## NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE PUBLIC HEALTH DRAFT GUIDANCE

# Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection

# Introduction: scope and purpose of this draft guidance

# What is this guidance about?

This guidance aims to ensure more people at increased risk of hepatitis B and C infection are tested. The recommendations cover:

- Awareness-raising among:
  - the general population
  - health professionals and others providing services for those at increased risk of hepatitis B or C infection
  - those at increased risk.
- Testing:
- in primary care
- in prisons, including youth offender institutions
- within drugs services.
- Contact tracing for hepatitis B.
- Delivering and auditing hepatitis B vaccination.
- Laboratory services for hepatitis B and C tests.
- Commissioning hepatitis B and C testing and treatment services.

This guidance does not provide detail on treatments for hepatitis B or C. (For treatment recommendations see other NICE guidance listed in section 7.)

# Who is this guidance for?

The guidance is for:

- Commissioners and providers of public health services, hepatitis testing and treatment services and laboratory services for hepatitis B and C testing.
- Local organisations providing services for children and adults at increased risk of chronic hepatitis B and C, including those in the NHS, local authorities, prisons and drugs services. It is also for voluntary sector and community organisations working with those at increased risk.

The guidance may also be of interest to groups at increased risk of viral hepatitis, for example, migrant populations from countries with an intermediate or high prevalence of hepatitis B infection or people who use drugs and their families. In addition, other members of the public may have an interest.

# Why is this guidance being produced?

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE) to produce this guidance.

The guidance should be implemented alongside other guidance and regulations (for more details, see sections 4 and 7 on implementation and related NICE guidance respectively).

## How was this guidance developed?

The recommendations are based on the best available evidence. They were developed by the Programme Development Group (PDG).

Members of the PDG are listed in appendix A.

The guidance was developed using the NICE public health programme process. See appendix B for details.

Supporting documents used to prepare this document are listed in appendix E.

# What evidence is the guidance based on?

The evidence that the PDG considered included: reviews of the evidence, economic modelling and the testimony of expert witnesses. Further detail on the evidence is given in the considerations section (section 3) and appendices B and C.

In some cases the evidence was insufficient and the PDG has made recommendations for future research.

More details on the evidence on which this guidance is based, and NICE's processes for developing public health guidance, are on the <u>NICE website</u>.

# Status of this guidance

This is draft guidance.

This document does not include all sections that will appear in the final guidance. NICE is now inviting comments from stakeholders (<u>listed on our website</u>).

Note that this document is not NICE's formal guidance on hepatitis B and C testing. The recommendations made in section 1 are provisional and may change after consultation with stakeholders.

The stages NICE will follow after consultation are summarised below.

- The Group will meet again to consider the comments and any additional evidence that has been submitted.
- After that meeting, the Group will produce a second draft of the guidance.
- The draft guidance will be signed off by the NICE Guidance Executive.

For further details, see '<u>The NICE public health guidance development process: An</u> overview for stakeholders including public health practitioners, policy makers and the public (second edition, 2009)'.

### The key dates are:

Closing date for comments: 8 August 2012.

Next PDG meeting: 12 and 13 September 2012.

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# 1 Draft recommendations

The Programme Development Group (PDG) considers that the recommended measures and approaches are cost effective.

The evidence statements underpinning the recommendations are listed in appendix C.

For the gaps in research, see appendix D.

# **Pre-requisites**

The recommendations are based on the assumption that hepatitis tests are delivered according to current best practice and are offered as part of a care pathway covering diagnosis and treatment.

The recommendations also assume that all frontline healthcare staff involved in testing for hepatitis B and C, including non-clinical staff, are trained in diversity issues. This means they are able to challenge the stigma of, and dispel the myths surrounding, hepatitis and testing for hepatitis. It also means they should be able to create a physical and emotional environment where both children and adults feel at ease.

### Testing

The recommendations assume that appropriate pre- and post-test discussions take place when testing for hepatitis B and C. The offer of a test should also:

- be accompanied by an agreed mechanism for getting the result to the person being tested
- be phrased in a way that suits a person's age and culture and be delivered in a non-judgmental, respectful way
- take into account potential barriers to testing such as the potential stigma associated with it or lack of access to services
- include information to enable people to make informed choices about their care.

### Treatment

Current best practice guidelines on managing <u>hepatitis B</u> and <u>C</u> are available from the European Association for the Study of the Liver (EASL). NICE has recommended a number of drugs to treat hepatitis B and C, see section 7 for details.

## Whose health will benefit?

Children and adults at increased risk of hepatitis B or C compared to the general UK population. This includes:

- People born or brought up in a country with an intermediate (more than 2.0%) or high (more than 8.0%) prevalence of chronic hepatitis B (and who may also be at increased risk of hepatitis C). This includes all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific islands.
- People who have injected recreational drugs (no matter how rarely) or who share drugs paraphernalia, such as straws (used for snorting drugs) or needles.
- Men who have sex with men, commercial sex workers and anyone who has unprotected sex and frequently changes sexual partners.
- Prisoners and young offenders.
- Children and young people living in care homes.
- Close contacts of someone known to be chronically infected with hepatitis B or hepatitis C.
- Babies born to mothers infected with hepatitis B or C.

# Recommendation 1 Awareness-raising about hepatitis B and C among the general population

#### Who should take action?

Commissioners and providers of national public health services working in partnership with:

- other government departments allied to health
- local commissioners and providers of public health services
- the commercial sector
- national voluntary sector, not-for-profit and non-governmental organisations.

#### What action should they take?

- Identify and make use of existing campaign messages and resources on hepatitis
   B and C to raise awareness of these infections. Include ideas from other
   countries, where available and appropriate. If nothing is available, generate
   messages and resources. These should include up-to-date information on the:
  - availability of effective treatment
  - benefits of testing and treatment, including the fact that earlier diagnosis and treatment can help prevent complications and serious illness such as liver disease
  - main routes of infection and transmission
  - mostly asymptomatic nature of chronic infection (that is, there are very few symptoms in the early stages).
- Ensure awareness-raising campaigns address common misconceptions about the risk of hepatitis B and C that can act as a barrier to testing. This includes the belief that treatments are not effective, or that treatment is not needed until the illness is advanced. Campaigns should also make it clear that testing and treatment is confidential and address any stigma surrounding these infections.
- Ensure messages to raise awareness of hepatitis B and C are integrated, where possible and relevant, within other health promotion campaigns or are used to Hepatitis B and C: ways to promote and offer testing Consultation draft

support interventions to prevent liver disease. Ensure they are consistent, clear and culturally appropriate.

 Ensure national awareness-raising activities take into account cultural, religious and group norms and needs, in terms of message format, the medium and the language used. For example, translated information should be provided to address the needs of non-English-speaking groups at increased risk.

# Recommendation 2 Awareness-raising among health professionals and others providing services for those at increased risk of hepatitis B or C

#### Who should take action?

- Directors of public health.
- NHS deaneries or other organisations responsible for the development of health and social care staff.

#### What action should they take?

- Ensure there is an ongoing education programme for professionals providing health and social care services for those at greatest risk of hepatitis B or C. This includes:
  - clinical and non-clinical staff in primary, secondary and tertiary care
  - nurses, health visitors and midwives
  - those working in drugs services
  - prison staff
  - staff in voluntary and community organisations that care for or support migrant populations or people who inject drugs
  - genitourinary and HIV clinics.
- Ensure the education programme is tailored to each target group, as appropriate. It should include accurate, up-to-date detail on the:

- routes of hepatitis B and C transmission, the clinical consequences of infection and treatment options
- local groups at increased risk
- people from groups at increased risk who have been offered a test, have been tested or have refused a test
- diagnostic tests and samples required
- way to interpret results
- social and cultural barriers to testing and treatment (for example, people's fear of stigma and staff attitudes towards hepatitis B and C)
- importance of confidentiality
- additional support and advice that people taking a test may need (for example, they may need advice on the impact a positive test may have on their employment prospects or insurance)
- local referral pathways, including who to refer to and how
- role of other professionals in awareness-raising, identifying cases and helping people complete treatment
- importance of testing at-risk populations whenever an appropriate opportunity arises
- importance of repeat testing for those who continue to adopt highrisk behaviours
- availability and indication for hepatitis B vaccination.
- Consider linking awareness-raising activities with existing education for health and social care professionals. This could take a variety of forms, for example, it could be offered as a taught or an electronic learning module.
- Deaneries in each region should ensure doctors and nurses involved in testing for hepatitis B and C partake in a programme of continuing professional development to develop their knowledge, skills and ability in this area.

 Directors of public health, in collaboration with the local deanery should use staff annual appraisals and personal development plans to reinforce training and education on hepatitis B and C.

# Recommendation 3 Awareness-raising among those at increased risk of hepatitis B or C infection

#### Who should take action?

- Directors of public health.
- Local organisations providing services for children and adults at increased risk including the NHS (primary, secondary and tertiary care), local authorities and community and voluntary sector organisations with a remit for these groups.
- Other local and national organisations involved in hepatitis testing or treatment.

#### What action should they take?

- Directors of public health should ensure there is a local programme of awarenessraising about hepatitis B and C among groups at increased risk.
- Local organisations should provide awareness-raising material tailored to these groups' needs. In addition to the information outlined in recommendation 1, this should:
  - tell them how and where to access local testing services
  - describe what having a hepatitis test involves
  - address the needs of non-English-speaking at-risk groups, for example, by providing translated information
  - be appropriate for all ages.
- Local organisations should, where possible, encourage people from groups at increased risk who have experienced viral hepatitis to contribute to awarenessraising activities.

 Local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and events frequented by groups at increased risk.
 Examples of possible venues include: faith centres, NHS and non-NHS drugs services, GP surgeries and prisons. Examples of relevant events could include cultural activities aimed at people from black and minority ethnic groups.

# Recommendation 4 Testing for hepatitis B and C in primary care

#### Who should take action?

Primary care practitioners.

#### What action should they take?

- Be aware of groups of adults and children who are at increased risk of infection from hepatitis B and C (see Whose health will benefit? at the beginning of this section). Whenever an appropriate opportunity arises, offer them a hepatitis B and C test.
- Offer a hepatitis B and C test to everyone who has newly registered, and who is
  part of an at-risk group. This includes both adults and children from countries with
  an intermediate or high prevalence of hepatitis. It also includes adults who are
  newly registered with the practice who have injected drugs. (Ask all adults
  whether or not they have ever injected drugs once they have registered with the
  practice.).

# Recommendation 5 Testing for hepatitis B and C in prisons

#### Who should take action?

- Local infection control team.
- NHS hepatitis treatment services.
- Prison healthcare services, including services for young offenders.
- Public Health England units.

#### What action should they take?

- Prison healthcare services should develop a viral hepatitis policy in conjunction with the hepatitis treatment service, the Public Health England unit, local infection control team and prison healthcare service commissioners.
- Prison healthcare services should designate a member of staff as the viral hepatitis lead for the prison or youth offender service. The lead should have the knowledge and skills needed to promote hepatitis B and C testing and treatment.
- The NHS treatment service lead for viral hepatitis (for example, this may be the community hepatitis nurse) should develop a care pathway for prisoners infected with hepatitis B or C. This should be developed in conjunction with prison healthcare services, drugs services, the Public Health England unit and prison healthcare service commissioners. As part of the care pathway:
  - Any suspected or confirmed cases should be reported to, and managed by, the local hepatitis treatment services, in liaison with prison healthcare services.
  - Investigations and follow-up should be undertaken within the prison (based on the in-reach model), wherever practically possible.
  - Prisoners should be treated by staff from the local hepatitis treatment service (the prison should support this by, for example, giving these staff security clearance).
- Prison healthcare services should ensure:
  - On entry into a prison, prisoners at increased risk of hepatitis B or C infection are offered a test. This could be offered when prisoners are being offered a hepatitis B vaccination (for the vaccination schedule refer to the <u>Green book</u>).
  - All prisoners are given information on hepatitis B and C and how to access confidential testing within 7 days of their arrival.
  - A mechanism is in place for prisoners to be tested for hepatitis B and C at any point during their stay in prison.

- Mechanisms are in place to give prisoners the results of a hepatitis B or C test, regardless of their location when the test results become available.
- Staff involved with testing prisoners for hepatitis B and C are appropriately trained and have up-to-date information about the infections, including treatments and local care pathways. They should also respect the need for confidentiality when dealing with these issues.
- The NHS treatment service lead for viral hepatitis in prisons should ensure prison healthcare services have contingency, liaison and handover arrangements before any prisoner being treated for hepatitis is transferred between prisons or released. Other agencies working with prisoners or detainees should also be involved in this planning.
- The person responsible for managing a prisoner's hepatitis treatment should ensure their continuity of care if they are transferred, or following their release. If necessary, prisoners due to be transferred should be retained on medical hold to help them complete their treatment.

# Recommendation 6 Testing for hepatitis B and C within drugs services

### Who should take action?

- Drugs services including drug and alcohol action teams.
- Hepatology service commissioners.
- NHS hepatitis treatment services.
- Public Health England units.

#### What action should they take?

- Commissioners from all of the above services should agree a local care pathway for people with hepatitis B and C who attend drugs services. Where possible, the pathway should include the possibility of providing hepatitis B and C treatment services in community settings.
- Medical staff should use their clinical judgment to determine who is suitable for hepatitis B or C treatment in a community setting.
- Drugs services should designate a member of staff as the hepatitis lead. The lead should have the knowledge and skills to be able to promote hepatitis B and C testing and treatment.
- Drugs services should have access to dried blood-spot and specialist phlebotomy services to help with testing and treatment for hepatitis B and C, particularly for people who inject drugs.
- Drugs services should be able to call on trained peers of people who are at increased risk of hepatitis B and C to promote testing and support them during testing and treatment. The people providing peer support should also be given support (for further information see NICE guidance on <u>community engagement</u>).
- Drugs services staff should:
  - Be trained to undertake dried blood-spot testing if carrying out hepatitis B and C testing.
  - Have the knowledge, confidence and skills to be able to promote the benefits of hepatitis testing, discuss the symptoms and the implications of a positive or a negative test.
  - Routinely check all clients, including those aged under 18, for hepatitis B and C risk factors.
  - Offer a hepatitis B and C test to all clients with any risk factors. If the client declines the offer, staff should explore their barriers to being tested, with the aim of dispelling their concerns and helping them to

get tested. They should also offer them information and peer support with a view to reviewing their decision.

 Consider giving information on hepatitis B and C testing and treatment to any client they are concerned about, whether or not the client has disclosed that they inject drugs or are involved in any other high-risk behaviour.

# Recommendation 7 Contact tracing for hepatitis B

#### Who should take action?

Public Health England units.

#### What action should they take?

- Be directly accountable for tracing the close contacts of all notified cases of hepatitis B.
- Oversee other local organisations that undertake close contact or household contact-tracing and regularly audit their activities to ensure they follow recognised <u>national standards</u>. For example, contacts may need to be vaccinated and, where relevant, referred for appropriate treatment.

## Recommendation 8 Delivering and auditing hepatitis B vaccination

#### Who should take action?

Directors of public health.

#### What action should they take?

- Ensure existing recommendations on hepatitis B vaccination, as detailed in the Green book and NICE guidance on reducing the differences on the uptake of immunisations, are implemented locally.
- Audit the hepatitis B vaccination programme for babies to gauge uptake. Note whether the babies involved were given all required doses, whether the doses were given at the right time and whether the babies were tested post-vaccination. Hepatitis B and C: ways to promote and offer testing Consultation draft

Also note vaccination failure rates among babies of chronically infected mothers. This audit should be carried out on an annual basis.

# Recommendation 9 Laboratory services for hepatitis B and C tests

#### Who should take action?

Commissioners of laboratory services offering hepatitis B and C tests.

#### What action should they take?

- Ensure laboratory services offering hepatitis B and C tests:
  - have Clinical Pathology Accreditation
  - can support the range of samples used for hepatitis B and C tests (for example, dried blood-spot or venipuncture samples)
  - can provide the full spectrum of tests needed to determine infection
  - can deliver the results within 2 weeks (for suspected acute hepatitis
     B, results should be delivered in 1 day, in line with <u>Health Protection</u>
     <u>Agency standards</u>)
  - can automatically perform an assay for detection of hepatitis C virus in the sample if the sample is antibody positive (for example, the polymerase chain reaction assay).
- In accordance with <u>national legislation</u>, ensure local public health services are notified of all newly diagnosed cases of acute and chronic viral hepatitis B and C.
- Provide the organisation or person requesting a test with an accurate interpretation of the laboratory results and guidance on how to manage positive results.
- Ensure laboratory services can provide accurate data on the following:
  - number of tests performed
  - referral source of samples (for example, primary care, secondary care, drug and alcohol services, prisons)
  - exposure category (where provided)

- number of positive tests.

# Recommendation 10 Commissioning hepatitis B and C testing and treatment services

#### Who should take action?

Commissioners of hepatitis testing and treatment services.

#### What action should they take?

- Undertake a regular needs assessment and a regular audit of hepatitis B and C services as part of the agreed local care pathway.
- Audit the uptake of testing and outcomes, including the number of:
  - hepatitis B and C tests performed
  - positive tests
  - people who test positive who are referred to a specialist
  - people who see the referral specialist
  - people who test positive and are offered therapy
  - people who test positive and are being treated
  - people with hepatitis C who achieve a sustained virological response.
- Working with services that provide hepatitis B and C tests and treatment in both primary and secondary care, develop and commission a fully integrated care pathway. This should:
  - take into account the needs of all local groups at increased risk of hepatitis B or C, including those who are in prison
  - consider all venues where testing and treatment services are, or could be offered, to ensure continuity of care (such as pharmacy testing and outreach testing and treatment)
  - consider the broader health and psychosocial needs of those at increased risk, for example, their nutritional, housing and financial needs

- ensure primary and secondary care staff are educated and trained in hepatitis B and C testing and treatment, as appropriate.
- Encourage the development of locally enhanced services for hepatitis B and C in areas where the population includes a higher than average number of people at increased risk (see 'Whose health will benefit?' at the beginning of this section).
- Ensure men who have sex with men are tested for hepatitis B and C, especially those who are HIV-positive.

# 2 Public health need and practice

# Hepatitis C

Hepatitis C is a blood-borne viral infection transmitted through contact with infected blood, for example, by sharing infected injecting equipment. It can also be transmitted through other body fluids. Around 70–75% of people who are infected develop a chronic condition and are at risk of liver failure and liver cancer.

In the UK, an estimated 216,000 people are thought to be chronically infected (Health Protection Agency 2011b). Around 161,000 of them live in England with 39,000, 12,000 and 4000 chronic cases in Scotland, Wales and Northern Ireland respectively (Health Protection Agency 2011b). The estimate for Scotland relates to the end of 2009, while the figures for England, Wales and Northern Ireland date to the mid-2000s. There is, therefore, considerable uncertainty about the current UK situation.

In England, 48,946 infections were diagnosed by the end of 2005, representing only 30% of the estimated chronic burden at that point. It is estimated that only around 12,400 of those people were treated between 2006 and 2008 (Health Protection Agency 2011b).

The burden of hepatitis C, in terms of hospitalisations, registrations for liver transplant and deaths from liver cancer, is steadily increasing throughout the UK. In England, the rates of 'end stage' disease caused by hepatitis C are likely to increase, if diagnosis and treatment rates do not improve (Health Protection Agency 2011b).

### **Risk factors**

In England, injecting drug use is the main cause of hepatitis C infection. Around 44% of the estimated number of people who are chronically infected inject drugs, 43% are former injectors, 5.6% are of South Asian descent and have never injected and 7.3% of cases have no history of injecting (Harris et al. 2011a). Similarly, 90% of the total laboratory reports including risk information attribute infection to injecting drug use (Health Protection Agency 2011c).

The prevalence of chronic disease varies by region. It is highest in London and the North West and increases with an increasingly aged population (Harris et al. 2011b). This is confirmed by data from the 2010 Unlinked Anonymous Monitoring (UAM) survey of people who inject drugs and attend specialist services (Harris et al. 2011b). The UAM survey suggests that more of this group are being tested (83% reported having a voluntary test for hepatitis C, compared to 40% in 2000). However, the numbers being tested is still low. Only 55% of those who tested positive were aware they were infected before they had the test.

# Hepatitis B

Hepatitis B infection is transmitted through contact with infected blood, as well as perinatally from mother to child.

Some adults can clear the infection naturally. However, the risk of progression depends on the age when someone is infected. About 85% of infections in newborns and 4% in adults become chronic and could lead to severe liver disease (Edmunds et al. 1993).

The most recent estimate from the Department of Health suggests that, in 2002, 180,000 people in the UK might have had chronic hepatitis B (DH 2002). However, other organisations believe that figure may have been closer to 360,000. Currently, information on the hepatitis B burden in England and Wales derives from a number of sources:

- laboratory reports
- serological studies of populations covered by screening programmes (pregnant women and blood donors)
- serological studies of populations at high risk (people who inject drugs)
- sentinel surveillance
- estimates of the size of the migrant population.

The DH study relied on the analysis of laboratory reports sent to the Health Protection Agency between1995 and 2000. On the basis of the 4040 reported 'acute

infections' over the period (on average, 673 reports per year), the annual incidence in England and Wales was estimated at around 7.4 per 100,000 people. This translates into around 3700 new acute infections a year and around 270 chronic cases per year.

#### **Risk factors**

Injecting drug use was the most frequently reported route of infection in the UK, according to the <u>Health Protection Agency</u>, and the number of such cases peaked in 1998 (251 HBsAg positive and anti-HBc IgM positive cases). Homosexual contact was the second most frequently reported risk factor. People of South Asian origin also appear to be at high risk: the prevalence of acute hepatitis B among this group was estimated to be more than double the estimated overall incidence. Over 95% of chronic infections were estimated to be associated with immigration (Hahné et al. 2004).

Since 2000, transmission routes of acute infection have followed a similar trend. For 2010, risk factor information (only available for 47% of acute cases) suggests the number of cases attributable to injecting drug use has continued to decline (Health Protection Agency 2011a). This is confirmed by the 2010 UAM survey, which reports a fall from 28% to 16% cases (Health Protection Agency 2011c). This decrease might be associated with an increase in the self-reported uptake of hepatitis B vaccine, from 35% in 2000 to 74% in 2010, among the people injecting drugs who were cited by the UAM survey (Health Protection Agency 2011c).

#### Prevalence broken down by ethnic group

The prevalence of hepatitis B among the population as a whole can be estimated by determining the prevalence of hepatitis B surface antigen (HBsAg), using data from the sentinel surveillance study. This study has been collecting information on hepatitis testing in a number of participating centres since 2002 (Health Protection Agency 2011d).

