ashm

# National Hepatitis C Testing Policy

2020

# National Hepatitis C Testing Policy v1.3

**Reviewed 2020**

**Disclaimer:** This Testing Policy has been developed as a concise source of standardised, currently available information to inform those involved in ordering and performing hepatitis C testing. This Policy is not a set of clinical guidelines and it should not be used as a guide for the clinical management of hepatitis C infection.

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

The views expressed in this Policy are not necessarily those of the Commonwealth Government of Australia. The Commonwealth, the Blood Borne Viruses and Sexually Transmissible Infections Standing Committee (BBVSS) of the Australian Health Protection Principal Committee (AHPPC) do not accept any liability for any injury, illness, damage or loss incurred by any person arising from the use of or reliance on the information or advice that is provided in this Testing Policy.

The web-based version of the National Hepatitis C Testing Policy allows for regular revision, and access to related resources (e.g. related policies, operational guidelines, evidence of best practice) with a download and print function which can be found at: http://testingportal.ashm.org.au. Any references or web links to products, services or information contained in this publication do not constitute an endorsement of those references or web links.

# National Hepatitis C Testing Policy

2020

The National Hepatitis C Testing Policy is supported by funding from the Australian Government Department of Health.

The National Hepatitis C Testing Policy has been endorsed by the Blood Borne Viruses and Sexually Transmissible Infections Committee, effective 22 October 2020.

# Contents

# EXECUTIVE SUMMARY

**Background and objectives**

Hepatitis C virus (HCV) infection is a major public health problem globally with an estimated 71 million people with chronic infection.[1] At the end of 2017, it was estimated that about 0.7% of Australia's population were living with hepatitis C infection.[2] **Chronic HCV infection is associated with progressive liver disease, which may lead to liver cirrhosis, liver failure and liver cancer in a large number of people.**

In 2016 the World Health Organization (WHO) set the ambitious target of eliminating HCV as a major public health threat by 2030 (defined as 90% reduction in incidence and 65% reduction in hepatitis C-related mortality compared to levels in 2015).[3]

**The testing target of the Fifth National Hepatitis C Strategy 2018-2022**[4] is to increase the proportion of people living with hepatitis C who are diagnosed to 90%.

Approximately 19% of people living with hepatitis C in Australia are unaware of their infection, and diagnosis of all those with hepatitis C infection is critical to ensure optimal clinical management and the prevention of ongoing transmission. The aim of this National Hepatitis C Testing Policy is to recommend evidence-based testing pathways for the diagnosis of hepatitis C infection.

This policy adheres to five key components outlined by WHO in relation to testing, also known as the 5 Cs:[5]

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

WHO notes that HCV testing for diagnosis must always be voluntary, and consent for testing informed by pre-test information. Testing should be linked to prevention, treatment, care and support services to maximise both individual and public heatttlth benefits.

**Diagnostic strategies**

Individuals suspected of exposure to HCV should first be tested for the presence of HCV antibody (anti-HCV antibody). A positive result will indicate exposure to HCV. It is then appropriate to test for HCV RNA to determine if the patient has a past or current infection. Both tests can be performed sequentially if the clinician requests that HCV RNA be assayed if the HCV antibody test is positive. The request form should request that two tubes of blood be provided to allow for both tests. The presence of HCV RNA indicates active infection and all such patients should be offered treatment with the new range of direct-acting antiviral (DAA) drugs.
With the ready availability of pangenotypic DAA regimens, genotyping is no longer a requirement for treatment initiation.

**Indications for HCV testing**

The majority of HCV infections in Australia are chronic (having persisted for more than 6 months' duration) and occur in:

- **people who have past or present injection drug use**
- **people born in countries of intermediate to high HCV prevalence**
- **people who have been incarcerated.**

Over 80% of people with HCV infection in Australia have injected drugs.

**Other priority populations** to be considered for HCV testing include, **healthcare workers, pregnant women** and **Aboriginal and Torres Strait Islander people**).

**Informed consent for testing**
Informed consent should be obtained for HCV testing and testing 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 C test results**
The healthcare provider conveying the outcome of the HCV 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

**Funding of HCV testing**
Funding for HCV testing is provided directly from the Commonwealth government on a fee-for-service basis through the Medicare funding arrangements (Medicare Benefit Schedule Items 69445, 69475, 69488, 69491, 69499) and also through state and territory funding arrangements. Benefits for these tests 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.

# 1.0 INTRODUCTION

## 1.1 Background and context

Hepatitis C infection remains a major public health problem in Australia. There were 10,537 hepatitis C notifications in Australia in 2017.[2] Influenced by multiple factors, infection persists in between 55–85% of those with the infection. In 2017, an estimated 182,144 Australians were living with chronic hepatitis C. Cirrhosis develops within 20 years in 5–10% of this group (usually associated with other comorbidities such as co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), obesity, insulin resistance, alcohol intake over 40 g each day) and in a further 10–15% after 40 years.[6] Hepatocellular carcinoma will develop in 3–5% of people per annum who develop cirrhosis.[7]

Preventive interventions have proven effective in decreasing HCV transmission and therapeutic interventions are effective in improving quality of life and clinical outcomes for people with HCV infection. New treatments subsidised on the Pharmaceutical Benefits Scheme (PBS) since March 2016 have greatly improved HCV sustained viral responses (SVR) and treatment numbers have risen dramatically from pre-DAA agent levels. The newest agents, which are pangenotypic have been shown to be safe and highly effective and, in 2019, almost 50% of prescriptions for these new drugs were written by doctors in primary-care settings.[8]

This edition of the Testing Policy seeks to define the current best practice for testing for exposure (or re-exposure) to the virus and for defining the current infective status of the person before, during and after treatment.

HCV testing can provide people with information regarding exposure to the virus. Appropriate testing indicates whether the person being tested has cleared the virus spontaneously or with antiviral therapy or has an ongoing (chronic) infection.

The benefits of reliable, timely testing are numerous, both for the person being tested and for public health. Detection of HCV infection followed by appropriate education can effectively reduce onward transmission by empowering people living with hepatitis C infection to modify their risk behaviour, modify their disease progression through earlier referral for advice and treatment, and protect the blood, tissue and organ donation supply. Despite the public health and individual benefits of testing, a

significant but undocumented number of people with hepatitis C infection in Australia remain undiagnosed.

It is therefore crucial that those people responsible for implementing this Policy (particularly those obtaining informed consent and providing test results) have the necessary skills and knowledge to fully communicate the significance of each of the available tests to the person being tested. This Policy document assumes that all staff involved in the testing process are appropriately trained.

### 1.2 Purpose, scope and objectives

This Policy sets out the framework for providing quality testing and removing real and perceived barriers to testing.

The Policy is aligned with the Fifth National Hepatitis C Strategy 2018- 2022[4] which identifies the need to implement approaches that maximise the number of people living with hepatitis C who are diagnosed, including regular testing of hepatitis C among priority populations and in priority settings. It supports health professionals to provide current, innovative and effective testing and care for people living with hepatitis C.

### 1.3 Principles of HCV testing

The eight basic principles that guide HCV testing in Australia:

- confidential, voluntary testing with informed consent and post-test discussion
- testing must be accessible to all those who are or have been at risk of HCV infection
- testing will be of the highest possible standard and provided in a timely manner
- testing is of benefit to the person being tested
- testing is critical to understanding the epidemiology of HCV infection in the community
- testing can be critical to interruption of transmission and can support harm reduction
- testing to monitor people with HCV before, during and after treatment is an integral part of their care
- people should not be denied testing because of fear of having their name associated with an HCV test (e.g. in a small community where confidentiality is harder to maintain). De-identified testing should be provided to protect privacy where relevant.

### 1.4 Policy implementation

Testing policies and practices must 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.[9,10,11]

Policies relating to HCV testing, specific to individual states, territories or institutions, should be consistent with the purpose, objectives and principles of this Policy.

Australia has a high quality, comprehensive multi-sector pathology service. The regulatory and quality framework for HCV diagnostic testing has evolved with a focus on formal laboratory settings. It is acknowledged that point-of-care testing will become more common practice in the coming years as test sensitivity and specificity have improved rapidly.

The National Pathology Accreditation Advisory Council (NPAAC) sets quality standards for pathology laboratories and the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) accredit medical testing facilities against these standards. Accreditation is required in order for pathology services to be eligible for the Medicare Benefits Schedule (MBS) rebates. Professional standards for pathology practice are established by the RCPA.

Diagnostic tests used in Australia must pass evaluation by the Therapeutic Goods Administration (TGA), before entry onto the Australian Register of Therapeutic Goods (ARTG) and the TGA can place conditions on this entry. The Medical Services Advisory Committee (MSAC) advises which tests

should be subsidised through the MBS. It also can recommend any restrictions on eligibility. Tests for blood-borne viruses including HIV tests undergo the most stringent of pathology test evaluations.

Some tests are performed outside of the diagnostic laboratory, e.g. in research or clinical trials or in settings where point-of-care testing is being evaluated. These uses may therefore be outside the regulatory framework offered by NATA accreditation and RCPA standards.

### 1.4.1 Voluntary confidential testing

Voluntary confidential testing is the standard form of service delivery for HCV testing in Australia. Testing is provided through a range of settings from general practice, remote community clinics to specialist HCV, liver and infectious diseases services.

