

Virtual Touch Quantification to diagnose and monitor liver fibrosis in chronic hepatitis B and C

Medical technologies guidance

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1 Recommendations

- 1.1 The case for adopting Virtual Touch Quantification (VTq) software to diagnose and monitor liver fibrosis is supported by the evidence. VTq is as accurate as transient elastography in diagnosing and staging liver fibrosis, and may offer other benefits in terms of imaging the liver and sampling selected areas to assess fibrosis and identify associated pathologies. By avoiding liver biopsies, it may also benefit people whose liver fibrosis needs monitoring. Cost savings through adopting VTq will be greater in hospitals in which liver biopsy is the primary method for diagnosing and monitoring liver fibrosis.
- 1.2 VTq should be considered as an option for people with chronic hepatitis B or C who need assessment of liver fibrosis.
- 1.3 Cost modelling suggests that using VTq is cost saving compared with transient elastography and liver biopsy, whether or not a compatible Siemens ultrasound machine needs to be purchased. Compared with transient elastography, the estimated overall cost saving for VTq is around £53 per person. This saving assumes that 10% of the ultrasound machine capacity would be used for VTq measurements, leaving 90% to be applied to other uses. Compared with liver biopsy, the corresponding saving is around £434 per person.

2 The technology

Description of the technology

- 2.1 The Virtual Touch Quantification (VTq; Siemens) software application uses acoustic radiation force impulse (ARFI) imaging technology to measure the elasticity of liver tissue. VTq is used in combination with a Siemens Acuson S2000 or S3000 ultrasound platform. Liver tissue can be damaged by inflammation, causing high levels of collagen to be deposited in the liver cells (fibrosis), which become stiff. ARFI imaging involves generating a shear wave by applying an acoustic 'push pulse' lateral to the area of interest identified during a conventional ultrasound scan. The speed of the shear wave is proportional to the stiffness of the tissue.
- 2.2 The VTq investigation comprises multiple measurements and is both non-invasive and painless. The software generates a report which includes a statistical summary of the median and mean shear-wave velocities. The reliability of VTq measurements is usually confirmed by calculating the ratio of the interquartile range to median, which should be less than 0.30. VTq is indicated for adults or children needing assessment of liver fibrosis.
- 2.3 This evaluation focuses on the use of VTq to diagnose and monitor liver fibrosis in adults and children with chronic hepatitis B or C. The use of VTq to assess liver fibrosis associated with other conditions was outside the scope and so is not considered here.
- 2.4 The cost of the VTq software stated in the company's submission is £4,415. A compatible Siemens Acuson S2000 ultrasound system costs from £50,000 with annual maintenance costs, starting in year 2, from £2,000. The cost varies with the system configuration; the cost model includes typical values of £59,700 for the ultrasound system and £2,246 for the annual maintenance costs. All costs are excluding VAT.
- 2.5 The claimed benefits of VTq as presented by the company are as follows:

- VTq is painless and may be safer than liver biopsy as the standard of care.
- No hospital stay or post-procedure monitoring is needed with VTq because it can be done in an outpatient setting.
- VTq may avoid the need for serial biopsies over several years to monitor fibrosis progression, improving quality of life and reducing procedure costs (if fibrosis progression is monitored with VTq).
- VTq provides a more complete assessment of the liver; during the procedure, a sonogram allows visualization of the liver parenchyma, portal and hepatic veins, portal and hepatic venous and arterial blood flow measurements, and the biliary tree for possible obstructions.
- Hepatic cellular carcinoma surveillance is included during the sonogram in patients with cirrhosis.
- Early identification of fibrosis in people with viral hepatitis may allow earlier intervention with antiviral drugs, which can reverse the course of early disease.
- Potential for increased capacity because the VTq procedure does not need to be done by a consultant.
- Reduced resource costs because no hospital admission or stay is needed for VTq measurements in an outpatient setting.

Current management

- 2.6 NICE's guideline on hepatitis B indicates that initial assessment usually takes place in primary care, through blood tests. All patients who test positive for hepatitis B surface antigen are then referred to a hepatologist, gastroenterologist or infectious diseases specialist with an interest in hepatology (children are referred to a similar paediatric specialist in a secondary or tertiary centre).
- 2.7 In secondary or tertiary care patients are provided with information on disease progress, long-term prognosis, transmission and antiviral treatment options. Adults are then offered transient elastography as an initial test for chronic liver

disease. Transient elastography (using, for example, the FibroScan device) is a non-invasive method of assessing liver fibrosis by measuring liver stiffness based on a mechanical wave generated by vibration. Children and young people are offered liver biopsy to determine the need for antiviral therapy, with appropriate information provided on biopsy limitations and risks.

2.8 NICE's guideline on hepatitis B recommends:

- Transient elastography as the initial test for chronic liver disease, offering antiviral treatment (without a liver biopsy) to patients with a transient elastography score of 11 kPa or above.
- Considering liver biopsy in patients with a transient elastography score of 6 to 10 kPa.
- Offering liver biopsy to patients with a transient elastography score of less than 6 kPa if they are younger than 30 years of age and have hepatitis B virus DNA of more than 2,000 IU/ml and abnormal alanine aminotransferase (ALT) on 2 consecutive tests conducted months apart.
- Annual reassessment of patients who are not taking antiviral treatment.

2.9 The therapy pathway for people with hepatitis C is described in NICE's clinical knowledge summary on hepatitis C. Presently, patients who test hepatitis C virus RNA-positive on a blood test are referred to a hepatology clinic. The degree of fibrosis is assessed and treatment options then depend on specific patient characteristics and the severity of their liver disease. There is a NICE guideline on the management and assessment of cirrhosis.

2.10 Liver biopsy is considered to be the gold standard for assessing liver fibrosis for both hepatitis B and C. Histological assessment uses the METAVIR score, based on an assessment of fibrosis and the degree of liver architecture disorganisation, and classifies the severity of liver disease from none (F0), through mild, moderate and severe (F1 to F3), to cirrhosis (F4).

3 Clinical evidence

Summary of clinical evidence

- 3.1 The key clinical outcomes for Virtual Touch Quantification (VTq) presented in the decision problem were:
- correlation in assessment of stage of liver disease and stage of fibrosis using METAVIR score
 - sensitivity and specificity (using area under receiver operating characteristic [AUROC] curve) in assessment of liver fibrosis
 - use of antiviral drugs
 - quality of life measures
 - hospital bed usage and length of stay
 - need for liver biopsy
 - device-related adverse events.
- 3.2 The company identified 23 published papers as suitable for full-text review. No unpublished studies were identified. After review, the company excluded 12 papers which were conference abstracts with insufficient information. Of the remaining 11 papers presented as the clinical evidence for VTq, 10 reported case-control observational studies and 1 was a meta-analysis of 8 studies.
- 3.3 The External Assessment Centre reviewed the literature presented by the company in its submission. It considered that 8 of the 11 papers included by the company should be excluded from further assessment because they reported on studies with overlapping cohorts. The External Assessment Centre carried out a further literature search using revised search terms and found an additional 7 papers; in total, it considered 10 papers to be relevant to this evaluation.
- 3.4 Seven of the papers evaluated VTq in people with hepatitis C and 3 evaluated

VTq in people with hepatitis B. Five studies compared VTq with transient elastography and liver biopsy and 5 compared it with liver biopsy only. Optimal cut-off values for VTq measurements were calculated to classify fibrosis stages by METAVIR score. Most studies describe VTq as acoustic radiation force impulse (ARFI) imaging carried out on a Siemens Acuson S2000 ultrasound machine.

- 3.5 Chen et al. (2012) carried out a prospective observational study evaluating ARFI (VTq) to measure fibrosis in 127 people with chronic hepatitis C attending a liver centre in Taiwan. ARFI measurements were compared with liver biopsy and blood tests (FibroTest) for staging of fibrosis. Necro-inflammatory activity was also measured. Histological fibrosis staging was done using METAVIR scoring by a pathologist blinded to the ARFI and FibroTest results. The Spearman correlation coefficient between ARFI and liver biopsy was 0.696 ($p < 0.001$). The AUROC curve measures for ARFI were: 0.847 for F1 compared with F2 to F4 (95% confidence interval [CI] 0.779 to 0.914); 0.902 for F1 to F2 compared with F3 to F4 (95% CI 0.835 to 0.97); and 0.831 for F1 to F3 compared with F4 (95% CI 0.723 to 0.939). The authors reported that the degree of necro-inflammatory activity artificially raised the severity of fibrosis detected by ARFI, but concluded that ARFI was a promising alternative technology to measure liver stiffness.
- 3.6 The paper by Friedrich-Rust et al. (2014) is a published abstract from a conference poster presentation reporting findings from a prospective international multicentre study. The study examined the use of ARFI (VTq) compared with transient elastography for fibrosis staging in 253 people with chronic hepatitis C, using liver biopsy as a reference method. Each person had ARFI, transient elastography and blood tests. The extent of fibrosis was staged from liver histology using METAVIR scoring by a single pathologist. The authors did an intention-to-diagnose analysis including 247 people and a per-protocol analysis including 182 people. They reported that both ARFI and transient elastography correlated significantly with the histological fibrosis staging and that no statistically significant differences were found between ARFI and transient elastography for identifying fibrosis at stage F2 or higher in the per-protocol analysis. The authors concluded that ARFI and transient elastography are comparable methods for non-invasive fibrosis staging.
- 3.7 Friedrich-Rust et al. (2013) report findings from a prospective, international multicentre study examining ARFI (VTq) used to assess liver fibrosis in people

with chronic hepatitis B. In the study, 131 people attending hospitals in 3 European centres were recruited consecutively and tested with ARFI to assess the extent of fibrosis. Of the 131 people, 105 also had transient elastography (FibroScan). Liver biopsy was used as a reference method for histological assessment using METAVIR scoring, and blood tests were taken to confirm the diagnosis of chronic hepatitis B. Following exclusions because of invalid biopsy or ARFI measurements, data from 114 people were included in the final analysis. Of those, 92 also had transient elastography and were included in an intention-to-diagnose analysis. A per-protocol analysis was done using data for 88 people who had valid ARFI and transient elastography measurements. Diagnostic accuracy was determined by AUROC curves. Both ARFI and transient elastography correlated significantly with liver biopsy results; the Spearman correlation coefficient was 0.415 ($p < 0.001$) for ARFI and 0.556 ($p < 0.001$) for transient elastography. The diagnostic accuracy of ARFI was 0.66 for mild fibrosis (F1), 0.73 for moderate fibrosis (F2), 0.94 for severe fibrosis (F3) and 0.97 for liver cirrhosis (F4). No statistically significant differences were found between ARFI and transient elastography in either the intention-to-diagnose or per-protocol analyses.

- 3.8 Kuroda et al. (2010) carried out a prospective diagnostic accuracy study for ARFI (VTq) used in 70 people in Japan; 30 with chronic hepatitis C, 30 with liver cirrhosis and hepatitis C, and 10 healthy controls. The assessment of fibrosis by ARFI was compared with blood tests for serum markers of liver function. Liver biopsy for METAVIR staging was done for 19 patients. Mean shear-wave velocity was 2.67 ± 1.18 m/s in the liver cirrhosis group, 1.33 ± 0.54 m/s in the chronic hepatitis C group and 0.99 ± 0.21 m/s in the control group. The authors reported that shear-wave velocity measured by ARFI was significantly higher in the liver cirrhosis group ($p < 0.001$) than in the chronic hepatitis C group, and significantly higher in the chronic hepatitis C group than in the control group ($p < 0.0023$). Mean shear-wave velocity in each stage of fibrosis was: 1.09 ± 0.22 m/s for F0 to F1; 1.24 ± 0.52 m/s for F2; 1.61 ± 0.79 m/s for F3; and 2.35 ± 1.11 m/s for F4. ARFI measurements correlated significantly with fibrosis staging ($r = 0.9772$, $p = 0.002$) and all except 1 of the serum marker test results. ARFI showed better diagnostic accuracy for liver cirrhosis than the serum marker tests (AUROC: 0.930, no CI reported). The most appropriate cut-off value for shear-wave velocity was judged to be 1.59 (sensitivity 95%, specificity 83%).

- 3.9 Liu et al. (2014) explored the diagnostic accuracy of ARFI (VTq) compared with transient elastography and a biochemical test that determines the aspartate aminotransferase-to-platelet ratio index, in 95 people with hepatitis B and 16 healthy volunteers. All 95 people with hepatitis had a liver biopsy to stage fibrosis using METAVIR scoring. The authors developed an optimal linear combination of the 3 intervention methods and evaluated its accuracy. Results were analysed for 108 people; 3 were excluded because of transient elastography failure. ARFI and transient elastography correlated strongly with histological staging ($r=0.85$, $p<0.001$ for ARFI; $r=0.81$, $p<0.001$ for transient elastography) and APRI correlated moderately ($r=0.63$, $p<0.001$). The AUROC curve results reported for ARFI were 0.91 for F2 and 0.96 for F4, and the results for transient elastography were 0.87 for F2 and 0.96 for F4. The authors compared the accuracy of the combined methods against their individual accuracy, and found that accuracy was superior when they were combined, particularly for diagnosis of moderate fibrosis (F2) and cirrhosis (F4).
- 3.10 Nishikawa et al. (2014) investigated the correlation between ARFI and fibrosis stage as well as other factors including BMI, hyaluronic acid blood level, gamma-glutamyltranspeptidase level and inflammation. ARFI (VTq) was used in 108 people with chronic hepatitis C attending hospital in Japan. All patients had liver biopsy for histological staging of fibrosis using METAVIR scoring, by assessors blinded to the clinical data. The investigators carrying out ARFI and clinical tests were blinded to the histological data. Multiple regression analysis showed that ARFI correlated significantly with fibrosis stage ($b=0.1865$, $p<0.0001$) and hyaluronic acid levels ($b=0.0008$, $p<0.0039$) independently, in all patients. ARFI correlated significantly with BMI in $F\leq 1$ fibrosis, with gamma-glutamyltranspeptidase level in F2 fibrosis, and with fibrosis stage and hyaluronic acid levels in F3 and F4 fibrosis, indicating that these factors could affect ARFI measurements. ARFI did not correlate with inflammation.
- 3.11 Rizzo et al. (2011) report findings from a study exploring the accuracy of ARFI (VTq) compared with transient elastography in people with chronic hepatitis C, using liver biopsy as a reference standard. In the study, 139 people were recruited consecutively from 2 hospitals in Italy and each had both ARFI and transient elastography as well as liver biopsy for histological staging. Fibrosis staging was done using METAVIR scoring by an assessor blinded to clinical data. No invalid measurements were reported for ARFI, but transient elastography

measurements were invalid in 9 people (6.5%). Using pairwise AUROC analysis, ARFI was significantly more accurate than transient elastography for diagnosing moderate (or higher) and severe (or higher) fibrosis (F2: 0.86 compared with 0.78, $p=0.024$; F3: 0.94 compared with 0.83, $p=0.002$) but not for cirrhosis (F4; 0.89 compared with 0.80, $p=0.09$). Partial AUROC analysis showed that ARFI was statistically significantly more accurate than transient elastography for all stages of fibrosis.

- 3.12 An international multicentre study was carried out by Sporea et al. (2012a) in 10 centres across 5 countries in Europe and Asia. Liver biopsy (using METAVIR scoring) and ARFI (VTq) measurements of fibrosis were compared for 911 people with chronic hepatitis C. A subset of 400 people also had transient elastography and their results were compared with ARFI and biopsy. Diagnostic accuracy was assessed using AUROC curves. ARFI correlated significantly with liver biopsy staging (Spearman correlation coefficient $r=0.654$, $p<0.0001$). In the subgroup having transient elastography and ARFI, the overall correlation with liver biopsy staging was reported as being similar for both ARFI and transient elastography ($r=0.689$, $p<0.001$ and 0.728 , $p<0.001$ respectively). The number of people with reliable measurements was significantly higher for ARFI (98.8%) compared with transient elastography (93.7%; $p=0.003$). The same reliability criteria were used for both ARFI and transient elastography, but different numbers of measurements were used; for ARFI, between 5 and 10 measures were used depending on the centre, and for transient elastography all centres used 10 measurements. The authors reported that ARFI was less effective than transient elastography in predicting liver cirrhosis (F4; AUROC 0.885 compared with 0.932; $p=0.01$). However, for moderate or severe fibrosis (F2 to F3), ARFI and transient elastography showed equivalent effectiveness. The authors also noted that the cut-off levels for ARFI to determine fibrosis at stages F2 and F4 were different for European and Asian people. It is not clear how these subgroups were identified. The authors noted that more people in the Asian group either did not have fibrosis or had mild fibrosis (F1), and that people in the Asian group were older and had a lower mean BMI than those in the European group.
- 3.13 A study done in Japan by Yamada et al. (2014) evaluated the accuracy of ARFI (VTq) in assessing liver fibrosis in people with chronic hepatitis C as well as the association between ARFI and the response to antiviral therapy. Of the 124 people enrolled in the study, 94 had genotype 1 hepatitis C virus, 46 of whom

had antiviral pegylated interferon and ribavirin combination therapy. Although not stated, it can be assumed that the remainder had genotype 2 hepatitis C virus, 15 of whom had antiviral therapy. Liver biopsy with histological analysis was used to determine fibrosis stage. Forty (30%) people were judged to have moderate (F2) fibrosis. ARFI was found to have a strong correlation with fibrosis stage (Pearson's $r=0.764$, $p<0.001$). People with the genotype 1 hepatitis C virus and less severe fibrosis (indicated by ARFI measurements of less than 1.40 m/s) showed a better response to treatment, indicating that ARFI could have some benefit in predicting response. ARFI could not predict treatment response in people with the genotype 2 hepatitis C virus.

- 3.14 Ye et al. (2012) assessed the performance of ARFI (VTq) to measure liver and spleen stiffness in 204 people with chronic hepatitis B and 60 healthy volunteers. Of those with hepatitis B, 66 had liver biopsy and 138 had been diagnosed previously as having cirrhosis. Histological staging using METAVIR scoring was done by an experienced pathologist for those people having biopsies. ARFI measurements showed good correlation with fibrosis stage using Spearman's correlation coefficient ($r=0.87$, $p<0.001$), and a high diagnostic accuracy for predicting severe fibrosis and cirrhosis using optimal measurement cut-off values for each stage (AUROC curve F3=0.99; F4=0.97).

Evidence synthesis

- 3.15 The company included a brief synthesis of the clinical evidence in its submission and concluded that VTq and transient elastography have equivalent accuracy, although transient elastography may be slightly more accurate in diagnosing mild fibrosis (F1). The External Assessment Centre considered that this conclusion was plausible, but noted that the company did not carry out a meta-analysis which would have provided a more definitive result.
- 3.16 The company provided an overall interpretation of the clinical evidence and concluded that VTq can be a good tool when used in clinical practice to diagnose moderate fibrosis (F2) and an excellent tool to diagnose severe fibrosis (F3) or cirrhosis (F4). The External Assessment Centre considered that this interpretation was reasonable and that the company's assessment of the strengths and weaknesses of the studies was fair.

3.17 As a result of its concerns about the studies selected by the company and the subsequent identification of additional clinical evidence, the External Assessment Centre did a meta-analysis of the 10 studies it selected for inclusion. A random effects approach was used to calculate pooled outcome data for correlation coefficients (between either VTq or transient elastography and liver biopsy METAVIR scores), and for sensitivity, specificity and prevalence for each disease type (hepatitis B, C or a combination) using liver biopsy as the reference standard. Proportions were transformed using the logit function where necessary to overcome skewness, and values of 0 were transformed to 0.5 to allow pooling of the data. Results were back-transformed to provide estimated pooled proportions and 95% confidence intervals. Nine outcome estimates were made from multiple studies and 6 from single studies. The pooled estimates for sensitivity, specificity and prevalence for each disease type (hepatitis B, C or a combination) are shown in tables 1 to 6.

Table 1 Pooled estimates from External Assessment Centre's meta-analysis with 95% confidence intervals for prevalence and diagnostic accuracy, using the reference standard (liver biopsy) of VTq: hepatitis B

Fibrosis stage	F≥1	F≥2	F≥3	F4
No. of studies	–	2	–	1
Prevalence	–	0.43 (0.06 to 0.79)	–	0.27 (0.19 to 0.36)
Sensitivity % (95% CI)	–	70.02 (31.59 to 92.19)	–	93.1 (77.23 to 99.15)
Specificity % (95% CI)	–	87.01 (78.69 to 92.40)	–	76.83 (66.40 to 85.90)

Table 2 Pooled estimates from External Assessment Centre's meta-analysis with 95% confidence intervals for prevalence and diagnostic accuracy, using the reference standard (liver biopsy) of transient elastography: hepatitis B

Fibrosis stage	F≥1	F≥2	F≥3	F4
No. of studies	–	1	–	1
Prevalence	–	0.61 (0.51 to 0.70)	–	0.27 (0.19 to 0.36)
Sensitivity % (95% CI)	–	81.8 (70.39 to 90.24)	–	88.1 (72.65 to 97.81)
Specificity % (95% CI)	–	71.24 (55.42 to 84.28)	–	86.67 (77.95 to 93.76)

Table 3 Pooled estimates from External Assessment Centre's meta-analysis with 95% confidence intervals for prevalence and diagnostic accuracy, using the reference standard (liver biopsy) of VTq: hepatitis C

Fibrosis stage	F \geq 1	F \geq 2	F \geq 3	F4
No. of studies	2	5	5	4
Prevalence	0.91 (0.83 to 0.95)	0.60 (0.48 to 0.71)	0.40 (0.32 to 0.484)	0.23 (0.18 to 0.29)
Sensitivity % (95% CI)	69.82 (66.82 to 72.66)	78.47 (70.04 to 85.03)	85.76 (75.94 to 91.99)	84.48 (79.78 to 88.24)
Specificity % (95% CI)	80.95 (70.44 to 88.34)	78.96 (73.49 to 83.55)	84.36 (80.69 to 87.45)	81.45 (75.43 to 86.27)

Table 4 Pooled estimates from External Assessment Centre's meta-analysis with 95% confidence intervals for prevalence and diagnostic accuracy, using the reference standard (liver biopsy) of transient elastography: hepatitis C

Fibrosis stage	F \geq 1	F \geq 2	F \geq 3	F4
No. of studies	–	1	1	1
Prevalence	–	0.63 (0.54 to 0.71)	0.39 (0.31 to 0.47)	0.22 (0.15 to 0.29)
Sensitivity % (95% CI)	–	71.0 (60.57 to 80.46)	77.0 (64.40 to 80.46)	70.0 (50.60 to 85.27)
Specificity % (95% CI)	–	71.0 (56.92 to 82.87)	85.0 (75.27 to 91.60)	82.0 (73.09 to 88.42)

Table 5 Pooled estimates from External Assessment Centre's meta-analysis with 95% confidence intervals for prevalence and diagnostic accuracy, using the reference standard (liver biopsy) of VTq: hepatitis B and C

Fibrosis stage	F \geq 1	F \geq 2	F \geq 3	F4
No. of studies	–	7	–	5
Prevalence	–	0.55 (0.42 to 0.67)	–	0.23 (0.18 to 0.29)
Sensitivity % (95% CI)	–	77.01 (68.88 to 83.52)	–	85.03 (80.59 to 88.60)
Specificity % (95% CI)	–	81.07 (75.83 to 85.39)	–	80.44 (75.57 to 84.54)

Table 6 Pooled estimates from External Assessment Centre's meta-analysis with 95% confidence intervals for prevalence and diagnostic accuracy, using the reference standard (liver biopsy) of transient elastography: hepatitis B and C

Fibrosis stage	F≥1	F≥2	F≥3	F4
No. of studies	–	2	–	2
Prevalence	–	0.62 (0.53 to 0.70)	–	0.23 (00.14 to 0.36)
Sensitivity % (95% CI)	–	76.16 (63.89 to 85.22)	–	79.43 (55.69 to 92.22)
Specificity % (95% CI)	–	71.11 (61.17 to 79.36)	–	83.82 (77.81 to 88.45)

- 3.18 The results of the meta-analysis showed that the prevalence of moderate fibrosis (F2) for both hepatitis B and C was lower with VTq (0.55) than transient elastography (0.62). However, the techniques had similar scores for cirrhosis (F4; 0.23 for VTq and 0.23 for transient elastography). Sensitivity and specificity values were similar for hepatitis B and C. VTq had slightly higher values for both sensitivity and specificity in diagnosing moderate fibrosis (F2; 77% and 81% respectively) than transient elastography (76% and 71% respectively) in people with hepatitis B and C. The sensitivity was higher than the specificity for identifying cirrhosis (F4) in the combined study population for VTq (85% and 80% respectively), but the opposite was found for transient elastography (79% and 84% respectively). The correlation coefficients for VTq and transient elastography were similar in the combined study population (0.68 to 0.69).
- 3.19 The External Assessment Centre noted that no adjustment could be made in the meta-analysis for confounding variables such as patient characteristics, other than disease type, study design and location, because there was insufficient information in the papers.

Adverse events

- 3.20 In its submission, the company stated that no adverse events have been reported for VTq. None were identified in the literature, or from searches of the MHRA website and US Food and Drug Administration database: Manufacturer and User Device Facility Experience (MAUDE). The External Assessment Centre repeated the literature searches and found no adverse events relating to the use of VTq.

Committee considerations

- 3.21 The Committee considered that despite some limitations, the clinical evidence was sufficient to demonstrate that VTq has equivalent accuracy to transient elastography for diagnosing liver fibrosis. The Committee recognised that there was no evidence specifically evaluating the use of VTq for monitoring of liver fibrosis, but considered that the technology was likely to be useful for this purpose. It was advised by clinical experts that the use of image-guided assessment of liver fibrosis in VTq allowed measurements to be taken from the same part of the liver at different times, which would be useful for monitoring changes in fibrosis relating to disease progression.
- 3.22 The Committee heard advice from clinical experts that VTq would be particularly useful in hospitals without access to transient elastography for determining the stage of fibrosis and informing the decision to start antiviral therapy, because those hospitals currently use liver biopsy as their primary method of diagnosis. The Committee considered that using VTq could avoid a considerable number of liver biopsies for both initial assessment and ongoing monitoring (particularly for people with hepatitis B), reducing the risks of morbidity and mortality.
- 3.23 For hospitals with access to transient elastography, the Committee was advised that using VTq could offer advantages by enabling image-guided assessment of the liver. This assessment offers the opportunity to select areas from which to assess fibrosis and to identify associated pathologies, for example cirrhosis and hepatocellular carcinoma.
- 3.24 The Committee noted that no evidence was available on the use of VTq in children and that the company's instructions for use do not distinguish between adults and children. However, clinical experts advised the Committee that there was no reason to suppose that VTq would be any less effective in children than in adults, although the range of readings considered normal may differ between them. It heard from clinical experts that avoiding liver biopsies would be particularly beneficial for children, who might need a general anaesthetic and an overnight stay in hospital, as well as facing restrictions to their daily activities following each biopsy.
- 3.25 The Committee also noted a lack of evidence for improved quality of life as a

consequence of using VTq, but it considered that reducing the need for liver biopsies would have a positive effect on quality of life.

- 3.26 The Committee noted comments made during consultation about the cut-off values used with VTq. It considered that the interpretation of these values was a matter for clinical judgement by specialists, taking into account results of other tests and the clinical context. It also noted several comments made during consultation that suggested a variety of factors, including obesity and hepatic inflammation, may influence the readings from both VTq and transient elastography. The Committee considered it unclear from the clinical evidence how exactly these factors influence the accuracy of the tests.

4 NHS considerations

System impact

- 4.1 The company claimed that use of Virtual Touch Quantification (VTq) had the potential to release resources within the NHS because the VTq procedure does not need to be carried out by a consultant and can be done in an outpatient setting. It also claimed that VTq could reduce the number of liver biopsies needed over several years if used to monitor fibrosis progression. The company was not able to identify any published evidence relating to these claims.
- 4.2 The published evidence provided data on the diagnostic accuracy of VTq compared with transient elastography and with liver biopsy, but none of the studies specifically explored the potential system impact of using VTq. Some authors (Friedrich-Rust et al. 2013, Yamada et al. 2014 and Rizzo et al. 2011) mentioned in their conclusions that VTq can be used for non-invasive assessment in people with obesity. Yamada et al. assessed the utility of VTq in predicting response to antiviral therapy and found that this had potential for people with genotype 1 hepatitis C: this could be useful in directing treatment with newer direct-acting antiviral agents to people who are not likely to respond to existing antiviral therapies.
- 4.3 Four of the studies reported higher failure rates or a greater number of unreliable measurements when using transient elastography compared with VTq (Friedrich-Rust et al. 2013, Liu et al. 2014, Rizzo et al. 2011, Sporea et al. 2012a). Sporea et al. reported that a significantly higher number of reliable measurements were taken using VTq compared with transient elastography (98.8% compared with 93.7%, $p=0.003$).

Committee considerations

- 4.4 The Committee acknowledged that no evidence was available to demonstrate that using VTq reduces the length of hospital stay. However, it considered that using VTq could reduce the need for liver biopsies. This is likely to have an effect

on resource use, particularly for children who may need a general anaesthetic and an overnight stay in hospital for liver biopsy.

- 4.5 The Committee considered that using VTq may provide system benefits by allowing assessment of liver fibrosis to be done at the same time as the initial diagnostic ultrasound test included in the current care pathway. The Committee heard expert clinical advice that patients being assessed for liver fibrosis usually have an ultrasound scan, and that adding VTq to the ultrasound may lead to a more streamlined care pathway. It also heard that the Siemens ultrasound machine needed for VTq can be used for other purposes. This was explored in the cost modelling (see [section 5](#)).
- 4.6 The Committee noted from the published evidence that VTq appears to have a lower failure rate than transient elastography, and this was confirmed by clinical expert advisers as being the case in clinical practice.
- 4.7 The Committee considered that VTq is likely to be used in an outpatient setting as part of the initial referral from primary care for people who test positive for chronic hepatitis B or C. Clinical experts advised that there is also potential for VTq to be used in primary care settings which offer ultrasound. The Committee was advised by clinical experts that VTq assessments should only be done by staff with specialist training in ultrasound imaging and its interpretation. The Committee also noted that transient elastography can be associated with a range of staff costs, which may be lower than those needed for VTq. The resource impact of these different staff needs was incorporated into the cost modelling done by both the company and the External Assessment Centre.
- 4.8 The Committee considered the issue of the VTq software package being usable only with a Siemens ultrasound machine. It noted that ultrasound machines from a variety of manufacturers are currently in use in the NHS but that individual hospitals are likely to have a number of machines. The Committee considered that the purchase of a compatible Siemens ultrasound machine for VTq can be considered as part of existing device renewal programmes.

5 Cost considerations

Cost evidence

- 5.1 The company carried out a literature search for economic studies related to Virtual Touch Quantification (VTq), transient elastography and liver biopsy in hepatitis. After applying inclusion and exclusion criteria, the company did not identify any relevant economic studies for VTq. However, 5 studies were presented relating to the comparators (transient elastography and liver biopsy).
- 5.2 The External Assessment Centre considered that the company's search strategy and inclusion/exclusion criteria were appropriate, but noted that the date range and search terms could have been broader and 2 further databases could have been searched. The External Assessment Centre carried out a revised search addressing these issues and did not find any relevant publications, confirming the company's conclusion that there was no published economic evidence relating to VTq. The External Assessment Centre considered that the 5 papers identified by the company relating to the comparators were useful for modelling purposes, and found 1 additional comparator paper.

Company's cost model

- 5.3 The company submitted a de novo cost analysis evaluating VTq plus liver biopsy (where needed) compared with transient elastography plus liver biopsy (where needed) and against liver biopsy alone. Costs were modelled from an NHS and personal social services perspective using 2013 prices. The population included in the model was patients with chronic hepatitis B or C needing assessment of liver fibrosis. The model structure was a decision tree based on a cohort of 1,000 patients referred by GPs and stratified according to the presence or absence of fibrosis, then sequentially across 3 groups according to stage of fibrosis determined by METAVIR score (F2, F3/F4, or F4). The External Assessment Centre confirmed that the model was internally valid.
- 5.4 The company used the estimated prevalence of fibrosis to stratify the cohort into

the 3 stages, and applied the sensitivity and specificity of each diagnostic strategy (VTq plus liver biopsy, transient elastography plus liver biopsy and liver biopsy alone) for each stage, creating estimated numbers of true or false negatives or positives. The External Assessment Centre generally agreed with this approach.

- 5.5 The model was based mainly on fibrosis assessment and did not include any treatment or monitoring costs for patients in the F2 group and the F3/F4 group. For F4 fibrosis (cirrhosis), patients in the true-positive group had antiviral therapy and those in the false-negative group had liver biopsy. According to the diagram of the company's model in its submission, false positives had antiviral therapy and true negatives had a biopsy. The External Assessment Centre questioned the rationale for this approach and whether this assumption was actually included in the model calculations.
- 5.6 The company did not state the time horizon for the model, but the External Assessment Centre considered that the outcomes were likely to be realised using a 1-year horizon, based on the duration of antiviral therapy.
- 5.7 The company's estimates of fibrosis prevalence at each stage were based mainly on clinical expert advice and on 1 study in patients with cirrhosis, because exact figures were difficult to determine. The External Assessment Centre sought additional clinical expert advice to validate these assumptions but the experts consulted were not able to provide any figures.
- 5.8 The diagnostic accuracy figures for VTq and transient elastography were taken from the available literature and liver biopsy was assumed to have 100% sensitivity and specificity. The External Assessment Centre agreed with the approach taken for liver biopsy and transient elastography (figures taken from a meta-analysis), but considered that the figures used for VTq were not sufficiently robust. The External Assessment Centre addressed this issue in its own meta-analysis of the clinical evidence.
- 5.9 The company included direct costs for VTq, transient elastography and liver biopsy, calculating the costs of VTq and transient elastography using a bottom-up approach which included capital, infrastructure, maintenance, staffing, training and consumable costs. The cost for transient elastography was

calculated based on a nurse carrying out the test with a throughput of 2,500 patients per year over the device lifespan (7 years), giving a per-patient cost of £25.33. This was compared with a report published by the Centre for Evidence-based Purchasing (Stamuli et al. 2009), which gave a per-patient cost of £18.68 (corrected for inflation by the company to £22.91). The cost for VTq was based on the purchase of the software and a Siemens Acuson S2000 machine, and use by a radiographer. It was assumed that VTq assessments would take up 10% of the ultrasound machine use and so this proportion of the annual capital, staffing and consumables costs was used in the estimation. The cost was calculated based on a throughput of 500 patients per year over the device lifespan (5 years), giving a per-patient cost of £15.02. The cost for liver biopsy was estimated from the 2013–14 payment by results tariff to be £615, based on a mix of procedures.

- 5.10 The External Assessment Centre agreed with the estimates for these costs but considered that they could be further explored in sensitivity analyses. The capital costs for VTq and transient elastography were not estimated using the annuity method, and the company did not describe the exact mix of procedures used to calculate the biopsy cost. The cost of antiviral therapy was estimated to be £10,000 per patient in the executable model; the External Assessment Centre was unsure about the rationale behind this figure.
- 5.11 The company carried out deterministic 1-way and multi-way sensitivity analyses varying the prevalence of liver disease, prevalence for different liver fibrosis stages, the diagnostic accuracy of VTq, technology and treatment costs and whether or not liver biopsy was done. The External Assessment Centre generally agreed with the company's approach but commented that the company did not explain the rationale for the variations in prevalence which it used.
- 5.12 The results of the company's base case indicated that VTq could result in a cost saving of £10.31 per patient when compared with transient elastography and £599.08 per patient when compared with liver biopsy.
- 5.13 Findings from the company's sensitivity analysis showed that if each patient had a biopsy, increasing the overall prevalence of liver fibrosis from 10% to 30% lowered the cost saving per patient from £527 to £447 (assuming the best-case diagnostic accuracy of VTq) and from £496 to £419 (assuming the worst-case

diagnostic accuracy of VTq). If only 20% of patients had a biopsy, the cost savings for VTq were reduced, and at high fibrosis prevalence levels or lower diagnostic accuracy it became cost-incurring. The cost of antiviral therapy was also varied from the base case assumption of £10,000 to £6,500. Over this range, assuming that 20% of patients had a biopsy, the cost savings for VTq varied from around £60 to £8.

- 5.14 The External Assessment Centre considered that the model addressed the decision problem in the scope, but that its structure did not accurately reflect current clinical pathways for people with liver fibrosis. It also did not include all the relevant costs and outcomes for diagnosing and treating the condition. No monitoring or treatment costs were included for patients in the F2 or F3/F4 fibrosis groups. The External Assessment Centre considered that this was erroneous, because people with less severe fibrosis may benefit from treatment.
- 5.15 The External Assessment Centre also questioned the assumption that patients falsely classified as negative for fibrosis would not incur any treatment costs and would re-enter the model as new patients. It considered that this was a misleading approach, because misdiagnosis may incur additional costs (from further diagnostic tests, inpatient or emergency episodes and treatment). The External Assessment Centre considered that a mortality arm would have been appropriate to account for the small increased risk associated with liver biopsy, but acknowledged that this was likely to have been incorporated in the chosen tariff cost. The External Assessment Centre also noted that the company had used a cohort approach rather than a per-patient approach as specified in NICE's methodology.

Additional work by the External Assessment Centre

- 5.16 The External Assessment Centre revised some parameters and re-ran the company's model to address these issues. The revised model included true positives, false positives, true negatives and false negatives at each of the $F \geq 2$, $F \geq 3$ and F4 stages. Revised prevalence and diagnostic accuracy parameters for the model were taken mainly from the External Assessment Centre's meta-analysis and applied at each sequential stage for VTq, transient elastography and liver biopsy. Liver biopsy was treated as the reference standard

with 100% sensitivity and specificity.

5.17 Key assumptions made by the External Assessment Centre in its revisions to the company's model were as follows:

- Patients categorised as false negative for fibrosis would return and be re-diagnosed as true positive within 1 year.
- Prevalence rates for stages of fibrosis were different for VTq and transient elastography based on the External Assessment Centre's meta-analysis. The combined hepatitis B and C prevalence rates for VTq were used for transient elastography and liver biopsy in the model to ensure compatibility.
- Combined hepatitis B and C prevalence and diagnostic accuracy figures for F3 fibrosis were not available from the meta-analysis. The External Assessment Centre therefore used figures for hepatitis C across the model for this stage.
- Treatment delay resulting from misdiagnosis was unlikely to have a clinical effect and so long-term modelling of disease progression was not needed. According to published clinical evidence and expert advice gathered by the External Assessment Centre, progression in both hepatitis B and C is relatively slow.
- Patients diagnosed as being at stage F2 had fibrosis and those at stage $F \leq 1$ did not.
- Most misclassified (false positive) patients for VTq and transient elastography would be diagnosed as having F2 fibrosis. A proportion of those with F2 fibrosis would be misclassified as having F3 or F4 fibrosis. These proportions were chosen arbitrarily and subjected to sensitivity analyses.
- Patients diagnosed with F3 or F4 fibrosis would have antiviral therapy.
- A mortality risk of 0.003 would apply to liver biopsy, based on available literature.

5.18 The unit costs for VTq and transient elastography were estimated using an annuity method and discounted at 3%, to give per-test figures of £15.24 for VTq and £25.90 for transient elastography. The cost for liver biopsy was estimated

from tariff costs to be £622. The costs for antiviral therapy were based on duration of treatment, which was estimated to be 12 weeks for patients with F3 fibrosis and 24 weeks for patients with F4 fibrosis, based on [NICE technology appraisal guidance on peginterferon alfa and ribavirin for the treatment of chronic hepatitis C](#). Costs for a compatible Siemens ultrasound machine were modelled in 2 scenarios: 1 including purchase costs and 1 assuming that a machine was already available.

- 5.19 Findings from the base case (incorporating the External Assessment Centre's revised parameters) showed that in a scenario where a compatible Siemens ultrasound machine would be purchased along with the VTq software, using VTq would generate cost savings of £53 per patient compared with transient elastography and £434 compared with liver biopsy. If a compatible ultrasound machine was already available, the cost savings for VTq increased slightly to £57 compared with transient elastography and £438 compared with liver biopsy.
- 5.20 The External Assessment Centre carried out deterministic sensitivity analyses varying prevalence rates, sensitivity and specificity for VTq and transient elastography, distribution of false positives between stages F2 and F3, unit costs of VTq and transient elastography, usage levels of transient elastography and antiviral therapy costs. Findings from the sensitivity analyses showed that VTq remained cost-saving across all scenarios. The key drivers affecting the cost savings per patient were prevalence of liver fibrosis, the distribution of false positives to other fibrosis stages, the specificity of VTq and transient elastography for stages F2 and F3, unit costs of VTq and transient elastography and antiviral treatment costs.
- 5.21 The External Assessment Centre acknowledged some limitations in its revised parameters. The lack of clear data on prevalence and diagnostic accuracy at each stage of fibrosis meant that figures were extrapolated for the stages in a sequential model, rather than each stage being presented separately. Figures for hepatitis C at stage F3 fibrosis were applied to the whole population because combined data were not available. Several assumptions were made to calculate technology and comparator costs, but the External Assessment Centre varied these parameters in sensitivity analyses to address uncertainty.

Committee considerations

- 5.22 The Committee recognised the limitations in the cost modelling presented by the company and in the adjustments made by the External Assessment Centre, but considered these revisions sufficiently robust to be plausible. The Committee considered that the External Assessment Centre's sensitivity analyses addressed the uncertainties in the evidence base and it concluded that cost savings for VTq compared with transient elastography and liver biopsy were likely to be realised in practice.
- 5.23 The Committee was satisfied that the cost modelling indicated that use of the VTq software would generate cost savings regardless of whether a compatible Siemens ultrasound machine was purchased.
- 5.24 The Committee noted that the cost modelling included the assumption that the Siemens ultrasound machine would be used for VTq measurements for only 10% of the time and for other scanning procedures for the rest of the time: it was advised by experts that this was reasonable. The External Assessment Centre stated that the findings from the model were robust even when the proportionate use of the machine for VTq (and so VTq's test costs) was raised in sensitivity analyses.
- 5.25 The External Assessment Centre also stated that the findings remained robust if treatment costs (for antiviral therapy) were not included in the model.
- 5.26 For the guidance review, the External Assessment Centre noted that the differences between the updated pooled estimates for the sensitivity and specificity of VTq for hepatitis C compared with the pooled estimates used in the original model (see [tables 3 and 4](#)) are minor, as seen in table 7. **[2020]**

Table 7 Updated pooled estimates for the sensitivity and specificity of VTq for hepatitis C

Disease	Sensitivity (update)	Sensitivity (original)	Specificity (update)	Specificity (original)
Hepatitis C F \geq 2	77%	79%	80%	79%
Hepatitis C F=4	85%	85%	85%	82%

6 Conclusions

- 6.1 The Committee concluded that the evidence supports the case for adopting Virtual Touch Quantification (VTq) for diagnosing and monitoring liver fibrosis in people with chronic hepatitis B or C. The Committee considered that the clinical evidence demonstrated that VTq is as accurate as transient elastography for diagnosing and staging liver fibrosis and may offer additional benefits, including image-guided assessment and a lower failure rate.
- 6.2 The Committee concluded that using VTq may offer particular advantages in hospitals without access to transient elastography, by providing a non-invasive method of assessment of liver fibrosis in place of liver biopsy. This may have major benefits for people who need monitoring for fibrosis progression for whom liver biopsy may have a substantial effect on quality of life.
- 6.3 Based on the revised cost model and sensitivity analyses, the Committee concluded that using VTq is likely to be cost saving compared with transient elastography and liver biopsy, whether or not the purchase of a compatible Siemens ultrasound machine is needed.

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

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

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

Professor Bruce Campbell (Chair)

Consultant vascular surgeon, Royal Devon and Exeter Hospital

Dr Peter Groves (Vice Chair)

Consultant cardiologist, Cardiff and Vale University Health Board

Ms Susan Bennett

Lay member

Professor Nigel Brunskill

Professor of renal medicine, University of Leicester

Mr Matthew Campbell-Hill

Lay member

Professor Daniel Clark

Head of clinical engineering, Nottingham University Hospitals NHS Trust

Dr Fiona Denison

Reader/honorary consultant in maternal and fetal health, University of Edinburgh

Professor Tony Freemont

Professor of osteoarticular pathology, University of Manchester

Professor Shaheen Hamdy

Professor of neurogastroenterology, University of Manchester

Dr Jerry Hutchinson

Independent medical technology adviser

Dr Cynthia Iglesias

Health economist, University of York

Professor Mohammad Ilyas

Professor of pathology, University of Nottingham

Dr Greg Irving

General practitioner and clinical lecturer, University of Cambridge

Professor Eva Kaltenthaler

Reader in health technology assessment, School of Health and Related Research (SchARR), University of Sheffield

Dr Paul Knox

Reader in vision science, University of Liverpool

Dr Rory O'Connor

Senior lecturer and honorary consultant physician in rehabilitation medicine, University of Leeds

Mrs Karen Partington

Chief executive, Lancashire Teaching Hospitals NHS Foundation Trust

Mr Brian Selman

Managing director, Selman and Company Limited

Professor Wendy Tindale

Scientific director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo

Professor of health economics, ScHARR, University of Sheffield

Mr John Wilkinson

Director of devices, Medicines and Healthcare Products Regulatory Agency

Dr Janelle Yorke

Lecturer and researcher in nursing, University of Manchester

Dr Amber Young

Consultant paediatric anaesthetist, Bristol Royal Hospital for Children

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Jo Higgins

Technical analyst

Ailish Higgins

Technical analyst

Bernice Dillon

Technical adviser

Colin Griffin

Lead expert adviser

David Sherman

Lead expert adviser

Philip Shorvon

Lead expert adviser

Nigel Brunskill

Non expert MTAC member

Anthony Freemont

Non expert MTAC member

Jennifer Summers

External assessment centre representative

Muralikrishnan Radhakrishnan Kartha

External assessment centre representative

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by King's Technology Evaluation Centre (KiTEC):

- Morris E, Summers J, Peacock J et al., Virtual Touch Quantification to diagnose and monitor liver fibrosis, August 2014

Submissions from the following sponsor:

- Siemens

The following individuals gave their expert personal view on Virtual Touch Quantification by providing their expert comments on the draft scope and assessment report.

- Mr Colin Griffin, ratified by the British Medical Ultrasound Society – clinical expert
- Dr Priya Narayanan, nominated by the Royal College of Radiologists – clinical expert
- Professor Paul Sidhu, ratified by the Royal College of Radiologists – clinical expert
- Dr David Sherman, ratified by the Royal College of Physicians – clinical expert
- Dr Philip Shorvon, ratified by the Royal College of Radiologists – clinical expert

The following individuals gave their expert personal view on Virtual Touch Quantification in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Ms Sophie Auld, ratified by the Society and College of Radiographers – clinical expert
- Dr Simon Elliott, ratified by the Royal College of Radiologists – clinical expert
- Dr Edmund Godfrey, nominated by the Royal College of Radiologists – clinical expert
- Mr Colin Griffin, ratified by the British Medical Ultrasound Society – clinical expert
- Dr Michael Heneghan, ratified by the British Association for the Study of the Liver – clinical expert

- Dr Priya Narayanan, nominated by the Royal College of Radiologists – clinical expert
- Professor Paul Sidhu, ratified by the Royal College of Radiologists – clinical expert
- Dr David Sherman, ratified by the Royal College of Physicians – clinical expert
- Dr Philip Shorvon, ratified by the Royal College of Radiologists – clinical expert
- Professor Roger Williams, ratified by The Foundation for Liver Research – clinical expert

Update information

January 2020: We updated this guidance to reflect new pooled estimates for the sensitivity and specificity of VTq for hepatitis C. Details of the modifications are explained in the [review decision](#). New evidence identified during the guidance review is denoted as [2020].

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Accreditation

