Hepatitis C - secondary care assessment

Assess level of hepatic fibrosis

No contraindications to treatment

Patient agrees to treatment - ensure baseline investigations complete

Go to hepatitis C - treatment

Contraindications to treatment - follow-up

Patient declines treatment - advise regular follow-up

Contraindications and special considerations

Minimal, moderate-to-severe fibrosis and/or inflammation or mild chronic hepatitis C

Discuss treatment options with patient

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Information resources for patients and carers

Updates to this care map

This care map was published by International. A printed version of this document is not controlled so may not be up-to-date with the latest clinical information.
Hepatitis C - secondary care assessment

1 Care map information

Quick info:
Scope:
• diagnosis of hepatitis C virus (HCV) in primary care
• management of HCV and elimination with antiviral therapy in people with chronic infection in secondary care
Out of scope:
• the diagnosis and management of HCV in children

Hepatitis C:
• flavivirus infection of the liver – several genotypes exist and have important clinical implications
• often asymptomatic – the majority of acutely infected patients are asymptomatic
• jaundice can occur – present in less than 25% of acute hepatitis C infections [5]
• acute symptoms, if present, are similar to those in other forms of acute viral hepatitis, eg:
  • malaise
  • nausea
  • right upper quadrant abdominal pain
• rarely presents with fulminant hepatic failure
• chronic infection occurs in 50-80% of patients [5]
• may be detected in the course of routine blood donor screening or screening high-risk individuals

Prevalence:
• worldwide HCV prevalence is 3.1% [3]
• in England and Wales, 200,000-500,000 people are estimated to be infected with HCV [5]
• there is variation in prevalence among sub-groups [5]:
  • blood donors – 0.04%
  • people attending genitourinary clinics – 1%
  • intravenous (IV) drug users attending drug misuse clinics – up to to 50%
• prevalence of different genotypes varies significantly geographically:
  • in the UK, genotype 1 and 3 are equally common [6,7]
  • only small numbers of patients in the UK are infected with genotypes 4, 5 and 6 [4] – most people will have acquired these genotypes overseas [5]

Prognosis:
• approximately [3]:
  • 25% of people will clear the virus at the acute stage
  • 75% will develop chronic disease
• of those who develop chronic disease:
  • some will remain well and never develop liver damage
  • many will develop mild to moderate liver damage (with or without symptoms)
  • most will progress to develop cirrhosis of the liver over a period of 20-40 years [2]
  • the proportion of patients affected accelerates with increasing age [5]
• of those with cirrhosis, approximately 5% per year will develop a life-threatening event, such as liver failure or primary hepatocellular carcinoma [3]

Risk factors:
• country of origin:
  • Egypt 14% – [2]
  • Europe – 0.7-1.2% [2]
  • Pakistan – 2-3% [7]
• blood and blood product transfusion received prior to the introduction of screening in 1991 [2,3,8]
• organ or tissue transplants received in the UK before 1992 [1]
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- IV drug use
- snorting cocaine
- tattoos or ear piercing
- sexual contact with infected people:
  - relatively uncommon
  - less than 5% of sexual partners are also infected [8]
- multiple sexual partners
- sharing household implements such as razors with infected individuals
- vertical (mother-to-neonate) transmission:
  - less than 6% in most studies – this doubles or triples if co-infection with HIV is present [1-3,8]
- healthcare in areas of the world where unsterile injections are given

Hepatitis C is a notifiable disease in the UK.

References:

2 Information resources for patients and carers

Quick info:
Patients and carers in England can access this care map through NHS Choices at http://healthguides.mapofmedicine.com/choices/map/hepatitis_c1.html

The following resources have been produced by organisations certified by The Information Standard:

- 'Hepatitis C' (URL) from Bupa at www.bupa.co.uk
- 'Hepatitis C' (URL) from Datapharm at www.medguides.medicines.org.uk
- 'Hepatitis C' (URL) from Patient UK at www.patient.co.uk
- 'Hepatitis C' (URL) from the Terrence Higgins Trust at www.tht.org.uk
- 'Are you at risk of hepatitis C?' (PDF) from The Hepatitis C Trust at www.hepctrust.org.uk
- 'HIV and Hepatitis C' (PDF) from The Hepatitis C Trust at www.hepctrust.org.uk
- 'Just diagnosed with hepatitis C?' (PDF) from The Hepatitis C Trust at www.hepctrust.org.uk

