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National Hepatitis B Testing Policy

2020

National Hepatitis B Testing Policy v1.2

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Disclaimer: This Testing Policy has been developed as a concise source of standardised, currently available information, to inform health professionals, government and industry about specific matters associated with hepatitis B testing. This Testing Policy is not a set of clinical guidelines or a description of the management of hepatitis B infection. It should not be used as a guide for the clinical management of hepatitis infections. It is designed primarily to inform those involved in ordering and performing hepatitis B tests, and receiving and interpreting results.

This Policy was written by the National Hepatitis B Virus (HBV) Testing Policy Expert Reference Committee, funded by the Australian Government Department of Health. The process was coordinated by the Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine (ASHM).

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The National Hepatitis B Testing Policy has been endorsed by the Blood Borne Viruses and Sexually Transmissible Infections Committee, effective 18 February 2021.

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EXECUTIVE SUMMARY

Background and Objectives
The aim of this National Hepatitis B Testing Policy is to recommend evidence-based testing pathways for the diagnosis of hepatitis B.

Hepatitis B virus (HBV) affects 250 million people globally and an estimated 230,000 or 1% of the Australian population. Chronic hepatitis B infection causes liver cirrhosis, liver failure and liver cancer. Liver cancer is the fastest increasing cause of cancer death in Australia. The World Health Organisation (WHO) has set ambitious targets of diagnosing 90% of persons living with hepatitis B, linking 80% of those to care with 80% of those eligible to be on treatment by 2030. The Third National Hepatitis B strategy set short-term targets of 80% of people living with hepatitis B diagnosed, 50% of those diagnosed linked to specialist care, and 20% on treatment in order to achieve a 30% reduction in mortality by 2022.

Currently it is estimated 30% of people living with hepatitis B in Australia are undiagnosed and unaware of their infection.
This policy supports the WHO in adhering to five key components in relation to testing, also known as the "5 Cs": Consent, Confidentiality, Counselling, Correct test results and Connection/linkage to prevention, care and treatment.

Who should be tested?
Indications for Hepatitis B Testing
Most infections in Australia are chronic (having persisted for more than 6 months' duration) and 60% of people with hepatitis B are from two priority populations:

- Adults and children born in countries of intermediate and high HBV prevalence. Indigenous peoples of such countries may have a higher prevalence.
- Aboriginal and Torres Strait Islander people.

Other populations to be considered a priority for hepatitis B testing include:

- Healthcare workers.
- Pregnant women.
- Patients prior to undergoing chemotherapy or immunosuppressive therapy.
- Unvaccinated persons at higher risk of infection or the consequences of infection – this includes partners and other household and sexual contacts of people who have acute or chronic hepatitis B infection, people who have ever injected drugs, men who have sex with men, people with multiple sex partners, people in custodial settings or who have ever been in custodial settings, people with HIV or hepatitis C (or both), patients undergoing dialysis, sex workers.

What tests should be ordered?
Diagnosis of hepatitis B
It is recommended all people at risk of infection are tested for three serological markers after obtaining appropriate consent and counselling. The tests are for hepatitis B surface antigen (**HBsAg**), antibodies to HBsAg (**anti-HBs**) and antibodies to hepatitis B core protein (**anti-HBc**) to diagnose infection or determine immunity. The presence of HBsAg indicates active infection (acute or chronic) while anti-HBs shows resolved infection or successful vaccination. Individuals suspected of acute HBV infection on their history, examination and investigation should have anti-HBc IgM added to the test panel.

HBV DNA testing is recommended for everyone living with chronic hepatitis B (HBsAg positive). HBV DNA levels, along with liver function test results and an assessment of liver fibrosis, help determine eligibility for antiviral therapy.

Medicare benefits for tests are only payable if the referring practitioner indicates on the request that the patient is **suspected of having acute or chronic hepatitis**.

Informed Consent for Testing should be obtained for hepatitis B testing and should be voluntary in a private setting without family members present. For people with low English proficiency, an accredited interpreter should be used to obtain informed consent.

Conveying Hepatitis B Test Results.
The healthcare provider conveying the outcome of the test is responsible for ensuring that the person receiving the result is able to understand its implications. Information provided in a single clinical consultation is often insufficient to meet their needs. Consideration should be given to referral of people to relevant community-based organisations for support after diagnosis.

1.0 INTRODUCTION

1.1 Background and context

Hepatitis B serology testing and hepatitis B virus (HBV) DNA testing is important to identify people living with chronic hepatitis B and to provide best quality healthcare. This document recommends testing pathways for hepatitis B. It provides a clear guide for testing that can be accessed by health professionals as well as links to further information for people with hepatitis B.

The prevalence of hepatitis B infection in Australia

HBV infection is a major global public health threat with over 250 million people living with chronic infection.[1] In 2017, it was estimated that 221,420 people, or 1% of the population in Australia were living with HBV infection.[2] Late diagnosis of hepatitis B is a missed opportunity for preventing liver cirrhosis, liver cancer and death from liver failure. Liver cancer is the fastest increasing cause of cancer death in Australia.[3]

The majority of hepatitis B infections in Australia are chronic (having persisted for more than 6 months duration) and occur in people born in countries of intermediate and high prevalence who contracted the infection at birth or during early childhood. Over 60% of people in Australia with hepatitis B are from two priority populations:

- adults and children from culturally and linguistically diverse (CALD) backgrounds, particularly people born in countries of intermediate and high HBV prevalence, including all indigenous peoples from overseas countries (**see section 3.1**)
- Aboriginal and Torres Strait Islander people.

Other priority populations for testing include anyone at risk of blood borne infection including people who are HIV positive, men who have sex with men, sex workers, people who inject drugs and people who have been incarcerated (**see section 3.0**).

In recognition of the global public health impact of hepatitis B, the World Health Organization (WHO) has set clear hepatitis B elimination targets of a 90% reduction in new infections and a 65% reduction in hepatitis B-related mortality WHO recommends achieving these targets with ambitious goals of diagnosing 90% persons living with hepatitis B, linking 80% to care and treating 80% of those eligible by 2030. The Third National Hepatitis B strategy sits within this global context and sets short-term targets of 80% of people living with hepatitis B diagnosed, 50% of those diagnosed linked to care, and 20% on treatment to achieve a 30% reduction in mortality by 2022.[4]

Australia has implemented prevention interventions including promotion of standard precautions; blood donor screening; vaccination programs for adolescents and universal birth dose and infant vaccination in 2000 and these strategies have reduced incidence among Australian-born children and adolescents. With ongoing high coverage of infant hepatitis B programs in many countries, the prevalence of chronic hepatitis B in migrants to Australia will fall in coming decades.[2]

The importance of hepatitis B testing

Hepatitis B testing is essential to ensure people living with hepatitis B infection are diagnosed, adequately informed and counselled, effectively linked to care and treatment in a timely manner to avoid adverse health outcomes and prevent ongoing transmission.[6] It is vital to ensure people at risk of exposure are vaccinated to prevent transmission. Appropriate testing indicates whether an individual has:

- current hepatitis B infection (acute or chronic)
- cleared the virus spontaneously (natural immunity)
- immunity through previous hepatitis B vaccination.

Hepatitis B testing determines the severity and stage of infection, and these results direct decisions about whether antiviral therapy is indicated.[5] Despite the public health and individual benefits of testing, it is estimated that around 30% of people with HBV infection in Australia remain undiagnosed.[2]

1.2 Purpose, scope and objectives

This Policy supports adherence to WHO in adhering to five key components in relation to testing, also known as the 5 Cs:[5]

- Consent
- Confidentiality
- Counselling
- Correct test results
- Connection (linkage to prevention, care and treatment).

The aim of this Policy is to recommend evidence-based hepatitis B testing pathways; it does not provide hepatitis B management guidelines. The Policy is aligned with priorities in the 3rd National Hepatitis B Strategy 2018-2022[4] which identifies that greater knowledge of hepatitis B across priority populations, the affected people and health professionals is essential to create a supportive environment for testing as well as a need for equitable access to testing services. Key areas for action related to testing contained in the Third National Hepatitis B Strategy 2018-2022 are to:

- further develop and deliver evidence-based risk assessment and hepatitis B testing pathways for key priority populations
- increase voluntary hepatitis B testing among priority populations in primary health and community settings
- review and promote national training and clinical guidelines for testing, treatment, monitoring and care, including guidance on pregnancy and follow up for babies born to mother with hepatitis B; and testing for hepatitis B before initiating chemotherapy, immunosuppressive therapies or treatment for chronic hepatitis C.

This Hepatitis B Testing Policy will undergo review by the National Hepatitis B Testing Policy Expert Reference Committee every 12 months to ensure the information provided is accurate and current.

1.3 Principles of hepatitis B testing

The basic principles that guide hepatitis B testing in Australia are in accordance with the WHO's 5 C approach to testing outlined above:[5]

- Confidential, voluntary testing with informed consent (**see section 4.0**) and use of an appropriate process to convey the test result (**see section 5.0)** are fundamental to Australia's response to hepatitis B.
- It is **recommended** that people have access to culturally appropriate information in their preferred language supported by access to an accredited interpreter when their primary staff contact is not familiar with their language.
- Testing is **recommended** to be accessible to all those who are or have been at risk of HBV infection.
- Testing will be of the highest possible standard and provided in a timely manner to individuals at every stage of their infection.
- Testing is of benefit to the person being tested (e.g. diagnosis is accompanied by provision of, or referral to, culturally and language-appropriate education, management, treatment (where relevant) and care and support services).

1.4 Policy implementation and legislation

It is **recommended** that testing policies and practices comply with all relevant Commonwealth, State and Territory anti-discrimination and public health legislation, and other relevant laws and regulations, including those governing Commonwealth funding of pathology tests.

