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: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Percutaneous mitral valve leaflet repair for mitral regurgitation**
Name of Specialist Advisor:	Dr David Hildick-Smith
Specialist Society:	British Cardiovascular Intervention Society

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

x☐ Yes.

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

1.1 Does the title used above describe the procedure adequately?

x☐ Yes.

☐ No. If no, please enter any other titles below.

Comments:

There are many technologies coming which would also fit this description however….

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

x☐ 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:

No controversy

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.

x☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

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.

x☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

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

x☐ 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:

3 Status of the procedure

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

x☐ 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:

This is established in Europe and America but unfortunately in the UK is not funded by NHS England

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

Most patients who have this procedure are not suitable for surgical repair of the mitral valve (which would be a comparator) and therefore the main comparator would be medical therapy for severe mitral regurgitation (with or without heart failure)

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.

x☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

Very few are able to do this procedure at all now as funding is currently in abeyance

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)

Vascular trauma, vascular repair, cardiac tamponade, left atrial perforation, thrombus formation, worsened mitral regurgitation, mitral stenosis, surgical repair of mitral valve, bleeding, clip detachment, death, stroke (Eggebrecht et al Catheterization and Cardiovascular Interventions 2015)

2. Anecdotal adverse events (known from experience)

As above

3. Theoretical adverse events

Included above

4.2 What are the key efficacy outcomes for this procedure?

In hospital mortality
In hospital complication-free survival
In-hospital technical completion of case
30-day mortality
Improvement in NYHA, exercise tolerance, 6 minute walk
Reduction in readmission rate for heart failure
5-year survival

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

The procedure is effective in the medium term. There is uncertainty about the efficacy of Mitraclip therapy in patients with heart failure, in the absence of associated annuloplasty

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

The procedure should only be done in centres with Cardiothoracic Surgery. The procedure requires Cardiac Anaesthesia, TOE and two operators. Experience in structural heart disease and left atrial instrumentation is essential

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

The COAPT and RESHAPE trials are due to report in 2018

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).

Nothing of major signficance

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

Yes. It used to be done in the UK but as there is no funding anymore it has fallen into disuse and teams will therefore need to progress through a second learning curve once the procedure is again commissioned.

5 Audit Criteria

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

There is a large dataset in existence for the CtE programme. This would need to be substantially reduced

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:

Quality of life SF12, Kansas Heart Failure, NYHA, 6 minute walk, Exercise capacity, Imaging parameters of LV function and degree of mitral regurgitation

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:

As above

6 Trajectory of the procedure

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

If it is adequately commissioned then within one year there will be ten centres in the UK doing it and within two years there will be 20 centres.

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

☐ Most or all district general hospitals.

x☐ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

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.

x☐ Minor.

Comments:
Probably about 200 patients per year

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?

All the documentation through the CtE process still ongoing.

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 family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	x	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	x	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	x	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	x	**NO**

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

Comments:
Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional **Professor Carole Longson, Director,**

[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).

Procedures Advisory Committee Chair **Centre for Health Technology Evaluation.**

Jan 2016

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 Advisor is responsible, but that is not received by the Specialist Advisor 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 Adviser 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.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Percutaneous mitral valve leaflet repair for mitral regurgitation**
Name of Specialist Advisor:	Anita Macnab
Specialist Society:	British Society of Echocardiography

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:

I would suggest "**Percutaneous mitral valve edge to edge repair for mitral regurgitation"**. At the moment the only device for this technique is the **MitraClip®** device (Abbott Laboratory).

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 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:

The caveat is that I was doing Mitraclip procedures regularly until April 2017. My institution was one of only three Trusts chosen by NHS England for the Commissioning through Evaluation (CtE) programme of the Mitraclip procedure. I provided all the Transoesophageal Echo (TOE) support for patient selection, Heart team MDTs and the 3D TOE guidance required for the actual procedure. The CtE programme was halted in April 2017 and I have not performed the procedural TOEs since then but am still doing the selection TOEs for recruitment to the RESHAPE-HF trial (see section 4.5) about to start in the UK.

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:

As mentioned above.

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:

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:

After obtaining CE mark approval in Europe in 2008, MitraClip was approved by the U.S. Food & Drug Administration in 2013. To date, more than 50,000 people have been treated by MitraClip in nearly 50 countries.

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

The standard procedure for symptomatic mitral regurgitation patients has been surgical mitral repair or replacement. However, the patients chosen for the mitraclip procedure don't really have a comparator as they are deemed too high risk for conventional surgery. Until now these patients have been treated medically with inevitable decline and death.

