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:	**Transcatheter implantation of a single chamber leadless cardiac pacemaker for patients at risk of bradyarrhythmias**
Name of Specialist Advisor:	Mr James Young
Specialist Society:	British Heart Rhythm Society (BHRS)

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: Transcatheter implantation of a single chamber leadless cardiac pacemaker for patients who are at risk of bradyarrhythmias or have bradyarrhytmias

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:

As a Cardiac Physiologist I am part of the team involved in implanting leadless Pacemakers and follow up these devices in clinic. I have wrote the guidelines for implanting and following up leadless pacemakers at my centre.

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)

Perforation, Cardiac Tamponade, Pericardial Effusion

Groin complications

Device Dislodgment

Death

All cited in El-Chjami et al. *(2016). 'Leadless Pacemakers'.* Am J Cardiol 2017;119:145-148

2. Anecdotal adverse events (known from experience)

None

3. Theoretical adverse events

DVT

Pulmonary Embolism

Surgery

4.2 What are the key efficacy outcomes for this procedure?

Prevention of brady arrhythmias and associated complications such as syncope, breathlessness and improved exercise tolerance for example.

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

No.

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

Experience gaining access to the venous system using a large access sheath.
Cardiothoracic surgical support
Company specific training and support
Adequate implanting lab with access to emergency pacing
Adequate team support including Cardiac Physiologists, nursing staff and radiographers sufficiently trained with the implantation technique for leadless pacemakers

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

Medtronic Registry

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?

No.

5 Audit Criteria

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

Standard patient demographics.
Indications for implant- symptoms, aetiology, pre device ECG
Date of implant
Screening time and Dose area Product
Operator & Supervising Operator name & GMC number
Model details and SN
Clinical complications
Late complications

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:

Absence of symptoms through patient assessment and follow up

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:

Potential early complications (within 4 weeks) Perforation, Cardiac Tamponade, Pericardial Effusion, Groin complications, Device Dislodgment, Death, DVT, Pulmonary Embolism, Surgery. Device extraction. Failure to sense, failure to capture

Potential Late complications (> 4 weeks) Infection, erosion, tamponade, failure to sense, failure to capture, battery failure,

6 Trajectory of the procedure

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

Use of leadless pacemaker implantation in my opinion will spread slowly and only to centres with adequate support such as territory centres who have the necessary experience and support in place to implant.

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?

Patient selection is important to ensure that the correct patients receive leadless pacemakers.
Good operator training should help maintain high standards and success rates.

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**
	☐	**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**

[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).

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.
Medtronic programmer training Honorarium: July 2016 & September 2017
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.

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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:	**Transcatheter implantation of a single chamber leadless cardiac pacemaker for patients at risk of bradyarrhythmias**
Name of Specialist Advisor:	Dr Paul Roberts
Specialist Society:	British Heart Rhythm Society (BHRS)

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:

There are currently 2 devices on the market that fulfil the definition of single chamber leadless pacing. These are the Micra device manufactured by Medtronic and the Nanostim device manufactured by Abbott Medical. I have been significantly involved with the former. I implanted the first device in the UK and so most of my expertise relates to this device though I have extensive knowledge of the other device but not first hand experience.

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 implanted just over 60 of these devices in the last 3 years.

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 regularly select patients for this procedure and then implant the device myself.

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 been involved in the pivotal IDE study of the Medtronic Micra leadless pacemaker and subsequent registry that has been published in the literature.

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:

I think it is difficult to clearly set it into anyone of these groups but the first is the most appropriate. The first devices were implanted in about 2013 with the first Micra device being implanted in December 2013. There have now been 11,000 Micra devices implanted worldwide and the safety performance has been very good. However long term follow up data beyond 3 years is unknown at this stage.

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

Single chamber transvenous pacemaker implantation though some patients who would normally have a dual chamber pacemaker would be eligible for this 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:

The numbers increasing of electrophysiologists trained in leadless pacing are increasinsing and so it might be that this figure has now exceeded 10%.

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)

   The paper below represents the most recent publication in the literature from the Micra leadless pacemaker. However, please not that I am an author on this publication. The key features of this registry publication are that there was a 99.6% successful implantation in 795 patients. The overall major complication rate was 1.5%. There were 13 major complications. These included 7 related to complications in the groin which is where the pacemaker is implanted from. There was one pericardial effusion and 2 events where the pacing threshold increased or there was dislodgement of the device. This complication rate compares favourably with conventional pacing where the rate has been reported variably between 4-8%.

   A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry. Roberts PR, Clementy N, Al Samadi F, Garweg C, Martinez-Sande JL, Iacopino S, Johansen JB, Vinolas Prat X, Kowal RC, Klug D, Mont L, Steffel J, Li S, Van Osch D, El-Chami MF.
   Heart Rhythm. 2017 Sep;14(9):1375-1379

   The Nanostim leadless pacemaker manufactured by Abbott Medical has less data available on it. In this manuscript the authors presented follow up data up to 12 months that showed excellent pacing outcomes. Previous studies of this technology have shown an implant success rate of 97% and a complication rate of 6%. There have been technological issues with the Nanostim device that have resulted in battery failure and inability for the device to communicate with pacemaker programmers. The device was withdrawn from the market when this was discovered. I understand that it will be reintroduced into clinical practice again soon once these issues have been resolved.

   Chronic performance of a leadless cardiac pacemaker: 1-year follow-up of the LEADLESS trial.Knops RE, Tjong FV, Neuzil P, Sperzel J, Miller MA, Petru J, Simon J, Sediva L, de Groot JR, Dukkipati SR, Koruth JS, Wilde AA, Kautzner J, Reddy VY.J Am Coll Cardiol. 2015 Apr 21;65(15):1497-504

   Permanent leadless cardiac pacing: results of the LEADLESS trial. Reddy VY, Knops RE, Sperzel J, Miller MA, Petru J, Simon J, Sediva L, de Groot JR, Tjong FV, Jacobson P, Ostrosff A, Dukkipati SR, Koruth JS, Wilde AA, Kautzner J, Neuzil P.Circulation. 2014 Apr 8;129(14):1466-71

2. Anecdotal adverse events (known from experience)

I do not have any other anecdotal adverse events experienced from my own practice. I have had a very good experience with this procedure with minimal complications and very good patient outcomes.

3. Theoretical adverse events

   There has been a lot of concern regarding the potential risk of pericardial effusion and cardiac perforation with leadless pacing. This has been seen with both the Nanostim device and the Micra device. During the initial experience with both devices the right ventricular apex was targeted for ideal device deployment. Subsequently there has been a change in the training to support deployment at the right ventricular apex as a safer location. Data from the original Micra study and the subsequent Registry data indicate that as the incidence of deployment at the septum has increased the risk of pericardial effusion and perforation has reduced.

4.2 What are the key efficacy outcomes for this procedure?

The evidence base and personal experience suggest that this is a procedure that can be performed reliably with a high success rate and with a complication rate that is lower than conventional pacing. There are some patients where conventional pacing is not possible e.g. occluded vasculature, recurrent infection, dialysis lines. These patients may face other major surgical approaches e.g. epicardial lead placement. Leadless pacing in this population is therefore very attractive.

Initial data suggest that the longevity of the leadless devices is better than conventional pacemakers with the median longevity of the Micra device projected to be in excess of 12 years. It is important to understand that this is a projection and the reality can be different.

Conventional pacemaker therapy has been plagued with complications related to pacemaker leads and the generator e.g. lead failure, infection, pneumothorax and lead displacement. Data from both Nanostim and Micra suggest that these are essentially eliminated. The cost savings of this to the NHS are likely to be very significant.

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

These devices are novel and untested beyond 4 years. There has been a major technical problem with the Nanostim device that has led to the devices being recalled and battery technology redesigned. Currently the Micra device does not appear to have had any technical issues. However, one has to be guarded in understanding this as there are only 4 years at most follow up of the first implants and some devices are projected to last 15 years.

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

The manufacturers of both devices have provided incredibly comprehensive training programs for this procedure. Most of my exposure has been to the Medtronic Micra device. Operators are selected on the basis of a very specific skill set. They receive on line didactic training followed by a 1-2 day training program that includes further training from an expert implanter followed by simulator training and then occasionally

the use of cadaver/animal models. It is my view that this training program has been, in part, responsible for the low complication rate seen with the Micra device.

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

There is a Post Market Registry for the Micra device that is a global registry. I am one of three chairs of this registry and represent the European arm. There is also representation from the United States and Japan. To date there have been more than 1,400 patients recruited to this registry. It is an ongoing study that aims to recruit approaching 2,000 patients and following them for the next 8 years. I recently presented updated data at the Asia Pacific Heart Rhythm Society congress in Japan in September. This demonstrated an ongoing highly successful implant rate along with a complication rate lower than conventional pacing. The vast majority of operators in this registry are first time implanters and so this suggests that this procedure is very safe in the hands of new implanters. I am very happy to provide further updated information on this registry if requested. The last data set that was published is described in the following publication:

A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry. Roberts PR, Clementy N, Al Samadi F, Garweg C, Martinez-Sande JL, Iacopino S, Johansen JB, Vinolas Prat X, Kowal RC, Klug D, Mont L, Steffel J, Li S, Van Osch D, El-Chami MF.
Heart Rhythm. 2017 Sep;14(9):1375-1379

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).

