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EDITORIAL

Position Statements for Transcatheter Valve Therapies in Australia: Accreditation Standards and Heart Team Opportunities

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Transcatheter heart valve therapy outcomes continue to improve with iterative device and procedural refinements, increased institutional/operator volume and experience, as well as expansion into lower risk groups. Operator and institutional accreditation are required for therapy providers to receive reimbursement for these relatively new procedures under the Medicare Benefits Schedule (MBS). The new joint Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) transcatheter mitral valve repair (TMVr) position statement and the updated joint CSANZ and ANZSCTS transcatheter aortic valve implantation (TAVI) position statement are published in this issue of *Heart, Lung and Circulation*.

The scope and terms of reference for these writing groups were established by the desire to have accredited, competent operators and institutions for what were newly reimbursable procedures. However, one could argue that this was also a lost opportunity to formally broaden the focus of the Heart Team to the surgical as well as transcatheter management of aortic and mitral valve disease. Despite recent "modernisation" of the MBS schedule for both surgical and transcatheter therapies, the Heart Team's central role in managing valvular heart disease patients is currently mandated only for transcatheter therapies. This is contrary to international guideline recommendations [1,2], resulting in theoretical inconsistencies in patient management. While we think it likely there was an initial desire to prevent patients receiving inappropriate transcatheter intervention, with the ever-expanding evidence base for TAVI in intermediate and low risk patients the present arrangement now potentially allows for patients to receive inappropriate surgical intervention. For example, in the modernised MBS schedule, an 80-year-old patient with symptomatic severe aortic stenosis could be referred to a cardiac surgeon for consideration of surgical aortic valve replacement (SAVR); this patient could then undergo SAVR with the SAVR MBS items claimed, without any requirement for the patient to be first considered by the Heart Team. The recently updated European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) Guidelines would give a Class 1a recommendation for TAVI for this patient [2]. Perhaps the

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inherent involvement of both a referring cardiologist and a surgeon as part of a patient's management in these cases is thought to eliminate the need for the Heart Team in patients undergoing surgery, although recent clinical data continues to suggest benefit of the Heart Team for patients who do undergo SAVR [3]. Whether enshrined in the MBS schedule or not, the future of valvular heart disease management is a Heart Team based, integrated approach.

The authors of these statements should be commended for the thought and significant time spent in creating these accreditation requirements. The volumes and outcome requirements are generally in line with their international counterparts, except for a slightly lower annual operator volume for TAVI in Australia, perhaps reflecting our unique geographical challenges [4–7]. However, the vast majority of new TAVI hospitals in Australia appear to be within metropolitan areas and near existing programs which may be unexpected. Valle *et al.* have recently shown that areas with a high density of TAVI centres for the population, with accompanying low procedural volumes, deliver suboptimal patient outcomes compared to areas with a low density [8]. Volumes need to be consolidated, otherwise quality drops. Valvular heart disease centres of excellence that can concentrate expertise and volume in transcatheter and surgical valve therapies should be championed. Streamlining the patient journey to these centres can then be a focus to provide access for all patients. Addressing the clustering of transcatheter centres in metropolitan areas in position statements is difficult. Raising minimum volume standards may be a solution for those in close proximity to other centres and will likely be necessary as we move into treating low risk cohorts. Nevertheless, it is unlikely that starting a new TAVI program when one exists less than 30 minutes away would be in the best interests of patients.

Although training in transcatheter mitral and aortic interventions is not a core component of interventional cardiology or cardiac surgical training, requiring most commonly international fellowship experience, we could perhaps ask why only TMVr and TAVI, but not surgical mitral valve repair (SMVr) and more complex SAVR (such as those requiring root enlargement), require re-accreditation every three years? Indeed, there is published data suggesting a significant learning curve [9,10], associated with favourable outcomes for surgical mitral valve repair. Similar surgical data was referenced in the TMVr consensus statement as supporting the need for volume based credentialling, yet only proposed for transcatheter and not surgical intervention. If part of the role of consensus statements is to ensure patients receive the correct therapy, as recommended by a Heart Team, performed by an operator with sufficient volume-based experience, then the societies and the MBS should consider volume-based credentialling for both surgical and transcatheter procedures, with Heart Team review for both as standard.

Volume-based credentialling does of course raise issues related to workforce planning, which to date in Australia has mainly been performed at a local departmental level, if at all. For example, there are already more TAVI credentialled hospitals in Australia (42) than in the United Kingdom (41). There is always a risk of producing an oversupply of low volume structural cardiologists and cardiac surgeons, all of whom have valid career aspirations, having spent a decade or more training in their chosen field. More freely available data about the projected case volumes, and therefore the projected number of operators needed for that volume, may help our trainees in making informed fellowship decisions.

The question now is whether these position statements and accreditation requirements have any "teeth". How strictly should credentialling guidelines be enforced, especially with regards to procedural volume and recent proctoring limitations? Given the self-reporting of outcomes, regular auditing is paramount, however, this is both costly and resource intensive. The implications for removing an operator's credentialling are profound, which may explain why after three years of TAVI credentialling, we are personally unaware of any program losing their accreditation. The committees will have to weigh up the risk of keeping lower volume programs on the register versus creating an environment where an incentive for overservicing or poor patient selection exists, if strict volume requirements must be met by an ever-expanding group of practitioners. Other issues that would come into consideration would be the geographical implications of closing programs in locations where no other service exists locally, with often elderly patients wishing to be treated closer to home. Certainly, the updated TAVI document allows for programs that are growing yet may not have met all volume criteria and this may be the best compromise. The COVID-19 pandemic has also affected volumes of established centres and, together with the significant limitations on interstate travel, has limited the availability of proctors to mentor new programs.

One final issue is where will this special focus end? Is this now to be the standard required for every new cardiac procedure or is this the first step towards MBS-mandated Heart Team based holistic management for cardiac patients where multiple treatment options may exist. Let's hope it's the latter.

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