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Final Protocol to
guide the assessment
of transient
elastography at 50Hz
for the diagnosis of
liver fibrosis in
patients with
hepatitis B or C

May 2015

1) Title of Application

Transient elastography (TE) at 50Hz for the diagnosis of liver fibrosis in patients with hepatitis B or C.

2) Purpose of application

This application is for a new MBS item using TE for the diagnosis of liver fibrosis in patients with chronic hepatitis B or C. TE is a type of ultrasound that measures the 'stiffness' in the liver, which correlates to the level of liver fibrosis. Liver fibrosis can progress to cirrhosis, hepatocellular carcinoma, liver failure and death. The application relates to the diagnosis of fibrosis in patients without previously diagnosed fibrosis.

This technology has been available for around five years in public hospitals in Australia, and therefore the cost of the test is currently borne by the States and jurisdictions. An MBS item for this test would enable it to be reimbursed when the procedure is undertaken in privately funded settings such as private hospitals and medical specialists' rooms.

PASC indicated that a separate item for monitoring of fibrosis should be considered in this protocol, and therefore is included in the PICO, algorithms and questions for the assessment.

3) Population and medical condition eligible for the proposed medical service

The medical conditions

Hepatitis B and C are communicable diseases which can result in serious health consequences. Hepatitis B is transmitted through blood or other bodily fluids and can cause either acute or chronic disease. The likelihood of the disease becoming chronic depends on the age at which an individual is infected, with children less than six years of age most likely to develop chronic infections. People with chronic hepatitis B have a significantly increased risk of developing liver cancer (Hepatitis Australia 2014c). Vaccination can prevent hepatitis B infection, and it is part of the Australian National Immunisation Program Schedule (Immunise Australia Program 2014).

Hepatitis C infection can also manifest as acute or chronic disease, with the acute infection rarely becoming life-threatening. However chronic infection, which develops in 55-85% of people with hepatitis C infection, poses a risk of progression to liver cirrhosis or liver cancer (World Health Organisation 2014). In Australia, hepatitis C is transmitted predominantly by the sharing of injecting drug equipment, but it can also be transmitted by unsterile tattooing or piercing procedures, unsterile medical procedures or vaccinations (particularly in countries with high rates of hepatitis C) and accidental exposure (for example through needle-stick injury) to infected blood or blood products (Hepatitis Australia 2014a). There is no vaccine

for hepatitis C. Although hepatitis C is curable, especially if treated early, only a small number of people with chronic infection receive treatment. There are several reasons for this, including relatively low treatment efficacy (although this is expected to improve with emerging drugs), long treatment duration, significant side effects of treatment and the high rate of comorbidities, such as psychiatric disorders, in people requiring treatment (Holmes 2013).

Burden of disease

According to the National Surveillance Program for HIV, viral hepatitis and sexually transmissible infections in Australia, there were an estimated 210 000 people living with chronic hepatitis B in 2013, a prevalence of 0.97%. There were also 389 deaths attributed to chronic hepatitis B infection in 2013 (The Kirby Institute 2014b). The estimated prevalence of hepatitis C in the Australian population was 1.4% in 2013 (The Kirby Institute 2014b). According to the Surveillance Program, in 2013 there were an estimated 310 000 people who had been exposed to hepatitis C at some time, with 80 000 estimated to have cleared the disease, and 230 000 with chronic hepatitis C infection.

Chronic hepatitis B or C infection can lead to damage in the liver, resulting in scarring known as fibrosis. Fibrosis can lead to cirrhosis, hepatocellular carcinoma, liver failure and death. The estimated rate of at least moderate liver disease has more than doubled in the past ten years (The Kirby Institute 2014b). The number of people with hepatitis C-related cirrhosis is expected to increase as the population with hepatitis C ages; moreover, hepatocellular carcinoma has the fastest rising incidence of any cancer in Australia (Holmes 2013). The Australian Institute of Health and Welfare predicts that the incidence of liver cancer will increase by 38% for males and 78% for females from 2007 to 2020 (Australian Institute of Health and Welfare 2012).

Populations at risk

Certain population groups are at higher risk of contracting hepatitis B or C. Despite incomplete reporting by Aboriginal and Torres Strait Islander status, it is known that newly diagnosed hepatitis B and C infections are disproportionately high in this population (The Kirby Institute 2014a). Between 2009 and 2013, the rate of newly diagnosed hepatitis C infection increased in Indigenous people, whereas it remained stable in the non-Indigenous population. There was a decrease in the rate of newly diagnosed hepatitis B infection for indigenous people over the same time period but the existing notification rate for hepatitis B for indigenous people living in outer regional, remote and very remote areas of Australia was still up to seven times higher than for non-Indigenous people in those regions. The reverse was true for hepatitis C, where notification rates were lower in remote and very remote areas in Indigenous populations (The Kirby Institute 2014a).

A high prevalence of hepatitis B is observed in people from culturally and linguistically diverse backgrounds, reflecting the endemicity of the condition in the countries of origin (Australian Government Department of Health 2014b).

The prison population is especially at risk of contracting and living with hepatitis B or C. Although medical services provided in custodial settings are not reimbursed by the MBS, this is a population of interest once people are released back into the community.

Population eligible for this test

Liver check-ups are strongly recommended by Hepatitis Australia in their report "Regular liver check-ups must be made available to avert a liver disease crisis" (Hepatitis Australia 2014b). This report, endorsed by a number of relevant stakeholder groups including the Gastroenterological Society of Australia, the Australasian Hepatology Association, the Australasian Society for Infectious Diseases and several Australian research institutes, advocates *all* patients with chronic hepatitis B or C undergo liver check-ups as part of their standard care. People aged over 40 years are at increased risk of liver damage related to hepatitis, and more than half of all people with chronic hepatitis B or C are in this category; with the ageing of the population, this will increase (Hepatitis Australia 2014b). This report suggests monitoring liver health every three, six or 12 months depending on the stage of liver disease, and input from clinician experts strongly supported this.

Thus, all people with chronic hepatitis B or C who have not already been diagnosed with fibrosis form the eligible population for the *diagnostic* TE test. Chronic hepatitis, as diagnosed by a positive HBsAg or HCV RNA test and clinical judgement, is the condition referred to in this protocol.

People with chronic hepatitis B or C who have been previously tested for fibrosis and are being monitored for progression of fibrosis (for example, people with treatment failure or those untreated with an initial TE result indicating an intermediate risk of cirrhosis) form the population for the *monitoring* TE test.

The applicant has indicated that once yearly scanning would be appropriate for monitoring; feedback suggests that there may be clinical reasons for monitoring more frequently in some patients. The assessment report should consider the patient indications for monitoring more frequently than annually and the evidence or assumptions to support these.

4) Intervention – proposed medical service

TE (often known by its trade name, Fibroscan™) is a technique for measuring the stiffness of the liver, which along with other clinical information, can be used to gauge the level of fibrosis present in the liver. TE at 50Hz uses ultrasound to make measurements of the stiffness of the liver. The velocity of a vibration wave (or shear wave) is measured by the time it takes to travel to a particular depth inside the liver (Kemp, W. & Roberts 2013). A minimum of 10 valid readings are taken in a single sitting and the median result expressed in kilopascals, which is then interpreted, along with other clinical and biochemical indications, to infer the level of fibrosis (Kemp, W. & Roberts 2013). The patient lies on a bed with their right arm raised, whilst a probe similar to an ultrasound probe is placed on their abdomen near the liver. The patient feels gentle clicks whilst the machine takes the measurements, however it is not painful (Kemp, W. & Roberts 2013).

The machine to perform the test is available as an in-clinic model and a recently upgraded transportable model with full capabilities for most of the population, including those who are overweight and obese. The test can be conducted by any adequately trained health professional; it does not require an ultrasound accredited professional as it is a measuring technology rather than an imaging technology. Results are available immediately, and need to be considered by the patient's clinician in light of other clinical information; that is, TE alone should not be used for management decisions. Therefore, as with any diagnostic test, there is the requirement for a consultation for the patient to receive the test results. In practice, TE takes place within a consultation and results are available immediately. Authorised training to operate the machinery is provided free of charge by the sponsor and operators are also required to undergo recertification to ensure correct use of the machine. The test is easy to conduct, is non-invasive, causes no patient discomfort and usually takes only around 10-20 minutes to perform (Kemp, W. & Roberts 2013; Tsochatzis et al. 2011; Wong 2013). The test is not recommended for people with pacemakers or for pregnant women, and inaccurate or unobtainable readings are more common in people who are obese, older, have ascites (a build-up of fluid between the abdominal wall and organs) or have features of metabolic syndrome (Kemp, W. & Roberts 2013).

Requirements for fasting before having TE vary. A 2013 paper published in Australian Family Physician suggested that patients should fast for two hours prior to the test, but also noted that specific instructions could vary according to the operator (Kemp, W. & Roberts 2013). The Department of Gastroenterology and Hepatology at St Vincent's Hospital in Sydney, and the Alfred Hospital in Melbourne require no patient preparation when they conduct the test (Department of Gastroenterology and Hepatology 2015; The Alfred Hospital 2015). However Sydney Norwest Gastroenterology, who refer their patients to the Storr Liver Clinic at Westmead or the Concord Hospital in Sydney for the test, require patients to fast for two hours (Sydney Norwest Gastroenterology 2015). The manufacturer of the Fibroscan™

machine makes no mention of fasting or any other patient preparation. Recent Australian consensus guidelines on TE recommend patients fast for two hours prior to the procedure (Kemp, William et al. 2015). An investigation of the impact of fasting on test results has been included in the protocol.

The makers of Fibroscan™ claim that the range of probes on offer: S, for paediatric use, M for use in most adults, and XL for overweight adults, cater for all categories of patients. The TE machine itself is able to detect when the XL probe is required.

TE is currently available in tertiary public hospitals, the NSW custodial system and one private setting (consultant's rooms) in Australia, on an outpatient basis.

5) Co-dependent information (if not a co-dependent application go to Section

Not applicable

6) Comparator – clinical claim for the proposed medical service

The TE test is used as part of liver investigations for people with hepatitis B or C. Non-invasive methods of assessing liver damage are now well established in practice and TE is one of these methods, along with imaging (such as ultrasound) and measurements of biomarkers of liver function (Kemp, W. & Roberts 2013). These tests are undertaken as a battery of tests; each measures something different and the results of all of these tests taken together form the clinical picture of liver damage.

As TE is already an established technology and widely used in clinical practice in the tertiary setting, the comparator for *direct evidence* is clinical assessment for liver fibrosis *without* TE. This may include ultrasound, liver function tests and physical examination for hardness of the liver. This comparator applies to the questions regarding safety, effectiveness and cost effectiveness of TE.

The reference standard for assessing accuracy in the measurement of liver fibrosis is liver biopsy. This is considered theoretical as it is no longer done in routine clinical practice and is reserved only for cases where there is genuine diagnostic uncertainty. Liver biopsy involves injecting local anaesthesia and entering the abdomen through the ribcage to remove a piece of the liver with a needle. There are safety risks associated with the procedure, and as a reference standard it is considered imperfect, due to sampling error and intra- and inter-rater variability in assessing histopathology (Wong 2013).

An additional service model comparator is included in this protocol given that TE is already standard practice in the tertiary health setting, and MBS listing of the test would result in the test being available in alternative settings.

7) Expected health outcomes relating to the medical service

The major expected patient-relevant outcomes associated with using TE are that it is more accurate than clinical assessment and non-invasive testing alone; and that it is a safer, more acceptable and more convenient method of measuring fibrosis than the reference standard, liver biopsy. As an ultrasound procedure it has virtually no risk associated with it, takes only a short time to perform and does not require any patient preparation (although some practitioners prefer patients to fast before TE). Liver biopsy, on the other hand, has some small but serious risks associated with bleeding or infection, can be painful for the patient and requires a considerable amount of time for recovery in hospital. TE may reduce the need for biopsy in some patients, where advanced fibrosis and cirrhosis can be excluded or diagnosed by TE. Moreover, more patients may have liver check-ups because a non-invasive alternative to biopsy is available outside of the public hospital setting. Greater uptake of liver testing may result in more patients electing to undergo treatment. The number of people electing to treat will also be affected by newer, more efficacious and shorter duration treatments that are likely to become available in the near future.

8) Fee for the proposed medical service

The applicant has not proposed a fee, but has suggested item 55014, ultrasound scan of the abdomen, as a similar item. The fee for item 55014 is \$55.65. However the applicant also notes that TE uses different ultrasound technology and is for measurement rather than imaging, is only used on the liver and requires multiple measurements (all done in the one sitting). The test only takes 10-20 minutes and can be undertaken by a suitably trained health professional, although the results must be interpreted by the patient's clinician with reference to the other clinical information that is available. Therefore, as with any diagnostic test, there is the requirement for a consultation for the patient to receive the test results; in practice, the TE is undertaken within the consultation and results are fed back immediately. Along with physical examination, other tests are also taken in conjunction with TE for assessing liver damage, namely liver function tests, biomarkers for liver disease, both of which are tested on a blood sample, and possibly ultrasound of the liver (to assess its structure). PASC suggested that a fee for the service in line with other point-of-care testing services may be appropriate.

The capital cost of the equipment for the full-capability in-clinic model with M and XL probes is around [REDACTED] plus GST, whilst the new transportable model with M and XL probes costs [REDACTED] plus GST. It costs [REDACTED] plus GST for the twice-yearly calibration of the two probes, and full maintenance of the unit and probes including backup. There are no consumables associated with the use of the equipment.

9) Clinical Management Algorithm - clinical place for the proposed intervention

Recently published consensus guidelines on the use of TE by the Australian Liver Association recommend that TE should be used in hepatitis patients to add to information clinicians use for informing treatment and management strategies, recognising that TE alone should not guide treatment decisions. (Kemp, William et al. 2015)

A position paper produced by Hepatitis Australia and endorsed by various craft groups, research institutes and special interest groups advocates regular liver check-ups as part of standard care for all people with hepatitis B or C (Hepatitis Australia 2014b). Monitoring is recommended at 12 months depending on the degree of liver damage. Specifically mentioned are non-invasive tests like blood tests, TE and ultrasound, however no further detail is provided (Hepatitis Australia 2014b).

NHMRC endorsed, evidence-based guidelines for hepatitis C are not available. Several other groups have produced guidelines for their members. There are guidelines for primary care produced by the Australasian Society for HIV Medicine (ASHM), and guidelines published by the Australian Family Physician (Australasian Society for HIV Medicine 2014b; Holmes 2013). Both of these guidelines mention TE, with the ASHM guidelines stating that TE can be used for measuring fibrosis and is a "simple, fast and accurate technique" (Australasian Society for HIV Medicine 2014b). The guidelines published in the Australian Family Physician were compiled by three physicians (without any craft group endorsements) and TE is classed in these guidelines as an optional investigation for patients with hepatitis C undergoing initial assessment; liver biopsy is not mentioned (Holmes 2013).

The Australasian Society for HIV Medicine also produced guidelines on hepatitis B for primary care practitioners, which mentions TE as a non-invasive method for assessing fibrosis (Australasian Society for HIV Medicine 2014a). Additional evidence-based guidelines for hepatitis B, published by the Digestive Health Foundation, suggest investigating '*clinical, laboratory or imaging evidence of cirrhosis*' as part of baseline investigations, and liver biopsy is recommended before antiviral therapy is commenced; these recommendations are considered level III (according to the grading system used in the guideline) and are based on the opinion of respected authorities or descriptive epidemiology (Digestive Health Foundation 2010). TE is not mentioned in these guidelines.

In Europe, guidelines for hepatitis C state that non-invasive monitoring of liver fibrosis is adequate initially, and suggest reserving liver biopsy for cases where there is uncertainty or potential additional aetiologies (European Association for the Study of the Liver 2014). American guidelines also recommend measuring liver fibrosis using non-invasive methods, biomarkers or liver biopsy before treatment is begun for hepatitis C; however, they do not

recommend one method over another (American Association for the Study of Liver Diseases 2014).

The management of hepatitis B or C is complex and involves assessments of liver damage, decisions about treatment for the virus and eventually may include treatment for cirrhosis or hepatocellular carcinoma. Management must also consider comorbidities, risk factors that may accelerate liver disease and psychosocial issues (Australian Government Department of Health 2014a). For the most part, people with hepatitis B or C are cared for by specialists. However the Australian National Hepatitis C Strategy highlights that as treatment duration decreases and drug tolerance improves, it will be important to transition care from specialist settings to primary care settings, and that

“this must be accompanied by strategies to improve access to the tools necessary for assessment, including access to the non-invasive diagnostic tools for assessing liver disease severity, which currently has limited availability beyond specialist services” (Australian Government Department of Health 2014a)

Clinical management algorithms were not provided by the applicant; thus the current and proposed clinical management algorithm as provided at

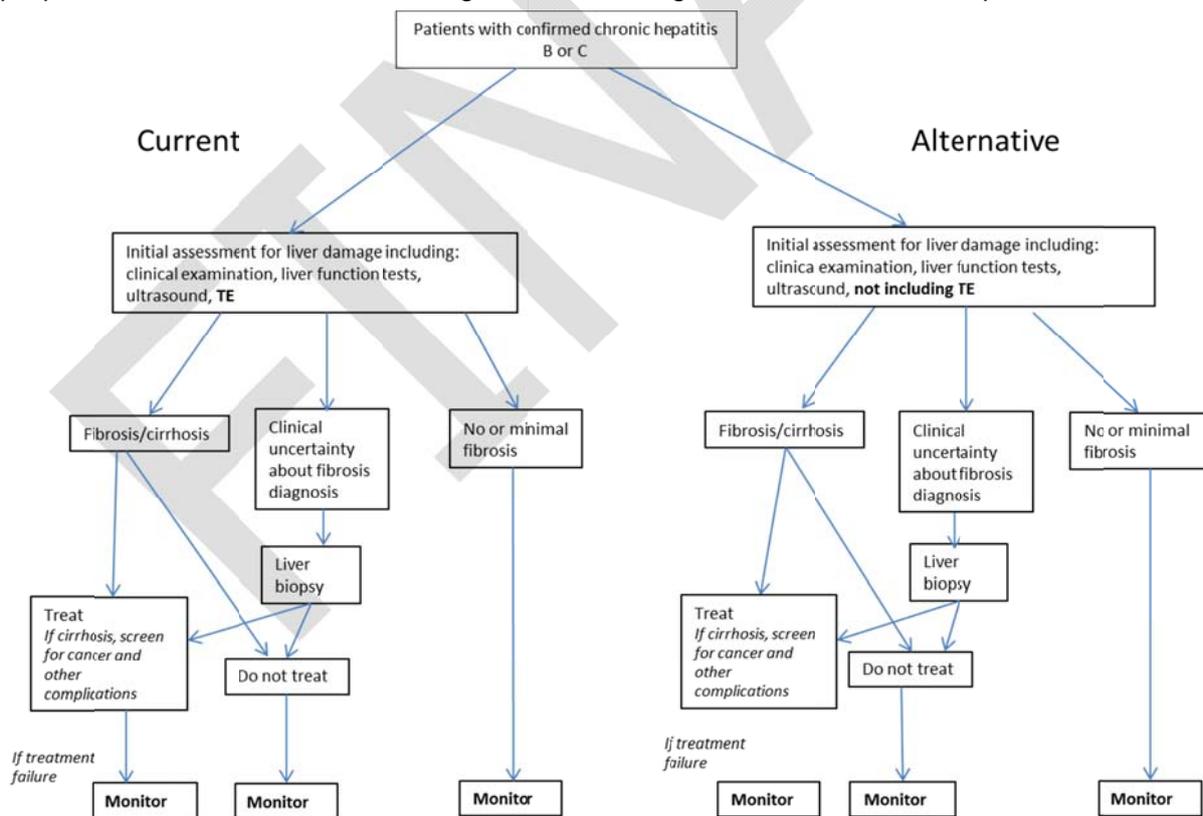


Figure 1 has been suggested by the assessors as the likely path for most (but not all) patients with hepatitis B or C. It is not a clinical practice guideline and does not show all tests used or all pathways that may lead to treatment of chronic hepatitis B or C. There are several points to consider when constructing the clinical management algorithm. As TE is

currently part of clinical practice in the tertiary health setting, and is undertaken on virtually every patient with newly diagnosed chronic hepatitis B or C, TE is actually already in the current practice pathway rather than the alternative pathway. There was some discussion about the most appropriate alternative pathway at the PASC first consideration meeting. Liver biopsy is not routinely done in this patient group and has not been since it was removed as an eligibility criterion for PBS-funded treatment for hepatitis C in 2006, so it was not considered to be an appropriate alternative pathway; PASC determined that clinical assessment for liver fibrosis, which includes blood tests for markers of liver disease, ultrasound and physical examination, but not TE, with the addition of liver biopsy to resolve uncertainty, was the most appropriate alternate pathway.

The addition of an item for monitoring was also requested by PASC and this has been included in the algorithms.

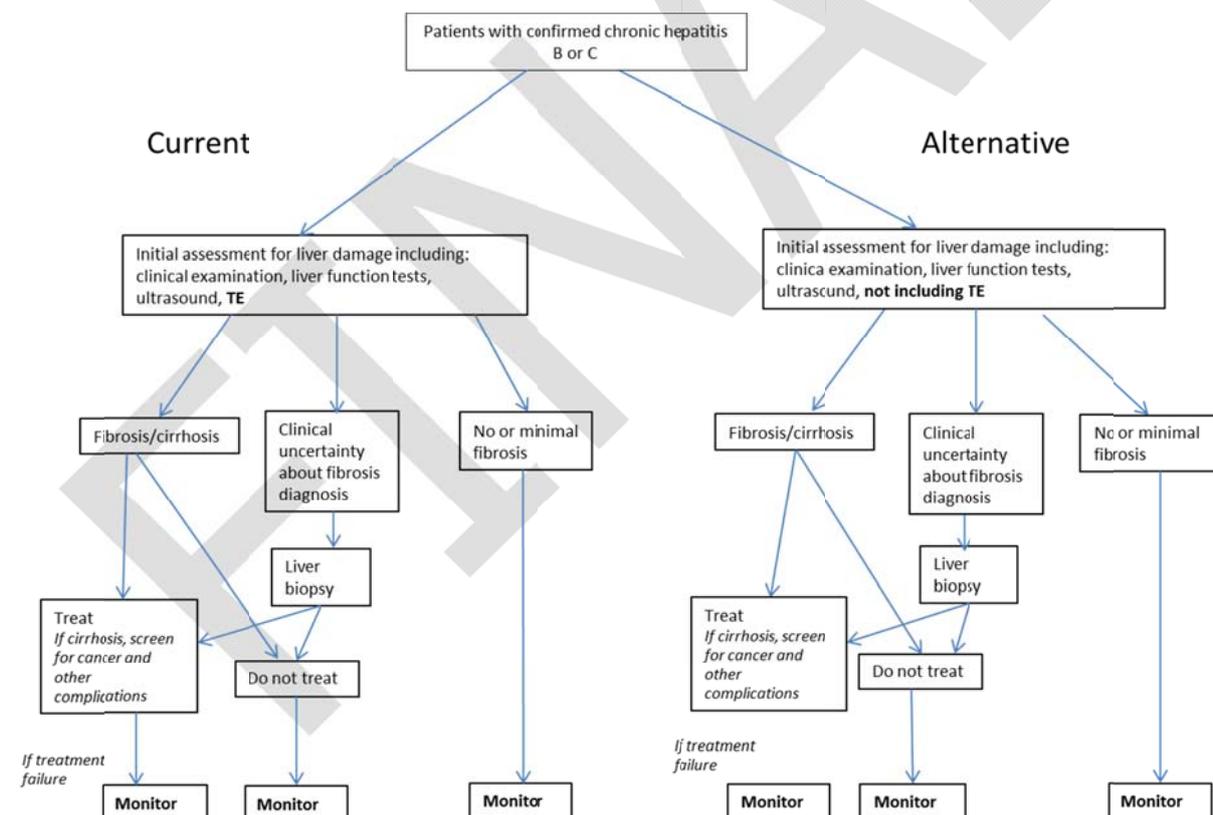


Figure 1 Clinical management algorithm for patients with hepatitis B or C undergoing investigation for diagnosis and monitoring of liver fibrosis¹

¹ The applicant has stated that once yearly scanning would generally be appropriate for monitoring, however it may be considered more often in certain patient indications to be assessed in the report.

Additionally, PASC considered that the current pathway occurs for the majority of patients in tertiary hospital settings, especially given that the currently available treatments for hepatitis are prescribed through the Section 100 Highly Specialised Drugs program. An alternative pathway would be the same care provided in primary care and private settings (Section 100 regulations notwithstanding; it is possible that emerging treatments for hepatitis, if listed on the PBS, may not be Section 100). The assessment report should consider the potential requirements for infrastructure and training in various alternate settings (such as primary care or specialised drug and alcohol clinics) and the potential for increased uptake of the test should it be available in different settings.

FINAL

10) Regulatory Information

The device that delivers transient elastography at 50Hz is registered on the Australian Register of Therapeutic Goods (151894) as 'External noninvasive ultrasound elastography device for measuring elasticity of organs such as the liver'. Also listed is the elastography 'applicator' under 206567.

The device is classified by the Therapeutic Goods Administration as a medical device Class IIa and is considered low-medium risk.

11) Decision analytic

Although the most likely result of listing TE on the MBS is a cost shift away from public hospitals and into private and primary care settings, the analysis will also need to consider if TE is as safe, effective and cost effective as clinical assessment without TE and/or liver biopsy. The analysis should consider:

Safety:

Physical and psychological harms associated with TE testing.

Diagnostic accuracy:

Sensitivity, specificity, positive predictive value, negative predictive value, false positive rate, false negative rate.

Effectiveness:

Mortality from, incidence of and morbidity associated with liver cancer, morbidity and mortality associated with cirrhosis and other liver complications including oesophageal varices, patient acceptability and convenience, number and characteristics of patients tested, change in referral patterns or treatment options, impact of treating patients with false positive or false negative results, the need for re-testing or additional tests, intra-individual reliability of TE, prognostic value of TE readings and changes in TE readings for predicting risk of cirrhosis (including prognostic value of any recommended TE cut-offs for diagnosing fibrosis) and subsequent impact on frequency of monitoring.

Cost effectiveness:

Cost per patient diagnosed with liver fibrosis, cost per quality adjusted life year.

Financial implications:

Cost of potential shift in funding from public hospitals to private or primary care settings, including the possibility of an increase in testing; infrastructure and training ramifications; cost ramifications of monitoring frequencies (including a sensitivity analysis if appropriate).

Should there be an absence of direct evidence comparing the safety, effectiveness and cost-effectiveness of TE with clinical assessment without TE and/or liver biopsy, a linked evidence approach should be undertaken.

The PICO criteria detailed in Table 1:

- (1) define the question for public funding,
- (2) guide selection of the relevant evidence to assess the safety, diagnostic accuracy, and effectiveness of TE for diagnosis and monitoring of liver fibrosis in people with hepatitis B or C, and outcomes relevant to the management of the populations diagnosed and monitored by each testing regimen;
- (3) provide the evidence-based inputs for any decision-analytical modelling to determine the cost-effectiveness of TE testing in the diagnosis and monitoring of liver fibrosis.

Table 1 PICO criteria for evaluating safety, diagnostic accuracy, effectiveness and cost effectiveness of TE for diagnosis of liver fibrosis in patients with hepatitis B or C

Patients	Intervention	Comparator	Outcomes to be assessed
<p>People with confirmed chronic hepatitis B or C who require assessment for liver fibrosis</p> <p>People with confirmed chronic hepatitis B or C who require monitoring for liver fibrosis*</p>	<p>Clinical assessment with transient elastography at 50 Hz to assess the level of liver fibrosis</p> <p>Subgroup analysis: TE before fast TE after fast</p>	<p>Clinical assessment without TE</p> <p>Liver biopsy</p>	<p>Safety</p> <p>Diagnostic accuracy</p> <p>Effectiveness</p> <p>Cost effectiveness</p> <p>Financial implications</p> <p>See section 11</p>

*patients with little or no fibrosis at initial assessment, or elect not to treat, who are monitored for progression, and patients with treatment failure

Questions for assessment:

What are the safety, diagnostic accuracy, effectiveness and cost effectiveness of clinical assessment plus TE for diagnosis of liver fibrosis compared to clinical assessment without TE and/or liver biopsy?

What are the safety, diagnostic accuracy, effectiveness and cost effectiveness of clinical assessment plus TE for monitoring of liver fibrosis compared to clinical assessment without TE and/or liver biopsy?

What is the financial impact on the MBS of listing transient elastography at 50 Hz for the diagnosis of liver fibrosis in patients with hepatitis B or C?

What is the financial impact on the MBS of listing transient elastography at 50 Hz for the monitoring of liver fibrosis in patients with hepatitis B or C?

12) Healthcare resources

The proposed new MBS item is for patients with confirmed hepatitis B or C. The use of non-invasive tests to stage the severity of liver disease is well established in Australia, and TE is already available in public, tertiary level settings. It is therefore expected that listing the test on the MBS would result in a shift away from funding the service in public hospitals (a State and Territory responsibility) or funding by individuals and private health insurers (who currently pay for the test in private clinical settings). The majority of patients currently receiving the service do so in public hospitals (as there is only one TE machine outside of this setting available, plus one in the NSW custodial setting). The list of resources to consider in an economic analysis is given in Table 2. The assessment will also need to consider the impact of frequency of monitoring, considering the patient indications in which more frequent monitoring may be appropriate. All other aspects of care, including identification of patients, other tests, and subsequent treatment are the same for TE and the comparators.

The applicant does not expect that there will be any uptake of the technology into private imaging companies as it is a measuring device rather than an imaging device, however clinician expert advice indicated that there may in fact be uptake in these settings, so that primary care providers could access them in the same way they use private pathology and imaging. There is some uptake expected in private hospitals and specialists' consulting rooms, in circumstances where these services would have a large pool of patients with hepatitis B or C. Depending on the uptake of the technology by the private and primary care sector, the availability of TE may increase, including in regional areas where patients may find it difficult or inconvenient to travel to large centres, either for TE or biopsy. The use of the transportable equipment may increase access in remote locations, which could benefit Indigenous populations who are overrepresented amongst people with hepatitis B or C.

The National Hepatitis C Strategy 2014-17 states that there should be increased options for assessment of liver disease outside of specialist settings, and the availability of TE in other healthcare settings, especially those commonly used by priority populations (such as drug and alcohol treatment services) could help to achieve this aim (Australian Government Department of Health 2014a). There was strong support in the public consultation for care providers other than specialists to be able to interpret TE results, given the drive for care for hepatitis patients to move into the primary care setting. The assessment should consider

current models of care for hepatitis patients to inform recommendations about appropriate providers.

13) Questions for public funding

Is there likely to be increased uptake of TE in the private sector if an MBS item is provided?

Should there be usage limits or patient restrictions in the proposed MBS item descriptors?

If this technology was made available in the primary care setting, what would the training and other requirements be for primary care providers to assess and monitor people with hepatitis B or C and liver fibrosis? Although the National Hepatitis C Strategy suggests that moving care into the primary health sector is desirable, it recognises that there are workforce, strategy and management issues with doing so, all of which will require significant investment (Australian Government Department of Health 2014a).

Table 2 List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other government budget	Private health insurer	Patient	Total cost
Resources provided to deliver proposed intervention: clinical assessment without TE										
Clinical assessment	Medical specialist	Specialist's rooms or public hospital outpatients*	100	1	\$132.10 /\$263.90**					\$263.90
Consultation to receive test results	Medical specialist	Specialist's rooms or public hospital outpatients*	100	1	\$132.10					\$132.10
Resources provided to deliver comparator: clinical assessment with TE										
Clinical assessment	Anaesthetist, medical specialist	Specialist's rooms or public hospital outpatients*	100	1	\$132.10/ \$263.90**		n			\$263.90
Perform TE	Nurse practitioner or medical specialist	Specialist's rooms or public hospital outpatients*	100	1	?					?

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other government budget	Private health insurer	Patient	Total cost
Consultation to receive test results	Medical specialist	Specialist's rooms or public hospital outpatients*	100	1	\$132.10					\$132.10
Resources provided to deliver intervention in primary care settings#										
Clinical assessment (Level D for first visit)	Primary care physician	GP surgery or other primary care setting	100	1	\$105.55		n			\$105.55
Perform TE	Appropriately trained health professional	Private hospital outpatients, private imaging	?							?
Consultation to receive test results (level B)	Primary care physician	GP surgery or other primary care setting	100	1	\$37.05					\$37.05

*no cost to MBS of services rendered through public hospitals

** cost dependent on length of consultation

#Note potential for medical specialists to also provide these services in primary care settings such as specialist drug and alcohol clinics.

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