

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

Transvenous implantation of a leadless cardiac pacemaker for managing bradyarrhythmias (IP1192)

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

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Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	Stephanie Parker
2. Name of organisation	AF Association
3. Job title or position	Assistant Projects & Comms Manager
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	AF Association is a UK registered charity providing information and support to individuals affected by, or involved in the care of, AF (atrial fibrillation); the most common arrhythmia. AF Association supports tens of thousands of AF patients, carers, and healthcare professionals. Funding is obtained through donations, sponsorship and grants.
<p>5. How did you gather the information about the experiences of patients and carers to help your submission?</p> <p>(For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)</p> <p>AF Association supports individuals and groups through our helpline, online forum, email, online communications and support groups held around the UK. This gives us the in-depth knowledge of the patient's experience at each stage of their 'journey'. In addition, we support and partner with a variety of healthcare professionals and groups to support our understanding, communications and information provided.</p>	

Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

On average there is a 2.6 year delay between symptoms and diagnosis of AF, leaving patients worried and unsure of what to do to prevent symptoms. This could be even longer for a bradyarrhythmia diagnosis, as it's less common and less well-known. Even at diagnosis, one in four AF patients do not receive or don't recall receiving any information about AF, with the problem intensified for older patients, as shown in studies. Worryingly, more than half of patients were unaware that AF increases their risk of stroke (AF-related stroke). This is reflected by carers and families "who are often suffering worse psychologically than the patient and who are completely in the dark", one carer describes.

This 'not-knowing' clearly has a huge impact on the patient, with our helpline receiving regular reports from patients feeling frustrated and depressed. On a daily basis, we are contacted by patients describing the worst part of having AF as the helplessness they feel, and the not knowing what to do. This often leads to patients stopping doing things they would normally do in case they have an attack.

"I had accepted there was nothing that could be done and accepted in my own mind that I was an invalid"

Of course another major impact on the patient's life is the symptoms they suffer, a patient describes that they are "convinced every time I feel a flutter that my time is up". This fear is widespread across many AF-patients, which results in the sufferer not going out, being less active, and ultimately reducing their quality of life.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are?

Patients feel a procedure such as this would enable them to do more of what they did prior to having the condition/diagnosis. This may be as basic as going back to work, going shopping, resuming a hobby or activity or simply having the confidence to leave the house. Ultimately patients hope implanting a pacemaker will restore their quality of life.

Disadvantages of the procedure or operation

8. What do patients (or carers) think the disadvantages of the procedure or operation are?

As with any operation/procedure, patients are concerned with associated risks such as bleeding or infection. However the nature of the leadless pacemaker reduces these risks.

Patient population
<p>9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.</p> <p>Individuals with bradyarrhythmia can experience debilitating symptoms, which the leadless pacemaker could reduce, so these individuals would be most likely to benefit from the pacemaker.</p>
Equality
<p>10. Are there any potential equality issues that should be taken into account when considering this topic?</p> <p>N/A</p>
Other issues
<p>11. Are there any other issues that you would like the Committee to consider?</p> <p>A key benefit of increasing implantation of these pacemakers would be to the NHS as this would reduce the need for long-term management of the condition, which may include A&E visits, GP visits and the need for psychological support.</p>
Key messages
<p>12. In no more than 5 bullet points, please summarise the key messages of your submission.</p> <ol style="list-style-type: none">1. Bradyarrhythmia is a scary and life-changing condition2. Symptoms of bradyarrhythmia can be debilitating3. The leadless pacemaker could restore the individual's quality of life4. The pacemaker could restore independence and the ability to work5. The treatment is cost-effective to the NHS

Thank you for your time.

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About you	
1. Your name	Trudie Lobban MBE
2. Name of organisation	Arrhythmia Alliance
3. Job title or position	Founder, Trustee & CEO
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	A-A is a collaboration of patients, carers, healthcare professionals, policy makers and all those affected by or involved in the care of cardiac arrhythmias. A-A is a registered charity and receives funds from Trusts, Grants, Foundations, individuals etc.
<p>5. How did you gather the information about the experiences of patients and carers to help your submission?</p> <p>We receive thousands of calls to our Helpline each year plus thousands of e mails, online forums, social media, our web site and correspondence – we gather the information and feedback from one to one and Patient Days. This enable us to be fully informed of the experience of patients and carers undergoing this treatment. We also work closely with healthcare professionals delivering this care and the issues they may face.</p> <p>(For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)</p>	

Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Living with bradycardia / bradyarrhythmia can be devastating and effect all aspects of everyday life. Bradyarrhythmia (an irregular, slow heart rhythm) often leads to loss of consciousness and subsequent injury from the fall as the patient losses consciousness. They can be banned from driving or operating machinery as well as unable to jon the armed forces or police/emergency services.

Severe cases of bradyarrhythmia result in the patient requiring a carer to safeguard them from injury and help with normal everyday functions.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are?

The advantages of this procedure is that it will provide the patient with a treatment restoring them back to a person able to work, function and be active without potential danger to themselves or others. They will be able to work and drive. They will no longer require a carer. This operation restores life to the patient, the carer, their family and loved ones. It is cost saving as the patient lead an active life and work, giving back to society rather than relying on the NHS and carers.

Disadvantages of the procedure or operation

8. What do patients (or carers) think the disadvantages of the procedure or operation are?

With any operation there are risks such as infection or bleeding however on this occasion the benefits of the procedure far outweighs any risk which is unlikely to occur.

Patient population
<p>9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.</p> <p>Those where bradyarrhythmias are severe enough to effect day to day living and activities will benefit the most as they will be able to lead a normal active life. However all patients with bradyarrhythmia will benefit as this technology ensures the heart is beating in rhythm, correcting the arrhythmia, and restoring and improving the quality of life for the patient and carer.</p>
Equality
<p>10. Are there any potential equality issues that should be taken into account when considering this topic?</p> <p>NO</p>
Other issues
<p>11. Are there any other issues that you would like the Committee to consider?</p> <p>Should be available to all who require this treatment, not just a few centres in the country.</p>
Key messages
<p>12. In no more than 5 bullet points, please summarise the key messages of your submission.</p> <ol style="list-style-type: none">1. Bradyarrhythmia is a life-changing condition2. Bradyarrhythmia can prohibit the patient from working, driving, fulfilling the career of choice3. This treatment will enable the patient to lead a normal, fulfilling life4. Both the patient, carer, family and loved ones will have an improved quality of life5. This treatment is cost-effective for the NHS and enables the patient to work and be independent

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