In 2010, 22 sentinel centres reported that 192,664 people had undergone HBsAg testing and 1.6% of them had tested positive. Of those who tested positive, 0.7% had

an acute infection. Around three quarters of those tested could be classified into four broad ethnic groups: white or white-British (77.8%), Asian or Asian-British (15%), 'other' or mixed ethnicity (4.3%), and black or black-British ethnicity (2.6%). The highest proportion of positive tests was among the 'other' or mixed ethnicity group (8.8%), followed by people of black or black-British (7.4%), Asian or Asian-British (2.6%) and people who were white or white-British (0.84%).

Where information on the reason for testing was available (31.2% of the tested population), injecting drug use was reported in 1.7% of cases – and for 0.5% of those who tested positive. Sexual exposure was reported by 7.1% of those tested and accounted for 4.3% of the positive results.

#### Antenatal screening

Antenatal screening for HBsAg has been carried out by the Infectious Diseases in Pregnancy Screening Programme since 2004 (Health Protection Agency 2011a). The results show an increasing uptake over time (94% in 2010) but with the percentage of positive tests remaining about the same (0.45% in 2010).

The sentinel surveillance identified that 24.6% (62,282) of the women who had been tested for HBsAg in 2010 had been tested as part of antenatal screening for HBsAg. Overall, 0.5% of them tested positive. Most of the 62,282 women were classified as white or white-British. More black or black-British (3.8%) and 'other' or mixed ethnicity (4.3%) women tested positive for HBsAg compared with their Asian/Asian-British (0.5%) and white- counterparts (0.3%).

#### **Complex picture**

The information above shows a complex picture with a heterogeneously distributed risk of infection among children and adults, affected by country of birth, ethnicity, injecting drug use and sexual practices.

## National recommendations

The national immunisation programme recommends that people from at-risk groups are immunised against hepatitis B. Due to an increased risk of chronic infection,

post-exposure immunisation is also recommended for babies born to chronically infected mothers (DH 2006).

NICE recommends a number of treatments for hepatitis B and hepatitis C (see section 7 for related NICE guidance). If someone who is infected can be identified and treated early enough, their risk of developing long-term complications, such as cirrhosis and liver cancer, can be reduced. For those with chronic hepatitis C, early therapy is associated with increased and sustained virological response rates (Corey et al. 2010).

# 3 Considerations

The Programme Development Group (PDG) took account of a number of factors and issues when developing the recommendations.

## Awareness-raising

- 3.1 The PDG was aware of the potential benefit of educating all health professionals about hepatitis B and C but was pragmatic in its approach, focusing on those who were likely to be providing services.
- 3.2 Recent developments in the treatment of hepatitis B and C are not reflected in the qualitative literature on the barriers and facilitators to testing. This is because much of the research was undertaken before the newer drugs (see section 7) were available. The Group felt that awareness of more effective treatments may have a positive impact on the uptake of testing.
- 3.3 The need for awareness-raising and training on hepatitis C for health professionals was a key theme in the qualitative review and was in accord with PDG members' experiences. The Group heard reports of people having to initiate testing for viral hepatitis and liver function and being left with misinformation and confusion about their diagnosis, its consequences and treatment pathways. The Group felt it important that professionals working in this area had the ability to help people make informed choices.

# Barriers and facilitators

3.4 There are many barriers to testing for hepatitis B and C for groups at increased risk of infection and many are similar for both infections. They include:

- Fear of stigma caused by both health professionals and family or friends. (When defining those at increased risk of hepatitis B and C the PDG was mindful not to further stigmatise these groups.)
- Knowledge and awareness in relation to the transmission of infection and the treatments available. The PDG was aware of a general lack of knowledge about hepatitis B and C, including among those promoting tests for these infections. Members felt that this contributed to the low uptake of testing among people at increased risk of infection. They also felt it contributed to the stigma surrounding these infections.
- Parental fears that they will not be able to cope with the issues their child may face if the child is found to have hepatitis B or C. (This is especially the case if no appropriate information and care pathways have been discussed with parents.)
- Staff attitudes and competency.
- 3.5 People who may have injected drugs in the past may not want to revisit that part of their lives. This may be a barrier to hepatitis testing and treatment. The PDG felt that positive messages about treatment – particularly the latest and forthcoming advances – and any attempts to 'normalise' testing might help reach these people.
- 3.6 The PDG acknowledged that, while it is important to conduct tests in a timely manner, some people at increased risk may face more pressing issues than the need to know if they are hepatitis B or C positive. For example, economic, social or other health needs may be more of a priority for them.
- The PDG recognised the important role that immediate relatives,
   'significant others' and other family members may play in encouraging
   people to get tested and complete treatment. The Group also recognised

a role for the peers of people at increased risk in promoting hepatitis B and C testing and supporting them.

- 3.8 The PDG noted that it was important to ensure people are not stigmatised by the way information on hepatitis B and C is delivered.
- 3.9 Transmission of hepatitis B from mother to child may be considered normal among some minority ethnic communities. Although this means there is less stigma associated with infection among this community, the Group felt that acceptance of infection may adversely impact on the uptake of testing and treatment. It noted a lack of qualitative evidence about this route of transmission, suggesting a lack of awareness and the need for preventive education.
- 3.10 In countries where there is a high prevalence of hepatitis B, employees may be routinely screened for infection and the stigma surrounding it may be higher among people from those countries.
- 3.11 The PDG noted that people who inject drugs and have hepatitis C could be stigmatised by the injecting drug community, as a diagnosis of hepatitis C suggests a history of sharing paraphernalia. This is in addition to the stigma people who inject drugs already face.
- 3.12 The PDG was mindful that offering universal testing in certain settings, rather than singling people out, may help reduce the stigma surrounding hepatitis B and C. Similarly, the stigma of having a test may be reduced for injecting drug users if it is possible to utilise dried blood-spot testing or if there is someone who specialises in blood-taking available. (It can be difficult to take blood from someone whose veins have been damaged and can lead to multiple attempts which can prove embarrassing, not to mention painful.)
- 3.13 The PDG discussed the need to train primary care staff in how to carry out pre- and post-test discussions with people at increased risk of hepatitis B Hepatitis B and C: ways to promote and offer testing Consultation draft

and C. It recognised that a barrier to the implementation of such training was time constraints.

## Testing

- 3.14 The PDG recognised that the use of dried blood-spot testing for diagnosis may be more acceptable to some of the target populations than taking a blood sample from a vein, especially if there is poor venous access. In addition, more staff would probably be able to could carry out such tests, so helping to increase the number of people who are tested. For this reason, the PDG felt that the provision of both dried blood-spot testing and access to specialist phlebotomy would play a pivotal role in increasing testing uptake.
- 3.15 It can be difficult to take a sample of blood from a person who has injected drugs, due to the damage done to their veins, which will be required to monitor treatment. For this reason, the PDG felt that access to specialist phlebotomy services would be an important aid to increasing uptake of treatment
- 3.16 No recommendations were made on the use of a mouth swab for hepatitis B or C testing. The PDG recognised that this method may be more acceptable to some people because it is less invasive than taking blood from a vein. However, if an oral fluid sample was used, a blood sample would then be required to confirm the initial positive results, and for polymerase chain reaction testing for hepatitis C.
- 3.17 The PDG acknowledged that different populations are at increased risk of hepatitis B or C. However, there is some overlap between them and, to simplify delivery, it made sense to recommend testing for both.
- 3.18 The PDG felt that the point of entry into a hepatitis B vaccination programme also provides an opportunity to test those considered to be at increased risk for both hepatitis B and C infection. The Group was aware

of cases where people had repeatedly been vaccinated against hepatitis B but not tested for infection and had later been found to have chronic infection and subsequent liver damage.

- 3.19 The PDG acknowledged that there may be opportunities to combine hepatitis B and C testing with broader, blood-borne virus prevention and testing activities.
- 3.20 The PDG felt that there may be merit in considering other venues, such as pharmacies, for testing (in terms of ease of accessibility). However, there was no evidence to support such a recommendation.

## Limitations of the evidence

- 3.21 There was little published evidence on effective interventions to promote and offer testing to those at increased risk of hepatitis B. There was also a lack of corresponding evidence for interventions addressing hepatitis C testing among migrants. The PDG, therefore, largely drew on practical experience to formulate the recommendations.
- 3.22 Research has focused on hepatitis B among minority ethnic groups and hepatitis C among people who inject drugs. The PDG was concerned about the potential cross over – between infections and groups at increased risk (for example, drug use may be a route for hepatitis B transmission). Members were also concerned about people who have previously injected drugs, and other groups at increased risk, because there was no evidence on how to effectively reach them. This includes, for example commercial sex workers and men who have sex with men. The group felt that the principles of the recommendations may apply to these groups.
- 3.23 The mapping review provided limited evidence of existing good practice on testing among those at increased risk.

# Economic modelling

- 3.24 The way hepatitis B and C are transmitted among different groups at greatest risk varies according to each group. For example, among people who inject drugs in the UK, in 90% of cases hepatitis C is transmitted by sharing injecting equipment. Among migrant groups (people from medium and high endemicity countries), while adult-to-adult transmission of hepatitis B does occur, only about 5% of such cases become chronic. The main transmission routes are via mother to baby and between children through exposure to contaminated blood. The majority of chronic infections of hepatitis B are acquired in the country of origin. The modelling analyses took these differences into account.
- 3.25 There was a lack of data on interventions to increase rates of case-finding and treatment in prison, and on continuity of treatment from prison into the community. This meant it was difficult to judge the cost effectiveness of such interventions and treatment rates following diagnosis.
- 3.26 The migration modelling was also severely hampered by lack of data on the prevalence of chronic hepatitis B among minority ethnic groups, the cost of finding infected people within these groups and treatment rates.
- 3.27 The cost effectiveness of primary care interventions to promote testing for hepatitis B and hepatitis C among men who have sex with men was not formally evaluated. The PDG acknowledged the existence of other NICE guidance promoting testing for other infections among this group. The modelling undertaken showed that, where there is a reasonably high prevalence of undiagnosed cases of hepatitis B and C, adding a test for these infections when testing for HIV would be cost effective.

## Prisons

3.28 The PDG noted a lack of evidence on interventions in specific settings, for example, prisons. Expert testimony was sought to address these gaps.

- 3.29 Given the prevalence of hepatitis B and the history of injecting drug use among the prison population, the PDG recognised the importance of prison as a setting for the promotion and offer of hepatitis B and C testing. It also acknowledged that the established hepatitis B vaccination programme in prisons provides an opportunity for discussing the benefits of being tested.
- 3.30 The PDG recognised that prisons vary in numbers and types and that a 'one-size-fits-all' approach on testing and subsequent treatment for hepatitis is not appropriate.
- 3.31 The PDG was aware of problems with the transfer of medical records and information between prison and community settings. However, it was beyond the remit of this guidance to make recommendations about sharing health data between custodial and community providers.
- 3.32 The PDG recognised the barriers to continuity of care when someone enters or is released from prison. However, the Group felt that these barriers should not be viewed as reasons not to test prisoners for hepatitis.
- 3.33 Prison testing for hepatitis B and C is cost effective if there is continuity of care when someone who is infected is referred to, from or between prisons and treatment is seamlessly completed in at least 40% of cases.
   Prison testing would also help ensure prisoners have the same access to healthcare as everyone else, thus addressing health inequalities.
- 3.34 The PDG was aware that a key factor impacting on treatment outcomes was the length of someone's remaining stay in prison following diagnosis
   many prisoners only live at one site for short periods of time, for example when on remand.
- 3.35 The PDG was aware that treatment success rates are greater when treatment is based on an 'in-reach' model of care in prisons (rather than Hepatitis B and C: ways to promote and offer testing Consultation draft

escorted outpatient treatment). However, the Group acknowledged that the necessary security arrangements in prison could act as a barrier to this approach.

