NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Review Proposal Project (RPP) decision paper

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

Final recommendation post consultation

An update to one of the recommendations (part review) in the guidance, recommendation 1.5, should be planned into the appraisal work programme. This update can be done without going through a full appraisal process and involve the following steps
 	
• Invite submissions from stakeholders on recommendation 1.5 only. Based on these submissions,
  ○ 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).

1. Background

This guidance was issued in January 2009.

At the Guidance Executive meeting of 12 December 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

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2. Proposal put to consultees and commentators

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.

3. Rationale for selecting this proposal

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 However, the eligibility criteria in section 1.5 of TA166 are now out of date and do not reflect clinical practice.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).

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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Respondent: University College London **Response to proposal:** Agree My comments and recommendations are closely aligned with those put forward by the British Cochlear Implant Group (BCIG) and the Action Group on Adult Cochlear Implants (AGACI); two organisations that based their recommendations on well-considered evidence. I will not restate all of their points but would like to explain some of the reasoning behind the recommendations and also register the support of UCL. **1) The suggested change in cut-off threshold to ≥80 dB HL at two or more frequencies from 0.5, 1.0, 2.0, 3.0, 4.0 kHz.** 1a. Action on Hearing Loss International Grant entitled 'A longitudinal comparison of outcomes for hearing-impaired children with either bilateral hearing aids or bilateral cochlear implants' This study was conducted at UCL and compared outcomes for children with bilateral cochlear implants and children with bilateral hearing aids, to determine audiometric threshold criteria for paediatric bilateral cochlear implantation. This was an observational study with 71 participants (28 simultaneous bilateral cochlear implant users and 43 bilateral hearing aid users). The findings suggested that a relaxation in audiometric candidacy criteria would be appropriate. Using a 4:1 odds ratio for achieving better outcomes with cochlear implants than hearing aids the findings support a shift in audiometric threshold criteria for implant candidacy to 80 dB HL or greater. *Relevant References* Lovett R, Vickers D, Summerfield Q. (2015) Bilateral cochlear implantation for hearing-impaired children: criterion of candidacy derived from an observational study. Ear & Hearing. Jan; 36(1):14-23 Vickers D, Summerfield Q, Lovett R. (2015) Candidacy criteria for paediatric bilateral cochlear implantation in the United Kingdom, Cochlear Implants International, 16:sup1, S48-S49 1b. BCIG working group 'Consensus meeting on cochlear implant candidacy criteria' A national consensus meeting was conducted with multiple stakeholders in which they considered clinical scenarios and whether the benefits of cochlear implantation for these cases would outweigh the risks. Through a Delphi process the consensus group developed	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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statements around implant candidacy and those statements with high levels of agreement have been considered when devising the recommended criteria. The clinical scenarios with 80 dB HL audiometric thresholds were typically deemed appropriate for implantation, adding further support for the 80 dB HL cut off criterion level. This was the case for both adults and children. This cut off is conservative compared to many countries, because of an international trend to adjust the audiometric threshold criteria to 70 dB HL.

Relevant References

Kitterick P, Vickers D (2017) Achieving consensus on candidacy for cochlear implantation ENT and Audiology News, September/October. 26 (4), 81-82

Kitterick P, Vickers D (2017) Consensus statement on cochlear implant candidacy. https://www.cicandidacy.co.uk/ (accessed 22 January 2018)

Vickers D, Kitterick P (2017). Delphi process to determine consensus on candidacy for cochlear implantation in the UK. Technical report prepared for the BCIG

1c. BCIG working group 'Issues in cochlear implant candidacy'

Clinicians and researchers were invited to submit papers for a special supplement in the Journal 'Cochlear Implants International' on 'Issues in Cochlear Implant Candidacy'. There was an overwhelming response. One of the biggest concerns was that there are many severe-to-profoundly deaf individuals, who the clinicians believed would benefit from an implant, who were not eligible because they had a non-standard audiogram or asymmetry between ears.

The non-standard audiogram becomes a particular issue for people with a reverse slope hearing loss (poorer in low frequency region than in high frequencies). An example scenario would be for an individual with audiometric thresholds that are < 90 dB HL at 2 and 4 kHz putting them outside criteria but with audiometric thresholds > 90 dB HL at 0.5 and 1 kHz. This individual would find it extremely difficult to understand speech because they would not be able to discriminate the important vowel information. It is known that individuals with low-frequency hearing loss do not have good speech perception abilities. It is also known that the frequency importance functions that indicate the most critical frequencies for good transmission of speech, are highest between 0.5 and 3 kHz.

To address this issue the BCIG and AGACI decided that the appropriate approach would be to use any two frequencies out of 0.5, 1, 2, 3 & 4 kHz for determining candidacy. This approach was also supported by the BCIG cochlear implant candidacy consensus.

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For the assymetric losses, I will highlight the issue with another example. If a child has a bilateral symmetric hearing loss with audiometric thresholds greater than 90 dB HL in both ears at 2 & 4 kHz they will receive bilateral implants. If however a child has thresholds greater than 90 dB HL at 2 & 4 kHz in one ear and greater than 90 dB HL at 4 kHz and 85 dB HL at 2 kHz in the other ear, they would not receive an implant at all. Both children would be likely to have similar difficulties in accessing speech in everyday life. Ideally the second case would at least be offered an implant for the ear that falls within criteria. This scenario may not be under review in current guidance, but reviewing each ear separately could be a consideration for overcoming this issue; again supported by the BCIG cochlear implant candidacy consensus. *Relevant References* Hanvey K, Ambler M, Maggs J, Wilson K. (2016) Criteria versus guidelines: Are we doing the best for our paediatric patients? Cochlear Implants International 17 (S1) Kates J (2013) Improved estimation of frequency importance functions. The Journal of the Acoustical Society of America 134, EL459 (2013) Kitterick P, Vickers D (2017). Assessment of the appropriateness and necessity of cochlear implantation in current and potential candidates. Technical report prepared for the BCIG. Leal C, Marriage J, Vickers D (2016) Evaluating recommended audiometric changes to candidacy using the Speech Intelligibility Index. Cochlear Implants International, 17 (S1). Sadadcharam M, Warner L, Henderson L, Brown N, Bruce I (2015) Unilateral cochlear implantation in children with a potentially useable contralateral ear. Cochlear Implants International 17 (S1) Studebaker G, Sherbecoe R(1991) Frequency-importance and transfer functions for recorded CID W-22 word lists Journal of Speech & Hearing Research 34, 427–438. Studebaker G, Sherbecoe R (1993). Frequency-importance functions for speech recognition, in Acoustic Factors Affecting Hearing Aid Performance, edited by G. A. Studebaker and I. Hochberg (Allyn and Bacon, Boston), 185–204. Vickers D, Kitterick P, Verschuur C, Leal C, Jenkinson L, Vickers F, Graham J (2016) Issues in Cochlear Implant Candidacy. Cochlear Implants International 17 (S1) Vinay, Moore B (2007). Speech recognition as a function of highpass filter cutoff frequency for people with and without low-frequency cochlear dead regions. Journal of the Acoustical Society of America, 122, 542-553.	

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Vinay, Baer T, Moore B (2008). Speech recognition in noise as a function of highpass-filter cutoff frequency for people with and without low-frequency cochlear dead regions. Journal of the Acoustical Society of America, 123, 606-609

Suggested speech perception cut off criteria change for adults, to use a phoneme score of 50% or greater on the AB word test

2a. Worldwide evaluation of candidacy

In 2016 an international survey was conducted to determine the indications used in different countries for cochlear implantation. This review was updated in 2017 for a special issue of ENT news with data from 20 countries. With respect to speech assessment fewer countries use sentence materials because performance with such measures can be greatly affected by cognitive processing. A monosyllable test is a better measure for determining an individual's access to speech cues, which is a more appropriate approach for assessing candidacy. In the survey 76% of countries use monosyllable testing to evaluate appropriateness for implantation in adults.

Relevant References

Raine C, Vickers D (2017) Worldwide picture of candidacy for cochlear implantation. ENT and Audiology news, september/october 26 (4) 76-78

Vickers D, De Raeve L, Graham J (2016) International survey of cochlear implant candidacy. Cochlear Implants International. 17 (S1)

2b. The BCIG working group on candidacy 'Service evaluation of adult patient performance over the first year of implant use: Exploring Optimal Speech Test Measures to Use'

The BCIG working group on candidacy collected speech test scores from pre-implant assessment over the first year of implant use. The goal was to determine the most appropriate speech test to use and the threshold score of that test for assessing cochlear implant candidacy for unilateral cochlear implants in adults.

