NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Health and social care directorate

# Quality standards and indicators

# Briefing paper

**Quality standard topic:** Hepatitis B

**Output:** Prioritised quality improvement areas for development.

**Date of Quality Standards Advisory Committee meeting:** 10 January 2014

## Contents

# 1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for hepatitis B. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

## *1.1 Structure*

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

## *1.2 Development source*

The key development sources referenced in this briefing paper are:

- Hepatitis B (chronic): Diagnosis and management of chronic hepatitis B in children, young people and adults. NICE clinical guideline 165 (2013).
- Hepatitis B and C: ways to promote and offer testing. NICE public health guidance 43 (2012).
- Reducing differences in the uptake of immunisations. NICE public health guidance 21 (2009).

# 2 Overview

## *2.1 Focus of quality standard*

This quality standard will cover hepatitis B testing, diagnosis and management of chronic hepatitis B in children, young people and adults.

## *2.2 Definition*

Hepatitis B is a viral infection that is transmitted by contact with the blood or body fluids of an infected person and is transmitted perinatally from mother to child. Some individuals clear hepatitis B infection naturally, whereas others develop a chronic infection. 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.

Most people remain healthy without any symptoms while they fight off the virus. Some will not even know they have been infected. However, until the virus has been cleared from their body, they can pass it onto others. If there are any symptoms, they will develop on average 60-90 days after exposure to the virus.

Chronic hepatitis B describes a spectrum of disease usually characterised by the presence of detectable hepatitis B surface antigen (HBsAg) in the blood or serum for longer than 6 months. In some people, chronic hepatitis B is inactive and does not present significant health problems, but others may progress to liver fibrosis, cirrhosis and hepatocellular carcinoma (HCC).

## *2.3 Incidence and prevalence*

The UK has been classified as a low incidence and prevalence country for hepatitis B infection; however it does pose a significant amount of potentially preventable mortality and morbidity[1]. There is considerable uncertainty over the size of the population with chronic hepatitis B in the UK – in 2002 the Department for Health estimated that chronic hepatitis B affects 180,000 people in the UK. Other estimates put the figure for the UK up to as much as 325,000[2].

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. 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 the main focus for hepatitis B finding and testing in the UK, and infection in childhood is the major route of transmission.

Prevalence varies across the UK. 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 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 sexual contact 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.

[1] Health Protection Agency (2011). Standards for local surveillance and follow up of hepatitis B and C.
[2] Hepatitis B Foundation UK (2007) Rising curve: Chronic Hepatitis B Infection in the UK

- Prisoners, including young offenders.
- Immigration detainees.
- Close contacts of someone known to be chronically infected with hepatitis B.

## *2.4 Management*

### Immunisation programme

The national hepatitis B immunisation programme recommends that people from at-risk groups are immunised against hepatitis B. This is covered by Public Health England 'Immunisation against infectious disease' (the Green Book) which provides information on hepatitis B vaccination procedures and schedule[3].

### Screening of pregnant women for hepatitis B and immunisation of babies at risk

Universal screening of pregnant women for hepatitis B and immunisation of babies at risk is recommended. This is part of the National Screening Committee 'hepatitis B antenatal screening and newborn immunisation programme' (this may also include hepatitis B immunoglobulin as well as hepatitis B vaccine)[4].

NICE public health guideline 21 focusses on increasing immunisation uptake among those aged under 19 years from groups where uptake is low, this includes ensuring babies born to mothers infected with hepatitis B are immunised. This NICE guidance is complementary to the National Screening Committee guidance.

The screening of pregnant women for hepatitis B is also integrated into the broader NICE routine antenatal care pathway (NICE clinical guideline 62).

### Testing

NICE public health guideline 43 focusses on the ways to promote and increase the uptake of the offer of hepatitis B and C testing to people at risk of infection[5].

The NICE guideline development group for PH43 acknowledged that different populations are at increased risk of hepatitis B and C. However, it was agreed that

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[3] Public Health England (2013). Immunisation against infectious diseases (The Green Book). See Hepatitis B, Chapter 18.

[4] Department of Health (2011). Hepatitis B antenatal screening and newborn immunisation programme.

[5] The NICE public health guideline 43 recommendations cover:

- awareness-raising
- knowledge and skills of healthcare professionals
- testing in primary care, prisons and youth offender institutions, immigration removal centres, drug services and genitourinary medicine and sexual health clinics.
- contact tracing
- providing and auditing neonatal hepatitis B vaccination, commissioning and laboratory services.

there is some overlap between them and the group concluded that it would simplify delivery if testing for both infections was recommended at the same time in people who are at risk of either.

The hepatitis B infection is diagnosed by having a blood test. People who are infected with the hepatitis B virus will test positive for a protein that sits on the surface of the virus (called hepatitis B surface antigen, or HBsAg).

**Chronic hepatitis B management**

NICE clinical guideline 165 covers the assessment and management of people with chronic hepatitis B.

People who remain HBsAg positive for at least 6 months are diagnosed with chronic hepatitis B.

Chronic hepatitis B affects the liver and can cause serious health problems if left untreated. These include scarring of the liver (called fibrosis or cirrhosis), liver failure (called decompensation) and liver cancer (called hepatocellular carcinoma, or HCC). The main goal of treatment is to prevent these conditions.

A member of the healthcare team should discuss chronic hepatitis B with the person and explain the tests and treatments in detail. The GP should offer further tests (including arrange to have an ultrasound to check for liver cancer) and make a referral to a specialist with results of the tests.

Pregnant women who have found out that they have chronic hepatitis B through antenatal screening are referred to a specialist who should see them within 6 weeks of being diagnosed. This is to ensure appropriate treatment later in the pregnancy to reduce the chance of the baby becoming infected.

Tests for liver disease are carried out in the specialist setting to make decisions about care and drug treatment. Chronic hepatitis B is treated with antiviral drugs which work by reducing the amount of virus that is found in the body. Although treatment leads to a full recovery in some people, most people with chronic hepatitis B will need lifelong treatment.

Factors which influence whether drug treatment is recommended include age, the amount of virus found in the bloodstream (called viral load), whether liver tests are normal (called liver function), and the extent of any liver disease (fibrosis, cirrhosis or inflammation).

Monitoring is a crucial part of clinical management of people taking drug treatment or who have stopped taking drug treatment. People who do not need drug treatment should also be regularly monitored according to the NICE guidance.

The management pathway for chronic hepatitis B is provided in appendix 1.

## *2.5 National Outcome Frameworks*

Tables 1 and 2 show the outcomes, overarching indicators and improvement areas from the framework that the quality standard could contribute to achieving.

**Table 1 NHS Outcomes Framework 2014/15**

| Domain | Overarching indicators and improvement areas |
|---|---|
| 1 Preventing people from dying prematurely | *Overarching indicator*<br>1a Potential years of life lost (PYLL) from causes considered amenable to healthcare i adults ii *children and young people*<br>*Improvement areas*<br>1.3 Under 75 mortality rate from liver disease* (PHOF 4.6) |
| 2 Enhancing quality of life for people with long-term conditions | *Overarching indicator*<br>2 Health-related quality of life for people with long-term conditions**<br>*Improvement areas*<br>Reducing time spent in hospital by people with long-term conditions<br>2.3 i Unplanned hospitalisation for chronic ambulatory care sensitive conditions (adults) |
| Alignment across the health and social care system<br>* Indicator complementary with Public Health Outcomes Framework (PHOF)<br>** Indicator complementary with Adult Social Care Outcomes Framework (ASCOF) | |

**Table 2 Public health outcomes framework for England, 2013–2016**

| Domain | Objectives and indicators |
|---|---|
| 4 Healthcare public health and preventing premature mortality | *Objective*<br>Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities<br>*Indicators*<br>4.6 Mortality from liver disease* |
| Alignment across the health and social care system<br>* Indicator shared with NHS Outcomes Framework (NHSOF) | |

# 3 Summary of suggestions

## *3.1 Responses*

In total 12 stakeholders responded to the 2-week engagement 07/11/2013 – 21/11/2013.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

Full details on the suggestions provided are given in appendix 5 for information.

**Table 3 Summary of suggested quality improvement areas**

| Suggested area for improvement | Stakeholders |
|---|---|
| **Vaccination**<br>• Universal vaccination<br>• Vaccination of all people at increased risk<br>• Infant hepatitis B vaccination | BHIVA<br>RCP<br>RCPCH<br>SCMs<br>UKCPA<br>WAGE and WVHTMG |
| **Testing for hepatitis B** | BASH<br>GS Ltd<br>SCMs |
| **Initial assessment for children, young people and adults who are HBsAg positive** | SCMs |
| **Referral to specialist** | SCMs<br>WAGE and WVHTMG |
| **Antiviral treatment**<br>• Treatment sequence<br>• Antiviral therapy initiated by a specialist in viral hepatitis | SCMs |
| **Monitoring in people taking antiviral treatment** | RP Ltd<br>SCMs |
| **Monitoring in people who do not meet criteria for antiviral treatment** | SCMs |
| **Surveillance testing for primary liver cancer** | UKCPA<br>WAGE and WVHTMG |
| **Patient education and personalised care plans for people with chronic hepatitis B** | SCMs<br>UKCPA |
| **Contact tracing** | BASH<br>RCP |

| | |
|---|---|
| **Awareness raising, education and training** | SCMs<br>UKCPA |
| **Additional areas**<br>• Occupational training<br>• Laboratory standards<br>• Shared care arrangements<br>• Improved hepatitis delta virus antibody (anti-HDV) testing<br>• Improved HIV testing | |
| NHS Sheffield CCG, NHS Sheffield Clinical Commissioning Group<br>BASHH, British Association for Sexual Health and HIV<br>BHIVA, British HIV Association<br>HBPT, Hepatitis B Positive Trust<br>GS Ltd, Gilead Sciences Ltd<br>RCPath, Royal College of Pathologists<br>RCPCH, Royal College of Paediatrics and Child Health<br>RCP, Royal College of Physicians<br>RP Ltd, Roche Products Limited<br>UK Clinical Pharmacy Association, UKCPA<br>WAGE and WVHTMG, Welsh Association Gastroenterology and Endoscopy (WAGE) and Wales Viral Hepatitis Treatment/Management Group<br>SCM, Specialist Committee Member. | |

# 4 Suggested improvement areas

## *4.1 Suggested improvement area: Vaccination*

### 4.1.1 Summary of suggestions

**Universal vaccination**

Universal vaccination was suggested by some stakeholders, including reference to World Health Organisation goals for universal childhood vaccination.

**Vaccination of all people at increased risk**

Stakeholders highlighted the importance of vaccination of all people at increased risk to reduce infection transmission.

**Infant hepatitis B vaccination**

Stakeholders highlighted the importance of appropriate and prompt vaccination of all infants born to infected mothers with proper follow up and the importance of prevention of hepatitis B transmission from mother to baby.

### 4.1.1 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 4 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Universal vaccination | No recommendations. |
| Vaccination of all people at increased risk | Hepatitis B vaccination is beyond the scope of NICE public health guidance 43. However, the NICE guideline developers for PH43 emphasised the existing hepatitis B vaccination programme and cross reference to the Green Book. |
| Infant hepatitis B vaccination | NICE public health guidance 21 and 43 provides specific recommendations relating to the provision and auditing neonatal hepatitis B vaccination.<br><br>The hepatitis B vaccination programme was not considered for any other age group. |

| | |
|---|---|
| | Relevant recommendations are as follows:<br><br>• NICE public health guidance 21 Recommendation 6 (hepatitis B immunisation for infants)<br><br>• NICE public health guidance 43 Recommendation 9 (Effective delivery and auditing of neonatal hepatitis B vaccination) |

NICE public health guidance 21- Recommendation 6: hepatitis B immunisation for infants

**What action should they take?**

- PCTs should have an identified person responsible for coordinating the local hepatitis B vaccination programme for babies at risk of hepatitis B infection. The person should also be responsible for scheduling and follow-up to ensure babies at risk are vaccinated at the right time. This may involve working within and across several PCT areas.

- A clear process for the local infant hepatitis B vaccination programme should be developed and implemented. Antenatal, postnatal, neonatal, paediatric, primary care and community support teams should communicate effectively and share information so that the children and families affected can be contacted and followed up.

- Babies born to hepatitis B-positive mothers should be given the first dose of the vaccine promptly, whether they are delivered in hospital or at home. They should then receive all other recommended doses, a blood test to check for infection and, where appropriate, hepatitis B immunoglobulin, in line with the 'Green book'.

- Health professionals should record the mother's hepatitis B status in the personal child health record as soon as possible after birth, before the midwife hands over care of the baby to the health visitor. The mother's hepatitis B status should also be entered on the child's record in the local Child Health Information System.

- Health professionals should provide parents with information, advice and support on how to prevent the transmission of hepatitis B. They should emphasise the importance of ensuring babies complete the recommended vaccination course at the right time. In addition, they should assess whether or not the baby's siblings need to be immunised against hepatitis B or tested for infection and should offer them vaccinations and blood tests if necessary.

- Health professionals should ensure administered doses of hepatitis B vaccination are recorded in the patient records and the personal child health record.

NICE public health guidance 43 - Recommendation 9: Effective delivery and auditing of neonatal hepatitis B vaccination

**What action should they take?**

- 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 Green book.

- 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.

### 4.1.2 Current UK practice

**Universal vaccination**

No routine data on hepatitis B vaccination uptake rates were identified for this report.

**Vaccination of all people at increased risk**

No routine data on hepatitis B vaccination uptake rates were identified for this report.

**Infant hepatitis B vaccination**

The NICE guidance developers for PH21 and PH43 noted the complexities and importance of the hepatitis B vaccination schedule for babies born to infected mothers.

It was noted that coverage for the initial dose of the vaccine to a baby born to a mother infected with the hepatitis B virus appears to be relatively high. However, subsequent doses are often delayed or never received. NICE PH21 (published in 2009) quoted coverage at age 12 months at 69%. More recent data are not available.

## *4.2 Testing for hepatitis B*

### 4.2.1 Summary of suggestions

There was a consistent stakeholder response highlighting the need for improvements in the testing for hepatitis B to people at increased risk of infection. Stakeholders reiterated that effective testing strategies leading to early detection and onward referral will reduce premature death from liver disease.

A number of groups at increased risk of hepatitis B infection where testing should be promoted and offered are set out in NICE public health guidance 43.

### 4.2.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development.

**Table 5 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Testing for hepatitis B | **NICE Public Health Guidance 43**<br>• Recommendation 4 Testing for hepatitis B and C in primary care<br>• Recommendation 5 Testing for hepatitis B and C in prisons and immigration removal centres<br>• Recommendation 6 Testing for hepatitis B and C in drugs services<br>• Recommendation 7 Testing for hepatitis B and C in sexual health and genitourinary medicine clinics |

NICE public health guideline 43 - Recommendation 4: Testing for hepatitis B and C in primary care

- 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 high-prevalence countries and people who inject or have injected drugs (see Whose health will benefit?).

- 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 Whose health will benefit?).

*See appendix 3 for full detail of above recommendation*

NICE public health guideline 43 – Recommendation 5: Testing for hepatitis B and C in prisons and immigration removal centres

- Prison and immigration removal centre 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 Green book)
    - 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

*See appendix 3 for full detail of above recommendation*

NICE public health guideline 43 - Recommendation 6: Testing for hepatitis B and C in drugs services

- Drugs services 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

*See appendix 3 for full detail of above recommendation*

NICE public health guideline 43 - Recommendation 7: Testing for hepatitis B and C in 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

*See appendix 3 for full detail of above recommendation*

### 4.2.3 Current UK practice

There is a lack of robust uptake data on testing rates for hepatitis B infection in people at increased risk of infection.

The NICE costing report for public health guidance 43 made assumptions for testing of hepatitis B which highlighted significant potential to increase uptake of testing following implementation of the NICE public health guidance[6].

The NICE costing report assumed the following:

- The baseline level of testing for people at increased risk of hepatitis B and C in general practice is 2.6% of new GP registrations.
- The baseline level of testing for people at increased risk of hepatitis B in prisons and immigration removal centres is 2.11%.

[6] NICE costing report for public health guidance 43 (2012)

## *4.3 Suggested improvement area: Initial assessment for children, young people and adults who are HBsAg positive*

### 4.3.1 Summary of suggestions

Stakeholders highlighted the importance of arranging a full series of tests for children, young people and adults who are identified as hepatitis B surface antigen (HBsAg) positive.

### 4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 6 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Initial assessment for children, young people and adults who are HBsAg positive | **Assessment and referral in primary care**<br>*Adults who are HBsAg positive*<br>NICE CG165 Recommendation 1.2.1 (key priority for implementation)<br><br>*Children and young people who are HBsAg positive*<br>NICE CG165 Recommendation 1.2.6 |

**Assessment and referral in primary care**

*Adults who are HBsAg positive*

NICE clinical guideline 165 - Recommendation 1.2.1 (key priority for implementation)

Arrange the following tests in primary care for adults who are hepatitis B surface antigen (HBsAg) positive:

- hepatitis B e antigen (HBeAg)/antibody (anti-HBe) status
- HBV DNA level
- IgM antibody to hepatitis B core antigen (anti-HBc lgM)
- hepatitis C virus antibody (anti-HCV)
- hepatitis delta virus antibody (anti-HDV)
- HIV antibody (anti-HIV)

- lgG antibody to hepatitis A virus (anti-HAV)
- additional laboratory tests including alanine aminotransferase (ALT) or aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), serum albumin, total bilirubin, total globulins, full blood count and prothrombin time
- tests for hepatocellular carcinoma (HCC), including hepatic ultrasound and alphafetoprotein testing.

*Children and young people who are HBsAg positive*

NICE clinical guideline 165 - Recommendation 1.2.6

Arrange the following tests for children and young people who are HBsAg positive:

- HBeAg/anti-HBe status
- HBV DNA level
- anti-HBc lgM
- anti-HCV
- anti-HDV
- anti-HIV
- anti-HAV
- additional laboratory tests, including ALT or AST, GGT, serum albumin, total bilirubin, total globulins, full blood count and prothrombin time

### 4.3.3 Current UK practice

The Guideline Development Group (GDG) for NICE clinical guideline 165 noted that current practice is highly variable in terms of where tests are arranged.

Issues identified include people being referred for specialist assessment without the necessary pre-therapeutic tests leading to a referral back to primary care, or results not properly communicated to the specialist leading to wasted time. The GDG found that while these tests are frequently undertaken at the first visit to the specialist, it may be both more efficient and cost effective if these standard tests were arranged within primary care prior to referral. This consideration informs the recommendation for tests to be arranged in primary care prior to referral to specialist.

## *4.4 Suggested improvement area: Referral to specialist*

### 4.4.1 Summary of suggestions

Stakeholders highlighted the need to ensure that all children, young people and adults who are hepatitis B surface antigen (HBsAg) positive are referred for specialist assessment in secondary care.

Pregnant women with hepatitis B was highlighted as a special group who require careful management to minimise opportunities for transmission between mother to child and for taking appropriate precautions during delivery. It is therefore important that pregnant women are referred to a specialist without delay as early referral of all pregnant women will ensure that appropriate treatment is initiated during pregnancy if necessary.

### 4.4.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 7 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Referral to specialist | **Assessment and referral in primary care**<br>*Adults who are HBsAg positive*<br>NICE CG165 Recommendations 1.2.2 and 1.2.3 (key priority for implementation)<br><br>*Pregnant women who test HBsAg positive at antenatal screening*<br>NICE CG165 Recommendation 1.2.4<br><br>*Children and young people who are HBsAg positive*<br>NICE CG165 Recommendations 1.2.7 and 1.2.8 |

**Assessment and referral in primary care**

*Adults who are HBsAg positive*

NICE clinical guideline 165 - Recommendation 1.2.2

Refer all adults who are HBsAg positive to a hepatologist or to a gastroenterologist or infectious disease specialist with an interest in hepatology.

NICE clinical guideline 165 – Recommendation 1.2.3 (key priority for implementation)

Include the results of the initial tests with the referral (see recommendation 1.2.1).

*Pregnant women who test HBsAg positive at antenatal screening*

NICE clinical guideline 165 - Recommendation 1.2.4

Refer pregnant women who are HBsAg positive to a hepatologist, or to gastroenterologist or infectious disease specialist with an interest in hepatology, for assessment within 6 weeks of receiving the screening test result and to allow treatment in the third trimester (see recommendation 1.5.39[7]).

*Children and young people who are HBsAg positive*

NICE clinical guideline 165 - Recommendation 1.2.7

Refer all children and young people who are HBsAg positive to a paediatric hepatologist or to a gastroenterologist or infectious disease specialist with an interest in hepatology.

NICE clinical guideline 165 - Recommendation 1.2.8

Include the results of the initial tests with the referral (see recommendation 1.2.6).

### 4.4.3 Current UK practice

A retrospective[8] audit examined the proportion of HBsAg positive patients referred to a specialist hepatology clinic in a large London hospital, comparing the source of request between primary care and the in-hospital setting. The authors concluded that referral rates were considerably better for patients tested within a hospital setting while patients tested in primary care were far less likely to reach specialist care (83% of patients in primary care did not reach hepatology clinic compared to 9% of patients in hospital settings did not reach hepatology clinic).

[7] NICE CG165 Recommendation 1.5.39 (Antiviral treatment: Women who are pregnant or breastfeeding) Offer tenofovir disoproxil to women with HBV DNA greater than 107 IU/ml in the third trimester to reduce the risk of transmission of HBV to the baby
8 Smith et al. 2010. Referenced in NICE full clinical guideline 165.

A survey[9] assessing GPs' knowledge of hepatitis B referral protocols (completed by 45 GPs) showed that many GPs did not know when to appropriately refer HBsAg positive patients to specialist care.

In addition, based on their expert knowledge stakeholders highlighted that many pregnant women detected with hepatitis B through antenatal screening are not being seen by appropriate specialist services.

The Guideline Development Group for NICE clinical guideline 165 noted variation in the levels of knowledge about hepatitis B in primary care and concluded that GPs should refer all patients who are HBsAg positive to secondary care.

[9] Taylor et al. (2010). Referenced in NICE full clinical guideline 165

## *4.5 Suggested improvement area: Antiviral treatment*

### 4.5.1 Summary of suggestions

**Treatment sequence**

In line with NICE clinical guideline 165, stakeholders highlighted the importance of appropriate antiviral treatment with the offer of peginterferon alfa-2a as first-line treatment in adults before starting tenofovir or entecavir at the appropriate time (where there is no treatment response or sub-optimal response).

Pharmacological strategies for antiviral treatments for chronic hepatitis B are outlined in NICE clinical guideline 165.

**Antiviral therapy initiated by a specialist in viral hepatitis**

One stakeholder noted that antiviral therapy should be initiated by a specialist in viral hepatitis.

### 4.5.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 8 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Treatment sequence | **Treatment sequence in adults with HBeAg-positive chronic hepatitis B and compensated liver disease**<br>NICE CG165 Recommendations 1.5.16, 1.5.18 and 1.5.19 (key priorities for implementation)<br><br>**Treatment sequence in adults with HBeAg-negative chronic hepatitis B and compensated liver disease**<br>NICE CG165 Recommendations 1.5.23 and 1.5.25 (key priorities for implementation) |
| Antiviral therapy initiated by a specialist in viral hepatitis | NICE CG165 Recommendation 1.5.15 |

NICE clinical guideline 165 - Recommendation 1.5.16 (key priority for implementation)

Offer a 48-week course of peginterferon alfa-2a as first-line treatment in adults with HBeAg-positive chronic hepatitis B and compensated liver disease[10].

NICE clinical guideline 165 - Recommendation 1.5.18 (key priority for implementation)

Offer tenofovir disoproxil as second-line treatment to people who do not undergo HBeAg seroconversion or who relapse (revert to being HBeAg positive following seroconversion) after first-line treatment with peginterferon alfa-2a.

NICE clinical guideline 165 – Recommendation 1.5.19 (key priority for implementation)

Offer entecavir as an alternative second-line treatment to people who cannot tolerate tenofovir disoproxil or if it is contraindicated.

**Treatment sequence in adults with HBeAg-negative chronic hepatitis B and compensated liver disease**

NICE clinical guideline 165 - Recommendation 1.5.23 (key priority for implementation)

Offer a 48-week course of peginterferon alfa-2a as first-line treatment in adults with HBeAg-negative chronic hepatitis B and compensated liver disease[11].

