



Australian Government

Medical Services Advisory Committee

**STAKEHOLDER MEETING MINUTES  
TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)  
Friday, 30 October 2015**

**Attendees**

Members of the Medical Services Advisory Committee (MSAC), clinicians with experience in managing patients who are symptomatic with severe aortic stenosis and who are determined to be at high risk for surgical aortic valve replacement or non-operable, and expertise in treating the condition, representatives of Edwards Lifesciences, Boston Scientific, Medtronic Australia and St Jude Medical Australia.

**1: Meeting open**

The MSAC Chair opened the meeting at 1.30pm.

The meeting agreed that all discussions were confidential except for the report of the meeting finalised by the MSAC Secretariat and Chair following a circulation of the draft to all participants for comment. The report, to be made public via the MSAC website, would summarise the outcomes of the meeting, but would not attribute any statement to any participant and would not breach any confidentiality of any information relating to any particular product.

The meeting accepted that the outcomes of the meeting would not be binding on MSAC or the government, and that the outcomes might include a description of any issues that could not be resolved in the meeting.

**Conflicts of interest**

The Chair noted the conflicts of interest were declared.

**2: Background**

At its April 2015 meeting, MSAC deferred Application 1361 – Transcatheter Aortic Valve Implantation (TAVI) via transfemoral or transapical delivery to allow the economic model to be re-presented.

At its July 2015 meeting, MSAC again deferred Application 1361 - TAVI via transfemoral delivery to allow the applicant to address further economic concerns. MSAC also raised other concerns in relation to the proposed clinical setting, and advised that a possible way forward to deal with these other matters would be to meet with relevant stakeholders.

### **3: Summary of discussion**

#### Patient selection and the role of the heart multidisciplinary team

In agreeing with MSAC's objectives of ensuring the intervention is provided to patients in whom transcatheter aortic valve implantation (TAVI) is safe, effective and cost effective, the meeting noted the centrality of the heart multidisciplinary team as a gatekeeper for patient selection to minimise leakage of TAVI to patients not suitable for standard aortic valve surgery, but for whom intervention would be futile. The meeting considered it essential to include a general medicine physician or geriatrician in this team. The rationale for this advice was that a medically trained person who is not providing the intervention is more likely to be impartial to any incentive related to the intervention. The meeting also suggested that an assessment of cognitive function and frailty be explicitly included as part of any MBS item descriptor. It was understood that, for many cases, this assessment would be a straightforward element of assessing the suitability of a patient and their routinely collected clinico-physiological characteristics during the team meeting. However, for some patients, a formal referral to a geriatrician for a comprehensive assessment of cognitive function and frailty may be necessary. It was agreed that there was no single frailty instrument or frailty assessment threshold that would satisfactorily assess frailty in all its manifestations.

In also agreeing with MSAC's objectives of minimising leakage of TAVI to patients for whom standard aortic valve surgery would constitute a low risk and effective intervention, the meeting again noted the centrality of the heart multidisciplinary team as a gatekeeper for patient selection.

The meeting defined two distinct functions of the heart multidisciplinary team: patient selection and procedural planning for suitable patients. It was agreed that, at a minimum, the team must comprise the following types of medical expertise:

- for patient selection: an interventional cardiologist, a cardiothoracic surgeon, a cardiac anaesthetist/intensivist, and a general physician/geriatrician
- for procedural planning: an interventional cardiologist, a cardiothoracic surgeon, a cardiac anaesthetist/intensivist, and an imaging cardiologist/radiologist.

The meeting understood that the heart multidisciplinary team may include or co-opt other appropriate expertise, but that only those considered essential to the team, as defined above, would be eligible to claim from the MBS for their medical decision-making responsibilities on the team. Such individuals would also only be able to claim from the MBS once per patient, even if separate meetings were held for the two separate functions. It was foreshadowed that some teams might hold a single meeting that would undertake both functions. It was also noted that only one provider from each category should bill MBS irrespective of the number of attendees at the heart meeting (e.g. only one cardiothoracic surgeon could bill per patient even if more than one surgeon attended the meeting).

The meeting also considered that the heart multidisciplinary team must also include a coordinator, to ensure the availability of essential clinical records for the heart multidisciplinary team to review; the assessment of each patient is adequately recorded in structured minutes of each meeting (suitable for audit purposes); and there is effective liaison between the patient and the team.

### Accreditation of suitable institutions and those involved in undertaking TAVI procedures

The meeting agreed that poorer patient outcomes have occurred when TAVI has been allowed to disseminate to a wider group of providers in an uncontrolled fashion, and that, in order to retain optimal patient outcomes, it is necessary to have appropriate accreditation of the institutions, their heart multidisciplinary teams, and the interventional cardiologists and cardiothoracic surgeons involved with TAVI procedures.

The meeting proposed that the preferred accreditation arrangement would involve the Royal Australasian Colleges of Physicians and Surgeons, and/or their relevant Professional Societies. This arrangement would both set standards for assessments (national and international guidelines already exist), and also perform the assessments of individual institutions undertaking TAVI procedures. Standards of assessment would include components such as unit structure; standard operating procedures to ensure functional heart multidisciplinary teams; adequate training of providers involved in the procedures; evidence of quality assurance and sufficient throughput of patients to maintain competency; and adequate reporting of outcomes in a TAVI registry for benchmarking purposes. It was agreed that MSAC would write to both Australian and New Zealand Society of Cardiothoracic Surgery and Cardiac Society of Australia and New Zealand asking whether they would be able to establish such a conjoint arrangement. This was considered to be similar to existing conjoint arrangements in other areas such as for endoscopy by the Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy (CCRTGE).

The meeting also recognised that the accreditation role would need to be separated from a regulatory role to disincentivize an institution undertaking TAVI procedures without accreditation. Such a regulatory role, for example, to deny providers linked with the institution the ability to claim MBS funding associated with TAVI procedures, would need to be managed by the government. This separation of roles would similarly apply when new institutions seek to undertake TAVI procedures, including the determination of any probationary periods.

### Referral process

The meeting did not support any proposal to require that only cardiac surgeons be permitted to refer patients for a TAVI procedure. The meeting agreed that the primary issue here would be to minimise self-referral, and noted that most referrals were made by cardiologists. The meeting considered that this issue was best handled by requiring that an adequately functioning heart multidisciplinary team as outlined above be involved in patient selection for a TAVI procedure.

### Mode of delivery

The meeting agreed that the strongest evidence for TAVI related to its administration via the transfemoral route, and that this was also the preferred route of administration in practice. It was clarified that there was no proposal to consider limiting any MBS funding to the transfemoral route only.

### Differentiation of TAVI device options

The meeting proposed no basis to differentiate TAVI device options in any MBS item descriptor, noting that the TAVI procedure varies very little across the device options, and that only devices listed on the Australian Register of Therapeutic Goods (ARTG) should be inserted.

### Definition of person performing the procedure

The meeting clarified that, so long as they are appropriately trained and accredited by the proposed conjoint committee, an MBS-funded TAVI procedure could be performed by either a cardiothoracic surgeon or an interventional cardiologist.

### Conclusion

The meeting noted that the following developments would need to occur in parallel:

- a suitable accreditation arrangement by the Royal Colleges and associated cardiac societies
- an associated compliance arrangement by the government
- a reconsideration of a revised application for TAVI from Edwards Lifesciences by MSAC.

### **4: Meeting close**

Participants were thanked for their valuable insights and it was hoped that they found the stakeholder meeting informative.

The meeting closed at 4.15pm.

Revised MBS item descriptors reflecting the stakeholder meeting discussion (changes highlighted by use of *italics font*)

**MBS item descriptor for TAVI procedure**

Transcatheter aortic valve replacement, via transfemoral delivery unless transfemoral delivery is contraindicated or not available, for the treatment of symptomatic severe aortic stenosis in a suitable patient formally assessed by *an accredited* heart multidisciplinary team to have an unacceptably high risk for surgical aortic valve replacement. (Anaes.) (Assist.)

The heart multidisciplinary team *must* formally document approval regarding the patient's suitability for TAVI treatment, *including an assessment of cognitive function and frailty*. The core personnel of the heart multidisciplinary team *must* include an interventional cardiologist, a cardiothoracic surgeon, *a cardiac anaesthetist / intensive care physician, a geriatrician / general medical physician, an imaging cardiologist / radiologist*, and a TAVI coordinator / nurse / case manager.

*The TAVI procedure must be performed in an accredited institution by an accredited interventional cardiologist or by an accredited cardiothoracic surgeon.*

**Explanatory notes**

Symptomatic severe aortic stenosis is defined as an aortic valve area of less than 0.8 cm<sup>2</sup> and a mean transaortic gradient of greater than 40 mmHg.

In most cases, this item is claimable once per lifetime. In a small subset of patients where a repeat procedure is indicated; formal documentation of reassessment and consensus approval by the heart multidisciplinary team is required.

Transfemoral delivery is preferred for TAVI.

The extended heart multidisciplinary team could additionally include: a general cardiologist and a vascular surgeon.

**Related MBS items**

[Further advice will be needed on the suitability of MBS items for multi-disciplinary team case conferencing, either as directly applicable to TAVI-related heart multi-disciplinary teams, or as the basis for creating new MBS items and their descriptors for use in the context of TAVI (including in relation to co-claiming rules).]