

Hepatitis B and C testing: people at risk of infection

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www.nice.org.uk/guidance/ph43

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

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This guideline is the basis of QS65.

Overview

This guideline covers raising awareness of and testing for hepatitis B and C infection. It aims to ensure that people at increased risk of hepatitis B and C infection are tested.

NICE has also produced guidelines on diagnosis and management of <u>hepatitis B</u> infection.

In March 2013, changes were made to <u>recommendation 7</u> to clarify that all the actions detailed in this recommendation relate to those at increased risk of hepatitis B and C infection.

Who is it for?

- Commissioners and providers
- People at increased risk of viral hepatitis
- Members of the public

Introduction: scope and purpose of this 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
 - people at increased risk of hepatitis B and C infection.
- Developing the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection.
- Testing:
 - in primary care
 - in prisons and youth offender institutions
 - in <u>immigration removal centres</u>
 - in drugs services
 - in genitourinary medicine and sexual health clinics.
- Contact tracing.
- Providing and auditing neonatal hepatitis B vaccination.
- Commissioning hepatitis B and C testing and treatment services.
- Laboratory services for hepatitis B and C testing.

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 hepatitis B and C infection, including those in the NHS, local authorities, <u>prisons</u>, <u>immigration removal centres</u> and drugs services. It is also for voluntary sector and community organisations working with people 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 or hepatitis C infection or people who inject drugs and their families. In addition, other members of the public may have an interest in this guidance.

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 <u>implementation</u> and <u>related NICE guidance</u> 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 <u>appendix B</u> for details.

Supporting documents used to prepare this document are listed in <u>appendix E</u>.

What evidence is the guidance based on?

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

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 **final** guidance.

The guidance complements but does not replace other NICE guidance on hepatitis B and C (for further details, see <u>section 7</u>).

1 Recommendations

Introduction

There has been a change in recommendation 7. See <u>Changes after publication</u> for details.

The evidence statements underpinning the recommendations are listed in <u>appendix C</u>.

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

For the research recommendations and gaps in research, see $\underline{section 5}$ and $\underline{appendix D}$ respectively.

Pre-requisites

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

Testing

The recommendations assume that:

- Testing facilities are equipped with sharps bins and follow advice on infection control and appropriate testing methods, particularly if testing is done outside healthcare settings.
- People being tested for hepatitis B and C are offered pre- and post-test discussions (see Box 1).
- Testing is undertaken with the person's consent.
- <u>Standards for local surveillance</u> are followed, including laboratory reporting to Public Health England centres and follow-up of hepatitis B and C.

Box 1. Areas to consider when offering a test for hepatitis B or C

Have issues of confidentiality and anxiety been addressed?

Has the offer been accompanied by an agreed mechanism for providing the result to the person being tested?

Has the offer been phrased in a way that suits the person's age, culture and literacy level and is respectful and non-judgemental?

Has the offer taken into account potential barriers to testing such as the stigma associated with hepatitis B and C or lack of access to services?

Has the offer included information to enable people to make informed choices about their care should they test positive, and to reduce their risk of hepatitis B and C infection should they test negative?

Has the offer been accompanied by details of support available for clinical and nonclinical needs, both while waiting for test results and following diagnosis?

Treatment

NICE has recommended a number of drugs to treat hepatitis B and C and also has clinical guidelines in development on the diagnosis and management of hepatitis B and C (see <u>section 7</u> for details). Guidance on managing co-infection with HIV-1 and hepatitis B or C is available from the <u>British HIV Association</u>^[1]. The European Association for the Study of the Liver (EASL)^[2] has published best practice guidelines on managing <u>hepatitis B</u> and <u>hepatitis C</u>.

Immunisation

 Guidance on hepatitis B vaccination is available in the <u>Green book: immunisation</u> <u>against infectious disease</u> and the <u>Hepatitis B antenatal screening and newborn</u> <u>immunisation programme</u>, both published by the Department of Health, and in the NICE guidance on <u>Reducing the differences in the uptake of immunisations</u>.

Whose health will benefit?

In the UK, the majority (95%) of new chronic hepatitis B infections occur in migrant populations, having been acquired perinatally in the country of birth. In contrast, approximately 90% of chronic hepatitis C infections are seen in people who inject drugs or

have done so in the past.

Groups at increased risk of hepatitis B compared with the general UK population include:

- People born or brought up in a country with an intermediate or high prevalence (2% or greater) of chronic hepatitis B. This includes all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific islands.
- Babies born to mothers infected with hepatitis B.
- People who have ever injected drugs.
- Men who have sex with men.
- Anyone who has had unprotected sex, particularly:
 - people who have had multiple sexual partners
 - people reporting unprotected <u>sexual contact</u> in areas of intermediate and high prevalence)
 - people presenting at sexual health and genitourinary medicine clinics
 - people diagnosed with a sexually transmitted disease
 - commercial sex workers.
- Looked-after children and young people, including those living in care homes.
- Prisoners, including young offenders.
- Immigration detainees.
- <u>Close contacts</u> of someone known to be chronically infected with hepatitis B.

For hepatitis C, groups at increased risk include:

- People who have ever injected drugs.
- People who received a blood transfusion before 1991 or blood products before 1986, when screening of blood donors for hepatitis C infection, or heat treatment for inactivation of viruses were introduced.

- People born or brought up in a country with an intermediate or high prevalence (2% or greater) of chronic hepatitis C. Although data are not available for all countries, for practical purposes this includes all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific islands.
- Babies born to mothers infected with hepatitis C.
- Prisoners, including young offenders.
- Looked-after children and young people, including those living in care homes.
- People living in hostels for the homeless or sleeping on the streets.
- HIV-positive men who have sex with men.
- <u>Close contacts</u> of someone known to be chronically infected with hepatitis 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, for example Public Health England, working in partnership with:

- other government departments allied to health
- local commissioners and providers of public health services, including local authorities and health and wellbeing boards
- primary and secondary care including genitourinary medicine and sexual health clinics
- the commercial sector, national and local voluntary sector, not-for-profit and nongovernmental organisations.

- Conduct awareness-raising campaigns, using campaign material and resources on hepatitis B and C. These should include up-to-date information on:
 - the main routes of infection and transmission
 - hepatitis B vaccination
 - the benefits of early testing and treatment, including the role of earlier treatment in preventing serious illness such as chronic liver disease and liver cancer
 - the potential for chronic infection to be asymptomatic, particularly in the early stages.
- Ensure national and local 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 the stigma surrounding these infections.
- Ensure messages to raise awareness of hepatitis B and C are coordinated and integrated within other health promotion campaigns, where possible or appropriate.
- Ensure national and local awareness-raising activities take into account age, culture and religious beliefs of groups at increased risk, and their needs in relation to format and the language used. For example, the needs of people with low literacy level and learning disabilities, and people with little interaction with statutory services should be considered.

Recommendation 2 Awareness-raising for people at increased risk of hepatitis B or C infection

Who should take action?

- Commissioners and providers of national public health services, for example Public Health England and the NHS Commissioning Board.
- Local authorities, in particular directors of public health.

- Local organisations providing services for children and adults at increased risk of hepatitis B or C infection.
- Other local and national organisations that raise awareness of hepatitis, promote testing or provide treatment.

- Public Health England, the NHS Commissioning Board and directors of public health should facilitate partnership working to ensure there is a coordinated national and local programme of awareness-raising about hepatitis B and C among groups at increased risk.
- Directors of public health should promote local testing and hepatitis B vaccination services.
- Local and national organisations should provide awareness-raising material tailored to the needs of groups at increased risk. In addition to the information outlined in recommendation 1, this should:
 - inform people how and where to access local testing and hepatitis B vaccination services
 - describe what testing for hepatitis B and C involves
 - explain how a positive diagnosis can affect lifestyle.
- Material should:
 - address the needs of non-English-speaking groups at increased risk, for example,
 by providing translated information or information in audio or visual formats.
 - be culturally and age appropriate
 - address the needs of people with low literacy levels or learning disabilities.
- Local organisations should encourage and support people from groups at increased risk who have been diagnosed with hepatitis B or C to contribute to awareness-raising activities (for further information see NICE guidance on <u>Community engagement</u>).

- Local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk. Examples of possible venues include: faith and cultural centres, NHS and non-NHS drugs services, GP surgeries, sexual health and genitourinary medicine services, immigration centres, hostels for the homeless, <u>prisons</u> and youth offender institutions.
- Local and national organisations should consider offering testing for hepatitis B and C at awareness-raising sessions. If this is not possible, information on where and how to access testing locally should be provided.

Recommendation 3 Developing the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection

Who should take action?

- Health Education England.
- Public Health England.
- Royal medical and nursing colleges.
- Local authorities, in particular directors of public health.
- Clinical commissioning groups.
- Local education and training boards.

- Ensure there is an ongoing education programme for professionals providing health and social care services for people at increased risk of hepatitis B or C infection. This includes:
 - clinical and non-clinical staff in primary and secondary care including nurses, health visitors, midwives, healthcare assistants and support workers as well as staff in sexual health, genitourinary medicine and HIV clinics
 - people working in drugs services
 - staff in community-based criminal justice services
 - social workers working with people at increased risk of hepatitis B or C infection
 - statutory and non-statutory staff working with looked-after children
 - prison, youth offender and immigration removal centre staff
 - staff in voluntary and community organisations that care for or support migrant populations, people who inject drugs, people with HIV, or men who have sex with men
 - people working in hostels for the homeless and providing outreach services to homeless people.
- Ensure education programmes address the following core topics and are designed to meet the needs of the target group:
 - incorporating the recommendations in national guidance to improve identification and testing of people at increased risk of hepatitis B and C infection
 - overcoming social and cultural barriers and improving access to testing and treatment for people at increased risk of hepatitis B and C infection
 - reducing morbidity and mortality associated with hepatitis B and C through early detection and diagnosis
 - improving clinical management and quality of life for people diagnosed with hepatitis B and C infection and reducing the number of people admitted to secondary and tertiary care with hepatitis B- and C-related morbidity, for example, liver disease.

