NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Technology Appraisal Review Proposal paper

Review of 324; Dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block

Original publication date:	November 2014
Review date	November 2017
Existing recommendations:	Recommended To see the complete existing recommendations and the original remit for TA324, see Appendix A.

1. Proposal

The guidance should be transferred to the 'static guidance list'.

2. Rationale

No new evidence has been published since NICE technology appraisal guidance 324. Therefore it is proposed that TA324 is moved to the static list.

3. Summary of new evidence and implications for review

Has there been any change to the price of the technology(ies) since the guidance was published?
The acquisition cost of pacemakers depends on the particular model. Prices are commercial in confidence and subject to commercial tender processes and subsequent contracts with NHS Trusts. In the original guidance, no list price for devices used in the included trials was available from the different manufacturers and therefore a weighted average of episode costs associated with relevant HRG codes (NHS reference costs 2012/13) were used. A threshold analysis conducted by the Assessment Group in the original guidance indicated that the price difference between dual- and single-chamber atrial pacemakers had to be increased substantially, and to a level unlikely to be seen in clinical practice, before dual-chamber pacemakers would not be cost-effective (≥ £20,000 per QALY gained). It is therefore unlikely that any

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price changes as a result of the tender process would lead to a change in the recommendations

Are there any existing or proposed changes to the marketing authorisation that would affect the existing guidance?

There are no changes or proposed changes to the CE marking that would affect the existing guidance.

Were any uncertainties identified in the original guidance? Is there any new evidence that might address this?

The original guidance compared permanent implantable dual-chamber pacemakers with single-chamber atrial pacemakers in people with symptomatic bradyarrythmias due to sick sinus syndrome without atrioventricular block. The evidence for clinical effectiveness came from 6 randomised controlled trials (3 parallel group trials (Albertsen 2008, DANPACE 2011, Nielsen 2003), 3 crossover trials (Gallic 1994, Lau 1994, Schwaab 2001)). The crossover trials were small and had limited follow-up and the parallel trials were larger, in particular DANPACE (2011), which was a large, high-quality trial that provided the best available evidence base for the guidance.

In the original guidance the committee concluded that there was uncertainty about:

1. the difference in quality of life because the evidence, which for most measures showed there were no statistically significant differences between dual- compared with single- chamber atrial pacemakers, came from only 2 relatively small trials with limited follow-up.
2. the base-case ICER (£6000/ QALY gained) because there is no difference in the effectiveness of dual-chamber pacing for outcomes including heart failure, and also because a list price for devices was not available for use within the economic model (average costs reported within the appropriate HRG codes were used instead, which incorporated the costs of device and implantation).

Since the original guidance was published, no new published trials and no ongoing trials have been identified that compared dual-chamber pacemakers with single-chamber atrial pacemakers in people with symptomatic bradyarrythmias due to sick sinus syndrome without atrioventricular block. It is therefore not possible to address the uncertainty around the difference in quality of life between dual- and single-chamber atrial pacemakers.

One of the manufacturers (Medtronic) has provided their average selling price for Bradycardia Dual Chamber devices for the financial year 2016/17 ([redacted]). In 2013, the Association of British Healthcare Industries estimated an average cost of dual-chamber pacemaker devices to be £1,265. Medtronic's current average selling price therefore represents a [redacted] in the average selling price to the NHS. Although this is information from only one company, given these products are subject to regular commercial tenders, and the original threshold analysis

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showed the price would need to be increased substantially before dual-chamber pacemakers would not be cost-effective, it is unlikely that any recent price changes would lead to a change in the recommendations.
Are there any related pieces of NICE guidance relevant to this appraisal? If so, what implications might this have for the existing guidance?
See Appendix C for a list of related NICE guidance.

The search strategy from the original ERG report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from May, 2014 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section above. See Appendix C for further details of ongoing and unpublished studies.

4. Equality issues

No equality issues relevant to the committee's recommendations were raised in the original guidance.

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Appendix A – Information from existing guidance

5. Original remit

6. To appraise the clinical and cost effectiveness of dual chamber (atrial and ventricular) pacemakers relative to single chamber ventricular pacemakers, and to advise on the patients for whom the former would be particularly appropriate.Current guidance

1.1 Dual‑chamber pacemakers are recommended as an option for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block.

7. Research recommendations from original guidance

N/A

8. Cost information from original guidance

The acquisition cost of pacemakers depends on the particular model. The Association of British Healthcare Industries estimates an average cost of dual‑chamber pacemaker devices of £1265, and for single‑chamber atrial pacemaker devices a price of £718. Costs may vary in different settings because of negotiated procurement discounts.

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Appendix B – Explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	Consequence	Selected – 'Yes/No'
A review of the guidance should be planned into the appraisal work programme. The review will be conducted through the technology appraisals process.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred for a trial date	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No

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Appendix B

Options	Consequence	Selected – 'Yes/No'
The guidance should be updated in an on-going clinical guideline[1].	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	No
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The guidance should be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. The guidance will be stood down and any funding direction associated with a positive recommendation will not be preserved.	No

[1] Information on the criteria for NICE allowing a technology appraisal in an ongoing clinical guideline can be found in section 6.20 of the guide to the processes of technology appraisal.

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Appendix C – other relevant information

1. Relevant Institute work

Published

Dual‑chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block (Published: 2014; Updated: 2014) NICE technology appraisal guidance 88 (This guidance has been partially updated by NICE technology appraisal 324)

Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014) NICE technology appraisal guidance 314. Added to the static list in August 2017.

In progress

Nothing relevant

Referred - QSs and CGs

Nothing relevant

Suspended/terminated

Nothing relevant

2. Relevant services covered by NHS England specialised commissioning

Nothing relevant

3. Additional information

Nothing relevant

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Appendix D – References

Albertsen AE, Nielsen JC, Poulsen SH, Mortensen PT, Pedersen AK, Hansen PS, et al. DDD(R)-pacing, but not AAI(R)-pacing induces left ventricular desynchronization in patients with sick sinus syndrome: tissue-Doppler and 3D echocardiographic evaluation in a randomized controlled comparison. *Europace* 2008;**10**:127-33.

Nielsen JC, Thomsen PE, Hojberg S, Moller M, Vesterlund T, Dalsgaard D, et al. A comparison of single-lead atrial pacing with dual-chamber pacing in sick sinus syndrome. *Eur Heart J* 2011;**32**:686-96.

Nielsen JC, Kristensen L, Andersen HR, Mortensen PT, Pedersen OL, Pedersen AK, et al. A randomized comparison of atrial and dual-chamber pacing in 177 consecutive patients with sick sinus syndrome: echocardiographic and clinical outcome. *J Am Coll Cardiol* 2003;**42**:614-23.

Gallik DM, Guidry GW, Mahmarian JJ, Verani MS, Spencer WH, III, Gallik DM, et al. Comparison of ventricular function in atrial rate adaptive versus dual chamber rate adaptive pacing during exercise. *Pacing Clin Electrophysiol* 1994;**17**:179-85.

Lau CP, Tai YT, Leung WH, Wong CK, Lee P, Chung FL, et al. Rate adaptive pacing in sick sinus syndrome: effects of pacing modes and intrinsic conduction on physiological responses, arrhythmias, symptomatology and quality of life. *Eur Heart J* 1994;**15**:1445-55.

Schwaab B, Kindermann M, Schatzer-Klotz D, Berg M, Franow H, Frohlig G, et al. AAIR versus DDDR pacing in the bradycardia tachycardia syndrome: a prospective, randomized, double-blind, crossover trial. *Pacing Clin Electrophysiol* 2001;**24**:1585-95.

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