NICE advice

LIVERFASt for assessing and monitoring liver fibrosis, activity and steatosis

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is LIVERFASt. It is used for detecting and staging liver fibrosis, activity and steatosis in people with non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH), hepatitis B and hepatitis C.
- The **innovative aspects** are that LIVERFASt may simplify diagnosing and monitoring liver disease and damage. It may improve disease management and understanding of disease progression.
- The intended **place in therapy** would be as an alternative to existing non- or minimally invasive tests and liver biopsy, to detect and monitor fibrosis and cirrhosis in people with suspected or diagnosed liver disease.
- The **main points from the evidence** summarised in this briefing are from 6 studies (5 prospective cohort studies and 1 retrospective study) including a total of 3,144 people with liver disease. They show that LIVERFASt performs as well as

transient elastography in detecting liver disease. It may also improve detection of severe disease when used with other tests.

- **Key uncertainties** around the evidence or technology are that 5 of the 6 reviewed studies were reported only as abstracts with limited details on study methods, patient demographics and discussion of findings.
- **Experts advised** that LIVERFASt may be used as a second-line tool or in combination with existing tests to improve diagnostic accuracy; however, its place in the NHS pathway was not clear and this would determine patient and system benefits. All experts advised that more evidence is needed on the use of LIVERFASt in the NHS.
- The **cost** of LIVERFASt is £55 per test (excluding VAT). The average cost of non- or minimally invasive tests in standard care ranges from £6 to £136. Costs of liver biopsy range from £358 (outpatient percutaneous liver biopsy) to £1,160 (outpatient transvenous liver biopsy).

The technology

LIVERFASt (Fibronostics) is a blood test for detecting and staging the fibrosis (scarring), activity (inflammation) and steatosis (fat build-up) of the liver. It can be used to help diagnose and monitor non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH), hepatitis B and hepatitis C.

People with suspected or diagnosed liver disease would be referred for a LIVERFASt test. The test can be done in any laboratory. Results are then inputted into the LIVERFASt online portal. This uses an artificial intelligence-based algorithm to analyse 10 biomarkers along with age, sex, weight and height to determine if someone has steatosis, fibrosis and steatohepatitis. Biomarkers include alpha-2 macroglobulin, haptoglobin, apolipoprotein A1, total bilirubin, gamma-glutamyl transferase, alanine transaminase, aspartate transaminase, fasting glucose, triglycerides and total cholesterol. The test has individual panels for fibrosis, activity and steatosis. For each panel, results are scored from 0 to 1 with higher scores meaning more severe disease. Scores are also mapped to histopathology classification stages and colour coded from green (healthy liver) to red (severe damage). The LIVERFASt report provides a qualitative interpretation of results. Results from the online portal are returned immediately.

Innovations

The biomarkers included are specific to each lesion. This allows LIVERFASt to discriminate fibrosis from steatosis and inflammatory activity, without the bias that may occur in other tests. LIVERFASt simplifies diagnosing and monitoring liver disease and damage. It may improve disease management and understanding of disease progression.

Current care pathway

NAFLD is caused by a build-up of fat in the liver. It develops in 4 main stages: steatosis, NASH, fibrosis and cirrhosis. Early stage NAFLD may not have symptoms and may only be detected when testing for other reasons. Liver disease is assessed using clinical examination, clinical history and various tests to identify the presence of risk factors and rule out other causes. People with suspected NAFLD should be offered first-line testing to assess the level of fibrosis, such as Fibrosis-4 (FIB-4) or NAFLD Fibrosis Score (NSF). People with a low score on these tests can have their condition managed in primary care and tested again in 3 years. In children and young people, NAFLD is diagnosed if a liver ultrasound shows fatty liver and if other suspected causes of fatty liver have been ruled out. NICE's guideline on NAFLD does not recommend routine liver blood tests to rule out NAFLD or to test for advanced liver fibrosis.

People with NAFLD are offered regular testing for advanced liver fibrosis. If advanced disease is not ruled out with first-line testing, people should be offered further testing using an enhanced liver fibrosis test or transient elastography such as FibroScan. This may be done in primary or secondary care depending on the locality.