A real world experience with a leadless pacemaker: a comparison to the initial experience. Roberts et al. Presented to APHRS on 16th September 2017 (full presentation available if required)

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

There are some challenges in understanding the appropriate patient population that should be considered for this procedure. The data are highly supportive of this being appropriate for any patient that is being considered for a single chamber pacemaker. However, the cost of the devices is significantly higher than a conventional pacemaker and so specific patient populations are currently being targeted. Equally, some patients who would normally get a dual chamber pacemaker are receiving Micra due to the perceived benefits of not having a lead based system.

The dissemination of this procedure is largely being defined by industry by selecting the operators that they consider have the skill set to implant these devices. This may be considered controversial by those that do not have this skill set. However, it is my

opinion that the very low complication rate seen with this procedure may, in part, be due to this selection process.

5 Audit Criteria

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

A minimum data set would include patient demographics, implant indication, implant success rate and major complications at 30 days.

Further knowledge would be gained from other procedure specific data such as procedural time, duration of hospitalisation and comparison with pathways using conventional lead based pacemakers.

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:

Simple measures of hospitalisation and adverse events would be important. Quality of life assessments will be very important though I am not aware of any validated tools that could be meaningfully applied to this therapy. These are likely to be in development at the moment.

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:

These can be divided into early complications up to 30 days and long term up to the duration of the devices longevity. The initial registry and published data indicate that important outcomes to capture are: vascular access complications, pericardial effusion/perforation and device malfunction.

6 Trajectory of the procedure

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

It is my understanding that as the current data is so compelling in its efficacy and safety that there is a very high demand for operators to be trained. In the UK, it is currently being confined to large pacemaker implanting centres that have cardiothoracic surgical back up. I understand that there have been pilot studies in non-surgical centres. The current data suggest that this would be a procedure that is safe to implant in a non-surgical environment.

As it currently stands I would estimate that in 5 years 20% of pacemakers implanted in the UK might be leadless devices. This number is likely to increase significantly as dual chamber devices or single chamber devices that can synchronise with the atrium are developed.

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 currently being implanted in at least 15 UK centres that are mostly Teaching/University Hospitals. I think that it is inevitable that this will expand out to a District General setting in the near future.

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:
This is largely determined on how you define minor, moderate and major. If all single chamber pacemakers that are currently lead based became leadless in 5 years then I would suggest that this was moderate to major. It is my opinion that cost at the moment is the main driver for its uptake in the UK.

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?

It is my opinion that this technology represents the future of cardiac pacing and I would predict that in ten years time it will represent the default position for pacing. As a consequence I am sure that this is a procedure that would benefit from NICE assessing it.

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**
	☐	**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:

[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).

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:
I have consulted for Medtronic on their advisory groups for leadless pacemakers. I am also paid by Medtronic for time to train new implanters of leadless pacemakers and provide training material. In the last 12 months this has totalled £8,000.

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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2.2 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.

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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)

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These might include, but are not limited to:

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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:	**Transcatheter implantation of a single chamber leadless cardiac pacemaker for patients at risk of bradyarrhythmias**
Name of Specialist Advisor:	Dr Francis Murgatroyd,
Specialist Society:	British Heart Rhythm Society (BHRS)

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**

☐ 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 is firmly in the specialty of cardiac rhythm management

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:

Not in patients, but I have extensive clinical experience of similar procedures and some research experience

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:

I have some research experience of this procedure (several years ago, in a large animal facility in the USA). I was part of an Expert Advisory Group convened by the MHRA committee on the dissemination of leadless cardiac pacing technology, and drafted its guidance (pub. March 2017).

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?

Permanent single chamber pacemaker implantation with (most commonly) a transvenous endocardial lead, or (occasionally) a surgically implanted epicardial lead.

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)

Cardiac perforation 1-2% requiring surgery in up to half of cases, device dislodgement 1%, vascular access problems 2-5%. Complication rates have varied greatly between published studies. Good recent review by Lee JZ et al Trends in Cardiovascular Medicine 2017. Unpredictable battery performance and premature battery depletion (see field advisory notice by St Jude Medical), mechanical failure (detachment of docking button, see field advisory notice by St Jude Medical).

2. Anecdotal adverse events (known from experience)

Infection (rare and difficult to diagnose), failure of extraction.