NICE clinical guideline 165 - Recommendation 1.5.25 (key priority for implementation)

Offer entecavir or tenofovir disoproxil as second-line treatment to people with detectable HBV DNA after first-line treatment with peginterferon alfa-2a.

**Antiviral therapy initiated by a specialist in viral hepatitis**

NICE clinical guideline 165 - Recommendation 1.5.15

Antiviral treatment should be initiated only by an appropriately qualified healthcare professional with expertise in the management of viral hepatitis. Continuation of therapy under shared-care arrangements with a GP is appropriate.

[10] Avoid use of peginterferon alfa-2a in pregnancy unless the potential benefit outweighs risk. Women of childbearing potential must use effective contraception throughout therapy.
[11] Avoid use of peginterferon alfa-2a in pregnancy unless the potential benefit outweighs risk. Women of childbearing potential must use effective contraception throughout therapy.

### 4.5.3 Current UK practice

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

The Guideline Development Group was mindful that antiviral treatment recommendations should be considered in conjunction with the recommendations on thresholds for treatment, monitoring and stopping treatment and patient information on the different types of treatment for chronic hepatitis B.

## *4.6 Suggested improvement area: Monitoring in people taking antiviral treatment*

### 4.6.1 Summary of suggestions

In line with NICE clinical guideline 165, stakeholders highlighted the importance of monitoring in people taking antiviral treatment.

A specific quality improvement area was highlighted in respect to improved access to quantitative surface antigen testing. It was suggested that will allow enhanced adherence to NICE guidance and appropriate use and stopping of designated pharmacotherapy.

### 4.6.2 Selected recommendations from development source

Table 9 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 9 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Monitoring in people taking antiviral treatment including access to surface antigen testing to guide treatment strategies | NICE CG165 Recommendations 1.6.9-1.6.18 |

**Children, young people and adults taking peginterferon alfa-2a**

NICE clinical guideline 165 - Recommendation 1.6.9

Review injection technique and adverse effects weekly during the first month of treatment in people taking peginterferon alfa-2a[12].

NICE clinical guideline 165 - Recommendation 1.6.10

Monitor full blood count, liver function (including bilirubin, albumin and ALT), renal function (including urea and electrolyte levels) and thyroid function (and in children, weight and height) before starting peginterferon alfa-2a and 2, 4, 12, 24, 36 and 48 weeks after starting treatment to detect adverse effects[10].

[12] At the time of publication (June 2013), peginterferon alfa-2a and entecavir did not have a UK marketing authorisation for use in children for this indication, and tenofovir disoproxil did not have a UK marketing authorisation for use in children younger than 12 years for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

NICE clinical guideline 165 - Recommendation 1.6.11

Monitor HBV DNA and quantitative HBsAg levels and HBeAg status before starting peginterferon alfa-2a at 12, 24 and 48 weeks after starting treatment to determine treatment response[13].

### Children, young people and adults with compensated liver disease taking entecavir or lamivudine

NICE clinical guideline 165 - Recommendation 1.6.12

Monitor full blood count, liver function (including bilirubin, albumin and ALT) and renal function (including urea and electrolyte levels) in people with compensated liver disease before starting entecavir or lamivudine, 4 weeks after starting treatment and then every 3 months to detect adverse effects[11].

NICE clinical guideline 165 - Recommendation 1.6.13

Monitor HBV DNA and quantitative HBsAg levels and HBeAg status before starting entecavir or lamivudine, 12, 24 and 48 weeks after starting treatment and then every 6 months to determine treatment response and medicines adherence[11].

NICE clinical guideline 165 - Recommendation 1.6.14

Monitor HBV DNA levels every 12 weeks in people with HBeAg-negative disease who have been taking lamivudine for 5 years or longer[11].

### Children, young people and adults with compensated liver disease taking tenofovir disoproxil

NICE clinical guideline 165 - Recommendation 1.6.15

Monitor full blood count, liver function (including bilirubin, albumin and ALT), renal function (including urea and electrolyte levels and urine protein/creatinine ratio), and phosphate levels in people with compensated liver disease before starting tenofovir disoproxil, 4 weeks after starting treatment and then every months to detect adverse effects[11].

[13] At the time of publication (June 2013), peginterferon alfa-2a and entecavir did not have a UK marketing authorisation for use in children for this indication, and tenofovir disoproxil did not have a UK marketing authorisation for use in children younger than 12 years for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

NICE clinical guideline 165 - Recommendation 1.6.16

Monitor HBV DNA and quantitative HBsAg levels and HBeAg status before starting tenofovir disoproxil, 12, 24 and 48 weeks after starting treatment and then every 6 months to determine treatment response and medicines adherence[14].

**Children, young people and adults with decompensated liver disease who are taking entecavir or lamivudine**

NICE clinical guideline 165 - Recommendation 1.6.17

Monitor full blood count, liver function (including bilirubin, albumin and ALT), renal function (including urea and electrolyte levels and urine protein/creatinine ratio), blood clotting, HBV DNA level and HBeAg status in people with decompensated liver disease before starting entecavir or lamivudine and weekly after starting treatment to assess treatment response and adverse effects. When the person is no longer decompensated, follow the recommendations in 'Children, young people and adults with compensated liver disease taking entecavir or lamivudine'.[12]

**Children, young people and adults with decompensated liver disease who are taking tenofovir disoproxil**

NICE clinical guideline 165 - Recommendation 1.6.18

Monitor full blood count, liver function (including bilirubin, albumin and ALT), renal function (including urea and electrolyte levels and urine protein/creatinine ratio) and phosphate, blood clotting, HBV DNA level and HBeAg status in people with decompensated liver disease before starting tenofovir disoproxil and weekly after starting treatment to assess treatment response and adverse effects. When the person is no longer decompensated, follow the recommendations in 'Children, young people and adults with compensated liver disease taking tenofovir disoproxil'[12].

### 4.6.3 Current UK Practice

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

[14] At the time of publication (June 2013), peginterferon alfa-2a and entecavir did not have a UK marketing authorisation for use in children for this indication, and tenofovir disoproxil did not have a UK marketing authorisation for use in children younger than 12 years for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

## *4.7 Suggested improvement area: Monitoring in people who do not meet criteria for antiviral treatment*

### 4.7.1 Summary of suggestions

One stakeholder highlighted the need for regular monitoring for children, young people and adults with chronic hepatitis B who do not meet the criteria for antiviral treatment.

Stakeholders highlighted that the management of chronic hepatitis B is a challenge for both patient and healthcare professional as it is a dynamic disease with patients moving between disease phases without the development of symptoms; therefore close monitoring and supervision are critical.

The Guideline Development Group of NICE clinical guideline 165 noted the need for clinical monitoring due to the often asymptomatic nature of chronic hepatitis B and its disease phases which can require watchful monitoring.

### 4.7.2 Selected recommendations from development source

Table 10 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 10 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Monitoring in people who do not meet criteria for antiviral treatment | NICE CG165 Recommendations 1.6.1-1.6.8 |

**Adults with HBeAg-positive disease in the immune-tolerant and immune clearance phases**

NICE clinical guideline 165 - Recommendation 1.6.1

Monitor ALT levels every 24 weeks in adults with HBeAg-positive disease who are in the immune-tolerant phase (defined by active viral replication and normal ALT levels [less than 30 IU/ml in males and less than 19 IU/ml in females]).

NICE clinical guideline 165 - Recommendation 1.6.2

Monitor ALT every 12 weeks on at least 3 consecutive occasions if there is an increase in ALT levels.

**Adults with inactive chronic hepatitis B (immune-control phase)**

NICE clinical guideline 165 - Recommendation 1.6.3

Monitor ALT and HBV DNA levels every 48 weeks in adults with inactive chronic hepatitis B infection (defined as HBeAg negative on 2 consecutive tests with normal ALT [less than 30 IU/ml in males and less than 19 IU/ml in females] and HBV DNA less than 2000 IU/ml).

Consider monitoring more frequently (for example, every 12–24 weeks) in people with cirrhosis who have undetectable HBV DNA.

**Children and young people**

NICE clinical guideline 165 - Recommendation 1.6.4

Monitor ALT levels every 24 weeks in children and young people with HBeAg positive disease who have normal ALT levels (less than 30 IU/ml for males and less than 19 IU/ml for females) and no evidence of significant fibrosis (METAVIR stage less than F2 or Ishak stage less than 3).

NICE clinical guideline 165 - Recommendation 1.6.5

Review annually children and young people with HBeAg-negative disease who have normal ALT (less than 30 IU/ml for males and less than 19 IU/ml for females), no evidence of significant fibrosis (METAVIR stage less than F2 or Ishak stage less than 3) and HBV DNA less than 2000 IU/ml.

NICE clinical guideline 165 - Recommendation 1.6.6

Review every 12 weeks children and young people with HBeAg-negative disease who have abnormal ALT (greater than or equal to 30 IU/ml for males and greater than or equal to 19 IU/ml for females) and HBV DNA greater than 2000 IU/ml.

**Children, young people and adults with HBeAg or HBsAg seroconversion after antiviral treatment**

NICE clinical guideline 165 - Recommendation 1.6.7

In people with HBeAg seroconversion after antiviral treatment, monitor HBeAg, anti-HBe, HBV DNA level and liver function at 4, 12 and 24 weeks after HBeAg seroconversion and then every 6 months.

NICE clinical guideline 165 - Recommendation 1.6.8

Monitor HBsAg and anti-HBs annually in people with HBsAg seroconversion after antiviral treatment and discharge people who are anti-HBs positive on 2 consecutive tests.

### 4.7.3 Current UK practice

It was noted that after initial assessment the majority of patients are referred back to primary care so further monitoring (liver function, hepatitis B serological markers and hepatocellular carcinoma risk, as appropriate) does not always take place.

## *4.8 Suggested improvement area: Surveillance testing for primary liver cancer*

### 4.8.1 Summary of suggestions

Hepatocellular carcinoma is the most common form of liver cancer and hepatitis B (and C) are a significant contributing cause of this.

Stakeholders highlighted the need for surveillance testing for primary liver cancer in adults with chronic hepatitis B as being essential to ensure early diagnosis and treatment options.

### 4.8.2 Selected recommendations from development source

Table 11 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 11 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Surveillance testing for primary liver cancer | **Surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B**<br><br>NICE CG 165 Recommendation 1.7.1 |

**Surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B**

NICE Clinical Guideline 165 - Recommendation 1.7.1

Perform 6-monthly surveillance for HCC by hepatic ultrasound and alphafetoprotein testing in people with significant fibrosis (METAVIR stage greater than or equal to F2 or Ishak stage greater than or equal to 3) or cirrhosis.

### 4.8.3 Current UK practice

Based on expert knowledge, stakeholders reported variation in UK surveillance practices with the need for improved dedicated surveillance services.

## *4.9 Suggested improvement area: Patient education and personalised care plans for people with chronic hepatitis B*

### 4.9.1 Summary of suggestions

Chronic hepatitis B is a long term condition which requires active monitoring and management and ongoing adherence. The provision of a personalised care plan for each person with chronic hepatitis B or carer was raised as important as this would allow for the patient to have an active role being involved in their self-care and management.

Non-adherence to hepatitis B antiviral treatment was also highlighted as a significant issue requiring improved patient education.

### 4.9.2 Selected recommendations from development source

Table 12 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 12 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Patient education and personalised care plans for people with chronic hepatitis B | **Patient information**<br>NICE CG165 Recommendations 1.1.1 and 1.1.2 |

**Patient information**

NICE clinical guideline 165 - Recommendation 1.1.1

Provide information on the following topics to people with chronic hepatitis B and to family members or carers (if appropriate) before assessment for antiviral treatment:

- the natural history of chronic hepatitis B, including stages of disease and long-term
- prognosis
- lifestyle issues such as alcohol, diet and weight
- family planning
- monitoring

- routes of hepatitis B virus (HBV) transmission
- the benefits of antiviral treatment, including reduced risk of serious liver disease and death and reduced risk of transmission of HBV to others
- treatment options and contraindications based on the patient's circumstances, including peginterferon alfa-2a and nucleoside or nucleotide analogues
- short- and long-term treatment goals
- causes of treatment failure, including non-adherence to prescribed medicines, and options for re-treatment
- risks of treatment, including adverse effects and drug resistance.