Policies relating to hepatitis B testing, specific to individual States, Territories or institutions, **should** be consistent with the purpose, objectives and principles of this Policy.[a]

[a] The word must has been used when the statement reflects something which is in legislation. The word should has been used to reflect best practice or a higher quality service.

1.4.1 Voluntary confidential testing

Voluntary confidential testing is the standard form of service delivery for hepatitis B testing in Australia. It involves providing information about the testing process; obtaining informed consent (**see section 4.0**) for the testing, and conveying the test results to the patient in an appropriate and meaningful way (**see section 5.0**).

1.4.2 Mandatory or compulsory testing

Mandatory testing refers to situations where people are prevented from participating in certain activities or from having access to certain services unless they agree to be tested. Circumstances in which mandatory testing is currently required under separate policy or legislation include:

- As a condition of blood, tissue and organ donation[6]
- Under the migration health requirements applicable to specified visa subclasses[7]
- As a condition for entering training or service in the armed forces
- As a condition for purchasing some types of insurance
- In the context of a legal instruction, including in forensic or coronial settings
- As a condition of health professionals performing exposure prone procedures (EPP).[8]

To all reasonable extents, the processes involved in mandatory testing should be in accordance with the principles in this Policy and basic human rights pertaining to privacy of health information.

1.4.3 De-identified testing

There may be circumstances where, on public health grounds (e.g. prevalence studies), de-identified testing is legitimately performed in accordance with this Policy. Such testing **should** occur only where there is compelling scientific justification. This testing for research **must** be independently judged by a Human Research Ethics Committee constituted in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research.[9]

1.4.4 Introduction of new technologies and strategies

It is **recommended** that introduction of new technologies or strategies (e.g. point-of-care testing or opt out testing in clinical settings) to increase testing be accompanied by appropriate community consultation, ethical consideration and workforce development to ensure that:

1. testing strategies are informed by the communities being tested
2. those offering hepatitis B testing are equipped with relevant skills with the health professional performing hepatitis B testing trained in:
   - up-to-date information about hepatitis B infection
   - procedures associated with using new technology
   - information related to referral pathways to culturally and language-appropriate care and support services
   - knowledge of the testing process, of how to obtain informed consent for testing (**see section 4.0**) and of conveying the test results to the patient in an appropriate and meaningful way (**see section 5.0**).

2.0 DIAGNOSTIC STRATEGIES

2.1 Types of hepatitis B virus diagnostic tests – also called in-vitro diagnostic devices

A range of serological and nucleic acid tests (NATs) are used for donor screening and diagnostic testing (**see table on p.11**).

Tests for HBV **must** comply with the regulatory framework for in-vitro diagnostic medical devices (IVDs)[12] under the Therapeutic Goods Act 1989[13] and subordinate legislation. Testing in laboratories **must** comply with standards specified by the National Association of Testing Authorities (NATA)[14] and the National Pathology Accreditation Advisory Council (NPAAC).[15]

2.1.1 Donor screening

It is mandatory for Australian laboratories screening blood or tissue before transfusion or transplantation to test the donor's serum or plasma for the presence of HBsAg and HBV DNA.[16] Blood donors and donors of most tissues are screened for the presence of HBV DNA using a multiplex NAT assay that detects human immunodeficieny virus-1 (HIV-1) RNA, hepatitis C (HCV) RNA and HBV DNA. Blood and tissue donor screening can only be performed by laboratories accredited by Therapeutic Goods Administration (TGA) to the code of good manufacturing practice. IVDs used for donor screening **must** be intended for that purpose and be included on the Australian Register of Therapeutic Goods (ARTG) as a Class 4 IVD.

2.1.2 Diagnostic tests

Individuals suspected of exposure to HBV may be tested for a range of diagnostic markers depending on their clinical history, symptoms and previous test results. Examples of the common serological patterns observed in acute and chronic HBV infection are shown below (**see section 2.2**). All assays intended by the manufacturer for the clinical diagnosis of HBV infection are Class 4 IVDs.

Common diagnostic testing strategies encompass:

- diagnosis of acute HBV infection (5% of notifications) – HBsAg, anti-HBc, anti-HBc IgM
- diagnosis of chronic HBV infection – HBsAg, anti-HBs, anti-HBc
- determination of protective immunity or its absence – anti-HBs; (if anti-HBs is negative, recommend HBsAg and anti-HBc testing to exclude undiagnosed infection or distant past infection)
- antenatal – HBsAg; (if possible, also perform anti-HBs, to assess the need for vaccination)
- insurance screening– HBsAg
- investigation of **degree** of infectivity **when** HBsAg positive or the assessment of disease phase in a person with chronic hepatitis B – HBV DNA; anti-HBe, HBeAg
- monitoring of therapy – quantitative HBV DNA, HBsAg, HBeAg, anti-HBs, anti-HBe.

Benefits for these tests (Medicare Benefit Schedule (MBS) items 69475 - 69484) are only payable if the request from the referring practitioner identifies in writing that the patient is suspected of having acute or chronic hepatitis, either by use of the provisional diagnosis or relevant clinical or laboratory information. More detail on HBV testing and the MBS are presented in **section 12.0** of this Policy or from MBS online – http://www.mbsonline.gov.au/.

2.1.3 Rapid Tests for Use at Point of Care

From 1 October 2020, changes to the supply of self-tests under the Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020 will come into effect. Sponsors and manufacturers will be able to apply for inclusion of allowable self-tests in the Australian Register of Therapeutic Goods (ARTG). Individual products will be evaluated by the TGA to ensure the tests are safe and perform as intended by the manufacturer. While there are settings where HBsAg Point of Care Test (POCT) would be useful (e.g. testing in remote communities and where there are barriers to accessing traditional

Table 1. Technology, purpose, and categorisation of assays used for hepatitis B testing

Marker	Abbreviations	Purpose or uses	Technology
Hepatitis B surface antigen (qualitative)	HBsAg	Donor screening – screening of blood and tissue donations	Immunoassay
		Diagnostic testing*	Immunoassay
Hepatitis B surface antigen neutralisation		Confirming the presence of HBsAg	Immunoassay
Hepatitis B surface antigen (quantitative)	HBsAg	Monitoring of therapy	Immunoassay
Hepatitis B surface antibody	anti-HBs or HBsAb	Determining protective immunity**	Immunoassay
Hepatitis B core total antibody	anti-HBc total or HBcAb total	Part of strategy to determine exposure to HBV	Immunoassay
IgM to hepatitis B core antigen	anti-HBc IgM or HBc IgM	Part of strategy to diagnose acute hepatitis B infection	Immunoassay
Hepatitis B e antigen	HBeAg	Determining infectivity of a person with HBV infection and phase of the infection for clinical management	Immunoassay
Hepatitis B e antibody	Anti-HBe or HBeAb	Determining seroconversion from hepatitis B e antigen and phase of the infection for clinical management	Immunoassay
Hepatitis B virus DNA (qualitative)	HBV DNA	Donor screening – screening of blood and tissue donations	NAT
Hepatitis B DNA Viral Load (quantitative)	HBV DNA VL	Monitoring and management- quantifies virus for clinical management	Quantitative NAT (viral load)
		Confirm the presence of circulating HBV	
		Determining HBV reactivation	
Hepatitis B genotype / mutation conferring resistance* **		Characterising virus for clinical management	Sequencing or Line probe assay

NAT: nucleic acid test **IgM:** immunoglobulin M

* During infection an excess of HBsAg is secreted into the blood. The immunoassay for HBsAg has proven to be the primary diagnostic test for HBV infection because its presence indicates active infection, which may be acute or chronic. Resolution of acute infection is marked by loss of HBsAg and the appearance of anti-HBs, while the persistence of HBsAg for longer than 6 months defines chronic infection. A transient HBsAg positivity may be detected for several days post-vaccination in adults and up to 2 weeks in neonates and immunosuppressed patients.[10]

** Anti-HBs levels fall over time and may become undetectable in people vaccinated several years ago or in those who have cleared the virus. In the setting of normal immune function, these individuals are still regarded as having effective immunity. Where relevant, the detection of anti-HBc may provide evidence of past exposure when anti-HBs has become undetectable. Refer to the Australian Immunisation Handbook for further advice.[11] People with immunosuppression from any cause, including advanced HIV, renal disease, chemotherapy or immune deficiency, may be at risk of HBV infection despite previous HBV vaccination if their anti-HBs titre is <10 mIU/mL[11] Testing for infection would be as for diagnosis of acute HBV infection, although HBV DNA may be the preferred first investigation due to poor antibody responses.

*** Hepatitis B genotype/mutation conferring resistance testing is not rebatable on the Medicare Benefit Scheme and a fee may be payable.

healthcare), HBsAg POCT are known to have a lower analytical sensitivity compared to standard laboratory immunoassays and may be unable to detect low levels of HBsAg. Some people in the community may access self-administered HBsAg POCT kits from overseas. Therefore, when a person indicates they have received a positive or negative result from a HBsAg POCT, the results **should** be confirmed by standard HBV testing in a NATA-certified diagnostic laboratory. A point of-care HBV DNA test (Cepheid Xpert HBV Viral Load assay) has recently been approved by the TGA, but the cost of this test is not rebatable through the MBS unless the patient has been shown to be HBsAg-positive.

2.1.4 Reference tests

The presence of HBsAg detected by screening tests must be confirmed by HBV neutralisation testing as recommended by the manufacturer's instructions as approved by the TGA. A reagent containing anti-HBs is added to an aliquot of the positive sample and a reduction in reading (signal strength) is observed in the neutralized sample to confirm the initial positive result. HBV and hepatitis D virus (HDV) genotyping can be useful tests for epidemiology studies and for investigating transmission and are available in specialised reference laboratories. They are not rebatable through the MBS.

