NICE National Institute for Health and Care Excellence

NICE quality standard

Hepatitis B

Quality standard

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Contents

This standard is based on CG165, PH21 and PH43.

This standard should be read in conjunction with QS15, QS22, QS23, QS83, QS145, QS152, QS156 and QS178.

Introduction

This quality standard covers testing, diagnosis and management of hepatitis B in children (from birth), young people and adults. 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 adults have an acute infection, in which the 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 infection. About 85% of hepatitis B infections in newborn babies become chronic compared with 4% in adults (Hepatitis B and C [NICE public health guidance 43]).

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 (Standards for local surveillance and follow up of hepatitis B and C [Health Protection Agency]). There is considerable uncertainty over the number of people with chronic hepatitis B infection in the UK. In 2002, the Department of Health estimated that chronic hepatitis B affected 180,000 people in the UK. Other estimates put the figure for the UK as high as 325,000 (Hepatitis B Foundation UK 2007).

Migrant populations are now the main focus for identifying and testing for hepatitis B infection in the UK. It is estimated that 95% of people with newly diagnosed chronic hepatitis B infection are immigrants, who predominantly become infected in early childhood in the country of their birth. Most of the remaining 5% of people with UK-acquired chronic hepatitis B infection acquired it either 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 hepatitis B surface antigen (HBsAg)-positive mother to child: babies identified as being hepatitis B-positive after 1 year
- enabling people to live better with this condition.

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measurable 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 hepatitis B infection are offered testing and vaccination.

Statement 2. People who test positive for hepatitis B surface antigen (HBsAg) are referred to specialist care for further assessment.

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

Statement 4. Babies born to hepatitis B surface antigen (HBsAg)-positive mothers receive a complete course of hepatitis B vaccination and, at age 12 months, receive a blood test for hepatitis B infection.

Statement 5. People with chronic hepatitis B infection, and their family members or carers (if appropriate), are offered a personalised care plan outlining the proposed treatment and long-term management of their infection.

Statement 6. People with chronic hepatitis B infection who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by their infection status and age.

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

Quality statement 1: Testing and vaccination for hepatitis B

Quality statement

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

Rationale

Children, young people and adults who are at increased risk of hepatitis B infection should be offered testing in a range of settings (for example, in GP practices including new registrations, prisons or immigration removal centres, drug services, sexual health and genitourinary medicine clinics) alongside appropriate vaccination. This is essential for ensuring early diagnosis, prompt treatment and prevention of infection.

Quality measures

Structure

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

Data source: Local data collection.

Process

a) Proportion of new GP registrants who belong to a group at increased risk of infection who are offered testing for hepatitis B.

Numerator – the number in the denominator offered testing for hepatitis B.

Denominator – the number of new GP registrants who belong to a group at increased risk of infection.

Data source: Local data collection.

b) Proportion of new GP registrants who test negative for hepatitis B but remain at increased risk of infection who are offered vaccination for hepatitis B.

Numerator – the number in the denominator offered vaccination for hepatitis B.

Denominator – the number of new GP registrants who test negative for hepatitis B but remain at increased risk of infection.

Data source: Local data collection.

c) Proportion of prisoners/immigration detainees who are offered vaccination for hepatitis B when entering prison or an immigration removal centre.

Numerator – the number in the denominator offered vaccination for hepatitis B.

Denominator – the number of prisoners/immigration detainees entering prison or an immigration removal centre.

Data source: Local data collection.

d) Proportion of prisoners/immigration detainees who are offered testing for hepatitis B when entering prison or an immigration removal centre.

Numerator – the number in the denominator offered testing for hepatitis B.

Denominator – the number of prisoners/immigration detainees entering a prison or an immigration removal centre.

Data source: Local data collection.

e) Proportion of prisoners/immigration detainees who are offered testing for hepatitis B during their detention in prison or an immigration removal centre.

Numerator – the number in the denominator offered testing for hepatitis B.

Denominator – the number of prisoners/immigration detainees detained in a prison or an immigration removal centre.

Data source: Local data collection.

f) Proportion of people using drug services who are offered vaccination for hepatitis B.

Numerator – the number in the denominator offered vaccination for hepatitis B.

Denominator – the number of people using drug services.

Data source: Local data collection.

g) Proportion of people using drug services who are offered testing for hepatitis B.

Numerator – the number in the denominator offered testing for hepatitis B.

Denominator – the number of people using drug services.

Data source: Local data collection.

h) Proportion of people at increased risk of infectionusing sexual health and genitourinary medicine clinics who are offered vaccination for hepatitis B.

Numerator – the number in the denominator offered vaccination for hepatitis B.

Denominator – the number of people at increased risk of infectionusing sexual health and genitourinary medicine clinics.

Data source: Local data collection.

i) Proportion of people at increased risk of infection using sexual health and genitourinary medicine clinics who are offered testing for hepatitis B.

