Heart, Lung and Circulation (2021) **30**, 1811–1818
1443-9506/21/$36.00
https://doi.org/10.1016/j.hlc.2021.07.017

POSITION STATEMENT

2021 CSANZ and ANZSCTS Position Statement on the Operator and Institutional Requirements for a Transcatheter Aortic Valve Implantation (TAVI) Program in Australia

Jayme Bennetts, MBBS, FRACS [a,b,*], Ajay Sinhal, MBBS, FRACP [c,d], Darren Walters, MBBS, MPhil, FRACP [e], Andrew MacIsaac, MBBS, FRACP [f], Trevor Fayers, MBBS, FRACS [e,g], Sidney Lo, MBBS, FRACP [h], Aubrey Almeida, MBBS, FRACS [i], David W.M. Muller, MBBS, MD, FRACP [j], On behalf of Cardiac Society of Australia and New Zealand (CSANZ) and Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS)

[a]Department of Cardiothoracic Surgery, Flinders Medical Centre, Southern Adelaide Local Health Network, Adelaide, SA, Australia
[b]Department of Surgery, College of Medicine and Public Health, Flinders University, Adelaide, SA, Australia
[c]Department of Cardiology, Flinders Medical Centre, Southern Adelaide Local Health Network, Adelaide, SA, Australia
[d]Department of Medicine, College of Medicine and Public Health, Flinders University, Adelaide, SA, Australia
[e]St. Vincent's Northside Medical Centre, Brisbane, Qld, Australia
[f]Department of Cardiology St. Vincent's Hospital Melbourne, Melbourne, Vic, Australia
[g]Gold Coast University Hospital, Southport, Gold Coast, Qld, Australia
[h]Department of Cardiology, Liverpool Hospital, Sydney, NSW, Australia
[i]Department of Cardiothoracic Surgery, Monash Medical Centre, Monash Health, Melbourne, Vic, Australia
[j]Department of Cardiology, St. Vincent's Hospital Sydney, Sydney, NSW, Australia

Received 3 August 2020; received in revised form 13 July 2021; accepted 20 July 2021; online published-ahead-of-print 2 September 2021

This document establishes the minimum standard for accreditation of institutions and operators as endorsed by the Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS). The original Joint Society Position Statement was ratified in August 2014. This 2021 update replaces the original and serves as a consensus within which the Conjoint Committee for Trancatheter Aortic Valve Implantation (TAVI) Accreditation will function, as recommended by Medical Services Advisory Committee (MSAC) Determination for TAVI. This is not a Guideline Statement but takes into consideration regional, legislative, and health system factors important to establishing requirements for TAVI accreditation in Australia.

Keywords Aortic valve stenosis • Aortic valve replacement • Transcatheter valve therapy • Operator requirements

Introduction

A group of experts was drawn from the Cardiac Society of Australia and New Zealand (CSANZ), and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) to establish the TAVI Accreditation committee in 2017. The TAVI Accreditation Committee and key opinion leaders from cardiology and cardiothoracic surgery, were

*Corresponding author at: Director, Department of Cardiothoracic Surgery, Flinders Medical Centre, Adelaide, SA, Australia; Email: Jayme.Bennetts@sa.gov.au

consulted to update existing published conjoint guidelines [1] and inform proceduralists and institutions consistent with current legislative framework for accreditation in Australia [2–4]. Major databases were searched to identify relevant systematic reviews, randomised controlled trials (RCT), jurisdictional/regional guidelines, and clinical case series in English.

Background

Transcatheter aortic valve implantation (TAVI) has become an established therapy for the treatment of aortic stenosis and has been evaluated in selected high [5–8], intermediate [9–11] and low risk [12,13] populations. This condition is the most common acquired form of valvular heart disease in western countries such as Australia and New Zealand [14–17]. Its prevalence increases with age and is projected to increase over time as the population continues to age. Around 30–50% of patients are rejected for surgery predominantly due to their age or significant co-morbidities [18–22].

In Australia and New Zealand, a range of transcatheter valves has been used since 2008 as part of Human Research Ethics Committee-approved clinical registries or under the Special Access Scheme [23–25]. Wider clinical use followed approval of several TAVI devices by the Therapeutic Goods Administration (TGA). In November 2017, the Department of Health and Ageing (DoHA), Government of Australia, agreed to fund the procedure for TGA approved devices in patients considered to be at unacceptably high risk (or inoperable) for surgical aortic valve replacement (AVR) [3]. As part of the approval process, DoHA required accreditation of individual operators and institutions for TAVI procedures, and the establishment of a national TAVI Registry.

The Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) joined together to guide a process for TAVI accreditation, and provide recommendations for institutions and individual operator eligibility for accreditation. The TAVI Accreditation Committee was formed as a conjoint committee of the two Societies to oversee the approval process [4]. This document updates the evidence for TAVI, and provides a guide for the minimum requirements for accreditation to be actioned by this committee. The updated recommendations aim to promote patient safety, and ensure that individual operators and hospitals are committed to high quality outcomes.

Development Framework

The initial accreditation guidelines [1] provided Individual training requirements and Institutional volume and infrastructure requirements, which were developed with reference to multi-society consensus statements from the USA and Europe [26,27]. Since then, the technology and required training, resources and operator competencies have continued to evolve [28–31]. While other jurisdictions have raised minimum requirements for both individuals and institutions [29,31], early national registry data suggest that outcomes in Australia with current training and institutional requirements are comparable to those of large international series and registries. However, it is expected that training and institutional requirements may be adjusted as local National TAVI Registry data specific to volume and outcome become available in an environment of increasingly low risk procedures. The updated recommendations include requirements for outcomes to be within two standard deviations of the average national outcomes. These outcomes will be adjusted as the Registry expands and the data volume increases, and as more precise confidence limits are developed.

Current Status in Australia

One (1) of the requirements for reimbursement of TAVI in Australia, as outlined by the MSAC Determination [2], was the establishment of a National Registry and mandatory contribution of outcome data from all accredited sites. The Australian Cardiac Outcomes Registry (ACOR) accepted responsibility for administering the national TAVI Registry and appointed the South Australian Health and Medical Research Institute (SAHMRI) to develop and maintain the database. Since April 2018, 45 sites have agreed to contribute outcome data to the Registry. This includes 19 public hospital institutions and 26 private hospitals, representing all of the hospitals performing TAVI procedures in Australia. As of June 2020, there were 91 proceduralists accredited as TAVI practitioners. Between April 2018 and May 2020, 4,098 TAVI procedures were performed. The penetration of TAVI in Australia has increased from 48 cases per million in 2016, to 81 cases per million in 2018, and 119 cases per million in 2019. By comparison, in France, which has a similar number of active sites to Australia (n=45), the TAVI rate increased from 136 per million in 2016 to 193 per million in 2018 [32]. These rates are considered low when compared with other European countries such as Germany and Switzerland.

Accreditation Requirements

A. Heart Team

In Australia, funding for TAVI in the private sector is currently approved for high surgical risk and prohibitive surgical risk populations. This approval may be expanded in the intermediate term as applications for funding of lower risk populations are currently being considered, and two vendors have received TGA approval for treatment of intermediate and low risk patient cohorts. The technical aspects of the procedure require a combination of skills in structural heart disease intervention and surgical approaches. Decision making in relation to the patients most likely to benefit from this technology is complex and will remain challenging once the indications are expanded to

lower risk populations. Fundamental to a successful transcatheter valve program is the development of a collaborative, well-functioning multi-disciplinary (MDT) "Heart Team" [33,34]. The MSAC Determination, and CMBS descriptors, mandate a Heart Team in institutions with Transcatheter Valve programs, with auditable documentation of MDT discussions and individual patient management plans. Individual patient risk assessed by independent clinical review of both cardiologist and cardiothoracic surgeon are key to providing optimised patient-based decisions within the MDT framework, including planning for emergency management of complications. It is anticipated that the role of the MDT will become particularly important with expansion of indications to lower risk groups. Additional factors that will need to be considered in younger patient cohorts include the extent of concomitant coronary disease and potential need for future revascularisation, the presence of an associated aortopathy in patients with congenitally bicuspid aortic valves, the likely need for, and long-term consequences of, pacemaker implantation, and options for re-do TAVI or surgical AVR in the event of prosthetic valve degeneration.

The Heart Team is defined as a multi-disciplinary team of professionals who are charged with the governance of, and accountability for, patient selection, procedural planning, and outcomes of transcatheter heart valve implantation within an institution. It consists of a formal multi-disciplinary collaboration between a broad range of health care personnel with expertise in the assessment and management of patients with valvular heart disease, especially through the peri-procedural period. It is expected the Heart Team will provide all the necessary skills and expertise to fully assess patients who are potential TAVI candidates and provide balanced judgement of the most appropriate management. The core members of a Heart Team are listed below and are mandated by the DoHA requirements [2,3]. A broad range of other specialists may also be involved.