#### Data

- 3.36 The PDG acknowledged the limitations and challenges of current surveillance systems for hepatitis B and C. The Group considered that the collection and collation of robust, service-level data on testing and treatment services was important for both monitoring and developing services.
- 3.37 The PDG discussed the need for a comprehensive hepatitis B and C database holding details on people who have been tested and treated and on those identified as being at increased risk but who have refused to be tested. It considered that an integrated system, bridging different healthcare providers and capturing a range of data, was the ideal. (It could include demographic details, exposure category, testing information, laboratory results, referrals and treatment outcomes.) It was felt that there needed to be a balance between the burden of collecting data and the value of that data. The Group acknowledged that it would be resource-intensive. Members also noted that such databases have been developed in other countries and have proven to be effective.
- 3.38 The PDG moved away from a focus only on those with chronic hepatitis infection, as regardless of whether infection is acute or chronic it contributes to transmission rates.
- 3.39 Snorting drugs and sex have been recently recognised as routes for hepatitis C infection about which there is little data.

## Other issues

- 3.40 The PDG discussed how hepatitis B and C compares with other diseases, such as HIV and coronary heart disease, in terms of the resources available for treatment.
- 3.41 It may not always be obvious when a particular group is at increased risk of hepatitis B or C. Examples include: children born to parents who inject drugs, and who may later be placed in care or adopted, foreign students – or children who have been adopted – from a country with a medium or high background endemicity. Other, smaller groups who are at increased risk of chronic infection include people who have:
  - Received blood or a blood product transfusion prior to the introduction of hepatitis C virus screening of the blood supply (1991) or prior to the introduction of heat treatment for clotting factor concentrates (1986).
  - Received medical or dental procedures abroad where infection control may be inadequate.
  - Been exposed to unsterile needles (for example, by having non-professional tattoos, body or ear piercing, or acupuncture.
- 3.42 The PDG noted the importance of ascertaining the identity of individuals being tested for hepatitis B and C. Members had been made aware of instances where NHS cards have been passed on or sold to illegal migrant workers by some Chinese immigrants. In some cases medical information has, as a result, been linked to the wrong people with potentially hazardous consequences.
  - 3.43 The PDG emphasised existing hepatitis B vaccination recommendations (as detailed in the <u>Green book</u>) because, although hepatitis B vaccination was beyond the scope of this guidance, case-finding may identify people who should be vaccinated.

- 3.44 In addition, the Group was aware of the complexities of the vaccination schedule for babies born to infected mothers. Specifically, members were aware of the apparent failure of the system to ensure babies receive a full course of vaccination and then have their immunity confirmed.
- 3.45 Staff working in drugs services have a diverse mix of skills. As a result, it would not be possible to adopt a universal approach to training them in hepatitis B and C testing. However, the PDG felt that all staff should be capable of encouraging people to have a test.
- 3.46 The PDG focused on people who inject drugs and migrants from medium and high endemicity countries. The Group noted that effective testing has already been implemented for other groups at increased risk, including men who have sex with men and people with multiple sexual partners. For other populations at increased risk there was no evidence that infection rates were sufficiently high to warrant a recommendation. (These groups include those who have been exposed to unsterile needles, for example, by having non-professional tattoos, body or ear piercing, or acupuncture.)

This section will be completed in the final document.

# 4 Implementation

NICE guidance can help:

- Commissioners and providers of NHS organisations, social care and children's services meet national priorities and the requirements of the DH's 'Operating framework for 2011/12'.
- National and local organisations improve quality and health outcomes and reduce health inequalities.
- Local authorities improve the health and wellbeing of people in their area.

- Local NHS organisations, local authorities and other local partners benefit from any identified cost savings, disinvestment opportunities or opportunities for redirecting resources.
- Provide a focus for integration and partnership working across social care, the NHS and public health organisations.

NICE will develop tools to help organisations put this guidance into practice. Details will be available on our website after the guidance has been issued.

# 5 **Recommendations for research**

The Programme Development Group (PDG) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to cost effectiveness and duration of effect. It also takes into account any harmful/negative side effects.

- 5.1 How many children in the UK are infected with chronic hepatitis B and C and which subgroups of the population do they come from?
- 5.2 What factors influence whether or not specific groups at increased risk of hepatitis B and hepatitis C infection are identified and tested?
- 5.3 What factors influence whether or not specific high-risk groups will comply with treatment following a positive hepatitis B or C test?
- 5.4 What are the most effective ways of getting people from high-risk groups involved in awareness-raising about, and promoting testing for, hepatitis B and C infection?
- 5.5 Which interventions aimed at healthcare practitioners are effective at increasing the number of high-risk people who are tested and treated for hepatitis B and C?
- 5.6 What impact does increased knowledge and awareness of hepatitis B and C among the general public have on the uptake of testing and treatment? Hepatitis B and C: ways to promote and offer testing Consultation draft

- 5.7 Which interventions for other communicable diseases could be effectively used to encourage people at increased risk of hepatitis B and C to take up the offer of testing and treatment?
- 5.8 What is the most cost effective method for contact tracing following notification of a new case of hepatitis B or C?

More detail on the gaps in the evidence identified during development of this guidance is provided in appendix D.

# 6 Updating the recommendations

This section will be completed in the final document.

# 7 Related NICE guidance

# Published

Hepatitis C (genotype 1) - boceprevir. NICE technology appraisal 253 (2012)

Hepatitis C (genotype 1) - telaprevir. NICE technology appraisal 252 (2012)

<u>Tuberculosis – hard to reach groups</u>. NICE public health guidance 37 (2012)

Increasing the uptake of HIV testing among men who have sex with men. NICE public health guidance 34 (2011)

Increasing the uptake of HIV testing among black Africans in England. NICE public health guidance 33 (2011)

Hepatitis C – peginterferon alfa and ribavirin. NICE technology appraisal 200 (2010)

Hepatitis B – tenofovir disoproxil fumarate. NICE technology appraisal 173 (2009)

<u>Reducing differences in the uptake of immunisations</u>. NICE public health guidance 21 (2009)

<u>Needle and syringe programmes</u>. NICE public health guidance 18 (2009) Hepatitis B and C: ways to promote and offer testing Consultation draft
Antenatal care. NICE clinical guideline 62 (2008)

Hepatitis B - telbivudine. NICE technology appraisal 154 (2008)

Hepatitis B – entecavir. NICE technology appraisal 153 (2008)

<u>Prevention of sexually transmitted infections and under-18 conceptions</u>. NICE public health guidance 3 (2007)

Hepatitis C – peginterferon alfa and ribavirin. NICE technology appraisal 106 (2006)

<u>Hepatitis B (chronic) - adefovir dipivoxil and pegylated interferon alpha-2a</u>. NICE technology appraisal 96 (2006)

<u>Hepatitis C – pegylated interferons, ribavirin and alfa interferon</u>. NICE technology appraisal 75 (2004)

# Under development

Hepatitis B: diagnosis and management. NICE clinical guideline (publication expected June 2013)

# 8 Glossary

#### **Close contacts**

The people in close contact with someone infected with hepatitis B or C virus, where there is a risk of spreading the infection (via blood or body fluids). This could include their family members, close friends, household contacts or sexual partners.

#### **Continuity of care**

Continuation of treatment and referral for treatment for people moving in, out or between prisons.

#### Household contact

A person sharing a bedroom, kitchen, bathroom or sitting room with the index case.

#### Locally enhanced services

Additional services provided by GPs, designed to meet specific local health needs.

#### Medical hold

A process to ensure prisoners are not transferred until they are medically fit enough.

#### **NHS** deaneries

Bodies responsible for managing and delivering postgraduate education and continuing professional development for medical staff.

#### Peers

Peers are members of the target population who have experienced hepatitis B and/or hepatitis C. They are often in a good position to help convey, with empathy, the need for testing or treatment. They may be recruited and supported to communicate health messages, assist with contact investigations or testing, and to offer people support while they are being tested or treated.

#### Prison

Her Majesty's prison establishments, including young offender institutions.

#### In-reach model

Healthcare services are brought into the prison, rather than the prisoner being taken out to the healthcare service (for example, to a hospital outpatient unit).

# 9 References

Corey KE, Mendez-Navarro J, Gorospe EC et al. (2010) Early treatment improves outcomes in acute hepatitis C virus infection: a meta-analysis. <u>Journal of Viral</u> <u>Hepatitis</u> 17 (3): 201–207.

Department of Health (2006) Immunisation against infectious disease – the green book. London: Department of Health

Department of Health (2002) Getting ahead of the curve: a strategy for combating infectious diseases (including other aspects of health protection). London: Department of Health

Edmunds WJ, Medley GF, Nokes DJ et al. (1993) The influence of age on the development of the hepatitis B carrier state. Proceedings B 253: 197–201

Hahné S, Ramsay M, Balogun K et al. (2004) Incidence and routes of transmission of hepatitis B virus in England and Wales, 1995–2000: implications for immunisation policy. Journal of Clinical Virology 29: 211–20

Harris RJ, Ramsay M, Hope V et al. (2011a) Hepatitis C prevalence in England remains low and varies by ethnicity: an updated evidence synthesis. European Journal of Public Health

Harris R, Hope V, Marongiou A (2011b) Spatial mapping of hepatitis C prevalence in recent injecting drug users in contact with services. Epidemiology and Infection

Health Protection Agency (2011a) Health protection report weekly report 4 (34). London: Health Protection Agency Centre for Infections

Health Protection Agency (2011b) Hepatitis C in the UK 2011. London: Health Protection Agency Centre for Infections

Health Protection Agency (2011c) Shooting up: Infections among people who inject drugs in the UK 2010. An update: November 2011. London: Health Protection Agency

Health Protection Agency (2011d) Sentinel surveillance of hepatitis testing in England. Hepatitis B and D 2010 report. Analysis of testing between 2007 and 2010. London: Health Protection

# Appendix A Membership of the Programme Development Group (PDG), the NICE project team and external contractors

# Programme Development Group

PDG membership is multidisciplinary. The Group comprises academics, clinicians, local authority officers, public health practitioners, social care professionals, teachers, technical experts and representatives of the public, as follows.