- Ensure training programme content is accurate and up-to-date, reflecting advances in testing, diagnosis and treatment of hepatitis B and C.
- Think about 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.
- Local education and training boards in each region should ensure that people involved in testing for hepatitis B and C take part in a programme of continuing professional development.
- Directors of public health should ensure all healthcare and public health managers, in collaboration with the local education and training board, use staff annual appraisals and personal development plans to reinforce training and education on hepatitis B and C.

Recommendation 4 Testing for hepatitis B and C in primary care

Who should take action?

- GPs and practice nurses.
- Antenatal services.
- Local community services serving migrant populations.

- GPs and practice nurses should offer testing for hepatitis B and C to adults and children at increased risk of infection, particularly migrants from medium- or highprevalence countries and people who inject or have injected drugs (see <u>Whose health</u> <u>will benefit?</u>).
- GPs and practice nurses should offer testing for hepatitis B and C to people who are newly registered with the practice and belong to a group at increased risk of infection (see <u>Whose health will benefit?</u>).

- GPs and practice nurses should ask newly registered adults if they have ever injected drugs, including image and performance enhancement substances at their first consultation.
- GPs and practice nurses should offer hepatitis B testing and vaccination to men who have sex with men who are offered a test for HIV and have not previously tested positive for hepatitis B antibodies (see NICE guidance on <u>Increasing the uptake of HIV</u> <u>testing among men who have sex with men</u>).
- GPs and practice nurses should offer hepatitis B vaccination to people who test negative for hepatitis B but remain at increased risk of infection (see the <u>Green book</u>).
- GPs and practice nurses should offer annual testing for hepatitis C to people who test negative for hepatitis C but remain at increased risk of infection.
- GPs and practice nurses should ensure people diagnosed with hepatitis B or C are referred to specialist care.
- Local community services serving migrant populations should work in partnership with primary care practitioners to promote testing of adults and children at increased risk of infection. This should include raising awareness of hepatitis B and C, promoting the availability of primary care testing facilities and providing support to access these services.
- Staff providing antenatal services, including midwives, obstetricians, practice nurses and GPs, should ask about risk factors for hepatitis C during pregnancy and offer testing for hepatitis C to women at increased risk. Women who are diagnosed with hepatitis C should be offered hepatitis A and B vaccination in line with the <u>Green book</u>.

Recommendation 5 Testing for hepatitis B and C in prisons and immigration removal centres

Who should take action?

- <u>Prison</u> healthcare services, including services for young offenders.
- Immigration removal centre healthcare services.
- Secondary care services that provide treatment for hepatitis B and C.

• Public Health England centres.

- <u>Prison</u> and <u>immigration removal centre</u> healthcare services should develop a policy on testing for hepatitis B and C with local partners, including secondary care services that provide treatment, the Public Health England centre, and commissioners of prison and immigration removal centre healthcare services.
- Prison and immigration removal centre healthcare services should designate a
 member of staff as the hepatitis lead in every prison, young offender service and
 immigration removal centre. The lead should have the knowledge and skills to promote
 hepatitis B and C testing and treatment and hepatitis B vaccination. Consideration
 should be given to training peer mentors and health champions from the prison and
 immigration removal centre populations to support this work.
- The NHS lead for hepatitis treatment (for example, a community hepatitis nurse) should develop a care pathway for prisoners and immigration detainees with diagnosed hepatitis B or C. This should be developed in conjunction with <u>prison</u> or <u>immigration removal centre</u> healthcare services (including commissioners), local drugs services and the Public Health England centre. The care pathway should ensure:
 - people with diagnosed hepatitis B and C should be referred to, and managed by, the local hepatitis treatment services, in liaison with prison or immigration removal centre healthcare services
 - investigations and follow-up should be undertaken in the prison or immigration removal centre, if possible
 - prisoners and immigration detainees with hepatitis B and C should be treated in the prison or immigration removal centre, using <u>in-reach</u> services involving local specialist secondary care providers or the prison or immigration removal centre healthcare team. The prison or immigration removal centre should support this, for example, by giving security clearance to healthcare staff.

- <u>Prison</u> and <u>immigration removal centre</u> healthcare services (coordinated with and supported by the NHS lead for hepatitis) should ensure that:
 - all prisoners and immigration detainees are offered hepatitis B vaccination when entering prison or an immigration removal centre (for the vaccination schedule, refer to the <u>Green book</u>)
 - all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention
 - prisoners and immigration detainees who test for hepatitis B or C receive the results of the test, regardless of their location when the test results become available
 - results from hepatitis B and C testing are provided to the prisoner's communitybased GP, if consent is given
 - all prison and immigration removal centre staff are trained to promote hepatitis B and C testing and treatment and hepatitis B vaccination (see <u>recommendation 3</u>).
- <u>Prison</u> services should have access to dried blood spot testing for hepatitis B and C for people for whom venous access is difficult.
- The NHS lead for hepatitis treatment in <u>prisons</u> should ensure continuity of hepatitis treatment through contingency, liaison and handover arrangements before the prisoner release date, or before any prisoner or immigration detainee receiving hepatitis treatment is transferred between prisons or removal centres. Once a prisoner has started treatment, it may be helpful to put them on <u>medical hold</u> to ensure <u>continuity of care</u> (which might be compromised by transfer between prisons). Planning should involve NHS, prison and <u>immigration removal centre</u> healthcare services and other agencies working with prisoners or detainees.

Recommendation 6 Testing for hepatitis B and C in drugs services

Who should take action?

• Drugs services, including drug and alcohol action teams.

- Commissioners of hepatitis testing and treatment services, including local authorities and clinical commissioning groups.
- Secondary care services that provide treatment for hepatitis B and C.
- Public Health England centres.

- Commissioners of hepatitis testing and treatment services should agree local care pathways for people with hepatitis B and C who use drugs services. If possible, the pathway should include provision of hepatitis C treatment services in the community.
- Drugs services should designate a hepatitis lead for the service. The lead should have the knowledge and skills to promote hepatitis B and C testing and treatment and hepatitis B vaccination. Consideration should be given to training <u>peer</u> mentors and health champions from the drugs service to support this work (for further information see NICE guidance on <u>Community engagement</u>).
- Drugs services should have access to:
 - dried blood spot testing for hepatitis B and C for people for whom venous access is difficult
 - specialist phlebotomy services in order to encourage hepatitis C treatment in the community, particularly for people who inject drugs.

- Drugs services should:
 - offer hepatitis B vaccination to all service users in line with the <u>Green book</u>.
 - offer and promote hepatitis B and C testing to all service users
 - offer annual testing for hepatitis C to people who test negative for hepatitis C but remain at risk of infection
 - ensure people diagnosed with hepatitis B and C are referred for specialist care; for hepatitis C this may involve offering hepatitis C treatment in the community for people who are unwilling or unlikely to attend hospital appointments, and whose hepatitis C treatment could be integrated with ongoing drug treatment (such as opiate substitution treatment)
 - ensure staff have the knowledge and skills to promote hepatitis B and C testing and treatment (see <u>recommendation 3</u>)
 - ensure staff who undertake pre- and post-test discussions and dried blood spot testing are trained and competent to do so
 - provide information to women with hepatitis C about the importance of testing in babies and children born after the woman acquired infection
 - provide information to injecting drug users about the importance of hepatitis B vaccination for sexual partners and children (see the <u>Green book</u>).

Recommendation 7 Testing for hepatitis B and C in sexual health and genitourinary medicine clinics

Who should take action?

- Commissioners of hepatitis testing and treatment services, including local authorities and clinical commissioning groups.
- Sexual health and genitourinary medicine clinics.

- Commissioners of hepatitis testing and treatment services should agree local care pathways for people with hepatitis B and C who use sexual health and genitourinary medicine clinics.
- Sexual health and genitourinary medicine clinics should:
 - offer hepatitis B vaccination to all service users in line with the Green book
 - offer and promote hepatitis B and C testing to all service users at increased risk of infection, including people younger than 18
 - ensure people diagnosed with hepatitis B or C are referred for specialist care
 - ensure staff have the knowledge and skills to promote hepatitis B and C testing and treatment (see <u>recommendation 3</u>)
 - ensure staff who undertake pre- and post-test discussions are trained and competent to do so.

Recommendation 8 Contact tracing

Who should take action?

- Public Health England centres.
- Primary care practitioners.

- Public Health England centres should:
 - take overall responsibility for tracing the <u>close contacts</u> of people with confirmed acute and chronic hepatitis B infection
 - advise and oversee the activities of other local organisations undertaking contact tracing, such as GP surgeries and genitourinary medicine clinics, to ensure the national <u>standards for local surveillance and follow-up of hepatitis B and C</u> are met. For example, GPs may need to offer <u>close contacts</u> hepatitis B vaccination and refer for treatment.
- Primary care practitioners should promote the importance of hepatitis C testing for children who may have been exposed to hepatitis C at birth or during childhood.

