The Action Group on Adult Cochlear Implants welcomes the invitation to comment on the proposal to conduct a review of Section 1.5 of the NICE guideline TA166; Cochlear implants for children and adults with severe to profound deafness. The Action Group represents a wide range of stakeholders from patient groups, professional organisations, clinics and academics working in the field. Our full membership and related resources can be accessed at; https://actiongrouponadultcochlearimplants.wordpress.com/

The Action Group welcomes the intention to review section 1.5 of TA166. The Action Group is clear that the current candidacy criteria are not fit for purpose and do not reflect the significant benefits which could be gained by patients from cochlear implants (CI) not currently covered by the guidelines. We therefore welcome and support the intention to review candidacy requirements. As the NICE document Appendix B acknowledges a number of elements of the candidacy requirements have been challenged by research and clinical developments. This is not surprising given the improvements in the technology, surgical practice, understanding of the benefits of CI and patient care (Vickers 2015, Lamb 2016, Raine 2016). Further while patients value their cochlear implant (Ng 2016) those who do not qualify under current criteria, but do not get enough benefit from hearing aids, feel their quality of life has been negatively impacted (Athalye 2014).

The UK currently has one of the highest candidacy requirements in the developed world (Vickers 2016a). Recent research has also found that CI’s would be appropriate for people with lower hearing thresholds than the current guidelines indicate (Lovett 2015, Lamb 2016, Leal 2016, Vickers 2016b, Kitterick 2017 b- see also appendix A, Vickers & Kitterick 2017). We would therefore propose a lowering of the threshold to a minimum of greater than or equal to 80 dBHL ( ≥80 dBHL) in line with the research.

Further the Bamford-Kowal-Bench (BKB) test needs reviewing and replacing with a different test as recent research concluded that; “Use of this measure (the BKB test) alone to assess hearing function has become inappropriate as the assessment is not suitable for use with the diverse range of implant candidates today.” (Vickers 2016c).

The BCIG Candidacy Working Group Service Evaluation included the objective of identifying the most appropriate threshold score for unilateral cochlear implantation in adults (Kitterick 2017a). The results indicate that patient outcomes have significantly improved since the evidence for TA66 was originally collated and this supports the requirement for re-evaluation of an appropriate criterion for performance. Further, that in order to achieve an 80% or better chance of achieving a higher score following implantation, that the most accurate parameter amongst those considered is a phoneme score of 50% or greater using the Arthur Boothroyd (AB) Word test.

This position is also supported by the following consensus statements:

- The current assessment used to determine whether someone receives sufficient benefit from their hearing aids (the BKB sentence test) does not adequately assess the difficulties with listening that adults and children experience in everyday life.
The BKB sentence test administered in quiet when the patient is in their best-aided condition is not an accurate way of assessing whether a patient is receiving sufficient benefit from hearing aids.

Word-based listening tests are more appropriate than sentence-based listening tests for assessing sufficient benefit from hearing aids in some patients. (Vickers & Kitterick 2017, BCIG Consensus statement 2017).

We would therefore propose changing from BKB sentence testing to AB phoneme recognition (Lamb 2016, Vickers 2016c, Sladen 2017, Vickers & Kitterick 2017). There is also strong evidence that we need to test at a wider range of frequencies reflecting the evidence that audibility of speech across the speech spectrum as a whole is a predictor of clinical outcomes and speech perception abilities (Govaerts 2007, Kates 2013, Vickers 2016, Hanvey 2016).

On the basis of this and other evidence, see full bibliography and special supplement of Cochlear Implants International Vol. 17, sup1, 2016, the Action Group would propose that NICE considers consulting on the following revisions of the current guidelines.

**Suggested revisions of section 1.5;**

Cochlear Implants should be considered for children and adults with deafness in the severe to profound range, with hearing function that is severely impaired, and for whom optimally fitted conventional hearing aids do not provide adequate benefit. For adults, adequate benefit from hearing aids is considered to be sufficient access to meet an individual’s communication, social, education and employment needs. For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

For the purposes of this guidance, severe to profound deafness is defined as hearing sounds that are greater than or equal to 80 dBLH (≥80dBHL) at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3,000Hz and 4000Hz) bilaterally without acoustic hearing aids.

Adequate benefit from acoustic hearing aids is defined for this guidance as:

- For adults, a phoneme score of 50% or greater on the AB word test.

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1 There is very good evidence that patients receive significant benefit from CI’s at greater than or equal to 80 dBLH and greater from recent research see; Leal 2016, Lovett 2015, Vickers 2015, 2016a, Raine 2016, Vickers & Kitterick 2017, Kitterick 2017b and appendix A).

2 We additionally propose to include three routinely-measured audiometric frequencies (500, 1000 and 3,000 Hz) within the speech region as part of proposed revised candidacy guidelines. This reflects evidence that audibility of speech across the speech spectrum as a whole is a predictor of clinical outcomes and speech perception abilities. Govaerts (2007) showed that access to cues across the speech spectrum are necessary to normal speech and language development. See also Kates 2013, Vickers 2015, Hanvey 2016.