The following resources have been written or recommended by national policy bodies or guideline producers whose content has informed this care map:

- 'Hepatitis C' (URL) from Clinical Knowledge Summaries (CKS) at www.cks.nhs.uk

Information for carers and people with disabilities is available at:

- 'Caring for someone' (URL) from Directgov at http://www.direct.gov.uk
- 'Disabled people' (URL) from Directgov at http://www.direct.gov.uk

Patient stories describing their care journeys are available at 'Healthtalkonline' (URL) from DIPE at http://www.healthtalkonline.org/

Explanations of clinical laboratory tests used in diagnosis and treatment are available at 'Understanding Your Tests' (URL) from Lab Tests Online-UK at http://www.labtestsonline.org.uk

The Map of Medicine is committed to providing high quality health and social care information for patients and carers. For details on how these resources are identified, please see 'Map of Medicine Patient and Carer information'.

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3 Updates to this care map

Quick info:
Date of publication: 29-Apr-2011
Three information points now appear at the top of each care map page. These provide:
- easy access to scope and background information on each page of the care map whilst reducing repetition between care points
- easy access to patient resources/leaflets
- information on care map updates

This care map has been updated in line with the following guidelines:

Further information was provided by the following references: [5,7]
For further information, please see the care map’s Provenance.

The care map has been completely restructured and redrafted in line with the Map of Medicine’s editorial methodology and to bring it in line with current clinical practice.

NB: This information appears on each page of this care map.

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Quick info:
The following investigations should be requested and performed prior to being seen in a viral hepatitis clinic [7]:
- full blood count (FBC) [2,3]
- urea and electrolytes [2,3]
- liver function tests (LFTs) [2,3], including liver biochemistry
- international normalised ratio (INR)
- full hepatitis C serology, RNA levels [3], and genotyping
- HIV serology [2,3]
- general liver screen to exclude other causes of liver disease, eg:
  - hepatitis:
    - A virus (HAV) serology [3]
    - B virus (HBV) serology [2,3]
    - D virus (HDV; delta)
    - liver auto-antibodies [3]
    - ferritin [2,3]
    - immunoglobulins (IgGs) [3]
  - consider other viral serology, eg:
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- hepatitis E
- Epstein-Barr virus (EBV)
- cytomegalovirus (CMV)
- herpes simplex virus (HSV)
- alpha-fetoprotein (AFP) [2,3]
- consider alpha-1 antitrypsin, copper, and caeruloplasmin
- liver ultrasound [2] is performed to [5]:
  - assess the state of the liver
  - exclude the presence of hepatocellular carcinoma

References:

5 Assess level of hepatic fibrosis

Quick info:
Consider:
- no further investigations if patient preference [5]
- the following have a high sensitivity for the presence or absence of cirrhosis and increasingly represent an alternative to biopsy, but they are not informative in the mild-to-moderate range of fibrosis [7]:
  - non-invasive markers of liver fibrosis – blood tests such as enhanced liver fibrosis (ELF) and hyaluronic acid
  - elastography [1]
- liver biopsy [1,2]:
  - considered the most accurate test to [3]:
    - determine if cirrhosis is present
    - gauge level of fibrosis and inflammation [8]
  - may also reveal concurrent liver disease [10], eg:
    - alcoholic liver disease [5]
    - non-alcoholic steatohepatitis (NASH) [3]
    - liver manifestations of haemochromatosis [5]
- patients with extrahepatic manifestations sufficient to warrant treatment in their own right may not require liver biopsy
- while liver biopsy may give patients added information on which to base their decision regarding when or if to have treatment [5], it is not essential, particularly in patients highly unlikely to have severe fibrosis (young, low alcohol intake, short duration of infection) [5]:
  - essentially, the information gained by the liver biopsy must be worth the small risk (pain and bleeding) to the patient and change some aspect of their care
  - it is cost effective to treat hepatitis C irrespective of the stage of fibrosis
  - the interpretation of results from a liver biopsy should be carried out by a pathologist with suitable experience, using a standardised scoring system [5]

Vaccinate against Hepatitis A and Hepatitis B [2,10].