Recommendation 9 Effective delivery and auditing of neonatal hepatitis B vaccination

Who should take action?

- Directors of public health.
- Public Health England.

- Directors of public health should ensure existing recommendations on hepatitis B prophylaxis for babies born to mothers with chronic hepatitis B infection are implemented locally by general practitioners, as described in the <u>Green book</u>.
- Public Health England should audit the hepatitis B vaccination programme for babies. The audit should note how many children received vaccines, whether vaccinated children were given all doses and if not how many doses they received, whether doses were given on schedule, whether babies were tested after completing the vaccination course and the rate of vaccination failure. This audit should be carried out annually and deficiencies addressed.

Recommendation 10 Commissioning locally appropriate integrated services for hepatitis B and C testing and treatment

Who should take action?

- Local authorities, in particular directors of public health and clinical commissioning groups
- Commissioners of hepatitis testing and treatment services.

- Local authorities, in particular directors of public health and clinical commissioning groups should ensure the inclusion of hepatitis B and C in the health and wellbeing board's joint strategic needs assessment. This should provide information on local prevalence of chronic hepatitis B and C and groups at increased risk, including by country of origin or risk behaviour.
- Commissioners should encourage the development of <u>locally enhanced services</u> for hepatitis B and C in areas where there is a higher than average number of people at increased risk (especially areas with a large migrant population or high prevalence of people who inject drugs).
- Commissioners should regularly undertake a health needs assessment, health equity audit and an audit of hepatitis B and C services as part of the agreed local care pathway and commission testing and treatment services accordingly.
- Commissioners should ensure mechanisms are in place for following up patients who defer treatment.

- Commissioners should audit the uptake of testing and outcomes, including:
 - the number of people tested for hepatitis B and C
 - the number of people diagnosed with hepatitis B and C
 - the number of people with chronic infection who:
 - $\diamondsuit\,$ are referred to a treatment service
 - \diamondsuit attend a treatment service
 - \diamond are receiving treatment in accordance with treatment guidelines
 - the number of people with hepatitis C who obtain a sustained virological response on antiviral therapy.
- Commissioners should develop and commission a fully integrated care pathway, working with services that provide hepatitis B and C testing and treatment in primary and secondary care (in the community or specialist services in hospital). This should:
 - take into account the needs of people who test positive for hepatitis B or C infection and are assessed for treatment, including their broader health and psychosocial needs
 - consider all venues where testing and treatment services are, or could be offered that can also ensure <u>continuity of care</u> and onward referral to specialist treatment for people who test positive (such as pharmacy testing and outreach testing and treatment)
 - ensure primary and secondary care staff are educated and trained in hepatitis B and C testing and treatment (see <u>recommendation 3</u>).

Recommendation 11 Laboratory services for hepatitis B and C testing

Who should take action?

• Commissioners of laboratory services for hepatitis B and C testing.

- Ensure that samples are transported from patients to laboratories within 24 hours (adjusted for weekends and bank holidays as necessary)
- Ensure service specifications specify that laboratory services providing hepatitis B and C testing:
 - have Clinical Pathology Accreditation (UK)
 - can support the range of samples used for hepatitis B and C testing (for example, dried blood-spot or venepuncture samples) or can refer the sample to a laboratory which can perform these tests
 - automatically test samples that are positive for hepatitis C antibody for the presence of hepatitis C virus (for example, using a polymerase chain reaction [PCR] assay), or refer the sample to a laboratory which can perform this test
 - can deliver results within 2 weeks of the sample being received
 - ensure local Public Health England centres are notified of cases of hepatitis B and C infection, in line with <u>national public health legislation</u>
 - provide the organisation or professional requesting a test with an accurate interpretation of the laboratory results and guidance on future management of confirmed cases, such as onward referral to specialist care.
- Ensure laboratory services provide accurate data on the following:
 - the number of people tested and the type of test performed
 - the referral source of samples (for example, primary care, secondary care, drug and alcohol services, <u>prisons</u>)
 - exposure category, if provided
 - the number of people testing positive:
 - \diamond for hepatitis B, this should include acute, chronic and past infection
 - for hepatitis C, this should include PCR positive/current and PCR negative/ resolved.

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¹¹ NICE has accredited the process used by the British HIV Association to produce UK national guidelines. Accreditation is valid for 5 years from 12 July 2012 and is applicable to guidance produced since 2011. The NICE Accreditation Scheme recognises organisations that demonstrate high standards in producing health or social care guidance. Users of the accredited guidance can therefore have high confidence in the quality of the information.

^[2] Guidance produced by EASL has not been reviewed by the NICE Accreditation Scheme. EASL guidelines may assist healthcare providers in the clinical decision-making process by describing a range of generally accepted approaches for diagnosing, treating and preventing hepatitis B and C. However, it should be ensured that action taken is in line with NICE guidance.

2 Public health need and practice

Chronic hepatitis B and C are the leading cause of liver disease worldwide (Perz 2006), and the second most common cause of liver disease in the UK, after alcohol.

Hepatitis **B**

The hepatitis B virus is transmitted perinatally from mother to child and through contact with infected blood. Some individuals clear hepatitis B infection naturally, whereas others develop a chronic infection that can result in severe liver disease. Rates of progression from acute to chronic infection vary according to age at the time of exposure. About 85% of hepatitis B infections in newborns become chronic compared with 4% in adults (Edmunds et al. 1993).

It has been estimated that 95% of people with new chronic hepatitis B in the UK are migrants, most of whom acquired the infection in early childhood in the country of their birth (Hahné et al. 2004). The remaining 5% of people with chronic hepatitis B acquired the infection in the UK, either through vertical transmission from mother to child or through exposure between adults. Migrant populations are therefore the main focus for hepatitis B case-finding in the UK, and infection in childhood is the major route of transmission. Other key risk groups for hepatitis B infection are described in <u>Whose health will benefit?</u>

There is considerable uncertainty about the number of people with chronic hepatitis B in the UK. In 2002 the Department of Health estimated that chronic hepatitis B affects 180,000 people in the UK (Department of Health 2002). Information on the burden of hepatitis B in England and Wales is derived from a number of sources:

- laboratory reports of confirmed acute and chronic infections
- serological studies of populations covered by screening programmes (that is, pregnant women and blood donors)
- serological studies of populations at high risk (for example, people who inject drugs)
- sentinel laboratory surveillance of people being tested

• estimates of the size of the migrant population.

In 2011, 589 acute or probable acute cases of hepatitis B were reported in England (Health Protection Agency 2012). The total number of acute infections will be greater than the number reported. The most recent study to estimate the annual incidence of hepatitis B in England and Wales was conducted between 1995 and 2000 (Health Protection Agency, Hahné et al. 2004). It estimated the annual incidence of hepatitis B, from laboratory reports, to be around 7.4 per 100,000 people. This translates into around 3700 acute infections per year and around 270 cases of chronic hepatitis B per year. Information about risk factors was available for about 50% of the acute cases. The most common reported risk was heterosexual exposure, followed by homosexual exposure. In comparison, fewer than 5% of cases were attributed to injecting drug use. The decline in the number of cases linked to injecting drug use is supported by the 2011 Unlinked Anonymous Monitoring (UAM) survey, which reported a fall in the proportion of injecting drug users who had ever been infected with hepatitis B, from 28% in 2001 to 16% in 2011 (Health Protection Agency 2011c). This decrease is probably associated with an increase in the uptake of hepatitis B vaccination (Judd et al. 2007; Hope et al. 2007). According to the UAM survey, selfreported rates of hepatitis B vaccination increased from 35% in 2000 to 76% in 2011 (Health Protection Agency 2011c).

Antenatal screening

A national antenatal screening programme for hepatitis B surface antigen (HBsAg) began in 2000 (Health Protection Agency 2011a). Uptake of screening during pregnancy has increased over time (up to 97% in 2011), but the proportion of women who test positive has remained stable (0.42% in 2011).

The sentinel surveillance programme identified that 28.5% (73,290) of women who had been tested for HBsAg in 2011 were tested through antenatal screening. Overall, 0.5% of the women tested in the antenatal programme tested positive. Most of the 73,290 women in the study were white or white-British. More black or black-British women (3.9%) and women from 'other' or mixed ethnicity (3.8%) tested positive for HBsAg compared with their Asian/Asian-British (0.5%) and white counterparts (0.3%).

Hepatitis C

Hepatitis C is a blood-borne viral infection transmitted through contact with infected blood. In the UK, hepatitis C is primarily acquired through injecting drug use.

Approximately 70–75% of people who are infected with acute hepatitis C develop a chronic condition that can result in liver failure and liver cancer.

The most recent national estimate suggests that around 216,000 people in the UK have chronic hepatitis C (Health Protection Agency 2012; Scottish Executive 2008). Of these, around 160,000 live in England (Harris 2012a). Injecting drug use is the main route of hepatitis C infection in England. Of the estimated number of people who are chronically infected, around 87% are current or past injection drug users. Of the remaining 13%, 6% are of South Asian descent and the other 7% are of white/other ethnicity (Harris et al. 2012a). Similarly, 90% of the total laboratory reports including risk information in the UK in 2010 attributed infection to injecting drug use (Health Protection Agency 2011c). The main focus for hepatitis C case-finding is therefore people who inject or have injected drugs. There is good evidence that HIV-positive men who have sex with men are at increased risk of hepatitis C infection, and British HIV Association guidelines recommend regular hepatitis C testing in this group. Emerging evidence suggests that people who inject image- and performance-enhancing drugs are also at increased risk of hepatitis C infection.