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:

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 quoted to patients in our institution include bleeding requiring blood transfusion (19%), major vascular complications (7%), pericardial effusion (1-2%), stroke (1%) and death (2%).

2. Anecdotal adverse events (known from experience)

Device embolization, oesophageal perforation and partial detachment of clip have all occurred in our institution

3. Theoretical adverse events

Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Arrhythmias; Atrial septal defect requiring intervention; Chordal entanglement/rupture; air emboli; Endocarditis; Esophageal stricture; Pulmonary thrombo-embolism; Renal failure; Respiratory failure/atelectasis/pneumonia; Septicemia; Skin injury or tissue changes due to exposure to ionizing radiation etc

4.2 What are the key efficacy outcomes for this procedure?

Reduction in mitral incompetence, improvement in NYHA symptom class, improved quality of life, favourable left ventricular remodelling, reduced heart failure hospitalisation.

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

In my experience procedural success is uncertain in specific mitral valve anatomies such as Barlow valves. I also have concerns about the symptomatic success in patients with concomitant right ventricular dysfunction. Trial data in these subsets is lacking.

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

This procedure has a very significant learning curve, much more so than any other structural intervention procedure I have done. The most important requirement is a dedicated Heart Team job planned to carry out stringent MDTs and patient selection within an established structural interventional programme. All operators directly involved in the delivery of the device (interventional cardiologist, echo cardiologist and cardiac surgeon in some cases) have to be very experienced in mitral valve disease, percutaneous procedures and 3D transoesophageal echo. Each member of the operational team needs a good understanding of the other's procedure in the catheter lab. The company organises simulation training, a visit to a reference unit and provide a clinical proctor for the first few cases. The company applications specialists continue to proctor every case.

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

RESHAPE- HF trial: The purpose of this **trial** is to further **study** the safety and effectiveness of the **MitraClip** System in the treatment of mitral regurgitation in patients with chronic heart failure. The **trial** will also collect information on healthcare economics

The COAPT **Trial** is a prospective, randomized, parallel controlled **clinical** evaluation of the **MitraClip**® device for the treatment of clinically significant functional MR in symptomatic heart failure patients. This multicenter **study** will examine the safety and efficacy of the **MitraClip**® device used in addition to standard care

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).

No

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

The only uncertainty is the lack of NHS funding for this procedure in the UK.

5 Audit Criteria

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

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:

The CtE programme agreed an extensive set of audit outcome measures to assess the efficacy and safety of this device. The full list has been submitted to NICOR. The measures are essentially echo parameters to assess reduction in mitral regurgitation grades, LV function, symptom assessment, complication rates and mortality.

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:

acute procedural events- bleeding requiring transfusion**,** major vascular complications, pericardial effusion, stroke, death, device embolization

30 day events- rest of the adverse events stated in section 4.

6 Trajectory of the procedure

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

Not very quickly if the CtE criteria are adhered to. For every 5 referrals sent to us during CtE, only 1 patient was deemed anatomically and clinically suitable for mitraclip. The criteria set are stringent and based on RCT data on feasibility, safety and effectiveness.

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:

This is a highly complex procedure that should be carried out in a small number of institutions to concentrate expertise and drive quality.

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:
At the moment the existing trial and registry data would support offering this procedure to mitral regurgitant patients who are symptomatic but deemed too high risk for surgery. In my experience, particularly the degenerative patients do very well with improved QOL and reduced hospitalisations post procedure. There is no feasible alternative for these patients and denying the technology to them in the UK seems completely unjustified. Further trial data will show whether this technology offers the functional mitral regurgitant patient any incremental benefit over and above intensive heart failure therapies.

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.

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Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	☒	**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	☐	**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).

of the healthcare industry	☒	**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:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

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 Advisor is responsible, but that is not received by the Specialist Advisor 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 Adviser 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.

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: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Percutaneous mitral valve leaflet repair for mitral regurgitation**
Name of Specialist Advisor:	Prof John Townend
Specialist Society:	**British Cardiovascular Intervention Society**

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

x Yes.

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

1.1 Does the title used above describe the procedure adequately?

x 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?

x Yes.

x 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 conventional approach to MV repair is open surgery. The balance between a surgical and a percutaneous approach can be a source of controversy.

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:

x I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

The procedure is currently not commissioned for NHS use, it is the subject of a CtE process which has yet to report.

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.

x 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:

I come across these patients regularly but refer very few due to the lack of a commissioned NHS service

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.

x I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

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.

x The first in a new class of procedure.

