NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards and indicators

Briefing paper

Quality standard topic: Liver disease

Output: Prioritised quality improvement areas for development.

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Contents

1 Introduction

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

1.1 Structure

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

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

1.2 Development sources

The key development sources referenced in this briefing paper are:

Cirrhosis in over 16s NICE guideline NG50 (2016). Next review July 2018.

Non-alcoholic fatty liver disease (NAFLD) NICE guideline NG49 (2016). Next review July 2018.

Hepatitis B (chronic) NICE guideline CG165 (2013). No review schedule presented.

Alcohol-use disorders: diagnosis and management of physical complications NICE guideline CG100 (2010). Review decision made April 2016 to update recommendations on corticosteroid treatment for alcohol‑related hepatitis.

2 Overview

2.1 Focus of quality standard

This quality standard will cover the identification, assessment and management of liver disease in adults, young people and children.

2.2 Definition

Liver disease is largely preventable. While approximately 5% of liver disease is attributable to autoimmune disorders (diseases characterised by abnormal functioning of the immune system), most liver disease is due to three main risk factors: alcohol, obesity and viral hepatitis.

Steatosis (fatty liver) is an accumulation of fat in the liver. Fatty liver disease is divided into:

- Alcohol-related fatty liver disease – due to excessive alcohol consumption.
- Non-alcoholic fatty liver disease (NAFLD) – not due to excessive alcohol consumption or other secondary causes.

Excess fat in the liver may lead to early fibrosis and over time may progress to cirrhosis. For example, NAFLD ranges from hepatic steatosis (accumulation of fat on the liver), through inflammatory non-alcoholic steatohepatitis (NASH – fatty accumulation combined with inflammation and the thickening and scarring of connective tissue), to fibrosis (where scar tissue is formed in an inflamed liver) or cirrhosis (a chronic disease of the liver marked by degeneration of cells, inflammation, and fibrous thickening of tissue). This process depends on a number of different elements including the mechanism of injury, whether the injury continues, other risk factors (such as alcohol intake and obesity) and genetic polymorphisms.

Cirrhosis occurs as a response to liver damage. It is characterised at a cellular level by distortion of the normal liver structure into nodules of liver tissue surrounded by fibrosis. Cirrhosis usually develops over a period of years following exposure to one or more risk factors which cause inflammation and cell death within the liver. Cirrhosis may cause liver failure and portal hypertension (raised blood pressure within the liver), and can cause liver cancer (hepatocellular carcinoma). Liver failure and portal hypertension can lead to serious complications such as ascites (fluid in the abdomen), oesophageal varices (enlarged blood vessels) which may bleed acutely or chronically and hepatic encephalopathy (accumulation of toxins in blood causing confusion, agitation, difficulty speaking and muscle tremors).

2.3 Incidence and prevalence

The prevalence of NAFLD in the general population is estimated at 20–30%. Around 2–3% of the population have NASH. The prevalence of NAFLD is increasing, placing a greater burden on healthcare resources. The rate of progression of NAFLD is variable; being overweight and having diabetes are associated with an increased risk of progressive disease. The average age of people with NASH is 40–50 years and for NASH-cirrhosis 50–60 years. However, the emerging epidemic of childhood obesity means that increasing numbers of younger people have NAFLD, with some prevalence studies showing that up to 38% of obese children have evidence of NAFLD. With NAFLD progressing through its spectrum even in childhood, the age that people develop significant liver disease is likely to fall and early diagnosis and management are therefore important at all ages.

It usually takes several years for liver damage to develop into cirrhosis and approximately 10–20% of people with 1 of the 3 most common chronic liver diseases

(non-alcoholic fatty liver disease, alcohol-related liver disease and chronic viral hepatitis) develop cirrhosis over a period of 10–20 years. Although people may have physical signs of cirrhosis or its complications, such as jaundice, abdominal swelling due to ascites, muscle wasting, and (in male patients) breast enlargement and testicular atrophy, the clinical identification of cirrhosis is imperfect, especially in people with compensated disease. In addition, 40% of people with cirrhosis have no symptoms of liver disease. People with cirrhosis face a significant risk of decompensated liver disease if they remain untreated. Five-year survival rates among people with untreated decompensated cirrhosis can be as low as 15%.

In 2011, the Chief Medical Officer[1] identified liver disease as one of the key issues for health in England because it is the only major cause of mortality and morbidity which is on the increase. Public Health England's Liver Disease Profiles identify that between 2001 and 2014 the number of people who died with an underlying cause of liver disease in England rose from 7,841 to 11,597. This represents a 48% increase in deaths associated with liver disease during this period and is in contrast to other major causes of disease which have been declining. NHS England's Five Year Forward View identifies that 90% of people who die from liver disease are under 70 years old. The most common underlying causes of death from liver disease are alcoholic liver disease and liver cancer (0.8 percent and 0.5 percent of all deaths).

2.4 Management

Early diagnosis and treatment (of those at risk and those with early stage disease) can lead to reversibility of liver disease. Unfortunately, liver disease often develops silently and frequently presents with late complications by which time morbidity and mortality is high.

NAFLD is usually first suspected in primary care incidentally either by abnormal liver blood tests or an abnormal liver ultrasound appearance picked up as part of an investigation for an unrelated condition. The care pathway in primary care for someone with suspected NAFLD has been unclear, and practice regarding further investigation and referral varies widely. NAFLD is increasingly being identified through case-finding in hospital outpatient departments for people with associated conditions such as diabetes, obesity or hypertension. Once people with NAFLD have been referred to secondary care, their condition may be investigated further to determine whether or not they have progressive disease, however, this tends to be ad hoc. As there is currently no licensed treatment for NAFLD, most people are discharged back to their GP. Some people are given advice on lifestyle, which is usually focused on achieving weight loss, but, this is highly variable.

There is currently variation in practice across England in referrals from primary care for people with suspected cirrhosis for assessment in secondary care and in

[1] Chief Medical Officer annual report 2011 Department of Health

diagnostic tests for cirrhosis. The management of patients with confirmed cirrhosis is directed either to the prevention of complications or early intervention to stabilise disease progression in order to avoid or delay clinical decompensation and the need for liver transplantation.

The new NICE guidelines NG49 and NG50 have defined the approach to management for NAFLD and cirrhosis and the approach should become more consistent over time. See appendices 1–3 for the associated care pathway and algorithms from NICE guidelines NG49 and NG50.

2.5 National outcome frameworks

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 2016–17

Domain	Overarching indicators and improvement areas
1 Preventing people from dying prematurely	***Overarching indicators*** 1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare i Adults 1b Life expectancy at 75 i Males ii Females ***Improvement areas*** **Reducing premature mortality from the major causes of death** 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*** **Ensuring people feel supported to manage their condition** 2.1 Proportion of people feeling supported to manage their condition
4 Ensuring that people have a positive experience of care	***Overarching indicators*** 4a Patient experience of primary care i GP services 4b Patient experience of hospital care 4c *Friends and family test* *4d Patient experience characterised as poor or worse* *I Primary care* *ii Hospital care* ***Improvement areas*** **Improving people's experience of outpatient care** 4.1 Patient experience of outpatient services **Improving people's experience of integrated care** *4.9 People's experience of integrated care***
Alignment with Adult Social Care Outcomes Framework and/or Public Health Outcomes Framework * Indicator is shared ** Indicator is complementary Indicators in italics in development	

Table 2 Public health outcomes framework for England, 2016–2019

Domain	Objectives and indicators
1 Improving the wider determinants of health	***Objective*** Improvements against wider factors which affect health and wellbeing and health inequalities ***Indicators*** 1.09 Sickness absence rate
2 Health improvement	***Objective*** People are helped to live healthy lifestyles, make healthy choices and reduce health inequalities ***Indicators*** 2.06 Child excess weight in 4–5 and 10–11 year olds 2.11 Diet 2.12 Excess weight in adults 2.15 Drug and alcohol treatment completion and drug misuse deaths 2.18 Alcohol-related admissions to hospital
4 Healthcare public health and preventing premature mortality	***Objective*** Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities ***Indicators*** 4.03 Mortality rate from causes considered preventable** 4.06 Under 75 mortality rate from liver disease*
Alignment with Adult Social Care Outcomes Framework and/or NHS Outcomes Framework * Indicator is shared ** Indicator is complementary	

3 Summary of suggestions

3.1 Responses

In total 17 stakeholders responded to the 2-week engagement exercise 19/08/16 to 02/09/16.

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

Two stakeholders[2] made comments about the scope of the quality standard. There was some concern that the broad scope may lead to areas such as autoimmune hepatitis, primary biliary cirrhosis/cholangitis and liver disease in children and young people being overlooked. Additional development sources, policy reports and audits were also suggested for inclusion.

Full details of all the suggestions provided are given in appendix 6 for information.

[2] Norgine Pharmaceuticals Limited and Children's Liver Disease Foundation

Table 3 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
Identification of liver disease in primary care	
• Identification of liver disease in high risk groups	• BASL, BioUK, BLT, CLDF, NPL, RCGP, SCM,
• Use of liver blood tests	• BSG, RCGP, SCM, UKNSC
• Identifying people with NAFLD who should be referred to a specialist	• RCGP, SCMs
Management and support (excluding cirrhosis)	
• Lifestyle modifications	• PHE, RCGP, SCM
• Statins for people with NAFLD	• SCM
• Care plans	• SCM
• Management of autoimmune or genetic liver disease	• BLT, PDL
Diagnosis and management of cirrhosis	
• Diagnosis of cirrhosis	• SCMs
• Surveillance for hepatocellular carcinoma	• BSG, FLR, SCM
• Managing complications of cirrhosis	• NPL, SCM
Additional areas	
• Prevention of liver disease	• BASL, FLR
• Alcohol interventions	• BLT, BSPGHAN, CLDF, SCM
• Hepatitis B and C	• BASL, BSPGHAN, CAFA, CLDF, FLR, HepCCo, MSD, PHE, SCM
• Transition of children with liver disease to adult services	• BSG, PHE
• Variation in secondary care liver service provision	• BASL
• Liver cancer treatment	• BioUK
• End of life care	• BLT, PHE

BASL, British Association for the Study of the Liver
BioUK, Biocompatibles UK Ltd
BLT, British Liver Trust
BSG, British Society of Gastrenterology
BSPGHAN, British Society of Paediatric Gastroenterology, Hepatology and Nutrition
CAFA, CoramBAAF Adoption and Fostering Academy
CLDF, Children's Liver Disease Foundation
FLR, Foundation for Liver Research
HepCCo, The Hepatitis C Coalition
MSD, MSD UK Ltd
NPL, Norgine Pharmaceuticals Limited
PDL, Perspectum Diagnostics Ltd
PHE, Public Health England
SCM, Specialist Committee Member
UKNSC, UK National Screening Committee

3.2 Identification of current practice evidence

Bibliographic databases were searched to identify examples of current practice in UK health and social care settings; 1117 papers were identified for liver disease. In addition, 51 papers were suggested by stakeholders at topic engagement and 28 papers internally at project scoping.

Of these papers, 11 have been included in this report and are included in the current practice sections where relevant. Appendix 4 outlines the search process.

4 Suggested improvement areas

4.1 Identification of liver disease in primary care

4.1.1 Summary of suggestions

Identification of liver disease in high risk groups

Stakeholders[3] emphasised the need to improve earlier identification of liver disease in primary care and community services. It was suggested[4] that this could focus on identification of liver disease in people not known to have liver disease but in whom risk factors for liver disease are present such as alcohol use, obesity and type 2 diabetes. Identifying NAFLD in children was also highlighted as a specific priority[5]. Identifying liver disease earlier will enable support to be provided to prevent progression to advanced fibrosis and cirrhosis.

Use of liver blood tests

There was a request[6] for greater clarity about the use and interpretation of liver blood tests including re-testing. A stakeholder[7] highlighted that there is currently inconsistency in the response to abnormal liver blood tests, with some patients not being followed up.

It was also suggested[8] that liver blood tests are not useful in assessing the degree of liver damage and should not be used to rule out NAFLD or cirrhosis. There was a concern[9] to ensure that liver blood tests are not used as screening.

Identifying people with NAFLD who should be referred to a specialist

A stakeholder highlighted that there is a distinct pathway for adults with NAFLD (in contrast to those with suspected alcohol-related liver disease) which requires risk stratification in primary care to ensure that only those with advanced liver fibrosis who are at high risk of developing more serious liver disease are referred to a specialist[10]. This will reduce unnecessary testing for people at low risk and ensure that those at high risk get the support that they need. It was suggested that this will require GPs to use the enhanced liver fibrosis (ELF) test to assess for risk of fibrosis, although currently awareness and access to the test in primary care is reported as low.

[3] Biocompatibles UK Ltd, British Liver Trust, and Norgine Pharmaceuticals Limited
[4] British Association for the Study of the Liver, British Liver Trust, Royal College of General Practitioners, and Specialist Committee Member
[5] Children's Liver Disease Foundation and Royal College of General Practitioners
[6] Royal College of General Practitioners
[7] British Society for Gastroenterology
[8] Specialist Committee Member
[9] UK National Screening Committee
[10] Royal College of General Practitioners and Specialist Committee Members

The need to ensure that **all** children and young people with NAFLD are referred to a paediatric hepatology service was also identified[11].

4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 4 to help inform the committee's discussion.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Identification of liver disease in high risk groups	**Alcohol-related liver disease** NICE CG100 Recommendations 1.3.1.1 and 1.3.1.2 **Assessment for NAFLD** NICE NG49 Recommendations 1.1.1, 1.1.2, and 1.1.4 **Non-invasive tests for diagnosing NAFLD in adults** NICE NG49 Research Recommendation 1
Use of liver blood tests	**Alcohol-related liver disease** NICE CG100 Recommendations 1.3.1.1 **Assessment and referral in primary care** NICE CG165 Recommendation 1.2.1 **Assessment for NAFLD** NICE NG49 Recommendations 1.1.3 **Assessment for advanced liver fibrosis in people with NAFLD** NICE NG49 Recommendations 1.2.3
Identifying people with NAFLD who should be referred to a specialist	**Assessment for NAFLD** NICE NG49 Recommendation 1.1.5 **Assessment for advanced liver fibrosis in people with NAFLD** NICE NG49 Recommendations 1.2.1, 1.2.2, 1.2.4, and 1.2.5 **Non-invasive tests for diagnosing NASH** NICE NG49 Research Recommendation 2 **Non-invasive tests for diagnosing NAFLD and advanced liver fibrosis in children and young people** NICE NG49 Research Recommendation 3

[11] Specialist Committee Member

Identification of liver disease in high risk groups

Alcohol-related liver disease

NICE CG100 Recommendation 1.3.1.1

Exclude alternative causes of liver disease in people with a history of harmful or hazardous drinking who have abnormal liver blood test results.

