NICE National Institute for Health and Care Excellence

NICE quality standard

Hepatitis B

Quality standard
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This standard is based on CG165 and PH43.

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

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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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

c) Proportion of prisoners or 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 or immigration detainees entering prison or an immigration removal centre.

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

d) Proportion of prisoners or 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 or immigration detainees entering a prison or an immigration removal centre.

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

e) Proportion of prisoners or 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 or immigration detainees detained in a prison or an immigration removal centre.

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified.

Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

h) Proportion of people at increased risk of infection using 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 infection using sexual health and genitourinary medicine clinics.

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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 the UK Health Security Agency's Immunisation against infectious disease: the Green book, chapter 18: Hepatitis B.

Commissioners 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.

People at 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 testing: people at risk of infection. NICE guideline PH43 (2012, updated 2013), 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's guideline on hepatitis B and C testing, section on whose health will benefit?]

Testing and vaccination

Testing strategies for hepatitis B should be implemented alongside hepatitis B vaccination in line with the UK Health Security Agency'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's guideline on hepatitis B and C testing, 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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

Structure

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

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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 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.

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

Source guidance

- Hepatitis B (chronic): diagnosis and management. NICE guideline CG165 (2013, updated 2017), recommendations 1.2.2 and 1.2.7
- Hepatitis B and C testing: people at risk of infection. NICE guideline PH43 (2012, updated 2013), 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's guideline on hepatitis B (chronic), 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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for

example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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.

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 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.

Pregnant women who 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): diagnosis and management. NICE guideline CG165 (2013, updated 2017), 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's guideline on hepatitis B (chronic), 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 experiencing homelessness.

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 the UK Health Security Agency'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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

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.

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by commissioning organisations, for example from service level agreements.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records

Outcome

Vertical transmission rates from mother to child.

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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 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.

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 testing: people at risk of infection. NICE guideline PH43 (2012, updated 2013), recommendation 9

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. [UK Health Security Agency's Immunisation against infectious disease: the Green book, chapter 18: Hepatitis B and Public health functions to be exercised by NHS England: Neonatal hepatitis B immunisation programme (Department of Health and Social Care)]

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 experiencing homelessness.

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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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 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.

Peoplewith 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): diagnosis and management. NICE guideline CG165 (2013, updated 2017), 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's guideline on hepatitis B (chronic)]

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's full guideline on hepatitis B (chronic)]

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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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 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.

Peoplewith 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): diagnosis and management. NICE guideline CG165 (2013, updated 2017), 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's guideline on hepatitis B (chronic)]

Recommended intervals for monitoring

Monitoring intervals for people who do not meet the criteria for antiviral treatment are outlined in NICE's guideline on hepatitis B (chronic). 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 to 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's guideline on hepatitis B (chronic). These vary with infection status, age and clinical

status. [NICE's guideline on hepatitis B (chronic), recommendations 1.5.1 to 1.5.50]

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: 6-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

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by provider organisations, for example from service pathways or protocols.

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: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

Outcome

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

Data source: No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

What the quality statement means for different audiences

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 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 NICE's guideline on hepatitis B (chronic), section 1.7.

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): diagnosis and management. NICE guideline CG165 (2013, updated 2017), 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's guideline on hepatitis B (chronic)]

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 NICE's full guideline on hepatitis B (chronic)]

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 website, accessed June 2014]

Surveillance testing

The 6-monthly surveillance testing for hepatocellular carcinoma is carried out by hepatic ultrasound and alpha-fetoprotein testing. [NICE's guideline on hepatitis B (chronic), recommendation 1.7.1]

Update information

Minor changes since publication

May 2022: Changes have been made to align this quality standard with the updated NICE guideline on vaccine uptake in the general population. Links, source guidance references and data sources have been updated throughout.

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.

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, this may not always be appropriate in practice. Taking account of safety, shared decision-making, choice and professional judgement, desired levels of achievement should be defined locally.

Information about how NICE quality standards are developed is available from the NICE website.

See our webpage on quality standards advisory committees for details about our standing committees. Information about the topic experts invited to join the standing members is available from the webpage for this quality standard.

NICE has produced a quality standard service improvement template to help providers make an initial assessment of their service compared with a selection of quality statements. This tool is updated monthly to include new quality standards.

NICE guidance and quality standards apply in England and Wales. Decisions on how they apply in Scotland and Northern Ireland are made by the Scottish government and Northern Ireland Executive. NICE quality standards may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Diversity, equality and language

Equality issues were considered during development and equality assessments for this quality standard are available. Any specific issues identified during development of the

quality statements are highlighted in each statement.

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.

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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 (RCGP)
- Royal College of Nursing (RCN)
- Royal College of Obstetricians and Gynaecologists