

***Intra-operative  
transoesophageal  
echocardiography***

**May 2002**

MSAC reference 08

**Assessment report**

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The Medical Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Ageing on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which medical services should attract funding under Medicare.

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***MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.***

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## **Executive summary**

### **The procedure**

Intra-operative transoesophageal echocardiography (TOE) is used to obtain high quality, ultrasonic images of the heart and associated structures during surgery. An examination of the heart and vessels may be performed pre-operatively and pre-bypass to assess the clinical situation; intra-operatively to review the surgical result and monitor ventricular function, and/or post-operatively to assist in management of intravascular volume and pharmacology.

### **Medical Services Advisory Committee – role and approach**

The Medical Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. A team from the Monash Institute of Health Services Research was engaged to conduct a systematic review of literature on intra-operative transoesophageal echocardiography. A supporting committee with expertise in this area then evaluated the evidence and provided advice to MSAC.

### **MSAC's assessment of intra-operative transoesophageal echocardiography**

#### **Clinical need**

Intra-operative TOE may be used in both cardiac and non-cardiac surgery to monitor and assess cardiac function of anaesthetised patients. In the current assessment, the literature revealed the use of intra-operative TOE for several indications including congenital heart lesions, coronary artery bypass grafting, valve replacement surgery, other cardiac and non-cardiac surgery. In Australia, the number of TOE services processed by Medicare has increased steadily from 416 services in 1996 to 4,382 services in 2001.

#### **Safety**

There are various potential risks for patients undergoing intra-operative TOE. The semi-invasive procedure has a small but definite risk. Most of the available data on adverse events are derived from case series or case reports, suggesting that estimates of incidence are uncertain although the nature of the event might be recognised. In addition, four controlled trials were also identified that evaluated the incidence of post-operative side effects, gastro-oesophageal injury and patient complaints following TOE. Data from 10

case reports and 15 case series described adverse events related either to the probe itself or to the procedure.

Probe-related complications included thermal or pressure injuries and compression of the aorta and trachea. Procedure-related adverse events involved the cardiovascular, pulmonary and upper gastrointestinal systems. Data from four controlled studies showed that patients undergoing TOE had no significant increase in cardiovascular, pulmonary and upper gastrointestinal injuries when compared with patients who did not undergo TOE, suggesting that TOE could be used without harmful post-operative effects and that inappropriate placement of the probe was not entirely responsible for gastro-oesophageal injury. The incidence of gastro-oesophageal injury was estimated at approximately one in 10,000 for anaesthetised patients.

## **Effectiveness**

### **Item 1 Diagnostic characteristics**

A systematic literature search was performed to identify the effectiveness of TOE as a diagnostic test. Cross-sectional studies evaluating the accuracy of TOE compared to an appropriate reference in a consecutive group of patients were included. The literature assessed the accuracy of TOE in detecting various disorders including thoracic aortic wall dissection, endocarditis and associated phenomena, thrombi and aortic plaques.

Sensitivities and specificities of TOE varied with indication. Likelihood ratios for a positive test result greater than 10 indicated that patients with a positive TOE result were likely to have the target disorder. High positive likelihood ratios were found in the detection of endocarditis, abscesses associated with endocarditis, coronary artery stenosis or left atrial thrombi. There was a high post-test likelihood that these disorders would be present if a positive TOE result was found, indicating that TOE may be a useful test for detection of these disorders.

Although not specifically assessed, TOE in an outpatient setting is also considered to have a high diagnostic accuracy in detecting congenital heart disease and acquired cardiac valve disorders. The variability in results may reflect not only the varying diseases under investigation but also the study design. Included studies were all flawed in some aspect of their study design, suggesting that they may have overestimated the accuracy of TOE. Therefore, results should be interpreted with caution.

### **Item 2 – Clinical effectiveness**

A systematic literature search was performed to identify the effectiveness of intra-operative TOE as a monitoring intervention on clinical management and patient outcomes. The ideal study design to assess the effectiveness of this intervention is a randomised controlled trial comparing the outcomes of patients assigned to undergo intra-operative TOE against those not receiving TOE. No such trials were identified in the literature search. Overall, evidence came from studies that were inappropriately designed for assessing the benefit of intra-operative TOE on patient outcomes.

Evidence for the effectiveness of intra-operative TOE on clinical management during surgery came from case series which suggested that intra-operative TOE may result in an alteration to the pre-surgical and medical plan.

Comparative studies provided evidence for the outcomes of patients undergoing intra-operative TOE against patients who did not have the intervention. Reported outcomes included mortality and various measures of cardiac morbidity. Evidence from the published literature suggested that the incidence of the majority of these outcomes was the same for patients who underwent TOE and those who did not. However, as studies were not ideally designed to assess patient outcomes, it is unclear whether the use of intra-operative TOE resulted in changes in morbidity or mortality.

Evidence from the published literature suggests that the use of intra-operative TOE may result in changes to the pre-operative surgical plans of patients. However any results should be considered with caution due to the failure of the studies to meet important validity criteria, for example randomisation and blinding. Whether TOE works in the real world or only in the ideal clinical setting remains unresolved.

### **Cost effectiveness**

Based on data from cardiac valve surgery, cost per case of TOE is estimated here at between A\$575 and A\$690 in the years following initial purchase of the ultrasound machine. Set up and training costs add around 40 per cent to year one costs. The literature estimates potential cost savings as high with the cost of a repeat operation potentially up to \$20,000 dollars more than the cost of repair at the time of initial surgery. No Australian data are available, but US data generally suggest savings with a rate of alteration of cardiac valve surgery of 3.0 to 6.6 per cent.

Depending on the number of patients receiving TOE, total costs could range from A\$2.3 to A\$11.5 million in the years following set up. If the revision rate were five per cent, there would be 200 and 1,000 revisions for 4,000 and 20,000 cases respectively.

If these led to cost savings of more than A\$11,500 per revision, ie costs of at least A\$11,500 on average are avoided by not having to re-operate, (if the minimum cost per case is assumed to be A\$575 for congenital and valve cases in the years following set up), or A\$13,800 of costs avoided per revision, (if cost per case is a maximum of A\$690 for congenital cases alone in the years following set up), then there would be cost savings overall, as cost savings would be greater than procedural costs. Although the Australian health care system figures in this economic evaluation are uncertain, these are reasonable assumptions given the complexity of the surgery involved. A trial of TOE with an associated economic evaluation would be desirable, particularly in non-valvular cardiac surgery and non-cardiac surgery.

### **Conclusion**

Based on clinical evidence and current best practice, it can be concluded that:

- i) Intra-operative TOE during valve and congenital surgery is considered standard care and is becoming routine for cardiac surgery in general. Its role in non-cardiac surgery is uncertain.
- ii) Intra-operative TOE is able to detect changes in cardiac function with high specificity.

- iii) Intra-operative TOE results in frequent changes in intra-operative management of patients with cardiac valve and congenital heart disease and other high-risk cases such as aortic dissection.
- iv) Intra-operative TOE is reported to be safe.
- v) There is no evidence to date that intra-operative TOE results in better patient outcomes.
- vi) Evidence suggests that intra-operative TOE is often associated with adjustment to clinical management.
- vii) There may be cost savings associated with the use of intra-operative TOE through a reduction in the number of repeated operations since the results of intra-operative TOE evaluation allow immediate surgical changes to be made.

## **Recommendation**

MSAC has found that there is limited evidence of the safety, effectiveness and cost effectiveness of intraoperative transoesophageal echocardiography. MSAC recommends that public funding for this procedure should be supported on an interim basis and restricted to intra-operative assessment of cardiac valve competence following valve replacement or repair.

The provision of funding should be reconsidered no later than June 2005 to ascertain whether further additional evidence has become available which supports continued funding.

- The Minister for Health and Ageing accepted this recommendation on 26 June 2002 -

# Introduction

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The Medical Services Advisory Committee (MSAC) has reviewed the use of intra-operative transoesophageal echocardiography, a technology used to monitor cardiac function during surgery. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are at Appendix A. MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer health and health administration.

This report summarises the assessment of current evidence for intra-operative transoesophageal echocardiography to monitor cardiac function during surgery.

# Background

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## Intra-operative transoesophageal echocardiography

### The Procedure

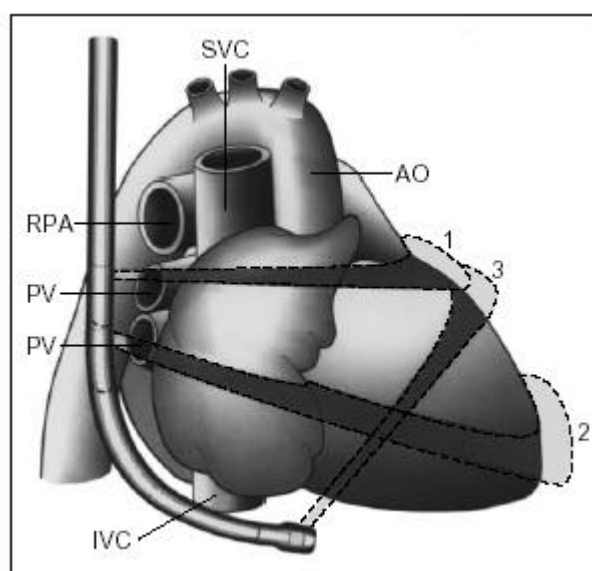
Echocardiography was first applied to the intra-operative management of heart disease in the 1980s with the development of epicardial imaging. Although this method contributed to improved post-operative outcomes, the benefits of echocardiographic imaging and Doppler evaluation during surgery were already apparent. With the increasing popularity of high quality, real time ultrasonic images of the heart, the foundation was laid for the introduction of intra-operative TOE (Bezold et al 1996, Oxorn et al 1996, Gillam 2000)

### Basic Views

Intra-operative TOE provides an image of the heart, the great vessels and the mediastinum by obtaining a view from at least three different positions (Figure 1). These are: (1) the upper oesophageal position, (2) the mid-oesophageal position, and (3) the trans-gastric position (Takuma & Homma 1998). Commonly, the mid-oesophageal and trans-gastric positions are used during intra-operative procedures.

In the mid-oesophageal position, the probe permits imaging of the chambers of the atria and ventricles, as well as the mitral and tricuspid valves. In the trans-gastric position, the TOE probe is used to visualise both left and right ventricles in a short-axis format (Daniel & Mugge 1995).

Figure 1. Three basic imaging planes of the heart that can be obtained with the transoesophageal probe in the oesophagus and stomach (Daniel & Mugge 1995)



### Types of TOE probes

The standard TOE probe consists of multi-element phased-array transducers for the transmission and reception of ultrasonic signals (Bezold et al 1996). These transducers

are mounted at the end of a flexible endoscope providing anterior, posterior and lateral flexion. The single-plane TOE probe is capable of imaging only in the horizontal plane, so can only be used to image in two primary planes of the heart: the short axis and the four-chamber plane. The biplane TOE probe has both horizontal and longitudinal arrays to allow imaging of all three primary planes of the heart: the short axis, four-chamber and long axis. The multi-plane TOE probe produces a continuum of horizontal and longitudinal images by rotation of the probe array, making it significantly easier to visualise the intermediate, transitional and off-axis images between the primary planes compared with the biplane probe (Takuma & Homma 1998).

### **Insertion of TOE probes**

TOE can be performed in conscious or anaesthetised patients. Pre-operative evaluations are conducted when the patient is conscious whereas intra-operative TOE, including pre-bypass and post-bypass assessments, is conducted when the patient is anaesthetised.

In conscious patients, the probe is introduced with the assistance of the patient's swallowing ability. However for the anaesthetised patient, the probe must pass blindly into the oesophagus, bypassing the endotracheal tube (Takuma & Homma 1998). After the probe is passed down the oesophagus, a systematic echocardiographic examination takes place with and without Doppler colour flow imaging based on the clinical situation. After a pre-operative TOE examination, the probe is advanced into the stomach and switched off to avoid thermal injury to surrounding tissue. During weaning from ventilation and after cardiopulmonary bypass, a more focused TOE examination is performed to review the surgical result, monitor ventricular function and assist in management of intravascular volume and pharmacology (Bezold et al 1996).

### **Training requirements**

Guidelines and recommendations for training in TOE have been developed by various professional organisations. The Australian and New Zealand College of Anaesthetists and the Cardiac Society of Australia and New Zealand have developed guidelines. In the USA, a task force from the American Society of Echocardiography and Society of Cardiovascular Anesthesiologists developed guidelines for training in peri-operative echocardiography. The American College of Physicians and the American College of Cardiology guidelines for the clinical application of echocardiography (Cheitlin et al 1997) assume optimal training for such studies as set out by the American Society of Echocardiography, the American College of Cardiology and the Society of Pediatric Echocardiography.

### **Australian and New Zealand College of Anaesthetists**

The Australian and New Zealand College of Anaesthetists has compiled recommendations for training and practice of diagnostic peri-operative TOE (Australian and New Zealand College of Anaesthetists 2001). Recommendations for the initial training for TOE include:

- Training should be performed under the supervision of experienced practitioners who shall have met standards as determined by the College.
- The period of training should be at least the equivalent of 50 days full time over a minimum period of 10 weeks to a maximum period of two years.

- During the period of training, the trainee should perform initially a number of supervised TOE procedures to achieve the competence to perform and report complete diagnostic TOE examinations. This would usually be expected to require 50 complete TOE examinations.
- During the period of training, the trainee should perform at least 50 unsupervised TOE examinations that have been reviewed by a supervisor and at least 100 additional supervised reviews and reports of TOE examinations of pre-recorded studies. The trainee must be exposed to a wide range of cardiovascular pathology and at least 50% of TOE examinations should be undertaken in the operating theatre.
- Attendance and participation in post-graduation courses, workshops and continuing medical education programs dedicated to peri-operative TOE examinations is strongly recommended during the training period and thereafter.

