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| **CLINICAL GUIDELINE** |
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| **British Association of Sexual Health and HIV Guidelines on the Management of Viral Hepatitis 2025** |
|  |
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1. CONTENTS

[1. CONTENTS 3](#_Toc189469166)

[2. ABSTRACT 7](#_Toc189469167)

[3. ABBREVIATIONS 8](#_Toc189469168)

[4. WHAT IS NEW IN THE 2025 GUIDELINE? 11](#_Toc189469169)

[5. INTRODUCTION AND METHODOLOGY 12](#_Toc189469170)

[5.1. Objectives 12](#_Toc189469171)

[5.2. Search Strategy 12](#_Toc189469172)

[5.3. Methods 12](#_Toc189469173)

[5.4. Equality Impact Assessment 13](#_Toc189469174)

[5.5. Stakeholder Involvement, Piloting and Feedback 13](#_Toc189469175)

[6. SUMMARY OF RECOMMENDATIONS 15](#_Toc189469176)

[6.1. Acute Viral Hepatitis in Sexual Health Clinics 15](#_Toc189469177)

[6.2. Assessment of HAV Immunity 15](#_Toc189469178)

[6.3. HAV Vaccination 15](#_Toc189469179)

[6.4. HBV Screening 16](#_Toc189469180)

[6.5. HBV Vaccination 16](#_Toc189469181)

[6.5.1. HBV Vaccine Schedules 17](#_Toc189469182)

[6.6. People with HBV (HBsAg Positive) 17](#_Toc189469183)

[6.7. Use of HIV PrEP in People with HBV Infection 18](#_Toc189469184)

[6.8. HCV Screening 18](#_Toc189469185)

[6.9. People with Positive Anti-HCV 19](#_Toc189469186)

[6.10. People with Positive HCV RNA or Core Antigen 19](#_Toc189469187)

[6.11. HCV Screening for Individuals with Past HCV Infection 19](#_Toc189469188)

[7. PREVENTION OF HEPATITIS A/B IN SEXUAL HEALTH 20](#_Toc189469189)

[7.1. HAV and HBV: Vaccination in Sexual Health 20](#_Toc189469190)

[7.2. HAV: Vaccination 20](#_Toc189469191)

[7.3. HAV: Management of Contact with Acute Hepatitis A 21](#_Toc189469192)

[7.4. HBV: Vaccination 21](#_Toc189469193)

[7.5. HBV Vaccination as Primary Prevention: Choice of Vaccine and Schedule 23](#_Toc189469194)

[7.6. Assessing HBV Vaccine-induced Immunity 24](#_Toc189469195)

[7.7. Incomplete HBV Vaccinations 24](#_Toc189469196)

[7.8. HBV: Vaccination in People with HIV 24](#_Toc189469197)

[7.9. HBV: Post-exposure Management of Contacts 25](#_Toc189469198)

[7.9.1. Vaccination as HBV PEP 25](#_Toc189469199)

[7.9.2. Specific HBIG 25](#_Toc189469200)

[7.9.3. General Advice for Contacts of HBV 26](#_Toc189469201)

[8. HEPATITIS A VIRUS INFECTION 27](#_Toc189469202)

[8.1. New in Hepatitis A Section 27](#_Toc189469203)

[8.2. Background 27](#_Toc189469204)

[8.3. Risk Factors and Epidemiology 27](#_Toc189469205)

[8.4. Acute HAV 28](#_Toc189469206)

[9. HEPATITIS B VIRUS INFECTION 31](#_Toc189469207)

[9.1. New in Hepatitis B Section 31](#_Toc189469208)

[9.2. Background 31](#_Toc189469209)

[9.3. Transmission 33](#_Toc189469210)

[9.4. Incubation Period and Window Period 33](#_Toc189469211)

[9.5. Acute HBV 34](#_Toc189469212)

[9.6. Chronic HBV 35](#_Toc189469213)

[9.6.1. Chronic HBV: Phases of Infection 35](#_Toc189469214)

[9.7. Progression risk to Cirrhosis and of HCC 36](#_Toc189469215)

[9.8. Co-infections with Chronic HBV 36](#_Toc189469216)

[9.8.1. Acute HAV 36](#_Toc189469217)

[9.8.2. HCV Infection 37](#_Toc189469218)

[9.8.3. HDV Infection 37](#_Toc189469219)

[9.8.4. HIV 37](#_Toc189469220)

[9.9. HBV: Screening in Sexual Health Settings 37](#_Toc189469221)

[9.9.1. Who to Screen for HBV in Sexual Health Settings? 37](#_Toc189469222)

[9.9.2. Which Tests to Perform for Chronic HBV Screening and Immunity Status?121-123 38](#_Toc189469223)

[9.9.3. How to Manage the Results? 38](#_Toc189469224)

[9.10. HBV: Management 39](#_Toc189469225)

[9.10.1. General Advice 39](#_Toc189469226)

[9.11. Chronic HBV: Initial Management in Sexual Health Settings 40](#_Toc189469227)

[9.12. Chronic HBV: Further Management (Usually Via Hepatology Specialist) 40](#_Toc189469228)

[9.12.1. Goals of Therapy 40](#_Toc189469229)

[9.12.2. Treatment 40](#_Toc189469230)

[9.12.3. HIV/HBV Coinfection 40](#_Toc189469231)

[9.12.4. Pregnancy and Breastfeeding 40](#_Toc189469232)

[9.13. Chronic HBV: Monitoring and Surveillance 41](#_Toc189469233)

[9.14. PrEP and PEP for HIV Infection in Individuals with HBV 127, 131 41](#_Toc189469234)

[10. HEPATITIS DELTA INFECTION 43](#_Toc189469235)

[10.1. HDV: Epidemiology and Transmission 43](#_Toc189469236)

[10.2. HDV: Risk Factors 43](#_Toc189469237)

[10.3. HDV: Investigations 43](#_Toc189469238)

[10.4. HDV: Management 44](#_Toc189469239)

[11. HEPATITIS C INFECTION 45](#_Toc189469240)

[11.1. New in Hepatitis C section 45](#_Toc189469241)

[11.2. Hepatitis C: Background and Epidemiology 45](#_Toc189469242)

[11.3. HCV: Transmission 46](#_Toc189469243)

[11.3.1. Parenteral Transmission 46](#_Toc189469244)

[11.3.2. Sexual Transmission 46](#_Toc189469245)

[11.3.3. Vertical Transmission 47](#_Toc189469246)

[11.3.4. Other Groups with Increased HCV Transmission 48](#_Toc189469247)

[11.4. HCV: Incubation Period 48](#_Toc189469248)

[11.5. HCV: Symptoms 48](#_Toc189469249)

[11.6. HCV: Who to Test for HCV in Sexual Health Settings? 49](#_Toc189469250)

[11.7. HCV Screening and Diagnostics: Which Tests to Perform? 49](#_Toc189469251)

[11.8. HCV: Further Investigations in Sexual Health Services 50](#_Toc189469252)

[11.9. HCV: Management 50](#_Toc189469253)

[11.10. HCV: Treatment 51](#_Toc189469254)

[11.11. Recognising and Managing Recently-acquired HCV 51](#_Toc189469255)

[11.12. HCV: Partner Notification and Contact Tracing 52](#_Toc189469256)

[11.13. HCV: Advice for People with Active HCV 53](#_Toc189469257)

[11.14. HCV: Primary Prevention 53](#_Toc189469258)

[11.15. HCV: Reinfection 54](#_Toc189469259)

[12. GUIDELINE APPLICATION 55](#_Toc189469260)

[13. AUDITABLE OUTCOME MEASURES 56](#_Toc189469261)

[14. RESOURCE IMPLICATIONS OF THESE GUIDELINES 57](#_Toc189469262)

[15. QUALIFYING STATEMENT 58](#_Toc189469263)

[16. REVIEW ARRANGEMENTS 58](#_Toc189469264)

[17. DISCLOSURES 59](#_Toc189469265)

[17.1. Acknowledgements 59](#_Toc189469266)

[17.2. Declaration of Conflicting Interests 59](#_Toc189469267)

[17.3. Funding 59](#_Toc189469268)

[17.4. Editorial Independence 59](#_Toc189469269)

[17.5. Membership of the Clinical Effectiveness Group 59](#_Toc189469270)

[17.6. ORCID ID 59](#_Toc189469271)

[18. TABLES AND FIGURES 60](#_Toc189469272)

[19. REFERENCES 66](#_Toc189469273)

[APPENDIX 1: GRADE System for Assessing Evidence 74](#_Toc189469274)

[APPENDIX 2: Equality Impact Assessment Table 79](#_Toc189469275)

[APPENDIX 3: AGREE II User Manual 81](#_Toc189469276)

[APPENDIX 4: Pilot Feedback Form 83](#_Toc189469277)

1. ABSTRACT

The 2025 British Association for Sexual Health and HIV (BASHH) guidelines for the management of viral hepatitis are in line with current evidence and practice within the United Kingdom. We provide evidence-based recommendations for the prevention, diagnosis and initial management of viral hepatitis A, B, C and D. Key updates are detailed at the start of the article.

**Keywords:** hepatitis virus; antiviral; vaccine.

1. ABBREVIATIONS

|  |  |
| --- | --- |
| AASLD | American Association for the Study of Liver Disease |
| AGREE II | Appraisal of Guidelines, Research and Evaluation |
| ALF | Acute Liver Failure |
| ALT | Alanine Transaminase |
| Anti-HBc | Antibody Against Hepatitis B core antigen |
| Anti-HBe | Antibody Against Hepatitis B ‘e’ antigen |
| Anti-HBs | Antibody Against Hepatitis B surface antigen |
| Anti-HCV | Antibody Against HCV |
| Anti-HDV | Antibody Against HDV |
| Anti-HEV | Antibody Against HEV |
| ART | Antiretroviral Therapy |
| BASHH | British Association for Sexual Health and HIV |
| BHIVA | British HIV Association |
| CDC | Centers for Disease Control and Prevention |
| CEG | Clinical Effectiveness Group |
| CrI | Credible Interval |
| DAA | Direct acting antiviral |
| DBS | Dried Blood Spot |
| DNA | Deoxyribonucleic Acid |
| EASL | European Association for the Study of the Liver |
| ECDC | European Centre for Disease Prevention and Control |
| EU | European Union |
| GBL | Gamma-butyrolactone |
| GBMSM | Gay, bisexual or other men who have sex with men |
| GHB | Gamma-hydroxybutyric Acid |
| GPP | Good practice point |
| GRADE | Grading of Recommendations, Assessment, Development, and Evaluation |
| GUMCAD | Genitourinary Medicine Clinic Activity Dataset |
| HAV | Hepatitis A Virus |
| HAV-IgM/G | HAV–specific Immunoglobulin Type M/G |
| HBeAg | Hepatitis B ‘e’ Antigen |
| HBIG | Hepatitis B Immunoglobulin |
| HBsAg | Hepatitis B Surface Antigen |
| HBV | Hepatitis B Virus |
| HBV-DNA | Hepatitis B Virus Deoxyribonucleic Acid |
| HCC | Hepatocellular Carcinoma |
| HCV | Hepatitis C Virus |
| HCV Ag | Hepatitis C Core Antigen |
| HCV-RNA | Hepatitis C Virus Ribose Nucleic Acid |
| HDV | Hepatitis Delta Virus |
| HEV | Hepatitis E Virus |
| HIV | Human Immunodeficiency Virus |
| HIVPA | HIV Pharmacy Association |
| HNIG | Human Normal Immunoglobulin |
| IgG | Immunoglobulin Type G |
| IgM | Immunoglobulin Type M |
| IUSTI | International Union Against Sexually Transmitted Infection |
| LFT | Liver Function Test |
| LGV | Lymphogranuloma Venereum |
| NHS | National Health Service |
| NICE | National Institute for Health and Care Excellence |
| PCR | Polymerase Chain Reaction |
| PEP | HIV Post-exposure Prophylaxis |
| POCT | Point-of-Care Testing |
| PrEP | HIV Pre-exposure Prophylaxis |
| RNA | Ribonucleic Acid |
| PWID | People Who Inject Drugs |
| SSHA | Society of Sexual Health Advisers |
| STI | Sexually Transmitted Infection |
| TAF | Tenofovir Alafenamide |
| TDF | Tenofovir Disoproxil Fumarate |
| UKHSA | UK Health Security Agency |
| US | United States |
| WHO | World Health Organisation |

1. WHAT IS NEW IN THE 2025 GUIDELINE?

* Offer screening for chronic hepatitis B virus (HBV) infection to all sexual health clinic attendees at least once;
* Expanded recommendation for opportunistic HBV vaccination as prevention in those with ongoing risk of sexually-transmitted HBV;
* Updated recommendations to include novel HBV vaccines in sexual health clinics;
* Guidance on use of human immunodeficiency virus (HIV) post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) in people with chronic HBV infection;
* Updated recommendations for hepatitis C virus (HCV) testing in sexual health clinics;
* Reduced detail on use of antiviral therapies in hepatitis B and C management. Clinicians should refer to European Association for the Study of the Liver (EASL) Guidelines.[1](#_ENREF_1), [2](#_ENREF_2)

1. INTRODUCTION AND METHODOLOGY
   1. Objectives

The objective of this guideline is to answer health questions about how to prevent, diagnose and manage viral hepatitis care within a sexual health service and to support the development of appropriate local care pathways. The guideline is primarily for use by clinicians and policymakers in sexual health services within the United Kingdom (UK). It is recommended that management of people diagnosed with viral hepatitis is via local pathways agreed with Hepatologists.

