NICE National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT 210 - Virtual Touch Quantification to diagnose and monitor liver fibrosis

Expert Adviser Questionnaire Responses

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Dr Edmund Godfrey	Consultant Radiologist	Royal College of Radiologists	Specialist Society	-
Dr Simon Elliott	Consultant Radiologist	Royal College of Radiologists	NICE	Yes
Mr Colin Griffin	Ultrasound Lead	British Medical Ultrasound Society	NICE	Yes
Ms Sophie Auld	Superintendent Radiographer	Society and College of Radiographers	NICE	Yes
Dr Priya Narayanan	Consultant Radiologist	Royal College of Radiologists	Specialist Society	-
Professor Paul Sidhu	Consultant Radiologist	Royal College of Radiologists	Sponsor	Yes
Dr Philp Shorvon	Consultant Radiologist	Royal College of Radiologists	Sponsor	Yes
Professor Roger Williams	Director	The Foundation for Liver Research	Sponsor	Yes
Dr David Sherman	Consultant Physician & Gastroenterologist	Royal College of Physicians	Sponsor	Yes
Dr Michael Heneghan	Consultant Hepatologist	British Association for the Study of the Liver	NICE	Yes

YOUR PERSONAL EXPERIENCE (IF ANY) WITH THIS TECHNOLOGY

Question 2: Please indicate your experience with this technology?

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Dr Edmund Godfrey Consultant Radiologist	No	No	No	Yes
Dr Simon Elliott Consultant Radiologist	Yes	Blank	Blank	Blank
Mr Colin Griffin Ultrasound Lead	Yes	No	No	No
Ms Sophie Auld Superintendent Radiographer	No	No	No	Yes
Dr Priya Narayanan Consultant Radiologist	Yes	Blank	Blank	Blank
Professor Paul Sidhu Consultant Radiologist	Yes	Yes	Yes	Blank
Dr Philip Shorvon Consultant Radiologist	Yes	No	Yes	No
Professor Roger Williams Director	No	No	No	Yes
Dr David Sherman Consultant Physician & Gastroenterologist	Yes	Blank	Blank	Blank
Dr Michael Heneghan Consultant Hepatologist	Yes	Yes	Yes	No

Any Comments?	
Dr Edmund Godfrey **Consultant Radiologist**	**Blank**
Dr Simon Elliott **Consultant Radiologist**	**Blank**
Mr Colin Griffin **Ultrasound Lead**	**Blank**
Ms Sophie Auld **Superintendent Radiographer**	**Blank**
Dr Priya Narayanan **Consultant Radiologist**	**Blank**
Professor Paul Sidhu **Consultant Radiologist**	**Currently using in Clinical and research studies**
Dr Philip Shorvon **Consultant Radiologist**	**I have used virtual touch for liver disease for over 2 years**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Extensive clinical and research experience since 2009 - can provide bibliography and publication / presentation record on request. Jointly awarded Grant by NHS Techology Adoption Centre for clinical assessment of this technology in 2009 - work now published.**
Dr Michael Heneghan **Consultant Hepatologist**	**Very useful if added with ultrasound**

Question 3: Have you been involved in any kind of research on this technology? If Yes, please describe?

Expert Advisers	Yes/No	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Yes**	**However, I have been involved in research on magnetic resonance elastography (MRE) which is a similar technology.**
Dr Simon Elliott **Consultant Radiologist**	No	Blank
Mr Colin Griffin **Ultrasound Lead**	**Yes**	**I am in the process of looking at the usefulness in diffuse liver conditions and I am hoping to begin another research project in the use of the technology in the evaluation of renal transplants when compared to diagnostic ultrasound and biopsy results.**
Ms Sophie Auld **Superintendent Radiographer**	No	Blank
Dr Priya Narayanan **Consultant Radiologist**	No	Blank
Professor Paul Sidhu **Consultant Radiologist**	**Yes**	**Studies on reproducibility and in liver fibrosis.**
Dr Philip Shorvon **Consultant Radiologist**	**Yes**	**True research no- however we have been auditing the results of the virtual touch against liver biopsy results and also looking at ways of using the results in scoring of portal hypertension**
Professor Roger Williams **Director**	No	Blank
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Yes**	**Multiple abstracts, presentations (local, national and international meetings) and some papers on clinical use of ARFI in non-invasive assessment of liver disease**

Dr Michael Heneghan **Consultant Hepatologist**	Blank	**Br J Radiol. 2012 Oct;85(1018):e858-63. doi: 10.1259/bjr/74797353. Epub 2012 Jul 4.** **Acoustic radiation force impulse quantification: repeatability of measurements in selected liver segments and influence of age, body mass index and liver capsule-to-box distance.** **Jaffer OS1, Lung PF, Bosanac D, Patel VM, Ryan SM, Heneghan MA, Quaglia A, Sidhu PS.** **Author information** • **1Department of Radiology, King's College Hospital, London, UK. ounali.jaffer@googlemail.com** **Abstract** **OBJECTIVE:** **To assess the inter- and intra-observer variability of acoustic radiation force impulse (ARFI) quantification in liver segments with influence of age, body mass index (BMI) and liver capsule-to-box (CB) distance.** **METHODS:** **10 healthy volunteers were examined twice, by three experienced operators, separated by a 1-week interval. 10 readings were obtained, from segments 3, 5/6 and 7/8. Age, BMI and the CB distance were noted. The Cronbach α statistic for analysis of reliability was performed for the inter- and intra-observer studies. Multivariate linear regression models determined significance of the other parameters.** **RESULTS:** **1800 velocity measurements were recorded. Mean values±standard deviation: segment 3, 1.31±0.19 m s(-1); segment 5/6, 1.12±0.22 m s(-1); segment 7/8, 1.12±0.17 m s(-1). For both the inter- and intra-observer study, the Cronbach α statistic was ≥0.7 (reliable) when taken from segments 5/6 and 7/8 but <0.7 (unreliable) for segment 3. BMI and age showed significant (p<0.0001) but contrasting correlation (segment 5/6: BMI r=0.02, age r=-0.02; segment 7/8: BMI r=-0.01, age r=0.01) with ARFI velocities when analysed for the segments deemed reliable. A weak negative correlation between ARFI velocities and liver CB distance was demonstrated for both assessed segments (segment 5/6, r=-0.08; segment 7/8, r=-0.06; p<0.001).** **CONCLUSION:** **With trained operators, ARFI is a reliable and reproducible method of liver stiffness quantification in segments 5/6 and 7/8 but acquisition of measurements from segment 3 should be avoided. Values obtained deeper to the liver capsule allow more reliable liver stiffness quantification**

THIS PRODUCT (TECHNOLOGY) AND ITS USE

Question 4: How would you best describe this technology?

Expert Advisers	It is a minor variation on existing technologies with little potential for different outcomes and impact	It is a significant modification of an existing technology with real potential for different outcomes and impact	It is thoroughly novel - different in concept and/ or design to any existing
Dr Edmund Godfrey Consultant Radiologist	No	Yes	No
Dr Simon Elliott Consultant Radiologist	Blank	Yes	Blank
Mr Colin Griffin Ultrasound Lead	Blank	Yes	Blank
Ms Sophie Auld Superintendent Radiographer	No	Yes	No
Dr Priya Narayanan Consultant Radiologist	Blank	Yes	Blank
Professor Paul Sidhu Consultant Radiologist	No	No	Yes
Dr Philip Shorvon Consultant Radiologist	No	Yes	No
Professor Roger Williams Director	Blank	Blank	Blank
Dr David Sherman Consultant Physician & Gastroenterologist	Blank	Blank	Yes
Dr Michael Heneghan Consultant Hepatologist	Blank	Yes	Blank

Any Comments?	
Dr Edmund Godfrey **Consultant Radiologist**	**Similar technology exists (e.g. Fibroscan) but VTq is different in that it enables targeted sampling of liver stiffness.**
Dr Simon Elliott **Consultant Radiologist**	**I believe VTq was the first shear-wave system incorporated into a standard US scanner for routine liver use, but other systems are now commercially available using similar technology.**
Mr Colin Griffin **Ultrasound Lead**	**This is the first of this type of technology to give a quantifiable value of tissue stiffness which is better than other colour based systems already available.**
Ms Sophie Auld **Superintendent Radiographer**	**Blank**
Dr Priya Narayanan **Consultant Radiologist**	**Blank**
Professor Paul Sidhu **Consultant Radiologist**	**New technique, new concept**
Dr Philip Shorvon **Consultant Radiologist**	**It is a novel type of elastography**
Professor Roger Williams **Director**	**I am unclear as to how VTq differs from standard Fibroscan and the advantages of it**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**It is the first device to measure liver stiffness that is integrated into a standard commercially available US platform. This is an important difference to Fibroscan (Transient Elastography), and the generation of the shear wave differs significantly. Importantly, recent meta-analysis data is now suggesting that it is at least as accurate as TE, and has a significantly higher success rate. Also, most hospitals in the UK do not have Fibroscan, but may already possess the US machine and could implement the technology via a software modification.**
Dr Michael Heneghan **Consultant Hepatologist**	**Blank**

Question 5: What is the most appropriate use (e.g. clinical indication) for the technology?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Assessment of liver fibrosis stage/presence of cirrhosis in patients with chronic liver disease.**
Dr Simon Elliott **Consultant Radiologist**	**Assessing the liver for the existence and grading of fibrosis. This can now form a part of the routine US exam. There is evidence that this can reduce the number of liver biopsies required.**
Mr Colin Griffin **Ultrasound Lead**	**Evaluation of liver patients with known risk factors for developing diffuse liver disease, cirrhosis, patients on long-term drugs that effect the liver (e.g. Methotrexate, etc).**
Ms Sophie Auld **Superintendent Radiographer**	**Looking at diseases of the liver, breast and thyroid**
Dr Priya Narayanan **Consultant Radiologist**	**Monitoring of patients with hepB/C /surveillance for liver fibrosis**
Professor Paul Sidhu **Consultant Radiologist**	**Diffuse liver disease and in many other organs e.g. thyroid, breast, testis where tissue 'hardness' needs to be assessed.**
Dr Philip Shorvon **Consultant Radiologist**	**Follow up of chronic hepatitis patients and other chronic liver disease. Identification of cirrhosis**
Professor Roger Williams **Director**	**Following progression of liver disease caused by alcohol, hepatitis viral infection and in initial assessment of severity of fibrosis**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Assessment of liver stiffness, non-invasive assessment of liver fibrosis, not only in viral hepatitis but also in a variety of liver diseases.** **Taking a wider view, the potentially enormous clinical impact includes : 1) Detection of unsuspected liver damage; 2) selection for treatment, for example in viral and auto-immune hepatitis; 3) assessing response to treatment; 4) identification of patients with cirrhosis who would require surveillance ultrasound for liver cancer; 5) for the first time, non-invasive identification of portal hypertension and selection for initial endoscopy and subsequent surveillance (our own preliminary data, published in abstract form only at present); 6) the avoidance of invasive liver biopsies and upper GI endoscopies in a proportion of patients; 7) Potentially providing greater information, which is also complementary to, that available from existing techniques – many experts now believe that liver biopsy may not entirely be the "gold standard" it was thought to be.**

Dr Michael Heneghan **Consultant Hepatologist**	**In conjunction with ultrasound in any patient referred with liver enzyme abnormalities** **Follow up on treatment**

COMPARATORS (including both products in current routine use and also "competing products")

Question 6: Given what you stated is the appropriate indication (clinical scenario) for its use, what are the most appropriate "comparators" for this technology which are in routine current use in the NHS?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Liver biopsy, Fibroscan, serum markers**
Dr Simon Elliott **Consultant Radiologist**	**Fibroscan (transient elastography). Liver biopsy.**
Mr Colin Griffin **Ultrasound Lead**	**Fibroscan**
Ms Sophie Auld **Superintendent Radiographer**	**Unsure**
Dr Priya Narayanan **Consultant Radiologist**	**Fibroscan**
Professor Paul Sidhu **Consultant Radiologist**	**A number of ultrasound manufacturer's are involved in developing this technology**
Dr Philip Shorvon **Consultant Radiologist**	**Fibroscan and serum markers for fibrosis**
Professor Roger Williams **Director**	**Fibroscan and attachments to standard ultrasound machine**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Main comparator is liver biopsy - Fibroscan is not widely available enough to be considered a comparator. No other equivalent widely available technology.**
Dr Michael Heneghan **Consultant Hepatologist**	**Fibroscan**

Question 7: "Competing products": Are you aware of any other products which have been introduced with the same purpose as this one?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Fibroscan, various other ultrasound elastography technologies, serum marker panels, magnetic resonance elastography**
Dr Simon Elliott **Consultant Radiologist**	**Shearwave elastography from Philps Healthcare (currently on iU22 platform). I have been involved in clinical and engineering development of this platform.**
Mr Colin Griffin **Ultrasound Lead**	**No**
Ms Sophie Auld **Superintendent Radiographer**	**No**
Dr Priya Narayanan **Consultant Radiologist**	**No**
Professor Paul Sidhu **Consultant Radiologist**	**There are other products that use this technology - on all main ultrasound maufacturer's machines**
Dr Philip Shorvon **Consultant Radiologist**	**Fibroscan. Some ultrasound companies are producing similar equipment**
Professor Roger Williams **Director**	**as above**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Fibroscan (Echosens); Supersonic (? manufacturer)**
Dr Michael Heneghan **Consultant Hepatologist**	**Fibroscan**

POSSIBLE BENEFITS FOR PATIENTS

Question 8: What are the likely additional benefits for patients of using this technology, compared with current practice/comparators?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**The current gold standard for liver fibrosis assessment is liver biopsy. This risks complications including pain, haemorrhage and death. If a non-invasive alternative could be used to replace some or all liver biopsies, this would reduce the number of complications experienced by patients.**
Dr Simon Elliott **Consultant Radiologist**	**Reduced number of attendances to clinic/hospital. Potential reduction in liver biopsy and assoicated risks.**
Mr Colin Griffin **Ultrasound Lead**	**This is an ultrasound guided system, so instead of blind sampling of the liver, the operator will now be anle to select an area of interest on a B-mode ultrasound image and this will allow for better and more valid results. This is also useful in the following up of patients having serial scans as the same are of interest can be selected every time so that true comparible and reliable quantifiable data can be provided for the area under investigation.**
Ms Sophie Auld **Superintendent Radiographer**	**Provides measurable information about tissue stiffness**
Dr Priya Narayanan **Consultant Radiologist**	**ARFI has the advantage of being able to visualise the liver (assessing for structural /focal parenchymal changes) in addition to assessing liver stiffness. Fibroscan only performs a liver stiffness measurement.**
Professor Paul Sidhu **Consultant Radiologist**	**Aid confidence in diagnosis and avoid 'liver biopsy'**
Dr Philip Shorvon **Consultant Radiologist**	**Better follow up of chronic liver disease. Reduced need for liver biopsy.Identification of patient for further investigation/follow up. Identification of portal hypertension.**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Main benefit is realising the aim of bringing non-invasive detection of liver fibrosis into mainstream use throughout the UK. Although complementary to liver biopsy, this technique is likely to provide further information about lievr disease, and is dynamic and repeatable. "One stop" liver clinics (as envisaged in the 2009 National Liver Plan) would become a reality, and lead to more efficient use of clinical time and money. Also see potential scenarios 1) to 7) in section 5 above.**

Dr Michael Heneghan **Consultant Hepatologist**	**2 procedures at same time. US and ARFI implies less visits**

Question 8.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Dr Edmund Godfrey Consultant Radiologist	It is likely that some liver biopsies will still need to be carried out for other reasons, or where the noninvasive technique gives unexpected or equivocal results. The main obstacle to replacing liver biopsy with a non-invasive technique is providing a sufficient evidence base to suppor the use of the latter.
Dr Simon Elliott Consultant Radiologist	Yes, already proven. Obstacles mainly acceptance by clinicians and requirement for additional software and training for sonographers.
Mr Colin Griffin Ultrasound Lead	I hope so. Education of the system is important and it is essential to "sell" the sysem as image guided elastography as this will give the referrer confidence in what they are getting.
Ms Sophie Auld Superintendent Radiographer	Unsure
Dr Priya Narayanan Consultant Radiologist	Liver biopsy is associated with both significant morbidity and mortality. ARFI may obviate /reduce the need for liver biopsy.Obstacle - cost associated with installation of software.
Professor Paul Sidhu Consultant Radiologist	Yes - obstacles are the availability of machines
Dr Philip Shorvon Consultant Radiologist	There are other causes or increased liver stiffness rather than just fibrosis
Professor Roger Williams Director	Blank
Dr David Sherman Consultant Physician & Gastroenterologist	Yes. Only obstacle is availability of machine, and Virtual Touch sofware modification.
Dr Michael Heneghan Consultant Hepatologist	Cost

Question 8.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for patients are being realised?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**A prospective audit of the number of liver biopsies carried out at an institution following the introduction of VTq. The number of biopsies would be the simplest outcome measure as capturing complications from biopsies may be more difficult.**
Dr Simon Elliott **Consultant Radiologist**	**Cost/time savings for not doing Fibroscan in these patients and reduced attendances. Reduced liver biopsies.**
Mr Colin Griffin **Ultrasound Lead**	**Blank**
Ms Sophie Auld **Superintendent Radiographer**	**Unsure**
Dr Priya Narayanan **Consultant Radiologist**	**Liver biopsy rate**
Professor Paul Sidhu **Consultant Radiologist**	**The cost saving of liver biopsy**
Dr Philip Shorvon **Consultant Radiologist**	**LIver biopsy rate before and after introduction.**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Not only reduction in rate of liver disease, but improved outcomes for liver patients - treatment of viral hepatitis, NAFLD and ALD; surveillance of HCC; also higher discharge rate of those without signficant liver fibrosis.**
Dr Michael Heneghan **Consultant Hepatologist**	**Less liver biopsy , More targeted screening of patients**

Question 8.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**The evidence that VTq (or any non-invasive test) can replace liver biopsy is evolving and would benefit from analysis by NICE(!). The evidence that liver biopsy causes complications (and therefore that a reduction would be potentially beneficial) is very good.**
Dr Simon Elliott **Consultant Radiologist**	**Good and growing evidence worldwide. In the UK, recent (2013) detailed assessment by the NHS Technology Adoption Centre - see their report entitled "The use of ultrasound elastography for the detection and assessment of liver fibrosis"**
Mr Colin Griffin **Ultrasound Lead**	**Trials and research are the best source of this evidence. A small amount of peer-reviewed published work are available at the moment.**
Ms Sophie Auld **Superintendent Radiographer**	**Unsure**
Dr Priya Narayanan **Consultant Radiologist**	**Good evidence but further multicentre studies needed**
Professor Paul Sidhu **Consultant Radiologist**	**Strong evidence form 'Fibroscan' another techniue that uses different technology**
Dr Philip Shorvon **Consultant Radiologist**	**Evidence not yet available**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**There is now an extensive body of evidence for ARFI, with meta-analyses also available (ARFI since around 2009, Fibroscan since around 2004-5). Although some studies are methodologically flawed, the evidence is of sufficient quality to state these outcomes are valid.**
Dr Michael Heneghan **Consultant Hepatologist**	**Marginal**

Question 8.4: Please add any further comment on the claimed benefits of the technology to patients, as you see applicable

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**A nom-invasive test would enable more frequent assessment of liver fibrosis than currently possible with biopsy. This would enable close monitoring of response to treatment.**
Dr Simon Elliott **Consultant Radiologist**	**Blank**
Mr Colin Griffin **Ultrasound Lead**	**As part of their normal liver ultrasound, the patient could have the VTq assessment at the same time, which would decrease the patient's waiting times**
Ms Sophie Auld **Superintendent Radiographer**	**I have not had personal experience with the technology so unsure of the full range of clinical applications and benefits.**
Dr Priya Narayanan **Consultant Radiologist**	**Standard b-mode ultrasound has a poor sensitivity for detection of liver fibrosis. This technology adds only a few minutes to the duration of the routine surveillance ultrasound and would detect alterations in liver stiffness alllowing more tailored management**
Professor Paul Sidhu **Consultant Radiologist**	**Blank**
Dr Philip Shorvon **Consultant Radiologist**	**Reassurance in patients with hepatitis that biopsy not necessary. Identification of patients who have signficant fibrosis but in whom standard imaging is normal. Seperation of benign liver lesions (eg haemangioma) from more sinister lesion**
Professor Roger Williams **Director**	**Have not see any evidence of this technology as opposed to Fibroscan**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**One of the major potential impacts is at the primary / secondary care interface (See NTAC publication online)**
Dr Michael Heneghan **Consultant Hepatologist**	**Blank**

POSSIBLE BENEFITS FOR THE HEALTHCARE SYSTEM

Question 9: What are the likely additional benefits for the healthcare system of using this technology, compared with current practice/comparators?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Liver biopsy is costly. A non-invasive alternative is likely to be cheaper**
Dr Simon Elliott **Consultant Radiologist**	**As para 8. Cost savings in attendances, liver biopsies and associated morbidity.**
Mr Colin Griffin **Ultrasound Lead**	**Combined examination would lead to better turn around and incorportaing the VTq software on US machines is much cheaper than the purchase of separate FibroScan equipment.**
Ms Sophie Auld **Superintendent Radiographer**	**Assist in more accurate diagnosis without the need for interventional**
Dr Priya Narayanan **Consultant Radiologist**	**cost saving, reduction in the number of liver biopsies being performed**
Professor Paul Sidhu **Consultant Radiologist**	**Reduction in costs.**
Dr Philip Shorvon **Consultant Radiologist**	**One stop assessment of chronic liver disease with ultrasound reducing number patient attendences. reduced number of liver biopsies**
Professor Roger Williams **Director**	**Blank**

Expert Advisers	Comment
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Given the increasing incidence of the most common liver diseases (alcohol- related, viral hepatitis and fatty liver) in the local population, and nationally as shown in the National Liver Plan 2010, the use of ARFI can only enhance the development of an improved liver service for local patients. ARFI based technology is likely to be the technology of choice for most hospital, as the competing version (Fibroscan) is expensive , has less wide applicability and may prove to be less accurate. ARFI based pathways also benefit current and future patients by reducing the number of invasive tests, avoiding complications and providing more accessible and accurate non-invasive investigation. Some of our results have already been published by the NHS Technology adoption Centre (see reference below), who were persuaded to sponsor our original work with a Project Grant. It is likely that increased resources to provide these services will need to be negotiated with local commissioners, and that it will form the basis for a more streamlined outpatient liver service, allowing clinicians to concentrate on those liver patients with the most severe damage, whilst interfacing more with general practitioners in the community.** **Reference: The use of ultrasound elastography for the detection and assessment of liver fibrosis: A technology implementation study within secondary care. NHS Technology Adoption Centre, 2013: www.ntac.nhs.uk/publications/**
Dr Michael Heneghan **Consultant Hepatologist**	**Less visits. Complementary technology to ultrasound.**

Question 9.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**As above the evidence base needs to be established.**
Dr Simon Elliott **Consultant Radiologist**	**Yes given current evidence**
Mr Colin Griffin **Ultrasound Lead**	**Yes. Some brave centres will need to lead the change to VTq.**
Ms Sophie Auld **Superintendent Radiographer**	**Blank**
Dr Priya Narayanan **Consultant Radiologist**	**Yes**
Professor Paul Sidhu **Consultant Radiologist**	**Yes**
Dr Philip Shorvon **Consultant Radiologist**	**yes- no obstacles. However the reduction in biopsies may be counterbalanced by increased pick up of patients with chronic liver disease**
Professor Roger Williams **Director**	**cannot answer**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**As above -obstacles are a) availabilityof ARFI machine; b) collaboration between interested hepatologist and radiologist(s; c) engagement with CCGs to fund the service, streamline and redesign the clinical pathway. None of these are particularly difficult, but may take time depending upon local expertise + resources etc.**
Dr Michael Heneghan **Consultant Hepatologist**	**cost**

Question 9.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for the healthcare system are being realised?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**A prospective audit of the number of biopsies at an institution before and after the introduction of VTq.**
Dr Simon Elliott **Consultant Radiologist**	**As para 8**
Mr Colin Griffin **Ultrasound Lead**	**Waiting times, patient feedback and questionnaires.**
Ms Sophie Auld **Superintendent Radiographer**	**Blank**
Dr Priya Narayanan **Consultant Radiologist**	**monitor number of liver biopsies being performed and audit both morbidity and mortality occurring secondary to liver biopsy**
Professor Paul Sidhu **Consultant Radiologist**	**Cost analysis studies**
Dr Philip Shorvon **Consultant Radiologist**	**The biopsy rate. However the number of biopsies may increase even though the rate per patient reduces because of the disastrous increase in chronic liver disease in the population and the increased ability to pick up these patients on routine imaging**
Professor Roger Williams **Director**	**cannot answer**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Eventually, increased referrals and reduced wiaiting times for liver clinics, reduced incidence rates of cirrhosis, admissions and HCC, and eventually reduced disease specific mortality rates and liver transplantation even.**
Dr Michael Heneghan **Consultant Hepatologist**	**appointments and biopsy numbers**

Question 9.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**I am not aware of a health economic analysis**
Dr Simon Elliott **Consultant Radiologist**	**ditto**
Mr Colin Griffin **Ultrasound Lead**	**Anecdotal and theoretical at the moment**
Ms Sophie Auld **Superintendent Radiographer**	**Blank**
Dr Priya Narayanan **Consultant Radiologist**	**Moderate, more work is needed**
Professor Paul Sidhu **Consultant Radiologist**	**Good**
Dr Philip Shorvon **Consultant Radiologist**	**Do not know of good studies**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Little work has been done as yet, most publications have concentrated on the accuracy / applicability of this new technique.**
Dr Michael Heneghan **Consultant Hepatologist**	**Moderate**

Question 9.4: Please add any further comment on the claimed benefits of the technology to the healthcare system, as you see applicable

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	Blank
Dr Simon Elliott **Consultant Radiologist**	Blank
Mr Colin Griffin **Ultrasound Lead**	**Better use of available equipment and software**
Ms Sophie Auld **Superintendent Radiographer**	**Decrease in cost of diagnosis as less intervention required**
Dr Priya Narayanan **Consultant Radiologist**	Blank
Professor Paul Sidhu **Consultant Radiologist**	Blank
Dr Philip Shorvon **Consultant Radiologist**	**Ther e may be further applications as time goes on. The equipment is part of routine ultrasound equipment and therefore will become widely available at a cost that was largely already going to be realised**
Professor Roger Williams **Director**	**non-invasive measurement of fibrosis is important area in clinical practice**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**See above paragraph beginning of section 9.** **Our personal experience over 5 years is that application of this technique can significantly improve both practice and patient experiences in this area, and that there is greater potential to be extracted from this exciting technology.**
Dr Michael Heneghan **Consultant Hepatologist**	Blank

FACILITIES, TRAINING AND FUNCTIONING

Question 10: Are there any particular facilities or infrastructure which needs to be in place for the safe and effective use of this technology?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**The appropriate equipment is required. Staff would require training in its use.**
Dr Simon Elliott **Consultant Radiologist**	**Yes. Hardware, software**
Mr Colin Griffin **Ultrasound Lead**	**Good applications support from the manufacturer. Set guidelines and competencies suggested by NICE.**
Ms Sophie Auld **Superintendent Radiographer**	**Ultrasound units with VTq technology, regular QA and research in to the technology.**
Dr Priya Narayanan **Consultant Radiologist**	**No**
Professor Paul Sidhu **Consultant Radiologist**	**Yes - machines capable of performing this and staff**
Dr Philip Shorvon **Consultant Radiologist**	**No**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**No - trained radiologist / sonographer and Siemens machine + software. The clinical hepatological input is, however, important.**
Dr Michael Heneghan **Consultant Hepatologist**	**US Department with enthusiast**

Question 11: Is special training required to use this technology safely and effectively?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Yes**
Dr Simon Elliott **Consultant Radiologist**	**Yes - sonographers and radiologist training, but in my expereience it is relatively easy and straightforward.**
Mr Colin Griffin **Ultrasound Lead**	**None, assuming the operator is already suitably trained in diagnostic medical ultrasound. **NB - There is a big difference in diagnostic medical ultrasound training for radiology staff. This would be my recommendation rather than those that use point of care US for guidance only!****
Ms Sophie Auld **Superintendent Radiographer**	**Yes**
Dr Priya Narayanan **Consultant Radiologist**	**Yes**
Professor Paul Sidhu **Consultant Radiologist**	**Yes**
Dr Philip Shorvon **Consultant Radiologist**	**Simple to use- just a session or 2 with an application specialist**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**No - just training on the scanning and validation techniques**
Dr Michael Heneghan **Consultant Hepatologist**	**Yes in us**

Question 12: Please comment on any issues relating to the functioning, reliability and maintenance of this technology which may be important to consider if it is introduced

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**It may not be suitable for use in all patients, for example the obese.**
Dr Simon Elliott **Consultant Radiologist**	**Seems to be stable and easy to use. No specific maintenance issues.**
Mr Colin Griffin **Ultrasound Lead**	**Qulaity control with phantoms and correlation with other tests already performed.**
Ms Sophie Auld **Superintendent Radiographer**	**Unsure as no experience to date**
Dr Priya Narayanan **Consultant Radiologist**	**Blank**
Professor Paul Sidhu **Consultant Radiologist**	**Needs to be part of a quality control ultrasound department**
Dr Philip Shorvon **Consultant Radiologist**	**It seems robust and just part of a normal ultrasound equipment**
Professor Roger Williams **Director**	**have no knowledg eof this technology**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**As I am not a radiologist, I may not be best qualified to comment ! However, apart from cost I am not aware of any such issues.**
Dr Michael Heneghan **Consultant Hepatologist**	**Not known**

COSTS

Question 13: Please provide any comments on the likely cost consequences of introducing this technology. In particular, please comment on the implications of this technology replacing the comparator/s you have described above

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**I would anticipate that introduction of this technique (if supported by evidence that it is accurate at staging fibrosis) would result in a cost saving.**
Dr Simon Elliott **Consultant Radiologist**	**See NTAC report. Likely medium to long term cost savings**
Mr Colin Griffin **Ultrasound Lead**	**This should, in theory reduce overall costs as the software is approximately £10k, rather than £70 for a FibroScan machine.**
Ms Sophie Auld **Superintendent Radiographer**	**Unsure**
Dr Priya Narayanan **Consultant Radiologist**	**Main cost is in purchase of appropriate ultrasound machine and software. the ultrasound machine can however be used for other general /routine ultrasound examinations**
Professor Paul Sidhu **Consultant Radiologist**	**If machine is already in use in the ultrasound department - minimal additional software costs**
Dr Philip Shorvon **Consultant Radiologist**	**There would be a one off cost of licence for the software for the technique (uncertain of amount but proabably less than £10K) and then there would be the increase time for each ultrasound examination it is used in (approx 5 mins) . Compared to Fibroscan this is big advantage as the equipment is stand alone around £50 K and can only be used for a single purpose. Also needs a separate visit and operator.**
Professor Roger Williams **Director**	**has to be compared with Fibroscan and ultrasound based technologies**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Im most Trusts without Fibroscan, introduction of this technology would be the first opportunity to measure liver stiffness by Shear wave. Apart from an obvious learning curve, the main costs depend upon the acquisition of the machine, software and training. However, these are not onerous, particularly when it is considered that elastography can also prove useful in the diagnosis of breast, salivary gland, prostate and other disease - an important point - the cost is mitigated by the wide potential range of other applications, unlike Fibroscan.**

Dr Michael Heneghan **Consultant Hepatologist**	**If included in ultrasound, could prevent tarriff being paid for Fibroscan**

GENERAL ADVICE BASED ON YOUR SPECIALIST KNOWLEDGE

Question 14: Is there controversy about any aspect of this technology or about the care pathway?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**There are a number of studies correlating liver stiffness with liver fibrosis stage. There are no studies to my knowledge for non-invasive techniques in general and VTq in particular that link these non-invasive assessments to differences in outcome for liver patients. In other words the prognostic significance of these findings is not established.**
Dr Simon Elliott **Consultant Radiologist**	**Very little controversy. I predict local acceptance in my institution soon.**
Mr Colin Griffin **Ultrasound Lead**	**Not really, but more reearch and peer-reviewed evidence would help to support its use.**
Ms Sophie Auld **Superintendent Radiographer**	**No**
Dr Priya Narayanan **Consultant Radiologist**	**No**
Professor Paul Sidhu **Consultant Radiologist**	**No**
Dr Philip Shorvon **Consultant Radiologist**	**There is concern about its ability to separate the intermediate grades of fibrosis which may make its usefulness in deciding therapy for Hep C for instance questionable**
Professor Roger Williams **Director**	**No controversy about need for assessing fibrosis**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Not that I am aware of, or in the literature.**
Dr Michael Heneghan **Consultant Hepatologist**	**No**

Question 15: If NICE were to develop guidance on this technology, how useful would this be to you and your colleagues?

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**It would be extremely useful if NICE developed guidelines on the non-invasive assessment of liver fibrosis looking at all techniques, rather than VTq in isolation. This would include:** **1. Serum markers** **2. Ultrasound elastography including Fibroscan, VTq etc.** **3. Magnetic resonance techniques including DWI, MRE etc.**
Dr Simon Elliott **Consultant Radiologist**	**Useful support for local implementaiton, but honestly I think the evidence base is in place already.**
Mr Colin Griffin **Ultrasound Lead**	**Very and I would strongly support this guidance. I would also be willing to actively be involved this if required.**
Ms Sophie Auld **Superintendent Radiographer**	**Very as it would make it easier to implement**
Dr Priya Narayanan **Consultant Radiologist**	**Very**
Professor Paul Sidhu **Consultant Radiologist**	**Useful**
Dr Philip Shorvon **Consultant Radiologist**	**Useful for colleagues**
Professor Roger Williams **Director**	**yes**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Very useful to the wider NHS, although the guidance should stress the clinical element of the input required in interpreting results, not just the scan + diagnostic technology**
Dr Michael Heneghan **Consultant Hepatologist**	**very**

Question 16: Do any subgroups of patients need special consideration in relation to the technology (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)? Please explain why

Expert Advisers	Comment
Dr Edmund Godfrey **Consultant Radiologist**	**Obese patients may not be suitable for assessment with ultrasound based techniques.**
Dr Simon Elliott **Consultant Radiologist**	No
Mr Colin Griffin **Ultrasound Lead**	**None that I am aware of**
Ms Sophie Auld **Superintendent Radiographer**	Blank
Dr Priya Narayanan **Consultant Radiologist**	No
Professor Paul Sidhu **Consultant Radiologist**	No
Dr Philip Shorvon **Consultant Radiologist**	**Patients who are adverse to liver biopsy may require this more frequently**
Professor Roger Williams **Director**	Blank
Dr David Sherman **Consultant Physician & Gastroenterologist**	**All the common liver diseases (ALD, VIral , NAFLD) are more prevalent amongst socially disavdantaged groups and ethnic minority groups also - see National Liver Plan 2009. This technology could facilitate greater access to assessment of liver disease for these groups.**
Dr Michael Heneghan **Consultant Hepatologist**	**Hep c, Post transplant patients, children, ivdu with infection**

CONFLICTS OF INTEREST

Question 18.1: Do you or a member of your family have a personal pecuniary interest? The main examples are as follows:

Expert Advisers	Consultancies or directorships	Fee-paid work	Shareholdings	Expenses and hospitality	Investments	Personal non-pecuniary interest
Dr Edmund Godfrey **Consultant Radiologist**	No	**Yes**	No	No	No	**Yes**
Dr Simon Elliott **Consultant Radiologist**	**Yes**	**Yes**	No	No	No	No
Mr Colin Griffin **Ultrasound Lead**	No	No	No	No	No	No
Ms Sophie Auld **Superintendent Radiographer**	No	No	No	No	No	No
Dr Priya Narayanan **Consultant Radiologist**	No	No	No	No	No	No
Professor Paul Sidhu **Consultant Radiologist**	No	No	No	No	No	No
Dr Philip Shorvon **Consultant Radiologist**	No	No	No	No	No	**Yes**
Professor Roger Williams **Director**	No	No	No	No	No	No
Dr David Sherman **Consultant Physician & Gastroenterologist**	No	**Yes**	No	No	No	No
Dr Michael Heneghan **Consultant Hepatologist**	No	**Yes**	No	**Yes**	No	No

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.	
Dr Edmund Godfrey **Consultant Radiologist**	**On 10.10.12. I was paid £300 to give a lecture on MR elastography to the Yorkshire LIver Forum by Bayer pharmaceuticals. In terms of public statements in this area I have published research on MR elastography.**
Dr Simon Elliott **Consultant Radiologist**	**I have received honoraria for lecturing and consultancy work for several ultrasound manufacturers, although not Siemens. I have also received fees for commissioned articles on ultrasound. However these have not included the technology mentioned in this assessment.**
Mr Colin Griffin **Ultrasound Lead**	**Blank**
Ms Sophie Auld **Superintendent Radiographer**	**Blank**
Dr Priya Narayanan **Consultant Radiologist**	**Blank**
Professor Paul Sidhu **Consultant Radiologist**	**Occasional lecture fees from Siemen's Healthcare**
Dr Philip Shorvon **Consultant Radiologist**	**I have been part of a team who have produced posters/ papers on this technique**
Professor Roger Williams **Director**	**Blank**
Dr David Sherman **Consultant Physician & Gastroenterologist**	**Fee paid work - I have a private medical practice at both the Clementine Churchill and BUPA Cromwell Hospitals. I do not believe that either constitutes a conflict of interest in this area, or in relation to this expert advice.**
Dr Michael Heneghan **Consultant Hepatologist**	**Speakers Bureau, Falk Pharma**

Question 18.2: Do you have a non-personal interest? The main examples are as follows:

Expert Advisers	Fellowships endowed by the healthcare industry	Support by the healthcare industry or NICE that benefits his/her position or department, e.g. grants, sponsorship of posts
Dr Edmund Godfrey **Consultant Radiologist**	No	No
Dr Simon Elliott **Consultant Radiologist**	No	No
Mr Colin Griffin **Ultrasound Lead**	No	No
Ms Sophie Auld **Superintendent Radiographer**	No	No
Dr Priya Narayanan **Consultant Radiologist**	No	No
Professor Paul Sidhu **Consultant Radiologist**	No	No
Dr Philip Shorvon **Consultant Radiologist**	No	No
Professor Roger Williams **Director**	No	No
Dr David Sherman **Consultant Physician & Gastroenterologist**	No	No
Dr Michael Heneghan **Consultant Hepatologist**	No	No
If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.		

Dr Edmund Godfrey **Consultant Radiologist**	Blank
Dr Simon Elliott **Consultant Radiologist**	Blank
Mr Colin Griffin **Ultrasound Lead**	Blank
Ms Sophie Auld **Superintendent Radiographer**	Blank
Dr Priya Narayanan **Consultant Radiologist**	Blank
Professor Paul Sidhu **Consultant Radiologist**	Blank
Dr Philip Shorvon **Consultant Radiologist**	Blank
Professor Roger Williams **Director**	Blank
Dr David Sherman **Consultant Physician & Gastroenterologist**	Blank
Dr Michael Heneghan **Consultant Hepatologist**	Blank