National Institute for Health and Care Excellence

IP685/3 – Transcatheter aortic valve implantation (transcatheter aortic valve replacement) for aortic stenosis

Consultation Comments table

IPAC date: May 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**1.1**	The (draft) recommendations in section 1 are the most important part of this document. They need to be as clear as possible and consistent with the evidence base for TAVI. The most important of all of the recommendations would seem to be the group of patients for whom TAVI should be considered. While there is a statement on page 1 in the introduction that TAVI may be an alternative to surgical aortic valve replacement in patients for whom conventional valve replacement is not suitable, or who are at high risk of serious complications, there is no recommendation in the body of the text which specifies, either in general or more specific terms, when TAVI is indicated or should be considered. This appears to be an important omission. We recommend that consideration is given to amending recommendation 1.1 so that it includes reference to the indications for TAVI that are supported by the evidence base. For example, "Current evidence on the safety and efficacy of transcatheter aortic valve implantation (TAVI) for aortic stenosis is adequate to support the use of this procedure ...in patients who are not suitable for surgical AVR or who are at high risk for surgical AVR...provided that standard arrangements are in place for clinical governance, consent and audit."	Thank you for your comment. TAVI for aortic stenosis was given standard arrangements leaving it to the multidisciplinary team to determine the level of risk for each patient. Therefore the committee decided not to change 1.1 in the guidance. A committee comment has been added to section 6 in the guidance to indicate that TAVI is a potential treatment for patients who would not otherwise be suitable for surgical aortic valve replacement
2	Consultee 2 Manufacturer Boston Scientific	**1-6**	Boston Scientific support all of the recommendations and the document.	Thank you for your comment. Consultee agrees with the recommendations.

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3	Consultee 3 Manufacturer Medtronic	**1 and general**	Thank you for the opportunity to provide comments. Given the substantive clinical evidence for high, intermediate and low risk patients, Medtronic support the decision to upgrade the IPG from "special" to "standard arrangements" for clinical governance, consent and audit. We wish to highlight that the longer term evidence available is for earlier generation TAVI devices and so it may be useful for the reader to understand that some newer TAVI devices are showing promise in terms of improved outcomes such as mortality, Stroke, paravalvular leak, major vascular complications and need for pacemaker.	Thank you for your comment. Consultee agrees with the recommendations. IPAC added a comment in section 6 as follows: '*the longer-term evidence on TAVI is from earlier generation TAVI devices and the technology is evolving'*.
4	Consultee 1 NHS professional	**1.3**	We don't have a cardiac anaesthetist in the MDT, and I do not think it is a good use of their time - in a centre where TF procedures are done under local anaesthetic. Suggest re-word 1.3? Perhaps - 'the opinion of a cardiac anaesthetist should be available where necessary'.	Thank you for your comment. IPAC amended1.3 *as follows:* *Patient selection should be carried out by an experienced 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 TAVI device most suitable for them.*
5	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**1.3**	The opinion of a cardiac anaesthetist is not required for all patients being considered for TAVI and will only be required for a minority of cases in centres where TAVI is undertaken under local anaesthetic (with or without sedation). Certainly a cardiac anaesthetic opinion should be available when required but anaesthetic attendance at TAVI MDTs should not be mandatory. This should be reflected in section 1.3.	Thank you for your comment. See response to comment 4.

