

Liver disease

NICE quality standard

Draft for consultation

December 2016

This quality standard covers the identification, assessment and management of chronic liver disease in adults, young people and children, and cirrhosis in adults and young people. It describes high-quality care in priority areas for improvement. It does not cover treatment for liver cancer.

It is for commissioners, service providers, health, public health and social care practitioners, and the public.

This is the draft quality standard for consultation (from 19 December 2016 to 2 February 2017). The final quality standard is expected to publish in June 2017.

Quality statements

[Statement 1](#) Adults, young people and children newly diagnosed with non-alcoholic fatty liver disease are given healthy lifestyle advice.

[Statement 2](#) Adults, young people and children with non-alcoholic fatty liver disease are offered regular testing for advanced liver fibrosis.

[Statement 3](#) Adults and young people with risk factors for cirrhosis are offered non-invasive testing for cirrhosis.

[Statement 4](#) Adults and young people with cirrhosis who do not have hepatitis B are offered 6-monthly ultrasound surveillance for hepatocellular carcinoma.

[Statement 5](#) Adults and young people with cirrhosis who have medium to large oesophageal varices are offered endoscopic variceal band ligation for the primary prevention of bleeding.

NICE has developed guidance and a quality standard on patient experience in adult NHS services (see the NICE pathway on [patient experience in adult NHS services](#)), which should be considered alongside these quality statements.

Other quality standards that should be considered when commissioning or providing liver disease services include:

- [Transition from children's to adults' services](#) Publication expected December 2016
- [Obesity: clinical assessment and management](#) (2016) NICE quality standard 127
- [Obesity in adults: prevention and lifestyle weight management programmes](#) (2016) NICE quality standard 111
- [Obesity in children and young people: prevention and lifestyle weight management programmes](#) (2015) NICE quality standard 94
- [Alcohol: preventing harmful use in the community](#) (2015) NICE quality standard 83
- [Hepatitis B](#) (2014) NICE quality standard 65

- [Acute upper gastrointestinal bleeding in adults](#) (2013) NICE quality standard 38
- [End of life care for adults](#) (2011) NICE quality standard 13
- [Alcohol-use disorders: diagnosis and management](#) (2011) NICE quality standard 11

A full list of NICE quality standards is available from the [quality standards topic library](#).

Questions for consultation

Questions about the quality standard

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

Question 2 Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?

Question 3 Do you have an example from practice of implementing the NICE guidelines that underpin this quality standard? If so, please submit your example to the [NICE local practice collection](#) on the NICE website. Examples of using NICE quality standards can also be submitted.

Question 4 Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Questions about the individual quality statements

Question 5 For draft quality statement 1: Lifestyle interventions for people who are overweight or obese are included in the NICE quality standards on [obesity in children and young people](#) and [obesity in adults](#). In this context, is it helpful for this quality standard to include this statement on healthy lifestyle advice for people of all ages who are diagnosed with non-alcoholic fatty liver disease?

Question 6 For draft quality statement 2: This statement currently includes adults, young people and children. Does the priority for quality improvement apply to adults and young people only?

Quality statement 1: Healthy lifestyle advice

Quality statement

Adults, young people and children newly diagnosed with non-alcoholic fatty liver disease are given healthy lifestyle advice.

Rationale

Adopting a healthy lifestyle can reduce the rate of progression of non-alcoholic fatty liver disease (NAFLD). Providing healthy lifestyle advice to people when they are diagnosed with NAFLD can encourage them to consider changes they can make to help them avoid more serious liver disease.

Quality measures

Structure

Evidence of local arrangements to provide healthy lifestyle advice to adults, young people and children newly diagnosed with NAFLD.

Data source: Local data collection.

Process

Proportion of adults, young people and children newly diagnosed with NAFLD who are given healthy lifestyle advice.

Numerator – the number in the denominator who are given healthy lifestyle advice.