The findings from the analysis have shown that average speech perception performance of unilaterally implanted adults has significantly increased since the original guidance was published. Of the measures reviewed, the Arthur Boothroyd (AB) word test with responses

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scored by phoneme was the most appropriate measure. The use of a monosyllable test was supported by the BCIG cochlear implant candidacy consensus. The preliminary analysis revealed that a cut off score less than 50% on the AB phoneme score would be appropriate. *Relevant References* Doran M, Jenkinson L (2016) Mono-syllabic word test score as a pre-operative assessment criterion for cochlear implant candidature in adults with acquired hearing loss. Cochlear Implants International. 17 (S1) Kitterick P, Vickers D (2017). Derivation of a candidacy criterion for sufficient benefit from hearing aids: an analysis of the BCIG service evaluation. Technical report prepared for the BCIG. Lamb B (2016) Expert opinion: Can different assessments be used to overcome current candidacy issues? Cochlear Implants International. 17 (S1) Vickers D, Riley A, Ricaud R, Verschuur C, Cooper S, Nunn T, Webb K, Muff J, Harris F, Chung M, Humphries J, Langshaw A, Poynter-Smith E, Totten C, Tapper L, Ridgwell J, Mawman D, de Estibariz UM, O'Driscoll M, George N, Pinto F, Hall A, Llewellyn C, Miah R, Al-Malky G, Kitterick P (2016) Preliminary assessment of the feasibility of using AB words to assess candidacy in adults. Cochlear Implants International. 17 (S1) 17-21 **Summary** At UCL we agree that this review relates only to section 1.5 of the original guidance (TA166), because that is the section most affected by new evidence available since the original publication. We agree with the proposed wording suggested by BCIG and AGACI: *For the purposes of this guidance, severe to profound deafness is defined as hearing sounds that are greater than or equal to 80dBHL (≥80dBHL) at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz 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* • *For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability*	

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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.	

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Respondent: The Ear Foundation **Response to proposal:** Agree The current candidacy criteria for cochlear implantation in the UK are not fit for purpose and we welcome the opportunity to comment on this important proposal to conduct a review of Section 1.5 of the NICE guidance TA166. The UK has one of the most stringent candidacy requirements in the developed world (Vickers, 2016a), yet current research demonstrates that cochlear implants would be appropriate for those with lower hearing thresholds than fulfil these criteria (Lovett, 2015; Lamb, 2016; Vickers, 2016b; Kitterick, 2017). There are also significant issues with the Bamford-Kowal-Bench (BKB) speech test. Vickers (2016 c) concluded, "*Use of this measure alone to assess hearing function has become inappropriate as the assessment is not suitable for use with the diverse range of implant candidates today*". In order to achieve an 80% or better chance of achieving a higher score following implantation, the most accurate parameter amongst those considered is a phoneme score of <50% using the Arthur Boothroyd (AB) Word test (Kitterick, 2017a). In addition, there is strong evidence to support 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); testing a wider range of frequencies is therefore recommended. The evidence considered for this review is provided in the references and Appendix 1 of the full document response of the Adult Cochlear Implant Action Group. The Ear Foundation wholeheartedly supports these findings and recommendations, specifically the suggested revisions of section 1.5, stating: 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 sufficient access to meet an individual's	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed, and therefore no review of the recommendation for bilateral implants in adults will be carried out. Treatments for intrusive tinnitus are outside the remit of this appraisal.

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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 dBHL (≥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 · 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. 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	

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implant. 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.	

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Respondent: Royal College of Speech and Language Therapists **Response to proposal:** Agree **1) What do you think of the proposed approach to updating the recommendation? (See Appendix B)** We would fully support a part review of the appraisal to be planned into the NICE's work programme, limited to an update to the eligibility criteria in Section 1.5.: a) We fully concur with the statement below, (taken from page 6 of Appendix B) and would support an urgent review of i) the definitions of severe to profound deafness and ii) adequate benefit from hearing aids : "The 90 dB (sic) threshold was based on input from the British Cochlear Implant Group at the time of the appraisal. Stakeholders have noted that the 90 dB (sic) threshold is one of the most restrictive in Europe, where the majority of clinics use a cut off between 75 and 80 dB (sic) at frequencies greater than 1 kHz (Vickers 2016a)" (The NICE guidelines should refer to a 90 **dBHL** threshold….and a cut-off of 75 and 80 **dBHL** so that the referent in the log ratio dB is explicit.) b) A recent paper from New Zealand (Leigh JR, Dettman SJ & Dowell RC, Int J Audiol 2016; 55: S9–S18) on "Evidence-based guidelines for recommending cochlear implantation for young children: Audiological criteria and optimizing age at implantation", found that…."Speech perception outcomes suggested that children with a PTA greater than 60 dB HL have a 75% chance of benefit over traditional amplification. More conservative criteria applied to the data suggested that children with PTA greater than 82 dB HL have a 95% chance of benefit." It is definitely time for a UK review. **2) Do you think there are any additional organisations that NICE should include as stakeholders in the future consultation? (see Appendix A)**	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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We would suggest that in addition to those listed in Appendix A, The Elizabeth Foundation (www.Elizabeth-foundation.org) also be approached to comment on a review of the eligibility. The Children's Hearing Evaluation & Amplification Resource (CHEAR) would also be worth approaching (http://www.chears.co.uk/)	

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Respondent: National Deaf Children's Society **Response to proposal:** Agree NDCS welcomes the intention to review section 1.5 of TA166. We are clear that the current candidacy criteria are not fit for purpose and do not reflect the significant benefits which could be gained by children 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, clinical developments. This is not surprising given the developments in the technology, surgical practice, understanding of the benefits and patient care (Vickers 2015, Lamb 2016, Raine 2016). The UK now 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 children with lower hearing thresholds than the current guidelines indicate (Lovett 2015, BCIG Consensus statement 2017, Kitterick 2018-see appendix A). We would therefore propose a lowering of the threshold to a minimum of ≥80 dBHL or greater in line with the research. On the basis of this and other evidence supplied by the British Cochlear Implant Group (BCIG) and the Action Group on Adult Cochlear Implants we would endorse their proposed revisions of the current guidelines. **Suggested revisions of section 1.5;** CI's should be considered for children 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 this purpose, the range of hearing considered is ≥80dBHL or greater at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, and 4000Hz) bilaterally. For all children, 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.	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed. Treatments for intrusive tinnitus are outside the remit of this appraisal.

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Adequate benefit from hearing aids for children is considered to be speech, language and listening skills appropriate to age, developmental stage and cognitive ability (No change from current TA 166). **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, BCIG Consensus Statement 2017) **New unilateral deafness indication**: Unilateral implantation in unilateral deafness for children with intrusive tinnitus in deaf ear or progression in their good ear. (BCIG Consensus Statement 2017) **References** BCIG (British Cochlear Implant Group Candidacy Working Group) (2017) Consensus statement on candidacy for cochlear implantation. https://www.cicandidacy.co.uk/ Greaver,. L, Eskridge,. H, Teagle, HFB. (2017) Considerations for Pediatric Cochlear Implant Recipients With Unilateral or Asymmetric Hearing Loss: Assessment, Device Fitting, and Habilitation. Am J Audiol. 2017 Jun 13;26(2):91-98. doi: 10.1044/2016_AJA-16-0051. Hanvey, K, Ambler, M, Maggs, J, & Wilson, K. (2016) Criteria versus guidelines: Are we doing the best for our paediatric patients? Cochlear Implants International Vol. 17, Iss. sup1, 2016 Kitterick, P. (2018) Summary of the assessment of appropriateness and necessity of cochlear implantation in the United Kingdom. Lovett RE, Vickers DA, Summerfield AQ. (2015) Bilateral cochlear implantation for hearing-impaired children: criterion of candidacy derived from an observational study. Ear Hear. Jan; 36(1):14-23 Raine, C., Atkinson, H., Strachan, D, R., & Martin, J M. (2016) Access to cochlear implants: Time to reflect, Cochlear Implants International, 17: S1, 42-46. Vickers, D. Summerfield, Q & Lovett, R. (2015) Candidacy criteria for paediatric bilateral cochlear implantation in the United Kingdom, Cochlear Implants International, 16:sup1, S48-S49	

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Vickers D, De Raeve L, Graham J (2016a) International survey of cochlear implant candidacy. Cochlear Implants International. 17 (sup1) 36-41.
Vickers et al. (2016b) Issues in Cochlear Implant Candidacy. Cochlear Implants International. 17(sup1) 1-2. DOI:10.1080/14670100.2016.1163104

Vickers, F. & Bradley, J. (2016c) Outcomes in implanted teenagers who do not meet the adult candidacy criteria. Cochlear Implants International Vol. 17 , Iss. sup1, 2016

Appendix 1.

