NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SINGLE TECHNOLOGY APPRAISAL

Cochlear implants for children and adults with severe to profound deafness [ID1469]

The following documents are made available to the consultees and commentators:

1. **Consultee and commentator views on this technology and its possible use in the NHS** from:
   - Cochlear Europe
   - Med-El
   - Oticon
   - Action on Hearing Loss
   - Action Group on Adult Cochlear Implants
   - Cochlear Implanted Children's Support Group
   - The Ear Foundation
   - National Cochlear Implant Users Association
   - National Community Hearing Association
   - British Association of Audiovestibular Physicians and the Royal College of Physicians
   - British Cochlear Implant Group
   - NHS England
   - UCL

2. **Draft wording for consultees and commentators**

3. **Consultee and commentator comments on the draft wording** from:
   - Advanced Bionics
   - Cochlear Europe
   - Med-El
   - Cochlear Implanted Children's Support Group
   - National Cochlear Implant Users Association
   - Action on Hearing Loss
   - Action Group on Adult Cochlear Implants
   - British Association of Audiovestibular Physicians
   - British Cochlear Implant Group
   - NHS England
   - UCL

4. **Committee briefing**

Any information supplied to NICE which has been marked as confidential, has been redacted. All personal information has also been redacted.

NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

About you	
1.Your name	**Timothy Mann**
2. Name of organisation	Cochlear Europe Ltd
3. Job title or position	Market Access Specialist
4a. Brief description of the organisation (including who funds it).	Manufacturer
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? x☐ other (please specify): Manufacturer

4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No
The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to:	For the purposes of this guidance, cochlear implantation is recommended for children and adults with a hearing loss 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 presented at 70 dBA • For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability
6. Please include any evidence for this suggested wording:	**"For the purposes of this guidance, cochlear implantation is recommended for children and adults with a hearing loss greater than or equal to 80dBHL (≥80dBHL)"** Action on Hearing Loss (AOHL, 2015) have estimated that 900,000 people in the UK have a severe or profound hearing loss (of at least 70 dB HL in their better ear) and that on average, people wait up to 10 years to seek help for their hearing difficulties. Adequately addressing hearing loss can improve an individual's independence, wellbeing and social engagement, however, it has been shown that access to, and quality of treatment is highly variable across the country (The King's Fund, 2014). Early interventions addressing hearing loss can have significant benefits in combating these challenges. More broadly speaking, cochlear implantation

should not be purely based on Pure Tone Audiometry (PTA) guidelines, and should take into consideration other factors such as work, quality of life, and social impact (Chundu & Flynn, 2014).

Diane Matthews, from South Yorkshire, struggled for many years with her hearing loss before receiving a cochlear implant (CI) in 2017:

"It was a seemingly endless cycle going back and forth to audiologists. Being told that I wasn't quite deaf enough. 'Come back next year' they would say.

I was being told that I was outside of criteria. I was actually going out of my mind. I had lost my confidence and was considering leaving my job within the police force. I could only communicate via email and text – I had withdrawn from everyday life.

Please remember that people, like me, hide hearing loss, it's something we are embarrassed about. Lots of people outside of guidelines would benefit from an implant. With the current pressures our NHS is under, sadly costs are becoming more and more of a factor in HCP's decisions.

It's not only about the fact that I was able to keep working, paying tax, and contributing to society but consider the impact of some of the longer term effects on the person and the community: depression, anxiety, social isolation and loneliness.

Please think of the person as a whole, not just an ear. Only < 7% of all the people who would benefit from implants have one."

- Diane Matthews, 42

Research shows that hearing loss doubles the risk of developing depression and increases the risk of anxiety and other mental health problems (Saito et al, 2010; Acar et al, 2011; Mulrow et al, 1992). There is also strong evidence that people with a severe hearing loss are at five times more risk of developing dementia than their normal hearing peers (Lin et al, 2011; Lin et al, 2013; Gurgel et al, 2013; Albers et al, 2015). Hearing loss has also been linked to increased incidence of cardiovascular disease, diabetes, stroke and obesity (AOHL, 2015).

When cochlear implantation first gained regulatory approval in the 1980s, clinical criteria stipulated that CI recipients should have a profound hearing loss and gain no benefit from conventional hearing aids (HAs). However, over time, clinical experience demonstrated superior outcomes for individuals with greater degrees of residual hearing (Briggs, 2011). The current Cochlear™ instructions for use for CI are as follows:

Group A

Individuals aged up to 17 years who have clinically established bilateral or unilateral sensorineural hearing loss and who have compromised functional hearing with hearing aids or would receive no benefit with hearing aids. Typical preoperative threshold levels in the impaired ears demonstrate a pure-tone average loss of moderately severe to profound degree.

Group B

Individuals aged 18 years and older who have clinically established postlinguistic bilateral or unilateral sensorineural hearing loss and who have compromised functional hearing with hearing aids, or would receive no benefit with hearing aids. Typical preoperative threshold levels in the impaired ears demonstrate a pure-tone average loss of moderately severe to profound degree

Group C

Prelinguistically or perilinguistically deafened individuals aged 18 years and older who have profound bilateral sensorineural hearing loss and who have compromised hearing with hearing aids.

Typically, reimbursement and selection criteria are much more conservative than the indications listed in the instructions for use. The UK currently has the most conservative clinical candidacy criteria for CI. Germany, Italy, Australia and Ireland have a much higher level of physician discretion when it comes to determining the appropriateness of implantation (Raine, 2013; Vickers et al, 2016a). The general consensus of appropriate audiometric candidacy is average pure tone thresholds >75-80 dB HL at frequencies above 1 kHz.

The following table summarises current selection criteria in different countries:

Current candidacy summary	
Germany and Italy	Flexible; the clinical team determines if an individual is an appropriate candidate
The Netherlands	Flexible; best aided Consonant-Vowel-Consonant (CVC) phoneme score <70% at 70dB in quiet
Ireland	Flexible; the clinical team determines if an individual is an appropriate candidate
Belgium NB – currently under review	Strict; average pure tone threshold >85dB + aided CVC phoneme score <30% at 70dB in quiet
Australia	Mean thresholds >70 dB HL above 1.5 kHz
Sweden	4 frequency average (4FA) (0.5, 1, 2 and 4 kHz) ≥70 dB HL (best ear)