NICE CG100 Recommendation 1.3.1.2

Refer people to a specialist experienced in the management of alcohol-related liver disease to confirm a clinical diagnosis of alcohol-related liver disease.

Assessment for NAFLD

NICE NG49 Recommendation 1.1.1

Be aware that non-alcoholic fatty liver disease (NAFLD) is more common in people who have:

- type 2 diabetes or
- metabolic syndrome.

NICE NG49 Recommendation 1.1.2

Take an alcohol history to rule out alcohol-related liver disease.

NICE NG49 Recommendation 1.1.4

Offer a liver ultrasound to test children and young people for NAFLD if they:

- have type 2 diabetes or metabolic syndrome and
- do not misuse alcohol.

Non-invasive tests for diagnosing NAFLD in adults

NICE NG49 research recommendation 1

Which non-invasive tests are most accurate and cost-effective in identifying non-alcoholic fatty liver disease (NAFLD) in adults with risk factors, type 2 diabetes and metabolic syndrome?

Use of liver blood tests

Assessment and referral in primary care

NICE CG165 Recommendation 1.2.1 (key priority for implementation)

Arrange the following tests in primary care for adults who are hepatitis B surface antigen (HBsAg) positive[12]:

- additional laboratory tests including alanine aminotransferase (ALT) or aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), serum albumin, total bilirubin, total globulins, full blood count and prothrombin time
- tests for hepatocellular carcinoma (HCC), including hepatic ultrasound and alpha-fetoprotein testing.

Assessment for NAFLD

NICE NG49 Recommendation 1.1.3

Do not use routine liver blood tests to rule out NAFLD.

Assessment for advanced liver fibrosis in people with NAFLD

NICE NG49 Recommendation 1.2.3

Do not use routine liver blood tests to assess for advanced liver fibrosis in people with NAFLD.

Identifying people with NAFLD who should be referred to a specialist

Assessment for NAFLD

NICE NG49 Recommendation 1.1.5

Refer children with suspected NAFLD to a relevant paediatric specialist in hepatology in tertiary care.

Assessment for advanced liver fibrosis in people with NAFLD

NICE NG49 Recommendation 1.2.1

Offer testing for advanced liver fibrosis to people with NAFLD.

NICE NG49 Recommendation 1.2.2

Consider using the enhanced liver fibrosis (ELF) test in people who have been diagnosed with NAFLD to test for advanced liver fibrosis.

[12] NB: Tests that do not relate to liver disease have been excluded.

NICE NG49 Recommendation 1.2.4

Diagnose people with advanced liver fibrosis if they have:

- an ELF score of 10.51 or above and
- NAFLD.

NICE NG49 Recommendation 1.2.5

Refer adults and young people diagnosed with advanced liver fibrosis to a relevant specialist in hepatology.

Non-invasive tests for diagnosing NASH

NICE NG49 research recommendation 2

Which non-invasive tests most accurately identify non-alcoholic steatohepatitis (NASH) in people with non-alcoholic fatty liver disease (NAFLD)?

Non-invasive tests for diagnosing NAFLD and advanced liver fibrosis in children and young people

NICE NG49 research recommendation 3

Which non-invasive tests most accurately diagnose NAFLD and advanced liver fibrosis in children and young people?

4.1.3 Current UK practice

Identification of liver disease in high risk groups

A small survey of GPs in the South West[13] found that only half of GPs indicated that they would think about the possibility of liver problems when they see obese patients presenting with a problem unrelated to their liver.

The guideline development group (GDG) for NAFLD[14] identified that NAFLD is usually first suspected in primary care incidentally either by abnormal liver blood tests or an abnormal liver ultrasound appearance picked up as part of an investigation for an unrelated condition. They agreed that many clinicians have the misperception that the finding of a person having normal liver blood tests is incompatible with them having NAFLD.

[13] Liver Disease in the South West: A health needs assessment Public Health England 2015
[14] Non-alcoholic fatty liver disease: Assessment and management NICE guideline NG49 (2016)

Use of liver blood tests

The survey of GPs in the South West[15] in 2015 found that in response to abnormal liver function tests (LFTs) all of the respondents (52) said they would repeat and carry out a number of further risk checks (screen for alcohol misuse, review BMI/waist circumference, screen for blood borne viruses, request ultrasound scan or use flowchart/guidelines). A number of GPs mentioned local guidelines and map of medicine guidelines for management of abnormal LFTs. Another survey question highlighted concern among GPs about a lack of evidence about management, especially in regards to management of abnormal LFTs.

A local audit in inner east London[16] concluded that large numbers of people with abnormal liver function tests have insufficient investigation to make a diagnosis.

Two Abnormal LFTs in the past 2 years	**11,235 Cases**	
Had Audit C	7,010	60.7%
Had Virology	3,228	31.8%
Had Ultrasound	438	3.5%
Had All 3 tests	139	1.1%

Identifying people with NAFLD who should be referred to a specialist

The GDG for NAFLD[17] identified that prior to the guideline he care pathway in primary care for someone with suspected NAFLD was unclear, and practice regarding further investigation and referral varies widely.

A retrospective case note review of all patients with a diagnosis of NAFLD seen in gastroenterology or hepatology clinics in 2010-11 in Somerset[18] found that non-invasive risk stratification was performed in less than half of secondary care patients with NAFLD and only 2% of primary care referrals. Almost half of newly referred patients with full NAFLD assessment were deemed dischargeable after the first visit and may not have required referral into secondary care.

The survey of GPs in the South West in 2015 asked about referral for treatment of liver disease and treatment of risk factors for liver disease, with only one-third feeling that there were clear pathways available in their area. Of those who did feel that there were clear pathways these were very rarely formally recorded. Approximately one-third of GP's would refer for NAFLD, with more (around half) referring for NASH. Many indicated that they would conduct certain investigations and use these to decide whether they would refer, and that there was limited evidence about who to

[15] Liver Disease in the South West: A health needs assessment Public Health England 2015
[16] Managing Abnormal Liver Tests in Primary Care Barts and the London Queen Mary's School of Medicine and Dentistry Clinical Effectiveness Group (2015)
[17] Non-alcoholic fatty liver disease: Assessment and management NICE guideline NG49 (2016)
[18] Non-alcoholic fatty liver disease: A Somerset service evaluation study Chalmers, Pugh and Matull United European Gastroenterology Journal Conference 2013

refer and the benefits of referral since a mainstay of treatment was weight loss and management of metabolic syndrome.

4.1.4 Resource impact

Alcohol-related liver disease

When the guideline was published in 2010, the costing report did not identify the recommendations for ruling out alternative causes of liver disease and referral to a specialist to confirm diagnosis as having a significant resource impact.

Hepatitis B

When the guideline was published in 2013, the costing report stated that current practice was for people identified as being HBsAg positive in primary care to be referred to secondary care for additional testing. In areas where this is still current practice, the recommendation to carry out additional testing (including tests for liver disease) in primary care would mean a consultant-led follow-up appointment in hepatology could be avoided. and the cost of testing would transfer from secondary care to primary care.

NAFLD

Current practice varies, with some people with NAFLD monitored in primary care and others referred to secondary care for testing and follow-up. Testing all people with NAFLD for advanced liver fibrosis using the ELF test before they are referred to secondary care is likely to have a cost impact. This would be a change in practice in areas where testing is currently done in secondary care. It is estimated that an ELF test could cost around £42 compared to £164 for transient elastography and £494 for liver biopsy. The resource impact will depend on local practice.

There may also be some savings where inappropriate referrals to secondary care, and therefore the more expensive transient elastography and liver biopsy tests, are avoided.

4.2 Management and support (excluding cirrhosis)

4.2.1 Summary of suggestions

Lifestyle modifications relating to NAFLD

Stakeholders suggested[19] that the link between NAFLD and obesity needs to be emphasised more with advice about weight loss and diet being given to people with NAFLD in primary care. It was felt that recognising that the management of liver disease in primary care overlaps with the monitoring and management of other long-term conditions such as cardiovascular disease may reassure GPs that liver disease does not require a separate set of interventions.

Statins for people with NAFLD

There was a concern[20] that statins are sometimes stopped prematurely in people with liver disease because of the perceived risk of causing liver damage. As people with liver disease are at risk of developing cardiovascular disease, diabetes and stroke it was felt to be important to improve confidence in continuing statin prescribing after diagnosis of NAFLD or NASH.

Care plans

It was suggested[21] that it would be beneficial for people with liver disease to have a care plan to outline treatments and lifestyle modifications in the same way that people with hepatitis B do.

Management of autoimmune or genetic liver disease

Stakeholders[22] felt that there is a need to improve monitoring and management for people with autoimmune or genetic liver disease. There is a need to improve monitoring so that medication, which has significant side effects, can be managed better. Currently the tests available are either inaccurate or invasive.

4.2.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 5 to help inform the committee's discussion.

[19] Public Health England, Royal College of General Practitioners and Specialist Committee Member
[20] Specialist Committee Member
[21] Specialist Committee Member
[22] Perspectum Diagnostics Ltd and British Liver Trust

Table 5 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Lifestyle modifications relating to NAFLD	**Assessment for advanced liver fibrosis in people with NAFLD** NICE NG49 Recommendations 1.2.6, 1.2.12 to 1.2.14, and 1.2.16
Statins for people with NAFLD	**People with NAFLD who are taking statins** NICE NG49 Recommendations 1.3.1 and 1.3.2
Care plans	Not directly covered in the development sources and no recommendations are presented
Management of autoimmune or genetic liver disease	Not directly covered in the development sources and no recommendations are presented

Assessment for advanced liver fibrosis in people with NAFLD

NICE NG49 Recommendation 1.2.6

Explain to people with an ELF score below 10.51 that:

- they are unlikely to have advanced liver fibrosis

Give the person advice about lifestyle modifications they may be able to make (see section 1.2).

NICE NG49 Recommendation 1.2.12

Offer advice on physical activity and diet to people with NAFLD who are overweight or obese in line with NICE's obesity and preventing excess weight gain guidelines.

NICE NG49 Recommendation 1.2.13

Explain to people with NAFLD that there is some evidence that exercise reduces liver fat content.

NICE NG49 Recommendation 1.2.14

Consider the lifestyle interventions in NICE's obesity guideline for people with NAFLD regardless of their BMI.

NICE NG49 Recommendation 1.2.16

Explain to people with NAFLD who drink alcohol the importance of staying within the national recommended limits for alcohol consumption.

People with NAFLD who are taking statins

NICE NG49 Recommendation 1.3.1

Be aware that people with NAFLD who are taking statins should keep taking them.

NICE NG49 Recommendation 1.3.2

Only consider stopping statins if liver enzyme levels double within 3 months of starting statins, including in people with abnormal baseline liver blood results.

4.2.3 Current UK practice

Lifestyle modifications relating to NAFLD

The GDG for NAFLD[23] agreed that weight reduction advice is now widely viewed by clinicians as part of routine care for people with NAFLD. They noted that currently only short-term lifestyle modifications programmes (up to 12 weeks) funded by the NHS are available in many areas.

Statins for people with NAFLD

No published studies on current practice were found for this suggested area for quality improvement.

Care plans

No published studies on current practice were found for this suggested area for quality improvement.

Management of autoimmune or genetic liver disease

An audit of the provision of care for patients with autoimmune hepatitis in 27 hospitals across the UK[24] concluded that in contrast to chronic viral hepatitis, there has been little development of subspecialisation amongst gastroenterology and hepatology physicians and nurses in regard to management of autoimmune hepatitis. There is variability in service provision for people with autoimmune hepatitis (including the availability of specialists and the overall management approach) but the study concluded that it is unclear if this influences outcome.

4.2.4 Resource impact

Resource impact information is not available in source guidelines because these areas were not expected to have a significant resource impact. Lifestyle

[23] Non-alcoholic fatty liver disease: Assessment and management NICE guideline NG49 (2016)
[24] Provision of care for patients with autoimmune hepatitis (AIH) in 27 hospitals across the UK Gordon (2015) Gut 2015;64(Suppl 1):A1–A584

interventions have been recommended in several NICE guidelines, including for people with NAFLD, risk factors of obesity and type 2 diabetes and therefore would not be anticipated to require significant additional investment.

4.3 Diagnosis and management of cirrhosis

4.3.1 Summary of suggestions

Diagnosis of cirrhosis

It was suggested[25] that there is currently variation in access to non-invasive diagnostic tests (transient elastography and acoustic radiation force impulse imaging) for cirrhosis in primary and secondary care. These tests avoid the need for a liver biopsy and are more acceptable to patients. There was a suggestion that improved access to these tests could help to break down barriers to the management of liver disease in primary care.

Surveillance for hepatocellular carcinoma

Stakeholders[26] identified the importance of surveillance for primary hepatocellular carcinoma (HCC) in people with cirrhosis to ensure early detection and improve clinical outcomes.

Managing complications of cirrhosis

It was suggested[27] that improving the management of complications of cirrhosis (ascites, hepatic encephalopathy and variceal bleeding) will improve clinical outcomes and reduce the burden on healthcare resources. In particular, it was suggested that priorities should include the prevention of variceal bleeding and hepatic encephalopathy and prophylactic intravenous antibiotics for people with cirrhosis who have upper gastrointestinal bleeding. These complications are associated with a high risk of mortality and improved management can reduce risk.

4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development sources that may support potential statement development. These are presented in full after table 6 to help inform the committee's discussion.

[25] Specialist committee members
[26] British Society for Gastroenterology, Foundation for Liver Research and Specialist Committee Member
[27] Norgine Pharmaceuticals Limited and Specialist Committee Member

Table 6 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Diagnosis of cirrhosis	**Diagnosis** NICE NG50 Recommendations 1.1.3 and 1.1.4 **Assessment of liver disease in secondary specialist care** NICE CG165 Recommendations 1.3.3 and 1.3.8
Surveillance for hepatocellular carcinoma	**Monitoring** NICE NG50 Recommendations 1.2.4 to 1.2.6 **Surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B** NICE CG165 Recommendations 1.7.1 to 1.7.3
Managing complications of cirrhosis	**Managing complications** NICE NG50 Recommendations 1.3.1 to 1.3.5 **Acute hepatic encephalopathy** NICE NG49 Research Recommendation 5 **Rifaximin for preventing episodes of overt hepatic encephalopathy** NICE TA337

Diagnosis of cirrhosis

Diagnosis

NICE NG50 Recommendation 1.1.3

Offer transient elastography to diagnose cirrhosis for:

- people with hepatitis C virus infection
- men who drink over 50 units of alcohol per week and women who drink over 35 units of alcohol per week and have done so for several months
- people diagnosed with alcohol-related liver disease.

NICE NG50 Recommendation 1.1.4

Offer either transient elastography or acoustic radiation force impulse imaging (whichever is available) to diagnose cirrhosis for people with NAFLD and advanced liver fibrosis (as diagnosed by a score of 10.51 or above using the enhanced liver fibrosis [ELF] test).