### 1.4.2 Mandatory and compulsory testing

- **Mandatory testing** refers to situations where people may not either participate in certain activities or access certain services unless they agree to be tested. Circumstances in which mandatory testing are currently required under separate policy or legislation include:
  - as a condition of blood, tissue and organ donation[12]
  - under the migration health requirements applicable to specified visa subclasses[13]
  - as a condition for entering training or service in the armed forces[14]
  - as a condition for purchasing some types of insurance[15]
  - in the context of a legal instruction, including in forensic or coronial settings.

- **Compulsory testing** refers to situations where a person has no choice in being tested, (e.g. in the context of a forensic or coronial inquiry, or under legislation in some jurisdictions that allows for forced testing of individuals accused of certain offences, or if a person suspected on reasonable grounds of being positive for hepatitis C infection persistently behaves in a way that is perceived to place others at risk of infection). Compulsory testing should only be used when there are no alternatives. The right of appeal against a decision or order to be tested should always exist.

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

### 1.4.3 Anonymous delinked testing

There may be circumstances where, on public health grounds (e.g. prevalence studies), anonymous delinked testing is legitimately performed in accordance with this Policy. Such testing should occur only where there is compelling scientific justification. This must be independently judged by an Ethics Committee constituted in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research.[16]

### 1.4.4 Introduction of new technologies and strategies

Introduction of new technologies[17] or strategies to target new priority populations[18] will continue to evolve (e.g. validating point-of-care tests and the use of dried blood spot sampling). In every case, the introduction of new testing processes must be accompanied by appropriate workforce development to ensure that those providing or offering HCV testing are equipped with:

- up-to-date information about HCV infection, pathophysiology, immunology and epidemiology
- the latest information about HCV treatment and management
- procedures associated with using any new technology
- information related to referral pathways to care and support services (see section 5.3 Referral for further support and section 10.0 Point-of-Care-tests for HCV).

# 2.0 DIAGNOSTIC STRATEGIES

## 2.1 Types and uses of HCV diagnostic tests

All testing technologies for HCV must be included on the Australian Register of Therapeutic Goods (ARTG) before their use in Australia. Inclusion on the ARTG requires pre-market assessment of the HCV diagnostic test commensurate with the purpose for which the test will be used.

### HCV screening tests

Screening tests are serological assays used by laboratories performing diagnostic testing or screening of blood donations to determine the presence or absence of HCV antibody (anti-HCV), and typically use serum or plasma from venous blood. Those samples yielding non-reactive results (HCV antibody not detected) do not need to be further tested unless clinical considerations demand it, such as suspicion of a very recent infection. Note that the seroconversion window period for HCV infection can be lengthy, on average 8 weeks but can be up to 12 weeks.[19,20,21] Reactive samples (HCV antibody detected) are subjected to a second alternative immunoassay to confirm true reactivity from false. The recombinant antigens used in the immunoassays are not an exact mimic of the virus proteins, so when screening a low prevalence population, some false reactivity can occur. Confirming reactivity in the alternative immunoassay minimises this risk.

### HCV RNA tests

The presence of HCV antibody (anti-HCV detected) shows that the patient has HCV infection but does not indicate whether the infection is acute, chronic or resolved. This diagnosis is most commonly determined by testing for the presence of HCV RNA. Testing for HCV RNA is recommended for all patients shown to have an HCV antibody (anti-HCV) reactive sample. There is also an immunoassay available for HCV core antigen (HCVcAg), which can also identify acute or chronic infection although few laboratories in Australia offer this test.

Further tests may be used once HCV RNA has been detected. These tests include assays to quantify viral load and characterise the virus genotype.

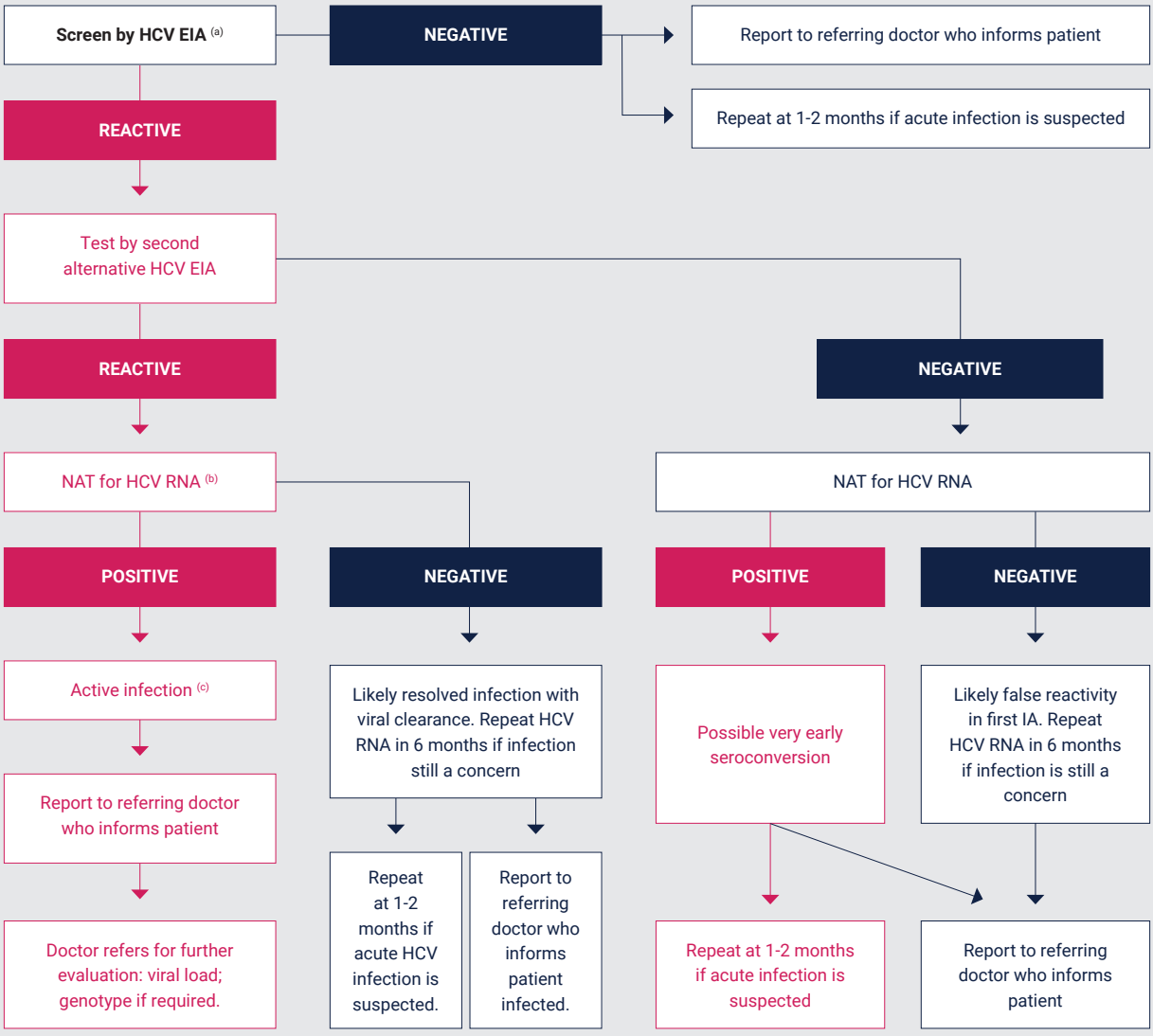
## 2.2 Testing for HCV

This section provides advice on minimum standards for laboratory diagnosis and investigation of HCV infection. It should be noted that, because of their unique requirements, blood services have developed their own strategies for screening donations. Laboratory investigations are directed towards answering one or more of the following questions:

1. **Has the person ever had HCV infection?** This finding should be determined by testing for HCV antibodies. HCV antibody (anti-HCV) reactive samples which are negative for HCV RNA most likely represent past infection with clearance (resolved or cured by therapy). However, HCV infection does not confer sterilising immunity and re-infection can occur.[22]
2. **Does the person have a current infection?** This finding is determined by testing for HCV RNA (or infrequently HCV core antigen, although it is less sensitive than HCV RNA testing). The presence of HCV RNA indicates active viral replication and is typically performed with a qualitative HCV RNA nucleic acid test.
3. **What is the current level of viral replication?** With most DAA treatments, the baseline HCV RNA has little impact on the likelihood of achieving a SVR. Some preliminary reports show that monitoring the viral load may help identify people who are eligible for shorter treatment duration with some DAA regimens, but these studies require further evaluation.[23]
4. **What is the infecting virus genotype?** With interferon-based treatment, HCV genotype (designated 1 – 6) was a strong predictor of

achieving an SVR. Several new, highly effective DAA therapies are pangenotypic. As from 1 April 2020, HCV genotyping is no longer a requirement to meet the PBS criteria but, where possible, should be documented in the patient's medical history.