	As criteria for cochlear implantation broadens there will be a point of overlap between where a person will receive adequate benefit from a HA but would also benefit from a CI. The primary decision problem is therefore trying to define the performance limits where CI criteria could confidently expect to achieve better outcomes with a CI compared to standard of care (e.g. HA's). The Candidacy Consensus Working Group of the British Cochlear Implant Group (BCIG) conducted a survey to answer this question. They developed a consensus statement on candidacy for cochlear implantation, the results of which are published online (BCIG Candidacy Working Group, 2017). The following are the primary conclusions supporting a change to 80 dB HL: 1. Cochlear implantation is appropriate for less profound degrees of hearing loss than currently permitted according to NICE guidance 2. 96% of the consensus group agreed that changing the audiometric threshold to 80 dB HL was both appropriate and necessary based on the current clinical evidence 3. 76% of the consensus group agreed that changing the threshold to 70 dB HL was both appropriate and necessary, however, at this point in time moving to a 70 dB HL threshold was considered less certain based on the currently available clinical evidence A number of clinical studies have been published which address CI candidature criteria or provide comparisons of performance achieved by HA and CI users, with hearing losses within the currently overlapping indications for the two types of devices. Research outcomes and methods differ from country to country, providing a heterogeneous pool of data which makes direct correlations to an 80 dB HL threshold more difficult to determine. A literature review carried out by Cochlear in 2017 (data available on request), identified peer reviewed evidence relating to CI candidature, and comparisons between outcomes from CIs and conventional HAs. Of the 35 articles that met the inclusion criteria of the review, we have highlighted three that are of particular relevance to this topic. <u>Leigh et al (2011)</u> This study formed part of the assessment for CI criteria in Australia to be set at 70 dB HL. Monosyllable and sentence recognition was measured in cohorts of children using CIs (N=80) and HAs (n=62). HA users were classified as moderate (mean PTA < 66 dB HL), severe (66 – 90 dB HL) or profound (> 90 dB HL). For monosyllables, the CI users scored significantly higher (mean of 54%) than the severe (26%) and profound (12%) HA users, and about the same as the moderate HA users. The pattern was similar for sentences, except that the CI users scored significantly higher only than the profound HA group. Regression analysis revealed that for children with thresholds <75 dB HL the recommendation would be to continue with HAs.

Lovett et al (2015)

Similar to the study by Leigh et al (2011), this study compared speech recognition outcomes in children with PTA thresholds >50 dB HL at 2 and 4 kHz bilaterally, who used either bilateral CIs (n=28) or HAs (n=43). The aim was to establish the preoperative threshold level at which there is an odds ratio of 4:1 for better outcomes with CI. For a 4FA (0.5, 1, 2, 4 kHz), an odds ratio of 4:1 was achieved at 79 dB HL in quiet; recommending that an average of 80 dB HL (in both ears) should be adopted as the criterion by policy makers.

Verhaegen et al (2008)

This study compared phoneme recognition scores between two cohorts; HA users versus CI users. It demonstrated that CI users were, on average, performing at an equivalent level to HA users with average thresholds of 80 dB HL (0.5, 1, 2 kHz).

Summary

It is now widely accepted that outcomes from CI have continued to improve over time, and this improvement is understood to have been due to both improvements in device technology and to implantation of individuals with greater degrees of residual hearing. Thus, globally there has been a gradual widening of the indications for cochlear implantation, which has been reflected to some degree by modifications to clinical guidelines. Currently the UK have the strictest criteria for cochlear implantation, and it is recognised by many clinicians, manufacturers and authorities that current CI criteria remain unduly conservative. This results in large numbers of people continuing to struggle with limited benefit from HAs, when they would be very likely to gain substantially more benefit from a CI.

"at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally without acoustic hearing aids."

Expanding to more than 2 and 4 kHz is in line with most other candidacy selection criteria around the world, except for the United States, who do not base candidacy selection on audiometric criteria, instead focusing on speech perception scores. Hoppe et al (2015) demonstrated the high predictive value of a 4FPTA in the decision process for referral for CI. Furthermore, audibility of speech across the whole speech spectrum is a good predictor of clinical outcomes and speech perception (Govaerts et al, 2006; Vickers et al, 2016b; Hanvey et al, 2016). The frequencies important for speech perception are between 750 – 3000 Hz (Kates, 2013) and therefore individuals with low-frequency hearing losses also struggle with speech understanding (Vinay & Moore, 2008).

This is further supported by the following BCIG consensus statements:

1. 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)

2. Other frequencies should be considered apart from 2 & 4 kHz

3. 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

"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 the purposes of this document, it is assumed that patients have been fitted with an appropriate HA. An appropriately fitted hearing aid would be defined as:

- HA with appropriate level of gain for the degree of hearing loss
- Fitted within manufacture guidelines
- Fitting verified using Real Ear Measurements according to the British Society of Audiology Practice Guidance "Guidance on the verification of hearing devices using probe microphone measurements" (2018)

The reason for moving from a BKB sentence test to an AB word test

The Bamford-Kowal-Bench (BKB) sentences were originally developed to test the speech recognition abilities of children, and therefore use fairly simple language and are possibly somewhat predictable. The BKB sentences have also been produced in a clear speaking style which may not represent everyday conversational speech. Additionally, native language, language level and cognitive level can all impact on an individual's score (Vickers et al, 2016b; Craddock et al, 2016; Lamb, 2016).

Countries such as Germany, Belgium and the Netherlands use a CVC phoneme test, instead of a sentence test, to assess candidacy. CVC tests are commonly used throughout the literature to assess CI performance. The AB word lists developed by Arthur Boothroyd in the 1960s are an example of a CVC phoneme test that is widely used across the UK. CVC phoneme tests, on the whole, make it more difficult to predict responses (by the patient) than tests such as the BKB sentences, and they can also be used to test a wider range of patients. The AB word lists are therefore considered to be a more appropriate test for determining the adequacy of hearing aid benefit.

This recommendation is also supported by the following BCIG Candidacy Working Group consensus statements:

1. 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
2. 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
3. Word-based listening tests are more appropriate than sentence-based listening tests for assessing sufficient benefit from hearing aids in some patients

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

We are not proposing any change to the criteria for children beyond what is proposed above in respect of the hearing thresholds and how they are measured.

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Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]:

2. Name of organisation	Royal College of Physicians (RCP) and British Association of Audiovestibular Physicians (BAAP)
3. Job title or position	RCP registrar
4a. Brief description of the organisation (including who funds it).	BAAP – British Association of Audiovestibular Physicians is the professional body of physicians practising in Audiovestibular Medicine in the UK. It is a Specialist Society of the Royal College of Physicians. It is funded by its members.
4b. Are you (please tick all that apply):	Joint organisational response
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	<u>Paediatric guidance</u>: Severe to profound deafness is defined as hearing only sounds that are equal or louder than 80 dB HL at the 4 frequencies or equal or louder than 85 dBHL of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as: For children , speech , language and listening skill appropriate to age, developmental stage and cognitive ability. Evaluation of speech perception by using tests appropriate to age and speech development is recommended. Medical investigations regarding the cause of hearing loss and associated co morbidities should be part of the assessment. <u>Adult guidance:</u> The definition of severe to profound deafness is the same as that of the paediatric population as specified by the British Society of Audiology (BSA) criterla for hearing loss. The BKB score of 50% or greater as sound intensity of 70 dB SPL is thought to be too restrictive. A sound intensity of 60 dBSPL has been suggested.
6. Please include any evidence for this suggested wording:	A recent systematic review by de Klejin et al in 2018 showed that lower audiologic hearing threholds >/= 80 B for 4 frequencies should be considered for referring children to cochlear implants. A study

by Lovett et al in 2015 showed that the thresholds should be lowered to >/- 80dB for 4 frequencies or >/=85 dB for 2 and 4 KHz.