In England, more than 95,000 individuals had been diagnosed with hepatitis C by the end of 2011, suggesting that a significant number of infections remain undiagnosed. Hospitalisations, registrations for liver transplant and deaths from liver cancer due to hepatitis C are steadily increasing throughout the UK. In England, rates of end-stage liver disease caused by hepatitis C are likely to increase if diagnosis and treatment rates do not improve (Health Protection Agency 2012).

The prevalence of chronic disease in current and past drug users varies by region, and is highest in London and the North West (Harris et al. 2012). An analysis of the 2010 UAM survey of people who inject drugs and attend specialist services estimated the overall prevalence of hepatitis C antibodies (indicating exposure to the virus) to be 43%, but ranging from 14% to 82% in different geographical sites (Harris et al. 2012b). Data from the UAM survey also suggest that over 83% of people surveyed had a voluntary test for hepatitis C in 2010, compared with 40% in 2000. However, only about half were aware they were hepatitis C antibody positive when comparing self-reported data with anonymous test results (Health Protection Agency 2011b).

National recommendations

The national hepatitis B immunisation programme recommends that people from at-risk groups are immunised against hepatitis B. Post-exposure immunisation (which may include

hepatitis B immunoglobulin as well as hepatitis B vaccine) is also recommended for babies born to chronically infected mothers (Department of Health 2006).

NICE recommends a number of treatments for hepatitis B and hepatitis C (see <u>section 7</u>). Early diagnosis and treatment can clear infection and reduce the risk of long-term complications, such as cirrhosis and liver cancer. For people with chronic hepatitis C, early therapy is associated with increased and sustained virological response rates (Foster 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 felt that awareness-raising in the general population was a very important issue. While it was always intended that the guidance would make specific recommendations for awareness-raising in professionals and in populations at increased risk, the group decided that it would also be helpful to raise awareness generally.
- 3.2 The PDG was aware of the potential benefit of educating all healthcare professionals about hepatitis B and C but was pragmatic in its approach, focusing on those who were likely to be providing services to people at increased risk of infection.
- 3.3 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 <u>section 7</u>) were available. The Group felt that awareness of more effective treatments may have a positive impact on the uptake of testing.
- 3.4 The need for awareness-raising and training on hepatitis C for healthcare professionals was a key theme in the qualitative review, and was in accord with PDG members' experiences. The Group heard reports of people with hepatitis C having to ask for 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.
- 3.5 The PDG considered there was a need for targeted education programmes for health and social care professionals, such as those

produced by <u>Hepatitis Scotland</u> and the Royal College of General Practitioners (RCGP). An outline of requirements on <u>Hepatitis C</u> <u>workforce education development</u> (NHS Education for Scotland 2010) has been produced as part of the <u>Hepatitis C Action Plan for Scotland</u> (Scottish Executive 2006, 2008). The RCGP programme is aimed at generalist clinicians such as GPs and nurses working in primary care, and covers detection, diagnosis and management of hepatitis B and C in primary care.

- 3.6 The PDG felt education programmes might cover, depending on the role of the health and social care professional, some or all of the following:
 - epidemiology, public health impact and clinical consequences of hepatitis B and C infection
 - risk factors for hepatitis B and C and population groups at increased risk of infection
 - detection and diagnosis of hepatitis B and C
 - factors to consider in a pre- and post-test discussion and how these discussions should be conducted
 - the importance of repeat testing and harm reduction interventions for people who remain at risk of infection, including hepatitis B vaccination
 - social and cultural barriers to testing and treatment (for example, stigma)
 - local testing, treatment and referral pathways
 - the main features of treatment for hepatitis B and C, in line with current best practice guidelines
 - tests used to monitor liver health
 - the benefits and risks of current treatment options, including their effectiveness, adverse events and barriers and facilitators to treatment adherence.

Barriers and facilitators

- 3.7 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 being stigmatised, whether by healthcare professionals, sexual partners, family or friends.
 - 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 people promoting tests for these infections. Members felt that this contributed to the low uptake of testing among people at increased risk of infection and to the stigma surrounding these infections. It was noted that lack of awareness among people at increased risk of infection may result from lack of access to statutory services.
 - 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 appropriate information and care pathways have not been discussed with parents.)
- 3.8 People who have injected drugs in the past may not want to disclose drug-using history. This may be a barrier to hepatitis B and C testing and treatment. The PDG felt that positive messages about the effectiveness of treatment and attempts to 'normalise' testing might help reach these people.
- 3.9 The PDG was keen for the guidance to convey the improvement in health outcomes associated with early identification of hepatitis C in people for whom treatment is indicated. However, they acknowledged that personal circumstances may influence the timing of testing, and that economic, social or other health needs may be a higher priority for some people.
- 3.10 The PDG recognised the important role that family, partners and friends may play in encouraging people to get tested and complete treatment. The Group also recognised a role for the <u>peers</u> of people at increased risk in promoting hepatitis B and C testing and supporting people who are diagnosed positive.

- 3.11 The PDG noted that it was important to ensure people are not stigmatised by the way information on hepatitis B and C is delivered.
- 3.12 The PDG was mindful that combining awareness-raising campaigns for hepatitis B and C with other health promotion campaigns, such as those for HIV, may risk alienating some populations at increased risk. For example, the PDG was made aware that some migrant populations are unlikely to engage with a campaign that associates hepatitis B with sexually transmitted infection. The need to target awareness-raising campaigns to different audiences was felt to be of considerable importance to the PDG.
- 3.13 Transmission of hepatitis B from mother to child may be considered normal among some minority ethnic communities. Although this suggests there is less stigma associated with infection among these communities, 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.
- 3.14 Employment-based screening and subsequent discrimination against workers who test positive for hepatitis B in countries where there is a high prevalence of hepatitis B may discourage voluntary testing among migrants from those countries.
- 3.15 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 injecting equipment.
- 3.16 The PDG was mindful that offering universal testing in certain settings may help reduce the stigma associated with hepatitis B and C.
- 3.17 Access to dried blood spot testing or a specialist phlebotomist can reduce pain and embarrassment associated with the difficulties of taking blood samples from people with poor vascular access – typically associated with long-term injecting or poor injecting technique.
- 3.18 The PDG discussed the need to train all healthcare staff who are involved

in hepatitis testing to carry out pre- and post-test discussions with people at increased risk of hepatitis B and C infection.

3.19 The PDG were mindful of the sensitivities of discussing people's sexuality and potential sexual exposure to hepatitis B or C.

Testing

- 3.20 The PDG noted the importance of all blood samples that test positive for hepatitis C antibody being routinely tested for hepatitis C virus, for example, by PCR. In addition, further consideration of and research on the use of PCR for initial testing in current injecting drug users, with follow-up antibody testing for people who test PCR positive, may be warranted to enable rapid diagnosis of recent infections.
- 3.21 While venepuncture samples remain the gold standard, the PDG noted that dried blood spot tests for hepatitis B and C have a high test sensitivity and specificity and can be useful in certain settings for people with poor venous access and where there may be no facilities or expertise to take venous blood samples (for example, in specialist drug treatment services or prisons).
- 3.22 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 or the person is needle phobic. In addition, more staff would probably be able to carry out such tests, so helping to increase the number of people who are tested. The PDG noted the success of the Scottish Hepatitis C Action Plan in place since 2008 (Scottish Executive 2006, 2008). Preliminary evidence from this programme suggests that hepatitis C testing in specialist drug clinics increased after the introduction of dried blood spot testing and wide-scale training of healthcare workers in hepatitis C.
- 3.23 The PDG recognised that oral fluid testing may be more acceptable to some people because it is less invasive than taking blood from a vein, but that oral fluid testing has a lower sensitivity and specificity than tests for hepatitis B and C performed on blood. If an oral fluid sample was

used, a blood sample would then be needed to confirm the initial positive results, and for PCR testing to diagnose chronic hepatitis C.

- 3.24 The PDG acknowledged that different populations are at increased risk of hepatitis B and C. However, there is some overlap between them, and it would simplify delivery if testing for both infections at the same time was recommended in people who are at increased risk of either.
- 3.25 The PDG felt that the point of entry into a hepatitis B vaccination programme also provides an opportunity to offer testing to people considered to be at increased risk for hepatitis B and C infection.
- 3.26 The Group was aware of cases where people had repeatedly been vaccinated against hepatitis B (for example in the <u>prison</u> setting) but not tested for infection, and had later been found to have chronic infection and subsequent liver damage. Nonetheless, the PDG felt that it is important for testing to be offered after vaccination, so as not to impede the success of the vaccination programme.
- 3.27 In line with the <u>Green book</u>, the PDG felt that drug services should offer hepatitis B vaccination to all service users who inject or have injected drugs and people with a risk of progression to injecting, for example people who are currently smoking heroin and/or crack cocaine, and heavily dependent amphetamine users, as well as non-injecting users who are living with current injectors.
- 3.28 The PDG felt that despite the focus of this guidance on primary and secondary care there may be a role for routine testing for hepatitis B and C in some tertiary clinical services (such as liver clinics, haemodialysis, rheumatology, cancer and fertility services) and as such staff should have access to appropriate training and a role in awareness-raising. The PDG was aware that evidence regarding the effectiveness of routine testing in tertiary clinical services has not been adequately considered in the development of this guidance, but felt this area should be acknowledged.
- 3.29 The PDG felt that there may be merit in commissioners considering a range of venues for hepatitis B and C testing in order to improve

accessibility. Mechanisms would need to be in place to ensure access to laboratory testing services, delivery of results and referral of people who test positive into the care pathway. In addition, venues would need to ensure adequate measures were taken to ensure infection control and privacy. The PDG acknowledged that there is encouraging evidence from pilot schemes where community pharmacists provide dried blood spot testing for hepatitis. Although the evidence is not strong enough to uniformly recommend that all community pharmacists provide this service, the PDG felt that it would be worthwhile considering extending pilot programmes. This extension could be considered for pharmacists already engaged with people at increased risk of hepatitis B and C, such as pharmacists providing needle exchange and NHS health checks.