Numerator – the number in the denominator offered testing for hepatitis B.

Denominator – the number of people at increased risk of infection using sexual health and genitourinary medicine clinics.

Data source: Local data collection.

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

Service providers (GP practices, prisons and immigration removal centres, drugs services and secondary care providers of sexual health and genitourinary medicine clinics) ensure that testing and vaccination for hepatitis B are offered to people who are at increased risk of infection. This

includes dried blood spot testing for hepatitis B in appropriate service settings for people in whom venous access is difficult.

Health and public health practitioners offer hepatitis B testing and vaccination to people at increased risk of infection and ensure pre- and post-test discussions with appropriate information about their risk of infection. Assurance about confidentiality and privacy should also be given. Healthcare professionals ensure that they have received appropriate training and have been assessed as competent for delivering vaccinations, in line with the recommendations in Public Health England's Immunisation against infectious disease: the green book, chapter 18: Hepatitis B.

Commissioners (local authority commissioners, NHS England area teams and clinical commissioning groups) work with service provider partners to ensure that testing (including dried blood spot testing) and vaccination for hepatitis B are offered to people who are at increased risk of infection.

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

Peopleat increased risk of hepatitis B infection are offered a blood test to check if they have the infection and a vaccination to help prevent 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 infection 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.

- People who may have been exposed to sexually acquired infection, particularly:
  - people who have had unprotected sex with 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 (these could include sexual, close friends, family and household) of someone known to be chronically infected with hepatitis B. [Adapted from NICE public health guidance 43, section on Whose health will benefit?]

Testing and vaccination

Testing strategies for hepatitis B should be implemented alongside hepatitis B vaccination in line with Public Health England's Immunisation against infectious disease: the green book, chapter 18: Hepatitis B 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 to 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, vaccination

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 surface antigen (HBsAg) are referred to specialist care for further assessment.

Rationale

Chronic hepatitis B infection affects the liver and can cause serious health problems if left untreated. It is important that people who test positive for HBsAg are referred for specialist care so that they can be assessed for the stage of hepatitis B and for other infections (such as HIV, hepatitis C and hepatitis D). Further assessment in specialist care is essential in determining whether and when to start pharmacological treatment. This statement does not apply to pregnant women who test HBsAg-positive at antenatal screening, which is the focus of quality statement 3.

Quality measures

Structure

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

Data source: Local data collection.

Process

a) Proportion of adults (aged 18 years and over) who test HBsAg-positive who are referred to specialist care for further assessment.

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

Denominator – the number of adults (aged 18 years and over) who test HBsAg-positive.

Data source: Local data collection. NICE Hepatitis B: clinical audit tool – primary care, audit standard 2.

b) Proportion of children and young people (under 18 years) who test HBsAg-positive who are

referred to specialist care 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 HBsAg-positive.

Data source: Local data collection. NICE Hepatitis B: clinical audit tool – primary care, audit standard 3.

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

Service providers (GP practices, prisons and immigration removal centres, drug services and secondary care providers of sexual health and genitourinary medicine clinics) ensure that local referral pathways are in place and that people who test positive for HBsAg are referred to specialist care for further assessment.

Healthcare professionals refer people who test HBsAg-positive to specialist care for further assessment.

Commissioners (local authority commissioners, NHS England area teams and clinical commissioning groups) work with providers of testing and vaccination services to ensure that people who test HBsAg-positive are referred to specialist care for further assessment.

Clinical commissioning groups work with partners in secondary care to ensure that specialist services provide further assessment for people who test HBsAg-positive.

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

People who are found to have hepatitis B infection are referred to a specialist for further assessment.

Source guidance

- Hepatitis B (chronic) (NICE clinical guideline 165), recommendations 1.2.2 and 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 to 7.

Definitions of terms used in this quality statement

Specialist care

- Adults who test HBsAg-positive are referred to a hepatologist, or to a gastroenterologist or infectious disease specialist with an interest in hepatology.
- Children and young people who test 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 to and assessment by specialist care for pregnant women who are identified as hepatitis B surface antigen-positive at antenatal screening

Quality statement

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

Rationale

Specialist assessment within 6 weeks of receiving the screening test result is important to allow antiviral treatment (tenofovir) in the third trimester if needed to reduce the risk of the baby becoming infected with hepatitis B.

Quality measures

Structure

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

Data source: Local data collection.

Process

Proportion of pregnant women who are identified as being HBsAg-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 being HBsAg-positive 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 (antenatal care) ensure that healthcare professionals refer all pregnant women who are identified as being HBsAg-positive at antenatal screening to specialist care.

Hospital-based specialist care demonstrates that pregnant women who are referred for specialist care assessment are assessed by a specialist within 6 weeks of receiving the screening test result.

