Pretest counselling and diagnosis

This update focusses on making a diagnosis of hepatitis C in general practice. The diagnosis of hepatitis C virus (HCV) is complicated but a clear diagnostic process helps to avoid potential misdiagnoses.

Who should be tested?

Patients may present with risk factors or symptoms suggestive of HCV, or may simply request HCV testing. Some may be referred from other sources, such as a blood bank for confirmatory testing after having been screened for HCV. In all situations, assessment of risk is the first step in diagnosing HCV infection followed by clinical examination and further laboratory tests.

People at high risk should be offered testing. A history of injecting drug use is particularly important. Some practical guidelines in the approach to obtaining an accurate history of drug using behaviours are summarised in Table 1.

In those with a significant (although lower) risk of HCV infection, clinicians should consider the need for HCV testing, especially if symptoms or signs of HCV coexist. In lower risk populations, further research is required to determine the exact level of risk of transmission, and this uncertainty may cause some patient anxiety. This is particularly relevant for sexual transmission.

Some patients may have accurately assessed their personal risk of HCV infection as high, but hide their risk from the clinician for personal reasons such as the stigma associated with injecting drug use. Thus, when any person requests HCV testing it is appropriate that this be performed.

Signs and symptoms

The clinical signs and symptoms of chronic HCV are the commonest clinical findings of HCV related disease. Hepatitis C virus can occasionally present as an acute infection or rarely as a result of extrahepatic manifestations of infection. Many people have no symptoms or signs. Many of the signs and symptoms are nonspecific and common to many diseases, but the diagnosis of HCV becomes more likely in the presence of coexistent risk behaviour.

Acute HCV infection is often asymptomatic and is uncommonly diagnosed. Fulminant HCV is rare. However, HCV should be considered in the differential diagnosis in the acutely ill patient presenting with an illness suggestive of a hepatitis, with anorexia, nausea, jaundice or abnormal liver function tests (LFTs). A recent history of possible HCV exposure may require follow up testing if the initial tests are negative.

Chronic HCV infection should be considered in all people with any clinical evidence of liver disease, such as lethargy, hepatomegaly, spider naevi or other stigma of chronic liver disease, and raised alanine aminotransferase (ALT). It is particularly important to exclude HCV if there is a risk factor, or no other causes of liver disease are apparent. Even in the presence of another cause such as HBV infection, coinfection with HCV should be considered as these two viruses share some modes of transmission.

Pretest counselling

Counselling for HCV testing is based on the principles of testing for HIV infection, which are well documented. Having identified risk behaviours, clinical features of hepatitis or a patient requesting HCV testing, informed consent is required before HCV testing is carried out. We advise counselling the patient before testing to:

- explain the benefits and risks of HCV testing
- educate the patient to reduce the risk of transmission, and
- ensure that appropriate support is available, especially in the event of a positive result.

The three Cs: counselling, confidentiality and consent

A thorough approach to counselling before HCV testing minimises potential adverse outcomes in the event of a positive diagnosis. Counselling not only involves giving information to patients so that they can make an informed choice about HCV testing, but is inextricably linked to education to
reduce the risk of HCV transmission. As well as ensuring privacy, reassurances of confidentiality increase the likelihood of disclosing illegal or stigmatised behaviours.

The level of patient fear attached to testing for blood borne viruses should not be underestimated and counselling also aims to assess and lessen the psychosocial impact of testing.

Assessing risk behaviours and educating patients for the reduction of risk

Considerable sensitivity is required to elicit transmission risk information from marginalised populations. For example, many patients will not readily reveal injecting drug use behaviours for fear of censure from health providers.

Overcoming discomfort in discussing alcohol and other drug use

Questions about drug use may be uncomfortable for both the patient and the doctor. Patients with drug related health problems may also fear discrimination upon disclosure of drug use and avoid accessing health services. Using exact, nonjudgmental language combined with a sincere concern for the patient’s welfare helps to build the patient’s trust. This should improve management and prevention outcomes.