Recommendations for the maintenance of standards include:

- Performance of at least 30 TOE examinations every year
- Reviews of at least 50 TOE study recordings with qualified colleagues every year
- Attendance and participation in post-graduate courses, workshops and continuing medical education programs on peri-operative TOE examinations and related subjects.

### **Cardiac Society of Australia and New Zealand**

The Cardiac Society of Australia and New Zealand recommends the following standards for training and competence in adult echocardiography.

“Advanced training: Advanced training in Cardiology in an approved training programme should include the performance and supervised reporting of echocardiograms, including the personal performance of no less than 300 cardiac ultrasound examinations and the supervised reporting of no less than 600 echocardiograms, at least 50 of which should be transoesophageal studies. Log book or other documentary evidence of the performance and reporting of these examinations should be certified by the trainee’s supervisor. It is intended that the 300 echocardiograms performed personally by the trainee may be included in the 600 echocardiograms reported under supervision.”

### **American Society of Echocardiography**

The American Society of Echocardiography guidelines for training in TOE (Pearlman et al 1992) were based on recommendations for training in transthoracic echocardiography and were for both operative and non-operative applications. These guidelines required the trainee to attain at least Level 2 training (six months full time training) in echocardiography and also to perform and interpret at least 50 supervised TOE examinations.

### **Society of Cardiovascular Anesthesiologists and American Society of Anesthesiologists**

A joint task force was established by the American Society of Echocardiography and Society of Cardiovascular Anesthesiologists to develop guidelines for training in peri-

operative echocardiography (American Society of Echocardiography and Society of Cardiovascular Anesthesiologists Task Force 2001). Table BA1 lists the recommendations for basic and advanced training.

Table BA1 Numbers of Examinations and training recommendations for basic and advanced peri-operative echocardiography.

	Basic	Advanced
<b>Minimum number of examinations</b> (examinations interpreted and reported by the trainee under supervision)	150	300
<b>Minimum number of examinations personally performed</b> (examinations performed, interpreted and reported by the trainee under supervision)	50	150
<b>Program director qualifications</b>	Advanced peri-operative echocardiography training	Advanced peri-operative echocardiography training plus a least 150 additional peri-operative TOE examinations
<b>Program qualification</b>	Wide variety of peri-operative applications of echocardiography	Full spectrum of peri-operative applications of echocardiography

A joint task force established by the American Society of Anesthesiologists and the Society of Cardiovascular Anesthesiologists also established guidelines for peri-operative TOE (Thys et al 1996). The task force recommends that two sequential levels of training, basic and advanced, be recognised for the anaesthesiologist. The specific objectives for basic and advanced training are listed in Table BA2.

Table BA2 Objectives for basic and advanced peri-operative echocardiography training.

<b>Basic</b>	<b>Cognitive skills</b>
	<ol style="list-style-type: none"> <li>1. Knowledge of the physical principles of echocardiographic image formation and blood flow velocity measurement</li> <li>2. Understanding the operation of the ultrasonographic instrument, including the function of all controls affecting the quality of data displayed</li> <li>3. Knowledge of the equipment handling, infection control and electrical safety recommendations associated with the use of TOE</li> <li>4. Knowledge of the indications and the absolute and relative contraindications to the use of TOE</li> <li>5. General knowledge of appropriate alternative diagnostic modalities, especially transthoracic and epicardial echocardiography</li> <li>6. Knowledge of the normal cardiovascular anatomy as visualised tomographically by TOE</li> <li>7. Knowledge of the commonly encountered blood flow velocity profiles as measured by Doppler echocardiography</li> <li>8. Detailed knowledge of the echocardiographic presentations of myocardial ischemia and infarction</li> <li>9. Detailed knowledge of the echocardiographic presentations of normal and abnormal ventricular function</li> <li>10. Detailed knowledge of the physiology and TOE presentation of air embolisation</li> <li>11. Knowledge of native valvular anatomy and function as displayed by TOE; knowledge of the manifestations of valve lesions and dysfunction and of the TOE techniques available for valve assessment</li> <li>12. Knowledge of the principal TOE manifestations of cardiac masses, thrombi and emboli; cardiomyopathies; pericardial effusions, and lesions of the great vessels</li> </ol>
	<b>Technical skills</b>
	<ol style="list-style-type: none"> <li>1. Ability to operate the ultrasonograph, including controls affecting the quality of the displayed data</li> <li>2. Ability to perform safely a TOE-probe insertion in anaesthetised, tracheally intubated patient</li> <li>3. Ability to perform a basic TOE examination</li> <li>4. Ability to recognise major echocardiographic changes associated with myocardial ischemia and infarction</li> <li>5. Ability to detect qualitative changes in ventricular function and haemodynamic status</li> <li>6. Ability to recognise major echocardiographic manifestations of air embolisation</li> <li>7. Ability to visualise cardiac valves in multiple views, ability to recognise gross valvular lesions and dysfunction</li> <li>8. Ability to recognise large intracardiac masses and thrombi</li> <li>9. Ability to detect large pericardial effusions</li> <li>10. Ability to recognise common artefacts and pitfalls in TOE examinations</li> <li>11. Ability to communicate the results of a TOE examination to the patient and to other health care professionals and to summarise these results cogently in the medical record</li> </ol>
<b>Advanced</b>	<b>Cognitive skills</b>
	<ol style="list-style-type: none"> <li>1. All the cognitive skills defined under basic proficiency</li> <li>2. Knowledge of the principles and methodology of quantitative echocardiography</li> <li>3. Detailed knowledge of the native valvular anatomy and function; knowledge of prosthetic valvular structure and function; detailed knowledge of the echocardiographic manifestations of valve lesions and dysfunction</li> <li>4. Knowledge of the echocardiographic manifestations of congenital heart disease</li> <li>5. Detailed knowledge of echocardiographic manifestations of pathologic conditions of the heart and great vessels such as cardiac aneurysms, HOCM, endocarditis, intracardiac masses, cardioembolic sources, aortic aneurysms and dissections, pericardial disorders and post surgical changes.</li> <li>6. Detailed knowledge of other cardiovascular diagnostic methods for correlation with TOE findings</li> </ol>
	<b>Technical skills</b>
	<ol style="list-style-type: none"> <li>1. All the technical skills defined under basic proficiency</li> <li>2. Ability to perform a complete TOE examination</li> <li>3. Ability to quantify subtle echocardiographic changes associated with myocardial ischemia and infarction</li> <li>4. Ability to utilise TOE to quantify ventricular function and haemodynamics</li> <li>5. Ability to utilise TOE to evaluate and quantify the function of all cardiac valves; ability to assess surgical intervention on cardiac valvular function</li> <li>6. Ability to utilise TOE to evaluate congenital heart lesions; ability to assess surgical intervention in congenital heart disease</li> <li>7. Ability to detect and assess the functional consequences of pathological conditions of the heart and great vessels; ability to evaluate surgical intervention in these conditions if applicable</li> <li>8. Ability to monitor placement and function of mechanical circulatory assistance devices</li> </ol>

### **American College of Cardiology**

The American College of Cardiology (ACC) published revised recommendations for training in adult cardiovascular medicine (American College of Cardiology 2002) that included a summary of training requirements for echocardiography (Table BA3). It was recommended that Level 2 training be achieved to perform intra-operative TOE.

Table BA3 Summary of ACC training requirements for echocardiography.

Level	Durations of training (months)	Cumulative duration of training (months)	Minimal total number of transthoracic echocardiography examinations performed	Minimal total number of transthoracic echocardiography interpretations performed	TOE and special procedures
1	3	3	75	150	Yes
2	3	6	150	300	Yes
3	6	12	300	750	Yes

### **La Societe d'Echocardiographie du Quebec**

La Societe d'Echocardiographie du Quebec recommendations for physician training in Doppler echocardiography (Dumensil et al 1991) specify a six-month period of training for residents in cardiology and inexperienced practising cardiologists. During this time, candidates should perform at least 300 examinations including M-mode and two-dimensional echocardiography and pulsed wave, continuous wave and colour flow Doppler. To maintain competence at least 600 examinations should be performed each year.

### **Intended purpose**

Since TOE has the ability to provide high-resolution images of both the blood flow and the structure of the heart and great vessels in almost all patients, the clinical indications for use include: evaluation of global ventricular function, regional ventricular function, thoracic aortic pathology, septal integrity and shunting, chamber contents (myxoma or thrombus), repairs of cardiac lesions, valvular function particularly for reparative surgery, and for pericardial tamponade; detection of pulmonary thromboemboli and air embolism during cardiac and other surgery; and monitoring vascular function of peripheral cardiac vessels (Lake 1994). Other procedures are also performed by the surgeon, for example epiaortic ultrasound to detect atheroma of the aortic arch. However, such procedures are outside the scope of this report and have not been considered.

Intra-operative TOE is also used to monitor the cardiac function of the patient in several surgical indications, listed in Table BA4.

Table BA4 Surgical indications for TOE.

<b>Closed Heart Surgery</b>	Coronary Artery Surgery - standard using cardiopulmonary bypass (CABG) - beating heart coronary artery surgery
<b>Open Heart Surgery</b>	Valve repair and valve replacement (aortic, mitral & tricuspid) with or without CABG including 'minimal access' surgery Atrial septal defect closure Hypertrophic obstructive cardiomyopathy Left atrial myxoma Ischaemic ventricular septal defect Left ventricular aneurysm Aortic aneurysm Bacterial endocarditis Congenital heart disease
<b>Other Surgery</b>	Carotid artery surgery Abdominal aortic aneurysm Aortic rupture Trauma

## Clinical need/burden of disease

The numbers of intra-operative TOE services performed throughout Australia in the years 1996-2001 are listed in Table CN1. Overall usage of intra-operative TOE has grown steadily from 416 services in 1996 to 4,382 services in 2001.

Table CN1 HIC data listing Medicare item number 55130 for TOE processed from 1996 to 2001.

Calendar Year	State								Total
	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	
	No. services								
1996	147	134	85	23	14	2	10	1	416
1997	208	216	83	10	174	2	6	0	699
1998	422	526	86	3	383	0	12	1	1,433
1999	948	807	95	25	447	9	28	2	2,361
2000	1,420	1,369	141	13	409	23	32	1	3,408
2001	1,886	1,717	171	22	524	20	41	1	4,382
<b>Total</b>	<b>5,031</b>	<b>4,769</b>	<b>661</b>	<b>96</b>	<b>1,951</b>	<b>56</b>	<b>129</b>	<b>6</b>	<b>12,699</b>

Source: www.hic.gov.au

## Existing procedures and comparators

TOE can be used to monitor cardiac function during any type of surgical procedure. Cardiac function during surgery has usually been monitored using one or more of arterial or venous cardiac catheterisation, electrocardiography and epicardial or transthoracic echocardiography. For the purposes of the literature search, no restriction was placed on comparators. Included in the evaluation were studies comparing TOE with any other form of cardiac monitoring.

## Marketing status of the technology

There are several echocardiography machines suitable for TOE on the market. All devices of this sort must be listed with the Australian Register of Therapeutic Goods. Those on the current register include the GE Medical Systems Cardio Q® (AustL number 73422), the Aloka® (AustL number 18146), the Philips System Sonos® (AustL number 27428), the HP Sonos® (AustL number 56734), and the Acuson® Ultrasonic Scanner (AustL number 61821).

## Current reimbursement arrangement

TOE is currently funded under the Medicare Benefits Scheme under item number 55130. Table CN2 includes the item description.

Table CN2 Medicare Benefits scheme item numbers for TOE.

Number	Description of procedures	Cost
55130	Intra-operative 2 dimensional real time transoesophageal echocardiography incorporating Doppler techniques with colour flow mapping and recording onto video tape or digital medium, performed during cardiac surgery incorporating sequential assessment of cardiac function before and after the surgical procedure (R) (Anaes. 17710 = 6B + 4T)	\$353.60

Source: www.hic.gov.au

# Approach to assessment

## Review of literature

The medical literature was searched to identify relevant studies and reviews. Table RL1 lists the electronic databases searched in this review. An Internet search of health technology assessment agency websites was undertaken, as well as a search for training guidelines. The Internet sites searched are listed in Appendix C. No health technology assessments of intra-operative TOE were identified. Reference lists of publications were scanned and relevant citations retrieved. Publications recommended by the supporting committee were also retrieved.

Table RL1 Electronic databases used in this review.

Database	Period/Issue covered
Cochrane Library including: The Cochrane Database of Systematic Reviews (CDSR) Database of Abstracts of Reviews of Effectiveness (DARE) The Cochrane Controlled Trials Register (CCTR)	2001, Issue 4
CINAHL (OVID)	1982-October Week 4 2001
Current Contents (OVID)	Week 26 1993-Week 49 2001
Medline (OVID)	1966-October Week 5 2001
PreMedline (OVID)	November 27th 2001
Biological Abstracts (OVID)	1980-September 2001
EMBASE (OVID)	1988-Week 6 2002
EBM Reviews - Cochrane, ACP Journal Club, DARE (OVID)	2nd Quarter 2001

Table RL2 lists the search terms used to identify citations.

Table RL2 Search terms used to identify citations for TOE.

