare whether they are complying with the CDNA Guidelines when they are renewing their annual health practitioner registration. HCWs are not required to provide the results of testing to the health practitioner Board that has registered them or to the Australian Health Practitioner Regulation Agency (AHPRA). However, the declaration that testing has occurred will form part of the HCW's compliance with their Board's *Guidelines for the regulatory management of registered health practitioners and students infected with blood-borne viruses, (under development)* (see role of AHPRA and National Health Practitioner Boards, Appendix 2: Roles). The relevant Board may take action under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), if a HCW is placing the public at risk.

If a HCW is at risk of acquiring a BBV through non-occupational exposure, the HCW should increase the frequency of BBV testing appropriately. Relevant risk factors are defined in the national testing policies for HIV, HBV and HCV [1-3].

Student HCWs

All student HCWs should be aware of their BBV status and should be offered testing for BBVs at or before entry to their course. Student HCWs who will be performing EPPs must be tested for BBVs in accordance with these Guidelines. Implementation of this is the responsibility of the educational facility/employer. The follow up of test results is the responsibility of the medical practitioner who conducts the test. Student HCWs found to have a positive BBV test result should be counselled by their medical practitioner about appropriate management, and about potential impacts on future career options. The medical practitioner can seek advice from a specialist in BBVs or the relevant area of the jurisdictional health department. These students should receive education to ensure they understand their obligations should they wish to continue performing EPPs.

False positives for BBV tests

BBV screening tests in Australia are extremely accurate, and involve a two-stage testing process to ensure the rate of false positives are very low. The specificity of the HBV, HCV and HIV screening serology tests are all greater than 99%. Despite this high specificity, it is possible to have the occasional false or non-specific reactivity in the screening test, as the tests are very sensitive.

For this reason, the Australian laboratory standard is not to report a positive HBV, HCV or HIV screening serology test result without supplemental testing to confirm the positive result. This false reactivity is quickly settled by a supplemental serology test with similar or higher specificities. If not settled by this, molecular testing can be used which adds another measure of specificity. Therefore, the risk of a health professional having to stop practice due to a false positive result will not occur due to appropriate testing algorithms being in place.

4.2 Benefits of early diagnosis and treatment

As BBVs can be asymptomatic for extended periods, or cause minor symptoms that may go unrecognised, it is possible for a HCW to be infected unknowingly. This delay in diagnosis can lead to the development of complications related to the infection and increase the risk of transmitting the virus to family, other close contacts, or patients.

Regular testing and early detection of BBVs in HCWs will ensure that appropriate and timely advice, management and support is provided to the HCW with a BBV. This will allow the HCW to be assessed, counselled and treated to reduce disease progression and transmission and to modify their:

- lifestyle to reduce disease progression and transmission, and
- work practices to avoid additional occupationally acquired infections that may exacerbate any existing infection and also reduce the risk of transmission to a patient (i.e. stop performing EPPs until under appropriate care and treatment).

In addition, early diagnosis of HBV, HCV and/or HIV infection enables the prompt treatment of the HCW, which is associated with better health outcomes. Timely diagnosis of:

- HBV will allow the assessment of liver disease and introduction of effective antiviral therapy when indicated which can reduce clinical progression.
- HCV will allow early initiation of treatment with direct acting antiviral (DAA) therapies, which are associated with very high cure rates.
- HIV (before the onset of symptoms) will allow the early start of combination antiretroviral therapy (cART) which can reduce the risk of clinical progression, transmission and morbidity and mortality associated with the disease.

A diagnosis with a BBV does not have to limit the careers of HCWs who perform EPPs. If the HCW with a BBV complies with these Guidelines, it is possible to return to performing EPPs.

5. Recommendations for the management of HCWs living with a BBV

Key recommendations for the management of HCWs living with a BBV*
All HCWs with a BBV must have appropriate and regular medical care.
All HCWs living with one or more BBVs must be tested for the respective BBV viral load levels, as well as for other BBVs, in accordance with the Guidelines.
HCWs who are HBV DNA positive are permitted to perform EPPs if they have a viral load below 200 IU/mL and meet the criteria set out in detail within these Guidelines.
HCWs must not perform EPPs while they are HCV RNA positive, but may be permitted to return to EPPs after successful treatment or following spontaneous clearance of HCV RNA.
HCWs who are HIV positive are permitted to perform EPPs if they have a viral load below 200 copies/mL and meet the criteria set out in detail within these Guidelines.

* Detailed information and recommendations are provided in the sections for each BBV.

5.1 Initial diagnosis of a BBV

When diagnosed with a BBV, HCWs must cease performing all EPPs immediately and seek appropriate medical care. HCWs with a BBV may return to performing EPPs once they meet the criteria set out within these Guidelines.

5.2 Support of HCWs living with a BBV

If a HCW has had a significant time away from practice they must meet the requirements specified by the relevant recency of practice registration standards of the relevant health profession boards. Further information on this requirement can be provided by the relevant health profession board.

The healthcare system should support a HCW living with a BBV, as for all other HCWs, by providing a work environment that minimises the risk of cross-infection or acquisition of other BBVs. Support may include appropriate training or retraining/supervision (if required), counselling, infrastructure, infection control measures and equipment. Healthcare facilities should provide an environment in which HCWs living with a BBV know their privacy and confidentiality will be respected and maintained. The support required by the HCW should be considered on a case-by-case basis. Guidance is provided in the *Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)* [5].

HCWs should understand their obligation to report their BBV status if required under jurisdictional legislation, and/or policies. They should understand their obligation to report all sharps injuries, whether or not there was a risk of patient exposure. Comprehensive reporting is required to enhance surveillance of possible BBV transmission.

5.3 Responsibilities of the HCW with a BBV

All HCWs have a professional obligation, on learning of their positive BBV status, to seek formal advice about personal care (e.g. if certain skin conditions are present), health monitoring and work practices from a medical practitioner with appropriate expertise. HCWs are not required to disclose their BBV status to their employer.

In addition, HCWs who are BBV positive and who undertake EPPs must be familiar with the current standards of infection prevention and control and have an action plan in place in the event of a potential transmission event that includes reporting the event as per local procedures. HCWs with a BBV should report all incidents where they are aware of accidentally exposing a patient to their blood to the appropriate person, according to local policies.

The HCW with a BBV must be under the care of a treating doctor with relevant expertise, and must accept that it is a condition of undertaking EPPs that they consent to ongoing management while they continue to practise EPPs, including:

- to be compliant with their prescribed treatment
- to have ongoing viral load monitoring at the appointed time
- to seek advice if a change in health condition may affect their fitness to practise or impair their health

- to release monitoring information to the treating doctor, and if required, de-identified information to the relevant area of the jurisdictional health department/Expert Advisory Committee (EAC), and
- to release health monitoring information (including viral load and relevant clinical information), to a designated person in their workplace in the event of a potential exposure incident to assess the requirement for further public health action (if required).

5.4 Responsibilities of the HCW's treating doctor

In the context of these Guidelines, “treating doctor” refers to “a specialist in the treatment of BBVs” and may include appropriately trained and experienced general practitioners as well as infectious diseases or sexual health physicians, hepatologists or immunologists experienced in the treatment of BBV(s). The treating doctor has a responsibility to:

- ensure that their skills and experience are of a standard that would deem them to have expertise in the treatment of the BBV(s), including contemporary treatment and prescribing guidelines
- identify any conflict of interest (whether actual or perceived) towards the HCW and be willing to report any breaches in compliance with these Guidelines. If there is a conflict of interest then the doctor should not manage the HCW
- ensure their own understanding of and compliance with the relevant jurisdictions' Health Practitioner Regulation National Law and the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia [7].
- ensure their own understanding of these Guidelines and any relevant jurisdictional policy in relation to HCWs with a BBV as well as relevant public health and privacy legislation
- ensure the HCW has scheduled appointments of appropriate frequency for the level of monitoring they require
- actively follow up missed HCW appointments to ensure timely rescheduling
- report concerns regarding HCW compliance with professional standards to the relevant area of the jurisdictional health department in a timely manner
- report concerns regarding actual or potential exposures constituting a public health risk to the relevant area of the jurisdictional health department, and
- Consider notification of the HCW to AHPRA under provisions of the National Law, particularly if the HCW is putting the public at risk and a mandatory notification is therefore necessary. Further information can be found in the health practitioner boards' *Mandatory notifications guidelines for registered health practitioners* [8], and *Guidelines for the regulatory management of registered health practitioners and students infected with blood-borne viruses* (in development at time of writing these Guidelines)

5.5 Failure of a HCW to attend appointments or refusal to be tested

All HCWs with a BBV who are performing EPPs should be advised by their treating doctor of the importance of regular monitoring of their viral load (as specified in sections 6 – 8), as appropriate, for the purposes of supervision and the implications of not doing so.