Use accurate, nonjudgmental language

Accurate language also helps to estimate the level of risk of HCV transmission. The term ‘intra-venous’ is particularly inaccurate as many patients at high risk of HCV infection inject intramuscularly or subcutaneously, such as steroid users and temazepam injectors.

Using terms such as ‘drug addict’ may not only be inaccurate, but may send signals to the patient that the discussion of injecting behaviours may result in discrimination with the potential to compromise treatment (Table 1). Occasional recreational and experimental injectors are also at high risk of acquiring HCV.

Language may also convey messages about disability that are inappropriately, albeit inadvertently, threatening to HCV infected persons.

Strategies for assessing drug use

One useful strategy for eliciting information on injecting drug use behaviours as a routine part of every medical assessment is to begin with questions about legal drug use and then gradually move to illegal use. Begin with questions about caffeine, smoking, alcohol and sedative use. Further nondirective questions such as: ‘Any other drug use?’ may elicit marijuana or other illegal drug use. Ifamphetamine use is disclosed, the question: ‘Was that taken orally or injected?’ is a gentle means of communicating that the clinician is prepared to discuss injecting behaviours.

An additional question such as: ‘Have you ever injected any other drugs?’ may disclose opiate or other drug use. This gradual disclosure of information allows wary patients some control over the risk assessment process while they judge the reactions of the clinician. Once trust has been established, direct questions can be asked.

In our experience, assessment of drug history can be easier in new patients at the first presentation. Clinicians may feel hesitant in questioning familiar patients about sensitive issues, but patients understand the need for questioning

<table>
<thead>
<tr>
<th>Table 1. Accurate assessment of drug related HCV risk</th>
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<tbody>
<tr>
<td><strong>Choice of language when talking to patients</strong></td>
</tr>
<tr>
<td>• Avoid the terms:</td>
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<tr>
<td>– addict, addiction, drug addict, drug abuse, drug abuser, intravenous</td>
</tr>
<tr>
<td>• Use the terms:</td>
</tr>
<tr>
<td>– injecting (rather than intravenous)</td>
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<tr>
<td>– drug use (not abuse)</td>
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<tr>
<td>– injecting equipment (not needles)</td>
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<tr>
<td>– reused not shared (eg. have you ever re-used another person’s injecting equipment?)</td>
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<tr>
<td>– ask about the presence of withdrawal symptoms and/or dependence, not addiction</td>
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<tr>
<td>• Clarify meaning of any colloquial, subcultural terms associated with marginalised groups</td>
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<tr>
<td><strong>Strategies to improve eliciting drug use practices</strong></td>
</tr>
<tr>
<td>• Routinely include questions on drug use in general history taking</td>
</tr>
<tr>
<td>• Start with questions about legal drug use eg. caffeine, cigarettes and alcohol before asking about illegal drugs</td>
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<tr>
<td><strong>Questions to Include</strong></td>
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<tr>
<td>• Do you or have you ever smoked?</td>
</tr>
<tr>
<td>• Do you or have you ever consumed alcohol?</td>
</tr>
<tr>
<td>• Do you or have you used any other drugs?</td>
</tr>
<tr>
<td>• Do you or have you ever injected drugs?</td>
</tr>
<tr>
<td>• Have you ever re-used another person’s injecting equipment?</td>
</tr>
<tr>
<td>• When did you first inject drugs? Which drug(s) did you inject?</td>
</tr>
<tr>
<td>• Have you ever injected any other drugs?</td>
</tr>
<tr>
<td>• How often would you inject drugs?</td>
</tr>
<tr>
<td>• Have you ever been tested for hepatitis or HIV? When, and what were the results?</td>
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</tbody>
</table>
about practices that may affect their health. Prefacing sensitive questions with a remark such as: ‘I need to ask a few sensitive questions because it may affect your treatment’ can help prepare patients for potentially uncomfortable situations.

