

NATIONAL HEPATITIS C TESTING POLICY

NATIONAL HEPATITIS C TESTING POLICY 2012

National HCV Testing Policy Expert Reference Committee – a joint working party of the BBVSS and MACBBVS

Disclaimer:

This Testing Policy has been developed as a concise source of standardised, currently available information, to inform government, health professionals and industry about specific matters associated with hepatitis C testing. This Testing Policy is not a set of Clinical Guidelines or a description of the management of hepatitis C 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 C testing.

This Policy was written by the National HCV Testing Policy Expert Reference Committee – a joint working party of the Blood Borne Virus and STI Subcommittee (BBVSS) and the Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections (MACBBVS). The review process was coordinated by the Australasian Society for HIV Medicine (ASHM).

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CONTENTS

1.0 INTRODUCTION	5
1.1 Background and context	5
1.2 Purpose, scope and objectives	6
1.3 Principles of HCV testing	6
1.4 Policy implementation	6
2.0 DIAGNOSTIC STRATEGIES	8
2.1 Types and uses of HCV diagnostic tests – also called Invitro Diagnostic Devices (IVDs)	8
2.2 Testing for HCV	8
2.3 Diagnostic strategies for HCV	9
2.4 Monitoring Treatment	9
3.0 INDICATIONS FOR HCV TESTING	10
3.1 Risk factors for exposure to HCV infection	10
4.0 INFORMED CONSENT FOR TESTING	13
5.0 CONVEYING HCV TEST RESULTS	14
5.1 Conveying a negative result – in the context of conventional testing	14
5.2 Conveying a confirmed positive result – in the context of conventional testing	14
5.3 Referral for further support.	15
5.4 People with complex needs	15
6.0 SURVEILLANCE AND RESEARCH	16
6.1 Sentinel site surveillance for HCV	16
6.2 Special annual survey.	16
6.3 Delinked blood surveys	16
6.4 Use of stored blood for research on diagnostic technologies	16
6.5 Use of unregistered Invitro Diagnostic Devices (IVDs)	16
7.0 HEALTH CARE WORKERS	17
8.0 ANTENATAL AND PERINATAL TESTING	18
8.1 Routine testing ⁴⁰	18
8.2 Testing of infants born to HCV-infected mothers.	18
9.0 QUALITY ASSURANCE OF HCV TESTING	19
9.1 Laboratories	19
9.2 Pre-marketing quality assurance of HCV IVDs.	19
9.3 Post-marketing quality assurance of HCV IVDs.	19

10.0 POINT OF CARE TESTS FOR HCV IN COMMUNITY SETTINGS	20
11.0 FUNDING OF HCV TESTING.	21
11.1 Funding arrangements for HCV diagnostic and monitoring tests.	21
12.0 RECENT ADVANCES IN MONITORING AND CHARACTERISING HCV INFECTIONS	22
13.0 GLOSSARY.	23
13.1 Abbreviations and acronyms	23
13.2 Glossary.	23
14.0 REFERENCES.	24

1.0 INTRODUCTION

1.1 Background and context

Hepatitis C infection is a major public health problem in Australia. Since testing began in 1990, it is estimated that over 280,000 people have been exposed to the hepatitis C virus (HCV) and that there are approximately 10,000 new infections each year. Influenced by multiple factors, infection persists in between 55–85% of those infected. Cirrhosis develops within 20 years in 5–10% of this group (usually associated with other co-morbidities such as co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), obesity, insulin resistance, alcohol intake > 40gm/day) and in a further 10–15% after 40 years.¹ Hepatocellular carcinoma will develop in 3–5% of people per annum who develop cirrhosis.² Preventive and therapeutic interventions have proven effective in decreasing HCV transmission and improving quality of life and clinical outcomes for people with HCV. Testing for HCV infection has evolved significantly since the virus was discovered in 1989 and this testing policy document seeks to define the current best practice for testing for exposure to the virus and for defining the current infective status of the person pre, during and post-treatment.

HCV testing provides people with information regarding contact with the virus. Appropriate testing indicates whether they have cleared the virus spontaneously or with antiviral therapy or have an ongoing (active) chronic infection.

The benefits of reliable, timely testing are numerous, both for the person and for public health. Detection of HCV infection followed by appropriate education can effectively reduce onward transmission by empowering people living with HCV to modify risk behaviour, modify disease progression through earlier referral for advice and/or treatment and protect the blood, tissue and organ donation supply. Despite the public health and individual benefits of testing, a significant but as yet undocumented number of infected people 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.

The previous HCV testing policy was released in 2007.³ Significant differences in this 2012 Policy include:

- change in terminology from pre-test discussion to informed consent;
- communication of a HCV-negative test result;
- web-based provision of policy allowing for regular revision to provide consistent management of emerging technologies such as Point of Care (PoC) testing, viral resistance testing; and
- access to related resources (e.g. related policies, operational guidelines, evidence of best practice).