If required, the treating doctor can seek advice from jurisdictional health departments. The treating doctor must inform AHPRA and then follow local jurisdictional processes as required/permitted under public health legislation in order to protect the public, where an HCW with a BBV:

- does not attend their appointments or fails to be tested within the prescribed timeframe without prior notification and adequate justification to their doctor
- refuses to have their viral load tested, or
- continues to perform EPPs when excluded by these Guidelines.

The treating doctor may also need to inform the relevant area of the jurisdictional health department that the HCW is no longer cleared to perform EPPs, until it has been established that the HCW is complying with these Guidelines (i.e. below the specified viral load where applicable).

6. HCWs and HBV

This Section must be read in conjunction with the remainder of these Guidelines, in particular Section 5. Recommendations for the management of HCWs living with a BBV.

6.1 Evidence of HBV transmission risk

HBV is the most readily transmitted BBV, and can be transmitted in the absence of visible blood [9-11]. HBV is transmitted through percutaneous (the most efficient mode), mucosal or non-intact skin (e.g psoriasis, eczema, burns, wounds) exposure to infectious blood or body fluid [9]. Published cases of HBV transmission from a HCW to a patient do occur but have decreased in frequency following the introduction of standard (universal) infection prevention and control precautions, routine HBV vaccination of HCWs, and adoption of enhanced percutaneous injury precautions, such as double-gloving during EPPs, avoiding recapping needles after use, or using retractable needles.

Transmission risk from an infected patient to a HCW

Historically, the risk of HBV transmission from a patient to a HCW has been linked to the hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg) status of the source. In studies of HCWs who sustained needle stick injuries (NSIs) from sharps contaminated with blood containing HBV, the risk of seroconversion for HBV infection ranged from 37% to 62% if the source patient was both HBsAg-positive and HBeAg-positive, and 23% to 37% if the source was HBsAg-positive but HBeAg-negative [9, 12]. The risk of developing clinical hepatitis after exposure ranged from 22% to 31% if the source patient was both HBsAg-positive and HBeAg-positive, and from 1% to 6% if the source was HBsAg-positive but HBeAg-negative [9, 12]. As viral load monitoring becomes more common, these risks will be re-evaluated using new data, though HBV is known to be infectious even at very low levels. Therefore when performing EPPs, HCWs are at risk for exposure to HBV from infected patients, and correspondingly, HCWs with HBV may potentially transmit HBV to patients.

Transmission risk from an infected HCW to a patient

Subsequent to HBV testing becoming available in the early 1970s, at least 55 reported HCWs with HBV have been implicated in the transmission of their infection to more than 500 patients [13, 14]. The reported risks of transmission of HBV from a HCW with HBV to a patient, calculated from published lookback exercises, ranged from 0.2% to 13.19% with an average risk of 2.96% [13-23] per EPP the HCW performed. Table 4 in Appendix 3: Results of published lookback investigations summarises the published cases of HCW to patient transmission of HBV since 1991. It is important to note that none of these cases are from countries of high prevalence and there would be more iatrogenic transmissions that are not reported or not recognised as linked to healthcare.

Setting a viral load limit

For the majority of published cases of HCW transmission of HBV to a patient (where the HBeAg status was known), the HCW was HBeAg-positive [24]. However, reports of HBV transmission from seven HBeAg-negative HCWs (pre-core mutants) to patients [18, 19, 24]

and the now widespread availability of HBV viral load testing has led to the use of viral load as an indicator of transmission risk in a number of international guidelines [25-29].

All reported cases of transmission from a HCW to a patient have occurred at viral load levels above 2×10^4 IU/mL^{vi} [28], except for one questionable case at a level of $\sim 7.4 \times 10^3$ IU/mL which was measured at least three months after the transmission event occurred [24, 30]. Serum HBV DNA levels can fluctuate during the course of chronic HBV infection, such that a single result must be interpreted with caution [31-33]. However, while the transmission of HBV from HCWs with lower levels of HBV DNA has yet to be documented it still may occur [30].

When setting the HBV DNA viral load limit of 200 IU/mL, for the purposes of these Guidelines, it was considered that transmission of HBV from a HCW to a patient was most likely to occur with HBV DNA levels above 2×10^4 IU/mL. The 2 log₁₀ margin was included to account for fluctuations in HBV DNA levels that can occur [27, 30].

6.2 Prevention and detection of HBV infection

All HCWs and student HCWs should be vaccinated against HBV prior to commencement of employment, studies or clinical placements if they have no documented evidence of pre-existing immunity (from resolved infection or prior vaccination). All HCWs should be assessed for immunity post-vaccination.

In the case of non-responders to the hepatitis B vaccine, treating doctors should refer to the latest edition of *The Australian Immunisation Handbook* [4] for further vaccination requirements and management after potential exposures to HBV.

6.3 Management of HCWs living with HBV who perform EPPs

6.3.1 HCWs with HBV must meet the following criteria before they can perform EPPs:

- a) be under the regular care of a specialist in the treatment of HBV who also has an understanding of the regulatory framework for HCWs living with BBVs,
- b) undergo HBV viral load monitoring every three months if not on treatment or every six months if on appropriate and effective antiviral treatment for the purposes of this supervision,

AND

- c) have a viral load below 200 IU/mL.

6.3.2 Initial health clearance for HCWs with HBV who wish to perform EPPs

For HCWs with HBV wishing to perform EPPs:

- Two tests from a NATA/RCPA accredited laboratory, taken no less than three months apart and with viral load levels below 200 IU/mL are required to ensure viral load stability. At this point, a decision should be made as to whether health clearance could be given for the HCW to commence or resume EPPs.

^{vi} Conversions from genome equivalents (geq/mL) to IU/mL were calculated using the WHO HBV standard preparation of 1IU is equivalent to 5.4 geq/mL. However, it is acknowledged that this can vary depending on the polymerase chain reaction based quantification assay so the values are approximations.

For HCWs with HBV currently restricted from EPPs:

- The decision to provide initial clearance for individual HCWs who have been previously excluded from work involving EPPs is the responsibility of the treating doctor. However, with more complex situations, the treating doctor may choose to consult with the relevant area of the jurisdictional health department. An example of a complex situation may include where other considerations apart from virological response are present such as recency of practice^{VII}, evidence of behaviour which could have affected the HCWs standard of practice, or individual work variances. Consulting with the relevant area of the jurisdictional health department on these more complex issues may assist in preserving the therapeutic relationship and remove potential conflicts of interest between the treating doctor's responsibilities to the HCW with HBV versus to public health.

6.3.3 Viral load monitoring and ongoing clearance for HCWs with HBV performing EPPs

HCWs with HBV who are cleared to perform EPPs must undergo viral load testing every three months if not on treatment or every six months while stable on treatment. The three or six month period should be taken from the date the previous sample was drawn, not from the date the result was received.

If a HCW's viral load rises above 1 000 IU/mL, they should be immediately restricted from performing EPPs until their viral load is again repeatedly below 200 IU/mL in at least two tests done no less than three months apart. The significance of any increase in viral load above 200 IU/mL but below 1 000 IU/mL should be assessed by the treating doctor with input from appropriate local experts (e.g. consultant virologist or microbiologist).

Table 2 sets out the expected course of action for viral load test results below and above the level for EPP clearance (200 IU/mL).

^{VII} If a HCW has had a significant time away from the field they must meet the requirements specified by the relevant recency of practice registration standards.

