



Complete Summary

GUIDELINE TITLE

Hepatitis A, B and C. In: Sexually transmitted infections: UK national screening and testing guidelines.

BIBLIOGRAPHIC SOURCE(S)

Gilson R, Brook MG. Hepatitis A, B and C. In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 85-96. [57 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
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SCOPE

DISEASE/CONDITION(S)

- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Hepatitis C (HCV)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Urology

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide advice on what tests for hepatitis A, B, and C (HAV, HBV, and HCV) are most appropriate in a United Kingdom (UK) genitourinary (GU) clinic setting
- To provide a basis for audit
- To support clinics when bidding for additional resources to meet national standards

TARGET POPULATION

- Individuals in the United Kingdom with suspected acute hepatitis and those with symptoms or signs of chronic liver disease or abnormal liver function tests (LFTs) consistent with acute or chronic hepatitis
- Asymptomatic sexually transmitted disease (STD) clinic attendees in the United Kingdom who are at increased risk of hepatitis A, B, or C

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening of asymptomatic patients in certain risk groups
2. Enzyme-linked immunosorbent assays (ELISAs)
3. Deoxyribonucleic acid (DNA) amplification
4. Testing prior to vaccination
5. Site of testing (serum, plasma, saliva)
6. Identification of risk groups
7. Frequency of testing
8. Follow-up testing for cure (not relevant)

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of test methods
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For each type of hepatitis, a Medline search was performed for the years 1966 - 2003 (June) for hepatitis types A and B and 1990-2003 (June) for hepatitis C. From the MeSH terms "hepatitis A", "hepatitis B", and "hepatitis C", the following sub-headings were used: Diagnosis, Epidemiology, Etiology, Prevention and Control, Transmission, Virology. Textword searches for "hepatitis A", hepatitis B", and "hepatitis C" were combined, as appropriate, with textword searches for "complication", "diagnosis", "prevention", "transmission", "HIV."

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines have been developed following the methodological framework of the Appraisal of Guidelines Research and Evaluation instrument (AGREE - adapted as described in *Int J STD and AIDS* 2004 15:297-305).

The extent to which the guideline represents the views of intended users has been addressed primarily by the authorship coming from the multidisciplinary membership of the Bacterial Special Interest Group (BSIG). As practising clinicians the authors were able to draw on their experience of applying the tests to symptomatic and asymptomatic patients, but it was not feasible to obtain formal input from representative patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

- A. Evidence at level Ia or Ib
- B. Evidence at level IIa, IIb, or III
- C. Evidence at level IV

COST ANALYSIS

A published cost analysis was reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The following published guidelines were reviewed and cross-referenced with the recommendations made in this guideline:

- Brook MG. European guideline for the management of Hepatitis B and C virus infections. *Int J STD AIDS* 2001;12(suppl 3):48-57
- Brook MG. National guideline for the management of the viral hepatitis A, B and C. (BASHH Clinical Effectiveness Group, July 2002)
- Cramp M, Rosenberg W. Guidance on the treatment of hepatitis C incorporating the use of pegylated interferons. (British Society of Gastroenterology 2003)

After drafting, other health care professionals and professional bodies in genitourinary (GU) medicine were asked to comment, the draft guidelines posted on the British Association for Sexual Health and HIV (BASHH) website for 3 months, and all comments reviewed before final publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the level of evidence (**I-IV**) and grade of recommendation (**A-C**) are provided at the end of the "Major Recommendations" field.

Screening/Diagnosis

Hepatitis A Virus (HAV)

- Diagnostic tests for HAV are recommended in anyone presenting with an acute illness or raised transaminase levels, suggesting acute hepatitis and in contacts of known cases (sexual, household or other close contact) (**Evidence Level II**).
- Screening of asymptomatic sexually transmitted disease (STD) clinic attendees is recommended to ascertain their immune status only if they meet the criteria for hepatitis A vaccination (see the National Guideline Clearinghouse [NGC] summary of the British Association for Sexual Health and HIV [BASHH] [National Guideline on Management of the Viral Hepatitis A, B & C](#)) which includes homosexual men in regions where an outbreak of hepatitis A has been reported, injecting drug users, and patients with chronic hepatitis B or C, or other causes of chronic liver disease (**Evidence Level III**).

Hepatitis B Virus (HBV)

- Diagnostic tests for HBV are recommended in anyone presenting with suspected acute hepatitis and in those with symptoms or signs of chronic liver disease, or abnormal liver function tests (LFTs) consistent with acute or chronic hepatitis (**Evidence Level II**).
- Screening of asymptomatic STD clinic attendees is recommended if they fall into one of the groups at increased risk of hepatitis B and who should be given vaccine if still susceptible. The testing strategy used should identify both those who are already immune to infection and those who are currently infected (most will be chronic carriers). Those who should be screened include homosexual men or their contacts, sex workers or their contacts, intravenous drug users or their contacts, recipients of blood/blood products, needlestick recipients, sexual assault victims, human immunodeficiency virus (HIV)-positive people and sexual partners of hepatitis B surface antigen (HBsAg)-positive people (**Evidence Level II**), and people from areas where hepatitis B is endemic.
- Screening of patients who have been born, raised or otherwise resident in endemic countries and travellers who have had sexual contacts in endemic countries, is also recommended to identify those who are currently infected and may be at risk of transmitting infection to others (those who are still

susceptible should be given vaccine only if they are at future risk of infection) (**Evidence Level II**).

