NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of 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. A review proposal for TA88 was carried out in September 2011, and following this, a second review proposal was carried out

Background

At the GE meeting of 19 June 2012 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.

Proposal put to consultees:	TA88 should be withdrawn in full and the existing funding direction removed.
Rationale for selecting this proposal	A limited amount of responses were received during the initial consultation on plans to review the guidance, and these were equally divided between support for and opposition to the review. One stakeholder requested that a review is not undertaken because only a limited number of patients (around 200) are currently receiving single-lead atrial pacing so an update would only potentially affect a small population. This suggests that the use of dual chamber pacing has already expanded to include the additional patients for whom the evidence suggests it might be indicated and that there may be little value in an update of the appraisal even though the evidence suggests that the recommendations require update.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	TA88 should be updated. The update should focus on the populations identified as excepted from the circumstances for using dual chamber pacing recommended in TA88.
Rationale for selecting this proposal	The previous proposal for reviewing this guidance was that it should go forward following the request of an updated remit from the Department of Health. This was to clarify the indications for which the technology would be appraised (this was not specified in the original remit) and to remove the comparator from the remit (consistent with other technology appraisal projects). Consultees disagreed with this proposal because they believed very few patients would be affected and therefore carrying out a review would not be a good use of resources. Consultees indicated that clinical practice has moved on to expand the use of dual chamber pacing in line with the evidence in the absence of updated technology appraisal guidance. Consultees now indicate that they would wish to preserve the funding direction for dual chamber pacing without updating the guidance by moving TA88 to the static list. This appears to be based on an assumption that the provision of pacing services would be reduced in the absence of the funding direction The results of the DANPACE study indicate that the recommendations require update in relation to the exceptions to the current positive recommendations for the use of dual chamber pacing. There is no requirement to review the evidence for the population for whom dual chamber pacing is currently recommended

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Association of British Healthcare Industries (on behalf of: Biotronik UK, Boston Scientific, Medtronic, Sorin Group UK, St Jude Medical UK)	Disagree	**Summary** In August 2012, the Institute issued a proposal that "….TA88 will be withdrawn in full and the existing funding direction removed". We believe that this is an inappropriate course of action. More than 22,000 patients receive dual-chamber pacemakers every year under the current TA88 guidance and withdrawing it would place these patients at risk of receiving poorer quality care that is less cost effective. We propose a hierarchy of preferred options from those that are available to the Institute. Our preference is that this guidance be designated as 'static'. Our less favoured option is that a full review should be undertaken. The rationale for our proposal is given below.	Keeping TA88 on the static list in not acceptable because new evidence (the results of the DANPACE study) indicates that the recommendations require update in relation to the exceptions to the current recommendation for dual chamber pacing.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Association of British Healthcare Industries (continued)		1. Withdrawal of TA88 could reduce the quality of care and introduce inequalities. Currently, TA88 ensures that >35,700 patients receive pacemaker implants, more than 22,000 of which are dual-chamber. Withdrawing this guidance would place these patients at risk of receiving poorer quality of NHS care that is less cost effective and in contradiction of the evidence, due to the perception that other treatments are easier to administer or potentially cheaper. Should this occur, mortality and long-term conditions objectives within the NHS Outcomes Framework could also be compromised. Furthermore, the 2010 National Clinical Audit for Cardiac Rhythm Management suggests that there is significant age-related and regional variation in the prescription of dual chamber pacemakers within the NHS. This inequality would only be exacerbated should the guidance be withdrawn.	TA88 was about the comparison of dual and single chamber pacing, not about the cost effectiveness of pacing services as a whole. In the original remit and scope for TA88, the sole comparator for dual-chamber pacemakers was single-chamber pacemakers.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Association of British Healthcare Industries (continued)		2. Review of TA88 would represent a disproportionate use of resources. We recognise that a sub-recommendation of TA88 is inconsistent with current clinical evidence, namely the statement that single-chamber atrial pacing is appropriate for patients with sick sinus syndrome and no evidence of atrioventricular block. Since the publication of TA88, the DANPACE study has shown that dual-chamber pacing is more beneficial for these patients. However, page 31 of the 2010 National Clinical Audit for Cardiac Rhythm Management (attached), records that only 201 pacemakers were implanted in single chamber, single lead atrial pacing mode. This shows that the majority of patients currently receiving pacemakers – including those with sick sinus syndrome and no evidence of atrioventricular block (that are the centre of concern in this review proposal) – are already being treated with dual-chamber devices. Furthermore, some of these 201 patients may not be suitable for dual-chamber for co-morbidity or frailty reasons, so the number of patients impacted could be even smaller. Whilst we understand that disparity between the Guidance and current evidence may not be ideal, it would seem to be a disproportionate use of resources to conduct a review that would not impact on clinical practice.	Comment noted. Because only a minority of patients are receiving a single-chamber pacemaker, carrying out a full review would not offer value to the NHS. The guidance will be updated only in relation to the exceptions to the current recommendation for dual chamber pacing.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Association of British Healthcare Industries (continued)		3. Efforts to promote more consistent implementation of the current TA88 would be a more productive use of resources. Page 33 of the 2010 National Clinical Audit for Cardiac Rhythm Management notes that there is still under-utilisation and variation in the rates of pacemaker implantation: "The national average for atrial-based pacing in SSS (NB: sick sinus syndrome) is 80%. However, the rate in individual pacing centres varies from 7% to 100%. The target rate is a 100%." We believe that resource use could be more productive, and health outcomes more efficiently improved, by focusing efforts on complete implementation of the existing TA88 to reduce the historical regional variation that continues to exist.	TA88 was about the comparison of dual and single chamber pacing, not about the cost effectiveness of pacing services as a whole. NICE has provided implementation tools for use with TA88. The responsibility for using these to successfully implement the guidance since it was published in 2005 lies with local NHS organisations.
Association of British Healthcare Industries (continued)		4. Published processes must be followed. The Institute's 'Guide to the Multiple Technology Appraisal Process' (October 2009) does not list 'withdrawal of the guidance and the existing funding direction', which has been proposed for TA88, as an option in the review process. We therefore propose that this guidance be designated as 'static'. If after further consideration of the evidence and process, the Institute is unable to place TA88 on the static list, then we would recommend a full review is planned into NICEs work programme.	Technology appraisal guidance is withdrawn, for example, if it is superseded by an update in a clinical guideline.