Table 2: HBV viral load monitoring and subsequent action

HBV viral load result	Action
less than 50 IU/mL or undetectable	No action – retest in three months if not on treatment or six months if on appropriate and effective antiviral treatment.
50 – 200 IU/mL	<p>A case-by-case approach based on clinical judgement, which may result in no action (as above) or a second test may be done 10 days later on a new blood sample to verify the first result. Further action would be informed by the subsequent test result.</p> <p>If the second result remains in the 50 – 200 IU/mL range, considered low level viraemia, no further action is required and there are no treatment guidelines that suggest a change in treatment at this level. Emphasising treatment compliance to ensure the individual remains in the low level viraemia classification is important.</p>
201 copies/mL – 999 IU/mL	A second test should be done 10 days later on a new blood sample to verify the first result. If the viral load is still in excess of 200 IU/mL, the HCW must cease conducting EPPs until their viral load, in two consecutive tests no less than three months apart, is below 200 IU/mL.
1 000 IU/mL or above	<p>The HCW must cease conducting EPPs immediately. A second test must be done on a new blood sample 10 days later to verify the first result. If the viral load is still in excess of 1 000 IU/mL, a full risk assessment should be initiated to determine the risk of HCW to patient transmission. At a minimum, this will include discussion between the treating doctor, the local communicable disease control unit or public health unit and the relevant infection prevention and control service if appropriate, on the significance of the result to the risk of HBV transmission.</p> <p>Following a risk assessment, patient notification may be indicated but would generally only be considered when a serious breach of infection prevention and control practices has been identified.</p>

6.3.4 Resuming EPPs

Resumption of EPP activities following a period of exclusion (for whatever reason) requires demonstration of consistent viral load suppression i.e. at least two viral loads below

200 IU/mL, no less than three months apart. Retraining and supervision for those HCWs returning to EPPs should be considered on a case-by-case basis.

6.3.5 Breaks in monitoring

HCWs with HBV who take a career break^{VIII} from performing EPPs may wish to continue monitoring during this period to facilitate a return to EPP activities. Individuals with a break in their monitoring record must meet the criteria for initial clearance (see 6.3.2 Initial health clearance for HCWs with HBV who wish to perform EPPs) before returning to EPP activities.

6.4 Treatment issues

6.4.1 Decisions about treatment

Hepatitis B treatment is currently (as of 2017) subsidised by the Pharmaceutical Benefits Scheme (PBS) only for patients that have high HBV DNA levels ($> 2 \times 10^4$ IU/mL for HBeAg positive patients and $> 2 \times 10^3$ IU/mL for HBeAg negative patients), persistently elevated alanine aminotransferase levels or evidence of liver inflammation [34]. HCWs with HBV may embark upon long-term antiviral treatment in an attempt to comply with these Guidelines to perform EPPs, rather than for their personal health. The cost of treatment would need to be considered if the criteria for PBS subsidised treatment are not met. This decision should be made by the individual HCW, in collaboration with their treating physician, weighing up the advantages and possible disadvantages to their health from such treatment.

6.4.2 Discontinuation of therapy

If a HCW stops antiviral treatment for any reason, they must immediately cease to perform EPPs and seek the advice of their treating doctor.

If after cessation of treatment the HCW with HBV remains HBsAg positive but with HBV DNA levels below 200 IU/mL (as for other HCWs with HBV not on treatment), the HCW may be permitted to practise EPPs provided there is regular three monthly viral load testing overseen by an appropriate specialist and the HBV DNA viral load remains below 200 IU/mL.

If, following treatment, the HCW with HBV is HBV DNA negative and HBsAg negative on two consecutive occasions at least three months apart, then the HCW can practise EPPs but must have HBV DNA and HBsAg testing three, six and 12 months after the cessation of treatment and annually thereafter. The loss of HBsAg is considered to be a complete response to HBV therapy, with reliable resolution of infection.

6.4.3 Management of treatment failure or suboptimal treatment response

If there is any suggestion that the HCW's infection is no longer controlled by their antiviral treatment, the clinician overseeing their care may consider it appropriate that viral load tests are performed sooner than the next scheduled test.

^{VIII} A career break can involve a HCW taking a break from all health-related work, or only taking a break from work involving EPPs. Upon returning to work, the HCW must meet the recency of practice requirements as described in Section 5.2 Support of HCWs living with a BBV.

6.5 HCWs with HBV not performing EPPs

HCWs with HBV and who do not perform EPPs may continue to provide clinical care to patients. It is in the best interest of the HCWs own health to remain under regular medical care.

7. HCWs and HCV

This Section must be read in conjunction with the remainder of these Guidelines, in particular Section 5. Recommendations for the management of HCWs living with a BBV.

7.1 Evidence of HCV transmission risk

Transmission risk from an infected patient to a HCW

Although HCV is present in various biological fluids of an infected person, HCV transmission is predominantly via blood or other fluids contaminated with blood [35]. Occupational transmission of HCV is well documented, with the risk of developing serological evidence of HCV after exposure to a known infected source ranging from 0%-7% [35-40]. The United States Centers for Disease Control and Prevention (CDC) calculates the risk of HCV infection after a NSI or sharps exposure to HCV RNA positive blood at approximately 1.8% [39].

Transmission risk from an infected HCW to a patient

From 21 published lookback exercises where HCWs with HCV transmitted their infection to over 400 patients, the risk of transmission of HCV from a HCW to a patient varied from 0.04% to 4.35% (excluding transmission from tampering with injectable anaesthetic opioids) [41-58]. This suggests that transmission is highly variable and heterogeneous [35]. All of these studies undertook genetic sequencing of the virus in infected HCWs and infected patients. There were two distinct modes of transmission:

- HCV transmission occurred from surgeons performing EPPs with the majority of reports involving cardiothoracic specialists and gynaecologists-obstetricians [44, 45, 48, 54, 59-66], and
- HCV transmission by anaesthetists or HCWs attending surgery wards following poor hygienic measures (including not wearing gloves). This group also included HCWs who were known to use illicit drugs and/or using patients' medications for their own use, which led to the direct infection of a large number of patients via needle sharing [43, 46, 47, 49, 50, 67-69].

7.2 Management of HCWs living with HCV who perform EPPs

7.2.1 HCWs with HCV must meet the following criteria before they can perform EPPs:

- a) be HCV RNA negative if untreated or achieved a sustained virological response (SVR) (measured 12 weeks after treatment completion) if treated.

7.2.2 Initial health clearance for HCWs with HCV who wish to perform EPPs

For HCWs with HCV wishing to perform EPPs:

- HCW must be HCV RNA negative, if untreated, or have undergone successful treatment (achieved SVR). Successful treatment is indicated by a negative HCV RNA test, performed at a NATA/RCPA accredited laboratory, at least 12 weeks after completion of treatment and if the advice from the treating clinician is that the likelihood of reinfection is very low.

For HCWs with HCV currently restricted from EPPs:

- The decision to provide initial clearance for individual HCWs who have been previously excluded from work involving EPPs is the responsibility of the treating doctor. However, with more complex situations, the treating doctor may choose to consult with the relevant area of the jurisdictional health department. An example of a complex situation may include where other considerations apart from virological response are present including recency of practice^{ix}, evidence of behaviour which could have affected the HCWs standard of practice, individual work variances etc. Consulting with the relevant area of the jurisdictional health department on these more complex issues may assist in preserving the therapeutic relationship and remove potential conflicts of interest between the treating doctor's responsibilities to the HCW with HCV versus to public health.

7.2.3 Viral load monitoring and ongoing clearance for HCWs with HCV performing EPPs

In 2016, the direct acting antiviral treatments for HCV were made publically available through the PBS. The new direct acting antiviral regimes for HCV are shorter, less complex, have fewer side effects and are usually associated with a high success rate (over 90%).

HCWs who have been successfully treated for HCV infection, that is HCV RNA negative 12 weeks after the cessation of treatment must have additional HCV RNA testing 12 months after treatment, to determine if relapse or reinfection has occurred.

If the test performed 12 months after treatment is negative, the HCW is no longer considered to be infected with HCV and should resume the prescribed BBV testing as specified in Section 4.1 Diagnosis and frequency of BBV testing. However HCV RNA testing should be performed instead of screening for HCV antibody as this will remain positive irrespective of the viral load.