1.2 Purpose, scope and objectives

This Policy sets out the framework for providing quality testing and removing real and perceived barriers to testing. It identifies requirements and provides guidance and/or links regarding procedures for the provision of HCV testing.

The Policy is aligned with the Third National Hepatitis C Strategy 2010–2013⁴ which identifies the need for a co-ordinated, accessible and affordable HCV testing system that allows for:

- access to appropriately resourced services for those diagnosed with HCV to optimise management and timely referral to treatment;
- minimisation of HCV transmission through knowledge of one's status;
- monitoring of transmission from a mother with HCV infection to her newborn; and
- documenting the epidemic to aid the development of evidence-based public health interventions.

Changes in the prevention, diagnostic and treatment knowledge base are occurring rapidly. Accordingly, this HCV testing policy will undergo six monthly reviews.

1.3 Principles of HCV testing

The eight basic principles that guide HCV testing in Australia are:

- confidential, voluntary testing with informed consent and post-test discussion as fundamental to Australia's response to HCV;
- testing is critical to understanding the epidemiology of HCV infection in the community;
- 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 can be critical to interruption of transmission and can support harm minimisation;
- testing to monitor people with HCV before, during and after treatment is an integral part of their care; and
- 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 considered to protect privacy where relevant.

1.4 Policy implementation

Testing policies and practices **must** comply with all relevant Commonwealth and State and Territory anti-discrimination and public health legislation, and other relevant laws and regulations, including those governing Commonwealth funding of pathology tests.^{6,7}

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

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 to specialist HCV and liver services.

1.4.2 Mandatory or 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;⁸
- under the migration Health Requirements applicable to specified visa subclasses;⁹
- as a condition for entering training or service in the armed forces;¹⁰
- as a condition for purchasing some types of insurance;¹¹ and
- in the context of a legal instruction, including in forensic or coronial settings.

To all extents reasonable, 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 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.¹²

1.4.4 Introduction of new technologies and strategies

Introduction of new technologies¹³ or strategies to target new priority populations¹⁴ **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;
- latest information about HCV treatment and management;
- procedures associated with using any new technology; and
- information related to referral pathways to care and support services (see section 10.0 Point of Care tests for HCV in community settings).

2.0 DIAGNOSTIC STRATEGIES

2.1 Types and uses of HCV diagnostic tests – also called *In Vitro* Diagnostic Devices (IVDs)

All tests for HCV must be entered on the Australian Register of Therapeutic Goods (ARTG) prior to their use in Australia. Entry on the ARTG requires pre-market assessment of the IVD commensurate with the purpose for which the test is used.

Screening tests

Screening tests may be used by laboratories performing diagnostic or donation screening testing to identify the HCV-negative antibody status of samples. Those samples yielding non-reactive results do not need to be further tested unless clinical considerations demand it. Reactive samples must be subjected to supplemental testing to distinguish true reactivity from false reactivity.

Supplemental tests

Supplemental tests are used by laboratories to conduct confirmatory or additional testing to confirm true positive status by distinguishing true from false reactivity. Usually this testing is conducted within a diagnostic strategy and a second immunoassay is used; but other supplemental testing situations occur (e.g. in a setting of possible seroconversion illness) when the first-used supplemental tests may include nucleic acid tests. Laboratories may also use rapid tests for supplemental testing in appropriate settings.

The supplemental testing must confirm the presence of specific antibody or virus before the result is accepted as a true positive.