Young people and adults with NAFLD, advanced liver fibrosis or other risk factors are also offered non-invasive testing for cirrhosis. This includes transient elastography or acoustic radiation force impulse imaging. Transient elastography may be offered to everyone at risk of cirrhosis, whereas acoustic radiation force impulse imaging is recommended only for NAFLD and advanced liver fibrosis. People who cannot have transient elastography may be offered a liver biopsy. Liver biopsy may also be used if there is diagnostic uncertainty after non-invasive testing. Liver biopsy is used to confirm NASH activity grade and fibrosis stage. It may also be used to confirm the level of fibrosis in some people with hepatitis B.

The following publications have been identified as relevant to this care pathway:

- NICE guideline on NAFLD

- NICE clinical knowledge summary on NAFLD
- NICE guideline on cirrhosis in over 16s
- NICE clinical knowledge summary on cirrhosis
- NICE guideline on hepatitis B (chronic)
- NICE quality standard on liver disease
- NICE medical technologies guidance on Virtual Touch Quantification to diagnose and monitor liver fibrosis in chronic hepatitis B and C
- NICE medtech innovation briefing on FibroScan for assessing liver fibrosis and cirrhosis in primary care
- NICE diagnostics guidance on MRI-based technologies for assessing NAFLD
- Guidelines on the use of liver biopsy in clinical practice from the British Society of Gastroenterology, the Royal College of Radiologists and the Royal College of Pathology

Population, setting and intended user

LIVERFASt is indicated for people with suspected or diagnosed liver disease or damage. About 20% of the population have NAFLD and in around 5% of patients, their condition will progress to NASH. In England and Wales, about 600,000 people have liver disease, of whom 60,000 have cirrhosis. It is estimated that 10% to 20% of people with NAFLD, alcohol-related liver disease and chronic viral hepatitis develop cirrhosis over a period of 10 to 20 years.

LIVERFASt would be used in primary care for the early detection of NAFLD and NASH in people with risk factors including type 2 diabetes, metabolic syndrome, insulin resistance, high blood pressure, high cholesterol and obesity. It can also be used in primary and secondary specialist care to help diagnose fibrosis and cirrhosis. People have an increased risk of cirrhosis if they have hepatitis B, hepatitis C, type 2 diabetes, if they misuse alcohol or are obese. LIVERFASt can also be used in regular surveillance to monitor disease progression and to assist in disease management.

Costs

Technology costs

LIVERFASt costs £55 per test excluding VAT. This includes use of the online portal and any training needed.

Costs of standard care

Costs of standard care vary depending on the test used. FIB-4 and NSF are both available online and calculate scores using results from several routine blood tests. NICE's guideline on NAFLD, published in 2016, reported unit costs for these tests of about £5 per test (about £6 when inflated to December 2022). Average costs per test of other tests are:

- enhanced liver fibrosis test: £136 (NICE's guideline on NAFLD from 2016, inflated to December 2022)
- ultrasound elastography, elective (cost code RD48Z): £57 (based on 1,857 cases)
- percutaneous liver biopsy, outpatient (cost code YG11A, YG11B): £358 (based on 569 cases)
- percutaneous liver biopsy, day case (cost code YG11A, YG11B): £1,068 (based on 6,434 cases)
- transvenous liver biopsy, outpatient (cost code YG10Z): £1,160 (based on 43 cases); transvenous liver biopsy, day case (cost code YG10Z): £1,038 (based on 203 cases).

Costs are from the national schedule for NHS costs 2020/21 and NICE guidelines. NHS costs include all taxes payable by the NHS, including VAT when applicable.

Resource consequences

LIVERFASt is not currently used in the NHS. It would be an alternative to tests for diagnosing or monitoring liver disease and damage. LIVERFASt could be used to detect NASH in people with NAFLD. NICE's guideline on NAFLD states that detecting and reducing the severity of NASH would reduce the risk of progression to fibrosis and advanced liver disease. LIVERFASt may help identify people who need treatment earlier, which could reduce their risk of developing fibrosis and severe liver disease. This could

lead to cost and resource savings by avoiding more intensive and costly treatments.

The company said LIVERFASt is more accessible to healthcare professionals and patients than liver biopsy. It is quicker, less invasive and cheaper to perform. LIVERFASt can also be done in primary care settings, which may result in fewer hospital visits. There is currently no evidence on the resource consequences of using LIVERFASt.

Regulatory information

LIVERFASt is a CE-marked class IVD general in vitro diagnostic medical device under the EU In Vitro Diagnostic Medical Devices Directive (IVDD).

