DECISION-MAKING IN HCV

HEPATITIS C: Testing

Could it be hepatitis C?

- **Patient request**
- **Abnormal liver function test (LFT)**
- **Doctor concern**
- **Presence of risk factors**
  - Injecting drug use
  - Sharing of snorting equipment
  - Birth in high prevalence country
  - Blood transfusions and blood products before 1990 in Australia
  - Unsterile tattooing and body piercing
  - Unsterile medical and dental procedures and blood transfusions in high prevalence countries
  - Time in prison
  - Needlestick injury
  - Mother to child transmission is around 5%
  - Household transmission is very rare
  - Sexual transmission is rare but can occur in certain populations, such as men who have sex with men (MSM) or those who are Human Immunodeficiency Virus (HIV) positive.
- **Jaundice** or acute hepatitis

Order:
Hep C antibody (Ab)
LFT

If possible acute hepatitis, also order HCV RNA

Review results

- **Hep C Ab -ve LFT normal (means hepatitis C unlikely, HCV RNA not needed)**
- **Hep C Ab -ve LFT abnormal or possible acute hepatitis C**
- **Hep C Ab +ve**

Check Hep C RNA

- **Hep C Ab -ve HCV RNA -ve** means hepatitis C unlikely
- **Hep C Ab -ve HCV RNA +ve** means acute hep C
- **Hep C Ab +ve plus repeated HCV RNA +ve** means chronic hepatitis C (chronic if > 6 months)
- **Hep C Ab +ve plus repeated HCV RNA –ve** means cleared hepatitis C

Follow up and referral

- **Repeat** Hep C Ab, LFT if recent (possible window period) or ongoing risk
- **Option 1** Further assessment and treatment in primary care – see next page
- **Option 2** Refer for assessment and treatment
- **Repeat** HCV RNA, LFT if on-going risk

Gain informed consent in a culturally appropriate manner

Discuss:

- Reason for test
- Risk factors
- Meaning of a positive antibody test
- Availability of treatment if HCV PCR positive
- Mechanism for communicating test results

Convey test result

If positive, results should always be provided in person and explain:

- Natural history
- Modes of transmission and risk reduction
- Availability of treatment
- Need for ongoing, potentially lifelong monitoring
- Life style factors e.g. alcohol minimisation, diet
- Availability of peer support services, information and support services
- Refer to Hepatitis Australia National Infoline 1800 437 222

* Check Medicare schedule rebates for HCV RNA testing

For further details on testing, see the National HCV Testing Policy, available at http://testingportal.ashm.org.au/hcv

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HEPATITIS C: A step-by-step guide to treating hepatitis C in primary care