6	Consultee 7 Independent consultancy Health Economics & Outcomes Research	**General, 1.3,1.4**	We are pleased that the IPG on TAVI has been updated some 5 years after the previous version but we have concerns that some of the comments in the recommendation are sensitive to the currently reviewed data. If there is another 5 years before this procedure guidance is updated again then some of the statements may be inappropriate. For example, *1.4 During the consent process patients should be told about all alternative treatment options and that there is currently a lack of information on the longer-term efficacy of TAVI.* The first TAVI procedures were performed in 2002 and commercial products launched in 2007. Although these were in relatively small numbers there are already potentially up to 15 years follow up available in addition to 5 year RCT follow up and almost 10 years from national registries. Although we conceded that this is not comparable with the experience in surgical aortic valve replacement there are many new surgical valves being implanted now also without this level of long-term efficacy data, for which there is no specific warning recommendation. Given the elderly nature of most TAVI patients we feel this comment should be placed into context and at the very least reworded to state something like "During the consent process patients should be told about all alternative treatment options, their advantages and disadvantages and any limitations on currently available data, for example on durability". Also the recommendation does not provide clinicians with information on the alternative TAVI devices available. Therefore we would suggest that an additional statement that the choice of	Thank you for your comment. IPAC amended 1.4 as follows: *"During the consent process patients should be told about all treatment options and their advantages and disadvantages".* IPAC amended 1.3 as follows:

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			device depends on the clinical decision making process and appropriate risk-benefit assessment. For example: Patient selection should be carried out by an experienced multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, a cardiac anaesthetist and an expert in cardiac imaging. The multidisciplinary team should determine the risk level for each patient and the TAVI device most suitable for that patient.	*Patient selection should be carried out by an experienced 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 TAVI device most suitable for them.*
7	Consultee 4 NHS professional	**1.3 – 1.5**	The current document only states the need for a multi-disciplinary team including both cardiology and cardiac surgeons for the patient selection process for TAVI, and does not make any recommendation in regard to the procedure and post-operative care. The recent USA - STS publication highlighted the USA experience where the multi-disciplinary involvement continued in both the intra-operative technical aspects and post operatively, with involvement of both cardiology and cardiac surgeons throughout in three quarters of procedures. If the role of the cardiac surgeon in the UK becomes merely a perfunctary formality for selection only, then continued engagement of cardiac surgeons will disappear.	Thank you for your comments. IPAC amended 1.5 as follows. *'TAVI is a technically challenging procedure that should only be done in specialised centres and only by clinicians and teams with special training and experience in complex endovascular interventions. Units doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care'.*

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8	Consultee 5 Relative/Representative of patient	**1.4**	Suggest to make wording of section 1.4 regarding uncertainty a little more SMART, by including a specific time-related component that is supported by evidence. Please incorporate into section 1.4 relevant text from section 6.4 which states that "there is a lack of evidence after 5 years follow-up". Please see my suggested change to Section 1.4 below as presented in parentheses at the end of the section: During the consent process patients should be told about all alternative treatment options and that there is currently a lack of information on the longer-term efficacy of TAVI (beyond 5 years follow-up).	Thank you for your comment. IPAC amended 1.4 as follows: *During the consent process patients should be told about all treatment options and their advantages and disadvantages.*
9	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**2**	This section is entitled "indications and current treatments" but it includes no reference at all to TAVI. Either the title should be modified so that it reflects what is included in this section (mostly comment about surgical AVR) or the indications for TAVI should be included in this section.	Thank you for your comment. IPAC amended section 2 in the guidance.

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10	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**2.1**	There is little or no reference in the document to the poor prognosis of symptomatic severe aortic stenosis. It would be worth considering modifying section 2.1 through the addition of a statement which describes the poor prognosis since this is one of the main reasons for treating this group of patients. For example: 2.1 Aortic stenosis causes impaired outflow of blood from the heart and is usually progressive. The increased cardiac workload leads to left ventricular hypertrophy and heart failure. Symptoms of aortic stenosis typically include shortness of breath and chest pain on exertion. Mortality rates are high in symptomatic patients.	Thank you for your comment. IPAC amended section 2.1 in the guidance.
11	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**2.2**	Aortic balloon valvuloplasty is rarely, if ever, a definitive treatment for aortic stenosis. Consider modifying the final sentence of section 2.2 to "Aortic balloon valvuloplasty is occasionally used...as bridging or palliative treatment."	Thank you for your comment. IPAC amended section 2.2 in the guidance.