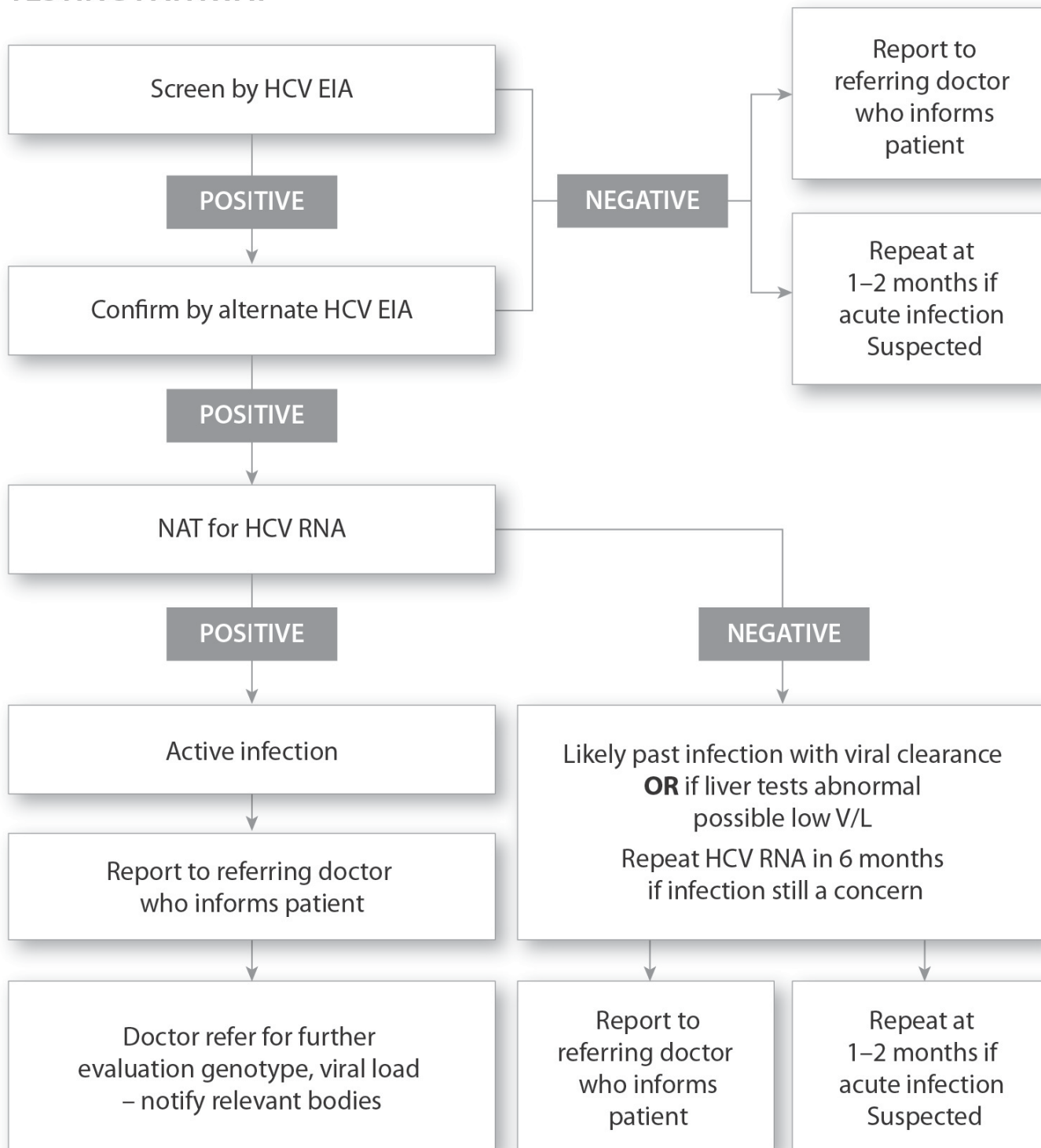
Other tests may be used once the HCV status is confirmed. These include tests to quantify viral load, characterise the virus strain or identify sensitivity of the virus to antiviral drugs.

2.2 Testing for HCV

This section provides advice on minimum standards for laboratory diagnosis and investigation of HCV. 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:

- Has the person been infected with HCV? This should be determined by testing for HCV antibodies (anti-HCV). RNA testing will not provide information on past infection with clearance.
- Does the person have current infection? This is determined by testing for HCV RNA or HCV antigen (HCV Ag). The latter test is not routinely undertaken at present and is not funded.
- What is the current level of viral replication? Viral load prior to treatment is a prognostic indicator of long-term response to interferon-based therapy and is used to monitor response while on therapy.
- What is the infecting virus genotype? Virus genotype is a key predictor of treatment response and guides treatment dose and duration of therapy for current standard therapy (interferon and ribavirin) and also with the new protease inhibitors (telaprevir and boceprevir) when they become available, initially for genotype-1 infected persons only.

TESTING PATHWAY



Note: EIA is used as a broad term to encompass all approved HCV immunoassays including RIBA and the HCV Ag test

