NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Diagnostics consultation document

FibroScan for assessing liver fibrosis and cirrhosis in primary or community care

The National Institute for Health and Care Excellence (NICE) is producing guidance on using FibroScan in primary or community care in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the company clinical and economic submissions, EAC assessment report, overview).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations

may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on FibroScan in primary or community care. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document and comments from the consultation. After considering the comments, the committee will prepare its final recommendations, which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the medical technologies evaluation programme manual.

Key dates:

Closing date for comments: 9 March 2022

Second diagnostics advisory committee meeting: 22 March 2022

1 Recommendations

1.1 Using FibroScan to assess liver fibrosis or cirrhosis for adults in primary or community care has potential to provide significant patient and healthcare system benefits. However, there is not enough certainty to recommend it as a clinically effective and cost saving option for routine use.

1.2 More evidence is needed to address uncertainty about the relative performance of FibroScan testing when done in primary or community care compared with its use in secondary or specialist care. Additional assessment of the total costs of doing the test in and outside secondary or specialist care is also needed. See further research and section 3.7 for more details.

Why the committee made these recommendations

There may be benefits to using FibroScan in primary and community care for assessing liver disease. These benefits may include improved convenience for patients, increased attendance at appointments and greater detection of liver disease. However, the company's analysis did not provide enough certainty that the test performance would be preserved when done in primary or community care, potentially by less experienced staff.

There is uncertainty if the cost for FibroScan used in the company's analysis is an accurate reflection of the true cost of doing the test, both in and outside secondary or specialist care. There was no evidence that using FibroScan in primary or community care would improve outcomes. This added to uncertainty about whether using FibroScan in primary or community care would be cost saving. Therefore, it cannot be recommended for routine use and more evidence is needed to address the uncertainties.

2 The diagnostic test

Clinical need and practice

2.1 Liver fibrosis happens when persistent inflammation of the liver causes excessive scar tissue to build up in the organ and nearby blood vessels. The presence of scar tissue can impair overall liver function and limit blood flow which may lead to the death of liver cells. Advanced liver fibrosis can develop into cirrhosis, liver failure, portal hypertension and possibly needing a liver transplant. Liver fibrosis is caused by hepatitis, non-alcoholic fatty liver disease and alcohol-related liver disease.

2.2 Cirrhosis is a late-stage liver disease that happens when inflammation and fibrosis has spread throughout the liver and disrupts the shape and function of the liver. Cirrhosis usually develops silently after exposure to 1 or more risk factors such as alcohol misuse and hepatitis B or C which cause inflammation in the liver, or obesity. However, not everyone with inflammation of the liver will eventually develop cirrhosis. Untreated cirrhosis can cause liver failure, liver cancer or death.

2.3 NICE's guideline on assessing and managing cirrhosis in over 16s recommends using transient elastography to diagnose cirrhosis in people with hepatitis C, high alcohol consumption, diagnosed alcohol-related liver disease, or non-alcoholic fatty liver disease advanced fibrosis.

2.4 NICE's clinical guideline on diagnosing and managing chronic hepatitis B recommends FibroScan as an initial test for liver disease in adults newly referred for assessment and for the annual reassessment of liver disease in adults who are not taking antiviral treatment.

2.5 NICE's guideline on assessing and managing non-alcoholic fatty liver disease states that the enhanced liver fibrosis test should be considered for people with non-alcoholic fatty liver disease to test for advanced liver fibrosis. Clinical experts highlighted that this test is not available everywhere, and FibroScan is often used instead of, or alongside the

enhanced liver fibrosis test. This is consistent with guidelines published by the British Society of Gastroenterology and in the British Medical Journal.

The intervention

FibroScan used in primary or community care

2.6 FibroScan (Echosens) is a non-invasive medical device that assesses liver fibrosis and cirrhosis by measuring the degree of liver stiffness. It can distinguish normal liver or minimal fibrosis from cirrhotic livers.

2.7 FibroScan uses proprietary vibration controlled transient elastography to quantify liver stiffness, which is essentially a measure of the extent of liver scarring.

2.8 There are multiple products in the FibroScan range with different features, but all measure liver stiffness using transient elastography. The full list of devices can be found in Table 1 of the scope.

2.9 Different sizes of probes (small, medium or extra-large) are available. The device comes with a medium probe. Small and extra-large probes are optional extras. The extra-large probe is designed to enhance signal penetration through deeper tissues, reducing device failure rates in people with obesity.

