**7NATIONAL 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 insertion of a temporary heart pump to assist during high risk Percutaneous Coronary Intervention** |
| Name of Specialist Advisor: | Dr Farzin Fath- Ordoubadi |
| Specialist Society: | The British Cardiovascular Intervention Society (BCIS) |

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

☒ Yes.

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

## 1.1 Does the title used above describe the procedure adequately?

☒ Yes.

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

**Comments:**

Currently the main device that fit this description is the Impella device. The other indication for use is in patients with cardiogenic shock

## 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 device is relatively expensive, data is relatively limited and not many people have experience of using it. It is not currently commissioned Therefore opinion regarding its utility and indication varies amongst cardiologists

**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 was the first to implant the Impella device. This was in late 2007.. We currently implant between 15-20 units a year. I lead the service in my institution

**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 the lead for the service I get all the referral and am involve with patient selection in almost all the cases in our institution

**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:**

I have published case report using Impella device

## 3 Status of the procedure

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

☐ Established practice and no longer new.

☒ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☒ The first in a new class of procedure.

**Comments:**

Although the technology has been available since late 2007 uptake has been slow in UK as emerging data is limited, device is expensive and not commissioned. There is a significant learning curve required for optimal usage. This not only involve technical aspect of inserting of the device but also understanding the functionality and ability to troubleshoot if the device is not working properly. The device is more commonly used in countries such as USA and Germany.

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

There are several other percutaneous devices including IABP (though strictly speaking this is not an assist device, it is used as support in high risk PCI cases), and Heartmate PHP from Abbott (currently withdrawn form market but due to be re-launched with modification). ECMO is another comparator procedure but this is more relevant to patients in cardiogenic shock

### 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:**

I have trained two of my interventional colleagues and as the program expands we are planning to train more
.Currently we run an ad hoc on call service for use of this device in cardiogenic shock patients between 3 of us

## 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)

Potential adverse events with the Impella device are: Acute renal dysfunction, Aortic valve injury, Bleeding, cerebral vascular accident/Stroke, Death, Haemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury. The risk is greater in patients in cardiogenic shock. For example the risk of vascular complication for elective high risk group is around 1.9% (Protect II study) but this rises to around 9.7% in cardiogenic shock patients (USpell and Euroshock studies)

Following data is from USpell and Euroshock studies and is relevant to Impella device in cardiogenic shock group.

| | |
|---|---|
| Limb ischaemia | up 4% |
| Haemolysis | 7.5-10.3% |
| Stroke | 1.9% |
| Infection | 13% |
| Major Bleed | 20-28% |
| Vascular complication | 9.7% |

Often in high risk PCI the device is taken out at the end of the procedure or soon after whereas in context of cardiogenic shock it may be kept in for a few days.

2. Anecdotal adverse events (known from experience)

Please note most reported data relates to Impella 2.5. However most commonly used device in UK is the new Impella CP (3.5 L version). This uses a bigger size sheath (14F) for insertion therefore potential risk of vascular complication maybe higher

3. Theoretical adverse events

Ventricular rupture during insertion

### 4.2 What are the key efficacy outcomes for this procedure?

High risk patients can tolerate the procedure better with device inserted. It leads to better haemodynamic response. Patients are able to tolerate period of ischaemia and low blood pressure during the procedure for longer time. High risk cases are often associated with calcified lesions requiring devices such as rotablation. Use of

rotablation is better tolerated when LV assist device is present. Consequently, it is more likely that full revascularisation can be achieved. Full revascularisation has been shown to be associated with better clinical outcome including reduction in cardiac death, CVA, all cause revascularisation and combined end point of Death/CVA & MI (Synthax study). In Protect II study in which Impella was compared to IABP during high risk PCI primary endpoint was a composite of 10 events including Death, Stroke, MI, Repeat Revascularisation, Acute renal dysfunction, severe hypotension and angio failure

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

As eluted to above the data remains limited. The landmark study protect II was stopped before completion by steering committee indicating futility of achieving positive outcome but later on when the date was analysed with more patients Per protocol primary endpoint at 30 days was in favour of impella arm vs IABP and at 90 days the difference became statistically significant. The device requires substantial learning curve and when the first few patients were excluded the benefit was more obvious

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

The procedure needs to be performed by experience interventionalist. Even then there is a learning curve. This is largely to avoid vascular complication. In addition, there is a need to understand how to use this device optimally to achieve best haemodynamic response. This requires understanding of baseline patient's status, positioning of the device and troubleshooting when the device is not functioning properly. The supportive team also need to be familiar with the device. This include cath lab staff and staff on CCU and Cardiac ITU if the device is kept in after the procedure. A short period of proctoring is recommended.