NICE clinical guideline 165 - Recommendation 1.1.2

Offer a copy of the personalised care plan to people with chronic hepatitis B and to family members or carers (if appropriate) outlining proposed treatment and long-term management, for example, a copy of the hospital consultation summary.

### 4.9.3 Current UK practice

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

## 4.10 Suggested improvement area: Contact tracing

### 4.10.1 Summary of suggestions

Partner notification and the management of sexual contacts of people with hepatitis B throughout the healthcare system was raised as important as this would lead to earlier detection.

### 4.10.2 Selected recommendations from development source

Table 13 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 13 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Contact tracing | NICE Public Health Guidance 43 Recommendation 8 |

NICE Public Health Guidance 43 - Recommendation 8 (Contact tracing)

**What action should they take?**

- Public Health England centres should:
    - take overall responsibility for tracing the close contacts 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 standards for local surveillance and follow-up of hepatitis B and C are met.

For example, GPs may need to offer close contacts hepatitis B vaccination and refer for treatment.

### 4.10.3 Current UK practice

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience. Stakeholders reported that the partners of people with hepatitis B are often forgotten outside of the setting of genitourinary medicine (GUM) clinics.

## 4.11 Suggested improvement area: Awareness raising, education and training

### 4.11.1 Summary of suggestions

**Training**

A number of stakeholders reported a gap in healthcare professional knowledge and skills in relation to hepatitis B which has proved a barrier to adequate diagnosis and treatment referral.

Increased healthcare professional education and training could improve clinical management and the patient's quality of life. It could also reduce secondary and tertiary care admissions and mortality associated with hepatitis B. In general, it was felt increased education and training would assist in a more robust and co-ordinated strategy against the spread of hepatitis B.

**Awareness raising**

Awareness raising about chronic hepatitis B through education and training was highlighted. It was felt important to include appropriate community groups, for example, BME and LGBT organisations as their role is key. It was suggested that the recognition of community groups needs further support and development.

### 4.11.2 Selected recommendations from development source

Table 14 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full to inform the Committee's discussion.

**Table 14 Specific areas for quality improvement**

| Suggested quality improvement area | Source guidance recommendations |
|---|---|
| Awareness raising, education and training | NICE Public Health Guidance 43:<br>• Recommendation 1 Awareness-raising about hepatitis B and C in the general population<br>• Recommendation 2 Awareness-raising for people at increased risk of hepatitis B or C infection<br>• 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 |

NICE Public Health Guidance 43 –

- Recommendation 1 (Awareness-raising about hepatitis B and C in the general population)
- Recommendation 2 (Awareness-raising for people at increased risk of hepatitis B or C infection)
- 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)

*See appendix 3 for full detail of above recommendations.*

### 4.11.3 Current UK practice

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

## *4.12 Additional areas*

### 4.12.1 Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise however were felt either to be outside the remit of the quality standard referral and the development source (NICE guidance) or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 10 January 2014.

- **Occupational training**

A stakeholder reported a need for occupational training in a number of work settings for people at high risk of hepatitis B infection including carers, prison guards and acupuncturists.

- **Laboratory standards**

A stakeholder reported that laboratory tests used for diagnosis and monitoring of hepatitis B, including HBV DNA should be standardised to ensure comparable results between laboratories and with international standards.

(See recommendation 10 of NICE public health guidance 43 relating to Laboratory services for hepatitis B and C testing).

- **Shared care arrangements**

A stakeholder highlighted that the evolving NHS will require better shared care models in order to cope with capacity issues, where potentially patients can be managed between primary care and the specialist clinic.

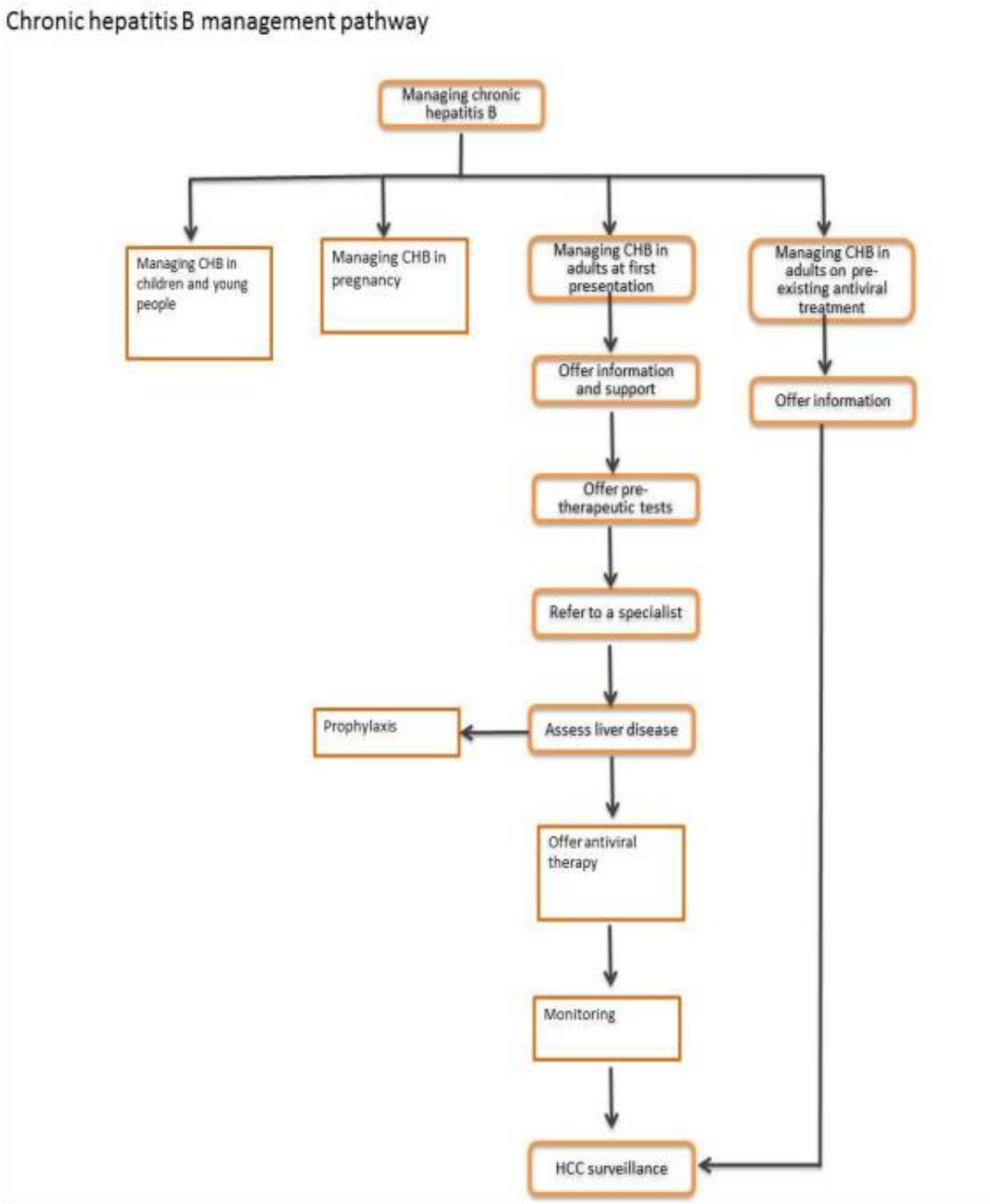
- **Improved hepatitis delta virus antibody (anti-HDV) testing**

One stakeholder suggested that improved HDV testing will allow more appropriate and accurate diagnosis, prognosis and treatment of HBsAg-positive patients as HDV infection can only be acquired through hepatitis B infection.

- **Improved HIV testing**

A number of stakeholders suggested HIV testing at baseline and pre-treatment of all patients with hepatitis B.

## Appendix 1: Chronic hepatitis B pathway (taken from NICE full clinical guideline 165)



## Appendix 2: Key priorities for implementation from NICE clinical guideline 165

Recommendations that are key priorities for implementation in the source guideline and which have been referred to in the main body of this report are highlighted in grey.

### Assessment and referral

Arrange the following tests in primary care for adults who are hepatitis B surface antigen (HBsAg) positive:

- hepatitis B e antigen (HBeAg)/antibody (anti-HBe) status
- HBV DNA level
- IgM antibody to hepatitis B core antigen (anti-HBc lgM)
- hepatitis C virus antibody (anti-HCV)
- hepatitis delta virus antibody (anti-HDV)
- HIV antibody (anti-HIV)
- lgG antibody to hepatitis A virus (anti-HAV)
- additional laboratory tests including alanine aminotransferase (ALT) or aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), serum albumin, total bilirubin, total globulins, full blood count and prothrombin time tests for hepatocellular carcinoma (HCC), including hepatic ultrasound and alphafetoprotein testing.

- Include the results of the initial tests with the referral (see recommendation 1.2.1).

### Treatment sequence in adults with HBeAg-positive chronic hepatitis B and compensated liver disease

- Offer a 48-week course of peginterferon alfa-2a as first-line treatment in adults with HBeAg-positive chronic hepatitis B and compensated liver disease[15]
- Offer tenofovir disoproxil as second-line treatment to people who do not undergo HBeAg seroconversion or who relapse (revert to being HBeAg positive following seroconversion) after first-line treatment with peginterferon alfa-2a.

[15] Avoid use of peginterferon alfa-2a in pregnancy unless the potential benefit outweighs risk. Women of childbearing potential must use effective contraception throughout therapy.

- Offer entecavir as an alternative second-line treatment to people who cannot tolerate tenofovir disoproxil or if it is contraindicated.

### Treatment sequence in adults with HBeAg-negative chronic hepatitis B and compensated liver disease

- Offer a 48-week course of peginterferon alfa-2a as first-line treatment in adults with HBeAg negative chronic hepatitis B and compensated liver disease[15].
- Offer entecavir or tenofovir disoproxil as second-line treatment to people with detectable HBV DNA after first-line treatment with peginterferon alfa-2a.

### Women who are pregnant or breastfeeding

- Offer tenofovir disoproxil to women with HBV DNA greater than $10_7$ IU/ml in the third trimester to reduce the risk of transmission of HBV to the baby[16]

### Prophylactic treatment during immunosuppressive therapy

- In people who are HBsAg positive and have HBV DNA greater than 2000 IU/ml, offer prophylaxis with entecavir or tenofovir disoproxil[17]

- Start prophylaxis before beginning immunosuppressive therapy and continue for a minimum of 6 months after HBeAg seroconversion and HBV DNA is undetectable.

- In people who are HBsAg positive and have HBV DNA less than 2000 IU/ml, offer prophylaxis:
- consider lamivudine[17] if immunosuppressive therapy is expected to last less than 6 months

  - monitor HBV DNA monthly in people treated with lamivudine and change to tenofovir disoproxil if HBV DNA remains detectable after 3 months

- consider entecavir or tenofovir disoproxil[17] if immunosuppressive therapy is expected to last longer than 6 months

- start prophylaxis before beginning immunosuppressive therapy and continue for a minimum of 6 months after stopping immunosuppressive therapy.

[16] At the time of publication (June 2013), tenofovir disoproxil did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

[17] At the time of publication (June 2013), entecavir, lamivudine and tenofovir disoproxil did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

# Appendix 3: Full wording of recommendations from NICE public health guidance 43

## 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 non-governmental organisations.

### What action should they take?

- 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.

### What action should they take?

- 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 Community engagement).
- 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, prisons 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.

### What action should they take?

- 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.

**What action should they take?**

- 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 high-prevalence countries and people who inject or have injected drugs (see Whose health will benefit?).
- 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 Whose health will benefit?).
- 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 Increasing the uptake of HIV testing among men who have sex with men).
- 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 Green book).
- 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 Green book.

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

### Who should take action?

- Prison 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.

### What action should they take?

- Prison and immigration removal centre 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 prison or immigration removal centre 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 in-reach 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.

- Prison and immigration removal centre 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 Green book)
  - 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 community-based 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 recommendation 3).
- Prison 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 prisons 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 medical hold to ensure continuity of care (which might be compromised by transfer between prisons). Planning should involve NHS, prison and immigration removal centre 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.

**What action should they take?**

- 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 peer mentors and health champions from

the drugs service to support this work (for further information see NICE guidance on Community engagement).

- 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 Green book.
  - 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 recommendation 3)
  - 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 Green book).

## 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.

### What action should they take?

- 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 recommendation 3)
- 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.