There is evidence that babies who have no responses on ABR are very likely to become cochlear implant recipients (Hang et al., 2015) and professionals should refer those children early to the cochlear implant departments.

Medical evaluation is vital in identifying the cause of hearing loss and significant associated medical problems and the decision of giving cochlear implants to children should be tailored to individual needs and parents should be fully informed about outcomes and expectations .

1. De Klejin JL et al Identification of Pure-Tone Audiologic Thresholds for Pediatric Cochlear Implant Candidacy: A Systematic Review. JAMA Otolaryngol Head Neck Surg. 2018 May 24

2. Lovett RE, Vickers DA, Summerfield AQ. Bilateral cochlear implantation for hearing-impaired children: criterion of candidacy derived from an observational study. Ear Hear. 2015;36(1):14-23.

3. Hang AX, Roush PA, Teagle HF, Zdanski C, Pillsbury HC, Adunka OF, Buchman CA Is "no response" on diagnostic auditory brainstem response testing an indication for cochlear implantation in children? Ear Hear. 2015 Jan;36(1):8-13.

4. Berrettini S1, et al. Analysis of the impact of professional involvement in evidence generation for the HTA Process, subproject "cochlear implants": methodology, results and recommendations. Acta Otorhinolaryngol Ital. 2011 Oct;31(5):273-80

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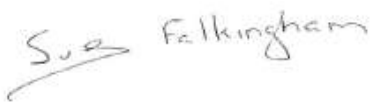
- Your response should not be longer than 10 pages.

About you	
1.Your name	**Tracey Twomey (submitting on behalf of BCIG), endorsed by Ted Killan (of the British Society of Audiology) and Sue Falkingham (of the British Academy of Audiology)**

2. Name of organisation	British Cochlear Implant Group (submission), endorsed by the British Society of Audiology and the British Academy of Audiology
3. Job title or position	**Tracey Twomey:** Chair of the British Cochlear Implant Group; Consultant Clinical Scientist, Head of Service, Nottingham Auditory Implant Programme, Nottingham University Hospitals NHS Trust  ***Endorsers:*** **Dr Ted Killan:** Chair of the British Society of Audiology; Deputy Head of Specialist Science Education Department & Audiological Science and Education Group Lead, LICAMM, Faculty of Medicine & Health, University of Leeds  **Sue Falkingham:** President of the British Academy of Audiology; Audiologist | Starkey Hearing Technologies 
4a. Brief description of the organisation (including who	**The British Cochlear Implant Group** represents professionals working in the field of cochlear implantation; 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

funds it).	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 objects of the BCIG are: for the public benefit, to advance knowledge, best practice and awareness in the field of hearing implantation, in particular through the dissemination of cochlear implant research to health professionals and information to the public in order to improve the hearing, communication and quality of life of hearing impaired people and their families. ***Endorsing 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. The BSA's mission is to advance audiological research, learning, practice and impact in hearing and balance. The vision is building knowledge and empowering professionals to improve the lives of adults and children with hearing and balance problems. One of the strengths of the BSA is that it provides an interface between researchers and healthcare practitioners as well as other groups (educationalists, government, independent sector, professional bodies, patient groups and third sector). **The British Academy of Audiology** is the largest organisation for professionals in hearing and balance in the UK. BAA's vision is to provide a clear and strong voice for professionals in audiology and to promote excellence in clinical knowledge and practice. Its mission is to: provide leadership, inspiration and guidance; develop and promote excellence in services for patients; to be a driving force for improving quality standards, training and education; to promote the profile of audiology as an autonomous profession.
4b. Are you (please tick all that apply):	☒ an employee or representative of a healthcare professional organisation that represents clinicians? ☒ a specialist in the treatment of people with this condition?

	☒ a specialist in the clinical evidence base for this condition or technology? ☐ other (please specify):
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	None
The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	**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 presented at 70 dBA** • **For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability** **(We provided the same definition in the review consultation but this definition now includes a measure for**

	the phoneme score of 70 dBA)
6. Please include any evidence for this suggested wording:	**"For the purposes of this guidance, severe to profound deafness is defined as hearing sounds that are greater than or equal to 80dBHL (≥80dBHL)"** **The UK currently has one of the strictest candidacy requirements in the developed world (for countries where audiometric criteria are in place). A survey of international cochlear implant candidacy by Vickers (2016a) found that these could be as low as 70 dB HL. Recent research has also found that CIs would be appropriate for people with lower hearing thresholds than the current guidelines indicate (Lovett 2015 et al., Lamb 2016, Leal 2016 et al., Vickers 2016b et al., Kitterick 2017 & Vickers b, Vickers & Kitterick 2017, Jasper et al., 2018).** **Audiometric definition of Severe-Profound Deafness** **The Candidacy Working Group of BCIG developed a consensus statement on candidacy for cochlear implantation in 2017, the results of which are published online (BCIG Candidacy Working Group 2017). The following are the major conclusions from the consensus statement supporting a change to 80 dB HL. Changing the audiometric 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).[1] 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. **Changing 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 currently deemed clinically necessary to provide a cochlear implant based on the available evidence, but it would also capture patients in whom there is considerable uncertainty over the size of the benefits.**

[1] 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.

