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Hepatitis C - the basics

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Testing and treating hepatitis C is now so much easier. Being involved in curing hepatitis C is one of the most important and satisfying things I do as a GP,”

– Fran, GP

Hepatitis C – the basics

Here you'll find all the information you need to diagnose and treat a patient with hepatitis C, including:



Who should you test?



How to test for hepatitis C



Getting your patient ready for treatment



Liver fibrosis assessment



When to refer



Before treatment



Starting treatment



Post-treatment follow-up and assessment of cure



Getting everyone involved in eliminating hepatitis C



Who should you test?⁶

- People who currently or have ever injected drugs
- People in custodial settings
(i.e. people who have ever been in prison)
- People with tattoos or body piercings (especially if received outside of Australia or outside of regulated settings)
- People who received a blood transfusion or organ transplant before 1990
- People with coagulation disorders who received blood products or plasma-derived clotting factor treatment products before 1993
- Children born to mothers with chronic hepatitis C infection
- People infected with human immunodeficiency virus (HIV) or hepatitis B virus (HBV)
- Sexual partners of a person infected with hepatitis C (people at a higher risk of sexual transmission include men who have sex with men, and people with HCV–HIV coinfection)
- People with evidence of liver disease (persistently elevated alanine aminotransferase level)
- Migrants from high-prevalence regions (Egypt, Pakistan, the Mediterranean, Eastern Europe, Africa and Asia)

We know that starting the conversation about hepatitis C testing can be tricky, so we've included some tips on *Starting the Conversation* in the Appendix booklet.

⁶Adapted from GESA. Australian recommendations for the management of hepatitis C virus infection: a consensus statement (August 2017), Table 1 page 10

How to test for hepatitis C:

Two tests are required to diagnose infection with hepatitis C virus (HCV):


- **Antibody test to screen for past exposure to hepatitis C**
- **RNA/PCR test to confirm current hepatitis C infection.**


The clinical definition of chronic hepatitis C infection is when someone is documented with a positive result for both HCV antibody and HCV RNA tests for longer than six months. Documented chronic hepatitis C infection is part of the PBS eligibility criteria for accessing DAA treatments.

TIP: Hepatitis C is a notifiable condition and requires written notification to the Department of Health and Human Services (DHHS) on initial diagnosis within 5 days.







Hepatitis C test result interpretation⁷

Legend:

 **Ab**
Anti-HCV Antibody test
Indicates if patient has been exposed to HCV

 **RNA**
RNA/PCR test
Indicates if patient is infected with HCV

Hepatitis C Test Results Interpretation

	+		=	Prior exposure to HCV and current HCV infection
	+		=	Prior exposure to HCV and not infected with HCV (due to spontaneous clearance of HCV or prior treatment)
	+		=	Never exposed to HCV and not infected with HCV

⁷ Adapted from ASHM/VHHITAL training slides

Getting your patient ready for treatment

Once you have diagnosed chronic hepatitis C in your patient, there is just a few simple steps to prepare them for DAA treatment.

Pre-treatment assessment includes:

- Taking their medical and social history
- A medication review
- A physical examination
- Blood tests and liver fibrosis assessment (APRI +/- FibroScan®).

See the Appendix booklet for Table 2 of the *Gastroenterological Society of Australia (GESA) Australian recommendations for the management of hepatitis C virus infection: a consensus statement*, which provides a full overview of the required pre-treatment assessment.

Diagnostic tests and pre-treatment assessments can all be done with just one pathology request, using a single blood draw with a request for reflex/reflexive testing.

TIP:

Use reflexive testing to reduce the number of blood draws and appointments!

Ask for the HCV RNA (qualitative) test if antibody positive; and for the pre-treatment assessment tests if HCV RNA positive.

TIP:

When requesting HCV diagnostic tests, run a comprehensive blood-borne virus screen by ordering hepatitis A virus (HAV), hepatitis B virus (HBV) and HIV tests

Diagnostic Tests:

- Anti-HCV antibody
- HCV RNA (qualitative) if HCV Ab pos
- HBV Serology (HBsAg, anti-HBc, anti-HBs)
- HIV Serology
- HAV Serology

Pre-treatment assessment (if HCV RNA positive):

- HCV RNA Level (Quantitative)
- HCV Genotype
- FBE
- LFT including AST
- INR
- U&Es including eGFR

TUBES						URINE						
GEL	PLAIN	EDTA	EDTA	GLUC	CITRATE	HEPARIN	BACTO	CYTO	24HR	PCR	OTHER	STUART
			6ml									

PATIENT COPY

Liver fibrosis assessment



Before starting your patient on DAA treatment, assess their level of liver fibrosis to determine whether they have cirrhosis. This will help you decide on the best treatment regimen and whether specialist care is required or not. It is also a requirement for PBS authority.