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

Ongoing studies with this device is focusing on cardiogenic shock group not high risk PCI. Two current ones are:

- Door To Unloading With IMPELLA CP System in Acute Myocardial Infarction (DTU): https://clinicaltrials.gov/ct2/show/NCT03000270
- Danish Cardiogenic Shock Trial (DanShock): https://clinicaltrials.gov/ct2/show/NCT01633502

Most relevant recent published study was by Flatherty et al , Circ Res. 2017;120(4):692-700. This study demonstrated that impella may protect against acute kidney injury during high risk PCI.

**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?**

Many units start using this device in patients in cardiogenic shock rather than starting with high risk PCI cases that will allow time for better training and understanding. Financial aspect is not clear and cases are done ad hoc with no obvious protocol

## 5 Audit Criteria

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

This should include patients baseline characteristics including co-morbidities such as diabetes, PVD, Renal function. Coronary anatomy (synthax score included) , Lv function. Procedural aspects such as number of stents, use of rotablation, number of vessel treated. contrast and radiation dose, length of procedure. Acute success. In-hospital, 30 days and 1 yr outcome/complications. (Death, MI, re-admission and repeat vascularisation, CVA, vascular problem and major bleed)

**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:**

Usual methodology as with other devices.

**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:**

Vascular and major bleeding complications occur early and can be identified during in-hospital period

## 6 Trajectory of the procedure

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

This will depend on whether the device is commissioned or not.

**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:**

Use of this device should be confined to high volume centres that have experience in dealing with complex high risk patients with ready access to cardiac surgery, vascular and renal services

**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:**
High risk PCI cases constitutes 10-15% of case load. However, there is also 5% of acute MI that is associated with cardiogenic shock where this device maybe also used.

## 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?**

High risk patients often get greatest benefit from revascularisation. However, PCI, is withheld in many of these patients. Having a supportive LV assist device such as impella device that makes the procedure safer and more feasible will help more high risk patients to have access to coronary revascularisation.

## 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.

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 and in accordance with the Data Protection Act 1998.

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### 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** |
| | ☒ | **NO** |
| **Fee-paid work** – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice** | ☐ | **YES** |
| | ☒ | **NO** |
| **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry | ☐ | **YES** |
| | ☒ | **NO** |
| **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences | ☐ | **YES** |
| | ☒ | **NO** |
| **Investments** – any funds that include investments in the healthcare industry | ☐ | **YES** |
| | ☒ | **NO** |
| Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? | ☐ | **YES** |
| | ☒ | **NO** |

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

| | | |
|---|---|---|
| **Fellowships** endowed by the healthcare industry | ☐ | **YES** |
| | ☒ | **NO** |

[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).

**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 insertion of a temporary heart pump to assist during high risk Percutaneous Coronary Intervention** |
| Name of Specialist Advisor: | Dr Stephen Hoole |
| Specialist Society: | The British Cardiovascular Society (BCS) |

## 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:**

It has broader indications than just high risk PCI including treating cardiogenic shock and acute/ chronic left (and right if Impella RP is used) ventricular failure as a bridge to recovery or transplantation and for support during intractable VT +/- ablation.

## 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:**

Interventional cardiologists

**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 am in the process of setting this service up in our institution and as such have researched and written a business case justifying its use.

**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:**

Although I have not selected patients, our hospital intends to implant in acute heart failure/ cardiogenic shock patients that would be eligible for cardiac transplantation.

**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:**

Bibliographic research for a book chapter and to support our institutional business case for its adoption.

## 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:**

This device is CE marked and FDA approved with a substantial body of research to support its safe and efficacious clinical use in carefully selected patients.

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

Intra-aortic balloon pump (IABP), central / peripheral veno-arterial extra-corporal membrane oxygenation (V-A ECMO) and/ or surgical mechanical ventricular assist devices (VADs)
A key advantage of Impella is that it vents/ unloads a failing ventricle whereas ECMO increases the afterload and work which is undesirable.