- 3.30 The PDG noted that abnormal liver function tests, such as raised ALT (alanine aminotransferase) can occur for a variety of reasons (for example, as a consequence of alcohol consumption and fatty liver, or use of statins). In primary care there is a requirement to investigate the cause of an abnormal liver function test, including testing for hepatitis. In secondary care, however, hepatitis tests should only be conducted if the cause of an abnormal liver function test is not known.
- 3.31 Active contact tracing for people who test positive for hepatitis C is not recommended, given low transmission rates to both sexual and <u>household contacts</u>. The PDG acknowledged that it would be sensible to discuss with people who test positive whether any of their contacts may have been exposed to infection, including the children of mothers with hepatitis C infection. Testing of identified contacts would be offered at clinical discretion.

Limitations of the evidence

3.32 There was little published evidence on effective or cost-effective interventions to promote and offer testing to people 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 economic modelling and other evidence presented to the PDG in order to formulate the recommendations.

- 3.33 The PDG was concerned about people who have previously injected drugs but are no longer doing so, and other groups at increased risk, because there was limited evidence on how to reach them effectively. 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.
- 3.34 The mapping review provided limited evidence of existing good practice on testing among people at increased risk of hepatitis B and C in England. The <u>Hepatitis C Action Plan for Scotland</u>, however, does provide a model for improving testing and treatment for hepatitis C (Scottish Executive 2006, 2008).
- 3.35 The PDG recognised the potential risk of hepatitis C transmission among people who inject performance and image-enhancing drugs (PIEDs) such as anabolic steroids (for non-medical reasons). However, there is a lack of published evidence on the extent of risk in this group or on their contribution to overall hepatitis C prevalence.
- 3.36 The PDG recognised and understood the potential risks associated with the transmission of hepatitis C via sharing straws to snort drugs (in theory, if nasal passages were bleeding a straw could transfer infected blood to others using the same straw), but there was a lack of strong biological evidence on which to base recommendations. The key risk was considered to be through sharing injecting equipment.
- 3.37 The PDG noted a lack of evidence specific to the role of <u>peer</u> support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that <u>peer</u> support could be beneficial for the groups of interest identified in the guidance.

Economic modelling

3.38 The way hepatitis B and C are transmitted among different groups at greatest risk varies by group. For example, in the UK 90% of hepatitis C infections are attributed to sharing injecting equipment among people who inject drugs. Among migrant groups from medium- and highprevalence countries, adult-to-adult transmission of hepatitis B within the UK is responsible for only about 5–10% of chronic cases. The main transmission routes for hepatitis B are from 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.

- 3.39 There was a lack of data on interventions to increase rates of casefinding and treatment in <u>prison</u>, 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. Modelling showed that if continuity of treatment (for a prisoner deemed appropriate for treatment) between prisons, from outside to inside prison, or from inside prison to release is at least 40% of the treatment rate of people diagnosed in the community then the treatment would be estimated to be cost effective.
- 3.40 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. Nevertheless, modelling showed that provided that the prevalence of chronic hepatitis B in migrants from minority ethnic groups was at least 2%, then it was estimated that it would be cost effective to find, test and treat within such communities.
- 3.41 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 HIV among this group. Modelling for that guidance 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.
- 3.42 The PDG discussed the possibility of testing all people between the ages of 40 and 65 or 70 for hepatitis C infection. Three recent studies have been carried out in the USA to estimate the cost effectiveness of hepatitis C screening in several different cohorts of people born between

1945 and 1975 (that is, people who were between 37 and 67 years of age in 2012). These studies estimate that such testing would be cost effective, and have led to a recommendation for cohort testing in the USA. The PDG was aware that it was not possible in the time available to carry out modelling for an equivalent cohort in England. The PDG does note, however, that the estimated prevalence of chronic hepatitis C infection in England for that part of the population that does not currently inject drugs would be substantially lower than the 1.6% assumed for the US cohort (Harris et al. 2012). This suggests that a comprehensive testing programme for people born between 1945 and 1975 is unlikely to be cost effective if it were carried out independently of other programmes.

3.43 The PDG discussed the possibility of linking a cohort testing programme for hepatitis C to the Health Check programme currently being introduced for people between 40 and 70 years in England. However, given that a potential extension of the Health Check programme had not been mentioned in the draft guidance sent for consultation, and that there was uncertainty about whether cohort testing offered as part of the Health Check programme would be cost effective, the PDG believed that it would be preferable to wait for more information before making a substantive recommendation in this area.

Prisons

- 3.44 The PDG noted a lack of evidence on interventions to promote testing for hepatitis B and C in specific settings, for example, <u>prisons</u>. Expert testimony was sought to address these gaps.
- 3.45 Given the prevalence of hepatitis B and the history of injecting drug use among the <u>prison</u> population, the PDG recognised the importance of prison as a setting for promoting and offering hepatitis B and C vaccination and testing. It also acknowledged that the established hepatitis B vaccination programme in prisons provides an opportunity for discussing the benefits of testing. The PDG felt testing should be offered in prisons after vaccination, so as not to hamper the success of the vaccination programme.

- 3.46 The PDG was aware of problems with transferring medical records and information between <u>prison</u> and community settings. However, it was beyond the remit of this guidance to make recommendations about sharing health data between custodial and community providers.
- 3.47 The PDG recognised the barriers to <u>continuity of care</u> when someone enters or is released from <u>prison</u>. However, the Group felt that these barriers should not prevent testing for hepatitis B and C being offered to prisoners.
- 3.48 Testing for hepatitis C in <u>prisons</u>, with prisoners' informed consent, is cost effective if there is <u>continuity of care</u> when someone who is infected is referred to, from or between prisons and treatment is at least 40% of the treatment rate of people diagnosed in the community. The PDG felt that prison testing would also help ensure that prisoners' right to the same access to healthcare as the general population would be met, and so address health inequalities.
- 3.49 The PDG was aware that a key factor affecting treatment outcomes was the length of someone's remaining stay in <u>prison</u> following diagnosis – many prisoners only live at one site for short periods of time, for example when on remand.
- 3.50 The PDG was aware that treatment success rates are greater when treatment is based on an 'in-reach' model of care in <u>prisons</u> (where healthcare services are brought into the prison rather than providing escorted outpatient treatment). However, the Group acknowledged that the necessary security arrangements in prison could act as a barrier to this approach.

Immigration Removal Centres

3.51 The PDG recognised the importance of <u>immigration removal centres</u> as a setting for promoting and offering hepatitis B and C testing. Many of the people detained in these centres originate from medium and high prevalence countries and so are at increased risk of hepatitis B and C infection. In 2011, approximately 27,000 migrants entered detention. Although the majority of immigration detainees are held for less than 2

months, many are held for 2 to 6 months, and some are held for more than 1 year.

Data

- 3.52 The PDG acknowledged the limitations and challenges of current surveillance systems for hepatitis B and C (for example, data on the number of people completing treatment successfully are not available). The Group considered that the collection and collation of robust, servicelevel data on testing and treatment services was important for both monitoring and developing services.
- 3.53 The PDG discussed the need for hepatitis B and C databases holding details on people who have been tested and treated. The importance of collecting data on treatment uptake and the need for this data collection to be built into the pathway at every point was noted. It considered that an integrated system, bridging different healthcare providers and capturing a range of data, was the ideal. However, it was felt that there needed to be a balance between the burden of collecting data and the value of those data. The Group acknowledged that it would be resource-intensive.

Other issues

- 3.54 It may not always be easy to identify people from groups at increased risk of hepatitis B or C infection. Examples include: children born to parents who inject drugs, and who may later be placed in care or adopted, or children who have been adopted from a country with a medium or high background prevalence.
- 3.55 Other smaller groups at increased risk of hepatitis B and C infection include people who:
 - have received medical or dental procedures, including renal dialysis, in countries where infection control may be inadequate

- have been exposed to unsterile needles (for example, by having nonprofessional tattoos, body or ear piercing, or acupuncture, or through vaccination in a developing country)
- are jaundiced or have abnormal liver function tests.
- 3.56 The PDG was aware of the need to test candidates for chemotherapy or immunosuppressive therapy for hepatitis B prior to treatment. In people with hepatitis B, chemotherapy or immunosuppressive therapy can result in a flare-up of liver disease and death by fulminant liver failure.
- 3.57 To increase testing in primary care the PDG considered recommending that GPs review patient notes to identify people at increased risk and invite them in for discussion and testing. However, there was insufficient evidence on which to decide whether such an approach would be effective or cost effective.
- 3.58 The PDG noted the importance of verifying the identity of people testing for hepatitis B and C. Members were made aware of instances where NHS cards have been passed on or sold to illegal migrant workers. In some cases medical information had, as a result, been linked to the wrong people.
- 3.59 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 contacts of infected individuals who should be offered vaccination.
- 3.60 In addition, the Group was aware of the complexities and the importance of the hepatitis B vaccination schedule for babies born to infected mothers. Adherence to the vaccination schedule provides an opportunity to prevent chronic infection in babies. The Group was aware that the current system is failing to ensure babies receive a full course of vaccination and are tested for hepatitis B surface antigen (HBsAg) at 12 months to exclude infection.
- 3.61 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 be vaccinated against hepatitis B and test for hepatitis B and C infection.