12	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**2**	The second sentence in section 2.3 seems out of place ("Patients for whom SAVR is suitable range from those considered to be high risk (for example, as defined in the PARTNER 1A trial) to those for whom the benefits of surgery clearly outweigh the risks of surgery.") It may be more logical to reorder some of the statements in section 2 so that the indications for surgical AVR come before the potential contraindications to surgical AVR, to change the statement about patients who are suitable for surgical AVR so that the most clear-cut (low risk) patients are mentioned first, and to conclude with a statement that it is these high risk patients who should be considered for TAVI. For example: 2.1 Aortic stenosis causes impaired outflow of blood from the heart and is usually progressive. The increased cardiac workload leads to left ventricular hypertrophy and heart failure. Symptoms of aortic stenosis typically include shortness of breath and chest pain on exertion. Mortality is high in patients with symptomatic aortic stenosis. 2.2 Surgical aortic valve replacement (SAVR) with an artificial (biological or mechanical) prosthesis is the conventional treatment for patients with severe symptomatic aortic stenosis who are well enough for surgery. Optimal medical care has traditionally been the only option for those whose condition is unsuitable for surgery. Aortic balloon valvuloplasty is occasionally used as bridging or palliative treatment.	Thank you for your comment. IPAC amend section 2 in the guidance.

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			2.3 Patients for whom SAVR may be suitable range from those in whom the benefits of surgery clearly outweigh the risks of surgery to those considered to be at high risk for surgery (for example, as defined in the PARTNER 1A trial) . 2.4 SAVR may not be suitable for patients because of medical comorbidities or technical considerations (for example, if the patient has a calcified aorta or scarring from previous cardiac surgery), which mean that the risks of SAVR outweigh the potential benefits. This is the group of patients who should be considered for TAVI.	
13	Consultee 1, 6 NHS professionals – members of British Cardiovascular Society	**3.1**	An important benefit of TAVI compared with surgical AVR is the avoidance of sternotomy. It would be sensible to modify section 3.1 so that it reads, Transcatheter aortic valve implantation (TAVI) aims to provide a less invasive alternative to open cardiac surgery for treating aortic stenosis, avoiding the need for sternotomy and cardiopulmonary bypass.	Thank you for your comment. IPAC amended section 3.1 in the guidance.
14	Consultee 1 NHS professional	**3.2**	Increasingly procedures are undertaken with local anaesthetic alone. Suggest reword 3.2. Perhaps ' ... local anaesthesia with or without sedation'.	Thank you for your comment. Section 6.2 states that *'there is a move towards using sedation rather than general anaesthesia for this procedure'.* IPAC amended 3.2 as follows: *'TAVI may be done with the patient under general anaesthesia or using local anaesthesia with or without sedation'*
15	Consultee 1 NHS professional	**3.2**	Most (?all) UK centres will be over 90% TF. I would have thought section 3.2 should at least state that most cases are undertaken via the transfemoral route.	Thank you for your comment. IPAC reworded section 3.2 to reflect this and dispensed the committee comment in section 6in the guidance.

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16	Consultee 6 NHS professionals – members of British Cardiovascular Society	**3.3**	Predilatation is now undertaken in a minority of TAVI cases. It might therefore be sensible to reword section 3.3. For example, Valve implantation may be preceded by balloon dilatation, depending on valve anatomy, prosthesis type and institutional preference.	Thank you for your comment. IPAC amended 3.3 as follows: Initially the aortic valve ring may be dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and inserted inside the existing aortic valve.
17	Consultee 8 Manufacturer- St Jude Medical	**1, 3.3**	We think that the draft guidance looks very good and the focus on the MDT for patient selection is a very important point. The only comment we would make, if it is not too late, is a minor one relating to the description of the procedure and section 3.3. The new prosthetic valve is inserted 'inside' the native diseased valve and not 'over' it. It may be a matter of interpretation on description, that's all.	Thank you for your comment. IPAC amended 3.3 as follows: Initially the aortic valve ring may be dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and inserted inside the existing aortic valve.
18	Consultee 7 Independent consultancy Health Economics & Outcomes Research	**3.3**	Although balloon pre-dilation of the aortic valve before TAVI is used widely the clinical practice is evolving. We suggest changing the wording of this slightly to reflect the contemporary reports, e.g. Initially the aortic valve ring may be dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and used over the existing aortic valve.	Thank you for your comment. IPAC amended section 3.3 as follows: Initially the aortic valve ring may be dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and inserted inside the existing aortic valve.
19	Consultee 7 Independent consultancy Health Economics & Outcomes Research	**3.4**	All commercially available TAVI devices in the UK contain animal derived material.	Thank you for your comment. IPAC amended 3.4 as follows *'Different devices are available for this procedure and contain material derived from animal sources'*.