**What action should they take?**

- Public Health England centres should:
  - take overall responsibility for tracing the close contacts 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 standards for local surveillance and follow-up of hepatitis B and C are met. For example, GPs may need to offer close contacts 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.

**What action should they take?**

- 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 Green book.
- 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.

### What action should they take?

- 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 locally enhanced services 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:
        - are referred to a treatment service
        - attend a treatment service
        - 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 continuity of care 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 recommendation 3).

## Recommendation 11 Laboratory services for hepatitis B and C testing

### Who should take action?

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

### What action should they take?

- 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 national public health legislation
  - 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, prisons)
  - exposure category, if provided
  - the number of people testing positive:
    - for hepatitis B, this should include acute, chronic and past infection

- for hepatitis C, this should include PCR positive/current and PCR negative/resolved.

## Appendix 4: Glossary

**Chronic hepatitis B -** Chronic hepatitis B is defined as persistence of hepatitis B surface antigen (HBsAg) for 6 months or more after acute infection with hepatitis B virus (HBV).

Chronic hepatitis B can be divided into e antigen- (HBeAg) positive or HBeAg-negative disease based on the presence or absence of e antigen. The presence of HBeAg is typically associated with higher rates of viral replication and therefore increased infectivity.

**Decompensated Liver Disease -** Liver disease known as cirrhosis commonly occurs in two stages, compensated and decompensated. In first stage of liver damage, the liver still has the ability to function normally or compensate for the damage. When extensive damage occurs and the liver can no longer function normally, decompensation occurs.

**HBV DNA -** HBV DNA level, or 'viral load', is an indicator of viral replication. Higher HBV DNA levels are usually associated with an increased risk of liver disease and hepatocellular carcinoma. HBV DNA level typically falls in response to effective antiviral treatment.

**Hepatitis B surface antigen (HBsAg) -** Hepatitis B surface antigen (HBsAg) is a viral protein detectable in the blood in acute and chronic hepatitis B infection.

## Appendix 5: Suggestions from stakeholder engagement exercise

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
|---|---|---|---|---|---|
| 001 | Royal College of Paediatrics and Child Health | Ensuring that all infants born to Hep B positive mothers receive appropriate immunisation | Immunisation of infants of women who are Hep B carriers can prevent 90% of vertical transmission of the virus | Currently there are many local processes for vaccination of newborn infants of positive mothers; efficacy and monitoring of these programmes are variable. | Example audit from a London Service: Coverage was initially incomplete and improvement required considerable effort and repeated checks at several levels of the system. The issues encountered will be echoed elsewhere and are inherent in a selective immunisation programme, organised locally. |
| 002 | NHS Sheffield Clinical Commissioning Group | Screening and vaccination of high risk groups | Could NICE be more specific about screening and vaccination of high risk groups particularly Roma Slovak | This population already number 200,000 in the UK and have a positive infection rate of 9.3%<br><br>It is particularly important to consider the issues and implications of high risk groups which are particularly new migrants and individuals born in countries with a high prevalence of Hep B. | A local study shows the positive infection rate as comparable with that of China<br><br>(Should Slovak-Roma patients be screened routinely for hepatitis B in primary care? Report of unexpected high prevalence in a cohort in Sheffield. Gregory, A et al (2013)) attached |
| 003 | NHS Sheffield Clinical Commissioning Group | National vaccination campaign | Is there a need for a national vaccination campaign? | If no - we should be identifying and proactively screening high risk groups far more effectively - and this should be national - not just left to local areas. | These populations are often highly mobile and local initiatives will be limited in their efficacy.<br>  <br>Hep B poster absrtact AG 5.7.13.p |
| 004 | NHS Sheffield Clinical Commissioning Group | Awareness of the changing UK population/ immigration | It is hoped that NICE appreciate the altering nature of UK population/immigration | All NHS professionals would find it most helpful to have some appropriate up to the minute guidance on this including | A local business case for Sheffield is being prepared for submission and approval to Governing Body in December regarding a LES to vaccinate Roma |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| 005 | United Kingdom Clinical Pharmacy Association | Promotion of testing – concerted action to improve testing of those at high risk of infection with a focus also on promotion of treatment and prevention of onward transmission of virus. Testing needs to be made available outside of traditional models and a greater emphasis being placed on testing in walk in centres, prisons, Sexual Health Clinics etc. | If a reinvigoration of the need of testing for Hepatitis B is not done then the numbers infected and the burden of Hepatitis B will increase. Thus leading to further economic and healthcare risks due to undiagnosed populations, heath care costs and evolving therapeutic options .The disease is significantly more prevalent in 'vulnerable' population's e.g. ethnic minorities, migrants, prisoners and IVDUs who do not interface well with traditional primary/secondary models of care. Screening can lead to decreased disease transmission and allows for prevention measures to be targeted more effectively. | The HPA outlines that predominant morbidity and mortality associated with hepatitis B is due to the long term consequences of chronic infection. Many people with chronic infection are asymptomatic and unaware of their infection and consequently will remain undiagnosed until they present with overt disease, unless they are tested.<br><br>e.g.Hepatocellular Carcinoma is on the increase in the UK and currently there are about 4,200 primary liver cancers diagnosed in the UK every year.Viral infection, either hepatitis B or C, carries a high risk, with either infection having approximately a 3-5% per year risk of HCC development. In some studies the risk is even higher, up to 12% per year in HBV infected patients.<br><br>Importantly there is strong support at a local and regional level to promote community pharmacist dried blood spot testing for Hepatitis B and C. Pilot programmes should be extended and supported at a national level with a primary focus on areas where prevalence is deemed high. Pharmacists both in primary and secondary care are becoming | NICE Guidance – Hepatitis B and C : Ways to promote and offer testing to people at increased risk of infection<br><br>Reducing Health Inequalities in London by addressing Hepatitis C – 2013 Hepatitis C Trust<br><br>Health Protection Agency – Hepatitis B in London Review 2011 Cancer Research UK www.cancerresearchuk.org<br>UK Guidelines for the management of suspected hepatocellular carcinoma (HCC) in adults; Ryder, S, 2011 On behalf of the HCC management in the UK (HUG) |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | | increasingly involved in the treatment of viral hepatitis and could play a vital role in providing diagnostics. | |
| 006 | United Kingdom Clinical Pharmacy Association | Practitioner Competence – Encourage training in the field of Hepatitis. There is a lack of knowledge around Hepatitis B amongst healthcare practitioners and this has proved a barrier to adequate screening, diagnosis and treatment referral. | Increased training amongst all Healthcare practitioners will assist in reducing morbidity and mortality associated with hepatitis B through early detection and diagnosis. This will therefore improve clinical management and quality of life for people diagnosed with the virus and reduces the number of people admitted to secondary and tertiary care with hepatitis B related morbidity.<br>Increasing overall competence in the field of Hepatitis B would also assist in a more robust and co-ordinated strategy against the spread of Hepatitis B. | Lack of practitioner competence in the area of Hepatitis B could potentially lead to missed diagnosis and referrals. Thereby leading to an increased number of individuals developing chronic liver disease and presenting to secondary care with advanced disease.<br><br>A recent bill presented to parliament from the Hepatitis C Trust outlines that low awareness of hepatitis amongst GPs has traditionally been the greatest barrier to diagnosis and treatment. Under the new arrangements, GPs will be responsible for commissioning services for hepatitis patients. This is very concerning in a disease area where GP awareness is so low. | Reducing Health Inequalities in London by addressing Hepatitis C – 2013 Hepatitis C Trust<br><br>NICE Guidance 43; Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection<br><br>Health and Social care Bill (HS72)via www.parliament .co.uk Memorandum submitted by The Hepatitis C Trust |
| 007 | United Kingdom Clinical Pharmacy Association | Patient Education –ensure comprehensive patient education including family planning, routes of transmission, adverse effects, long terms prognosis, importance of adherence and goals of treatment. | Non adherence in Hepatitis B has not been extensively studied however it has been estimated that approx. 40% of patients on antivirals are non-adherent.<br>Hepatitis B is a major global health problem and the drugs used ultimately improve survival, but patients require potentially life long therapy in order to derive continued clinical benefit. | Education on a condition necessitating treatment and the treatment itself is the biggest predictor of adherence.<br><br>Non adherence to antiviral agents can exacerbate pre existing liver disease increasing the risk of cirrhosis and HCC. There is also the risk the patient will develop drug resistant strains therefore limiting | NICE Clinical Guidance 76 –Medicines Adherence<br><br>World J Hepatol. 2012 February 27; 4(2): 43–49. Lessaa, Giang-Evaluation of adherence to oral antiviral hepatitis B treatment using structured questionnaires. |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | Unlike other chronic conditions the rapid viral replication potential and mutations rates of Hepatitis B require high levels of adherence to achieve and maintain virological suppression hence why sub optimal adherence is classed as <100%. | therapeutic option and thus posing a public health risk due to the likelihood of transmitting drug resistant strains. | |
| 008 | United Kingdom Clinical Pharmacy Association | Pregnant Women and post natal vaccination-All pregnant women should undertake a Hepatitis B viral screen and if found to be HBsAg +ve then should be appropriately refereed to a Hepatologist or specialist practitioner. All babies born to mothers with Hepatitis B should be vaccinated | It is widely recognised that treating pregnant women who are found to be HBsAg+ve decreases the risk of transmission to their child. It is essential that pregnant mothers are informed about their treatment options. Post natal care should involve the vaccination of the new-born against Hepatitis B.<br><br>A complete course of vaccinations is essential and is required for full protection. The DoH recommends the baby is vaccinated at birth and 1,2 and 12 months following birth. In addition, if the mother is HBeAg positive, the baby will also require immunoglobulin (HBIG).<br><br>It is important to note that even the full course of vaccinations may not stop infections in all cases. Hence the need for consistent follow up with the primary or secondary care setting. | A new-born not vaccinated at the time of the birth has a 90% chance of becoming a carrier thus leading to a greater likelihood of developing advanced liver disease if virus is not detected early. This poses an economic burden and a public health risk due to lack of awareness of infection. | Hepatitis B antenatal screening and newborn immunisation programme Best practice guidance –Department of Health 2011<br><br>NICE-PH21 Reducing differences in the uptake of immunisations |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| 009 | United Kingdom Clinical Pharmacy Association | Surveillance Testing for Hepatocellular Carcinoma in adults with chronic Hepatitis B is essential to ensure early diagnosis and treatment of this cancer. | In the UK, almost 4000 new cases of liver cancer are diagnosed each year. Hepatocellular Carcinoma is on the increase in the UK and currently there are about 4,200 primary liver cancers diagnosed in the UK every year. Almost 9 out of 10 cases are diagnosed in people over the age of 55 years. Viral infection, either hepatitis B or C, carries a high risk, with either infection having approximately a 3-5% per year risk of HCC development. In some studies the risk is even higher, up to 12% per year in HBV infected patients. | Increased screening and surveillance is essential for early detection and treatment of HCC.<br><br>HCC remains one of the commonest malignant diseases in the world but it has not previously been a leading cause of death in the Western world. There is now conclusive evidence from the USA and a strong suggestion from the UK that HCC is becoming a more common cancer, primarily due to the Hepatitis C epidemic which again could be extrapolated to include Hepatitis B. | www.macmillan.org.uk<br><br>UK Guidelines for the management of suspected hepatocellular carcinoma (HCC) in adults; Ryder, S, 2011 On behalf of the HCC management in the UK (HUG) |
| 010 | British Association for Sexual Health and HIV | HIV testing at baseline and pre-treatment of ALL patients with hepatitis B | If the HIV status is unknown, sub-standard HIV-active therapy may be given leading to drug-resistant HIV | It seems that many hepatology services are not routinely offering an HIV test | http://www.easl.eu/assets/application/files/b73c0da3c52fa1d_file.pdf |
| 011 | British Association for Sexual Health and HIV | All Men who have sex with men (MSM) in all settings should be tested for Hepatitis B infection | This part of the population is at high risk of hepatitis B and yet most MSM are screened for hepatitis B in GUM clinics only | This would lead to an earlier recognition of infection (leading to treatment) or non-immunity (leading to vaccination) | http://www.bashh.org/documents/1927.pdf |
| 012 | British Association for Sexual Health and HIV | Partner notification and management of sexual contacts of people with hepatitis B throughout the healthcare system | The partners, who are at high risk of infection, are often forgotten outside of the setting of GUM clinics | This would lead to an earlier recognition of infection (leading to treatment) or non-immunity (leading to vaccination) | http://www.bashh.org/documents/1927.pdf |
| 013 | British Association for Sexual Health and HIV | Universal vaccination against hepatitis B | This has been a WHO recommendation for about a decade. | This is the only way through which hepatitis B will be eradicated | http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5236a5.htm |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| 014 | British Association for Sexual Health and HIV | Vaccination of all higher risk patients especially MSM. All MSM in all settings should receive hepatitis vaccination | The vaccine is highly effective and if universal vaccination is not instituted, then high risk patients, especially MSM, must be vaccinated instead. | Vaccination is highly effective at preventing HBV | http://www.bashh.org/documents/1927.pdf |
| 015 | The Hepatitis B Positive Trust | DIAGNOSTICS for 12 MILLION at risk<br>Click below for a Quality Communication to gain 50% HBV UK diagnosis levels<br><br>http://www.youtube.com/watch?v=k_GRwozWvIY<br><br>Using Tried Trusted Messages, Prevalencing Tools, Patient Lexicon and Education. Once audited a target of 50% diagnosis in endemic regions and practices is a must. | Our hepatitis b infections have tripled to over 500,000<br><br>Almost none of these people have any idea of hbv, its risks, (96%) especially the ones they have run or access to testing or care. see We are still being destroyed by the notion our prevalence is Scandinavian by our JCVI and other outdated HPA etc orgs.<br><br>1 in 6 children on Earth catch HBV mainly during susceptible childhood see and no nhs employee knows<br><br>The reason why 80% of our 1 million viral hepatitis sufferers are undiagnosed is poor facts about healthcare and social HBV/HCV<br><br>As with the equally dangerous smoking carcinogen viral hepatitis is only fatally dangerous to the long term undiagnosed. We need to try to diagnose 400,000 patients fast. Using Proven Tools.<br><br>With Quality Indicators Adjusted to | Quite Simply undiagnosed patients die and get liver disease far far more often. We are the most unaware and undiagnosed nation for viral hepatitis on Earth.<br><br>Our safety testing for hbv risk has been so poor we do not even realise our hbv population has tripled to plus 500,000 and our inner cities and their schools are going endemic fast. This trend is unstoppable. With up to 25,000 new hep b/c infections due in from Bulgaria/Rumania to add to our expected 35,000 from elsewhere over the next 3 years, can we please use diagnostic care at our borders, better 20 years late than never?<br><br>http://www.youtube.com/watch?v=mJgDwSmkMGk&list=UUJuwQZEitfUQsioHuKTsxgQ&index=1<br><br>The absolute key paradigm globally since 1993 is diagnosing those who have had or are carrying hepatitis virally, not any nedications, IS THE CURE. The UK has simply never tried this approach. Without it deaths and morbidity rockets in the way we | Going Endemic UK HBV Prevalence https://app.box.com/files/0/f/0/1/f_9074833361 This document records our 500,000 plus infections and charts their unmet needs and commonly overlooked major infection routes. It highlights where and when areas and which cities and nationalities are going or will go endemic for hbv in the foreseeable future.<br><br>The doc below is good but only counts the 3 million from endemic areas in London |