Summary of the assessment of appropriateness and necessity of cochlear implantation in the United Kingdom

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

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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.	

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Respondent: National Cochlear Implant Users Association **Response to proposal:** Agree Regarding bilateral implantation we note the reference to the FOUNDATION study in which NCIUA is a participant. We ask that there is an opportunity for further review when the results of that study are available. We submit that the following statements should be adopted in a revised TA 166. CI's should be considered for adults and children with deafness in the severe to profound range, with hearing function that is severely impaired, and for whom optimally fitted acoustic hearing aids do not provide adequate benefit. For adults, adequate benefit from acoustic hearing aids is considered to be sufficient access to meet an individual's communication, social, education and employment needs. For children, adequate benefit from acoustic hearing aids for children is considered to be 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 by acoustic hearing aids. For the purpose of assessing candidacy, the range of hearing considered is ≥80dBHL or greater (1) at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally (2) Adequate benefit from acoustic hearing aids for adults should be measured by a phoneme score of 50% or greater on the AB word test. (3) Unilateral implantation for children with asymmetric losses (better ear <80 dB HL) as long as implanted ear is >80 dB HL (4) 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 (5) References:	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed. Once this update has been carried out, the guidance will be considered for future review in line with NICEs processes. Treatments for intrusive tinnitus are outside the remit of this appraisal.

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(1) There is very good evidence that patients receive significant benefit from CI's at 80 dBHL and greater from recent research. There is strong research evidence for 80 dB HL or greater in recent studies (see Leal 2016, Lovett 2015, Vickers 2015, 2016a, Raine 2016, BCIG Consensus statement 2017). (2)There is also very good evidence of using a wider range of frequencies to address a wider range patients hearing profiles. This includes Vickers 2015, (3) There is strong evidence that the current BKB test is not fit for purpose as it is currently administered (Vickers 2016b,d) and that this could be addressed by using instead the Arthur Boothroyd (AB) word test (Lamb 2016, Vickers 2016c, Sladen 2017, Vickers & Kitterick 2017). (4) Greaver 2017, Vickers & Kitterick 2017. (5) Vickers & Kitterick 2017	

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Respondent: National Community Hearing Association **Response to proposal:** Agree **Feedback on TA166** 1. We welcome this opportunity to comment on recommendation 1.5 in TA166. 2. We agree that eligibility criteria in recommendation 1.5 *"are now out of date and do not reflect clinical practice"*[1] 3. We agree that recommendation 1.5 needs to be updated. 4. In our view, this is also an important opportunity to update the language used in TA166 and to address some practical (real-world) challenges with this NICE guidance. For example a- most audiologists in England and Wales (where TA166 is currently used) do not measure or describe hearing loss in the way that NICE describes it in TA166 b- this has, in our view, contributed to poor dissemination and uptake of TA166, yet c- there is no robust evidence-base to support NICE's definition of "severe to profound" hearing impairment, or its current measurement/definition of hearing loss. Addressing this issue should help improve dissemination and implementation of TA166 – i.e. also help NICE meet its duties to advance equality and improve patient outcomes. 5. We make recommendations below. We expect the impact of our recommendations to be as follows a- improve dissemination of TA166 b- provide a consistent standard of what constitutes "severe to profound" hearing loss, reducing confusion among non-specialist clinicians and the public c- increase the probability that patients already eligible are referred for assessment	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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d- no significant increase in the number of people receiving NHS funded Cochlear implants **<u>Recommendations: criteria and language (typology)</u>** ***Criteria*** 6. We understand that the original economic analysis for TA166 was particularly sensitive to utility weights and that significant supplier discounts would be required in order to make any fundamental changes to eligibility criteria. 7. We also understand the various issues with transferability of health economic studies (costs, funding models and effectiveness etc) that are more likely to emerge in these scenarios – e.g. the fact the UK has some of the most stringent eligibility criteria for Cochlear implants[2] might not be sufficient, in itself, to justify NICE updating its recommendations. We factor this and other variables into our feedback below. 8. We recommend that NICE a- changes its criteria to ≥80dB HL (averaged 0.5, 1, 2 and 4 KHz) to better reflect clinical practice b- reviews use of the Bamford-Kowal-Bench (BKB) test, which research suggests might create inequalities in access[3]. That, as part of its commitment to advancing equality, NICE therefore also considers removing this test from recommendation 1.5 c- considers replacing the BKB test with the Arthur Boothroyd (AB) monosyllabic word test[4] ***Language (typology)*** 9. In addition to reviewing recommendation 1.5, the language used in TA166 should be reviewed to aid dissemination of eligibility criteria.	

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10. The current definition of severe to profound hearing loss is unique to TA166, not evidence-based, and overlooks other definitions of hearing impairment. This can be very confusing for stakeholders, for example a- recommendation 1.5 states, *"For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90dB HL at frequencies of 2 and 4kHZ…"*[5] b- no other widely used classification system uses this definition of hearing loss (Table 1)[6] c- to understand the difference in opinion – i.e. not evidence – somebody has to find and read a single sentence on page four of a 41-page NICE's TA166, and understand that many readily available definitions of "severe to profound hearing loss" are not related to NICE's definition in TA166 d- eligibility criteria in TA166 are therefore confusing for the public and non-specialist clinicians. 11. In **Table 1** we share various classification systems. NHS England currently uses an abridged version of the Global Burden of Disease (GBD) expert group criteria[7]. A forthcoming national JSNA guide (coproduced by NHS England, the Local Government Association and the Association of Directors of Public Health) will also use the NHS England abridged GBD version. 12. We recommend that NICE a- uses the same categories/descriptors of hearing loss as NHS England guidance. This will improve consistency and aid dissemination. The original criteria can be found in Stevens et al. 2011[8], for ease of reference this is also highlighted in green in **Table 1** below. stops using its own definition of "severe to profound hearing loss" which can mislead the public and non-specialist clinicians into assuming that all people with "severe" losses	

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(ranging from 71-90) might be eligible if they fail a specified word test. Whereas, based on existing criteria in TA166 and prevalence data, the vast majority of people with a "severe" loss are unlikely to be eligible. NICE should therefore make clear that TA166 is most likely to apply to people with profound hearing loss that do not benefit from conventional hearing aids, setting out *more* clearly whether it recommends a threshold of 80dBHL (as recommended above) or 90dBHL (as per existing guidance) and at which frequencies this should be measured.

	Classification system		
Hearing impairment category	WHO[9]	BSA[10]	GBD Group[11]
Unilateral	NA	NA	<20 in the better ear; ≥35 in the worse ear
Mild	26-40	20-40	20-34
Moderate	41-60	41-70	35-49
Moderately/Severe	NA	NA	50-64
Severe	61-80	71-95	65-79
Profound	>80	>95	80-94

Table 1: Classification systems for the severity of hearing loss, better ear threshold in decibels over average frequencies 0.5, 1, 2 and 4kHZ (dB HL)

Other comments

13. Changing the criteria from 90dBHL to 80dBHL is unlikely to have a significant impact on NHS resources, especially given additional eligibility criteria (e.g. need to try conventional hearing aids and also undertake a specified word test). For example
    a- the prevalence data in **Table 2** show that very few adults are likely to meet the 80dBHL or 90dBHL threshold criteria
    b- an estimated 0.4% to 0.7% of the adult population might have a loss of at least 80dBHL
    c- an estimated 0.1% to 0.2% of children might have a profound hearing loss[12]

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d- therefore taking a very conservative[13] estimate that 0.3% of the population would meet a 80dBHL threshold, this would amount to make a maximum of 163,000 people theoretically eligible for Cochlear implants in England. Most of these people would however benefit from conventional hearing aids or pass an AB word criteria, and therefore not actually be eligible[14]

14. In summary, implementing recommendations in this submission, NICE is likely to improve dissemination of guidance and therefore make it more likely those people already eligible for NHS funded Cochlear implants are actually referred, rather than increase the actual number of procedures by changing a treatment threshold in any meaningful way.