The guideline offers recommendations for the prevention, diagnosis and initial management of viral hepatitis A, B, C and D. This is an update to the 2017 British Association for Sexual Health and HIV (BASHH) National Guidelines for the Management for Viral Hepatitides.[3](#_ENREF_3)

The guideline is aimed primarily at patients aged 16 years or older presenting to healthcare professionals working in departments offering specialist level 3 care in sexually transmitted infections (STIs) management within the UK. However, the principles of the recommendations are applicable across levels of STI care providers, and non-specialist services may need to develop, where appropriate, local referral pathways

* 1. Search Strategy

This guideline was produced according to specifications set out in the Clinical Effectiveness Group’s (CEG) document ‘Framework for guideline development and assessment’ (2015, updated 2019) accessed at <https://www.bashh.org/_userfiles/pages/files/resources/2020_guidelines_framework.pdf>.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE, refer to APPENDIX 1 system was used to assess the evidence and make recommendations as detailed in the guidance.

* 1. Methods

This work reviews and updates the 2017 BASHH guidelines[3](#_ENREF_3) and incorporates the findings of a comprehensive literature review on hepatitis A, B, C and D infections. In addition, sections on hepatitis in relevant national and international guidelines were reviewed including the European International Union Against STI (IUSTI) Guideline for the Management of Hepatitis B and C infections in Sexual Health Settings 2017[4](#_ENREF_4); the EASL Guidelines for the Management of Hepatitis B[1](#_ENREF_1) and Hepatitis C[2](#_ENREF_2); the British HIV Association (BHIVA) guidelines for the Management of Hepatitis Viruses (2013)[5](#_ENREF_5), the American Association for the Study of Liver Disease (AASLD) Guidelines for Hepatitis B[6](#_ENREF_6) and Hepatitis C[7](#_ENREF_7) and the BHIVA guidelines on Use of Vaccines in people living with HIV[8](#_ENREF_8). Vaccine updates were cross-referenced with the Green Book.[[9](#_ENREF_9)](#_ENREF_9) Forward and backward searching from key references was also conducted. All writing group members underwent GRADE training. The strength of the recommendation is graded as 1 (strong) or 2 (weaker/conditional) and the quality of the evidence is graded from A (high‑quality) to D (low-quality). Good practice points (GPP) are recommendations based on the clinical judgement of the working group. The recommendations are the result of a series of meetings of the writing committee and incorporate input from the public consultation process (comments available on request).

* 1. Equality Impact Assessment

An assessment of the guideline and its recommendations was undertaken to ensure the principles of equality and diversity were adhered to and is available in APPENDIX 2.

The BASHH has adopted an anatomical approach without assuming gender in the majority of guidelines and uses gender terminology in line with BASHH ‘sexual health standards for trans, including non-binary, people’.

* 1. Stakeholder Involvement, Piloting and Feedback

The guideline working group included patient representatives; clinicians from Sexual Health/HIV, Infectious Diseases, Hepatology, Virology; representatives from BASHH, BHIVA, Society of Sexual Health Advisers (SSHA), HIV Pharmacy Association (HIVPA), The Hepatitis C Trust and UK Health Security Agency (UKHSA).

The first draft was produced by the writing group and then circulated to the BASHH CEG for review using the Appraisal of Guidelines, Research and Evaluation (AGREE, refer to APPENDIX 3) tool. The second draft of the guideline was posted on the BASHH website for wider consultation (two months) and any comments received during the consultation period were reviewed by the authors and acted on appropriately. The document was also reviewed by a patient representative, target users and the public panel of BASHH, and their feedback was considered by the authors and used to inform the guideline. The final draft was presented to the CEG for review and piloting in sexual health clinics.

Once the guideline is published, the CEG will keep it under review should critical new evidence become available that affects the current recommendations. The guideline will be formally reviewed and updated, if necessary, every five years.

1. SUMMARY OF RECOMMENDATIONS
   1. Acute Viral Hepatitis in Sexual Health Clinics

* If acute viral hepatitis is suspected, we recommend the following tests to establish hepatitis aetiology and assess severity: liver function tests (LFT), clotting, hepatitis A virus‑specific immunoglobulin type M (HAV-IgM), hepatitis B surface antigen (HBsAg), antibody against hepatitis B core antigen (anti-HBc) IgM, antibody against HCV (anti-HCV), HCV ribonucleic acid (RNA)/core antigen, antibody against hepatitis E virus (anti-HEV) and HEV RNA (**1B**);
* Following clinical assessment, a management plan for acute viral hepatitis should be devised in conjunction with Hepatology (**1A**);
* Public health authorities should be notified (**1C**);
* Perform contact tracing in conjunction with public health colleagues where appropriate. (**1C**).
  1. Assessment of HAV Immunity
* We recommend HAV immunity and vaccine assessment for the following people: gay, bisexual or other men who have sex with men (GBMSM), trans women who have sex with men, people who inject drugs (PWID), people with HBV, HCV or HIV (**1B**);
* Screening for pre-existing HAV immunity before vaccination may be performed in a non-outbreak situation if the person is likely to re-attend (**2B**);
* If HAV antibody test is performed, the first dose of vaccine can be given at the same time. (**1B**) The antibody result will aid decision-making regarding further doses.
  1. HAV Vaccination
* HAV monovalent vaccine schedule: 2 doses (at 0, 6-12 months) provide 95% protection for at least 10 years. (**1A**) If using Twinrix® a 3-dose schedule should be used;
* There is increasing evidence that HAV vaccine-induced immunity may be >25 years and possibly lifelong, so no further booster doses are needed after the primary course in immunocompetent individuals (**1B**).
  1. HBV Screening
* We recommend that all sexual health clinic attendees should be offered testing for chronic HBV infection at least once (**1D**);
* We recommend HBsAg +/- anti-HBc are used to screen for the presence of chronic HBV infection (**1B**);
* We recommend hepatitis B surface antigen antibody (anti-HBs) titre and anti‑HBc tests are performed to assess HBV immunity in those eligible for vaccination to aid decision making for subsequent doses of vaccine (**1B**).
  1. HBV Vaccination
* We recommend prophylactic HBV vaccination (**1B**) for:
  + GBMSM, trans people who have sex with men;
  + Sex workers;
  + People requesting HIV PEP/PrEP;
  + People from, or with sexual partners from, countries of HBV prevalence >2% (see Figure 1)
  + People who have injected drugs or who are smoking heroin/crack cocaine;
  + People with HIV;
  + Close contacts of people with HBV or at increased risk of HBV;
  + Prisoners;
  + Immigration detainees;
  + People with chronic liver disease.
* We recommend clinicians consider opportunistic prophylactic HBV vaccination for people who may be at increased risk of sexual HBV acquisition including (**GPP**):
  + People with more than one sexual partner during the previous 3 months;
  + People seeking treatment for a STI.
* We recommend HBV vaccination is initiated promptly following potential HBV exposure (**GPP**):
  + After sexual assault;
  + After occupational/community risk exposures.
    1. HBV Vaccine Schedules
* We recommend people commence an HBV vaccine course which provides optimal uptake, completion and immunity in accordance with schedules published in the Green Book (see Section 217.4).[10](#_ENREF_10) (**GPP**)
* HBV-monovalent or combined HAV/HBV vaccines have been widely used in sexual health services for HBV prevention.
* The recommended schedules for conventional HBV vaccines include:
  + HBVaxPRO® and Engerix B® preferred accelerated course (doses at 0, 1, 2, 12 months), alternative course (0, 1, 6 months);
  + If need to provide rapid immunity, the super accelerated or very rapid schedule can be used: Engerix B® or Twinrix Adult® (0, 1, 3 weeks and 12 months);
  + For people with HIV or renal insufficiency, HBVaxPRO® 40 mcg, Engerix B® 40 mcg dose or Fendrix adjuvanted 20 mcg can be used (schedule 0, 1, 2, 6 months);
  + Heplisav B®, an HBV vaccine with a novel adjuvant and faster 2-dose schedule has demonstrated superior immunogenicity when compared with Engerix B®. If available, Heplisav B® (0, 1 month) may be preferred in those who are likely to have a poorer response to vaccine, have not responded to other monovalent vaccines, where a rapid response is required or if compliance may be an issue. (**GPP**).
  1. People with HBV (HBsAg Positive)
* Check for HAV immunity and vaccinate if non-immune (**1D**);
* Test for HIV, HCV and hepatitis delta virus (HDV) infection (**1D**);
* Test for other sexual infections; (**1D**)
* Refer to Hepatology specialist for ongoing management and hepatocellular carcinoma (HCC) surveillance (**1B**);
* Partner notification and contact tracing (**1B**);
* Provide information on HBV, alcohol avoidance and transmission (**GPP**).
  1. Use of HIV PrEP in People with HBV Infection
* HIV PrEP may be initiated while HBV serology results are pending (**GPP**);
* Any individual found to be HBsAg positive should be referred to a Hepatology specialist service whilst remaining on PrEP (**GPP**);
* People with chronic HBV taking HIV PrEP are recommended to use daily dosing, NOT event-based dosing schedules (**1D**);
* There is a risk of HBV rebound viraemia and liver dysfunction upon stopping PrEP in people with HBV infection. The management of stopping PrEP should be discussed in advance with a Hepatology specialist. (**GPP**)
  1. HCV Screening
* Testing individuals from the following groups for HCV infection is recommended in (**1B**):
  + People with a past/current history of injecting drug use;
  + People with HIV;
  + GBMSM with risk factors for acquiring HCV (see further details section 11.3.2);
  + People with a history of HBV, syphilis or lymphogranuloma venereum (LGV);
  + People born in a country of intermediate or high HCV prevalence.
* Consider testing individuals with other risk factors for HCV acquisition (**2D**):
  + People with a history of intranasal/inhaled recreational drug use; have exchanged sex for money, goods or favors; have experienced homelessness; have been in prison or other secure/detained settings; with parenteral exposures in unregulated settings (e.g. tattoos, piercings); with a possible healthcare‑related exposure in a low- or middle- income country (e.g. non‑sterile needle use).
  1. People with Positive Anti-HCV
* Confirm active HCV infection using HCV RNA or core antigen. (**1B**).
  1. People with Positive HCV RNA or Core Antigen
* Check for HAV and HBV immunity and vaccinate if non-immune (**1D**);
* Test for HIV infection (**1D**);
* Test for other sexual infections. (**1D**);
* Refer to Hepatology specialist for ongoing management and antiviral therapy;
* Partner notification and contact tracing;
* Provide information on HCV, alcohol avoidance and transmission.
  1. HCV Screening for Individuals with Past HCV Infection
* Use HCV RNA or core antigen testing for individuals with ongoing risk for HCV reinfection. (**1D**)

1. PREVENTION OF HEPATITIS A/B IN SEXUAL HEALTH
   1. HAV and HBV: Vaccination in Sexual Health

Table 1 presents a summary of HAV and HBV vaccination in sexual health.

* 1. HAV: Vaccination
* We recommend that all GBMSM, trans women who have sex with men, people who have injected drugs, people with HBV, HCV and/or HIV attending a sexual health clinic should be opportunistically offered HAV vaccine, where available, unless they have documented evidence of two doses of HAV vaccine or of previous HAV illness.[11](#_ENREF_11)
* Screening for pre-existing HAV exposure before vaccination has been found to be cost‑effective in one study and therefore may be performed, depending on other factors such as funding, local epidemiology and clinic access.[12](#_ENREF_12) (**2B**) Data from the ANRS IPERGAY trial document that out of 427 men who have sex with men (median age 34.8 years), 50.1% were not immune to HAV at baseline, and lack of immunity was associated with younger age.[13](#_ENREF_13)
* If HAV antibody test is performed, or if it is likely that the individual will not return, the first dose of vaccine should be given at the same time. (**1B**) The antibody result will aid decision making regarding further doses.[14](#_ENREF_14)
* To prevent sustained outbreaks, it is estimated that at least 70% of GBMSM should have HAV immunity.[15](#_ENREF_15)
* Vaccination should be obtained via alternative sources e.g. primary care or travel clinic for people with travel or occupational risk.
* HAV vaccine schedule: doses at 0 and 6-12 months confers 95% protection for at least ten years. (**1A**) There is increasing evidence that vaccine induced immunity may be >25 years and possibly lifelong, so no further booster doses are needed after the primary course in immunocompetent patients.[11](#_ENREF_11), [16](#_ENREF_16) (**1B**)
* People with HIV respond to HAV vaccine (as demonstrated by antibody production in 46-88%) but titres are lower than in HIV-negative individuals, and correlate with CD4 count.[17](#_ENREF_17), [18](#_ENREF_18)
* Patients vaccinated with a low CD4 count (<300 cells/µL), should be revaccinated if CD4 count rises above 500/µL as a result of effective HIV treatment, if their HAV immunoglobulin type G (IgG) remains negative at retesting.[[17](#_ENREF_17), [19-21](#_ENREF_19)](#_ENREF_13) (**1C**)
* Side effects of hepatitis A vaccines: these are usually mild and likely only for the first few days following immunisation. Very common side effects can include mild injection site pain and redness. Common side effects include fever, myalgia, headache, nausea, vomiting, decreased appetite, diarrhoea and abdominal pain.
  1. HAV: Management of Contact with Acute Hepatitis A
* Non-immune contacts (no history of vaccination or lab-confirmed immunity) maybe given HAV vaccine up to 14 days following exposure, providing exposure took place within the source’s period of infectiousness (i.e. during the prodromal illness or first week of jaundice).[[11](#_ENREF_11)](#_ENREF_11) (**1A**)
* For exposures presenting at beyond 14 days, HAV vaccine should be offered to those with chronic liver disease and to members of the household if there is >1 contact to prevent tertiary cases.[[11](#_ENREF_11)](#_ENREF_11) Vaccine should also be offered to those at ongoing sexual risk.
* Human normal immunoglobulin (HNIG) 1000 mg intramuscularly should be considered in addition to HAV vaccine for patients who are less able to respond to the vaccine or are at higher risk of complications (e.g. concurrent chronic HBV or HCV, chronic liver disease, patients with advanced HIV (CD4+ cell count <200 cells/µL) or other forms of immunosuppression, or age >60 years).[[11](#_ENREF_11)](#_ENREF_11) (**1A**)
* HNIG works best if given in the first few days after first contact with an efficacy of 90% and is unlikely to give any protection if given more than two weeks after first exposure, but may reduce disease severity if given up to 28 days after exposure.[[11](#_ENREF_11)](#_ENREF_11) Where HNIG is being considered, prompt discussion with Virology and Public Health authorities is recommended.[[22](#_ENREF_22)](#_ENREF_22)
  1. HBV: Vaccination

We recommend prophylactic HBV vaccination for the following people, if non-immune, in sexual health settings.[[10](#_ENREF_10), [23-33](#_ENREF_23)](#_ENREF_22) (1A)

* GBMSM, trans people who have sex with men;
* Sex workers;
* People requesting HIV PEP/PrEP;
* People from, or with sexual partners from, countries of HBV prevalence >2%;
* People who have injected drugs or who are smoking heroin/crack cocaine;
* People with HIV;
* Close contacts of people with HBV or at increased risk of HBV;
* Prisoners;
* Immigration detainees;
* People with chronic liver disease.