Hepatitis C Virus (HCV)

- Diagnostic tests for HCV are recommended in anyone presenting with suspected acute hepatitis, and in those with symptoms or signs of chronic liver disease, or abnormal LFTs consistent with acute or chronic hepatitis (**Evidence Level II**).
- Screening of asymptomatic STD clinic attendees is recommended if they fall into one of the groups at increased risk which includes intravenous drug users, recipients of blood/blood products, needlestick recipients, HIV-positive people and sexual partners of HCV-positive people (**Evidence Level II**).

Recommended Tests

NOTE: For simplicity the following recommendations refer to tests, such as enzyme-linked immunosorbent assay (ELISA) or deoxyribonucleic acid (DNA) amplification which are all, unless otherwise stated, conducted on blood samples. Most commercial serological assays for hepatitis virus infections can be used with either serum or plasma. Local protocols should be agreed with relevant laboratory departments.

Hepatitis A

- To diagnose suspected acute hepatitis: ELISA for anti-HAV immunoglobulin M (IgM) (detectable at or before the onset of symptoms and persists for up to six months) (**Evidence Level II**).
- To determine if immune to infection: ELISA for anti-HAV (total antibody - standard tests detect both IgM and IgG antibody) (**Evidence Level II**).
- Sensitivities and specificities approach 100% (**Evidence Level II**).
- Assays for salivary samples exist but are not generally available for routine use. They have a sensitivity of about 80% for IgA (**Evidence Level II**).

Hepatitis B

- To diagnose suspected acute hepatitis: ELISA for HBsAg and IgM anti-hepatitis B core (anti-HBc) antibody. If HBsAg-positive, proceed to hepatitis B 'e' antigen (HBeAg) and antibody (HBeAb) (**Evidence Level II**).
- Screening in asymptomatic patients may include tests for HBsAg, anti-HBc and anti-HBs on all samples, or may follow a sequential testing algorithm (**Evidence Level II**). (The flow charts in the original guideline document show algorithms starting with anti-HBc or HBsAg).
- Testing for anti-HBs alone prior to vaccination may also be considered, but must be followed by serological investigation of any patient who remains anti-HBs-negative post-vaccine, because they may already be HBsAg-positive. Testing for anti-HBc antibody and anti-HBs prior to vaccination may also be considered (**Evidence Level II**).
- Assays for anti-HBc and HBsAg in saliva samples have been used for surveillance and research purposes but are not currently available commercially for diagnostic use (**Evidence Level II**).

Hepatitis C

- To diagnose suspected acute hepatitis C: serum anti-HCV by second or third generation ELISA or other immunoassays (e.g., chemiluminescence) (**Evidence Level II**).
- Different strategies exist to confirm a positive result. These include a recombinant immunoblot assay (RIBA), using another ELISA, or proceeding directly to an assay for HCV-RNA (**Evidence Level II**). Seroconversion for HCV antibody may take 3 months so antibody tests may give negative results when a patient presents with acute hepatitis (**Evidence Level II**). Detection of HCV-RNA by reverse-transcriptase polymerase chain reaction (RT-PCR) or another genome amplification assay will establish or exclude the diagnosis at this time (**Evidence Level II**). HCV-RNA can be detected as early as two weeks after infection. An HCV-antigen ELISA can be used to diagnose acute infection in HCV-antibody negative cases, but is not as sensitive as genome detection (**Evidence Level II**).
- HCV-RNA detection should be repeated 6 months after acute hepatitis C to confirm whether the infection has become chronic (**Evidence Level II**).
- Screening in asymptomatic patients: As for acute infection but test all patients with detectable HCV-antibody for HCV-RNA, to confirm persistent viral replication (**Evidence Level II**). Antibody-negative patients do not require further testing unless recent infection is suspected, or there is a strong suspicion of infection in an immunocompromised patient in whom persistent infection has occasionally been reported without detectable antibody (**Evidence Level III**).

Recommended Samples for Testing

Serum or plasma

Factors Which Alter Tests Recommended (see flow charts in the original guideline document)

- Hepatitis A:** Some clinics do not test for anti-HAV in patients who are being considered for vaccination. This may be more cost-effective depending upon the age and risk group, but the additional cost may be small if, for example, HAV testing is carried out at the same time as HBV screening (**Evidence Level III**).
- Hepatitis B:** Serum HBV-DNA may be detectable in patients with anti-HBc but without detectable HBsAg. In patients with abnormal LFTs other causes should be excluded before attributing liver disease to HBV infection in such cases (**Evidence Level II**). Some patients have detectable anti-HBc but neither anti-HBs nor HBsAg are detectable. These patients should be considered immune (**Evidence Level I**).
- Hepatitis C:** In patients with abnormal LFTs serum HCV-RNA may be the only test that is positive during acute HCV infection, or rarely in immunosuppressed patients (see above) (**Evidence Level II**).