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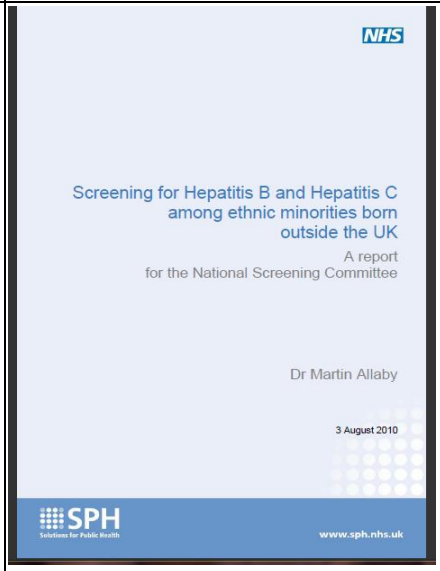
| | | | each Practice Prevalence | are witnessing without counting see p 91 -98 . Diagnosed patients do not need anything from us but simple wisdom 80% of the time. High diagnosis levels have visibly lowered death rates in all our developed nation partners. Only allowing the 10 million endemic community survivors access to testing will reveal the scale of child, social and work infections. |  |
| 016 | The Hepatitis B Positive Trust | UNIVERSAL VACCINATION<br><br>for 12 million high risk migrants, children & staff | The last 4 years of testing in our Hospital wards has revealed 1 in 140 children therein are already incurably HBV infected and 1 in 61 adults are positive also.<br><br>If we adjust the adult figure by half we have the actual UK Prevalence (from 1.6% to 0.8%)<br>So seeing hospitalisation has a 50% inflation a 0.35% infected rate or 60,000 undiagnosed infectious children is probable from the records of the last 4 years of HPA testing. In the UK these children will be almost solely in endemic areas. See Going | Of over 4 million at risk endemic community children in our country we have protected just 2%.<br>These children are as or up to 5 times as likely to acquire chronic hbv as say a illegal injector. See P69<br><br>This tidal wave of infections has been happening to our children for at least a decade, as proved by the Liverpool School of Tropical Medicine these infections are happening in the UK with a range of up to 10 % of migrant children catching hbv by 5.<br>http://adc.bmj.com/content/86/1/67.3.full | UK horizontal child infections among endemic populations, we have over 100 endemic populations now. Here is a report from somali's.<br>http://adc.bmj.com/content/86/1/67.3.full<br><br>Facts about our 14,000 UK child transmissions 1993 2013 And this video explains how the major risk and up to 30% of infections for hbv is unvaccinated childhood<br>http://www.youtube.com/watch?v=bmMmmbTvO5Y<br><br>Vaccination Committee utterly deluded |

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| | | | Endemic Appendix P68<br><br>Which indicates possibly 1 in 30 to 50 may be catching HBV in many classrooms in the UK<br><br>Up to 30% of infections are horizontal during susceptible childhood - 10 to 20,000 of our total 100,000 child infections are happening here. http://www.youtube.com/watch?v=WNtw4oGQ6e4&list=UUJuwQZEitfUQsioHuKTsxgQ&index=1 | With all developed nations eradicating hbv in their schools by now through universal vaccination and not allowing children to attend without proof of hbv immunity.<br><br>Here we have witnessed a generation sacrificed to daily hbv risk and therefore a tragic number of our children are now incurably infected. The vast bulk migrant children who had a right to basic healthcare and protection advised by WHO.<br>A Quality Indicator aiming Practices at vaccinating the 12 million at risk is needed.<br><br>With millions of travellers to endemic areas forgetting their vaccinations annually we record large numbers of travel infections. see<br>see you tube 10 mins 40sec Palin encouraging infection via healthcare he goes on to a razor shave | by Scandinavia and blissfully imagining 90% of infections are happening elsewhere without any proof whatsoever...<br><br>http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2812%2960347-X/fulltext |
| 017 | The Hepatitis B Positive Trust | PATIENT/PUBLIC/<br>DR EDUCATION & CARE | Nationally we are unaware of the RISK of blood and gateway wounds and of healthcare and close relatives for HBV transmission.<br><br>1 in 4 humans has caught hbv from blood and no one in the UK knows<br><br>QALY - HBV diagnosis is one of the most devastating possible, we have | Most patients and clinicians do not understand the risks for hbv infection and this leads to hundreds of infected callers each year.<br><br>Most patients are reduced to unnecessary clinical depression by poor information from most UK NHS sources. QALY is usually destroyed by diagnosis with NHS choices | |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | had suicides and suicidal and depressed callers as a general rule, before we teach them Hep B Positive.<br><br>Nationally we are unaware that more people are dying from hbv than ww2. Nationally we are unaware that in half the world more than half the people catch hbv.<br><br>Decent Patient Information is needed with every diagnosis, most patient currently have very poor ideas of what they have, how they got it, what it means. 72% of callers did not understand what can kill them or what can infect.<br><br>DESTROYING FALSEHOODS CREATING ATTITUDES<br>See pages 1 to 20<br>https://app.box.com/files/0/f/0/1/f_11047092171<br><br>REWRITE ALL NHS INFO<br>minus biases<br><br>GP's currently get 1 in 4 hepatitis questions wrong<br><br>After meeting 450,000 endemic community Londoners on the Tube we noted 96% had no idea they were | information<br><br>We note vast improvements in patients lives when they study HEP B POSITIVE, https://docs.google.com/document/d/1kdkI1S2xs3nsC5jgQxoqh7jSjglM9VN7dAH7w1sPzh4/edit<br><br>which combines<br>our forum 400,000 viewers<br>our patient education see<br>one hour of helpline support/audited education<br>a patient buddy, especially mums<br>our websites and groups<br><br>We provide in depth accelerated learning that avoids depression, childlessness, lovelessness, onward infections, liver disease and death. We educate how easy to manage hbv is and why most patients should expect to live longer healthier lives post diagnosis. (2600 so far see see) We note that nearly all NHS hbv public and patient information is filled with flaws and awful assumptions and half facts. Most reading it feel deep depression at it is seen as a badge of being gay, addicted or unhygienic. They are then erroneously informed they have a sex disease 100 times more infectious than HIV in many bodily fluids. see | |

| ID | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| | | | a 1 in 50 plus risk the mosr common comments were What is that?<br>I have/know someone with it<br><br>http://www.youtube.com/watch?v=7AITXWg7ew&list=UUJuwQZEitfUQsioHuKTsxgQ | The need for GP education is paramount see P85 | |
| 018 | The Hepatitis B Positive Trust | A GP PATHWAY CREATION<br><br>that is aware of patients needs with<br><br>Diagnostic Posters<br>Patient Literature<br>Results Factsheets<br>Maternity Packs<br>Vaccination Tools<br>Patient Support | Current Unmet Needs<br>QUALITY INDICATORS for uptake and use<br><br>GP's usually provide the same emotionally destroying info as other NHS agencies, patients are even assumed to be sex or drug abusing. see<br><br>GP's often misinterpret results diagnosing hbv in the uninfected<br><br>GP's are constantly leaving large numbers at high risk, this practice over decades has made them poor at learning hepatitis information, they actively resist information that means they should vaccinate or test people.<br><br>GP's are best placed to do both<br><br>GP's are the most likely threat of death to the undiagnosed, fully 70% of A n E hbv cases admitted were as the result of long term prescriptions. | The Diagnostic Maps in Surgery backed up with the GP questions "Have you safety checked your hepatitis risk?" "Do you have a memory of jaundice?" "Do you have a history of liver illness in the greater family?" see<br><br>https://app.box.com/files/0/f/0/1/f_11769019883<br><br>Are simple, non stigmatic, reach 80% of those at risk, and stress the need to avoid missing your check and dying of an easily prevented illness.<br><br>The Occupational posters heads up hbv is a hero's bug several million workers and sports people need to avoid<br><br>See https://app.box.com/files/0/f/0/1/f_11769026349<br><br>The Vac card allows partners and | |

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| | | | Binge medicating has been repeatedly noted to have pushed patients into liver failure even death. We had 3 in AnE over xmas 2011 alone | children<br><br>The Hygiene card prevents transmission<br><br>The Counselling card prevents depression<br><br>The Results and Charts prevent confusion<br>The Avoid card prevents many deaths<br><br>The Anti Viral Card creates adherance<br><br>The Patient Downloads create wisdom | |
| 019 | The Hepatitis B Positive Trust | OCCUPATIONAL/ SOCIAL RISK & PREMIERSHIP BLOOD HYGIENE<br><br>WHO proven tools and policies | http://www.youtube.com/watch?v=2-neAOHG3QU&list=UUJuwQZEitfUQsioHuKTsxgQ<br>Occupational Risks are run by 2 million workers we have overseen 200,000 vaccinations that are still desperately needed<br><br>During 2010 – 2013 we have overseen some 24 industries that need hbv vaccinations, some 200,000 plus vaccinations in all.<br>We estimate some 2 million workers with blood are poorly advised and vaccinated including school first aiders and st john. | In the US it is understood that a nurse dies every day from HBV. In the UK we have not understood a worker with blood dies daily and 2 million are at growing risk.<br><br>For example one industry (travel) see page 3, the hbv helpline traveller callers 2013 https://app.box.com/files/0/f/0/1/f_9722609097<br><br>see further http://www.hepb.org.uk/information/resources/hbv_vaccination_packs_for_industries | I attach an audit of 1100 HBV helpline Callers 2011 -2013 https://app.box.com/files/0/f/0/1/f_11047092171<br><br>Pages detail over 100 companies trying to get vaccinations, usually after decades of work force risk. |