	75dBHL	85 dBHL	95 dBHL
Prevalence	0.7%	0.4%	0.2%

Table 2: Prevalence by age group (18-80), better ear over 0.5, 1, 2 and 4kHZ[15]

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Respondent: NHS England - Clinical Reference Group (CRG) **Response to proposal:** Agree 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.* **Pure tone thresholds** The use of 90 dB HL at 2 and 4 kHz without hearing aids is overly restrictive. Hearing loss is often not equal across frequencies; 2 and 4 kHz are not representative of the difficulty in hearing out with surrounding frequencies and only partially represent the speech frequencies Evaluation of the speech frequencies 0.5, 1.0, 2.0, 3.0 & 4 kHz should be considered where an average of ≥80 dB at two adjoining frequencies could be analysed. The UK criteria are much more stringent than guidelines in other European countries where thresholds above 70dBHL are considered for implantation depending on clinical review of benefit (Vickers, De Raeve et al. 2016). The Cochlear implant services in the UK have gained significant expertise and research has shown that lowering the thresholds would be appropriate (Lovett, Vickers et al. 2015, Lamb 2016, Leal, Marriage et al. 2016, Vickers, Kitterick et al. 2016) **BKB Sentence testing** BKB sentence testing at 70 dB SPL in quiet, with bilateral acoustic hearing aids does not represent 'real world' of hearing. The test also discriminates against experienced English speakers who are able to guess or anticipate sentences despite very poor hearing. There is no one ideal process but clinical experience would support the use of the alternative Arthur Boothroyd (AB) word list. This is a single word list and would be more appropriate as	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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a tool to assess speech understanding. As it is single words it is hard to guess and is a more equitable test – however, the methodology of presentation would need to be formulated so that it would represent the challenges of hearing conditions in the best aided condition. Speech tests alone should not be used as a specific criterion or cut-off for candidacy, but their results should be considered by the multi-disciplinary team (MDT). **Children** For children the guidance is appropriate and allows clinical assessment of speech and language development. There are several clinically relevant situations which sit uncomfortably with the current guidance. These include: **Asymmetrical hearing loss** Adults and children who have a 'better ear' just above implant thresholds, but a 'poorer ear' which is profound – these individuals struggle especially in background noise and would certainly benefit from implantation of the 'poorer ear' . This is especially relevant now than many of the manufacturers support multimodal combined stimulation from a combination of unilateral CI and contralateral hearing aid. **Cochlear hair cell dysfunction** These are patients whose speech discrimination is disproportionately worse than predicted by their pure tone audiogram. These patients often have cochlear dead regions as detected by the TEN(HL) test and may gain significant benefit from cochlear implantation. A more comprehensive literature review can be supplied Lamb, B. (2016). "Expert opinion: Can different assessments be used to overcome current candidacy issues?" Cochlear Implants Int **17 Suppl 1**: 3-7. Leal, C., J. Marriage and D. Vickers (2016). "Evaluating recommended audiometric changes to candidacy using the speech intelligibility index." Cochlear Implants Int **17 Suppl 1**: 8-12.	

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Respondent: MED-EL **Response to proposal:** Agree **Introduction** Cochlear implantation (hereafter referred to as CI) provides well-documented substantial benefit to individuals with severe to profound sensorineural hearing loss. These benefits have been increasing through, not only developing cochlear implant technology, but also broadening indication criteria. These developments along with greater understanding of how binaural hearing can affect speech intelligibility has led more adults to undergo bilateral CI – sequentially and simultaneously. As such, there has been a growth in the knowledge base, contributing high quality evidence investigating the economic and health benefits of CI technology for both adults and children. This has led to the current need to review the guidelines for cochlear implantation within the UK. Supplementary to earlier evidence submitted, additional recent study results detailing the benefits of bilateral implantation in adults indicate the need for the provision of bilateral cochlear implantation in adult candidates in the UK to be reconsidered. This document also includes recent evidence indicating benefits for adults with better hearing thresholds than currently recommended within the NICE guidance. **Comparison of UK candidacy criteria to other countries** The same CI devices are provided globally, yet the candidacy guidelines for provision vary significantly with no global consensus. As the worldwide trend demonstrates a move to expand CI candidacy, the UK guidelines become more conservative compared to European and global counterparts (Raine *et al.,* 2016). Vickers, De Raeve & Graham (2016) collated candidacy evidence from 17 countries, noting the UK had the one of the most conservative audiometric criteria. As detailed within this collated evidence base, the majority of countries who apply audiometric thresholds used levels of 75-85dB HL at frequencies above 1 kHz compared to the UK using >90 dB HL at 2 and 4 kHz. An example of this can be seen from the subproject analysis from Berrettini *et al.* (2011). They conducted a systematic review in Italy to analyse which cohort of potential candidates	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed. Treatments for tinnitus are outside the remit of this appraisal.

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could benefit from cochlear implants. Results of their systematic review found individuals with bilateral severe to profound hearing loss with a mean hearing threshold greater than 75 dB HL between 500 Hz and 2 kHz are suitable candidates to benefit from cochlear implantation. In regards to the current USA FDA guideline (American Medical Association, 2017), Sladen *et al*. (2017) reported studies investigating monosyllabic word recognition and HINT (Hearing in Noise Test) sentence recognition in a within-subjects design, have demonstrated significantly higher performance levels for sentences compared to monosyllables. The performance rates when using sentence tests versus monosyllabic tests may be an influencing factor explaining the low the number of successful candidates that are eligible for cochlear implantation in the UK whereby it is understood that there is a 5% implantation rate in adults with the Bamford-Kowal-Bench (BKB) sentence testing (Raine, 2013 & 2016). This is in part due to candidacy guidelines and testing that does not reflect real world conditions, including speech in noise / background noise test environment. This would support the need to revise current adult candidacy indications for cochlear implantation from a BKB sentence test to an appropriate monosyllables word. The author reported that the adult participants who had better preoperative hearing and speech understanding abilities compared to the current FDA candidacy guidelines, showed significant benefit from cochlear implantation. Based on the results outlined above, the study also suggests that Consonant-Nucleus-Consonant (CNC) word scores, rather than sentence scores, should be used to determine candidacy and measure long-term outcomes for adults with post-lingual hearing loss. This study is indicative of the use of monosyllabic word performance for determining implant candidacy within European countries such as France, Germany, and Spain. In addition, Vickers et al. (2016) reports for countries using speech-based adult candidacy assessments, the majority (40%) used word tests, 24% used sentence tests, and 36% used a mixture of both. Travelling further afield, Australia's guidelines are also more liberal compared to the UK with guidance suggesting average thresholds should be >70 dB HL for frequencies greater than 1500Hz (Leigh *et al.* 2011). Similarly, Germany's audiometric criteria are 70 dB unaided with	

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candidates also considered if they understand <50% monosyllables and / or <60% sentences in background noise (Najran 2013). Furthermore, many countries in Vickers *et al.* (2016) review focussed on functional outcomes, something which isn't prominent in UK practice and has been raised by Chundu & Flynn (2014) as a method which should be employed more so within UK guidance. **Expanding UK candidacy criteria for bilateral cochlear implantation in adults** Benefits bilateral CI compared with unilateral CI in adults Binaural hearing found within normal hearing individuals provides major benefits including the localisation of sounds, and improved, targeted hearing in noisy environments. However, even though unilateral cochlear implants significantly help in understanding speech in a quiet environment, background noise remains a challenge for those with single CIs (Dingemanse and Goedegebure, 2015). Therefore, consideration of the following evidence should be made in regards to reviewing access of bilateral cochlear implants (simultaneous and sequential) for adults candidates. Significant improvements in sound localisation and speech understanding in noise have been achieved with bilateral implant recipients. Kraaijenga *et al.* (2017) reported 38 (i.e. 19 simultaneous bilateral CIs and 19 sequential bilateral CIs) participants within a randomised controlled trial underwent simultaneous bilateral CIs and sequential bilateral CIs. In the sequential bilateral CIs group, the author reported that participants had significant improvements in spatial speech-in-noise and localisation abilities compared with their unilateral situation. In the performed speech-noise tests, a significant benefit was seen in the worst performing situation as well as in the best performing situation, which lost its significance after correction for multiple testing. In addition, participants performed better on all localisation tests compared with the previous years. In the simultaneous bilateral CIs group, a significant improvement was seen for the best performing situation on the sequential bilateral CIs between year 1 and year 3. The author mentioned all analyses were 2-tailed, and a P <.05 was considered statistically significant. The results of this study indicate why revised NICE guidelines for adults will help to improve the functional outcomes for adult CI recipients.	

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Blamey *et al.* (2015) also reported both intelligibility scores in quiet and in noise were significantly greater with bilateral CI (CI/CI) than with a unilateral CI group. The improvement with CI/CI (+11% and +16% in quiet and in noise, respectively) was significantly better than with a CI/Hearing Aid (HA) (+6% and +9% in quiet and in noise, respectively) emphasising that the improvements are not just seen from the provision of bilateral stimulation. Furthermore, only subjects from the CI/HA group with preoperative aided speech scores >60% performed as well as CI/CI participants. Yet, CI/CI subjects displayed significantly lower preoperative aided speech scores on average compared with those displayed by CI/HA subjects. Overall, the retrospective study, based on basic speech audiometry, indicates that a second CI is likely to provide better postoperative speech outcome than an additional hearing aid (i.e. bi-modal) for people with very low preoperative performance and should be taken into consideration when refining CI indications. There were also recent studies that indicated the unmet needs of current outcome measures. Moeller *et al*. (2017), using semi-structured interviews, also reported adult participants demonstrated multiple functional changes following bilateral CIs use, often translating to enhanced social communication. In this study, 15 adult bilateral CI recipients were implanted bilateral CIs sequentially. Electronic transcripts of the interview responses were coded for perceived changes or lack thereof in 23 behaviours following bilateral CIs. Extent of reported benefit was quantified for each subject within and across these behaviours and at the group level as a function of age. The author described that the semi-structured nature allowed the interviewer to seek clarification as needed to ensure understanding of perceptions reported by the participant. The sets of interviews contained questions that were categorised as follows: (1) demographic information, (2) warm-up, (3) generic questions about overall benefit, (4) overhearing, (5) listening in noise and localisation, (6) discrimination/identification, (7) ease of listening, and (8) wrap-up, which encouraged additional comments not covered. The adult interviews consisted of 27 sets of extensive questions. The results suggested that many bilateral cochlear implant users experience meaningful functional benefits that may be underestimated by traditional outcome measures. The author suggested the need to expand measurement approaches to better quantify the nature of these benefits from bilateral CI in adults. The outcome measure of this study implied	

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that the current outcome measure, which is heavy reliance on audiometric tests, should be reviewed with the update for the current NICE guideline. (Leal *et al.*, 2016) In addition, Crowson et al. (2017) noted limitations with the current quality of life (QoL) outcome measure within their narrative review of unilateral and bilateral implantation in children and adults. The review of health-related quality of life (HRQoL) evidence highlighted that current QoL measures are not sensitive or robust enough to assess real-life benefit derived from functional gains in localisation and speech in noise that bilateral CI patients experience. This should be included when the current NICE guideline for the bilateral CI for the adult population is reviewed. **Beneficial for people with better hearing thresholds than are currently recommended** As mentioned in MED-EL UK's earlier submission, a presentation given by Associate Professor Padraig Kitterick in June 2017 outlined recommendations for changes to adult bilateral implantation. His research concluded that adult's with pure tone average thresholds of >90 dB HL at 2 and 4 kHz in both ears should be considered appropriate candidates. He also concluded that sequential implantation is recommended if the ear to be implanted has a pure tone average threshold >80 dB HL at 2 and 4 kHz. Vickers *et al.* (2015) specifically investigated the appropriateness of current CI guidelines with the aim of providing up-to-date evidence to inform candidacy guidelines in the UK. Results found that the type of speech test or assessment used by clinicians impacted on the dBHL required to match the 4:1 odds ratio for CIs providing a better outcome than hearing aids. The authors propose that instead of the current guidelines "hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids (TAG166; 2009)", criteria should be based on either a 4 frequency (0.5, 1, 2, 4 kHz) pure tone average poorer than or equal to 80 dBHL or a 2 frequency (2 and 4 kHz) pure tone average poorer than or equal to 85 dBHL. These findings provide evidence to extend inclusion criteria to patients who are currently missing out on this effective treatment for severe and profound hearing impairment. Furthermore, Leal *et al.* (2016) also notes the heavy reliance on audiometric tests restricts candidacy for individuals who may not be able to effectively report what they can hear. This	

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is particularly pertinent as the UK becomes more culturally diverse and larger proportions of people do not use English as their first language and also the inclusion of additional complex needs. By assessing speech intelligibility through the Speech Intelligibility Index (SII) and including this within the guidelines for CI assessment, it provides clinicians with an additional test to assess whether implantation is appropriate. The authors propose the use and inclusion of SII in collaboration with extended criteria to encompass results of 80 dBHL at 2 and 4 kHz. Moreover, Raine (2013) reports the UK implants around 5% of eligible adults, a far lower penetration rate than other European countries. This is in part due to candidacy guidelines that do not reflect real world conditions. Raine concludes that testing in noise with monosyllabic words would be more appropriate than the current candidacy benchmark of "<50% on BKB sentence testing at 70 dB SPL with adequate hearing aid provision in quiet and Pure Tone thresholds of 90 dB or higher at 2 and 4 kHz (TAG166; 2009)". Lamb (2016) also recommended that a CI should be based on functional hearing, taking into account the difficulties faced by the patients and their families in real-life situations rather than strictly adhering to the audiological criteria. Support for these suggestions are reiterated by Vickers *et al.* (2016) who also suggested AB monosyllabic words combined with CUNY (City University of New York) audio-visual sentence tasks should be incorporated into testing to better evaluate lower performing candidates. Additional evidence for inclusion of monosyllabic word testing in UK guidelines comes from use in other European countries. Belgium uses this test in the assessment of adults whose PTA thresholds are worse than 85 dB HL at 500Hz, 1 and 2 KHz showing how the combination of wider criteria and more varied testing can benefit the assessment of cochlear implant candidates in the UK (De Raeve & Wouter, 2013). <u>Broadening CI criteria</u> It is recommended that cochlear implants should be considered as a treatment option for tinnitus, even when the restoration of speech understanding is not the primary aim. There is a wealth of evidence to suggest that patients with severe tinnitus would benefit from cochlear implantation. The prevalence of tinnitus within implant candidates ranges between 67-100%	

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suggesting a significant number of patients could regain control of tinnitus percept through this treatment (Baguley & Atlas 2007). Kleinjung (2009) reported the physiological benefits in a case study of a single male with short-term sudden deafness. Cochlear implantation provided initial reduction in tinnitus and total abolishment after electrical stimulation from implant activation, when tested 3 months postoperatively. Consistent outcomes were documented by Beuchner *et al.* (2010) for 3 of 5 unilateral participants whereby tinnitus was significantly reduced alongside enhancement in speech recognition scores only when the implant was active. Additional evidence for the successful use of cochlear implants for tinnitus alleviation is reported by Kompis *et al.* (2012). Authors noted some level of retained benefit from implantation up to 6 months post-surgery. They found tinnitus in 25 of 174 subjects was abolished and 51.2% reporting some improvement, for which 60 participants indicated a 10% decrease in tinnitus loudness. Outcomes such as these suggest a presiding role for electrical stimulation in tinnitus management. <u>Summary</u> In summary, this outline of current research indicates UK candidacy guidelines for adults is in need of review, particularly considering the impact of a growing proportion of the UK population who are not able to access implantable treatment options for hearing loss. The reliance on audiological thresholds by clinical commissioning groups without further consideration of functional hearing ability in real world situations adds a further barrier to hearing solutions for adults. Two retrospective case studies presented by Chundu & Flynn (2014) demonstrate how strict adherence to audiological criteria, rather than the inability to benefit from functional hearing aids led to the decline of funding and the denial of timely access to treatment. As the current NICE guideline indicates a score of 50% or greater on BKB sentence testing at a sound intensity of 70 dB SPL for candidacy guideline for adult, for whom the above evidence indicates, is a now an outdated and poor method for assessing implantations suitability. Based on the body of evidence, it is suggested that the guidelines are reconsidered to also adopt more relevant testing methods that are reflective of real-world setting.	

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In conclusion it is clearly evidenced that UK guidelines when compared to other countries are far more stringent. MED-EL supports the recommendations made by current researchers to open criteria to individuals whose pure tone average threshold at 2 and 4 kHz is >80 dB HL and include greater weighting on a candidates' functional hearing using monosyllabic word tests and speech in noise, which will ultimately bring the UK candidacy in line with the rest of the world.

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Respondent: Cochlear Europe Ltd **Response to proposal:** Agree Cochlear Europe Ltd 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. Cochlear is the global leader in implantable hearing solutions with over 30 years' experience in innovation, design, development and continuous improvement of cochlear implant technology, with over 300,000 users of our hearing systems worldwide. Cochlear are in agreement with the consensus view of others in the UK closely involved with cochlear implantation that the current candidacy criteria as defined by NICE TAG 166 are no longer 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 the intention to review candidacy requirements. Research and clinical developments since the 2009 guidance now make a revision of the candidacy requirements essential to ensure that all those who might benefit from cochlear implants in the UK have access to the technology. This reflects the ongoing developments in the technology, surgical practice, and understanding of the benefits and patient care that have occurred in recent years (eg: Vickers 2015, Lamb 2016, Raine 2016). The UK now has one of the strictest candidacy requirements in the developed world (Vickers 2016a). Recent research has found that CIs would be appropriate for people with lower hearing thresholds than the current guidelines indicate (Lovett 2015, Lamb 2016, Leal 2016, Vickers 2016b, BCIG Consensus statement 2017). We therefore support a	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed, and therefore no review of the recommendation for bilateral implants in adults will be carried out.

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relaxation of the threshold criterion to a minimum of ≥80 dB HL or greater in line with the recent available evidence and research. We also propose that audiometric assessment for cochlear implant candidacy should include a wider range of test frequencies (ie at 500, 1000, 20000, 3000 and 4000 Hz) beyond the two frequencies specified by TAG166. There is convincing evidence that audibility of speech across the speech spectrum as a whole is a predictor of clinical outcomes and speech perception abilities (Govaerts 2007, Vickers 2016, Hanvey 2016) and clinical experience shows that a number of possible candidates with low frequency hearing loss who might benefit from cochlear implantation do not meet the current criteria based on thresholds in the high frequencies only. The BCIG Candidacy Working Group Service Evaluation (BCIG, 2017) 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 speech discrimination criterion for performance. The data from that evaluation also indicates 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 phoneme score of <50% using the Arthur Boothroyd (AB) Word test. The consensus statement (BCIG, 2017) also stated that the current assessment used to determine sufficient benefit from hearing aids (the BKB sentence test presented in quiet) does not adequately assess the difficulties with listening that potential candidates experience in everyday life, and that word-based listening tests are more appropriate than sentence-based listening tests for assessing sufficient benefit from hearing aids (Vickers & Kitterick 2017). Based on this, Cochlear Europe support adoption of an assessment of speech discrimination to determine candidacy for a cochlear implant using a word test (the	

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most commonly used monosyllable test used conventionally in audiology practice in the UK is the AB word test). **Suggested revisions of section 1.5:** Cochlear Implants should be considered for children and adults with severe to profound hearing loss, and for whom optimally fitted conventional hearing aids do not provide adequate benefit. For adults, adequate benefit from hearing aids is considered to be that providing sufficient hearing abilities to meet an individual's communication, social, education and employment needs. For this purpose, unaided hearing thresholds are ≥80dBHL or greater at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally. For all candidates, assessment by a multidisciplinary clinical team should determine that cochlear implantation is likely to provide greater benefit than that which can be provided through conventional, optimally fitted hearing aids. Benefit should be measured by a monosyllable test (eg: the AB word test), with inadequate benefit from hearing aids defined by a score of <50% correct phonemes. Adequate benefit from hearing aids for children is considered to be that providing sufficient hearing performance to support speech, language and listening skills appropriate to age, developmental stage and cognitive ability (NB; this represents no change from current TA 166). **Other Issues.** There are a number of other categories of clinical scenarios in which there is published evidence of the benefits of cochlear implantation which we recommend adding to the current criteria:	

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Bilateral Implantation in Adults We note the conclusion by NICE 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, and as the cost of the technology has not changed sufficiently, bilateral implants for adults are not being considered for inclusion in the guidance at this time. 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. We are aware that there is currently a proposal for the 'Foundation' study aimed at assessing the feasibility of conducting a randomised controlled trial of bilateral cochlear implants in adults. In view of this, and the widespread evidence available globally regarding the benefits of bilateral cochlear implants in adults (eg., Blamey et al 2015), we recommend that the data pertaining to this extended indication for cochlear implants is kept under close review with a view to reconsideration by NICE in the near future. **Asymmetric hearing losses:** Unilateral implantation for children or adults with asymmetric losses (better ear <80 dB HL) as long as implanted ear is >80 dB HL (Greaver 2017, BCIG Consensus Statement 2017); there is growing clinical experience that candidates in this category could also benefit significantly from cochlear implantation and we recommend that this extended indication is kept under review with a view to consideration by NICE.	

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Respondent: Cochlear Implanted Children's Support Group (CICS) **Response to proposal:** Agree The Cochlear Implanted Children's Support Group (CICS) is a national voluntary support group representing some 1,500 families whose deaf children, aged 3 months to 25 years, either already have cochlear implants or are being assessed for implantation. Run by parents of children who use cochlear implants, the group provides contact, information, support and events for families at any time before, during or after their child's cochlear implant/s. www.cicsgroup.org.uk CICS has been in existence for 25 years and we have seen not only how life-changing cochlear implantation is for deaf people of all ages, but also the very great improvements in the technology that have taken place over recent years. The vast majority of children who are profoundly deaf are able to develop listening skills and intelligible speech, making mainstream school, further and higher education, university degrees and employment far more accessible and achievable. Cochlear implants have transformed the lives of the current generation of deaf children and young people, and it is no longer rare for young deaf adults to achieve university degrees. We are delighted that NICE intends to review Section 1.5 of TA 166 as we believe this is no longer fit for purpose, and we are grateful for this opportunity to comment. We are also pleased that other organisations with whom we work and liaise such as the Adult Cochlear Implant Action Groupwill be submitting comments including many academic references. As a user group our experience goes beyond that of research and academia. We live with the proof of the value of this wonderful technology in our everyday lives when we see deaf children achieving far better outcomes than ever before, making hearing friends, managing well in mainstream schools, taking part in local sport clubs, etc. Twenty five years ago the expectations from cochlear implants were to achieve an awareness of sound. Nowadays cochlear implant users are listening and speaking on the phone, learning two spoken languages, enjoying music and integrating into the hearing world. Families whose children use cochlear implants have first-hand experience of the real benefit of this technology.	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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From our perspective you cannot put a price on this technology and process that can take deaf individuals from a world of silence and isolation to one where they can integrate into the hearing world, need far less support, achieve so much more and be able to contribute to society. It is therefore imperative that as many deaf people as possible who are suitable candidates can access this technology. However, we believe that the current candidacy requirements exclude children and adults who would greatly benefit from implantation, and denies them the greater access to education, employment and social life that implantation would afford them. Countries such as Australia, America and certain parts of Europe are using a criteria of 70 dB HL and yet in the UK the threshold is still 90 dB HL which we believe is much too conservative and demanding relative to the benefits that can be experienced. Given that adequate benefit from hearing aids for children is considered to be speech, language and listening skills appropriate to age, developmental stage and cognitive ability, we believe that cochlear implantation should be available to children who have less of a hearing loss than the current TA 166 guidance allows. We have conducted some everyday research from within our membership where, for various reasons, children have been implanted despite falling outside the current NICE threshold criteria. Information has been provided by their parents and is summarised in the attached Appendix 1 which clearly shows the great benefit those children are gaining not only in terms of how much more they can hear than pre-implant but also in their quality of life. Broadly speaking we can see that children who have hearing losses around 85 dB HL at 2 and 4 kHz are achieving audiograms of 30 dB HL across all frequencies. This is clearly far better than could possibly have been achieved with the best available hearing aids. The parents' brief comments are also clear indicators of the tremendous value the cochlear implants have brought to their children not only in what they can hear, but in increasing confidence, giving access to social opportunities such as sport, and accessing educational videos and cinema without the need for subtitles. Several of these children have had progressive losses and have had prolonged periods of struggling with hearing aids until	