We recommend sexual health clinicians to consider opportunistic HBV vaccination for people who may be at increased risk of sexual HBV acquisition (GPP) including:[10](#_ENREF_10), [33](#_ENREF_33), [34](#_ENREF_34)

* People with more than one sexual partner during the previous three months;
* People seeking treatment for a STI.
* **It is acknowledged that this recommendation may have logistical and/or financial implications for sexual health services**.

HBV vaccination should be initiated promptly following potential HBV exposure:

* After sexual assault;
* After occupational/community risk exposures.

In addition, the Green Book Chapter 18[10](#_ENREF_10)also recommends HBV vaccination for the following individuals:

* Foster carers and families adopting children from intermediate/high HBV prevalence countries;
* People receiving regular blood products and their carers;
* Recipients of solid organ transplants;
* People with chronic kidney failure (stage 4 or 5) or chronic liver disease;
* People resident in prison or detention centres;
* People in residential care for people with learning disabilities;
* Individuals with travel or occupational risk.

Side effects of hepatitis B vaccines: Very common side effects can include irritability, pain and redness at injection site and fatigue. Common side effects include loss of appetite, drowsiness, headache, nausea, vomiting, diarrhoea, abdominal pain and fever.

* 1. HBV Vaccination as Primary Prevention: Choice of Vaccine and Schedule

The recommended schedules for conventional HBV vaccines include:

* HBVaxPRO® and Engerix B® preferred accelerated course (doses at 0, 1, 2, 12 months), alternative course (0, 1, 6 months);
* If need to provide rapid immunity, the super accelerated or very rapid schedule can be used: Engerix B® or Twinrix Adult® (0, 1, 3 weeks and 12 months);
* For people with HIV or renal insufficiency, HBVaxPRO® 40 mcg, Engerix B® 40 mcg or Fendrix® adjuvanted 20 mcg can be used (schedule 0, 1, 2, 6 months);
* Fendrix® 20 mcg can also be used for others who have not responded to conventional vaccine (**1A**);[[35-38](#_ENREF_35)](#_ENREF_35)
* Heplisav B®, a HBV vaccine with a novel adjuvant and faster 2-dose schedule has demonstrated superior immunogenicity when compared with Engerix B®. Heplisav B® showed 95% protective immunity after two doses compared to 81.3% for Engerix B® 3‑dose schedule in people aged 18-55 years. Observational efficacy data has also been published showing 93.4% seroprotection after two doses of Hepislav B® in people with HIV on antiretroviral therapy (ART) when compared with 53.6% of people vaccinated using Engerix B®;[[39-41](#_ENREF_39)](#_ENREF_39)
* If available, Heplisav B® (0, 1 months) may be preferred in those who are likely to have a poorer response to vaccine, have not responded to other monovalent vaccines, where a rapid response is required or if compliance may be an issue. (**GPP**)
  1. Assessing HBV Vaccine-induced Immunity

Post vaccination immunity testing is not routinely recommended in the Green Book Chapter 18[[10](#_ENREF_10)](#_ENREF_10) as conventional vaccines are highly effective. Testing for HBV immunity should be performed for:

* People with HIV, renal insufficiency and immunosuppression;
* People presenting following a significant exposure;
* People considered to be at ongoing high risk of HBV acquisition (GPP).

The recommended time to check anti‑HBs titre is 4-8 weeks following the last dose of vaccine course.

Antibody responses vary widely between individuals (Table 2). It is preferable to achieve anti‑HBs levels >100 mIU/ml, although levels of 10 mIU/ml or more are generally accepted as enough to protect against infection.

Following a full primary course:

Responders with anti-HBs levels greater than or equal to 100 mIU/ml do not require any further doses. In immunocompetent individuals, once a satisfactory response has been established, further assessment of antibody levels is not indicated.

Responders with anti- HBs levels of 10 to 100mIU/ml should receive one additional dose of vaccine at that time (or whenever identified, even if years later). In immunocompetent individuals, further assessment of antibody levels or any booster are not required

An antibody level below 10mIU/ml (taken at the correct interval, one to two months after a primary course), is classified as a non-response to vaccine. In non-responders, a repeat course of vaccine is recommended, followed by retesting 4-8 weeks after the second course.

A low antibody level (<10 mIU/ml) in someone tested at the wrong interval, may not indicate non-response, as they may still have immune memory. If a booster is given, testing at the correct interval should be undertaken to inform future management. Interval titre checking and reinforcing doses should be considered for people in the following categories:

* People with HIV, renal insufficiency and immunosuppression;
* People presenting following a significant exposure.
* People with occupational risk
  1. Incomplete HBV Vaccinations

Evidence suggests that if vaccine courses are not completed in immunocompetent patients, the outstanding doses can be given years later without the need to restart a course. (**1B**). One or two doses of vaccine may provide immunity in 40% and over 90% of immunocompetent patients, respectively.[42](#_ENREF_42), [43](#_ENREF_43)

* 1. HBV: Vaccination in People with HIV
* People living with HIV show a reduced response rate to HBV vaccine and become anti‑HBs negative more quickly, although higher dose vaccine increase the response by 13%.[3](#_ENREF_3), [44-46](#_ENREF_44) (**1B**) Response correlates with CD4 count if not on ART but also with viral load and ART use. Vaccine response improves if the CD4 count rises, and the viral load is undetectable on ART.
* BHIVA recommends high dose vaccination (40 μg EngerixB® or HBvaxPro40®) or Fendrix® 20 mcg at 0, 1, 2, 6 months.[[47](#_ENREF_47)](#_ENREF_47) Only to use a single dose 0, 1, 3 weeks ultra‑rapid course if CD4 count >500 and a rapid course is essential. Anti-HBs levels should be measured 4-8 weeks after completion of the primary course, and regularly monitored at routine follow‑up.
  1. HBV: Post-exposure Management of Contacts

We recommend consulting the Green Book Chapter 18[[10](#_ENREF_10)](#_ENREF_10) for further information on HBV PEP. Recommendations depend upon the HBsAg status of the source, the vaccination status of the contact and timing of exposure. Where the presenting contact is non-immune or has unknown immunity after a single sexual or parenteral exposure to HBsAg positive index, baseline HBV serology should be undertaken and vaccination initiated whilst awaiting the results.

* + 1. Vaccination as HBV PEP
* Following an exposure, the accelerated course of recombinant vaccine should be offered to all sexual and household contacts as soon as possible, ideally within 24‑48 hours. Vaccination should also be offered following possible HBV exposure in occupational or community needlestick exposures.
* For PEP, an accelerated schedule of monovalent HBV vaccine (or a combined vaccine of equivalent strength) should be used, with vaccine given at 0, 1, 2 months. A dose at 12 months should be given if they remain at higher risk.[[10](#_ENREF_10)](#_ENREF_10)
* If previously partially vaccinated, one dose should be given immediately and the course completed.
* If previously fully vaccinated, a booster dose should be given if last dose was >1 year ago.
  + 1. Specific HBIG
* Contact details for hepatitis B immunoglobulin (HBIG) use are in the Green Book Chapter 18 supplies section.[[10](#_ENREF_10)](#_ENREF_10)
* HBIG provides passive immunity and can give immediate but temporary protection after exposure. HBIG does not affect the development of active immunity when given with HBV vaccine. If infection has already occurred at the time of immunisation, severe illness and development of chronic HBV may be prevented.
* HBIG is used after exposure to give rapid protection until HBV vaccine, which should be given at the same time, becomes effective. As vaccine alone is highly effective, the use of HBIG in addition to vaccine is only recommended in high-risk situations or in a known non-responder to vaccine. Whenever immediate protection is required, immunisation with the vaccine should be given.
* If indicated, HBIG works best within 12 hours and ideally within 48 hours. It is not indicated after 7 days.[10](#_ENREF_10), [48](#_ENREF_48), [49](#_ENREF_49) (**1A**)
* Any sexual partner of people with acute should be offered vaccine, and if seen within one week of last contact, should also be offered HBIG.
* HBIG dose for individuals >10 years old = 500 IU IM.[10](#_ENREF_10), [48](#_ENREF_48)
* HBIG is in limited supply in the UK.
  + 1. General Advice for Contacts of HBV
* Contacts should avoid sexual contact, especially unprotected penetrative sex, until it is shown that infection has not been acquired and it has been shown that vaccination has been successful (anti-HBs titres >10 IU/L).[10](#_ENREF_10), [30](#_ENREF_30), [50-55](#_ENREF_50) (**1D**)
* Discuss condom use and how to reduce the risk of catching HBV through avoiding needle sharing. (**1C**)

1. HEPATITIS A VIRUS INFECTION
   1. New in Hepatitis A Section

* Updated HAV epidemiology;
* Hepatitis A vaccine updates including booster doses and duration of immunity.
  1. Background

HAV belongs to the *Picornaviridae* family and is an RNA virus. It is particularly common in areas of the world with poor access to clean water and adequate sanitation. It is transmitted via faeco-oral route (via ingestion of contaminated food or water, or via close personal contact).[[56-62](#_ENREF_56)](#_ENREF_56)

* 1. Risk Factors and Epidemiology
* Non-immune travellers to areas with a high or intermediate prevalence[[63](#_ENREF_63)](#_ENREF_63), GBMSM linked to oro-anal or digital-rectal contact, individuals with multiple sexual partners, anonymous partners, sex in public places and group sex[[64-71](#_ENREF_64)](#_ENREF_64); people at occupational risk (e.g. sewage workers, laboratory personnel). More information for travel health can be found via the National Travel Health Network and Centre website (https://nathnac.net).
* Higher HAV viral load and more protracted HAV viraemia may occur with HIV, which may prolong faecal shedding and increase the risk of HAV transmission to others.[72-74](#_ENREF_72)
* People who experience homelessness; migrants; refugees; incarcerated persons.[[75](#_ENREF_75)](#_ENREF_75)
* People with chronic liver disease and older patients are at higher risk of adverse outcomes.[76](#_ENREF_76), [77](#_ENREF_77)
* Outbreaks have been reported amongst PWID[78](#_ENREF_78), in institutions for people with learning difficulties[79](#_ENREF_79), and following ingestion of contaminated food products e.g. shellfish, fruit and frozen berries.[80](#_ENREF_80)
* The European Centre for Disease Prevention and Control (ECDC) reported that between June 2016 and June 2017, 1,500 confirmed HAV cases and 2,660 probable or suspected cases were reported in the European Union (EU), predominantly among adult MSM. The viruses identified belonged to three separate clusters based on genetic sequencing of HAV: Event 1-Cluster VRD\_521\_2016, Spain; Event 2- Cluster RIVM‑HAV16-090 (‘Europride strain’) initially linked to men who have sex with men who participated in the EuroPride festival in Amsterdam (23 July to 7 August 2016); Event 3 -Cluster V16‑25801 (‘Berlin Strain’), initially reported in Berlin in November and December 2016.[81](#_ENREF_81)
* A total of 797 confirmed or probable cases were identified in England and Wales associated with the 2016 to 2018 outbreak in men who have sex with men. This incident was declared over in June 2018. A number of incidents of the outbreak spilling over into the community were also identified.[56](#_ENREF_56)
* In 2019, 503 laboratory confirmed cases of HAV infections were reported in England and Wales, with the greatest proportion (31.8%) from the London region.[56](#_ENREF_56)
* In 2021, ECDC reported 3,864 cases of HAV, with a notification rate of 0.9 cases per 100,000 population, which is the lowest number of reported case and notification rate since the beginning of EU surveillance in 2007. This was most likely due to the impact of the COVID19 pandemic, with reduced international travel, restaurant closures, and limited gatherings and social interactions.
  1. Acute HAV
* People with acute HAV may present to sexual health services. The incubation period can range from 15–45 days (average 28 days).
* People with acute HAV are most infectious for approximately two weeks before jaundice onset and one week after the period of jaundice.
* Up to half of adults are asymptomatic or have mild non-specific symptoms with little or no jaundice. The prodromal illness is characterised by flu-like symptoms (i.e. malaise, myalgia, fatigue), often with right upper abdominal pain. This phase lasts for 3-10 days. The icteric illness follows, which is characterised by jaundice, anorexia, nausea and fatigue. The icteric phase usually lasts for 1-3 weeks. It can persist for 12 or more weeks in a minority who have cholestatic symptoms (pruritus and jaundice).[[82](#_ENREF_82)](#_ENREF_82)
* Over 99% of people with HAV have full resolution of infection and immunity is presumed to be lifelong. Individuals may develop severe hepatitis during acute infection requiring hospitalisation but acute liver failure (ALF) is extremely rare and the overall mortality rate is <0.1%.[82](#_ENREF_82), [83](#_ENREF_83)
* HAV infection in pregnancy does not have any teratogenic effects but there is an increased rate of miscarriage and premature labour, proportional to the severity of the illness.[84](#_ENREF_84), [85](#_ENREF_85)
* Laboratory tests for suspected acute HAV should include serum HAV-IgM which usually remains positive for 45‑60 days.[86](#_ENREF_86), [87](#_ENREF_87) HAV-IgG does not distinguish between current or past infection and may remain positive for life.[86](#_ENREF_86) Liver function tests and clotting studies should be performed and results discussed with Hepatology colleagues. All individuals with suspected acute hepatitis should also be tested for other pathogens including (but not limited to) acute HBV, HCV and HEV.
* Most people with acute HAV can be managed as an outpatient, emphasising rest and oral hydration.[83](#_ENREF_83) Severe disease with vomiting, dehydration or signs of hepatic decompensation (change in conscious level or personality) requires hospital admission with specialist Hepatology input.[83](#_ENREF_83), [88](#_ENREF_88) (**1A**)
* Information should be provided with advice on minimising transmission to contacts.
* People are most infectious for two weeks before the onset of jaundice or other symptoms consistent with hepatitis if no jaundice (i.e. before the illness is recognised).[[22](#_ENREF_22)](#_ENREF_22)
* Sexual intercourse and food-handling should be avoided while infectious (from two weeks before to one week after the onset of jaundice) (**1B**). Employment should be considered.
* Acute HAV (and all forms of acute hepatitis) should be notified formally to the appropriate health protection team based on patient’s postcode.
* Screening for other STIs and assessing for other sexual health need (e.g. HIV PrEP) is recommended.[[70](#_ENREF_70)](#_ENREF_70)
* Pregnancy and Breast Feeding: pregnant women should be advised of the increased risk of miscarriage/premature labour and the need to seek medical advice if this happens.[63](#_ENREF_63), [84](#_ENREF_84), [85](#_ENREF_85)(**1B**) The risk from breast feeding is uncertain although there are no reported cases of HAV transmission from breast milk. Even if the infant acquires HAV, the disease is normally mild or asymptomatic. Therefore, the balance of risks between infection and stopping breast feeding should be considered on an individual basis. (**2C**)
* Partner notification should be performed for at-risk sexual contacts (i.e. oro/anal, digital/rectal and penetrative anal sex) within the period two weeks before, until one week after, the onset of jaundice. (**1D**) This should be recorded and the outcome documented at subsequent follow-up visits. Other at-risk individuals (e.g. household contacts, those at risk from shared food/water contamination) should be contacted via public health authorities.[[89](#_ENREF_89)](#_ENREF_89) (**1D**)
* For management of contact with acute HAV see section 7.3