	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 size of benefit may be too small to be clinically meaningful.** **"at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally without acoustic hearing aids."** **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 et al., Vickers 2016b et al., Hanvey 2016 et al.). It is known that the important frequencies for speech perception are between 750 – 3000 Hz (Kates 2013) and that individuals with low-frequency hearing losses struggle with speech understanding (Vinay & Moore, 2008) **This is further supported by the following BCIG consensus statements:** • **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** **"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" **The Bamford-Kowal-Bench (BKB) test needs reviewing and replacing with a different test as recent research concluded that; "*Use of this measure (the BKB test) alone to assess hearing function has become inappropriate as the assessment is not suitable for use with the diverse range of implant candidates today.*" (Vickers 2016c et al.)** **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 Arthur 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 et al., Craddock 2016 et al., Lamb 2016).** **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 (Vickers 2016c et al., Sladen 2017 et al., Kitterick & Vickers 2017b, Lamb 2016). 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. **"For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability"** We are not proposing any change to the criteria for children beyond what is proposed above in respect of the hearing thresholds and how they are measured. **References** British Cochlear Implant Group Candidacy Working Group) (2017) Consensus statement on candidacy for

	cochlear implantation. https://www.cicandidacy.co.uk/ British Cochlear Implant Group Quality Standards Cochlear Implant Services for Children and Adults. http://www.bcig.org.uk/bcig-quality-standard-2016/ Craddock L, Cooper H, Riley A, Wright T (2016) Cochlear implants for pre-lingually profoundly deaf adults. Cochlear Implants International. 17 (sup1) 36-41 Govaerts PJ, Daemers K, Yperman M, De Beukelaer C, De Saegher G, De Ceulaer G. (2006) Auditoryspeech sounds evaluation (A(section)E): a new test to assess detection, discrimination and identification in hearing impairment. Cochlear Implants Int. 2006 Jun;7(2):92-106. 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 Jasper L. de Kleijn, Ludwike W. M. van Kalmthout, Martijn J. B. van der Vossen, Bernard M. D. Vonck, Vedat Topsakal, Hanneke Bruijnzeel. (2018) Identification of Pure-Tone Audiologic Thresholds for Pediatric Cochlear Implant Candidacy A Systematic Review. JAMA Otolaryngol Head Neck Surg. Published online May 24, 2018. doi:10.1001/jamaoto.2018.0652 Kates, J. (2013) Improved estimation of frequency importance functions. The Journal of the Acoustical Society of America 134, EL459 (2013) Kitterick & Vickers (2017a). Assessment of the appropriateness and necessity of cochlear implantation in current and potential candidates. Technical report prepared for the BCIG.

	Kitterick & Vickers (2017b). 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 Vol. 17, (Sup1) (2016)** **Leal, C., Marriage, J., Vickers, D. 2016. Evaluating recommended audiometric changes to candidacy using the Speech Intelligibility Index. Cochlear Implants International, 17(S1).** **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** **Sladen DP, Gifford RH, Haynes D, Kelsall D, Benson A, Lewis K, Zwolan T, Fu QJ, Gantz B, Gilden J, Westerberg B, Gustin C, O'Neil L, Driscoll CL. (2017) Evaluation of a revised indication for determining adult cochlear implant candidacy. Laryngoscope. doi: 10.1002/lary.26513 [epub ahead of print].** **Vickers D, De Raeve L, Graham J (2016a) International survey of cochlear implant candidacy. Cochlear Implants International. 17 (sup1) 36-41.** **Vickers D, Kitterick P, Verschuur C, Leal C, Jenkinson L, Vickers F, Graham J. (2016b) Issues in Cochlear Implant Candidacy. Cochlear Implants International. 17(sup1) 1-2. DOI:10.1080/14670100.2016.1163104** **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, Kitterick PT.(2016c), Preliminary assessment of the feasibility of using AB words to assess candidacy. Cochlear Implants International Vol.**

	17, Iss. sup1, 2016. **Vickers, F. & Bradley, J. (2016d) Outcomes in implanted teenagers who do not meet the adult candidacy criteria. Cochlear Implants International Vol. 17, Iss. sup1, 2016.** **Vickers & Kitterick (2017). Delphi process to determine consensus on candidacy for cochlear implantation in the UK. Technical report prepared for the BCIG** **Vinay & Moore (2008). Speech recognition as a function of high-pass filter cut off frequency for people with and without low-frequency cochlear dead regions. The Journal of the Acoustical Society of America 122, 542 (2007); https://doi.org/10.1121/1.2722055**

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

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- Your response should not be longer than 10 pages.

About you	
1.Your name	**Specialised Ear and Ophthalmology Clinical Reference Group (CRG)**

2. Name of organisation	NHS England
3. Job title or position	Regional Clinical Lead of the CRG
4a. Brief description of the organisation (including who funds it).	
4b. Are you (please tick all that apply):	**x**☐ an employee or representative of a healthcare professional organisation that represents clinicians? **x**☐ a specialist in the treatment of people with this condition? **x**☐ a specialist in the clinical evidence base for this condition or technology? ☐ other (please specify):
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	The members of the CRG feel that the current criteria below is overly restrictive : *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 -* The suggested new wording is therefore: • ***Adults with severe to profound deafness is defined as hearing only sounds that are louder than 80dBHL should considered for implantation depending on clinical review of benefit (Vickers, De Raeve et al. 2016).*** • ***Evaluation of the speech frequencies 0.5, 1.0, 2.0, 3.0 & 4 kHz should be considered where an average at two adjoining frequencies could be analysed*** The members of the CRG feel that the current criteria below for sound testing does not represent 'real world' hearing and discriminates against experienced English speakers who are able to guess or anticipate sentences despite very poor hearing. *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*

	The suggested new wording is therefore: • ***for adults, the Arthur Boothroyd (AB) Word list should be used to assess speech understanding. 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).*** The members of the CRG feel that the current criteria below for children is appropriate and allows clinical assessment of speech and language development. However, the current threshold of 90dBHL is too stringent and should be revised to 80dBHL. • ***for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*** In addition, two areas not covered by the current guidance that the CRG feel should be included are: • ***For adults and children who have asymmetrical severe / profound hearing loss, with profound hearing loss in one ear, the above (revised) criteria should be applied to implantation in the poorer ear.*** (note: manufacturers support multimodal combined stimulation from a combination of unilateral CI and contralateral hearing aid) • ***For adults and children with cochlear hair cell dysfunction, whose speech discrimination is disproportionately worse than predicted by their pure tone audiogram, and have cochlear dead regions as detected by the TEN(HL) test should be considered for cochlear implantation following discussion with the multi-disciplinary team (MDT).***

6. Please include any evidence for this suggested wording:	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. Lovett, R. E., D. A. Vickers and A. Q. Summerfield (2015). "Bilateral cochlear implantation for hearing-impaired children: criterion of candidacy derived from an observational study." Ear Hear **36**(1): 14-23. Vickers, D., L. De Raeve and J. Graham (2016). "International survey of cochlear implant candidacy." Cochlear Implants Int **17 Suppl 1**: 36-41. Vickers, D., P. Kitterick, C. Verschuur, C. Leal, L. Jenkinson, F. Vickers and J. Graham (2016). "Issues in Cochlear Implant Candidacy." Cochlear Implants Int **17 Suppl 1**: 1-2.

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Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

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- Your response should not be longer than 10 pages.

