Hepatitis C

CDNA National Guidelines for Public Health Units

Revision history			
Version	**Date**	**Revised by**	**Changes**
1.0	February 2015		Developed by the Hepatitis C SoNG working group

The Series of National Guidelines ('the Guidelines') have been developed by the Communicable Diseases Network Australia (CDNA) and endorsed by the Australian Health Protection Principal Committee (AHPPC). Their purpose is to provide nationally consistent guidance to public health units (PHUs) in responding to a notifiable disease event.

These guidelines capture the knowledge of experienced professionals and provide guidance on best practice based upon the best available evidence at the time of completion.

Readers should not rely solely on the information contained within these guidelines. Guideline information is not intended to be a substitute for advice from other relevant sources including, but not limited to, the advice from a health professional. Clinical judgement and discretion may be required in the interpretation and application of these guidelines.

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Endorsed by CDNA: 21 May 2015
Endorsed by AHPPC: 18 August 2015
Released by Health: 1 September 2015

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1. Summary

Public health priority

Routine

Case management

Individual case management is the responsibility of the treating clinician. Determine if the case is newly acquired and whether associated with injecting illicit drugs, or may be another source of exposure.

Contact management

Counselling and offer of testing may be arranged for contacts by the treating clinician and/or the jurisdictional or regional public health unit (PHU) if indicated. This would apply where a person had known, relevant contact with the case or if any other aspects of a case's history indicated likely exposure of the contact.

2. The disease

Infectious agents

The hepatitis C virus (HCV) is a positive strand RNA virus and a member of the flavivirus family of ribonucleic acid (RNA) viruses. At least six HCV genotypes and a large number of subtypes have been described. Each genotype contains numerous subtypes, labelled a, b, or c. Genotypes 1 and 3 are the most common genotypes in Australia (1). The virus mutates frequently so that many variants may coexist in a single patient (2).

Reservoir

Humans are the only known natural host. People with chronic infection, as defined by persistent serum HCV RNA, are the major reservoir of infection.

Mode of transmission

HCV is transmitted primarily through blood to blood contact, predominantly through the following modes of infection:

- Injecting drug use: The highest risk is related to reuse of needle/syringes, with associated blood contamination, but sharing of other contaminated injecting equipment (swabs, filters, water, spoons, and tourniquets) can lead to transmission.
- Receipt of donated blood, blood products, and organs: Donor screening was introduced in early 1990 in Australia, with current nucleic acid testing virtually eliminating risk of transmission through blood products in Australia. Blood transfusion may still represent a risk for HCV transmission in countries with limited resources.
- Iatrogenic exposure in health care settings: HCV transmission has occurred in a small number of cases in Australia through blood exposures to health care workers and patients, generally as a result of inadequate infection control practice. Such exposures are likely to occur more frequently in resource limited countries, particularly those with high HCV prevalence.

- Other procedures involving skin penetration: Tattooing and body piercing may be associated with a small number of cases in Australia, particularly in circumstances where there is poor infection control, eg. in prisons.

Other routes of exposure are also associated with HCV transmission:
Perinatal exposure: The risk of HCV transmission from a mother who has chronic HCV infection to a newborn or infant is from 4 to 7%, with a four to five-fold higher risk if HIV infection is also present in the mother (3).

Sexual exposure: HCV transmission is more common in people with HIV infection, particularly in men who have sex with men (MSM) (4, 5). People with HIV who are heterosexual partners of those with HCV are also more likely to acquire HCV (6, 7). Transmission to people without HIV through heterosexual unprotected sex has been reported but the risk is extremely low, even in the context of long-term regular partnerships.

Other potential sources of HCV exposure, including sharing of household equipment (razors, toothbrushes) with potential exposure to blood are considered to be extremely uncommon modes of HCV transmission.

Incubation period

HCV RNA is detectable within 2 weeks following exposure/infection (8) with anti-HCV antibody detectable from 20 to 150 days (9). The majority of people with newly acquired HCV infection are asymptomatic or mildly symptomatic. When present, acute HCV symptoms and peak elevations in liver enzymes occur at around 6 weeks following infection (10). As noted below, most people will progress to chronic infection, and a minority will spontaneously clear infection.

Infectious period

People infected with HCV become infectious very early in the course of infection and certainly from the time that RNA is detectable in the blood. Those who clear infection spontaneously are no longer infectious, but are not immunologically protected so may be re-infected through subsequent HCV exposure. Those who progress to chronic HCV infection remain infectious unless they successfully clear infection through treatment. Infectiousness is thought to be influenced by HCV RNA level (viral load), but the viral load range is relatively narrow among people with chronic HCV infection (5 to 7 logIU/mL) (9). There is limited variation in the viral load of an individual case over time.

Clinical presentation and outcome

The majority of people with newly acquired HCV infection are asymptomatic or mildly symptomatic (lethargy, abdominal discomfort). From 15 to 45% of people undergo spontaneous viral clearance (generally within 6 to 12 months of infection) as defined by loss of detectable HCV RNA in the absence of treatment (11). Only a minority of cases will have an acute HCV illness with jaundice and elevated alanine aminotransferase (ALT) (9). Fulminant acute hepatitis C is rare.