3. Theoretical adverse events

Electronic failure, inability to capture or sense the heart. Endocarditis, embolization to pulmonary artery, device-device interaction. Inability to communicate with programmer

4.2 What are the key efficacy outcomes for this procedure?

Acute: percutaneous implantation without major complications and acceptable electrical parameters (pacing and sensing threshold).
Chronic: long-term mechanical integrity, lack of displacement from implant location, maintained electrical performance (acceptable pacing and sensing threshold, rate response to exercise, electronic performance, telemetry and programmability)

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

New battery technology, endocardial fixation mechanism mean that there will not be longterm efficacy data until clinical implants have been in place for several years. One manufacturer St Jude has suspended market release because of implant safety issues as well as device failures of at least two types, another Medtronic) seems to have had few post-implant problems.

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

The MHRA document drawn up by a panel of implanters and non-implanting experts gives detailed guidance on this. I have attached a copy in my email to Deonee Stanislaus

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

In addition to the major NEJM paper (Reynolds DW, Ritter P 2016) et al, both Medtronic and St Jude have established registries.

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).

Not aware of any recently

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

There is some concern that some patients may receive this new treatment rather than established pacing (with transvenous leads) because of the enthusiasm of implanters rather than any proven benefit. Indeed, some patients may be receving single chamber pacing using this technology where conventionally dual chamber pacing would be more appropriate. I think this probably varies by centre, and hope it is not too common.
My impression is that one manufacturer (Medtronic) is disseminating this technology in a very mature and cautious fashion, with careful selection of centres, maintenance of standards etc; while another (St Jude) may have been a little incautious in its initial dissemination of the technology, and got into difficulties with high complication rates as a result.
It should be mentioned that a third manufacturer (Boston Scientific) is planning to release a similar device (whose fixation mechanism is more akin to that of St Jude) possibly within the next year. Finally a startup company (EBR systems) is disseminating an ultrasound-powered leadless pacing system (WiCS-LV) for cardiac resynchronization therapy, on the basis of CE marking (for which only ~30 patient datasets were submitted). Uncontrolled market release of such a device would not be advisable.

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:

Short term: satisfactory implant (device placement without complications, satisfactory electrical performance (pacing and sensing thresholds, telemetry/programmability). Ability to mobilise without groin pain.

Medium – long term: continued satisfactory mechanical performance (no device detachment/breakage, no dislodgement); satisfactory electrical performance (pacing and sensing thresholds); device longevity/battery life; satisfactory electronic performance (stored data, ability to telemeter and programme etc). Lack of syncope. Patient reported outcomes could be collected but most pacing is for prognostic grounds or to prevent syncope and quality of life is somewhat less critical

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 complications (up to 1 week): cardiac perforation, tamponade, early dislodgement of device. Vascular access issues including groin bleeding, haematoma, AV fistula or pseudoaneurysm. As some of these issues can be trivial and some very serious, I would suggest that the threshold for reporting be that the complication requires intervention (drainage of pericardium, transfusion, thrombin injection/stenting etc) or prolongs hospitalization so that postop length of stay is > 1 night. This would be in line with reporting to national audit (NICOR)

6 Trajectory of the procedure

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

At present this procedure should be considered a niche, for patients in whom (i) single chamber ventricular pacing (as opposed to dual chamber pacing or cardiac resynchronization therapy, as per NICE and international guidance) is recommended, and (ii) in whom there is an explicit reason to prefer leadless pacing. Most commonly this would be patients with subclavian access problems or on haemodialysis. With accrual of data over the next 5 years, it may become clear that leadless pacing has clear benefits (especially lower infection risk) in which case it may become more widespread

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:
If this remains (as I think it should) a niche procedure with clear indications. Subsequently, depending on outcomes, it may become more widespread. In the long term (>5 years) technology may develop to deliver dual chamber pacing or cardiac resyncrhonization therapy via leadless pacing, in which case it could have a major impact.

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?

NICE will need to decide whether to include the EBR Wyse-LV technology in its appraisal, as well as the imminent Boston Scientific leadless pacemaker that will offer the additional feature of antitachycardia pacing.

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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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**
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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**

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:
In the last 2 years I have received payments for the following activities

[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).

- *Medtronic, Inc (Medical Advisory Committee for new defibrillator technology), speaker honoraria*
- *St Jude, Inc (Advisory Board), speaker honoraria – catheter ablation technology*
- *Boston Scientific (preclinical research) catheter ablation technology, Advisory Board (subcutaneous defibrillation)*

None of these were in any way related to leadless pacing technology but the companies concerned are the manufacturers of the devices relevant to this interventional procedure evaluation.

Personal non-pecuniary interest:

- *Council member, British Heart Rhythm Society*
- *Clinical lead for the national audit of cardiac rhythm management devices and ablation (NICOR)*
- *On executive of Arrhythmia Alliance, have presented to All-Party Parliamentary Group on Arrhythmias*
- *Member, MHRA Clinical Expert Advisory Group on Leadless Cardiac Pacing*

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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