TOE terms	Operative terms	Diagnostic terms	Safety terms
<b>MeSH terms</b>			
exp echocardiography, transesophageal/ <b>Textwords:</b> transesophageal echocardiogra\$.mp transoesophageal echocardiogra\$.mp TOE.mp TEE.mp	intraoperative care/ intraoperative complications/ intraoperative period/ monitoring, intraoperative/ <b>Textwords:</b> intraop\$.mp perop\$.mp	Exp sensitivity/and specificity False negative reactions/or false positive reactions/ <b>Textwords:</b> (sensitivity or specificity).mp (predictive adj1 value\$.mp (likelihood adj1 ratio\$.mp (false adj1 (negative\$ or positive\$)).mp	Safety/ Intraoperative Complications/ Postoperative Complications/ <b>Textwords:</b> complicat\$.mp advers\$.mp

<sup>a</sup> \$ represents a truncation symbol that replaces a series of letters at the end of a word segment so that any letters following the symbol are searched

## Inclusion and exclusion criteria for studies

The following criteria were developed *a priori* to determine eligibility of relevant studies for inclusion in the systematic review.

## Item 1 Diagnostic characteristics

### **Patient population**

- *Inclusion* – clinical studies in humans

### **Characteristics of the test**

- *Inclusion* – use of TOE

### **Characteristics of the indication**

- *Exclusion* – coronary artery stenosis

### **Characteristics of the outcome**

- *Inclusion* – all outcomes that address the diagnostic characteristics of TOE

### **Characteristics of the study design**

- *Inclusion* – studies that evaluate diagnostic characteristics of TOE against an appropriate comparator in a cross-sectional study in a consecutive group of patients
- *Exclusion* – cross-sectional studies that compare the diagnostic characteristics of TOE in two or more groups of patients, case series, case reports, narrative reviews, editorials, letters or foreign language studies

### **Characteristics of the publication (date, language, specific journals)**

- *Inclusion* – English-language articles

## Item 2 Clinical effectiveness

### **Subject characteristics**

- *Inclusion* – patients undergoing closed-heart, open-heart and other surgery including trauma, general, abdominal or thoracic surgery
- *Exclusion* – non-surgical patients

### **Characteristics of the intervention**

- *Inclusion* – intra-operative TOE to monitor cardiac function
- *Exclusion* – TOE used to monitor patients not undergoing surgery

**Characteristics of the outcome** *Inclusion* – patient management during surgery and health outcomes

**Characteristics of the study design** *Inclusion* – prospective or retrospective studies that compare patients receiving intra-operative TOE as an intervention with patients receiving either no intervention, or an alternative intervention, to monitor cardiac function during surgery.

In the absence of such studies for part of Item 2, case series were selected using the following *a priori* criteria:

- *Inclusion* – prospective or retrospective studies of 10 or more consecutive patients.

- *Exclusion* – case reports, narrative reviews, letters, other opinion pieces, diagnostic or reliability studies of TOE and studies in which the ascertainment of study subjects has not been described.

**Characteristics of the publication (date, language, specific journals)** *Inclusion* – English-language articles and foreign language article level III and higher.

- *Exclusion* – Level IV foreign language articles

## Search results

Articles that did not meet the selection criteria were excluded outright. Ambiguous or unclear citations were included in the next assessment stage for examination in full text. Three reviewers examined each citation for inclusion. Discrepancies in selection were discussed and resolved through consensus. A final decision to reject or accept articles was based on a thorough reading of the complete article. Only studies that successfully passed this process were included in this report.

### Item 1 Diagnostic characteristics

Of 86 articles on reporting diagnostic characteristics of TOE, 38 were rejected and the remaining 48 articles were assessed in full text. Of these, 10 met inclusion criteria and were eligible for critical appraisal (Appendix D). Appendix E cites articles that were excluded from further assessment and their reason for exclusion.

### Item 2 Change in clinical management

A total of 1,224 articles on the effectiveness of intra-operative TOE for clinical management were retrieved of which 1,066 were rejected and 158 were assessed in full text. Of these, 24 met inclusion criteria and are cited in Appendix D. No randomised controlled trials published in English or non-English were identified. Case series were included. Appendix E cites articles that were excluded after assessment in full text and the reason for exclusion.

## Assessment of validity

### Item 1 Diagnostic characteristics

The most rigorous study design for assessing the validity of diagnostic tests is considered to be a prospective blind comparison of the test and a reference, or 'gold,' standard in a consecutive series of patients from a relevant clinical population (Jaeschke et al 1994, Sackett et al 2000). The Cochrane Methods Working Group on Systematic Review of Screening and Diagnostic Tests (1996) expands on this definition and recommend the following criteria for assessment of validity of evidence pertaining to diagnostic tests:

- test being evaluated (study test) is compared with a reference standard (gold standard);
- study test and reference test are measured independently (blind) of each other;
- choice of patients who were assessed by the reference standard was made independently of the study test's results;

- study test was measured independently of all other clinical information;
- reference standard was measured before any interventions were started with knowledge of test results; and
- tests were compared in a valid study design ranked as most to least valid according to the following:
  - tests done independently on each person (most valid);
  - different tests done on randomly allocated individuals;
  - all tests done on each person but not assessed independently; and
  - different tests on different individuals, not randomly allocated (least valid).

All accepted articles underwent assessment of study validity based on criteria that focused on important aspects of study design for diagnostic studies (Jaeschke et al 1994, Cochrane Methods Working Group 1996, Sackett et al 2000).

Validity of the methodology of included articles was assessed against the following checklist (Table AV1):

Table AV1 Criteria and definitions for assessing validity of diagnostic studies.

Validity criterion	Definition
Test is compared with a reference standard (gold standard)	Patients in the study should have undergone both the diagnostic test in question and a reference test that would provide confirmatory proof that they do or do not have the target disorder.
Appropriate spectrum of consecutive patients	Study included patients that the test would normally be used on in clinical practice ie patients covering the spectrum of mild to severe cases of the target disorder, early and late cases, and patients with other, commonly confused, diagnoses. An inappropriate spectrum compares patients already known to have the disorder with a group of normal non-diseased patients (case-control) or with patients diagnosed with another condition.
Masked assessment of study and reference test results	The study test and the reference test should be interpreted separately by persons unaware of the results of the other (avoidance of review bias).
All study subjects tested with both study and reference tests	The reference test should be applied regardless of result from the study test (avoidance of work-up / verification bias).
Study test measured independently of clinical information	The person interpreting the test should be masked to clinical history and results of any other tests performed previously.
Reference test measured prior to any interventions	No treatment interventions initiated prior to the application of the reference or study test.

## Item 2 Clinical effectiveness

The evidence presented in the selected studies are assessed and classified using the dimensions of evidence defined by the NHMRC (2000).

These dimensions (Table AV2) consider important aspects of the evidence supporting a particular intervention and include three domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the

literature identified as informing a particular intervention. The last two require expert clinical input as part of its determination.

Table AV2 Evidence dimensions.

Type of evidence	Definition
Strength of the evidence	The study design used, as an indicator of the degree to which bias has been eliminated by design.* The methods used by investigators to minimise bias within a study design. The <i>p</i> -value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Level	
Quality	
Statistical precision	The <i>p</i> -value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the "null" value and the inclusion of only clinically important effects in the confidence interval
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

\*See Table AV3

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence. The designations of the levels of evidence are shown in Table AV3.

Table AV3 Designations of levels of evidence\*.

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

\*Modified from (NHMRC 2000)

All accepted articles were assessed for study validity (Table AV4) based on criteria that focus on important aspects of study design for intervention studies (Schulz et al 1995, Jadad et al 1996).

Table AV4 Criteria and definitions for assessing validity of intervention studies.

Validity criterion	Definition
<b>Randomisation</b>	
Adequate	Adequate measures to conceal allocations such as central randomisation and serially numbered, opaque, sealed envelopes or other descriptions that contain convincing elements of concealment
Unclear	Unclearly concealed trials in which the author failed to describe the method of concealment with enough detail to determine its validity
Inadequate	Method of allocation is not concealed, such as alternation methods or the use of case numbers
None	No randomisation method was employed
<b>Masking</b>	Masking strategy applied (triple, double, etc.)
<b>Losses to Follow-up</b>	Losses specified

Level II, randomised controlled trials have well-established instruments to assess validity and their subjectivity to bias (Table AV4), while level IV case series lack such instruments. Case series are inherently subject to bias and likely to overestimate the benefit of an intervention. However, in instances when higher-level evidence is unavailable, case series require consideration including critical appraisal to provide some objective assessment about their likely exposure to bias. Case series included for critical appraisal in this report were assessed against criteria that ascertain whether the authors were aware of methodological issues. We adopted criteria based on guidelines by the NHS Centre for Reviews and Dissemination (2001):

- was the study based on an appropriate sample selected from a suitable sampling population?
- are the criteria for inclusion in the sample stated?
- were outcomes assessed using objective criteria?
- were outcomes measured pre- and post-intervention so that a change in an outcome measure could be extracted from the paper?

Critical appraisal was undertaken by three reviewers with expertise in basic science, clinical research, epidemiology and biostatistics. Articles that presented difficulties in interpretation were discussed among reviewers and consensus reached.

## Expert advice

A supporting committee with expertise in trans-oesophageal echocardiography, cardiac surgery, cardiology and anaesthesia was established to evaluate the evidence and provide advice to MSAC from a clinical perspective. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is provided at Appendix B.

# Results of assessment

## Is it safe?

There are various potential risks for patients undergoing intra-operative TOE. Although comparative studies exist, most of the available data on adverse events are from case series or case reports. Reports in the literature of properly designed studies are lacking, suggesting that estimates of incidence are uncertain, although the nature of the event might be recognised.

Ten case reports described adverse events associated with intra-operative TOE, of which nine illustrated the use of TOE during cardiac surgery and one during a liver transplant. The narrative reviews were rich in clinical description and detail very similar probe-related adverse events (Table S1).

Table S1 Adverse events associated with intra-operative TOE – Case reports

Author	Age (yrs), Sex	Type of surgery	Type of adverse event	Outcome
Bensky et al 1995	5mo, F	Repair of ASD	Probe compression of right subclavian artery	Full recovery
Dewhirst et al 1990	77, F	AVR	Mallory-Weiss tear	Full recovery
DeVries et al 2000	74, M	CABG	Mallory-Weiss tear	Death
Gilbert et al 1992	5.5, M	Pulmonary arterioplasty	Bronchial obstruction	Monitoring abandoned
Latham & Hodgins 1995	65, M	AVR	Gastric laceration	Full recovery
Lunn et al 1992	5mo, F 22mo, F	Repair of VSD Repair of ASD and VSD	Aortic compression	Full recovery
Massey et al 2000	59, F	MVR	Oesophageal perforation	Death
Olenchock et al 2001	55, F	CABG and MVR	Splenic hilar laceration	Full recovery
St.Pierre et al 1998	50, M	CABG	Gastrointestinal haemorrhage	Full recovery
Suriani & Tzou 1995	66, M	Liver transplant	Bradycardia	Full recovery

ASD: atrial septal defect; AVR: aortic valve replacement; VSD: ventricular septal defect; MVR: mitral valve replacement; CABG: coronary artery bypass graft surgery

Fifteen case series reported adverse events associated with intra-operative TOE. Adverse events were either related to the probe itself or to the procedure. Probe-related complications included thermal or pressure injuries and compression of the aorta and trachea. Procedure-related adverse events involved the cardiovascular, pulmonary and upper gastrointestinal systems (Table S2).

The largest series by Daniel (1991) included 10,419 patients, however of these 9,240 were conscious inpatients or outpatients at the time of the TOE examination. It is not known whether the complications listed in Table S2 occurred in patients undergoing intra-operative TOE. The one reported death was from severe haematemesis due to a malignant lung tumour (mortality rate, 0.0098%).

Adverse events reported in these circumstances do not necessarily imply a preponderance of adverse event due to the intervention.

Table S2 Adverse events associated with intra-operative TOE – Case series.

Author	Study size	Types of adverse event	Number of events	Total number of events	Total Number of events (%)
Chee et al 1995	901	Buckling of probe Gastric mucosal contusion Cerebral vascular accident Jaw dislocation	2 1 1 1	5	0.55
Daniel et al 1991	10,419	Mortality (severe haematemesis due to malignant tumour) Bronchospasm Hypoxia Nonsustained ventricular tachycardia Transient atrial fibrillation Third-degree atrioventricular block Severe angina pectoris Minor pharyngeal bleeding Vomiting	1 6 2 3 3 1 1 1 5	23	0.22
Gentles et al 1994	46	Arterial desaturation Pulmonary vein narrowing	2 2	4	8.60
Hogue et al 1995	869	Swallowing dysfunction	34	34	3.90
Greene et al 1999	50	Vascular compression	2	2	4.00
Kallmeyer et al 2001	7200	Odynophagia Gastric haemorrhage Oesophageal perforation Dental injury Endotracheal tube malposition	7 2 1 2 2	14	0.19
Rafferty et al 1993	846	Chipped tooth Pharyngeal abrasions	1 3	4	0.47
Schmidlin et al 2001	1891	Arterial hypertension Coughing Tooth damage Arrhythmia Pharyngeal lesion Gastric mucosal lesion	48 3 2 1 1 1	56	2.96
Sheil & Baines 1999	200	Transient vascular compression Interference with ventilation Accidental extubation Pharyngeal bleeding Airway obstruction Inability to pass probe Marked vascular compression	4 4 1 1 6 4 1	21	10.50
Sloth et al 2001	532	Tracheal extubation Tracheal or bronchial compression Traces of blood on probe	1 1 9	11	2.06

Stevenson 1999	1650	Airway obstruction	14	52	3.15
		Failure to insert probe	13		
		Tracheal extubation	8		
		Vascular compression	10		
		Advancement of ETT	3		
		Lip laceration	1		
		Gastric incision	1		
		PVR obstruction	1		
		Intubation for sedation	1		
Stevenson 1995	667	Failure to insert probe	8	24	3.5
		Airway obstruction	6		
		Vascular compression	5		
		Tracheal extubation	1		
		Gastric incision	1		
Stumper et al 1990	240	Oesophageal bleeding	1	3	1.25
		Arrhythmia	2		
Suwanchinda et al 1995	113	Ruptured aortic dissection after probe insertion	1	1	0.8

Four comparative studies evaluated the incidence of post-operative side effects, gastro-oesophageal injury and patient complaints following TOE. Overall, the results suggested that TOE could be used without harmful post-operative effects and that inappropriate placement of the TOE probe was not entirely responsible for gastro-oesophageal injury. A description of the studies is given below.