3.62 The PDG focused on people who inject drugs and migrants from medium- and high-prevalence countries. The Group noted that effective vaccination and testing for hepatitis B has already been implemented for other groups at increased risk, including men who have sex with men and people with multiple sexual partners. For example, see the Royal College of General Practitioners' <u>Guidance for the prevention, testing, treatment</u> <u>and management of hepatitis C in primary care</u> (Appendix 5) for information on hepatitis B vaccination in men who have sex with men and other groups at increased risk. For other populations at increased risk there was no evidence that infection rates were sufficiently high to warrant a recommendation for case-finding amongst these groups. (These groups include people who have been exposed to unsterile needles, for example, by having non-professional tattoos, body or ear piercing, or acupuncture.)

4 Implementation

NICE guidance can help:

- Commissioners and providers of NHS services to meet the quality requirements of the DH's <u>Operating framework for 2012/13</u>. It can also help them to deliver against domain one of the NHS outcomes framework (preventing people from dying prematurely).
- Local health and wellbeing boards to deliver on their requirements within <u>Healthy lives</u>, <u>healthy people</u> (2010).
- Local authorities, NHS services and local organisations determine how to improve health outcomes and reduce health inequalities during the joint strategic needs <u>assessment</u> process.

NICE has developed tools to help organisations put this guidance into practice. For details, see <u>our website</u>.

5 Recommendations for research

Intervention development and promotion

- 5.1 How can case-finding for hepatitis B and C be improved? What modifiable factors influence whether or not specific groups at increased risk of hepatitis B and hepatitis C infection are identified and tested?
- 5.2 How can the uptake of hepatitis C treatment be improved? What factors influence whether or not specific groups at increased risk will begin and complete hepatitis C treatment?
- 5.3 What cost-effective interventions can be used to increase hepatitis B case-finding among migrant populations in primary and secondary care?
- 5.4 What cost-effective interventions ensure <u>continuity of care</u> for prisoners who are diagnosed with chronic hepatitis B or C in <u>prison</u>?
- 5.5 How cost effective are alternative testing sites, such as community pharmacist programmes, for increasing the number of people who are tested and treated for hepatitis B and C?
- 5.6 What are the most effective ways of involving people from groups at increased risk in awareness-raising about, and promoting testing and treatment for, hepatitis B and C infection? Specifically, how cost effective are <u>peer</u> mentor programmes at increasing the number of people at increased risk who are tested and treated for hepatitis B and C?
- 5.7 What impact does increased knowledge and awareness of hepatitis B and C among the general public have on the uptake of testing and treatment?
- 5.8 Which interventions for other communicable diseases could be used to encourage people at increased risk of hepatitis B and C infection to take up the offer of testing and treatment?

Epidemiology

- 5.9 How many children in the UK are infected with chronic hepatitis B and C and which subgroups of the population do they come from?
- 5.10 How many people in the UK are infected with chronic hepatitis B and C and which subgroups of the population do they come from?
- 5.11 How cost effective are cohort testing programmes:
 - as a stand-alone programme, or
 - as an extension of the NHS Health Check programme?

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

6 Updating the recommendations

This guidance will be reviewed 3 years after publication to determine whether all or part of it should be updated. Information on the progress of any update will be posted at the <u>NICE</u> <u>website</u>.

7 Related NICE guidance

Published

Patient experience in adult NHS services. NICE clinical guidance 138 (2012)

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

<u>Hepatitis C (genotype 1) – telaprevir</u>. NICE technology appraisal 252 (2012)

Tuberculosis – hard-to-reach groups. 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)

Looked-after children and young people. NICE public health guidance 28 (2011)

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

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

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

Needle and syringe programmes. NICE public health guidance 18 (2009)

Community engagement. NICE public health guidance 9 (2008)

Antenatal care. NICE clinical guideline 62 (2008)

<u>Hepatitis B – telbivudine</u>. NICE technology appraisal 154 (2008)

<u>Hepatitis B – entecavir</u>. NICE technology appraisal 153 (2008)

Prevention of sexually transmitted infections and under-18 conceptions. 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)

Hepatitis C (children and young people) – peginterferon alfa and ribavirin. NICE technology appraisal (publication expected August 2013)

Hepatitis C. NICE clinical guideline (publication date to be confirmed)

8 Glossary

Close contacts

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

Continuity of care

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

Household contacts

People sharing a bedroom, kitchen, bathroom or sitting room with a person infected with hepatitis B or C.

Immigration removal centres

In addition to housing people who remain in the UK illegally, immigration removal centres house people who are waiting for their immigration claims to be resolved or to have their identities established. Detainees are entitled to primary healthcare facilities during their stay, equivalent to those available in the community.

In-reach model

A model of prison-based healthcare provision in which healthcare services are brought into the prison, instead of the prisoner being taken out to the healthcare service (for example, to a hospital outpatient unit).

Joint strategic needs assessment

A process that identifies the current and future health and wellbeing needs of a local

population, leading to agreed commissioning priorities that aim to improve outcomes and reduce health inequalities.

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.

Past infection

Hepatitis B and C can be cleared by the body's own immune system. An antibody test determines whether a person has ever been infected with hepatitis in the past. If the test is positive further tests are carried out to establish whether the virus is still present in the body.

Peers

Peers are members of the target population who have been diagnosed with hepatitis B or C. They may be recruited and supported to communicate health messages, including promoting testing and treatment, assist with contact tracing or testing, and to offer people support during testing and treatment.

Prison

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

Sexual contact

Intimate contact with others, including kissing and oral, anal, and vaginal intercourse. Hepatitis B is transmitted by direct contact with infected blood. However, it can also be transmitted by contact with semen, vaginal fluids and other body fluids. Hepatitis C is primarily transmitted by contact with infected blood.

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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.

VijayAnand GP, Worcester

NeilConnelly Community Member

DanielaDeAngelis Programme Leader, Medical Research Council Biostatistics Unit, Institute of Public Health, Cambridge

KateDrysdale Clinical Nurse Specialist, Dudley Group Community Services

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

OpalGreyson Viral Hepatitis Specialist Nurse, NHS Bedford and Luton

RichardGrieve Senior Lecturer in Health Economics, London School of Hygiene and Tropical Medicine

MattHickman (Chair) Professor in Public Health and Epidemiology, School of Social and Community Medicine, University of Bristol and Honorary Public Health Consultant, NHS Bristol

WillIrving Professor and Honorary Consultant in Virology, University of Nottingham and Nottingham University Hospitals NHS Trust

JeremyJones Principal Research Fellow, Southampton Health Technologies Assessments Centre (SHTAC), University of Southampton

EmilyKam-YinLam Community Member

DeirdreKelly Professor of Paediatric Hepatology, Birmingham Children's Hospital NHS Foundation Trust

SalimKhakoo Professor of Hepatology, University of Southampton

DannyMorris Independent Consultant, UK Harm Reduction Alliance

CristinaOsorio Community Member

KylieReed Psychiatrist and Clinical Research Worker, National Addiction Centre

AprilWareham Community Member

JamesWindsor Community Member

NatWright Clinical Director Vulnerable Groups, NHS Leeds

NICE project team

MikeKelly CPHE Director

AntonyMorgan Associate Director

KayNolan Co-lead Analyst

ClareWohlgemuth Co-lead Analyst

HilaryChatterton Analyst

JamesJagroo Analyst

AlastairFischer Technical Adviser, Health Economics

VictoriaAxe Project Manager

MelindaKay Coordinator

SueJelley Senior Editor

AnnaPoppa Senior Editor

JamesHall Editor

AlisonLake 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 Beynon, 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 $\underline{appendix E}$ for the titles of the above reports.

Key information for modelling was obtained from Hepatitis C Action Plan for Scotland (especially from Sharon Hutchinson, Avril Taylor and their colleagues).

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:

VivianHope, Health Protection Agency

ProfessorMartinLombard, Department of Health

CatherineStephens, International Union of Sex Workers

ProfessorHowardThomas, Imperial College London

JennyWong (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 <u>appendix E</u> and are available at the <u>NICE 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 highrisk 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 people 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 handsearched. 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 <u>close contacts</u> 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 in relation to 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 of hepatitis B and C testing services among people from high-risk groups.
- Encouraged people from high-risk groups and their '<u>close contacts</u>' 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 <u>Methods for the</u> <u>development of NICE public health guidance</u> (see <u>appendix E</u>). 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 were 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 <u>appendix A</u>). 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 people at increased risk of hepatitis B and C infection. 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.

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 people tested, but little impact on the incidence of chronic infection, because most new cases have not been caused by infection within the UK.)

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'.

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 <u>appendix</u> \underline{C} for details). Where a recommendation was inferred from the evidence, this was indicated by the reference '**IDE**' (inference derived from the evidence).

The draft guidance, including the recommendations, was released for consultation in June 2012. At its meeting in September 2012, the PDG amended the guidance in light of comments from stakeholders and experts. The guidance was signed off by the NICE Guidance Executive in November 2012.

Appendix C The evidence

This appendix lists the evidence statements from two reviews, provided by external contractors (see <u>appendix A</u> and <u>appendix E</u>) and links them to the relevant recommendations. See <u>appendix B</u> 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.