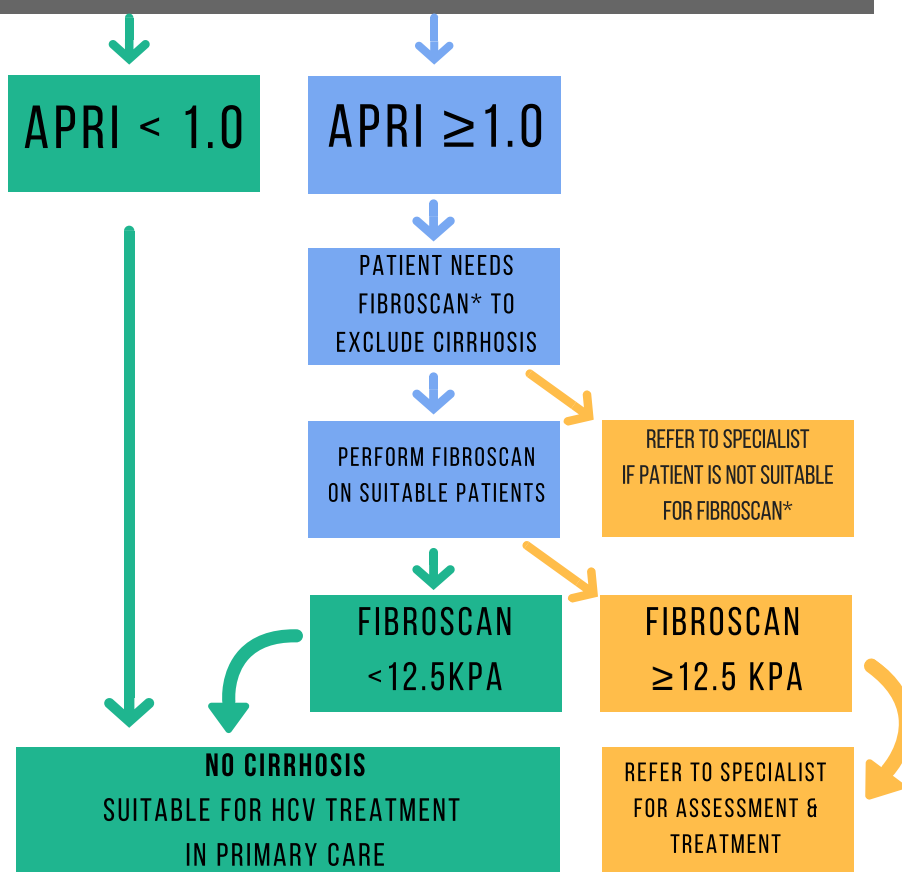
You can assess fibrosis using APRI (AST to platelet ratio index) initially and/or using FibroScan® if required. You'll also find the *Pathways to Liver Fibrosis Assessment in Primary Care* Diagram in the Appendix booklet.

PATHWAYS TO LIVER FIBROSIS ASSESSMENT FOR PATIENTS IN PRIMARY CARE

Created by EC Partnership

PATIENT CONFIRMED WITH CHRONIC HEPATITIS C (PCR +VE)

INITIAL LIVER FIBROSIS ASSESSMENT USING APRI SCORE



*FibroScan is not approved for use in people <18 years, women who are pregnant, people with ascites and people with a pacemaker or implantable defibrillator

FibroScan and APRI results should be interpreted in conjunction with a full clinical picture by a trained clinician

APRI Calculator available here: <https://www.hepatitisc.uw.edu/page/clinical-calculators/apri>

Note: suitable specialists include gastroenterologists, hepatologists and infectious disease physicians. Appropriate specialist depends on your local referral processes



When to refer

While most patients can be treated for hepatitis C in primary care practices, there are some who will need to see a specialist⁸ for treatment and management. Your patient will need to be referred to a specialist if they have:



Liver related

- Advanced fibrosis or cirrhosis (FibroScan® liver stiffness score ≥ 12.5 kPa)
- Persistently abnormal LFTs after treatment



Co-infections & comorbidities

- HCV-HIV co-infection
- HCV-HBV co-infection
- Complex co-morbidities
- Renal impairment (eGFR <50 mL/min/1.73m²)



Treatment related

- Failed first-line DAA treatment
- Complex drug-drug interactions
- Experienced major adverse events during treatment

You can use *HealthPathways* (an online portal run by the Primary Health Network (PHN) – see page 51 for details) to find your local hospital liver clinic. See the **Provider Support Section** for more information on how to access specialist support.

Before treatment

Goals of treatment

Discuss with your patient their goals for treatment, such as:

- Being cured of the viral infection
- Minimising their liver damage, preventing liver failure, and reducing the risk of developing a cancer
- Improving their quality of life
- Reducing the risk of passing on hepatitis C to someone else

⁸Adapted from GESA Australian recommendations for the management of hepatitis C virus: a consensus statement (August 2017) & ASHM Decision-making in HCV.

Explain to your patient that advanced fibrosis and cirrhosis are irreversible, but treating and curing their hepatitis C will avoid further liver damage from the virus.

Side effects

Side effects from DAA treatments are uncommon, usually mild, and get better with time. Discuss with your patient the possibility of side effects and explain what you can do about them. You can also help them plan for any disruptions to their work and personal life.

Side effects could include:

- Nausea: taking the tablet with food could help this
- Insomnia and fatigue: make sure your patient is prepared for how this could impact their life
- Headache: make sure your patient stays well hydrated and uses pain relief medications as needed

Is your patient ready to start treatment today?

Sticking with hepatitis C treatment is really important. Anyone starting treatment could experience difficulty with adhering to it.

You'll need to take a patient-centered approach to help your patients stick with their hepatitis C treatment. This means working with them to identify factors that could get in the way before starting treatment, and developing a personalised support strategy to help keep them on track.

The Australasian Hepatology Association has produced consensus guidelines for how to provide adherence support to patients with hepatitis C on DAAs.

You can find them here:

bit.ly/adherenceguidelines

Quick Reference Guide can be accessed here:

bit.ly/aha_adherencesupport

We've also included some tips on having this conversation with your patient - see our *Treatment Readiness Tool* in the Appendix booklet.



Starting treatment

Choosing a treatment regimen

Pan-genotypic treatment options are now available, making treatment choice much easier.

They can be used to treat all genotypes of hepatitis C.

There are six different HCV genotypes (Gt 1 - 6). Here in Australia, the most common genotypes are genotype 1 (1a and 1b), and genotype 3. You must know your patients HCV genotype for the PBS authority. It will also help you choose a treatment regimen, and can help distinguish between relapse and reinfection if your patient is not cured of their hepatitis C.

More detailed information on treatment protocols is available in *Clinical guidance for treatment hepatitis C virus infection: a summary* (see the Appendix booklet). If you are not experienced in prescribing DAAs, you may need to seek specialist advice to prescribe 'in consultation' using a *Primary Care Consultation Request Form*. See **Provider Support Section** for more information.

Five key questions to answer to help you select the most appropriate treatment regimen:⁹

1. What is the HCV genotype?

Knowing the HCV genotype can help you choose the right treatment regimen for your patient. It is also required for the PBS authority of the prescription.

2. Is cirrhosis present?

Excluding cirrhosis can be done by assessing level of fibrosis and is generally performed using APRI and/or FibroScan®. If APRI ≥ 1.0 , perform a FibroScan® to measure liver stiffness. If FibroScan® shows liver stiffness ≥ 12.5 kPa, specialist referral is recommended.

See *Pathways to Liver Fibrosis Assessment for Patients in Primary Care* in the Appendix booklet.



TIP:

If you are not experienced in managing hepatitis C - you can still prescribe in consultation with a specialist experienced in the treatment of chronic hepatitis C infection.

⁹Adapted from GESA Clinical guidance for treatment hepatitis C virus infection: a summary, August 2017

3. Is HBV–HCV or HIV–HCV coinfection present?

It's recommended that patients with HBV or HIV coinfection are referred to a specialist. If seronegative, vaccinate against HAV and HBV.

