DIAGNOSTICS ASSESSMENT PROGRAMME

FibroScan for assessing liver fibrosis and cirrhosis in primary or community care
Diagnostics Consultation Document – Comments
Diagnostics Advisory Committee date: 22 March 2022
THEME: Current use of FibroScan in primary or community care

Comment number	Name and organisation	Section number	Comment
1	Echosens	1.1	• FibroScan is already used in settings outside of secondary care. To the best of our knowledge all 22 Operational Delivery Networks (ODNs) incorporate significant outreach beyond hospital walls and their use of FibroScan should be considered clinically effective. • 12 of these ODNs have very recently (in 2022) been commissioned to pilot HCC screening in the community setting. • There are many drug and alcohol services either operated by local authorities or outsourced to specialist service providers such as Change Grow Live (CGL), Turning Point, Forward, Developing Health & Independence (DHI), HumanKind all utilising FibroScan effectively. • Mid Hampshire Healthcare and Solent Medical Services in Southampton have both operated a community FibroScan service since 2019.
2	Echosens	3.3	• Echosens estimates that roughly 15% (circa 70 device) of all installed FibroScan devices in the UK are being used outside the hospital setting.
3	Echosens	3.6	Please see again details below from the Mid Hampshire Pathway (figure 3 taken from; New dimensions for hospital services and early detection of disease: a Review from the Lancet Commission into liver disease in the UK). A Community FibroScan Service operated 5 days per week across 4 to 5 GP practices and commissioned since 2019. A simple pathway integrated with secondary care that enables at risk patients to be referred onto specialist care if necessary. GP's with access to this service also receive pop up reminders on their EMIS system to consider referral to the FibroScan service based on specific Snowmed or Read Codes. The FibroScan in this

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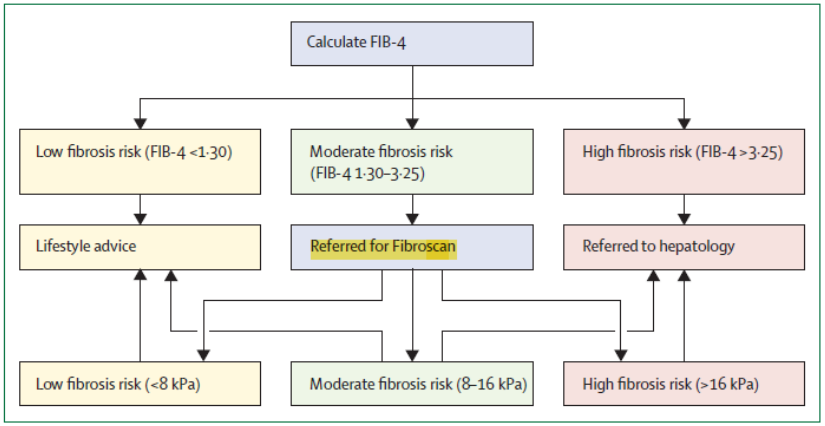
			pathway sits exclusively outside of secondary care, with a community based senior nurse, radiographer or HCA running 1 clinic in secondary care outpatients per week in addition to clinics at selected GP practices. The Southampton primary care liver pathway was designed with collaboration between primary care and secondary care. The Company economic model based some the assumptions on this pathway.  *Figure 3:* **The Mid-Hampshire FibroScan 1-year pilot project** This pilot project was done at 18 participating general practitioner surgeries and assessed patients in high-risk groups (ie, those with diabetes, a high body-mass index, and high-risk alcohol drinking). FIB-4=Fibrosis-4 Index for Liver Fibrosis.

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4	British Liver Trust	General	6. New dimensions for hospital services and early detection of disease: a Review from the Lancet Commission into liver disease in the UK (published on March 11, 2021) was led by more than 30 of the leading liver disease clinicians in the UK. It has 8 key recommendations to address the unacceptably high mortality of patients with liver disease admitted to acute hospitals. It also reinforces the need for integrated clinical services. Recommendation 5 within this paper specifically recommends expanding primary care access to FibroScan to detect severe fibrosis or cirrhosis in asymptomatic individuals within high-risk groups. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32396-5/fulltext

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5	Echosens	1.2	Echosens acknowledge that there is currently no published evidence in the format of a study that directly compares the performance of FibroScan in a community setting vs secondary or specialist care. However, in addition to comment 1 relating to section number 1.1, Echosens would like to highlight the following: • The vast majority of clinical staff trained by Echosens to use FibroScan in secondary care are not imaging specialists or have any prior point of care ultrasound experience. • Echosens maintains that ease of use, simplicity and standardisation of the exam process are what has made FibroScan so very widely utilised globally as well as in NHS hospitals. • Any healthcare professional including HCA's and AHP's can and currently are trained to accurately perform FibroScan examinations and technique. • Echosens delivers the same operator training to new and existing users of FibroScan regardless of the care setting. A FibroScan examination can be performed equally effectively in and outside secondary care provided that staff in any clinical setting have been trained correctly. It is important that staff have their initial operator training delivered by Echosens to ensure the correct standardised protocol is learnt and followed before they could be considered competent. Echosens provides a certificate to demonstrate the users competency
6	Echosens	3.3	• Echosens have to date had no cause for concern or any feedback that the performance or accuracy of FibroScan technology is affected by the setting in which it is used: outside primary care vs secondary care. What is more likely to affect test accuracy is the type of patient being scanned, e.g., high Body Mass Index (BMI) or Obese, in this instance correct and proper training is crucial. In order to tackle this, the FibroScan says when M or XL probe is required All operators trained by Echosens are taught how to ensure the FibroScan test has been performed correctly, reviewing the elastograms after each measurement and acoustic feedback during acquisition (TM and A mode). The FibroScan models that would be used in a primary or community care setting do not require the operator to review or interpret live anatomical images or organs in order to be able to perform the examination. One does not need a specialist imaging background to learn effective and accurate FibroScan technique.
7	Echosens	3.5	• There is no evidence to support a specific number of scans or time spent using FibroScan in order to maintain competence in performing the examination technique.

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			• Echosens will develop a competency checklist and assessment framework to help clinicians review and evaluate competency. This could be used as an annual assessment in practice. The assessment framework developed by Echosens will be restricted to the correct and accurate use of the technology and assessing the accuracy of elastograms. Much of which is also covered in initial training. Interventional and behavioural change discussion will not form part of the assessment or training. • Echosens will also look to develop an optional onsite assessment as a service and will consider hiring nurses to support the assessment and training if necessary. • Echosens will consider developing an online competency assessment available for free and easily accessible via our online learning academy. • Echosens are currently exploring Continuing Professional Development (CPD) accreditation for its training in the UK. Echosens are considering introducing a best practice review for all new FibroScan operators 1 month post initial training. This would be to review and reaffirm best practice and understanding, help individuals assess actual exams performed (elastogram reviews), and provide additional guidance on examination technique for patients where shear wave acquisition has proved challenging.
8	Tawazun Health	1.2	As all current community scanning is provided by specialist hepatology/gastro services the performance is unaffected by location. Ensuring Fibroscan performance in new teams / locations would be the responsibility and governance of the area developing this service. CQC regulation is a requirement for Fibroscan for any independent service. Policies, guidelines and competencies have been developed in most if not all specialist centres to ensure their quality. The effect of the pandemic on increased alcohol consumption, weight gain and delayed cancer assessments will significantly increase referals.
9	Tawazun Health	2.11	This is correct a fully trained and supervised operator can do this test accuratly in any location. It is deployed to hostels, hotels, drug and alcohol areas - no affect on the quaility should be experienced due to the location.

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10	Tawazun Health	3.4	Fibroscan is a regulated diagnostic. NHS/all providers must be able to comply with regulatory requirements to be able to provide Fibroscan. Fibroscan performed in any setting should meet the same regulated requirements and guarantees. Location is not the concern, there are numbers of staff trained to Fibroscan who do not scan regularly in specialist settings. This is an area which would fall under the governance of the area operating a fibroscan clinic and the quality standards set. Regular scanning is advisable, keeping updated with the research and developments. If companies are currently assessing the competence in primary care regularly of the GP / practice nurse undertaking ultrasound with handheld equipment then this is easily adapted for fibroscan, regulated under the same pathway. If this is not being undertaken Fibroscan would be no different.
11	Tawazun Health	3.5	This is a valid point, where only individual users are trained this may be an issue. This also occurs where in areas with many trained users, only 1 -2 peices of equipment and large lists - ensures the service is delivered by only a few. No current pathway exists to detail the skill of the user or number of scans they undertake per month in specialist units.
12	Tawazun Health	4	Previous apporval processes do not reflect the current health landscape. This data is unlikley be gained in the current covid landscape and what detailed and world revered is already provided by skilled operators from specialist units (Southampton, Nottingham), enriching the referals recieved from GP's to the direct access clinincs. This is evidence of pathways working Fib-4, to Fibroscan as

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Comment number	Name and organisation	Section number	Comment
			Southampton show enables more referals of the correct patients. The lmits used ensure those at higher risk get earlier access to care. Much of this data would still rely on these highly specialised units who currently face the backlog in liver referals created by the pandemic. COVID has been the perfect storm for increasing poor liver health the average BMI has increased, alcohol consumption has increased and we many have moved less.
13	Tawazun Health	4.1	'Further evidence is needed to support considerations about the impact of experience and training on test performance.' This needs to be considered in all settings - many specialist settings have trained staff who do low numbers of scans - location is not the concern for accuracy. A trila of all users and the outcomes should be undertaken
14	British Liver Trust	General	FibroScan is a very easy test to conduct and it does not need to be undertaken by imaging specialists. Healthcare Assistants and technicians on a low pay grade can be easily trained to accurately perform these tests. This is already happening with non-liver and non-imaging specialists providing community FibroScans in alcohol and addiction recovery units. We need the same service to be available in the community for heavy drinkers (who are not accessing alcohol dependency services) and those with metabolic risk factors.
15	British Liver Trust	General	3. There are examples of FibroScan being effective in the community and we are very concerned that many more people with liver disease will be diagnosed at a point when they already have advanced disease and it is too late for effective treatment or intervention if we do not increase fibrosis testing in the community.

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16	University Hospital Southampton NHS Foundation Trust	1	This procedure is quick to perform, non-invasive, mobile therefore hard to reach people can be scanned and risk stratified. It is not perfect but it can at least identify the patients with advanced liver fibrosis early to avoid them decompensating. It is quick to performed and can be performed anywhere as long as a person can lay down on their back.

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17	Echosens	1.1	Regarding cost, Echosens have updated the initial economic model to incorporate the EAC model and capital purchase as an option.
18	Tawazun Health	1.2	'Additional assessment of the total costs of doing the test in and outside secondary or specialist care' The cost system described during the meeting did and does not reflect what occurs in any unit. No two units have the sam process so the cost of a fibroscan is not standardised. Any outreach scans in my service were all recorded using the same process as there is NO fibroscan code on the tariff system - Elastography tarif relates to ARFI (provided in radiology) not fibroscan which is not a radiology peformed procedure - location differences were not recorded.
19	Tawazun Health	3.5	'The committee noted that it is unclear how many FibroScan tests are currently done in the NHS' This has markedly reduced throughout and following the pandemic which has now created significant backlog in those awaiting fibroscan and impacting current and future care. My previous unit we were performing > 3500 scans per year . Experienced an increased demand for fibroscan of 91.5% between 2015 – 2018. This is not sustainable on the current models reviewed by the committee. The pandemic effect on changing the landscape of strain on NHS resources needs to be fully considered when considering these questions as the volume of awaited scans remains large.

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20	Tawazun Health	3.6	The models demonstrated from the NICE team at the meeting does not appear to be reflective of the current system. Fibroscan has developed from individual units purchasing and developing their own system. HRG still does not have a tariff for VCTE/Fibroscan. The one described - elastography is for ARFI – a radiology elastography The key model assumptions were that fibroscan follows the same process and cost reporting in all areas. It also appeared to assume that all scans performed in the community are reported as this location and again this is incorrect. Personal - example 100% of all new referrals were and remain Consultant tariff appointments. From this the request is made for a Fibroscan (the unit does not do direct access referrals). Real time scanning at the time of first consultant appointment enabled the discharged of 75% of all new referrals back to primary care, these consultant tariffs could have been saved if access to community scans. These patients block the current pathway. If not scanned on the day the patient is brought to the scheduled lists adding additional appointments and time to the pathway. Tariff Coding for every scan, location of the scan does not alter this and comprises of Nurse specialist code, Ultrasound code and elastography code – three codes for every scan performed. The pathway did not appear to account for those who have a Fibroscan from Endocrinology, Rheumatology or any other speciality service. They first through the tariff ststem for their first condition. No access to fibroscan given lack of ability to cross speciality refer, resultsin patients going back to the primary care physician for referal through the hepatology/gastro pathway to access Fibroscan.

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21	Tawazun Health	3.7	As in previous comment The models demonstrated from the NICE team at the meeting does not appear to be reflective of the current cost system. All scans are provided by specialist centres and comparisson to any other model was was not demonstrated. This ensures the costs remain high and higher in the commuity setting due to additional resource and infastrucrure costs. This is highly likley to be replaced with a community access model. Cost model for fibroscan did not include the current/ future/cost alternative for diagnosis or assessment. Where fibroscan is not available, MRI, CT, and Liver Biopsy would be the primary alternatives for obtaining the information. There was no cost comparison in patients in areas without fibroscan to those with access to fibroscan. The quality of care and the time to obtain diagnosis.
22	Tawazun Health	3.8	'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.' Whilst this is likley correct, it is worth noting however that the current nHS DNA policy and post COVID-19 catch up means the patient is discharged back to primary care. To access fibroscan and will need to be referred back through the entire pathway incurring dupication of costs for, blocking appointments and for those in communities who are disadvantaged/high risk this results in them being less likley to engage with care. This delivers inequality of access and equity to those who may be at greatest need.

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23	Tawazun Health	3.8	'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.' Unfortunatley the committe did not review or request submissions from independant regulated providers of fibroscan services. All the recommendations made are already inplace for quality, quantity and staff supervision.
24	Tawazun Health	3.8	'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.' This elastography code reflects ARFI not fibroscan - and we would use this code as one of three to record each fibroscan. There is no code for VCTE/Fibroscan. Most diagnostics are assumed to be in radiology. The radiology systems are well developed and subject to different monitoring criteria. Fibroscan is not a radiology performed diagnostic so direct informatiuon on the scans needs to collected from individual units and collated.

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THEME: Potential benefits not captured in economic analyses

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25	British Liver Trust	General	NICE have looked at a direct cost comparison between conducting FibroScan in a secondary care setting versus a primary care setting. However, it is only a 'cost comparison' and does not really consider 'effectiveness'. We strongly believe that this decision should not be made on the basis that it may be marginally more expensive (based on direct healthcare costs only) and instead we should consider the opportunity/economic cost for the patient and how this will improve quality of life and save lives. The clinical and cost effectiveness should consider for example • the reduced need for unnecessary ultrasounds in hospital • the reduced need for long patient journeys, car parking at hospital costs, carer costs. The report alludes to this but this is a major issue for patients. • loss of economic productivity as patients (and/or their carer or family members) have to spend a whole day travelling to hospital rather than having a scan close to home • decrease in hospital visits; and reduce waiting times and allow hospitals to treat urgent cases rather than have resources used undertaking routine FibroScan tests. We therefore do not believe that the patient experience and QOL aspects have been fully considered. From a patient perspective being able to access Fibrosis testing locally (rather than travelling 20+ miles to a hospital) makes sense - reduced need for long patient journeys, car parking at hospital costs, carer costs, loss of economic productivity as patients have to spend a whole day travelling to hospital rather than having a scan close to home. Many patients with liver disease have complex lives and because of this attendance and concordance with appointments can be an issue. Having a FibroScan in the community will improve access and compliance for these patients and reduce "Do not attends". It's also much more likely for patients who have complex needs to attend if it's local etc. Having FibroScan locally should allow hospitals to treat urgent cases rather than have resources used undertaking routine tests.

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26	British Liver Trust	General	Are the recommendations sound, and a suitable basis for guidance to the NHS?' The UK Liver Alliance (comprising over 30 organisations committed to improving liver health including the British Liver Trust, Society of Gastroenterology, British Association for the Study of the Liver, British Liver Nurses Association, RCGP) have endorsed this submission and believes that the recommendations have the potential to seriously impede progress in addressing the liver disease crisis that the UK is seeing and that additional lives will be lost due to late diagnosis. https://britishlivertrust.org.uk/uk-liver-alliance/ NICE have looked at a direct cost comparison between conducting FibroScan in a secondary care setting versus a primary care setting and said there is not the evidence. However, it is only a 'cost comparison' and does not really consider 'effectiveness'. We strongly believe that this decision should not be made on the basis that it may be marginally more expensive (based on direct healthcare costs only) and instead we should consider the opportunity/economic cost for the patient and how this will improve quality of life and save lives. The British Liver Trust and UK Liver Alliance urges NICE to reconsider their decision
27	British Liver Trust	General	1. We do not believe that all of the evidence has been considered or that where evidence has been taken into account that it has been given sufficient emphasis or weighting. We understand that the focus for is very specific – and that enough data may not be available to directly compare FibroScan in a community setting as opposed to a secondary care setting. 2. We are concerned that NICE have looked at a direct cost comparison between conducting FibroScan in a secondary care setting versus a primary care setting and said there is not the evidence. We recognise that this is what the committee was asked to do. However, it is only a 'cost comparison' and does not really consider 'effectiveness'. We strongly believe that this decision should not be made on the basis that it may be marginally more expensive (based on direct healthcare costs only) and instead we should consider the opportunity/economic cost for the patient and how this will improve quality of life and save lives.

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THEME: Improving assessment and detection of liver disease

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28	British Liver Trust	General	4. Deaths from chronic liver disease have more than doubled in the last 20 years and even before the pandemic, liver disease was the second biggest cause of premature mortality and lost working years of life in England and Wales behind ischaemic heart disease. It is set to become the leading cause within 2 to 3 years. https://ukhsa.blog.gov.uk/2021/07/15/reducing-liver-death-a-call-to-action/ https://pubmed.ncbi.nlm.nih.gov/29198562/ 5. A major reason for the rise in deaths is late diagnosis – liver disease is often asymptomatic until disease is advanced. Three quarter of people are currently diagnosed with cirrhosis when it is too late for intervention or treatment.https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(14)61838-9.pdf … 7. Case finding by FIB 4 and Fibro scanning has been shown to be effective in detecting liver disease. This pilot (which was not considered by the EAC) demonstrates a scanning service can be portable, bringing the service closer to patients and overcoming barriers to access and is low cost compared to hospital based alternative delivery models. https://gut.bmj.com/content/70/Suppl_4/A115.1 8. There is evidence that non-invasive liver fibrosis tests being used in primary care can increase early detection of advanced liver disease and reduce unnecessary referral of patients with mild disease and that it is cost efficient. https://bmcgastroenterol.biomedcentral.com/articles/10.1186/s12876-019-1039-4 … 13. Since the early 1990s, liver cancer incidence rates have increased by more than two-and-a-half times (167%) in the UK. The NHS LTP sets out stretching ambitions and commitments to improve cancer outcomes and services in England over the next ten years. One in three people will cirrhosis will go on to develop liver cancer – by diagnosing liver disease early and ensuring that those diagnosed enter into cancer surveillance programmes will help the NHS meet its target that by 2028, 75% of people with cancer will be diagnosed at an early stage (stage one or two); and that 55,000 more people each year will survive their cancer for five years or more. We need to make assessing fibrosis much more accessible if we are to meet these targets.

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			NHS England's Cancer Programme have recognised the value of FibroScan and are currently using it in community settings to pilot whether it can assist in the early diagnosis of cancer. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/liver-cancer#heading-Zero https://www.journal-of-hepatology.eu/article/S0168-8278(18)30215-0/fulltext
29	Tawazun Health	1.1	Fibroscan appeared to be discussed as a diagnostic currently considered as a test only accessed by people with liver disease. It should be noted it is a diagnostic for anyone who may have poor liver health. In keeping with ECG which is not only a diagnostic only for those accessed with a heart condition but a diagnostic for those who may have poor heart health. This review should take into consideration the pandemic that has forced fibroscan lists to be suspended for long periods, creating backlog, specialist nurses now redeployed to look after sicker liver admissions and catching up on increasing Fibroscan requirements with reduced resources. Liver function tests are not advocated in any guideline for ruling in or out liver disease or the severity of the condition - these are used in both primary and secondary care, with poorer sensitivity and specificity than Fibroscan. Fibroscan can locate poor liver health / increased stiffness in the absence of blood tests and has a high NPV (97%) to rule out disease which provides superior certainty when compared to liver function tests. Fibroscan is not a walk in walk out dignostic with daily clinics just performing the scans It is specialist staff delivered scan in liver/gastro/outpatinet clinics and every patient retained from the scan result reduces ongoing and furture capacity in the unit to perform future scans within set staffing resources.

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30	Tawazun Health	2.2	Untreated cirrhosis can cause liver failure, liver cancer or death.' Liver cancer is now the fastest growing cancer, the 9th most common and the third most deadly with 75% beyond treatment when they are located. Fibroscan has a high PPV in location of cirrhosis and monitoring.
31	Tawazun Health	3.1	'However, they clarified that there was no evidence showing long-term behavioural change after FibroScan use.' Long term follow up in hepatology units measure serial Fibroscans, in NAFLD this is recommended only 3-5 yearly and short term measures based on 1 year would be inappropriate. Hepatology units discharge NAFLD patients as their Fibroscans reduce - with no approved medication for this condition much of this change is anecdotally lifestyle / behavioural alteration. HCV patients were discharged, following DAA cure of the virus and improved liver stiffness by fibroscan. Fibroscan has a growing body of clinical trial evidence for being able to predict and track outcomes of care interventions. There is evidence in alcohol detoxification that measurements enhance the withdrawal and monitor the reduction in stiffness and fat content as the % alcohol of the drinks reduce.

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32	Echosens	3.2	It makes sense for those operating FibroScan to give specialized advice and intervention if needed there and then. This is how many early adopters of FibroScan outside of the secondary care setting run their clinics currently.
33	Echosens	3.6	The following liver pathway published and recommended by EASL in 2021 provides good guidance on a potential pathway incorporating a variety of tests which can be used for detecting and characterising liver disease (source provided in the initial application, available upon request).

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			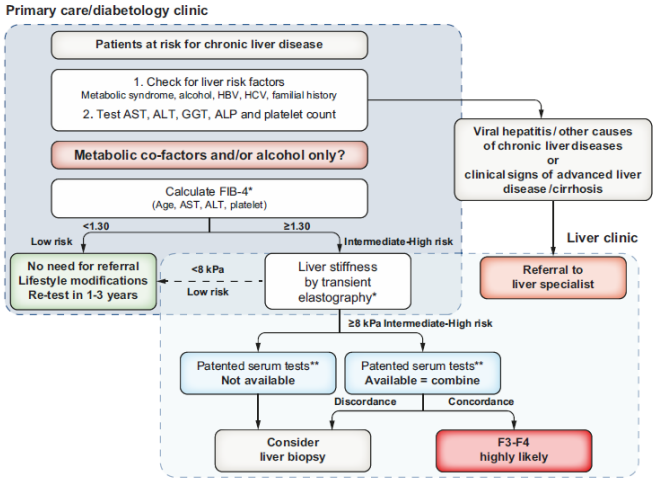 **Fig. 1. Proposed use of NITs in patients observed in primary care or outside the liver clinic.** As shown, FIB-4 can be used in patients with metabolic co-factors and/or alcoholic liver disease to identify patients requiring referral to the specialist liver clinic. *Transient elastography or FIB-4 may be performed before or after referral to liver specialist according to local availability and pathways. **Cut-offs to use: ELF™ 9.8 (NAFLD/ALD); FibroMeter 0.45 (NAFLD), Fibrotest 0.48 (NAFLD). ALD, alcohol-related liver disease; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ELF, enhanced liver fibrosis; FIB-4, fibrosis-4; NAFLD, non-alcoholic fatty liver disease.
34	British Liver Trust	General	The report suggests that lifestyle interventions need to be given in secondary care but we believe that in the vast majority of cases primary care is best placed to do this. Targeting lifestyle modification in people with NAFLD is vitally important, not only due to the high disease prevalence but also since excess liver fat is an independent risk factor for the development of cardiovascular disease and T2DM. Primary care is already providing these interventions for other conditions. GPs should therefore be part of the multi-disciplinary team that provides early lifestyle interventions for this condition. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4764638/

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35	British Liver Trust	General	9. Many areas of the UK do not have an effective pathway in primary care for the early detection of liver disease. Including an assessment for liver fibrosis in primary care will help to address this. https://www.journal-of-hepatology.eu/article/S0168-8278(18)30215-0/fulltext 10. FibroScan is just one non-invasive test but it needs to be part of the mix along with Enhanced Liver Fibrosis (ELF) blood tests as current primary care approaches result in the referral of many patients that do not have significant liver fibrosis, placing a burden on secondary care services, incurring unwarranted costs and generating unnecessary inconvenience and anxiety for patients. https://www.journal-of-hepatology.eu/article/S0168-8278(19)30227-2/fulltext
36	Tawazun Health	2.3	This will not be met with the current limited number of devices only located in specialist centres. The British liver Trust review (2021) demonstartes only 19% of the UK have access to fibroscan or complete liver pathways.
37	Tawazun Health	2.5	This guideline is due for review in light of other international guideleins having been published during 2020 and 2021 incrreasing access to fibroscan at primary, tretiary levels. With no / little access the countries most prevelent condition NAFLD >16 million in the UK (Younousi 2015) will be a growing burden of severe disease and health concerns.
38	Tawazun Health	3.6	New and updated guidlelines from APASL, EASL and the AGA should be used to highlight new approved and evidence based pathways for assessing liver care. The Consensus statement last year highlighted the strength of the UK in the specialist direct referal pilots as best practice. Pathways selecting the right patients, with the highest risk are advised. This will NOT be an option to NICE going forward as pathways are designed if Fibroscan only available in and from specialist settings. Skilled operators can address many issues and upskill as an education program tertiary areas.

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THEME: Liver testing pathways

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12 (repeat)	Tawazun Health	4	Previous apporval processes do not reflect the current health landscape. This data is unlikley be gained in the current covid landscape and what detailed and world revered is already provided by skilled operators from specialist units (Southampton, Nottingham), enriching the referals recieved from GP's to the direct access clinincs. This is evidence of pathways working Fib-4, to Fibroscan as Southampton show enables more referals of the correct patients. The lmits used ensure those at higher risk get earlier access to care. Much of this data would still rely on these highly specialised units who currently face the backlog in liver referals created by the pandemic. COVID has been the perfect storm for increasing poor liver health the average BMI has increased, alcohol consumption has increased and we many have moved less.

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THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment
39	British Liver Trust	General	'Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.' 1. Promoting equality and addressing health inequalities are at the heart of NHS England's values. Liver disease disproportionally affects the poorest in society. People in the most deprived population fifth who die from liver disease typically do so almost one decade earlier than those who die from liver disease in the most affluent population fifth. These people find it more difficult to meet the cost of travelling to hospitals and would be better served with diagnostic testing in the community. https://fingertips.phe.org.uk/profile/atlas-of-variation file:///C:/Users/VANESS~1/AppData/Local/Temp/FINAL_LiverAtlas-2.pdf 2. Many patients with liver disease come from disadvantaged backgrounds and have complex lives (for example have drug and alcohol dependency issues) and because of this attendance and concordance with appointments can be an issue. Having a FibroScan in the community will improve access and compliance for these patients and reduce "Do not attends".

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40	Tawazun Health	3.8	'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.' Whilst this is likley correct, it is worth noting however that the current nHS DNA policy and post COVID-19 catch up means the patient is discharged back to primary care. To access fibroscan and will need to be referred back through the entire pathway incurring dupication of costs for, blocking appointments and for those in communities who are disadvantaged/high risk this results in them being less likley to engage with care. This delivers inequality of access and equity to those who may be at greatest need.

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Comment number	Name and organisation	Section number	Comment
41	Siemens Healthineers	1	Risk stratification of liver disease using laboratory based blood tests, as recommended by NICE, BSG, EASL guidelines, is evidenced by 7 early adopter sites in England and Scotland. The combination of universally available FIB4 with ELF scores for resolution of indeterminate FIB4 scores is in routine clinical practise at these sites. The challenge for wider adoption of this cost effective strategy is commissioner engagement, where liver disease is a low priority despite the continued rise in obesity, type II diabetes and alcohol misuse. The impact of the COVID 19 pandemic means that liver clinic waiting lists are in excess of 6 months. NHS Tayside have used ELF to safely refer 44% of their liver clinic waiting list back to primary care.
42	Siemens Healthineers	1.1	The enhanced liver fibrosis ELF test used in combination with FIB4 is being used effectively in 7 UK NHS laboratories aligned to BSG and EASL guidelines with substantial published evidence to support its clinical utility, quality and cost effectiveness
43	Siemens Healthineers	1.2	Real world evidence of the utility of ELF in a primary care setting has been published and the test is in routine use using guidelines published by the BSG, EASL, NICE on the use of non invasive tests for assessing liver fibrosis. It is currently performed in 7 UKAS accredited NHS laboratories in England and Scotland. The quality of performance of the tests is monitored internal laboratory quality control schemes and by a UKNEQAS scheme which has been operational for the last 2 years. This was set up and is managed by Dr Cathie Sturgeon at Edinburgh Royal Infirmary.
44	Siemens Healthineers	2.1	There is published evidence on the use of the ELF test in viral hepatitis, alcohol use disorder, NAFLD/NASH and autoimmune liver disease.
45	Siemens Healthineers	2.2	An ELF score of 9.8 or more is indicative of advanced liver fibrosis whilst a value of 11.3 or more is indicative of liver cirrhosis. ELF is a simple blood test that can be used by primary care in collaboration with their local hospital laboratory service to stratify patients at risk of liver fibrosis/cirrhosis and thereby identify those individuals that should be referred for secondary care assessment
46	Siemens Healthineers	2.3	ELF in combination with FIB4 can be used in primary care to identify those patients at high risk of liver fibrosis/cirrhosis for referral to secondary care where transient elastography services are supported by the appropriately skilled staff and clinical services.

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47	Siemens Healthineers	2.5	NG49 from 2016 is overdue for review and includes a number of errors which were pointed out at the time by Siemens Healthineers. The cut off for ELF of 10.5 is derived from a paediatric population. The cut off for high risk of advanced fibrosis is 9.8 as defined in the instructions for use. The price of the test is quoted as £108 per ELF score. Siemens Healthineers provide ELF at £30 to £45 per score based on volume of tests and whether an analyser deployment needs to be considered.
48	Siemens Healthineers	2.5	Deploying imaging technology in primary care is difficult from a staffing, skill, quality, logistics and cost perspective. However, the combination of laboratory blood tests such as FIB4 and ELF to risk stratify patients who should be referred for liver clinic assessment is evidenced in 7 early adopter sites in the UK, 6 in England and 1 in Scotland. Every laboratory in the NHS is capable of generating FIB4 scores at no additional cost to commissioners. Where the FIB4 score is indeterminate then the use of ELF as outlined in the BSG guidelines and evidenced in the Camden & Islington NAFLD pathway, (Srivastava A, et al. J Hepatol. 2019;71:371–378) resolves who should and should not be referred. This pathway has led to an 80% reduction in inappropriate referrals, whilst delivering a 5 fold increase in advanced fibrosis patients discovered in primary care. As a result of the COVID19 pandemic every NHS laboratory now has the capability through NPEx to electronically request and receive a test from any other laboratory providing the required test. Wider adoption of ELF in each of the 29 pathology networks in England would provide universal service coverage for primary care. In Scotland the intelligent liver function test (iLFT) pathway has been adopted as best practice, with NHS Tayside currently providing ELF as a referral service for the whole of Scotland. The logistics infrastructure for transporting blood samples between UK laboratories already exists as part of routine pathology services. Evidence of this type of approach is demonstrated in the heart failure pathway where an elevated NTproBNP result from a blood test requested in primary care is used to justify referral to cardiology for echocardiography.
49	Siemens Healthineers	2.10	Existing laboratory services are capable of generating FIB4 scores from routine liver enzyme and platelets counts along with patient age. Indeterminate FIB4 scores can be resolved using the same serum sample either as part of a reflex algorithm within the laboratory or using the national pathology exchange NPEx to refer the sample to a neighbouring laboratory running ELF. This provides the scale required to deliver an effective primary or community care service where Fibroscan is used for those patients referred into secondary care. The Camden & Islington pathways for NAFLD and alcohol misuse are real world evidence of the cost effectiveness of this approach. The NAFLD pathway demonstrated an 80% reduction in

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			inappropriate referrals whilst delivering a 5 fold increase in advanced liver fibrosis and a 3 fold increase in cirrhosis detected. Liver clinic waiting lists in many areas of the UK are in excess of 6 months. NHS Tayside have clearly demonstrated that 44% of patients on their waiting list were safely referred back to primary care using ELF
50	Siemens Healthineers	2.10	A single ADVIA Centaur or Atellica IM immunoassay analyser is capable of generating over 3000 ELF scores per week compared with a single Fibroscan unit producing 150 to 200 assessments per week. The use of existing phlebotomy services, a simple blood collection and the existing laboratory services infrastrucure across the UK, offers the opportunity of risk assessment at scale in primary care. At risk individuals can then be assessed in the appropriate liver clinic setting where Fibroscan is an established secondary care tool
51	Siemens Healthineers	3.1	Do not attends and a Fibroscan failure rate of 5 to 15% in the literature are a significant financial burden when considering deployment into primary care. If we consider the socially marginalised communities, the homeless, people who inject drugs, attendees at drug and alcohol dependency units and the prison population, then the logistics of collecting a blood sample versus clinic attendance for a Fibroscan, would suggest that a blood collection would be a more successful strategy. In addition this offers the opportunity to test for Hepatitis B and C in these higher prevalence populations.
52	Siemens Healthineers	3.2	Universal access to phlebotomy, sample transport and laboratory services using existing liver tests, to generate smart scores such as FIB4 along with ELF, would overcome the logistics of transporting patients to clinics many miles from home. This offers a more sustainable, cost effective service in both urban and remote community settings
53	Siemens Healthineers	3.3	Liver enzymes AST & ALT along with platelet count from a full blood count are standard tests universally available in every hospital laboratory. These parameters can be used for simple fibrosis risk scores e.g FIB4 with ELF used to resolve indeterminate FIB4 scores. Every laboratory in the UK is subject to regular inspection and accreditation by UKAS and all methodologies are scrutinised for quality using internal and external quality assurance schemes e.g UKNEQAS. A pilot UKNEQAS scheme for liver fibrosis biomarkers has been operational for the last 2 years managed by Dr Cathie Sturgeon at Edinburgh Royal infirmary. There are currently 7 UK laboratories reporting ELF scores into this scheme. They also receive referral

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			samples from multiple neighbouring pathology networks using the national pathology exchange NPEx to request and receive ELF scores
54	Siemens Healthineers	3.4	All UK laboratories are capable of generating FIB4 scores from routine blood tests. Those producing ELF scores are UKAS accredited and have internal and external quality assurance schemes aimed at delivering standardised good laboratory practise.
55	Siemens Healthineers	3.5	All UK NHS laboratories are UKAS accredited and regularly inspected to ensure compliance with good laboratory practise. Internal and external quality assurance schemes ensure blood test results used to generate FIB4 and ELF scores are compliant and comparable across the UK.
56	Siemens Healthineers	3.6	NICE, EASL and BSG guidelines clearly indicate the utility of using non invasive tests for liver fibrosis risk assessment. The combination of blood tests such as FIB4 and ELF in a primary care setting is evidenced in the literature allowing those at high risk to be assessed using Fibroscan in the appropriately skilled secondary care setting.
57	Siemens Healthineers	3.7	The Camden & Islington NAFLD pathway clearly demonstrated cost effectiveness delivering an 80% reduction in inappropriate referrals to secondary care versus standard of care, whilst delivering a 5 folds increase in advanced liver fibrosis and 3 fold increase in cirrhosis patients discovered. The primary care referral cost savings provide the financial incentive for commissioning the service whilst delivering the appropriate patients for investigation into secondary care. A blood test delivered at clinically appropriate time intervals offers the opportunity to monitor patients in the appropriate primary or secondary care setting based on disease severity. Long term patient outcomes of using ELF in the clinical pathway are part of the ongoing ELUCIDATE study led by Prof William Rosenberg at The Royal Free
58	Siemens Healthineers	3.8	The cost of using indirect fibrosis scores such as FIB4 are already part of standard liver blood tests profiles so there is no additional cost to consider. ELF scores at the 7 routine service provider laboratories cost between £30 and £45 per ELF score based on test volumes and whether any additional analysers are required. Once laboratory overheads are considered then these laboratories are offering an ELF score at a referral service cost of £50 to £60. The national pathology exchange NPEx deployed in all UK hospital laboratories as a result of the COVID19 pandemic, allows electronic requesting and receipting of ELF scores from any UK laboratory requesting the test. Evidence for this is seen in Scotland where NHS

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			Tayside provide ELF as a referral test service for the whole of Scotland as part of the national deployment of the intelligent liver function test (iLFT) pathway developed at Dundee. Leeds Teaching Hospitals provide referral testing for Humberside, Lincolnshire and parts of Lancashire. Southampton University Hospitals provide a service for Oxfordshire and parts of Dorset, Hampshire and Bristol. HSL provide services for Camden & Islington CCGs and other parts of north London. St George's Hospital Tooting is seeking to expand their ELF service to cover the 3.5 million people served by SW London Pathology services. University Hospital of North Midlands provide a service for Stoke and Staffordshire. Dudley Hospitals is seeking to expand their ELF service to the whole of the Black Country. All of these service developments have been slow and hampered by a lack of awareness or engagement from CCG commissioners around liver disease, which is seen as a low priority. Commissioning at NHS England level would allow ELF to be provided at the scale required to address the liver pandemic.
59	Siemens Healthineers	4.1	All NHS Laboratories in the UK are regularly inspected and subject to UKAS accreditation. All the tests associated with generating FIB4 and ELF scores are subject to internal and external quality assurance schemes. Staff condiucting these tests are state registered biomedical scientists.
60	Siemens Healthineers	5	7 UK based laboratories have successfully implemented FIB4 and ELF into routine practice for liver fibrosis investigation of NAFLD/NASH, alcohol misuse, viral hepatitis and autoimmune liver disease. Implementation at scale using the existing NHS laboratory and IT infrastructure will deliver the tools for investigating liver fibrosis in the primary/community setting at the scale required to address the liver pandemic.
61	Siemens Healthineers	6	NICE ng49 was produced in 2016 and is currently out of step with BSG and EASL guidelines on the use of non invasive tests for risk stratifying patients with liver disease.