About you	
1.Your name	**Dr Deborah Anne Vickers**

2. Name of organisation	University College London (UCL)
3. Job title or position	Reader of Speech and Hearing Sciences
4a. Brief description of the organisation (including who funds it).	UCL is one of the UKs leading higher educational institutions. It values academic and health science partnerships demonstrated through the UCL Partners programme and the UCL National Institute of Health Research Biomedical Research Centre. Through applied research programmes such as these, our goal is to provide academic rigour to clinical research such that we transform the health and well-being of the population. It is funded by the Higher Education Funding Council for England
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☒ a specialist in the clinical evidence base for this condition or technology? ☐ other (please specify):
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	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: 1. For adults, a phoneme score of 50% or greater (≥50%) on the AB word test presented at 70dBA 2. For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability This is the same definition as in the review consultation but now includes a presentation level specification (70 dBA) for greater clarity
6. Please include any evidence for this suggested wording:	**This evidence was originally collated for the initial response from UCL but this has been checked and updated where appropriate.** **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 <u>1b. BCIG working group 'Consensus meeting on cochlear implant candidacy criteria'</u> 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 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. When reviewing the different cut off points we analysed different sample cases to decide if they were: Appropriate (benefits outweigh any harms) and also Necessary (improper care not to provide implantation) for implantation. For 90 dBHL and 80 dBHL the percentage of configurations of hearing loss falling within criteria that were deemed appropriate and necessary for implantation were 96% and 97% respectively. This percentage dropped to 76% for 70 dBHL so at this stage we think that the more cautious change to 80 dBHL is most appropriate because 70 dBHL captures too high a *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) Raine C, Vickers D, (2017) Worldwide picture of candidacy for cochlear implantation ENT and Audiology News, September/October. 26 (4), 76-78 Vickers D, Verschuur C, Kitterick P (2018) Recommendations for a change in the audiometric criteria used to determine candidacy for cochlear implantation in the UK. Invited presentation at the British Cochlear Implant Group Annual Conference.

	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. 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) 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)

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, 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 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) 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

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2. Name of organisation	MED-EL UK Ltd.
3. Job title or position	Tender and Special Projects Manager
4a. Brief description of the organisation (including who funds it).	MED-EL is a leading provider of hearing implants and hearing device systems with 31 offices (over 1900 employees) globally supporting professionals and patients in over 3100 clinics in 123 countries providing the gift of hearing with the help of a product from MED-EL. MED-EL's Corporate Headquarters, based in Innsbruck, Austria, form the company's research and manufacturing base, and is the largest staff location globally. Within the UK, MED-EL has offices in Sheffield, London, and Edinburgh. MED-EL's status as a private company is very important to its identity. Being privately-owned allows MED-EL to focus on further developing new products and technologies regardless of changes in international financial markets, short-term financial goals, or shareholder demands. The two Austrian scientists Ingeborg and Erwin Hochmair developed the world's first microelectronic-multichannel cochlear implant, now considered the modern cochlear implant, which was implanted in 1977. In 1990 the Hochmairs laid the foundation for the successful growth of the company when they hired their first employees. Ingeborg Hochmair remains CEO of MED-EL, leading the mission top overcome hearing loss as a barrier to communication and quality for life. MED-EL offers the widest range of hearing solutions worldwide to treat various degrees of hearing loss: • MAESTRO and SYNCHRONY cochlear implant and EAS (combined Electric Acoustic Stimulation) system • VIBRANT SOUNDBRIDGE (VSB) middle ear implant system • Auditory brainstem implants (ABI) • Active bone conduction implant, the BONEBRIDGE (BB). • Non-surgical bone conduction system, the ADHEAR. MED-EL UK, founded in 1996, goes from strength to strength. Our expansion in staff and premises match our commitment to patients and professionals in the UK, with a threshold increase in hearing implants and hearing device sales. Providing excellent support to clinics and patients in an ethical way is our focus.

4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? ☑ other (please specify): an employee representing a medical device company
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says:

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.*

5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	As mentioned in our earlier submission, (MED-EL UK evidence summary for TA166, 2018), MED-EL supports the recommendations made by current researchers to widen criteria to individuals whose pure tone average threshold at 2 and 4 kHz is >80 dB HL and include greater weighting on a candidate's functional hearing using monosyllabic word tests and speech in noise, which will ultimately bring UK candidacy in line with the rest of the world. MED-EL's recommendations (*Please refer to the parts underlined.) **The provisional guidance in recommendation 1.5 says:** For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than *80 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: *- Include a test without contextual cues e.g. mono-syllabic test.* *- Include a more challenging test e.g. Speech in noise, HINT test.*

	• for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability. **Suggestion 1: '80 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids'** As we suggested in our earlier submission ('MED-EL UK evidence summary for TA166', 2018), the outline of current research indicates the section 1.5 in the TA 166 which is the UK candidacy guidelines for adults is an area where an update to reflect current research is most needed, Raine (2013) reports that the UK implants around 5% of eligible adults, a far lower rate than other European countries. This indicates that the majority of adults who could potentially benefit from a CI do not have access to the treatment. This is in part due to candidacy guidelines that do not reflect real world conditions. The reliance on audiological thresholds of 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids by clinical commissioning groups without further consideration of functional hearing ability in real world situations adds a further barrier to accessing hearing solutions for adults. Two retrospective case studies were presented by Chundu & Flynn (2014). These studies demonstrated how strict adherence to audiological criteria, rather than patients' functional hearing, leads to the decline of funding and the denial of timely access to treatment for potential cochlear implant recipients. It is evident that the current Section 1.5 of TA166 when compared to other countries is far more stringent in comparison 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 appear even more conservative compared to European counterparts. Vickers, De Raeve & Graham (2016) collated candidacy evidence from 17 countries, noting the UK had the one of the most conservative audiometric criteria. 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 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.

	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 criterion is 70 dB unaided with candidates (Vickers *et al.,* 2016). Furthermore, many countries in Vickers *et al.* (2016) review focussed on functional hearing, something which isn't prominent in UK practice and has been raised by Chundu & Flynn (2014) as a method which should be employed more within UK guidance. 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 dB HL 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. In addition, Leal *et al.* (2016) notes the heavy reliance on audiometric tests restricts candidacy for individuals who may not be able to effectively report what they can hear. The authors propose the use and inclusion of Speech Intelligibility Index (SII) in collaboration with extended criteria to encompass results of 80 dB HL at 2 and 4 kHz. On this review, it has been recommended that the cut-off audiometric level need to be reduced to 80 dB HL at 2 and 4 kHz in the UK for all implant candidates, compared to the current threshold of 90 dB HL. However, there are also concerns (Vickers *et al.*, 2016) that even this change would not sufficiently cover all of the unusual audiometric configurations that an appropriate candidate could have. Vickers *et al.* (2016) points out that pure tone audiometry has important limitations and that possibly other measures, such as the speech intelligibility index could be added to the test battery as a way to support candidacy decisions regardless of where the hearing threshold level is set. The following suggestion 2 includes the current researchers' recommendations to implement this limitation.