4. Are there potential drug–drug interactions?

Check for drug–drug interactions using hep-druginteractions.org – a comprehensive, free and easy to use website. It takes the confusion and concerns out of assessing drug–drug interactions and includes prescribed, over-the-counter herbal and illicit drugs. If you can't find a prescribed or herbal drug on the website, check with your local liver clinic or hospital pharmacy attached to a liver clinic about whether it has any drug–drug interactions.

5. What is the renal function (eGFR)?

This can affect which treatment regimen you choose.

- Sofosbuvir is not recommended with eGFR <30mL/min/1.73m².
- Ribavirin is renally cleared and needs dose reduction if eGFR <50mL/min/1.73m²

Writing the prescription

You'll need to have the PBS authority before prescribing these treatments under the PBS.



**For Medicare prescription authority
call 1800 888 333**

**For Department of Veteran Affairs
prescription authority call 1800 552 580***

*When seeking an Authority number, prescribers will be asked:

- Length of treatment: 8, 12, 16 or 24 weeks
- Genotype
- Cirrhosis: present or not
- Does the patient meet the General Statement for Drugs for the Treatment of Hepatitis C?
- Evidence of chronic hepatitis C infection with documented positive results for HCV antibody and HCV RNA for more than six months

See the PBS General Statement for Drugs for the Treatment of Hepatitis C online here:
bit.ly/pbsgeneralstatement

Post-treatment follow-up and assessment of cure

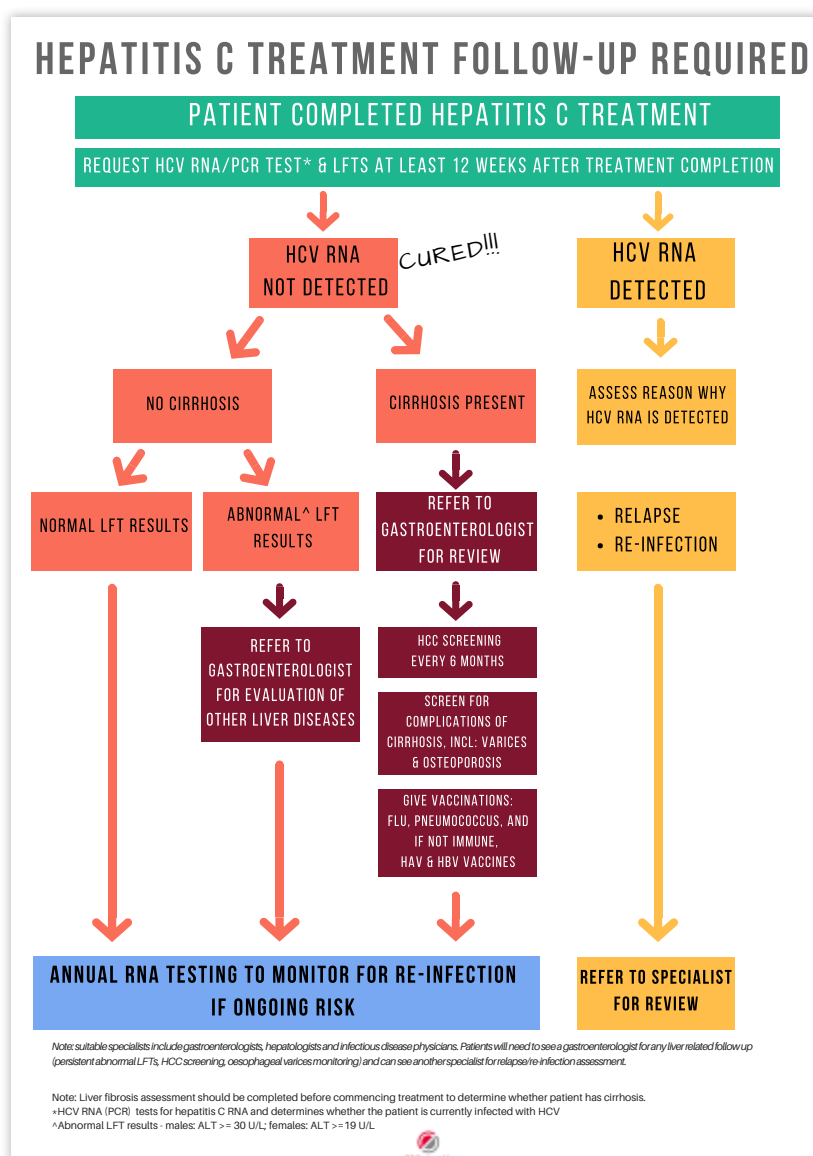
It is important to wait for 12 weeks after treatment completion to test for cure. At this time order an HCV RNA (qualitative) test and liver function tests. The HCV RNA test will show if there has been a sustained virological response (SVR) to treatment.