Approximately 55 to 85% of those with acute infection will develop chronic HCV infection (7) with persistent viraemia and HCV-related liver disease (8). Liver disease progression, through stages of inflammation, fibrosis (mild, moderate, severe) and cirrhosis, occurs in a proportion of those with chronic infection but is not inevitable and is generally slow with a highly variable course. An estimated one third of those who become chronically infected will develop liver cirrhosis or hepatocellular carcinoma in the long term (7, 12).

Based on the most recent consensus estimates, 310,000 people living in Australia in 2013 had serological evidence of past or current HCV infection. Of these, 80,000 people had cleared their infection; of the estimated 230,000 with chronic HCV infection, 155,000 had early liver disease; 64,000 had moderate liver disease, and 11,400 had cirrhosis (13).

Factors that have been associated in observational studies with higher rates of disease progression include older age at infection, heavy alcohol intake (14), regular marijuana smoking, HIV or chronic HBV co-infection, obesity and diabetes (15-17). Among people with HCV-related cirrhosis, the risk of hepatocellular carcinoma is 2-3% per annum (7) with a similar risk of progression to liver failure.

In addition to liver disease, HCV has been associated with several extra-hepatic manifestations or syndromes, including autoimmune disorders, mild cognitive impairment and chronic fatigue.

Successful HCV treatment, defined by viral eradication, alters the natural history of the infection. Liver disease regression is generally seen, with reductions in the extent of fibrosis or cirrhosis, even if advanced disease is present pre-treatment. Viral eradication also improves quality of life, including improvements in lethargy and other non-specific symptoms and cognitive impairment.

People at increased risk of infection

Population groups at increased risk are:

- People who inject drugs (PWID)
- Those in custodial settings (currently or in the past), because of the high prevalence of both HCV and use of non-sterile injecting, tattooing and piercing equipment in prison populations (18, 19)
- People from regions of the world with high HCV prevalence, in particular Egypt, Pakistan, Central Asia and Eastern Europe (20). Cases of HCV in people from these regions may be diagnosed late and be associated with liver disease at the time of diagnosis
- People who have been medically treated with blood or blood products in Australia or other high income countries prior to 1990, or in low and middle income countries at any time
- Aboriginal and Torres Strait Islander people
- People with HBV or HIV infection, which share HCV risk factors.

Disease occurrence and public health significance

HCV is one of the most frequently notified communicable diseases in Australia (21), with the most recent consensus estimates indicating 6,600–13,200 new infections annually (22-25).

There is however an indication that the incidence of infection is declining slightly, based on the reported annual number of notifications of newly acquired hepatitis C infection. Notifications fell from 11,480 (52.7 per 100,000) in 2009 to 10,698 (46.3 per 100,000) in 2013. Declines have been observed in all age groups. In the past ten years, the rate declined in most age groups but most prominently in the 25–29 year age group (by 50%), and by 43% in the 20–24 year age group (13). There is a similar decline in the number of notifications of newly acquired (as opposed to newly diagnosed) infections (13), but it is important to recognise that data on notification of newly acquired HCV infection are not reliable because they are highly dependent on testing patterns and are likely to substantially underestimate the true incidence of the infection. In general, due to the frequently

asymptomatic nature of HCV the overall burden of disease is likely to be underestimated (26).

HCV prevalence and incidence are considerably higher in selected populations compared with the general population. PWID are the population at greatest risk of HCV infection in Australia with 80% of notifications estimated to come from people who are past or current users of injected illicit drugs. In one study the incidence of HCV among people under 20 who have recently injected drugs was 75.6/100 person years (27). In cohort studies of PWID, HCV prevalence is estimated to be around 40-50% (28).

Australia's early introduction and high coverage of needle and syringe programs (NSPs) and other harm reduction strategies led to very low prevalence of HIV among PWID as well as lower HCV rates (29) and there is evidence that HCV incidence in PWID has fallen nationally, from 30.8 per 100 person-years in 2003 to 4.0 in 2009 (30). Nevertheless some recent cohort studies of PWID have reported HCV incidence at around 10 to 15% (30-33). The ratio of HCV diagnoses in males to females is 2.1:1, likely reflecting the higher proportion of males who inject drugs (22).

The high prevalence and incidence of HCV in prisoner populations (28) is associated with multiple risk factors, such as unsafe injecting drug use and unsterile tattooing (34).

Aboriginal and Torres Strait Islander peoples constitute 2.4 per cent of the Australian population yet make up 8.3 per cent of the estimated Australian population living with HCV (35). It is estimated that 22,000 Aboriginal and Torres Strait Islander peoples have serological evidence of past or current HCV infection, of which 16,000 have chronic HCV infection. The notification rate of newly diagnosed HCV infection in the Aboriginal and Torres Strait Islander population resident in the Northern Territory, South Australia, Tasmania and Western Australia increased from 110 in 2009 to 142 per 100,000 population in 2013 while it remained stable in the non-Indigenous population at 44 and 41 per 100,000 in the same period (36).

3. Routine prevention activities

Vaccination

There is no vaccine.