Healthcare professionals refer pregnant women who are identified as being HBsAg-positive at antenatal screening to a specialist within 6 weeks of receiving the screening test result.

Commissioners (clinical commissioning groups) work with partners in secondary care to ensure that specialist services are available to provide pregnant women who are identified as being HBsAg-positive at antenatal screening with specialist assessment within 6 weeks of receiving the test result.

Clinical commissioning groups and NHS England area teams (screening and immunisation teams) work together to ensure that providers of antenatal care refer pregnant women who are identified as being HBsAg-positive at antenatal screening to a specialist.

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

Pregnant womenwho are found to have hepatitis B infection during antenatal testing are 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 assessment

Pregnant women who are identified as HBsAg-positive are seen by a hepatologist, or 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 years
- have experienced domestic abuse
- are living in poverty
- are homeless.

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

Quality statement 4: Complete course of neonatal hepatitis B vaccination and blood testing at 12 months

Quality statement

Babies born to hepatitis B surface antigen (HBsAg)-positive mothers receive a complete course of hepatitis B vaccination and, at age 12 months, receive a blood test for hepatitis B infection.

Rationale

Hepatitis B infection can be transmitted from mothers with hepatitis B to their babies. Babies who acquire the infection 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 Immunisation against infectious disease: the green book, chapter 18: Hepatitis B.

If vaccinations are delayed or missed, it is more likely that the child will become infected.

Quality measures

Structure

a) Evidence of local commissioning arrangements to ensure that babies born to HBsAg-positive mothers are given a complete course of hepatitis B vaccination.

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 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 HBsAg-positive mothers who receive the complete course of hepatitis B vaccination.

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

Denominator – the number of babies born to HBsAg-positive mothers.

Data source: Local data collection. NICE Reducing the differences in the uptake of immunisations: audit support tool, criterion 3.

b) Proportion of babies born to HBsAg-positive mothers who receive a blood test for hepatitis B infection at age 12 months.

Numerator – the number in the denominator who receive a blood test for hepatitis B infection.

Denominator – the number of babies at age 12 months born to HBsAg-positive mothers.

Data source: Local data collection. NICE Reducing the differences in the uptake of immunisations: audit support, criterion 3.

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 (maternity, paediatric, primary care and community support teams) ensure that babies born to HBsAg-positive mothers are given a complete course of hepatitis B vaccination through a coordinated programme that includes an identified person who is responsible for scheduling vaccinations and follow-up to ensure that babies at risk are vaccinated at the right time.

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

Commissioners (clinical commissioning groups and NHS England area teams for screening and immunisation) work together to ensure that a coordinated hepatitis B neonatal vaccination programme is in place to vaccinate babies born to HBsAg-positive mothers, which includes

scheduling of vaccinations and follow-up to ensure that babies at risk are vaccinated at the right time.

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

Babies born to mothers with hepatitis B infection are given a complete course of hepatitis B vaccinations, and when they are aged 12 months they are given a blood test to check whether 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), 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 and of hepatitis B immunoglobulin where indicated 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 HBsAg should be performed at 12 months (at the time of the fourth dose) to check for vaccine failure.

The blood test at age 12 months should be performed regardless of the uptake of the vaccination course. [Public Health England's Immunisation against infectious disease: the green book, chapter 18: Hepatitis B. Public Health England's Public health functions to be exercised by NHS England: Neonatal hepatitis B immunisation programme (service specification 1)]

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.

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).

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 years
- have experienced domestic abuse
- are living in poverty
- are homeless.

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

Quality statement 5: Personalised care plan

Quality statement

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

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 infection (and their family members or carers if appropriate).

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 any necessary 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, and minimises non-attendance, inadequate monitoring and poor patient outcomes.

Quality measures

Structure

Evidence of local arrangements to ensure that people with chronic hepatitis B infection, and their family members or carers (if appropriate), are given a personalised care plan outlining the proposed treatment and long-term management of their infection.

Data source: Local data collection.

Process

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

Numerator – the number in the denominator who receive (or whose family members or carers

receive) a personalised care plan outlining the proposed treatment and long-term management of their infection.

Denominator – the number of people with chronic hepatitis B infection.

Data source: Local data collection.

Outcome

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

*Data source:*Local data collection.

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

Service providers (within secondary care) ensure that personalised care plans outlining the proposed treatment and long-term management of their infection are given to people with chronic hepatitis B infection, and their family members or carers (if appropriate).

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

Commissioners (clinical commissioning groups) ensure that secondary care service providers have protocols in place for healthcare professionals to offer personalised care plans to people with chronic hepatitis B infection, and their family members and carers (if appropriate), outlining the proposed treatment and long-term management of their infection.

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

People with chronic hepatitis B infection (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 treatment and long-term care.