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Department of Health	No comment	The Department of Health will not be submitting any substantive comments regarding NICE's proposals.	Comment noted. No action required.
Arrhythmia Alliance	Disagree	As requested we are submitting comments regarding the proposed withdrawal of NICE Guidance TA88 and the removal of the existing funding direction which we believe will be detrimental to patient care and access to appropriate treatment. Currently the UK lags behind its European neighbours with one of the lowest implant rates and well below recommended guidelines. Geographical variations across England and Wales (www.devicesurvey.com) demonstrate the need and implementation of these guidelines. If TA88 is withdrawn in full, the lack of guidance for commissioning pacemaker services will be lost and therefore detrimental to patient services and care. Not only will this impact on the individual patient and their family but also be detrimental to the work being undertaken to improve implant rates across the country and working towards removing the 'postcode lottery' effect. The withdrawal of TA88 and the associated funding direction will have a direct impact on patients suffering with bradycardia. We would urge you to reconsider.	New evidence (the results of the DANPACE study) indicates that the recommendations require update. The guidance will be updated only in relation to the exceptions to the current recommendation for dual chamber pacing. TA88 was about the comparison of dual and single chamber pacing, not about the cost effectiveness of pacing services as a whole. NICE has provided implementation tools for use with TA88. The responsibility for using these to successfully implement the guidance since the guidance was published in 2005lies at the local level.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Heart Rhythm UK	Disagree	We write with concern at the proposed withdrawal of NICE Guidance TA88 and the removal of the existing funding direction. We believe that this may have unintended deleterious consequences on the provision and quality of pacemaker services across England and Wales. **Background:** Guidance TA88 was originally issued in 2005. Its conclusions, based on the data available at the time, were broadly in line with international professional recommendations. Subsequent review updates in 2007 and 2010 found that formal review was not necessary because of the lack of new evidence. However, the results of a large randomized study published in 2011 (DANPACE) found that the current recommendations for a subgroup of patients were inappropriate. Specifically, in patients with sick sinus syndrome and no atrioventricular block, TA88 recommended (and international guidance permitted) implantation of a single chamber atrial pacemaker. The DANPACE investigators found that this resulted in an increased frequency of atrial fibrillation, and a doubling of the reoperation rate, when compared with implantation of a dual chamber pacemaker. They concluded that these patients should therefore routinely be implanted with dual chamber pacemakers.	New evidence (the results of the DANPACE study) indicates that the recommendations require update. The guidance will be updated only in relation to the exceptions to the current recommendation for dual chamber pacing. NICE has provided implementation tools for use with TA88. The responsibility for using these to successfully implement the guidance lies at a local level.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Heart Rhythm UK (continued)		In fact, professional practice had anticipated these findings: the majority of patients in England and Wales with sick sinus syndrome (with or without atrioventricular block) already receive dual chamber pacemakers. Only approximately 200 patients per year are implanted with single chamber atrial pacemakers, probably for very specific individual reasons. **The current proposal:** It was felt therefore that revision of TA88, while bringing national guidance in line with current clinical evidence, would have little impact on clinical practice. Rather than conduct such a revision, it has been proposed to simply withdraw TA88 in full. Heart Rhythm UK understands the wish to avoid the process of a full review. However, we believe that the withdrawal of TA88 and the associated funding direction could have a significant deleterious impact on the treatment of patients with bradycardia. TA88 has provided an invaluable benchmark against which to examine practice in England and Wales. Since its issuance, the overall provision of pacemakers of the correct type (single/dual chamber) has improved considerably across England and Wales. However, implantation rates remain well below the recommended level (and the European average), and there remain considerable geographic variations (annual National and Network reports from the national database, available from NICOR website).	In the original remit and scope for TA88, the sole comparator for dual-chamber pacemakers was single-chamber pacemakers. The cost effectiveness of pacing services as a whole was not appraised and the guidance cannot be regarded as a benchmark for examining the overall provision of pacemakers. The guidance will be updated only in relation to the exceptions to the current recommendation for dual chamber pacing.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Heart Rhythm UK (continued)		Our concern is that following the withdrawal in full of TA88, there would be no guidance against which to measure centres whose clinical performance is poor, and that commissioning of appropriate pacemaker services may also be affected. This could result in a reversal of national progress towards the appropriate level of provision of a well-established and highly cost-effective treatment, and increasing inequality of access. We feel that the best response to the changed evidence base (largely DANPACE) would be a revision or addendum to TA88, limited to the subgroup of patients with sick sinus syndrome and no atrioventricular block. A second best option would be to simply retain TA88 unchanged on the static list, with no plans for review unless significant new data appear (none is immediately anticipated). The proposed full withdrawal of TA88 and the associated funding direction, though understandable, could have significant unintended consequences.	TA88 compared the costs and effectiveness of dual chamber pacing with single chamber pacing. It does not give guidance on the appropriate level of provision of services against which providers can be assessed. The guidance will be updated only in relation to the exceptions to the current recommendation for dual chamber pacing.

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Medtronic	Disagree	We are not in support f the institutes proposal to withdraw guidance TA88 and the associated funding direction. We believe to do so would introduce further inequities in accessing this cost effective intervention. These inequities have been consistently highlighted by the professional bodies in the CCAD/Device Survey Annual report. Medtronic propose that TA88 should be placed onto the 'static' list. Further rationale for the static list recommendation are contained within the response submitted by the ABHI on behalf of the industry consultees, therefore can it be noted that Medtronic are in full agreement with those comments, and these comments should also be taken as our own submission	Comment noted. (see response to APHI)
Boston Scientific	Disagree	We fully supports the response and comments from the Association of British Healthcare Industries (ABHI).	Comment noted. (see response to APHI)
St Jude Medical	Disagree	In response to the Institute's proposal to withdraw TA88, following consultation on the merits of conducting a review of this guidance, St Jude Medical UK supports the ABHI position that neither withdrawal or review would be the most appropriate course of action. We further support the Association's rationale behind this position and wish to highlight that designation of TA88 as 'static guidance' would be our preferred outcome.	Comment noted. (see response to APHI)

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Nursing	No comment	Feedback received from nurses working in this area of health suggest that there are no additional comments to submit on the review proposal of the above appraisal	Comment noted. No action required.
STARS	Disagree	On behalf of patients who suffer with bradycardia I submit comments as requested. Patients with slow heart rhythms benefit from duel chamber pacemakers and studies have shown their quality of life is greatly improved – restoring the patient back to a person. Unfortunately for many the access to treatment will depend on where they live due to limited access to services across England and Wales. If these guidelines are removed and the associated funding even fewer patients will receive this potentially life-saving and life-enhancing treatment. Patients are already disadvantaged from their European counterparts as implant rates are well below suggested guidelines in the UK, the removal of TA88 will only make matters worse for these patients. Clinical evidence exists proving the benefits of duel chamber pacemakers and the advantages to those suitable to receive this treatment. To remove the associated funding will only act as a further barrier to patients receiving appropriate treatment. We recommend that TA88 remains as is until clinical evidence dictates otherwise.	Keeping TA88 on the static list in not acceptable because new evidence (the results of the DANPACE study) indicates that the recommendations require update. However, carrying out a full review of all the recommendations would not offer value to the NHS. because only a minority of patients are currently receiving single-chamber pacemakers. NICE has provided implementation tools for use with TA88. The responsibility for using these to successfully implement the guidance lies at a local level.

No response received from:

Patient/carer groups

- Action Heart
- Afiya Trust
- Black Health Agency
- Blood Pressure Association
- British Cardiac Patients Association
- Counsel and Care
- Equalities National Council
- Grown Up Congenital Heart Patients Association
- Heart Care Partnership (UK)
- HEART UK
- Muslim Council of Britain
- Muslim Health Network
- Network of Sikh Organisations
- SADS UK
- South Asian Health Foundation
- Specialised Healthcare Alliance
- The Stroke Association

Professional groups

- Association of Surgeons of Great Britain and Ireland
- British Association for Nursing in Cardiovascular Care
- British Association for Services to the Elderly
- British Association of Surgical Oncology
- British Atherosclerosis Society
- British Cardiac Intervention Society
- British Cardiovascular Society
- British Geriatrics Society
- British Heart Foundation

General

- Board of Community Health Councils in Wales
- British National Formulary
- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- EUCOMED
- Healthcare Improvement Scotland
- Medicines and Healthcare Products Regulatory Agency
- National Association of Primary Care
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Comparator manufacturers

- None

Relevant research groups

- Antithrombotic Trialists' (ATT) Collaboration
- British Society for Cardiovascular Research [BCS affiliated]
- Cardiac and Cardiology Research Dept, Barts
- Cardiovascular Diseases Specialist Library (CVDSL)
- Cardiovascular Research Initiative, University of Oxford
- Cochrane Heart Group
- Cochrane Peripheral Vascular Diseases Group
- Cochrane Stroke Group

• British Hypertension Society • British Nuclear Cardiology Society • British Society of Cardiac Radiology • College of Emergency Medicine • National Heart Forum (UK) • Primary Care Cardiovascular Society • Royal College of Anaesthetists • Royal College of General Practitioners • Royal College of Pathologists • Royal College of Physicians • Royal College of Surgeons • Royal Society of Medicine • Society for Cardiological Science and Technology [BCS affiliated] • Society of Cardiothoracic surgeons • United Kingdom Clinical Pharmacy Association • Vascular Society <u>Others</u> • NHS Westminster • Trafford PCT • Welsh Government	• CORDA • European Council for Cardiovascular Research • MRC Clinical Trials Unit • National Heart Research Fund • National Institute for Health Research <u>Assessment Group</u> • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme <u>Associated Guideline Groups</u> • National Clinical Guidelines Centre <u>Associated Public Health Groups</u> • None

GE paper sign-off: Janet Robertson, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: Linda Landells

Project Manager: Andrew Kenyon

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