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: tristan.mckenna@nice.org.uk

Procedure Name:	IP1012/2 Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death
Name of Specialist Advisor:	Mr Murgatroyd
Specialist Society:	**Royal College of Physicians**

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

☑ Yes.

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

1.1 Does the title used above describe the procedure adequately?

☑ Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☑ Yes.

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

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

Comments:

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

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

☐ I have never done this procedure.

☐ I have done this procedure at least once.

☑ I do this procedure regularly.

Comments:

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?

Implantation of (transvenous) implantable cardioverter defibrillator

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)

- *There is a substantial literature. Adverse events include device erosion/infection, inappropriate shocks. Occasional lead displacement. I'm not aware of a single death related directly to implant. Adverse events that are specifically related to transvenous implants (e.g. pneumothorax, haemothorax, cardiac perforation/tamponade, endocarditis and systemic infection) have not to my knowledge been reported in the literature for subcutaneous devices.*
- *Early experience was of (fairly high complication rates 16/118 patients) and higher frequency of inappropriate shocks (33 in 15/118 pts). However, improved surgical technique and programming halved these (Olde Nordkamp L et al JACC 2012;**60**:1933-9)*
- *Similar findings in early US experience for IDE study (Weiss R et al Circulation 2013;**128**:944-53)*
- *EFFORTLESS Study, {Lambiase, P et al European Heart Journal 2014} was first largescale registry*
- *Combined US (IDE) Study and European Registry (EFFORTLESS), total n=882 showed considerable falls in complications and inappropriate shocks between first and last quartile of enrolment. This reflected surgical experience and technique, and improved detection algorithms and programming. (Burke MC et al JACC 2015;65: 1605-15)*
- *Failure of therapy (shocks) appears to be acceptably low. Apart from references above latest EFFORTLESS registry data, n=985 showed high efficacy for treating both isolated episodes, and "storms", of ventricular tachycardia/fibrillation (Boersma, L et al, Late-Breaking trials session, Heart Rhythm 2016)*

2. Anecdotal adverse events (known from experience)
    - *See above. In addition, my clinical impression is that the published evidence may slightly underestimate the incidence of patient discomfort, and device explantation due to discomfort or erosion. This is due to the generator being approximately 2x the volume of modern conventional ICDs, and its location (in the axilla rather than anterior chest wall). However, this is only anecdote from local experience and informal talks with colleagues.*
3. Theoretical adverse events
    - *The device has not been shown to be as effective in preventing sudden cardiac death as conventional, transvenous ICDs. An RCT versus medical treatment would be unethical and no RCT versus conventional devices has been performed or is planned, using all-cause or arrhythmic mortality as an endpoint. The FDA in its wisdom decided that this was not necessary. The PRAETORIAN trial, currently recruiting, is randomising suitable patients to subcutaneous vs transvenous ICDs, but it is a noninferiority trial whose primary endpoints are inappropriate shocks and complications. (Am Heart J. 2012 May;163(5):753-760.e2)*
    - *Although the device has shown high efficacy for the episodes of ventricular tachycardia/fibrillation that it has <u>detected</u>, it is theoretically possible that it under-detects. Episodes that are not detected are not recorded by the device so there is no way of knowing this denominator. Conventional ICDs, on the other hand, have "monitor zones" and store a considerable amount of data*

that give some indication about VT/VF episodes that were not diagnosed by the device.

- *Unlike conventional ICDs, the device is incapable of delivering pacemaker therapy for bradycardia; nor does it record bradycardia episodes. It is possible therefore that patients are suffering or even dying because of such episodes. We only have indirect evidence that this is not the case (e.g. (Boersma, L et al, Late-Breaking trials session, Heart Rhythm 2016).*

4.2 What are the key efficacy outcomes for this procedure?

Detection and successful termination of ventricular tachycardia and ventricular fibrillation. Device related complications.

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

No. Available literature supports its efficacy (see references above)

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

Procedure needs to be performed in a cardiac catheter lab with full resuscitation facilities, as per British Heart Rhythm Society Standards document for implantable devices. Most centres perform implants under general anaesthesia for patient comfort (the induction of ventricular fibrillation, test shock, and post-shock pacing arguably cause more discomfort than the implant procedure itself). Implanters should be qualified and trained cardiac electrophysiologists (or, exceptionally, surgeons – esp in other countries). As the implant technique is very different from that of conventional transvenous devices, specific training and supervision of early cases is required, both to avoid complications and to maximise the likelihood of a successful implant (i.e. one that will deliver effective shocks). This is, for example, highly dependent on accurate tunnelling of the shock electrode and placement of the generator in a suitable location (1 cm out of position may result in a failed implant). The manufacturers are aware of these issues, and my experience is that the standard of training and support they offer is very high.

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

EFFORTLESS registry (now continuing to a second, long-term phase intended to capture both long term efficacy and complications related to device replacement at end of battery life).
PRAETORIAN trial – head to head against conventional devices, examining inappropriate shocks and device-related complications.

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).

Boersma et al late-breaking sessions at Heart Rhythm 2016 (proceedings of Heart Rhythm Society) gave latest update on EFFORTLESS study with important data on shock efficacy and frequency of upgrade to devices with pacing therapy.

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

Not to my knowledge

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):

- *Mortality: all-cause, cardiac, and arrhythmic.*
- *Quality of Life: probably EQ50D and SF30. NB EFFORTLESS has a major focus on QoL, led by a Dutch expert (see "Pedersen, S." AND "defibrillator")*
- *Cost/QALY (the device is considerably more expensive than its transvenous counterpart)*

5.2 Adverse outcomes (including potential early and late complications):

- *Major implant related complications include infection, erosion, pneumothorax and major bleeding, lead displacement. Any device re-intervention within the first year is a probable reflection of early or late device- or implant- related complication. It should be noted that death is a fantastically rare complication of ICD implants, and drowned out by the background mortaility in this group of patients, it is therefore probably not a useful "complication". NICOR is planning to report 1-year reintervention as an index of implant related complications.*

6 Trajectory of the procedure

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

- It is already fairly widespread. It is expected to replace a substantial proportion of single chamber transvenous defibrillators – I would guess eventually 30%. If the device becomes smaller, this proportion may be higher still. However, at present I imagine it only has 10-20% of the single chamber ICD market.

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:

- *Costs are somewhat higher than for conventional ICDs, and implants take a little longer. However, it is substitutional and does not treat a new group of patients.*

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?

The original model (S-ICD) had a relatively short battery life (we are changing them out typically after ~6 years). It would be relevant to know what concrete steps have been taken to provide longer device longevity in the current device (Emblem)

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:

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:

- *I was an investigator for the original "first in human" studies undertaken at Papworth Hospital for the then manufacturer (Cameron Health), leading to the NEJM publication and contributing to FDA approval*
- *I am an Investigator and on the Steering Committee for the Effortless Registry sponsored by Boston Scientific.*
- *I am an Investigator, and on the Steering Committee for a competing product under development by Medtronic.*
- *I have received no payment for any involvement as Investigator, though my department is reimbursed according to national guidance. I have received occasional honoraria (within established guidelines for "reasonable reimbursement") from Boston Scientific and Medtronic for work on Advisory Boards and Steering Committees. I am happy to detail these if required.*
- *For the last four years I have been a council member of the British Heart Rhythm Society, and as such have been involved in developing and maintaining national standards for the implantation of cardiac implantable electronic devices.*
- *For the last four years I have also been the clinical lead for the cardiac rhythm management (device and ablation) audits of the national cardiac audit programme, held by NICOR.*
- *I am also an advisor on cardiac rhythm management for the MHRA*

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: tristan.mckenna@nice.org.uk

Procedure Name:	IP1012/2 Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death
Name of Specialist Advisor:	Dr Rajappan
Specialist Society:	**Arrhythmia Alliance**

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:

Subcutaneous implantable cardioverter defibrillator insertion for treatment of life threatening arrhythmias and prevention of sudden cardiac death

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 is no inter-specialty controversy but perhaps some intra-specialty variation in opinion. Some specialists in this area will propose that there is a very selected patient population for whom this technology is applicable and supported by data, whilst others will be of the opinion that the technology is suitable for a much larger patient population. There is currently a randomised controlled trial addressing this specifically, but non randomised data already exists.

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 many of these devices and continue to do so.

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 select patients, counsel them, and then implant 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 reviewed literature pertaining to these devices and been involved in a randomised controlled trial with them.

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:

In my opinion this is now standard practice. There is still some debate on who these devices are most appropriate for.

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

A standard transvenous implantable cardioverter defibrillator is the closest comparator but the fundamental difference between the two devices is that one has a lead that is in the blood stream (the transvenous one) and one does not (the subcutaneous one).

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 number is steadily increasing and may now be over the 10% mark but not by much I believe.

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)

There are adverse events related to the procedure of implanting the device. This includes bruising, bleeding, pain, and infection. Once implanted there is a small risk of the device giving therapy (a shock) when it is not meant to. The incidence has been investigated in studies and now is very similar to the comparator device.

M.C. Burke et al. Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-year Results from a Pooled Analysis of the IDE Study and EFFORTLESS Registry. JACC 2015

2. Anecdotal adverse events (known from experience)

No other major adverse events other than those described in the literature.

3. Theoretical adverse events

No others theoretical ones.

4.2 What are the key efficacy outcomes for this procedure?

The device is intended to treat life

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

Some operators are concerned that the device cannot provide a certain type of therapy known as anti-tachycardia pacing, or pacing for slow heart rates (bradycardia) which a standard transvenous ICD can. But studies have shown that for the majority of patients that need an ICD for prevention of life-threatening arrhythmia then there is no need for these features. In terms of treating the life threatening arrhythmias themselves there are no concerns.

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

Most operators will receive training from the company that manufacture the device as well as support from the company by specialist representatives when the devices are implanted. They will also normally have a physician who is very experienced at implanting them assist in their first few procedures. There are specialist courses that provide training for these as well.

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

The most important studies are the PRAETORIAN study which is randomising the S-ICD with the transvenous ICD, and the UNTOUCHED study which will look at its use specifically in primary prevention ICD patients.

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).

None that are significantly different to the published literature.

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 significant controversy. Some operators will perform these procedures with just sedation but most use general anaesthetic. Also some use 2 incisions and some use 3 but these are relatively minor variations, rather than areas of controversy.

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):

Implant success, complication rates, appropriate and inappropriate therapy from the ICD. QoL is more difficult to assess as in many of these patients there life is normal and the device is precautionary so will not alter QoL unless there is an event.

5.2 Adverse outcomes (including potential early and late complications):

The well described ones are as outlined previously so implant complications and later complications including inappropriate shocks.

6 Trajectory of the procedure

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

It has already spread rapidly and will probably continue to do so. This will potentially be accelerated when the PRAETORIAN study reports, if it shows the S-ICD is at least as effective as a transvenous ICD.

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:

I would expect far more than 10 (there are already more than that) but probably not most district general hospitals. Those with larger cardiology units may well start to implant these as they already often implant the transvenous type.

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:
Patient eligibility will not change as they are already eligible for a transvenous ICD. But they will have a choice of device.

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 directly in line with guidance already issued by NICE on implantation of implantable cardioverter defibrillators. Traditionally this has been assumed to be transvenous devices but these subcutaneous ones would also be subject to many of the same criteria for patient selection.

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**

[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).

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:
I have received speaker fees, and sponsorship to attend meetings and run courses from the company (Boston Scientific) that manufacture the currently available S-ICD.

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: tristan.mckenna@nice.org.uk

Procedure Name:	IP1012/2 Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death
Name of Specialist Advisor:	Mr Lowe
Specialist Society:	**Royal College of Physicians**

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

x☐ Yes.

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

1.1 Does the title used above describe the procedure adequately?

x☐ Yes.

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

Comments:

2 Your involvement in the procedure - implanter

2.1 Is this procedure relevant to your specialty?

x☐ Yes.

x☐ Is there any kind of inter-specialty controversy over the procedure?

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

Comments:

Can be carried out potentially by non arrhythmia specialists
Paediatric S-ICD experience has not been favourable in some centres

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.

x☐ I do this procedure regularly.

Comments:

Implanter in both adults and children

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.

x☐ 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.

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

☐ Other (please comment)

Comments:

3 Status of the procedure

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

x☐ Established practice and no longer new.

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

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

Has been performed for a number of years but indications / results and complications still under evaluation in my opinion

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

Trans venous ICD implantation

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

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

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

☐ Cannot give an estimate.

Comments:

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)

Undersensing leading to delay in VF therapy

T wave oversensing leading to inappropriate shocks

2. Anecdotal adverse events (known from experience)

As above

Failure of post shock pacing due to oversensing leading to asystole

Lead and device infection

3. Theoretical adverse events

Undersensing and oversensing as ECG vector dependent

4.2 What are the key efficacy outcomes for this procedure?

Successful sensing of VF and delivery of shock to restore normal rhythm

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

No aside from above 1 and 2, also reported in transvenous devices

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

Cardiac catheter lab, full resuscitation facilities

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

'Untouched' – currently on hold I gather

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?

No

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):

Successful therapies for VF / VT

5.2 Adverse outcomes (including potential early and late complications):

Undersensing of VF/VT leading to inhibition of appropriate therapy
Inappropriate shocks
Lead displacement
Lead or device generator infection

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?
Limited number of patients suitable so spread not likely to be quick

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

☐ Most or all district general hospitals.

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

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

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

☐ Major.

x☐ 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

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

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

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

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

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

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

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

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

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

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

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

Comments:
Sponsorship personal and departmental by Boston Scientific to perform studies, attend meetings and for research fellowships
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

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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).

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2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

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2.2 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: tristan.mckenna@nice.org.uk

Procedure Name: IP1012/2 Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death

Name of Specialist Advisor: Professor Nicholas John Linker

Specialist Society: Royal College of Physicians
British Heart Rhythm Society

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

☒ Yes

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

1.1 Does the title used above describe the procedure adequately?

☒ Yes

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

Comments:

2. Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes

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

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

Comments:

I don't understand the second/third questions. There is no "inter-specialty" controversy but I presume you would still wish me to complete the questionnaire as the procedure is relevant to my specialty.

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:

2.2 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 not personally undertaken research in this area but I am aware of the literature and research studies that have been undertaken.

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?

S-ICD is now established as "standard" practice, however the comparator would be transvenous ICD implantation

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:

Difficult to know for certain but I would estimate over 10% of "device implanters" would implant these devices. This would clearly be less than 10% if one considered cardiologists overall.

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)

   No significant adverse events reported. There is a potential issue of inappropriate shocks due to T wave over-sensing and QRS morphology changes but this can be avoided to a large extent by appropriate screening of patients. There is always a small incidence of inappropriate shocks with any ICD.

2. Anecdotal adverse events (known from experience)

   No other significant adverse events specific to this technology.

3. Theoretical adverse events

   No other significant adverse events specific to this technology.

4.2 What are the key efficacy outcomes for this procedure?

Effectiveness of detection of ventricular arrhythmias
Effectiveness of defibrillation therapy
Low rate of inappropriate shocks

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

There is an issue that the device is capable of delivering shock therapy but does not, at present, have the ability to deliver anti-tachycardia pacing. This is likely to be resolved with the introduction of an additional leadless pacemaker.

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

The implant technique is quite different from conventional transvenous devices and it is recommended by the manufacturers that all implanters go on an approved training programme and receive appropriate proctoring for their initial procedures. There are no additional facilities required for a centre that already implants transvenous ICDs.

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

PRAETORIAN Trial – randomised comparison of subcutaneous versus transvenous ICDs.

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).

I am not aware of any.

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 issues.

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):

Indications for implant
Implant numbers per centre and per operator
Quality of life measures in terms of post-operative pain and cosmetic result

5.2 Adverse outcomes (including potential early and late complications):

Mortality
Early complications: lead reposition, haematoma
Late complications: Infection / reoperation within a year

6. Trajectory of the procedure

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

With current technology, this is likely to be a procedure that will slowly increase in numbers. It will be restricted by the size of the pulse generator and the lack of anti-tachycardia pacing ability. It is likely that the size of the pulse generator will be reduced and with the introduction of an additional leadless pacemaker, this may increase usage.

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:

I do not think there will be a major increase in demand in the short term. However, this procedure is not identifying a new group of patients but giving the option of an alternative type of ICD to patients who already warrant ICD implantation in line with NICE guidance TA314.

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?

Post CE-marking data from the manufacturers

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 purposes 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:

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, e.g. 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:

My department has received funding for a research fellow to the amount of £60,000 from Medtronic, a medical device manufacturer. This company does not manufacture S-ICDs.

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)

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.

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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

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: tristan.mckenna@nice.org.uk

Procedure Name:	IP1012/2 Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death
Name of Specialist Advisor:	Dr Stuart Harris
Specialist Society:	**Royal College of Physicians**

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:

Where this fits in the prevention of sudden cardiac death. The evidence for mortality benefit comes from transvenous endocardial defibrillators. May be better suited for younger patients and those with venous access issues.

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

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

√ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

The Cardiothoracic Centre which I lead provides this service for suitable patients.

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:

We run an MDT process to decide on an appropriate device for a patient to prevent sudden death

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:

Established as a procedure in clinical practice

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

A comparator would be a standard transvenous single chamber ICD

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:

We have 8 ICD implanters in my centre and 2 clinicians are active implanters of subcutaneous ICD's

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)

Inappropriate shocks for non-life threatening arrhythmias

Failed shock

2. Anecdotal adverse events (known from experience)

Failed shocks or failure to recognise a life-threatening arrhythmia

Infection

Discomfort around the device

3. Theoretical adverse events

Inability to reliably pace the heart if patients have a significant bradycardia after been successful cardioversion from a life theatening arrhythmia

4.2 What are the key efficacy outcomes for this procedure?

Prevention of sudden death
Treatment of life threatening arrhythmias
Failure to treat life-threatening arrhythmia

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?

The institution should be an experience ICD implanting centre and comply with BHRS guidelines

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

Boston Scientific Effortless Registry
Praetorian Trial (S-ICD vs Conventional transvenous ICD)

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?

Only if they are as efficacious as a conventional ICD. Praetorian Trial will help with this

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):

Survival compared to standard tranvenous ICD population
PROMS compared to standard transvenous ICD population

5.2 Adverse outcomes (including potential early and late complications):

Inapproriate shocks
Failure to cardiovert
Infection
Re-intervention rate
Death

6 Trajectory of the procedure

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

Depends on Registry and Trial data. Needs to show equivalence to transvenous ICD. Limited currently by cost, longevity and lack of pacing ability

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:

Generally limited to centres who already have an established ICD service consistent with BHRS guidance.

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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	√	**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 am an elected council member for BHRS.
I am paid to teach and lecture for Boston Scientific and Medtronic. I am paid to Chair an advisory board on cardiac rhythm management for St Jude Medical (Now Abbott)

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Thank you very much for your help.

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