2.10 In this assessment, the intervention is FibroScan used in primary or community care (for example, in GP practices or community services). The population tested included only those who would have FibroScan as per current NHS practice. The assessment focused on where the test should be done, rather than who should have the test.

The comparator

FibroScan used in secondary or specialist care

2.11 The comparator is FibroScan used in the same way as the intervention, but in secondary or specialist care.

3 Committee discussion

Increased access to FibroScan may improve early detection of liver disease

3.1 Clinical experts explained that bringing FibroScan testing closer to patients improves attendance which could help with earlier detection of liver disease. They highlighted that there is a need to easily enable early detection of liver disease to reduce the number of cases being identified late in the disease course, and that fibrosis is reversible at early stages. Experts commented that patients generally have a positive opinion of FibroScan and could be motivated by the test results to make behavioural changes that can reverse the course of their liver disease if detected early. However, they clarified that there was no evidence showing long-term behavioural change after FibroScan use.

There may be benefits to local testing

3.2 Patient experts reported that people often have to travel long distances for FibroScan, especially in rural areas. Easier access to the test could reduce time and costs associated with travelling longer distances. It could also help people with disabilities that make it difficult to travel. The committee commented that these benefits may not be seen if use by staff who are unable to give specialised advice leads to multiple appointments being needed to first do the FibroScan and separately deliver lifestyle advice.

Clinical effectiveness

There is uncertainty about the performance of FibroScan when used outside of secondary or specialist care

3.3 There was no evidence comparing the accuracy of FibroScan for measuring liver fibrosis when it is used in primary or community care with when it is used in secondary or specialist care.

Performance of FibroScan may depend on the experience of the user

3.4 Clinical experts explained that how well FibroScan works depends on the experience of the user. They stated that if FibroScan is used often enough to maintain competence with the device, performance between settings would be comparable.

It is unclear how often FibroScan would need to be used to maintain competence

3.5 The committee considered the level of use that would be needed for users to maintain competence with FibroScan. The company commented that it encouraged users to ensure that competency is validated in practice, but that it does not provide guidance on requirements for the level of use. Clinical experts highlighted that there is no independent accreditation scheme for users. They explained that FibroScan users in primary or community care in their areas had close links with local hepatology departments which could provide support where needed. The company explained that pilot schemes in primary care networks typically saw 20 to 30 people a month. The committee noted that it is unclear how many FibroScan tests are currently done in the NHS (see section 3.8). Clinical experts highlighted that there is no clear evidence to define a number or frequency of tests that need to be done to achieve and maintain expertise. The committee concluded that if used in primary or community care, it would be important to ensure that operators used the FibroScan often enough to maintain ability to accurately use the test, and for centres to consider having an accreditation framework in place. It noted that sufficient levels of use may not be achieved if the test was available in individual GP practices, but use in locations which covered larger numbers of people, such as community diagnostic hubs, might test enough patients to maintain operator proficiency.

FibroScan should be used as part of a clear pathway

3.6 Clinical experts and GP committee members emphasised that clear guidance on what to do with the results of FibroScan is vital, particularly if

testing is done outside a specialist setting. FibroScan done outside secondary or specialist settings could reduce the number of unnecessary referrals to hepatology services. However, if there is uncertainty about what to do based on a result, a referral to specialist services, or contact with these services to ask advice, may still be made. Experts highlighted that this could be a common occurrence if multiple conflicting test results (including FibroScan) were available. Liver pathways should be designed in agreement with primary and secondary centres, and incorporate all tests used for detection and characterisation of liver disease, not just FibroScan. The committee concluded that establishing clear pathways, with advice and guidance on what to do based on a FibroScan result, would be essential to ensure appropriate clinical management of people who have FibroScan tests done outside secondary or specialist settings.

Cost effectiveness

The time horizon of the company's model does not consider potential long-term impacts of testing

3.7 The company's model used a 1-year time horizon. The committee commented that this omits potential costs or cost savings that would only appear many years after testing, such as the costs of treating previously undetected liver disease. The committee noted that increased attendance at FibroScan appointments outside of secondary or specialist care increased costs in the model, because more people were referred for follow-up appointments in hepatology. However, any potential cost savings or health benefits of greater detection of liver disease were not considered (see section 3.1). The committee noted that the effect of lifestyle advice may differ depending on who provides it, for example a GP compared with a liver specialist, but experts said that there was no evidence on this. Clinical experts commented that referrals to hepatology services may go up after adoption of FibroScan in primary or community care, but this may mean that more people who would benefit from specialist care are able to access it. However, clinical experts also

commented there was uncertainty about the long-term impact of using the test outside secondary or specialist care, for example on levels of hospitalisation. The committee concluded that a longer time horizon considered in the model would have been preferable to help assess impact of the test.

There is uncertainty around whether costs used in the model in either setting reflected NHS practice

3.8 The committee discussed the costs used in the model submitted by the company, and the revised costs used by the external assessment centre (EAC). The EAC removed a cost from the company's model for staff time to do and evaluate FibroScan in secondary or specialist care because this time was already incorporated within an existing cost used in the model. This meant that, using the figure proposed by the company for testing in this setting, the cost of doing the FibroScan was greater per scan when done outside secondary or specialist care. The company used Health Resource Group (HRG) bundled costs for ultrasound elastography to estimate the cost of FibroScan in secondary or specialist care, at £43.93 in the base case, and this cost was also used by the EAC. The company highlighted that a scenario analysis done by the EAC in which a higher cost per use in secondary or specialist care (£61.98) was used, based on a weighted average of 2 different costs attributed to the HRG code, and suggested that this might be more appropriate. The EAC commented that the results of this scenario still indicated that use of FibroScan outside secondary or specialist care was cost incurring. In their report, the EAC highlighted difficulties in evaluating the costs of doing FibroScan in the different settings that were a consequence of comparing a bundled HRG cost from secondary care with a cost obtained by micro-costing in a non-hospital setting where an HRG code does not currently exist. The committee noted that the HRG code for ultrasound elastography was used only 3,561 times for outpatients in 2019 to 2020, which likely underestimated the number of FibroScan tests done in the NHS. Further scans may be done during outpatient appointments and recorded as such,

potentially at higher cost. The committee also noted that the cost the company has provided for FibroScan in primary or community care is higher (£58.00 per scan, plus £10.50 staff time to do and evaluate FibroScan result) than the HRG code cost used in the EAC's base case and scenario analysis for FibroScan in secondary or specialist care. The committee recalled that moving FibroScan testing to primary or community care would potentially move workload to other settings for activities that happen based on test results, such as lifestyle advice, and questioned whether the time taken by healthcare professionals to do this has been adequately captured in costs of doing the test outside secondary or specialist care. They further highlighted that even if a person is not referred to a specialist service after a test done outside this setting, advice from staff in these services may be sought. Any need for further appointments to explain the results of testing done in primary or community care and provide lifestyle advice (see section 3.2) should also be considered in the costs of doing testing. The committee also questioned whether the full costs of a referral for testing in secondary or specialist care had been incorporated. Missed appointments were included as a separate cost in the model. A clinical expert commented that the cost of missed appointments was likely to already be captured in the cost of doing scans used in the company's model. If so, including an additional cost for missed appointments was not appropriate. The committee concluded that there was considerable uncertainty about whether the costs of doing the FibroScan in and outside secondary and specialist care used in the company's model were accurate reflections of the true cost of testing.

4 Recommendations for further research

Further evidence is needed to address uncertainty about the relative performance of the FibroScan test when done in primary or community care

4.1 Performance of FibroScan is dependent on the experience of the user (see section 3.3), therefore test performance in primary or community care may depend on who is doing the test and how often they do it (see section 3.4). Clarification on who would do the test in these settings and their likely experience is needed. Further evidence is needed to support considerations about the impact of experience and training on test performance. This could be the extent of use needed to obtain and maintain experience in using the test, how experience in using the test impacts on performance, and potentially impact of the extent of training on test performance.

5 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for developing specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 5 into its guidance research recommendations database and highlight these recommendations to public research bodies.

6 Review

NICE reviews the evidence 3 years after publication to ensure that any relevant new evidence is identified. However, NICE may review and update the guidance at any time if significant new evidence becomes available.

Mark Kroese

Chair, diagnostics advisory committee

February 2022

8 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be assessed. If it is considered there is a conflict of interest, the member is excluded from participating further in that assessment.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Jacob Grant
Topic lead

Thomas Walker
Technical adviser

Donna Barnes
Project manager

ISBN: