

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read [Conflicts of Interest for Specialist Advisers](#). Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction

Name of Specialist Advisor: Dr Douglas Muir

Specialist Society: British Cardiovascular Intervention Society (BCIS)

1 Do you have adequate knowledge of this procedure to provide advice?

- Yes.
- No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

- Yes.
- No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

- Yes.
- Is there any kind of inter-specialty controversy over the procedure?

- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The procedure is one of the 2 options to correct a failing surgical valve. Historically, the only option to a failing surgical valve was medical therapy (ineffective) or repeat surgery. Repeat surgery is always higher risk than first time and more than doubles the risk in most cases. Valve in valve TAVI is a substantially less invasive alternative to surgery – thus there are now 2 potential modes of re-intervention for surgical valve failure.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

Valve in valve TAVI has been one of the routine treatment options for failing surgical valve for several years in most surgical centres.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

In addition to implanting, I also refer patients for consideration of intervention (via the MDT) from my own practice.

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have done bibliographic research on this procedure.

- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

In addition to bibliographic research, I have presented clinical cases of valve in valve TAVI in national and international meetings. I have been directly involved in several aspects of clinical research in other aspects of TAVI unrelated to valve in valve procedures.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

Although there are some technical considerations related to the type and size of the surgical valve, valve in valve TAVI is the standard of care in most centres.

3.2 What would be the comparator (standard practice) to this procedure?

Repeat surgical valve replacement (or conservative / palliative therapy for inoperable patients)

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

Only interventional cardiologists or surgeons with a subspecialty interest in TAVI will perform this procedure. TAVI is authorised only in surgical centres.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Risks include all of the same adverse events which are seen in TAVI in native valve disease. These include vascular injury, bleeding, myocardial infarction, stroke, permanent pacemaker, renal failure, death and paravalvar leak.

Some types of surgical valves have anatomical characteristics, which may increase the risk of myocardial infarction due to coronary artery occlusion compared with native valve TAVI. In addition, placement of a TAVI valve within a surgical valve may result in a small orifice with more obstruction to left ventricular outflow than a first time valve.

Recently, a modified technique has been described where the sewing ring of the surgical valve is deliberately fractured with a balloon during valve in valve TAVI. This reduces the degree of obstruction and demonstrates better acute haemodynamic results, though requires further evaluation to determine overall risks and longer term outcomes.

2. Anecdotal adverse events (known from experience)

As documented above

3. Theoretical adverse events

The smaller effective orifice area which occurs with valve in valve may reduce the chance of full symptom resolution compared with native TAVI. In addition, the smaller orifice could have an impact of valve longevity. This has not yet been demonstrated but should be the focus of further study.

4.2 What are the key efficacy outcomes for this procedure?

1. Acute improvement in valve haemodynamics (reduction of stenosis and / or regurgitation)
2. Subsequently improved symptoms
3. Improved prognosis compared with palliative therapy or repeat surgery

4.3 Are there uncertainties or concerns about the efficacy of this procedure? If so, what are they?

In part. As mentioned above, the main questions relate to the clinical significance of higher valve gradients than in native TAVI and in valve longevity.

4.4 What training and facilities are needed to do this procedure safely?

1. A fully trained and accredited TAVI centre with on site cardiac surgery,
2. Detailed knowledge of the characteristics of candidate surgical valves for valve in valve procedures.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Uncertainties exist about whether one design of TAVI valve may be better than another for this procedure. Additional uncertainty also exists about the efficacy of modifications to the technique in certain situations – deliberate surgical valve fracture or deliberate surgical leaflet laceration in particular.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

A minimum dataset for TAVI in the UK already exists and should be completed for all TAVI patients. This would also be sufficient for valve in valve TAVI.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

1. The UK TAVI dataset for complications and baseline data
2. Any standard QOL measure would be reasonable

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

The standard for all of the database complications, including mortality should be recorded up to one month post implant.

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

I suspect that this is already the most commonly performed procedure for failing surgical bioprostheses, other than those relating to endocarditis. However, patients undergoing first time aortic valve surgery are now increasingly more likely to receive a bioprosthetic valve than a mechanical valve, with the expectation that valve in valve TAVI will be an option in the future. Therefore, one might expect to see a steady rise in valve in valve TAVI over future years.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

All guidelines suggest that TAVI should be performed in centres with on site cardiac surgery.

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

- Major.
- Moderate.
- Minor.

Comments:

Valve in valve TAVI is probably already the de facto standard of care for failing surgical valves, excluding repeat surgery for endocarditis.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the “Conflicts of Interest for Specialist Advisers” policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family¹ have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional **YES**

¹ ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

- payments in cash or kind **NO**
- Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** **YES**
 NO
- Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry **YES**
 NO
- Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences **YES**
 NO
- Investments** – any funds that include investments in the healthcare industry **YES**
 NO
- Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? **YES**
 NO
- Do you have a **non-personal** interest? The main examples are as follows:
- Fellowships** endowed by the healthcare industry **YES**
 NO
- Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts **YES**
 NO

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

1. Proctor for Edwards Lifesciences and Abbott Vascular (both TAVI manufacturers)
2. Departmental grant for TAVI Fellow (Edwards Lifesciences)
3. Departmental fees for training new TAVI teams (Abbott Vascular)

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair **Mark Campbell
Acting Programme Director
Devices and Diagnostics**

June 2018

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

- 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
- 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

- 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘**specific**’ or to the industry or sector from which the product or service comes, in which case it is regarded as ‘**non-specific**’. The main examples are as follows.
 - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
 - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 2.2 No personal interest exists in the case of:
 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
 - 2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

5 **Non-personal interests**

- 5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Adviser is responsible, but that is not received by the Specialist Adviser personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific**,' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples are as follows.

- 5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.
- 5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:
- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
 - a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Advisor is responsible. This does not include financial assistance for students
 - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
 - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.