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they dropped closer to the NICE threshold for implantation. This means that they have been denied access to better hearing while they effectively waited to fail audiologically, losing schooling, social interaction and confidence while their hearing loss got progressively worse. It is vital to close, not widen the gap that invariably exists between the achievement of deaf and hearing children. (evidence of gap http://www.ndcs.org.uk/for_the_media/press_releases/post_16_attainment.html) It must not be forgotten that it is not enough to just hear normal conversation well. A great deal of what children learn is by overhearing what hearing people are saying a few feet away and soft speech is at about 30-35 dB HL. When audiograms of 30 dB HL can be achieved with the provision of cochlear implants it is vital that deaf people of all ages who are not achieving this through hearing aids are given the opportunity to do so through cochlear implants, and we, therefore, strongly believe that the NICE threshold must change as quickly as possible. The attached table (*appendix provided but not reproduced here*) and explanation above show just how much benefit these children who were outside the current threshold criteria have gained over and above what they could access with hearing aids, and we submit that this is real life evidence that the current criteria should certainly be relaxed to ≥80dBHL at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally. Furthermore, we believe, there should be a provision that clinical judgement should be allowed as to whether in particular circumstances an individual with a loss of between 70 and 80 dB HL should be implanted. Lowering the threshold will not only make implants accessible to those who meet a required 80 dB HL criteria (or between 70 dB HL and 80 dB HL with clinical judgement) but will also mean that those with a progressive loss will not have to wait as long for an implant/s. For children it is vital to have the best possible access to sound as early as possible while they are still in their formative years. If they are not able to access speech	

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across the frequencies and there is a procedure that will give them that access, then they should have it as soon as possible. Given the enormous benefit clearly available from implantation we also believe that unilateral cochlear implantation should be provided for: • children with asymmetric hearing losses where the better ear has a loss of >80 dB HL (or between 70 and 80 dB HL with clinical judgement) at two or more of 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz frequencies. • children with unilateral deafness who have intrusive tinnitus in the deaf ear or progression in their good ear, and for • adults who have both intrusive tinnitus in the deaf ear and progression in the good ear and unilateral losses that meet the dB and frequency requirements. For adults, given that adequate benefit from hearing aids is considered to be sufficient access to meet an individual's communication, social, education and employment needs, we believe that the candidacy criteria should be the same as for children and should include bilateral implantation. Furthermore, we believe that the current BKB test is not an accurate way of assessing whether an individual is receiving sufficient benefit from hearing aids. Hearing conditions in this test are unrealistic as they are nothing like hearing in the outside world. Deaf children and adults do not live in a soundproof bubble. They are in a hearing world where there is always background noise, be it people talking, the clatter of plates in a canteen, the hum of machinery in an office. To make sense of general conversation in everyday life it is necessary to hear it all. Missing even a small percentage of a sentence, or guessing at part of it, can lead to great misunderstandings and loss of confidence for deaf people having to ask again and again for repetition. We believe that a word-based listening test would be more appropriate than a sentence-based listening test for assessing benefit from hearing aids. The AB (Arthur Boothroyd)	

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word test should replace the BKB test, and be used at a range of frequencies across the speech spectrum, with adequate benefit from acoustic hearing aids being defined as a phoneme score of 50% or greater on this test. We look forward to commenting further on NICE proposals as part of the process following this consultation.	

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Respondent: Chear Ltd **Response to proposal:** Agree Chear is an independent centre for second opinion for children with hearing loss. In addition to assessment of detection levels (audiogram thresholds) Chear specialises in functional assessment of hearing for speech for children and adolescents. This includes evaluation of the hearing aid fitting provided by the local audiology team under the NHS. In a recent paper in Ear and Hearing, Marriage et al (2018), children fitted with hearing aids were assessed using the Aided SII score and full assessment of individual speech scores on a range of functional tests through hearing aids. The case studies of individual children with a cochlear implant in one ear and hearing aid in the other allows for direct comparison of speech understanding for different levels of hearing loss. On the basis of clinical information, research findings and case studies of children with hearing aids and cochlear implants we propose the following eligibility criteria for children: **Chear submission on an eligibility criterion for bilateral CI in children with cochlear or sensori-neural hearing loss:** 1. **Audiometric thresholds of >= 80dB HL at any 2 octave frequencies.** **And/Or:** 2. **Aided SII score of less than 65 % (0.65 SII) for 65 dB input speech signal.** **Evidence base for this criterion derived from Stiles et al (2012), Tomblin et al. (2015) and Leal et al (2016).** **And/Or:** 3. **Speech score on pre-recorded open set monosyllables/single words presented in quiet at 65 dB SPL of <74%.**	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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Or on closed set testing using familiar vocabulary items: Error rate of 20% or greater, eg 32 items correct out of 40 in closed set speech task eg CCT or CAPT presented in quiet at 65 dB SPL. This presentation level of 65 dB SPL represents typical conversational hearing in quiet at 1 meter from talker and relates to the input signal used for deriving the Aided SII score (Item 2). Evidence derived from Chear case studies of children with CI and HA with appropriate speech testing. (Case Study 1 – *provided but not reproduced here*)	

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Respondent: British Cochlear Implant Group **Response to proposal:** Agree The British Cochlear Implant Group (BCIG) welcomes the review of TA166 and our feedback into this process in also endorsed by the British Society of Audiology. BCIG represents professionals working in the field of cochlear implantation; our membership includes clinicians and researchers who are highly experienced in both applying and exploring the effectiveness and suitability of the guidance in TA166. Cochlear implantation is a multidisciplinary field and BCIG's position on this matter is informed by the collaborative activities over many years of our membership, which comprises a range of professional groups including audiologists, clinical scientists, doctors and surgeons, speech and language therapists, teachers of the deaf, clinical psychologists and associated third sector organisations. The British Society of Audiology is the learned society in audiology in the UK, its membership is similarly multidisciplinary and promotes excellence in clinical practice and is active in informing national public sector policy. Specifically, NICE has recommended that the review pertains to part of section 1.5 of the original guidance (TA166), as it acknowledges that evidence which has become available since publication of that guidance suggests that criteria stated in 1.5 no longer reflects clinical practice and should be updated. BCIG advocates consideration of cochlear implantation 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 acoustic hearing aids do not provide adequate benefit. For adults, we consider adequate benefit from hearing aids to be sufficient access to meet an	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed, and therefore no review of the recommendation for bilateral implants in adults will be carried out. Treatments for intrusive tinnitus are outside the remit of this appraisal.

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individual's communication, social, education and employment needs. For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability. **In summary, BCIG's review of recommendation 1.5 is to propose the following new draft wording of this section:** *For the purposes of this guidance, severe to profound deafness is defined as hearing sounds that are greater than or equal to 80dBHL (≥80dBHL) at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz 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* • *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.* **Background to BCIG's recommendations:** BCIG undertook a membership survey in 2015, the results of which indicated that, by a very wide margin, our members' primary concern was that the organisation should move to facilitate a review cochlear implant candidacy in the UK. Our members gave this 5 times greater importance than the next highest ranked area, which reflects the enormous concern in the field that severe and profoundly deaf people, who we know could benefit from cochlear implantation, are being denied access to this intervention.	

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BCIG has a Candidacy Working Group in place to focus on this important issue. It has undertaken a Service Evaluation study to inform the question around cochlear implant candidacy. This study is currently under preparation for publication and BCIG Council has received an early report which has informed our recommendation (Kitterick & Vickers 2017b). This report will be made available to NICE on request. The Candidacy Working Group also developed a consensus statement on candidacy for cochlear implantation in 2017, the results of which are published online (BCIG Candidacy Working Group 2017). This consensus was reached amongst 160 representatives from over 30 stakeholder organisations through consideration of 600 patient scenarios. These reflected potential cochlear implant candidature situations, for which the respondents rated the benefits of the intervention to outweigh the risks. *Recommendation to lower hearing thresholds* BCIG proposes a lowering of hearing threshold to greater than or equal to 80dBHL (≥80dBHL) at two or more frequencies (from 500Hz, 1000Hz, 2000Hz, and 4000Hz) bilaterally. This proposal is based on studies which indicate that those with lower hearing thresholds benefit from cochlear implantation (Lovett 2015, Lamb 2016, Leal 2016, Vickers 2016b, Kitterick & Vickers 2017a. 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 2006, Kates 2013, Vickers 2016b, Hanvey 2016). We are also aware that NICE guidance threshold criteria are currently the highest in the developed world (Vickers 2016a), which (where audiometric criteria are in place) can be as low as 70dBHL. This is further supported by the following BCIG consensus statements:	

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• Expanding candidacy to include some groups of adults and children with less profound forms of hearing loss would be appropriate because the benefits would outweigh the risks • Cochlear implantation is appropriate for less profound degrees of hearing loss than currently permitted according to NICE guidance • The audiometric frequencies used to determine candidacy should vary depending on the nature of the patient's audiogram (e.g. different frequencies for rising/reverse slope, flat, and downward-sloping losses) • Other frequencies should be considered apart from 2 & 4 kHz • Candidacy criteria in the UK should better align with changes in candidacy that are taking place in other countries *Recommendation for a revised assessment for adequacy of hearing aid benefit for adults* The BCIG Candidacy Working Group Service Evaluation included the objective of identifying the most appropriate threshold score for unilateral cochlear implantation in adults. The results of the study 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, the study indicated 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 phoneme score of <50% using the Aurthur Boothroyd (AB) Word test. The BKB test has well recognised limitations including impact of native language, language level and cognitive level on the score, as those with higher English language skills are better able to guess correctly, whereas and those with lower (or no) understanding of spoken English cannot and often cannot be assessed using this test (Vickers 2016b, Craddock 2016)	

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A word-based test scored by phonemes will expand the number of candidates who can be assessed by this method as a standard approach. As a result, we advocate changing from BKB sentence testing to AB phoneme recognition as a measure of adequacy of hearing aid benefit (Lamb 2016, Vickers 2016c, Sladen 2017, Kitterick & Vickers 2017b). The protocol for undertaking this assessment will be in line with the service evaluation protocol and will be detailed in the forthcoming revision of the BCIG Quality Standards document, due April 2018 and the current version of which is available online. This recommendation 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 Bamford-Kowal-Bench (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. **Additional issues** Whilst we appreciate that the current review is focussing on section 1.5 of the current guidance, additional issues for consideration include the following: *Asymmetric losses* Unilateral implantation for children with asymmetric losses (with the better hearing ear <80 dB HL) as long as the ear to be implanted is >80 dB HL (Sadadcharam 2015, Franco-Tobin 2015, Greaver 2017, Vickers & Kitterick 2017). This is supported by the consensus statement:	

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• Cochlear implantation can be appropriate where the degree of hearing loss is different in the two ears, and in patient groups where only one ear would be considered appropriate for implantation. *Bilateral implantation in adults* In our view bilateral cochlear implantation should be clinically considered in adult patients at risk of cochlear ossification (Caye-Thomasen 2012, Vickers & Kitterick 2017). This is supported by the consensus statement: • Adult patients at risk of ossification (bone growth within the cochlea that could prevent insertion of the implant electrode) should be considered for bilateral implantation. *New unilateral deafness indication* Unilateral implantation in unilateral deafness for children with intrusive tinnitus in the deaf ear or progression in their good ear, and for adults who have both intrusive tinnitus in the deaf ear and progression in good ear (Vickers & Kitterick 2017). This is supported by the consensus statement: • Cochlear implantation is not only appropriate where the primary motivation for treatment is the restoration of speech understanding but can also be appropriate where it is for the alleviation of tinnitus.	

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Respondent: Action on Hearing Loss **Response to proposal:** Agree Action on Hearing Loss welcomes the opportunity to comment on the NICE's proposal to update NICE Technology Appraisal (TA) 166: Cochlear implants for children and adults with severe to profound deafness. Hearing loss is a major public health issue that affects 11 million people across the UK, around one in six of the population. Evidence shows that hearing loss is a serious health condition that can have an adverse impact on a person's health and quality of life. People with hearing loss also have an increased risk of other health problems such as depression and dementia. For example, a recent study identified hearing loss as the largest modifiable risk factor for dementia. If removed, the study states that 9% of dementia cases could be prevented. The NICE Hearing loss (adult onset) draft guideline also states that unaddressed hearing loss in people with dementia will "significantly affect understanding and will exacerbate underlying cognitive difficulties". Diagnosing and managing hearing loss and taking hearing loss into account during the diagnosis and management of other conditions is crucial for good communication and care[i]. However, evidence suggests that people wait on average ten years before seeking help for their hearing loss and when they do, GPs fail to refer up to 45% of people reporting hearing loss to hearing services. There are currently no national screening programmes for adults with hearing loss and more could be done to encourage people to seek help and check their hearing. Since 2009, cochlear implantation has been approved by NICE as a cost effective form of treatment for children and adults with severe or profound levels of hearing loss. However, evidence suggests that more people could benefit from cochlear implantation than are currently doing so. For example, one study found only 5% of adults who could benefit from a cochlear implant receive one.	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

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The Department of Health and NHS England's *Action Plan on Hearing Loss* states that urgent action is needed reduced the hearing loss and also improve access to hearing technologies. The Action Plan calls for better access to cochlear implants and also lists "improved access to a choice of support to manage hearing loss, including innovative technologies (e.g. hearing aids and implants)" as a key outcome measure for service improvement. The World Health Assembly also recently adopted a resolution which called for improved "access to affordable, cost-effective, high-quality, assistive hearing technologies and products". **Tackling the growing prevalence and impact of hearing loss and improving access to cochlear implantation is now a national priority and we welcome NICE's decision to review its guidelines to ensure cochlear implantation is available for all those who could benefit from it.** **We welcome NICE's decision to update Recommendation 1.5.** As Appendix B acknowledges in the Technology Appraisal Review proposal paper, there is growing evidence that the current candidacy criteria are excluding some people who could benefit from cochlear implantation. The research referenced in the proposal paper shows that the 90 dB threshold used in the current criteria to define to severe to profound deafness is one of the most restrictive in Europe. There is good evidence that cochlear implantation would be appropriate for adults with levels of hearing loss lower than 90 dB. New research also supports the case for testing at a wider range or frequencies across the speech spectrum as predictor of clinical outcomes and speech perception abilities. **We support the Adult Cochlear Implant Action group's proposal for NICE to consult on revising the audiology threshold used in Recommendation 1.5 to 80 dBHL or greater at two or more frequencies.** As stated in NICE's proposal paper, concerns have also been raised about the use of the BKB (Bamford-Kowal-Bench) test as the sole means of assessing hearing function in adults. Research shows that other speech tests would be a more appropriate way of determining whether individuals are suitable for cochlear implantation. **We support the Action Group's proposal for NICE to consult on replacing the BKB test with an Arthur Boothroyd (AB) test.**	

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We acknowledge the conclusion in the proposal paper that the cost of cochlear implants has not come down enough to affect NICE's recommendations on cochlear implantation. We note the conclusion that new research is unlikely to affect NICE's recommendations on bilateral cochlear implantation in adults due to the requirements of the cost-effectiveness model used to develop the current recommendations. The proposal paper also states that NICE cannot consider other cost-utility studies for bilateral cochlear implantation because NICE must independently conduct their own assessments of cost-effectiveness. We welcome the fact that research is already underway to assess the feasibility of conducting a Randomised Control Trial (RCT) of bilateral cochlear implantation in adults. An RCT would satisfy the research recommendation in TA 166 and potentially lead to a future expansion of the current criteria. As stated in the proposal paper, new research shows that bilateral cochlear implantation in adults may provide additional benefits compared to unilateral implantation. **We urge NICE to continue to review the evidence in this area to ensure bilateral cochlear implantation is available to everyone who could benefit from it**. We also urge NICE to consider other research[ii] not referenced in the proposal paper, which proposes alternative methodologies for assessing the cost utility gain of bilateral cochlear implantation. **If NICE's requirement for an RCT cannot be satisfied, we urge NICE to conduct a further review of how best to assess the benefits of bilateral cochlear implantation in adults**. A further review will also support the aims of the Department of Health and NHS England's *Action Plan on Hearing Loss* to improve access to cochlear implantation.	

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Respondent: Adult Cochlear Implant Action Group **Response to proposal:** Agree 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*	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed, and therefore no review of the recommendation for bilateral implants in adults will be carried out. Treatments for intrusive tinnitus are outside the remit of this appraisal.

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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).	

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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 dBHL (≥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 · 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).	

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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. **References** Athalye,S, Mulla, I, Archbold, S. (2014). The experiences of adults assessed for cochlear implantation who did not proceed. Cochlear Implants International 2014 VoL. 15 No. 6	

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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

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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.	

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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.	

Respondent: Royal College of Physicians **Response to proposal:** Agree We have liaised with the British Association of Audiovestibular Physicians (BAAP) and would be happy to support the updated process.	**Comment from Technology Appraisals** Comment noted. Section 1.5 of the guidance will be updated as proposed.

Paper signed off by: Elisabeth George, 02 05 2018

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