	Suggestion 2: ***- Include a test without contextual cues e.g. mono-syllabic test.*** ***- Include a more challenging test e.g. speech in noise e.g. Speech in noise, HINT test*** As already reviewed in Suggestion 1, it can be seen that UK guidelines in comparison to other countries are far more stringent. 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 also include greater weighting on a candidates' functional hearing using monosyllabic word tests and speech in noise would bring UK candidacy more into line with the rest of the world. There are studies that indicate a score of 50% or greater on BKB sentence testing in quiet, at a sound intensity of 70 dB SPL as a candidacy guideline for adults is now outdated, and suggest alternative assessment methods for assessing cochlear implantation suitability. Raine (2013) suggests 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). Athalye *et al.* (2014) reports the need to revise audiological criteria and modify speech testing methods to better resemble hearing challenges in everyday life. Indeed, this study suggests moving beyond audiological criteria to include the impact of hearing loss on social, emotional, and work aspects of life. Doran and Jenkinson (2016) also reported that current evidence in the UK regarding the use of alternative test material is limited and several studies (Dorman and Gifford, 2010; Gifford et al., 2008; Lamb and Archbold, 2013; Vickers et al., 2015) state that sentence testing in quiet may not give a true representation of functional hearing ability. The authors mentioned that several studies have suggested that mono-syllabic word testing may provide a more accurate representation of an individual's hearing ability, as this removes contextual information from the listener (Dorman and Gifford, 2010; Gifford et al., 2008). They suggest that CI programmes should consider using more challenging material along with measures of listening effort and quality of life to determine CI candidacy. The study also suggests reducing the presentation level of BKB sentence testing e.g. 60 or 50 dB SPL.

	Sladen *et al*. (2017) reports studies investigating monosyllabic word recognition and HINT (Hearing in Noise Test) sentence recognition which reflects more real-life hearing, 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 eligible adults with the current test method, Bamford-Kowal-Bench (BKB) sentence testing. (Raine, 2013 & 2016). This is in part due to the current 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 monosyllabic word test. Sladen *et al.* (2017) reports 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 could be an alternative test which may be considered for this review. The author concludes the results of this study demonstrate that monosyllabic words are appropriate for determining preoperative candidacy and measuring long-term postoperative speech recognition performance. The conclusion is supportive 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) report 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. 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. Furthermore, as it is already mentioned in the Suggestion 1, 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 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 is relevant to the inclusion of those with 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.

	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 and Wouter, 2013). There is a study to suggest the audiological results of the Monosyllabic (CVC) words for both phonemes and word score. Leigh *et al,* (2016) suggested that Cochlear implantation can be confidently recommended for postlingually deafened adults who obtain open-set phoneme scores in quiet of up to 55% and/or word scores of up to 26% in the ear to be implanted. This could be the basis for a rationale once TA166 includes the mono-syllabic test which would not be influenced contextual cues.
6. Please include any evidence for this suggested wording:	Athalye, S., Mulla, I., Archbold, S. (2014) The experiences of adults assessed for cochlear implantation who did not proceed. *Cochlear Implants International*. Volume. 0 (0) Berrettini, S., Arslan, E., Baggiani, A., Burdo, S., Cassandro, E., Cuda, D., Filipo, R., Rossi, P.G., Mancini, P., Quaranta, A., turchetti, G. & Forli, F. (2011) Analysis of the impact of professional involvement in evidence generation for the HTA Process, subproject "Cochlear Implants": methodology, results and recommendations. *Acta Otorhinolaryngologica Italica*. Volume. 31; pp. 273-280. Chundu, S. & Flynn, S.L. (2014) Audiogram and cochlear implant candidacy – UK perspective. *Cochlear Implants International.* Volume. 15(4); pp. 241-244. De Raeve, L. & Wouters, A. (2013) Accessibility to cochlear implants in Belgium: State of the art on selection, reimbursement, habilitation, and outcomes in children and adults. *Cochlear Implants International*. Volume. 14(S1); pp. S18-S24. Lamb, B., OBE and Archbold, S. (2013) Adult Cochlear Implantation: Evidence and experience, *The Ear Foundation.*

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	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); 1-2. Vickers, D., Summerfield, Q., & Rosemary Lovett (2015) Candidacy criteria for paediatric bilateral cochlear implantation in the United Kingdom. *Cochlear Implants International*. 16(S1); S48-S49. American Medical Association (2017), Medical Policy: FDA cochlear implant candidacy guideline, page on 3. MED-EL UK _evidence summary for TA166 (2018): previous submission to NICE in 2018, page on 6

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

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- Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]

2. Name of organisation	Oticon Medical
3. Job title or position	Research Manager
4a. Brief description of the organisation (including who funds it).	Oticon Medical is a manufacturer of implantable auditory prostheses such as cochlear implants and bone anchored hearing systems. Oticon Medical is a part of the William Demant Holdings A/S whose majority shareholder is the Oticon Foundation. The Oticon Foundation was setup for the advancement of hearing healthcare.
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? **x**☐ a specialist in the treatment of people with this condition? **x**☐ a specialist in the clinical evidence base for this condition or technology? ☐ other (please specify):
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	Oticon Medical believes that the wordings in the existing guidance in recommendation 1.5 should be changed to the following: For the purpose of this guidance, severe to profound degree of hearing loss is defined as hearing only to sounds that are 80 dB HL or louder at any two audiometric test frequencies between 250 Hz and 4000 Hz without any acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as: - for adults, a phoneme recognition score of greater than 50% on the AB (Aurthur-Boothroyd) word test. - for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.
6. Please include any evidence for this suggested wording:	Based on the evidence discussed below, Oticon Medical suggested wording differs from the existing guidance in recommendation 1.5 in the following three areas: **i) <u>Degree of hearing loss:</u>** We suggest that the degree of hearing loss used for the definition of severe to profound hearing loss be lowered to 80 dB HL or louder as compared to the current guidance of louder than 90 dB HL. A lower hearing threshold for the definition of severe to profound hearing loss has been suggested as recent reports indicate that individuals with lower hearing thresholds do benefit from cochlear implantation (Lovett et al., 2015, Leal et al., 2016). The development of atraumatic cochlear implant

electrodes along with improvements in cochlear implant surgical techniques have resulted in enhanced benefit from cochlear implants in individuals who have some amount of residual hearing. The suggestion for lowering the threshold may also be justified considering the test retest variability of 5 -10 dB HL when performing pure tone audiometry (Stuart et al., 1991; Schmuziger et al., 2004.). The UK has one of the strictest cochlear implant eligibility criteria based on hearing thresholds (Vickers et al., 2016a) and not considering the test retest variability may deny many patients from receiving the benefits of a cochlear implant.