2.1.5 Hepatitis D testing

HDV, also known as hepatitis delta virus) is a defective RNA virus dependent on HBsAg for its viral envelope and thus requires the presence of HBV for virion packaging and transmission. Infection with HDV can occur concurrently with an HBV infection (co-infection) or it may occur in a person with chronic HBV as a superinfection. It is important to consider testing for HDV in all patients with HBV as there is evidence this co-infection is substantially under-diagnosed in Australia.[17] Particular situations which should prompt testing for HDV infection include people presenting with a severe illness (suggesting superinfection), those with a flare of more stable chronic HBV (co-infection) or those from a region where HDV infection has a high prevalence. Testing for HDV initially involves anti-HDV serology (both IgM and immunoglobulin G (IgG) antibodies can be requested). If the anti-HDV results are positive then HDV RNA should be requested. HDV RNA assays are not performed in many

2.2 Diagnostic strategies for HBV

Suspected acute HBV

TESTS TO BE ORDERED	RESULTS	SEROLOGY INTERPRETATION	FOLLOW UP
• Hepatitis B surface antigen (HBsAg) • Hepatitis B core total antibody (anti-HBc) • Hepatitis B core IgM antibody (anti-HBc IgM)	• HBsAg positive • anti-HBc positive • anti-HBc IgM positive (high titre)*	Acute infection	• Assess disease severity and monitor the clinical status of the patient. • Follow-up as appropriate to confirm acute or to exclude chronic infection (HBsAg positive > 6 months) • HDV testing recommended

* Note that anti-HBc IgM can often be detected during an exacerbation of chronic hepatitis B infection.
HBV is a notifiable disease and a positive result should be notified to the relevant Public Health Authority.

Suspected chronic HBV [i]

RESULTS	SEROLOGY INTERPRETATION	FOLLOW UP
• HBsAg negative • anti-HBs negative • anti-HBc negative	• Susceptible to infection [ii, iii]	Vaccinate
• HBsAg negative • anti-HBs positive • anti-HBc positive	Immune due to past resolved infection	No further action required. Record result in file [iv,v, vi,vii]
• HBsAg negative • anti-HBs positive [viii] • anti-HBc negative	Immune due to vaccination	Record result. No need for further action
• HBsAg positive • anti-HBs negative • anti-HBc positive	Likely chronic infection	• Manage as per guidelines for chronic hepatitis B • HDV testing recommended
• HBsAg negative • anti-HBs negative • anti-HBc positive	• Waning immunity from past infection OR • Window period before anti-HBs response in acute infection OR • False positive anti-HBc OR • Occult hepatitis B	• Consider HBV DNA testing [ix] • Consider repeat serology if possiblility of recent infection • Consider single dose vaccination and retest for anti-HBs in 1 month

i. Write in lab request 'testing for possible chronic HBV'
ii. anti-HBs levels fall over time and may become undetectable in people vaccinated years ago or in those who have cleared the virus. These individuals are still regarded as having acquired immunity. Refer to The Australian Immunisation Handbook for further advice[11]
iii. HBsAg is usually detected 6-12 weeks after exposure (in high-risk situations, consider post-exposure prophylaxis as appropriate)
iv. Note that there is some risk of HBV reactivation in the setting of intense immunosuppression[19]
v. Consider family screening and contact tracing given possible exposure risks
vi. People at risk of already having advanced liver disease or liver cancer despite resolved HBV infection, which includes people from CALD backgrounds, people who acquired HBV infection perinatally or in early childhood, and people with other risk factors for liver disease, should be referred for assessment of liver fibrosis severity and further specialist management as required
vii. Consider passive transfer in patients who recently received plasma derived products eg. IV Immunoglobulin [20, 21]
viii. Lab report must either say positive or >10 mIU/mL
ix. Occult hepatitis B is defined as the presence of HBV DNA in blood or liver in the absence of HBsAg. Generally, another HBV serological marker, such as anti-HBc and/or anti-HBs are present along with low levels HBV DNA. The condition is uncommon in low prevalence countries like Australia and in the great majority of cases does not lead to progressive liver disease. Nonetheless, HBV reactivation can occur in persons on immunosuppressive therapies and transmission of HBV to blood or organ transplant recipients has been reported (Raimondo et al J Hepatol 2019 71: 397-408).
x. HBV DNA viral load is NOT rebatable in patients who are HBsAg negative
Please note: A variety of unusual test results may be found in active HBV infection and where these results conflict with standard results, the advice of a specialists should be sought to clarify the interpretation, e.g. in active infection, HBsAg and anti-HBs may co-exist.

laboratories but HDV RNA requests can be referred to a specialist reference laboratory (note this test is not MBS rebatable).

3.0 INDICATIONS FOR HBV TESTING

Testing is indicated in all people in the priority populations described in this section. Most new cases of chronic hepatitis B infection diagnosed in Australia occur in people from CALD backgrounds. Testing people born in countries with intermediate and high prevalence of HBV, including new arrivals to Australia is a crucial part of Australia's public health response to HBV. **Section 3.1** and Figure 1 identify populations that are at greater risk of infection.

It is **recommended** that an individual's risk of HBV infection should inform the decision to perform an HBV test. In appropriate clinical circumstances, the absence of a declared risk **should not** preclude HBV testing. Clinical suspicion of HBV infection may occur in the context of:

- birth in an intermediate or high prevalence country (**see figure 1**)
- being an Aboriginal or Torres Strait Islander person
- children of women who are HBsAg positive
- unvaccinated adults at higher risk of infection (**see section 3.1**)
- individual or family history of chronic liver disease or liver cirrhosis
- individual or family history of hepatocellular carcinoma (HCC)
- evaluation of abnormal liver function tests
- acute hepatitis
- family, sexual or household contact with a person known or suspected to have hepatitis B.

Other situations where HBV testing may be indicated:

- pregnant women or women contemplating pregnancy (**see section 8.1**)
- healthcare workers who perform or may be expected to perform EPPs. Healthcare workers **must** take reasonable steps to know their hepatitis B , HIV and hepatitis C status
- contact tracing where exposure to blood or body fluids of a person with the infection is documented
- diagnosis of another infection with shared mode of acquisition, such as hepatitis C virus (HCV) or HIV
- a person who reports a reactive HBV result from a test not licensed in Australia;
- on the diagnosis of other conditions that may be caused by HBV infection e.g. glomerulonephritis, vasculitis
- a person who requests an HBV test in the absence of declared risk factors – a small number of individuals request an HBV test but choose not to disclose their risk factors. An individual's choice not to declare risk factors **should** be recognised and it is recommended that HBV testing be offered.

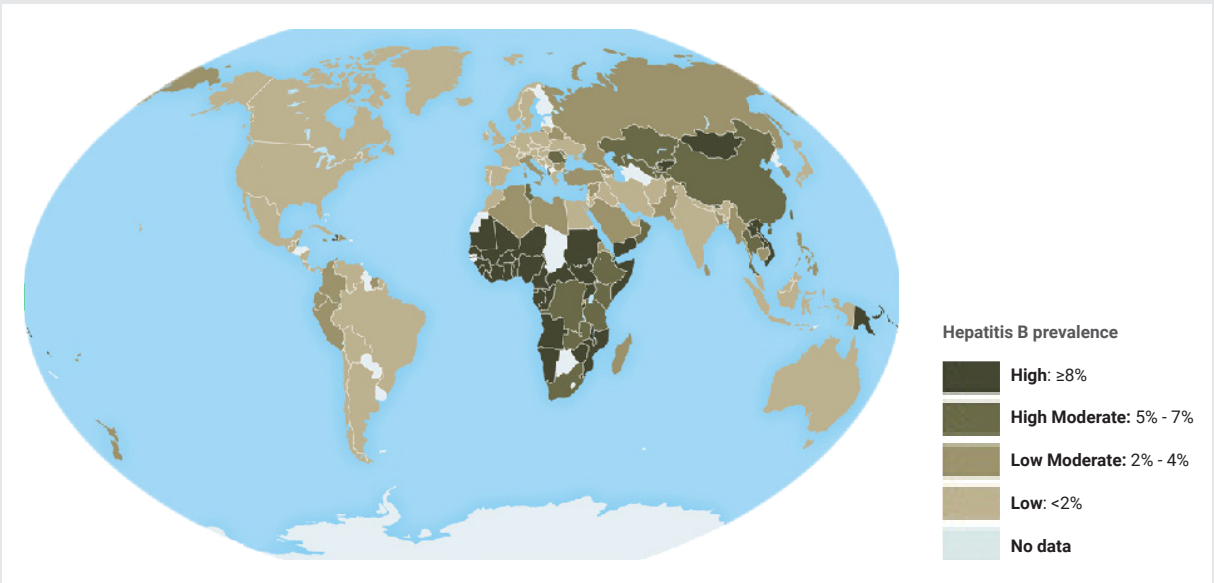
3.1 Priority populations for HBV testing

People from priority CALD communities [a, b] **See Figure 1 below. Please note indigenous populations in these countries often have a higher prevalence.**
Aboriginal and Torres Strait Islander peoples [a, b]
Healthcare workers
Pregnant women
All patients before to undergoing chemotherapy or immunosuppressive therapy (due to risk of reactivation)
Unvaccinated adults at higher risk of infection • Partner and other household and sexual contacts of people who have acute or chronic hepatitis B infection [a, b] • People who have ever injected drugs [a, b] • Men who have sex with men [b] • People with multiple sex partners [a, b] • People in custodial settings or who have ever been in custodial settings [a, b] • People with HIV or hepatitis C, or both [b] • Patients undergoing dialysis [b] • Sex workers [a, b] • People from established communities that originate from high prevalence countries • Mobile populations, including international students

a. If HBsAg-positive persons are found in the first generation, subsequent generations should be tested;

b. Those who are seronegative should receive hepatitis B vaccine. Vaccine is not funded for all at-risk groups and cost may be a barrier to vaccine uptake. Some jurisdictions provide vaccine free of charge for certain at-risk groups.18 Check with the relevant State or Territory health department for details.