2.3 Diagnostic strategies for HCV

- Past exposure to HCV is determined by testing for HCV antibodies (anti-HCV) in serum or plasma.
- A sample not reactive in the screening immunoassay can be generally regarded as anti-HCV negative. If doubt exists, repeat the test or consider qualitative HCV RNA testing.
- Immunoassays are available that test for the presence of HCV antibody and antigen simultaneously. This facilitates earlier detection of people with recently acquired HCV infection. An immunoassay for detection of HCV antigen only is also entered on the ARTG. This assay can be used to confirm whether reactivity in an antigen/antibody screening test is attributable to the presence of HCV antigen. Antigen assays are not currently used regularly in clinical practice¹⁵
- 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 method of preparation. Validation using the two tests together should be undertaken to show that samples falsely reactive in the first test are not also falsely reactive in the second. This is necessary because all immunoassays show a degree of false reactivity and it is important to eliminate to the extent possible, false reactivity that is common between two tests that will be used as part of a diagnostic strategy. Information on appropriate immunoassay combinations is available through pre-market evaluation reports of HCV immunoassays.¹⁶ A sample reactive in two approved immunoassays can be reported as anti-HCV positive.
- Current HCV infection is determined by qualitative testing for HCV RNA. Although quantitative HCV RNA tests have lower limits of detection than their qualitative counterparts, the manufacturers of quantitative HCV RNA assays specify that they are not for use as diagnostic tests to confirm the presence of HCV infection. If a laboratory uses a test outside the test's intended use, it becomes an in-house test and the laboratory is responsible for its inclusion as such on the ARTG.
- All anti-HCV positive people must be tested for current viraemia by either a qualitative HCV RNA assay or an HCV Ag assay. Ideally, blood should be set aside at the time of collecting a sample for anti-HCV to allow HCV RNA testing to be done if anti-HCV is confirmed positive. This procedure will save unnecessary duplication of visits for people being tested for HCV. This may be achieved by either collecting a second tube of blood initially or dividing a single specimen to allow the two separate tests to be done as appropriate.
- All persons being evaluated for treatment must be tested for genotype and viral load as these both determine treatment responsiveness and treatment duration.

2.4 Monitoring Treatment

The introduction of new direct acting antiviral drugs for the treatment of HCV will modify current testing protocols in order to allow termination of futile treatment. Testing frequency and type (quantitative or qualitative) should be dictated by current treatment guidelines.

3.0 INDICATIONS FOR HCV TESTING

Testing is indicated for people who have risk factors associated with transmission of HCV. A history considering risk factors for acquisition of HCV infection should be taken to help determine whether a HCV test is indicated. In appropriate clinical circumstances, the absence of a declared risk factor should not preclude HCV testing. Clinical suspicion of HCV infection may occur in the context of:

- chronic liver disease or liver cirrhosis;
- hepatocellular carcinoma (liver cancer);
- evaluation of abnormal liver function tests; and
- acute hepatitis.

A number of clinical conditions and symptoms are associated with HCV where clinical suspicion leads to a HCV test.¹⁷

Other situations where HCV testing may be indicated include:

- health care workers who perform or may be expected to perform exposure prone procedures (EPPs) must be aware of their HCV (and HIV and hepatitis B) status;¹⁸
- contact tracing where exposure to blood of an infected person is documented;
- diagnosis of another infection with shared mode of acquisition, such as hepatitis B virus or HIV;
- a person who reports a reactive result on a HCV test not licensed 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 recognised and HCV testing should be offered.

3.1 Risk factors for exposure to HCV infection

3.1.1 People with a history of injecting drug use¹⁹

Over 80% of existing and almost 90% of all new HCV infections are among people with a history of injecting drug use (IDU). People with a history of IDU often experience significant barriers to accessing health services including HCV testing and treatment services. In this context, it is critical that testing is conducted in an appropriate and non-judgemental setting to assist people with a history of IDU through the testing and diagnosis process. This will have a profound effect on 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 reporting and is recommended where these resources are available. Staff in specialist and primary health care services should be cognisant of issues relating to illicit drug use, harm reduction, addressing stigma and discrimination and managing vein care issues.

3.1.2 People who are or have ever been incarcerated²⁰

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%. 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. For those currently incarcerated, indicators to discuss testing should be based on thorough risk assessment, including any history of drug use or previous incarceration. A positive anti-HCV result should lead to appropriate assessment for current infection and the nature and severity of any liver disease. It may be appropriate to refer for treatment while people are still in custody but not all jurisdictions can offer this across the prison system.

3.1.3 Recipients of organs, tissues, blood or blood products before February 1990 in Australia, or before the implementation of mandatory screening of blood donors in other countries (or at any time where this is not the case)²¹

HCV is efficiently transmitted by transfused blood or blood products. Infections acquired in this way account 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 testing commenced (February 1990 in Australia) who have not been tested or who do not know 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.²² People who received blood products or organ or tissue donations at any time in overseas countries where screening of the blood/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, all organs and organ donors are screened for HCV at the time a donation is made. An HCV-positive organ may still be used in an HCV-positive recipient.

3.1.4 People with tattoos or skin piercings²³

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. tattooing and skin piercings in custodial settings or any other situation where non-registered tattooists perform the task).

3.1.5 People born in countries with high HCV prevalence²⁴

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.²⁴ 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. In many of these countries HCV transmission is not predominantly associated with IDU 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.

3.1.6 Aboriginal and Torres Strait Islander populations

In 2006, Aboriginal and Torres Strait Islander people were estimated to account for between 13,000 and 22,000 or 8.3% of all HCV diagnoses, with 16,000 chronically infected. Given that Aboriginal and Torres Strait Islander people constitute just 2.4% of Australia's total population, 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 unsafe injecting drug use practices and disproportionately high rates of incarceration where risk for HCV acquisition is greatly enhanced.