### 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)

Vascular access site damage/ haematoma, haemolysis, stroke

2. Anecdotal adverse events (known from experience)

Mechanical interaction with mitral subvalvular apparatus causing MR

3. Theoretical adverse events

Device thrombosis

### 4.2 What are the key efficacy outcomes for this procedure?

Survival: bridge to recovery or transplantation

Haemodynamic: cardiac output, systemic blood pressure, pulse and systemic vascular resistance, pulmonary capillary wedge pressure

Reduced support: shorter ICU stay, fewer inotropic requirements

Biomarker evidence of end organ damage: creatinine or lactate

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

Duration of support provided by Impella may be limited to days

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

Cath lab based facilities – it requires fluoroscopic and echocardiographic screening for optimal safe implantation.
The implantation skills required are standard interventional cardiological skills – vascular access and crossing the aortic valve. This may need company/ proctor support initially.
Patients will need to be nursed in at least a level 2 setting by experienced critical care/ HDU nurses although perfusionist support is not required (unlike ECMO) and for these reasons it may be cheaper than ECMO if support is required for >48hrs.

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

Not that I am aware of.

**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).**

SHOCK II trial is the key paper.

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

Impella is not cheap - £8,500 per catheter (although the consoles are FOC) and therefore careful patient selection is mandatory. It is reimbursed through a temporary VAD tariff from NHS England but only in those patients who are transplant candidates (ie the Impella was implanted in recipients as a bridge to transplant or recovery ie they were transplant candidates).
In some trials there was selection bias (ie those most deserving e.g. severe cardiogenic shock were not recruited/ randomised) and this may have diluted the observed beneficial effect of Impella. In addition the benefit may be different for different indications.
The maximal duration of "temporary" Impella support is not clear.
Impella RP in RV failure and Impella for weaning of ECMO and in intractable haemodynamically compromising VT (requiring ablation) are emerging indications.
There is a competitor device from Thoratec/ Abbott vascular that is only CE marked and approved for short-term (hours) use in high risk PCI but not cardiogenic shock.

## 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:**

Survival for cardiogenic shock/ high risk PCI
Duration in ICU/CCU (bed days) and/or inotropic support
Haemodynamic right heart catheterisation data: CO/BP/SVR/PCWP/HR
Arterial blood gas: Oxygenation and acidosis
Biomarkers of CCF/ multi-organ failure: pro-NT BNP, lactate, creatinine, CRP
Quality of Life: NYHA class and SF-36

**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:**

Early: vascular damage, bleeding (BARC) and haemolysis measured by Hb drop, stroke and arrhythmia

Late: unlikely due to temporary nature of device implantation

## 6 Trajectory of the procedure

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

Will probably be needed in all heart attack centres plus transplant centres and roll out will likely be rapid. Indeed, roll out is already underway.

### 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:**

It is likely to be adopted by all large volume PPCI centres (>500 PPCI/yr).

### 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:**
The cost burden without rigorous control on case selection/ patient eligibility is likely to be large. In my opinion, the cost-benefit for high-risk PCI is prohibitive but it could be viable as a rescue for cardiogenic shock/ acute heart failure that are bridged to recovery or transplant. This latter group is likely to be smaller in number.

## 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?

Suggest engaging with Abiomed and Abbott vascular (Thoratec) who market these devices.

## 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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### 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** |
| | ☒ | **NO** |
| **Fee-paid work** – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice** | ☒ | **YES** |
| | ☐ | **NO** |
| **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry | ☐ | **YES** |
| | ☒ | **NO** |
| **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, | ☐ | **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).

| | | |
|---|---|---|
| meals and travel to attend meetings and conferences | ☒ | **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:**

**Fee-paid work:** I have a cardiology private practice and also provide professional advice/ educational material/ lectures for the health-care industry including Abbott Vascular, Boston Scientific, Astra Zeneca and Bayer. These are all non-specific to the product being assessed.

**Support by the healthcare industry:** I have received unrestricted educational research grants paid directly to my institution from Abbott Vascular, Gore Medical and Astra-Zeneca.

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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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.

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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)

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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.

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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

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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 insertion of a temporary heart pump to assist during high risk Percutaneous Coronary Intervention** |
| Name of Specialist Advisor: | Steven Tsui |
| Specialist Society: | Society of Cardiothoracic Surgeons of Great Britain and Ireland |

## 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:**

Temporary blood pump inserted percutaneously for haemodynamic support during high risk percutaneous coronary intervention.

## 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:**

This procedure would be carried out by Interventional Cardiologists who carry out percutaneous coronary interventions.

**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:**

**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:**

**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:**

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

### 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)

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

**4.2 What are the key efficacy outcomes for this procedure?**

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

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

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

**4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.**
**Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).**

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

## 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:**

**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:**

## 6 Trajectory of the procedure

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

**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?

## 8 Data protection and conflicts of interest

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

### 8.1 Data Protection

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**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.

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**Jan 2016**

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