Risk mitigation

The risk of transmission of HCV can be reduced by:

- Promotion of safe injecting drug use practices, which in turn require the provision of equipment and education
- Screening of donated blood and tissues
- Maintenance of infection control standards in health care settings and all skin penetration procedures
- Promotion of safe sex practices
- Education of people with chronic HCV infection and relevant care givers about the nature of the infection and the means of minimising transmission (see section 'Education' below)
- Making testing available to those at risk
- Treatment that in the majority of cases is curative and therefore eliminates the risk of onward transmission (37)

4. Surveillance objectives

Surveillance of HCV aims to collect data to monitor epidemiological trends in HCV, with particular regard to time, place, population groups and risk factors. These data are used to identify and characterise clusters of cases; inform and evaluate policies, interventions and services to reduce the transmission and consequences of HCV infections; and contribute to reporting on the progress of national strategies.

5. Data management

Newly acquired cases should be entered onto the jurisdictional notifiable diseases database within 5 working days of notification (after evidence is obtained for a case being categorized as either newly acquired or unspecified). Core data and (for newly acquired cases) enhanced data sought from clinicians and laboratories should be entered as soon as information becomes available. Data from jurisdictions are collated in the National Notifiable Diseases Surveillance System (NNDSS) and further analysed by the Kirby Institute. Enhanced surveillance information for newly acquired HCV is collected from states and territories[1] but not included in the core national dataset. Unspecified cases also need to be entered and reported to the NNDSS[1]. These data are defined in the national core and enhanced HCV datasets (NNDSS Dataset – Enhanced Hepatitis C (Newly Acquired) Surveillance Dataset Field Specifications). Appendix 2 has a sample case report form/data collection based on these specifications for use by PHUs.

6. Communications

Laboratories performing HCV testing must notify the relevant state and territory health authorities of any new HCV positive laboratory diagnosis in accordance with the relevant legislation/regulations. In some states and territories medical practitioners and/or hospital CEOs must also notify the relevant State and Territory health authorities. On receipt of a notification a state or territory PHU will contact diagnosing clinician to obtain additional information to determine the appropriate category for the notification and the need for further case investigation.

7. Case definition

HCV surveillance notifications are classified as either 'newly acquired' (infection acquired within 24 months prior to diagnosis) or 'unspecified' (infection acquired more than 24 months prior to diagnosis or duration not known).

[1] In practice, the majority of newly acquired cases will be entered as unspecified cases and then revised to the newly acquired category after information is collected which satisfies the case definition.

Australian national notifiable diseases case definitions

Hepatitis C (newly acquired)

Reporting

Only confirmed cases should be notified.

Confirmed case

A confirmed case requires either:
Laboratory definitive evidence
OR
Laboratory suggestive evidence AND clinical evidence.

Laboratory definitive evidence
Detection of anti-hepatitis C antibody from a person who has had a negative anti-hepatitis C antibody test recorded within the past 24 months
OR
Detection of hepatitis C virus by nucleic acid testing from a person who has a negative anti-hepatitis C antibody test result currently, or has had, within the past 24 months
OR
Detection of anti-hepatitis C antibody from a child aged 18 months to 24 months
OR
Detection of hepatitis C virus by nucleic acid testing in a child aged 3 months to 24 months

Laboratory suggestive evidence
Detection of anti-hepatitis C antibody, or hepatitis C virus by nucleic acid testing in a patient with no prior evidence of hepatitis C infection.

Clinical evidence
Clinical hepatitis within the past 24 months (where other causes of acute hepatitis have been excluded) defined as
Jaundice
OR
Bilirubin in urine
OR
Alanine transaminase (ALT) ten times upper limit of normal.

Hepatitis C (unspecified)

Reporting

Only **confirmed cases** should be notified.

Confirmed case

A confirmed case requires **laboratory definitive evidence** AND that the case does not meet any of the criteria for a newly acquired case AND is aged more than 24 months.

Laboratory definitive evidence
In a person with no prior evidence of hepatitis C virus infection
1. Detection of anti-hepatitis C antibody
OR
2. Detection of hepatitis C virus by nucleic acid testing.

The most recent Australian national notifiable diseases case definitions for newly acquired and unspecified HCV infections can be found at the Department of Health website (www.health.gov.au/casedefinitions).

8. Laboratory testing

Testing Guidelines

Two classes of assays are used in the diagnosis of HCV infection: serologic assays that detect specific antibody to HCV (anti-HCV), or HCV antigen; and molecular assays that detect viral nucleic acid.

Refer to the National Hepatitis C Testing Policy for further information on the national approach to testing (http://testingportal.ashm.org.au/hcv). The Public Health Laboratory Network of Australia (PHLN) has developed laboratory case definitions for 'recent', 'chronic', 'unspecified' and 'confirmed anti-HCV antibody' HCV infection which are available from the Department of Health website (http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-phlncd-hepc).

Serology

Current tests are both sensitive and specific (the specificity of current immunoassays for anti-HCV is greater than 99%). However, false positive results may occur. A positive result is more likely to be a false positive when testing is performed among populations where the prevalence of HCV is low and/or where the reactivity of the assay is low. Therefore a second immunoassay using an assay with a different antigen source or an immunoblot is routinely performed to confirm new positives. False negative results may occur with severe immunosuppression such as infection with HIV, solid organ transplant recipients, hypo- or aggammaglobulinaemia or in patients on haemodialysis (38).

