

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read [Conflicts of Interest for Specialist Advisers](#).

Please respond in the boxes provided.

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

Procedure Name: Percutaneous repair of paravascular leak following surgical mitral or aortic valve replacement

Name of Professional Expert: Dr David Northridge

Job title: Consultant Cardiologist
Royal Infirmary of Edinburgh

Professional Regulatory Body: GMC
Other (specify)

Registration number: 2847087

Specialist Society: British Cardiovascular Society
Fellow of RCPE

Nominated by (if applicable): British Cardiovascular Society

1 About you and your speciality's involvement with the procedure

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

Yes.

No – please answer no more questions and return the form

Comments:

I lead the PVL closure programme in Edinburgh which is funded by NSD. We have done circa 100 procedures to date, which is probably the greatest experience in the UK.

1.2 Is this procedure relevant to your specialty?

- Yes.
- No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

The procedure is performed by interventional cardiologists: In Edinburgh myself and Dr Behan

1.3 Is this procedure performed by clinicians in specialities other than your own?

- Yes – please comment
- XNo

Comments:

1.4 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:

Aprox 12-15 procedures PA

1.5 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:

Heart valve disease is my main specialty interest and I do TOE as well as intervention. TOE is the main imaging modality for PVL patients. I see secondary and tertiary referrals

1.6 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:

Our cases were included in the UK registry published approx 2 years ago and I have published several case reports and given many presentations including the Scottish Cardiac Society and the British Cardiac Intervention Society

1.7 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:

There are only approx 10 UK sites doing this procedure. I act as a proctor to support some of these sites

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

- Yes
- No - If no, please suggest alternative titles.

Comments:

2.2 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:

My personal experience has been extremely positive but there are no published RCTs. Outcomes from surgery are poor and I am not sure an RCT is ethical

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Re-do surgical revision which is very high risk

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

European registry just started, the UK registry has been published (Calvert, Northridge et al)

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

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

Embolitic complications including device embolisation

Cardiac Tamponade

Vascular Complications

Anecdotal adverse events (known from experience)

Theoretical adverse events

3.2 Please list the key efficacy outcomes for this procedure?

QOL including heart failure symptoms
Measures of haemolysis

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

No concerns but there are uncertainties due to the lack of clinical trials

3.4 What clinician training is required to do this procedure safely?

Lots. It requires advanced training in Interventional cardiology, as well as good interpretation of the TOE images

3.5 What clinical facilities are needed to do this procedure safely?

A cath lab in a surgical cardiac centre plus excellent imaging experience.
Procedure needs 2 Interventionists, and imager and usually an anaesthetist

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

The approach is pretty standard in most of the world but the devices available are limited in North America

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

- 4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:**

Living with Heart failure type questionnaires, NYHA Class etc. Our experience is that most patients notice improved symptoms almost immediately when procedure is successful. Improvement in haemolysis may be delayed

- 4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.**

In hospital complications are all that is required

5 Uptake of the procedure in the NHS

- 5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?**

- Rapidly (within a year or two).
 Slowly (over decades)
 I do not think the NHS will adopt this procedure

Comments:

Already 'adopted' by the NHS. In Scotland we are the fully funded National service

- 5.2 If it is safe and efficacious, in your opinion, will this procedure 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:

It should be done in specialist 'valve centres' ie NOT all cardiac surgical centres because I think centres should be doing a minimum of around 10 procedures PA. Some UK centres are doing only 1 or 2 procedures, this isn't the best way forward

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

Major.

Moderate.

Minor.

Comments:

We have well developed referral guidelines and pathways in Scotland and we do only 12-15 PA. I think UK need in therefore circa 150 procedures PA, which could be done by circa 10 centres with geographical spread

6 Other information

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

Comments:

7 Data protection and conflicts of interest

7.1 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 professional expert 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.

Xi 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. For more information about how we process your personal data please see our [privacy notice](#)

7.2 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. [Conflicts of Interest for Specialist Advisers](#)

Declarations of interest form			
Type of interest	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct Financial	<i>I am a paid proctor for Abbott who distribute the AVP2, AVP3 and AVP4 devices used in this procedure</i>	2015	Ongoing

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	<p>Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest.</p> <p>Types of interest:</p> <p>Direct interests</p> <p>Financial interests - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. <i>For examples of financial interests please refer to the policy on declaring and managing interests.</i></p> <p>Non-financial professional and personal interests - Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. <i>For examples of non-financial interests please refer to the policy on declaring and managing interests.</i></p> <p>Indirect interests - Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit.</p> <p>A benefit may arise from both a gain or avoidance of a loss.</p>
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair **Mirella Marlow Programme Director**