1. HEPATITIS B VIRUS INFECTION
   1. New in Hepatitis B Section

* Updated HBV epidemiology;
* New recommendation to offer screening for chronic HBV infection to all adults attending sexual health services at least once;
* Expansion of targeted HBV vaccination to prevent morbidity and mortality from future HBV acquisition;
* Inclusion of novel HBV vaccines;
* Guidance on use of HIV PrEP in people with chronic HBV;
* Shortened section on HBV staging and management.
  1. Background
* HBV is an hepadna (deoxyribonucleic acid [DNA]) virus. It is endemic worldwide with variable prevalence (see Figure 1). In high prevalence regions, such as Southeast Asia, China and Sub‑Saharan Africa, up to 8% of the population have chronic HBV.[10](#_ENREF_10), [90](#_ENREF_90), [91](#_ENREF_91)
* HBV continues to be an important global cause of mortality, with 820,000 deaths attributed to HBV in 2019, predominantly from HCC and cirrhosis.[92](#_ENREF_92) In 2019, an estimated 296 million people (3.8%) were living with chronic HBV globally, with an incidence of 1.5million new infections annually.[92](#_ENREF_92) In the EU/EEA there were approximately 3.6 million people living with chronic HBV infection in 2024.[93](#_ENREF_93)
* In May 2016, the UK signed up to the World Health Organisation (WHO) Global Health Sector Strategy on Viral Hepatitis committing to meet targets that include a 90% reduction in incidence of hepatitis B infection and a 65% reduction in mortality from hepatitis B by 2030 from a 2015 baseline.[90](#_ENREF_90)
* In England there are an estimated 270,000 people living with chronic HBV, which equates to approximately 0.6% of the population, increasing to 1.5% in London. UKHSA figures demonstrate that over 95% of cases are amongst migrant populations, with infections acquired abroad. They may not present to services until they have advanced liver disease or attend for antenatal care.[94](#_ENREF_94)
* Other groups at higher risk include GBMSM, sex workers, PWID and people detained within prisons.[94](#_ENREF_94)
* Of those with newly diagnosed HBV infection in England (1999-2021), 57% were in men. The proportion aged 34 years and over increased from 41.2% in 1999 to 63.7% in 2021.[94](#_ENREF_94)
* The cascade of care for HBV in the UK (from testing, diagnosis to treatment) remains poorly understood and work is underway to estimate the proportion of people with chronic HBV that are unaware of the infection.[94](#_ENREF_94)
* Vaccination is the cornerstone of control of HBV in adult risk group populations and improved vaccine implementation and uptake is required in prisons, sexual health services for GBMSM, and drug services. The Green Book: Immunisation against Infectious Disease recommends HBV vaccination in people who change sexual partners frequently, GBMSM and sex workers.[90](#_ENREF_90)
* At sexual health clinics, rates of HBV vaccination coverage in GBMSM fell from 95% in 2008 to below 20% (varying between clinics) of non-immune first-time attendees receiving first dose HBV vaccination in 2019 based on Genitourinary Medicine Clinic Activity Dataset (GUMCAD) data. These rates fell further during COVID-19 pandemic.[94](#_ENREF_94)
* Between 2015 and 2021 an average of 350 acute HBV infections were reported annually to UKHSA (range 175 to 457). Since 2015, cases of acute hepatitis B in England have continued to decrease.[94](#_ENREF_94) In 2022, 213 cases of acute hepatitis B were reported across England (confirmed, probable and possible). Where information was provided, the most likely route of transmission was heterosexual then GBMSM.[95](#_ENREF_95)
* In 2022 a programme funded by National Health Service (NHS) England began opt‑out testing for blood borne viruses (HIV, HBV, HCV) in selected Emergency Departments in areas of very high HIV diagnosed prevalence across England. In the first two years, the highest number and proportion of new diagnoses was for HBV (1957 new HBV diagnoses). Similar to diagnosis in other settings, new HBV diagnoses were higher in men than women. A greater proportion of new HBV diagnoses through the programme were among people living in the most deprived quintiles compared to people diagnosed in other settings.[[96](#_ENREF_96)](#_ENREF_96)
* 2023 Centers for Disease Control and Prevention (CDC) recommendations include testing all adults over 18 years for chronic HBV at least once in their lifetime.[[97](#_ENREF_97)](#_ENREF_97)
  1. Transmission

HBV is transmitted by parenteral or mucosal exposure to HBV infected blood or body fluids.[[90](#_ENREF_90)](#_ENREF_90)

Transmission mostly occurs:

* Through perinatal transmission perinatally or more rarely in utero.[[92](#_ENREF_92)](#_ENREF_92) 95% of chronic HBV infections in the UK occur in migrant populations and were acquired perinatally or during childhood in endemic countries.[[94](#_ENREF_94)](#_ENREF_94) Infection during early childhood (perinatal or <5 years old) leads to chronic infection more frequently than at older ages;[92](#_ENREF_92), [98](#_ENREF_98)
* Through vaginal or anal sex;[23](#_ENREF_23), [24](#_ENREF_24), [26](#_ENREF_26), [28](#_ENREF_28), [94](#_ENREF_94), [99](#_ENREF_99)
* As a result of blood-to-blood contact through percutaneous exposure (e.g. sharing needles, syringes and other paraphernalia; occupational needlestick injuries; transfusion of unscreened blood products; and non-sterile acupuncture, piercings and tattoo needles.[10](#_ENREF_10), [94](#_ENREF_94), [95](#_ENREF_95)

Other transmissions:

* Sporadic horizontal transmission can occur between non-sexual contacts in people without apparent risk factors, e.g. within institutions for people with learning difficulties; children in countries of high background prevalence; or in household contacts. In these cases, the mode of transmission is poorly understood but may involve transmission via small cuts and open wounds, sharing of dental hygiene products or bites. [10](#_ENREF_10), [94](#_ENREF_94), [100](#_ENREF_100), [101](#_ENREF_101)
  1. Incubation Period and Window Period
* Incubation period 40-160 days.[[10](#_ENREF_10)](#_ENREF_10)
* Window period. 30-60 days.[10](#_ENREF_10), [93](#_ENREF_93), [94](#_ENREF_94)
* The virus can survive outside of the body for at least 7 days.[[92](#_ENREF_92)](#_ENREF_92)
  1. Acute HBV
* Acute infection is asymptomatic in up to 70% of adults. Virtually all infants and children have asymptomatic acute infection. [82](#_ENREF_82), [102-104](#_ENREF_102)
* During the prodromal phase symptoms are often subclinical or non-specific and include a flu-like illness, anorexia and nausea. Approximately two weeks later the icteric phase (jaundice with pale stools and dark urine) occurs in 30-50% of adults, and in less than 10% of children. Liver enlargement and tenderness are common. This phase may last up to 3 months.
* ALF occurs in less than 1% of symptomatic cases of acute HBV and is associated with a poorer prognosis than if caused by HAV.[[82](#_ENREF_82)](#_ENREF_82) It may present with worsening coagulopathy, encephalopathy, and cerebral oedema. There is an increased rate of miscarriage or premature labour during acute HBV. In acute HBV during pregnancy, the risk of transmission ranges from 10-60% depending on pregnancy trimester, with greatest risk of transmission with acute HBV infection around the time of delivery.[[85](#_ENREF_85)](#_ENREF_85)
* Laboratory tests for suspected acute HBV should include HBV serology including HBsAg. Liver function tests and clotting studies should be performed and results discussed with Hepatology.
* Patients with mild/moderate acute HBV can often be managed as an outpatient with rest and oral hydration. Where patients have severe hepatitis or evidence of ALF, liaise with Hepatology specialist for ongoing management.
* Patients with acute HBV should be seen at one or two weekly intervals until transaminases are normal (usually 4-12 weeks). Arrangements should be decided locally in discussion with Hepatology. Serology should be repeated after 6 months even if the LFT are normal to assess for chronic HBV. Immunity after recovery from infection (HBsAg negative, anti‑HBc positive/negative, anti‑HBs positive) is life‑long in over 90%.[103](#_ENREF_103), [104](#_ENREF_104)
* Acute HBV infection is a clinically notifiable disease (seropositivity for HBV is reported upon laboratory testing, regardless of acute or chronic as HBV is a notifiable organism too).[[10](#_ENREF_10)](#_ENREF_10)
* Acute HBV partner notification should be performed and documented, and the outcome documented at subsequent follow-up. Contact tracing should include any sexual contact (penetrative vaginal or anal sex or oro/anal sex) or needle sharing partners during the period in which the index case is thought to have been infectious.[105](#_ENREF_105), [106](#_ENREF_106) (**1D**) The infectious period is from 2 weeks before the onset of jaundice until the patient becomes surface antigen negative. In index cases without an episode of jaundice, assess the risk to estimate when infection might have occurred, and use that period to guide partner notification.[[105](#_ENREF_105)](#_ENREF_105)
* For management of contact with acute HBV see section 7.9
  1. Chronic HBV
* The persistence of HBsAg in serum/plasma for 6 months or more after acute infection.[[10](#_ENREF_10)](#_ENREF_10) This occurs in 5-10% of HBV infections acquired in adulthood.[[103](#_ENREF_103)](#_ENREF_103)
* There is a higher risk of chronic infection seen in immunocompromised patients (e.g. people with HIV, renal insufficiency, taking immunosuppressive medicines).[10](#_ENREF_10), [107](#_ENREF_107), [108](#_ENREF_108)
* Over 90% of infants born to hepatitis B ‘e’ antigen [HBeAg] positive women will develop chronic HBV infection unless immunisation is commenced immediately at birth and infant immunisation schedule completed.[10](#_ENREF_10), [85](#_ENREF_85) The likelihood of developing chronic HBV infection decreases with increasing age in childhood.[[90](#_ENREF_90)](#_ENREF_90)
* Around 20 to 25% of individuals with chronic HBV infection worldwide have progressive liver disease, leading to cirrhosis in some people.
* For management of contact with HBV see section 7.9
  + 1. Chronic HBV: Phases of Infection

Chronic HBV infection represents the balance between viral replication and host response, with active liver inflammation (hepatitis) not occurring in all states. The natural history of chronic infection is divided into five phases, taking into account both viral and host factors, such as the presence of antigens, antibodies and transaminase levels. Progression through the phases is non-linear and can be non-sequential. More detailed information is available in the EASL guidelines.[[1](#_ENREF_1)](#_ENREF_1)

* In HBeAg positive infection (phases 1 and 2), there are high levels of HBV DNA detectable, and the presence or absence of raised transaminases gives an indication of associated inflammation, or disease. These phases are extended in perinatally acquired and childhood infections.
* Spontaneous seroconversion to HBeAg negative infection (phases 3 and 4) occurs at a rate of around 10-15%/year. During these phases, there is less HBV DNA detected, and transaminase levels are lower, but the level of active inflammation differentiates HBeAg negative infection (phase 3) from HBeAg negative disease (phase 4). The latter is associated with progression to cirrhosis, and monitoring of alanine transaminase (ALT) and DNA levels are essential.
* Finally, in some people who have cleared HBsAg and remain anti-HBc positive, there is HBV DNA present in the liver and serum (phase 5). Known as occult HBV infection, there is a risk of reactivation particularly in those with severe immunosuppression from other conditions, or during administration of chemotherapy, which may lead to ALF. Another group has detectable serum/plasma HBV DNA, usually at low level (<200 IU/ml) and detection is often intermittent. Anti-HBc is usually positive. In a subset with S gene or other mutations, altered HBsAg is produced which is not recognised by some assays but HBV DNA levels are high.[109](#_ENREF_109), [110](#_ENREF_110)
  1. Progression risk to Cirrhosis and of HCC
* Progression to cirrhosis may occur during the HBV phases associated with inflammation with an annual incidence rate of 8-20%.
* HCC may complicate chronic HBV infection at any stage, but most commonly after development of cirrhosis. It is estimated there is an annual incidence rate of 2-5% in HBV patients with cirrhosis.
* Host and viral factors associated with a higher risk of developing HCC include older age, male sex, African origin, alcohol excess, diabetes, smoking, HBV genotypic mutations and coinfection with hepatitis C, hepatitis D, or HIV.[[1](#_ENREF_1), [107](#_ENREF_107), [108](#_ENREF_108)](#_ENREF_104)
  1. Co-infections with Chronic HBV
     1. Acute HAV (see Chapter 8)
* Acute HAV can be severe in patients with chronic HBV.[[111](#_ENREF_111)](#_ENREF_111)
  + 1. HCV Infection (see Chapter 11)
* Concurrent HCV and HBV infections can be associated with increased hepatitis severity and greater risk of cirrhosis and liver cancer.[[112-114](#_ENREF_112)](#_ENREF_112)
  + 1. HDV Infection (see Chapter 10)
* HDV co-infection or superinfection is associated with hepatitis of increased severity, and may be associated with more rapidly progressive fibrosis, cirrhosis and end-stage liver disease.
* HDV is likely under diagnosed, but may be identified in 5% of adults with chronic HBV globally.[[92](#_ENREF_92)](#_ENREF_92)
* Between 10-50% of chronic HBV and HDV carriers will develop cirrhosis
* 10% or more of cirrhotic patients will progress to liver cancer.
* Premature death occurs in approximately 50%.[[114-117](#_ENREF_114)](#_ENREF_114)
  + 1. HIV
* Concurrent HIV increases the risk of HBV fibrosis progression and of both liver-related and all-cause mortality.[108](#_ENREF_108), [118](#_ENREF_118)
  1. HBV: Screening in Sexual Health Settings

Table 3 presents the available serological and biochemical tests for HBV.

* + 1. Who to Screen for HBV in Sexual Health Settings?
* Previous BASHH guidelines advised a risk-factor based approach to screening for chronic HBV infection in sexual health clinic attendees.[[3](#_ENREF_3)](#_ENREF_3)
* National Institute for Health and Care Excellence (NICE) guidelines (2013) recommend sexual health and genitourinary medicine clinics should offer and promote HBV and HCV testing to all service users at increased risk of infection, including people younger than 18.[103](#_ENREF_103)
* NHS England have begun opt-out testing for blood borne viruses (HIV, HBV, HCV) in selected Emergency Departments in areas of very high HIV prevalence across England. In the two years, the highest number of new diagnoses identified was for HBV. New HBV diagnoses were higher in men, people aged 35 to 64 years and in people of black African ethnicity.[[95](#_ENREF_95)](#_ENREF_95) Expanded offer of HBV testing in sexual health settings is an opportunity to identify chronic liver disease, link in for Hepatology care and prevent transmission to sexual partners.
* A recent retrospective study of general practice medical records in England found associations of HBsAg positivity with lower area deprivation index, being from high HBV prevalence country, GBMSM sexual risk group, close HBV contacts, people with a history of injection drug use or a recorded diagnosis of HIV, HCV, or syphilis.[119](#_ENREF_119)
* Modelling studies based on a United States (US) model suggest HBV testing is cost‑effective in adults seeking care for STIs.[[120](#_ENREF_120)](#_ENREF_120)
* The CDC now recommend all adults>18 years are tested for chronic HBV at least once in their lifetime.[[97](#_ENREF_97)](#_ENREF_97)
* **Due to the opportunity to identify HBV infections and link people to care preventing progression to chronic liver disease, we now recommend that all sexual health clinic attendees should be tested at least once for chronic HBV infection**.
* **It is acknowledged that this recommendation may have financial implications for sexual health services**.
  + 1. Which Tests to Perform for Chronic HBV Screening and Immunity Status?[[121-123](#_ENREF_121)](#_ENREF_121)
* HBsAg +/- anti-HBc serological test;
* Anti-HBs titre to assess immunity if required. (**1B**)
  + 1. How to Manage the Results?
* If non-immune (anti-HBc negative; HBsAg negative; anti-HBs <10 IU/L) offer vaccination if at ongoing risk. (**1A**)
* If HBV screening test is reactive then further serology is required for staging HBV infection including:
  + HBsAg;
  + HBeAg;
  + Antibody against hepatitis B ‘e’ antigen (anti-HBe);
  + HBV DNA polymerase chain reaction (PCR);
  + Anti-HBc – IgG and IgM.
* In people who test anti-HBc positive and HBsAg negative, measure anti-HBs and anti‑HBe. If both are negative the isolated anti-HBc may be a false positive, or may indicate occult HBV or past HBV exposure. HBV DNA should be measured and if negative a single HBV vaccine dose will induce anti-HBs if there has been past natural HBV exposure (anamnestic response, measured four weeks after single dose of HBV vaccine). If anti-HBs is still negative after a single booster, regard as non-immune and give a full course of vaccine (**1C**). If HBV DNA is positive the patient should be referred to Hepatology for ongoing management and surveillance.
  1. HBV: Management
     1. General Advice
* People who are HBsAg positive (and/or HBV DNA positive) should be referred to a Hepatology service for ongoing management.
* They should be given detailed information about their condition, the implications on the health of themselves, and sexual partners, as well as about the routes of transmission. [92](#_ENREF_92), [124](#_ENREF_124), [125](#_ENREF_125)
* Advice should be given to avoid unprotected sexual intercourse (including oro-anal and oro-genital contact), unless their partners have been successfully vaccinated (see below). (**1D**) They should not donate organs/semen/blood.[10](#_ENREF_10), [92](#_ENREF_92), [124](#_ENREF_124), [125](#_ENREF_125) (**1B**) They should avoid drinking alcohol.
* Further information is available at https://www.nhs.uk/conditions/Hepatitis-B. and via the British Liver Trust.[122](#_ENREF_122), [124](#_ENREF_124)
* Partner notification for chronic HBV should attempt to trace contacts as far back as any episode of jaundice or to the time when the infection is thought to have been acquired although this may be impractical for periods of longer than 3 years.[[106](#_ENREF_106)](#_ENREF_106) (**1D**)
* Arrange screening for HBV of children who have been born to HBsAg positive women if the child was not vaccinated at birth[1](#_ENREF_1), [10](#_ENREF_10), [106](#_ENREF_106) (**1C**) via primary care/Paediatrics depending on local pathways.
* For screening of other nonsexual partners who may be at risk, discuss with the public health authorities.[1](#_ENREF_1), [10](#_ENREF_10) (**1C**)
  1. Chronic HBV: Initial Management in Sexual Health Settings
* Check for HAV immunity and vaccinate if non-immune.[[1](#_ENREF_1)](#_ENREF_1) (**1D**)
* Test for HIV, HCV and HDV infection. (**1D**)
* Test for other sexual infections.[[10](#_ENREF_10), [23](#_ENREF_23), [24](#_ENREF_24)](#_ENREF_22) (**1D**)
* Refer to Hepatology specialist for ongoing management and HCC surveillance.[103](#_ENREF_103), [116](#_ENREF_116)
  1. Chronic HBV: Further Management (Usually Via Hepatology Specialist)
     1. Goals of Therapy
* To improve survival and quality of life by prevent disease progression to cirrhosis and reduce risk of HCC.
* To prevent vertical transmission, HBV reactivation, and prevent and treat HBV‑associated extrahepatic manifestations.
  + 1. Treatment
* The decision to treat depends on serum ALT, HBV DNA level, and severity of associated liver disease. Treatment decisions should be made in conjunction with Hepatology specialists. See EASL and WHO guidelines for further information.[1](#_ENREF_1), [126](#_ENREF_126)
  + 1. HIV/HBV Coinfection
* HIV treatment (ART) should be started as soon as possible, including tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) as part of ART, in order to suppress HBV replication and prevent HBV associated liver damage during treatment,[3](#_ENREF_3), [31](#_ENREF_31) irrespective of CD4 count.
* There is a high risk of hepatitis flare and decompensation if ART containing TDF/TAF are stopped.
  + 1. Pregnancy and Breastfeeding
* The management of pregnant women with HBV should be in conjunction with Hepatology.
* In the absence of intervention, vertical transmission occurs in 90% of pregnancies where the mother is HBeAg positive and in about 10% of HBsAg positive and HBeAg negative mothers.
* Most (>90%) infants acquiring HBV perinatally develop chronic HBV infection.[[127](#_ENREF_127)](#_ENREF_127)
* Infants born to women with HBV infection are vaccinated from birth. HBIG is also given in certain situations where the risk of transmission is deemed to be high such as a viral load during that pregnancy of ≥1,000,000 IU/ml.[[10](#_ENREF_10)](#_ENREF_10) (**1A**) This intervention reduces vertical transmission by 90%. See Green Book chapter 18 for criteria for HBIG in neonates.
* TDF monotherapy may be recommended for pregnant women at week 24 if HBV DNA >200,000 IU/ml or quantitative HBsAg>4 log10 IU/ml to reduce the risk of transmission of HBV to the baby (**1A**) , and should continue up to 12 weeks following delivery.[[128](#_ENREF_128)](#_ENREF_128) HBV replication may increase immediately following pregnancy but is seldom associated with clinical consequences.
* Breastfeeding is not contraindicated in HBsAg positive women off-treatment, or on TDF-based treatment.
  1. Chronic HBV: Monitoring and Surveillance
* HCC surveillance is offered for some individuals with chronic HBV and should be discussed in a Hepatology specialist clinic. Risk factors for HCC in individuals without cirrhosis include: ethnicity, gender, age, family history of HCC and stage of infection.[129](#_ENREF_129), [130](#_ENREF_130)
* PAGE-B score may be used in specialist clinics to assess the risk of progression to HCC.[[130](#_ENREF_130)](#_ENREF_130)
  1. PrEP and PEP for HIV Infection in Individuals with HBV [127](#_ENREF_127), [131](#_ENREF_131)
* Tenofovir disoproxil/Emtricitabine or Tenofovir alafenamide/Emtricitabine may be used as HIV PrEP or as part of PEP when clinically indicated.
* PrEP/PEP may be initiated while HBV serology results are pending.
* People found to be HBsAg positive should be referred to a Hepatology specialist service whilst remaining on PrEP/PEP.
* People with HBV are recommended to use daily dosed PrEP, NOT event-based or ‘on‑demand’ dosing schedules.
* There is a risk of HBV rebound upon stopping PrEP/PEP, and the management of stopping these therapies should be discussed in advance with a Hepatology specialist.
* Further details can be found in BASHH/BHIVA PrEP guidelines and PEP guidance.

1. HEPATITIS DELTA INFECTION

HDV is a small incomplete RNA virus that can only be acquired in the presence of HBsAg carriage and is associated with a higher rate of fulminant hepatitis, progression to cirrhosis, and HCC.[132](#_ENREF_132), [133](#_ENREF_133)

* 1. HDV: Epidemiology and Transmission
* It is estimated that 5% of people with chronic HBV also have HDV infection globally.
* Transmission routes are similar to HBV and occurs through broken skin and contact with infected blood and blood products.
* HDV has an incubation period of 3-7 weeks, and acute illness may present with a non‑specific flu like illness with associated transaminitis.[134](#_ENREF_134) Chronic HDV is defined as the presence of HDV infection for greater than 6 months.[132](#_ENREF_132)
  1. HDV: Risk Factors

HDV may occur in any person with HBV, but is observed at higher frequency in:

* People who have acquired HBV infection abroad;
* PWID and their sexual partners;
* Sex workers;
* People with HCV or HIV infection.

HDV should be suspected if:

* The acute hepatitis is severe;
* If there is a further acute hepatitis episode in patients with chronic HBV;
* If liver disease is rapidly progressing in chronic HBV and HBV is well-controlled.
  1. HDV: Investigations
* All people with HBV should be screened for HDV using antibody against HDV (anti‑HDV) test. Active infection is confirmed via HDV RNA testing. Local pathways should agree whether this test should be performed in Sexual Health or Hepatology.
  1. HDV: Management
* All people with HDV should be referred to Hepatology for ongoing management.
* Until recently, pegylated interferon alpha was the only treatment strategy available with a 20% virological response rate. Novel therapies are being developed following the research into the mechanism of HDV persistence. Bulevirtide (Hepcludex) was NICE approved for use in the UK in 2023, for selected patients who have not responded/cannot have pegylated interferon with compensated liver disease and significant fibrosis (METAVIR stage F2 or above or Ishak stage 3 or above. Buleviritide is an entry inhibitor of the HBsAg and HDV into hepatocytes.[135](#_ENREF_135) Compared to standard care, bulevirtide resulted in significantly improved virological response at 48 weeks with continuous treatment, with ongoing benefit seen at 96 weeks.[134](#_ENREF_134)