Anti-HCV IgG can be detected in the serum or plasma using a number of immunoassays. However, detection of specific antibody does not differentiate between acute and chronic infection, previous exposure, or passive antibody transfer. IgM tests, which usually indicate acute infection, are not clinically useful for HCV. Cases with spontaneous viral clearance will usually remain HCV antibody positive for life.

Nucleic acid testing

A nucleic acid test (e.g. PCR test) detects HCV RNA and is therefore a marker of viraemia and current infectivity. A single negative PCR does not rule out infection, as viraemia may be intermittent, particularly during acute infection. Currently available assays have excellent specificity (from 98 to 99%) (38). Both qualitative and quantitative HCV PCR tests are available but only the former are registered as diagnostic tests. Quantitative HCV PCR tests are only registered for patient management.

Genotyping Assays

Determining the specific HCV genotype can be useful in epidemiological studies and in clinical management because it is associated with treatment outcome (38).

Test interpretation

The diagnosis of acute, chronic or cleared HCV infection requires testing of serum for both antibody to HCV (anti-HCV) and for HCV RNA. The differentiation of acute from chronic HCV infection may be difficult or impossible in the short-term, and require individual assessment of clinical information including history of symptoms and risk factors and previous test results including any previous liver function tests.

After exposure, HCV RNA is usually detectable in serum before antibody; HCV RNA can be identified within two weeks following exposure (8) whereas anti-HCV is detectable between 20 to 150 days following exposure (9).

Table 1. Interpretation of test results

Anti-HCV	HCV RNA	Interpretation	Clinical action
Positive	Positive	Acute or chronic HCV depending on the clinical context*	Either assessed and monitored by GP with appropriate skills and knowledge or referred for specialist case management
Positive	Negative	Cleared HCV infection or false positive serology result[2]	Retest in 2-3 weeks, only if ALT is raised
Negative	Positive	Early acute HCV infection* or chronic HCV with immunosuppression or false positive HCV RNA test	Retest in 2-3 weeks; Refer for specialist case management
Negative	Negative	Absence of HCV infection	Provide information and retest. Retest if exposure was known to be recent

* A newly acquired infection is defined as a positive anti-HCV test together with evidence of a negative HCV antibody test result within the past two years; or a positive HCV PCR and negative antibody test, followed by a positive result on both tests within at most two years.

Detection of anti-HCV in a person with a negative test for HCV RNA usually represents past, cleared HCV infection. Rarely this result can indicate acute HCV infection during a period of transient clearance of HCV RNA, or a false positive or false negative result on the antibody and RNA results respectively. Re-testing for HCV RNA is recommended to confirm the resolution of HCV infection.

A negative anti-HCV test with a HCV RNA detection may represent:

- the early stage of acute infection prior to the development of antibody, or
- chronic infection in an immunosuppressed individual, or
- a false positive HCV RNA result.

Again, re-testing for anti-HCV and HCV RNA is recommended (38).

9. Case management

Response times

Public health action should commence within 3 working days of notification of a newly acquired confirmed case. Unspecified cases should be provided with information (refer Appendix 2 Sample HCV information sheet) and followed up at the discretion of the PHU director.

[2] After recent exposure viral loads can oscillate widely, and can fall below the limit of detection

Response procedure

Determining the source of infection for newly acquired cases may permit identification of other cases and interrupt infection transmission. Information regarding exposures during the period six weeks to six months before onset of the illness should be sought. A PHU investigation checklist is provided in Appendix 1.

Case investigation

The response to a notification (newly acquired cases only) will normally be carried out in collaboration with the case's health care providers. Regardless of who does the follow-up, PHU staff should ensure that action has been taken to determine whether the case has any history of injecting illicit drugs in a time period relevant to the acquisition of HCV. If so, the case should be provided with information about the disease (refer Appendix 2 Sample HCV information sheet). If not, information should still be provided about the disease and an exposure investigation carried out.

Exposure investigation

For newly acquired cases not associated with injecting illicit drugs, the possible time period of acquisition should be defined. Information should then be sought regarding potential exposures during the period six months before the start of this period with the purpose of 1) ascertaining the source of the infection and 2) determining whether there might have been others exposed to the same source. This should include information about history of:

- Receipt of blood or blood products
- Dental or surgical procedures, renal dialysis or other medical procedures
- Tattooing, ear or body piercing, or acupuncture
- Needle stick or similar injury
- Accidental exposure of skin, eyes, mucous membranes, or a wound to blood of another person
- Work in occupational settings with potential for blood exposure.

Further investigation of any identified potential exposures depends on their nature, and other factors including whether or not any other HCV cases have been reported that share an association with the same potential exposure. Inform the jurisdictional health authority.

If 2 or more cases are determined to be linked with the same putative source of exposure, then a search for additional cases is strongly indicated as part of the investigation (see *Contact Management* below).

Case treatment

Cases should be tested for other blood borne virus (HBV and HIV) infections and vaccinated against HBV if non-immune.