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| | | | We find far more infections reported from the above than say sex or drugs.We have noted locally 4 emergency staff contract cancer from hbv.<br><br>We need to teach our children that they are 30 times more likely to get a blood virus from forgetting their plasters and blood hygiene than say sex, many schools have no idea of the risk or why millionaire footballers and boxers NEVER play with a bleed | We get calls from people at high risk but denied vaccination every week, vast numbers of cleaners, carers, security, beauty, boxing, rugby, sanitation, nhs patients, morticians, fosters, diabetics, policemen, prison guards, piercers, acupuncturists are all unaware of the risks.<br><br>We get large (hundreds) numbers of calls from workers infected or at risk in these roles<br><br>Nationally we have almost zero hygiene for blood in schools or numerous contact venues. Spray plaster is urgently required at every event school break and class room. 3 pricks from a hbv compass or milk tooth, 3 rounds with a hbv boxing glove or sometimes just a day unplastered and your child will have it. Many schools have reported outbreaks | Premiership Blood Hygiene still needs to taught at school http://www.youtube.com/watch?v=3QU3jzsy1yA&feature=youtu.be |
| 020 | Roche Products Limited | Increased routine GP based Hepatitis B testing in areas of high risk populations | In order to aid the identification and treatment of HBV to prevent vertical transmission of HBV in high risk populations and limit the spread of HBV within family units through lifestyle or horizontal transmission where vaccination could be used to protect at risk groups.<br>1 person in 350 is thought to have chronic hepatitis B (CHB) in the UK | Hepatitis care in the UK is predominantly seen as being HCV focused, while a lack of a PHE report into HBV highlights the lack of focus on HBV despite its significant impact on NHS services. As such routine testing for HBV surface antigen positive status is not prioritised within diminishing CCG resources.<br>Identifying and treating those who are | Please find the supporting information in the links below:<br>http://www.who.int/mediacentre/factsheets/fs204/en/<br>http://www.patient.co.uk/doctor/hepatitis-b |

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| | | | Although HBV is uncommon in England, it is much more common in other parts of the world. Migrant workers coming into the UK from across the world where HBV is a more common cause of hepatitis have an increased risk of HBV infection, and therefore to others. Increased routine testing in these higher risk populations will help identify and manage a preventable yet difficult to cure disease. | HBV surface antigen positive, whilst also identifying those who are in immediate contact for prophylaxis via vaccination, would address the avoidable transmission of what is a preventable but difficult to cure disease, and therefore also avoid the increased burden on specialist clinics in the NHS in managing this chronic condition. | |
| 021 | Roche Products Limited | Improved and increased access to quantitative surface antigen testing | NICE clinical guideline 165 on Hepatitis B recommends a 48-week course of peginterferon alfa-2a as first-line treatment in adults with HbeAg-positive or HbeAg-negative with compensated disease. NICE guidelines also recommend stopping peginterferon treatment at week 24 if HBV DNA levels have decreased by < 2log10 IU/ml and/or if hepatitis B surface antigen (HbsAg) is > 20,000 IU/ml (HbeAg-positive) or if HbsAg has not decreased (HbeAg-negative) Improved access to quantitative surface antigen testing will allow enhanced adherence to NICE guidance and appropriate use and stopping of designated pharmacotherapy | Stopping rules require physicians to monitor the treatment response for patients treated with peginterferon alfa-2a for hepatitis B and appropriately stop treatment where necessary if they believe patients would not benefit from a full 48-week treatment course. It also allows for individualised therapy for patients commenced on hepatitis B treatment with peginterferon alfa-2a. | Please find the studies below which supports the monitoring of HbsAg loss or decline in HbeAg-positive or HbeAg-negative patients:<br>- Piratvisuth et al. Hepatol Int 2013; 7: 429–436<br>- Rijckborst et al. Hepatology 2010; 52:454-461<br>- Marcellin et al. Hepatol Int 2013; 7:88–97<br>- Sonneveld et al. Hepatology 2013; epub |
| 022 | Roche Products Limited | Improved Hepatitis delta (HDV) testing | HDV infection can only be acquired through HBV infection, and has been shown to be associated with the most severe forms of acute and chronic | Chronic HBV carriers are at risk of HDV infection. HDV infection of chronically infected HBV-carriers may lead to fulminant acute hepatitis or | Please refer to the following: http://www.who.int/csr/disease/hepatitis/whocdscsrncs20011/en/index1.html http://79.170.44.126/britishlivertrust.org |

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| | | | hepatitis in many HBsAg-positive patients<br>Improved HDV testing will allow more appropriate and accurate diagnosis, prognosis and treatment of HBsAg-positive patients | severe chronic active hepatitis, often progressing to cirrhosis. Chronic hepatitis D may also lead to the development of hepatocellular carcinoma, therefore reducing the burden on liver transplant resources<br>Improved HDV testing will allow more appropriate and accurate diagnosis, prognosis and treatment of HBsAg-positive patients | .uk/wp-content/uploads/2012/12/Hepatitis-D-and-E-low-res1.pdf |
| 023 | Welsh Association Gastroenterology and Endoscopy (WAGE) and Wales Viral Hepatitis Treatment/Management Group | Pregnancy and Hepatitis B<br><br>1) Serology and Viral load testing of mother<br>2) Offering of antiviral therapy to pregnant women as appropriate (>10 to the 7 iu/ml)<br>3) Administration of immunoglobulin and vaccination as appropriate | Assessment of the mother before the third trimester of pregnancy and appropriate treatment can reduce the risk of vertical transmission to the neonate | There is some variability in referral of mothers found at antenatal screening to be Hepatitis B positive | *No additional information provided by stakeholder.* |
| 024 | Welsh Association Gastroenterology and Endoscopy (WAGE) and Wales Viral Hepatitis Treatment/Management Group | Follow up testing of babies born from mothers with hepatitis B | Potential to miss babies infected with hepatitis B and therefore future problems which could be avoided | Improve the equality of services around the country | *No additional information provided by stakeholder.* |
| 025 | Welsh Association Gastroenterology and Endoscopy | Surveillance for primary liver cancer | Identification of early lesions will allow many more treatment options including the possibility of cure | Variable surveillance practices around the country even within different hospitals of the same trust board. Improved dedicated | Data from Japan on reduction in late presentation HCC with dedicated robust surveillance practices |

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| | (WAGE) and Wales Viral Hepatitis Treatment/Management Group | | | surveillance services with quality assurance and auditable measures in this aspect of liver care will also improve the service for other aspects | |
| 026 | Welsh Association Gastroenterology and Endoscopy (WAGE) and Wales Viral Hepatitis Treatment/Management Group | Vaccination of all close contacts of subject with Hepatitis B, ideally universal vaccination as per WHO | Reduces transmission of hepatitis B and in long term reduces risk of chronic liver disease/cirrhosis and primary liver cancer | Reduces infection transmission and therefore future cost effective in regards to demand for complex liver services | Korean and Chinese data on reduction in liver disease from Hepatitis B |
| 027 | Royal College of Pathologists | Tests used for diagnosis and monitoring of hepatitis B, including HBV DNA, should conform to agreed standards of sensitivity and for HBV DNA should be expressed in international units | Tests vary in sensitivity levels and in quality parameters. Where in house tests are used validation and verification data may not always be comparable and so tests may not all be of equivalent quality | Testing should be standardised so that patients and individuals such as HBV-infected health care workers have results comparable from laboratory to laboratory and comparable with international standards. Results of HBsAg should be of similar sensitivity so as to reduce the possibility of false negative results, and appropriate confirmation is needed to ensure true serology results especially in low prevalence populations. | Heermann KH, Gerlich WH, Chudy M, Schaefer S, Thomssen R. Quantitative detection of hepatitis B virus DNA in two international reference plasma preparations. Eurohep Pathobiology Group. J Clin Microbiol. 1999;37:68-73.<br><br>http://www.hpa.org.uk/ProductsServices/MicrobiologyPathology/UKStandardsForMicrobiologyInvestigations/TermsOfUseForSMIs/AccessToUKSMIs/SMIVirology/smiV04HepatitisBdiagnosticserology/ |
| 028 | Royal College of Pathologists | Quality standards should be developed and standardised for diagnostic tests that are not based on analysis of recommended quantities of serum or plasma and which may be | Specimens such as dried blood spots are to be encouraged for hard to reach/hard to bleed groups and for children but have tended to be developed independently and may vary in sensitivity and specificity | National standards will ensure quality testing from non-standard specimens and clear guidance on when specimens are not acceptable, guidance on appropriate paper to use etc. Private providers as well as NHS providers offer these services, and a | *No additional information provided by stakeholder.* |

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| | | difficult to accurately quantitate i.e. elution from dried blood spot, oral fluid | | clear set of guidelines will ensure comparable performance across laboratory sectors. | |
| 029 | Gilead Sciences Ltd | This quality standard will cover hepatitis B testing, diagnosis and management of chronic hepatitis B in children, young people and adults, including immunisation against hepatitis B. | Targeted screening or case finding of risk groups for viral hepatitis B in order to facilitate early diagnosis can reduce serious health risk associated with chronic HBV such as cirrhosis, liver failure and liver cancer | •Undiagnosed chronic hepatitis B is highly prevalent in risk groups like British-Chinese and South East Asians<br>•The frequency of HBV vaccination is low these groups in this high-risk group.<br>Interventions are required to increase hepatitis B and C testing among migrant populations. | Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection<br><br>http://publications.nice.org.uk/hepatitis-b-and-c-ways-to-promote-and-offer-testing-to-people-at-increased-risk-of-infection-ph43/considerations |
| 030 | British HIV Association (BHIVA) | Hepatitis B vaccination – who offers them and in HIV setting | | | British HIV Association (BHIVA) Guidelines for the management of hepatitis viruses in adults infected with HIV 2013, HIV Medicine (2013), 14 (Suppl. 4), 1–71.<br><br>British Association for Sexual Health and HIV, Guidance on reporting cases of hepatitis in GU medicine clinics, http://www.bashh.org/BASHH/Guidelines/Guidelines/BASHH/Guidelines/Guidelines.aspx?hkey=072c83ed-0e9b-44b2-a989-7c84e4fbd9de |
| 031 | British HIV Association (BHIVA) | HIV testing in people with HBV and HCV | | | *No additional information provided by stakeholder.* |
| 032 | The Hepatitis B Positive Trust | Would you like to express an interest in endorsing this quality standard? XXX No, excluded as they are from any input at Committee level patients fear the 32 will again create something as awful as the last 20 years for patients. How can you leave 3600 patient voices, the only deep audit of hbv in the UK unseated yet again. I can almost guarantee the committee will | | | |

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| | | Completely underestimate infections we still have NHS choices with 180,000 not 511,000<br>Completely miss the main transmission routes eg for every maternal infection we avoid we allow 1.5 horizontal ones,<br>Completely misunderstand the patient experience, 81% of patients suffer a serious mental social problem and are perfectly healthy<br>Completely overlook 197 nations cost effectively benefiting from a simple smallpox eradication strategy<br>Focus hugely on medications 80% of patients do not need and only 2.5% currently access<br><br>It particularly depends if the standard urgently ensures a universal protecting of our children and a first effort at diagnosing the "innocent" 400,000 HBV patients in the UK and includes a new factual not "borrowed lexicon" and our patient clinician education to rapidly minimise the tidal wave of patient depressions, lost careers, lost families and suicides from poor information.<br><br>As is, our viral hepatitis standards are simply and measurably the world's worst and many decades of preventable booming infection and death is their fruit.<br>We are 20 times more likely to catch HBV and 3 times more likely to die of it in the UK than say France or the US, this is our standard.<br><br>Having produced prevalence and policy research documents. Having produced Care Guideline Documents, GP and Patient Tool Kits, may we state that this form is not designed to gain the full set of lessons that patients demonstrate. Has everyone read "Going Endemic" on the QSAC committee? Or studied the GP Tools 300 Practices find greatly improve diagnostics and care? Or read "Confessions of a Helpline" to understand patients experiences? | | | |
| 033 | Royal College of Physicians | The RCP has received the following feedback from our experts in genitourinary medicine. They feel that the following are important areas for quality improvement :<br>HIV testing at baseline and pre-treatment of all patients with hepatitis B<br>All Men who have sex with men (MSM) in all settings should be tested for Hepatitis B infection<br>Partner notification and management of sexual contacts of people with hepatitis B throughout the healthcare system<br>Universal vaccination against hepatitis B, but if not:<br>Vaccination of all higher risk patients especially MSM. All MSM in all settings should receive hepatitis vaccination | | | |
| 034 | Royal College of Nursing | This is to inform you that there are no comments to submit on behalf of the Royal College of Nursing to inform on the Hepatitis B quality standards topic engagement at this present time | | | |
| 035 | SCM1 | Early detection of Hepatitis B | Evidence that early detection of hepatitis B with prompt treatment means better outcomes with reduced incidence advanced liver disease and | Leads to achievement of improved patient outcomes and early treatment is health economically advantageous. | 'A Time to Act' British association for gastroenterologists www.bsg.org |