3.1.7 Sexual partners of people with HCV²⁵

The risk of sexual transmission of HCV is low. There is an increased risk of sexual transmission of HCV for men who have sex with men who are also HIV positive. Testing for infection in this setting should be undertaken regularly. This **should** take place annually in those who are aware of risk and practising safe sex and every six months for those who have:

- had more than 10 partners in the past 6 months;
- engaged in unprotected anal sex;
- used recreational drugs; and/or
- engaged in group sexual activities.

Testing **should** occur in appropriate settings, such as HIV clinics, sexual health clinics or GP surgeries for those with ongoing risk of infection.

3.1.8 Children born to HCV-positive mothers

See section 8

3.1.9 Transmission and infection control in healthcare settings

- HCV testing of health care workers should be conducted in accordance with the general principles set out in this document with regard to privacy, confidentiality and access to appropriate health care and support services;²⁶
- Health care workers who test positive for HCV RNA must not perform EPPs;²⁷
- Testing for all BBVs should be undertaken for health care workers following occupational exposure to blood or body substances, for example through needle stick injury; and
- People on regular haemodialysis should be tested every six months for anti-HCV.²⁸

4.0 INFORMED CONSENT FOR TESTING

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 is able to assess the personal implications. Informed consent is required for HCV testing, except for rare occasions when a legal order is made for compulsory testing or in emergency settings. On these rare occasions where informed consent cannot be attained, pre-test provision of all appropriate information to the person **should** still take place. The person performing the test **should** use their clinical judgment in securing informed consent. This **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, prevalence and individual initiation; and
- an assessment of the understanding of the HCV testing process and the consequences of the result to the person being tested.

General principles of professional conduct apply in the case of HCV testing and informed consent should **not** be sought from sexual partners or family members of the person being tested.

People involved in HCV testing must use whatever additional support is necessary to assist the person considering testing to become adequately informed. This process involves a referral to the support groups listed in section 5.3, including access to telephone interpreters (available nationally for use by private and public health care professionals).²⁹ Culturally relevant information **should** be provided when seeking informed consent and providing results.³⁰

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/agency legally authorised to make such decisions on their behalf.

The person being tested needs to be made aware of confidentiality considerations and protections.³¹

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 affected by the type of test performed, the setting of the consultation, and 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 anti-HCV test has been the only test requested, discussion of the need to progress to viral studies will need to be addressed in the process of informing the person of their actual HCV status. In presenting results to people from countries where English is not the primary language, interpreter services should be accessed.

5.1 Conveying a negative result – in the context of conventional testing

This may be a negative anti-HCV result or a negative HCV RNA result. The decision on how a negative HCV test result is provided (e.g. in person, by phone, etc.) **should** be based on the clinical judgement of the person responsible for conveying the result. This assessment **should** take into account the psychological capacity of the person being tested to deal with the outcome of testing and his/her understanding of the testing process as evident at the time of the sample collection. It is imperative that the meaning of a negative result is fully understood and that the person being tested receives appropriate information about harm reduction in relation to the spread of BBVs. Further testing following a negative result (anti-HCV or HCV RNA) is indicated in persons who may be in:

- a window period prior to seroconversion (negative anti-HCV or HCV RNA in a high-risk situation); and/or
- the situation of having a known previous infection with persistent anti-HCV positivity but a negative HCV RNA. In this latter 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.

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

- confirming the person's identity;
- making repeated contact to ensure the person is aware of the availability of the result; and
- documenting all efforts to contact the person.

5.2 Conveying a confirmed positive result – in the context of conventional testing

A positive HCV test result can have a significant impact for a person and their clinician. Laboratories **should** provide information and the opportunity for consultation to assist the requesting clinician at the time of diagnosis³² A positive result **should** always be provided in person by the clinician, except in extenuating circumstances where, for example, it is suspected that the person who has been tested may not return for the result and/or may engage in risk behaviour(s) based on the wrong assumption that they are HCV negative.

The discussion when conveying a positive result **should** include:²⁵

- giving the test result in person and in a confidential manner that is sensitive and appropriate to the gender, culture, behaviour, language and literacy level of the person who has been tested;
- assessing the need for and providing information about support mechanisms and making provisions for immediate referral to a support agency as required, providing information on the next steps in staging HCV disease and discussing potential treatment options. It may be necessary to cover these issues over a period of time, in which case a subsequent consultation **should** be arranged at the time of diagnosis;

- disclosure strategies to partner, family and friends;
- legal obligations to disclose HCV status relevant to where the diagnosis is made; and
- the transmission of HCV and how onward transmission may be prevented.