1. HEPATITIS C INFECTION
   1. New in Hepatitis C section

* Updated HCV epidemiology;
* Updated information on management of recently-acquired HCV.
  1. Hepatitis C: Background and Epidemiology
* HCV is a single stranded RNA virus in the family *Flaviviridae*.
* HCV is endemic worldwide and, in 2020, an estimated 57 million individuals were living with active HCV, with a global prevalence of 0.7% 95% UI 0.7–0.9. Prevalence varies by region, with the highest prevalence in Eastern Europe (2.9% [95% UI 2.3‑3.2]).[[136](#_ENREF_136)](#_ENREF_136)
* In 2022 in England, approximately 62,600 (95% credible interval (CrI) 48,900- 77,800) were estimated to be living with chronic HCV infection in 2022, a 51.6% decrease from 2015. This is equivalent to a prevalence of 0.14% (95% CrI 0.11- 0.17%) The reduction was predominantly driven by the roll out of highly effective, oral direct acting antiviral (DAA) therapies which provide cure rates of ~95%.
* This has led to significant declines in the incidence of HCV-related end stage liver disease and HCC.[[137](#_ENREF_137)](#_ENREF_137) In 2022, HCV-related deaths in England were 0.44 per 100,000 population.
* In 2016, The World Health Assembly proposed the elimination of HCV as a public health threat by 2030. Updated 2030 global targets aim to reduce the number of new HCV cases to 350,000 (5 per 100,000) and the number of people dying from HCV to 40,000 deaths (2 per 100,000).[138](#_ENREF_138), [139](#_ENREF_139)
* A proxy measure set is the reduction in HCV viraemia prevalence by 80% from 2015 baseline (in general population and PWID). In 2022 in England this figure was 51.6% in general population and 60.8% in PWID.
* Achievement and maintenance of HCV elimination is likely to require early diagnosis and access to treatment for all first and re-infections, as well as additional preventive measures, both in the UK and internationally.
* Around 4% of people who have been treated for HCV have a re-infection.
* There are eight currently recognised HCV genotypes, which are further divided into subtypes, and in some cases may show differences in susceptibility to different DAA regimens.[[140](#_ENREF_140)](#_ENREF_140) Most (~90%) UK infections are caused by subtypes 1a or 3a.[[137](#_ENREF_137)](#_ENREF_137)
  1. HCV: Transmission
     1. Parenteral Transmission
* Parenteral spread accounts for most HCV cases and the majority of people with HCV in the UK report a history of injection drug use. Transmission usually occurs through sharing needles or injecting equipment.[[137](#_ENREF_137)](#_ENREF_137)
* Other parenteral routes include:
  + Sharing personal hygiene items which have come into contact with blood such as razors;
  + Tattoos or body piercings in an unregulated setting;
  + Blood transfusions and organ transplants in the UK before 1992;
  + Healthcare related transmissions such as re-use of needles or haemodialysis;
  + Occupational exposure such as needlestick injury.[[137](#_ENREF_137)](#_ENREF_137)
* In many low and middle income countries, iatrogenic transmission remains a major HCV transmission route.[[141](#_ENREF_141)](#_ENREF_141)
  + 1. Sexual Transmission
* Amongst monogamous heterosexual couples without HIV, sexual transmission is extremely rare (<0.1%/year)[[142-146](#_ENREF_142)](#_ENREF_142) but this risk increases in the context of HIV coinfection.[[147](#_ENREF_147)](#_ENREF_147)
* Amongst GBMSM with HIV and without a history of injection drug use, the prevalence of anti-HCV is greater (4.1%) compared to the general population[[108](#_ENREF_108)](#_ENREF_108) and an increased risk of HCV sexual transmission has been described.[147](#_ENREF_147), [148](#_ENREF_148)
* A global epidemic of recently acquired HCV was described amongst GBMSM with HIV from 2000 onwards, driven by permucosal and parenteral transmissions. Specific risk factors were identified, both behavioural (receptive condomless anal sex, traumatic sex, sex in a group environment, sharing sex toys, use of recreational drugs [chems] during sex, and seroadaptive behaviours) and biological (concurrent STIs, especially ulcerative conditions such as LGV and syphilis).[[149-154](#_ENREF_149)](#_ENREF_149)
* Chems may be injected (slamming) or non-injected, and may cause loss of attention to safer sex, mucosal exposure such as from nasal administration and/or parenteral exposures.[[154](#_ENREF_154)](#_ENREF_154) Chems include methamphetamine (crystal), mephedrone, gamma‑hydroxybutyric acid/gamma-butyrolactone.
* The epidemic has also been characterised by a high incidence of HCV reinfection (3.8/100 person-years (95%CI 2.8-5.1).[[155](#_ENREF_155)](#_ENREF_155)
* However, data from the UK and internationally suggest a declining incidence of recently-acquired HCV in GBMSM with HIV since 2016, likely driven by expanded DAA access.[[156-158](#_ENREF_156)](#_ENREF_156)
* Sexual transmission of HCV may also be more frequent amongst HIV-negative GBMSM groups who share risk factors with HIV-positive GBMSM and are involved in the same HCV transmission networks, including those eligible for or using HIV PrEP.[148](#_ENREF_148), [159](#_ENREF_159), [160](#_ENREF_160)
* Amongst HIV negative GBMSM overall, HCV prevalence is only slightly higher than in the general population. HCV diagnosis rates in English Sexual Health clinics were 113/100,000, 24/100,000 and 12/100,000 in HIV-positive GBMSM/HIV-negative GBMSM / all attendees, respectively.[137](#_ENREF_137), [148](#_ENREF_148)
* There are currently insufficient data on HCV incidence in transgender persons.
  + 1. Vertical Transmission
* HCV vertical transmission is estimated at 5-7%, increasing to 10-12% for women with HIV and HCV coinfection.[161](#_ENREF_161), [162](#_ENREF_162)
* Transmission risk has reportedly been correlated with maternal HCV RNA level in blood.[[163-166](#_ENREF_163)](#_ENREF_163)
  + 1. Other Groups with Increased HCV Transmission

Compared to the general population, an increased prevalence of HCV infection has been reported in:

* People who have been in prison;[137](#_ENREF_137), [167](#_ENREF_167)
* People who have exchanged sex for money, goods or services;[27](#_ENREF_27), [168](#_ENREF_168)
* People who have experienced homelessness;[[169](#_ENREF_169)](#_ENREF_169)
* People with links to countries where HCV is endemic; [[137](#_ENREF_137)](#_ENREF_137)
* People who snort/inhale recreational drugs;[170](#_ENREF_170), [171](#_ENREF_171)
* People with high levels of alcohol consumption.[[172](#_ENREF_172)](#_ENREF_172)

However, amongst UK blood donors, 25% of individuals with HCV did not report any risk factors.[[173](#_ENREF_173)](#_ENREF_173)

* 1. HCV: Incubation Period
* The HCV incubation period is four to 20 weeks. HCV antibody conversion may take 12 weeks or more. However, HCV RNA will usually be detectable within two weeks. [136](#_ENREF_136), [137](#_ENREF_137), [140-144](#_ENREF_140)
* HCV antibody seroconversion may be delayed in people living with HIV, particularly in those with a low CD4 count (<200 cells/µL). HCV antibody production may rarely be absent in these individuals, or in other immunocompromised people.[141](#_ENREF_141), [142](#_ENREF_142)
* Spontaneous viral clearance is estimated to occur in occurs in up to 37% of individuals (24.4% of PWID and 15.4% of GBMSM living with HIV). Other factors affecting clearance rates include gender, age, ethnicity, presence of symptoms, HBV coinfection and HCV genotype. The variation in estimates may relate to both the impact of HIV on the natural history of HCV and the relative rates of HCV reinfection.[174](#_ENREF_174)
  1. HCV: Symptoms

The majority (>60%) have asymptomatic infection or non-specific symptoms.[175](#_ENREF_175)

* 1. HCV: Who to Test for HCV in Sexual Health Settings?

Table 4 presents a summary of who to test for HCV in sexual health settings.

* 1. HCV Screening and Diagnostics: Which Tests to Perform?
* HCV antibody testing should be performed if the possible HCV risk exposure occurred more than three months ago. If HCV antibody is negative, a repeat should be considered at six months. It may take three months or more for the anti-HCV test to become positive after exposure, increasing to six months or more in people with HIV.[176](#_ENREF_176)
* Where HCV antibody is positive, further testing for hepatitis C ribonucleic acid (HCV RNA) or hepatitis C core antigen (HCV Ag) should be performed to determine whether there is active infection. (**1A**)
* HCV Ag is a surrogate marker of HCV replication and can be used instead of HCV RNA to diagnose acute or chronic HCV infection. HCV Ag assays are less sensitive than HCV RNA assays (lower limit of detection equivalent to approximately 500 to 3000 HCV RNA IU/ml, depending on HCV genotype.[137](#_ENREF_137), [140](#_ENREF_140), [177](#_ENREF_177), [178](#_ENREF_178)
* HCV Ag or HCV RNA testing can be performed in cases where possible HCV risk exposure occurred less than six months ago to allow earlier detection. (**1A**)
* Where there is a high suspicion of recently-acquired HCV and anti-HCV is negative, consider HCV RNA testing, with HCV Ag as an alternative.
* HCV Ag or HCV RNA testing should be performed to detect reinfection in people who have previously resolved HCV infection (spontaneously or through treatment). (**1A**)
* HCV Ag or HCV RNA testing should be considered for people with HIV and CD4 count <200 cells/µL and other immunocompromised people at risk for HCV, particularly where clinical suspicion remains despite negative antibody testing. (**2C**)
* Rapid diagnostic tests for HCV antibody using serum, plasma, fingerprick blood or saliva are available and may be useful in outreach settings and in individuals who decline venepuncture or are difficult to bleed.
* Dried blood spot (DBS) testing on fingerprick blood is an alternative to venepuncture and can be used to test for the presence of HCV antibody or RNA. Cartridge-based RNA point-of-care testing (POCT) is available and can be performed on fingerprick blood, serum or plasma. Self-sampling antibody testing can be undertaken as part of online sexual health screening using fingerprick blood.
  1. HCV: Further Investigations in Sexual Health Services

HCV shares transmission routes with other blood borne viruses and therefore people with HCV are at increased risk for HBV and HIV exposure. People with HCV who acquire HBV or HAV are at greater risk of severe liver disease.

* HAV IgG testing should be performed in individuals with no history of HAV vaccination or previous infection, and HAV vaccination is recommended whilst awaiting results.
* All people with HCV should therefore be tested for HBsAg, anti-HBc and anti-HBs, and offered HBV vaccination if susceptible.
* HIV testing should be performed.
* An STI screen is recommended in people who may have acquired HCV sexually, including treponemal serology and chlamydia and gonorrhoea testing.
  1. HCV: Management
* Individuals with active HCV infection should be referred to a Hepatology specialist service for further assessment and ongoing management.
* Bloods tests including liver function tests, renal function, full blood count and clotting studies should be performed.
* Assessment of liver fibrosis is recommended in all people with HCV as (1) this may inform antiviral treatment decisions and (2) individuals with advanced (>/=F3) fibrosis may require monitoring for complications of end stage liver disease and HCC.
* Liver ultrasound should be performed in people with active HCV and is particularly important in individuals with advanced (>/=F3) fibrosis to exclude hepatocellular carcinoma.
* In some settings, it may not be possible to assess liver disease stage and this should not be a barrier to starting HCV treatment.
  1. HCV: Treatment
* The primary goal of HCV treatment is cure, in order to prevent liver fibrosis, cirrhosis, decompensation of cirrhosis, HCC, extrahepatic manifestations and death.
* Secondary goals of HCV treatment are to improve quality of life and reduce stigma and to prevent onward transmission.
* HCV cure is defined by undetectable HCV RNA in serum or plasma 12 weeks after the end of treatment (SVR12, sustained virological response). In some settings, depending on resources, HCV antigen may be used as an alternative to HCV RNA.
* All people with detectable HCV RNA should be considered for treatment with DAAs without delay, according to local pathways.
* Determination of genotype is recommended if available but does not limit access to treatment. Treatment with pan-genotypic regimens can be initiated without knowledge of the genotype and subtype with a high probability of success.
* A treatment history including prior HCV treatment, current prescribed medication, over-the-counter remedies and herbal supplements should be obtained in order to check for a small number of drug-drug interactions that may influence choice of regimen. The University of Liverpool website should be consulted for potential interactions: Liverpool HEP Interactions (hep-druginteractions.org).
* The same all-oral DAA regimens should be used in people living with HIV and HCV.
  1. Recognising and Managing Recently-acquired HCV
* Historically, HCV infection has been classified as acute (the first 6 months of infection) or chronic (absence of spontaneous clearance of HCV within the first 6 months of infection).
* Acute HCV is usually asymptomatic and sub-clinical. Precise timing of infection is therefore difficult to establish. The term ‘recently acquired’ hepatitis C is now preferred and is defined by the presence of anti-HCV antibodies, HCV RNA and/or HCV Ag that were not detectable in previous samples up to 12 months prior. In practice, historical results are often unavailable and DAA treatment in the early phase of infection is thought to be both cost-effective and useful to achieve elimination. Most care pathways now adopt a ‘test and treat’ strategy with immediate treatment offered to all individuals with a positive HCV RNA or core antigen by point of care test or venepuncture.
* All patients with detectable HCV RNA or core antigen should be referred directly to their local specialist team without delay.
  1. HCV: Partner Notification and Contact Tracing
* Individuals diagnosed with HCV should preferably be referred to a sexual health advisor.
* Partner notification should be performed and documented. The outcome should be documented at subsequent follow-up.
* Contract tracing should include any contacts during the period in which the index case is thought to have had HCV viraemia. This should include sexual contacts reporting condomless sex and needle sharing partners.
* Sexual contacts with HIV should be advised of the increased risk of HCV transmission, with regular testing and condom use encouraged.[108](#_ENREF_108), [147](#_ENREF_147)
* If the HCV infection was not known to be recently-acquired, trace back to the likely time of infection (e.g. blood transfusion, first needle sharing) although this may be impractical for periods longer than two or three years.
* Screen contacts for evidence of past or current HCV infection. For contacts who were exposed within the window period (six months), consider use of HCV RNA or core antigen testing.
* Test children born to women with HCV viraemia.[161](#_ENREF_161), [162](#_ENREF_162) This can be arranged in conjunction with primary care or Paediatrics.
* For other non-sexual contacts thought to be at risk, consider on a case-by-case basis.
* Spontaneous resolution of HCV infection and previous successful treatment do not provide protection against re-infection if further HCV exposure occurs.[161](#_ENREF_161), [162](#_ENREF_162)
* There is currently no vaccine or immunoglobulin which will prevent HCV transmission.
* Use of HCV DAA as PrEP or PEP is not currently recommended.
  1. HCV: Advice for People with Active HCV
* All people with detectable HCV RNA or core antigen should be given information on how to reduce the risk of onward transmission including avoiding sharing injecting equipment and personal hygiene items which may contain traces of blood such as toothbrushes and razors.
* People with HCV viraemia should be advised to avoid condomless vaginal or anal sex. Consistent condom use is likely to prevent sexual transmission. However, HIV‑negative heterosexual individuals in monogamous relationships should be advised of very low rates of sexual HCV transmission.[142-147](#_ENREF_142)
* GBMSM with HCV should be recommended to use condoms for anal sex, single person only sex toys/condoms on sex toys and changed between partners and recommended not to share lube and avoid group sex situations, given the risk of mucosal transmission from HCV RNA in semen, rectal fluid and blood.
* All people with HCV should be referred to specialist services for early treatment with DAA therapies.
* People with HCV should be reassured that HCV is curable.
* People with HCV should be advised not to donate blood, semen or organs and provided advice on other routes of transmission.
* People with HCV should be given a detailed explanation of their condition with particular emphasis on the long-term implications for the health of themselves and their partner(s). This should be reinforced by providing clear and accurate written information.
* As an acute infectious hepatitis, recently-acquired HCV is a notifiable disease and should be reported to the local Health Protection Team.
  1. HCV: Primary Prevention
* GBMSM with HCV-acquisition risk factors should be given advice on safer practices including not sharing injecting equipment, safe disposal of syringes/needles, not sharing straws for nasally administered drugs, condom use for anal sex, not sharing anal douches or sex toys.
* All people reporting injection drug use should be offered referral to needle and syringe exchange schemes.
* Where harmful use of psychoactive substances is identified in people with or at risk of HCV, psychological and medical support should be offered, including opioid substitution therapy for opiate dependence and general harm reduction advice/support. Referral to specialist drug services may be indicated.
  1. HCV: Reinfection
* Individuals with ongoing risk behaviours should be offered testing with HCV antigen or HCV RNA at least annually. (**1A**)
* People who are found to have HCV reinfection should be re-referred for treatment. (**1A**).
* Discuss risk reduction for HCV reinfection in all individuals with ongoing risk for acquisition. (**1D**)
* Use of HCV DAA PrEP or PEP is not currently recommended.