Vijay Anad GP, Worcester

Neil Connelly Community Member

**Daniela De Angelis** Programme Leader, Medical Research Council Biostatistics Unit, Institute of Public Health, Cambridge

Kate Drysdale Clinical Nurse Specialist, Dudley Group Community Services

**Erika Duffell** Expert in Surveillance for HIV, STI and Hepatitis, European Centre for Disease Prevention and Control (ECDC), Stockholm

Opal Greyson Viral Hepatitis Specialist Nurse, NHS Bedford and Luton

**Richard Grieve** Senior Lecturer in Health Economics, London School of Hygiene and Tropical Medicine

**Matt Hickman** (Chair) Professor in Public Health and Epidemiology, School of Social Community Medicine, University of Bristol

**Will Irving** Professor and Honorary Consultant in Virology, University of Nottingham and Nottingham University Hospitals NHS Trust

Emily Kam-Yin Lam Community Member

**Deirdre Kelly** Professor of Paediatric Hepatology, Birmingham Children's Hospital NHS Foundation Trust

Salim Khakoo Professor of Hepatology, Imperial College, London

Danny Morris Independent Consultant, UK Harm Reduction Alliance

Cristina Osorio Community Member

Kylie Reed Psychiatrist and Clinical Research Worker, National Addiction Centre

April Wareham Community Member

Helen Wilks (Co-Chair) National Needle Exchange Forum

James Windsor Community Member

Nat Wright Clinical Director Vulnerable Groups, NHS Leeds

#### NICE project team

Mike Kelly CPHE Director

Antony Morgan Associate Director

Kay Nolan Co-lead Analyst

Clare Wohlgemuth Co-lead Analyst

Hilary Chatterton Analyst

James Jagroo Analyst

Alastair Fischer Technical Adviser, Health Economics

Victoria Axe Project Manager

Melinda Kay Coordinator

Sue Jelley Senior Editor

#### Alison Lake Editor

# **External contractors**

#### **Evidence reviews**

Review 1 was carried out by Liverpool John Moores University. The principal authors were: Lisa Jones, Amanda Atkinson, Lorna Porcellato, Geoff Bates, Ellie McCoy, Caryl Beyon, Jim McVeigh and Mark Bellis.

Review 2 was carried out by Liverpool John Moores University. The principal authors were: Lisa Jones, Geoff Bates, Ellie McCoy, Caryl Beynon, Jim McVeigh and Mark Bellis.

The mapping review was carried out by Liverpool John Moores University. The principal authors were: Lisa Jones, Geoff Bates, Ellie McCoy, Amy Luxton, Caryl Beynon, Jim McVeigh and Mark Bellis.

#### **Cost effectiveness**

The review of economic evaluations was carried out as part of review 2.

Economic modelling was carried out by the London School of Hygiene and Tropical Medicine. It comprised two reports. The principal authors were: Natasha Martin, Alec Miners, Peter Vickerman and Anjan Ghosh.

See appendix E for the titles of the above reports.

# Expert testimony

Presentation 1 by Annie Mackie, UK National Screening Committee.

Presentation 2 by Mary Ramsay, Health Protection Agency Centre for Infections.

Presentation 3 by Dr Eamonn O'Moore, Health Protection Agency.

Presentation 4 by Jaswant Sira, Birmingham Children's Hospital NHS Foundation Trust.

Presentation 5 by Jez Thompson, Royal College of General Practitioners.

Presentation 6 by Magdalena Harris, London School of Hygiene and Tropical Medicine.

Further expert testimony was given verbally by:

Professor Martin Lombard, Department of Health

Catherine Stephens, International Union of Sex Workers

Jenny Wong (on behalf of Chinese interpreters), Manchester Chinese Centre.

# Appendix B Summary of the methods used to develop this guidance

# Introduction

The reviews and economic modelling report include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Programme Development Group (PDG) meetings provide further detail about the Group's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in appendix E and are available at the <u>NICE</u> <u>website</u>.

# Guidance development

The stages involved in developing public health programme guidance are outlined in the box below.

- 1. Draft scope released for consultation
- 2. Stakeholder meeting about the draft scope
- 3. Stakeholder comments used to revise the scope
- 4. Final scope and responses to comments published on website
- 5. Evidence reviews and economic modelling undertaken and submitted to PDG
- 6. PDG produces draft recommendations
- 7. Draft guidance (and evidence) released for consultation and for field testing
- 8. PDG amends recommendations
- 9. Final guidance published on website
- 10. Responses to comments published on website

# Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by the PDG to help develop the recommendations. The overarching questions were:

- Which interventions are effective and cost effective in encouraging people from high-risk groups to use services that currently (or potentially could) offer hepatitis B or C testing?
- What prevents people in high-risk groups from seeking and accepting a hepatitis B or hepatitis C test? How do these factors differ for each group – and what factors increase the likelihood that they will seek and accept a test?

- Which interventions are effective and cost effective at overcoming the barriers to hepatitis B or C testing faced by high-risk groups and professionals?
- What type of services and activities need to be commissioned to encourage people who have tested positive to continue to seek support?

These questions were made more specific for each review (see reviews for further details).

# Reviewing the evidence

#### **Qualitative review**

One qualitative review was conducted (review 1).

#### Identifying the evidence

A number of databases were searched in March/April 2011 for qualitative studies exploring the views on, and experiences of, hepatitis B and C testing and treatment among those at greatest risk. Five journals with the highest yield of references were selected as follows:

- Australian Health Review
- Gastroenterology Nursing
- International Journal of Drug Policy
- Journal of Community Health
- Journal of Viral Hepatitis.

All journal issues (113) and supplements published between 2008 and 2011 were hand-searched. A number of websites were also searched. For details, see the review.

#### Selection criteria

Studies were included in review 1 if they considered:

- Groups at an increased risk of hepatitis B and C infection, their close contacts and practitioners who treat them or are involved in preventive activities.
- Mixed 'low' and 'high'-risk populations where it was possible to attribute the findings to particular high-risk populations.
- The views and experiences of groups at increased risk towards case-finding, testing, communication of test results or subsequent treatment.
- Patient and practitioner perspectives on the barriers to, and opportunities for, changing behaviour in relation to hepatitis B and C testing and subsequent care and treatment.

Studies were excluded if they:

- Focused solely on general population groups or groups at low risk of hepatitis B or C.
- Used structured questionnaires as the sole method of data collection.
- Only reported quantitative data not elicited from the patients or providers themselves.

#### **Effectiveness review**

One review of effectiveness was conducted (review 2).

#### Identifying the evidence

A number of databases were searched in July 2011 for studies from 1990 onwards.

#### Selection criteria

Studies were included in the effectiveness review if they:

- Targeted groups at increased risk of hepatitis B and C infection.
- Targeted healthcare professionals involved in hepatitis B and C testing and treatment.

- Aimed to raise awareness among people from high-risk groups of hepatitis B and C testing services.
- Encouraged people from high-risk groups and their 'close contacts' to use hepatitis B and C testing services.
- Improved access to testing services.

Studies were excluded if they focused on changing the behaviour of people who inject drugs (in relation to injecting or sharing practices but without reference to case-finding or testing).

See each review for details of the inclusion and exclusion criteria.

#### **Quality appraisal**

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in the NICE technical manual 'Methods for the development of NICE public health guidance' (see appendix E). Each study was graded (++, +, -) to reflect the risk of potential bias arising from its design and execution.

#### Study quality

++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.

+ Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are unlikely to alter the conclusions.

- Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

The evidence was also assessed for its applicability to the areas (populations, settings, interventions) covered by the scope of the guidance. Each evidence statement concludes with a statement of applicability (directly applicable, partially applicable, not applicable).

#### Summarising the evidence and making evidence statements

The review data was summarised in evidence tables (see full reviews).

The findings from the reviews were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the external contractors (see appendix A). The statements reflect their judgement of the strength (quality, quantity and consistency) of evidence and its applicability to the populations and settings in the scope.

#### Mapping review

The mapping review comprised a survey of awareness-raising and other activities to encourage groups at increased risk of hepatitis B and C to seek support.

#### Identifying the evidence

Telephone interviews and an online questionnaire were used with healthcare professionals and representatives of voluntary and community sector organisations who work with those at higher risk of hepatitis B and C. See the review for details.

# Cost effectiveness

There was a review of economic evaluations and two economic modelling exercises.

#### **Review of economic evaluations**

There was a review of economic evaluations as part of the effectiveness review (review 2). Studies were included if they reported both costs (regardless of how estimated) and outcomes (regardless of how specified).

#### **Economic modelling**

Three economic models were constructed to incorporate data from the reviews of effectiveness and cost effectiveness.

A dynamic model was developed to estimate the cost effectiveness of interventions to promote hepatitis testing among people who inject drugs. The model had to be dynamic to account for the ongoing transmission of hepatitis C between people who inject drugs and secondary infections and transmission among others. Hepatitis B and C: ways to promote and offer testing Consultation draft

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Two static models were developed to evaluate interventions aimed at migrant groups. (Hepatitis B and C case finding and treatment in the UK will have an effect on morbidity among those tested, but less impact on the incidence of chronic infection.)

The results are reported in: 'An economic evaluation of finding cases of hepatitis B and C infection in UK migrant populations'; and 'Assessing the cost-effectiveness of interventions aimed at promoting and offering hepatitis C testing to injecting drug users: An economic modelling report'.

# Fieldwork

This section will be completed in the final document.

# How the PDG formulated the recommendations

At its meetings in May, July, September, November and December 2011 and February, March and April 2012, the Programme Development Group (PDG) considered the evidence, and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- where relevant, whether (on balance) the evidence demonstrates that the intervention or programme/activity can be effective or is inconclusive
- where relevant, the typical size of effect (where there is one)
- whether the evidence is applicable to the target groups and context covered by the guidance.

The PDG developed draft recommendations through informal consensus, based on the following criteria:

- Strength (type, quality, quantity and consistency) of the evidence.
- The applicability of the evidence to the populations/settings referred to in the scope.

- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.
- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).
- Balance of harms and benefits.

.

• Ease of implementation and any anticipated changes in practice.

Where possible, recommendations were linked to an evidence statement(s) (see appendix C for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

# Appendix C The evidence

This appendix lists the evidence statements from two reviews, provided by external contractors (see appendix A and appendix E) and links them to the relevant recommendations. See appendix B for the meaning of the (++), (+) and (-) quality assessments referred to in the evidence statements.

The two reviews are:

- Review 1: 'A systematic review of qualitative research on the views, perspectives and experiences of hepatitis B and C testing among practitioners and people at greatest risk of infection'.
- Review 2: 'A systematic review of the effectiveness and cost effectiveness of interventions aimed at raising awareness and engaging with groups who are at increased risk of hepatitis B and C infection'.

The evidence statements are short summaries of evidence, in a review, report or paper (provided by an expert in the topic area). Each statement has a short code indicating which document the evidence has come from. The letter(s) in the code refer to the type of document the statement is from, and the numbers refer to the document number, and the number of the evidence statement in the document.

Evidence statement Q1 indicates that the linked statement is numbered 1 in review 1. Evidence statement E3 indicates that the linked statement is numbered 3 in review 2.

The reviews and economic analysis are available online. Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by **IDE** (inference derived from the evidence).

Where the Programme Development Group (PDG) has considered other evidence, it is linked to the appropriate recommendation below. It is also listed in the additional evidence section of this appendix.

Recommendation 1: evidence statements: Q1, Q2, Q3, Q4, Q5, Q8, Q9, Q10, E1; IDE

**Recommendation 2:** evidence statements: Q2, Q18, Q20, Q21, Q28, Q29, Q30, E2, E5, E8; IDE

**Recommendation 3:** evidence statements: Q1, Q2, Q3, Q4, Q5, Q8, Q9, Q10, Q14, Q15, Q16, Q23, Q28, Q29, E1; IDE

Recommendation 4: evidence statements: Q28, E5, E6, E11

Recommendation 5: evidence statements: Q16, Q27, Q28, E1, E6; IDE

**Recommendation 6:** evidence statements: Q18, Q20, Q21, Q24, Q25, Q28, Q29, Q30, E1, E4, E5, E6, E7, E8, E9; IDE

Recommendation 7: IDE

Recommendation 8: IDE

Recommendation 9: IDE

Recommendation 10: evidence statements: Q7, E5; IDE

#### Evidence statements

Please note that the wording of some evidence statements has been altered slightly from those in the evidence review(s) to make them more consistent with each other and NICE's standard house style.