5.3 Referral for further support

The information and support needs of people who are preparing for diagnostic testing for HCV, 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, peer-based drug user groups and haemophilia organisations are well placed to assist people who are newly diagnosed to better understand the HCV testing and diagnosis process and provide appropriate support through this critical period. Providing referral to relevant community-based organisations or if available, on-site peer support, to one or more of the following organisations is therefore highly recommended when informed consent for testing is being obtained and as appropriate at other stages of HCV testing and management process.

Hepatitis Australia

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

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 with complex needs

5.4.1 People unconvinced by a negative or positive result

Responding to the needs of this group of people can be time-consuming and there may be complex psychological issues that need to be addressed. Assistance in dealing with these people can be obtained from a range of specialist services which can offer help to refer a person in this predicament to an alternative service for a second opinion.³³

5.4.2 People who do not return for positive 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 try and contact these people. This **should** be done by phone to the person or in written correspondence. The request **should** be for the person to re-contact the service provider without providing the result per se. Public health units and sexual health clinics can provide advice on person follow-up.

The decision to stop trying to follow-up a person can be a difficult one. Attempts to make contact **should** be documented in the person's file. General practice in particular has limited capacity to perform person follow-up and GPs **should** pass this responsibility on to the local public health unit if they have exhausted their resources. General practitioners should refer to the Royal Australian College of General Practitioners (RACGP) guidelines on follow-up of pathology results.³⁴ All practitioners should be aware of their legal obligations and indemnity cover should they be unable to deliver a positive result.³⁵

5.4.3 Post-mortem testing

HCV tests are not standardised in the post-mortem setting. A pathologist undertaking HCV testing as part of the process of a coronial examination or other post-mortem examination is responsible for ensuring that the other provisions in this policy are adhered to.

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.³¹

6.1 Sentinel site surveillance for HCV

HCV testing is routinely carried out at a number of sentinel sites such as sexual health clinics, Aboriginal Community Controlled Health Services, prisons, primary health care sites, drug-user organisations and blood transfusion services. The numbers of people tested and the proportion with diagnosed HCV infection are reported on a regular basis from these sites and provide estimates of HCV prevalence and incidence across various population groups.

6.2 Special annual survey

The Australian Needle and Syringe Program Survey is co-ordinated by The Kirby Institute (formerly NCHECR) and has been carried out over one week each year since 1995.³⁶ During the designated survey week, needle and syringe programs staff ask all clients who attend to complete a brief, self-administered questionnaire and provide a finger-prick blood sample. The subjects are assured that the specimens are tested under code, so the results cannot be linked back to individuals.

This survey, however, provides limited information on comparisons of HCV infections between jurisdictions and over time.

6.3 Delinked blood surveys

Delinked anonymous surveys are studies in which specimens taken for other purposes (e.g. the neonatal heel-prick specimen survey in 1989–90) are tested for HCV infection without consent after they have been coded so that the results cannot be linked back to the individual who originally provided the specimen. This 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.

6.4 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/or be subject to appropriate ethical review.

6.5 Use of unregistered In Vitro Diagnostic Devices (IVDs)

IVDs not currently approved for use in Australia may be required in international collaborative research. Application **must** be made to the Therapeutic Goods Administration (TGA)³⁷ 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). 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*.³⁸

7.0 HEALTH CARE WORKERS

Communicable Diseases Network of Australia,³⁹ professional societies, colleges and registration boards may from time to time publish guidelines regarding the testing of health professionals. Any testing done in that context **should** be done in accordance with this Policy.

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

Health care workers **must** not perform tests on themselves.

8.0 ANTENATAL AND PERINATAL TESTING

8.1 Routine testing⁴⁰

Women contemplating pregnancy or seeking antenatal care **should** be made aware of the benefits of diagnosis of HCV infection and management and prevention strategies available for both the mother and the infant.

Antenatal testing **must** only be performed with informed consent of the woman. HCV testing **must** be offered in the context of appropriate risk assessment and discussion.⁴¹ Testing should be encouraged for those at risk of past infections (see section 3.1). There is a greater risk of a false positive anti-HCV result during pregnancy and HCV RNA testing should be used to confirm the HCV status of a person shown to be anti-HCV positive.

8.2 Testing of infants born to HCV-infected mothers

The risk of perinatal HCV transmission is 4% to 6%, and is two to threefold higher for mothers with HIV/HCV co-infection. 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 HCV-infected mothers is established by testing for HCV RNA. It is recommended that HCV RNA be tested at 8 weeks and again 4 to 6 weeks later to confirm ongoing infection and to exclude transient viraemia which can occur in infants. If the test returns positive on both occasions, the child should be referred to a Paediatric Gastroenterology or Infectious Diseases Unit for 6 monthly monitoring of liver function (this may require travel to a major centre where this service is available).