Figure 1: Geographic distribution of chronic hepatitis B virus (HBV) infection[23]



For multiple countries, estimates of prevalence of HBsAg, a marker of chronic HBV infection, are based on limited data and might not reflect current prevalence in countries that have implemented childhood hepatitis B vaccination. In addition, HBsAg prevalence might vary within countries by subpopulation and locality. HBsAg prevalence is shifting in many endemic countries which have adopted universal infant vaccination. China, for example, is now an intermediate prevalence country with the age-adjusted prevalence of hepatitis B dropping from 9.8% in 1992 to 7.2% in 2009.[24]

3.1.1 People from priority culturally and linguistically diverse communities

The term CALD communities refers to individuals and their families who were born in, or born to parents, who came from overseas countries or speak different languages. Many of these countries have intermediate (2-7%) to high (≥ 8%) prevalence of HBV infection (**see section 9.0**). Priority CALD communities may include first and subsequent generations who may have been exposed through perinatal and horizontal transmission in Australia before the start of HBV screening during pregnancy and universal neonatal vaccination.

Most people living with chronic hepatitis B in Australia were born overseas, particularly in the Asia Pacific region, Europe, Africa, and the Middle East.[25] The Victorian Hepatitis B Serosurvey found a strong association between the proportion of residents born overseas in any local government area and HBV prevalence.[26] A recent Australian study has found that women from high-prevalence HBV countries now living in Australia have comparable rates of infection to those of their countries of birth.[27]

It is **recommended** that all adults from priority CALD communities be tested once for HBsAg, anti-HBc and anti-HBs to establish whether they have chronic hepatitis B, are immune through past infection or vaccination, or are susceptible to infection. Vaccination **should** be encouraged for those without immunity who are susceptible or at risk of infection. The purpose and implications of the test **should** be clearly explained before testing (**see section 4.0**), with the assistance of accredited interpreters or multilingual health workers as needed (**see section 9.4**). The result **should** be appropriately conveyed to the patient (**see section 5.0**) and documented clearly in the patient summary.

3.1.2 Aboriginal and Torres Strait Islander peoples

Aboriginal and Torres Strait Islander people consist of approximately 3.3% of the Australian population,[28] but are estimated to represent 11% of people living with chronic hepatitis B (**see section 10.0**). Estimates of prevalence in 2000 vary from approximately 2% of urban Aboriginal and Torres Strait Islander populations to 8% for rural Aboriginal and Torres Strait Islander populations, with prevalence likely to be even higher in remote communities.[29] More than one in five of Aboriginal and Torres Strait Islander people live in remote or very remote areas.[30] There are higher rates of death from liver-related causes in the Indigenous population compared with non-indigenous Australians,[31] linked to HBV infection. The majority of cases of chronic hepatitis B in the Aboriginal and Torres Strait Islander population are believed to have been acquired by perinatal transmission at birth, or infection in early childhood, increasing the likelihood of unknown long-term infection and long term complications.[32] Clinicians **should** stress that perinatal and early childhood exposures have been the primary routes of exposure for Aboriginal and Torres Strait Islander people.

Hepatitis B vaccine was introduced in many Aboriginal and Torres Strait Islander communities in the mid-1980s to early 1990s, with catch-up hepatitis B vaccination programs for Aboriginal and Torres Strait Islander children and adolescents in the late 1990s, or earlier in some jurisdictions.[11] There is some evidence of early vaccination program failure, thought to be due to limited program roll-out and imperfect adherence to vaccine storage/refrigeration (cold-chain) guidelines.[33] Cold-chain guidelines were revised and improved in 2005.[11]

All Aboriginal and Torres Strait Islander people **should** be tested once in adulthood for HBsAg, anti-HBc and anti-HBs to establish whether they have chronic hepatitis B, are immune through past infection, or are susceptible to infection[a]. Vaccination **should** be discussed with those without immunity who are remaining at high risk.[11] The purpose and implications of the test **should** be clearly explained before testing (**see section 4.0**), with the assistance of Aboriginal health workers, as needed. The result **should** be

appropriately conveyed to the patient (**see section 5.0**) and documented clearly in the patient summary.

[a] These recommendations should take into account local epidemiology, historical vaccination program uptake and local policy.

3.1.3 Healthcare workers - Transmission and infection control in healthcare settings

HBV testing of healthcare workers and students exposed to clinical settings **should** be conducted in accordance with the general principles set out in this Policy with regard to privacy, confidentiality and access to appropriate healthcare and support services (**see section 7.0**).

Health-care workers who test positive for HBV DNA 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 the new Communicable Diseases Network Australia Guidelines (https://www1.health.gov.au/internet/main/publishing.nsf/Content/cda-cdna-bloodborne.htm).[8] They should be encouraged and supported to undergo regular testing.

Testing for all blood borne viruses **should** be undertaken for healthcare workers following occupational exposure to blood or body substances, for example through needle stick injury, however, healthcare workers with immunity to hepatitis B do not need to be tested for hepatitis B after occupational exposure. Principles of informed consent (**see section 4.0**) and conveying a test result (**see section 5.0**) should be conducted with both the source of the occupational exposure and the recipient. Where patients are involved in occupational exposures, their informed consent to be tested must be sought (**see section 1.4.2 for exceptions**).

3.1.4 Pregnant women and children born to mothers who are HBV DNA or HBsAg positive.

Screening pregnant women for hepatitis B is an important strategy for reducing mother-to-child transmission (**see section 8.0**). Universal hepatitis B vaccination is available for all newborns. For those mothers positive for HBsAg, the timely administration of hepatitis B vaccination and hepatitis B immunoglobulin to the infant within 12 hours of birth will prevent the majority of mother-to-child transmission. Despite this immunotherapy, mother-to-child transmission can still occur in up to 10% of vaccinated infants when there is a high maternal viral load (HBV DNA >200,000 or $\log_{10}$ 5.3 IU/mL). Antiviral prophylaxis given at 28-30 weeks can further reduce the risk of transmission.

3.1.5 All patients undergoing chemotherapy or immunosuppressive therapy

Patients who are undergoing any sort of chemotherapy, high dose or prolonged oral steroid therapy (e.g. more than 20mg/day of prednisolone or equivalent for more than 2 weeks) or significant immunosuppressive therapy should be tested for HBV infection.

Patients with chronic hepatitis B (HBsAg positive) are at risk of a serious and sometimes life-threatening flare of their disease, often occurring after chemotherapy has finished. All HBsAg-positive patients **should** therefore receive prophylaxis with antiviral therapy starting at the same time or as soon as possible after the start of chemotherapy or immunosuppressive therapy.

Patients undergoing B cell depleting, B cell active, anti-CD20 (e.g. rituximab) therapy or haematopoietic stem cell transplantation are at particularly high risk of HBV reactivation. If these patients have serology suggestive of prior exposure to HBV (anti-HBc positive) including the high risk subgroup occult HBV (low level but detectable HBV DNA), they should be given antiviral prophylaxis for the duration of their treatment and for 18-24 months afterwards.

3.1.6 Partners and other household and intimate contacts of people who have acute or chronic hepatitis B infection

Unvaccinated individuals who have frequent and prolonged contact with a person with HBV infection have a higher risk of acquiring hepatitis B. The virus can be transmitted by blood through sharing personal or sharp objects such as razors, toothbrushes, earrings and nail clippers; it **cannot** be transmitted by casual contact through kissing, touching, sharing food or utensils. Because hepatitis B has the potential, in the right environmental conditions, to survive for at least 7 days on surfaces and objects contaminated with traces of blood, these objects can remain infectious for a long time after their use by a person with HBV infection. Child-to-child transmission, through everyday occurrences such as cuts, bites, abrasions, skin sores and scratches, has been documented.

When an individual with hepatitis B infection is identified, close contacts including household, family and intimate contacts, including all children, **should** be offered testing for HBsAg, anti-HBs and anti-HBc. Those without immunity **should** be vaccinated.[11] Post-vaccination serological testing 4 to 8 weeks after completion of the primary course is recommended (anti-HBs). Non-immune household members **should** have repeat testing for HBsAg after 3 months. For further information please see The Australian Immunisation Handbook.[11]

3.1.7 People with a history of injecting drug use

In 2011, the estimated prevalence of hepatitis B among people who inject drugs was 4%.[1] Historically, up to 50% of people who have injected drugs have serological markers of HBV infection, and PWID continue to be a population at greater risk of HBV infection given the significant barriers to accessing health services including HBV testing, vaccination and treatment.

Access to free hepatitis B vaccination for people who inject drugs is not consistent across Australian jurisdictions.[22] In this context, it is critical that testing is conducted in an appropriate and non-judgemental setting to assist people with a history of injecting drug use through the testing and diagnosis process. How testing is carried out will have a profound effect on the person's understanding of their condition and their likelihood of future engagement with the health system. A supportive environment includes understanding the current relevance of injecting drug use in the person's life. Peer education and support may optimise testing uptake and is recommended where these resources are available. Staff in specialist and primary healthcare services **should** be mindful of issues relating to illicit drug use, harm reduction, addressing stigma and discrimination and managing vein care issues. Hepatitis B vaccination **should** be offered if testing reveals neither immunity nor current infection.[11]

As people with a history of injecting drug use are also at increased likelihood of having acquired HCV or HIV infection, it is **recommended** that testing for these infections be considered (**see section 2.1**).