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified related to the use of LIVERFASt. LIVERFASt has not been validated for use in people with acute hepatitis or after a liver transplant. It is also contraindicated in people with comorbidities that could interfere with blood biomarker levels such as chronic haemolytic anaemia and acute inflammatory syndrome.

The risk of liver disease may be higher in people from Black African, Caribbean and South Asian family backgrounds. Liver cirrhosis can be chronic and may affect a person's ability to do their normal day-to-day activities. Race and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Six studies are summarised in this briefing including a total of 3,144 people with liver disease. These included 5 prospective cohort studies and 1 retrospective study. The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

There is also an additional abstract (de Lédinghen et al. 2021a) and full-text paper (Aravind et al. 2020) that were not summarised for brevity. Aravind describes the development of LIVERFASt and evaluates its performance in 13,068 people with suspected fatty liver disease in Asia. It showed LIVERFASt scores were highly correlated with FibroTest (BioPredictive). But its accuracy was not evaluated against established diagnosis or liver biopsy as references.

Overall assessment of the evidence

The evidence in this briefing included 1 full-text peer-reviewed paper and 5 abstracts or posters. Abstracts were limited in detail on methods and patient demographics. Many contained detailed findings but often lacked discussion. The evidence would be strengthened by more full-text peer-reviewed papers to better explain findings and their implications for clinical practice.

Most studies were prospective cohort studies comparing LIVERFASt to other non- or minimally invasive tests. Several studies used comparators that were relevant to standard care in the NHS, including transient elastography and Fibrosis-4 (FIB-4). Liver biopsy was also used as a reference in 3 studies. Studies had within-group designs, with tests done at the same time. This meant participants acted as their own controls, and reduced confounding factors such as time and between-group differences. Although no studies were done in the UK, the populations were reflective of NHS patient groups and included non-alcoholic fatty liver disease (NAFLD) and hepatitis B.

The evidence suggests that LIVERFASt performs as well as transient elastography and better than FIB-4 in detecting liver disease. It may also improve detection of severe disease when used with other tests. But there is no evidence on the resource or cost benefits of using LIVERFASt. The evidence base would therefore benefit from prospective studies on the cost effectiveness or resource consequences of using LIVERFASt in the NHS compared with existing tests in primary and secondary care.

Tangvoraphonkchai et al. (2022)

Study size, design and location

Prospective cohort study comparing non- or minimally invasive tests in 192 people with chronic liver disease from a tertiary liver centre in Thailand. Overall, 26% of people had NAFLD, 24% chronic hepatitis B and 50% chronic hepatitis C. Also, 50% had advanced fibrosis and 10% had cirrhosis.

Intervention and comparators

LIVERFASt-fibrosis compared with transient elastography (FibroScan), enhanced liver fibrosis test and FIB-4.

LIVERFASt-steatosis compared with vibration control transient elastography (controlled attenuation parameter).

Liver biopsy was used as a reference.

Key outcomes

Mean LIVERFASt scores (ranging 0 to 1) were 0.29 for fibrosis, 0.29 for inflammatory activity and 0.35 for steatosis. Area under the receiver operating characteristics curve (AUC-ROC) for advanced fibrosis (n=157) was FibroScan 0.79 (95% confidence interval [CI] 0.71 to 0.85), LIVERFASt-fibrosis 0.77 (95% CI 0.61 to 0.77), FIB-4 0.69 (95% CI 0.61 to 0.77) and enhanced liver fibrosis test 0.63 (95% CI 0.53 to 0.71). AUC-ROC was similar for bridging fibrosis.

LIVERFASt-steatosis and controlled attenuation parameter AUC-ROC were 0.75 (95% CI 0.59 to 0.85) and 0.81 (95% CI 0.67 to 0.89) for mild steatosis, 0.75 (95% CI 0.61 to 0.85) and 0.81 (95% CI 0.68 to 0.89) for moderate steatosis and 0.70 (95% CI 0.47 to 0.83) and 0.74 (95% CI 0.55 to 0.86) for marked steatosis, respectively. There was no significant difference between LIVERFASt performance and FibroScan or controlled attenuation parameter.

Strengths and limitations

The study was reported in an abstract and therefore lacked detailed methods, patient

demographics and findings. It included people who had liver biopsy that was used to determine performance of each test. LIVERFASt was compared with other tests that are reflective of standard care in the NHS. The findings are therefore relevant but limited by brevity.

Decraecker et al. (2022)

Study size, design and location

Prospective cohort study on repeated LIVERFASt performance for liver fibrosis regression rate in 401 people with metabolic dysfunction associated fatty liver disease (MAFLD) in France. Median follow-up was 3.6 years.

Intervention

Repeated LIVERFASt-fibrosis testing along with body mass index (BMI) and liver enzymes alanine transaminase (ALT). The abstract did not report what treatment people had over the course of the study. Significant improvement in clinical endpoints was defined as a decrease in BMI of 10% or more and ALT of 50% or more from baseline.

Key outcomes

At baseline, LIVERFASt-fibrosis found 45% of people had no fibrosis (stage F0), 29% had minimal fibrosis (F1), 6% moderate (F2), 12% significant (F3) and 8% severe (F4). Overall, 13 people (3%) had liver fibrosis regression based on a decrease in LIVERFASt-fibrosis score of 0.15 or more from baseline. ALT regression of 50% or more from baseline was found in 109 people (27%) while 75 people (19%) had significant improvement in BMI. LIVERFASt-fibrosis half-stage liver fibrosis improvement was more likely with ALT regression of 50% or more from baseline (Cox–Mantel hazard ratio [HR] 3.47; 95% CI 1.08 to 11.19) than without (HR 0.29; 95% CI 0.09 to 0.93). Authors concluded LIVERFASt-fibrosis correlates with clinical endpoints and could be used for long-term monitoring.

Strengths and limitations

The study was reported in an abstract and poster only and was limited in detail. It did not report treatment after baseline or if LIVERFASt scores were used in clinical decision making. Data was collected prospectively for people with at least 1 repeated LIVERFASt-fibrosis test. Overall, 87 people had 7 repeated tests but the median number of tests was

not reported. The study had a relatively large sample size but only 13 people (3%) showed half-stage liver fibrosis improvement based on a decrease in LIVERFASt score of 0.15 or more. This should be considered when interpreting findings comparing improvement on LIVERFASt scores with clinical endpoints.

Decraecker et al. (2021)

Study size, design and location

Prospective cohort study evaluating the clinical utility of tests of fibrosis in 1,239 people with MAFLD in France. Median follow-up was 62 months.

Intervention and comparators

LIVERFASt compared with FibroScan and FIB-4. Everyone had a minimum follow-up of 1 year and at least 2 measurements from each test.

Key outcomes

Independent predictors of overall survival included LIVERFASt score (HR 2.5; 95% CI 1.91 to 3.27; p<0.001), FibroScan measurement (HR 1.62; 95% CI 1.41 to 1.86; p<0.001) and FIB-4 value (HR 1.26; 95% CI 1.16 to 1.36; p<0.001). The risk of overall complications was also significantly associated with LIVERFASt-fibrosis score (odds ratio [OR] 2.04; 95% CI 1.78 to 2.34; p<0.001), FibroScan measurement (OR 1.92; 95% CI 1.67 to 2.21; p<0.001) and FIB-4 value (OR 1.89; 95% CI 1.62 to 2.21; p<0.001).

Clinical models showed LIVERFASt, FibroScan and FIB-4 all had good performance for predicting overall and liver-related mortalities and morbidities. Performance increased when tests were combined, with maximum accuracy achieved by combining any 2 tests and clinical parameters.

Strengths and limitations

Data was collected prospectively and consecutively from a single centre. A total of 4,378 people with a diagnosis of alcoholic fatty liver disease or NAFLD were screened. Of these, 265 did not have MAFLD and 1,494 were excluded because of a lack of data from tests. Despite this, the study had a large sample size and benefited from everyone having all tests. Comparators align with standard care tests for NAFLD although the study

population was specific to MAFLD.

de Lédinghen et al. (2021b)

Study size, design and location

Prospective cohort study comparing liver fibrosis tools in 588 people with NAFLD in France. Of these, 51% had type 2 diabetes. This study included the same sample as de Lédinghen et al. (2020).

Intervention and comparators

LIVERFASt compared with FibroScan and FIB-4, with liver biopsy as a reference.