References:
6 Contraindications and special considerations

Quick info:
Conditions that may require extra monitoring or special considerations include:

• mental health problems:
  • close psychiatric monitoring of patients with known mental health problems should be arranged prior to and throughout treatment [2,3,10]
• ongoing alcohol or drug dependency [5]
• pregnancy and risk of pregnancy [10]:
  • pregnant women must not be prescribed:
    • ribavirin [2]
    • pegylated interferon
  • pregnancy should be excluded in women of child bearing age before commencing treatment with pegylated interferon and ribavirin
  • two forms of contraception should be used by couples when one partner is on treatment with pegylated interferon and ribavirin [3] – for the duration of treatment and up to 6 months after it has ended [2,3]
• HIV co-infection [5]
• renal failure – careful monitoring is necessary for patients with renal failure [2,3,10]
• liver transplant – antiviral therapy should [5]:
  • not be given to patients in the pretransplant or peritransplant stages, except as part of a clinical trial
  • be considered in the post-transplant stage

Relative contraindications include [5]:

• non-compliant patients
• active:
  • autoimmune disease
  • bacterial infection
• heart disease
• uncontrolled diabetes mellitus
• white cell count less than 3.5x10^9/L or neutrophils less than 1.5x10^9/L
• thrombocytopenia with platelet count less than 75x10^9/L
• anaemia

References:

8 Contraindications to treatment - follow-up

Quick info:
Follow-up:
• encourage patient to continue attending clinic for follow-up [3,10]
• 3 to 6-monthly clinical and biochemical monitoring is recommended:
  • the type and frequency of monitoring depends on the individual clinical scenario [5]
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- counselling and support on lifestyle issues relating to hepatitis C should be available [10]

References:

9 Minimal, moderate-to-severe fibrosis and/or inflammation or mild chronic hepatitis C

Quick info:
Predisposing factors for fibrosis include [5]:
- alcohol
- HIV
- male gender – severe fibrosis is more likely in males

In mild chronic hepatitis C, liver biopsy may not be required as guidelines now suggest that treatment can be initiated early and routinely [5].
If a watchful waiting strategy without treatment is adopted for mild chronic disease, an interval liver biopsy can be considered to determine whether (and when) fibrosis reaches a moderate stage [5].
Reference:

10 Discuss treatment options with patient

Quick info:
Discuss treatment options with patient:
- as well as considering antiviral treatment, patients should be vaccinated against hepatitis A and B if they are not already immune or infected [10]
- co-infection with hepatitis A or B worsens prognosis of hepatitis C [3]
- first-line treatment for moderate or severe chronic hepatitis C is combination therapy [2-4] with ribavirin and either:
  - peginterferon alpha-2a; or:
  - peginterferon alpha-2b
- if ribavirin is contraindicated or not tolerated, consider monotherapy with peginterferon alpha-2a or peginterferon alpha-2b [2,4,8]
- based on lack of evidence, treatment with peginterferon alpha cannot be recommended in people [5]:
  - under age 18 years
  - following a liver transplant
- subsequent courses of treatment are recommended, where appropriate, following first course of combination or monotherapy with peginterferon alpha [5]

Discuss effects of treatment, including:
- efficacy [5]
- adverse effects, eg:
  - flu-like symptoms early in therapy, eg:
    - fever [2]
    - myalgia [2]
    - rigors [3]
    - arthralgia [2]
    - headache [2]
  - possible consequences of adverse effects on daily life, work, etc [7]
  - psychological ill effects with depression later in therapy [3]

References:
11  Patient agrees to treatment - ensure baseline investigations complete

Quick info:
Ensure the following baseline investigations are completed prior to initiating therapy [5]:
- full blood count (FBC) and differential
- platelet count
- liver function tests (LFTs)
- uric acid
- serum creatinine and estimated glomerular filtration rate (eGFR)
- auto-antibodies
- thyroid function tests (TFTs)
- pregnancy test
- retinoscopy
- hepatitis C virus (HCV) genotype – determine prior to combination therapy
- HIV – consider testing in high-risk groups as people with co-infection (HCV and HIV) should have early consideration for antiviral therapy, irrespective of their genotype

Reference:

12  Patient declines treatment - advise regular follow-up

Quick info:
Follow-up:
- encourage patient to continue attending clinic for follow-up [3,10]
- 3 to 6-monthly clinical and biochemical monitoring is recommended:
  - the type and frequency of monitoring depends on the individual clinical scenario [5]
  - counselling and support on lifestyle issues relating to hepatitis C should be available [10]

References:
Overview

This document describes the provenance of Map of Medicine's Hepatitis C care map.

This Map of Medicine care map is scheduled to be updated every 37 months, the process beginning 30 months after the last scheduled update. Between scheduled updates, interim updates are possible should important information come to light.

Published: 29 April 2011
Interim update: None
Next scheduled update: 31 May 2014

For information on changes in the last scheduled update and any interim updates, see the information point entitled 'Updates to this care map' on each page of the care map.

To cite this care map, use the following format:


Accreditations

There are two levels of accreditation available to a care map:

- Accreditation of the clinical content by a relevant professional group (optional)
- Accreditation of the editorial methodology used

The editorial methodology used to create this care map is accredited by:

The Chief Knowledge Officer of the NHS

Disclaimer

Editorial methodology

Map of Medicine uses critically-appraised secondary literature when constructing its care maps. The initial search for secondary literature is within Medline and EMBASE and of websites of known producers of guidelines. The search goes back ten years. The drafted care map is then checked by individuals with front-line clinical experience (see Contributors section of this document). Such individuals can nominate further references to be added to a care map; these are clearly marked (E) to indicate they were recommended by experienced colleagues. The resulting care map is peer reviewed before publication.

After publication, Map of Medicine runs searches of secondary literature sources every two months, which include critical appraisal of the results to determine whether the care map requires an interim update in response to new, important information. Information not deemed to require an interim update is considered as part of the scheduled update. The same process is applied to feedback received from users.
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References

This care map has been developed according to the Map of Medicine editorial methodology (http://mapofmedicine.com/whatisatemap/editorialmethodology). The content of this care map is based on high-quality guidelines [1-4,6,8,9-11]. Practice-based knowledge has been added by Map of Medicine (MoM) Clinical Editorial team and Fellows [5] and contributors with front-line clinical experience [7]:


7. Contributors representing the Department of Health (DH) National Liver Disease Strategy (NLDS); 2011. [E]


The classification employed by Map of Medicine is as follows:

[G] guideline
[M] meta-analysis
[S] systematic review
[A] randomised controlled trial
[B] nonrandomised prospective study
[C] retrospective study
[Q] cost- or decision-analysis
[P] performance measure or policy document
[E] practice-based information (expert opinion)

Contributors

Map of Medicine’s care maps are created by individuals with knowledge of evidence-based medicine together with individuals with practice-based knowledge. The former are members of Map of Medicine’s editorial team, the latter are named as contributors.

Selected members of Map of Medicine Clinical Editorial team and Fellows.

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Conflicts of interest:
Conflict of interests can be found on the Map of Medicine corporate website (www.mapofmedicine.com)

Mr Charles Gore: Chief Executive, The Hepatitis C Trust, London, UK.

Conflicts of interest:
In participating in the development of the MoM HCV care map I have no conflict of interest since I am a HCV patient running a HCV charity entirely for the benefit of HCV patients. However, there might be some perceived conflict of interest in that The Hepatitis C Trust has received some unrestricted funding from Roche, MSD and Janssen, all makers of HCV drugs and I have been supported by them with small travel grants.

Dr Stephen David Ryder: Consultant Hepatologist, Nottingham University Hospitals NHS Trust, Nottingham, UK.

Conflicts of interest:
I have no conflicts of interest to declare

Disclaimers

The Chief Knowledge Officer of the NHS
It is not the function of the Chief Knowledge Officer of the NHS to substitute for the role of the clinician, but to support the clinician in enabling access to know-how and knowledge. Users of the Map of Medicine are therefore urged to use their own professional judgement to ensure that the patient receives the best possible care. Whilst reasonable efforts have been made to ensure the accuracy of the information on this online clinical knowledge resource, we cannot guarantee its correctness or completeness. The information on the Map of Medicine is subject to change and we cannot guarantee that it is up-to-date.