3.1.8 Men who have sex with men

Historically, unvaccinated men who have sex with men (MSM) had a prevalence of past or current HBV infection of approximately 38%[2,3,4] although more recent estimates are substantially lower.[29] As these men commonly acquire the infection in adulthood, most MSM will clear acute HBV infection, while a small percentage of them remain HBsAg positive. Despite their increased risk of HBV infection, uptake of vaccination remains suboptimal.[24] MSM **should** be tested for HBsAg, anti-HBs and anti-HBc (**see section 2.2**). It is **recommended** that hepatitis B vaccination be offered if testing reveals neither immunity nor current infection.[11]

Knowledge of hepatitis B status is particularly important in MSM considering pre-exposure prophylaxis (PrEP) for HIV as on demand use of PrEP is contraindicated in people with chronic hepatitis B infection with daily PrEP the only regimen

that is recommended for people living with chronic hepatitis B. (See ASHM guidelines).

3.1.9 People in custodial settings or who have ever been in custodial settings

Imprisonment is an independent risk factor for hepatitis B transmission and a history of ever being in custodial settings is an indication to offer testing for HBV with appropriate discussion of risk and benefits (**see section 4.0**). People entering custodial settings have higher rates of previous hepatitis B infection compared to the general community but only around 50% of people entering custodial settings have immunity to hepatitis B. People **should** be screened upon entering custodial settings if their hepatitis B status is unknown. Hepatitis B vaccination **should** be offered if testing reveals neither immunity nor current infection.[11]

An overrepresentation of people from CALD backgrounds and Indigenous communities and people who inject drugs can contribute to the risk of transmission in custodial settings. The situation requires further consideration to ensure screening, treatment and care are delivered in a culturally competent and culturally safe manner.

3.1.10 People living with HIV or hepatitis C, or both

People with HIV infection or HCV infection or both are at a greater risk for HBV infection because of shared transmission routes. Routine screening and immunisation are recommended for all people living with HIV or HCV to prevent primary HBV infection. Double dosing of hepatitis B vaccine is recommended for people living with HIV, and booster vaccination every 6-12 months as dictated by anti-HBs titres.[11] For further information, refer to the Australian Immunisation Handbook.[11]

3.1.11 Patients undergoing dialysis

The frequency of HBV infection is higher in dialysis patients than in the general population because of their potential greater exposure to blood, frequent transfusions and sharing of dialysis equipment, reduced response to vaccination, and reduced durability of vaccine-derived immunity. It is **recommended** that all people receiving renal dialysis have hepatitis B vaccination. Vaccination is strongly recommended for patients with chronic kidney disease, dialysis-dependent or not, who are candidates for kidney transplantation. Patients **should** be tested every 6 months for HBsAg/anti-HBs.[36] Double dosing of hepatitis B vaccine is recommended for people receiving dialysis, and booster vaccination every 6-12 months as dictated by anti-HBs titres.[11] For further information please see The Australian Immunisation Handbook.[11]

3.1.13 Sex workers

Sex workers are at an increased risk of HBV infection, particularly if engaging in unprotected sex. Hepatitis B vaccination **should** be offered if testing reveals neither immunity nor current infection.[11]

4.0 INFORMED CONSENT FOR TESTING

It is recommended that informed consent be obtained for HBV testing. Exceptions may occur for rare occasions when a legal order is made for compulsory testing or in an emergency. On these occasions, if informed consent cannot be obtained, all appropriate information should be provided to the person before the test. In the case of compulsory testing, appropriate information includes advising the person being tested of any third-party recipients of test results.

Informed consent for testing means that the person being tested agrees to be tested on the basis of understanding the testing procedures, the reasons for testing and being able to assess the personal implications of potential test results.

The person requesting the test should use their clinical judgment in securing informed consent. Clinical judgment should be based on their understanding of the context in which the test is being performed, taking into account:

- any factors which indicate an urgent need for testing such as clinical presentation, risk exposure, disease prevalence in country of origin, and individual request
- confirmation that the person being tested understands the testing process, the implications of the possible result, and how to effectively respond to the diagnosis
- that patients should also be advised of how the test result will be conveyed and the implications of HBV being a notifiable disease.

General principles of professional conduct and privacy apply when obtaining informed consent for HBV testing. In the case of testing children or people who are incapable of giving consent, then the responsibility for providing consent rests with the guardian or other person or agency legally authorised to make such decisions on the person's behalf.

Clinicians and healthcare workers involved in HBV testing must use whatever additional supports are necessary to assist the person considering testing to become adequately informed in order to understand the implications of a positive or negative result, minimise the personal impact of any positive diagnosis, adopt health promoting behaviours and reduce anxiety. Additional supports can include access to professional on-site and telephone interpreters and referral to community hepatitis organisations and multicultural health services. Health promotion information that is culturally sensitive and language-appropriate should be provided when seeking informed consent and providing results. These resources can be accessed from community hepatitis organisations and multicultural health services.

When offering testing to patients with low English proficiency, clinicians who do not speak the preferred language of the patient should use an accredited interpreter to obtain informed consent. There are publicly funded health interpreting services available in most States and Territories. The Translating and Interpreting Service (TIS National) is available to registered health services 24 hours a day. **TEL: 1300 131 450**.

5.0 CONVEYING HEPATITIS B TEST RESULTS

The process of conveying a hepatitis B test result to the person being tested (irrespective of the specific result) is informed by:

- their understanding, experience and health literacy
- the potential implications of the result in the individual circumstances for each person
- the type of test performed and the need for additional testing to determine the individual's liver health and health status
- the context in which the test is being performed and the setting of the consultation
- the healthcare provider's own capacity to convey test results.

The healthcare provider conveying the test results is responsible for ensuring that the person receiving the result is able to understand its implications and address the issues that the result raises. In presenting results to people with low English proficiency, accredited interpreter services should be accessed (**see section 4.0 for details**).

In all cases, healthcare providers should be mindful of health literacy levels and possible misinterpretations of the terms 'positive' and 'negative' when discussing test results. People may interpret a so-called 'positive' result as good and 'negative' result as bad. There may not be a word for,

or understanding of 'hepatitis' and using words like virus can lead to confusion or a misunderstanding that they have been diagnosed with HIV. The term 'healthy carrier' or 'carrier' should not be used when providing a diagnosis, as all people living with chronic hepatitis B are at elevated risk of developing liver disease.

The decision of how results from a hepatitis B test indicating infection or otherwise (**see section 2.1**) are provided (e.g. in person, by phone) should be based on the assessment of the health-care provider responsible for conveying the result. This assessment should take into account the capacity of the person being tested to respond to the test result and their understanding of the testing process at the time of the sample collection.

It is imperative that the clinician make all attempts to ensure that the result is provided to the person who was tested. This includes:

- confirming the person's identity by asking for the spelling of all their names
- making repeated contact to ensure the person is aware of the availability of the result
- documenting all efforts to contact the person.

5.1 Conveying a hepatitis B test result: susceptible (non-immune)

A susceptible individual is one for whom there is no documented history of completed vaccination, and the **anti-HBs, anti-HBc and HBsAg results are all negative**. It is imperative that the person being tested fully understands meaning of a susceptible (negative) result and that they receive appropriate information about and opportunity for hepatitis B vaccination, and are made aware of other prevention strategies in relation to the transmission of blood borne viruses and sexually transmissible infections. Follow-up testing of a person shown to be anti-HBs negative and/or HBsAg negative is indicated in people who may:

- be in a window period before to seroconversion (negative HBsAg, anti-HBc and anti-HBs in a high-risk situation – with consideration of post-exposure prophylaxis as appropriate)
- have been completely vaccinated against hepatitis B without previous confirmation of anti-HBs seroconversion
- be in a group recommended for post vaccination testing (possible non-response to the vaccine, or a fall in anti-HBs titre over time).[11]

5.2 Conveying a hepatitis B test result: immune

The health-care provider should clearly document in the medical record when a person is identified as being immune, either through resolved infection (anti-HBc and anti-HBs positive) or vaccination (anti-HBs positive). The result should be conveyed to the person being tested to avoid unnecessary repeat testing or vaccination.

People immune through resolved infection should be advised that they may be at risk of reactivation in the future if receiving treatment for cancer or other immunosuppressive therapy.[37] (**see section 3.1.3**)

5.3 Conveying a hepatitis B test result: confirmed infection

A test result that confirms infection (**HBsAg positive**) can have a significant effect on an individual and their close contacts, including families. This result may indicate either an acute or a chronic HBV infection and the information provided will reflect the clinical situation.

Laboratories should provide requesting clinicians with information and the opportunity for consultation and expert advice at the time of diagnosis. Laboratories should include standard explanatory text with the test results to prompt appropriate follow up testing and management. Examples of suggested wording are in the ASHM publication "Interpreting hepatitis B serology: Recommended wording for national laboratories to report hepatitis B diagnostic test results".

In providing results to people with low English proficiency, accredited interpreter services should be accessed when healthcare staff do not speak the person's preferred language (**see section 4.0**). The accredited interpreter may lack the vocabulary to explain the meaning of "hepatitis B" and it is important to check the tested person's understanding. The use of family members as interpreters is strongly discouraged.