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20	Consultee 3 Manufacturer Medtronic	**6.1**	Section 6.1 states that the risk of needing a permanent pacemaker implanted after the procedure is influenced by the technique and by the type of valve used. It is important to highlight here that other key outcome measures (mortality, Stroke, paravalvular leak, major vascular complications) are also influenced by the technique and type of valve used.	Thank you for your comment. IPAC amended 6.1 as follows *'The risk of needing a permanent pacemaker and other complications after the procedure depends on the technique and the type of valve used'.*
21	Consultee 7 Independent consultancy Health Economics & Outcomes Research	**6.1**	The difference in the incidence of permanent pacemaker following TAVI is known to differ between devices. The difference in absolute incidence of other complications and procedural factors such as vascular complications, need for post-dilatation, etc. are also known and influence the clinical decision making for the selection of the most appropriate device. There should be an acknowledgement that the MDT decision on TAVI also encompasses the access route and device selection for optimal patient outcome.	Thank you for your comments. IPAC amended 6.1 as follows. *'The risk of needing a permanent pacemaker and other complications after the procedure depends on the technique and the type of valve used'.*

22	Consultee 4 NHS professional	**6.4**	This document, apart from a single mention in regard to the paucity of evidence beyond 5 years, has made no attempt to investigate/advice on the current expected longevity of TAVI bioprosthetic valves. There is a wealth of data on the expected durability of current surgically implanted bioprosthetic valves that can be used for comparative purposes, as well as the importance of specific manufacturing processes such as anticalcification agents/processes, and importance of patient age. The European & USA guidelines stratify the recommended age for bioprosthtic valves vs. mechanical valves, and in this context recommend surgical bioprosthetic valves if age > 65-70 yrs, based on an estimate 50% surgically implanted bioprosthtic valve degeneration at approximately 15yrs or more. Recently at EuroPCR 2016 a study investigating the long-term durability of transcatheter aortic valve implantation (TAVI) was reported; showing an estimate that the eight-year rate of structural valve degeneration of TAVI bioprosthetic valves was already approximately 50%. The mode of degeneration of TAVI valves also appears to differ to current surgically implanted valves and hence TAVI bioprosthetic valve degeneration should not & cannot be deemed to be similar to surgical bioprosthetic valves. This is important known information that should be included in this report, especially as more intermediate risk patients are now being deemed potential TAVI candidates.	Thank you for your comment. IPAC added a committee comment as follows: '*the longer-term evidence on TAVI is from earlier generation TAVI devices and the technology is evolving. Longer-term evidence is needed and this should be taken into account by the multidisciplinary team'.*

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23	Consultee 7 Independent consultancy Health Economics & Outcomes Research	**6.4**	RCT follow up has only been reported for 5 years but TAVI data is available for 10 years from commercial devices and 15 years since the earliest patient implants. This data is not available for all devices though, reinforcing the need to allow clinical decision making to take priority when deciding if, to perform a TAVI, and which device to use.	Thank you for your comments. IPAC added a committee comment as follows : *'There is a need for longer-term evidence and this should be taken into account by the multidisciplinary team. Longer-term evidence is needed and this should be taken into account by the multidisciplinary team'.*