ii) Frequency Range:

We suggest that the range of frequencies considered for the definition of severe to profound hearing loss be extended to audiometric test frequencies between 250 – 4000 Hz as compared to considering 2 kHz and 4 kHz only. The current guideline limits the access to a cochlear implant to individuals with only a sloping or flat audiogram. This means that individuals with high degrees of low frequency hearing loss with a rising audiogram, who might be suitable candidates for cochlear implantation, may be denied of the benefits of a cochlear implant. Although the occurrence of a rising audiogram is limited, Bauman (2015) has reported benefits from cochlear implants in such patients. Furthermore, as the ability to perceive speech depends on the access to speech sounds over a wide range of the speech spectrum (Govaerts et al., 2006), it is important to consider all the audiometric test frequencies between 250 and 4000 Hz.

iii) Definition of Benefit from Hearing Aid:

We suggest that the benefit of hearing aid be defined in terms of phoneme recognition scores i.e. AB word list in comparison to words in a sentence recognition score i.e. BKB sentence testing. Raine and Vickers (2017) highlighted that the data informing 2009 NICE guidelines indicated that one year post implantation, the 20th percentile was 50% BKB scores, and due to developments in cochlear implants as well as clinical practice, at present 50% BKB scores is the 10th percentile, whereas scores for the 20th percentile currently would be around 70% BKB scores. This highlights that cochlear implant candidacy based on the 50% BKB scores parameter is outdated. As reported in Vickers et al., (2016a), many developed countries now use phoneme recognition scores for

determining cochlear implant candidacy. The use of phoneme recognition scores overcomes the limitation of a sentence recognition tests (such as BKB) where language skills and redundant information within a sentence may lead to some individuals guessing correctly. A phoneme recognition score is also useful in cases where BKB sentence testing is not an option due to lack or no understanding of spoken English (Craddock et al., 2015; Vickers et al., 2016b).

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

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- Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]

2. Name of organisation	Action on Hearing Loss
3. Job title or position	Senior Research and Policy Officer
4a. Brief description of the organisation (including who funds it).	Action on Hearing Loss, formerly RNID, is the UK's largest charity working for people with deafness, hearing loss and tinnitus. Our vision is of a world where deafness, hearing loss and tinnitus do not limit or label people and where people value and look after their hearing. We help people confronting deafness, tinnitus and hearing loss to live the life they choose, enabling them to take control of their lives and removing the barriers in their way. We give people support and care; develop technology and treatments and campaign for equality. Action on Hearing Loss is registered as a charity (No. 207720 England and Wales and SC038926 Scotland) and governed by its Articles of Association, adopted on 14 May 1948, and last amended on 7 November 2008. Action on Hearing Loss receives income from charitable donations and non-charitable trading activities through its wholly owned subsidiary, RNID Activities Ltd. In some parts of the country, Action on Hearing Loss provides support services for people with deafness, tinnitus and hearing loss under contact to the NHS and local authorities. A full income breakdown can be found in Action on Hearing Loss' Annual Report 2017. To find out more, please visit: https://www.actiononhearingloss.org.uk/how-we-help/information-and-resources/publications/annual-reports/annual-report-2017/
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? ☒ other (please specify): charity supporting people with deafness, tinnitus and hearing loss

4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	Action on Hearing Loss has never received any material funding from the tobacco industry and has no direct or indirect links with the tobacco industry.
The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	Action on Hearing Loss supports the Adult Cochlear Implant Action Group's proposal to change the wording of recommendation 1.5 to the following: ***"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 presented at 70 dBA*** • ***For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability"*** The Action Group submitted the same wording to NICE in the Review Consultation. Please note, this definition now includes a phoneme score measure of 70 dBA, based on evidence highlighted in the Adult Cochlear Implant Action Group's submission to this consultation.

6. Please include any evidence for this suggested wording:	Action on Hearing loss welcomes the opportunity to submit evidence to NICE's part-review of the NICE Technology Appraisal (TA) 166: Cochlear implants for children and adults with severe to profound deafness. We support NICE's decision to consult on changing the wording of recommendation 1.5. This review supports the aims of The Department of Health and NHS England's *Action Plan on Hearing Loss*[1] and the World Health Organisation's (WHO) recent resolution on deafness and hearing loss, [2] which called for better access to cochlear implants. The review is also aligned with NICE's recently published *Hearing Loss in Adults Guideline*[3] which calls for better access to hearing aids and other forms support to help reduce the impact of hearing loss. As stated in our response to the Review Consultation, we think that the current wording of recommendation 1.5 is not fit for purpose and excluding some people who could benefit from cochlear implantation. Below, we provide evidence that supports our proposed change to the wording of recommendation 1.5.[4] **1. Changing the audiometric threshold from ≥90 dBHL to ≥80 dBHL** As acknowledged in Appendix B of the Technology Appraisal Review Proposal Paper, research shows that the 90 dBHL threshold used in the current criteria to define severe to profound deafness is one of the most restrictive in Europe.[5] There is good evidence that cochlear implantation would be appropriate for adults with levels of hearing loss lower than 90 dBHL.[6] As stated in the Action Cochlear Implant Action

[1] Department of Health and NHS England, 2015. The Action Plan on Hearing Loss. Available at: https://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf
[2] World Health Organization. (2018). Seventieth World Health Assembly update, 30 May 2017. Available at: http://www.who.int/mediacentre/news/releases/2017/vector-control-ncds-cancer/en/
[3] NICE, 2018. Hearing Loss: assessment and management. Available at: www.nice.org.uk/ng98
[4] More information on the prevalence and impact of hearing loss, the relationship between hearing loss and other long-term conditions and the broader policy context can be found in our response to the Review Consultation.
[5] Vickers et al, 2016a. International survey of cochlear implant candidacy. *Cochlear Implants International*. 17 (sup1) 36-41.
[6] Leal et al, 2016. Evaluating recommended audiometric changes to candidacy using the Speech Intelligibility Index. *Cochlear Implants International*, 17(S1); Vickers et al, 2016a. International survey of cochlear implant candidacy. *Cochlear Implants International*. 17 (sup1) 36-41; Raine et al, 2016. Access to cochlear implants: Time to reflect,