1. AUDITABLE OUTCOME MEASURES

* Proportion of new attendees at sexual health clinic with risk factors for HAV‑acquisition offered HAV vaccine/immunity check (target 90%);
* Proportion of new attendees at sexual health clinic with risk factors for HBV‑acquisition offered HBV vaccine/immunity check (target 90%);
* In those offered HAV or HBV vaccination, completed vaccine course if non‑immune (target 70%);
* Proportion of new attendees at sexual health clinic offered testing for HBV (target 90%);
* Proportion of individuals diagnosed with chronic HBV referred to Hepatology (target 90%) and evidence of attendance for HBV care (target 70%);
* Proportion of sexual health clinic attendees at risk of HCV infection being screened for chronic HCV (target 90%);
* Proportion of people testing anti-HCV positive undergoing HCV RNA or core antigen test for active infection (target 90%);
* Proportion of individuals with active HCV referred to Hepatology services for DAA therapy (target 90%) and evidence of attendance for HCV care (target 70%).

1. RESOURCE IMPLICATIONS OF THESE GUIDELINES

Recommendations for testing and prophylactic vaccination in this guideline may incur additional costs for Sexual Health clinics including laboratory tests; vaccination costs and additional clinic attendances.

1. QUALIFYING STATEMENT

The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on professional clinical judgement, consideration of individual patient circumstances and available resources.

All possible care has been undertaken to ensure specification of the correct dosage of medication and route of administration. However, it remains the responsibility of the prescribing clinician to ensure the accuracy and appropriateness of the medication they prescribe.

1. REVIEW ARRANGEMENTS

An author group will be invited by the BASHH CEG to review and revise the guideline in 2030 using the BASHH framework for guideline development. However, addenda may be issued sooner than 2030, particularly if relevant new data are available relating to testing or treatment options.

1. DISCLOSURES

<Text>

* 1. Declaration of Conflicting Interests

All members of the guideline writing committee completed the BASHH conflict of interest declaration and submitted it to the CEG. No authors had any relevant conflicts of interest to declare, and the content of the guideline is not attributed to any organisation they are associated with.

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The author(s) received no financial support for the research, authorship, and/or publication of this article.

* 1. Editorial Independence

This guideline was commissioned, edited, and endorsed by the BASHH CEG without external funding being sought or obtained. All members of the guideline writing committee completed the BASHH conflicts of interest declaration detailed below at the time the guideline’s final draft was submitted to the CEG.

* 1. Membership of the Clinical Effectiveness Group

Current membership of the BASHH Clinical Effectiveness Group is available at <https://www.bashh.org/bashh-groups/clinical-effectiveness-group/>

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1. TABLES AND FIGURES

Table 1. Vaccinations in Sexual Health

|  | **HAV** | **HBV** |
| --- | --- | --- |
| **Offer vaccine to following people in sexual health clinics** | * GBMSM; * Trans people who have sex with men; * PWID; * People with HBV, HCV or HIV. | * GBMSM; * Trans people who have sex with men; * Sex workers; * People requesting PEP/PrEP; * People from/with sexual partners from countries of HBV prevalence >2%; * PWID or who are smoking heroin/crack cocaine; * People with HIV; * Close contacts of people with HBV or at increased risk of HBV; * Prisoners; * Immigration detainees; * People with chronic liver disease; * Consider offering HBV vaccine to people with more than one sexual partner in the previous 3 months and people seeking treatment for a sexually transmitted infection. |
| **Type of vaccines for adults >16 years** | **Monovalent HAV vaccines e.g.:**   * Havrix Monodose® 1 mL (>16 years); * Avaxim® 0.5 mL (>16 years); * Vaqta® 1 mL (>18 years).   **Combined HAV/HBV vaccines:**   * Twinrix Adult® 1 mL (>16 years. | **Monovalent HBV vaccines e.g.:**   * Engerix B® 20 mcg/1 mL (>16 years); * Engerix B® 2 x 20 mcg/1 mL (>16 years and dialysis/pre-dialysis); * HBvaxPRO® 10 mcg/1 mL (>16 years); * HBvaxPRO® 40 mcg/1 mL (in people living with HIV and adults with renal insufficiency [dialysis/pre-dialysis]).   **Adjuvanted:**   * Fendrix® 20 mcg/0.5 mL (>15 years and dialysis/pre-dialysis); * Heplisav B® 20 mcg/0.5 mL (>18 years);   **Combined HAV/HBV vaccines:**   * Twinrix Adult® 1 mL (>16 years). |
| **Under 16 years** | * Havrix Junior Monodose® 0.5 mL (1-15 years); * Avaxim Junior® 0.5 mL (1‑15 years); * Vaqta Paediatric® 0.5 mL (1‑17 years). | * Engerix B® 10 mcg/0.5 mL (0-15 years); * HBvaxPRO Paediatric® 5 mcg/0.5 mL (0‑15 years). |
| **Route of administration** | **Monovalent HAV vaccines e.g.**:   * Intramuscularly into the upper arm or anterolateral thigh. Vaccine should not be administered in the gluteal region.   **Twinrix® Adult:**   * intramuscular in the deltoid region | **Engerix B®/HBvax PRO®:**   * Intramuscularly in the upper arm or anterolateral thigh. The buttock must not be used because vaccine efficacy may be reduced.   **Heplisav B/Twinrix Adult**®**:**   * Intramuscular in the deltoid region. |
| **Schedule (adults)** | **Monovalent HAV vaccine:**   * Two doses at 0 and 6-12 months provides protection for up to 25 years; * Delays in second dose (even up to several years) results in successful boosting so restarting schedule not required.   **Twinrix Adult**®  0,1 and 6 months. | **Engerix B®/HBvax PRO®:**   * Accelerated schedule: 0, 1, 2 and 12 months (preferred); * Standard schedule: 0,1 and 6 months; * If need to provide rapid immunity, the super accelerated or very rapid schedule can be used: Engerix B® or Twinrix Adult® (0, 1, 3 weeks and 12 months). Although unlicensed, can be used in 16‑18years if rapid immunity required to maximise compliance.   **Fendrix® 20 mcg/Engerix B® (double dose = 2 x 20 mcg):**   * 0, 1, 2 and 6 months – adults with renal insufficiency.   **Heplisav B\*:**   * 2 doses (0, 1 months); * Adults with severe renal impairment (eGFR <30 ml/min including patients undergoing haemodialysis): 0, 1, 2 and 4 months. |
| **People with HIV. Further details in BHIVA immunisation guidelines**[**47**](#_ENREF_47) | Havrix Monodose® 0, 1, 6 months. | **HBvaxPRO® 40 mcg, Engerix B® 40 mcg (2x20 mcg doses), Fendrix® 20 mcg:**   * Standard schedule: 0, 1, 2, and 6 months.   **Heplisav B®:**   * Two doses (0, 1 months). The need for a third dose at 6 months is less clear at present, but it is recommended in individuals with age 40 years, CD4 counts <500 cells/mm3, viraemia, chronic renal disease or diabetes. |

BHIVA = British HIV Association; eGFR = Estimated glomerular filtration rate; HAV = Hepatitis A virus; HBV = Hepatitis B virus; HCV = Hepatitis C virus; HIV = Human immunodeficiency virus; PEP = Post-exposure prophylaxis; PrEP = Pre‑exposure prophylaxis; PWID = People who inject drugs.

\*Additional eligibility criteria in Green Book Chapter 18

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Table 2. HBV vaccine-induced immunity

|  |  |
| --- | --- |
| **Anti-HBs titre following full course of vaccine** |  |
| **>100 mIU/mL** | No further doses or titre check required in absence of immunosuppressive medication or morbidity |
| **>10-100 mIU/mL** | One immediate additional dose vaccine |
| **<10 mIU/mL** | Test for markers of current infection (HBsAg and anti-HBc)  If no evidence of infection:  Repeat a full course of vaccine  Re-test Anti-HBs titre 4-8 weeks after completion of course  If still <10 mIU/mL non-responder. Consider use of adjuvanted vaccine (e.g. Fendrix® Heplisav B®) if at ongoing risk. |

Anti-HBc = Antibody against hepatitis B core antigen; Anti-HBs = Antibody against hepatitis B surface antigen; HBsAg = Hepatitis B surface antigen;

Table 3. Serological and biochemical tests for HBV

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **Serological and Biochemical tests** | | | | | | | | **Liver disease/**  **necroinflammation** | **Relative Infectivity** |
| **HBsAg** | **HBeAg** | **IgM Anti-HBc** | **IgG Anti-HBc** | **HBV DNA (PCR)** | **Anti-HBe** | **Anti-HBs** | **ALT** |
| **Stage of infection** | **Acute** | **Early** | + | + | + | + | + | - | - | +++ | Moderate to severe. Fulminant in ALF. | +++ |
| **Resolving** | + | - | + | + | - | +/- | - | ++ | Moderate/resolving. | ++ |
| **Chronic** | **Phase 1** | + | + | - | + | >107 | - | - | N | None/minimal | +++ |
| **Phase 2** | + | + | - | + | 104-107 | - | - | + | Moderate/severe | +++ |
| **Phase 3** | + | - | - | + | <2000 | + | - | N | None | + |
| **Phase 4** | + | - | - | + | >2000 | +/- | - | + | Moderate/severe | ++ |
| **Immune** | **Phase 5 - past infection** | | - | - | - | + | <10 | +/- | +/- | N | None | - |
| **Vaccinated** | | - | - | - | - | - | - | + | N | N/A | Immune |

ALF = Acute liver failure; ALT = Alanine transaminase; Anti-HBc = Antibody against hepatitis B core antigen; Anti‑HBe = Antibody against hepatitis B ‘e’ antigen; Anti-HBs = Antibody against hepatitis B surface antigen; DNA = Deoxyribonucleic Acid; HBeAg = Hepatitis B ‘e’ antigen; HBsAg = Hepatitis B surface antigen; HBV = Hepatitis B virus; IgG = Immunoglobulin type G; IgM = Immunoglobulin type M; N/A = Not applicable.

Table 4. Who to test for HCV in sexual health settings?

|  |  |
| --- | --- |
| **Group** | **Notes** |
| People with a past/current history of injection drug use. This includes people who injected only once. Injected drugs may be recreational, anabolic steroids, other image/performance enhancing drugs | Test every 3-6 months if ongoing IDU. |
| People with HIV | Test at least annually unless confirmation of no risk. Test every 3-6 months if high risk for acquiring HCV.\* |
| GBMSM with risk factors for HCV\* | Test every 3-6 months if ongoing risk\*  Routine HCV screening in HIV-negative GBMSM is not recommended in the absence of HCV risk factors.\* (**1B**) |
| People newly diagnosed with syphilis, LGV or HBV |  |
| People born in a country of intermediate or high HCV prevalence | Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East, and the Pacific islands.[179](#_ENREF_179) |
| People with a history of intranasal/inhaled recreational drug use |  |
| People who have exchanged sex for money, goods or favors |  |
| People who have shared personal items which may have come into contact with blood e.g. razors |  |
| People who have experienced homelessness |  |
| People who have been in prison or other secure/detained settings |  |
| People with parenteral exposures in unregulated settings e.g. tattoos, piercings |  |
| People with a possible healthcare-related exposure in a low- or middle-income country e.g. non-sterile needle use |  |
| People with a history of haemodialysis |  |
| Children born to women with viraemic HCV |  |
| People who received a blood product or organ transplant in the UK before 1992 and are previously unscreened |  |
| People reporting an occupational exposure e.g. needlestick injury from a source with viraemic HCV or of unknown HCV status | UKHSA guidance[180](#_ENREF_180) |
| People with abnormal liver function tests |  |
| People with symptoms or signs of acute hepatitis, such as jaundice |  |
| Close contacts of people with viraemic HCV including sexual partners, also family members, close friends or household contacts[179](#_ENREF_179) |  |

GBMSM = Gay, bisexual or other men who have sex with men; HBV = Hepatitis B virus; HCV = Hepatitis C virus; HIV = Human immunodeficiency virus; IDU = Injection drug use; LGV = Lymphogranuloma venereum; PrEP = Pre‑exposure prophylaxis; UKHSA = UK Health Security Agency

\*Risk factors in GBMSM: condomless anal sex, chemsex, injection drug use, sex in a group environment, traumatic sex, sharing sex toys, individuals eligible for or using PrEP.