Assessment of liver disease in secondary specialist care

NICE CG165 Recommendation 1.3.3

Offer transient elastography as the initial test for liver disease in adults newly referred for assessment.

NICE CG165 Recommendation 1.3.8

Offer an annual reassessment of liver disease using transient elastography to adults who are not taking antiviral treatment.

Surveillance for hepatocellular carcinoma

Monitoring

NICE NG50 Recommendation 1.2.4

Offer ultrasound (with or without measurement of serum alpha‑fetoprotein) every 6 months as surveillance for hepatocellular carcinoma (HCC) for people with cirrhosis who do not have hepatitis B virus infection.

NICE NG50 Recommendation 1.2.5

For people with cirrhosis and hepatitis B virus infection, see the surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B section in NICE's hepatitis B (chronic) guideline.

NICE NG50 Recommendation 1.2.6

Do not offer surveillance for HCC for people who are receiving end of life care.

Surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B

NICE CG165 Recommendation 1.7.1[28]

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

NICE CG165 Recommendation 1.7.2

In people without significant fibrosis or cirrhosis (METAVIR stage less than F2 or Ishak stage less than 3), consider 6-monthly surveillance for HCC if the person is older than 40 years and has a family history of HCC and HBV DNA greater than or equal to 20,000 IU/ml.

[28] NB: This recommendation is the evidence base for statement 7 in QS65 Hepatitis B on six-monthly surveillance testing for hepatocellular carcinoma in adults with chronic hepatitis B infection who have significant liver fibrosis or cirrhosis.

NICE CG165 Recommendation 1.7.3

Do not offer surveillance for HCC in people without significant fibrosis or cirrhosis (METAVIR stage less than F2 or Ishak stage less than 3) who have HBV DNA less than 20,000 IU/ml and are younger than 40 years.

Managing complications of cirrhosis

Managing complications

NICE NG50 Recommendation 1.3.1

Offer endoscopic variceal band ligation for the primary prevention of bleeding for people with cirrhosis who have medium to large oesophageal varices.

NICE NG50 Recommendation 1.3.2

Offer prophylactic intravenous antibiotics for people with cirrhosis who have upper gastrointestinal bleeding.

NICE NG50 Recommendation 1.3.3

Review intravenous antibiotics prescriptions in line with the prescribing intravenous antimicrobials section in NICE's antimicrobial stewardship guideline.

NICE NG50 Recommendation 1.3.4

Consider a transjugular intrahepatic portosystemic shunt for people with cirrhosis who have refractory ascites.

NICE NG50 Recommendation 1.3.5

Offer prophylactic oral ciprofloxacin or norfloxacin[1] for people with cirrhosis and ascites with an ascitic protein of 15 g/litre or less, until the ascites has resolved.

Acute hepatic encephalopathy

NICE NG50 Research Recommendation 5

In people with cirrhosis and an acute episode of hepatic encephalopathy secondary to a clearly identified, potentially reversible precipitating factor, does management of the precipitating event alone improve the hepatic encephalopathy without specific treatment?

Rifaximin for preventing episodes of overt hepatic encephalopathy

NICE TA337

Rifaximin is recommended, within its marketing authorisation, as an option for reducing the recurrence of episodes of overt hepatic encephalopathy in people aged 18 years or older.

4.3.3 Current UK practice

Diagnosis of cirrhosis

No published studies on current practice were found for this suggested area for quality improvement. An example of local practice in this area identifies the potential benefits of non-invasive testing.

Frimley Park Hospital NHS Foundation Trust[29] introduced transient elastography to improve the management of liver disease in people with chronic hepatitis B in 2013. This enabled them to achieve early diagnosis of hepatic fibrosis and cirrhosis. For some patients diagnosed early with hepatic fibrosis, cirrhosis was either prevented or delayed. Long-term financial gains from the early diagnosis of cirrhosis with implementation of screening protocols should lead to a decrease in hospital admissions for these patients in the future.

Surveillance for hepatocellular carcinoma

A 2014 survey of the provision of ultrasound surveillance for the detection of HCC in the UK[30] (responses from 131 acute hospital trusts) found that although the majority of hospitals (97%) carried out ultrasound surveillance, only 62% ensured this was carried out on a regular 6-monthly basis. The true interval between scans was often unknown due to poor data collection. Clinicians were often unaware of how their surveillance programme was performing. There was also some difference of opinion as to who should be entered into a surveillance programme. The study concluded that the provision of surveillance was poor overall, with many hospitals lacking the necessary mechanisms to make abnormal results, if detected, known to referring clinicians. For the majority of new cases of HCC diagnosis was being made only at an incurable late stage (60%).

Following a local audit of cirrhotic patients managed at the Royal United Hospital in Bath which found that only 24.1% of eligible patients received regular 6 monthly surveillance over an 18 month period, a survey was carried out in 2014 to assess policy and practice in the South West and Wales[31]. 81 responses were received from 16 NHS trusts. This found that while there was general agreement that 6 monthly surveillance should be afforded to patients with cirrhosis secondary to

[29] Use of transient elastography to assess liver disease in people with chronic hepatitis B NICE shared learning database 2013
[30] A national survey of the provision of ultrasound surveillance for the detection of hepatocellular carcinoma Cross et al (2015) Frontline Gastroenterology doi:10.1136/flgastro-2015-100617
[31] Surveillance of hepatocellular carcinoma – consistent or confused? Hudson, Lee and Maltby Gut 2014;63:A181

haemochromatosis and alcohol when abstinent, opinion was divided in respect to patients who continued to drink, and in those with non-cirrhotic chronic hepatitis B. Poor patient compliance and insufficient resources and expertise to co-ordinate surveillance programmes were cited as the main barriers to successful surveillance. 86% of respondents felt HCC surveillance could be improved within their institution.

A 2013 survey of 42 gastroenterologists and hepatologists in Wales[32] found that 39/42 offered surveillance to patients with cirrhosis although some offered it only annually and some used either ultrasound or alphafetoprotein but not both. Only 78.5% agreed surveillance should be offered to all patients with cirrhosis. Others would only offer it to patients who are abstinent from alcohol or only to people with viral hepatitis and cirrhosis.

Managing complications of cirrhosis

The NICE resource impact report for cirrhosis[33] indicates that variceal band ligation is usually performed in people who have already had bleeding from varices (NB: there is a quality statement on this in QS38 acute upper gastrointestinal bleeding). The current standard of care to prevent bleeding in people with medium to large varices is to offer beta blockers. Analysis of hospital episode statistics shows that around 26% (693) of people with medium to large varices are given variceal band ligation to prevent bleeding. Not all people may be able to undergo variceal band ligation because of risks associated with the surgery and their condition.

A 2012 study of service provision for liver disease in the UK[34] with responses from 106 hospitals found that most hospitals use banding for variceal bleeding. Although almost all hospitals routinely used antibiotics, a significant proportion were using untested combinations that may not offer the necessary spectrum of cover, and the spectrum used remains broad.

A 2013 review of patients who died with alcohol-related liver disease[35] found that in the 39 patients with variceal bleeding, three were not given antibiotics.

The GDG for the cirrhosis guideline[36] noted that there is considerable variation in practice regarding the type of antibiotic and the route of delivery for upper gastrointestinal bleeding. NB: There is a quality statement on prophylactic antibiotic therapy for variceal bleeding in QS38 acute upper gastrointestinal bleeding in adults which does not specify intravenous antibiotics.

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[32] Variation in practice of hepatocellular carcinoma (HCC) surveillance Sugumaran and Ch'ng United European Gastroenterology Journal.Conference: 21st United European Gastroenterology Week Berlin Germany.Conference

[33] Resource impact report: Cirrhosis in over 16s: assessment and management NICE (2016)

[34] Service provision for liver disease in the UK: a national questionnaire-based survey Scott et al Clin Med April 1, 2012 vol. 12 no. 2 114-118

[35] Measuring the Units: A review of patients who died with alcohol-related liver disease National Confidential Enquiry into Patient Outcome and Death (2013)

[36] Cirrhosis in over 16s: Assessment and management NICE full guideline NG50 (2016)

The GDG also noted wide variation in UK practice and were concerned that there are patients who may benefit from transjugular intrahepatic portosystemic shunt but who are not being offered this service either as a holding procedure for transplant or as a definitive procedure.

A 2013 survey of 25 gastroenterologists and endoscopists in Wales[37] found that 16.7% do not start prophylactic antibiotics after an episode of spontaneous bacterial peritonitis in people with cirrhosis and ascites but others favoured Ciprofloxacin (50%) and Norfloxacin (30%).

The GDG for the cirrhosis guideline[38] identified that there is currently variation in the treatment of an acute hepatic encephalopathy episode on a national level. They wanted to develop a recommendation to standardise practice but evidence was sparse and low quality. They discussed that the most commonly used intervention currently is lactulose, and agreed that this current practice should continue until further research is carried out (see NG50 research recommendation 5).

4.3.4 Resource impact

Diagnosis of cirrhosis

In the resource impact tools for CG165, from the recommendations listed above, the recommendation to offer transient elastography as the initial test for liver disease in adults newly referred for assessment was considered to have a significant resource impact.

The report states that in 2013 there was wide variation nationally regarding the use of transient elastography as a method for assessing liver disease, and not all trusts had the technology. Non-recurrent capital expenditure was estimated at £50,000–£80,000 to purchase and install a transient elastography machine, and maintenance costs are estimated at £200 per annum. Although availability may have improved since 2013 there may be a resource impact in areas where access is still restricted.

The resource impact tools for NG50 identified the unit cost of transient elastography (FibroScan) as £164, comprising an ultrasound scan more than 20 minutes = £56, plus follow-up appointment as a hepatology outpatient = £108.

Surveillance for hepatocellular carcinoma

In the resource impact tools for NG50, from the recommendations listed above, the recommendation to offer ultrasound (every 6 months as surveillance for

[37] Variation in practice of management of spontaneous bacterial peritonitis Sugumaran Gut June 2013 Vol 62(Suppl 1):A1–A306
[38] Cirrhosis in over 16s: Assessment and management NICE full guideline NG50 (2016)

hepatocellular carcinoma (HCC) for people with cirrhosis who do not have hepatitis B virus infection was considered to have a significant resource impact.

The estimated number of people with cirrhosis in England who are eligible for 6-monthly surveillance for HCC is 50,706. Currently 62% of NHS Trusts offer surveillance every 6 months. If we assume that 62% of eligible people are currently offered and take up 6-monthly surveillance for HCC. After the NICE guideline is implemented it is estimated this could rise to 90%. The cost per person of 6-monthly surveillance for HCC is £331 per year, which results in an estimated resource impact of £2,349,000 in England each year.

Managing complications of cirrhosis

In the resource impact tools for NG50, from the recommendations listed above, the recommendation to offer endoscopic variceal band ligation for the primary prevention of bleeding for people with cirrhosis who have medium to large oesophageal varices was considered to have a significant resource impact.

Oesophageal varices are present in approximately 50% (25,353) of people who have cirrhosis. People with small varices develop large varices at a rate of 10.6% (2,687) per year. Analysis of hospital episode statistics shows that around 26% (693) of people with medium to large varices are given variceal band ligation to prevent bleeding. It is estimated that this could rise to 80% (2,150) of people in future practice. Between 2 and 3 procedures are needed per person over a year, giving an estimated cost of £1,235 per person. This results in an estimated resource impact of £1,799,000 in England each year or £12,350 for every extra 10 people treated. There may be savings from preventing bleeding events, the cost of which may range from £3,110 to £6,710. Estimated savings from reduced bleeding events range from £0.5 million to £1 million.

4.4 Additional areas

Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise. However they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or require further discussion by the committee to establish potential for statement development.

There will be an opportunity for the committee to discuss these areas at the end of the session on 13th October 2016.

Prevention of liver disease

Approaches to preventing liver disease focussed on reducing alcohol consumption and obesity were highlighted as a priority by stakeholders[39]. Other quality standards already cover these areas including alcohol: preventing harmful use in the community (QS83), obesity in adults: prevention and lifestyle weight management programmes (QS111) and obesity in children and young people: prevention and lifestyle weight management programmes (QS94). In addition, it would be beyond the scope of a quality standard to recommend minimum unit pricing for alcohol.

Alcohol interventions

Stakeholders[40] emphasised the importance of helping people with liver disease to stop or reduce the amount of alcohol they drink. It was suggested that Assertive Community Treatment and Alcohol Care Teams are effective at ensuring engagement and improving outcomes. Interventions for people who are drinking in a harmful way are included in a separate quality standard on alcohol-use disorders (QS11).

Hepatitis B and C

A number of stakeholder suggestions were received in relation to hepatitis B and C. These are either addressed in the separate quality standard on hepatitis B (QS65) or are likely to be within the scope of a future quality standard on hepatitis C:

- Improved awareness raising and testing for viral hepatitis in high risk groups, including babies and children of those at risk, in primary care and community

[39] British Association for the Study of the Liver and Foundation for Liver Research
[40] British Society for Gastroenterology and Public Health England

settings[41]. Hepatitis B and C are currently underdiagnosed and can progress to liver disease.

- Hepatitis B vaccination for people at risk, including babies, children and young people.[42]
- Referral of children and young people infected with hepatitis B and C to a specialist in paediatric infectious disease or hepatology.[43]
- Access to treatment for people with hepatitis B and C.[44]
- Collection of data on the Public Health England hepatitis C outcomes[45].

Transition of children with liver disease to adult services

It was highlighted[46] that there is a need to improve the transition to adult services for young people with liver disease as there is no clear transition pathway. This can have an impact on ongoing management and influence long term outcomes in adults. There was also a concern[47] about young people being cared for on adult liver wards. These issues will be addressed by the transition from children's to adult's services quality standard currently in development.

Variation in secondary care liver service provision

There was a concern[48] about geographical variation in access to secondary care services for people with liver disease. The specification of services is not covered in the development sources. By focussing on specific areas for quality improvement, including inappropriate variation in the quality of care, the quality standard will help to ensure services have the capacity to meet local needs.