#### **Kawahito et al 1999**

This non-randomised control trial examined the incidence of recurrent laryngeal nerve palsy in 64 patients assigned to TOE and in 52 patients not assigned to TOE during cardiovascular surgery. The authors also compared patient demographics, the duration of surgery, cardiopulmonary bypass and tracheal intubation in patients with and without nerve palsy. Five of the 64 patients (7.8%) in whom TOE was monitored and three of 52 patients (5.8%) in whom TOE was not monitored were diagnosed with laryngeal nerve palsy. There was no statistically significant difference between the two groups.

#### **Hulyalkar & Ayd 1993**

This non-randomised control trial examined the incidence of gastro-oesophageal bleeding or post-operative gastro-oesophageal symptoms of anorexia, dysphagia or sore throat in 41 patients assigned to TOE and in 40 patients not assigned to TOE during cardiac surgery. A retrospective chart review of 200 patients who underwent TOE was also performed. Data extracted from patient interviews and chart reviews included:

- the development of both frank and occult upper gastrointestinal bleeding;
- the patient's pre-operative anticoagulation status; and
- the patient's subjective complaints of symptoms of anorexia, dysphagia or sore throat.

The incidence of post-operative occult or frank gastrointestinal bleeding was not increased in the groups that underwent TOE. Additionally, the incidence of post-operative gastrointestinal symptoms was comparable amongst the groups (Table S3).

Table S3 Types of Incidence in Control, Prospective and Retrospective TOE Groups.

Type of incident	Control (%)	Prospective TOE Group (%)	Retrospective TOE Group (%)
Presence of Occult Blood	31/40 (78.0)	16/33 <sup>a</sup> (48.0)	94/173 <sup>b</sup> (54.0)
Subjective complaints	6/40 (15.0)	4/41 (10.0)	22/200 (11.0)
Frank GI bleeding	1/40 (2.5)	1/41 (2.4)	4/200 (5.5)

GI: Gastrointestinal; <sup>a</sup> Nasogastric aspirate not recorded in 8 patients; <sup>b</sup> Nasogastric aspirate not recorded in 27 patients;

#### Rousou et al 2000

This retrospective cohort evaluated the incidence of dysphagia and its relationship to TOE by examining the charts of 838 consecutive patients undergoing cardiac surgery. Patients were categorised into those who received TOE for specific indications versus those who did not receive TOE. Dysphagia was recorded when symptoms were confirmed by barium cineradiography. The overall incidence of dysphagia was 10 of 126 (7.9%) in TOE patients and 13 of 712 (1.8%) in non-TOE patients. Of these TOE patients with dysphagia, three patients had a stroke, three patients had prolonged intubation and four patients had no clear-cut risk factor for developing dysphagia. Similarly, in the non-TOE group, nine patients had strokes, three patients had prolonged intubation and one had no other identifiable risk factors for dysphagia.

#### Owall et al 1992

This randomised control trial evaluated the incidence of post-operative side effects and patient complaints following TOE. Fifty-seven patients were randomised to undergo surgery with or without intra-operative TOE. A second interview and examination were performed in 48 patients on the second post-operative day using a double blind protocol. With 24 patients in each group, there was no difference between controls and TOE patients with regard to painful swallowing, nausea, findings on pharyngeal inspection and time elapsed from extubation to the first oral intake (Table S4).

Table S4 Complaints on the second post-operative day.

Type of incident	Control Group (%)	TOE Group (%)
Post-operative nausea	2/24 (8.3)	2/24 (8.3)
Reddened pharynx	2/24 (8.3)	3/24 (12.5)
Minor injury to lip	3/24 (12.5)	5/24 (20.8)

## Conclusion

Reports of a number of serious adverse events indicate that the semi-invasive procedure is associated with a small but definite risk. The risk of death from intraoperative and non-intraoperative TOE is approximately one in 10,000. Expert opinion estimates the risk of oesophageal rupture to be approximately one in 20,000 in the outpatient setting. It is expected to be higher in the anaesthetised patient with expert opinion suggesting approximately one in 10,000. The controlled studies have not shown TOE to be

associated with a significant increase in cardiovascular, pulmonary and upper gastrointestinal injuries. Furthermore, it is important to recognise that the results have come from patients with unique characteristics, anatomic variations or pathologic features.

## Is it effective?

### Item 1 Diagnostic characteristics

Two factors are considered necessary to determine the effectiveness of a diagnostic test:

- accuracy of the test; and
- usefulness of the test in improving outcomes for affected individuals.

#### Accuracy of the tests

The accuracy of a diagnostic test is primarily determined by its ability to identify the target disorder compared to the recognised 'gold standard' test. Accuracy is measured by diagnostic characteristics such as sensitivity and specificity.

The diagnostic characteristics of each test were reviewed, subject to the availability of studies in which subjects are assessed with at least two of the diagnostic tests under investigation and the reporting of sufficient data. The minimum requirement for computing sensitivity is sufficient data to determine the proportion of subjects with the disorder whose tests were correctly identified as positive. The minimum requirement for computing specificity is sufficient data to determine the proportion of patients without the disorder whose tests were correctly identified as negative.

Diagnostic test results have been summarised in Table E1. Individuals who test positive for the disease in both the study test under investigation and the reference test are represented in cell 'a' and are called true positives (TP). Individuals without the disease who test negative in both tests (the 'd' cell) are called true negatives (TN).

A diagnostic test may produce discordance between the test result and the true disease status of the subject. When this occurs a false result is reported. These situations are illustrated by cells containing 'b' and 'c' in Table E1. For 'b', the test is positive in individuals without the disease. For 'c', the test is negative in diseased individuals. These two sets of false results are called false positives (FP) and false negatives (FN), respectively.

Table E1 The generic relationship between results of the diagnostic test and disease status.\*

Study Test Results	True Disease Status (Reference test)		
	Diseased	Not Diseased	Total
Positive	a	b	a+b
Negative	c	d	c+d
<b>Total</b>	<b>a+c</b>	<b>b+d</b>	<b>a+b+c+d</b>

\*Abbreviations: a=number of diseased individuals detected by the test; b=number of individuals without disease detected by the test; c=number of diseased individuals not detected by the test; d=number of individuals without disease not detected by the test; a+b=total number of individuals testing positive; c+d=total number of individuals testing negative; a+c=total number of diseased individuals; b+d=total number of individuals without disease; a+b+c+d=total number of individuals studied.

**Sensitivity** is the proportion of diseased individuals who test positive. It is a measure of the probability of correctly diagnosing a case, or the probability that any given case will be identified by the test. Referring to Table E1,

$$Sen = \frac{a}{a + c} = \frac{TP}{TP + FN}$$

**Specificity** is the proportion of individuals without disease who test negative. It is the probability of correctly identifying a non-diseased person with the study test.

$$Spe = \frac{d}{b + d} = \frac{TN}{TN + FP}$$

The complement of specificity is called the false positive rate (FPR).

$$FPR = 1 - Spe$$

Likelihood ratios (LR), which indicate by how much a given diagnostic test result will raise or lower the pre-test probability of the target disorder, were also computed if appropriate data could be extracted from individual articles. Likelihood ratios express the odds that a given level of a test result would be expected in a patient with the condition compared to one without the condition. The likelihood ratio for a positive test result is related to sensitivity and the false positive rate by:

$$LR+ = \frac{Sen}{FPR}$$

The likelihood ratio for a negative test result is calculated by:

$$LR- = \frac{1 - Sen}{Spe}$$

Note that large positive likelihood ratios of 10 or more, and small negative likelihood ratios of <0.1 indicate large changes in disease likelihood. If the likelihood ratio for a positive test result is below two and the likelihood ratio for a negative test result is above 0.5, then there is little or no likelihood that the presence of disease will be diagnosed as a result of the test.

### **Patient outcomes**

Detection of pathology is not a good indicator of the usefulness of the diagnostic test. Application of the test should enhance patient management options otherwise the test is of limited use. The ideal method for assessing patient outcomes after using the diagnostic test is a randomised controlled trial that compares outcomes of patients who have had the test to those who have not had the test. No trials of this type were identified.

## Findings

### Item 1 Diagnostic characteristics

Ten studies met inclusion criteria for critical appraisal. Descriptive characteristics of these studies are presented in Table E2. Studies examined the accuracy of TOE in detecting various cardiac disorders or haemodynamic states including thoracic aortic wall dissection (Nienaber et al 1992), endocarditis or associated phenomena (Shively et al 1991, Daniel & Mugge 1995), thrombi (Manning et al 1995, Vaduganathan et al 1992) and aortic plaques (Kim et al 1999). Singh et al (1998) examined the accuracy of TOE in detecting characteristics of lesions, rather than detecting lesions *per se*, and Muhiudeen et al (1991) detected changes in cardiac output. Different reference tests were used to verify TOE findings depending on disease. Visual inspection at surgery or autopsy was used for detecting aortic dissection, endocarditis, thrombi and lesions. Aortic plaques were detected by angiography and changes in cardiac output were detected by thermodilution.

Table E2 General characteristics of studies meeting entry criteria for Item 1.

Study	Setting, dates of enrolment	Spectrum of patients			Detecting	Selection criteria	Reference
		Sample size	Age in years± SD (range)	Patient No. male:female			
Daniel et al 1991	Germany, Jan 1984-May 1989	118	47.8±14.4 (17-74)	80:38	Abscesses associated with endocarditis	Acute infective endocarditis	Visual inspection at surgery or autopsy
Vaduganathan et al 1997	USA (1 centre) during 1995	31	64	Not stated	Aortic thrombi	Patients undergoing repair of aortic aneurysm or dissection	Pathologic findings
Manning et al 1995a	USA, Oct 1989-Aug 1995	231	64±13	103:128	Left atrial thrombi	Elective repair or replacement of mitral valve or excision of left atrial tumour	Visual inspection
Muhiudeen et al 1991	USA, dates not stated	35	34-77	Not stated	Cardiac output	Cardiac or vascular surgery	Thermodilution
Singh et al 1998	USA, Jan 1993-Dec 1994	16	7.9±5.7 (0.25-20)	11:5	Characteristics of lesions	Children with left ventricular outflow tract obstructive lesions as a result of prior surgery for congenital heart defects	Surgery
Kim et al 1999	Korea (1 centre) Jan 1996 – May 1998	131	54±10 (17-75)	73:58	Detection of aortic plaques	Open heart surgery	Angiography to detect CAD
Shively et al 1991	USA, Jan 1988-Oct 1989	62 (66 episodes)	53±?	54:8	Endocarditis	Clinically suspected endocarditis	Positive TOE: surgery/autopsy, negative TOE: clinical follow-up
Nienaber et al 1992	Germany, Mar 1988-Jul 1991	53	52±15 (20-76)	35:18	Thoracic aortic wall dissection and epi-phenomena <sup>a</sup>	Clinically suspected aortic dissection	Visual inspection at surgery or autopsy (n=31), contrast angiography (all)

<sup>a</sup> results for primary outcome only reported in this document; CAD: coronary artery disease.

## Validity

Critical appraisal of the nine included studies against the validity criteria is summarised in Table E3. Failure to meet validity criteria suggests non-appraisable bias within the results of the study (Lijmer et al 1999). No studies met all of the validity criteria. Only studies that examined consecutive series of patients were included, thus the majority of studies appeared to meet the criterion of including an appropriate consecutive spectrum of patients to be tested. However, it is unclear if Daniel et al (1991) selected patients already diagnosed with the target disorder under investigation, which brings into question the appropriateness of the spectrum of patients. Three studies explicitly stated the assessors of the study test were masked to the results of the reference test and vice-versa (Muhiudeen et al 1991, Manning et al 1995, Vaduganathan et al 1997). One study used different reference tests to verify positive and negative TOE results (Shively et al 1991).

Table E3 Validity of studies meeting entry criteria for Item 1.

Study	Appropriate spectrum of consecutive study subjects	Masked assessment of TOE and reference test results	All study subjects tested with both TOE and reference test	Reference test measured prior to any interventions	TOE measured independently of clinical information
Daniel et al 1991	Consecutive patients, but selected with same tests used to detect presence of abscess	Not stated	Yes	Not stated	Unclear
Vaduganathan et al 1997	Yes	Yes	Yes	Yes	No (as TOE requested)
Manning et al 1995	Yes	Yes	Yes	Yes	Yes
Muhiudeen et al 1991	Yes	Yes	Yes	Yes	Not stated
Singh et al 1998	Yes	Not adequately stated	Yes	Yes (pre bypass)	No
Kim et al 1999	Yes	Not stated (says angiography assessors were unaware of TOE result)	Yes	Yes	Not stated
Shively et al 1991	Yes, but four patients used twice	Not stated	Different reference to verify positive and negative TOE <sup>a</sup>	Not stated	Yes
Nienaber et al 1992	Yes	Not stated	Yes	Not stated	Yes

<sup>a</sup> Negative TOE results verified with clinical follow-up and further imaging studies (presumably for ethical reasons)

### Summary of findings

The diagnostic characteristics for intra-operative TOE extracted from the included studies are presented in Table E4. The diagnostic characteristics of TOE outside of the theatre setting, which were not examined, may differ from those presented in this evaluation. In addition, other diagnostic procedures that may be performed by the surgeon, such as epiaortic ultrasound to detect atheroma of the aortic arch, were not considered in this report.

Sensitivities of TOE from identified studies ranged from 54 to 100 per cent and specificity was between 82 and 100 per cent (Table E4). Specificities were generally high, indicating that a positive TOE result could rule in the diagnosis of the target disorder.

Positive likelihood ratios ranged from 0.81 to 18.5, with values greater than 10 indicating that patients with a positive TOE result are likely to have the target disorder. Negative likelihood ratios were between 0.00 and 0.51. These values are unlikely alter to the post-test likelihood of having the disorder. Thus a positive TOE test is highly likely to detect endocarditis, abscesses associated with endocarditis or left atrial thrombi. Note that the positive likelihood ratio of TOE in detection of aortic thrombi of 0.81 indicates that a positive TOE result is not indicative of the presence of this type of thrombus. This latter finding is unlikely to be of clinical significance as clinical opinion indicates epiaortic ultrasound, which places the probe directly on the aorta, is now used to detect aortic thrombi. The variability in results may reflect not only the varying diseases under

investigation but also the study design. Failure to meet validity criteria is likely to result in an overestimation of the test's accuracy (Lijmer et al 1999), therefore results should be interpreted with caution.

Table E4 Diagnostic characteristics of studies meeting entry criteria for Item 1.

Study	Reference test	Detecting	Sample size	Sensitivity (%)	Specificity (%)	LR+	LR-
<sup>a</sup> Daniel et al 1991	Surgery/autopsy	Abscesses associated with endocarditis	118	87	94.6	18.5	0.14
Vaduganathan et al 1997	Pathologic findings	Aortic Thrombi	31 (62 segments)	91	90	0.81	0.1
Manning et al 1995	Visual inspection	Left atrial thrombi	231	100 <sup>b</sup>	99 <sup>b</sup>	100	0
<sup>a</sup> Muhiudeen et al 1991	Thermodilution	Cardiac output	35	>15% increase 71 decrease 54	>15% increase 82 decrease 90	>15% increase 3.9 decrease 5.4	>15% increase 0.35 decrease 0.51
Singh et al 1998	Surgery	Characteristics of left ventricular outflow tract obstructive lesions	16	93.8 <sup>b</sup>	100 <sup>b</sup>	-	0.062
Kim et al 1999	Angiography	aortic plaques, CAD	131	93	82	5.17	0.09
Shively et al 1991	Surgery/autopsy, follow-up	Endocarditis	66 (62 patients)	94 <sup>c</sup>	98 <sup>c</sup>	47	0.06
<sup>a</sup> Nienaber et al 1992	Surgery/autopsy, angiography	Aortic dissection	53	100	68.2	3.1	-

<sup>a</sup>Unable to verify diagnostic characteristics independently (raw data not extractable); <sup>b</sup>Unclear if diagnostic characteristics calculated on results of all 70 patients not marked in table; <sup>c</sup>Based on diagnostic criteria of disease being present as 'probable or almost certain'; using 'almost certain' as diagnostic: sensitivity = 94%, specificity = 100%; CAD: coronary artery disease

## Item 2 Clinical Effectiveness

TOE was also evaluated for its therapeutic usefulness. The ideal study design to assess the clinical effectiveness of a therapeutic intervention is a randomised controlled trial. However, no such evidence was identified in the English or non-English language literature. As previously stated, low level evidence can be utilised but it is highly susceptible to bias and, therefore, effectiveness data from such studies must be considered with caution.

Two measures of clinical effectiveness were considered:

- change in clinical management; and
- patient outcomes

### Change in clinical management

Change in clinical management is taken as occurring when the use of intra-operative TOE results in an alteration to the agreed pre-operative surgical and medical plan. Changes in clinical management data were reported only in case series.

There were 22 identified and included studies, of which half were conducted in the United States and most were published in the latter half of the 1990s and the early 2000's. Studies were organised into three groups according to surgical indication – congenital heart disease and valve surgery (Table E5), other cardiac surgery (Table E6) and non-cardiac surgery (Table E7). Table E8 lists studies that included patients with mixed surgical indications. The majority of studies specified the type of TOE that was used (usually one), however some studies (Deutsch et al 1991, Stevenson et al 1993, Bezold et al 1996, Click et al 2000, Couture et al 2000, Durongpisitkul et al 2000, Ionescu et al 2001) used two or all three types of TOE. Participant ranged from infants to those over 60 years of age.

Table E5 General characteristics of studies meeting entry criteria for Item 2 – Change in clinical management for congenital heart disease and valve surgery.

Study	Location	Enrolment period	Type of TOE	Type of surgery or indication	Study population		
					Sample size	Males n (%)	Age years, mean± SD (range)
Bengur et al 1998	North Carolina, USA	July 1993-January 1998	Not stated	Congenital heart disease	493	Not stated	Not stated
Bezold et al 1996	Texas, USA	1990-1995	Single and biplane	Congenital heart disease	341	Not stated	4.0 (2d-49yr)
Durongpitsikul et al 2000	Bangkok, Thailand	January 1998-June 2000	Biplane and multiplane	Congenital heart disease	104	Not stated	(1wk-50yr)
Ionescu et al 2001	Cardiff, UK	1 June 1995-1 December 1997	Biplane or multiplane	Valve replacements with or without concomitant coronary artery bypass grafting	300	140 (47)	66.5±9.4
Loick et al 1997	Munster, Germany	Not stated	Not stated	Congenital heart disease	500	Not stated	(1d-17yr)
Muhiudeen & Silverman 1993	California, USA	Not stated	Biplane	Congenital heart disease	53	Not stated	(2d-17yr)
O'Leary et al 1995	Minnesota, USA	Not stated	Biplane	Congenital heart disease	104	61 (59)	(1-56yr)
Sheikh et al 1990	North Carolina, USA	October 1985-July 1988	Biplane	Cardiac valve surgery	154	74 (48)	Not stated
Sheil & Baines 1999	New South Wales, Australia	August 1997-1999	Biplane	Paediatric cardiac surgery for congenital heart disease	200	104 (52)	33.5±43.0 months (2d-16yr)
Singh et al 1998	Oregon, USA	January 1993-December 1994	Biplane	Left ventricle outflow tract lesions – Congenital heart disease	16	11 (69)	7.9±5.7 (3mo-20yr)
Siwik et al 1999	Ohio, USA	1995-1996	Not stated	Complex elective open heart surgery	62	Not stated	4.8±3.9
Stevenson et al 1993	Washington, USA	Not stated	Single plane and biplane	Paediatric surgery for relief of left ventricular outflow tract – congenital heart disease	27	Not stated	6.3 (0.5-17.9)

Table E6 General characteristics of studies meeting entry criteria for Item 2 – Change in clinical management for other cardiac surgery.

Study	Location	Enrolment period	Type of TOE	Type of surgery or indication	Study population		
					Sample size	Males n (%)	Age years, mean±SD (range)
Savage et al 1997	Ohio, USA	March 19-November 1995	Multiplane	Coronary artery bypass grafting	82	Not stated	68.4

Table E7 General characteristics of studies meeting entry criteria for Item 2 – Change in clinical management for non-cardiac surgery.

Study	Location	Enrolment period	Type of TOE	Type of surgery or indication	Study population		
					Sample size	Males n (%)	Age years, mean±SD (range)
Suriani et al 1998	New York, USA	July 1992-January 1996	Biplane	Non-cardiac surgery (abdominal, head/neck/chest wall, vascular and hepatic resection)	123	72 (59.)	64.9 ± 14.3 (15-91)

Table E8 General characteristics of studies meeting entry criteria for Item 2 – Change in clinical management for combined surgeries.

Study	Location	Enrolment period	Type of TOE	Type of surgery or indication	Study population		
					Sample size	Males n (%)	Age years, mean± SD (range)
Click et al 2000	Minnesota, USA	1993-1997	Single, biplane or multiplane	Cardiac surgery	3245	1947 (60)	62±15 (18-93)
Couture et al 2000	Quebec, Canada	October 1993-February 1997	Single plane or multiplane	Cardiac surgery	851	Not stated	Not stated
Deutsch et al 1991	New York, USA	September 1993-June 1995	Single plane and biplane	Cardiac surgery	100	Not stated	Not stated
Kolev et al 1998	Multicenter – Western European Countries	January 1995-December 1996	Biplane or multiplane	Elective non-cardiac or cardiac surgery	224	149 (67)	61±12 (34-79)
Michel-Cherqui et al 2000	Suresnes, France	December 1995-March 1996	Multiplane	Elective or emergency cardiac surgery	203	Not stated	Not stated
Poelaert et al 1995	Ghent, Belgium	January 1991-July 1991	Not stated	Critically ill patients in ICU	108	76 (70)	62 (8-83)
Sutton & Kluger 1998	Victoria, Australia	October 1993-August 1995	Not stated	Cardiac surgery	238	151 (63)	63 (23-84)
Wake et al 2001	Ontario, Canada	July 1997-June 2000	Multiplane	Elective or emergency open heart surgery	130	80 (62)	61 (22-83)

Results of the critical appraisal demonstrated that few studies met all the validity criteria stated above (see 'Assessment of validity'). Only three papers (Singh et al 1998, Michel-Cherqui et al 2000, Ionescu et al 2001) described the inclusion criteria for participants, specified the pre-surgical assessment and listed the actual changes in clinical management (Tables E9 to E12). All but two studies (Stevenson et al 1993, Bengur et al 1998), met at least one of the validity criteria and half of the studies explicitly defined the change in clinical management. Sixteen studies were prospective in design and six were retrospective.

Table E9 Validity of studies meeting entry criteria for Item 2 – Change in clinical management for congenital heart disease and valve surgery.

Study	Retrospective / prospective study design	Definition of changed surgical / medical management	Are the patient criteria for inclusion explicit?	Pre-surgical assessment specified	Changed surgical / medical management explicitly described
Bengur et al 1998	Prospective	Not stated	No	No	No
Bezold et al 1996	Retrospective	Not stated	No	No	Yes
Durongpisitkul et al 2000	Prospective	Significant impact = findings that revealed new information that altered the previously planned surgical procedure	Yes	No	Yes
Ionescu et al 2001	Prospective	Not stated	Yes	Yes	Yes
Loick et al 1997	Prospective	Additional surgery based on the findings of TOE	No	No	Yes
Muhiudeen & Silverman 1993	Prospective	Not defined	No	Yes	No
O'Leary et al 1995	Retrospective	Significant impact pre-bypass = disclosure of a previously unsuspected lesion that altered the planned surgical procedure or changed a pre-operative diagnosis in some way that altered the surgical procedure  Significant impact post-bypass = resulted in the immediate surgical revision of the initial repair.  Post-bypass TOE findings that did not need immediate revision were considered "significant residual abnormalities" if they altered medical management or resulted in more than a mild disturbance in cardiovascular function	No	No	Yes
Sheikh et al 1990	Prospective	Major = resulted in either new or additional unplanned surgery	No	No	Yes
Sheil & Baines 1999	Prospective	A major variance was one that would have affected or did affect the planned surgery	No	Yes	Yes
Singh et al 1998	Prospective	Major change = altered surgical plan	Yes	Yes	Yes
Siwik et al 1999	Retrospective	Not stated	Yes	No	Yes
Stevenson et al 1993	Prospective	Not stated	No	No	No

Table E10 Validity of studies meeting entry criteria for Item 2 – Change in clinical management for other cardiac surgery.

Study	Retrospective / prospective study design	Definition of changed surgical / medical management	Are the patient criteria for inclusion explicit?	Pre-surgical assessment specified	Changed surgical / medical management explicitly described
Savage et al 1997	Prospective	Major surgical = axillary or femoral cannulation, circulatory arrest, coronary artery operation without bypass, intra-aortic balloon pump, unplanned grafts, repair/replace grafts, emergent initiation of bypass, return to bypass, unplanned valve operation, mechanical support, left ventricular rupture and aortic dissection  Major anaesthetic/haemodynamic = perfusion pressure & transfusion, Ca <sup>2+</sup> channel blockers, slow heart rate, change of anaesthetic agents, inotropes, vasodilators, inodilators (global dysfunction treatment), treatment of global right ventricular dysfunction, haemodynamic management of valve disease	No	Yes	Yes

Table E11 Validity of studies meeting entry criteria for Item 2 – Change in clinical management for non-cardiac surgery.

Study	Retrospective / prospective study design	Definition of changed surgical / medical management	Are the patient criteria for inclusion explicit?	Pre-surgical assessment specified	Changed surgical / medical management explicitly described
Suriani et al 1998	Retrospective	Major impact on patient care was defined as: (1) treatment of a potentially life-threatening event; (2) altered surgical technique; (3) altered anaesthetic management; or (4) further evaluation in the post-operative period	Unclear	No	Unclear

Table E12 Validity of studies meeting entry criteria for Item 2 – Change in clinical management for combined surgeries.

Study	Retrospective / prospective study design	Definition of changed surgical / medical management	Are the patient criteria for inclusion explicit?	Pre-surgical assessment specified	Changed surgical / medical management explicitly described
Click et al 2000	Prospective	Not stated	No	Yes	Yes
Couture et al 2000	Prospective	TOE was considered to have altered surgical management if the cardiac surgeon stated that the surgical procedure would not have been performed without the TOE findings	No	No	Yes
Deutsch et al 1991	Prospective	Essential = information could not be provided by any other means; the therapeutic procedure was significantly influenced	No	No	Yes
Kolev et al 1998	Prospective	Driving force data=TOE was the major driver behind the intervention	Yes	No	Yes
Michel-Cherqui et al 2000	Prospective	Not stated	Yes	Yes	Yes
Poelaert et al 1995	Retrospective	Not stated	Yes	No	Yes
Sutton & Kluger 1998	Prospective	Essential = information provided by TOE led directly to an altered surgical procedure and could not be obtained from haemodynamic analysis or direct inspection of the heart by the surgeon  Valuable = Information provided by TOE led to an altered surgical procedure. Similar information may have been obtained by haemodynamic analysis or direct inspection of the heart by the surgeon but usually with a greater delay and less certainty	No	No	Yes
Wake et al 2001	Retrospective	Not stated	No	No	Yes

### Summary

Changes in clinical management data were reported for surgical and medical interventions and for type of surgery (Tables E13 to E16). Only six papers stated whether the medical or surgical changes were solely due to TOE (Deutsch et al 1991, Savage et al 1997, Bengur et al 1998, Kolev et al 1998, Sutton & Kluger 1998, Couture et al 2000).

Three papers reported changes in medical management. The lowest percentage of patients with alterations in their medical management was 0.8% (Suriani et al 1998) and the highest was 51.2% (Savage et al 1997).

Twenty two papers reported changes in the surgical management ranging from 1.7 to 32.9 per cent of patients. In papers that reported whether the changes made were solely due to TOE the percentage range was 2.0 to 32.9 per cent. For type of surgery, changes in surgical management were 1.7 to 37.5 per cent for congenital heart disease and valve

surgery, 32.9 per cent for other cardiac surgery and 8.1 per cent for non-cardiac surgery. The range for the combined surgeries was 2.0 to 29.9 per cent. In addition, there was no discernable difference in the percentage ranges for different age groups of patients.

Table E13 Change in clinical management reported in studies meeting entry criteria for Item 2 for congenital heart disease and valve surgery

Study	n	Change due to TOE monitor alone	Number of patients with changes in medical management (anaesthetic / haemodynamic)		Number of patients with changes in surgical management			
			Sample size	% changes in medical management	Pre-bypass n	Post-bypass n	Un-specified n	% changes in surgical management
Bengur et al 1998	493	Yes	-	-	-	34	-	6.9
Bezold et al 1996	341	Not stated	-	-	32	-	17	14.4
Durongpisitkul et al 2000	104	Not stated	-	-	7	15	-	21.2
Ionescu et al 2001	300	Not stated	-	-	3	2	-	1.7
Loick et al 1997	500	Not stated	-	-	-	-	27	5.4
Muhiudeen & Silverman 1993	53	Not stated	-	-	0	4	-	7.5
O'Leary et al 1995	104	Not stated	-	-	11	9	-	19.2
Sheikh et al 1990	154	Not stated	-	-	-	-	14	9.1
Sheil et al 1999	200	Not stated	-	-	1	6	-	3.5
Singh et al 1998	16	Not stated	-	-	3	0	3	37.5
Siwik et al 1999	62	Not stated	-	-	-	-	2	3.2
Stevenson et al 1993	27	Not stated	-	-	-	8	-	29.6

Table E14 Change in clinical management reported in studies meeting entry criteria for Item 2 for other cardiac surgery.

Study	n	Change due to TOE monitor alone	Number of patients with changes in medical management (anaesthetic / haemodynamic)		Number of patients with changes in surgical management			
			Sample size	% changes in medical management	Pre-bypass n	Post-bypass n	Un-specified n	% changes in surgical management
Savage et al 1997	82	Yes	42	51.2	-	-	27	32.9

Table E15 Change in clinical management reported in studies meeting entry criteria for Item 2 for non-cardiac surgery.

Study	n	Change due to TOE monitor alone	Number of patients with changes in medical management (anaesthetic / haemodynamic)		Number of patients with changes in surgical management			
			Sample size	% changes in medical management	Pre-bypass n	Post-bypass n	Un-specified n	% changes in surgical management
Suriani et al 1998	123	Not stated	1	0.8	-	-	10	8.1

Table E16 Change in clinical management reported in studies meeting entry criteria for Item 2 for combined surgeries.

Study	n	Change due to TOE monitor alone	Number of patients with changes in medical management (anaesthetic / haemodynamic)		Number of patients with changes in surgical management			
			Sample size	% changes in medical management	Pre-bypass n	Post-bypass n	Un-specified n	% changes in surgical management
Click et al 2000	3245	Not stated	-	-	441	121	-	17.3
Couture et al 2000	851	Yes	67	7.9	-	-	38	4.5
Deutsch et al 1991	100	Yes	-	-	-	2	-	2.0
Kolev et al 1998	224	Yes	-	-	-	-	67	29.9
Michel-Cherqui et al 2000	203	Not stated	-	-	-	-	22	10.8
Poelaert et al 1995	108	Not stated	10	9.3	-	-	26	24.1
Sutton & Kluger 1998	238	Yes	-	-	4	3	4	4.6
Wake et al 2001	130	Not stated	56	43.1	-	-	20	15.4

## Patient outcomes

A monitor that informs the surgeon and results in a change to the preoperative plan is not necessarily defined as effective. A corresponding improvement in patient outcomes must also follow. In the absence of randomised controlled trials, three lower level comparative studies were identified that examined outcomes in patients who received intra-operative TOE with those who did not (Hulyalkar & Ayd 1993, Rousou et al 2000, Savage et al 1997).

Table E17 summarises the general characteristics of these studies. All were conducted in the United States and were published within the last decade. All patients in the trials underwent cardiac surgery. The type of cardiac surgery was not defined in Hulyalkar & Ayd (1993), while all patients reported in Savage et al (1997) underwent CABG.

Coronary artery bypass surgery and valve surgery and other unspecified surgeries were reported in Rousou et al (2000). Hulyalkar & Ayd (1993) did not report the ages of participants. Those in the other two studies were over sixty years of age.

Table E17 General characteristics of studies meeting entry criteria for Item 2 – Patient outcomes.

Study	Location	Enrolment period	Type of surgery	Control group			TOE group		
				Sample size	Males n (%)	Age years, mean± SD	Sample size	Males n (%)	Age years, mean± SD
Hulyalkar & Ayd 1993	Maryland, USA	August 1990- November 1990	Cardiac surgery	40	Not stated	Not stated	41	Not stated	Not stated
Rousou et al 2000	Massachusetts, USA	Not stated	Coronary artery bypass, valve replacement or combined/other operations.	712	79 (63)	66.9±12	126	482 (68)	66.9±0.4
Savage et al 1997	Ohio, USA	March 1995- November 1995	Coronary artery bypass grafting	478	Not stated	64.8	82	Not stated	68.4

Critical appraisal of these studies revealed that they were of overall low quality and failed to meet the validity criteria set out in Table AV4. The participants were not randomised and authors did not state whether blinding had taken place or whether any losses to follow up had occurred (Table E18). Each study had a control group, however one had as its comparator a historical control group (Savage et al 1997) making it lower level as defined by evidence hierarchy (NHMRC 2000). Overall, study participants were comparable at baseline except that participants in the study of Rousou et al (2000) were similar for age and sex but not type of surgery. Different types of TOE were used between studies but they were consistent within studies, although Rousou et al (2000) did not specify the type of TOE. Patient selection criteria were specified by Savage et al (1997) but not by Rousou et al (2000) and Hulyalkar & Ayd (1993).

Table E18 Validity of studies meeting entry criteria for Item 2.

Study	Study Design	Randomisation	Blinding	Losses to Follow up	Type of TOE	Are the groups comparable at baseline?	Patient selection criteria
Hulyalkar & Ayd 1993	Comparative study III-2	No	Not stated	Not stated	Single plane TOE	Yes the groups were matched for age, race & sex	Retrospective study group participants chosen at random from the first 300 patients undergoing TOE at Johns Hopkins from 1986 to 1989.
Rousou et al 2000	Comparative study III-2	No	Not stated	N/A	Not stated	For age and gender but not type of surgery	Not stated
Savage et al 1997	Comparative with historical control III-3	No	Not stated	Not stated	Multiplane TOE	Yes	Both groups were 'high risk' patients with a preoperative severity score using the Severity Score model of $\geq 4$ , who were at higher risk of complications after CABG.

Overall and cause-specific mortality were reported for each study. However, for all parameters except operative mortality (Rousou et al 2000), none of the differences was statistically significant (Table E19). Operative mortality was higher in patients who had an intra-operative TOE than in patients who did not ( $p=0.002$ ) and TOE patients were more likely to die than control patients ( $OR=2.91$ , 95% CI 1.48-5.77). However due to study design, there was a higher percentage of non-cardiopulmonary bypass patients in the TOE group than in the control group (60.3% in the TOE group compared with 20.7% in the control group,  $p<0.001$ ). Patients undergoing TOE had longer intubation times ( $p<0.050$ ), cardiopulmonary bypass times ( $p<0.001$ ) and operating times ( $p>0.005$ ) which may indicate that these patients were more ill at baseline and that the increased mortality was influenced by patient characteristics rather than an adverse consequence of TOE monitoring. However, as the study did not adjust for these potential confounders, the relative contributions to mortality of TOE and the differences in patient groups cannot be determined.

Various outcomes of morbidity were also reported. The differences between the TOE and control groups in the incidence of myocardial infarction (Savage et al 1997) and stroke (Rousou et al 2000) were not statistically significant. Cardiac morbidity and central nervous system morbidity in the intensive care unit and hospital did not differ between TOE and control patients (Savage et al 1997). Abnormal left ventricular ejection function measured by Rousou et al (2000) was lower in patients who had TOE than in patients who did not ( $p=0.005$ ). TOE patients were less likely to have abnormal left ventricular ejection function than control patients ( $OR=0.39$ , 95% CI 0.20-0.76).

Table E19 Patient outcomes in studies meeting entry criteria for Item 2.

Study	Outcome	Control group sample size	Event rate in control group	TOE group sample size	Event rate in TOE group	P values	Odds ratios (95% Confidence intervals)
Hulyalkar & Ayd 1993	Death – peri-operative myocardial infarction	40	2	41	1	0.542	OR=0.48 (0.00,3.81)
	Death – multisystem organ failure		1		1	0.986	OR=0.98 (0, undefined)
Rousou et al 2000	Stroke	712	37	126	10	0.218	OR=1.57 (0.77,3.21)
	Operative mortality		27		13	0.002	OR=2.91 (1.48,5.77)
	Abnormal left ventricular ejection function		128		10	0.005	OR=0.39 (0.20,0.76)
Savage et al 1997	Hospital Deaths	478	18	82	1	0.239	OR=0.32 (0.00,1.89)
	Myocardial Infarction		14		1	0.376	OR=0.57 (0.00,3.44)
	Cardiac morbidity		7		1	0.863	OR=0.83 (0.00,5.27)
	Intensive care unit central nervous system morbidity		18		3	0.962	OR=0.97 (0.30,3.16)
	Hospital central nervous system morbidity		16		1	0.299	OR=0.04 (0.00,0.21)

### Other surgical indications

Discussion of the effectiveness of TOE to monitor cardiac function resulting in intra-operative changes to pre-operative surgical and medical plans has been limited to congenital heart disease, valve surgery and CABG. Other included studies reported on TOE in groups of patients undergoing unspecified cardiac or other surgery. This suggests the evidence base is largely limited to those specific surgeries. However, other surgical indications were identified by the expert committee in which intra-operative TOE may be useful as a monitoring device. These indications are presented in Table E20.

In addition, intra-operative TOE is often used to monitor wall motion and myocardial ischaemia. For each of these surgical indications and wall motion, the literature search failed to identify studies that met inclusion criteria. However, other evidence from case reports of the effectiveness of TOE during surgery was identified. The descriptive nature of such evidence precluded extraction and quantification of data on the effect of intra-operative TOE on pre-surgical and medical plans or patient. These case studies were not further evaluated. They are cited in Appendix F.

Table E20 Other surgical indications in which intra-operative TOE may be useful but for which no studies meeting inclusion criteria were identified.

<b>Cardiac Surgery</b>	<b>No. case reports identified</b>
Atrial septal defect closure	9
Hypertrophic obstructive cardiomyopathy	3
Left atrial myxoma	1
Ischaemic ventricular septal defect	3
Left ventricular aneurysm	3
Bacterial endocarditis	5
Aortic aneurysm/dissection	25
<b>Non-cardiac Surgery</b>	<b>No. case reports identified</b>
Abdominal aortic aneurysm	1
Carotid artery surgery	0
Trauma	6
Wall motion/ischaemia	37

### Summary

Due to the poor overall quality of included studies, it was not possible to determine the effect of intra-operative TOE as an adjunct on modifying patient management from plans agreed pre-surgery. Consideration of randomisation, blinding, validity and poor reporting quality has provided empirical evidence of bias in study reports (Schultz et al 1995, Khan et al 1996, Smith et al 2000) which suggests overestimation of effect sizes. The use of TOE to monitor cardiac function appears to result in intra-operative changes to the pre-operative surgical and medical plans of patients. The increase in mortality and decrease in abnormal left ventricular function in patients who underwent TOE were statistically significant, but likely confounded by patient characteristics and therefore cannot be attributed solely to the use of TOE. The failure of the studies to meet important validity criteria, the lack of randomisation and blinding and the general poor quality of reporting suggest that any estimates of effect of TOE should be considered with caution.

## What are the economic considerations?

### General framework:

The framework for the economic evaluation of any medical technology considered by MSAC is the comparison of the costs and benefits of that technology with the current alternative treatment for patients. The approach taken is to calculate an incremental cost effectiveness ratio  $(C_i - C_c) / (O_i - O_c)$  where  $C_i$  is the total cost of resources used associated with the intervention,  $C_c$  is the total cost of resources used by the comparator,  $O_i$  is the outcome associated with the intervention, and  $O_c$  is the outcome associated with the comparator. The broad perspective is societal and includes costs borne by governments and individuals.

Where there are two comparators or patient groups, a weighted average of cost and outcome can be calculated where the weights are the proportion of patients who are likely to receive each of the comparator treatments.

This proposal refers to the assessment of cost effectiveness of TOE, as performed by anaesthetists during surgery.

### Economic evaluation:

A literature review of the published economic evidence was conducted using Medline (1966 to March 2002) and economics databases such as HEED and Embase. Results are summarised in Table CE1.

Table CE1 Literature on economic costs.

Publication	Assumptions	Costs	Outcomes	Results
Benson & Cahalan 1995	TOE during and after cardiac surgery	Equipment, personnel, administration and complications (for breakdown see Table 1)	<b>Congenital heart disease:</b> surgical course (revision of repair); <b>Valvular heart disease:</b> unsatisfactory repairs leading to further surgery. Repair and replacement separate. <b>Coronary artery disease:</b> reduced morbidity from mitral regurgitation, revision of grafts preventing infarction. Stroke prevention	<b>Congenital heart disease:</b> overall benefit US\$600 per case. <b>Valvular heart repair:</b> benefit \$450 per case. <b>Valve replacement</b> overall cost \$150 per case. <b>Coronary artery disease:</b> \$100-\$300 benefit
Kinch & Davidoff 1995	TOE and cardioversion	US\$223-\$1,000		
McNamara et al 1997	TOE and management of stroke	Public hospital costs, US\$360 (range \$180-\$720)		
Murphy 1997	TOE during cardiac surgery	US\$150,000 for equipment, US\$50,000 per year maintenance	Reduced need for repeat procedures	<b>Congenital heart disease:</b> US\$5,000-\$45,000 saving per patient. <b>Valve pathology:</b> \$12,500-\$44,000 saving per patient
Rosen et al 1999	TOE to determine the duration of therapy for intravascular catheter associated <i>Staphylococcus aureus</i> bacteremia	Fees US\$ 507 (\$254-\$1,014)		
Seto et al 1997	TOE and cardioversion	TOE US\$432. Complications: Oesophageal perforation, US\$1,602. Death due to perforation, US\$5,980		
Seto et al 1999	TOE and cardioversion	TOE US\$635. Complications: Oesophageal perforation, US\$2,008. Death due to perforation, US\$7,496		
Siwik et al 1999	TOE during heart surgery, retrospective case control study, 63 children, complex and simple repairs	Labour, materials, overheads, equipment, physician	Altering of surgical strategy, complications	Surgical therapy altered in 3 % of patients. Complications rare. Complex group cost: TOE US\$376, control cost \$343. Simple group cost: TOE \$377, control \$219
Stevenson 1995	TOE in pediatrics – 400 cases for costs, 667 cases in total	Total savings \$158,777	Complications, return to bypass	Complications 3.5%; return to bypass 6.6%, cost saving US\$397 per case
Ungerleider et al 1995	Intra-operative TOE, 1,000 cases – 71 per cent < 3 years	Difference between patients requiring re-operation and revision during procedure	Complications, change in surgery	4 per cent change in intraoperative repair; cost for reoperation US\$94,180, cost for

				revision during procedure \$21,416
Warner & Momah, 1996	TOE and stroke	US\$1,510		

Five studies estimated the costs and benefits of TOE during surgery, and six estimated the costs of TOE for other purposes, for example diagnostic procedures. Benson & Cahalan (1995) estimated the costs and outcomes associated with TOE during and after cardiac surgery. They assessed outcomes in terms of money and lives saved. The direct costs estimated are shown in Table CE2.

Table CE2 Direct Medical Costs for TOE as routine diagnostic tool for cardiac surgery.

	Item	Unit cost (US\$)
<b>Equipment</b>	Ultrasound machine	85,000-150,000
	TOE probe	30,000-45,000
	Maintenance agreement	45,000-68,000
	Total interest – 5%	16,000-22,000
	Total interest – 10%	32,000-43,000
	Acoustic gel	3/bottle
	Mouth guard	2 each
	Cleaning	13/2 weeks
<b>Personnel</b>	Anaesthesiologist training	50,000
	Echocardiographer	250,000/year
	Anaesthesia technician	40,000/year
<b>Administrative</b>	SVHS Video tape	10
	Paperwork, storage	3/patient

Although the circumstances described may have been superseded by current practice, Benson and Cahalan (1995) stated that neither anaesthesiologists nor echocardiographers alone were able to run properly an intra-operative TOE service. Anaesthesiologists would face diagnostic dilemmas, and echocardiographers could not be present throughout surgery. They noted that the single most difficult task was the training of physicians. Anaesthesiologists were presumed to be trained to an intermediate level, practising in close collaboration with experts in TOE. A full time echocardiographer is assumed. Bryden and Hall (1997) also recognise training and practical experience as essential.

Benson and Calahan (1995) measured outcomes in terms of the alteration of surgical course and the consequent avoidance of costs of increased morbidity. They demonstrated that patients with congenital heart disease derive the greatest overall benefit of about US\$600 per case if 500 cases are performed each year. Patients having valvular repair surgery derived the next greatest benefit of about US\$450 per case studied if 500 cases are performed, while patients having valve replacement had an overall cost of US\$150 per case. Depending on the effect of TOE in preventing intraoperative strokes, patients having surgery for coronary artery disease may derive an overall benefit of between US\$100 and US\$300 per case.

Murphy (1997) looked at valve and congenital surgery and noted that although intra-operative TOE had been shown to alter surgical management, there had been arguments against its routine use due to a lack of evidence of its cost effectiveness. Murphy (1997) described TOE as expensive with the cost of an ultrasound machine and probe at about US\$150,000. However, if complicated repeat cardiac operations for valve pathology and evaluation of surgical repair cost between US\$30,000 and US\$70,000, and taking into account the US\$150,000 start up and US\$50,000 maintenance costs for TOE equipment, the estimated savings for 16 patients whose management was changed over a 32-month period would be US\$12,500 to US\$44,000 per patient. With the same TOE costs and costs of surgery avoided for congenital heart disease and evaluation of corrective repair of between US\$180,000 and US\$420,000, the estimated savings for six patients would be US\$5,000 to US\$45,000 per patient. With a longer time scale and more patients, cost savings would be greater.

### **Congenital surgery**

Looking only at congenital surgery, Stevenson (1995) estimated minimum cost savings at US\$158,777 for 400 cases of open heart repair, while acknowledging that indicators for return to bypass and economic factors can influence cost effectiveness in other centres. Cases were matched for age, size and difficulty with a cohort that underwent successful repair of the problem at hand. The average cost saving per case was US\$397. The author stated that to realise fully the impact of TOE on detecting significant post-bypass problems it would need to be performed routinely.

Siwik (1999) reported on a retrospective case control study and estimated the cost of routine TOE in congenital heart surgery in 63 children undergoing simple and complex repairs. Costs included labour, materials, overheads, physicians and equipment. For the complex group, costs were estimated at US\$376 for the TOE arm and US\$343 for the control arm with no significant difference. For the simple group, costs for the TOE arm were US\$377 compared with US\$219 for the control arm ( $p = 0.03$ ). It is noted that surgical therapy was altered in three per cent of cases and complications were rare. Given the alteration in surgical course, there may be cost savings overall.

Ungerleider et al (1995) looked at the costs of intra-operative echocardiography in 1,000 congenital cases, 70 per cent of whom were less than three years of age. Although TOE was favoured, in many instances both TOE and epicardial examination were performed. The average cost of patients returning to the operating room during hospitalisation for revision of a repair was US\$94,180 ( $\pm 33,882$ ), compared with costs of US\$21,416 ( $\pm 8,216$ ) for patients whose repairs were revised before they left the operating room. Four per cent of patients underwent revision based on echocardiograph findings. There were no significant complications attributable to echocardiography.

### **Other indications**

Uses of TOE in non-intra-operative cardiac surgery including the use of TOE in cardioversion have been costed at US\$223 to US\$1,000 (Kinch & Davidoff 1995), at US\$432 (Seto et al 1997, who also noted complication costs of US\$1,602 for oesophageal perforation and US\$5,980 for death due to perforation), and at US\$635 (Seto 1999 who also noted complication costs of US\$2,008 for oesophageal perforation and US\$7,496 for death due to perforation). Costs of the use of TOE in clinical management of stroke at a public hospital are estimated at US\$360 with a range of US\$180-US\$720 (McNamara et al 1997), and US\$1,510 (Warner 1996). For use of TOE in intravascular catheter-

associated *Staphylococcus aureus* bacteraemia, fee costs are estimated at US\$507 with a range of US\$254-US\$1014 (Rosen et al 1999).

### Cost per case for Australia

The submission itself does not suggest any specific costs for TOE although it refers to Benson & Cahalan (1995). Estimation of Australian costs for intra-operative cardiac procedures only based on Benson & Cahalan (1995) gave the values listed in Table CE3.

Table CE3 Hospital costs for TOE, based cases per annum in one unit.

Item	Year one costs (A\$)	Year two costs (A\$)
Ultrasound machine	\$170,000	
TOE probes (2)	\$120,000	\$120,000
Maintenance	\$90,000	\$90,000
<b>Total for equipment</b>	<b>\$380,000</b>	<b>\$210,000</b>
Anaesthetist training	\$50,000	
Echocardiography	\$125,000	\$125,000
Other costs	\$10,000	\$10,000
<b>Total</b>	<b>\$565,000</b>	<b>\$345,000</b>
500 congenital cases	\$1,130 per case	\$690 per case
100 valve cases	\$5,650 per case	\$3,450 per case
<b>600 total cases</b>	<b>\$942 per case</b>	<b>\$575 per case</b>

<sup>a</sup>At exchange rate A\$1=US\$0.5

If a given unit treats 500 patients with TOE per annum, costs per case for the first year for congenital surgery would be A\$1,130. Assuming that the ultrasound machine was paid for in one year, which may not be the case, we estimated that the corresponding costs would be A\$690 in subsequent years. Five hundred cases is a realistic assumption for congenital heart surgery, but 100 per annum per unit may be a more realistic figure for valve surgery. If only valve surgery was undertaken, costs would be A\$5,650 per case in the first year and A\$3,450 per case in subsequent years assuming all costs of the ultrasound machine were met in the first year. For a more realistic combined output of 600 cases for both modes of surgery, costs per case would be A\$942 in the first year and A\$575 in subsequent years.

The non intra-operative literature suggests a mean cost per case of TOE of A\$1,018 which may not translate to intra-operative cardiac procedures.

### Key areas of economic uncertainty

- TOE may be used in between 4,000 and 20,000 cases.
- It is unclear from the literature what rate of surgical revision will result from TOE.
- Cost savings from these revisions in the Australian setting are unclear.
- Cost per case is sensitive to the number of cases undertaken in a given unit.

- Although complication rates are low, potential costs of complications may be high if they led to death.

### Likely number of patients per year

The benefits schedule listed TOE as being used more than 4,000 times in 2001. Expert opinion of the supporting committee suggests that this could increase to 20,000 given the increasing number of cardiac cases.

### Financial cost

Societal costs for intra-operative TOE will depend on the number of cases undertaken. We estimated that costs could range from A\$2.3 million currently to a potential A\$11.5 million, based on cost per case for years following the initial purchase of the ultrasound machine. It should be noted that set up and training costs in the first year may be about \$220,000 per unit.

Table CE4 presents a sensitive analysis of TOE.

Table CE4 Total costs of TOE, sensitivity analysis (A\$).

Year one		Year two	
No of congenital only	Costs (A\$)	No of congenital only	Costs (A\$)
1	1,130	1	690
4,000	4,520,000	4,000	2,760,000
6,000	6,780,000	6,000	4,140,000
8,000	9,040,000	8,000	5,520,000
12,000	13,560,000	12,000	8,280,000
15,000	16,950,000	15,000	10,350,000
20,000	22,600,000	20,000	13,800,000
No of congenital and valve		No of congenital and valve	
1	942	1	575
4,000	3,767,000	4,000	2,300,000
6,000	5,650,000	6,000	3,450,000
8,000	7,534,000	8,000	4,600,000
12,000	11,304,000	12,000	6,900,000
15,000	14,125,000	15,000	8,625,000
20,000	18,830,000	20,000	11,500,000

Table CE4 shows the costs for year one assuming that a single unit treats congenital cases alone (A\$1,130 per case) or congenital and valve cases (A\$942 per case), and costs for years two and beyond as either A\$690 or A\$575 per case respectively. Total procedural costs of TOE are given for 4,000 to 20,000 cases.

If the rate of revision of surgery is estimated to be five per cent, there will be an estimated 200 revisions for 4,000 cases and 1,000 revisions for 20,000 cases.

If each revision led to cost savings of more than A\$11,500 by avoidance of re-operation, ie costs of at least A\$11,500 on average are avoided by not having to re-operate, (if the minimum cost per case is assumed to be A\$575 for congenital and valve cases in the years following set up), or A\$13,800 of costs avoided per revision, (if cost per case is a maximum of A\$690 for congenital cases alone in the years following set up), then there would be cost savings overall, as cost savings would be greater than procedural costs. This is simply calculated by dividing the potential total costs for the procedure by the potential number of reoperations (eg \$2,300,000 divided by 200 = \$11,500 or \$2,760,000 divided by 200 = \$13,800). So if each revision would have cost more than this, on average, there would be cost savings for the procedure overall.

### Summary

Cost per case of TOE is estimated here at between A\$575 and A\$690 in the years following initial purchase of the ultrasound machine. These estimates are similar to those of Siwik et al (1999) of about A\$750. The literature estimates potential cost savings as high, with the cost of a repeat operation potentially running into tens of thousands of dollars more than the cost of repair at the time of initial surgery. No Australian data are available, but US data generally suggest savings with a rate of alteration of surgery of between 3 and 6.6 per cent, especially for complex surgery. These revision rates may be specific to medical practice in the US system rather than the natural course of the disease and thus are likely to be context specific.

While total costs could range from A\$2.3 to A\$11.5 million in the years following set up depending on the numbers of cases, the use of TOE could lead to between 200 revisions for 4,000 cases treated and 1,000 revisions for 20,000 cases, assuming a revision rate of five per cent.

If these led to cost savings of more than A\$11,500 per revision, ie costs of at least A\$11,500 on average are avoided by not having to re-operate, (if the minimum cost per case is assumed to be A\$575 for congenital and valve cases in the years following set up), or A\$13,800 of costs avoided per revision, (if cost per case is a maximum of A\$690 for congenital cases alone in the years following set up), then there would be cost savings overall, as cost savings would be greater than procedural costs. Given the complexity of surgery involved, these may not be unreasonable assumptions. However, current data, such as the the context specific available estimates of surgery revision rates, do not provide a guide for the Australian health care system, figures in this economic evaluation are uncertain. Thus, a trial of intra-operative TOE with an associated economic evaluation under Australian conditions or in a comparable health care system is desirable.

# Conclusions

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## Safety

There are various potential risks for patients undergoing intra-operative TOE. The semi-invasive procedure has a small but definite risk. Most of the available data on adverse events are derived from case series or case reports, suggesting that estimates of incidence are uncertain even though the nature of the event might be recognised. In addition, four controlled trials were identified that evaluated the incidence of post-operative side effects, gastro-oesophageal injury and patient complaints following TOE. Data from 10 case reports and 15 case series described adverse events related either to the probe itself or to the procedure.

Probe-related complications included thermal or pressure injuries and compression of the aorta and trachea. Procedure-related adverse events involved the cardiovascular, pulmonary and upper gastrointestinal system. Data from four controlled studies showed that patients undergoing TOE had no significant increase in cardiovascular, pulmonary and upper gastrointestinal injuries when compared with patients who did not undergo TOE, suggesting that TOE could be used without harmful post-operative effects and that inappropriate placement of the probe was not entirely responsible for gastro-oesophageal injury. The incidence of gastro-oesophageal injury was estimated at approximately one in 10,000 for anaesthetised patients.

## Effectiveness

### Item 1 Diagnostic characteristics

A systematic literature search was performed to identify the effectiveness of TOE as a diagnostic test. Cross-sectional studies evaluating the accuracy of TOE compared to an appropriate reference in a consecutive group of patients were included. Reports in the literature assessed the accuracy of TOE in detecting various disorders including thoracic aortic wall dissection, endocarditis and associated phenomena, thrombi and aortic plaques.

Sensitivities and specificities of TOE varied with indication. High positive likelihood ratios were found in the detection of endocarditis, abscesses associated with endocarditis, coronary artery stenosis or left atrial thrombi. There was a high post-test likelihood of having these disorders if a positive TOE result was found, indicating that TOE may be a useful test for detecting them.

Although not specifically assessed in this evaluation, TOE used in an outpatient setting is also considered to have a high diagnostic accuracy in detecting congenital heart disease and acquired cardiac valve disorders. The variability in results may reflect not only the varying diseases under investigation but also the study designs. Included studies were all flawed in some aspect of their design and as a result may have overestimated the accuracy of TOE. Results should therefore be interpreted with caution.

## **Item 2 Clinical effectiveness**

A systematic literature search was also performed to identify the effectiveness of intra-operative TOE as a monitoring intervention on clinical management and patient outcomes. The ideal study design to assess the effectiveness of this intervention is a randomised controlled trial comparing the outcomes of patients assigned to undergo intra-operative TOE against those not receiving TOE. No such trials were identified in the literature search. Overall, evidence came from studies that were inappropriately designed to assess the benefit of intra-operative TOE on patient outcomes.

Evidence for the effectiveness of intra-operative TOE on clinical management during surgery came from case series which suggested that it may result in an alteration to the pre-surgical and medical plan.

Comparative studies provided evidence for the outcomes of patients undergoing intra-operative TOE against patients who did not have the intervention. Reported outcomes included mortality and various measures of cardiac morbidity. Evidence from the published literature suggested that the incidence of the majority of these outcomes did not differ between patients who underwent TOE and those who did not. However, as studies were not designed to assess patient outcomes, it is unclear whether the use of intra-operative TOE resulted in changes in morbidity or mortality.

Evidence from the literature suggests that the use of intra-operative TOE may result in changes to the pre-operative surgical plans of patients. However any results should be considered with caution due to the failure of the studies to meet important validity criteria, for example randomisation and blinding. Whether TOE works in the real world or only in the ideal clinical setting remains unresolved.

## **Cost effectiveness**

Based on data from cardiac valve surgery, cost per case of TOE is estimated here at between A\$575 and A\$690 in the years following initial purchase of the ultrasound machine. Set up and training make year one costs about 40 per cent higher than these figures. The literature estimates potential cost savings as high with the cost of a repeat operation being up to \$20,000 dollars more than the cost of repair at the time of initial surgery. No Australian data are available, but US data generally suggest savings with a rate of alteration of cardiac valve surgery of 3.0 to 6.6 per cent.

So, although total costs could range from A\$2.3 to A\$11.5 million (in the years following set up), depending on numbers of cases TOE is used in, this could lead to between 200 revisions (in 4,000 cases) and 1,000 revisions (in 20,000 cases) (at a revision rate of five per cent).

If these led to cost savings of more than A\$11,500 per revision, ie costs of at least A\$11,500 on average are avoided by not having to re-operate, (if the minimum cost per case is assumed to be A\$575 for congenital and valve cases in the years following set up), or A\$13,800 of costs avoided per revision, (if cost per case is a maximum of A\$690 for congenital cases alone in the years following set up), then there would be cost savings overall, as cost savings would be greater than procedural costs. Given the complexity of surgery involved, these may not be unreasonable assumptions, although given current data does not provide a guide for the Australian health care system figures in this economic evaluation are uncertain. A trial of TOE with an associated economic

evaluation is desirable, particularly in non-valvular cardiac surgery and non-cardiac surgery.

## Recommendation

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MSAC has found that there is limited evidence of the safety, effectiveness and cost effectiveness of intraoperative transoesophageal echocardiography. MSAC recommends that public funding for this procedure should be supported on an interim basis and restricted to intra-operative assessment of cardiac valve competence following valve replacement or repair.

The provision of funding should be reconsidered no later than June 2005 to ascertain whether further additional evidence has become available which supports continued funding.

- The Minister for Health and Ageing accepted this recommendation on 26 June 2002 -

# Appendix A: MSAC terms of reference and membership

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MSAC's terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to AHMAC.

The membership of MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	Expertise or Affiliation
Dr Stephen Blamey (Chair)	general surgery
Professor Bruce Barraclough	general surgery
Professor Syd Bell	pathology
Dr Paul Craft	clinical epidemiology and oncology
Professor Ian Fraser	reproductive medicine
Associate Professor Jane Hall	health economics
Dr Terri Jackson	health economics
Ms Rebecca James	consumer health issues
Professor Brendon Kearney	health administration and planning
Mr Alan Keith	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Ageing
Associate Professor Richard King	internal medicine
Dr Ray Kirk	health research
Dr Michael Kitchener	nuclear medicine
Mr Lou McCallum	consumer health issues
Emeritus Professor Peter Phelan	paediatrics
Dr Ewa Piejko	general practice
Dr David Robinson	plastic surgery
Professor John Simes	clinical epidemiology and clinical trials
Professor Richard Smallwood	Chief Medical Officer, Commonwealth Department of Health and Ageing
Professor Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council
Associate Professor Ken Thomson	radiology
Dr Douglas Travis	urology

# Appendix B: Supporting committee

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## Supporting committee for MSAC Reference 08 Intra-operative transoesophageal echocardiography

<b>Professor Bryant Stokes</b> (Chair) AM RFD FRACS FRCS St John of God Hospital Perth	Member of MSAC
<b>Dr David Barton</b> MBBS FRACGP Medical Advisor Diagnostics and Technology Branch Department of Health and Ageing Canberra	Advisor to MSAC
<b>Dr Leeanne Grigg</b> MBBS FRACP Director of Cardiology Royal Melbourne Hospital Melbourne	Nominated by the Cardiac Society of Australia and New Zealand
<b>Associate Professor Peter Klineberg</b> MBBS FANZCA Associate Professor & Director Westmead Hospital Westmead	Nominated by the Royal Australian College of Anaesthetists
<b>Professor Thomas Marwick</b> MBBS FRACP UQ Department of Medicine Princess Alexandra Hospital Brisbane	Nominated by Royal Australian College of Physicians
<b>Mr Richard McCluskey</b> Consumers' Health Forum & Heart Support Australia Latham	Consumer representative nominated by the Consumers' Health Forum of Australia
<b>Mr Hugh Wolfenden</b> MBBS FRACS Department of Cardiothoracic Surgery Prince of Wales Hospital Randwick	Nominated by the Royal Australasian College of Surgeons

## Appendix C: HTA and other relevant websites and databases searched

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Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (AÉTMIS). <http://www.aetmis.gouv.qc.ca/> (Accessed 15 November 2001).

Agency for Healthcare Research and Quality. <http://www.ahrq.gov/> (Accessed 15 November 2001).

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American Society of Anesthesiologists (ASA) <http://www.asahq.org/homepageie.html> (Accessed 29 April 2002)

American Society of Echocardiography (ASE) <http://www.asecho.org/index.shtml> (Accessed 24 April 2002)

Australian and New Zealand College of Anaesthetists (ANZCA) <http://www.anzca.edu.au/> (Accessed 1 May 2002)

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NHS Centre for reviews and dissemination, University of York.  
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<http://www.hta.nhsweb.nhs.uk/> (Accessed 15 November 2001).

National Horizon Scanning Centre. <http://www.bham.ac.uk/PublicHealth/horizon/> (Accessed 15 November 2001).

National Institute for Clinical Excellence (NICE). <http://www.nice.org.uk/> (Accessed 15 November 2001).

New Zealand Health Technology Assessment (NZHTA). <http://nzhta.chmeds.ac.nz/> (Accessed 15 November 2001).

The Swedish Council on Technology Assessment in Health Care (SBU).  
<http://www.sbu.se/admin/index.asp> (Accessed 5 September 2001).

The Norwegian Centre for Health Technology Assessment (SMM).  
<http://www.oslo.sintef.no/smm/news/FramesetNews.htm> (Accessed 15 November 2001).

Society of Cardiovascular Anesthesiologists (SCA). <http://www.scahq.org/> (Accessed 29 April 2002).

Swiss Science Council/Technology Assessment (SWISS/TA). <http://www.ta-swiss.ch/> (Accessed 15 November 2001).

TNO Prevention and Health (TNO). [http://www.health.tno.nl/homepage\\_pg\\_en.html](http://www.health.tno.nl/homepage_pg_en.html) (Accessed 15 November 2001).

Veterans Affairs Technology Assessment Program (VATAP).  
<http://www.va.gov/resdev/ps/pshsrd/mdrc.htm#HealthCareTechnologyAssessment> (Accessed 15 November 2001).

WHO Health Technology Assessment Programme Collaborating (Collaborating Centres). [http://www.who.int/pht/technology\\_assessment/index.html](http://www.who.int/pht/technology_assessment/index.html) (Accessed 15 November 2001).

## Appendix D: Studies included in the review

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### Item 1 Diagnostic characteristics

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# Appendix E: Studies excluded after full text assessment

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## Item 1 Diagnostic characteristics – excluded

### TOE compared in two groups of patients

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## Appendix F: Case reports on the effect of intra-operative TOE

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# Abbreviations

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ACC	American College of Cardiology
ANZCA	Australian and New Zealand College of Anaesthetists
ASD	atrial septal defect
ASA	American Society of Anesthesiologists
ASE	American Society of Echocardiography
AVR	aortic valve replacement
CABG	cardiopulmonary bypass graft
CAD	coronary artery disease
CSANZ	Cardiac Society of Australian and New Zealand
ETT	endotracheal tube
GIT	gastrointestinal tract
FN	false negative
FP	false positive
FPR	false positive rate
LR	likelihood ratio
MeSH	medical subject headings
MVR	mitral valve replacement
NHMRC	National Health and Medical Research Council
NHS	National Health Service
TEE	transesophageal echocardiography
TOE	transoesophageal echocardiography
TP	true positive
TN	true negative
TTE	transthoracic echocardiography
SCA	Society of Cardiovascular Anesthesiologists
VSD	ventricular septal defect

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