## Laboratory testing pathway




a) **EIA** = Enzyme immunoassay. Encompasses all approved HCV immunoassay included on the ARTG for screening.
b) Qualitative HCV RNA NAT (HCV core antigen immunoassay may be considered an alternative if available).
c) Laboratory notifies relevant State/Territory public health authority

### 2.3 Diagnostic strategies for HCV

- Exposure to HCV is determined by testing for HCV antibodies in serum or plasma.
- A sample non-reactive in the screening immunoassay can be generally regarded as HCV antibody (anti-HCV) not detected. If doubt exists, repeat the test or consider qualitative HCV RNA testing.
- A sample reactive in the screening immunoassay **must** be subject to a minimum of one alternative immunoassay to confirm the result. The alternative immunoassay should include antigens different from the screening test in both specificity, and where possible, the method of preparation. Diagnostic laboratories can access the suitability of immunoassay combinations by consulting with state or national infectious diseases reference laboratories. As all immunoassays show a degree of false reactivity, it is important to eliminate as much as possible any common false reactivity between two tests that are to be used as part of a diagnostic strategy. A sample reactive in two approved immunoassays can be reported as HCV antibody (anti-HCV) detected.
- Current HCV infection is determined by qualitative testing for HCV RNA, or HCV core antigen testing.
  - The manufacturers of quantitative HCV RNA assays specify that these tests are not for use as diagnostic tests to confirm the presence of HCV infection.
  - HCV RNA will not be detected in past infection with clearance (resolved infection or cured by therapy) but may also be negative in the very early period post infection.
  - Ideally, a second blood sample specifically for HCV RNA testing should be used, consistent with NPAAC guidelines for nucleic acid testing and following the manufacturer's instructions for use.
  - Instead of obtaining a follow-up sample from a second patient visit, a blood or plasma sample could be set aside at the time of initial collection or processing to allow for any subsequent HCV RNA testing if the HCV antibody (anti-HCV) test is confirmed positive (**reflex testing**). The latter may be achieved by dividing a single blood draw into two tubes at sample collection or splitting a single specimen into two aliquots at the sample processing stage. Clinicians can facilitate this process by requesting that HCV RNA testing is to be performed if HCV antibody (anti-HCV) is positive and by providing the two sample tubes. Such procedures offer the benefit of less patient visits to obtain venous access which should improve testing, diagnosis and treatment of at-risk people.
  - HCV core antigen assays are an alternative to HCV RNA assays but are not currently used regularly in clinical practice. They do offer the advantage that a single sample can be used for both HCV antibody (anti-HCV) testing and HCV core antigen. HCV RNA tests are the most common option chosen due to their widespread availability and superior sensitivity.
  - A point-of-care test for detection and quantification of HCV RNA was approved by the Therapeutic Goods Administration in May 2020– see Chapter 10.0 Point-of-Care Tests for HCV.
  - The availability of effective pangenotypic DAA therapies means that HCV genotyping is no longer required before treatment initiation to meet the PBS criteria. Nevertheless, some genotype-specific treatments remain in use and HCV genotype may be clinically useful in certain regimens when treating cirrhotic or treatment-experienced patients. Furthermore, HCV genotyping can provide helpful information for at-risk populations where there is a high risk of re-infection. A genotype or subtype change can indicate a re-infection rather than treatment relapse.

### 2.4 Monitoring treatment

The introduction of highly efficacious and well-tolerated DAA agents for the treatment of HCV infection has reduced the need for frequent on-treatment monitoring of patients. Eligibility for treatment requires evidence of chronic hepatitis

C, meaning detectable HCV antibody (anti-HCV) and a baseline HCV RNA assessment (qualitative or quantitative HCV RNA test). Generally, routine on-treatment assessment of HCV RNA levels is not necessary due to the lack of a role for response-guided therapy. In practice, qualitative HCV RNA testing is often performed at the end of treatment to confirm an end-of-treatment response. A further qualitative HCV PCR test is required to confirm sustained virological response (SVR), which is defined as an undetectable HCV RNA and should be performed at 12 weeks after the end of DAA therapy.

Patients who may require more intense monitoring include those for whom adherence is a concern or where there is a high risk of re-infection, those on ribavirin-containing regimens and those with advanced liver disease (portal hypertension or hepatic decompensation).

For more details on testing frequency and type, see section 6 of the **Australian Recommendations for the Treatment of Hepatitis C Infection: a Consensus Statement (June 2020)** available at: www.hepcguidelines.org.au

# 3.0 INDICATIONS FOR HCV TESTING

Despite significant effort to encourage testing of populations within the community which are at high risk of having acquired HCV infection, it is evident many have still not been tested.

HCV infection should be considered in patients with abnormal liver function tests, acute hepatitis, chronic liver disease or liver cirrhosis, hepatocellular carcinoma (liver cancer), or in the presence of other clinical conditions associated with HCV (e.g. porphyria cutanea tarda, vasculitis, cold agglutinin presentations).[24]

Other situations where HCV testing may be indicated include:

- healthcare workers who perform or may be expected to perform exposure prone procedures (EPPs) must be aware of their hepatitis C (and HIV and hepatitis B) status[25]
- contact tracing where exposure to blood of a person with a potential infection is documented; testing of a source person in an occupational exposure
- diagnosis of another infection with shared mode of acquisition, such as hepatitis B virus or HIV
- the report of a reactive result on a HCV test not approved for supply in Australia
- a person who requests a HCV test in the absence of declared risk factors – a small number of people may request a HCV test but choose not to disclose risk factors. A person's choice not to declare risk factors should be respected and HCV testing should be offered.

A history considering risk factors for acquisition of HCV infection should be taken and where risk exists, patients should be informed of their risks and of the benefits of testing.

In appropriate clinical circumstances, the absence of a declared risk factor should not preclude HCV testing.

### 3.1 Populations in which HCV Testing should be undertaken:[26]

- People who inject drugs or who have ever injected drugs
- People in custodial settings
- People with tattoos or body piercing
- People who received a blood transfusion or organ transplant before 1990
- People with coagulation disorders who received blood products or plasma-derived clotting factor treatment products before 1993
- Children born to mothers with HCV infection
- Sexual partners of a person with HCV infection (individuals at higher risk of sexual transmission

include men who have sex with men and people with HCV–HIV co-infection)
- People with HIV or hepatitis B virus infection
- People with evidence of liver disease (persistently elevated alanine aminotransferase level)
- People who have had a needle-stick injury
- Migrants from high-HCV prevalence regions (Egypt, Pakistan, Mediterranean and Eastern Europe, Africa and Asia).

## 3.2 Risk factors for exposure to HCV infection

### 3.2.1 People with a history of injecting drug use

Over 80% of existing and almost 90% of all new HCV infections are among people with a history of injecting drug use (IDU).[27] Testing in this population includes diagnosis, monitoring treatment and monitoring possible re-activation or re-infection post treatment.

#### 3.2.1.1 HCV testing frequency in people who inject drugs (PWID)[28]

**Recommendation for the frequency of testing in PWID who disclose sharing injecting equipment:**

- In those people who continue to inject drugs who are HCV antibody (anti-HCV) negative, repeat testing for HCV antibody (anti-HCV) every 3-6 months is indicated if there is high risk behaviour, e.g. needles are shared, or if the individual expresses a concern that they may have been exposed to HCV.

**Recommendations for the frequency of testing in PWID who disclose not sharing injecting equipment:**

- Annual testing (every 12 months) is indicated in PWID who avoid sharing injecting equipment and who do not have HCV infection (i.e. HCV antibody negative) on first testing. Testing should also be offered following a high-risk injecting episode.

PWID who are HCV antibody (anti-HCV) positive and HCV RNA negative (through spontaneous or treatment-induced clearance) should receive regular HCV RNA testing every 12 months or following a high-risk injecting episode.

### 3.2.2 People who are, or have ever been, incarcerated[29]

Imprisonment is an independent risk factor for HCV transmission. HCV prevalence for all prisoners in Australia is estimated at 30–40% and is higher for women at 50–60%.30 A history of previous incarceration is a very strong indication to offer testing for HCV and it should be offered with appropriate discussion of risk and benefits.

Imprisonment poses an immediate risk for infection and a thorough risk assessment should be undertaken on all individuals currently incarcerated and testing offered with appropriate counselling.

HCV infection treatment is now offered in most custodial settings and those in custody should be made aware of their options for treatment after testing.

### 3.2.3 Recipients of organs, tissues, blood or blood products[31]

HCV is efficiently transmitted by transfused blood or blood products. Infections acquired in this way have accounted for 5–10% of all cases in Australia. Individuals in Australia, or other major developed countries, who were transfused or received organ or tissue donations or blood products before HCV screening commenced (February 1990 in Australia) who have not been tested or who do not know their test results should be offered testing. A number of countries (predominantly in low-resource settings) still do not screen all donated transfusion blood for transmissible infections, including HCV.[32] People who received blood products or organ or tissue donations at any time in overseas countries where screening of the blood and organ donor population has not been routine, or where the screening policy at the time of transfusion or receipt of organ or tissue donation is uncertain, should be offered testing. In Australia, recipients and organ donors are

screened for HCV at the time a donation is made. Organs from HCV-positive donors may be offered to both HCV-positive and HCV-negative recipients according to clinical circumstances.

### 3.2.4 People with tattoos or skin piercings[33]

Skin penetration practices are not independent risk factors for HCV transmission. The indications to test will include a consideration of other factors that may contribute to increased transmission such as population prevalence or poor infection control procedures (e.g. tribal scarring in Indigenous populations, tattooing and skin piercings in custodial settings or any other situation where non-registered tattooists perform the task).