Key outcomes

Overall, 45% of people had bridging fibrosis. Test cut-offs detected bridging fibrosis in 44% of people with FibroScan, 40% with LIVERFASt and 15% with FIB-4. Discordance rate compared with liver biopsy was 32% for LIVERFASt, 24% for FibroScan and 17% for FIB-4. This did not include non-applicable FibroScan values (n=67) or indeterminate FIB-4 scores (n=280). Concordance rate with liver biopsy was 27% (n=160) for all tests and 61% (n=356) for at least 2 tests. Evaluation of sequential and combinatory models showed best performance for LIVERFASt plus FibroScan (sensitivity 75%, specificity 84%, positive predictive value 79%, negative predictive value 81%).

Strengths and limitations

The study was reported in a poster and had limited details on methods, patient demographics and findings. Liver biopsy was used as a reference and comparators included non- and minimally invasive tests that are used in NHS standard care. The findings are therefore relevant to current clinical practice. The study also explored the use of tests in combination and suggested that using LIVERFASt with standard care tests could improve detection of severe NAFLD. More evidence on this is needed to show the value to the NHS.

de Lédinghen et al. (2020)

Study size, design and location

Retrospective study comparing performance of tests for severe fibrosis in 583 people with NAFLD in France. This study included the same sample as de Lédinghen et al. (2021b).

Intervention and comparators

LIVERFASt compared with FibroScan, Fibrosure FibroTest, Hepascore, FIB-4, aspartate aminotransferase (AST) to platelet ratio index (APRI) and Forns index for cirrhosis, with liver biopsy as a reference.

Key outcomes

LIVERFASt-fibrosis AUC-ROC was 0.72 (95% CI 0.68 to 0.76) for severe fibrosis. Intention-to-diagnose analysis reported LIVERFASt AUC-ROC for cirrhosis as 0.80 (95% CI 0.75 to 0.84), with no significant difference from Fibrosure (0.81; 95% CI 0.75 to 0.85), Hepascore (0.77; 95% CI 0.71 to 0.82), Forns (0.78; 95% CI 0.73 to 0.83), FibroScan (0.75; 95% CI 0.68 to 0.80) and FIB-4 (0.76; 95% 0.69 to 0.81). It performed better than APRI (0.65; 95% CI 0.59 to 0.71; $p<0.001$). There was no difference in LIVERFASt performance for severe fibrosis or cirrhosis in people with or without type 2 diabetes.

Strengths and limitations

The study was reported in an abstract and poster with limited details on methods, patient demographics and discussion of findings. Liver biopsy was used as a reference and comparators included non- and minimally invasive tests that are used in NHS standard care. The findings are therefore relevant to current clinical practice. Some study authors were affiliated with the company.

Lim et al. (2020)

Study size, design and location

Prospective cohort study comparing testing in 724 people with chronic hepatitis B in Singapore.

Intervention and comparators

LIVERFASt compared with acoustic radiation force impulse, FIB-4 and APRI.

Key outcomes

Spearman correlations of LIVERFASt-fibrosis and LIVERFASt-activity (respectively) with other tests were acoustic radiation force impulse 0.18 and 0.21, FIB-4 0.47 and 0.11 and APRI 0.23 and 0.69 (all $p<0.01$). No or minimal liver disease was discriminated from moderate or severe disease by LIVERFASt-fibrosis, LIVERFASt-activity and APRI but not FIB-4 and acoustic radiation force impulse. The negative predictive value (NPV) for people who were hepatitis B e antigen (HBeAg) negative was 77% for LIVERFASt-fibrosis, 82% for LIVERFASt-activity and 27% for APRI. NPV for people who were HBeAg positive was 89% for LIVERFASt-fibrosis, 62% for LIVERFASt-activity and 12% for APRI.

Strengths and limitations

The study was reported in an abstract and had limited methods, patient demographics and discussion. Findings reported negative predictive value and 3 cases of false positive, but overall positive predictive value was not stated. The abstract presented quite detailed results but would be strengthened by more discussion particularly of their relevance to clinical practice and outcomes. Two study authors were affiliated with the company.

Sustainability

The company claims LIVERFASt may result in the use of less resources associated with hospitalisation for liver biopsy. There is no published evidence to support these claims.

Recent and ongoing studies

Clinical performance of LIVERFASt compared with liver biopsy in people with NAFLD: a prospective single-arm trial. ClinicalTrials.gov identifier: NCT04579874. Status: completed (July 2022). Devices: LIVERFASt. Last updated: August 2022. Country: US.