Liver cancer treatment

There was a concern[49] about underfunding for liver cancer treatment in the NHS. Although treatment options are currently limited it was suggested that there needs to

[41] British Association for the Study of the Liver, British Society of Paediatric Gastroenterology, Hepatology and Nutrition, Coram BAAF Adoption and Fostering Academy, the Hepatitis C Coalition, MSDUK Ltd, Public Health England, Specialist Committee Member
[42] British Society of Paediatric Gastroenterology, Hepatology and Nutrition, Children's Liver Disease Foundation, Foundation for Liver Research, Public Health England
[43] British Society of Paediatric Gastroenterology, Hepatology and Nutrition and Specialist Committee Member
[44] The Hepatitis C Coalition, Public Health England
[45] The Hepatitis C Coalition
[46] British Liver Trust, British Society of Paediatric Gastroenterology, Hepatology and Nutrition and Specialist Committee Member
[47] Children's Liver Disease Foundation
[48] British Association for the Study of the Liver
[49] Biocompatibles UK Ltd

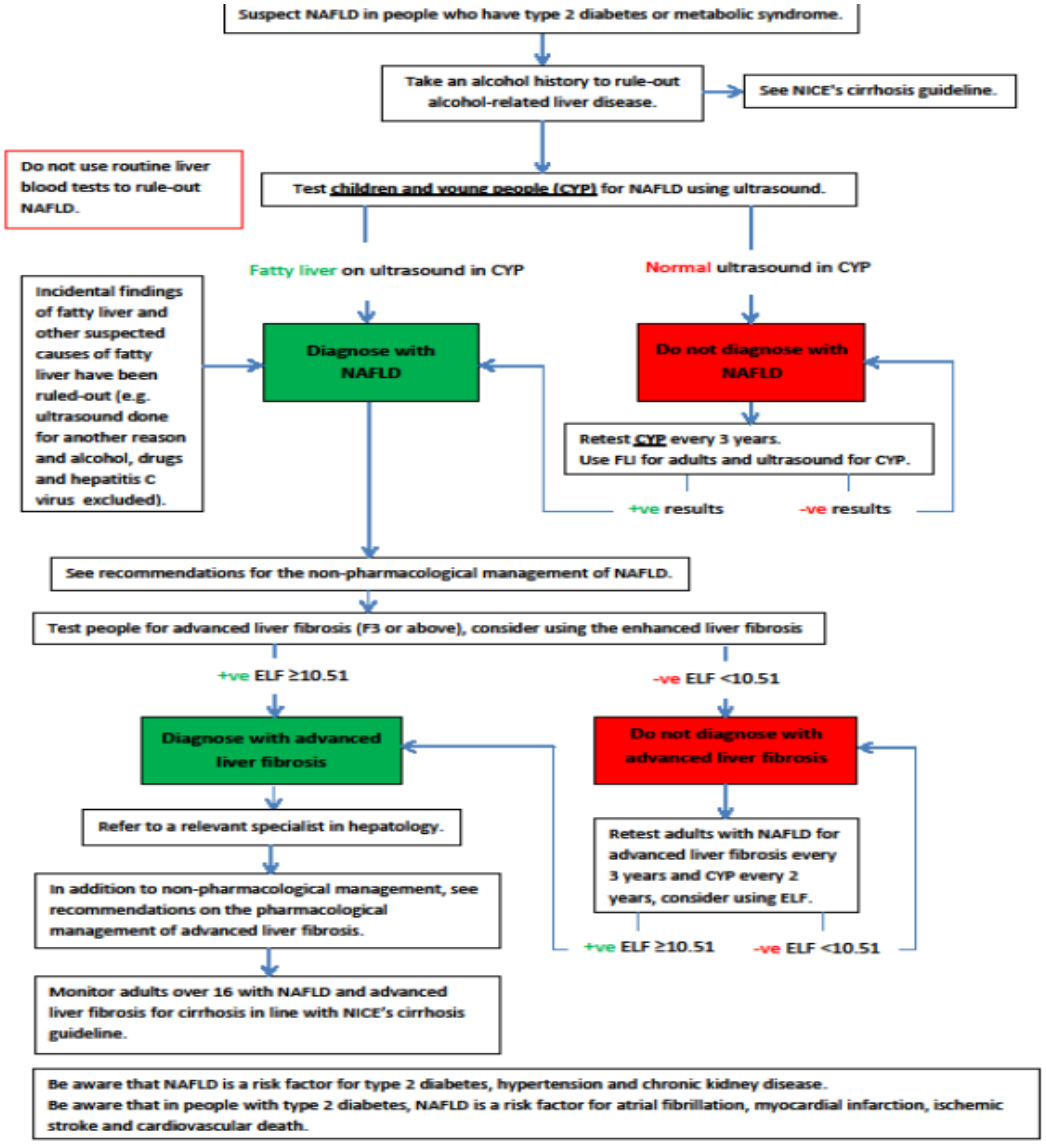
be more emphasis on providing access to emerging therapies such as selective internal radiation therapy. Liver cancer is beyond the scope of this quality standard.

End of life care

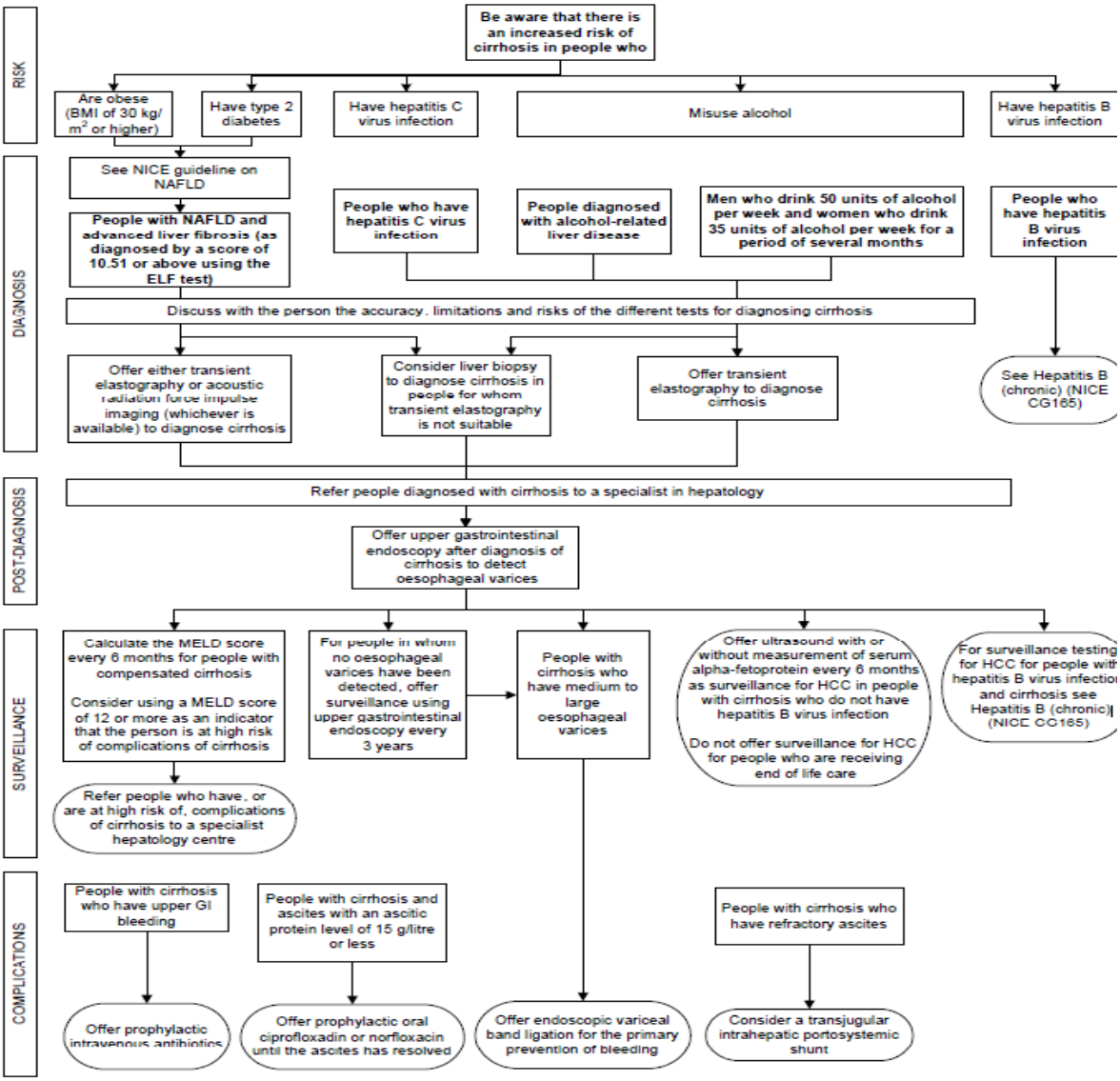
Stakeholders[50] were concerned that people with liver disease do not receive appropriate end of life care, with poor recognition and planning for death. These issues are covered in separate quality standards on end of life care for adults (QS13) and care of dying adults in the last days of life currently in development.

[50] British Liver Trust and Public Health England

Appendix 1: Assessment and monitoring of NAFLD in adults, children and young people

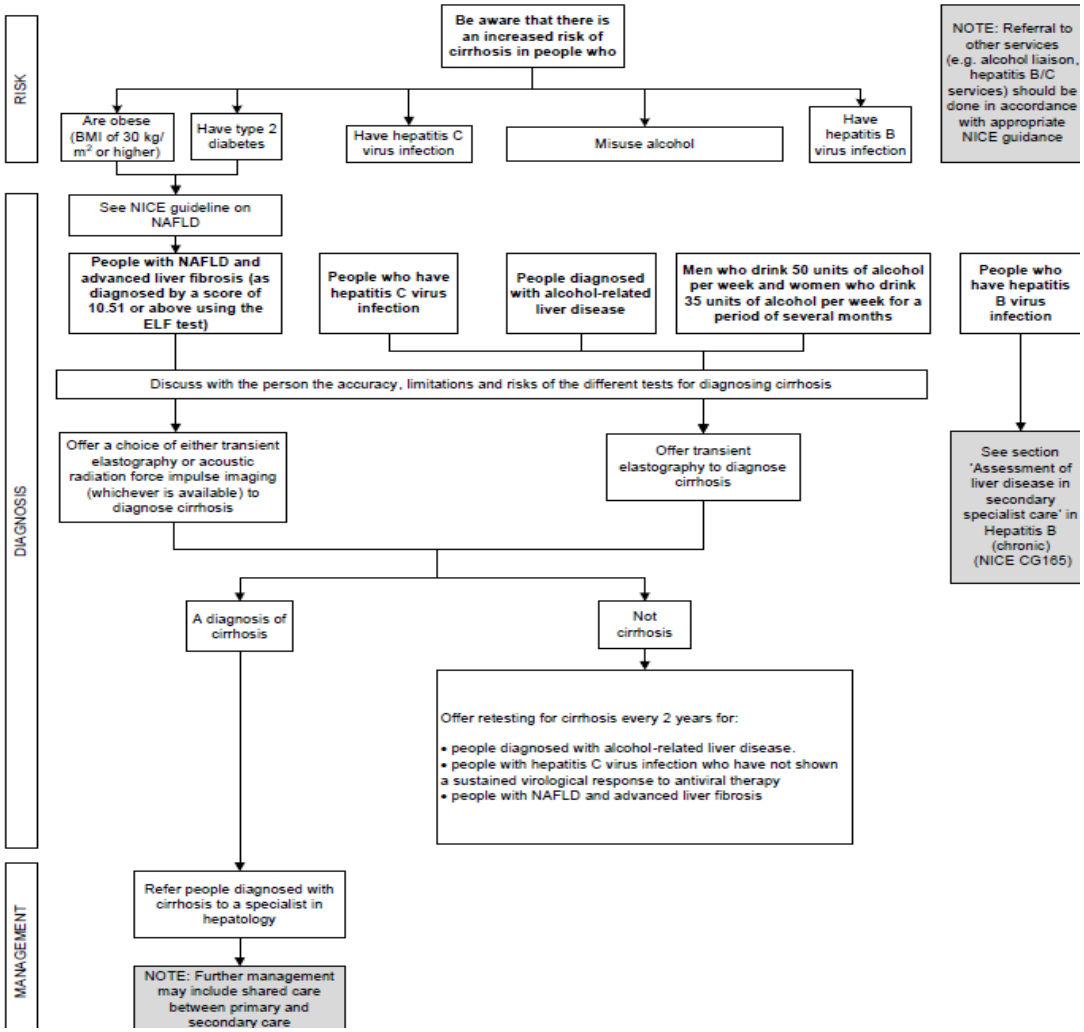


Appendix 2: Cirrhosis in over 16s: assessment and management

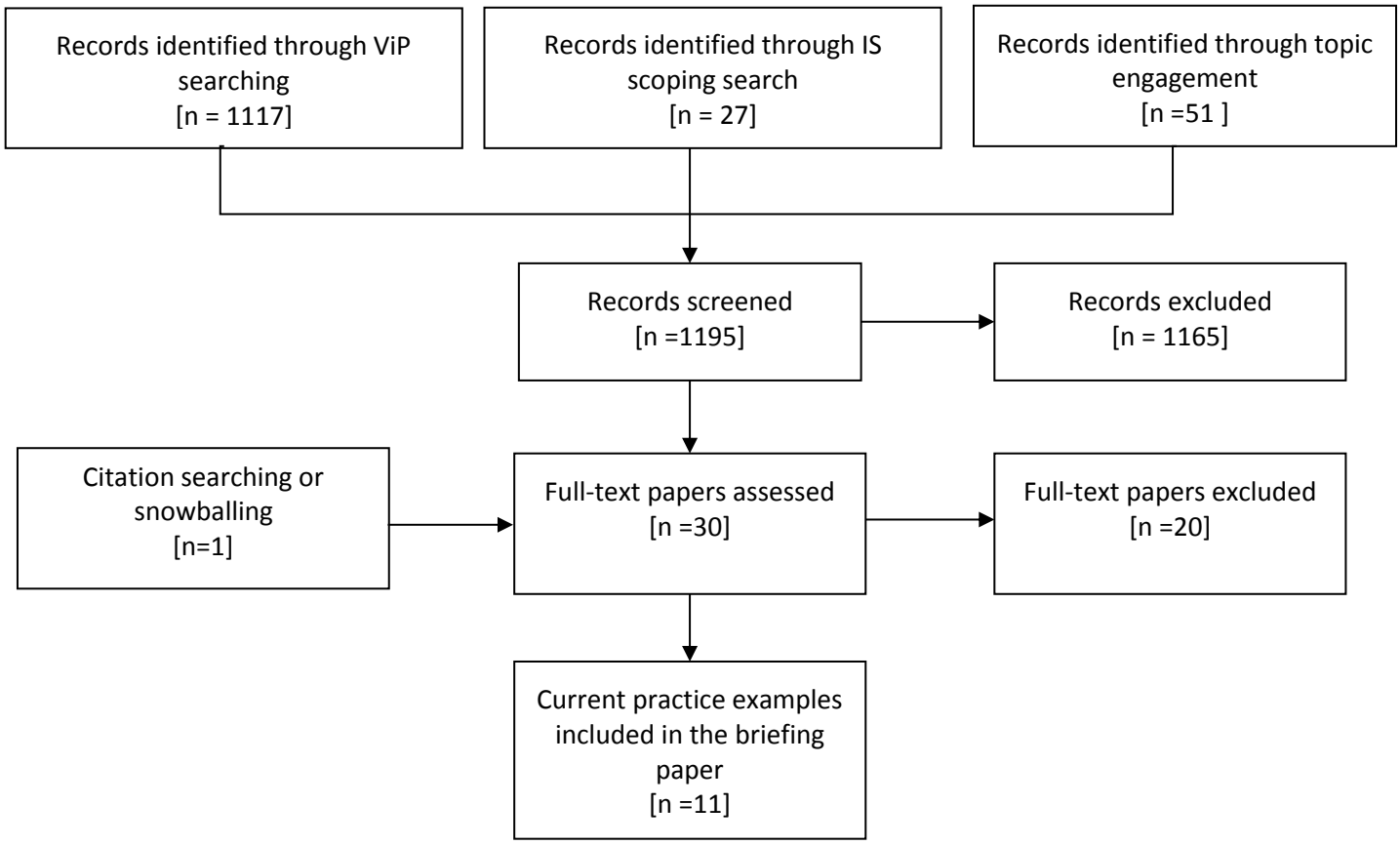


Appendix 3: Cirrhosis in over 16s: primary care pathway

Grey boxes indicate management outside of primary care.



