Hepatitis B

NICE quality standard

Draft for consultation

March 2014

Introduction

This quality standard covers testing, diagnosis and management of hepatitis B from birth in children, young people and adults, and immunisation. For more information see the topic overview.

Why this quality standard is needed

Hepatitis B is a viral infection that is transmitted by contact with the blood or body fluids of an infected person and is also transmitted perinatally from mother to child (vertical transmission). Some people have an acute infection, in which the hepatitis B virus is cleared from the body naturally, whereas other people 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 newborn babies become chronic compared with 4% in adults[1].

The UK has been classified as a low incidence and prevalence country for hepatitis B infection. However, mortality and morbidity associated with chronic hepatitis B could be prevented in a significant number of people[2].There is considerable uncertainty over the number of people with chronic hepatitis B in the UK. In 2002, the Department of Health estimated that chronic hepatitis B affects 180,000 people in the UK. Other estimates put the figure for the UK up to as much as 325,000[3].

[1] Edmunds et al (1993) in Hepatitis B and C: ways to promote and offer testing. NICE public health guidance 43 (2012).
[2] Health Protection Agency (2011) Standards for local surveillance and follow up of hepatitis B and C.
[3] NICE press release on NICE clinical guideline on the diagnosis and management of chronic hepatitis B

Migrant populations are now the main focus for identifying and testing for hepatitis B in the UK. It is estimated that 95% of people with newly diagnosed chronic hepatitis B are immigrants, who predominantly acquire the infection in early childhood in the country of their birth. Most of the remaining 5% of people with UK acquired chronic hepatitis B infection is through horizontal transmission between adults or through vertical transmission from mother to child.

The quality standard is expected to contribute to improvements in the following outcomes:

- mortality from liver disease attributable to hepatitis B virus
- vertical transmission from mother to child: babies identified as hepatitis B-positive after one year

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measureable quality improvements within a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 2 outcomes frameworks published by the Department of Health:

- NHS Outcomes Framework 2014/15
- Improving outcomes and supporting transparency: a public health outcomes framework for England 2013–2016, Part 1 and Part 1A.

Tables 1 and 2 show the outcomes, overarching indicators and improvement areas from the frameworks 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*** 1a Potential years of life lost (PYLL) from causes considered amenable to healthcare i adults ii *children and young people* ***Improvement areas*** 1.3 Under 75 mortality rate from liver disease*

2 Enhancing quality of life for people with long-term conditions	***Overarching indicator*** 2 Health-related quality of life for people with long-term conditions** ***Improvement areas*** Reducing time spent in hospital by people with long-term conditions 2.3 i Unplanned hospitalisation for chronic ambulatory care sensitive conditions (adults)
Alignment across the health and social care system * Indicator complementary with Public Health Outcomes Framework (PHOF) ** 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*** Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities *Indicators* 4.6 Mortality from liver disease*
Alignment across the health and social care system * Indicator shared with NHS Outcomes Framework (NHSOF)	

Coordinated services

The quality standard for hepatitis B specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole hepatitis B care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to people with hepatitis B in primary and secondary care settings.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality. Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality hepatitis B service are listed in Related quality standards.

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All health and public health practitioners involved in assessing, caring for and treating people with hepatitis B in primary and secondary care settings should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard.

Role of families and carers

Quality standards recognise the important role families and carers have in supporting people with hepatitis B. If appropriate, health and public health practitioners should ensure that family members and carers are involved in the decision-making process about investigations, treatment and care.

List of quality statements

Statement 1. People who are at increased risk of infection are offered testing for hepatitis B.

Statement 2. People who test positive for hepatitis B infection are referred to specialist care for further assessment.

Statement 3. Pregnant women who are identified as being hepatitis B-positive at antenatal screening are assessed by a specialist within 6 weeks of receiving the screening test result.

Statement 4. Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination and a blood test for hepatitis B at 12 months.

Statement 5. People with chronic hepatitis B who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by infection status and age.

Statement 6. People with chronic hepatitis B, and their family members or carers (if appropriate), are offered a personalised care plan outlining the proposed treatment and long-term management of their hepatitis B.

Statement 7. Adults with chronic hepatitis B with significant liver fibrosis or cirrhosis are offered 6-monthly surveillance testing for hepatocellular carcinoma.

Questions for consultation

Questions about the quality standard

Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement?

Question 2 If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Question 3 For statement 5 ‘Monitoring people who do not meet the criteria for hepatitis B antiviral treatment’ – are there any specific groups to prioritise for quality improvement, i.e. are there any groups who are not currently monitored?

Quality statement 1: Testing for hepatitis B

Quality statement

People who are at increased risk of infection are offered testing for hepatitis B.

Rationale

Children, young people and adults who are at increased risk of hepatitis B infection should be offered testing in a range of settings. This is essential for ensuring early diagnosis, prompt treatment and timely monitoring.

People at increased risk may also benefit from hepatitis B immunisation. Public Health England's The Green Book (Hepatitis B: chapter 18) provides recommendations on immunisation of at-risk groups.

Quality measures

Structure

Evidence of local arrangements to ensure that people at increased risk of infection are offered testing for hepatitis B.

Data source: Local data collection.

Process

Proportion of people at increased risk of infection who receive testing for hepatitis B.

Numerator – the number of people in the denominator who receive testing for hepatitis B.

Denominator – the number of people at increased risk of hepatitis B infection.

Data source: Local data collection.

What the quality statement means for service providers, health and public health practitioners, and commissioners

Service providers ensure that systems are in place to offer hepatitis B testing to people at increased risk of infection.

Health and public health practitioners ensure that they offer hepatitis B testing to people at increased risk of infection and ensure pre- and post-test discussions with appropriate information about their risk of infection and refer them to a specialist. Assurance about confidentiality and privacy should also be given.

Commissioners ensure that they commission services to offer hepatitis B testing to people at increased risk of infection as part of local testing and referral pathways.

What the quality statement means for patients, service users and carers

People with a high risk of hepatitis B infection are offered a blood test to check if they have the infection.

Source guidance

- Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection (NICE public health guidance 43), recommendations 4 to 7.

Definitions of terms used in this quality statement

People at increased risk of hepatitis B infection

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

- People born or brought up in a country with an intermediate or high prevalence (2% or greater) of chronic hepatitis B. This includes all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific islands.
- Babies born to mothers infected with hepatitis B.
- People who have ever injected drugs.
- Men who have sex with men.
- Anyone who has had unprotected sex, particularly:
  - people who have had multiple sexual partners
  - people reporting unprotected 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.
- Prisoners, including young offenders.
- Immigration detainees.
- Close contacts of someone known to be chronically infected with hepatitis B.

[NICE public health guidance 43, Whose health will benefit?]

Testing strategies for hepatitis B should be implemented in the following settings:

- GP practices including new registrations
- Prison or an immigration removal centre
- Drug services
- Sexual health and genitourinary medicine clinics.

[NICE public health guidance 43, recommendations 4, 5, 6 and 7]

Equality and diversity considerations

The offer of hepatitis B testing in a range of settings should take into account the age and culture of groups at increased risk, and their needs in relation to the format of the information and the language used. Services should be responsive to social and cultural barriers to testing and treatment (for example, stigma). Good communication between healthcare professionals, public health practitioners and the people at increased risk of hepatitis B infection is essential.

Quality statement 2: Referral for specialist care

Quality statement

People who test positive for hepatitis B infection are referred to specialist care for further assessment.

Rationale

Chronic hepatitis B affects the liver and can cause serious health problems if left untreated. It is important that people who test positive for hepatitis B are referred for specialist care so that they can be assessed for the stage of hepatitis B and other infections (such as HIV, hepatitis C and hepatitis D) and liver health. Assessment in specialist care is essential in determining whether and when to start pharmacological treatment.

Quality measures

Structure

Evidence of local arrangements to ensure that people who test positive for hepatitis B infection are referred to specialist care for further assessment.

Data source: Local data collection.