HCV RNA not detected = SVR achieved = your patient is CURED!

Remember: all patients who have achieved SVR will continue to have anti-HCV antibodies, but this does not mean they have a current hepatitis C infection. It also doesn't mean that they are immune to reinfection.

You'll also find the *Hepatitis C Treatment Follow-up Required* Diagram in the Appendix booklet.



Reinfection can happen

Reinfection is possible, but you can treat for hepatitis C again. It's important to treat people who are currently injecting drugs to stop ongoing transmission of hepatitis C.



If your patient engages in activities that put them at risk of hepatitis C - here are three things to discuss:

- Staying safe by using sterile injecting equipment
- Encouraging injecting partners to be tested and treated
- Remind them they can get treated again if re-infected



The Department of Health and Human Services website hosts a list and map of needle and syringe exchange programs (NSPs) across Victoria, which can be accessed here: bit.ly/dhhs_nsplocations

Hepatitis C treatment in prisons

Your patient can access hepatitis C treatment in prison.

St Vincent's Hospital Melbourne are responsible for delivering the Justice Health State-wide Hepatitis Program (SHP), on behalf of the Department of Justice, State Government of Victoria. The Statewide Hepatitis Program is delivered primarily by skilled Clinical Nurse Consultants who visit each prison in person every 2-4 weeks, with support from two part-time hepatologists and a pharmacist.

The program is integrated into the local prison primary healthcare team with close collaboration with prison primary care nurses, who routinely offer hepatitis C testing to all prison entrants.

If you would like to transfer the care of your patient for commencement or continuation of hepatitis C treatment or would like further information on the SHP, please contact **Clinical Nurse Consultants Lucy McDonald or Anne Craigie** via **phone 03 9231 3788** or email: lucy.mcdonald@svha.org.au or anne.craigie@svha.org.au

**“ It is nice seeing people’s
health status transform ”**

– David, Nurse Practitioner

Getting everyone involved in eliminating Hepatitis C

This Hep C Task List¹⁰ helps you easily involve everyone in your practice. Different tasks can be assigned to reception staff, community health workers, NSP program workers, case managers, alcohol and other drug (AOD) workers/counsellors, nurses and GPs.

TIP:

Create a hep C friendly space

TIP:

See the **Practice Support Guide** section on our website for instruction sheets on these patient management system tasks

TIP:

Request reflexive testing to reduce number of blood draws needed – if antibody positive, do PCR; if PCR positive, do genotype and viral load

TIP:

Set up recalls/reminders/actions for each relevant task and involve case workers when planning follow-up

Hep C Task List	
Task	People who can do this:
Promoting that your practice tests, treats and cures hepatitis C (see Health Promotion Catalogue)	e.g. nurse, reception staff, NSP staff, community health workers, Aboriginal health workers
Getting patients onboard with hepatitis C testing and treatment	e.g. GP, nurse, reception staff, NSP staff, community health workers, Aboriginal health workers
Searching patient management systems and recalling patients	e.g. GP, nurse, reception staff
Establishing patient management system shortcuts to make hepatitis C management easier	e.g. practice manager, nurse
Testing patients for hepatitis C	e.g. GP, nurse, community health worker, NSP worker
Giving patients their results and completing pre-treatment workup	e.g. GP, and if reviewed by GP and in their scope of practice, nurse and community health workers can deliver result
Entering information into practice management system to improve data collection	e.g. practice manager, nurse
Reviewing blood test results and creating a treatment plan	e.g. GP, nurse
Prescribing medications and planning treatment follow-up	e.g. GP, Nurse Practitioner
Follow-up appointments to find out if your patient has been cured of their hepatitis C	e.g. nurse, GP



¹⁰ Adapted from MSD Primary Healthcare Tool Kit – Hepatitis C