The process of providing a result of confirmed hepatitis B infection (HBsAg) should include:

- conveying the test result in person and in a manner that is sensitive and appropriate to the gender, culture, emotional wellbeing, family history, language and literacy level of the person who has been tested.
- providing information about hepatitis B, and the importance of monitoring to identify resolution of acute infection (95% of adults) or, in the case of chronic hepatitis B, regular, ongoing clinical monitoring to detect liver disease and determine the need for treatment and reduce the risk of HCC.
- providing recommended lifestyle advice - in particular about smoking, weight loss, exercise, alcohol consumption and the management of diabetes.
- assessing use of hepatotoxic medications, traditional or complementary medicines and over the counter preparations.
- advising how hepatitis B is and is not transmitted, and how onward transmission may be prevented (including promoting hepatitis B testing and vaccination for partners, household contacts and other intimate contacts).
- disclosure strategies to partner and family members, including discussion relevant to whether the person has acute or chronic disease about:
  - the importance of disclosure to children
  - current and future household and sexual contacts being tested for hepatitis B and subsequently vaccinated if they are susceptible.
- providing information about the person's rights and responsibilities around disclosure of hepatitis B status and confirming that there is no need to disclose in most situations to schools or workplaces.
- explaining that the State or Territory health department is informed of the result, and the role of the health department including maintaining confidentiality.
- the provision of information about (and referral to) available support services such as community hepatitis organisations and multicultural health services.

It is usually necessary to cover these issues over **more than one visit**, in which case a subsequent consultation should be arranged at the time of diagnosis.

5.4 Contact tracing and family notification

Contact tracing of family members, partners and other household and sexual contacts of people diagnosed with hepatitis B can be complicated by reluctance of the individual to disclose their status to others. Discussion with the patient regarding how to proceed with contact tracing may take place over several consultations, as they understand more about the protection of vaccination and the value of testing their family members. Bilingual community health workers and accredited interpreters should be involved where necessary. **See section 5.6.3** for information on hepatitis B testing for close contacts and family members of the person with hepatitis B.

5.5 Special situations

5.5.1 People who do not return for test results

These people can be unaware of factors that may help them in living with chronic infection and may unknowingly place others at risk. It is important to contact these individuals. Taking into account the person's communication and language needs, it may be more effective to contact these people by phone using accredited interpreters rather than by written correspondence. Bilingual health-care workers can also be used. The request should be for the person to re-contact the service provider without providing the actual result. Attempts to make contact should

be documented in the person's file. Public health units and sexual health clinics can provide advice on individual follow-up if required.

5.5.2 Hepatitis B testing of close contacts and family members of the person with hepatitis B

Chronic hepatitis B occurs most commonly through mother-to-infant transmission antenatally, during birth, or soon after birth, or between young children early in life. It is possible that siblings in families born in high prevalence countries may all be living with hepatitis B. However, some families may be unaware of their hepatitis B status until a family member is diagnosed (**see section 5.4 Contact tracing**). The diagnosing clinician may not always have an established relationship with the person's close contacts and family members. Therefore, adequately preparing the person to inform their close contacts and family members about their positive diagnosis and the need for these contacts to be tested is critical. For people with low English proficiency, accredited interpreter services should be accessed. Referral to a local hepatitis organisation or multicultural health service may be useful. Notification of family members after a positive diagnosis may encourage screening and subsequent diagnosis, which may lead to medical management and a reduced risk of developing serious liver disease and HCC.

5.6 Referral for further support

The information and support needs of people who are preparing for diagnostic testing for hepatitis B, or have just received a test result are considerable and diverse. Information provided in a single clinical consultation is often insufficient to meet their needs as understanding develops and different personal factors arise over time. Community-based organisations including hepatitis organisations, multicultural health and support agencies, Indigenous health services and peer-based drug user groups can assist people who are newly diagnosed to better understand the hepatitis B testing and diagnosis process and provide appropriate support through this critical period. Providing referral to relevant community-based organisations is therefore recommended when informed consent for testing is being obtained at diagnosis and as appropriate at other stages of the hepatitis B diagnosis and management process.

Hepatitis Australia
National Helpline: 1300 437 222 (1300 HEP ABC)
www.hepatitisaustralia.com

Multicultural Health Services in each State and Territory

Cancer Council Helpline
13 11 20
www.cancer.org.au

The National Aboriginal Community Controlled Health Organisation:
www.naccho.org.au

The Australian Injecting and Illicit Drug Users' League (AIVL)
Telephone: 02 6279 1600
www.aivl.org.au

6.0 SURVEILLANCE AND RESEARCH

Laboratories performing HBV testing **must** notify the relevant State and Territory health authorities of any new HBsAg-positive laboratory diagnosis in accordance with the relevant legislation and regulations. In some States and Territories medical practitioners **must** also notify the relevant State and Territory health authorities.

Where information is available to identify newly acquired HBV infection, such as detection of HBsAg in a person shown to be negative within the last 24

months; or detection of HBsAg and IgM to hepatitis B core antigen (IgM anti-HBc), in the absence of prior evidence of HBV infection; or detection of HBV by nucleic acid testing, and IgM anti-HBc, in the absence of prior evidence of HBV infection, these cases **should** be reported to the local State or Territory health authorities as a case of newly acquired HBV infection.[38]

6.1 Delinked blood surveys

Delinked anonymous surveys are studies in which specimens taken for other purposes (e.g. residual serum following routine diagnostic testing) are tested for markers of HBV infection and immunity without consent after they have been coded so that the results cannot be linked to the individual who originally provided the specimen.

The survey method **should** be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data and **should** be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the NHMRC.[9]

6.2 Use of unregistered in-vitro diagnostic devices (IVDs)

HBV IVDs must be included in the Australian Register of Therapeutic Goods. IVDs not currently supplied in Australia may be required to be used in international collaborative research. Application **must** be made to the TGA under the Clinical Trial or Special Access Scheme to allow for use of these IVDs where they are used for a therapeutic purpose, e.g. to diagnose infection or determine treatment for a patient. IVDs to be used for research only, e.g. where results are de-identified and not used to determine patient treatment, are exempt under Clause 1.3, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

7.0 HEALTHCARE WORKERS

All healthcare workers, including all workers and students directly caring for patients, or handling human tissue, blood or body fluids are recommended to receive hepatitis B vaccination.[11]

Information and recommendations concerning hepatitis B vaccination and serological testing of healthcare workers can be found online in the Australian Immunisation Handbook. Advice is provided for non-responders to hepatitis B vaccine. Persistent non responders to hepatitis B vaccination are considered non immune to hepatitis B.[11]

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, provide hepatitis B testing recommendations for healthcare workers who perform exposure prone procedures and healthcare workers living with hepatitis B.[38]

As for all tests where testing of a healthcare worker is undertaken, confidentiality needs to be maintained. Health-care workers who are exposed to blood borne viruses should have access to testing and counselling in their practice, institution or through specialist referral. They should not be required to request or perform tests on themselves. Health-care workers who are known to be living with blood borne viruses should be in the care of their own medical practitioner and should not initiate diagnostic tests on themselves.

Support and advice for healthcare workers living with a blood borne virus is available from their specialist college or from the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine at www.ashm.org.au.

8.0 ANTENATAL AND PERINATAL TESTING

8.1 Routine testing

Women contemplating pregnancy or seeking antenatal care **should** be made aware of the benefits of diagnosis of hepatitis B infection and management, and prevention strategies available to protect the infant from infection.[39]

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines state that all pregnant women **should** be screened using the HBsAg test.[39] It is **recommended** that this take place at the first antenatal visit. If a woman is identified as HBsAg positive, further testing (HBeAg and HBV DNA) **should** be performed to determine the risk of transmission to the infant and the degree of infectivity in general, to inform clinical decision making.[40]

The risk of perinatal HBV transmission is determined by maternal hepatitis B viral factors; highly replicative infection characterised by high HBV DNA viral load and HBeAg positivity is associated with a higher risk of transmission. Timely administration of hepatitis B vaccination and hepatitis B immunoglobulin (HBIG) to the infant within 12 hours of birth will prevent most mother-to-child transmission. This strategy is highly effective, except in the setting of high maternal viral load (HBV DNA >200,000 IU/mL or $\log_{10}$ 5.3 IU/mL), when mother-to-child transmission can still occur in up to 10% of the vaccinated infants. Assessment of maternal HBV DNA early in the second trimester, and start of antiviral therapy at 28-30 weeks is recommended in the RANZOG guidelines.[39] Women with a high viral load **should** receive specialist advice about the role of antiviral treatment during the third trimester to further reduce the risk of transmission. Current first-line choice for antiviral therapy is tenofovir, which has a favourable safety profile, high potency and low rates of resistance.[41-47]

Any woman diagnosed with hepatitis B infection in pregnancy **should** be assessed by an experienced clinician who will determine the phase and stage of her hepatitis B so that appropriate recommendations about treatment and monitoring can be made.

Jurisdictions **should** develop operational directives that support the RANZCOG guidelines through education, feedback on compliance and periodic auditing of antenatal medical records to provide evidence of recommended best practice.

8.2 Testing of infants born to HBsAg positive mothers

HBsAg and anti-HBs levels can be measured in infants born to mothers with chronic HBV infection to allow identification of cases of mother-to-child transmission and vaccine failure. Follow-up testing should optimally be performed at 9-12 months of age, at least three months after completing the primary vaccine course, to confirm vaccine response and to avoid detection of passive anti-HBs from HBIG administered at birth or transient antigenaemia from vaccine.[46] Recent Australian data has shown that mother-to-child transmission of HBV has not occurred in infants who received per protocol immunoprophylaxis with vaccine and HBIG if their mothers did not have a high viral load.[47] Thus, while not harmful, testing these infants may be unnecessary and it is reasonable to focus serological follow-up efforts on those infants born to women with a high viral load. A positive HBsAg result from infant blood indicates infection and, in this case, the infant **should** be referred to a paediatric gastroenterologist, hepatologist or infectious diseases physician for further assessment.