If HCV RNA is detected, the HCW must be immediately restricted from carrying out EPPs until once again undergoing successful treatment as assessed by their treating doctor.

7.2.4 Resuming EPPs

Resumption of EPP activities following a period of exclusion (for whatever reason) requires proof of successful treatment^x.

Returning to EPP activities within 12 weeks of treatment completion

The HCW must not return to performing EPPs less than 12 weeks after completion of treatment.

Returning to EPP activities after 12 weeks but before 12 months since treatment completion

The HCW must provide proof of successful treatment by a negative HCV RNA test at least 12 weeks after completion of treatment and clearance by their treating doctor. In addition, the HCW must have their HCV RNA tested 12 months after the completion of treatment.

^{ix} If a HCW has had a significant time away from the field they must meet the requirements specified by the relevant recency of practice registration standards

^x Proof of successful treatment is demonstrated by a negative HCV RNA test at least 12 weeks after completion of treatment and clearance by the treating doctor.

Returning to EPP activities 12 months after treatment

The HCW must be HCV RNA negative and have clearance by their treating doctor.

7.2.5 Treatment issues

All HCWs with HCV should be offered treatment in accordance with standard treatment guidelines [70]. The combination of medicines used will depend on a range of individual factors including the HCV genotype, prior treatment experience and the presence of cirrhosis.

The treating doctor should counsel the HCW about the importance of following the prescribed treatment regimen and the impact that missed doses may have.

7.3 HCW with HCV not performing EPPs

HCWs with HCV and who do not perform EPPs may continue to provide clinical care to patients. It is in the best interest of the HCWs own health to remain under regular medical care.

8. HCWs and HIV

This Section must be read in conjunction with the remainder of these Guidelines, in particular Section 5. Recommendations for the management of HCWs living with a BBV.

8.1 Evidence of HIV transmission risk

The UK document, *The Management of HIV-infected Healthcare Workers who perform exposure prone procedures: updated guidance, January 2014* states that: worldwide, there have been three reports of healthcare associated HIV transmission from HCWs with HIV during EPPs. They are a Florida dentist, where the exact route of transmission (to the five infected patients) was never established; a French orthopaedic surgeon; and a gynaecologist in Spain. In the latter two cases transmission occurred during cases meeting the EPP definition. A further transmission has been reported involving a French nurse who was co-infected with hepatitis C; this did not involve an EPP and the exact route of transmission remains unclear. These four cases of transmission involved HCWs who were not taking antiretroviral therapy at the time of transmission [71].

Lookback exercises associated with these four instances of HCW-to-patient transmission tested approximately 4 627 patients (1 100 for the Florida dentist and 3 527 for the latter three combined). In total eight patients were found to be HIV positive with HIV viral nucleotide sequencing very similar to that of the source HCWs virus [72-75].

In the UK between 1988 and 2008, 39 patient notification exercises were conducted in which almost 10 000 patients were tested. In Israel in 2007, 545 patients operated on by a cardiothoracic surgeon with HIV were tested. There was no detectable transmission in any of these exercises [71, 75-78].

These data support the conclusion that the overall risk of transmission of HIV from untreated HCWs with HIV is very low, with estimates varying in the order of 2.4 to 24 per million procedures (0.0000024% - 0.000024%) [79]. Plasma HIV RNA or viral load is known to be the critical risk factor in HIV transmission risk and treatment-associated viral load reduction substantially reduces this risk in sexual and mother-to-child transmission [80, 81]. In the era of effective antiretroviral therapy, which is both recommended and widely available in Australia, almost all individuals are able to achieve an undetectable blood HIV viral load.

Conversely, the risk of transmission of HIV after sharps injury to a HCW from a HIV positive source patient who is not on cART has been calculated to be 0.23% [82].

8.2 Management of HCWs living with HIV who perform EPPs

8.2.1 HCWs with HIV must meet the following criteria before they can perform EPPs:

- a) be under the regular care of a specialist in the treatment of HIV who also has an understanding of the regulatory framework for HCWs living with BBVs,

AND

- b) undergo HIV viral load monitoring every three months for the purposes of this supervision,

AND

Either

- c) be on effective cART, and
d) have a HIV viral load below 200 copies/mL (see section 8.2.2 Initial health clearance for HCWs with HIV who wish to perform EPPs).

Or

- e) meet the definition of an elite controller (see section 8.2.7 Elite controllers).

8.2.2 Initial health clearance for HCWs with HIV who wish to perform EPPs

For HCWs with HIV wishing to perform EPPs:

- Two test results from a NATA/RCPA accredited laboratory, taken no less than three months apart and with viral loads below 200 copies/mL are required to ensure viral load stability. At this point, a decision should be made as to whether health clearance could be given for the HCW to commence or resume EPP activities.

For HCWs with HIV currently restricted from EPPs:

- Being on combination cART with a viral load below 200 copies/mL, measured on two occasions no less than three months apart, with the most recent result being no more than three months ago, should be considered as consistent viral suppression by the treating doctor when considering to give health clearance for the HCW to resume EPP activities.
- The decision to provide initial clearance for individual HCWs who have previously been excluded from work involving EPPs is the responsibility of the treating doctor. However, with more complex situations, the treating doctor may choose to consult with the relevant area of the jurisdictional health department. An example of a complex situation may include where other considerations apart from virological response are present including recency of practice^{xI}, evidence of behaviour which could have affected the HCWs standard of practice, individual work variances etc. Consulting with the relevant area of the jurisdictional health department on these more complex issues may assist in preserving the therapeutic relationship and remove potential conflicts of interest between the treating doctor's responsibilities to the HCW with HIV versus to public health.

For HCWs with HIV who are elite controllers:

- See section 8.2.7 Elite controllers.

^{xI} If a HCW has had a significant time away from the field they must meet the requirements specified by the relevant recency of practice registration standards.

8.2.3 Viral load monitoring and ongoing clearance for HCWs with HIV performing EPPs

HCWs with HIV who are cleared to perform EPPs must undergo viral load testing every three months while continuing to perform such procedures. The three month period should be taken from the date the previous sample was drawn, not from the date the result was received.

If a HCW's plasma viral load rises above 1 000 copies/mL, they should be immediately restricted from carrying out EPPs until their viral load is again consistently below 200 copies/mL in at least two tests done no less than three months apart. The significance of any increase in plasma viral load above 200 copies/mL but below 1 000 copies/mL should be assessed by the treating doctor with input from experts (e.g. consultant virologist or microbiologist) if appropriate.

Table 3 sets out the expected course of action for viral load test results below and above the level for EPP clearance (200 copies/mL).

Table 3: HIV viral load monitoring and subsequent action

HIV viral load result	Action
less than 50 copies/mL or undetectable	No action – retest in three months
50 – 200 copies/mL	<p>A case-by-case approach based on clinical judgement, which may result in no action (as above) or a second test may be done 10 days later on a new blood sample to verify the first result. Further action would be informed by the subsequent test result.</p> <p>If the second result remains in the 50 – 200 copies/mL range, considered low level viraemia, no further action is required and there are no treatment guidelines that suggest a change in antiretroviral treatment at this level.</p> <p>Emphasising treatment compliance to ensure the individual remains in the low level viraemia classification is important.</p>
201 copies/mL – 999 copies/mL	<p>A second test should be done 10 days later on a new blood sample to verify the first result. If the viral load is still in excess of 200 copies/mL, the HCW must cease conducting EPPs until their viral load, in two consecutive tests no less than three months apart, is reduced to below 200 copies/mL.</p> <p>A change in antiretroviral treatment may be required [83].</p>
1 000 copies/mL or above	<p>The HCW must cease conducting EPPs immediately. A second test must be done on a new blood sample 10 days later to verify the first result. If the viral load is still in excess of 1 000 copies/mL, a full risk assessment should be initiated to determine the risk of HCW to patient transmission. At a minimum, this will include discussion between the treating doctor, the local communicable disease control unit or public health unit and the relevant infection control service if appropriate, on the significance of the result to the risk of HIV transmission.</p> <p>Following a risk assessment, patient notification may be indicated but would generally only be considered when a serious breach of infection prevention and control practices has been identified.</p> <p>A change in antiretroviral treatment may be required.</p>

8.2.4 Resuming EPPs

Resumption of EPP activities following a period of exclusion (for whatever reason) requires demonstration of consistent viral load suppression i.e. at least two test results, with viral load levels below 200 copies/mL, no less than three months apart. Retraining and supervision for those HCWs returning to EPPs should be considered on a case-by-case basis.