Step	Primary Care Provider	Additional Information	Refer for specialist review if:
1	Confirm chronic HCV infection	• Anti-HCV +ve indicates exposure to HCV virus • HCV RNA +ve confirms current infection	
2	Check HCV genotype, viral load and baseline screening	• HCV genotype determines treatment choice and is a PBS requirement • Quantitative HCV RNA test - if low viral load, may allow shorter duration of therapy if genotype 1 • Full Blood Evaluation (FBE) • Urea, electrolytes, creatinine (UEC) • Liver function test (LFT) • INR	Genotype 5,6
3	Assess liver fibrosis: could they have cirrhosis?	• Documentation of the presence or absence of cirrhosis is a PBS requirement • Cirrhotic status determines treatment regimen and length of treatment • Detect signs of chronic liver disease in physical exam: spider naevi, palmar erythema, jaundice, asterixis, hepatomegaly, splenomegaly, ascites, peripheral oedema • Undertake non-invasive assessment of fibrosis: ○ FibroScan assessment if available (>12.5 kPa consistent with cirrhosis) ○ Serum bio markers such as APRI (if score >1.0, significant risk of cirrhosis), FIB-4, HepaScore • A low albumin and/or a low platelet count suggests cirrhosis • Liver ultrasound if cirrhosis suspected to detect portal hypertension (splenomegaly, dilated portal vein, ascites, varices) and HCC screening	Cirrhosis is present
4	Detect other causes of liver disease	• Check for viral coinfection: ○ HIV Ab ○ Hepatitis A – check hep A IgG; vaccinate if -ve ○ Hepatitis B – check HBsAg, anti-HBc and anti-HBs; vaccinate if all –ve • Heavy alcohol intake • Fatty liver disease • Further investigations (e.g. iron studies) if indicated or abnormal LFT post treatment	Coinfected with HIV, HBV
5	Detect other major co-morbidities	• Renal disease • Mental health • Drug and alcohol use • Heart disease- may not be able to use ribavirin (causes anaemia); perform ECG if ribavirin prescribed and patient has risk factors for CVD	Renal impairment (eGFR <50)
6	Review previous HCV treatment	• Choice and length of treatment is influenced by genotype and prior HCV treatment experience / response	Treatment failure of DAAs
7	Consider contraception, pregnancy	• DAAs are not recommended for use in pregnant or lactating women • Ribavirin is a Category X drug. Dual forms of contraception are required during treatment and for 6 months post-treatment if ribavirin is prescribed	
8	Assess adherence	• Determine likelihood of adherence with medication, readiness to have treatment	
9	Select treatment regimen and review drug interactions (Table 1)	• Refer to the Australian recommendations for the treatment of hepatitis C Infection: a consensus statement 2017[2] and the General Statement for Drugs for the Treatment of Hepatitis C[1] • Check for potential drug interactions with current medications including over the counter drugs at www.hep-druginteractions.org. DAA selection and dose may need to be modified or current medication may need to be reviewed prior to treatment	Complex drug interactions
10	[Consult with a specialist]	• If not experienced in hepatitis C treatment, a Remote Consultation Request for Initiation of Hepatitis C Treatment[2,3] form may be completed or consult with a specialist via phone or email	
11	Treat and monitor	• Call the PBS Authority Script Line for approval to prescribe • Monitoring should be individualised, see Table 2 • Side effects of DAA therapy are generally mild	Major adverse events
12	Post treatment follow-up (Table 2)	• No further follow-up for HCV is required for people with no cirrhosis who are cured (SVR 12) and have normal LFTs • People who have SVR12 but persistent elevated LFTs require further evaluation for other liver diseases • People with cirrhosis require life-long monitoring: ○ 6-monthly abdominal ultrasound (hepatocellular carcinoma screening) ○ Endoscopic surveillance for oesophageal varices ○ Osteoporosis; 2-yearly DEXA scans and monitor serum vitamin D	Treatment failure of DAAs Persistently abnormal LFTs

APRI: AST to Platelet Ratio Index; FIB-4: Fibrosis 4; SVR12: undetectable plasma HCV RNA 12 weeks post treatment

Table 1: HCV treatment summary (for full details, see www.hepcguidelines.org.au)

Genotype	Treatment regimen	Duration of therapy
1	Sofosbuvir + Ledipasvir (Harvoni)	8 – 24 wks
	Sofosbuvir (Sovaldi) + Daclatasvir (Daklinza) ± Ribavirin (Ibavyr)	12 – 24 wks
	Ombitasvir + Paritaprevir/Ritonavir + Dasabuvir ± Ribavirin (Viekira Pak)	G1a: 12 – 24 wks ± RBV G1b: 12 wks
	Grazoprevir + Elbasvir (Zepatier) ± Ribavirin (Ibavyr)	12 –16 wks ± RBV
2	Sofosbuvir (Sovaldi) + Ribavirin (Ibavyr)	12 wks
3	Sofosbuvir (Sovaldi) + Daclatasvir (Daklinza)	12 – 24 wks
4	Grazoprevir + Elbasvir (Zepatier) ± Ribavirin (Ibavyr)	12 – 16 wks ± RBV
5,6	Sofosbuvir + Peginterferon alfa + Ribavirin (Ibavyr)	12 wks

RBV = Ribavirin (Ibavyr)

Table 2: Monitoring on-treatment and post-treatment

Routine monitoring for a 12-week treatment regimen		
	Blood tests	HCV virology
Week 0	FBE, U&Es, LFTs	HCV RNA (quantitative)
Week 4, 8*	LFTs	
Week 12 (End of Treatment)	LFTs	
Week 12 after End of Treatment (SVR)	LFTs	HCVRNA(qualitative)

*LFTs at week 8 instead of week 4 if taking Zepatier

Note: At each visit, assess for medication adherence, treatment adverse events and drug-drug interactions. Some people will require closer monitoring[3]

Additional copies and electronic version available at: http://www.ashm.org.au/publications

Links to resources

[1]www.pbs.gov.au
[2]www.hepcguidelines.org.au
[3]www.gesa.org.au

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Supporting the HIV, Viral Hepatitis and Sexual Health Workforce

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