Process

(a) Proportion of adults (excluding pregnant women) who test positive for hepatitis B who are referred to a specialist for further assessment.

Numerator – the number in the denominator who are referred to a specialist care for further assessment.

Denominator – the number of adults (excluding pregnant women) who test positive for hepatitis B.

Data source: Local data collection.

(b) Proportion of children and young people who test positive for hepatitis B who are referred to a specialist for further assessment.

Numerator – the number in the denominator who are referred to specialist care for further assessment.

Denominator – the number of children and young people (under 18 years) who test positive for hepatitis B.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers ensure that systems are in place to refer people who test positive for hepatitis B infection to specialist care for further assessment.

Healthcare professionals refer people who test positive for hepatitis B infection to specialist care for further assessment.

Commissioners ensure that they commission services with local arrangements to refer people who test positive for hepatitis B infection to specialist care for further assessment.

What the quality statement means for patients, service users and carers

People who are found to have the hepatitis B infection are referred to specialist care for an assessment to check the stage of the hepatitis B infection, the health of their liver, if they might have other infections and whether they need treatment.

Source guidance

- Hepatitis B (chronic) (NICE clinical guideline 165), recommendation 1.2.2 and recommendation 1.2.7
- Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection (NICE public health guidance 43), recommendations 4, 5, 6 and 7

Definitions of terms used in this quality statement

Specialist care

Specialist care referrals include the following:

- Adults who are HBsAg (hepatitis B surface antigen) positive are referred to a hepatologist, or to a gastroenterologist or infectious disease specialist with an interest in hepatology.
- Children and young people who are HBsAg positive are referred to a paediatric hepatologist, or to a gastroenterologist or infectious disease specialist with an interest in hepatology.

[NICE clinical guideline 165 recommendations 1.2.2, and 1.2.7]

Quality statement 3: Referral and assessment by specialist care for pregnant women who are identified as being hepatitis B-positive at antenatal screening

Quality statement

Pregnant women who are identified as being hepatitis B-positive at antenatal screening are assessed by a specialist within 6 weeks of receiving the screening test result.

Rationale

Pregnant women who are identified as being hepatitis B-positive at antenatal screening should be referred to and seen by a gastroenterologist or infectious disease specialist with an interest in hepatology within 6 weeks of receiving the screening test. This is important to allow treatment (tenofovir) in the third trimester if needed to reduce the risk of the baby becoming infected with the hepatitis B virus.

Quality measures

Structure

Evidence of local arrangements to ensure that pregnant women who are identified as being hepatitis B-positive at antenatal screening are assessed by a specialist within 6 weeks of receiving the screening test result.

Data source: Local data collection.

(a) Proportion of pregnant women who are identified as being hepatitis B-positive at antenatal screening who are assessed by a specialist within 6 weeks of receiving the screening test result.

Numerator – the number in the denominator who are assessed by a specialist within 6 weeks of receiving the antenatal screening test result.

Denominator – the number of pregnant women who are identified as having hepatitis B at antenatal screening.

Data source: UK National Screening Committee Key performance indicators – KPI ID2 (Antenatal infectious disease screening – timely referral of hepatitis B-positive women for specialist assessment).

Outcome

Vertical transmission rates from mother to child.

Data source: Local data collection

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers ensure that systems are in place to refer pregnant women who are identified as having hepatitis B at antenatal screening are referred to and assessed by a specialist within 6 weeks of receiving the screening test result.

Healthcare professionals refer pregnant women who are identified as having hepatitis B at antenatal screening and are assessed by a specialist within 6 weeks of receiving the screening test result.

Commissioners ensure that they commission services with local arrangements to assess pregnant women who are identified as having hepatitis B at antenatal screening by a specialist within 6 weeks of receiving the screening test result.

What the quality statement means for patients, service users and carers

Pregnant women who are found to have the hepatitis B infection during antenatal testing are referred to and assessed by a specialist within 6 weeks of receiving the screening test result.

Source guidance

- Hepatitis B (chronic) (NICE clinical guideline 165), recommendation 1.2.4

Definitions of terms used in this quality statement

Specialist care

Pregnant women who are HBsAg (hepatitis B surface antigen) positive are seen by a hepatologist, or to a gastroenterologist or infectious disease specialist with an interest in hepatology.
[NICE clinical guideline 165 recommendation 1.2.4]

Equality and diversity considerations

Pregnant women with complex social needs may be less likely to access or maintain contact with antenatal care services. Examples of women with complex social needs include, but are not limited to, women who:

- have a history of substance misuse (alcohol and/or drugs)
- have recently arrived as a migrant, asylum seeker or refugee
- have difficulty speaking or understanding English
- are aged under 20
- have experienced domestic abuse
- are living in poverty
- are homeless.

It is therefore appropriate that special consideration is given to these groups of women within the measures.

Quality statement 4: Neonatal hepatitis B vaccination

Quality statement

Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination and a blood test for hepatitis B at 12 months.

Rationale

Hepatitis B infection can be transmitted from mothers with hepatitis B to their babies at or around the time of birth (perinatal transmission). Babies who acquire the infection at this time have a very high risk of developing chronic hepatitis B. Vaccination of babies is highly effective in preventing transmission. It is important that the babies of mothers with hepatitis B (whether they are delivered in hospital or at home) are given the first vaccine dose promptly and that the recommended vaccination course is completed at the right time, including, when appropriate, hepatitis B immunoglobulin, in line with Public Health England's The Green Book (Hepatitis B: chapter 18).

If vaccinations are delayed or missed, it is more likely that the child will become infected. The transfer of care between maternity services and primary care can be a key issue and it is important that there is effective coordination and communication between services.

Quality measures

Structure

(a) Evidence of local commissioning arrangements to ensure that babies born to mothers with hepatitis B are given a full course of hepatitis B vaccination.

Data source: Local data collection.

(b) Evidence of local arrangements to ensure that there is an identified person responsible for coordinating the local hepatitis B vaccination programme for babies at risk of hepatitis B infection. This person should also be responsible for scheduling vaccinations and follow-up to ensure that babies at risk are vaccinated at the right time.

Data source: Local data collection.

Process

(a) Proportion of babies born to mothers with hepatitis B who receive the full course of hepatitis B vaccination.

Numerator – the number of babies in the denominator who receive a full course of hepatitis B vaccination.

Denominator – the number of babies reaching the age of 1 year born to mothers with hepatitis B.

Data source: Local data collection.

(b) Proportion of babies born to mothers with hepatitis B who receive a blood test for hepatitis B infection at 12 months.

Numerator – the number of babies in the denominator who receive a blood test for hepatitis B infection at 12 months.

Denominator – the number of babies reaching the age of 1 year born to mothers who have the hepatitis B infection.

Data source: Local data collection.

Outcome

Vertical transmission rates from mother to child.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

Service providers ensure that systems are in place to give babies born to hepatitis-B positive mothers a complete course of hepatitis B vaccination and a blood test for hepatitis B at 12 months.

Healthcare professionals give babies born to hepatitis-B positive mothers a complete course of hepatitis B vaccination and a blood test for hepatitis B infection at 12 months.

Commissioners ensure that they commission services with local arrangements to give babies born to hepatitis-B positive mothers a complete course of hepatitis B vaccination and a blood test for hepatitis B infection at 12 months.

What the quality statement means for patients, service users and carers

Babies born to mothers with hepatitis B are given a complete course of hepatitis B vaccination and a blood test when they are 12 months of age to check whether the vaccination has prevented the infection passing from mother to baby.

Source guidance

- Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection (NICE public health guidance 43), recommendation 9
- Reducing differences in the uptake of immunisations (NICE public health guidance 21), recommendation 6

Definitions of terms used in this quality statement

Complete course of hepatitis B vaccination and a blood test for hepatitis B

A complete course consists of an initial dose of vaccine within 24 hours of birth, with further doses at 1 month, 2 months and 12 months and an additional booster at preschool age. A blood test for hepatitis B surface antigen (HBsAg) should be performed at 12 months (at the time of the fourth dose) to check for vaccine failure.

[Public Health England's Immunisation against infectious disease: the green book (Hepatitis B: chapter 18). Public Health England's Public health functions to be exercised by NHS England: Neonatal hepatitis B immunisation programme (service specification 1)]

Equality and diversity considerations

The implications of hepatitis B neonatal vaccination should be understood by all women to enable them to make informed decisions. Information should be provided in an accessible format (particularly for women with physical, sensory or learning disabilities and women who do not speak or read English).

Quality statement 5: Monitoring people who do not meet the criteria for hepatitis B antiviral treatment

Quality statement

People with chronic hepatitis B who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by infection status and age.

Rationale

Monitoring starts shortly after a person is diagnosed with chronic hepatitis B. For people who do not need antiviral treatment, continuous follow-up is needed to determine the stage of hepatitis B, whether treatment needs to be started and if they are at risk of developing fibrosis.

Quality measures

Structure

Evidence of local arrangements to ensure that people with chronic hepatitis B who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by infection status and age.

Data source: Local data collection.

Process

Proportion of people with chronic hepatitis B who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by infection status and age.

Numerator – the number of people in the denominator who are monitored regularly at intervals determined by infection status and age.

Denominator – the number of people with chronic hepatitis B who are not receiving antiviral treatment.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

Service providers ensure that systems are in place for people with chronic hepatitis B who do not meet the criteria for antiviral treatment to be monitored regularly at intervals determined by infection status and age.

Healthcare professionals ensure that people with chronic hepatitis B who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by infection status and age.

Commissioners ensure that they commission services with local arrangements to regularly monitor people with chronic hepatitis B who do not meet the criteria for antiviral treatment at intervals determined by infection status and age.

What the quality statement means for patients, service users and carers

People with chronic hepatitis B (which is hepatitis B infection that has lasted for 6 months or more) who do not meet the criteria for hepatitis B antiviral treatment are monitored regularly to check the stage of the infection, whether they need to start treatment and if they are at risk of developing fibrosis (scarring of the liver).

Source guidance

- Hepatitis B (chronic) (NICE clinical guideline 165), recommendations 1.6.1 to 1.6.8

Definitions of terms used in this quality statement

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. [NICE clinical guideline 165]

Recommended intervals for monitoring

Monitoring intervals for people who do not meet the criteria for antiviral treatment are outlined in NICE clinical guideline 165. These vary with infection status and age, and include:

- Adults with HBeAg-positive disease in the immune-tolerant and immune clearance phases (recommendations 1.6.1 and 1.6.2).
- Adults with inactive chronic hepatitis B (immune-control phase) (recommendations 1.6.3).
- Children and young people (recommendations 1.6.4, 1.6.5 and 1.6.6).
- Children, young people and adults with HBeAg or HBsAg seroconversion after antiviral treatment (recommendations 1.6.7 and 1.6.8).

[NICE clinical guideline 165, recommendations 1.6.1 to 1.6.8]

Equality and diversity considerations

The information on monitoring people (including children, young people and adults) with chronic hepatitis B who do not meet the criteria for antiviral treatment should be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. Adults receiving information should have access to an interpreter or advocate if needed. The information should be tailored to the age of the person.

Quality statement 6: Personalised care plan

Quality statement

People with chronic hepatitis B, and their family members or carers (if appropriate), are offered a personalised care plan outlining the proposed treatment and long-term management of their hepatitis B.

Rationale

Personalised care plans are important to promote regular discussion and involvement in decision-making about proposed treatment and long-term management between the healthcare professional and the person with chronic hepatitis B (and their family members or carers if appropriate).

Treatment is needed for many years and is usually life-long. It is important that people are actively involved in decisions about their care, and that they fully understand their treatment plan. People with hepatitis B should be encouraged to follow their care plan and take an active role in ensuring that required any monitoring, treatment and/or screening tests happen in a timely way. Engaging patients in their care planning and management helps to ensure that they adhere to long-term treatment, minimising non-attendance, inadequate monitoring and poor patient outcomes.

