Technology Appraisal Review Proposal paper

Review of TA166; Cochlear implants for children and adults with severe to profound deafness

<table>
<thead>
<tr>
<th>Original publication date:</th>
<th>January 2009</th>
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</thead>
<tbody>
<tr>
<td>Review date</td>
<td>N/A – TA166 was added to the static list in 2011.</td>
</tr>
<tr>
<td>Existing recommendations:</td>
<td>Optimised</td>
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<tr>
<td></td>
<td>To see the complete existing recommendations and the original remit for TA166, see Appendix A.</td>
</tr>
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</table>

1. Proposal

An update to one of the recommendations (part review) in the guidance should be planned into the appraisal work programme. This update can be done without going through a full appraisal process. That we consult on this proposal.

2. Rationale

The new evidence for the technology, and the changes to the prices of the technology, are not likely to affect the recommendations in section 1.1 to 1.4 of TA166. However, the eligibility criteria in section 1.5 of TA166 are now out of date and do not reflect clinical practice. As these eligibility criteria were not linked to the recommendations in sections 1.1 to 1.4 they can be updated through consultation with stakeholders without the need for a full appraisal.

For this we would:

- Invite submissions from stakeholders on recommendation 1.5 only. Based on these submissions, we would
  - Develop new draft wording for recommendation 1.5
  - Expose the draft recommendation 1.5 to stakeholders, and clinical, patient, and NHS experts (in line with the proposed technical engagement step for adjusted technology appraisal)
  - Hold a committee discussion on the new wording/ definition of the eligibility criteria.
- Issue an ACD or FAD (should the committee diverge substantively from the draft wording that went out for technical engagement or the suggestions made by stakeholders during the technical engagement, we would consult on the preliminary new section 1.5; otherwise issue the new recommendations for 1.5 as an update to TA166, in a FAD for appeal).
3. Summary of new evidence and implications for review

NICE is aware that there has been substantial research and development in cochlear implants since guidance was published (TA166), including the collection of clinical trial and real-world data, patient-reported outcome studies and cost-effectiveness analyses. According to an Ear Foundation Report by Lamb (2016a), there have been improvements in the effectiveness of cochlear implants. The objective of this review exercise is to determine whether any of this new evidence is likely to lead to a change in the recommendations of the published guidance. Because bilateral implants were recommended only for a subgroup of adults in TA166, the main evidence of interest for this review is that which demonstrates the benefits and costs of bilateral cochlear implantation compared with unilateral cochlear implantation (preferably in a randomised controlled trial) in adults with severe to profound deafness. In TA166, the estimate of cost-effectiveness for bilateral implantation in adults was sensitive to the technology’s cost and the utility gain (quality of life gain) associated with the second implant, and therefore the focus of the review of new clinical data is on costs and health-related quality of life.

Several publications have updated the systematic literature review and meta-analysis conducted as part of TA166, to include studies published up to 2011 (Crathorne et al. 2012; Gaylor et al. 2013; Van Schoonhoven et al. 2013). These publications reported evidence of a consistent effect in favour of bilateral compared with unilateral cochlear implantation in adults. However, these results are unlikely to affect the recommendations for bilateral implantation in adults because the cost-effectiveness model was driven by the utility gain. Several other studies, not considered during TA166, have reported quality of life benefits with bilateral implantation. However, none of these studies collected data using a standardised and validated generic quality of life instrument and there is no evidence that the utility benefit is greater than that assumed in TA166. Therefore this evidence is unlikely to affect the recommendations. The reduction in the technology’s price, in the absence of improved utility data, is not big enough to affect the recommendations.

However, there is evidence to suggest that cochlear implantation would be beneficial for people with lower hearing thresholds than are recommended in section 1.5 of the current guidance (Lovett 2015, Vickers 2015, Leal 2016). Therefore a part review of section 1.5 of the guidance is proposed.

<table>
<thead>
<tr>
<th>Has there been any change to the price of the technology(ies) since the guidance was published?</th>
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<tr>
<td>The price of the technology has decreased since TA166, but the reduction alone is unlikely to be big enough to affect the recommendations.</td>
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</table>

**Details:**

The costs of the implant systems used in TA166 were based on the long-term national procurement contract between the four manufacturers and the NHS Supply Chain (which applied until October 2008); see chapter 3 of the final guidance. There is currently a procurement contract in place until 3 January 2018 (with an option to extend by 24 months). In addition to the main procurement contract, companies offer local discounts based on volume of sales and therefore
costs may vary in different settings, but these cannot be used in a NICE appraisal because they are not nationally available (see the Institute’s methods guide section 5.5.2). Discounts for second implant systems for bilateral implantation are not part of the NHS Supply Chain contract, but are offered nationally by some companies, and the recommendations in TA166 were based on assuming a discount of 40% for the second implant (equivalent to a 30% discount on the whole system, which includes the implant and processor). The committee could not recommend routine bilateral cochlear implantation in adults as a cost-effective use of NHS resources, and noted that discounts on the second implant system had to be greater than 75% for the ICER to fall even below £30,000 per QALY gained.

According to the Ear Foundation Report by Lamb (2016a), there has been a ~15% reduction in costs since TA166 (based on communication with industry).

The companies (Cochlear, MED-EL and Advanced Bionics) have provided pricing information including list prices, average price paid by the NHS (under the NHS Supply Chain contract), and the discount offered for second implant systems in bilateral implants. The average price paid by the NHS (under the NHS Supply Chain contract) appears to have decreased by between approximately 5% and 20% since TA166. The discount for the second implant appears broadly the same as that assumed in TA166: MED-EL currently offers a 30% discount on the second implant system when given simultaneously (equivalent to a 40% discount on the implant alone), and 20% when given sequentially. Advanced Bionics currently offers a 50% discount on the second implant system when given simultaneously, and no discount on sequential implants. Cochlear currently offers a 40% discount on the implant when given simultaneously. The price reductions and discounts are not large enough to bring the ICER below £30,000 per QALY gained, based on the modelling in TA166.

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

No

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

The original guidance recommended further research to assess the benefits of bilateral cochlear implantation compared with unilateral cochlear implantation in adults with severe to profound deafness (section 6.1). Bilateral implantation was not recommended in adults because:

- it was not cost effective (ICER £36,500 to £43,000/QALY for simultaneous implantation, depending on the level of discount on the second implant, and higher for sequential implantation)
- there was uncertainty in the utility benefit of the second implant, assumed to be 0.03 (a key model driver)
- the clinical benefits of bilateral implantation had not been adequately evaluated the published studies (owing to the small number of studies and the small numbers of participants).
The appraisal committee also recommended collecting data on the health-related quality of life for children with bilateral cochlear implants (section 6.2), because the cost effectiveness analysis was very sensitive to utility gains and no health-related quality of life data were available for children.

**New clinical effectiveness evidence for bilateral implantation in adults**

Three publications have updated the systematic literature review conducted as part of TA166, to include studies of bilateral cochlear implantation in adults published up to 2011 (Crathorne et al. 2012; Gaylor et al. 2013; Van Schoonhoven et al. 2013). A total of 18 new studies, not included in TA166, were identified across these 3 literature reviews. The authors of the reviews reported evidence of a consistent effect in favour of bilateral compared with unilateral implants in adults, mostly from cross-sectional and cohort studies. However they suggested that the evidence was not strong and recommended studies of longer duration and higher-quality reporting (Crathorne et al. 2012; Gaylor et al. 2013).

To address the research recommendations in TA166 (section 6.1), the FOUNDATION study is assessing the feasibility of conducting a randomised controlled trial of bilateral cochlear implants in adults. Focus groups met in July 2017 to discuss information about a future trial, including a draft of the patient information materials. The final decision about study feasibility is expected mid-2019.

According to an Ear Foundation Report by Lamb (2016a), cochlear implant technology has improved since the original guidance. For example by:

- upgrading the analogue sound processors in to digital sound processors
- introducing dual microphones for improved directional hearing particularly in background noise
- introducing input processing of the sound signal for improved hearing in background noise and in quiet conditions.

However, it is not clear if the recently published studies include these improvements. Regardless of this, new clinical data are unlikely to affect the recommendations for bilateral implantation in adults because the cost-effectiveness model was driven by the utility gain associated with the second implant.

**New quality of life data for bilateral implantation in adults**

The utility estimates for bilateral implantation in the economic model for TA166 were based on Health Utility Index 3 (HUI3) data from a randomised controlled trial in adults (Summerfield et al. 2006). Other quality of life data were reviewed as part of the appraisal. Despite the limitations of the Health Utilities Index (HUI), it is preferred over other generic health-related quality of life measures (such as the SF-36 or EQ-5D) in studies of deafness, because it is the only standard instrument which includes statement items relating to functional limitations due to impaired hearing or speech.

Recent systematic literature reviews (Crathorne et al. 2012; Gaylor et al. 2013; Van Schoonhoven et al. 2013) identified 2 studies reporting quality of life outcomes (Noble 2008; Noble 2009) that had not been considered during TA166.
Lamb et al. (2016b) also cites studies on quality of life after cochlear implantation. However, none of these studies collected data using a standardised and validated generic quality of life instrument. The NICE method’s guide states that utility values in cost-effectiveness assessments should be based on a standardised and validated generic quality of life instrument, and for which the value of changes in health states have been based on public preferences elicited using choice-based methods. The Assessment Group for TA166 noted that there is no tool to enable mapping (i.e. reliable prediction) from these disease-specific self-reported instruments (such as the Hearing Handicap Inventory and Hearing Handicap Questionnaire) to validated generic utility assessment instruments. Therefore, the new evidence on health-related quality of life of bilateral implantation is unlikely to affect the recommendations.

Other new evidence
There is also new evidence for bilateral implants in children, and for unilateral cochlear implants in adults and children. However, given that unilateral implants are already recommended by NICE, and children are eligible for both unilateral and bilateral implants, this new evidence would not impact the recommendations for unilateral implants and for implants in children. See additional comments for discussion of the eligibility criteria described in section 1.5 of TA166.

Several cost-utility analyses of cochlear implants have been published, but these have little bearing on the review process because NICE independently assesses cost effectiveness according to its own published methods.

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.

Additional comments

Stakeholders have urged reconsideration of the definitions of severe to profound deafness and adequate benefit from hearing aids

The current guidance specifies in Section 1.5 that, for the populations in which cochlear implantation is recommended, people must have severe to profound deafness (audiological deafness) and inadequate benefit from acoustic hearing aids (functional deafness), where:

- severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids
- adequate benefit from acoustic hearing aids is defined as:
  - for adults, a score of 50% or greater on Bamford–Kowal–Bench (BKB) sentence testing at a sound intensity of 70 dB SPL
  - for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.
Stakeholders have urged that both criteria should be reviewed and updated (BCIG 2017).

Although the trials underpinning the published guidance were all in people with “severe to profound deafness”, it needs to be emphasised that the inclusion criteria of these trials were not well reported, and most did not state the definition of “severe to profound”. But in several trials, severe-profound deafness was defined as ≥70 dB HL. Further, the TA166 scope defines severe using the 70 dB threshold. This was informed by scoping consultation comments and was based on standards from the British Society of Audiology at the time. The threshold used in Section 1.5 was informed by experts involved in the appraisal, not the trial criteria.

**Audiological deafness**

The 90 dB threshold was based on input from the British Cochlear Implant Group at the time of the appraisal. Stakeholders have noted that the 90 dB threshold is one of the most restrictive in Europe, where the majority of clinics use a cut off between 75 and 80 dB at frequencies greater than 1 kHz (Vickers 2016a). It has been suggested that there are limited data to support the 90 dB criterion, and that the published evidence available at the time of the original guidance was based on earlier generations of cochlear implant, unilateral rather than bilateral implants, and/or analogue rather than digital hearing aids (Vickers 2015). Recent research has found that bilateral cochlear implants would be appropriate for people with lower hearing thresholds than specified in the published guidance. Specifically, people hearing only sounds that are louder than 80 or 85 dB showed benefit from bilateral cochlear implants compared with bilateral hearing aids (Leal 2016, Lovett 2015, Vickers 2015).