EvidencestatementQ1 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 <u>online</u>. 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 <u>additional evidence</u> <u>section</u> of this appendix.

Recommendation1: evidence statements: Q1, Q2, Q3, Q4, Q5, Q8, Q9, Q10, E1; IDE

Recommendation2: evidence statements: Q1, Q2, Q3, Q4, Q5, Q8, Q9, Q10, Q14, Q15, Q16,

Q23, Q28, Q29, E1; IDE

Recommendation3: evidence statements: Q2, Q18, Q20, Q21, Q28, Q29, Q30, E2, E5, E8; IDE

Recommendation4: evidence statements: Q28, E5, E6, E11

Recommendation5: evidence statements: Q16, Q27, Q28, E1, E6; IDE

Recommendation6: evidence statements: Q18, Q20, Q21, Q24, Q25, Q28, Q29, Q30, E1, E4, E5, E6, E7, E8, E9; IDE

Recommendation7: IDE

Recommendation8: IDE

Recommendation9: IDE

Recommendation10: Q7, E5; IDE

Recommendation11: evidence statements: 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. The superscript numbers refer to the studies cited beneath each statement. The full references for those studies can be found in the reviews.

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 [+])^{1,2,3}.

¹Burke et al. 2004.

² Burke et al. 2011.

³ 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 [++])^{3,4} may contribute to or compound inadequate knowledge about hepatitis B among groups at a high risk of infection.

¹Burke et al. 2011.

² van der Veen et al. 2009.

³ Wallace et al. 2011.

⁴ 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 [+])^{1,2,3,4}. 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 a sexually transmitted infection (three [++])^{4,5,6}.

¹Burke et al. 2004.

² Burke et al. 2011.

³ Chen et al. 2006.

⁴ Choe et al. 2005.

⁵ van der Veen et al. 2009.

⁶ 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 [++])^{1,2,3,4}. 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 [+])^{1,2,5,6,7,8}. Religious influences on preventive health strategies may also be apparent, for example among Muslim men (one [++])³.

¹ Choe et al. 2005.

² Chen et al. 2006.

³ van der Veen et al. 2009.

⁴ Wallace et al. 2011.

⁵ Burke et al. 2004.

⁶ Burke et al. 2011.

⁷ Chang et al. 2008.

⁸ Hwang et al. 2010.

Evidence statement Q5

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

¹Buck et al. 2006.

² van der Veen et al. 2009.

³ Chen et al. 2006.

⁴ Chang et al. 2008.

Evidence statement Q7

Barriers to testing for hepatitis B 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 [++])¹.

¹van der Veen et al. 2009.

Evidence statement Q8

The perception 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 a sexually transmitted infection was viewed by one study ([++])¹as potentially contributing to increased stigma.

¹van der Veen et al. 2009.

Evidence statement Q9

One study ([++])¹ 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.

¹Wallace et al. 2011.

Evidence statement Q10

There was evidence that safe and responsible injecting practices are employed by injecting drug users (IDUs) to avoid the transmission of hepatitis C from 6 studies (5 [++] and 1 [+]^{1,2,3,4,5,6}. There was a lack of consensus as to whether safe practices are strictly adhered to in relation to the sharing of drug related paraphernalia^{3,5,7}.

¹Davis et al. 2004.

² Ellard 2007.

³ Rhodes et al. 2004.

⁴ Southgate et al. 2005.

⁵ Wright et al. 2005.

⁶ Fraser 2004.

⁷ Coupland et al. 2009.

Evidence statement Q14

There is strong evidence from 18 studies (eleven [++], five [+], one [-] and one not rated [NR])^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18} that 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])^{4,11,12,17}. There is evidence that some IDUs are aware of their limited knowledge of hepatitis C (three [++])^{3,4,12}.

¹Copeland 2004.

² Coupland et al. 2009.

³ Davis and Rhodes 2004.

⁴ Davis et al. 2004.

⁵ Ellard 2007.

⁶ Fraser 2004.

⁷ Fraser 2010.

⁸ Gyarmathy et al. 2006.

⁹ Harris 2009a.

¹⁰ Munoz-Plaza et al. 2004.

¹¹ Rhodes and Treloar 2008.

¹² Rhodes et al. 2004.

¹³ Sosman et al. 2005.

¹⁴ Southgate et al. 2005.

¹⁵ Sutton and Treloar 2007.

¹⁶ Swan et al. 2010.

¹⁷ Tompkins et al. 2005.

¹⁸ 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])^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15}.

¹Copeland 2004.

² Davis and Rhodes 2004.

³ Davis et al. 2004.

⁴ Ellard 2007.

⁵ Faye and Irurita 2003.

⁶ Harris 2009a.

⁷ Munoz-Plaza et al. 2010.

⁸ Rhodes et al. 2004.

⁹ Roy et al. 2007.

¹⁰ Southgate et al. 2005.

¹¹ Sutton and Treloar 2007.

¹² Swan et al. 2010.

¹³ Rhodes and Treloar 2008.

¹⁴ Treloar and Rhodes 2009.

¹⁵ 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])^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17}. Three studies (two [+] and one [-])^{7,18,19} 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.

¹Craine et al. 2004.

² Davis et al. 2004.

³ Fraser 2004.

⁴ Fraser 2010.

⁵ Gyarmathy et al. 2006.

⁶ Harris 2009a.

⁷ Khaw et al. 2007.

⁸Lally et al. 2008.

⁹ Perry et al. 2003.

¹⁰ Rhodes and Treloar 2008.

¹¹ Rhodes et al. 2004.

¹² Temple-Smith et al. 2004.

¹³ Sosman et al. 2005.

¹⁴ Southgate et al. 2005.

¹⁵ Strauss et al. 2008.

¹⁶ Sutton and Treloar 2007.

¹⁷ Swan et al. 2010.

¹⁸ Dyer and Tolliday 2009.

¹⁹ 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 $[+])^{1,2,3,4,5,6,7,8}$. There is evidence (two [++] and two [+])^{3,9,10,11} 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.

¹Gyarmathy et al. 2006.

² Munoz-Plaza et al. 2004.

³ Rhodes et al. 2004.

⁴ Roy et al. 2007.

⁵ Sosman et al. 2005.

⁶ Swan et al. 2010.

⁷ Strauss et al. 2008.

⁸ Temple-Smith et al. 2004.

⁹ Munoz-Plaza et al. 2005b.

¹⁰ Perry and Chew-Graham 2003.

¹¹ Tompkins et al. 2005.

Evidence statement Q20

Trust and rapport with healthcare professionals and drug treatment staff motivated people to get tested. Support and encouragement from healthcare professionals also facilitated testing among IDUs (four [+])^{1,2,3,4}.

¹Munoz-Plaza et al. 2004.

² Perry et al. 2003.

³ Sosman et al. 2005.

⁴ 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])^{1,2,3,4,5,6,7,8,9,10,11,12,13}. Limited and inadequate information provision by healthcare professionals can lead to confusion over the meaning of a positive diagnosis and substantial gaps in knowledge.

¹Copeland 2004.

² Cullen et al. 2005.

³ Faye and Irurita 2003.

⁴ Khaw et al. 2007.

⁵ Kinder 2009.

⁶ Lally et al. 2008.

⁷ Rhodes and Treloar 2008.

⁸ Rhodes et al. 2004.

⁹ Southgate et al. 2005.

¹⁰ Strauss et al. 2008.

¹¹ Sutton and Treloar 2007.

¹² Swan et al. 2010.

¹³ Tompkins et al. 2005.

Evidence statement Q23

Fear of the adverse effects associated with hepatitis C treatment and the circulation of 'horror stories' and unsuccessful treatment cases among <u>peers</u> discouraged IDUs from engaging with treatment (three [++], one [+] and two [-])^{1,2,3,4,5,6}. 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 [+])^{3,5,7}. 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 [+])^{3,5,8}.

¹Cullen et al. 2005.

² Fraser 2010.

³ Kinder 2009.

⁴ Munoz-Plaza et al. 2008.

⁵ Swan et al. 2010.

⁶ Treloar and Holt 2008.

⁷ Strauss et al. 2008.

⁸ Munoz-Plaza et al. 2004.

Evidence statement Q24

Socioeconomic and family circumstances can lead to treatment being de-prioritised among IDUs (three[++] and one [-])^{1,2,3,4}. 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 [++])^{1,3,5}. The assumption of abstinence as a requirement for hepatitis C treatment and continued substance use among IDUs acted as a barrier to treatment (six [++] and one [-])^{1,3,5,6,7,8,9}.

¹Coupland et al. 2009.

² Fraser 2010.

³ Swan et al. 2010.

⁴ Treloar et al. 2010.

 5 Lally et al. 2008.

⁶ Cullen et al. 2005.

⁷ Roy et al. 2007.

⁸ Wozniak et al. 2007.

⁹ Wright et al. 2005.

Evidence statement Q25

Receiving support from family, partners and <u>peers</u>, 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 [++])^{1,2,3}.

¹Faye and Irurita 2003.

² Kinder 2009.

³ Swan et al. 2010.

Evidence statement Q27

One study ([-])¹ found that being in <u>prison</u> was viewed by healthcare 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 <u>peer</u> support during treatment were regarded as beneficial. ¹ 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 $[++])^{1,2}$. Increasing knowledge of hepatitis C through the provision of information by healthcare professionals encouraged IDUs to consider their treatment options (one [++], two [+] and one $[-])^{1,3,4,5}$.

¹Swan et al. 2010.