9.0 PEOPLE FROM CULTURALLY AND LINGUISTICALLY DIVERSE BACKGROUNDS

Over 50% of people living with chronic hepatitis B in Australia are people from priority CALD communities (**see section 3.1.1**).[25] Clinicians need to be equipped to provide culturally sensitive and competent services, to improve health outcomes for this priority population.[48]

'Culturally and linguistically diverse' is an umbrella term designed to include migrants, temporary residents, international students, refugees, and asylum seekers, as well as their descendants. It draws attention to cultural factors that can influence patterns of health access and outcomes even in people who were born in Australia and speak English proficiently. Understanding a person's health belief systems and level of health literacy can support the clinician to tailor each episode of care specifically to improve the health outcomes of their patients.

9.1 Testing CALD patients at highest risk of HBV

Clinicians **should** routinely ask patients to identify their country of birth, parents' countries of birth, languages spoken at home and any family history of liver disease. Answers to these questions can establish the relevance of an offer of testing particularly for patients born in countries of high (≥ 8%) and intermediate (2-7%) prevalence rates for HBV (**see figure 1, section 3.1**).[19]

Clinicians should stress that many people from priority CALD backgrounds were not vaccinated at birth and therefore perinatal and early childhood exposure are the primary routes of transmission for these people

9.2 Confidentiality and using interpreters

Clinicians **should** advise that interpreters are available and are free of charge.

Clinicians **should** reassure the person that all people involved, including interpreters and clinicians, will keep confidentiality.

Clinicians **should** brief any face-to-face or telephone interpreter about maintaining confidentiality regarding everything they learn from the consultation and ensure the interpreters understand the language and concepts to be conveyed. Professional interpreters are bound by a professional code of conduct to respect confidentiality. Where patients are concerned about confidentiality (e.g. in smaller communities), telephone interpreters may be used, and the clinician may refer to the patient using a pseudonym to disguise their identity.

Clinicians **should** use simple language to explain privacy and when exceptions to privacy may apply.

Clinicians **should** encourage patients to bring and involve family members in testing, vaccination, monitoring and care as many view health issues as a collective issue. However the use of family members as interpreters is strongly discouraged. Clinicians should also be aware that in certain cultures hepatitis B is highly stigmatised and working with patients in a culturally competent and culturally safe way is crucial for improving the long-term health of individual patients, families and communities.

9.3 Screening

9.3.1 Opportunistic testing

Opportunistic testing depends on clinicians proactively offering HBV testing to CALD patients. Patients may see clinicians at multiple practices or different clinicians within the same practice. Clinicians **should** use patient records to document both the offers and the outcomes of HBV testing in order to avoid repeated offers of testing that may result in unnecessary duplication of testing or vaccination. Medical records **should** include reasons for any refusal of testing. Information about the need for an interpreter, what language is spoken, and the preferred mode of interpreting (face-to-face or telephone) **should** also be recorded.

Clinicians **should** be sensitive to any cultural barriers when a person refuses a blood test and **should** offer the option of involving a multicultural health service which are available in most states.

9.3.2 Family testing

Contact tracing, screening and provision of vaccination for household contacts[11] **should** be guided by reference to cultural understandings of the family in the patient's own community (such as reconfigured refugee families), as these are what determine the level of risk (for example, frequency of occasions where horizontal transmission may occur).

9.4 Cultural competency in healthcare

Cultural competence in healthcare describes the ability of systems to provide care to patients with diverse values, beliefs and behaviours, including tailoring delivery to meet the patient's social, cultural and linguistic needs.[49]

All cultural and ethnic groups have concepts related to health and illness, whether they are cultural or individual beliefs, that influence their health behaviour. These **should** be considered when communicating with a patient.
Clinicians and practice staff **should** be equipped with knowledge, skills and tools to work with people from CALD backgrounds to achieve better health outcomes.

10.0 ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES

The fifth National Aboriginal and Torres Strait Islander Blood Borne Virus & Sexually Transmissible Infections Strategy 2018-2022 recommends increasing the assessment of hepatitis B status, immunisation coverage for those at risk, and management of those with chronic hepatitis B.[50] It acknowledges that access to services in remote communities remains a challenge and that innovative and flexible solutions are required to address these inequities (**also see section 3.1.2**).

10.1 Identifying Aboriginal and Torres Strait Islander peoples

Clinical service providers **should** ask people whether they identify as an Aboriginal or Torres Strait Islander person, and what languages they speak at home. It is also crucial to include Aboriginal and Torres Strait Islander status with notifications.

10.2 Testing in Aboriginal and Torres Strait Islander populations

In order to enable informed consent as detailed in **section 4.0** it is crucial to pay attention to language, communication, worldview of health and use of interpreters. Bilingual resources such as the Hep B Story app can be helpful (https://www.menzies.edu.au/page/Resources/Hep_B_Story/)

Testing for HBV infection and offering appropriate management for all those affected by a positive diagnosis are essential for this priority population (**see section 3.1.2**). Introducing new screening policy in the Indigenous setting requires community consultation. Local health boards or community-controlled health organisations may make decisions about screening the population they serve for HBV infection based on knowledge of local prevalence, health service factors, regional vaccine funding and consultation with the community. Stigma, shame and blame can often be triggered by discussion of hepatitis B testing, being mindful of who else is present. Cultural protocols around women's and men's business are important particularly when mother to child transmission is the most common route or transmission.

11.0 QUALITY ASSURANCE OF HBV TESTING

11.1 Laboratories

Laboratories that perform HBV testing and that claim Medicare Benefits:

- **must** be accredited for medical testing in accordance with ISO 15189, National Pathology Accreditation Advisory Council (NPAAC) standards and NATA rules and regulations
- **must** be enrolled, participate and demonstrate acceptable performance continually in appropriate external quality assurance programs (EQAS)
- **should** contribute testing statistics to National Serology Reference Laboratory (NRL) to ensure the completeness of test denominator data
- **should** report any adverse events to both the IVD sponsor and the TGA.

11.2 Pre-market regulatory requirements for HBV in-vitro diagnostic devices

The TGA has regulatory responsibility for IVDs through the Therapeutic Goods Act 1989[14] and Therapeutic Goods (Medical Devices) Regulations 2002.[51] All commercially supplied IVDs must be listed on the ARTG. Before inclusion on the ARTG, all commercially supplied IVDS are evaluated to ensure they are safe and perform as intended. For regulation of HBV IVDs refer to the TGA website In vitro diagnostic medical devices: http://www.tga.gov.au/industry/ivd-guidance.htm

11.3 Post-market monitoring of HBV in-vitro diagnostic devices

IVD manufacturers, sponsors and the TGA have the responsibility for post-market monitoring of the IVDs. The manufacturer and sponsor **must** inform the TGA of all reportable adverse events. Corrective action **must** be initiated by the manufacturer and sponsor of an IVD in consultation with the TGA. This action **must** occur as soon as practicable after becoming aware of information relating to any adverse events, malfunction or deterioration in the performance, or inadequacy in the design production and labelling of an IVD. Users are encouraged to report any adverse event to the TGA through the Medical Device Incident Reporting and Investigation Scheme as well as to the sponsor of the IVD.[52]

12.0 FUNDING OF HBV TESTING

Funding for HBV testing is provided directly from the Commonwealth Government on a fee-for-service basis through the Medicare funding arrangements and also through State and Territory funding arrangements.

12.1 Funding arrangements for hepatitis B diagnostic and monitoring tests

More detailed information on Medicare benefits for hepatitis B tests can be found on MBS Online (Medicare Benefits Schedule Book Category 6).[53]

A Medicare benefit for pathology testing for hepatitis B and hepatitis D if conducted (**see section 2.1**) will be payable where the service was determined to be necessary by the patient's medical practitioner, was provided by an accredited pathology laboratory, and the patient meets the requirements for the relevant MBS item. Benefits are payable for the attendance and tests which are considered reasonably necessary according to a patient's individual circumstances.

12.2 Schedule interpretation

Inquiries concerning matters of interpretation of MBS items, including patient eligibility, should be directed to the Department of Health in the first instance. This can be done via email to: askMBS@health.gov.au. Services Australia is responsible for the day-to-day administration and payment of benefits under the Medicare arrangements. For enquiries relating to Medicare payments, **phone 132 150**.

13.0 GLOSSARY

13.1 Abbreviations and acronyms

AHPPC	Australian Health Protection Principal Committee
ARTG	Australian Register of Therapeutic Goods
ASHM	Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine
BBVSS	Blood Borne Virus and Sexually Transmissible Infections Standing Committee
CALD	Culturally and Linguistically Diverse
DNA	Deoxyribonucleic acid
EPP	Exposure Prone Procedure
EQAS	External Quality Assessment Scheme
GPs	General Practitioners
HBIG	Hepatitis B immunoglobulin
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B virus
HCC	Hepatocellular carcinoma
HCV	Hepatitis C virus
HDV	Hepatitis D virus
HIV	Human Immunodeficiency Virus
IgM	Immunoglobulin M
IVD	In-Vitro Diagnostic Devices
MBS	Medicare Benefits Schedule
MSM	Men who have sex with men
NAT	Nucleic Acid Test
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
NRL	National Serology Reference Laboratory, Australia
POCT	Point of Care Testing
PWID	People who inject drugs
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RNA	Ribonucleic acid
TGA	Therapeutic Goods Administration

13.2 Glossary

Analytical sensitivity

The smallest amount of the target marker that can be precisely detected.

