

Decision Summary

Meeting Date	Tuesday 3 February 2009		
Application #	09002V		
Title of TCP	Transient tissue elastography (TSE)		
<input checked="" type="checkbox"/> New TCP	<input checked="" type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
TSE is a new technology that has the potential to replace liver biopsy in diagnosis of hepatic cirrhosis. It involves transmission of a vibration wave through the liver tissue which is then measured with ultrasound technology.			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest	
Committee	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest	
SAFETY			
<input checked="" type="checkbox"/> Safer than current practice	<input type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
Transient elastography is a non-invasive ultrasound technology with no significant side effects or adverse events. Liver biopsy is the current alternative and has risks of bleeding and, although rare, may result in death. Patients for whom liver biopsy is contraindicated, particularly those with bleeding disorders, will be able to undergo TSE.			
EFFECTIVENESS			
High quality evidence?	Two high quality systematic reviews summarise multiple primary studies that score moderate to excellent on the QUADAS scale of quality in diagnostic test studies.		
Consistent, clinically important benefit?	Both reviews found that TSE is accurate in diagnosis of cirrhosis but of limited utility in earlier stages of fibrosis		
Applicable to Southern Health?	Yes, Southern Health has a large population of patients with conditions predisposing to cirrhosis that reflect the populations in the studies reviewed		
TSE will be used as a diagnostic tool in patients for whom the presence or absence of cirrhosis will affect treatment decisions. Given the lack of accuracy in differentiating between degrees of fibrosis, TSE will not be used as a screening tool in patients unlikely to have cirrhosis or to monitor progression of fibrosis.			
COST			
No specific cost-effectiveness studies were provided with this application. It anticipated that, after purchase of the equipment, TSE will be significantly less costly than liver biopsy as it can be done as an outpatient (biopsy requires an inpatient day procedure bed), can be undertaken in 10-15 mins, and has less complications. Significant outlay for equipment is required. Southern Health has been invited to participate in a joint application for external (VPACT) funding led by The Alfred Hospital.			
CLINICAL FEASIBILITY			
Resource implications	This patient population is already being treated at Southern Health. The TSE service will be implemented within existing services such as the private consulting rooms and endoscopy suite.		
Credentialing and competency assurance undertaken	Southern Health staff will attend the training program provided by the manufacturer.		
This is feasible within current operational capacity. Capability will be addressed by appropriate training of gastroenterologists.			
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
Southern Health patients in Hepatitis clinics at MMC Clayton, Special Medicine Centre, Cranbourne, Springvale and from our rural hospital network will be eligible to receive this service. No other issues related to access, equity, legal or ethical requirements were identified.			

Final decision by the Southern Health Technology/Clinical Practice Committee	
<input type="checkbox"/>	Recommended: Approved with no further need for assessment.
<input checked="" type="checkbox"/>	Restricted Recommendation – Audit: Approval subject to implementation under audit conditions. Conditions are specific to the technology.
<input type="checkbox"/>	Restricted Recommendation – Clinical Trial: Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.
<input checked="" type="checkbox"/>	Restricted Approval – Operational Restrictions: Endorsed, however financial or operational restrictions apply.
<input type="checkbox"/>	Not Recommended
Conditions	
Audit	
<ul style="list-style-type: none"> ▪ Data collection tool (spreadsheet/database) to be forwarded to TCPC ▪ Data to be collected on all patients and reports provided to TCPC at six monthly intervals for two years ▪ Adverse events to be reported immediately to TGA and TCPC 	
Operational restrictions	
<ul style="list-style-type: none"> ▪ Approval is conditional upon availability of full funding for equipment 	

SH Policy	Quality and Risk Management	ACHS	Leadership and Management
Reviewer	Director, Centre for Clinical Effectiveness	Last review date	January 2008
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	August 2010

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