Denominator – the number of adults, young people and children newly diagnosed with NAFLD.

Data source: Local data collection.

Outcome

Rate of disease progression among adults, young people and children diagnosed with NAFLD.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (general practices and community healthcare providers) ensure that they give healthy lifestyle advice to adults, young people and children who are newly diagnosed with NAFLD.

Healthcare professionals (such as GPs and practice nurses) give healthy lifestyle advice to adults, young people and children who are newly diagnosed with NAFLD.

Commissioners (such as clinical commissioning groups and NHS England) commission services that provide healthy lifestyle advice to adults, young people and children who are newly diagnosed with NAFLD.

People diagnosed with non-alcoholic fatty liver disease are given advice on weight loss (if needed), exercise and staying within the government's guidelines on how much alcohol is safe to drink. Following this advice can help to improve the non-alcoholic fatty liver disease or stop it from getting worse.

Source guidance

[Non-alcoholic fatty liver disease \(NAFLD\): assessment and management](#) (2016)
NICE guideline NG49, recommendations 1.2.12, 1.2.13 and 1.2.16.

Definitions of terms used in this quality statement

Adults, young people and children

Adults are aged over 18. Young people are aged 16 and 17. Children are aged under 16. [NICE's guideline on [non-alcoholic fatty liver disease](#)]

Healthy lifestyle advice

People diagnosed with non-alcoholic fatty liver disease should be advised that:

- there is some evidence that exercise reduces liver fat content
- it is important to stay within the national recommended limits for alcohol consumption.

People diagnosed with non-alcoholic fatty liver disease who are overweight or obese should be offered advice on physical activity and diet.

[NICE's guideline on [non-alcoholic fatty liver disease](#) recommendations 1.2.12, 1.2.13 and 1.2.16]

Question for consultation

Lifestyle interventions for people who are overweight or obese are included in the NICE quality standards on [obesity in children and young people](#) and [obesity in adults](#). In this context, is it helpful for this quality standard to include this statement on healthy lifestyle advice for people of all ages who are diagnosed with non-alcoholic fatty liver disease?

Quality statement 2: Testing for advanced liver fibrosis in people with non-alcoholic fatty liver disease

Quality statement

Adults, young people and children with non-alcoholic fatty liver disease are offered regular testing for advanced liver fibrosis.

Rationale

There is a risk that non-alcoholic fatty liver disease (NAFLD) will progress to fibrosis and then to cirrhosis. Regular testing for advanced liver fibrosis for people with NAFLD will enable those at high risk of disease progression to be identified so that they can receive the support they need. Children with NAFLD who are diagnosed with advanced liver fibrosis should already be supported by a paediatric specialist in hepatology in tertiary care. Adults and young people who are diagnosed with advanced liver fibrosis should be referred to a specialist in hepatology for support. Identifying people at low risk of disease progression will ensure that they are not offered unnecessary tests.

Quality measures

Structure

Evidence that GP practices and paediatric hepatology services have arrangements to offer regular testing for advanced liver fibrosis to adults, young people and children with NAFLD.

Data source: Local data collection.

Process

a) Proportion of adults, young people and children newly diagnosed with NAFLD who are tested for advanced liver fibrosis.

Numerator – the number in the denominator who are tested for advanced liver fibrosis.

Denominator – the number of adults, young people and children newly diagnosed with NAFLD.

Data source: Local data collection.

b) Proportion of adults with NAFLD identified as having a low risk of advanced liver fibrosis (such as an ELF score below 10.51) who were tested for advanced liver fibrosis within the past 3 years.

Numerator – the number in the denominator who were tested for advanced liver fibrosis within the past 3 years.

Denominator – the number of adults with NAFLD identified as having a low risk of advanced liver fibrosis (such as an ELF score below 10.51).

Data source: Local data collection.

c) Proportion of children and young people with NAFLD identified as having a low risk of advanced liver fibrosis (such as an ELF score below 10.51) who were tested for advanced liver fibrosis within the past 2 years.