8.2.5 Breaks in monitoring

HCWs with HIV who take a career break from performing EPPs may wish to continue three monthly monitoring during this period to facilitate a return to EPP activities. Individuals with a break in their monitoring record must meet the criteria for initial clearance (See Section 8.2.2 Initial health clearance for HCWs with HIV who wish to perform EPPs) before returning to EPP activities.

8.2.6 Treatment issues

In accordance with the *Australian HIV Treatment Guidelines* [84], HCWs with HIV should be offered cART, irrespective of CD4 count, by their treating doctor.

The treating doctor should counsel the HCW about the importance of following the prescribed treatment regimen and the impact that missed doses may have on their viral load. In addition, advice on drug interactions or other factors that might influence their viral load should be provided to the HCW as soon as is practicable and before further EPPs are performed.

8.2.7 Elite controllers

Elite controllers represent a small proportion (0.2 – 0.55%) of all people living with HIV, who are not receiving cART yet have maintained their viral load below the limits of assay detection for at least 12 months, based on at least three separate viral load measurements [71].

A HCW who meets the definition of being an elite controller can be cleared for EPP activities without being on treatment, but remains subject to three monthly viral load monitoring to ensure they maintain their viral load below 200 copies/mL and to identify any rebound promptly.

8.2.8 Management of treatment failure or suboptimal treatment response

If there is any suggestion that the HCW's infection is no longer controlled by their cART treatment, the clinician overseeing their care may consider it appropriate that viral load tests are performed sooner than the next scheduled three month test.

8.3 HCWs with HIV not performing EPPs

HCWs who are known to be HIV-positive and who do not perform EPPs may continue to provide clinical care to patients. They have a professional duty to remain under regular medical care in accordance with good practice.

Part B

Guidelines for Public Health Authorities Managing Healthcare Workers Living with a Blood Borne Virus

9. Introduction

All Australian health departments are committed to providing an environment which is as safe as possible for patients and HCWs. These Guidelines provide information and recommendations for use in relation to HCWs living with HBV, HCV or HIV and provide the basis for development of detailed policy relevant to particular settings in jurisdictions. This part of the Guidelines provides advice and recommendations for public health authorities (PHA's) managing or investigating a HCW with a BBV, when to consult with EACs or the National Expert Reference Panel (NERP), and when and how to conduct a lookback exercise. Part B of the Guidelines should be read in conjunction with Part A of the Guidelines. All states and territories should have implementation procedures that are consistent with these Guidelines.

10. Managing HCWs living with BBVs

State and territory health departments are the primary agencies responsible for surveillance of, and response to, notifiable diseases. This encompasses preventative programs, such as immunisation, BBV policy and program responses, contact tracing where appropriate, surveillance of disease trends and, in some jurisdictions, infection control coordination.

Jurisdictional health departments may also be requested to provide advice or guidance on complex situations involving a HCW with a BBV or issues of non-compliance with these Guidelines.

10.1 Establishment of EACs or panels

Jurisdictions may form an EAC or equivalent to provide expert advice when required. This may include when an exposure incident occurs involving a HCW with a BBV who is not complying with these Guidelines. The relevant area of the jurisdictional health department should be responsible for convening the EAC.

A NERP will provide advice and support to EACs, if required, on issues related to these Guidelines, including the management of individual workers with a BBV and advice on risk assessments^{xii} and lookbacks^{xiii} in the event of an incident. The NERP can also provide this support and advice to jurisdictions that do not have an EAC on request, and will guide nationally consistent decision making.

The role and definition of an EAC and the NERP is further detailed in Appendix 2: Roles.

10.2 When the jurisdictional health department, EAC or NERP may be consulted for advice

^{xii} Risk assessment includes the standard of practice of the HCW and the general health of the HCW.

^{xiii} Lookback: the process of identifying, tracing, recalling, counselling and testing patients or HCWs who may have been exposed to an infection in a healthcare setting.

When managing HCWs with BBVs, complex situations may arise. In these situations, examples of which are detailed below, the treating doctor can consult with a jurisdictional health department who may then decide to consult with an EAC or the NERP for advice.

10.2.1 Initial health clearance for HCWs with a BBV who wish to perform EPPs

The decision to provide initial clearance for individual HCWs who have been previously excluded from work involving EPPs is the responsibility of the treating doctor. However, with more complex situations, the treating doctor may choose to consult with the relevant area of the jurisdictional health department who may then also refer the request onto the local EAC. An example of a complex situation may include where other considerations apart from virological response are present and further advice may be required including recency of practice, evidence of behaviour which could have affected the HCWs standard of practice, individual work variances etc.

Advice provided by the jurisdictional health department at this time may assist where there is a potential conflict of interest between the treating doctor's responsibilities to the HCW with a BBV versus to public health.

10.2.2 Failure of a HCW with a BBV to attend appointments or refusal to be tested

As well as informing AHPRA, the treating doctor may inform the relevant area of the jurisdictional health department when a HCW is no longer cleared to perform EPPs. Situations when this may arise include when a HCW with a BBV:

- does not attend their appointments or fails to be tested within the prescribed timeframe without prior notification and adequate justification to their doctor,
- refuses to have their viral load tested, or
- continues to perform EPPs when excluded by these Guidelines.

11. Recommendations for responding to patient exposure (possible or realised) to the blood or bodily fluid of a HCW with a BBV

11.1 Management of patients following exposure to the blood and/or body fluid of a HCW with a BBV

When a HCW with a BBV accidentally exposes a patient to their blood, the incident should be reported to the appropriate person according to local policies.

A detailed risk assessment should be performed by the designated person, in discussion with the HCW's treating doctor that includes:

- assessment of the significance of the exposure
- the status of the exposed patient
- the status of the HCW with a BBV, in particular their current viral load, and

- the history of the HCW with a BBV including their adherence to treatment, the frequency and magnitude (if any) of fluctuations in their viral load and the presence of factors which might increase the HCW's viral load.

Standard procedure, as dictated in local policies, should be followed to evaluate the significance of the exposure and then determine the follow-up required for both the HCW and patient.

When completing the risk assessment, the following information should also be considered:

- exposure to the blood or bodily fluids of a HCW with a BBV, who has been complying with these Guidelines would pose an extremely low risk of transmission of a BBV to a patient.
- if there is concern that the viral load of the HCW is above what is stipulated in the Guidelines (200 copies/mL for HIV, 200 IU/mL for HBV or HCV RNA positive), the HCW's viral load should be tested immediately, and local policies should be followed in regard to offering appropriate post exposure prophylaxis and follow-up to the patient(s).

11.2 Indications for investigation and/or lookback exercises

Potential iatrogenic BBV transmission

If a patient presents with an acute BBV infection after undergoing an EPP, and the origin of the infection is unclear, the need for a full risk assessment should be decided in consultation with the relevant area of the jurisdictional health department, who may choose to consult their EAC (where available) or the NERP.

This should include an investigation into the circumstances of the transmission including possible system failures (such as staff to patient ratios, acuity of area/situation, faulty equipment, poor HCW training or supervision), HCW factors (such as inexperience, inappropriate deployment), and patient factors.

If there is evidence of iatrogenic transmission of a BBV from a HCW, a lookback must be conducted.

New BBV diagnosis in a HCW who performs EPPs

When a HCW is diagnosed with a BBV infection, but no iatrogenic transmission to a patient has been identified, the decision on whether a lookback should be undertaken on all or some patients who have undergone an EPP^{XIV} performed by the HCW should be made on a case-by-case basis using the following assessment criteria:

- a. the nature and history of the clinical practice of the HCW, including the type of procedural practice
- b. HCW medical considerations such as viral load
 - i. lookback exercises connected with HCWs with HIV on cART should generally only be considered in circumstances in which their viral load had risen above 1 000 copies/mL
- c. evidence of physical or mental impairment or behaviour which could have affected the HCW's standard of practice

^{XIV} The specialist Colleges can provide advice on which procedures in their respective specialties are EPPs. Their contact details are provided in Appendix 2: Roles.