Appendix 4: Review flowchart



Appendix 5: Suggestions from stakeholder engagement exercise – registered stakeholders

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
1	3.1	Norgine Pharmaceuticals Limited	· In the absence of a national database for liver disease it is unclear how adherence to the QS would be monitored. Establishing a national liver disease database would help monitor the implementation of these quality standards · The scope of this QS covers a broad disease area and diverse populations. Is it possible that the attempt to capture this broad area in a single set of QS may lead to areas being overlooked? · Will the population for this QS be limited to those groups listed in the topic overview? If so key populations e.g. AutoImmune Hepatitis, Primary Biliary Cirrhosis/Cholangitis would not be included. · The QS does not mention identification or management of complications of liver disease, should these be explicitly included in the topic overview? · The following NICE produced evidence should be added under other sources that may be used: o TA337 - Rifaximin for preventing episodes of overt hepatic encephalopathy o IPG535 - Living-donor liver transplantation o IPG479 - Subcutaneous implantation of a battery-powered catheter drainage system for managing refractory and recurrent ascites o IPG392 - Stent insertion for bleeding oesophageal varices o IPG316 - Extracorporeal albumin dialysis for acute liver failure · The following reports should be added under key policy documents, reports, and national audits: o Williams R, Aspinall R, Bellis M, et al. Addressing Liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity, and viral hepatitis. Lancet 2014; 384; 1953-1997. § The QS should reflect the ten key recommendations of the initial Lancet Commission report o Juniper et al. Measuring the Units: A review of patients who died with alcohol-related liver disease. http://www.ncepod.org.uk/2013report1/downloads/MeasuringTheUnits_FullReport.pdf			
2	3.1	Children's Liver Disease Foundation	Our feelings were that the current focus misses children and young people out to a great extent and focuses on preventable liver disease without any focus on childhood liver disease.			
Identification of liver disease in high risk groups						
3	4.1	Biocompatibles UK Ltd	Increasing prevalence	With changing migration patterns, increasing alcohol	Liver disease poses a significant societal burden. Identifying and	file:///C:/Users/ankld/Chrome

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
				consumption and an obesity epidemic, liver disease is an increasing problem. Liver cancer has increased by more than 50% in men and women in the last 10 years.	supporting disadvantaged patient groups could lead to improved outcomes. There is more to be done to lower UK liver cancer mortality rates, especially when we compare stats with the EU ranking.	%20Local%20Downloads/090625_NCIN_Incidence_and_Survival_by_Ethnic_Group_Report.pdf http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/liver-cancer/mortality#heading-Three

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
4	4.1	BASL	Key area for quality improvement 3	Improved identification of liver injury in primary care related to alcohol, obesity, type-2 diabetes mellitus	Newer techniques to detect liver injury are available. Subsequent interventions benefit patients	Please see the Lancet commission reports 2015 & 2016 Both Williams R et al. for ALL possible standards targets in primary, secondary and tertiary care.
5	4.1	British Liver Trust	Key area for quality improvement 1	EARLIER DIAGNOSIS IN PRIMARY CARE	CURRENTLY >75% OF PEOPLE WITH LIVER DISEASE ARE NOT DIAGNOSED UNTIL THEY ARE IN HOSPITAL WITH ADVANCED FIBROSIS or CIRRHOSIS	RCGP CLINICAL PRIORITY - LIVER DISEASE http://www.rcgp.org.uk/clinical-and-research/our-programmes/clinical-priorities.aspx LANCET COMMISSION ON LIVER DISEASE http://www.thelancet.com/commissions/crisis-of-liver-disease-in-the-UK
6	4.1	British Liver Trust	Key area for quality improvement 4	CLOSER ASSOCIATION OF TYPE 2 DIABETES AND NON ALCOHOL-RELATED FATTY LIVER DISEASE	ANYONE WITH TYPE 2 DIABETES IS AT RISK OF NAFLD	DIABETES UK - http://www.diabetes.co.uk/diabetes-complications/diabetes-and-fatty-liver-disease.html
7	4.1	Children's Liver Disease Foundation	The initial diagnosis of children with NAFLD			*No additional information provided by stakeholder*
8	4.1	Norgine Pharmaceuticals Limited	Strengthening detection of early liver disease and its treatment in primary care	As noted in Williams et al (2015), progression to more serious illness can be prevented by earlier	Williams et al (2015) reported analysis of 4313 first hospital admissions for cirrhosis or liver disease and compared this against	Data presented by Williams et al is taken from data for University Southampton Hospitals.

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
				detection.	time since referral to a liver clinic. Approximately 75% of patients had never been referred to a liver clinic at the time of their first admission. There is a need to ensure appropriate care earlier in the pathway to reduce admissions associated with liver disease.	Further discussion can be found in the Lancet paper: Williams R, Aspinall R, Bellis M, et al. Addressing Liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity, and viral hepatitis. Lancet 2014; 384; 1953-1997.

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
9	4.1	Norgine Pharmaceuticals Limited	Improvement of support services in the community for screening of people at high risk of liver disease	Williams et al (2015) noted the need for a greater quality of care to be provided at a local level in order to introduce management at an earlier stage and reduce morbidity and mortality caused by liver disease.	Williams et al (2015) reported analysis of 4313 first hospital admissions for cirrhosis or liver disease and compared this against time since referral to a liver clinic. Approximately 75% of patients had never been referred to a liver clinic at the time of their first admission. Improving support within the community may increase the number of patients that are referred to liver clinics, potentially reducing morbidity and mortality associated with liver disease.	Further discussion can be found in the Lancet paper: Williams R, Aspinall R, Bellis M, et al. Addressing Liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity, and viral hepatitis. Lancet 2014; 384; 1953-1997.
10	4.1	Royal College of General Practitioners	The management of NAFLD (JM)	The quality standard shall include the management of NAFLD within the context of the management of metabolic syndrome and obesity. The management in children as well as adults as they are being affected as well, and we are not routinely looking for it yet. It is even more worrying than in adults. (JM)		http://www.ncbi.nlm.nih.gov/pubmed/23329465 http://www.ncbi.nlm.nih.gov/pubmed/19921118 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3372499/
11	4.1	SCM 1	Promote NAFLD testing for those people who have Type 2 diabetes.	Many people with type 2 diabetes are not aware of the increased risk of NAFLD.		*No additional information provided by stakeholder*

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
				Statistics suggest people with Type 2 diabetes are more likely to have NAFLD. Raising awareness could improve the quality of life following a diagnosis and heath advice, e.g. lifestyle changes. Emergent		

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
Use of liver blood tests						
12	4.1	British Society for Gastroenterology	Interpretation and extent of investigation of abnormal liver blood tests	There is good evidence indicating that patients with abnormal liver blood tests are not being followed-up appropriately. This poses a clinical risk as an opportunity is being missed to intervene in patients with advanced liver disease. This is compounded by the rising burden of liver disease in the UK.	Standardising the response to abnormal liver blood tests will improve the quality of care to patients across the UK and also ensure more efficient utilisation of NHS resource.	NCEPOD as evidence of poor care National Confidential Enquiry into Patient Outcome and Death. Measuring the units: a review of patients who died with alcohol-related liver disease. Internet. London: NCEPOD; 2013. Available from: http://www.ncepod.org.uk/2013report1/downloads/Measuring%20the%20Units_full%20report.pdf Lancet Commission Addressing liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excessive consumption of alcohol, obesity and viral hepatitis Williams R, Aspinall R, Bellis M et al Lancet 2014 http://www.thelancet.com/commissions/crisis-of-liver-disease-in-the-UK

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
13	4.1	Royal College of General Practitioners	Liver function tests (JM)	The quality standard shall include the predictive value of normal and abnormal liver function tests, and horizon scanning about better tests. (JM)		*No additional information provided by stakeholder*
14	4.1	Royal College of General Practitioners	The value of screening (JM)	It would be recommended also to include: 1. How far we need to go in investigating abnormal liver function in terms of tests recommended, and how often we need to re test liver function tests. (JM)		http://www.ncbi.nlm.nih.gov/pubmed/25088047 (JM)

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
15	4.1	SCM 1	Do not use routine blood tests to rule out NAFLD. Variation in care.	It is a mistake to assume that a normal liver function test result implies a normal healthy liver. However it is unclear whether this is understood by all medical practitioners. This lack of awareness could mean that people who should be referred or given further tests are missed out. Area of variation in care. This is paramount for the diagnosis of NAFLD and other liver disease. Normal liver function test results do not infer a healthy liver free from NAFLD etc.	Why is this a key area for quality improvement? Many people may not be diagnosed because there liver function test are normal and no further action is taken. Are all medical practitioners aware of this? My personal experience would suggest that they are not. Whilst anecdotal evidence may not be acceptable this may be considered as an area for research or information gathering. Raising awareness.	*No additional information provided by stakeholder*
16	4.1	UK national screening committee	Key area for quality improvement 1	Liver disease is difficult to pick up, common and there are simple blood tests that people use to look for liver abnormalities. I think that in those circumstances NICE could easily find itself being faced with calls to test everyone using LFTs. This would be a national screening recommendation and subject to different governance		*No additional information provided by stakeholder*

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
				processes. I think an early discussion about how NICE and the UKNSC can ensure clear policy water between clinical quality standards and national screening programmes in relation to liver disease would be very useful and avoid difficulties further into the process when harder to unpick.		

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
Identifying people with NAFLD who should be referred to a specialist						
17	4.1	Royal College of General Practitioners	Clear guidance and route of referral for risk stratification of NAFLD in primary care required, with evaluation of impact on service use across the NHS. (RG)	NAFLD is common and increased detection of the diagnosis in primary care without robust risk stratification of high risk individuals leads to secondary care Hepatology services seeing high numbers of low risk patients (better managed in primary care) with low cirrhosis detection rates. In light of the new NICE guidance recommending risk stratification with ELF, clear guidance regarding referral from primary care has potential to change service usage across the NHS. (RG)	Further confidential information provided	Further confidential information provided
18	4.1	Royal College of General Practitioners	User friendly IT solutions encourage GPs to appropriately use risk stratification tools for NAFLD. (RG)	With increasing demand on GP time, IT solutions which aid quick risk stratification encourage them to do this accurately and to incorporate clinical judgment into decision-making. (RG)	Further confidential information provided	Further confidential information provided
19	4.1	SCM 2	Key area for quality	NAFLD has very high	Currently the ELF test is largely	The ELF test is not available

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			improvement 1 GPs are enabled to offer patients with NAFLD the ELF test to assess for risk of fibrosis and are reminded that LFTs are not useful in assessing degree of liver damage or confirming diagnosis of either NAFLD or cirrhosis.	prevalence but low risk of fibrosis. Picking out those at high risk will improve care by differentiating those who need close monitoring and reducing unnecessary testing of those at low risk.	unheard of by GPs and not available in most areas. Steps to promote awareness of a test that is not accessible may have a negative impact on primary care engagement in improving liver disease, as well as result in more expensive or less reliable tests being chosen (eg AST/ALT ratio or fibroscan). AST/ALT ratio is also not widely available because AST is not routinely included in the standard panel of LFTs unless it is individually requested – impractical for widespread uptake.	in my locality and there are no plans for it to be commissioned at present. Steps to drive prioritisation of investment in ELF testing by biochemistry labs would also provide an incentive to train primary care in the NAFLD pathway, for example by initiatives through the RCGP Clinical Priority Liver Disease programme.

ID	Report Section	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
20	4.1	SCM 3	Key area for quality improvement 2 Identification and referral or people with NAFLD and advanced liver fibrosis.	NAFLD is a common condition affecting 20-30% of the general population. A proportion of people with NAFLD will develop advanced liver fibrosis and cirrhosis, and may die from liver failure or hepatocellular carcinoma (HCC), or need a liver transplant. Early diagnosis and management of those with more advanced disease is therefore important. NICE recommends offering testing for advanced liver fibrosis to people with NAFLD and referral of adults and young people diagnosed with advanced liver fibrosis to a relevant specialist in Hepatology.	In the absence of previous established guidance, the care pathway in primary care for someone with suspected NAFLD has historically been unclear, and practice regarding further investigation and referral varies widely. In my own unit, introduction of local guidance to GP aimed at reducing referral of those with NAFLD and a low risk for advanced fibrosis actually led to an increase in total referrals, but weighted more towards those at intermediate or high risk of advanced fibrosis. This suggested that there was significant variation in practice prior to the guidance's introduction. In particular, it suggested that some GPs had been under-referring patients with NAFLD and advanced liver fibrosis. Such practice is likely to be replicated across England & Wales. A recent NAFLD clinical practice survey of UK gastroenterology and hepatology society members revealed wide variation in practice,	*No additional information provided by stakeholder*

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					including only 23% of respondents having local guidelines for NAFLD management (Sheridan DA et al. abstract in press.)	