Discussing, offering and providing treatment are the responsibility of the case's clinician. Curative therapies have been available for a number of years and can now cure more than 90% of HCV infections, even covering genotypes that were once poorly responsive to treatment (7). Currently licensed treatments for HCV infection include pegylated and standard interferon alpha (IFN), ribavirin (RBV), the protease inhibitors boceprevir, telaprevir and simeprevir; and the NS5B nucleotide polymerase inhibitor inhibitor sofosbuvir (7). Emerging antiviral therapies promise further increases in virological response, as well as improved tolerability, reduced duration of therapy, and will eliminate the need for interferon use in the majority of patients (39).

The viral suppression and eradication achieved with treatment is important for the individual patient because it prevents disease progression, and for public health control because it eliminates the risk of viral transmission from that person. Reinfection following treatment can nevertheless occur in association with ongoing injecting illicit drug use (40) and sexual transmission in HIV infected MSM.

Education

The case (or care-provider as appropriate) should be informed of measures needed to prevent onward transmission while the case is infectious. Standard precautions include:

- Not sharing items that have the potential to transfer blood (for example razors and toothbrushes, injecting equipment)
- Covering any open wound with an impermeable dressing
- Undertaking safe sex practices if HIV co-infection is present.
- Not donating blood.

A fact sheet on HCV infection should be made available to the case and family and other potentially exposed individuals to provide information about the nature of the infection and the mode of transmission (refer Appendix 2 *Sample HCV information sheet*). Information sheets in different languages are available at:
http://www.ashm.org.au/default2.asp?active_page_id=431

Isolation and restriction

The risk of transmission of HCV through personal contact not involving blood is very low (except sexual contact if HIV co-infection is present). Hence, no specific precautions are required other than standard infection control measures.

There may be work restrictions if a case occurs in some occupational groups (see 'special cases' and jurisdictional specific requirements in appendices). Isolation and restrictions are otherwise generally not required.

Active case finding

Active case finding entails the encouragement of voluntary testing of populations at high risk of HCV infection (see page 4 for populations).

10. Environmental evaluation

None required, except when a cluster of cases is reported.

11. Contact management

Contacts include all people who have had exposure to blood from a person with current HCV infection, including through the use of the same injecting equipment as the case subsequent to the date when infection was acquired in the case. Also included is a child born to a woman with HCV whose infection could have occurred prior to the birth of the child. Contacts may also include sexual partners with HIV infection. Other sexual partners may be considered if they are long-term.

For infections acquired through a procedure involving skin penetration in a medical or other setting, contacts are those who received the same procedure in the same setting, within the time period that the risk was considered, on the best available evidence, to be present.

Household contacts of a person with HCV are not at risk of person-to-person transmission. For cases where there is evidence that HCV acquisition occurred through medical or other skin penetration procedures (generally considered to be a very small minority of cases in the Australian setting), the public health response should include identification and notification of others who may have been exposed in the same setting and should be done in conjunction with the jurisdictional health authority.

Notification of those potentially exposed to HCV infection will alert them to the risk, and thereby enable counselling, testing, medical management as required and education regarding behavioural risk modification if indicated. The responsibilities for contact tracing and management vary between jurisdictions, and may include clinicians, sexual health centres and/or PHUs or Departments of Health. There are some situations in which it is important that relevant jurisdictional health authorities are informed (see Section 12 – Special Situations) even if contact tracing is managed at a local level. For cases acquired through a skin penetration procedure, contact tracing can serve the additional purposes of further investigating or determining the degree of contact with the source, and identifying and ultimately eliminating the risk of further exposure to the identified source of HCV - refer *Australian Contact Tracing Manual* (http://ctm.ashm.org.au/).

The extent of contact tracing will depend on an assessment of both the duration and likely source of infection. If the case is determined to be newly acquired and there is a history of injecting drug use in the relevant time period, the notifying doctor may discuss contact tracing of drug-use partners with the case; PHU support may be made available if requested by the doctor. The *Australian Contact Tracing Manual* provides guidance.

If the case is newly acquired and the source of infection has been determined (or assessed as likely) to be a medical or other skin penetration procedure, trace back using medical or other records to identify others potentially exposed in the same setting up to 6 months prior to onset of acute symptoms in the index case. Depending on the nature of the source, this process can be complex and involve significant logistical and resource challenges and should occur in conjunction with the jurisdictional health authority. It may require a public announcement to alert potentially exposed people if appropriate records are not available. It may also require resources additional to those available routinely. For cases with an unspecified duration of infection, or those for which the procedure took place many years ago, trace back of this kind may not be feasible.

Prophylaxis
Nil

Education
Nil

Isolation and restriction
Nil

12. Special situations

Cases among health care workers
If the case occurs is a health care worker who performs exposure prone procedures, it should be assessed and monitored in accordance with *Australian National Guidelines for the Management of Health Care Workers known to be Infected with Blood-Borne Viruses* at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdna-bloodborne.htm.

Suspected health care/iatrogenic acquired infection

If more than one case occurs among patients of the same health care provider or facility, or tattooist or other skin penetration service provider, or in other circumstances which might suggest the possibility of iatrogenic infection, initiate an investigation and notify the relevant state/territory communicable diseases branch immediately.

