

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Consultation responses on review proposal**

**Review of TA88; Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block**

This guidance was issued February 2005 with a review date of September 2011.

**Background**

At the GE meeting of 20 September 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<p><b>Original proposal put to stakeholders:</b></p>	<p>A review of TA88 'Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block' will be planned into the NICE's work programme.</p> <p>A revised remit will be sought from the Department of Health to clarify the indications for which the technology will be appraised. The following revised remit is suggested: <i>"To appraise the clinical and cost effectiveness of dual chamber (atrial and ventricular) pacemakers for the treatment of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block."</i></p> <p>Recommendation is that we consult on this proposal.</p>
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<p><b>Rationale for selecting this proposal</b></p>	<p>According to the technology section of TA88, dual chamber pacemakers are indicated for use in the treatment of atrioventricular block in the absence of continuous atrial fibrillation, and in sick sinus syndrome with atrioventricular block. As noted in the post script to the guidance “more complex pacing indications” were not addressed. It appears that the committee recommended the technology in the patients for whom it was clinically indicated at the time; the ‘exceptions’ in the bulleted list relate to conditions for which the technology was not indicated or was contraindicated.</p> <p>The results of the DANPACE study suggest that the indications for dual chamber pacing may be expanded to include sick sinus syndrome without atrioventricular block. The current guidance recommends single chamber pacing when there is no evidence of impaired atrioventricular conduction.</p> <p>The remit for this appraisal is unusual in two ways; firstly it specifies the comparator technology and secondly it does not specify the indication for which the technology is to be appraised, but instead leaves it to the appraisal committee to advise on the patients for whom the technology would be particularly appropriate. Perhaps in line with the unusual nature of the remit, the guidance actively recommends the use of the comparator technology (single chamber pacing) for those in whom dual chamber pacing is not recommended. It would be helpful if the remit could be clarified to confirm the indications for which the technology will be appraised.</p>
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### Responses received during consultation

Respondent	Response to proposal	Details
British Cardiovascular Intervention Society	No Comment	The British Cardiovascular Intervention Society (BCIS) will leave to the British Cardiovascular Society (BCS) and Heart Rhythm UK to contribute to this re-appraisal.

Respondent	Response to proposal	Details
Healthcare Improvement Scotland	No Comment	Healthcare Improvement Scotland has no comment to make on the proposal to update the existing guidance, and we look forward to receiving further details in due course.
Association of British Healthcare Industries on behalf of members: Biotronik, Boston Scientific, Medtronic, Sorin, St Jude Medical	Disagree	<p>The ABHI on behalf of its members do not believe a review is warranted and we would like to draw your attention to the following points:</p> <ul style="list-style-type: none"> <li>• DANPACE does indeed provide the evidence that suggests Dual Chamber pacing is more beneficial than Single Chamber Single lead Atrial based pacing in patients without Atrio Ventricular block. <ul style="list-style-type: none"> <li>○ However advances in Dual Chamber pacing systems and programming options have overcome the issues identified by the DANPACE investigators, the evidence to support this statement can be found in the 2010 audit of current UK clinical practice contained within The National Clinical Audit for Cardiac Rhythm Management.</li> </ul> </li> <li>• In follow up to the above point, we would also like to draw your attention to pg31 of the 2010 National Clinical Audit for Cardiac Rhythm Management (attached), which clearly outlines the pacing mode prescription for implants taking place within the UK, as you will see from a total of &gt; 35,000 pacemaker implants in the UK only 201 were implanted for the single chamber, single lead atrial pacing mode. This recent data is consistent with previous audit findings by this group.</li> <li>• NICE TA88, historically and currently is not being implemented consistently in the NHS. The National Clinical Audit, suggests an implant rate of 700 pacemaker implants per million population. It is clearly illustrated on pg19 of the 2010 report (attached) that there is significant variation between Cardiac Networks in England, these findings are again consistent with previous audit findings.</li> </ul> <p>Given the limited impact this review would have on clinical practice (201 patients) within the NHS we feel that this would not be best use of the Institutes valuable time and resources. Additionally we believe that NICEs valuable resource could be directed to implementation efforts rather than a review of TA88, and we would welcome further discussions with NICE on the topic of implementation.</p> <p>In conclusion we do not feel a review of TA88 is warranted.</p>

Respondent	Response to proposal	Details
Heart Care Partnership (UK)	Agree	I am fully in sympathy with and approve of the NICE approach to this subject and I am certain that I have the backing of my membership. Anything which improves the health and outcome of heart patients has my full support.
Medtronic	Disagree	For the record please can it be noted that Medtronic are in agreement with those comments submitted by the ABHI and have no further additions to make.
Royal College of Nursing	No Comment	There are no comments to make at this stage on behalf of the Royal College of Nursing.
Arrhythmia Alliance	Agree	We are supportive of the views on this appraisal.

#### No response received from:

<u>Patient/carer groups</u>	<u>General</u>
<ul style="list-style-type: none"> <li>• Action Heart</li> <li>• Afiya Trust</li> <li>• Black Health Agency</li> <li>• Blood Pressure Association</li> <li>• British Cardiac Patients Association</li> <li>• Chinese National Healthy Living Centre</li> <li>• Counsel and Care</li> <li>• Equalities National Council</li> <li>• Grown Up Congenital Heart Patients Association</li> <li>• HEART UK</li> <li>• Muslim Council of Britain</li> <li>• Muslim Health Network</li> </ul>	<ul style="list-style-type: none"> <li>• Board of Community Health Councils in Wales</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• EUCOMED</li> <li>• Medicines and Healthcare Products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• NHS Alliance</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> </ul>

<ul style="list-style-type: none"> <li>• Network of Sikh Organisations</li> <li>• SADS UK</li> <li>• South Asian Health Foundation</li> <li>• Specialised Healthcare Alliance</li> <li>• The Stroke Association</li> </ul> <p><u>Professional groups</u></p> <ul style="list-style-type: none"> <li>• Association of Surgeons of Great Britain and Ireland</li> <li>• British Association for Nursing in Cardiac Care</li> <li>• British Association for Services to the Elderly</li> <li>• British Association of Surgical Oncology</li> <li>• British Atherosclerosis Society</li> <li>• British Cardiovascular Society</li> <li>• British Geriatrics Society</li> <li>• British Heart Foundation</li> <li>• British Hypertension Society</li> <li>• British Nuclear Cardiology Society</li> <li>• British Society of Cardiac Radiology</li> <li>• College of Emergency Medicine</li> <li>• National Heart Forum (UK)</li> <li>• Primary Care Cardiovascular Society</li> <li>• Royal College of Anaesthetists</li> <li>• Royal College of General Practitioners</li> <li>• Royal College of Pathologists</li> <li>• Royal College of Physicians</li> <li>• Royal College of Surgeons</li> <li>• Royal Society of Medicine</li> <li>• Society for Cardiological Science and Technology [BCS affiliated]</li> <li>• Society of Cardiothoracic surgeons</li> </ul>	<ul style="list-style-type: none"> <li>• Public Health Wales NHS Trust</li> <li>• Scottish Medicines Consortium</li> </ul> <p><u>Comparator manufacturers</u></p> <ul style="list-style-type: none"> <li>• None</li> </ul> <p><u>Relevant research groups</u></p> <ul style="list-style-type: none"> <li>• Antithrombotic Trialists' (ATT) Collaboration</li> <li>• British Society for Cardiovascular Research [BCS affiliated]</li> <li>• Cardiac and Cardiology Research Dept, Barts</li> <li>• Cardiovascular Diseases Specialist Library (CVDSL)</li> <li>• Cardiovascular Research Initiative, University of Oxford</li> <li>• Cochrane Heart Group</li> <li>• Cochrane Peripheral Vascular Diseases Group</li> <li>• Cochrane Stroke Group</li> <li>• CODA</li> <li>• European Council for Cardiovascular Research</li> <li>• MRC Clinical Trials Unit</li> <li>• National Heart Research Fund</li> <li>• National Institute for Health Research</li> </ul> <p><u>Assessment Group</u></p> <ul style="list-style-type: none"> <li>• Assessment Group tbc</li> <li>• National Institute for Health Research Health Technology Assessment Programme</li> </ul> <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> <li>• National Clinical Guidelines Centre</li> </ul>
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<ul style="list-style-type: none"><li>• United Kingdom Clinical Pharmacy Association</li><li>• Vascular Society</li></ul> <p><u>Others</u></p> <ul style="list-style-type: none"><li>• Department of Health</li><li>• NHS Westminster</li><li>• Trafford PCT</li><li>• Welsh Government</li></ul>	
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