Numerator – the number in the denominator who were tested for advanced liver fibrosis within the past 2 years.

Denominator – the number of children and young people with NAFLD identified as having a low risk of advanced liver fibrosis (such as an ELF score below 10.51).

Data source: Local data collection.

Outcome

Incidence of advanced liver fibrosis in people with NAFLD.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (such as general practices and tertiary paediatric hepatology services) ensure that processes are in place to offer regular testing for advanced liver fibrosis to people diagnosed with NAFLD. Adults and young people diagnosed

with advanced liver fibrosis should be referred to a specialist in hepatology. Children diagnosed with advanced liver fibrosis will continue to be cared for by a tertiary paediatric hepatology service.

Healthcare professionals (such as GPs and paediatric hepatologists in tertiary care) offer testing for advanced liver fibrosis to adults, young people and children newly diagnosed with NAFLD and regular re-testing to those identified as having a low risk of advanced liver fibrosis (such as an enhanced liver fibrosis score below 10.51). Healthcare professionals should refer adults and young people diagnosed with advanced liver fibrosis to a specialist in hepatology. Children diagnosed with advanced liver fibrosis will continue to be cared for by a tertiary paediatric hepatology service.

Commissioners (such as clinical commissioning groups and NHS England) commission services that offer initial testing and re-testing for advanced liver fibrosis to adults, young people and children diagnosed with NAFLD. Commissioners ensure that there is sufficient capacity in hepatology services to meet expected demand for referrals for adults and young people with NAFLD who are diagnosed with advanced liver fibrosis. Commissioners ensure that tertiary paediatric hepatology services have capacity to support children diagnosed with advanced liver fibrosis.

People diagnosed with non- alcoholic fatty liver disease have a test to check if their liver is scarred. The test will be repeated every 3 years for adults and every 2 years for children and young people. If liver scarring is found, adults and young people will be referred to a specialist in hepatology so that they can get the help they need to prevent their liver disease getting worse. Children will get the help they need from a paediatric specialist in hepatology.

Source guidance

[Non-alcoholic fatty liver disease \(NAFLD\): assessment and management](#) (2016)

NICE guideline NG49, recommendations 1.2.1 and 1.2.7.

Definitions of terms used in this quality statement

Adults, young people and children

Adults are aged over 18. Young people are aged 16 and 17. Children are aged under 16. [NICE's guideline on [non-alcoholic fatty liver disease](#)]

Regular testing for advanced liver fibrosis

Testing for advanced liver fibrosis, for example with the enhanced liver fibrosis (ELF) test, should be offered to adults every 3 years and to children and young people every 2 years. [NICE's guideline on [non-alcoholic fatty liver disease](#) recommendations 1.2.2, 1.2.7 and 1.2.8]

Advanced liver fibrosis

A grade of F3 or above using the Kleiner (NASH-CRN) or the steatosis, activity and fibrosis (SAF) score. This is referred to as bridging fibrosis (the presence of fibrosis linking hepatic veins to portal tracts). [NICE's guideline on [non-alcoholic fatty liver disease](#)]

Question for consultation

This statement currently includes adults, young people and children. Does the priority for quality improvement apply to adults and young people only?

Quality statement 3: Non-invasive testing for cirrhosis

Quality statement

Adults and young people with risk factors for cirrhosis are offered non-invasive testing for cirrhosis.

Rationale

Cirrhosis may cause few or no symptoms and the condition may not be identified until serious complications arise. Adults and young people with risk factors for cirrhosis should therefore be tested to find out if they have cirrhosis. Diagnosing cirrhosis will ensure that they get the treatment and support that they need to manage their condition. Non-invasive testing is more acceptable to patients than a liver biopsy and allows liver fibrosis to be assessed in an outpatient setting with results available immediately.