All children born to anti-HCV positive mothers should have antibody testing at 18 months of age to detect the rare instance where transmission has occurred from mothers with low and/or fluctuating HCV RNA levels. Where the mothers RNA status is unknown at time of delivery it should be assumed to have been positive unless previous viral clearance has been demonstrated.

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;⁴²
- **must** participate in an external quality assessment scheme (EQAS);⁴³
- **must** comply with the National Pathology Accreditation Advisory Council (NPAAC) standards;⁴⁴ and
- should contribute testing statistics to National Serology Reference Laboratory (NRL) to ensure the completeness of test denominator data.¹⁶

9.2 Pre-marketing quality assurance of HCV IVDs.

The TGA has regulatory responsibility for IVDs through the Therapeutic Goods Act 1989 (the Act) and its associated regulations.⁴⁵

9.3 Post-marketing quality assurance 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 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.

10.0 POINT OF CARE TESTS FOR HCV IN COMMUNITY SETTINGS

No Point of Care (PoC) tests for HCV are currently approved for use in Australia, however, a number of anti-HCV tests which show a similar sensitivity and sensitivity to commercial laboratory anti-HCV enzyme immunoassays have Federal Drug Administration (FDA) approval and European Union CE marking. Such rapid assays may yet find a niche in HCV testing in Australia; they offer an opportunity for testing of people who may otherwise not seek help from traditional medical settings and can provide a result without the individual returning to the site at a later date.

These tests are likely to be inappropriate for testing of low prevalence populations.

When a Point of Care test is approved for use in Australia, this section of the policy will be updated.

Further information on Point of Care testing for HCV can be found here.⁴⁶

11.0 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 clinically indicated.

- There is a Medicare Benefits Schedule (MBS) rebate for anti-HCV antibody testing.
- There is a MBS rebate for qualitative and quantitative nucleic acid testing and genotype testing.

11.1 Funding arrangements for HCV diagnostic and monitoring tests

More detailed information on HCV funding under the MBS is available here: <http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Medicare-Benefits-Schedule-mbs-downloads> (See the most recent schedule Category 6– Pathology items and descriptions).⁴⁷

11.2 Schedule Interpretation

Medicare Australia is responsible for the day-to-day administration and payment of benefits under the Medicare arrangements. Any inquiries concerning matters of interpretation of Schedule items should be directed to Medicare Australia in the first instance. For enquiries relating exclusively to the Schedule, you can phone 132 150.

Alternatively you can send an email with your query to medicare@medicareaustralia.gov.au.

12.0 RECENT ADVANCES IN MONITORING AND CHARACTERISING HCV INFECTIONS

HCV management continues to evolve rapidly and new tests have become available to assist in the assessment of patients before and during treatment to optimise their care and to minimise drug resistance emerging as a problem. Links are provided to brief discussions on IL 28B testing and HCV resistance testing.⁴⁸

13.0 GLOSSARY

13.1 Abbreviations and acronyms

ARTG	Australian Register of Therapeutic Goods
ASHM	Australasian Society for HIV Medicine
BBVSS	Blood Borne Viruses and Sexually Transmissible Infection Subcommittee
CDNA	Communicable Diseases Network of Australia
EPP	Exposure Prone Procedure
EQAS	External Quality Assessment Scheme
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IVD	In-vitro diagnostic device
MBS	Medicare Benefits Schedule
MACBBVS	Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections
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
PoC	Point of Care testing
RNA	Ribonucleic acid
STI	Sexually transmissible infection
TGA	Therapeutic Goods Administration

13.2 Glossary

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 health care 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 health care 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.

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ATTACHMENT A: MEMBERSHIP OF THE EXPERT REFERENCE COMMITTEE (JOINT WORKING PARTY OF BBVSS AND MACBBVS)