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| | | | risk of hepatocellular carcinoma. One way of doing this would be offering testing on new to GP new registrants | | (National Liver Plan) |
| 036 | SCM1 | Case finding exercise | As we do have evidence that early detection is advantageous, a case finding exercise in primary care should also be considered due to potential volumes of patients who are hepatitis B positive | If patients have not been offered screening on registration, they are at greater risk of developing liver disease so should be identified as early as possible | National Liver Plan and also 'European Orientation towards the better management of Hepatitis B in Europe (www.ilcuk.org.uk) |
| 037 | SCM 1 | A more robust pathway for test results/ information for pregnant women with hepatitis B | As care of antenatal patients is not always in one place (but across community and hospitals) so test results/information is also, a more robust pathway for pregnant women with hepatitis B and their babies must be developed | In order to effectively use prophylaxis to prevent onward transmission, along with the effective use of appropriate vaccination regimes | UK National Screening Committee – IDPS Programme Standards<br>Midwives Report<br>www. rcm.org.uk<br>Antenatal provision in GP notebook<br>www.gpnotebook |
| 038 | SCM2 | Testing of high risk groups | Patients from the high risk groups should be tested for Chronic Hepatitis B NICE guideline hepatitis B and C | Currently these patients are not routinely identified and tested in primary care. | NICE public health guidance 43 hepatitis B and C –ways to promote testing and uptake |
| 039 | SCM2 | Referral to hospital specialist for full assessment and management | Patients who tested positive should be referred to a hospital specialist for full assessment and management | Nature of disease pathway demands specialist assessment and overview in order that the condition can be appropriately and safely managed to achieve good patient outcomes. | NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 040 | SCM2 | NICE clinical pathway | Patient should be managed according to Clinical care pathway accredited by NICE, covering diagnosis, investigations, treatment and surveillance | At present there is significant variation in how the condition is being treated and managed leading to variable outcomes for patients. It is important to promote practice according to best evidence based standards in order to achieve high quality care and consistency for all | NICE CG165- Clinical guidelines for Chronic Hepatitis B |

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| | | | | NHS patients. | |
| 041 | SCM2 | Personalised care plan | Each patient or carer should be provided with a personalised care plan, and be actively and optimally involved in self-care and management | Currently patients are not always fully aware of their condition, the treatment goal and monitoring plan. This will restrict their contribution towards their care and management, and prevent them in fully complying with treatment and monitoring programme to achieve best outcomes. | NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 042 | SCM2 | Awareness raising and training | Awareness raising and training about Chronic Hepatitis B through education and training should include health care professionals and appropriate community groups , e.g. BME and LGBT organisations. | There are known knowledge and skills gap among professionals in respect of this condition, which leads to under-diagnosis of this preventable disease, with detriment to personal, family and public health in the affected population. The role of community groups is to be further developed and supported to combat this disease. | NICE Public Health guidance 43 hepatitis B and C –ways to promote testing and uptake |
| 043 | SCM3 | Testing in GP practises first generation migrants from countries with prevalence of CHB >2% (eastern Europeans, Africans, SE Asians and Chinese) | CHB is asymptomatic until the late stages when liver failure and HCC occur. Testing and treating those from high prevalence countries is the only way of identifying these subjects and is cost effective. Also allows opportunity to vaccinate family members. | Treatment as described in NICE CG for CHB prevents liver failure and HCC and currently many of the 250,000 cases in UK have not been identified. | NICE Public Health guidance 43 hepatitis B and C –ways to promote testing and uptake<br>NICE CG165- Clinical guideline for Chronic Hepatitis B<br>Data from Advisory Group on Hepatitis. |
| 044 | SCM3 | All patients with CHB should under serological tests as recommended in | Further management is complex and involves assessment of viral load and liver fibrosis and then treatment. | | NICE CG165- Clinical guideline for Chronic Hepatitis B (management section) |

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| | | NICE CG on CHB and then referral to hepatologist or gastroenterologist or ID physician. | | | |
| 045 | SCM 3 | Have all patients with HBV DNA >10,000iu and liver fibrosis been offered treatment | | | NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 046 | SCM3 | Have all patients been offered PEG interferon before starting tenofovir or entecavir | Most cost effective sequence | Rarely happens | NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 047 | SCM3 | Have all patients been offered screening for HCC. | Only treatable if found early at asymptomatic stage | | NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 048 | SCM4 | Initial assessment for patients who are HBsAg positive | All patients with positive HBsAg should have testing for full Hepatitis B serological markers, blood-borne viruses (HIV, Hep C, Hep D), Liver Function Tests and Hepatic Ultrasound and for HCC. | This has been identified as a key priority for implementation within NICE guidance on this topic. A full assessment is fundamental to planning further management. | http://publications.nice.org.uk/hepatitis-b-chronic-cg165/key-priorities-for-implementation#assessment-and-referral |
| 049 | SCM4 | Care of pregnant women | All pregnant women with positive HBsAg should have a specialist assessment within 6 weeks of the screening test.<br>This statement could be expanded or amended (if necessary) to include key messages on the antiviral treatment for mother and prophylaxis for infant. | As per NICE guidance.<br><br>Pregnant women with Hep B are a special category and require careful management to minimise opportunities for vertical transmission and for taking appropriate precautions during delivery. | An audit in London found that the vast majority of patients tested in primary care are not referred to secondary care.<br>http://gut.bmj.com/content/59/Suppl_2/A40.2.abstract<br><br>A similar audit in Northern Ireland found this proportion to be 50%<br>http://www.hepcni.net/userfiles/file/Dr%20McDougall%20-Antenatal%20HBV%20final.ppt |

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| 050 | SCM4 | Antiviral treatment | Children, young people and adults with chronic Hepatitis B, who are likely to benefit from treatment, should have antiviral therapy initiated by a specialist in viral hepatitis. | As per NICE guidance.<br><br>This is a broad statement to ensure that NICE guidance on treatment is followed. | http://publications.nice.org.uk/hepatitis-b-chronic-cg165/recommendations#assessment-of-liver-disease-in-secondary-specialist-care |
| 051 | SCM4 | Monitoring | Children, young people and adults with chronic Hepatitis B, who are not initiated on treatment, should have regular monitoring of their liver function, Hep B serological markers and HCC as appropriate. | As per NICE guidance.<br><br>Anecdotally, this is known to be an issue as majority of patients after initial assessment are referred back to primary care. Further monitoring of relevant markers does not always take place. | http://publications.nice.org.uk/hepatitis-b-chronic-cg165/recommendations |
| 052 | SCM4 | Utility of quantitative HBsAg assay to improve treatment strategies in CHB | Treatment strategies in CHB are evolving and the recent NICE guidelines have acknowledged this. The application of early stopping rules is dependent on the utility of HBsAg quantitative assay to individualise treatment strategies (based on sAg decline). The NICE guidelines, while advocating PEG-Interferon (PEG-INF) as first line therapy, accept that a significant proportion of people do NOT respond to PEG-INF and therefore should be switched to a second line agent if they demonstrate no response or a sub-optimal response. | The inclusion of on-treatment monitoring of HBsAg (quantitative HBsAg assay) would standardise current treatment practice in the UK. It would also ensure patients were being offered the appropriate first line therapy and switched to a second line agent at the most appropriate time. | NICE guidelines 2013<br>NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 053 | SCM4 | Case finding and screening in the community | 25% of those with CHB infected at birth, perinatally or in early childhood will develop cirrhosis or | Screening programmes have the potential to identify patients with CHB and make the appropriate referral to | NICE Public Health guidance 43 hepatitis B and C –ways to promote testing and uptake |

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| | | | hepatocellular carcinoma (WHO factsheet). The early identification of CHB is critical to better management and more timely intervention to prevent progressive liver disease secondary to CHB. This is why case finding and community screening are essential elements to achieving better outcomes over the long-term. | the specialist clinic for further evaluation, treatment and management. Early case finding and early referral to the specialist clinic will avoid late presentations with more advanced disease and the complications of progressive liver disease, decompensated cirrhosis and HCC. | |
| 054 | SCM4 | Screening for HCC | All patients with CHB are at risk for the development of HCC. The persistence of HBsAg in the absence of an inflammatory profile is associated with an increased relative risk for the development of HCC. | HBsAg positive (CHB) patients need appropriate clinical evaluation in the context of the specialist clinic. This underlines the importance of CHB patients being referred to and evaluated in a specialist clinic. Within this specialist clinic, patients meeting appropriate risk criteria should be appropriately screened for HCC with regular (6 monthly USS). | NICE guidelines 2013<br>NICE CG165- Clinical guidelines for Chronic Hepatitis B |
| 055 | SCM4 | The management of the CHB patient in the evolving NHS. | The management of CHB is a challenge for patient, physician and the NHS. CHB is a dynamic disease with patients moving between disease phases without the development of symptoms. Therefore close monitoring and supervision are critical. The evolving NHS will require better shared care models in order to cope with capacity issues, where potentially patients can be managed between primary care and the specialist clinic. | At present clinics are struggling with the volume of CHB patients- clinic numbers are cumulative with growing numbers of patients being referred, monitored and treated. At present, a small proportion of these patients can be safely discharged from the specialist clinic. In order to maintain quality in the specialist clinic, it is imperative that better strategies are in place for the long-term management of these patients. A greater and more active role for primary care is essential and represents a potential strategy to relieve the burden of patient numbers | NICE guidelines 2013<br>NICE CG165- Clinical guidelines for Chronic Hepatitis B |

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| | | | | in the specialist clinic. | |
| 056 | SCM5 | Transmission prevention | Prevention of mother-to-baby transmission of HBV | Self-evident – prevention is better than cure. | I don't have this to hand, but would be good to see the national data on how well antenatal screening is done, what percentage of babies who should be vaccinated actually receive a full course of vaccination, and what percentage of babies acquire HBV infection from their mothers. PHE would have this data I'm sure. |
| 057 | SCM5 | Increased diagnosis of chronic HBV | Increase diagnosis of patients with HBV | Self-evident. Unless patients are diagnosed, they cannot be treated. | Similar comment to above. PHE may well have data on how many patients have been diagnosed as having chronic HBV infection through their sentinel surveillance study. Comparison with estimates of how many patients we believe are out there would indicate the size of the problem. |
| 058 | SCM5 | Increased testing | Increase testing for HBV infection | Related to number 2 above. Better education of healthcare workers as to who is at risk and therefore who should be tested will lead to increased diagnosis | *No additional information provided by stakeholder.* |
| 059 | SCM5 | Increased vaccination | Increase vaccination rates for those identified as targets for vaccination | We have a selective vaccination policy therefore it is essential that we maximise vaccination of target groups | The most accessible data would be vaccination rates in prisons, and also in the unlinked anonymous studies on injecting drug users. |
| 060 | SCM5 | Increase referral of diagnosed patients for appropriate expert assessment and | Increase referral of diagnosed patients for appropriate expert assessment and management – and hand-in-hand, develop better IT | No good diagnosing someone in a vacuum. Some action has to follow. We currently have no idea how many patients are being treated, with what, | *No additional information provided by stakeholder.* |

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| | | management | systems so we have a better idea of how many patients are on what sort of therapies with what sort of results | and with what outcomes. How can we possibly plan service delivery in the absence of such key data? | |