Quality measures

Structure

Evidence of local arrangements and written clinical protocols to ensure that adults and young people with risk factors for cirrhosis are offered non-invasive testing for cirrhosis.

Data source: Local data collection.

Process

Proportion of adults and young people with risk factors for cirrhosis who are offered non-invasive testing for cirrhosis.

Numerator – the number in the denominator who are offered non-invasive testing for cirrhosis.

Denominator – the number of adults and young people with risk factors for cirrhosis.

Data source: Local data collection.

Outcome

Incidence of cirrhosis.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (such as general practices and secondary care services) ensure that they offer adults and young people with risk factors for cirrhosis non-invasive testing for cirrhosis and provide them with information about the accuracy, limitations and risks of the different tests for diagnosing cirrhosis.

Healthcare professionals (such as GPs, mental health practitioners, gastroenterologists and hepatologists) offer non-invasive testing for cirrhosis to adults and young people with risk factors for cirrhosis, and discuss the accuracy, limitations and risks of the different tests for diagnosing cirrhosis with them.

Commissioners (such as clinical commissioning groups and NHS England) commission services that offer non-invasive testing for cirrhosis to adults and young people with risk factors for cirrhosis and provide information about the accuracy, limitations and risks of the different tests for diagnosing cirrhosis.

Adults and young people who have a risk of cirrhosis either because they drink alcohol in a harmful way, or they have hepatitis B or C, alcohol-related liver disease or non-alcoholic fatty liver disease with advanced fibrosis, are offered a scan to check for cirrhosis. If cirrhosis is found, they will be offered support to manage their condition.

Source guidance

- [Cirrhosis in over 16s: assessment and management](#) (2016) NICE guideline NG50 recommendations 1.1.3 and 1.1.4
- [Hepatitis B \(chronic\) : diagnosis and management](#) (2013) NICE guideline CG165 recommendation 1.3.3

Definitions of terms used in this quality statement

Adults and young people

Adults are aged over 18. Young people are aged 16 and 17. [NICE's guideline on [non-alcoholic fatty liver disease](#)]

Risk factors for cirrhosis

Adults and young people have risk factors for cirrhosis if they:

- drink alcohol in a harmful way, defined as more than 50 units of alcohol per week for men and more than 35 units per week for women, and have done so for several months
- have hepatitis C virus infection
- have been newly referred for assessment for hepatitis B virus infection
- have been diagnosed with alcohol-related liver disease
- have been diagnosed with non-alcoholic fatty liver disease with advanced liver fibrosis.

[NICE's guideline on [cirrhosis in over 16s](#) recommendations 1.1.3 and 1.1.4 and NICE's guideline on [hepatitis B \(chronic\)](#) recommendation 1.3.3]

Non-invasive testing for cirrhosis

Non-invasive testing for cirrhosis includes:

- transient elastography (for all people with risk factors for cirrhosis) or
- acoustic radiation force impulse imaging (for adults and young people with non-alcoholic fatty liver disease and advanced liver fibrosis).

[NICE's guideline on [cirrhosis in over 16s](#) recommendations 1.1.3 and 1.1.4 and NICE's guideline on [hepatitis B \(chronic\)](#) recommendation 1.3.3]

Equality and diversity considerations

Community outreach services should support people who are homeless and known to be drinking alcohol in a harmful way to enable them to have access to non-invasive testing for cirrhosis.

Quality statement 4: Surveillance for hepatocellular carcinoma

Quality statement

Adults and young people with cirrhosis who do not have hepatitis B virus infection are offered 6-monthly ultrasound surveillance for hepatocellular carcinoma.

Rationale

The NICE quality standard on [hepatitis B](#) includes the statement: 'Adults with chronic hepatitis B infection who have significant liver fibrosis or cirrhosis are offered 6-monthly surveillance testing for hepatocellular carcinoma'. Cirrhosis is a substantial risk factor for hepatocellular carcinoma and the same surveillance is needed for adults and young people who have cirrhosis but do not have hepatitis B.