Quality measures

Structure

Evidence of local arrangements to ensure that people with chronic hepatitis B, and their family members or carers (if appropriate), are given a personalised care plan.

Data source: Local data collection.

Process

Proportion of people with chronic hepatitis B, and their family members or carers (if appropriate), who are given a personalised care plan.

Numerator – the number of people in the denominator who receive (or whose family members or carers receive) a personalised care plan.

Denominator – the number of people with chronic hepatitis B.

Data source: Local data collection.

Outcome

People with chronic hepatitis B and their family members and carers (if appropriate) feel informed about their proposed treatment and their long-term management plan.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers ensure systems are in place for people with chronic hepatitis B, and their family members or carers (if appropriate), to be offered a personalised care plan outlining the proposed treatment and long-term management of hepatitis B.

Healthcare professionals ensure that people with chronic hepatitis B, and their family members or carers (if appropriate), are offered a personalised care plan outlining the proposed treatment and long-term management of hepatitis B.

Commissioners ensure that they commission services with local arrangements to offer people with chronic hepatitis B, and their family members or carers (if appropriate), a personalised care plan outlining the proposed treatment and long-term management of hepatitis B.

What the quality statement means for patients, service users and carers

People with chronic hepatitis B (which is hepatitis B infection that has lasted for 6 months or more) and their family members or carers (if appropriate), are offered a personalised care plan that outlines their proposed treatment and long-term management of their hepatitis B.

Source guidance

- Hepatitis B (chronic) (NICE clinical guideline 165), recommendations 1.1.1 and 1.1.2

Definitions of terms used in this quality statement

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. [NICE clinical guideline 165]

Personalised care plan

A personalised care plan should outline the proposed treatment and long-term management specific to the patient's chronic hepatitis B condition (for example, it should include a copy of the hospital consultation summary) to help promote regular discussions between the patient, and their family members or carers (if appropriate), and the healthcare professional.

[Adapted from NICE full clinical guideline 165]

Equality and diversity considerations

A personalised care plan should be tailored to the person with chronic hepatitis B. For some people with hepatitis B (for example, children, older people and people with learning disabilities), it may be appropriate for a family member or carer to be involved in the review of the personalised care plan.

Quality statement 7: Surveillance testing in adults with chronic hepatitis B for hepatocellular carcinoma

Quality statement

Adults with chronic hepatitis B with significant liver fibrosis or cirrhosis are offered 6-monthly surveillance testing for hepatocellular carcinoma.

Rationale

Hepatocellular carcinoma is the most common form of liver cancer. Significant fibrosis or cirrhosis is a substantial risk factor for hepatocellular carcinoma and people with chronic hepatitis who develop liver damage are at increased risk. This form of cancer develops quickly and may be asymptomatic until it is advanced. Regular surveillance at 6-month intervals helps to ensure that hepatocellular carcinoma is detected early, which can lead to earlier treatment and may improve chances of survival.

Quality measures

Structure

Evidence of local arrangements to ensure that adults with chronic hepatitis B with significant fibrosis or cirrhosis are offered 6-monthly surveillance testing for hepatocellular carcinoma.

Data source: Local data collection.

Process

Proportion of adults with chronic hepatitis B with significant fibrosis or cirrhosis who receive 6-monthly surveillance testing for hepatocellular carcinoma.

Numerator – the number of adults in the denominator who received their most recent hepatocellular carcinoma surveillance testing within 6 months of their previous one or within 6 months of having significant fibrosis or cirrhosis identified.

Denominator – the number of adults with chronic hepatitis B with significant fibrosis or cirrhosis.

Data source: Local data collection.

Outcome

Stage of hepatocellular carcinoma at diagnosis for people with chronic hepatitis B.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

Service providers ensure that systems are in place to offer adults with chronic hepatitis B with significant fibrosis or cirrhosis 6-monthly surveillance testing for primary liver cancer.

Healthcare professionals ensure that they offer adults with chronic hepatitis B with significant fibrosis or cirrhosis 6-monthly surveillance testing for primary liver cancer.

Commissioners ensure that they commission services with local arrangements to offer adults with chronic hepatitis B with significant fibrosis or cirrhosis 6-monthly surveillance testing for primary liver cancer.

What the quality statement means for patients, service users and carers

Adults with chronic hepatitis B (which is hepatitis B infection that has lasted for 6 months or more) and significant scarring of the liver (called fibrosis or cirrhosis) are offered an ultrasound scan and a blood test every 6 months to check for primary liver cancer.

Source guidance

- Hepatitis B (chronic) (NICE clinical guideline 165), recommendation 1.7.1

Definitions of terms used in this quality statement

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. [NICE clinical guideline 165]

Significant fibrosis or cirrhosis

Fibrosis is a progressive form of liver disease that can be caused by hepatitis B. Damage to liver cells results in scarring that prevents the liver from working normally. Significant fibrosis is determined by histological assessment and semi-quantitative scoring systems (METAVIR and Ishak score). Significant fibrosis is METAVIR stage F2 or higher, or Ishak stage 3 or higher. Cirrhosis occurs when liver inflammation and fibrosis spread to disrupt the shape and function of the liver. Cirrhosis is permanent cell damage and can lead to liver failure or liver cancer if left untreated.

[Adapted from NICE full clinical guideline 165]

Surveillance testing

The 6-monthly surveillance testing for hepatocellular carcinoma is carried out by hepatic ultrasound and alphafetoprotein testing.

[NICE clinical guideline 165, recommendation 1.7.1]

Status of this quality standard

This is the draft quality standard released for consultation from 10 March to 7 April 2014. It is not NICE's final quality standard on hepatitis B. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 7 April 2014. All eligible comments received during consultation will be reviewed by the Quality Standards Advisory Committee and the quality statements and measures will be refined in line with the Quality Standards Advisory Committee's considerations. The final quality standard will be available on the NICE website from July 2014.

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its Indicators for Quality Improvement Programme. If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's What makes up a NICE quality standard? for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something

should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in Development sources.

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and equality assessments are available.

Good communication between health and public health practitioners and children, young people and adults with hepatitis B, and their families or carers (if appropriate), in primary and secondary care, is essential. Treatment, care and support, and the information given about it, should be both age-appropriate and culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. Children, young people and adults with hepatitis B, and their families or carers (if appropriate), in primary and secondary care, should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

Development sources

Further explanation of the methodology used can be found in the quality standards Process guide on the NICE website.

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

- Hepatitis B (chronic). 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).

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- Public Health England (2013). Immunisation against infectious disease: the green book (Hepatitis B: chapter 18).
- Department of Health (2011). Hepatitis B antenatal screening and newborn immunisation programme: best practice guidance.

Related NICE quality standards

Published

- Drug use disorders. NICE quality standard 23 (2012).
- Antenatal care. NICE quality standard 22 (2012).
- Patient experience in adult NHS services. NICE quality standard 15 (2012).

In development

- None identified

Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- Cirrhosis

- Liver disease (non-alcoholic).
- Medicines optimisation (covering medicines adherence and safe prescribing).

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 1.

Membership of this committee is as follows:

Dr Bee Wee (Chair)
Consultant in Palliative Medicine, Oxford University Hospitals NHS Trust; Senior Lecturer in Palliative Medicine, Oxford University

Mr Lee Beresford
Head of Strategy and System Restore, NHS Wakefield Clinical Commissioning Group

Dr Gita Bhutani
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Mrs Jennifer Bostock
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Mr Gavin Maxwell

Lay member

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Clinical Audit Programme Manager, The Health and Social Care Information Centre

Ms Jane Worsley

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Dr Arnold Zermansky

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The following specialist members joined the committee to develop this quality standard:

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Professor Will Irving

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

Professor Howard Thomas

Emeritus Professor, Gastroenterology and Hepatology Section, Department of Medicine, Imperial College London

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About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the quality standards process guide.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

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