Core personnel (minimum required):

- Interventional Cardiologist
- Cardiothoracic Surgeon
- TAVI Nurse Case Manager/Co-Ordinator
- Physician or Surgeon not otherwise directly participating in performance of the TAVI procedure

Extended Team (may include):

- Interventional Cardiologist
- General Cardiologist
- Cardiothoracic Surgeon
- Anaesthetist
- Geriatrician
- General Medicine Physician
- Radiologist/Imaging cardiologist (computed tomography [CT], transoesophageal echocardiography [TOE])
- Vascular Surgeon
- Intensive Care Physician

The use of this type of multi-disciplinary team has been shown to improve outcomes in complex procedures such as TAVI [26,27,34]. One of the principal roles of the team is to ensure that patients are adequately evaluated (clinical and imaging assessments) and appropriately selected for the procedure. This is to ensure all co-morbidities and risks for the patient are assessed fully and the best treatment option for the patient (medical therapy, traditional surgery, or transcatheter valve therapy, including alternate access) is considered. In addition, the group can give advice on the best type of device, consider the preferred route, correct sizing of the device, mode of anesthesia, postoperative care pathways, and specific supports that may be required during the peri-procedural period. As access to TAVI is expanded to lower risk groups, it is anticipated that all patients with aortic valve disease, including those best treated surgically, will be discussed by the Heart Team.

Standardised templates are useful to ensure all information is presented succinctly. Minutes of the meeting, including a synopsis of the discussion and the eventual decision, should be documented and available for audit. The function of the team is best facilitated by regular scheduled meetings/case conferences. Management of procedural emergencies, including appropriateness of emergency surgical management of complications, must be planned prior to the procedure and discussed at the pre-operative briefing.

B. Procedure

The current generation of devices requires two operators, described as primary and secondary operator, who consistently work well together as a high functioning team, both contributing to the optimal procedural outcome. The working group believe a two-operator model remains the standard for Australia to ensure best procedural outcomes. It is accepted the primary operator leads the case and would usually position the valve. These recommendations apply to both operators, who may have been trained in interventional cardiology and/or cardiothoracic surgery.

Individuals will be accredited by the Conjoint Committee for TAVI Accreditation [4]. Reaccreditation will be 3-yearly. Institutions will be accredited by DoHA as recommended by the Conjoint Committee. Reaccreditation of TAVI sites will also occur 3-yearly. Specific volume and infrastructure requirements for initial accreditation and re-accreditation for individuals and institutions are listed below and in Table 1.

1. Interventional cardiologist

The interventional cardiologist should be trained in accordance with CSANZ guidelines [35]. A background in structural intervention is a pre-requisite for competency in TAVI [26,30]. It is likely a dedicated training pathway in structural heart intervention may be developed and become a subspeciality of interventional cardiology. TAVI is a complex procedure. While expertise in all of the following is not essential, the TAVI interventionist should have a broad procedural experience, which should include:

- Complex coronary intervention
- Placement of temporary pacing wires

Table 1 Key individual, institutional, and programatic requirements for TAVI Accreditation of new operators and TAVI hospitals.

Operator	Institution	Program
≥250 career PCIs OR ≥20 career surgical AVRs	≥1,000 caths/year and ≥300 PCIs/year	Multidisciplinary heart team with auditable meeting minutes
≥30 TAVI cases as primary or secondary operator including:	≥150 open heart surgical procedures/ year including ≥30 surgical AVRs/year	TAVI co-ordinator and database manager
≥10 proctored device-specific TAVI cases	At least 2 on-site cardiac surgeons and appropriate operating room staff	TAVI database with facility to export data to TAVI National Registry
Annual volume ≥30 TAVI cases	On-site vascular surgery with ≥30 endovascular procedures/year	
	Annual TAVI volume ≥50 cases	
	Cath lab/hybrid lab with appropriate resources for TAVI	
	Expertise in TAVI imaging including TTE, TOE and CT aortography	
	Cardiac anaesthesia support	
	Postoperative ICU/HDU/CCU support	
	Electrophysiology/pacing support	

Abbreviations: AVR, aortic valve replacement; CCU, coronary care unit; HDU, high dependency unit; ICU, intensive care unit; PCI, percutaneous coronary intervention; TAVI, transcatheter aortic valve implantation; TOE, transoesophageal echocardiogram; TTE, transthoracic echocardiogram.

- Pericardiocentesis
- Balloon aortic valve dilatation
- Peripheral vascular access and closure—large sheath placement
- Peripheral vascular diagnostic procedures
- Peripheral vascular interventions
- Intra-aortic balloon pump (IABP) insertion
- Catheter placement to allow initiation of percutaneous cardiopulmonary bypass/ECMO or other cardiac support.

For interventionalists implanting prior to 1 November 2017, the following minimum procedural experiences were required:

a) ≥60 TAVI procedures performed in Australia and/or New Zealand in the past 2 years as primary or secondary operator, **AND**;
b) ≥400 career percutaneous coronary interventions (PCIs).

As evidenced by a completed log book:

- with UR numbers/unique identifiers
- procedure dates
- outcomes—mortality, major complications, access site, hospital outcome.

It is expected that this category will be superseded by the reaccreditation process, which will commence in 2021.

For interventionalists having completed formal TAVI training (TAVI fellowship or similar), the Conjoint Committee will consider training experience—including volume, institution and trainee procedural independence. The following minimum is expected:

a) ≥30 TAVI procedures (as primary or secondary operator) in an established TAVI training program or accredited institution, **AND**;
b) a minimum of 10 device-specific proctored TAVI cases in Australia or New Zealand with certification of completion of training, **AND;**
c) ≥250 career percutaneous coronary interventions.

It is expected these will have occurred over the 2 years prior to application for accreditation and are documented in a completed log book:

- with Institution UR numbers/unique identifiers
- procedure dates
- outcomes—mortality, major complications, access site, hospital outcome.

The interventionist should have been trained and proctored on the devices being used. Interventional cardiologists in established clinical practice who wish to be accredited as a TAVI operator without undergoing a formal TAVI fellowship should arrange a period of mentoring by an accredited TAVI operator in an accredited Australian or New Zealand TAVI hospital. Applications for accreditation will be considered once they have performed >30 cases as first or second operator, 10 of which have been formally proctored.

2. Cardiothoracic (CT) surgeon

The cardiothoracic surgeon should be trained in accordance with RACS fellowship requirements and hold FRACS or equivalent. Two (2) potential levels of involvement in TAVI procedures may occur:

i. Support of TAVI program/Heart Team member

Surgeons involved in MDT meetings or supporting TAVI procedures should be experienced in operating on high-risk surgical AVR patients [28,29,36,37].

The following experience and training is recommended:

- ≥50 surgical AVR career, at least 10 of which are "high-risk" (STS score ≥10), **OR;**
- 20 AVR per year, **OR;**
- 40 AVR in 2 years, **AND;**
- at least 20 AVR in last year prior to TAVI initiation;
- Experience with, and management of, peripherally inserted cardiopulmonary bypass;
- Experience with open retroperitoneal exposure of, and surgical intervention on, the femoral and iliac arteries;
- Experience with hemi-sternotomy and rght anterior thoracotomy exposure of the ascending aorta;
- Experience with surgical exposure and cannulation of the subclavian arteries.

Definition and requirements of Surgical Support for TAVI procedures is described later.

ii. Implanting proceduralist

Surgeons involved in TAVI procedures should be experienced in operating on high-risk surgical AVR patients [26,27,36,37] and have training/experience in endovascular intervention as outlined. While expertise in all of the following is not essential, useful clinical experience for the TAVI interventionist could include:

- Wire and catheter skills
- Temporary pacing wire placement
- Pericardiocentesis
- Peripheral vascular access and closure—large sheath placement
- Peripheral vascular diagnostic procedures
- Peripheral vascular interventions
- Intra-aortic balloon pump (IABP), other cardiac support
- Device placement, including initiation of percutaneous cardiopulmonary bypass
- Percutaneous ventricular assist device placement
- Endovascular aneurysm repair (EVAR) or thoracic endovascular aortic repair (TEVAR) procedures.

AND

Expertise in Alternate Access surgical approaches including but not limited to:

- Hemi sternotomy
- Right anterior thoracotomy
- Transapical access
- Subclavian access

For CT surgeons implanting prior to 1 November 2017, the following minimum procedural experiences were required:

a) ≥60 TAVI procedures performed in Australia and/or New Zealand in the past 2 years as primary or secondary operator, **AND;**
b) ≥40 career aortic valve replacements.

As evidenced by a completed log book

- with Institutional UR numbers/unique identifiers
- procedure dates
- outcomes—mortality, major complications, access site, hospital outcome.

It is expected that this category will be superseded by the reaccreditation process commencing in November 2020.

For CT surgeons having completed formal TAVI training (TAVI fellowship or similar) the Conjoint Committee will consider training experience—including volume, institution, and trainee procedural independence. The following minimum is expected:

a) ≥30 TAVI procedures (as primary or secondary operator) in a recognised TAVI training program, **AND**;
b) a minimum of 10 device-specific proctored TAVI cases in Australia or New Zealand with certification of completion of training, **AND;**
c) ≥20 career aortic valve surgeries.

It is expected these will have occurred over the 2 years prior to application for accreditation and documented in a completed log book

- with Institutional UR numbers/unique identifiers
- procedure dates
- outcomes—mortality, major complications, access site, hospital outcome.

The surgeon should have been trained and proctored on the devices being used. Cardiothoracic surgeons in established clinical practice who wish to be accredited as a TAVI operator without undergoing a formal TAVI fellowship should arrange a period of mentoring by an accredited TAVI operator in an accredited Australian or New Zealand TAVI hospital. Applications for accreditation will be considered once they have performed >30 cases as first or second operator, 10 of which have been formally proctored.

3. Institutional requirements

TAVI programs should be established in high volume interventional cardiology and cardiothoracic surgical centres, where on-site surgery is available at the time of TAVI procedures being undertaken. The requirements for Provision of Surgical Support of TAVI are outlined below.

The following activity levels for institutions undertaking TAVI programs are required for accreditation [28,29]:

i. Interventional cardiology annual volume:
   a) ≥1,000 diagnostic catheter studies, **AND**
   b) ≥300 percutaneous coronary interventions.

ii. Institutional surgery annual volume/staffing:
   a) Procedural volume of a minimum 150 major heart surgeries per year at that site, performed by a cardiothoracic surgeon, **AND**
   b) ≥30 surgical aortic valve replacements, **AND**
   c) Minimum of two institution credentialled cardiac surgeons, skilled in aortic valve surgery, with staff, equipment, and theatre accessibility to provide urgent surgical backup (as outlined in requirements for Surgical Support of TAVI), **AND**
   d) On-site vascular surgery with expertise and facility to manage major arterial access/complications (≥30 arterial endovascular procedures/yr).

The facilities should include but are not limited to:

- Cardiac catheterisation laboratory or hybrid operating room (OR)
  - angiography suite equipped with a fixed radiographic imaging system with high resolution fluoroscopy and cineangiography
- Non-invasive imaging
  - Echocardiographic laboratory with transthoracic and transoesophageal echocardiographic capabilities. Sonographers and echocardiographers experienced in valvular heart disease.
  - Access to a vascular laboratory (non-invasive) with vascular specialists capable of performing and interpreting vascular studies.
  - Access to a CT laboratory with CT technologists and specialists who can acquire and interpret cardiac CT studies.
- Sterile environment that meets operating room standards or standards necessary for pacemaker/ICD implantation.
- Sufficient space to accommodate the necessary equipment for implantations including anaesthesia (including anaesthesia machine), echocardiography, and cardiopulmonary bypass/ECMO equipment and personnel;
- Appropriate equipment for the procedure and dealing with possible complications, including coronary artery occlusion, complete heart block, large vessel rupture, pericardial tamponade, cardiac perforation, annular rupture and haemodynamic collapse;
- A post procedure intensive care facility, high dependency unit (HDU), or coronary care unit (CCU) experienced in managing complex cardiac patients, including patients following conventional cardiac surgery;
- The following are desirable, but may not be available in most current interventional cardiology suites:
  - Circulating heating, ventilation, and air conditioning laminar flow diffusers
  - High-output lighting for surgical intervention.
  - Capability of running cardiopulmonary bypass/extracorporeal membrane oxygenator (ECMO) in addition to anaesthesia gas and power supplies (ie. dual outlets)
- Interventional equipment—appropriate equipment for the procedure and for dealing with possible complications should be stocked. At a minimum, this should include the following equipment:
  - Balloon catheters and stents for endovascular arterial repair and/or aortic/arterial occlusion
  - Pericardiocentesis tray
  - Temporary/permanent pacing
  - Balloon catheters and stents for coronary revascularisation.

4. Maintenance of accreditation

Data from large registries have clearly established that high volume institutions and operators have better procedural outcomes than lower volume centres and individuals [38–41]. Based on these studies [38–41] and other guidelines [28,29,31], the following are the minimum volume **AND** outcome requirements for approved TAVI programs and practitioners:

Volume Requirements

a) Program volume of at least 50 TAVIs per year **OR** 100 per 2 years for Institutions:
   - This total volume may be undertaken by multiple individual proceduralists.
   - Total institutional volume and outcome will be monitored.
   - Where public and private hospital programs are co-located and function as a single program, volumes can be combined if the same team (including medical and nursing staff) perform the procedures at both sites.

b) Procedural volume of at least 30 TAVIs per year **OR** 60 per 2 years for individuals:
   - This individual volume may be accumulated at more than 1 institution.
   - Total individual volume and outcome, and each institutional volume and outcome will be monitored and will form the basis for reaccreditation.

It is anticipated that some programs will fall short of the volume requirements at the time of their reaccreditation review. Accreditation may be extended for a 1-year probationary period at the discretion of the Accreditation Committee if there is evidence of growth in volume and excellent outcomes during the 3-year accreditation period. Operators and institutions that have volumes well below the requirements listed above will not be reaccredited but may reapply for accreditation once a further 12 months of procedural volume and outcome data are available. Re-approval would then be granted if the volume (50 cases/year for institutions and 30 cases/year for individuals) and outcome requirements for reaccreditation are met.

Outcome Requirements

The following key performance outcome measures will be evaluated:

- 30-day mortality
- 1-year mortality

- 30-day all-cause neurological events
- Major vascular complications
- Pacemaker implantation rate

Institutions and individuals will be expected to achieve outcomes that are consistently within two standard deviations from the average outcomes of peer institutions in the TAVI Registry as determined by funnel plot quality reviews. Institutions and individuals will also be required to have >90% submission of complete data, including 1-year follow-up, to the National TAVI registry. Data submitted to the National TAVI Registry will be audited periodically to ensure accuracy and completeness of all submissions. Outcomes from the Australian National Registry will be compared periodically with international registries to ensure that these benchmarks are representative of best medical practice.

The clinical oversight of the National TAVI Registry outcomes will be undertaken by the Conjoint Committee for TAVI Accreditation on behalf of CSANZ and ANZSCTS. This oversight, and requirements as listed above, provides a framework for Reaccreditation by the Conjoint Committee and will be adjusted as data volume and outcomes from the National Registry become available, and as indications for TAVI evolve. These outcome data will be reviewed 6-monthly and reported back to proceduralists and institutions.

5. Surgical support of TAVI procedures

While the incidence of conversion to open heart surgery is low with transfemoral TAVI, the need is usually emergent, and time to surgical intervention is associated with survival. Recent low risk trials report major vascular complication rates up to 3.8% and need for conversion to open surgery in <1% of cases [12,13]. Recent TVT Registry reports emergent surgical intervention rates up to 1.17% with an associated mortality of 50% [42].

The following are considered **absolute** requirements for transfemoral **and** alternate access TAVI procedures:

- TAVI be performed when the cardiac OR is staffed and accessible at the institution;
- Cardiac surgeon is part of the implanting team, or is on-site and available to intervene emergently if complications arise;
- The team required to undertake cardiac surgical procedures, including OR nursing, perfusion, and anaesthesia, are available on-site;
- Cardiac ICU is available for management post procedure.

It is expected that a cardiac operating theatre be accessible and staffed consistent with a high-volume institution's ability to manage emergency clinical events. While staffing an empty cardiac theatre is not the intent of this consensus, it may be required at remote and small volume sites not able to provide emergency access as outlined above.

It is expected that provision of support within these guidelines is the responsibility of the cardiac surgeon agreeing to provide support, **and** the Interventionalist who has requested support, when a surgeon is not part of the implanting team. This is the recommended standard for TAVI implantation and is assessable by the Conjoint Committee for Accreditation.

This statement provides a framework for the establishment and maintenance of a successful TAVI program. It is designed to ensure optimal patient outcomes and to provide guidance to individual operators and prospective institutions considering the establishment of a TAVI program.

Funding Source

This research did not receive any specific grant or funding.

Competing Interests

We report no competing interest associated with the work reported in this manuscript.

Author Conflicts

Jayme Bennetts: - Advisory Board member Medtronic, Edwards Lifesciences, Abbott Medical, and Liva Nova. Proctor Medtronic and Edwards Lifesciences. Research grant support Edwards Lifesciences, Medtronic, and Abbott Medical.

Ajay Sinhal: - Advisory Board member Medtronic, Edwards Lifesciences, and Boston Scientific. Proctor Medtronic and Edwards Lifesciences. Research grant support Edwards Lifesciences and Medtronic.

Darren L. Walters: - Advisory Board member and proctor for Edwards Lifesciences and Boston Scientific; Proctor and consultant Abbott Vascular.

Andrew MacIsaac: - no conflicts.

Trevor Fayers: - no conflicts.

Sidney Lo: - no conflicts.

Aubrey Almeida: - Advisory Board member Edwards Lifesciences, Medtronic, Liva Nova, Abbott Medical.

David W.M. Muller: - Advisory Board member and consultant to Medtronic, Boston Scientific; consultant to Abbott Vascular; research grant support Abbott Vascular, Medtronic; proctor for Medtronic, Abbott Vascular.

References

[1] Walters DL, Webster M, Pasupati S, Walton A, Muller D, Stewart J, et al. Position statement for the operator and institutional requirements for a transcatheter aortic valve implantation (TAVI) program. Heart Lung Circ. 2015;24(3):219–23.

[2] MSAC Determination 1361 – Public Summary Document: Application No. 1361 – Transcatheter Aortic Valve Implantation. Available at: www.msac.gov.au/internet/msac/publishing.nsf/Content/1361-public. [accessed 12.6.20].

[3] MBS Online. Available at: www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Factsheet-TAVI. [accessed 12.6.20].

[4] TAVI Accreditation Committee. Available at: www.tavi.org.au. [accessed 12.6.20].

[5] Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med. 2014;370(19):1790–8.

[6] Gleason TG, Reardon MJ, Popma JJ, Deeb GM, Yakubov SJ, Lee JS, et al. 5-year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. J Am Coll Cardiol. 2018;72(22):2687–96.

[7] Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363(17):1597–607.

[8] Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011;364(23):2187–98.

[9] Makkar RR, Thourani VH, Mack MJ, Kodali SK, Kapadia S, Webb JG, et al. Five-year outcomes of transcatheter or surgical aortic-valve replacement. N Engl J Med. 2020;38(9):799–809.

[10] Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017;376(14):1321–31.

[11] Van Mieghem NM, Popma JJ, Deeb GM, Yakubov SJ, Serruys PW, Windecker S, et al. Complete 2-year results confirm Bayesian analysis of the SURTAVI Trial. JACC Cardiovasc Interv. 2020;13(3):323–31.

[12] Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380(18):1695–705.

[13] Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380(18):1706–15.

[14] Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Barwolf C, Levang OW, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. Eur Heart J. 2003;24(13):1231–43.

[15] Layland JJ, Bell B, Mullany D, Walters DL. Percutaneous management of aortic stenosis in high-risk patients. Med J Aust. 2010;192(9):520–5.

[16] Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. Lancet. 2006;368(9540):1005–11.

[17] Thaden JJ, Nkomo VT, Enriquez-Sarano M. The global burden of aortic stenosis. Prog Cardiovasc Dis. 2014;56(6):565–71.

[18] Bouma BJ, van den Brink RB, Zwinderman K, Cheriex EC, Hamer HH, Lie KI, et al. Which elderly patients with severe aortic stenosis benefit from surgical treatment? An aid to clinical decision making. J Heart Valve Dis. 2004;13(3):374–81.

[19] Charlson E, Legedza AT, Hamel MB. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis. 2006;15(3):312–21.

[20] Frey N, Steeds RP, Rudolph TK, Thambyrajah J, Serra A, Schulz E, et al. Symptoms, disease severity and treatment of adults with a new diagnosis of severe aortic stenosis. Heart. 2019;105(22):1709–16.

[21] Pellikka PA, Sarano ME, Nishimura RA, Malouf JF, Bailey KR, Scott CG, et al. Outcome of 622 adults with asymptomatic, hemodynamically significant aortic stenosis during prolonged follow-up. Circulation. 2005;111(24):3290–5.

[22] Durko AP, Osnabrugge RL, Van Mieghem NM, Milojevic M, Mylotte D, Nkomo VT, et al. Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections. Eur Heart J. 2018;39(28):2635–42.

[23] Meredith IT, Walton A, Walters DL, Pasupati S, Muller DW, Worthley SG, et al. Mid-term outcomes in patients following transcatheter aortic valve implantation in the CoreValve Australia and New Zealand Study. Heart Lung Circ. 2015;24(3):281–90.

[24] Quine EJ, Duffy SJ, Stehli J, Dick RJ, Htun NM, Stub D, et al. Comparison of early outcomes in patients at estimated low-, intermediate- and high-risk undergoing transcatheter aortic valve implantation: a multicentre Australian experience. Heart Lung Circ. 2020;29(8):1174–9.

[25] Walters DL, Sinhal A, Baron D, Pasupati S, Thambar S, Yong G, et al. Initial experience with the balloon expandable Edwards-SAPIEN Transcatheter Heart Valve in Australia and New Zealand: the SOURCE ANZ registry: outcomes at 30 days and one year. Int J Cardiol. 2014;170(3):406–12.