Hepatocellular carcinoma develops quickly and may be asymptomatic until it is advanced. Regular surveillance of adults and young people with cirrhosis at 6-month intervals helps to ensure that it is detected early so that treatment can begin promptly which can improve the person's chances of survival.

Quality measures

Structure

Evidence of local arrangements to ensure that adults and young people with cirrhosis who do not have hepatitis B virus infection are offered 6-monthly ultrasound surveillance for hepatocellular carcinoma.

Data source: Local data collection.

Process

Proportion of adults and young people with cirrhosis who do not have hepatitis B virus infection who received ultrasound surveillance for hepatocellular carcinoma within the past 6 months.

Numerator – the number in the denominator who received ultrasound surveillance for hepatocellular carcinoma within the past 6 months.

Denominator – the number of adults and young people with cirrhosis who do not have hepatitis B virus infection.

Data source: Local data collection.

Outcome

Proportion of adults and young people with cirrhosis who are diagnosed with hepatocellular carcinoma at an early stage.

Numerator – the number in the denominator who are diagnosed with hepatocellular carcinoma at an early stage.

Denominator – the number of adults and young people with cirrhosis who are diagnosed with hepatocellular carcinoma.

Data source: Local data collection. Early-stage diagnosis may be based, for example, on stages 0 or A of the Barcelona Clinic Liver Staging classification.

What the quality statement means for different audiences

Service providers (such as general hospitals and specialist liver centres) ensure that adults and young people with cirrhosis who do not have hepatitis B virus infection are offered 6-monthly ultrasound as surveillance for hepatocellular carcinoma.

Healthcare professionals (such as consultants and hepatologists) offer 6-monthly ultrasound as surveillance for hepatocellular carcinoma to adults and young people with cirrhosis who do not have hepatitis B virus infection.

Commissioners (such as clinical commissioning groups) commission services that offer 6-monthly ultrasound as surveillance for hepatocellular carcinoma to adults and young people with cirrhosis who do not have hepatitis B virus infection.

Adults and young people with cirrhosis who do not have hepatitis B should have an ultrasound scan to check for liver cancer every 6 months. This will ensure that treatment can be provided as early as possible if liver cancer develops.

Source guidance

[Cirrhosis in over 16s: assessment and management](#) (2016) NICE guideline NG50 recommendation 1.2.4.

Definitions of terms used in this quality statement

Adults and young people

Adults are aged over 18. Young people are aged 16 and 17. [NICE's guideline on [non-alcoholic fatty liver disease](#)]

People with cirrhosis who do not have hepatitis B virus infection

People diagnosed with cirrhosis who do not have hepatitis B virus infection excluding people who are receiving end of life care. [NICE's guideline on [cirrhosis in over 16s](#) recommendations 1.2.4 and 1.2.6]

Equality and diversity considerations

Adults and young people with cirrhosis who are homeless may need additional support from community outreach services to ensure that they attend for 6-monthly surveillance for hepatocellular carcinoma.

Quality statement 5: Variceal band ligation for the primary prevention of bleeding

Quality statement

Adults and young people with cirrhosis who have medium to large oesophageal varices are offered endoscopic variceal band ligation for the primary prevention of bleeding.

Rationale

People with cirrhosis who have oesophageal varices are at risk of bleeding, which can result in death. Band ligation can prevent the occurrence of variceal bleeding and bleeding-related mortality in people who have medium to large oesophageal varices.

Quality measures

Structure

Evidence of local arrangements and written clinical protocols to ensure that adults and young people with cirrhosis who have medium to large oesophageal varices are offered endoscopic variceal band ligation for the primary prevention of bleeding.

Data source: Local data collection.

Process

Proportion of adults and young people with cirrhosis who have medium to large oesophageal varices who receive endoscopic variceal band ligation for the primary prevention of bleeding.