**History and HCV testing**

The time course of risk behaviours and testing provides information on the possible date of first exposure to HCV and duration of infection. A prior negative anti-HCV test may help establish the date of acquisition.

**Education for risk reduction**

Education for reducing the risk of HCV transmission usually occurs simultaneously with risk assessment. As each possible risk is examined, patients are given information on how HCV is and is not transmitted. Patients need to know what constitutes risk behaviour so that they can assess their own risks in their daily environment. This key issue is addressed in Chapter 2.

Education should be in words that the patient understands, which may require an interpreter if the patient’s first language is not English.

**Practical consequences of HCV infection**

Patients need to understand about HCV and the nature of the HCV test – whether it is a test for antibodies or for the virus. Carefully explain the difference between a positive, negative or an indeterminate result. Some patients misunderstand the term ‘positive’, thinking that this is a good outcome. Explain how HCV causes the antibody test to turn positive, including the length of time required for this to occur.

Give accurate information about the possible medical consequences of HCV infection, including its prognosis and treatment. Questions about the vertical transmission of HCV are common, as many HCV infected people are of child bearing age.

Patients need to understand the possibility of discrimination in housing, medical and dental treatment, employment, insurance and the value in maintaining privacy about their potential diagnosis. Laws regarding notification of positive results to health departments should be told to patients before testing.

Clinicians may need to assist the patient to think through the repercussions of a positive, negative or indeterminate result. This essential aspect is considered in Chapter 7.

**Laboratory tests for HCV**

The routine test for HCV infection is an antibody test. A positive test usually indicates exposure to HCV but does not prove active infection. Polymerase chain reaction (PCR) testing may be carried out to determine if active infection is present in anti-HCV positive people with normal ALT levels. Accurate testing to detect the presence of HCV infection can be complicated due to current difficulties in serological and virological assays.

All tests need to be performed and interpreted within the context of a thorough clinical assessment, ALT levels and risk factors. Clinicians should not hesitate to contact their local pathology laboratory, or state or national reference laboratories, in the event of problems in interpreting HCV results. Difficulties in interpreting results may also require specialist referral.

This uncertainty around HCV testing can be a significant source of concern, but warning of this possibility during pretest counselling helps patients prepare for this outcome.

**HCV RNA testing**

The detection of HCV RNA is not a first line investigation in the diagnosis of HCV infection; it should not be viewed as a confirmatory test of serological status. The low level of viral HCV RNA requires highly sensitive detection systems such as PCR. This is important for monitoring disease during antiviral treatment.

Hepatitis C virus viraemia fluctuates over time, and may be undetectable even in the presence of active HCV infection. Therefore, a negative PCR result does not completely exclude HCV infection. There may be a supplementary role in diagnosing HCV in patients before the development of antibodies during seroconversion, or in immunocompromised patients. This is best done in a specialist setting.

**Testing for HCV genotype and viral load**

At present, HCV genotype and viral load testing is not required for the diagnosis of HCV, but is valuable in consideration of treatment. Its use is currently limited to specialist units.
**Chapter 5: Pretest counselling and diagnosis**

### Table 2. Anti-HCV EIA (enzyme immunoassay)

<table>
<thead>
<tr>
<th>Possible results</th>
<th>Interpretation</th>
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</thead>
<tbody>
<tr>
<td>Anti-HCV positive</td>
<td>• All initial reactive EIA tests confirmed (automatically by the laboratory) with a second EIA test using a different assay&lt;br&gt;• Average time for the appearance of antibodies is 10 weeks, although this may vary from 2–26 weeks (‘window period’)&lt;br&gt;• A positive antibody test result is no guide to the severity of hepatitis&lt;br&gt;• HCVAb positive patients should be considered currently infected with HCV and therefore infectious&lt;br&gt;• 80–85% of patients with acute infection remain infected, while 15–20% clear the virus. However, they remain HCVAb positive&lt;br&gt;• False positive results are unlikely, especially in the presence of raised ALT and an identified risk factor&lt;br&gt;• Children less than 12 months of age (occasionally up to two years) born to HCVAb positive mothers may reflect maternal antibody persistence</td>
</tr>
<tr>
<td>Anti-HCV negative</td>
<td>• Repeat EIA at six months if possibly within ‘window period’&lt;br&gt;• False negative results are possible if a patient is within the ‘window period’, especially in the presence of an identified risk factor&lt;br&gt;• Immunocompromised patients (HIV/AIDS) may not produce HCV antibodies, but still be infected with HCV</td>
</tr>
<tr>
<td>Indeterminant</td>
<td>• Where initial reactive EIA test is not confirmed by second EIA test using different assay, HCV PCR test should be conducted (rebatable by Medicare under these circumstances). Refer to specialist if still in doubt</td>
</tr>
</tbody>
</table>

### Table 3. Qualitative HCV RNA by PCR

The Medicare Benefits Schedule covers one qualitative HCV RNA PCR test per person per year for patients who:<br>• have tested HCVAb positive and who have had two normal liver function tests over the past six months<br>• have inconclusive HCVAb test results<br>• are immunocompromised and may not be producing antibodies to HCV<br>• may have acute HCV before seroconversion, eg. needlestick injury

<table>
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<tr>
<td>HCV RNA positive</td>
<td>HCV present in the body. Patient considered infectious</td>
</tr>
<tr>
<td>HCV RNA negative</td>
<td>HCV not detected in the body. The patient could have cleared the virus but does not completely rule out infection as viraemia may fluctuate</td>
</tr>
</tbody>
</table>

### Pretest

- Explain the virus (HCV) and hepatitis C
- Describe the HCVAb test and possible results
- Explore psychosocial issues and support
- Obtain informed consent
- Investigate coinfection
- Provide prevention information/education
- Provide further information and support

### Post-test

- Provide and explain the result in person
- Assess and address patient’s psychosocial reaction

**Negative result**

- Explore need for repeat test
- Offer HAV/HBV vaccination
- Provide prevention information/education
- Discuss harm reduction options
- Provide further information and support

**Positive result**

- Describe natural history and discuss prognosis
- Discuss self management and harm reduction options
- Explain relevant legal issues
- Investigate coinfection
- Provide prevention information/education
- Provide further information and support

**Indeterminate result**

- Explain need for repeat testing
- Provide prevention information/education
- Provide further information and support

Figure 1. HCV test counselling checklist
Post-test counselling

Post-test counselling aims to minimise the psychological trauma of HCV testing and educate patients about how to reduce the risk of HCV transmission. HBV and/or HIV results are often given in conjunction with HCV results and post test counselling should also be given for these.

Test results should always be given in person, and wherever possible by the individual who performed pretest counselling. Even a negative result may cause distress, and the need to be given the results personally should be emphasised in pretest counselling. Results should never be given over the telephone, even if patients are persistent in their demands. All clinic staff, including nursing and reception staff, should only inform patients via telephone as to whether test results have returned, not to disclose the actual result.

Possible test outcomes

Hepatitis C virus testing may result in positive, negative or equivocal results (Table 2). Post-test counselling and initial management of patients with a positive HCV result is detailed in Chapter 6 and Figure 1.

The negative result

This provides an ideal opportunity for reinforcing harm reduction behaviours and lifestyle modification. Patients should be offered repeat testing if potential exposure to HCV has occurred within the past six months (2–26 weeks), especially if there are clinical symptoms or signs of acute HCV infection. These patients may need close monitoring. If patients continue to be at significant risk of HCV exposure, repeat the HCV test after 12 months.

Equivocal results

Sometimes the anti-HCV result is neither clearly positive (high antibodies, reproducibly detected) nor negative. Examples include a positive result by one test kit, but negative by a second assay, or a weakly positive result by two assay systems. Such results are reported as ‘indeterminate’ or equivocal.

The uncertainty associated with receiving an indeterminate result is likely to cause major anxiety for patients. Some patients may actually be in the process of developing antibodies (‘seroconverting’).