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21	4.1	SCM 4	Children and young people with NAFLD are referred to an appropriate paediatric Hepatology service	To ensure all children and young people with NAFLD have access to the same diagnostic, monitoring and management options and facilities	Currently there is wide variation in referral practice to the 3 paediatric liver centres as well as variation in how patients are managed and monitored. This could impact differently on long term outcome and health in adulthood	Clinical guideline NG49
Lifestyle modifications						
22	4.2	Public Health England - Lead for Liver disease	Education of both Liver Disease and Obesity teams of the links between obesity and NAFLD, and of the prevention and treatment steps that can be taken	Obesity is an important risk factor for non-alcoholic fatty liver disease (NAFLD). Liver Disease teams should be aware that obesity treatment will help with NAFLD, and in addition Obesity teams should be aware that for their obese patients, obesity is a risk factor for NAFLD.	Our understanding of obesity related liver disease is still in its infancy. Non-alcoholic fatty liver disease (NAFLD) often goes undetected, not everyone with NAFLD has symptoms or abnormal LFT's. Obesity is a major risk factor for NAFLD. It is more prevalent among people who are obese.	Non-alcoholic fatty liver disease (NAFLD): assessment and management https://www.nice.org.uk/guidance/ng49
23	4.2	Royal College of General Practitioners	Increased guidance for patients and their GPs regarding advice for management of low risk NAFLD in primary care. (RG)	Simple NAFLD can progress to significant liver fibrosis in the absence of weight loss. Risk Stratification as per the NICE guidelines has the potential to increase the number of low risk patients remaining in primary care for management. (RG)	Further confidential information provided	Further confidential information provided
24	4.2	Royal College of General	Weight loss (AC)	Studies have found significant improvements with	Significant weight loss difficult to achieve – bariatric surgery needs to	Hepatology. 2004 Jun;39(6):1647-54

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		Practitioners		weight loss. (AC)	be considered. (AC)	(AC)

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25	4.2	Royal College of General Practitioners	Diet (AC)	Diets aimed at reducing cholesterol levels – accompanied by weight loss achieved by dietary means and exercise have been shown to be effective in reversing NAFLD. (AC)	NAFLD can occur in children – with the explosion in childhood obesity in UK and elsewhere, children's dietary habits need to be altered to avoid this. (AC)	*No additional information provided by stakeholder*
26	4.2	Royal College of General Practitioners	Diet (JM)	The quality standard shall include a comparison of different diets and the impact of a low carbohydrate diet on NAFLD. Children and transplant in relation to NAFLD and also a mention of low GI being better than low fat diets (JM)		http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4621466/ Dr David Unwin has some figures, http://www.diabesityinpractice.co.uk/media/content/_master/4311/files/pdf/dip4-3-102-8.pdf http://www.ncbi.nlm.nih.gov/pubmed/15598336
27	4.2	Royal College of General Practitioners	The value of screening (JM)	It would be recommended also to include: 1. How far we need to go in investigating abnormal liver function in terms of tests recommended, and how often we need to re test liver function tests. 2. Behaviour change in relation to both high junk food		http://www.ncbi.nlm.nih.gov/pubmed/25088047 (JM)

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				diets- resources in many media- face to face, written in print and digital media, group support , psychotherapeutic large group behaviour change. 3. Family and community approach would be useful as there is evidence that whole families often have varying degrees of obesity and NAFLD, and we know that overweight and obesity run at 65%. (JM)		

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28	4.2	SCM 2	Key area for quality improvement 3 Increased awareness that promotion of lifestyle improvement is linked to benefits in liver disease, as well as other health domains, in order to increase understanding of the breadth of benefits from encouraging lifestyle change	In order for liver disease to be considered as one of the 'big five' comorbidities there needs to be increased awareness that lifestyle advice applies to liver disease in the same way that it applies to CV and CKD risk etc, This step may reassure reluctant GPs that liver disease does not need a separate set of interventions or 'new work'. Much of the management crosses over with other chronic disease monitoring and management.	As there are no QOF drivers for improving liver disease, care needs to be taken to show that good care requires improved awareness rather than significant additional work for GPs, because much of the relevant monitoring and lifestyle management advice is already being issued for shared co-morbidities.	See panel 11, p 1981 R Williams et al. Lancet Commission: Addressing liver disease in the UK a blueprint for attaining excellence in health care and reduced premature mortality from lifestyle issues of excess consumption of alcohol, obesity and viral hepatitis. Lancet 2014; 384:1953-97
Statins for people with NAFLD						
29	4.2	SCM 2	Key area for quality improvement 2 Statin prescribing should be continued in the presence of metabolic liver disease unless liver enzyme levels double within 3 months of starting statins, even from an abnormal baseline.	Steps to improve confidence in continuing statin prescribing after diagnosis of NAFLD or NASH are likely to have knock-on benefits in relation to NAFLD awareness more generally. As the majority of people with NAFLD are at higher risk of CVD than of cirrhosis, statin prescribing is more likely to improve outcomes than risk liver damage, but confidence	Most people with liver disease carry significant risks of cardiovascular disease, diabetes and stroke, for which statins are indicated, but concern / confusion about the caution of using statins in liver disease means they are sometimes prematurely stopped http://www.sciencedirect.com/science/article/pii/S1590865814005970	There are conflicting messages regarding risk of statins in liver disease – for example http://www.slcsn.nhs.uk/files/prescribing/statins/statins-guidance-022009.pdf Clarity would be useful

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				in this message is low in primary care.		

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Care plans						
30	4.2	SCM 1	Care Plans are suggested for Hepatitis B might this practice be beneficial for all chronic liver disease.	These plans could outline treatments, lifestyle changes and could be updated as the condition progresses		*No additional information provided by stakeholder*
Management of autoimmune or genetic liver disease						
31	4.2	British Liver Trust	Key area for quality improvement 3	ACKNOWLEDGEMENT OF AND BETTER CARE FOR PEOPLE WITH AUTOIMMUNE OR GENETIC LIVER DISEASE	THESE CAUSES ARE OFTEN OVERSHADOWED BY THE NEEDS OF PEOPLE WITH PREVENTABLE LIVER DISEASE	UK AIH - http://www.uk-aih.com/ UK PBC - http://www.uk-pbc.com/ PSC UK - http://www.pscsupport.org.uk/
32	4.2	Perspectum Diagnostics Ltd	Efficient monitoring of patients with Autoimmune Hepatitis	AIH is a chronic, debilitating disease which is difficult to diagnose, variable and unpredictable. The disease affects every demographic, is becoming more prevalent and causes life-changing disability. Untreated or inadequately treated, AIH can progress to liver failure unless transplant is an option. Correct diagnosis and management of care is key and can significantly improve outcomes for patients.	Practice management of AIH differs widely. Current drug therapies have significant side effects and duration of medication varies. Current monitoring processes are via the use of Fibroscan, blood Liver Function Tests and Liver Biopsy. Fibroscan requires subjective evaluation and is not widely available, despite the fact that this is relatively outdated technology. Fibroscan measures liver elasticity but is not an accurate way to assess spread or severity of disease.	A review by the American Association for Study of Liver Disease (AASLD) outlining the limitations of tools currently used for assessment of fibrosis, while highlighting the advantages of MR Imaging. Morling, J. R. and Guha, I. N. (2016), Biomarkers of liver fibrosis. Clinical Liver Disease, 7: 139–142. doi:10.1002/cld.555 http://onlinelibrary.wiley.com/doi/10.1002/cld.555/full

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					Accurate monitoring of this disease in an accurate, non-invasive, cost-effective manner is urgently required. AIH has a high flare rate and confirmation of absence of inflammation is key to reduction of medication. Current available medication...steroid and immunosuppressive drugs, have significant adverse side effects both short and long term. Patient non-compliance is common. Blood Liver Function Tests are used widely. However, LFT scores can be well within normal ranges even though patients still have debilitating symptoms AND active disease remains present (evidenced by biopsy). This is an expensive procedure requiring intensive vital sign observation afterwards, and six hours of supervised bed rest as an outpatient. It is not popular with patients due to pain levels and they are therefore resistant to referral. The method is invasive, high risk and costly. Variable clinical treatment	

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					programmes do not inspire confidence. Parity of clinical approach is hampered by inadequate monitoring systems which are also often inaccessible to patients.	

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Diagnosis of cirrhosis						
33	4.3	SCM 2	Key area for quality improvement 4 Increased community access to transient elastography	Community access to TE would improve uptake of screening harmful drinkers for cirrhosis, (as well as NAFLD patients with positive ELF) which may influence their commitment to reducing alcohol intake and addressing other lifestyle factors	Diagnosis of cirrhosis is currently considered a secondary or even tertiary referral issue. Steps to increase facility for testing appropriate risk groups in the community would help to break down barriers to managing liver disease in primary care, as well as reduce pressure on hospital referrals for tests that could be done in the community.	Nick Sheron, Mike Moore, Stacey Ansett, Camille Parsons, AdrianBateman Br J Gen Pract Sep 2012, 62 (602) e616-e624; DOI:10.3399/bjgp12X654588
34	4.3	SCM 3	Key area for quality improvement 1 Non-invasive diagnosis of cirrhosis in at-risk individuals.	People with cirrhosis may show no symptoms or signs of liver disease for many years and do not come to attention until their disease progresses and they develop one or other of the major complications. Thus, opportunities to intervene often come late. Liver biopsy has been the definitive diagnostic method for confirming cirrhosis but is invasive and associated with a small but appreciable risk of complications. Several non-invasive tests to	There is currently variation in practice across England and Wales for diagnostic tests for cirrhosis. As of Jan 2015 there were ~120 transient elastography (Fibroscan) units installed in the UK (source: NICE MT210 consultation comments), suggesting that a number of hospitals do not have direct access to this technology. Acoustic radiation force impulse imaging is a newer technology, which to my knowledge is less utilised and probably also less available in the UK than Fibroscan.	*No additional information provided by stakeholder*

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				predict cirrhosis have been developed, based on combining the results of routine laboratory liver blood tests, proprietary blood test panels, or imaging methods to measure the 'stiffness' of the liver (e.g. transient elastography) and there is good evidence that these may accurately diagnose cirrhosis. Moreover, they are more acceptable to patients. NICE recommends offering transient elastography to diagnose cirrhosis for people with hepatitis C virus infection, men who drink over 50 units of alcohol per week and women who drink over 35 units of alcohol per week and have done so for several months and people diagnosed with alcohol-related liver disease. For people with NAFLD, NICE recommends offering either transient elastography or acoustic radiation force impulse imaging (whichever		

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				is available) to diagnose cirrhosis in those advanced liver fibrosis.		

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Surveillance for hepatocellular carcinoma						
35	4.3	British Society for Gastroenterology	Surveillance for HCC in populations at risk	There is good evidence that surveillance for HCC in at risk populations increases their survival.	Standardising and establishing a programme of screening in the UK in high-risk population will improve clinical outcomes	NCEPOD as evidence of poor care National Confidential Enquiry into Patient Outcome and Death. Measuring the units: a review of patients who died with alcohol-related liver disease. Internet. London: NCEPOD; 2013. Available from: http://www.ncepod.org.uk/2013report1/downloads/Measuring%20the%20Units_full%20report.pdf Lancet Commission Addressing liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excessive consumption of alcohol, obesity and viral hepatitis Williams R, Aspinall R, Bellis M et al Lancet 2014 http://www.thelancet.com/commissions/crisis-of-liver-disease-in-the-UK

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36	4.3	Foundation for Liver Research	Surveillance for primary hepatocellular cancer to allow early detection and better treatment/cure	because of the rising rates of primary hepatocellular cancer in this country consequent on fatty liver disease, cirrhosis and chronic HBV and HCV infection	because despite guidelines, implementation of 6 monthly or 12 monthly routine surveillance by ultrasound examination Is not being implemented in NHS district hospitals	Lancet Commission into Liver Disease in the UK (2014). Addressing liver diseasein the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity and viral hepatitis Lancet Commission into Liver Disease in the UK (2015). Implementation of the Lancet Standing Commission on Liver Disease in the UK
37	4.3	SCM 3	Key area for quality improvement 3 Surveillance for hepatocellular carcinoma in people with cirrhosis.	People with cirrhosis are at high risk of developing hepatocellular carcinoma (HCC) and there is good evidence that the prognosis in people with HCC critically depends on tumour stage at the time of diagnosis. Regular surveillance for HCC in people with cirrhosis endeavours to detect a tumour at an early stage when potentially curative treatment can be offered.	A recent UK national survey of the provision of ultrasound surveillance for the detection of hepatocellular carcinoma found that provision of surveillance was poor overall. See Cross TJ et al Frontline Gastroenterology. Published online 02 Dec 15 doi:10.1136/flgastro-2015-100617	Nb. NICE recommends that adults with chronic hepatitis B infection who have significant liver fibrosis or cirrhosis are offered 6-monthly surveillance testing for hepatocellular carcinoma (NICE quality standard [QS65])

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				NICE recommends offering ultrasound (with or without measurement of serum alpha-fetoprotein) every 6 months as surveillance for HCC for people with cirrhosis.		

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Managing complications of cirrhosis						
38	4.3	Norgine Pharmaceuticals Limited	Identification and management of liver disease complications including ascites, hepatic encephalopathy and variceal bleeding	The management of complications of liver disease have been incorporated in the recently published NICE guidelines for management of cirrhosis. Quality Standards should be specified that drive uptake of these guidelines.	The NHS England Innovation Scorecard provides evidence on the variability of uptake of NICE recommendations. For example there is considerable regional variation in the uptake of technology appraisals e.g. TA337. In the NCEPOD report clinicians reported that during admissions for alcohol related liver disease opportunities were missed to alter outcomes for patients. This occurred in approximately 10% of patients. Mismanagement of complications results in an unnecessary burden placed on patients and health care resources.	Please see NHS England's website which publishes the innovation scorecard: https://www.england.nhs.uk/ourwork/innovation/innovation-scorecard/ Further discussion can be found in the Lancet paper and the NCEPOD report: Williams R, Aspinall R, Bellis M, et al. Addressing Liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity, and viral hepatitis. Lancet 2014; 384; 1953-1997. Juniper et al. Measuring the Units: A review of patients who died with alcohol-related liver disease. http://www.ncepod.org.uk/2013report1/downloads/MeasuringTheUnits_FullReport.pdf

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39	4.3	SCM 3	Key area for quality improvement 4 Primary prevention of variceal bleeding in people with cirrhosis.	Variceal bleeding occurs in 25–40% of patients with cirrhosis and each bleeding episode is associated with a 10–30% mortality rate. Consequently, prevention of variceal bleeding is an important goal in the management of patients with cirrhosis. NICE recommends offering upper gastrointestinal endoscopic surveillance for oesophageal varices to people with cirrhosis and offering endoscopic variceal band ligation for the primary prevention of bleeding to those with medium to large oesophageal varices.	Data on provision of endoscopic surveillance for varices in the UK are sparse. However, there is good data from other Western countries that surveillance is under-implemented, that other aspects of variceal care are sub-optimal and that compliance with other practice guideline recommendations is associated with reduction in the incidence of a first variceal bleed. For examples see: Barritt, A.S. et al. Digestive and Liver Diseas. 2009 41(9):676-82. Buchanan PM et al. Am J Gastroenterol. 2014 Jul;109(7):934-40. Moodley J et al. Clin Gastroenterol Hepatol. 2010 Aug;8(8):703-8.	*No additional information provided by stakeholder*
40	4.3	SCM 3	Key area for quality improvement 5 Antibiotic prophylaxis for people with cirrhosis who have upper gastrointestinal bleeding.	There is good evidence that people with cirrhosis and upper GI bleeding that are diagnosed with bacterial infection within 48 hours of admission have a higher risk of death and a higher risk of early re-bleeding and that early use of antibiotics is associated with reduced	The 2015 NCEPOD report on GI haemorrhage found that 39% (14/38) of patients who died after a variceal upper GI bleed did not receive prophylactic antibiotics. Variation in practice has also been identified in other Western countries. See : Buchanan PM et al. Am J	*No additional information provided by stakeholder*

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				mortality. NICE recommends offering prophylactic intravenous antibiotics for people with cirrhosis who have upper gastrointestinal bleeding.	Gastroenterol. 2014 Jul;109(7):934-40. Moon AM et al. Clin Gastroenterol Hepatol. 2016 Jun 14. pii: S1542-3565(16)30306-8.	