- d. evidence of poor infection prevention and control practice by the HCW or at the relevant healthcare setting during the time the HCW was probably infected with the BBV
- e. known episodes of high risk exposure to a patient, for example sharps injuries, and
- f. any other relevant considerations.

Any investigation should be purposeful, practical and proportionate to the risk of transmission.

11.3 Significant risk of transmission identified

In instances where the risk assessment and subsequent lookback identifies significant risk, the patient notification exercise may include contacting the patients, offering a pre-test discussion and encouraging testing for the relevant virus(es). The decision on how far back patient notification should go should be determined on a case-by-case basis.

11.4 HCW confidentiality

The disclosure of the identity of a HCW to a patient should not be necessary and the right to confidentiality of the HCW should be respected, even if the HCW with a BBV has died or has already been identified publicly. Healthcare facilities should provide an environment in which HCWs living with a BBV know their privacy and confidentiality will be respected and maintained.

Appendix 1: Definitions and examples of EPPs

Non-exposure prone procedures (non-EPPs) are procedures where the hands and fingers of the HCW are visible and outside of the body at all times and procedures or internal examinations that do not involve possible injury to the HCW's hands by sharp instruments and/or tissues, provided routine infection prevention and control procedures are adhered to at all times.

Examples of non-EPPs include routine oral examination (gloved with mirror and/or tongue depressor); vaginal and rectal examinations (except where there is a possibility of pelvic fractures in trauma); insertion and maintenance of intravenous or central lines; incision of superficial abscesses and incision and drainage of superficial haematomas; percutaneous drainage of abscesses and haematoma under radiation or ultrasound guidance; minor suturing of uncomplicated skin lacerations; risk from handling sharps (such as handling needles and scalpels outside of a patient's body).

Exposure prone procedures (EPPs) are procedures where there is a risk of injury to the HCW resulting in exposure of the patient's open tissues to the blood of the HCW. These procedures include those where the HCW's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times. [5, 76].

Examples of EPPs include:

- **Cardiothoracic surgery:** generally all cardiothoracic procedures.
- **Dentistry:** including maxillofacial surgery and oral surgical procedures, including the extraction of teeth (but excluding extraction of highly mobile or exfoliating teeth), periodontal surgical procedures, endodontic surgical procedures, implant surgical procedures.
- **Gynaecological surgery:** including perineal surgery, trans-vaginal surgery, and open abdominal gynaecological surgery.
- **Neurosurgery:** that involves exposure to sharp bone fragments e.g. trauma and some spinal surgery.
- **Obstetric or midwifery procedures:** including caesarean birth, instrumental birth, infiltration of the perineum with local anaesthetic, episiotomy, repair of an episiotomy or perineal/vaginal tear, application of a fetal scalp electrode, and fetal blood sampling.
- **Open surgical procedures:** including open abdominal or thoracic general surgery, open abdominal or thoracic vascular surgery and open urological procedures.
- **Orthopaedic procedures:** including procedures involving the cutting or fixation of bones or the distant transfer of tissues from a second site (such as in a thumb reconstruction), and open surgical procedures where there is the possibility of bone fragments and/or bone spicules, mechanical drilling is involved, or the procedure involves deep tunneling using sharp instruments.

- **Otolaryngology, head and neck surgery:** in particular bony facial reconstructive surgery (elective or after trauma).
- **Plastic surgery:** where it involves extensive cosmetic procedures that involve bony reconstruction or free tissue transfer involving bone or in the thorax.
- **Trauma:** including open head injuries, facial and jaw fracture reductions, extensive soft tissue trauma, rectal examination in the presence of suspected pelvic fracture, deep suturing to arrest haemorrhage and internal cardiac massage.

Examples of procedures that are generally considered to be non-EPP but have the potential to escalate to open or trauma procedures that will require access to a colleague who can perform EPPs include:

- **Minimally invasive procedures:** including laparoscopy, endovascular procedures, thoracoscopic procedures, Natural Orifice Transluminal Endoscopic Surgery (NOTES), cystoscopic procedures, arthroscopic procedures, and robotic surgery.
- **Trauma/emergency situations:** there is the risk in trauma/emergency situations that a previously non-EPP may escalate (and quickly) into an EPP. This context must be considered for paramedics, emergency department staff, and HCWs who work in rural or remote areas.

These lists are intended as a guide only and do not cover all eventualities and must be interpreted with caution. Moreover, it is recognised that variations in practice may exist in Australia, and may change over time. It is therefore recommended that the over-arching EPP definition given is used as the primary guidance when deciding whether a particular practice/procedure is exposure prone or not. The relevant specialist College can provide more detailed information about what procedures are considered exposure prone in their specialities. The relevant specialist Colleges may recommend a greater frequency of BBV testing for their speciality, particularly when high risk EPPs are commonly performed, and their contact details are provided in Appendix 2: Roles of these Guidelines.

Appendix 2: Roles

Communicable Diseases Network Australia (CDNA)

CDNA is the national expert advisory committee on communicable disease surveillance, prevention and control and offers strategic advice to governments and other key bodies on public health actions to minimise the impact of communicable diseases.

Expert Advisory Committee (EAC)

Jurisdictions may form an EAC or equivalent to provide expert advice when an incident involving a HCW with a BBV occurs or in other specific situations where advice is required. The relevant area of the jurisdictional health department is responsible for convening the EAC.

Jurisdictional health departments

State and territory health departments are the primary agencies responsible for surveillance of, and response to, notifiable diseases. This encompasses preventative programs, such as immunisation, BBV policy and program responses, contact tracing where appropriate, surveillance of disease trends and, in some jurisdictions, infection control coordination. Jurisdictional health departments should be consulted for advice on complex situations when managing HCWs with a BBV.

National Expert Reference Panel (NERP)

If requested, the NERP can provide advice on issues related to these Guidelines, including the management of individual workers with a BBV and on risk assessments and lookbacks in the event of an incident. The NERP can also provide support to EACs and to jurisdictions that do not have an EAC when requested by state and territory health authorities, and will also guide nationally consistent decision making. The NERP will meet regularly and will include expertise in public health, relevant clinical areas including treatment, infection control and policy and legal aspects of communicable disease control, as well as representatives from local EACs. The NERP may also second expert members from specific areas of practice as required.

Australian Health Practitioner Regulation Agency (AHPRA) and the National Health Practitioner Boards

AHPRA supports the National Boards that are responsible for regulating registered health practitioners. The primary role of the National Boards is to protect the public; additionally, they set standards and policies that all registered health practitioners must meet. On behalf of the National Boards, AHPRA manages investigations into the professional conduct, performance or health of registered health practitioners, except in NSW and Queensland who are co-regulatory authorities. The National Boards have developed *Guidelines for the*

regulatory management of registered health practitioners and students infected with blood borne viruses (under development). Rather than reproducing guidance, AHPRA refers to these Guidelines and informs practitioners that they are required to comply with them.

Contact details:

- The Australian Health Practitioner Regulation Agency
 - www.ahpra.gov.au
 - 1300 419 495

Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine

The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) supports the health workforce in HIV, viral hepatitis and sexually transmissible infections, and can provide expert clinical advice and referral for HCWs who are living with a BBV.

Contact details:

- The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
 - www.ashm.org.au
 - ashm@ashm.org.au
 - (02) 8204 0700

Relevant Specialist Colleges

The relevant specialist Colleges can provide advice and guidance on which procedures in their particular specialties constitute an EPP. The relevant specialist Colleges can also provide advice on the risk of EPPs and appropriate testing frequency for their associated specialties. Furthermore, support and advice to HCWs living with a BBV is available from their relevant specialist College.