Comments:

Percutaneous intervention for aortic valve disease for cases at high risk from conventional surgery is well established with a range of devices. In contrast, such intervention for mitral valve disease is at a much earlier phase of development with many devices in early phase trials but only one device (mitraclip) which is both CE and FD approved an in regular use internationally

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

Surgical mitral valve repair

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.

x Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

No NHS commissioning, very few centres have funding to do this work

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)

Adverse events include procedural mortality (circa 5%), access site bleeding and vascular complications, pericardial tamponade, stroke, air embolism, device embolization, mitral leaflet detachment, residual atrial septal communication, infection, arrhythmia eg atrial fibrillation, need for emergency surgery to relieve complications.

Literature – Bleeding complications Am J Cardiol 2018; 121:94, Complications CCI 2015; 86: 728.

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Device infection/endocarditis, development of mitral stenosis, pulmonary embolism

4.2 What are the key efficacy outcomes for this procedure?

Rates of procedural success (immediate and 30 day), rates of achievement of less than moderate (grade 2 or lower) mitral regurgitation at 30 days and 1 year, rates of achievement of NYHA symptomatic status 1 or 2 (pre procedure usually 3 or 4) at 30 days and 1 year; rates of admission for heart failure by 1 year.

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

Yes. In the EVEREST II trial the primary event (freedom from death, need for mitral surgery or residual severe MR was 55% in the device group compared to 73% in the surgery group though this was mainly driven by need for subsequent MV surgery. Residual severe MR was present in 20%. The procedure replicates a surgical technique that is seldom used due to limited efficacy. The procedure should be seen as the first clinically useful percutaneous MV procedure but it is inferior to open surgical techniques and is used when surgery is considered to be a high risk procedure. As and when newer devices become available, mitraclip may be used less frequently.

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

Training is required by course, proctoring and mentoring. Facilities are those in a standard cardiac catheter lab, the procedure is suitable for sites with on-site cardiac surgery only because of the potential need for immediate surgery to relieve complications including device embolization and tamponade resistant to direct drainage. Decisions on appropriateness of mitraclip treatment must be made by a heart team which should include an expert mitral valve surgeon and a cardiologist experienced in the mitraclip procedure.

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

Many registries are underway in US, Germany , France and the UK; the only RCT I am aware of is COAPT (functional MR in heart failure)

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).

No

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

Current UK arrangements are ad hoc with no NHS commissioning and only a few centres performing the procedure using internal funding. In Europe and the US, the procedure is reimbursed and is becoming a standard approach to the management of severe MR in high risk surgical patients. Many UK centres with on-site cardiac surgery have the abilities and facilities required to do this procedure if funded.

5 Audit Criteria

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

Procedural success device implant with reduction in MR to grade 2 or less
MR severity at 30 days
30 day mortality
30 day morbidity
Complication rates (see above) in hospital and at 30 days

One year mortality
One year rate of grade 2 MR or less
One year admission rates for heart failure
QoL meaures at 30 days and 1 year

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:

Standard non specific QoL measures and disease specific (heart failure) measures eg Minnesota,

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:

In hospital and 30 day rates

6 Trajectory of the procedure

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

On clinical grounds this could and should quickly become a routine procedure (like TAVI) in surgical cardiac centres. Although imperfect, a large majority of patients will gain major benefit and hospital admissions and short term mortality will be reduced. The rate of uptake will depend on funding.

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

☐ Most or all district general hospitals.

x A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

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.

x Minor.

Comments:
The numbers of patients will not be huge, volumes may be similar or lower than TAVI numbers, maybe 100 procedures per centre per annum. The recovery time is short and there is little need for post procedural ITU care so hospital resource utilisation is low (and lower than equivalent surgical procedures).

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?

Should be assessed in the context of both the surgical MV repair comparator and in light of the very rapid progress in the development of new percutaneous MV devices. All major commercial device companies are developing mitral valve repair/replacement devices. By the time the mitraclip assessment is complete, newer devices including full percutaneous valve replacement may be available and may displace some mitraclip activity.

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 family[1] have a **personal pecuniary** interest? The main examples are as follows:

[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).

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	x	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	x	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**
Do you have a **non-personal** interest? The main examples are as follows:		
Fellowships endowed by the healthcare industry	☐	**YES**
	x	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	x	**NO**

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

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

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.

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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.

