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

DECISION-MAKING IN HCV

Hepatitis C assessment and treatment

Primary Care Provider		Specialist review if:
Testing and Diagnosis		
Confirm chronic HCV infection	• Anti-HCV +ve indicates exposure to HCV virus • HCV RNA +ve confirms current infection	
Check HCV genotype, viral load and baseline screening	• HCV genotype determines treatment choice and is a PBS requirement • Quantitative HCV RNA test. If viral load <6 million IU/mL, consider shorter duration of therapy if prescribing sofosbuvir/ledipasvir • Full Blood Evaluation (FBE) • Urea, electrolytes, creatinine (UEC) • Liver function test (LFT) and INR	
Pre-treatment Assessment		
Assess liver fibrosis: could they have cirrhosis?	• Cirrhotic status determines treatment regimen and length (and is a PBS requirement) • Detect signs of chronic liver disease: spider naevi, palmar erythema, jaundice, asterixis, hepatomegaly, splenomegaly, ascites, peripheral oedema • Undertake non-invasive assessment of fibrosis: o FibroScan assessment if available (>12.5 kPa consistent with cirrhosis) o 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
Detect other causes of liver disease	• Check for viral coinfection: o HIV Ab o Hepatitis A – check hep A IgG; vaccinate if -ve o 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
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 IHD	Renal impairment (eGFR <50)
Review previous HCV treatment	• Choice and length of treatment is influenced by genotype and prior HCV treatment experience / response	Treatment failure of DAAs
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	
Assess adherence	• Determine likelihood of adherence with medication, readiness to have treatment and the need for adherence support	

Primary Care Provider		Specialist review if:
Treatment, Monitoring and Follow-up		
Review drug interactions	• Check for potential drug interactions with current medications (including over the counter, recreational drugs and supplements) 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
Select treatment regimen[2]	• Refer to the General Statement for Drugs for the Treatment of Hepatitis C[1] and the Australian recommendations for the management of hepatitis C virus infection: a consensus statement[2]	
[Consult with a specialist]	• If not experienced in hepatitis C treatment, consult with a specialist by phone, email or complete a Remote Consultation Request for Initiation of Hepatitis C Treatment[2,3] or use the online portal at www.reach-C.ashm.org.au	[Specialist approval is required]
Treat and monitor	• Call the PBS Authority Script Line for approval • Monitoring should be individualised, see Table 1 • Side effects of DAA therapy are generally mild	Major adverse events
Post treatment follow-up (Table 1)	• SVR (cured), normal LFT, no cirrhosis – no further follow-up needed • SVR (cured) but persistently elevated LFTs – require evaluation for other liver diseases and specialist referral • No SVR (not cured, HCV detectable 12 weeks post-treatment) need specialist referral • Cirrhosis – lifelong monitoring and specialist care o 6-monthly abdominal ultrasound (hepatocellular carcinoma screening) o Endoscopic surveillance for oesophageal varices o Osteoporosis; 2-yearly DEXA scans and monitor serum vitamin D	Treatment failure of DAAs Persistently abnormal LFTs

PBS: Pharmaceutical Benefits Scheme; INR: International Normalised Ratio; IHD: Ischaemic Heart Disease; DAAs: Direct Acting Antivirals; APRI: AST to Platelet Ratio Index; FIB-4: Fibrosis 4; SVR12: undetectable plasma HCV RNA 12 weeks post treatment

APRI SCORE CALCULATOR

$$APRI = \left(\frac{\text{AST Level (IU/L)}}{\text{AST (Upper Limit of Normal) (IU/L)}} \right) \times 100$$

Platelet count (10^9/L)

Online calculator at:

www.hepatitisc.uw.edu/page/clinical-calculators/apri

Table 1: Monitoring on-treatment and post-treatment

Routine monitoring for an 8–12 week treatment regimen		
	Blood tests	HCV virology
Week 0	FBE, U&Es, LFTs	HCV RNA (quantitative)
[Week 8]*	[LFTs]*	
Week 12 after End of Treatment (SVR)	LFTs	HCV RNA (qualitative)

*LFTs at week 8 to assess for hepatotoxicity if prescribing elbasvir + grazoprevir

Note: Some people will require more frequent monitoring[2] e.g. to assess for medication adherence, treatment adverse events and drug-drug interactions

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

Links to resources

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

www.ashm.org.au

ashm
Developing a sustainable HIV, viral hepatitis and sexual health workforce

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