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 infection is defined as persistence of hepatitis B surface antigen (HBsAg) for 6 months or more after acute infection with hepatitis B virus. Chronic hepatitis B infection 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 Hepatitis B (chronic) (full guideline)]

Equality and diversity considerations

A personalised care plan should be tailored to the person with chronic hepatitis B infection. 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 6: Monitoring people with chronic hepatitis B infection who do not meet the criteria for antiviral treatment

Quality statement

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

Rationale

Monitoring starts shortly after a person is diagnosed with chronic hepatitis B infection. For people who do not need antiviral treatment, continuous follow-up is needed to determine the stage of infection, 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 infection who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by their infection status and age.

Data source: Local data collection.

Process

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

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

Denominator – the number of people with chronic hepatitis B infection who do not meet the criteria for antiviral treatment.

Data source: Local data collection.

What the quality statement means for service providers, healthcare

professionals and commissioners

Service providers (hospital-based specialist care) ensure that competent healthcare professionals are in place to meet the commissioned levels of activity through outpatient clinics.

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

Commissioners (clinical commissioning groups and hospital-based specialist care providers) ensure that systems and facilities are in place for monitoring and follow-up of people with chronic hepatitis B who do not meet the criteria for antiviral treatment.

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

People with chronic hepatitis B infection (infection that has lasted for 6 months or more) who do not meet the criteria for 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 infection

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

Monitoring people with chronic hepatitis B infection who meet the criteria for antiviral treatment

Monitoring intervals for people who meet the criteria for antiviral treatment are outlined in NICE clinical guideline 165. These vary with infection status, age and clinical status. [NICE clinical guideline 165, recommendations 1.5.1 to 1.5.53]

Equality and diversity considerations

The information on monitoring people (including children, young people and adults) with chronic hepatitis B infection 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 7: Six-monthly surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B infection who have significant liver fibrosis or cirrhosis

Quality statement

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

Rationale

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

Quality measures

Structure

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

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

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

Data source: Local data collection.

Outcome

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

Data source:Local data collection.

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

Service providers (hospital-based specialist care providers) ensure that competent healthcare professionals are in place to meet the commissioned levels of activity through outpatient clinics and may demonstrate outcomes to commissioners by monitoring the stage of hepatocellular carcinoma at diagnosis for adults with chronic hepatitis B infection.

Healthcare professionals offer adults with chronic hepatitis B infection and significant liver fibrosis or cirrhosis 6-monthly surveillance testing for hepatocellular carcinoma.

Commissioners (clinical commissioning groups) ensure that hospital-based specialist care providers have systems and facilities in place to provide 6-monthly surveillance testing for hepatocellular carcinoma for adults with chronic hepatitis B and significant liver fibrosis or cirrhosis. For more information on surveillance testing see Hepatitis B (chronic): diagnosis and management of chronic hepatitis B in children, young people and adults (NICE clinical guideline 165) section 1.7.

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

Adults with chronic hepatitis B infection (infection that has lasted for 6 months or more) and severe scarring of the liver (called fibrosis or cirrhosis) are offered an ultrasound scan and a blood test every 6 months to check for 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 infection is defined as persistence of hepatitis B surface antigen (HBsAg) for 6 months or more after acute infection with hepatitis B virus. Chronic hepatitis B infection 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 liver fibrosis or cirrhosis

Fibrosis is a progressive form of liver disease that can be caused by hepatitis B infection. 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. Even with no signs or symptoms of liver disease, the working capacity of liver cells has been badly impaired and they are unable to repair the liver. This is permanent cell damage and can lead to liver failure or liver cancer. [Adapted from Hepatitis B (chronic) (full guideline)]

Hepatocellular carcinoma

People with cirrhosis of the liver are at a small but significantly increased risk of developing a type of liver cancer called hepatocellular carcinoma.

[NHS choices, accessed June 2014]

Surveillance testing

The 6-monthly surveillance testing for hepatocellular carcinoma is carried out by hepatic ultrasound and alpha-fetoprotein testing. [NICE clinical guideline 165, recommendation 1.7.1]

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.

Information for commissioners

NICE has produced support for commissioning that considers the commissioning implications and potential resource impact of this quality standard. This is available on the NICE website.

Information for the public

NICE has produced information for the public about this quality standard. Patients, service users and carers can use it to find out about the quality of care they should expect to receive, as a basis for asking questions about their care, and to help make choices between providers of social care services.

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, 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, chapter 18: Hepatitis B
- Department of Health (2011) Hepatitis B antenatal screening and newborn immunisation programme: best practice guidance.

Related NICE quality standards

- 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).

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:

Mr Lee Beresford
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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.

This quality standard has been incorporated into the NICE pathways for hepatitis B (chronic), hepatitis B and C testing and immunisation for children and young people.

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.

Changes after publication

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Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social

Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- Addaction
- Children's Liver Disease Foundation
- Maslaha
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists