National Institute for Health and Care Excellence

IP1013/2 Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction

IPAC 11/04/19

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Society for Cardiothoracic Surgery (SCTS)		On behalf of SCTS we would like to thank NICE for sending us their provisional recommendation and information from the literature and the opportunity to comment on the document. We would be grateful if you would consider the following comments and references to the literature. Patient selection should be done by a multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons experienced in redo surgery and an expert in cardiac imaging. In order to make the MDT meaningful, a standardised definition of structural valve degeneration for surgical and TAVI prosthesis should be used. It is hoped that the adoption of these criteria by both the cardiological and surgical communities will lead to improved comparability and interpretation of durability analysis (Dvir et al. Circulation 2018;137:388-399 - White Paper on behalf of VIVID International data).	Thank you for your comments. 1.4 currently states that *'patient selection should be done by a multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging and, when appropriate, a cardiac anaesthetist and a specialist in elderly medicine. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them'.* IPAC considered your comment but did not make any changes to section 1.4 in the guidance as there is no standardised definition of structural valve degeneration.
2	Consultee 1 Society for Cardiothoraci	**2**	2. There is no mention of concomitant disease (e.g. coronary artery disease and previous grafts). This point is important to mention in the 'Overview', especially whether the patient will need a 2-3 stage procedure if having transcatheter treatment.	Thank you for your comment. The overview only provides summary details on the procedure and indication. IPAC considered your

	c Surgery (SCTS)		We suggest a whole new section is added on the presence of concomitant coronary artery disease and other concomitant valve pathology.	comment but declined to include a new section on concomitant coronary artery disease. However, they added a committee comment in section 3.10 which states that: *"the committee was informed that some of these patients may have concomitant coronary artery disease, and that this needs to be considered by the multidisciplinary team when planning treatment. "*.
3	Consultee 1 Society for Cardiothoracic Surgery (SCTS)	**General**	3. Mention of valve thrombosis and need for anticoagulation or dual anti platelet therapy following VIV is recommended. This is an increasingly recognised complication where anticoagulation therapy has reduced the post-procedure gradient significantly (Abdel-Wahab M, Simonato M, Latin A et al Circ Cardiovasc Intervention 2018).	Thank you for your comment. Valve thrombosis has been reported in the overview. Section 2.4 in the guidance has been amended as follows: '*prophylactic antibiotics and anticoagulant medication are used*'. Also section 2.6 has been amended as follows: '*Anticoagulation and/or antiplatelet therapy may be continued after the procedure'*.
4	Consultee 1 Society for Cardiothoracic Surgery (SCTS)	**Page 43 in overview**	4. **Review of redo surgery** - There are no randomised comparisons between VIV and surgical redo procedures. Several surgical series have reported favourable mortality and overall outcomes (Timek TA et al. Ann Thorac Surg 2015;99:518-23. Onorati F et al BMJ Open. 2018; 8(2). Bleiziffer S et al. J Thorac Dis. 2015 Sep; 7(9): 1494–1500).	Thank you for your comment. Bullet point 2 on page 43 has been amended as follows: *'evidence mainly from observational studies and registry data has reported favourable outcomes'.*
5	Consultee 1 Society for Cardiothoracic Surgery (SCTS)	**3**	5. **Safety Summary**. Up to 35% of patients develop patient-prosthesis mismatch. Therefore, the use of VIV in the younger population impacting on their quality of life and those with small annuli exacerbating post-procedural gradients should be noted. This is particularly important since the reported implantation of a second VIV in the meta-analyses was 6% and 10% required retrieval of the self-expanding TAVI valve.	Thank you for your comment. Section 3.8 and 3.9 in the guidance specifies these points.