Contact details:

- The Australasian College for Emergency Medicine (ACEM)
 - www.acem.org.au
 - (03) 9320 0444
- The Australasian College of Dermatologists (ACD)
 - www.dermcoll.edu.au
 - (02) 9736 2194
- The Australasian College of Podiatric Surgeons (ACPS)
 - www.acps.edu.au
 - podiatric.surgeons@rsm.com.au
 - (03) 9286 8188
- The Australian College of Emergency Nursing (ACEN)

- www.acen.com.au
- admin@acen.com.au
- (02) 9629 8688
- The Australian and New Zealand College of Anaesthetists (ANZCA)
 - www.anzca.edu.au
 - (03) 9510 6299
- The Australian College of Midwives (ACM)
 - www.midwives.org.au
 - admin@midwife.org.au
 - (02) 6230 7333
- The Australian College of Nursing
 - www.acn.edu.au
 - acn@acn.edu.au
 - (02) 6283 3400
- The Australian College of Perioperative Nurses (ACORN)
 - www.acorn.org.au
 - administrator@acorn.org.au
 - 1300 781 924
- The Australian College of Rural and Remote Medicine (ACRRM)
 - www.acrrm.org.au
 - (07) 3105 8200
- The College of Emergency Nursing Australasia (CENA)
 - www.cena.org.au
 - national@cena.org.au
 - (03) 6231 2722
- The College of Intensive Care Medicine of Australian and New Zealand (CICM)
 - www.cicm.org.au
 - cicm@cicm.org.au
 - (03) 9514 2888
- The Royal Australasian College of Dental Surgeons (RACDS)
 - www.racds.org
 - (02) 9262 6044
- The Royal Australasian College of Surgeons (RACS)
 - www.surgeons.org

- college.sec@surgeons.org
 - (03) 9249 1200
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
 - www.ranzcog.edu.au
 - ranzcog@ranzcog.edu.au
 - (03) 9417 1699
- The Royal Australian College of General Practitioners (RACGP)
 - www.racgp.org.au
 - racgp@racgp.org.au
 - 1800 472 247

Appendix 3: Results of published lookback investigations

Table 4: Worldwide cases of infected HCW to patient transmission of HBV, 1991- 2015

Lookback timeframe	Ref	Country	Occupation	Patients infected (probable, possible)^	Patients tested/	% patients confirmed infected (all)	Viral load of HCW
1991	[85]	Canada	Orthopaedic surgeon	0 (1,1)	n/a	n/a	n/a
1991-1992	[17]	USA	Cardiothoracic surgeon	9 (4,6)	144	6.25 (13.19)	n/a
1991-1993	[15]	UK	Cardiothoracic surgeon	20	310	6.45	n/a
1990-1996	[86]	Canada	Electroencephalogram technician	4 (0,71)	10244	0.04 (0.73)	n/a
1992-1993	[15]	UK	Cardiothoracic surgeon	20	310	6.57	n/a
1993	[16]	UK	General surgeon	2	16	12.5	n/a
1993	[18]	UK	Obstetrics trainee	1 (2)	92	1.09 (3.26)	~8.1x10 ⁵ IU/mL*
1993-1994	[18]	UK	Obstetrics trainee	1 (0,4)	111	0.9	~1x10 ⁶ IU/mL
1993-1994	[20]	UK	General surgeon trainee	1 (0,10)	390	0.26 (2.82)	n/a
1994	[20]	UK	General surgeon trainee	0 (0,2)	96	(2.08)	n/a
1994	[20]	UK	Urologist trainee	0 (0,1)	28	(3.57)	n/a
1994-1995	[18]	UK	General surgical	1	21	4.76	4.6x10 ⁴ IU/mL
1995-1999	[22]	Netherlands	General surgeon	8 (2,18)	1564	0.51 (1.79)	~9.3x10 ⁸ IU/mL
1996	[19]	UK	Orthopaedic surgeon	1	189	0.53	n/a
1999	[21]	UK	Cardiothoracic surgeon	2	123	1.63	~1.9x10 ⁵ IU/mL
2001	[87]	UK	General surgeon	3	n/a	n/a	>1.9x10 ⁵ IU/mL
2009	[88]	USA	Orthopaedic surgeon	2 (0,6)	232	0.86 (3.45)	>17.9 x10 ⁶ IU/mL
2010	[14]	Japan	Obstetrician-gynaecologist	1	62	1.61	>1.9 x10 ⁸ IU/mL

^ Confirmed transmissions are defined as cases where the HCW and patient(s) were epidemiologically linked and genetic relatedness of the viruses was confirmed through partial or complete DNA sequencing. Probable transmissions are defined as cases in which the subtype of HBV infecting the HCW and patient were identical in investigations of epidemiologically-linked HCW and patient HBV infections. Possible transmissions are defined as cases in which epidemiologic links were established, infected patients had no other risk factors for HBV acquisition but virologic subtyping data was not available to confirm transmission.

*Conversions from geq/mL to IU/mL were calculated using the WHO HBV standard preparation of 1IU is equivalent to 5.4 geq/mL. However, it is acknowledged that this can vary depending on the PCR based quantification assay so the values are presented as approximations [89].

Table 5: Worldwide cases of infected HCW to patient transmission of HCV

Lookback period	Ref	Country	Occupation	Patients infected	Patients tested	% patients infected	Risk factor
1988-1994	[59]	Spain	Cardiac surgery	5	227	2.25	EPPs (suggested percutaneous injuries)
1988-1997	[41]	Spain	Anaesthetist	275	N/A	N/A	IDU
1989-2001	[42]	US	Cardiac surgery	4	941	0.43	EPPs
1991-1992	[43]	US	Surgical (scrub) technician	11	108	10.2%	IDU
1993-1994	[44]	UK	Cardiothoracic surgeon	1	278	0.36	EPPs
1993-2000	[45]	Germany	Obstetrician/ gynaecologist	1	2286	0.04	EPPs
1996	[46]	US	Anaesthesiologist	1	348	0.29	unknown
1998	[47]	Germany	Anaesthesiology assistant*	5	838	0.6	Numerous breaches of infection control practices
1999-2000	[48]	Germany	Orthopaedic surgeon	1	207	0.48	EPP
2001	[49]	Germany	Anaesthesiologist	3	479	0.63	Breaches of infection control practices
2001-2003	[50]	Israel	Anaesthesiologist	33	1200	2.75%	IDU
2002-2005	[51]	Germany	Surgeon	0	1193	0.0%	EPPs
2004-2007	[52]	Norway	Cardiac surgeon*	10	270	3.7%	EPPs
2004	[53]	US	Nurse anaesthetist Infected with 2 different genotypes	15	196	7.65	Suspected IDU
2005	[54]	UK	Dentist	0	2665	0	EPPs
2004-2010	[55]	US	Radiological technologist	5	3444	0.15	IDU
2008-2009	[56]	US	Surgical technologist	18	5249	0.34	IDU
2006-2009	(7 and Victoria n DoH)	Australia	Anaesthetist	49	4099	1.20	IDU
2010	[57]	Spain	Haemodialysis staff member	2	46	4.35	unknown
2010-2012	[58]	US	Cardiac technologist	32	1074	2.98	IDU

2011	[90]	UK	Midwife	1	69	1.45	unknown
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* HCW infected occupationally then subsequently infects patients
IDU – injecting drug user

Table 6: Published cases of infected HCW to patient transmission of HIV

Year reported	Ref	Country	Occupation	Patients infected	Patients tested	% patients infected
1992	[72]	USA	Dentist	5	1100	0.45%
1999	[73]	France	Orthopaedic surgeon	1	983	0.10%
2002	[91]	France	Nurse	1	2294	0.04%
2003	[92]	Spain	Obstetrician	1	250	0.40%

Appendix 4: Technical working group members

2016 – 17 Advisory Group

Dr Jenny Firman (Chair)	Commonwealth Department of Health representative Principal Medical Advisor Office of Health Protection, Commonwealth Department of Health.
Associate Professor Ann Koehler (Deputy Chair)	CDNA representative Director, Communicable Disease Control Branch, System Performance & Service Delivery, SA Health
Dr. Ranil Appuhamy	CDNA representative Public Health Physician Health Protection Service, ACT Health (from May 2016)
Dr Paul Armstrong	CDNA representative Director, Communicable Disease Control Directorate, WA Health
Dr I-Hao Cheng	Principal Public Health Medical Officer Office of the Chief Health Officer, Department of Health and Human Services, Victoria (from December 2016 to March 2017)
Mr Dean Gloede	HIV Case Coordinator, Communicable Disease Control Branch, SA Department for Health and Ageing
Dr Vanessa Johnston	CDNA representative Public Health Physician Health Protection Service, ACT Health (from January – May 2016)
Associate Professor Anthony Lawler	ACEM representative President, ACEM
Professor Michael Permezel	RANZCOG representative President RANZCOG (from February 2016 to February 2017)
Associate Professor Jeffrey Post	ASHM representative Infectious Diseases Physician, Prince of Wales Hospital / University of NSW.
Dr John Quinn	RACS representative Executive Director for Surgical Affairs, RACS
Professor Steve Robson	RANZCOG representative President RANZCOG (from February 2017)

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2011 Technical Working Group

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Aboriginal and Torres Strait Islander Health Practice	Occupational Therapy
Chinese Medicine	Optometry
Chiropractic	Osteopathy
Dental	Pharmacy
Medical	Physiotherapy
Medical Radiation Practice	Podiatry
Nursing and Midwifery	Psychology

Australian Health Practitioner Regulation Agency

Statement of assessment

Boards' statement of assessment against AHPRA's *Procedures for the development of registration standards, codes and guidelines* and COAG principles for best practice regulation

Draft Guidelines for registered health practitioners and students in relation to blood-borne viruses

The Australian Health Practitioner Regulation Agency (AHPRA) has *Procedures for the development of registration standards, codes and guidelines* which are available at: www.ahpra.gov.au

These procedures have been developed by AHPRA in accordance with section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) which requires AHPRA to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

The Dental, Medical, Nursing and Midwifery, Paramedicine and Podiatry Boards of Australia have agreed to consult on draft guidelines for registered health practitioners and students in relation to blood-borne viruses. These Boards all regulate practitioners whose scope of practice may include exposure-prone procedures that carry a higher risk of transmission of virus.

Below is the Boards' assessment of their proposal for its draft revised guidelines against the three elements outlined in the AHPRA procedures.

1. The proposal takes into account the National Scheme's objectives and guiding principles set out in section 3 of the National Law

Boards assessment

The Boards consider that the draft revised guidelines meet the objectives and guiding principles of the National Law.

The proposal takes into account the National Scheme's key objective is to **protect the public** by setting out the standards of conduct expected of practitioners in relation to their scope of practice if they are living with a blood-borne virus. It also supports protection of the public by informing treating practitioners when they may have an obligation to report a practitioner that they are treating for a blood-borne virus to AHPRA.

The guidelines will also help to **facilitate access to services** provided by health practitioners in accordance with the **public interest**. The Boards' guidelines require health practitioners to comply with the CDNA (Communicable Diseases Network Australia) *Australian national guidelines for the management of healthcare workers living with blood borne viruses and healthcare workers who perform exposure prone procedures at risk of exposure to blood borne viruses*. The CDNA guidelines have already been the subject of wide-ranging consultation and have been endorsed by AHMAC.

The CDNA guidelines and Board guidelines are explicit that practitioners living with a blood-borne virus can practise their profession if they comply with the CDNA guidelines. The CDNA guidelines

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

also define the circumstances when a practitioner living with a blood-borne virus can resume performing exposure-prone procedures.

The draft guidelines support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way. The proposal gives clear guidance that the Board expects practitioners to comply with the CDNA guidelines. It also states clearly that practitioners with a blood-borne virus do not need to be reported to the Board if they are complying with the CDNA guidelines.

The draft guidelines inform practitioners of the actions the Board might take if they are not complying with the CDNA guidelines, including a potential report to the jurisdictional health department and the way that conditions might be expressed on the Register of practitioners. In particular, Boards will not state that a practitioner has a blood-borne virus.

2. The consultation requirements of the National Law are met

Board assessment

The National Law requires wide-ranging consultation on proposed guidelines. The National Law also requires the Board to consult the other National Boards on matters of shared interest. All National Boards have been consulted on this proposed guideline.

This public consultation follows a preliminary consultation with key relevant stakeholders.

The Boards previously consulted on a similar guideline in 2014 and the feedback from that consultation has informed minor changes to this guideline. The 2014 guidelines were not approved by Boards as we received feedback that while there was in principle support for aligning the Board and CDNA guidelines, there was also feedback that the CDNA guidelines at that time were out of date and we should wait till they have been updated. Now that the CDNA guidelines have been updated and endorsed, the Dental, Medical, Nursing and Midwifery, Paramedicine and Podiatry Boards of Australia are again undertaking a further consultation. We will undertake an eight-week public consultation process. The process will include the publication of the consultation paper on Board websites, informing practitioners via Board newsletters and drawing the paper to the attention of key stakeholders.

The Boards will take into account the feedback it receives when finalising the draft guidelines.

3. The proposal takes into account the COAG Principles for Best Practice Regulation

Board assessment

In developing the draft revised guidelines, the Boards have taken into account the Council of Australian Governments (COAG) *Principles for Best Practice Regulation*.

As an overall statement, the Boards have taken care not to propose unnecessary regulatory burdens that would create unjustified costs for the profession or the community. In fact, ten out of the 15 Boards have decided to not develop guidelines as the practitioners they regulate do not perform exposure-prone procedures and guidelines in that instance would be an unnecessary regulatory burden.

The participating Boards make the following assessment specific to each of the COAG principles expressed in the AHPRA procedures.

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

COAG Principles

A. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public

Board assessment

The Boards consider that their proposal is the best option for achieving the stated purposes. The draft guidelines make clear the expectations of practitioners and students in relation to blood-borne viruses.

The proposed guidelines:

1. maintain the balance between protecting the public and the impact on health practitioners by requiring practitioners to comply with guidelines that are:
 - contemporary and evidence-based guidelines
 - clear about the limits of practice for practitioners living with a blood-borne virus but are also explicit that practitioners can practise as long as they comply with the guidelines
2. provide guidance to treating practitioners about the circumstances when they may need to notify AHPRA if their practitioner patient is putting the public at risk. They are also clear that treating practitioners do not need to notify AHPRA if their practitioner patient is complying with the CDNA guidelines
3. confirm that practitioners are not required to inform AHPRA that they are living with a blood-borne virus if they are complying with the CDNA guidelines
4. confirm that practitioners are not required to provide test results to AHPRA
5. require compliance with a single national standard developed by the CDNA, the national expert advisory committee on communicable disease surveillance, prevention and control. The single national standard will lead to less confusion for practitioners and will support compliance.

B. Whether the proposal results in an unnecessary restriction of competition among health practitioners

Boards' assessment

The proposal will not restrict competition. To the contrary, it will allow a small number of practitioners who were previously precluded from performing exposure-prone procedures to resume that class of procedures.

C. Whether the proposal results in an unnecessary restriction of consumer choice

Boards' assessment

The proposal will not result in any unnecessary restrictions of consumer choice as the guidelines do not add any restrictions to practitioners. By allowing a small number of practitioners who were previously precluded from performing exposure-prone procedures to resume that class of procedures, consumer choice may be (slightly) less restricted.

D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

Boards' assessment

The Board considered the overall costs of the draft revised guidelines to members of the public, medical practitioners and governments and concluded that the likely costs are minimal as the Boards are merely confirming a requirement that practitioners comply with the CDNA guidelines. The Boards' guidelines should not result in additional costs to the public, registrants or governments.

Public consultation

Draft guidelines for registered health practitioners and students in relation to blood-borne viruses

Requiring compliance with the CDNA guidelines means that costs to the Boards can be contained. The Boards will not need to revise their guidelines every time the CDNA updates their guidelines on the basis of new evidence.

E. Whether the proposal's requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants

Boards' assessment

The Boards consider the draft guidelines have been written in plain English that will help practitioners to understand their obligations in relation to blood-borne viruses.

F. Whether the Boards have procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time

Boards' assessment

If approved, the Boards will review the revised guidelines at least every five years, including an assessment against the objectives and guiding principles in the National Law and the COAG principles for best practice regulation.

However, the Boards may choose to review the guidelines earlier, in response to any issues which arise or new evidence which emerges to ensure the guidelines continued relevance and workability.

As stated above, requiring compliance with the CDNA guidelines will support the guidelines to remain relevant and effective over time as updates to the CDNA guidelines will be instantly applicable to registered health practitioners.