Blood transfusion and transplantation

The Australian Red Cross Blood Service and relevant jurisdictional office should be notified immediately if a person with acute or chronic HCV infection has donated blood or plasma, or if transfused blood or blood products are suspected as the possible source of infection in a newly diagnosed case of HCV.

Cluster of cases

Additional actions may be required where a cluster of cases in place or time is detected through analysis of case exposure history. The goal of these actions would be is to identify the source of infection and potential risk factors, thereby informing public health action.

Screening to detect infection

Guidelines on whom to offer screen to can be found in the *National HCV C Testing Policy* (http://testingportal.ashm.org.au/hcv) and include people in population groups specified in section 2 and pregnant women with known risk factors. People at risk of contracting HCVHCV through ongoing injecting drug use should be offered testing on a regular basis but there are no formal guidelines recommending frequency of testing.

Some jurisdictions offer regular HCVHCV screening for people in custodial settings.

Infants who are anti-HCV antibody positive

Children under 18 months of age who test positive for anti-HCV antibody should be followed up with either:

- testing for HCV by a nucleic acid test at or after 3 months of age; or
- repeat anti-HCV antibody at 18 months of age

to determine whether or not the child is a confirmed newly acquired case.

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14. Appendices

Appendix 1: PHU Checklist for newly acquired HCV cases

Contact the patient's doctor to:
Obtain patient's history
Confirm results of relevant laboratory tests

Assist patient's clinician to contact the patient's care giver to:
Confirm possible exposure/onset date (if possible)
Identify contacts and obtain contact details
Complete HCV notification and case report form
Provide with HCV Information Sheet

Confirm case:
Assess information against case definition

Assist patient's clinician to contact patient's contacts to:
Assess risk of HCV infection
Provide with HCV Information Sheet

Other issues:
Assess and arrange best method for delivering information to contacts
Enter case data onto notifiable diseases database

Appendix 2

Sample Hepatitis C Information Sheet

Description/What is Hepatitis C?

Hepatitis means inflammation of the liver. It can be caused by viruses such as hepatitis A, B, C, D, E and G, alcohol, some chemicals and drugs. Hepatitis C (HCV) is one of the most serious types of hepatitis.

Symptoms

Most symptoms of short-term (acute) HCV illness go unnoticed. The small number of people who experience symptoms may have:

- Yellow skin and eyeballs (jaundice)
- Dark orange or tea coloured urine
- Nausea
- Tiredness
- Swollen and painful liver (right-hand side of abdomen).
- Loss of appetite
- Nausea and vomiting
- Soreness under the ribs
- Fever

Symptoms of acute infection disappear within a few weeks but this does not mean that the infection has disappeared. Anyone with hepatitis symptoms should seek medical advice. When the infection has remained for at least 6 months, the illness is called long-term or chronic

About 25% of people with acute HCV will clear the virus themselves without any treatment. In these cases the person will test positive for HCV antibody, but negative for the virus. They will remain positive for HCV antibody for life. However, they are not immune and can be re-infected with HCV.

The other 75% of people with acute HCV infection go on to have chronic HCV infection. Those who develop chronic infection are at long-term risk of cirrhosis (scarring of the liver), hepatocellular carcinoma (liver cancer) and liver failure. People with chronic infection remain infectious to others.

Transmission/How is HCV spread?

HCV is a blood-borne infection. It is passed on when infected blood enters another person's bloodstream. In Australia, most HCV infections occur in people who inject drugs and result from the sharing of contaminated injecting equipment, including needles, syringes, spoons and tourniquets, with others who have HCV infection.

There are other less common ways that HCV can be spread from person to person. These include:

- Sharing personal items that can have traces of blood on them, such as razors, toothbrushes and dental floss
- Via a needle stick injury
- From poorly sterilised equipment and poor infection control used by doctors, nurses, dentists, tattooists, acupuncturists, hairdressers, body piercers, beauty therapists and others or sharing tattooing or piercing equipment

- Having unprotected sex involving blood or damage to the skin with someone who has both HCV and HIV or other sexually transmitted infection. Otherwise, the risk of infection during sex is very low.

There is around 4 to 7% risk of an infected mother passing on HCV to her baby either during pregnancy, or at birth. This risk is higher if the mother is in the acute phase of infection or is co-infected with HIV. There is almost no risk from breast milk.

Australians are very unlikely to get HCV through blood transfusion or organ transplantation. Since February 1990 all donated blood in Australia has been screened and is regarded as safe. HCV cannot be spread through everyday social contact, such as shaking hands, kissing, sharing food or cutlery or sharing a bathroom or toilet, or by donating blood.

How do I know if I have HCV ?

The only way to check if someone has HCV is with a blood test. The HCV antibody test shows if a person has ever been infected. A positive result is usually evident from several weeks after exposure, but may sometimes take up to 6 months from the time of infection. So if a test result is negative straight after potential exposure, a repeat test in 3–6 months is needed. The HCV antibody test can't show if a person has a chronic infection, so if a test result is positive, another test (called the HCV RNA test, NAAT test, or PCR test) is needed to tell if the virus is present. Further information about HCV C testing is available from the web sites indicated below, GPs, and other health care workers.

Prevention/ How do I reduce the risks of getting HCV?