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Prevention of liver disease						
41	4.4	BASL	Key area for quality improvement 2	Improved screening and interventions for excess alcohol consumption in primary and secondary care	Interventions benefit patients	Please see the Lancet commission reports 2015 & 2016 Both Williams R et al. for ALL possible standards targets in primary, secondary and tertiary care.
42	4.4	Foundation for Liver Research	Introduction of MUP to reduce alcohol consumption in heavy drinkers	Mortality figures and hospital admissions are continuing to escalate largely relating to those drinking heavily.	because improvements can be seen within 12 months in mortality/admission rate as acutely damaging effects of high alcohol intake are reduced.	References: Lancet Commission into Liver Disease in the UK (2014). Addressing liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity and viral hepatitis Lancet Commission into Liver Disease in the UK (2015). Implementation of the Lancet Standing Commission on Liver Disease in the UK
43	4.4	Foundation for Liver Research	Reduction in obesity rates in middle life as well as in children	to reduce a wide spectrum of health consequences including liver disease, primary hepatocellular	because of major health burden to UK population and costs to society. Achievement of significant calorie reduction has been shown to be of	References: Lancet Commission into Liver Disease in the UK (2014).

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				carcinoma, strokes, heart attacks and diabetes	major benefit in prevention and in treatment of established disease.	Addressing liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity and viral hepatitis Lancet Commission into Liver Disease in the UK (2015). Implementation of the Lancet Standing Commission on Liver Disease in the UK

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Alcohol interventions						
44	4.4	British Society for Gastroenterology	Alcohol CareTeams	There is good evidence that Alcohol care teams can help reduce recidivism thus reducing readmissions and improving long-term outcomes for patients.	Establishing the requirement for alcohol care teams (hospital based with outreach) will improve outcomes.	Alcohol Care Teams: reducing acute hospital admissions and improving quality of care. 2016. NICE Quality and Productivity: Proven Case Study. Provided by the British Society of Gastroenterology and Bolton NHS Foundation Trust. http://www.nice.org.uk/localPractice/collection PUBLIC HEALTH ENGLAND. 'Alcohol care in England's hospitals: An opportunity not to be wasted'.Public Health England. http://www.alcohollearningcentre.org.uk/News/NewsItem/?cid=6859
45	4.4	Public Health England - Alcohol Team	Develop a local system of Assertive Community Treatment for alcohol dependent individuals to ensure their engagement and retention in alcohol treatment services	50% of patients diagnosed with alcohol-related liver disease will stop drinking or reduce to a level where alcohol is no longer a risk factor. But 50% do not stop drinking and will continue to deteriorate.	Assertive Community Treatment improves on standard care for alcohol dependence in that it includes an aggressive system of follow-up and case management to ensure engagement and compliance with treatment.	Assertive Community Treatment is described and discussed in NICE CG 115 (starting page 100). https://www.nice.org.uk/guidance/cg115/evidence/full-guideline-136423405 Few research studies were

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						available to inform this guideline, but studies from mental health were used to draw parallels to possible effectiveness. Since publication of NICE CG 115, more studies are now reporting on the value of this approach.

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Hepatitis B and C						
Testing for hepatitis B and C						
46	4.4	BASL	Key area for quality improvement 4	Improved awareness and detection of viral hepatitis in primary care	Effective treatment for HBV and cure for HCV readily in our grasp.	Please see the Lancet commission reports 2015 & 2016 Both Williams R et al. for ALL possible standards targets in primary, secondary and tertiary care.
47	4.4	BSPGHAN	All children at risk of hepatitis B and C infection are identified and screened in order to ascertain all cases that are infected.	Children with hepatitis B and C are usually asymptomatic and therefore will only be diagnosed though targeted screening.	Screening of at risk populations is poorly co-ordinated. Undiagnosed children are at risk of progressing to cirrhosis in adulthood.	NICE Quality Standard Q65
48	4.4	CoramBAAF Adoption and Fostering Academy	Key area for quality improvement 1 Universal screening for hepatitis C in pregnancy should be considered.	Universal prenatal screening is an ideal opportunity to determine the hepatitis C status of pregnant women, facilitating maternal treatment where needed and to prevent transmission to the foetus.	We know from statutory assessments on looked after children that often their mothers are in an at-risk group but have not been tested for hepatitis C during pregnancy.	Recommendation 4 of PH 43 published in 2012 states "Staff providing antenatal services, including midwives, obstetricians, practice nurses and GPs, should ask about risk factors for hepatitis C during pregnancy and offer testing for hepatitis C to women at increased risk". However when our members undertake statutory health assessments on looked after children they still come

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						across looked after infants whose mothers are in an at-risk group but have not been tested for hepatitis C during pregnancy. This recommendation does not highlight the risk in mothers who are historical IV drug users, sex workers, etc, or address the fact that mothers may deny current or historical risk-taking behaviour. Also no mention of postnatal testing in infants. Statutory assessments on looked after children provide a second opportunity to consider risk status however children with vertically acquired hepatitis C who don't become looked after will likely not be identified. With improved treatment for hepatitis C now available, is there now a case for universal antenatal screening, as is already in place for hepatitis B and HIV?

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49	4.4	CoramBAAF Adoption and Fostering Academy	Key area for quality improvement 2 The importance of and need for training in various areas should be addressed and the resource implications acknowledged if NICE recommendations are to be carried out effectively.	If existing NICE guidance and the QS to be developed are to be effective, health and social care professionals need a good understanding and expertise in the following areas which may be particularly complex where looked after children are concerned: -Consent to test for BBI -Information sharing -risk factors for BBI - addressing stigma	Our members continue to report difficulties in these areas due to poor understanding of the issues outlined, compounded by insufficient capacity to deal with these complex and sensitive issues which take time to address. It has been documented that drug and alcohol services fail to take into account the welfare of children of substance misusing parents, and that health services for children may not be aware that these children are at high risk. All involved need training to raise awareness and to develop skills and pathways of communication and referral and support. It is therefore essential to add to this list that drug services staff should routinely consider the needs of the children of their clients who have hepatitis B and C risk factors so that appropriate action re testing, referral and support can be offered.	*No additional information provided by stakeholder*
50	4.4	The Hepatitis C Coalition	Testing for hepatitis C and other blood-borne viruses to be provided in a range of healthcare settings to maximise	Guidance on testing that is applicable to a range of settings will be vital to tackling hepatitis C.	Public Health England's annual report says that levels of awareness of infection are well above the 5% global average and are likely to have met the first target	Public Health England's Annual report on hepatitis C in the UK is available at: https://www.gov.uk/governme nt/uploads/system/uploads/att

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			coverage, working to nationally-agreed performance standards as part of structured care pathways	NHS England's service specification for hepatitis C Operational Delivery Networks policy requires services to accept referrals from 'primary care, substance misuse services, genito-urinary medicine services and all other services undertaking HCV testing or subsequent care.' In its annual report on hepatitis C in the UK, Public Health England highlights testing as critical to tackling HCV infection in the UK and working towards elimination of the virus as a major public health threat by 2030. The report also notes that, "testing in alternative/ community settings, using alternative technologies like dried blood spot (DBS) testing, will be key in reducing the levels of undiagnosed infection" Existing NICE guidance on this topic is set out in PH43.	in the Global strategy on viral hepatitis, for 30% of people infected to know their status by 2020. However the report adds that more needs to be done if the UK is to reach the target of 90% of people infected knowing their status by 2030. The UK does not yet have a figure for the percentage of people with hepatitis C who are aware of their status, however studies suggest that in the UK, only around one half of people who inject drugs are aware of their HCV antibody positive status; this figure has remained relatively stable at this level over the last five years	achment_data/file/541317/Hepatitis_C_in_the_UK_2016_report.pdf NHS England's service specification for hepatitis C Operational Delivery Networks is available at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/10/hep-c-netwrks-spec.pdf

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51	4.4	MSD UK Ltd	Identification and uptake of HCV testing within populations that may be considered high risk, or for those persons who have been exposed to a HCV risk.	1) MSD support the topics outlined within the QS; namely the "identification, assessment, and management of liver disease… associated with hepatitis B and C", and agree that those who are considered at risk of HCV should be tested to confirm disease status and minimise the likelihood for progression to advanced stages of liver disease. MSD would like to draw attention to the burden of HCV infection, and the potentially large number of people who are undiagnosed. A 2016 report by Public Health England suggested that more than 200,000 people have chronic HCV. The report also states that the level of HCV awareness (known infection) is suboptimal, which is further exacerbated by a failing to often link individuals to treatment and care services	The 2016 PHE report concludes by advocating increased diagnoses, and easier access to testing and treatment (1).	Public Health England 2016 Hepatitis C report, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/541317/Hepatitis_C_in_the_UK_2016_report.pdf Public Health England 2015 Hepatitis C report, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/448710/NEW_FINAL_HCV_2015_IN_THE_UK_REPORT_28072015_v2.pdf

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				(1). The prevalence and proportion of patients diagnosed with HCV was assumed to be 0.4% and 52%, respectively in the recent NICE costing template (2). This burden of disease and restricted access to HCV treatment, as stipulated by the NHSE CCP, attests to the potential scalability of liver disease within the population, i.e. those patients who are infected with their status unknown, therefore not seeking treatment. A very basic calculation of population, prevalence, assumed diagnosed status, and a non-cirrhotic liver status would suggest ~68,000 people who could be at risk of liver disease. The 2016 PHE report comments that the number of patients progressing to advanced liver disease has increased over the past		

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				decade (1). References Public Health England 2016 Hepatitis C report, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/541317/Hepatitis_C_in_the_UK_2016_report.pdf NICE costing template, TA365, assumptions of prevalence, and HCV population distribution, https://www.nice.org.uk/guidance/ta365/resources		

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52	4.4	Public Health England - National Infection Service	Ensure testing for both hepatitis B and C are carried out in appropriate settings in particular primary care, (e.g. GP and community drug services) and prisons and genitourinary medicine (GUM) clinics for those at increased risk of infection with recording of an individual's risk factors for acquisition.	Appropriate testing will be effective in significantly improving the number of diagnosed cases of hepatitis B and C. A number of settings have been identified as appropriate for testing to be encouraged and carried out.	There is a substantial amount of undiagnosed hepatitis B and C infection. Most of these are chronic cases of hepatitis B and C. The number of settings offering testing for all individuals entering primary care needs to be increased and improved to increase numbers diagnosed. Testing is recommended within existing NICE guidance. Hepatitis B and C testing: people at risk of infection (2013) NICE guideline PH43 https://www.nice.org.uk/guidance/ph43	Hepatitis C in the UK annual report 2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/448710/NEW_FINAL_HCV_2015_IN_THE_UK_REPORT_28072015_v2.pdf J Clin Virol. 2004 Apr;29(4):211-20. Incidence and routes of transmission of hepatitis B virus in England and Wales, 1995-2000: implications for immunisation policy. Hahné S1, Ramsay M, Balogun K, Edmunds WJ, Mortimer P. http://www.ncbi.nlm.nih.gov/pubmed/15018847 Annual report from the sentinel surveillance study of blood borne virus testing in England: data for January to December 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/345716/hpr2914_senthep.pdf

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						Shooting up: infections among people who inject drugs in the UK, update November 2015 https://www.gov.uk/government/publications/shooting-up-infections-among-people-who-inject-drugs-in-the-uk UAM for HBsAg and anti-HCV testing Public Health England Health & Justice report 2014 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/434951/HJ_report_11_6.pdf

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53	4.4	Public Health England - National Infection Service	Ensure adequate awareness raising activities in high risk groups to encourage update of testing and treatment		Effective new antiviral treatments are available and more will become available and there should be an equitable access to the new fast acting antivirals. .	NICE guidance on fast acting HCV antivirals
54	4.4	SCM 4	All children and young people at risk of hepatitis B and C infection are identified and screened in order to ascertain all cases that are infected.	Children with hepatitis B and C are usually asymptomatic and therefore will only be diagnosed though targeted screening.	Screening of at risk populations is poorly co-ordinated.	All children and young people at risk of hepatitis B and C infection are identified and screened in order to ascertain all cases that are infected
Vaccination for hepatitis B						
55	4.4	BSPGHAN	Children at risk of hepatitis B are immunised by a well-co-ordinated service to ensure delivery and uptake, with resulting immunity being checked	To prevent perinatal transmission from infected mothers	Very patchy delivery of immunisation to at risk infants	Leeds and Birmingham have data relating to this
56	4.4	Children's Liver Disease Foundation	Liver disease associated with Hep B or C specifically in children and young people but also the care and vaccination of the families of those with Hepatitis B and C.			*No additional information provided by stakeholder*

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57	4.4	Foundation for Liver Research	Implementation if universal vaccination to decrease numbers of persons acquiring hepatitis B virus infection in this country	because of large number of undetected chronic HBV infections coming not the country through immigration	because it is a WHO recommendation of proven benefit worldwide with only two countries, including UK, not following it	References: Lancet Commission into Liver Disease in the UK (2014). Addressing liver disease in the UK: a blueprint for attaining excellence in health care and reducing premature mortality from lifestyle issues of excess consumption of alcohol, obesity and viral hepatitis Lancet Commission into Liver Disease in the UK (2015). Implementation of the Lancet Standing Commission on Liver Disease in the UK
58	4.4	Public Health England - National Infection Service	Ensure local coordinators oversee antenatal screening and vaccination and testing of infants born to hepatitis B infected mothers	Infants born to hepatitis B infected mothers are at highest individual risk of chronic infection. Vaccination coverage and testing of infants is variable and remains suboptimal. There is a need to ensure this selective immunisation programme is not compromised when a universal infant immunisation programme is introduced. A	Audits demonstrate that uptake of vaccination and testing of at risk infants at 12 months is poor	Hepatitis B antenatal screening and newborn immunisation programme Best practice guidance https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215622/dh_132637.pdf The national DBS service for infants of hepatitis B positive mothers

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				key component is a coordinator role at the level of the primary care organisation to prospectively follow up infants for vaccination and testing		https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/343748/The_national_DBS_service_for_infants_of_hepatitis_B_positive_mothers.pdf Hepatitis B NICE quality standard [QS65]Published date: July 2014 https://www.nice.org.uk/guidance/qs65/chapter/introduction Quarterly vaccination coverage statistics for children aged up to five years in the UK (COVER programme): January to March 2016 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/531021/hpr2016_COVER.pdf