### 3.2.5 People born in countries with high HCV prevalence[34]

The risk of HCV infection may be greater for people born in or who have spent considerable time in countries where there is a high prevalence of HCV infection than it is for people born in Australia.[34] It is estimated that 11% of people in Australia who have been exposed to HCV are immigrants from countries where there is a high prevalence of HCV. These regions include Africa, the Middle East (in particular Egypt), the Mediterranean, Eastern Europe, and South Asia. In many of these regions HCV transmission is not predominantly associated with injecting drug use and the disease can be acquired from medical and dental procedures or from occupational exposure to infected materials. Indications to offer testing include a history of HCV in a family member or exposure to medical procedures. In these people, HCV RNA positivity should prompt testing of other family members.

### 3.2.6 Aboriginal and Torres Strait Islander populations[35]

In 2017, 1,210 (or 11% of the total 10,530) people newly diagnosed with HCV infections in Australia identified as Aboriginal and Torres Strait Islander people. Unfortunately, 49% (or 5,182 individuals) of new HCV cases were notified without an indication of Indigenous status. This is a critical gap which can be addressed through a greater focus by medical staff on the identifier.

In people aged under 25, the rate of hepatitis C notification in 2017 among Aboriginal and Torres Strait Islander people was six times higher than in non-Indigenous people (76.7 vs 12.2 per 100 000).[2] Given that Aboriginal and Torres Strait Islander people constitute just 3.3% of Australia's total population,[36] the disproportionate HCV-related burden of disease borne by this group is striking. Risk factors for increased HCV antibody prevalence in this population include higher rates of syringe and other drug equipment sharing.[35] Aboriginal and Torres Strait Islander people also experience a disproportionately high rate of incarceration, which is an independent risk factor for HCV acquisition.[37]

### 3.2.7 Sexual partners of people with HCV [38]

The risk of heterosexual transmission of HCV is low. However, there is an increased risk of sexual transmission of HCV for men who have sex with men.

Testing for infection **should** take place annually in those who are aware of risk and practising safe sex.

Testing for infection **should** take place every 6 months for those who have:

- had more than 10 partners in the past 6 months
- engaged in unprotected anal sex
- engaged in unsterile injecting drug use
- engaged in group sexual activities.

### 3.2.8 Children born to HCV-positive mothers

See section 8. Antenatal and Perinatal Testing.

The rate of mother-to-child transmission of HCV is low and is essentially confined to women with detectable HCV RNA. Thus, pregnant women who are HCV antibody (anti-HCV) positive on routine screening need to be tested for HCV RNA. The diagnosis of HCV in neonates is complicated by the

passive transfer of maternal antibodies to the baby: HCV antibody testing is not recommended before 18 months of age (see section 8.0 Antenatal and Perinatal Testing).

### 3.2.9 Transmission and infection control in healthcare settings

- People on regular haemodialysis should be tested every 6 months for HCV antibody [39]
- In rare situations, clients of healthcare services may need to be offered testing as part of an outbreak investigation or due to failure of infection control practices.

# 4.0 INFORMED CONSENT FOR TESTING

All pathology testing requires informed consent, given verbally. Informed consent for testing means that the person being tested agrees to be tested on the basis of understanding the testing procedures and the reasons for testing, and is able to assess the personal implications. As people with a history of injecting drug use often experience significant barriers to accessing health services, it is critical that testing is conducted in an appropriate, non-judgemental and non-stigmatising setting to assist people with a history of injecting drug use through the testing and diagnosis process. This approach will markedly improve a person's understanding of their condition and their likelihood of future engagement with the health system. Peer education and support will optimise testing uptake and risk disclosure and is recommended where these resources are available. All clinical staff should be cognisant of issues relating to illicit drug use, harm reduction, addressing stigma and discrimination and managing vein care issues.

Informed consent is required for HCV testing, except for rare occasions when a legal order is made for compulsory testing or in emergency settings. See section 1.4.2 Mandatory and compulsory testing.

On these rare occasions where informed consent cannot be attained, the person being tested should be given all appropriate information before the test. The person performing the test should use their clinical judgement in securing informed consent. The decision **should** be based on their understanding of the context in which the test is being performed, taking into account:

- the factors which indicate a need for testing such as clinical presentation, risk exposure, community prevalence and patient request for testing
- an assessment of the understanding of the HCV testing process and the consequences of the result to the person being tested
- that patients should also be advised how the test result will be conveyed and the implications of HCV being a notifiable disease.

General principles of professional conduct apply in the case of HCV testing and informed consent. See: Fact sheet for clinicians: Informed consent in health care.[40] Consent to test should **not** be sought from sexual partners or family members of the person being tested. In the case of testing a child or person who is incapable of giving consent (perhaps due to mental illness or cognitive disability) then the responsibility for consent rests with the guardian or other person or agency legally authorised to make such decisions on their behalf.

Additional supports are available to assist the person considering testing to become adequately informed and to maintain equality of health outcomes. This information includes referral to the support groups listed in section 5.3, and access to publicly funded and accredited telephone interpreters (available nationally for use by private and public healthcare professionals).[41]
The Translating and Interpreting Service (TIS National) is available to doctors 24 hours a day. **TEL: 1300 131 450**. Culturally relevant information should be provided when seeking informed consent and providing results.[42]
The person being tested needs to be made aware of patient rights and responsibilities.[43]

Where data generated through testing are also used for research, the principles and requirements set out in the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research must be followed.[16]

# 5.0 CONVEYING HCV TEST RESULTS

The process of conveying an HCV test result (previously post-test counselling) to the person being tested, irrespective of the specific result, is shaped by the type of test performed, the setting of the consultation, the reason for testing and the extent, if any, of additional testing required in determining the true HCV status of the person. The person who requests the test is responsible for ensuring that the delivery of the test result is carried out in a setting conducive to discussing the implications of the result and addressing the issues that the result raises (see section 5.2). Where an HCV antibody test has been the only test requested, it is important to convey to the person being tested that further viral studies are required to determine their actual HCV status. In presenting results to people from countries where English is not the primary language, interpreter services should be accessed. Care should be taken to provide adequate privacy of consultation in a prison setting.

## 5.1 Conveying a negative result

The outcome may be a negative HCV antibody result or a negative HCV RNA result. A negative result should ideally be provided in person to allow for adequate reassurance of the patient, identification of ongoing risk factors for infection and appropriate prevention strategies.

Further testing following a negative result (HCV antibody or HCV RNA) is indicated in persons who may be in:

- a window period before seroconversion (negative HCV antibody or HCV RNA in a high-risk situation)
- the situation of having a known previous infection with persistent HCV antibody positivity but a negative HCV RNA. In this situation, a single HCV RNA negative result is highly likely to reflect viral clearance. If liver tests remain abnormal or if re-exposure is possible, two HCV RNA results 6 months apart should be negative before assurance is given that the infection has been cleared.

## 5.2 Conveying a confirmed positive result

This outcome may be a positive HCV antibody or a positive HCV RNA result. A positive result should ideally be provided in person by the clinician. Please note: a positive HCV antibody result does not confirm current HCV infection and will need to be confirmed by further testing for HCV RNA to clarify whether the person still has HCV infection or has cleared the virus. See section 2.2.

The discussion when conveying a positive result (HCV antibody or HCV PCR) **should** include:[38,44]

- giving the test result in person and in a confidential manner that is sensitive and appropriate to the gender, culture, emotional state language, literacy level and environment (i.e. in the community or prison) of the person who has been tested
- the mode of transmission of HCV and prevention strategies to prevent possible onward transmission.

If the person tests HCV antibody positive, the discussion **should** also include:

- information on further testing that may be required to confirm current infection (HCV PCR) or clearance.

If the person tests HCV PCR positive, the discussion **should** also include:

- treatments available for those who are HCV RNA positive
- disclosure strategies to partner, family and friends, as well as injecting partners and networks for patients who may be sharing injecting equipment (particularly those within prison)

- their rights and responsibilities
- the mode of transmission of HCV and how onward transmission may be prevented.

People diagnosed with hepatitis C may have misconceptions about treatment eligibility, cost and side-effects based on the experiences of those treated with the previous interferon-based regimens.[45] Care should be taken to communicate to patients that DAA agents are available with substantially fewer restrictions than previous hepatitis C therapies. For example, patients who continue to inject drugs or are incarcerated are now eligible for treatment. There are few out-of-pocket expenses, with access to DAA treatments made available on the PBS and testing costs covered by the MBS. DAA treatments are safe and well tolerated but these drug features need to be emphasised by engaging with people considering treatment, as recent public health messaging indicates that some mistrust remains about treatment side-effects and DAA treatment efficacy.[46]

### 5.3 Referral for further support

The potential psychological impact of a diagnosis of hepatitis C has changed considerably since the availability of the DAA agents, which have led to very high cure rates with shortened treatment courses and high tolerability of treatment. However, not all people may be aware of this change and it is important to proactively manage this potential source of anxiety, and any other issues that may arise from a positive diagnosis. Where more support is required, a referral can be made to the relevant community-based organisation or, if available, a peer-support service.