**Functional deafness**

The BKB testing method was included in the recommendations based on input from the British Cochlear Implant Group at the time of the appraisal.

Accounts from people who are deaf or hard of hearing have indicated that the BKB sentence test is not a true measure of a person’s hearing ability. The test is conducted in a sound-proof room which does not reflect a ‘real world’ setting where individuals need to decipher sentences from background noise. In light of these concerns, stakeholders have urged a review of the BKB testing method (Vickers 2016b). There is recent evidence to support using alternative or supplementary measures of performance, such monosyllabic word recognition or the Arthur Boothroyd word test (Lamb 2016b, Sladen 2017).

Concern has also been raised that the BKB test may be discriminatory towards individuals who have a good grasp of the English language as they are more likely to be able to ‘guess’ sentences even if they have not heard all of the words. This is addressed to some extent by section 1.7 of the guidance.

**The cost of not providing cochlear implants**

It has been argued that NICE should consider the costs to the health, social care and social welfare system, and the economic impact of lost work productivity, of not addressing severe-to-profound hearing loss (Lamb 2016a). This cannot be addressed by a review because these costs are not part of the Institute’s [Guide to the Methods of Technology Appraisal](https://www.nice.org.uk/guidance) (see chapter 5: the reference case).
4. Equality issues

Section 1.7 of the original guidance notes that when considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team should be mindful of the need to ensure equality of access. It is stated that tests should take into account a person’s disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, and that tests may need to be adapted. It is further stated that if it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment should be considered.

Additionally, it was considered that those making the hearing assessments should take into account whether the speech, language and listening skills required by the assessment tools are appropriate to the age, development stage and cognitive ability of the child, and that modification of the testing procedure or alternative tests may be required.

Furthermore it was concluded that the potential benefits of bilateral auditory stimulation would apply to both prelingual and postlingual children because neurosensory development continues after the development of language, and that a distinction between children based on the time of language development would not be appropriate.

In TA166 additional considerations for people who are deaf and also have other disabilities were made. This was because people who are deaf and blind and people with some other co-disabilities rely more on auditory stimuli for spatial awareness.

GE paper sign off: Meindert Boysen, 29 November 2017

Contributors to this paper:

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Appendix A – Information from existing guidance

5. Original remit
To appraise the clinical and cost effectiveness of cochlear implants in severe to profound deafness in children and adults.

6. Current guidance
This technology appraisal examined the currently available devices for cochlear implantation. No evidence was available to the committee to allow recommendations to be made for devices manufactured by Neurelec.

1.1 Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined in 1.5.

If different cochlear implant systems are considered to be equally appropriate, the least costly should be used. Assessment of cost should take into account acquisition costs, long-term reliability and the support package offered.

1.2 Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined in 1.5:

- children
- adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

Acquisition of cochlear implant systems for bilateral implantation should be at the lowest cost and include currently available discounts on list prices equivalent to 40% or more for the second implant.

1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.

1.4 People who had a unilateral implant before publication of this guidance, and who fall into one of the categories described in 1.2, should have the option of an additional contralateral implant only if this is considered to provide sufficient benefit by the responsible clinician after an informed discussion with the individual person and their carers.

1.5 For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:

- for adults, a score of 50% or greater on Bamford–Kowal–Bench (BKB) sentence testing at a sound intensity of 70 dB SPL
• for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

1.6 Cochlear implantation should be considered for children and adults only after an assessment by a multidisciplinary team. As part of the assessment children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).

1.7 When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team should be mindful of the need to ensure equality of access. Tests should take into account a person’s disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, and may need to be adapted. If it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment should be considered.

7. Research recommendations from original guidance

6.1 The committee recommended that a randomised controlled trial should be carried out to examine the benefit of bilateral cochlear implantation compared with unilateral cochlear implantation in adults with severe to profound deafness.

6.2 The committee recommended that data on the health-related quality of life of children with bilateral cochlear implants should be collected and measured in accordance with the NICE ‘Guide to the methods of technology appraisal’.

8. Cost information from original guidance

Clarion CII Bionic Ear System and the HiResolution Bionic Ear System (Advanced Bionics UK)

The current NHS Supply Chain list price of the implant system (which includes the implant and processor) is £16,550 and the price paid by the NHS Supply Chain for the implant system is £14,900. Information supplied by the manufacturer indicates that a 40% discount on the list price for a second implant (list price for implant without processor and without discount: £10,500) is only offered when the second implant is used for simultaneous bilateral implantation. A 25% discount on the list price of £10,500 is offered when the second implant is used for sequential bilateral implantation. No discounts are offered for the purchase of a second processor. Costs may vary in different settings because of negotiated procurement discounts.

Nucleus 24 and Nucleus Freedom cochlear implants (Cochlear Europe)

The current NHS Supply Chain list prices of the Nucleus 24 and Nucleus Freedom cochlear implant systems are £14,350 and £15,250–£15,550 respectively. The price paid by the NHS is based on the volume acquired by each cochlear implant centre and the manufacturer offers a 10% discount for every 10 implant systems purchased. Additional information supplied by the manufacturer indicates that discounts for a second implant system (implant and processor) for bilateral cochlear implantation are offered on a case-by-case basis. Costs may vary in different settings because of negotiated procurement discounts.
The Pulsar CI-100 (MED-EL UK)

The current list price of the Pulsar CI-100 cochlear implant system is £17,375 and the price paid by the NHS is £15,600. Discounts are available from the manufacturer, but the details of the discounts were provided as commercial in confidence.

The Digisonic SP (Neurelec)

The price paid by the NHS Supply Chain for the Digisonic cochlear implant system is £12,250. A 50% discount on the second implant system for bilateral implantation is currently in place with the NHS Supply Chain (equating to £18,375 for two implant systems).
**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:

<table>
<thead>
<tr>
<th>Options</th>
<th>Consequence</th>
<th>Selected – ‘Yes/No’</th>
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<tbody>
<tr>
<td>A part review of the guidance should be planned into the appraisal work programme. This can be done without a full appraisal.</td>
<td>A part review of the appraisal will be planned into the NICE’s work programme, this will be limited to an update to the eligibility criteria in Section 1.5.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision to review the guidance should be deferred to specify date or trial.</td>
<td>NICE will reconsider whether a review is necessary at the specified date.</td>
<td>No</td>
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<tr>
<td>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.</td>
<td>A review of the appraisal(s) will be planned into NICE’s work programme as a Multiple Technology Appraisal, alongside the specified related technology.</td>
<td>No</td>
</tr>
<tr>
<td>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.</td>
<td>A review of the appraisal(s) will be planned into NICE’s work programme as a Multiple Technology Appraisal, alongside the newly referred technology.</td>
<td>No</td>
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<tr>
<td>The guidance should be incorporated into an on-going clinical guideline.</td>
<td>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.</td>
<td>No</td>
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<tr>
<td>Options</td>
<td>Consequence</td>
<td>Selected – ‘Yes/No’</td>
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<tr>
<td>The guidance should be updated in an on-going clinical guideline¹.</td>
<td>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).</td>
<td>No</td>
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<tr>
<td>The guidance should be transferred to the 'static guidance list'.</td>
<td>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.</td>
<td>No</td>
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<tr>
<td>The guidance should be withdrawn</td>
<td>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.</td>
<td>No</td>
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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](#).
Appendix C – other relevant information

Relevant Institute work

Published
Auditory brain stem implants (2005) NICE interventional procedures guidance 108

In progress
Hearing loss (adult onset) NICE guideline. Publication expected May 2018
Appendix D – References


Lamb B (2016b) Expert opinion: Can different assessments be used to overcome current candidacy issues? *Cochlear Implants International*. 17 (sup1) 3-7. DOI:10.1080/14670100.2016.1161382