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Figure 1. Map showing seroprevalence of HbsAg (all ages)[91](#_ENREF_91)

A map of the world

Description automatically generated

HBsAg = Hepatitis B surface antigen.

Created with mapchart.net

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APPENDIX 1: GRADE System for Assessing Evidence

**Introduction:**

There has been a general move to using the GRADE system by many guideline producing bodies in recent years and the BMJ published a series of papers about the method in 2008 [[1]](#footnote-1),[[2]](#footnote-2),[[3]](#footnote-3),[[4]](#footnote-4),[[5]](#footnote-5),[[6]](#footnote-6).

The GRADE system applied in its purest form requires scientific analyses of evidence to produce “tables” from a series of “PICO” questions: Questions that identify the patient problem or population (P), intervention (I) (or aetiology/diagnosis/frequency/prognosis), comparison (C) and outcome(s) (O). Practically this is very labour intensive and requires someone very experienced in this area, and many large guideline writing bodies employ a scientist to do this for them. However, some bodies adapt the GRADE system according to their own needs, assess the evidence in the way they have done in the past, and then make strengths of recommendations according to the GRADE system, which when applied in this way is quite simple to do and understand. BASHH have adopted GRADE to use in this manner.

**The principles of GRADE:**

1. Assessment of the evidence

GRADE offers four levels of evidence quality: high, moderate, low, and very low, with randomised trials classed as high-quality evidence and observational studies as low-quality evidence. Quality may be downgraded because of limitations in study design or implementation, imprecision of estimates (wide confidence intervals), variability in results, indirectness of evidence, or publication bias. Quality may be upgraded because of a very large magnitude of effect, a dose-response gradient, and if all plausible biases would reduce an apparent treatment effect.

Summary of factors affecting quality of evidence:

|  |  |  |
| --- | --- | --- |
| Study limitations | Imprecision | Large magnitude of effect |
| Inconsistency of results | Publication bias | Dose-response gradient |
| Indirectness of evidence | Factors that might increase quality of evidence | Plausible confounding, which would reduce a demonstrated effect |

Based on the analysis of the evidence with these factors borne in mind the evidence should be graded as follows:

|  |  |
| --- | --- |
| **A** | A body of evidence of high-quality meta-analyses, systematic reviews of and RCTs directly applicable to the target population |
| **B** | As above but relating to high quality case control or cohort studies with low risk of bias or confounding and high probability that a relationship is causal |
| **C** | As B but trials may have some flaws |
| **D** | Non-analytic evidence (e.g. case reports or series or expert opinion) |

However, when reviewing evidence graded A-D as above the grading can be altered follows:

* + The strength of recommendation should be higher if the following apply:
    - A large effect of an intervention is demonstrated.
    - Dose response/evidence of gradient.
    - All plausible confounding would reduce a demonstrated effect or would suggest a spurious effect when results show no effect.
* Lower if there is evidence of:
  + - Serious/very serious study limitations
    - Inconsistency
    - Indirectness
    - Imprecision
    - Publication bias
    - Study limitations
    - Inconsistency of results
    - Indirectness of evidence
    - Imprecision
    - Publication bias

1. Formulating recommendations

There are only two strengths of recommendation, which may be either for or against an intervention: 1 = strong or 2 = weak. Pragmatically, this means the following:

* Strong recommendation for intervention:

For patients — Most people in this situation would want the recommended course of action and only a small proportion would not.

For clinicians — Most people should receive the intervention.

For quality monitors — Adherence to this recommendation could be used as a quality criterion or performance indicator. If clinicians choose not to follow such a recommendation, they should document their rationale.

* Weak recommendation for intervention:

For patients — Most people in this situation would want the suggested course of action, but many would not.

For clinicians — Examine the evidence or a summary of the evidence yourself and be prepared to discuss that evidence with patients, as well as their values and preferences.

For quality monitors — Clinicians’ discussion or consideration of the pros and cons of the intervention, and their documentation of the discussion, could be used as a quality criterion.

* No specific recommendation:
  + The advantages and disadvantages are equivalent.
  + The target population has not been identified.
  + Insufficient evidence on which to formulate a recommendation.

1. Consideration of using PICO

This may be helpful if guideline writing committee wish to utilise this method, this is explained in the NICE guideline manual; chapter 4:6.

|  |  |
| --- | --- |
| **Patients/population** | Which patients or population of patients are we interested in? How can they be best described? Are there subgroups that need to be considered? |
| **Intervention** | Which intervention, treatment or approach should be used? |
| **Comparison** | What is/are the main alternative/s to compare with the intervention? |
| **Outcome** | What is really important for the patient? Which outcomes should be considered, such as intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning? Should other measures such as quality of life, general health status and costs be considered? |

1. Consideration of costs

These may or may not legitimately be included in the GRADE system, but it would be sensible in the current climate to always consider these, and if they are not considered this should be stated and why – for example, there is no significant difference in cost between the recommended treatments.

Generally speaking, GRADE suggests a balance sheet should inform judgments about whether the net benefits are worth the incremental costs. Evidence profiles should always present resource use, not just monetary values.

1. Using the GRADE grid to resolve differences:

This supports the Delphi technique we already adopt, i.e. to develop a consensus within the group.

1. GRADE training for BASHH guideline authors

Authors need to be familiar and confident in using the GRADE system, and training for this is available as follows:

* The papers from the BMJ series in 2008, as listed in the introduction to this appendix. The articles can be accessed through the grade working group web site at: <http://www.gradeworkinggroup.org/publications/index.htm>
* McMaster GRADE online modules: these have been recommended by the GRADE working group and take about 20 minutes each to complete. The web address is: <http://cebgrade.mcmaster.ca/>
* Journal of Clinical Epidemiology 2011: published a 20-part series that is available through the GRADE working group website (link above).

**Summary:**

BASHH have now moved to the GRADE system for evaluating evidence and making recommendations by asking guideline authors and reviewers to apply the principles outlined in sections 1-3 above. Authors should consider structuring their analysis of evidence into PICO questions addressing Population / Intervention / Comparison / Outcome as stated in section 4. Costs should be included in the evaluation and formulation of recommendations as stated in section 5. When resolution of conflicting opinions is required, the GRADE grid should be used. This appendix is a brief summary of the GRADE system how it is to be adopted by BASHH guideline authors.

APPENDIX 2: Equality Impact Assessment Table

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **BASHH Guideline Equality Impact Assessment**  *(based on NICE documentation shared with BASHH August 2019)* | | | | |
| **Guidance title: BASHH Guidelines for the Management** | | **Completed by: Lucy Garvey** | | **Date: 21 July 2025** |
| **How relevant is the topic to equality?** | **Inequalities in health impact of the condition or public health issue** | **Potential of guidance to add value** | **Priority for NHS or other government department** | **Topic relevance; conclusions and outcomes** |
| **Sex/gender** | Men have higher prevalence of HCV than women; women may present with atypical symptoms and face stigma in antenatal care. | The guideline encourages universal HBV testing and risk-based HCV testing rather than sex-based assumptions. | Aligns with NHS Hepatitis C Elimination Programme and BBV priorities. | Guidance supports sex-sensitive approaches to care, testing, and reproductive health. |
| **Race** | People from Black African and Asian backgrounds have higher prevalence of chronic hepatitis B. Language, immigration status, and stigma are additional barriers. | Promotes culturally competent care, inclusive health promotion, and wider BBV testing and vaccination and supporting linkage to hepatitis care. | Supports NHS Core20PLUS5 and public health equality goals. | Recommends targeted approaches in high-risk ethnic groups, ensuring equitable access. |
| **Disability** | People with physical, sensory, or learning disabilities may face access barriers or difficulty understanding care pathways. | Encourages reasonable adjustments and inclusive communication strategies. | Supports the NHS legal duty to make reasonable adjustments. | Ensures guidance is usable by and applicable to services caring for disabled individuals. |
| **Age** | Older adults may have longstanding undiagnosed hepatitis and co-morbidities; young people may be under-tested due to low perceived risk. | Promotes testing and care across the life course, | Aligned with NHS preventative health strategies and liver disease pathways. | Ensures age is not a barrier to access; encourages inclusive and appropriate screening. |
| **Sexual orientation** | GBMSM and some LGBTQ+ groups are at higher risk for hepatitis A, B and C; fear of stigma may reduce access to services. | Highlights specific risk factors in GBMSM and endorses non-judgmental, inclusive care. | Supports sexual health commissioning priorities and national vaccination programmes. | Reinforces inclusive practice and risk-based assessment irrespective of sexual orientation. |
| **Gender reassignment** | Trans people may experience stigma, misclassification, or lack of risk-based care. Under-testing may occur. | Uses inclusive language and encourages gender-affirming, individualised care pathways. | Supports NHS England LGBTQ+ inclusion strategy. | Emphasises risk-based, person-centred approaches to care. |
| **Religion/belief** | Some religious beliefs may influence attitudes toward vaccination, blood testing, or treatment. | Encourages shared decision-making, cultural sensitivity and respectful communication. | Aligns with NHS policies on spiritual care and patient dignity. | Promotes awareness among clinicians and avoids discriminatory assumptions. |
| **Pregnancy & maternity** | Risk of vertical transmission of HBV and HCV; management and treatment during pregnancy/breastfeeding may need modification. Some may experience stigma or fear accessing care. | Recommends specialist clinical pathways for pregnancy, including testing and treatment where appropriate. | Supports NHS antenatal screening and perinatal transmission reduction strategies. | Reinforces need for integrated care and supports access during maternity. |
| **Other definable characteristics & socioeconomic factors, including:**  **• Prisoners and young offenders**  **• Refugees and asylum seekers**  **• Migrant workers**  **• Looked after children**  **• Homeless people**  **• Deprivation**  **• Disadvantage associated with geographical distinctions** | These groups may have higher rates of undiagnosed and/or untreated hepatitis due to stigma, poor access to care, and marginalisation. | The guideline encourages low-threshold services, integration with drug services. | Aligned with NHS and UKHSA targets for hepatitis elimination, and inclusion health strategies. | Supports wider testing and use of preventative vaccination and local collaboration to address structural barriers. |

APPENDIX 3: AGREE II User Manual

The AGREE II consists of 23 key items organized within 6 domains followed by 2 global rating items (“Overall Assessment”). Each domain captures a unique dimension of guideline quality [[7]](#footnote-7).

**DOMAIN 1.** SCOPE AND PURPOSE

**1.** The overall objective(s) of the guideline is (are) specifically described.

**2.** The health question(s) covered by the guideline is (are) specifically described.

**3.** The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

**DOMAIN 2.** STAKEHOLDER INVOLVEMENT

**4.** The guideline development group includes individuals from all relevant professional groups.

**5.** The views and preferences of the target population (patients, public, etc.) have been sought.

**6.** The target users of the guideline are clearly defined.

**DOMAIN 3.** RIGOUR OF DEVELOPMENT

**7.** Systematic methods were used to search for evidence.

**8.** The criteria for selecting the evidence are clearly described.

**9.** The strengths and limitations of the body of evidence are clearly described.

**10.** The methods for formulating the recommendations are clearly described.

**11.** The health benefits, side effects, and risks have been considered in formulating the recommendations.

**12.** There is an explicit link between the recommendations and the supporting evidence.

**13.** The guideline has been externally reviewed by experts prior to its publication.

**14.** A procedure for updating the guideline is provided.

**DOMAIN 4.** CLARITY OF PRESENTATION

**15.** The recommendations are specific and unambiguous.

**16.** The different options for management of the condition or health issue are clearly presented.

**17.** Key recommendations are easily identifiable.

**DOMAIN 5.** APPLICABILITY

**18.** The guideline describes facilitators and barriers to its application.

**19.** The guideline provides advice and/or tools on how the recommendations can be put into practice.

**20.** The potential resource implications of applying the recommendations have been considered.

**21.** The guideline presents monitoring and/or auditing criteria.

**DOMAIN 6.** EDITORIAL INDEPENDENCE

**22.** The views of the funding body have not influenced the content of the guideline.

**23.** Competing interests of guideline development group members have been recorded and addressed.

APPENDIX 4: Pilot Feedback Form

|  |  |
| --- | --- |
| Guideline |  |
| Dates for the period of guideline piloting |  |
| Name |  |
| Affiliation |  |
| Date |  |
| **Good points about the guideline** |  |
| **Points for improvement** |  |
| **Any other general comments** |  |

1. Guyatt GH, Oxman AD, Vist G, et al; GRADE Working Group. BMJ 2008; 336:924-926. [↑](#footnote-ref-1)
2. Guyatt GH, Oxman AD, Kunz R, et al; GRADE Working Group. BMJ 2008; 336(7651):995-8. [↑](#footnote-ref-2)
3. Schünemann HJ, Oxman AD, Brozek J, et al; GRADE Working Group. BMJ 2008; 336(7653):1106-10. [↑](#footnote-ref-3)
4. Guyatt GH, Oxman AD, Kunz R, et al; GRADE Working Group. BMJ 2008; 336(7654):1170-3. [↑](#footnote-ref-4)
5. Guyatt GH, Oxman AD, Kunz R, et al; GRADE Working Group. BMJ 2008; 336(7652):1049-51. [↑](#footnote-ref-5)
6. Jaeschke R, Guyatt GH, Dellinger P, et al; GRADE working group. BMJ 2008; 337:a744. [↑](#footnote-ref-6)
7. Appraisal of Guidelines for Research & Evaluation (AGREE) II User Manual, update from December 2017. Access: <https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf> [↑](#footnote-ref-7)