#### **Evidence statement Q1**

Understanding and awareness of hepatitis B among people born in countries with intermediate and high endemicity may be strongly influenced by their personal experiences and cultural beliefs (two [++], one [+])<sup>1,2,3</sup>.

<sup>1</sup> Burke et al. 2004.

<sup>2</sup> Burke et al. 2011.

<sup>3</sup>Wallace et al. 2011.

#### Evidence statement Q2

People born in countries with intermediate and high endemicity for hepatitis B may confuse the various forms of hepatitis and the relationship between hepatitis and HIV, and they may commonly hold inaccurate beliefs about transmission risks (two [++], one  $[+])^{1 \, 2 \, 3}$ . The lack of, or gaps in, knowledge about hepatitis B identified among some healthcare professionals (two  $[++])^{4,3}$  may contribute to or compound inadequate knowledge about hepatitis B among groups at a high risk of infection.

- <sup>1</sup> Burke et al. 2011.
- <sup>2</sup> van der Veen et al. 2009.
- <sup>3</sup>Wallace et al. 2011.

<sup>4</sup> Hwang et al. 2010.

#### **Evidence statement Q3**

People born in countries with intermediate and high endemicity for hepatitis B may commonly cite access to or contamination of food, or cultural practices associated with sharing food and communal eating, as the main cause of hepatitis B transmission (three [++] and one [+])<sup>1,2,3,4</sup>. Although vertical transmission of hepatitis B was acknowledged in some studies, sexual transmission of hepatitis B was infrequently mentioned; overall, the evidence suggests that groups at a high risk of infection do not perceive hepatitis B as an STI (three [++])<sup>4,5,6</sup>.

- <sup>1</sup> Burke et al. 2004.
- <sup>2</sup> Burke et al. 2011.
- <sup>3</sup> Chen et al. 2006.
- <sup>4</sup> Choe et al. 2005.
- <sup>5</sup> van der Veen et al. 2009.
- <sup>6</sup>Wallace et al. 2011.

#### **Evidence statement Q4**

As with their beliefs about the causes and prevention of hepatitis B, people born in countries with intermediate and high endemicity may express beliefs about prevention that are influenced by their personal experiences and cultural background (four [++])<sup>1,2,3,4</sup>. Among people originating from East and South East Asia, prevention strategies may commonly reflect the practice of traditional medicine and vaccination may not generally be considered as a primary means of prevention (five [++] and one [+])<sup>1,2,5,6,7,8</sup>. Religious influences on preventive health strategies may also be apparent, for example among Muslim men (one [++])<sup>3</sup>.

- <sup>1</sup> Choe et al. 2005.
- <sup>2</sup> Chen et al. 2006.
- <sup>3</sup> van der Veen et al. 2009.
- <sup>4</sup> Wallace et al. 2011.
- <sup>5</sup> Burke et al. 2004.
- <sup>6</sup> Burke et al. 2011.
- <sup>7</sup> Chang et al. 2008.
- <sup>8</sup> Hwang et al. 2010.

#### **Evidence statement Q5**

Despite some participants expressing generally positive attitudes towards vaccination and people at high risk being receptive to vaccination (one [++] and one [+])<sup>1,2</sup> some studies (two [++] and one [+])<sup>1,3,4</sup> indicated that there is significant confusion and uncertainty surrounding vaccination among groups at a high risk of infection.

- <sup>1</sup> Buck et al. 2006.
- <sup>2</sup> van der Veen et al. 2009.
- <sup>3</sup> Chen et al. 2006.
- <sup>4</sup> Chang et al. 2008.

#### **Evidence statement Q7**

Barriers to testing include an absence of clear symptoms of infection, practical obstacles such as inconvenience and time constraints, and language and cultural barriers, all of which may discourage some people from seeking care and may limit the role that healthcare providers play in providing education and outreach to immigrant communities (one [++])<sup>1</sup>.

<sup>1</sup> van der Veen et al. 2009.

#### **Evidence statement Q8**

The conception of hepatitis B as a 'liver' or 'blood' illness rather than a sexually transmitted infection (STI) appears to play an important role in tempering stigma associated with hepatitis B. Increasing awareness of hepatitis B as an STI was viewed by one study ([++])<sup>1</sup>as potentially contributing to increased stigma.

<sup>1</sup> van der Veen et al. 2009.

#### **Evidence statement Q9**

One study reported that people with a diagnosis of chronic hepatitis B, including first and second generation immigrants, had little recollection of providing consent to test and did not receive adequate information at diagnosis. This lack of information and knowledge was perceived as impacting negatively on their health and preventing opportunities for behaviour change. Both patients and community workers expressed concerns about a lack of provider knowledge with regards to hepatitis B (one [++])<sup>1</sup>.

<sup>1</sup> Wallace et al. 2011.

#### **Evidence statement Q10**

One study ([++])<sup>1</sup> reported that people with a diagnosis of chronic hepatitis B, including first- and second-generation immigrants, had little recollection of providing consent to test and did not receive adequate information at diagnosis. This lack of information and knowledge was perceived as impacting negatively on their health and preventing opportunities for behaviour change. Both patients and community

workers expressed concerns about a lack of provider knowledge with regards to hepatitis B.

<sup>1</sup> Wallace et al. 2011.

#### **Evidence statement Q14**

There is strong evidence from 18 studies (eleven [++], five [+], one [-] and one [NR])<sup>1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18</sup> that injecting drug users (IDUs) have an uncertain and incomplete knowledge of hepatitis C. Studies showed that IDUs are confused over what the disease is, how it differs from other forms of hepatitis, how the infection is transmitted and what symptoms are involved. This confusion was reinforced by the perception that expert and scientific knowledge on hepatitis C is shifting and uncertain (three [++] and one [NR])<sup>4,11,12,17</sup>. There is evidence that some IDUs are aware of their limited knowledge of hepatitis C (three [++])<sup>3,4,12</sup>.

<sup>1</sup> Copeland 2004.

<sup>2</sup> Coupland et al. 2009.

<sup>3</sup> Davis and Rhodes 2004.

<sup>4</sup> Davis et al. 2004.

<sup>5</sup> Ellard 2007.

<sup>6</sup> Fraser 2004.

<sup>7</sup> Fraser 2010.

<sup>8</sup> Gyarmathy et al. 2006.

<sup>9</sup> Harris 2009a.

<sup>10</sup> Munoz-Plaza et al. 2004.

<sup>11</sup> Rhodes and Treloar 2008.

<sup>12</sup> Rhodes et al. 2004.

<sup>13</sup> Sosman et al. 2005.

<sup>14</sup> Southgate et al. 2005.

<sup>15</sup> Sutton and Treloar 2007.

<sup>16</sup> Swan et al. 2010.

<sup>17</sup> Tompkins et al. 2005.

<sup>18</sup> Wright et al. 2005.

#### **Evidence statement Q15**

Hepatitis C is often understood in relation to HIV in a way that trivialises the seriousness of contracting hepatitis C and may have implications for the use of safe injecting practices and the uptake of hepatitis C services (eleven [++], two [+] and two [NR])<sup>1,2,3,4,5,6,7,8,9,10,11,12,13,14,15</sup>.

<sup>1</sup> Copeland 2004.

<sup>2</sup> Davis and Rhodes 2004.

<sup>3</sup> Davis et al. 2004.

<sup>4</sup> Ellard 2007.

<sup>5</sup> Faye and Irurita 2003.

<sup>6</sup> Harris 2009a.

<sup>7</sup> Munoz-Plaza et al. 2010.

<sup>8</sup> Rhodes et al. 2004.

<sup>9</sup> Roy et al. 2007.

<sup>10</sup> Southgate et al. 2005.

<sup>11</sup> Sutton and Treloar 2007.

<sup>12</sup> Swan et al. 2010.

<sup>13</sup> Rhodes and Treloar 2008.

<sup>14</sup> Treloar and Rhodes 2009.

<sup>15</sup> Wozniak et al. 2007.

#### **Evidence statement Q16**

A number of barriers to hepatitis C testing among IDUs were identified. People perceiving themselves to be at low risk of hepatitis C infection, a lack of visible symptoms of hepatitis C infection, fear of a positive test result, the use of needles and fear of disclosure were found to prevent the uptake of hepatitis C testing among IDUs (seven [++], eight [+], one [-] and one [NR])<sup>1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17</sup>. Three studies(two [+] and one [-])<sup>7,18,19</sup> reported barriers to testing specific to the prison setting including long waiting times, lack of information provision, prioritisation of detoxification and withdrawal, and movement between prisons.

<sup>1</sup> Craine et al. 2004.

<sup>2</sup> Davis et al. 2004.

<sup>3</sup> Fraser 2004.

<sup>4</sup> Fraser 2010.

<sup>5</sup> Gyarmathy et al. 2006.

<sup>6</sup> Harris 2009a.

<sup>7</sup> Khaw et al. 2007.

<sup>8</sup> Lally et al. 2008.

<sup>9</sup> Perry et al. 2003.

<sup>10</sup> Rhodes and Treloar 2008.

<sup>11</sup> Rhodes et al. 2004.

<sup>12</sup> Temple-Smith et al. 2004.

<sup>13</sup> Sosman et al. 2005.

<sup>14</sup> Southgate et al. 2005.

<sup>15</sup> Strauss et al. 2008.

<sup>16</sup> Sutton and Treloar 2007.

<sup>17</sup> Swan et al. 2010.

<sup>18</sup> Dyer and Tolliday 2009.

<sup>19</sup> Munoz-Plaza et al. 2005b.

#### Evidence statement Q18

Convenient and opportunistic testing and a 'one-stop shop' approach for all hepatitis C services was regarded as a convenient approach among IDUs (three [++] and five [+])<sup>1,2,3,4,5,6,7,8</sup>. There is evidence (two [++] and two [+])<sup>3,9,10,11</sup> that some IDUs were unaware that they had been tested for hepatitis C and concern over informed consent to testing was noted by a number of authors. Although an opportunistic approach can increase testing compliance, a lack of informed consent may also contribute towards uncertain knowledge of hepatitis C among IDUs and limit the impact of testing on behaviour.

<sup>1</sup> Gyarmathy et al. 2006.

<sup>2</sup> Munoz-Plaza et al. 2004.

<sup>3</sup> Rhodes et al. 2004.

<sup>4</sup> Roy et al. 2007.
<sup>5</sup> Sosman et al. 2005.
<sup>6</sup> Swan et al. 2010.
<sup>7</sup> Strauss et al. 2008.
<sup>8</sup> Temple-Smith et al. 2004.
<sup>9</sup> Munoz-Plaza et al. 2005b.
<sup>10</sup> Perry and Chew-Graham 2003.
<sup>11</sup> Tompkins et al. 2005.

#### **Evidence statement Q20**

Trust and rapport with health professionals and drug treatment staff motivated people to get tested. Support and encouragement from health professionals also facilitated testing among IDUs (four [+])<sup>1,2,3,4</sup>.

<sup>1</sup> Munoz-Plaza et al. 2004.

<sup>2</sup> Perry et al. 2003.

<sup>3</sup> Sosman et al. 2005.

<sup>4</sup> Strauss et al. 2008.