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59	4.4	Public Health England - National Infection Service	Ensure those at risk from hepatitis B are offered hepatitis B vaccine and doses are recorded and reported.	Persons at risk of hepatitis B include those who are eligible for vaccination and are described in the Green Book This includes persons who attend community drug services, GUM and prison settings, Uptake of selective hepatitis B immunisation programmes is variable. It should be improved in all settings particularly where those at highest risk of infection attend. This practice will prevent both acute and chronic hepatitis B infection in high risk groups decreasing both the morbidity and mortality associated with infection, and contribute to tackling inequalities in outcomes as many people with hepatitis B and C are from marginalised populations (people who inject drugs, prisoners, migrant populations).	In closed settings such as prisons, hepatitis B immunisation is a cost effective way of delivering early prevention. Targeting prisoners and GUM attenders has wider implications for preventing spread of the infection in the wider community.	Genitourinary medicine clinic activity dataset (GUMCADv2) https://www.gov.uk/guidance/genitourinary-medicine-clinic-activity-dataset-gumcadv2 Green book: Immunisation against infectious disease. Department of Health 2006, www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH4097254 Reducing differences in the uptake of immunisations (including targeted vaccines) among children and young people aged under 19 years' NICE public health guidance 21, September 2009 www.nice.org.uk/PH21 Hepatitis B NICE quality standard [QS65]Published date: July 2014 https://www.nice.org.uk/guidance/qs65/chapter/introduction Health & Justice report 2014 (PHE)

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						https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/434951/HJ_report_11_6.pdf

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60	4.4	SCM 4	Children and young people at risk of hepatitis B are immunised by a well-co-ordinated service to ensure delivery and uptake, with resulting immunity being checked	To prevent perinatal transmission from infected mothers	Very patchy delivery of immunisation to at risk infants	Leeds and Birmingham have data relating to this
Referral of children and young people with hepatitis						
61	4.4	BSPGHAN	Children infected with hepatitis B and C are referred to an appropriate specialist in paediatric infectious disease or hepatology for further management	Specialist will be aware of recent advances in management and also research trials, with other non-specialist professionals may not have access to	Wide variation in referral practice	Clinical guideline G165
62	4.4	SCM 4	Children and young people infected with hepatitis B and C are referred to an appropriate specialist in paediatric infectious disease or hepatology for further management	Specialist will be aware of recent advances in management and also research trials, with other non-specialist professionals may not have access to	Wide variation in referral practice	Clinical guideline G165
Treatment for hepatitis B and C						
63	4.4	The Hepatitis C Coalition	Ensuring the availability of services and NICE-approved treatments for	With the right diagnosis and treatment, hepatitis C is curable in the vast majority of	As reported in Public Health England's annual report, at present only 4.2% of those chronically	The report from the London Joint Working Group is available at:

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			all patients diagnosed with hepatitis C in line with international guidelines	cases. Research from the London Joint Working Group found that it was cheaper to treat chronic HCV than to allow the disease to progress, and that treating just 10% of those people with hepatitis C could save £200 million in London alone. Modelling from Public Health England confirmed that by treating 3,500 people with cirrhosis each year, new cases of HCV-related end-stage liver disease and cancer could be reduced from 1100 cases per year in 2015 to about 630 in 2020. However these reductions would not be sustained beyond 2020 without these therapies being available to those with moderate disease (people who don't yet have severe disease and cancer).	infected receive treatment each year. For a number of years before this, treatment rates were stable at 3%.	http://ljwg.org.uk/wp-content/uploads/2013/05/LJWG-2013-Public-Health-Report-on-Commissioning-of-HCV-services-in-London-for-People-who-Inject-Drugs.pdf The Public Health England modelling of the predicted impact of treatment are published in an article titled, 'Increased uptake and new therapies are needed to avert rising hepatitis C-related end stage liver disease in England: Modelling the predicted impact of treatment under different scenarios in the Journal of Hepatology. This is also available online: http://www.journal-of-hepatology.eu/article/S0168-8278(14)00318-3/abstract

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64	4.4	The Hepatitis C Coalition	Proactive work on providing advice and support to patients with hepatitis C and developing prevention strategies targeted at people at risk of contracting the virus	NHS England's service specification for hepatitis C Operational Delivery Networks includes an objective for networks of, 'Ensuring that people with hepatitis C are given sufficient, high quality information and advice so they are fully informed about the timing of treatment and treatment choices, which can be complex issues.' Clinical guidance from the British Society of Gastroenterology states that, 'The diagnosis of HCV causes considerable anxiety to patients and it is therefore essential that all patients receive adequate counselling from a health carer with knowledge and experience in this field'	The Hepatitis C Trust has launched a number of peer-to-peer education services to improve the information and advice available to people with hepatitis C. Reports from these projects suggest that myths and misinformation are widespread and that this is particularly the case with mixed messages about access to new treatments.	The British Society of Gastroenterology clinical guidance on hepatitis C is available at: http://www.bsg.org.uk/pdf_word_docs/clinguidehepc.pdf Further information on peer-to-peer education and information is available at: http://www.hepctrust.org.uk/services/drug-services-team
65	4.4	Public Health England - National Infection Service	Improve and ensure commissioning of treatment pathways to allow timely referral of individuals who are diagnosed with	The proportion of the diagnosed population meeting NHS England criteria for treatment is poor. Local services have to ensure clinical pathways are in place	NICE guidance recommends treatment for both chronic HBV and HCV infections . The new antivirals for HCV pose a major challenge around affordability	NHSE and PHE hepatitis C treatment monitoring Hepatitis C in the UK 2016 report

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			hepatitis B or C into treatment services.	to ensure patients are referred for treatment.	and access to those at greatest unmet clinical need, but offer opportunity of treatment as prevention. It is important to monitor equity of access and outcome of treatment	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/541317/Hepatitis_C_in_the_UK_2016_report.pdf

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Data collection for hepatitis C outcomes						
66	4.4	The Hepatitis C Coalition	Ensuring that service providers collect and report data on their hepatitis C outcomes to standards set by Public Health England	NHS England's service specification for the hepatitis C Operational Delivery Networks includes an objective of, 'Reporting objective measures to demonstrate high quality treatment using a national standardised monitoring and outcomes dataset and through supporting development of an outcome collection system' Consistent reporting of high quality data is also necessary for monitoring tools such as the local liver disease profiles.	The importance of good practice in data collection has been emphasised by the roll out of Blueteq systems to the Operational Delivery Networks. Public Health England has also restructured its annual report 'to support UK monitoring of the recently agreed GHSS goals' It also notes that, 'targets also need to be feasible and developed based on country realities, the best possible data, trends and responses, and should be monitored through a set of standard, measurable indicators'	Public Health England's Annual report on hepatitis C in the UK is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/541317/Hepatitis_C_in_the_UK_2016_report.pdf NHS England's service specification for hepatitis C Operational Delivery Networks is available at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/10/hep-c-netwrks-spec.pdf
Transition of children with liver disease to adult services						
67	4.4	British Liver Trust	Key area for quality improvement 5	TRANSITIONAL CARE	SUPPORT FOR IMPROVED TRANSITIONAL CARE YOU YOUNG PEOPLE MOVING FROM PAEDIATRIC TO ADULT SERVICES	LANCET COMMISSION ON LIVER DISEASE http://www.thelancet.com/commissions/crisis-of-liver-disease-in-the-UK
68	4.4	BSPGHAN	Liver disease in children	Children with liver disease become adults with liver disease. By focussing only on	Managing transition of children from paediatric to adult services impacts on the ongoing	Transition standards

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				cirrhosis in people over 16 the quality standard will ignore the opportunity to advise on this group	management and outcome of adults with cirrhosis	

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69	4.4	Children's Liver Disease Foundation	The care of young adults on adult liver wards			*No additional information provided by stakeholder*
70	4.4	SCM 4	Children and young people with NAFLD are referred to appropriate services once they reach transition age.	Children and young people with NAFLD become adults with NAFLD and currently there are no clear transition pathways for this patient group	There is wide variation in transition practice from paediatric to adult services for young people with NAFLD. This will impact on long term outcome and health in adulthood.	Clinical guideline NG49
71	4.4	SCM 4	Liver disease in children and young people	Children with liver disease become adults with liver disease. By focussing only on cirrhosis in people over 16 the quality standard will ignore the opportunity to advise on this group	Managing transition of children from paediatric to adult services impacts on the ongoing management and outcome of adults with cirrhosis	Transition standards
Variation in secondary care liver service provision						
72	4.4	BASL	Key area for quality improvement 1	Regional inequality in delivery of secondary care for liver patients	Dependent on better use of current resources	Please see the Lancet commission reports 2015 & 2016 Both Williams R et al. for ALL possible standards targets in primary, secondary and tertiary care.
Liver cancer treatment						
73	4.4	Biocompatibles UK Ltd	Equality analysis	The correlation between funding for liver cancer is disproportionate compared to other cancers, and although	Liver cancer deaths in England are more common in people living in the most deprived areas. Ensuring this disease area, and the	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3411479/ http://www.ncbi.nlm.nih.gov/pubmed/26526609

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				treatment options are limited, there remains little commitment from the NHS financially to address this inequity. Given its societal burden (i.e. death, disability and associated economic factors) liver cancer treatment options appears proportionally underfunded in comparison to other common cancers e.g. breast cancer. We believe that this is worth consideration in your equality analysis.	specific patient groups within it, equitable access to care and funding is essential.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4835015/

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74	4.4	Biocompatibles UK Ltd	Areas of emergent practice	Emerging transcatheter therapies such as Radiopaque Drug Eluting Bead Trans Arterial Chemo Embolisation and ongoing research into Dendritic cells have the potential to offer better care, improve outcomes, and offer more choice to this patient group. Further consideration should be given to emergent interventional therapies such as these.	Providing patients and health care professionals earlier access to emergent therapies would be beneficial. Patients with HCC have very limited treatment options, partly due to commissioning constraints or liver cancer treatment and management being a low priority for commissioners in the UK.	*No additional information provided by stakeholder*
75	4.4	Biocompatibles UK Ltd	Additional developmental areas of emergent practice	Raising the awareness, removing the stigma associated with liver disease and improving education is essential. Identifying high risk populations and intervening earlier in these populations could improve outcomes and reduce societal burden. Increased screening carries its own costs and risks and therefore the problem is complex and more research is required. With Sorafenib's funding currently under review, patients and physicians are	The funding of new technologies and treatments has potentially often been limited in the UK because of the lack of support. Historically this patient group has often been overlooked when funding decisions are being made.	https://www.nice.org.uk/guidance/ipg460 https://www.nice.org.uk/advice/mib62 https://www.nice.org.uk/advice/mib63 http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0066343/

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				left with very few treatment options in intermediate and advanced HCC. Transcatheter therapies such as Selective Internal Radiation Therapy (SIRT) have been considered by NICE through both IPAC and MIB process; both concluded that this therapy was safe and efficacious and had a place in therapy for patients yet funding for this therapy is still not available in the UK. In addition, with the potential removal of sorafanib as a funded therapy through the CDF, treatment options are further limited. Providing this relatively small number of patients treatment options as a bridge to transplant (who no longer meet the eligibility criteria), or for patients with PVT or indeed as a curative therapy, as suggested in the NICE reviews , would offer physicians and patients more options.		

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End of life care						
76	4.4	British Liver Trust	Key area for quality improvement 2	IMPROVED END OF LIFE CARE	THE VAST MAJORITY OF PEOPLE WITH LIVER DISEASE DO NOT RECEIVE EXPERT END OF LIFE CARE	Marie Curie Palliative Care Research Department https://www.mariecurie.org.uk/research/research-centres/marie-curie-palliative-care-research-unit-london
77	4.4	Public Health England - Lead for Liver disease	End of Life Care for Liver Disease Patients	Liver disease is the third commonest cause of death in people of working age. In 2015 there were 15,232 deaths in which liver disease was mentioned on the death certificate and of these 10,746 had liver disease as the underlying cause. The median age at death is young at 67 but even younger for alcohol related liver disease (56) and viral liver disease (59). Patients dying from liver disease are more likely to come from more deprived and marginalised backgrounds, many will be dependent on alcohol and or drugs. They often have poor social/ family infrastructure for support.	The majority of deaths occur in hospital (66.1%) which is statistically higher than the national average for all causes at just under half and is even higher in patients dying from alcohol related liver disease (78.8%) but lower for those dying from Hepatocellular Carcinoma (41.2%). One in six patients (17.1%) die in their first admission and it is around one in four (25.1%) for people dying from ARLD. However, analysis undertaken by the National End of Life Care intelligence Network show that even for patients with multiple admission in their last year of life, this has not impact on their chances of dying outside hospital. Work currently being undertaken by the NEOLCIN has found that many Hepatologists are reluctant to	NEOLCIN Report of Death from Liver disease. http://www.endoflifecare-intelligence.org.uk/resources/publications/deaths_from_liver_disease Raising the profile of end of life care needs for patients dying from liver disease - using national mortality data, NEOLCIN poster presented at EASL conference London April 2014, http://www.endoflifecare-intelligence.org.uk/resources/abstracts Local Authority Liver disease Profiles http://fingertips.phe.org.uk/profile/liver-disease

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					discuss end of life care. They prefer the concept of parallel planning – saving lives but preparing for the worst. Patients spend up to a month of their last year of life in hospital, sometimes across several admissions but there is little evidence of discussions about the risk of death or preparation for it. More could be done to explore what patients want if they were to be in a terminal state and to help plan for this. There is evidence that if services are planned rather than emergency the patient has a better chance of dying out of hospital and not being subjected to futile ITU intervention, bed days are also reduced.	
General						

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78		NHS England	Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.			
79		Royal College of Nursing	This is to inform you that the Royal College of Nursing has no comments to submit to inform on the above topic engagement.			
80		Royal College of Physicians	We would like to formally endorse the response submitted by the British Society of Gastroenterology.			
81		CoramBAAF Adoption and Fostering Academy	This response is being submitted on behalf of the CoramBAAF Health Group, which is also a special interest group of the Royal College of Paediatrics and Child Health (RCPCH). The Health Group was formed to support health professionals working with children in the care system, through training, the provision of practice guidance and lobbying to promote the health of these children. With over 500 members UK-wide, an elected Health Group Advisory Committee with representation from community paediatricians working as medical advisers for looked after children and adoption panels, specialist nurses for looked after children, psychologists and psychiatrists, the Health Group has considerable expertise and a wide sphere of influence. Our area of concern is the particularly vulnerable group comprised of looked after and adopted children and young people. The main risk of liver disease in this population is from acquiring a blood borne infections (BBI) related to parental substance misuse or sexual abuse and from high risk behaviour in adolescence leading to a blood borne infection.			