6	Consultee 1 Society for Cardiothoracic Surgery (SCTS)	**General**	6. **Economic analysis.** There is no mention of economic analysis on VIV TAVI and review of the literature comparing redo surgery with VIV TAVI. There is little information available in the literature on economic analysis.	Thank you for your comment. Cost-analysis is not part of the remit of the IP Programme.
7	Consultee 1 Society for Cardiothoracic Surgery (SCTS)	**1.2**	7. **Audit Criteria.** We suggest a minimum dataset of criteria by which VIV TAVI could be audited. It is also important to ensure that all morbidity is recorded – ie vascular complications, permanent pacemakers and endocarditis. Equally patients undergoing redo valve surgery should have comparable outcome data recorded. The current UK database is too small to produce any meaningful results.	Thank you for your comments. Section 1.2 of the guidance states that '*Details of all patients should be entered into the **UK TAVI registry**'*. This database has a minimum data set which records all morbidity data and has published a few papers.
8	Consultee 1 Society for Cardiothoracic Surgery (SCTS)	**Specialist Adviser questionnaire 4.7**	**Summary** and reply to: '**Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?'** This technique would appear to have significant potential to treat failing / dysfunctional biological valves. This would avoid the risks and trauma of redo cardiac surgery. Many of these patients are quite frail and such a technique would be a welcome alternative to conventional surgery. However, the morbidity and the complications of this new procedure have to be assessed properly and not necessarily just comparing it to surgery but analysing the actual procedure and its complications. The reason is that many younger patients undergoing first time heart valve surgery may be promised a tissue valve as opposed to a mechanical valve, in the hope that they can have 'redo' procedure of TAVI valve-in-valve when the bipoprosthetic tissue valve fails. The risk and benefits have to be assessed with appropriate informing and consenting of patients. It may be the risks of conventional surgery are being overestimated to justify performing this new technique and we (SCTS) would recommend cardiac surgeons remain part	Thank you for your comments. IPAC discussed and acknowledged the concerns raised but no changes were made to the guidance. They agreed that the multidisciplinary team should determine the level of risk for each patient and the device most suitable for this. This has been clearly mentioned in section 1.4 in the guidance.

			of the discussion / MDT to weigh up the risks and benefits of the two techniques. In this way the patients can be better informed of their choices.	
9	Consultee 2 British Cardiovascular Intervention Society (BCIS)	**Overview**	**General comments on Overview:** Appears to be a very thorough assessment of existing data. Smaller studies not included in overall conclusions. This appears reasonable, especially as many of the smaller studies were in the early days of valve in valve.	Thank you for your comments.
10	Consultee 2 British Cardiovascular Intervention Society (BCIS)	**2.3/page 2 in overview**	**Minor comments:** **Page 2/74** It can be used for treating failed bioprosthetic aortic valves originally placed either by open heart surgery or TAVI. In particular, it has been used for rescue of suboptimal TAVI. This is a less common indication for valve in valve; much more common for failing surgical valves.	Thank you for your comment. The following sentence *'in particular, it has been used for rescue of suboptimal TAVI'* has been removed from the overview (page 2) to keep it in line with the guidance document.
11	Consultee 2 British Cardiovascular Intervention Society (BCIS)	**2.4/page 3 in overview**	**Page 3/74** Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is very occasionally used. This is so rare that I think it should be removed.	Thank you for your comment. **'**Temporary peripheral extracorporeal circulatory' has been removed from section 2.4 in the guidance document.
12	Consultee 2 British Cardiovascular Intervention Society (BCIS)	**Page 3-4 in overview**	**Page 3 & 4 /74** <u>Clinical assessment of severity of aortic stenosis</u> The logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) measures patient risk at the time of surgery using a logistic-regression equation on a 0-100% scale (higher scores indicating greater risk; a score higher than 20% indicates very high surgical risk). This should probably be updated to Euroscore 2, or at least	Thank you for your comment. The overview has been updated with the new refined risk score Euroscore 2.

			Euroscore 2 should be added as a more up to date indicator of surgical risk.	
13	Consultee 3 Company Medtronic	**1**	Medtronic wish to thank NICE for the opportunity to comment on the IPG for Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction. We agree that the evidence on the safety and efficacy of this procedure is adequate and therefore support the classification of standard arrangements. We have no further comments to make.	Thank you for your comments. Consultee agrees with the recommendation.
14	Consultee 4 NHS clinician	**2.4**	*usually transoesophageal echocardiography. (TOE is not usually used in most centres – local anaesthesia and trans thoracic echo is more common)* *Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used. (This is factually accurate but extraordinarily rare, so it may be better to leave this sentence out)*	Thank you for your comments. Reference to TOE has been removed from the overview and consultation document before consultation. 'Temporary peripheral extracorporeal circulatory' has been removed from section 2.4 in the guidance document.

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