Sexual History

No change

Risk Groups

- Homosexual men – no change
- Sex workers – no change
- Young patients – no change
- Other groups:
 - Pregnant women – no change
 - Patients who are known contacts – tests as for suspected acute hepatitis

Recommendations for Frequency of Repeat Testing in an Asymptomatic Patient

- The frequency of testing depends on the history of sexual exposure and number of sexual partners. However, in the case of hepatitis A and B, once the patient has completed a course of vaccination no further repeat testing is required.
- For those at continuing risk and who have not received a course of vaccination, the following is recommended:
 - Hepatitis A:
 - No routine repeat screening (**Evidence Level IV**)
 - If a previously non-immune homosexual man gives a history of contact with a known case of hepatitis A, post-exposure prophylaxis with vaccine (and possibly immunoglobulin if over 50 years old, immunocompromised, or with co-existing liver disease) should be offered as soon as possible (**Evidence Level II**). Prophylaxis needs to be given within 1 to 2 weeks of exposure, although immunoglobulin may be of additional value for up to 2 to 3 weeks (**Evidence Level II**). Screening for anti-HAV should be offered at the same time as prophylaxis with further tests if indicated clinically (**Evidence Level IV**).
 - Hepatitis B:
 - If a previously non-immune person gives a history of unprotected anal or vaginal sex with a known case of infectious hepatitis B, post-exposure prophylaxis with vaccine should be offered as soon as possible (if less than six weeks post exposure) (**Evidence Level II**) and screening repeated and again at three months post-exposure. Hepatitis B specific immunoglobulin should only be given if within 72 hours of first exposure (**Evidence Level II**).
 - Otherwise repeat screening at yearly intervals if risk behaviour continues (**Evidence Level IV**).
 - Hepatitis C:
 - The rate of seroconversion after unprotected vaginal or anal sex is about two percent per year if neither partner is HIV-positive but the risk rises to over ten percent if there is HIV infection in either partner (**Evidence Level II**). Repeat screening should be offered to contacts with an HCV-infected partner who continues to be exposed to infection. The optimum frequency has not been defined but may be every 6 to 12 months (**Evidence Level IV**).
 - Repeat screening of others considered to be at risk, as listed above may be offered. No frequency of screening has been

defined, but annual testing may be considered (**Evidence Level IV**).

- There is value in screening at 6 and 12 weeks using an HCV-RNA assay after a high-risk incident (e.g., parenteral exposure from an HCV-positive source) to detect acute infection early, when therapy may reduce the risk of ensuing chronic infection, at least in HIV-uninfected patients (**Evidence Level II**). Antibody tests should be repeated at 3, 6 and 12 months (**Evidence Level III**).
- Patients with high-risk exposures to any of these viruses should be informed about the symptoms of acute hepatitis and encouraged to seek advice immediately if these develop.

Recommendation for Test of Cure

- Not relevant for these infections.
- Patients with newly diagnosed infection due to HBV or HCV should have serological markers of infection (HBsAg or HCV-RNA) measured three and six months later to establish whether the infection has become chronic (**Evidence Level II**).
- Serological follow-up after antiviral therapy is beyond the scope of this guideline.

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

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Grading of Recommendations

- A. Evidence at level Ia or Ib
- B. Evidence at level IIa, IIb, or III
- C. Evidence at level IV

CLINICAL ALGORITHM(S)

The original guideline document contains clinical algorithms for:

- Hepatitis B screening using anti-hepatitis B core antibody (anti-HBc) as the primary screening test
- Hepatitis B screening using hepatitis B surface antigen (HBsAg) as the primary screening agent
- Hepatitis C testing using antibody assay

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening and diagnosis of hepatitis A, B or C infection

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The guideline includes the routine use of hepatitis C virus- ribonucleic acid (HCV-RNA) testing which is not available in all microbiology or virology laboratories; however, all centres have access to these tests through reference laboratories.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Gilson R, Brook MG. Hepatitis A, B and C. In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 85-96. [57 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUIDELINE COMMITTEE

Screening Guidelines Steering Committee
Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Dr Richard Gilson, University College London and Camden Primary Care Trust, The Mortimer Market Centre, London; Dr M Gary Brook, Patrick Clements Clinic, Central Middlesex Hospital, London

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflicts of interest:

Richard Gilson has received support from Gilead Sciences, Roche Products and Schering-Plough to attend conferences, and has received departmental support for research from Gilead Sciences.

M. Gary Brook: None

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from [British Association for Sexual Health and HIV Web Site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Specifications for the development of UK guidelines on the management of sexually transmitted infections (STIs) and closely related conditions 2005. London (UK): British Association of Sexual Health and HIV (BASHH); 2005. 14 p. Electronic copies: Available in Portable Document Format (PDF) from the [British Association for Sexual Health and HIV Web site](#).

Additionally, auditable outcome measures can be found in the [original guideline document](#).

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 25, 2008. The information was verified by the guideline developer on October 20, 2008.

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