- For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

For all candidates, the multidisciplinary clinical team should consider that cochlear implantation is likely to provide additional benefit beyond that which can be provided through conventional hearing aids.

**Other Issues.**

Additionally there are a number of other categories which we may want to consider adding to the current criteria following evidence from the Consensus statement.

These are;

**Asymmetric losses:** Unilateral implantation for children with asymmetric losses (better ear <80 dB HL) as long as implanted ear is >80 dB HL (Greaver 2017, Vickers & Kitterick 2017).

**New unilateral deafness indication:** Unilateral implantation in unilateral deafness for children with intrusive tinnitus in deaf ear or progression in their good ear, and for adults who have both intrusive tinnitus in deaf ear and progression in good ear. (Vickers & Kitterick 2017).

These suggestions to be integrated with current wording as appropriate.

**Bilateral Implantation in Adults**

We also note NICE’s conclusion that there has not been enough change in the cost of CI’s, and that 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. Further that NICE would not be able to take account of other cost utility studies given its requirement to conduct its own study. We note that Appendix B nevertheless did not directly reference some more recent work on the cost effectiveness of CI’s which proposed a different methodology that does not simply use the benefit from the second implant as the only comparator (Foteff 2016) and that if different means of measuring utility are used better cost utility gains are obtained. It would be helpful to explore further how studies can be constructed that weight the benefits from the second implant and benefits overall, and also how cost effectiveness is assessed over longer timescales (Smulders 2016) where it has been shown to be cost effective.

As the NICE Appendix B document states there is currently a proposal for the Foundation study which is assessing the feasibility of conducting a randomised controlled trial of bilateral cochlear implants in adults. Depending on the feasibility of pursing that research in the way envisaged by NICE the Action Group would want there to be the option to review how we assess the benefit from bilateral implants further.

We look forward to commenting further on NICE proposals as part of the process following this consultation. For further information on this response please contact Brian Lamb, Chair of the Action Group on Adult Cochlear Implants brian.actiongroupci@gmail.com
References


Appendix 1.

Summary; of the; Assessment of the appropriateness and necessity of cochlear implantation in current and potential candidates.

Current NICE guidance

The results of the consensus exercise suggests that current NICE guidance is very successful at identifying clinical scenarios (patient groups) for whom implantation is both appropriate (the benefits outweigh any harms) and necessary (it would be improper care not to provide implantation). Of the 60 scenarios that are captured by the current guidance, implantation is considered appropriate in all of them and also considered necessary in all but two.

However, NICE guidance captures only 3 in every 20 clinical scenarios where implantation is considered appropriate and only 1 in every 5 scenarios where implantation is considered necessary. Thus, there are many patients that clinicians believe could benefit from implants, and in whom it is considered improper care not to provide a cochlear implant, but who cannot currently get one due to NICE guidance.
Audiometric definition of Severe-Profound Deafness

Increasing the threshold to 80 dB HL would include additional clinical scenarios for whom implantation is both appropriate and necessary. It would mean that the guidance would capture 1 in every 3 scenarios where implantation is appropriate (up from 3 in 20) and 4 in every 10 scenarios where implantation is both appropriate and necessary (up from 1 in 5). The 80 dB HL threshold would not capture any clinical scenarios where implantation is not considered appropriate, and would only capture an additional 2 scenarios where implantation is appropriate but not necessary. Thus, many more patients for whom the consensus is that they need an implant would have access to them without inadvertently including unsuitable patient groups at the same time. The revised guidelines would also still overwhelmingly target scenarios in which implantation is considered necessary clinical care.

Increasing the threshold to 70 dB HL would have the benefit of capturing slightly more scenarios where implantation is appropriate (4 in every 10) and necessary (1 in every 2). However, it has two considerable downsides. First, it would capture far more clinical scenarios (47, almost 12 times as many compared to the 80 dB HL threshold) where implantation is appropriate but not considered necessary; i.e. patients who may benefit but for whom not providing implants is not considered improper care. Second, and most importantly, a 70 dB HL threshold would capture scenarios where the appropriateness of implantation is unclear according to the consensus process. Thus, such a threshold would not only capture far more patients where it is not clinically necessary to provide a cochlear implant, but it would also capture patients in whom the harms may outweigh the benefits.

Definition of insufficient benefit from hearing aids

If one considers the 80 dB HL threshold as the better option, then one can consider what would be the effect of including patients who may get sufficient benefit from their HAs in quiet but have significant difficulties in noise. The effect would be to increase even further the capture of scenarios where implantation is appropriate (4 in every 10, up from 1 in 3) and necessary (1 in every 2, up from 4 in 10). All additional scenarios captured by including those with difficulties in noise are those in which implantation is both appropriate and necessary.

Summary

In summary, when considering the definition of the eligible patient group, the results of the consensus process support the change to an 80 dB HL threshold and the inclusion of patients who do not get sufficient benefit from their hearing aids in noise. These revisions to guidance would mean that many more patients for whom providing implants is considered clinically necessary would have access to them without expanding the criteria to those where the harms may outweigh the risks or where the size of benefit may be too small to be meaningful.