There is no vaccine against HCV. However, there are ways to reduce the risk of catching HCV:

- Never inject drugs with needles and syringes that have been previously used. Clean equipment is available from most chemists, needle and syringe exchange outlets, and at country hospitals after hours. Never share needles, syringes, filters, water or spoons. Wash hands and swab fingers before touching another person's injection site. Always dispose of used equipment in rigid-walled, puncture-resistant, sealable containers to reduce risk of needle stick injury to others. Use Needle and Syringe Program (NSP) disposal bins instead of household waste bins where possible.
- Before considering any body tattooing or piercing make sure the practitioner uses only sterilised equipment and new razors and needles each time.
- Don't share personal hygiene items, such as razors, toothbrushes and dental floss.
- For men who have sex with men, particularly those with HIV infection, safe sex practices should be followed.
- Health care workers should always use infection control procedures at work.
- Always use gloves when handling blood or body fluids. Supplies of clean gloves should be available in all households, childcare centres, schools and sporting venues. Wipe up blood spills using gloves and newly opened hospital strength bleach (one part bleach to nine parts water).
- Cover cuts and wounds with waterproof adhesive dressing.
- Dispose of blood stained tissues, tampons, sanitary napkins and other dressings in a sealed plastic bag or an approved collection bin.

Treatment

HCV treatment is only required for people with acute or chronic infection. It is not necessary for those with positive antibody test but no evidence of viral infection on a HCV RNA test. When treatment is necessary, the goal of HCV treatment is to clear HCV from the body. The cure rate depends on several factors including the strain of the virus and the type of treatment given. HCV treatment has advanced rapidly in the past few years and around

80% of people with some genotypes and about 50% to 60% of all people treated with current therapy clear the virus. Careful screening is necessary before starting the treatment to determine the most appropriate approach for the patient.

The current standard treatment for hepatitis C is a combination course of the drugs pegylated interferon and ribavirin (plus either telaprevir or boceprevir for those with genotype 1). Interferon is poorly tolerated in some patients so management of the treatment is complex. Treatment is usually given for 6 to 12 months. Regular check-ups by a GP or specialist are essential during treatment to monitor progress and respond to any issues associated with treatment. Scientific advances have led to the development of new antiviral drugs for HCV, which are much more effective, safer and better-tolerated than existing therapies. These therapies, known as oral directly acting antiviral agent (DAAs) therapies simplify HCV treatment by significantly decreasing monitoring requirements and by increasing cure rates. Interferon-free DAA regimens should become the standard of care for treatment in the next few years.

To reduce the risk of further liver damage, people with HCV should:

- • Limit or avoid alcohol
- • Get rest and exercise and eat a healthy diet
- • Get vaccinated for hepatitis a and hepatitis b.

Confidentiality

Under most circumstances, there is no obligation to tell anyone that a person has HCV. However, there is a legal requirement to inform the Red Cross of HCV status if a person is intending to donate blood. Also, a person's HCV status must be declared to the Australian Defence Force if applying as an entrant. Health care workers with HCV must not perform exposure-prone procedures.

Preventing spread to others

Those with hepatitis C need to take responsibility for not spreading the infection to anyone else. Those who have shared injecting equipment with a person who has hepatitis C should be tested if possible. A doctor, nurse or health worker can contact these people if the person with hepatitis C feels uncomfortable or embarrassed about telling friends, partner or partners. This is a confidential process and the person's name need not be mentioned.

Even if a person is already infected with HCV, they can still catch a different type of the HCV. If someone has been successfully treated such that the infection is gone, they can become infected with HCV again.

Help and Assistance

For more information on hepatitis C, contact:

- your local doctor
- your local sexual health clinic
- your local Family Planning clinic
- your local public health unit

A list of helpful resources can be found at www ashm.org.au/resources and at www.hepatitisc.org.au

Appendix 3

Hepatitis C notification and case report form (sample)

Notification decision: Hepatitis C (newly acquired/other

☐ Unspecified hepatitis C ☐ Confirmed anti-HCV

HCV RNA detection: ☐ Yes ☐ No ☐ Unknown

Disease code: _____ Organism code: _____ Organism name: _____

Confirmation status: _____ Detection code: _____

HCV date last negative test: ____/____/____

Notifier _____ Notification date: ____/____/____

Notification receive date: _____

Notification ID: _____ State: _____

Health Centre/Practice/Lab _____ Phone No_

Treating Doctor SURNAME _____ Initial _____ Phone No _____

Permission to contact the patient directly Yes / No Notification ID _____

Case details

First Name _____ Surname _____

Date of birth: ____/____/____

Age at onset: _____ Occupation: _____

Country of birth: Australia (1101) ☐

Overseas (SACC code): _ _ _ _ Unknown (0004) ☐

Patient UR No.: _____

Indigenous status: Aboriginal ☐ Torres Strait Islander ☐ Both ☐ Sex: ____

Resident location: _____ Phone No: _____ Resident Post Code: ___

Suburb/Community _____ Mobile _____

True Onset Date ____/____/____ **Public health response date** ____/____/____

Does the laboratory and/or clinical evidence fulfil the case definition? Yes / No