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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 Advisor is responsible, but that is not received by the Specialist Advisor 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 Adviser 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.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Percutaneous mitral valve leaflet repair for mitral regurgitation**
Name of Specialist Advisor:	Dr Mamta Buch
Specialist Society:	British Cardiovascular Intervention Society

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:

This title encompasses a spectrum of technical approaches and devices. The efficacy and safety of individual devices are examined separately and would need to be specified eg percutaneous mitral valve repair: direct annuloplasty, indirect annuloplasty, leaflet directed (edge-to-edge coaptation, plication, ablation), chordal implantation, LV remodelling.

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 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:

Percutaneous mitral valve repair: edge-to-edge technique. Recent reduction in procedural exposure due to funding constraints. Expertise and skills being supported through participation in trials.

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:

Work in a specialist valve centre with multidisciplinary team delivered patient selection and treatment. This includes assessment of patients potentially suitable for percutaneous mitral valve repair approach.

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:

Involved in original pivotal randomised controlled trial (EVEREST II – continued access). PI in RCT for percutaneous mitral valve repair: edge-to-edge, in functional MR

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:

Established outside UK in Europe and USA

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

Optimal medical therapy incl device/CRT in patients with heart failure who have secondary/functional MR
Mitral valve surgery in primary/degenerative MR

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:

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)

Literature:
Initial data EVEREST II RCT
Non-randomised data: ACCESS-EU
Meta-analysis:
A systematic review on the safetyand efficacyof percutaneous edge-to-edge mitral valve repair with the MitraClip system for high surgical risk candidates Munkholm-Larsen et al, Heart 2014;100:473–478

<u>30-day adverse events</u>
Mortality: 3%
Major vascular complication: 3%
Major bleeding (requiring transfusion): 5%
Stroke: 1-1.5%
Myocardial infarction: <1%
Pericardial tamponade:1-2%
Clip related chordal rupture: 1%
Clip embolisation: <1%

2. Anecdotal adverse events (known from experience)

Oesophageal tear/perforation due to trans-oesophageal echocardiography: <1%
Arterio-venous fistula: <1%

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

- Freedom of death
- Freedom from mitral valve surgery or re-intervention
- Freedom from re-hospitalisation due to heart failure
- Acute procedural success: ≤ 2+ mitral regurgitation post-procedure
- New York Heart Association (NYHA) class of breathlessness

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

Primary/degenerative MR: established RCT and registry data demonstrating efficacy of this procedure
Secondary/functional MR: subgroup of RCT and registry data signalling effectiveness in this group. Uncertainty about predictable benefit exists.

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

- Formal mitral valve programme with MDT process
- Heart failure service with MDT role
- Development of referral network with secondary care cardiology services
- Presence of on-site cardiac surgery
- Significant experience in mitral valve repair techniques (>50 per year per centre) with evidence of appropriate clinical results
- On-site trans-oesophageal (including 3D) echocardiography
- Diagnostic imaging facilities including CMR to assess valve and myocardial disease
- Implantation team made up of at least two operators who are dedicated to the programme – either two interventional cardiologists or one interventional cardiologist working with a cardiac surgeon

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

Yes: randomised controlled trials investigating percutaneous mitral valve repair: edge-to-edge leaflet, in patients with functional mitral regurgitation
COAPT: recruitment completed 2017
RESHAPE-HF2: ongoing recruitment
MATTERHORN: ongoing recruitment

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?

Uncertainty about role of percutaneous mitral valve repair, edge-to-edge, in functional MR.
European guidelines accept registry data are sufficient
US guidelines have only approved for degenerative MR, and await RCT data.

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

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:

- Acute procedural success: post-procedural ≤ 2+ mitral regurgitation
- 30-day and 1-year freedom from death, mitral valve surgery, and re-hospitalisation for heart failure
- New York Heart Association (NYHA) class of breathlessness
- Quality Of Life questionnaire: Kansas City Cardiomyopathy Questionnaire
- 6-minute walk test
- NT-proBNP/BNP assay

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:

30-day mortality
Major bleeding complication (VARC2 criteria): in-hospital and 30-day
Stroke: in-hospital and 30-day
Myocardial infarction: in-hospital and 30-day
Pericardial tamponade: in-hospital
Clip embolisation: peri-procedural
Single leaflet device attachment

6 Trajectory of the procedure

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

Relatively slow trajectory as referral pathways and networks are established, and team expertise developed.
Limited number with primary/degenerative MR group will be suitable for consideration.
Likely that only a small proportion of patients with heart failure and secondary MR would be treated, pending randomised controlled trial data.

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:

Number of centres need to ensure equity of access and also development of expertise and experience to ensure optimal outcomes.
10 centres to start with would likely achieve both aims to an acceptable level.