[26] Tommaso CL, Bolman 3rd RM, Feldman T, Bavaria J, Acker MA, Aldea G, et al. Multisociety (AATS, ACCF, SCAI, and STS) expert consensus statement: operator and institutional requirements for transcatheter valve repair and replacement, part 1: transcatheter aortic valve replacement. J Am Coll Cardiol. 2012;59(22):2028–42.

[27] Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Barón-Esquivias G, Baumgartner H, et al. Guidelines on the management of valvular heart disease (version 2012): the joint task force on the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur J Cardiothorac Surg. 2012;42(4):S1–44.

[28] Bavaria JE, Tommaso CL, Brindis RG, Carroll JD, Deeb GM, Feldman TE, et al. 2018 AATS/ACC/SCAI/STS expert consensus systems of care document: operator and institutional recommendations and requirements for transcatheter aortic valve replacement: a joint report of the American Association for Thoracic Surgery, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. 2019;73(3):340–74.

[29] Bonow RO, Brown AS, Gillam LD, Kapadia SR, Kavinsky CJ, Lindman BR, et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 appropriate use criteria for the treatment of patients with severe aortic stenosis: a report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. J Am Soc Echocardiogr. 2018;31(2):117–47.

[30] Feldman T, Ruiz CE, Hijazi ZM. The SCAI Structural Heart Disease Council: toward addressing training, credentialing, and guidelines for structural heart disease intervention. Cathet Cardiovasc Interv. 2010;76(4):E87–9.

[31] Asgar AW, Ouzounian M, Adams C, Afilalo J, Fremes S, Lauck S, et al. 2019 Canadian Cardiovascular Society position statement for transcatheter aortic valve implantation. Canadian J Cardiol. 2019;35(11):1437–48.

[32] Valve for Life - France. Available at: www.escardio.org/Sub-specialty-communities/European-Association-of-Percutaneous-Cardiovascular-Interventions-(EAPCI)/Advocacy/valve-for-life-france. [accessed 12.6.20].

[33] Adams H, Roberts-Thomson R, Patterson T, Prendergast B, Redwood S. The Low-Risk TAVI Trials for severe aortic stenosis: future implications for Australian and New Zealand Heart Teams. Heart Lung Circ. 2020;29(5):657–61.

[34] Holmes DR Jr, Mohr F, Hamm CW, Mack MJ. Venn diagrams in cardiovascular disease: the Heart Team concept. Eur Heart J. 2014;35(2):66–8.

[35] The Cardiac Society of Australia and New Zealand: guidelines for competency in Percutaneous Coronary Intervention (PCI). Available at: https://www.csanz.edu.au/wp-content/uploads/2014/12/Competency_in_PCI.pdf. [accessed 12.6.20].

[36] Crawford FA Jr, Anderson RP, Clark RE, Grover FL, Kouchoukos NT, Waldhausen JA, et al. Volume requirements for cardiac surgery credentialing: a critical examination. The Ad Hoc Committee on Cardiac Surgery Credentialing of The Society of Thoracic Surgeons. Ann Thorac Surg. 1996;61(1):12–6.

[37] Peterson ED, Coombs LP, DeLong ER, Haan CK, Ferguson TB. Procedural volume as a marker of quality for CABG surgery. JAMA. 2004;291(2):195–201.

[38] Alli OO, Booker JD, Lennon RJ, Greason KL, Rihal CS, Holmes DR Jr. Transcatheter aortic valve implantation: assessing the learning curve. JACC Cardiovasc Interv. 2012;5(1):72–9.

[39] Carroll JD, Vemulapalli S, Dai D, Matsouaka R, Blackstone E, Edwards F, et al. Procedural experience for transcatheter aortic valve replacement and relation to outcomes: the STS/ACC TVT Registry. J Am Coll Cardiol. 2017;70(1):29–41.

[40] Vemulapalli S, Carroll JD, Mack MJ, Li Z, Dai D, Kosinski AS, et al. Procedural volume and outcomes for yranscatheter aortic-valve replacement. N Engl J Med. 2019;380(26):2541–50.

[41] Wassef AWA, Rodes-Cabau J, Liu Y, Webb JG, Barbanti M, Muñoz-García AJ, et al. The learning curve and annual procedure volume standards for optimum outcomes of transcatheter aortic valve replacement: findings from an International Registry. JACC Cardiovasc Interv. 2018;11(17):1669–79.

[42] Pineda AM, Harrison JK, Kleiman NS, Rihal CS, Kodali SK, Kirtane AJ, et al. Incidence and outcomes of surgical bailout during TAVR: insights from the STS/ACC TVT Registry. JACC Cardiovasc Interv. 2019;12(18):1751–64.