Attach laboratory form and contact lists if applicable to this notification form. Ensure information is entered on the State/Territory data record system and the National Notifiable Diseases Surveillance System (NNDSS)

Case closed by Name _____

Signature_____Date_____/____/____

Clinical/Testing Details:	
Has the patient had symptoms of hepatitis[3] in the last 2 years? ☐Yes ☐No ☐Unknown	
Reason for testing (more than 1 can be ticked)	
Screening ☐Drug and alcohol screening ☐Patient request ☐Prison screening ☐Antenatal screening ☐Postnatal screening in a child with a HCV positive mother ☐Blood or organ donor screening ☐Occupational exposure ☐Source person ☐Exposed person ☐Psychiatric screening ☐Other screening – Specify	Other ☐Acute disease ☐Chronic disease ☐Abnormal liver function ☐Symptoms and signs of hepatitis[4]/ Date of onset of symptoms of hepatitis ____/____/____ ☐Other medical problem ☐Asymptomatic sexual contact of a HCV case ☐Asymptomatic household contact of a HCV positive case ☐Monitoring of a HCV case

HCV other reason for testing: History of clinical illness[1]/comments (include relevant comment such as possible source of infection, others with similar illness, etc)

_____

_____

Exposure:

Indicate any identified risk factors for the patient and supply details below:

Risk factor exposure	
Ever injected illicit drugs ☐Yes ☐No ☐Unknown Age or year first injected drugs____	Illicit drug use only in previous 2 years ☐Yes ☐No ☐Unknown
Exposure to blood, blood products, body fluids or tissue in Australia ☐Yes ☐No ☐Unknown	Exposure to blood, blood products, body fluids or tissue overseas ☐Yes ☐No ☐Unknown
Haemodialysis ☐Yes ☐No ☐Unknown	Perinatal transmission ☐Yes ☐No ☐Unknown
Health care worker with needle stick/biohazard injury ☐Yes ☐No ☐Unknown	Non-health care worker with needle stick/biohazard injury ☐Yes ☐No ☐Unknown
Health care worker with no documented exposure ☐Yes ☐No ☐Unknown	Tattoos ☐Yes ☐No ☐Unknown
Ear or body piercing ☐Yes ☐No ☐Unknown	Acupuncture ☐Yes ☐No ☐Unknown

_____

[3] Symptoms of HCV can include abdominal pain, anorexia, vomiting, fatigue and jaundice

[4] Clinical HCV, defined as: 1. Jaundice OR 2. Bilirubin in urine OR 3. Alanine transaminase (ALT) ten times the upper limit of normal.

Surgical procedure/endoscopy ☐Yes ☐No ☐Unknown	Major dental surgery ☐Yes ☐No ☐Unknown
Household contact with hepatitis C ☐Yes ☐No ☐Unknown	Imprisonment ☐Yes ☐No ☐Unknown
Heterosexual contact with HCV + case ☐Yes ☐No ☐Unknown	Homosexual contact with HCV + case ☐Yes ☐No ☐Unknown
Organ transplant in Australia ☐Yes ☐No ☐Unknown	Organ transplant overseas ☐Yes ☐No ☐Unknown
Other risk within the previous 2 years ☐Yes ☐No ☐Unknown	Other risk but not within the previous 2 years ☐Yes ☐No ☐Unknown

Other details:_____

Contact management**:**

During the exposure period was there contact with confirmed/suspected case(s)? ☐Yes ☐No ☐Unknown

If yes, please complete:

Name of contact	Type of contact	Age	Testing

Laboratory:

Newly acquired hepatitis C:

Confirmed because the patient has: *(tick at least one of the three boxes below)*

☐ Detection of anti-HCV antibody from a person who has had a negative anti-HCV antibody test recorded within the past 24 months

☐ Detection of HCV by nucleic acid testing from a person who has a negative anti-HCV antibody test result currently, or has had, within the past 24 months

☐ Detection of anti-HCV antibody from a child aged 18 months to 24 months

☐ Detection of HCV by nucleic acid testing in a child aged 3 months to 24 months

Unspecified hepatitis:

Confirmed because the patient has: *(tick at least one of the two boxes below)*

☐ Detection of confirmed anti-HCV antibody in a patient >24 months of age

AND

☐ Does not meet the criteria for recent or chronic hepatitis CI

Confirmed anti-HCV antibody:

Confirmed because the patient has either:

☐ Supplemental immunoassay based on different antigens and different formats

OR

☐ Recombinant immunoblot assay

Investigations

Serology: Date sample collected: ___/___/___

HBC RNA ☐ Detected ☐ Not detected ☐ Unknown

Liver function test? Date sample collected: ___/___/___ ☐ Yes ☐ No ☐ Normal ☐ Abnormal

Has the patient had previous HCV testing? _____

☐ Yes ☐ No ☐ Unknown Date of test ___ / ___ / ___

Has the patient had a negative test HCV in the last 6 months?
☐ Yes ☐ No ☐ Unknown Date of test ___ / ___ / __

Please attach pathology results to this notification

Is this case associated with a known disease outbreak? ☐ Yes ☐ No ☐ Unknown

Comments:

If you have any comments that could improve the data collection process or the form, please write in the space below or attach another page.