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:
Paucity of epidemiological data limit extrapolations for potential numbers.
Rough estimate of patients eligible for treatment = 300-400
These factors will influence the potential impact of this procedure on the NHS and use of resources:
Patients who would otherwise rely on medical therapy alone: increasing cost burden of palliating symptoms through primary and secondary care services.
Patients who undergo high risk mitral valve surgery: percutaneous mitral valve repair is significantly less invasive and does not require post-procedural intensive care unit support. Recovery is quicker and length of stay following intervention is on average 3 days.

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?

No

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.

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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.

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	☒	**NO**
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	☒	**NO**
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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**

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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.

[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).

Comments:
I have delivered speaker roles as expert faculty for national and international professional educational meetings.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair	**Professor Carole Longson, Director, Centre for Health Technology Evaluation.**

Jan 2016

Conflicts of Interest for Specialist Advisers

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These might include, but are not limited to:

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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

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- 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 Adviser 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.

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: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Percutaneous mitral valve leaflet repair for mitral regurgitation**
Name of Specialist Advisor:	Dr Robert Smith
Specialist Society:	British Cardiovascular Intervention Society

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 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:

I have carried out this procedure with the MitraClip device more than 100 times

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:

I have assessed more than 200 patients for percutaneous mitral valve repair

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:

Mostly retrospective analysis and audit.

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:

Percutaneous mitral repair has been performed in the UK for nearly 10 years (with the MitraClip device). A few centres have considerable experience. Its safety is well proven but the efficacy is largely confined to registry data and a single early RCT.

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

Surgical valve repair or medical therapy

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:

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)

Quoted risk of in hospital major adverse events and death is approximately 1%. Events include cardiac tamponade, stroke, damage to valve leaflets, clip detachment and embolisation and death (all less than 1%). Mitral stenosis is a theoretical risk but can be predicted and avoided by not deploying the clip after measurement of transmitral gradient.

2. Anecdotal adverse events (known from experience)

Few. Clip detachment is generally partial and can be remedied by placing another clip next to the first. I have never witnessed full detachment and embolization. Femoral access complications and bleeding are seen as with any transfemoral procedure.

3. Theoretical adverse events

Clip embolization. Very rare – not seen in our experience of more than 180 cases.

4.2 What are the key efficacy outcomes for this procedure?

Reduction in mitral regurgitation, improvement in NYHA class symptoms, improvement in 6 minute walk distance, Quality of life improvements (eg Kansas City Questionnaire) reduction in BNP, reduction in left atrial pressure including V-wave.

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

Yes. We are aware that this procedure is probably inferior to surgical repair in terms of efficacy. Consequently, we consider the procedure currently for patients unable to undergo surgery. There are currently doubts about the predictability and duration of response in patients with functional mitral regurgitation

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

Training is initially theoretical at the company training centre. Thereafter training is undertaken on live cases with proctor supervision (usually for the first 20-30 cases).

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

COAPT for FMR, should terminate soon. RESHAPE HF 2 is due to start recruiting in the UK soon

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?

Just the debate as to its use for FMR vs DMR. It is widely agreed that results are better in high volume centres

5 Audit Criteria

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

The efficacy endpoints entered above. The NICOR dataset for CtE is a comprehensive but manageable dataset

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:

As above. The ECHO and clinical data from the CtE NICOR dataset in addition to intra-procedural haemodynamic data (eg LA and PA pressures, mitral valve gradients).

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:

Acute: Tamponade, procedural death, stroke, MI. In hospital: Death, pulmonary oedema, major bleeding, vascular access complications, acute renal impairment. Up to 12 months: Death, stroke, Mitral stenosis, need for surgical mitral intervention, MR grade 2+, device related infection – endocarditis.

6 Trajectory of the procedure

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

Quickly if funding were secured

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:

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:

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?

This procedure has been shown to have a major symptomatic outcome on the lives of patients with mitral regurgitation. It is generally performed at a very low risk (1%). It is therefore potentially a very important option for those patients in whom surgical intervention is not justified – particularly patients with degenerative mitral regurgitation.

8 Data protection and conflicts of interest

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

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Comments:

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I currently have an ad hoc paid contract with Abbott Vascular to provide Proctoring support for MitraClip in other UK centres. Abbott Vascular have provided limited support with funding to the department at The Royal Brompton Hospital to employ a specialist cardiac nurse. This funding was in the form of a one-off payment to the Trust.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

Jan 2016

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