Numerator – the number in the denominator who receive endoscopic variceal band ligation for the primary prevention of bleeding.

Denominator – the number of adults and young people with cirrhosis who have medium to large oesophageal varices.

Data source: Local data collection.

Outcomes

a) Hospital admission rate for adults and young people with cirrhosis who have primary upper gastrointestinal bleeding due to oesophageal varices.

Data source: Local data collection. NHS Digital [Hospital episode statistics](#) collect data on emergency admissions for people with cirrhosis.

b) Bleeding-related mortality rate in adults and young people with cirrhosis.

Data source: Local data collection.

What the quality statement means for different audiences

Service providers (such as general hospitals and specialist liver centres) ensure that local arrangements and written clinical protocols are in place for adults and young people with cirrhosis who have medium to large oesophageal varices to be offered endoscopic variceal band ligation for the primary prevention of bleeding.

Health care professionals (such as consultants and hepatologists) offer endoscopic variceal band ligation to adults and young people with cirrhosis who have medium to large oesophageal varices for the primary prevention of bleeding.

Commissioners (such as clinical commissioning groups) commission services that offer endoscopic variceal band ligation to adults and young people with cirrhosis who have medium to large oesophageal varices for the primary prevention of bleeding.

Adults and young people with cirrhosis who have medium to large swollen veins inside the oesophagus have a procedure to tie off the swollen veins. This is to prevent bleeding.

Source guidance

[Cirrhosis in over 16s: assessment and management](#) (2016) NICE guideline NG50 recommendation 1.3.1.

Definitions of terms used in this quality statement

Adults and young people

Adults are aged over 18. Young people are aged 16 and 17. [NICE's guideline on [non-alcoholic fatty liver disease](#)]

Medium to large oesophageal varices

Dilated blood vessels in the oesophagus that arise as a result of portal hypertension. Medium varices are defined as tortuous veins occupying less than one-third of the oesophageal lumen, and large varices are those occupying more than one-third of the oesophageal lumen. [NICE's full guideline on [cirrhosis in over 16s](#) and expert opinion]

Endoscopic variceal band ligation

A procedure in which an enlarged vein or a varix in the oesophagus is tied off or ligated by a rubber band delivered via an endoscope. [NICE's full guideline on [cirrhosis in over 16s](#)]

Equality and diversity considerations

Adults and young people with cirrhosis who are homeless may need additional support from community outreach services to ensure that they attend for checks to detect oesophageal varices.

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.

Information about [how NICE quality standards are developed](#) is available from the NICE website.

See [quality standard advisory committees](#) on the website for details of standing committee 2 members who advised on this quality standard. Information about the topic experts invited to join the standing members is available on the [quality standard's webpage](#).

This quality standard has been incorporated into the NICE pathway on [liver conditions](#).

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 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.

Improving outcomes

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

- diagnosis of liver disease

- progression of liver disease
- detection of hepatocellular carcinoma
- health-related quality of life for people with liver disease
- hospital admissions for people with liver disease
- length of hospital stay for people with liver disease
- hospital re-admission rates for people with liver disease
- mortality associated with liver disease.

It is also expected to support delivery of the Department of Health's outcome frameworks:

- [Adult social care outcomes framework 2015–16](#)
- [NHS outcomes framework 2016–17](#)
- [Public health outcomes framework for England, 2016–19](#).

Resource impact

NICE quality standards should be achievable by local services. The potential resource impact is considered by the quality standards advisory committee, drawing on resource impact work for the source guidance. Organisations are encouraged to use the resource impact products for the source guidance to help estimate local costs:

- [resource impact template](#) for the NICE guideline on non-alcoholic fatty liver disease
- [resource impact template](#) for the NICE guideline on cirrhosis
- [costing template](#) for the NICE guideline on hepatitis B.

Diversity, equality and language

During the development of this quality standard, equality issues were considered and [equality assessments](#) 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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