**Hepatitis Australia**
National Helpline: 1800 437 222 (1800 HEP ABC)
www.hepatitisaustralia.com

Note: This number will route the caller to the relevant state or territory hepatitis organisation and can be dialled toll free from within prisons

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

**Haemophilia Foundation Australia (HFA)**
Telephone: 03 9885 7800
www.haemophilia.org.au

### 5.4 People who do not return for positive test results

People who are unaware of their positive result can unknowingly place others at risk and may be unaware of current options for treatment, so it is important to contact people who do not return for results. Contact **should** be by phone to the person who was tested or in written correspondence.
The person who has ordered the test is ultimately responsible for providing adequate follow-up. The request should be for the person to re-contact the service provider to receive the test result. Public health units and sexual health clinics can provide advice on individual follow-up if required.
People in prison may be released unexpectedly from court, or before receiving test results if there are pathology delays. Follow the Justice Health guidelines of the relevant state or territory regarding patient follow-up for people in prison who are released (or are transferred to another prison within the state or territory) before obtaining their results.

Attempts to make contact **should** be documented in the person's file. General practitioners should refer to the Royal Australian College of General Practitioners (RACGP) guidelines on follow-up of pathology results.[47]

## 6.0 SURVEILLANCE AND RESEARCH

Laboratories performing HCV testing must notify the relevant state and territory health authorities of

any new positive laboratory diagnosis in accordance with the relevant legislation.[43]

### 6.1 Sentinel site surveillance for HCV

HCV testing is routinely carried out at clinical sites such as sexual health clinics, Aboriginal Community Controlled Health Services, prisons, primary healthcare sites, drug-user community clinics, and blood transfusion services. The number of people tested and the proportion with diagnosed HCV infection are reported on a regular basis from some of these sites (e.g. blood transfusion services) and included in surveillance networks (e.g. ACCESS) to monitor HCV prevalence and incidence across various population groups.

### 6.2 Special annual survey

The Australian Needle and Syringe Program Survey is coordinated by The Kirby Institute and has been carried out over one week each year since 1995.[48] During the designated survey week, needle and syringe programs staff in a national network of sites ask all clients who attend to complete a brief, self-administered questionnaire and provide a finger-prick dried blood sample (DBS). The subjects are assured that the specimens are tested anonymously under code, so the results cannot be linked back to individuals.

HCV antibody prevalence has been monitored since 1995, with the addition of HCV RNA testing of DBS samples since 2015 to monitor viraemic prevalence in relation to HCV elimination strategies.[49] The survey also provides estimates of previous HCV testing, including antibody and RNA testing.

### 6.3 Use of stored blood for research on diagnostic technologies

Retrospective analysis of stored samples, particularly for the testing of new diagnostic technology or testing epidemiological hypotheses **must** only be conducted on delinked or de-identified samples and be subject to appropriate ethical review.

### 6.4 Use of unregistered in vitro diagnostic devices (IVDs)

IVDs not currently approved for use in Australia may be required in international collaborative research. Note that IVDs that may be approved by TGA for use with blood samples may not be approved for alternative sample types such as dried blood spot (DBS) tests. Application must be made to the TGA under the Clinical Trial or Special Access Scheme when IVDs are intended for therapeutic use (e.g. to diagnose infection or determine treatment for an individual).[50] IVDs for research only (e.g. where results are de-identified and not used to determine individual treatment) are exempt under Clause 1.3, Schedule 4 of **the Therapeutic Goods (Medical Devices) Regulations 2002**.[51]

DBS testing is not a TGA approved IVD, however there are various provisions for exemption, such as for a clinical trial, that allow for regulated access to unapproved devices. DBS testing is available in NSW by participating in the NSW DBS Research Study either online or through registered sites.[52] These studies are in development and validation phase. If the DBS test is positive for hepatitis C, this should be confirmed by standard HCV testing.

## 7.0 HEALTHCARE WORKERS

There are two major circumstances concerning HCV transmission and healthcare workers. One is the risk of a healthcare worker with HCV infection transmitting the infection to a patient, and the other is the risk of a patient with HCV infection transmitting the infection to the healthcare worker. The risk of transmission of HCV in either direction is low.

Transmission risk to patients from healthcare workers may arise during exposure prone

procedures. The Centers for Disease Control and Prevention in the USA have estimated that the risk of HCV infection after a needlestick or sharps injury to be less than 2%.[53] Other exposures involving mucous membrane or splash injuries are probably lower risk than percutaneous injuries. Individual health service providers have developed their own diagnostic algorithms for testing healthcare workers who have undergone a blood or body fluid exposure. In general, they recommend confirming HCV viraemia in the exposure source, and following up the recipient for up to 3 months after exposure for the detection of HCV antibodies.

The Communicable Diseases Network Australia recently published new guidelines regarding the testing of health professionals and the settings in which healthcare workers might need to limit performing exposure prone procedures (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).[54] Any testing, counselling and follow-up performed in that context **should** be done in accordance with this Policy.

As for all tests where testing of a healthcare worker is undertaken, confidentiality must be maintained.

Healthcare workers who are exposed or potentially 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. Healthcare 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 or monitoring tests on themselves.

# 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 routine screening for HCV infection. Hepatitis C antibody (anti-HCV) testing should be offered and individuals who are HCV antibody positive need to be tested for HCV RNA because the small risk of perinatal transmission is conditional on the presence of maternal HCV RNA. Awareness of a woman's HCV status provides the opportunity for counselling, as treatment may be an option for those considering future pregnancies.[55]

## 8.2 Testing of infants born to mothers with HCV infection

The risk of perinatal HCV transmission is 4% to 6% and is two- to three-fold higher for mothers with HIV/HCV co-infection.[56] Maternal antibodies may persist in an infant born to an HCV - positive mother for up to 18 months. Diagnosis of HCV infection in infants born to mothers with hepatitis C infection is established by testing the child for HCV RNA. Infants and children at risk of vertical HCV transmission may be lost to follow up before 18 months of age. HCV-RNA testing during infancy from 8 weeks of age may enable early identification and early referral to a paediatric hepatology or infectious diseases clinic for appropriate follow up.[57]

All children born to HCV-antibody positive mothers should have antibody testing at 18 months of age because in rare instances transmission occurs from mothers with low and fluctuating HCV RNA levels and who test negative at the time of delivery.

# 9.0 QUALITY ASSURANCE OF HCV TESTING

For more information and background on HCV IVD regulation and quality assurance, refer to the TGA.

### 9.1 Laboratories

Laboratories that perform HCV testing:

- **must** be NATA accredited for medical testing[58]
- **must** participate in an external quality assessment scheme (EQAS)[59]
- **must** comply with the National Pathology Accreditation Advisory Council (NPAAC) standards[60]
- **should** contribute testing statistics to the National Serology Reference Laboratory (NRL) to ensure the completeness of test denominator data.[61]

### 9.2 Pre-market regulatory requirements for HCV IVDs

The TGA has regulatory responsibility for IVDs through the Therapeutic Goods Act 1989 (the Act) and its associated regulations.[62] All commercially supplied IVDs must be listed on the Australian Register of Therapeutic Goods (ARTG). Before inclusion on the ARTG, all commercially supplied IVDS are evaluated to ensure they are safe and perform as intended.

Laboratory users of commercially available hepatitis C assay kits can determine which assays are currently registered for use in Australia by searching the publicly accessible ARTG at: https://www.ebs.tga.gov.au/

To obtain a complete list of all available assays enter either 'hepatitis C' into the 'Search for' field. Avoid using the abbreviation 'HCV', as only partial lists will be displayed. To find a particular assay, you may search by either the sponsor or assay name. Users of commercially available assays should seek advice from the sponsors of these kits to determine the purpose for which the assay is registered.

### 9.3 Post-marketing monitoring of HCV IVDs

IVD manufacturers, sponsors and the TGA have responsibility for post-market monitoring of the IVDs. Corrective action must be initiated by the manufacturer and sponsor of an IVD in consultation with the TGA. This correction **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 issues with an IVD to the sponsor and the TGA. Reports to the TGA can be submitted through the TGA's Incident Reporting Investigation Scheme (IRIS) at: https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris

# 10.0 POINT-OF-CARE AND SELF-TESTS FOR HCV

Point-of-care testing for HCV infection has the potential to simplify testing algorithms, increase diagnoses, and facilitate linkage to treatment. In overseas studies, point-of-care testing has been shown to increase uptake of HCV testing and linkage to HCV care.[63,64,65,66] Experts on HIV and tuberculosis diagnostic testing have defined a point-of-care test as "a diagnostic test that is performed near the patient or treatment facility, has a fast turnaround time, and may lead to a change in patient management."[67]

In May 2020, a point-of-care test for detection and quantification of HCV RNA was approved by the TGA with some conditions. The assay needs to be performed by a laboratory accredited by NATA for HCV testing or by trained health professionals (e.g. in a community health setting) that have an

established relationship with a NATA accredited laboratory. The assay shows a similar sensitivity and specificity to traditional commercial HCV RNA assays. Sample type is capillary finger-stick EDTA whole blood. The ability to use finger-stick blood offers a great advantage as it avoids the need for phlebotomy, a major advantage where venous access is difficult or where phlebotomy services are unavailable.[68,69] HCV RNA detection and quantification assays are usually performed in specialist centralised laboratories where samples can be batch tested. This procedure can result in longer turnaround times, especially for externally referred samples, resulting in delays in clinical management. The ability to obtain an on-site result in a single visit using the approved point-of-care HCV RNA test is a significant development for increasing the number of people diagnosed with HCV infection and linking directly to care.

A number of point-of-care HCV antibody (anti-HCV) tests which show a similar sensitivity and specificity to commercial laboratory HCV antibody enzyme immunoassays have Food and Drug Administration (FDA) approval and CE marking (subject to one or more of the European product safety Directives).[70] None are currently approved for use in Australia.

Some people in the community may access self-administered point-of-care test from overseas for their personal use (self-tests). The safety and performance of these devices may not been independently assessed and verified.

From 1 October 2020, changes to the supply of self-tests under the Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020 came into effect.[71] Sponsors and manufacturers can apply for inclusion of allowable self-tests in the ARTG. Individual products will be evaluated by the TGA to ensure the tests are safe and perform as intended by the manufacturer.

# 11.0 FUNDING OF HCV TESTING

## 11.1 Funding of HCV testing

Funding for HCV testing is provided both directly from the Commonwealth on a fee-for-service basis through the Medicare funding arrangements and also through specific state and territory funding arrangements, which may include provision of free and de-identified HCV testing when used to inform treatment or when clinically indicated.

## 11.2 Funding arrangements for HCV diagnostic and monitoring tests

More detailed information on Medicare benefits for hepatitis C tests can be found on MBS Online (schedule Category 6– Pathology items and descriptions).[11]

A Medicare benefit for pathology testing for hepatitis C 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 where the patient meets the requirements for the relevant MBS Item. Benefits would be payable for the attendance and tests which are considered reasonably necessary according to a patient's individual circumstances.

## 11.3 Medicare Benefit Schedule interpretation

Any inquiries concerning matters of interpretation of MBS Items, including eligibility, should be directed to the Department of Health in the first instance 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.

# 12.0 GLOSSARY

## 12.1 Abbreviations and acronyms

| | |
|---|---|
| **ACCESS** | Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of sexually transmitted infections and bloodborne viruses |
| **ARTG** | Australian Register of Therapeutic Goods |
| **ASHM** | Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine BBVSS Blood Borne Viruses and Sexually Transmissible Infections Standing Committee of the Australian Health Protection Principal Committee (AHPPC) |
| **CDNA** | Communicable Diseases Network of Australia |
| **CE** | Conformité Européene |
| **DAA** | Direct acting antiviral |
| **EDTA** | Ethylenediaminetetraacetic acid |
| **EPP** | Exposure Prone Procedure |
| **EQAS** | External Quality Assessment Scheme |
| **FDA** | Food and Drug Administration (US) |
| **HCV** | Hepatitis C virus |
| **HIV** | Human immunodeficiency virus |
| **IDU** | Injecting Drug Use |
| **IVD** | In-Vitro Diagnostic Device |
| **MBS** | Medicare Benefits Schedule |
| **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 |
| **NSP** | Needle and Syringe Program |
| **PCR** | Polymerase chain reaction |
| **PoC** | Point-of-care |
| **PWID** | People who inject drugs |
| **RNA** | Ribonucleic acid |
| **STI** | Sexually transmissible infection |
| **SVR** | Sustained virological response |
| **TGA** | Therapeutic Goods Administration |

## 12.2 Glossary

**Anti-HCV antibody**
Antibody to HCV, which can be detected in the blood usually within two or three months of HCV infection or exposure. The terms HCV antibody and anti-HCV antibody are equivalent, but in these guidelines, HCV antibody is used throughout

**CE marking**
Conformité Européene: subject to one or more European product safety Directives. It indicates a product's compliance with the applicable EU regulations and enables the commercialisation of a product in 32 European countries

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

**Exposure Prone Procedure**
Defined by the Infection Control Guidelines26 as a subset of 'invasive procedures' characterised by the 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 disease from healthcare worker to patient during medical or dental procedures

**Mandatory testing**
Refers to situations where people may neither 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 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**
Is testing for the presence, evidence of, or quantity of antibodies specific for infectious or other agents, biochemistry, or substances in blood (serum or plasma or whole blood)

**Specificity**
The probability that a person without the disease will have a negative test result

**Sustained virological response (SVR12)**
Undetectable viral load 12 weeks after completion of antiviral therapy for HCV

# 13.0 REFERENCES


**1.0 Introduction**

1. World health Organization (WHO). Hepatitis C Fact Sheet. 9 July 2019. Available at: http://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c (last accessed 21 May 2020).
2. Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018. Available at: https://kirby.unsw.edu.au/sites/default/files/kirby/report/KI_Annual-Surveillance-Report-2018.pdf (last accessed 22 May 2020).
3. World Health Organization (WHO). Global health sector strategy on viral hepatitis 2016–2021. Towards ending viral hepatitis. Geneva: Geneva: World Health Organization; 2016. http://www.who.int/hepatitis/strategy2016-2021/ghss-hep/en (last accessed 21 May 2020).
4. Australian Government Department of Health. Fifth National Hepatitis C Strategy 2018-2022. Available at: https://www.hepatitisaustralia.com/Handlers/Download.ashx?IDMF=156a7a64-fe6a-4aee-b2b8-8959ca2ca183 (last accessed 21 May 2020).
5. World Health Organization (WHO). Guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.
6. Ghany MG, Strader DB, Thomas DL, Seeff LB; American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009;49:1335-74.
7. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of hepatitis C virus infection. J Hepatol 2011;55:245-64.
8. The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 10). The Kirby Institut: UNSW Sydney NSW; June 2019. Available at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-10-june-2019 (last accessed 21 May 2020).
9. Australian Government Attorney-General's Department. Australia's anti-discrimination law [internet]. Available at: https://www.ag.gov.au/RightsAndProtections/HumanRights/Pages/Australias-Anti-Discrimination-Law.aspx (last accessed 22 May 2020).
10. Australian Government Department of Health. Pathology under Medicare [internet]. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pathology-aboutus-index.htm (last accessed 22 May 2020).
11. Australian Government Department of Health. Medicare Benefits Schedule (MBS) online [internet]. Available at: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home (last accessed 22 May 2020).
12. Australian Government Federal Register of Legislation. Therapeutic Goods Order No. 88 - Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products online [internet}]. Available at: https://www.legislation.gov.au/Details/F2013L00854 (last accessed 19 June 2020).
13. Australian Government. Department of Home Affairs. Meeting our requirements: health [internet]. Available at: https://immi.homeaffairs.gov.au/help-support/meeting-our-requirements/health (last accessed 22 May 2020).
14. Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM). National HIV Testing Policy 2011 v1. Available at: http://testingportal.ashm.org.au/library/item/condition-for-entering-training-or-service-in-the-armed-forces (last accessed 22 May 2020).
15. HIV/AIDS Legal Centre Inc. (NSW) (halc). Disclosure and insurance. 2012. Available at: http://halc.org.au/wp-content/uploads/2012/10/Insurance.jpg (last accessed 22 May 2020.
16. The National Health and Medical Research Council, the Australian Research Council and Universities Australia. National statement on ethical conduct in human research 2007 (Updated 2018). 2018. Available at: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 (last accessed 23 May 2020).
17. Australian Government. Department of Health.Therapeutic Goods Administration. Medical devices [internet]. Available at: https://www.tga.gov.au/medical-devices (last accessed 23 May 2020).
18. Australian Government. Department of Health. National Strategies 2018 – 2022. Eighth National HIV Strategy 2018-2022; Fourth National Sexually Transmissible Infections Strategy 2018-2022; Fifth National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Strategy 2018-2022; Fifth National Hepatitis C Strategy 2018-2022; Third National Hepatitis B Strategy 2018-2022. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1 (last accessed 23 May 2020).

**2.0 Diagnostic strategies**

19. Kleinman SH, Lelie N, Busch MP. Infectivity of human immunodeficiency virus-1, hepatitis C virus, and hepatitis B virus and risk of transmission by transfusion. Transfusion 2009;49:2454-2489.
20. Netski DM, Mosbruger T, Depla E, et al. Humoral immune response in acute hepatitis C virus infection. Clin Infect Dis 2005;41:667-75.
21. Marwaha N, Sachdev S. Current testing strategies for hepatitis C virus infection in blood donors and the way forward. World J Gastroenterol 2014;20:2948-54.

22. Grebely J, Prins M, Hellard M, et al. for the International Collaboration of Incident HIV and Hepatitis C in Injecting Cohorts (InC3). Hepatitis C virus clearance, reinfection, and persistence, with insights from studies of injecting drug users: towards a vaccine. Lancet Infect Dis 2012;12:408-14.
23. Dasgupta S, Imamura M, Gorstein E, et al. Modeling-based response-guided therapy for chronic hepatitis C under glecaprevir/pibrentasvir may identify patients for ultra-short treatment duration. J Infect Dis 2020 May 4;jiaa219.

**3.0 Indications for HCV testing**

24. Khong E, Cheng W, Dore G. Chapter 7. Assessment of the patient with chronic viral hepatitis. In: Australasian Society for HIV Medicine (ASHM). HIV, viral hepatitis, STIs: a guide for primary care providers (4th edition). Sydney: ASHM; 2014. Available at: https://www.ashm.org.au/products/product/1976963411 (last accessed 23 May 2020).
25. Australasian Society for HIV Medicine (ASHM). Hepatitis C strategies and policies [internet]. Available at: https://www.ashm.org.au/HCV/strategies/ (last accessed 23 May 2020).
26. Hepatitis C Virus Infection Consensus Statement Working Group. Australian recommendations for the management of hepatitis C virus infection: a consensus statement (June 2020). Box 1. p 9. Melbourne: Gastroenterological Society of Australia, 2020. Available at: https://www.gesa.org.au/public/13/files/Hepatitis%20C/hepatitis%20C%20virus%20infection%20a%20consensus%20statement%20Jun%202020.pdf (last accessed 26 June 2020).
27. Razali K, Thein HH, Bell J, et al. Modelling the hepatitis C virus epidemic in Australia. Drug Alcohol Depend 2007;91:228-35.
28. Grebely J, Robaeys G, Bruggmann P, et al. for the International Network for Hepatitis in Substance Users. Recommendations for the management of hepatitis C virus infection among people who inject drugs. Int J Drug Policy 2015;26:1028-38.
29. Australian Government. Department of Health. Hepatitis C prevention, treatment and care: guidelines for Australian custodial settings. July 2008 [internet]. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/phd-hepc-guidelines-custodial-h (last accessed 24 May 2020).
30. Dolan K, Sacha-Krol D, Vumbaca G. A needs analysis for people living with HCV after leaving custodial settings in Australia. Australian Injecting and Illicit Drug Users League: Canberra; 2017. Available at: http://aivl.org.au/wp-content/uploads/2018/05/Needs-analysis-for-people-living-with-HCV-after-leaving-custodial-settings-in-Australia.pdf (last accessed 24 May 2020).
31. Australian Government. Senate Committee Report. Hepatitis C and the blood supply in Australia. Canberra: Commonwealth of Australia; 2004. Available at: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2002-04/hepc/report/index (last accessed 23 May 2020).
32. World Health Organization. Blood safety and availability [internet]. 14 June 2019. Available at: https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability (last accessed 24 May 2020).
33. Government of Western Australia Department of Health. Code of practice for skin penetration procedures1998. Minor update 24 January 2017. Available at: https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/communicable%20diseases/PDF/Code_of_Practice_for_Skin_Penetration.ashx (last accessed 24 May 2020).
34. Centers for Disease Control and Prevention. CDC Yellow Book 2020. Health Information for International Travel. Chapter 4. Travel-Related Infectious Diseases. New York. Oxford University Press. 2020. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/hepatitis-c (last accessed 24 May 2020).
35. Kirby Institute. Bloodborne viral and sexually transmissible infections in Aboriginal and Torres Strait Islander people: annual surveillance report 2018. Available at: https://kirby.unsw.edu.au/sites/default/files/kirby/report/KI_Aboriginal-Surveillance-Report-2018.pdf (last accessed 24 May 2020).
36. Australian Bureau of Statistics. 3238.0.001 - Estimates of Aboriginal and Torres Strait Islander Australians, June 2016. Available at: https://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/3238.0.55.001Main+Features1June%202016?OpenDocument (last accessed 24 May 2020).
37. Australian Government. Australian Law Reform Commission. Disproportionate incarceration rate. Updated 9 January 2018. Available at: https://www.alrc.gov.au/publication/pathways-to-justice-inquiry-into-the-incarceration-rate-of-aboriginal-and-torres-strait-islander-peoples-alrc-report-133/executive-summary-15/disproportionate-incarceration-rate/ (last accessed 16 September 2020).
38. Hepatitis Australia. Testing for hepatitis C [internet] Updated March 2019. Available at: https://www.hepatitisaustralia.com/testing-for-hepatitis-c (last accessed 24 May 2020).
39. The dialysis and transplant subcommittee of the AKF and the ANZSN. Consensus statement 2001. Recommendations for hepatitis B, C, G and HIV in maintenance dialysis patients. Available at: http://testingportal.ashm.org.au/resources/Consensus_Statement_Hepatitis_Dialysis_Patients.pdf (last accessed 24 May 2020).

**4.0 Informed consent for testing**

40. Australian Commission on Safety and Quality in Health Care. Fact sheet for clinicians: Informed consent in health care. Available at: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/informed-consent-fact-sheet-clinicians (last accessed 9 October 2020)

41. Australian Government Department of Home Affairs. Translating and Interpreting Service (TIS). TIS National services [internet]. Available at: https://www.tisnational.gov.au (last accessed 24 May 2020).
42. Multi Cultural HivhepC. Multicultural Hivhepc services [internet]. Available at: http://www.multiculturalhivhepc.net.au/ (last accessed 24 May 2020).
43. Hepatitis Australia. Factsheet: your rights and responsibilities. Updated April 2020 [internet]. Available at: https://www.hepatitisaustralia.com/factsheet-rights-and-responsibilities (last accessed 24 May 2020).

**5.0 Conveying HCV test results**

44. Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM). Decision making in HCV. 2019. Available at: https://www.ashm.org.au/products/product/Decision-Making-in-HCV (last accessed 24 May 2020).
45. Chong S, Brown G, Crawford S, et al. Hepatitis C treatment: peer insights on barriers and motivators to direct acting antiviral (DAA) treatment uptake (Broadsheet No. 2). Melbourne: Australian Research Centre in Sex, Health and Society, La Trobe University; 2018. Available at: https://www.latrobe.edu.au/__data/assets/pdf_file/0017/1011905/ARCSHS-Peer-Insights-Hep-C-Treatment-Uptake-Broadsheet-2.pdf (last accessed 25 May 2020).
46. Bryant J, Rance J, Hull P, Mao L, Treloar C. Making sense of 'side effects': counterpublic health in the era of direct-acting antivirals. Intl J Drug Policy 2019;72:77-83.
47. Royal Australian College of General Practitioners. Standards for general practices. 5th edition. East Melbourne; The Royal Australian College of General Practitioners: 2020. Available at: https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed (last accessed 25 May 2020).

**6.0 Surveillance and research**

48. The Kirby Institute and University of New South Wales. Australian Needle and Syringe Program Survey (ANSPS) National Data Reports. Prevalence of HIV, HCV and injecting and sexual behaviour among Needle and Syringe Program attendees [internet]. Available at: https://kirby.unsw.edu.au/project/ansps (last accessed 25 May 2020).
49. Iversen J, Dore GJ, Catlett B, Cunningham P, Grebely J, Maher L. Association between rapid utilisation of direct hepatitis C antivirals and decline in the prevalence of viremia among people who inject drugs in Australia. J Hepatol 2019;70:33-9.
50. Australian Government. Department of Health. Therapeutic Goods Administration [internet]. Available at: http://www.tga.gov.au/ (last accessed 25 May 2020).
51. Australian Government. Federal Register of Legislation. Therapeutic Goods (Medical Devices) Regulations 2002: F2011C00295. Available at: http://www.comlaw.gov.au/Details/F2011C00295 (last accessed 25 May 2020).
52. NSW Ministry of Health. Do you need a DBS test [internet]? Available at: https://www.dbstest.health.nsw.gov.au/ (last accessed 26 May 2020).

**7.0 Healthcare workers**

53. U.S. Public Health Service. Updated U.S. Public Health Service Guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. MMWR Recomm Rep 2001;50:1-52.
54. Australian Government. Department of Health. Communicable Diseases Network Australia (CDNA). 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. June 2018. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/cda-cdna-bloodborne.htm (last accessed 25 May 2020).

**8.0 Antenatal and perinatal testing**

55. Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG). Clinical Statement. Management of hepatitis C in pregnancy. Revised March 2020. Available at: https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical-Obstetrics/Management-of-Hepatitis-C-in-Pregnancy-(C-Obs-51).pdf?ext=.pdf (last accessed 25 May 2020).
56. Benova L MY, Calvert C, Abu-Raddad LJ. Vertical transmission of hepatitis C virus: systematic review and meta-analysis. Clin Infect Dis 2014 Sep;59:765-73.
57. HCV in Children: Australian Commentary on AASLD Guidance– in development. Will be available at https://www.hepcguidelines.org.au/ in Oct 2020

**9.0 Quality assurance of HCV testing**

58. National Association of Testing Authorities Australia (NATA). Accreditation criteria and guidance. Available at: https://www.nata.com.au/accreditation-information/accreditation-criteria-and-guidance (last accessed 25 May 2020).
59. National Reference Laboratory (NRL). External Quality Assessment Schemes (EQAS) [internet]. Available at: https://www.nrlquality.org.au/eqas (last accessed 25 May 2020).
60. Australian Government Department of Health. National Pathology Accreditation Advisory Council (NPAAC). Requirements for Laboratory Testing of Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV). Third Edition 2013. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/DF536CB04A025BA3CA257BF0001A043A/$File/V0.22%20%20HIV%20and%20HCV.pdf (last accessed 25 May 2020).

61. National Reference Laboratory (NRL) [internet]. Available at: https://www.nrlquality.org.au (last accessed 25 May 2020).

62. Australian Government. Federal Register of Legislation. Therapeutic Goods Act 1989. C2011C00379. Available at: http://www.comlaw.gov.au/Details/C2011C00379 (last accessed 25 May 2020).

**10.0 Point-of-care tests for HCV**

63. Coats JT, Dillon JF. The effect of introducing point-of-care or dried blood spot analysis on the uptake of hepatitis C virus testing in high-risk populations: a systematic review of the literature. Int J Drug Policy 2015;26:1050-5.
64. Morano JP, Zelenev A, Lombard A, Marcus R, Gibson BA, Altice FL. Strategies for hepatitis C testing and linkage to care for vulnerable populations: point-of-care and standard HCV testing in a mobile medical clinic. J Community Health 2014;39:922-34.
65. Bottero J, Boyd A, Gozlan J, et al. Simultaneous human immunodeficiency virus-hepatitis B-hepatitis C point-of-care tests improve outcomes in linkage-to-care: results of a randomized control trial in persons without healthcare coverage. Open Forum Infect Dis 2015;2:ofv162.
66. Beckwith CG, Kurth AE, Bazerman LB, et al. A pilot study of rapid hepatitis C virus testing in the Rhode Island Department of Corrections. J Public Health (Oxf) 2016;38:130-7.
67. Schito M, Peter TF, Cavanaugh S, et al. Opportunities and challenges for cost-efficient implementation of new point-of-care diagnostics for HIV and tuberculosis. J Infect Dis 2012;205(Suppl 2):S169-80.
68. Grebely J, Lamoury FMJ, Hajarizadeh B, et al; LiveRLife Study Group. Evaluation of the Xpert HCV viral load point-of-care assay from venepuncture-collected and finger-stick capillary whole-blood samples: a cohort study. Lancet Gastroenterol Hepatol 2017;2:514-20.
69. Lamoury FMJ, Bajis S, Hajarizadeh B, et al; LiveRLife Study Group. Evaluation of the Xpert HCV viral load finger-stick point-of-care assay. J Infect Dis 2018;217:1889-96.
70. Shivkumar S, Peeling R, Jafari Y, Joseph L, Pai NP. Accuracy of rapid and point-of-care screening tests for hepatitis C: a systematic review and meta-analysis. Ann Intern Med 2012;157:558-66.
71. Australian Government. Federal Register of Legislation. Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020. Available at: https://www.legislation.gov.au/Details/F2020L01150 (last accessed 16 September 2020.

# APPENDIX A

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

(name, position, organisation, affiliation with ERC)

**Robert Batey**
Staff Specialist Department of Medicine, Alice Springs Hospital NT
Alice Springs Hospital NT
Chair

**William Rawlinson**
Senior Medical Virologist, Director of Serology, Virology and OTDS Laboratories (SAViD), NSW Health Pathology Randwick
Prince of Wales Hospital/SEALS; Royal College of Pathologists of Australasia (RCPA)
Public Health Laboratory Network (PHLN) representative

**Rosemary French**
Principal Scientist, National Serology Reference Laboratory (NRL)
National Serology Reference Laboratory
NRL representative

**Scott Bowden**
Professor, Head of Molecular Microbiology
Victorian Infectious Diseases Reference Laboratory (VIDRL)
VIDRL representative

**Juliette Holland**
Microbiology Advisory Committee
The Royal College of Pathologists of Australasia (RCPA)
RCPA representative

**Edmund Tse**
Gastroenterologist
Royal Adelaide Hospital; Australasian Lymphology Association (ALA) / Gastroenterological Society of Australia (GESA)
ALA/GESA representative

**Joseph Doyle**
Associate Professor, Infectious Diseases
The Alfred & Monash University Department of Infectious Diseases; Chair, Viral Hepatitis Special Interest Group, Australasian Society of Infectious Diseases (ASID)
ASID representative

**Gregory Dore**
Program Head, Viral Hepatitis Clinical Research Program
The Kirby Institute, UNSW Sydney
Kirby Institute representative

**Jason Grebely**
Professor, Viral Hepatitis Clinical Research Program
The Kirby Institute, UNSW Sydney
Kirby Institute representative

**Judy Gould**
Policy Officer
Blood Borne Viruses, Sexually Transmissible Infections & Torres Strait Health Section
Australian Government Department of Health; CDNA representative

**Michael Lidman**
Policy Officer
Blood Borne Viruses, Sexually Transmissible Infections & Torres Strait Health Section
Australian Government Department of Health; CDNA representative

**Lise Lafferty**
Research Fellow
Centre for Social Research in Health (CSRH)
CSRH representative

**Kari Lancaster**
Senior Research Fellow and Scientia Fellow
Centre for Social Research in Health (CSRH)
CSRH representative

**Gregory Smith**
Senior Evaluator
Therapeutic Goods Administration (TGA)
TGA representative

**John Didlick**
Policy Analyst
Hepatitis Australia
Community organisation representative

**Lauren Bradley**
Senior Project Coordinator
Australian Injecting and Illicit Drug Users League (AIVL)
AIVL representative

**Kate Turner**
Clinical Nurse Consultant
BBV Policy and Projects Tasmania
Tas Blood Borne Viruses and Sexually Transmissible Infections Standing Committee (BBVSS) representative

**Jeff Stewart**
Public Health Nurse
Flinders Medical Centre
SA Health BBVSS representative

**Judith Bevan**
Senior Policy and Planning Officer
Sexual Health and Blood-borne Virus Program, Department of Health WA
WA BBVSS representative

**Vicky Sheppeard**
Director of Communicable Diseases
NSW Health
NSW BBVSS representative

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

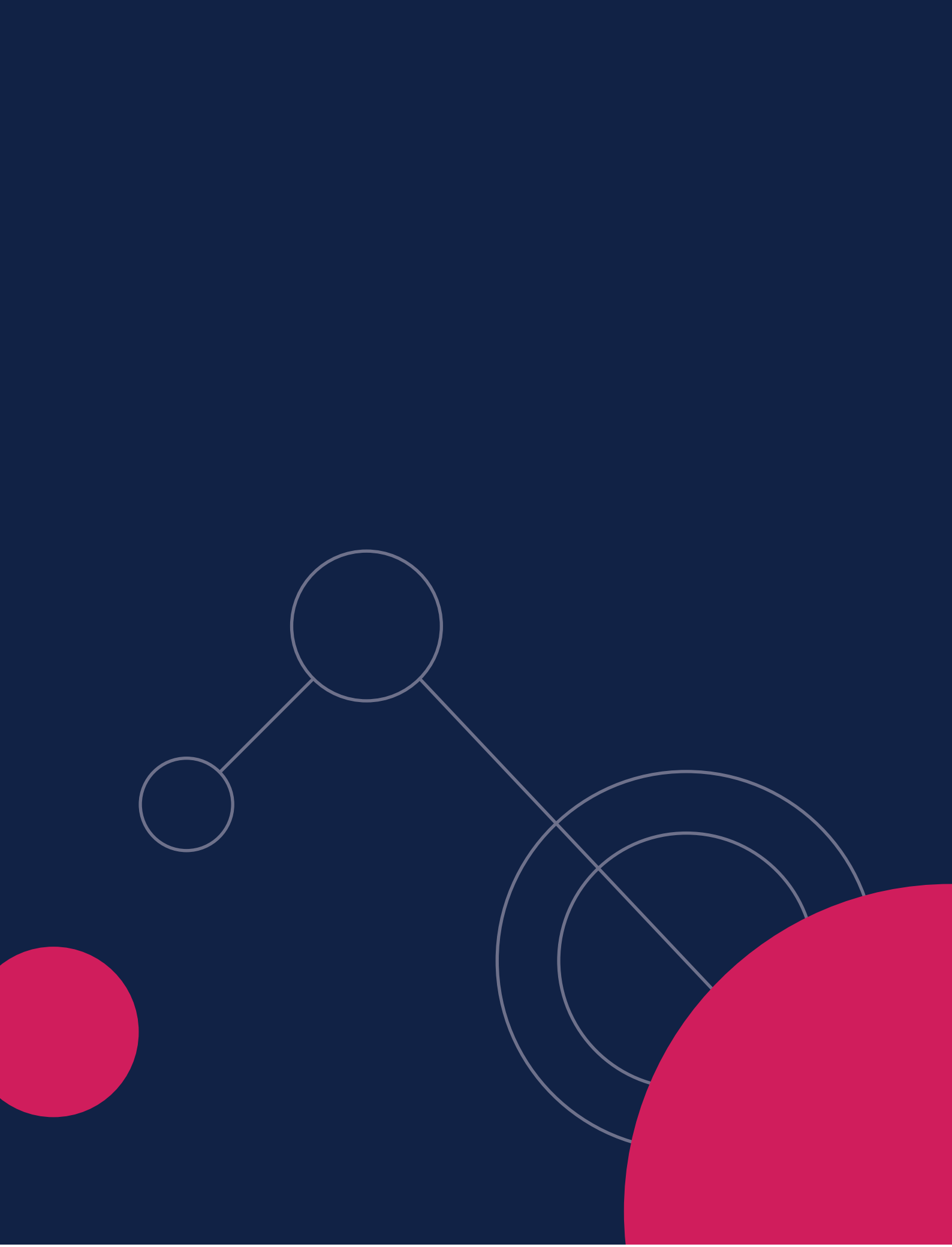
**Elizabeth Birbilis**
Senior Policy Officer Sexual Health and Viral Hepatitis
Department of Health and Human Services VIC
Vic BBVSS representative

**Belinda Greenwood-Smith**
General Practitioner
Northern Territory Department of Health
NT BBVSS representative

**Kirsty Whybrow**
Senior Policy Officer
Health Protection Service, Public Health, Protection and Regulation, ACT Health Directorate
ACT BBVSS representative

**Olivia Dawson**
Senior Project Officer
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
ASHM representative

**Sonja Hill**
Senior Project Officer
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
ASHM secretariat



ashm