#### **Evidence statement Q21**

Studies showed that the experience of being informed about the outcome of hepatitis C testing can be highly confusing (nine [++], two [+], one [-] and one [NR])<sup>1,2,3,4,5,6,7,8,9,10,11,12,13</sup>. Limited and inadequate information provision by health professionals can lead to confusion over the meaning of a positive diagnosis and substantial gaps in knowledge.

<sup>1</sup> Copeland 2004.
<sup>2</sup>Cullen et al. 2005.
<sup>3</sup>Faye and Irurita 2003.
<sup>4</sup>Khaw et al. 2007.
<sup>5</sup>Kinder 2009.
<sup>6</sup>Lally et al. 2008.
<sup>7</sup>Rhodes and Treloar 2008.

<sup>8</sup>Rhodes et al. 2004.
<sup>9</sup>Southgate et al. 2005.
<sup>10</sup>Strauss et al. 2008.
<sup>11</sup>Sutton and Treloar 2007.
<sup>12</sup>Swan et al. 2010.
<sup>13</sup>Tompkins et al. 2005.

#### **Evidence statement Q23**

Fear of the side effects associated with hepatitis C treatment and the circulation of 'horror stories' and unsuccessful treatment cases among peers discouraged IDUs from engaging with treatment (three [++], one [+] and two [-])<sup>1,2,3,4,5,6</sup>. A fear of needles was also common and using needles during the treatment process was a challenge to overcome when considering treatment (two [++] and one [+])<sup>3,5,7</sup>. In contrast, anxiety over hepatitis C, witnessing peers suffer from symptoms of hepatitis C infection and hearing stories of successful treatment cases among peers encouraged treatment uptake (two [++] and one [+])<sup>3,5,8</sup>.

<sup>1</sup> Cullen et al. 2005.

<sup>2</sup> Fraser 2010.

<sup>3</sup> Kinder 2009.

<sup>4</sup> Munoz-Plaza et al. 2008.

<sup>5</sup> Swan et al. 2010.

<sup>6</sup> Treloar and Holt 2008.

<sup>7</sup> Strauss et al. 2008.

<sup>8</sup> Munoz-Plaza et al. 2004.

#### Evidence statement Q24

Socioeconomic and family circumstances can lead to treatment being de-prioritised among IDUs (three[++] and one [-])<sup>1,2,3,4</sup>. Studies have shown that a preoccupation with drug use, chaotic lifestyles, long waiting times between appointments and employment contributed towards IDUs missing and forgetting treatment appointments, thus increasing the possibility of treatment dropout (three [++])<sup>1,3,5</sup>. The assumption of abstinence as a requirement for hepatitis C treatment and Hepatitis B and C: ways to promote and offer testing Consultation draft continued substance use among IDUs acted as a barrier to treatment (six [++] and one [-])<sup>1,3,5,6,7,8,9</sup>

<sup>1</sup> Coupland et al. 2009.

<sup>2</sup> Fraser 2010.

<sup>3</sup> Swan et al. 2010.

<sup>4</sup> Treloar et al. 2010.

<sup>5</sup> Lally et al. 2008.

<sup>6</sup> Cullen et al. 2005.

<sup>7</sup> Roy et al. 2007.

<sup>8</sup>Wozniak et al. 2007.

<sup>9</sup>Wright et al. 2005.

#### **Evidence statement Q25**

Receiving support from family, partners and peers, starting family life and concerns over the impact of hepatitis C on significant others (for example partners and children) motivated IDUs to engage with hepatitis C treatment (three [++])<sup>1,2,3</sup>.

<sup>1</sup> Faye and Irurita 2003.

<sup>2</sup> Kinder 2009.

<sup>3</sup> Swan et al. 2010.

#### **Evidence statement Q27**

One study ([-])<sup>1</sup> found that being in prison was viewed by health professionals as both a barrier and a facilitator for hepatitis C treatment. Transportation of prisoners between prisons and short sentences were viewed as interfering with the treatment process whereas the structured environment of prison and availability of peer support during treatment were regarded as beneficial.

<sup>1</sup> Dyer and Tolliday 2009.

#### **Evidence statement Q28**

Two studies found that a lack of access to treatment and a lack of information on treatment options act as barriers to hepatitis C treatment (two [++])<sup>1,2</sup>. Increasing Hepatitis B and C: ways to promote and offer testing Consultation draft

knowledge of hepatitis C through the provision of information by health professionals encouraged IDUs to consider their treatment options (one [++], two [+] and one [-])<sup>1,3,4,5</sup>.

<sup>1</sup> Swan et al. 2010.

<sup>2</sup> Treloar et al. 2010.

<sup>3</sup> Cullen et al. 2005.

<sup>4</sup> Munoz-Plaza et al. 2004.

<sup>5</sup> Munoz-Plaza et al. 2008.

#### **Evidence statement Q29**

The experience of stigma prevented IDUs from seeking hepatitis C testing because of fear of disclosure, and prevented IDUs from disclosing a positive hepatitis C status because of fear of a negative reaction, isolation and social exclusion (eight [++], three [+], one [-] and one [NR])<sup>1,2,3,4,5,6,7,8,9,10,11,12,13</sup>. Stigma also prevented engagement with further prevention education, investigations and treatment and resulted in IDUs receiving inadequate and judgemental care by health professionals (seven [++], six [+], one [-] and two [NR])<sup>5,6,7,9,12,14,15,16,17,18, 19,20,21,22, 23,24</sup>.

<sup>1</sup> Craine et al. 2004.

<sup>2</sup> Ellard 2007.

<sup>3</sup> Harris 2009b.

<sup>4</sup> Khaw et al. 2007.

<sup>5</sup> Lally et al. 2008.

<sup>6</sup> McCreaddie et al. 2011.

<sup>7</sup> Roy et al. 2007.

<sup>8</sup> Sosman et al. 2005.

<sup>9</sup> Strauss et al. 2008.

<sup>10</sup> Sutton and Treloar 2007.

<sup>11</sup> Tompkins et al. 2005.

<sup>12</sup> Treloar and Rhodes 2008.

<sup>13</sup>Wright et al. 2005.

<sup>14</sup> Carrier et al. 2005.

<sup>15</sup> Coupland et al. 2009.

- <sup>16</sup> Faye and Irurita 2003.
- <sup>17</sup> Habib and Adorjany 2003.
- <sup>18</sup> Munoz-Plaza et al. 2004.
- <sup>19</sup> Paterson et al. 2007.
- <sup>20</sup> Perry et al. 2003.
- <sup>21</sup> Swan et al. 2010.
- <sup>22</sup> Temple-Smith et al. 2004.
- <sup>23</sup> Treloar and Hopwood 2004.
- <sup>24</sup> Treloar et al. 2010.

#### Evidence statement Q30

Perceiving health care professionals to be supportive, concerned and caring, and being encouraged to undertake treatment by health professionals was found to motivate IDUs to engage in hepatitis C treatment (four [++], one [+] and one [-])<sup>1,2,3,4,5,6</sup>. There was evidence across a number of studies that IDUs preferred hepatitis C services, including treatment, to be situated in one setting such as drug treatment programmes and methadone substitution settings (two [++] and one [+])<sup>5,7,6</sup>. These services were also seen as useful in providing information on hepatitis C treatment (one [++] and three [+])<sup>5,6,8,9</sup>

- <sup>1</sup> Fraser 2010.
- <sup>2</sup> Coupland et al. 2009.
- <sup>3</sup> Kinder 2009.
- <sup>4</sup> McCreaddie et al. 2011.
- <sup>5</sup> Munoz-Plaza et al. 2004.
- <sup>6</sup> Swan et al. 2010.
- <sup>7</sup>Treloar et al. 2010.
- <sup>8</sup> Munoz-Plaza et al. 2005a.
- <sup>9</sup> Munoz-Plaza et al. 2006.

#### **Evidence statement E1**

There is moderate evidence from three RCTs (one [++] and two [+])<sup>1,2,3</sup> and one uncontrolled (UBA) study (-)<sup>4</sup> to suggest that providing information and education on hepatitis B to migrant populations may improve their knowledge about risk, screening and prevention; moderate evidence from three RCTs (one [++] and two [+])<sup>1,2,3</sup> to suggest that providing information and education on hepatitis B to migrant populations does not improve testing uptake; and weak evidence from one case series (-)<sup>5</sup> to suggest that testing supplemented with culturally appropriate education may encourage the uptake of follow-up care among migrant populations.

<sup>1</sup> Taylor et al. 2009a.
 <sup>2</sup> Taylor et al. 2009b.
 <sup>3</sup> Taylor et al. 2011.
 <sup>4</sup> Hsu et al. 2007; 2010.
 <sup>5</sup> Chao et al. 2009.

#### **Evidence statement E2**

There is moderate evidence from one RCT (+)<sup>1</sup> to suggest that a strategy to promote cancer prevention activities among doctors serving migrant populations does not improve their practices in relation to hepatitis B testing. There is weak evidence from one UBA study (-)<sup>2</sup> to suggest that providing information and education on hepatitis B to complementary and alternative medicine (CAM) practitioners (including those practising traditional Chinese medicine and acupuncture) may improve their knowledge about risk, screening and prevention. However, the wider impact of this change in knowledge on their practices regarding referral for testing is not clear.

<sup>1</sup>Nguyen et al. 2000.

<sup>2</sup> Chang et al. 2007.

#### **Evidence statement E4**

There is moderate evidence from one RCT  $(+)^1$  and one CBA study  $(-)^2$  to suggest that offering dried blood-spot (DBS) testing to IDUs attending substance misuse services may increase uptake of hepatitis C testing compared to venipuncture alone

being offered. The increase in uptake may reflect an increase in testing availability, as more staff can be trained to deliver DBS testing than venipuncture, as well as higher acceptability to IDUs. There is weak evidence from one CS study (-)<sup>3</sup> to suggest that providing high-risk groups with access to DBS testing kits via a telephone hotline is not an effective use of resources compared to testing via state laboratories.

- <sup>1</sup> Hickman et al. 2008.
- <sup>2</sup> Craine et al. 2009.
- <sup>3</sup> Rainey et al. 2005.

#### **Evidence statement E5**

There is moderate evidence from one RCT  $(+)^1$  to suggest that although providing GPs with both training and assistance with screening (through the use of patient-targeted materials) may increase patient requests for testing, it does not impact upon the number of patients tested for hepatitis C overall. There is moderate evidence from two non-randomised controlled trials (NRCTs) (two [+])<sup>2,3</sup> to suggest that targeted case finding in primary care for patients with a history of injecting drug use may have a positive impact on the number of patients who are offered and accept a hepatitis C test. Although the level of referral of patients identified with infection was relatively high, the number of subsequent dropouts prior to treatment indicates that there is a need for further support beyond the intervention offered in these studies.

<sup>1</sup> Roudot-Thoraval et al. 2000.

<sup>2</sup> Anderson et al. 2009.

<sup>3</sup>Cullen et al. in press.

#### **Evidence statement E6**

There is moderate evidence from one RCT (+) and two case series  $(two [-])^{1,2,3}$  to suggest that providing hepatitis C services in community settings may have a positive impact on testing acceptance and uptake. In particular, there is weak evidence from two case series  $(two [-])^{4,5}$  to suggest that a multidisciplinary or shared care approach to hepatitis C testing and treatment for IDUs is associated with high

uptake of follow-up services and treatment outcomes comparable with non-drugusing populations. In two studies conducted in the USA (two [-])<sup>6,7</sup>, hepatitis testing was added to routine blood work undertaken on entry to drugs services and therefore a high testing rate was inevitable; There is moderate evidence from one RCT (+)<sup>8</sup> to suggest that the provision of testing services via outreach may have a positive impact on testing acceptance and uptake. The impact may be greatest when testing is offered on-site rather than by referral; There is weak evidence from one UBA study (-)<sup>9</sup> to suggest that the provision of hepatitis C outreach services for new prisoners may lead to relatively low uptake of testing.