Compulsory testing

Where a person has no choice in being tested, e.g. as directed under a Public Health Order.

Exposure Prone Procedure

The Australian guidelines for the prevention and control of infection in healthcare[54] defines exposure prone procedures (EPP) as invasive procedures where there is potential for direct contact between

the skin (usually finger or thumb) of the healthcare worker and sharp surgical instruments, needles or sharp tissues (spicules of bone or teeth) in body cavities or in poorly visualised or confined body sites (including the mouth). In the broader sense, an exposure-prone procedure is considered to be any situation where there is a potentially high risk of transmission of blood borne viruses from healthcare worker to patient during medical or dental procedures.

Mandatory testing
Refers to situations where people are not allowed to participate in certain activities nor access certain services unless they agree to be tested. Examples of circumstances in which mandatory testing is appropriate include before blood, tissue and organ donation, and for immigration purposes.

Occupational exposure
An exposure that may place an employee at risk of HIV, HBV or HCV infection through percutaneous injury (e.g. a needlestick or cut with a sharp object, contact of mucous membranes, or contact of skin with blood, tissues or other potentially infectious body fluids to which Universal Precautions apply).

Serology
Refers to testing for the presence, evidence of, or quantity of antibodies or antigens specific for infectious or other agents, biochemistry, or substances in blood (serum or plasma or whole blood).

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APPENDIX A

Expert Reference Committee Membership

Membership of The National Hepatitis B Testing Policy Expert Reference Committee (ERC) 2020

(name, position, organisation, affiliation with ERC)

Scott Bowden
Senior Scientist, Molecular Microbiology
VIDRL at The Doherty Institute for Infection and Immunity
Adjunct Professor
Dept of Microbiology Monash University
Chair

Alison Coelho
Senior Project Officer, Multicultural Health & Support Service
Centre for Culture, Ethnicity & Health
Member of Class

Alister Keyser
Senior Acting Medical Officer
Apunipima
Member of Class

Antje Janssen
IVD Reforms
Therapeutic Goods Administration
TGA representative

Aye Aye Khaing
Volunteer
Hepatitis Victoria
Member of class

Brendan Kennedy
Infectious disease physician
Royal Adelaide Hospital
SA BBVSS representative

Charles Alpren

Elizabeth Birbilis
Senior Policy Officer
Victorian Department of Health and Human Services
VIC BBVSS representative

Jack Wallace
Senior Research Officer
Burnet Institute
Adjunct Research Fellow
LaTrobe University
Adjunct Lecturer
Centre for Social Research in Health.
Burnet Institute
Member of class

Jacqueline Mein
Director Medical Services, Wuchopperen
Aboriginal and Torres Strait Islander populations
Member of class

Jacqui Richmond
MPH, RN, Program Manager, The Burnet Institute, Melbourne Honorary Research Fellow, ARCSHS, La Trobe University
Australian Research Centre in Sex, Health and Society and Melbourne Health
Member of Class

Jane Davies
ID physician, Aboriginal and Torres Strait Islander health
Menzies, Royal Darwin Hospital
NT BBVSS representative

Jessica Howell
Gastroenterologist, St Vincent's Hospital Melbourne
ALA
ALA representative

Jill Benson
Discipline of General Practice
University of Adelaide, Prideaux Centre for Medical Education, Flinders University
Member of Class

Joe Doyle
MPH PhD FRACP FAFPHM, Deputy Director, Disease Elimination Program, Co-Head, Viral Hepatitis Elimination, Principal Research Fellow, Infectious Diseases Physician, NHMRC Career Development Fellow
The Alfred & Monash University
ASID representative

John Didlick
Policy Analyst
Hepatitis Australia
Hepatitis Australia representative

Judy Gould
Policy Officer
Australian Government Department of Health
CDNA representative

Julie Wang
General Practitioner & Epidemiologist
Whitehorse Medical Centre
Member of Class

Kate Turner
Clinical Nurse Consultant
Public Health Services, Dept of Health
TAS BBVSS representative

Lloyd Einsiedel
Infectious Diseases Physician
Flinders Medical Centre and University; and Alice Springs Hospital
Member of Class

Michael Lidman
Policy officer, Blood Borne Viruses, Sexually Transmissible Infections and Torres Strait Health Section
Australian Government Department of Health
CDNA representative

Michael West
Manager, Sexual Health and Viral Hepatitis program
Victorian Department of Health and Human Services
VIC BBVSS representative

Miriam Levy
Gastroenterologist
Liverpool Hospital
Member of Class

Nicole Allard
General Practitioner
Joslin Clinic
Member of Class

Peter Kaylock
Devices Conformity Assessment Section Offices Of Devices Authorisation
Therapeutic Goods Administration
TGA representative

Phil Kiely
Blood Safety Analyst
Clinical Services and Research, Australian Red Cross Lifeblood
Member of class

Prof Ben Cowie
ID physician and epidemiologist
Doherty Institute
Director
WHO collaborating centre for viral hepatitis
Member of Class

Robert Kemp
Principal Public Health Officer, Viral Hepatitis
Queensland Health, BBV/STI Unit
QLD BBVSS representative

Sarah Norris
Acting Assistant Secretary
Australian Government Department of Health
Member of Class

Stephanie Marion
Assistant director
ACT Health
ACT BBVSS representative

ToveLysa Fitzgerald
A/Manager NSW BBVSTI Unit
NSW Health
NSW BBVSS representative

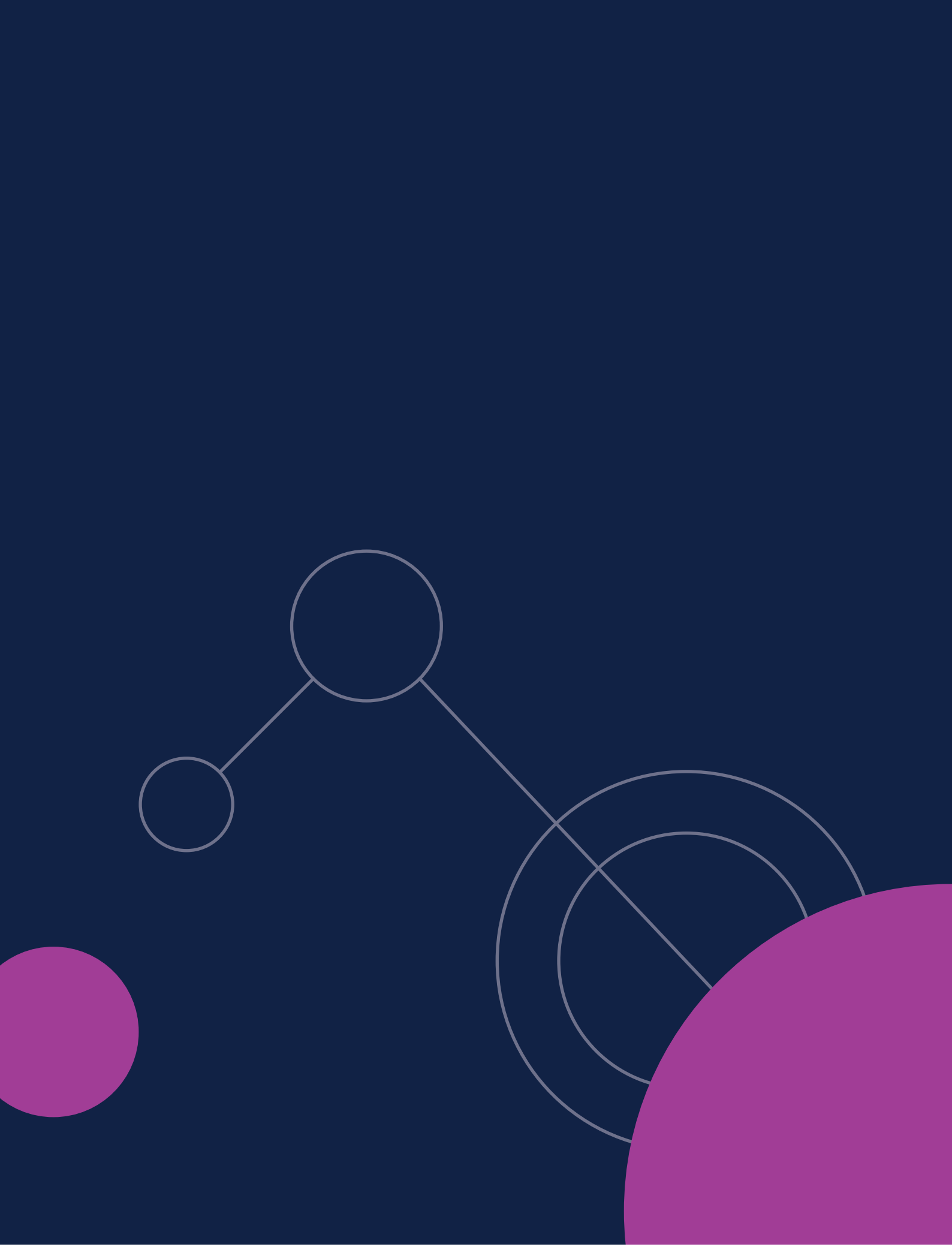
Vicky Shepeard
Director of Communicable Diseases
NSW Health
NSW BBVSS representative

Wayne Dimech
Executive Manager –
Scientific and Business Relations
National Serology Reference Laboratory
NRL representative

Wendy Cheng
Head, Liver Service, Dept of Gastro & Hepatology
Royal Perth Bentley Group
BBVSS WA

Emily Vintour-Cesar
Project Officer
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
ASHM secretariat

Zindia Nanver
Senior Project Officer
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
ASHM Secretariat



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