Expert comments

Comments on this technology were invited from clinical experts working in the field. The

comments received are individual opinions and do not represent NICE's view. Five experts commented on this briefing. All were familiar with tests for liver disease and fibrosis but none had used LIVERFASt.

Level of innovation

Experts considered LIVERFASt to be a minor variation to current tests for non-alcoholic fatty liver disease (NAFLD). Experts mentioned that other similar technologies are available.

Another expert commented that there are several biomarkers that examine the degree of fibrosis. These are increasingly used in combination with transient elastography and perform well, streamlining diagnostic and referral pathways and the need for liver biopsy. The expert added that there is not enough data to suggest LIVERFASt would improve on this. The assessment of fibrosis, steatosis and inflammatory activity as part of staging non-alcoholic steatohepatitis (NASH) is an area of active research. One expert said that LIVERFASt may be innovative as a minimally invasive test to diagnose NASH.

Potential patient impact

One expert said that the evidence suggested LIVERFASt performed similarly to established fibrosis tests. They considered the benefit of LIVERFASt to be increased choice in tests. Another expert thought that LIVERFASt could reduce the need for transient elastography and liver biopsy. It could also help with treatment decisions in people with coexisting NAFLD and hepatitis B. One expert said that people like to know the severity of their liver disease using rating scales. They thought this could motivate people with NAFLD to make healthy lifestyle changes. But they cautioned that there are other risk factors that need to be considered and relying on LIVERFASt scores alone could be falsely reassuring. There are other tests that assess liver fibrosis and disease activity to detect who may benefit from therapy. But there are currently no licensed treatments for advanced liver fibrosis. Experts said tests to monitor treatment would therefore only be beneficial once these treatments have been developed and used in the NHS.

Potential system impact

Experts advised that LIVERFASt is currently unlikely to replace Fibrosis-4 (FIB-4) or transient elastography in people with abnormal liver blood tests. It could be used as a

second-line tool or in combination with existing tests to improve diagnostic accuracy. One expert said it would be a major benefit if LIVERFASt could replace FibroScan as the preferred second-line test because this is currently limited by healthcare professional capacity and availability of the device. But more evidence is needed including evidence on the use of LIVERFASt in the NHS care pathway. One expert cautioned that LIVERFASt would not be used to assess chronic hepatitis B or C. But another said it could replace the need for liver biopsy in people with chronic hepatitis B and coexisting NAFLD. Experts commented that LIVERFASt has potential as a minimally invasive test for NASH. NASH is currently diagnosed using liver biopsy and possibly MRI technologies such as Perspectum. LIVERFASt would be cheaper and could be done at scale in primary care. One expert said that testing is being adopted in primary care settings to stratify referrals to secondary care. They believed uptake will increase because of the rising prevalence of liver disease. LIVERFASt could be used for better risk stratification and serial monitoring, but more evidence is needed.

General comments

One expert was uncertain where LIVERFASt would fit into the diagnostic or prognostic pathway. They advised that the clinical context would determine the relevance of the evidence to support its use. Use as a first-line test should be measured against FIB-4 for ruling out advanced fibrosis in a primary care population. For use as a second-line test, it would need to be compared with transient elastography (FibroScan) and the enhanced liver fibrosis test. This should be in people referred to secondary care for further assessment, either for more accurate staging or because of diagnostic uncertainty. The expert advised that comparison with liver biopsy would be as a third-line test to diagnose NASH in people at risk who were referred to secondary care. The patient and system benefits of using LIVERFASt would depend on how and where the test was used in the NHS. All experts said more evidence is needed to validate the test including larger well-designed studies reported in full-text peer-reviewed papers.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Ahmed Elsharkawy, consultant hepatologist, University Hospitals Birmingham. Did not declare any interests.

- Professor Alastair O'Brien, professor of hepatology, University College London. Did not declare any interests.
- Dr David Sheridan, associate professor and honorary consultant hepatologist, University Hospitals Plymouth NHS Trust. Co-investigator on the Echosens M118 study for FibroScan between 2016 and 2019.
- Dr Gautam Mehta, associate professor in hepatology, University College London and Royal Free London NHS Foundation Trust, and principal investigator, Foundation for Liver Research. Involved in NIHR-funded study on transient elastography and FibroTest.
- Dr Michael Allison, consultant hepatologist, Cambridge University Hospitals NHS Foundation Trust. Co-investigator on the Echosens M118 study for FibroScan between 2016 and 2019.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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