FIRST NAME	LAST NAME	POSITION in FULL	ORGANIZATION	AFFILIATION ON ERC
Bob	Batey	Clinical Director Viral Hepatitis Program	ASHMAustralasian Society for HIV Medicine	ASHM – Co- Chair
Geoff	McCaughan	Assistant Director, Faculty and Head, Liver Immunobiology Group	Royal Prince Alfred Hospital - A W Morrow Gastroenterology and Liver Centre	ALA/GESA representative – Co-Chair
Bill	Rawlinson	Senior Medical Virologist (POW/SEALS) & Chairman (RCPA)The 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) QAP)	Prince of Wales Hospital/SEALS & Royal College of Pathologists of Australasia (RCPA)	PHLN representation
Susan	Best	Director	National Serology Reference Laboratory (NRL)National Serology Reference Laboratory, Australia)	NRL representative
Scott	Bowden	A/Prof	Victorian Infectious Diseases Reference Laboratory (VIDRL)	VIDRL representative
Judith Lisa	Bevan Bastian	Senior Policy and Planning Officer	Sexual Health and Blood-borne Virus Program, Department of Health WA	BBVSSBlood Borne Virus and Sexually Transmissible Infection Subcommittee representative
Brent Danilo	Allan diGiacomo	Manager Sexual Health and Viral Hepatitis	Department of Health Victoria	BBVSS representative
Louise	Owen	General Practitioner and Sexual Health Physician	Royal Hobart Hospital	Invited member
Krispin	Hajkowicz	Infectious Diseases Physician	Royal Darwin Hospital/ASID	ASID representative
Carla	Treloar	Professor	National Centre in HIVhuman immunodeficiency virus Social Research	MACBBVSMinisterial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections representative
Helen	McNeill	Chief Executive Officer	Hepatitis Victoria	MACBBVS representative
Peter	Kaylock	Acting Director, IVDin-vitro diagnostic device Assessment Section	Therapeutic Goods Administration	TGATherapeutic Goods Administration representative
James	Ward	Senior Lecturer, Head of the Aboriginal and Torres Strait Islander Health Program	Kirby Institute University of NSW	Kirby Institute representative
Annie	Madden	Executive Officer	Australian Injecting and Illicit Drug Users League (AML)	AVL representative
Tia	Harrison	Project Officer	Australian Injecting and Illicit Drug Users League (AML)	AVL representative
Helen	Tyrell	Chief Executive Officer	Hepatitis Australia	Community representative
Megan Victoria	Parrish Bryant	Director	BBVS Policy section - DOHA)Department of Health and Ageing	DOHA representative
Nikki	Woolley	Manager, Viral Hepatitis Program	ASHM	ASHM representative
Stephanie Vanessa	McLean Towell	Senior Project Officer	ASHM	ASHM secretariat

ATTACHMENT B: COMMUNICATION NETWORK

- ACH2 - Australian Centre for HIV and Hepatitis Virology Research
- NCHECR - National Centre in Epidemiology and Clinical Research
- ARCSHS - Australian Research Council for Sex Health and Society
- NCHSR -National Centre for HIV Social Research
- NPAAC -National Pathology Accreditation Advisory Committee
- MSAC - Medical Services Advisory Committee
- NATA - National Association of Testing Authorities
- ANA - Anwernekenhe National Alliance
- AIVL - Australian Injecting and Illicit Drug Users League
- Multicultural HIV/AIDS & Hepatitis C Service
- HFA- Haemophilia Foundation Australia
- AGPN - Australian General Practice Network
- AChSM -Australasian Chapter of Sexual Health Medicine
- RACP - Royal Australian College of Physicians
- RACGP- Royal Australasian College of General Practitioners
- AHA - Australasian Hepatology Association
- ALA- Australian Liver Association
- RCPA- Royal College of Pathologists of Australia
- ARCBS - Australian Red Cross Blood Service
- ACM - Australian College of Midwives
- RANZCOG - The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- Justice Health
- BBVSS- Blood Borne Virus and STI Subcommittee
- MACBBVS- Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections

ATTACHMENT C: 2012 NATIONAL HCV TESTING POLICY REVIEW– COMBINED CONSULTATION SUBMISSIONS

1st Round of Consultations (August 2011)	2nd Round of Consultations (September- October 2011)
	Australian College of Midwives (Caroline Homer)
	Australian Federation of AIDS Organisations (Michael Frommer)
	Australasian Society for HIV Medicine (David Baker)
	Australasian Society for HIV Medicine (David Fowler)
Children's Hospital at Westmead (Janine Sawyer)	
	Graeme Cooksley – ASHM Board Member – University of Queensland
	Ethnic Communities Council of Queensland (Zhihong Gu)
	Haemophilia Foundation Australia (Sharon Caris)
	Hepatitis NSW (Stuart Loveday and Andrew Smith)
	Hepatitis Australia (Helen Tyrell)
	Hunter New England Health Infection Prevention & Control (John Ferguson) late submission (31/10/11)
	Multicultural HIV/AIDS and Hepatitis C Service (Tadgh McMahon)
	National Centre for HIV Social Research (Max Hopwood)
	Pathology Queensland (Graeme Nimmo)
	Pathwest (David Speers)
	Public Health Laboratory Network PHLN (David Smith)
	Glenn Smith – (Personal submission)
	Queensland Health Communicable Diseases Branch (Christine Selvey)
Royal College of Pathologists Australia - RCPA Quality Assurance Programs Pty Ltd (A/Prof Peter Stewart)	
RCPA (Debra Graves – Chief Executive Officer)	
	Roche Diagnostics (Christian Hawkins)
	St George Liver Clinic (Christine Janssen)
	South Australia Pathology (Paul Goldwater)
	SHAIDS, Sexual Health Clinic, Lismore (Natalie Edmiston)
	UCSD (Robert Gish) – late submission (28/10/11)