² Treloar et al. 2010.

³ Cullen et al. 2005.

⁴ Munoz-Plaza et al. 2004.

⁵ 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])^{1,2,3,4,5,6,7,8,9,10,11,12,13}. Stigma also prevented engagement with further prevention education, investigations and treatment and resulted in IDUs receiving inadequate and judgemental care by healthcare professionals (seven [++], six [+], one [-] and two [NR])^{5,6,7,9,12,14,15,16,17,18,19,20,21,22,23,24}.

¹Craine et al. 2004.

² Ellard 2007.

³Harris 2009b.

⁴ Khaw et al. 2007.

 5 Lally et al. 2008.

⁶ McCreaddie et al. 2011.

⁷ Roy et al. 2007.

⁸ Sosman et al. 2005.

⁹ Strauss et al. 2008.

¹⁰ Sutton and Treloar 2007.

¹¹ Tompkins et al. 2005.

¹² Treloar and Rhodes 2009.

¹³ Wright et al. 2005.

¹⁴ Carrier et al. 2005.

¹⁵ Coupland et al. 2009.

¹⁶ Faye and Irurita 2003.

¹⁷ Habib and Adorjany 2003.

¹⁸ Munoz-Plaza et al. 2004.

¹⁹ Paterson et al. 2007.

²⁰ Perry et al. 2003.

²¹ Swan et al. 2010.

²² Temple-Smith et al. 2004.

²³ Treloar and Hopwood 2004.

²⁴ Treloar et al. 2010.

Evidence statement Q30

Perceiving health care professionals to be supportive, concerned and caring, and being encouraged to undertake treatment by healthcare professionals was found to motivate IDUs to engage in hepatitis C treatment (four [++], one [+] and one $[-])^{1,2,3,4,5,6}$. 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 [+])^{5,7,6}. These services were also seen as useful in providing information on hepatitis C treatment (one [++] and three [+])^{5,6,8,9}.

¹Fraser 2010.

² Coupland et al. 2009.

³ Kinder 2009.

⁴ McCreaddie et al. 2011.

⁵ Munoz-Plaza et al. 2004.

⁶ Swan et al. 2010.

⁷Treloar et al. 2010.

⁸ Munoz-Plaza et al. 2005a.

⁹ Munoz-Plaza et al. 2006.

Evidence statement E1

There is moderate evidence from three randomised controlled trials (RCTs) (one [++] and two [+])^{1,2,3} and one uncontrolled before and after (UBA) study (-)⁴ 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 [+])^{1,2,3} 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 (-)⁵ to suggest that testing supplemented with culturally appropriate education may encourage the uptake of follow-up care among migrant populations.

¹Taylor et al. 2009a.

² Taylor et al. 2009b.

³ Taylor et al. 2011.

⁴ Hsu et al. 2007; 2010.

⁵ Chao et al. 2009.

Evidence statement E2

There is moderate evidence from one RCT (+)¹ 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 (-)² to suggest that providing information and education on hepatitis B to complementary and alternative medicine 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.

¹Nguyen et al. 2000.

² Chang et al. 2007.

Evidence statement E4

There is moderate evidence from one RCT $(+)^1$ and one controlled before and after (CBA) study $(-)^2$ to suggest that offering dried blood spot testing to IDUs attending substance misuse services may increase uptake of hepatitis C testing compared to venepuncture alone being offered. The increase in uptake may reflect an increase in testing availability, as more staff can be trained to deliver dried blood spot testing than venepuncture, as well as higher acceptability to IDUs. There is weak evidence from one case series (CS) study (-)³ to suggest that providing high-risk groups with access to dried blood spot testing via state laboratories.

¹Hickman et al. 2008.

² Craine et al. 2009.

³Rainey 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 (two $[+])^{2,3}$ 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.

¹Roudot-Thoraval et al. 2000.

² Anderson et al. 2009.

³ Cullen et al. 2012.

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-drug-using populations. In two studies conducted in the USA (two [-])^{6,7}, 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 (+)⁸ 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 (-)⁹ to suggest that the provision of hepatitis C outreach services for new prisoners may lead to relatively low uptake of testing.

¹Rosenberg et al. 2010.

² Lindenberg et al. 2011.

³Jack et al. 2009.

⁴ Lindenberg et al. 2011.

⁵ Jack et al. 2009.

⁶ Harris et al. 2010.

⁷ Hagedorn et al. 2007.

⁸ Sahajian et al. 2011.

⁹ Skipper et al. 2003.

Evidence statement E7

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

¹Foucher et al. 2009.

² Aitken et al. 2002.

Evidence statement E8

There is moderate evidence from one RCT $(++)^1$, one non-randomised controlled trial $(+)^2$ and one UBA study $(-)^3$ to suggest that complex interventions that provide support to primary care professionals when offering hepatitis C testing may have a positive impact on testing acceptance and uptake. One repeated cross-sectional study $(+)^4$ 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 $[-])^{1,5,6}$ to suggest that

educational interventions aimed at healthcare 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 $(-)^4$ suggested that a continuing medical education programme had a limited impact on testing uptake. There is mixed evidence from two studies (one [++] and one[+])⁷ that examined the effectiveness of interventions aimed at professionals on treatment initiation. There is moderate evidence from a repeated cross-sectional study $(+)^4$ 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 $(++)^1$ 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.

¹Cullen et al. 2006.

² Helsper et al. 2010.

³ Sahajian et al. 2004.

⁴ Defossez et al. 2008.

⁵ D'Souza et al. 2004.

⁶ Fischer et al. 2000.

⁷ Garrard et al. 2006.

Evidence statement E9

There is weak evidence from one controlled before and after (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 $(-)^5$ 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 healthcare professionals. There is weak evidence from a CBA study (-)⁶ 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.

¹Moussalli et al. 2010.

² Wilkinson et al. 2008.

³ Grebely et al. 2007.

⁴ Grebely et al. 2010.

⁵ Doucette et al. 2009.

⁶ Surjadi et al. 2011.

Evidence statement E11

There is moderate evidence from one cost utility analysis (+)¹ to suggest that communitybased screening and treatment for hepatitis B among migrant populations is cost effective.

¹Veldhuijzen 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 blood-spot testing for hepatitis C infection.
- Educating and supporting GPs to identify patients at risk of the infection.
- Training prison nurses to undertake dried blood-spot testing for hepatitis C infection.

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

Educating GPs about hepatitis C infection and targeted paid testing also resulted in an increase in testing and was also cost effective, yielding an estimated cost per QALY of £14,000. (Clinical administration systems were reviewed to identify registered patients aged 30-54 who had indicators of past injecting drug use. These individuals were offered testing for hepatitis C when they attended the practice for a non-urgent consultation. Practices received £100 remuneration for each test offered). Training prison nurses to undertake dried blood spot testing also increased the proportion of hepatitis C cases found, compared with not offering this sampling method. However, the cost effectiveness of this training depended on whether the resulting treatment was completed. The baseline scenario considered no continuity of care between prison and the community - in which case the cost per QALY of finding a new case was estimated to be £59,000 per QALY and therefore was not cost effective. The estimated cost per QALY of case-finding in prison will be less than £20,000 per QALY gained if there is continuity of care between prison and the community and the treatment rate of people diagnosed in prison is at least 40% of the treatment rate of people diagnosed in the community. Higher treatment rates in the community make prison case-finding more cost effective as long as there is continuity of care.

A second model looked at finding and testing UK migrants for hepatitis C infection. This was found to be cost effective if 2% of the migrant 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 to be £10,000. If the cost of finding and testing someone was £50, the estimated cost per QALY was £18,000. For a given cost of testing, it became more cost effective to find and test people if more than 2% of the population group were infected.

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.

1. 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:

a) 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) 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, <u>prisons</u>.

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.

c) knowledge of, barriers against, and facilitators for preventing hepatitis B and C among men who have sex with men.

d) knowledge of, barriers against, and facilitators for improving the prevention of 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 the practitioner's level and type of knowledge.

i) prisoners' views of hepatitis testing and treatment and the views of those working with them.

j) the acceptability of different sampling methods for testing for hepatitis.

k) factors which encourage people to have a liver biopsy or discourage them from this.

I) the knowledge GPs have regarding identification of at-risk patients.

m) why people referred by GPs for a hepatitis test drop out of appropriate care pathways and whether or not an integrated services/one-stop-shop approach would improve uptake rates.

n) understanding of hepatitis B and C care pathways.

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 people:

a) at risk of hepatitis B and C.

b) who have been identified and/or tested and/or treated.

c) 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 dried blood spot 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.

The Group made 12 recommendations for research into areas that it believes will be a priority for developing future guidance. These are listed in <u>section 5</u>.

Appendix E Supporting documents

Supporting documents include the following (see supporting evidence).

- 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 (third edition, 2012)
- The NICE public health guidance development process (third edition, 2012)

About this guidance

NICE public health guidance makes recommendations on the promotion of good health and the prevention of ill health.

This guidance was developed using the NICE <u>public health programme</u> guidance process.

The recommendations from this guidance have been incorporated into a <u>NICE Pathway</u>. Tools to help you put the guidance into practice and information about the evidence it is based on are also <u>available</u>.

Yourresponsibility

This guidance represents the views of the Institute and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Changes after publication

March 2013: recommendation 7 has been clarified by adding the text: 'at increased risk of infection' to the sentence 'offer and promote hepatitis B and C testing to all service users at increased risk of infection, including people younger than 18'.

April 2013: minor maintenance.

Accreditation