- <sup>1</sup> Rosenberg et al. 2010.
- <sup>2</sup> Lindenberg et al. 2011.
- <sup>3</sup>Jack et al. 2009.
- <sup>4</sup> Lindenberg et al. 2011.
- <sup>5</sup> Jack et al. 2009.
- <sup>6</sup> Harris et al. 2010.
- <sup>7</sup> Hagedorn et al. 2007.
- <sup>8</sup> Sahajian et al. 2011.
- <sup>9</sup> Skipper et al. 2003.

# Evidence statement E7

There is weak evidence from one case series (-)<sup>1</sup> to suggest that offering a noninvasive liver evaluation technique in outreach settings provides an opportunity to subsequently test IDUs for hepatitis C. There is weak evidence from one case series (-)<sup>2</sup> that education by a peer outreach worker may improve short-term knowledge about hepatitis C transmission among IDUs.

<sup>1</sup> Foucher et al. 2009.

<sup>2</sup> Aitken et al. 2002.

# Evidence statement E8

There is moderate evidence from one RCT  $(++)^1$ , one NRCT  $(+)^2$  and one UBA study  $(-)^3$  to suggest that complex interventions that provide support to primary care

professionals in offers of hepatitis C testing may have a positive impact on testing acceptance and uptake. One repeated cross-sectional study (CSS)  $(+)^4$  demonstrated that without support, offers of testing may increase, but not within the desired high-risk groups. There is weak evidence from three UBA studies (three [-])<sup>1,5,6</sup> to suggest that educational interventions aimed at health professionals may have short-term benefits on knowledge about hepatitis C. However, there is no clear evidence that an increase in knowledge leads to an increase in testing. Weak evidence from one UBA study (-)<sup>4</sup> suggested that a CME programme had a limited impact on testing uptake. There is mixed evidence from two studies (one [++] and one[+])<sup>7</sup> that examined the effectiveness of interventions aimed at professionals on treatment initiation; There is moderate evidence from a repeated CSS (+)<sup>4</sup> that a national campaign had no impact on the management of drug users following a positive hepatitis C test. However, there is strong evidence from one RCT (++)<sup>1</sup> that a complex intervention providing support in primary care had a positive impact on number of referrals and attendance at follow-up appointments after testing.

<sup>1</sup> Cullen et al. 2006.

- <sup>2</sup> Helsper et al. 2010.
- <sup>3</sup> Sahajian et al. 2004.
- <sup>4</sup> Defossez et al. 2008.
- <sup>5</sup> D'Souza et al. 2004.
- <sup>6</sup> Fischer et al. 2000.

<sup>7</sup> Garrard et al. 2006.

#### **Evidence statement E9**

There is weak evidence from one CBA study  $(-)^1$  and one case series  $(-)^2$  to suggest that the provision of hepatitis C treatment in community settings for IDUs had a positive effect on treatment initiation and outcomes. There is weak evidence from two case series (both  $[-])^{3,4}$  that attendance at a support group for hepatitis C may have a positive effect on treatment initiation. However, it was unclear due to the study design used whether attendance at the support group was higher among more highly motivated individuals who may have been more likely to initiate treatment

regardless of their attendance at the group. There is weak evidence from one cohort study (-)<sup>5</sup> to suggest that allowing patients, such as those who have not been referred by their doctor, to self-refer to speciality liver clinics for assessment was associated with treatment uptake and completion at rates similar to those referred by health professionals. There is weak evidence from a CBA study (-)<sup>6</sup> to suggest that ensuring patients receive education about hepatitis C prior to referral appointments may have a positive effect on attendance at follow-up appointments, and on short to medium-term knowledge.

<sup>1</sup> Moussalli et al. 2010.

- <sup>2</sup>Wilkinson et al. 2008.
- <sup>3</sup> Grebely et al. 2007.
- <sup>4</sup> Grebely et al. 2010.
- <sup>5</sup> Doucette et al. 2009.
- <sup>6</sup> Surjadi et al. 2011.

#### **Evidence statement E11**

There is moderate evidence from one cost utility analysis (CUA) (+)<sup>1</sup> to suggest that community-based screening and treatment for hepatitis B among migrant populations is cost-effective.

<sup>1</sup> Veldhuijzen et al. 2010.

#### Additional evidence

A mapping review was also carried out. This was a practice survey of activities and interventions that aim to raise awareness among, and/or engage with, groups who are at an increased risk of hepatitis B and C infection.

#### Economic modelling

There were three models. One model looked at three scenarios for increasing testing for hepatitis C among people who inject drugs and people who used to inject drugs, with the emphasis on training and education:

- Training specialist addiction services in the community to undertake dried bloodspot testing for chronic hepatitis C.
- Educating GPs about the infection.
- Training prison nurses to undertake dried blood-spot testing for chronic hepatitis
   C.

Training for dried blood-spot testing in the community resulted in a substantially greater proportion of cases of chronic hepatitis C being identified, compared with not offering this blood sampling method. This lead to an estimated cost per quality of life years (QALY) gained of £15,000, which is below the threshold of £20,000 generally accepted by NICE as cost effective.

Educating GPs about chronic hepatitis C also resulted in an increase in testing and was also cost effective, yielding an estimated cost per QALY of £14,000. Training prison nurses to undertake dried blood-spot testing also increased the proportion of chronic hepatitis C cases found, compared to not offering this sampling method. However, the cost effectiveness of this training depended on whether the resulting treatment was completed. In such cases, the estimated cost per QALY gained was £10,000. If the treatment was halted at any point, the cost per QALY of finding a new case was estimated to rise to £59,000 per QALY and thus, was not cost effective. The estimated cost per QALY will be less than £20,000 per QALY gained if treatment is seamlessly completed in at least 40% of cases.

A second model looked at finding and testing UK migrants for chronic hepatitis C. This was found to be cost effective if 2% of the population group were infected and it cost no more than £20 to find and test each person. In such a case, the cost per QALY gained was estimated at £10,000. If the cost of finding and testing someone was £50, the estimated cost per QALY was still cost effective – at £18,000. It became more cost effective to find and test people if more than 2% of the population group were infected – and it cost no more than £20 per person to find and test them.

A third model looked at finding and testing UK migrants for chronic hepatitis B. If there was a 2% prevalence within the population group and it cost £20 to find and test each infected person, the estimated cost per QALY gained would be £21,000,

marginally above the NICE £20,000 threshold for cost effectiveness. However, it would be cost effective if the prevalence of infection was 3% or higher. At 20% prevalence, as is believed to be the case among some migrant groups, the estimated cost per QALY of finding and testing people falls to £12,000 and was, therefore, deemed cost effective.

Based on the modelling, the PDG considered that it would be cost effective to simultaneously find and test people at risk for both hepatitis B and C, provided there was a 2% prevalence of both infections and it cost up to £75 to find and test each person.

# Appendix D Gaps in the evidence

The Programme Development Group (PDG) identified a number of gaps in the evidence related to the programmes under examination, based on an assessment of the evidence. These gaps are set out below.

- There is a lack of robust, quantitative studies on identifying, testing and treating hepatitis B and C (that is, studies that are applicable to the UK context). In particular there is a lack of:
  - Reliable data on the number of people in the UK with chronic hepatitis
     B and C. In particular, there is no national information on the number of children infected.
  - b) Reliable local information on the number of people with chronic hepatitis B and C.
  - c) Interventions to increase hepatitis B and C testing among migrant populations.
  - d) Interventions to increase hepatitis B and C testing in non-health settings, for example, prisons.
  - e) Data looking at injecting drug use as a transmission route for hepatitisB.
- 2. There is a lack of qualitative studies on hepatitis B and C, including studies focused on:
  - a) Cultural issues which may act as a barrier to testing and treatment.
  - b) Knowledge of, barriers against and facilitators for hepatitis C testing and treatment among migrant populations.
  - Knowledge of, barriers against and facilitators for preventing hepatitis B and C among men who have sex with men.
- Knowledge of, barriers against and facilitators for preventing maternal transmission of hepatitis B.
- e) Knowledge of, barriers against and facilitators for preventing hepatitis B among injecting drug users.
- f) How former drug users, both from a service user and provider perspective, regard testing for hepatitis.
- g) The views, perspectives and experiences of hepatitis B and C testing among people whose past behaviour has put them at risk but who choose not to disclose this information. This includes people who have previously injected drugs or worked as commercial sex workers.
- h) The views, perspectives and experiences of hepatitis B and C testing among practitioners and people at increased risk of infection, according to level and type of practitioner knowledge.
- Prisoners' views of hepatitis testing and treatment and the views of those working with them.
- j) The acceptability of different types of hepatitis test.
- Factors which encourage people to have a liver biopsy or discourage them from this.
- The knowledge GPs need to be able to identify people at-risk and to be able to test and treat them.
- m) Why people referred by GPs for a hepatitis test drop out and whether or not an integrated services/one-stop-shop approach to see if this improves uptake rates.
- n) Understanding of hepatitis B and C care pathways generally and linked to the use of laboratory services.

- 3. There is a lack of evidence on the role of the voluntary sector in promoting and offering tests for hepatitis B and C.
- 4. There is a lack of evidence on what is happening in the 'real world'. This includes the views of those:
  - o) at risk of hepatitis B and C
  - p) who have been identified and/or tested and/or treated
  - q) who have dropped out at different stages of the care pathway.
- 5. There is a lack of qualitative and quantitative evidence on the acceptability of non-invasive approaches to testing among different communities.
- 6. There is a lack of evidence on how hepatitis B and C status could be assessed when testing for other diseases and blood-borne viruses.

## **Appendix E Supporting documents**

Supporting documents include the following.

- Evidence reviews:
  - Review 1: 'A systematic review of qualitative research on the views, perspectives and experiences of hepatitis B and C testing among practitioners and people at greatest risk of infection'
  - Review 2: 'A systematic review of the effectiveness and cost effectiveness of interventions aimed at raising awareness and engaging with groups who are at increased risk of hepatitis B and C infection'
  - Mapping review: 'A practice survey of activities and interventions that aim to raise awareness among, and/or engage with, groups who are at an increased risk of hepatitis B and C infection'.
- Economic modelling:
  - 'An economic evaluation of finding cases of hepatitis B and C infection in UK migrant populations'
  - 'Assessing the cost-effectiveness of interventions aimed at promoting and offering hepatitis C testing to injecting drug users: An economic modelling report'.
- Expert testimony:
  - Presentation 1: 'UK National screening Committee and case finding versus screening'
  - Presentation 2: 'Hepatitis B vaccination in England and Wales'
  - Presentation 3: 'Hepatitis testing in prisons'
  - Presentation 4: 'Paediatric hepatitis testing and treatment'
  - Presentation 5: 'The role of GPs in promoting hepatitis B and C testing among at risk populations'
  - Presentation 6: 'Perspective on barriers to hepatitis testing and treatment for people who inject drugs'.

For information on how NICE public health guidance is developed, see:

- 'Methods for development of NICE public health guidance (second edition, 2009)'
- '<u>The NICE public health guidance development process: An overview for</u> stakeholders including public health practitioners, policy makers and the public (second edition, 2009)'.