	Group's response to this consultation, lowering the threshold from ≥90 dBHL to ≥80 dBHL would mean that more people who could benefit from cochlear implants would be able to access them. **2. Increasing the range of frequencies from "2khz and 4khz" to "two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz)"** New research supports the case for testing at a wider range or frequencies across the speech spectrum as predictor of clinical outcomes and speech perception abilities.[7] The British Cochlear Implant Group (BCIG) consensus process[8] also found that there was agreement between clinicians and stakeholder groups on the need to vary the frequencies used to determine candidacy for cochlear implants, depending on the nature of the patient's audiogram. **3. Replacing the Bamford-Kowal-Bench (BKB) test with the Arthur Boothroyd (AB) test** As acknowledged in Appendix B of the Technology Appraisal Review proposal paper, concerns have been raised about the use of the BKB test as the sole means of assessing hearing function in adults.[9] Research shows that other speech tests are a more appropriate way of determining candidacy for cochlear implantation.[10] The BCIG consensus statement[11] also states that word-based listening tests are more appropriate than sentence-based listening tests for assessing sufficient benefit from hearing aids in some patients. As stated in the Action Group's response to this consultation, the results of BCIG's service

Cochlear Implants International, 17: S1, 42-46; British Cochlear Implant Group (BCIG), 2017. *Consensus statement on candidacy for cochlear implantation*. Available at: https://www.cicandidacy.co.uk/

[7] Hanvey et al, 2016. Criteria versus guidelines: Are we doing the best for our paediatric patients? *Cochlear Implants International,*17 (sup 1);

[8] 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. To find our more, please visit: https://www.cicandidacy.co.uk/

[9] Vickers et al, 2016. Preliminary assessment of the feasibility of using AB words to assess candidacy. *Cochlear Implants International,* 17 (sup1); British Cochlear Implant Group (BCIG), 2017. *Consensus statement on candidacy for cochlear implantation*. Available at: https://www.cicandidacy.co.uk/

[10] Lamb, 2016. Expert opinion: Can different assessments be used to overcome current candidacy issues? *Cochlear Implants International,* 17 (sup1); Vickers et al, 2016. Preliminary assessment of the feasibility of using AB words to assess candidacy. *Cochlear Implants International,* 17 (sup1); British Cochlear Implant Group (BCIG), 2017. *Consensus statement on candidacy for cochlear implantation*. Available at: https://www.cicandidacy.co.uk/

[11] British Cochlear Implant Group (BCIG), 2017. Consensus statement on candidacy for cochlear implantation. Available at: https://www.cicandidacy.co.uk/

	evaluation shows that the AB test is more accurate than the BKB test at predicting patient outcomes from cochlear implantation.

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

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Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]

2. Name of organisation	Adult Cochlear Implant Action Group
3. Job title or position	Chair
4a. Brief description of the organisation (including who funds it).	The organisation consists of patient groups, voluntary organisations, CI Clinicians, Academics and other professionals working in the field with an interest in improving access to cochlear implants. Membership includes; Action on Hearing Loss, British Academy of Audiology, British Cochlear Implant Group, British Society for Audiology, Cochlear Implanted Children's Support Group, Ear Foundation, Hearing Link, National Cochlear Implant Users' Association, National Association of Deafened People and implant centres throughout the UK. See https://actiongrouponadultcochlearimplants.wordpress.com/ for more details. It is funded by the Ear Foundation. This response is also supported by the Hearing Loss and Deafness Alliance https://hearinglossanddeafnessalliance.wordpress.com/.
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? **x**☐ other (please specify): Chair of Specialist Representative Group of Clinicians and other hearing professionals, patients groups and voluntary organisations.
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	NO

The existing guidance in recommendation 1.5 says: 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.	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	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 presented at 70dB SPL A • For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability (We provided the same definition in the review consultation but this definition now includes a measure for the phoneme score of 70dB SPL A)
6. Please include any evidence for this suggested wording:	**“For the purposes of this guidance, severe to profound deafness is defined as hearing sounds that are greater than or equal to 80dBHL (≥80dBHL)”** The UK currently has one of the strictest candidacy requirements in the developed world (for countries where audiometric criteria are in place). A survey of international cochlear implant candidacy by Vickers (2016a) found that these could be as low as 70 dB HL. Recent research has also found that

	CIs would be appropriate for people with lower hearing thresholds than the current guidelines indicate (Lovett 2015 et al., Lamb 2016, Leal 2016 et al., Vickers 2016b et al., Kitterick & Vickers 2017b, Vickers & Kitterick 2017, de Kleijn et al., 2018). **Audiometric definition of Severe-Profound Deafness** The Candidacy Working Group of BCIG developed a consensus statement on candidacy for cochlear implantation in 2017, the results of which are published online (BCIG Candidacy Working Group 2017). The following are the major conclusions from the consensus statement supporting a change to 80 dB HL. Changing the audiometric 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. Changing 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 currently deemed clinically necessary to provide a cochlear implant based on the available evidence, but it would also capture patients in whom there is considerable uncertainty over the size of 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 size of benefit may be too small to be clinically meaningful. **“at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally without acoustic hearing aids.”** 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 et al., Vickers 2016b et al., Hanvey 2016 et

	al.). It is known that the important frequencies for speech perception are between 750 – 3000 Hz (Kates 2013) and that individuals with low-frequency hearing losses struggle with speech understanding (Vinay & Moore, 2008) This is further supported by the following BCIG consensus statements: • 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 "**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"**

	The Bamford-Kowal-Bench (BKB) test needs reviewing and replacing with a different test as recent research concluded that; “Use of this measure (the BKB test) alone to assess hearing function has become inappropriate as the assessment is not suitable for use with the diverse range of implant candidates today.” (Vickers 2016c et al.) 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 Arthur 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 et al., Craddock 2016 et al., Lamb 2016). 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 (Vickers 2016c et al., Sladen 2017 et al., Kitterick & Vickers 2017b, Lamb 2016). 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. **"For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability"** We are not proposing any change to the criteria for children beyond what is proposed above in respect of the hearing thresholds and how they are measured. **References** British Cochlear Implant Group Candidacy Working Group) (2017) Consensus statement on candidacy for cochlear implantation. https://www.cicandidacy.co.uk/ British Cochlear Implant Group Quality Standards Cochlear Implant Services for Children and Adults. http://www.bcig.org.uk/bcig-quality-standard-2016/ Craddock L, Cooper H, Riley A, Wright T (2016) Cochlear implants for pre-lingually profoundly deaf adults. Cochlear Implants International. 17 (sup1) 36-41 Govaerts PJ, Daemers K, Yperman M, De Beukelaer C, De Saegher G, De Ceulaer G. (2006) Auditoryspeech sounds evaluation (A(section)E): a new test to assess detection, discrimination and identification in hearing impairment. Cochlear Implants Int. 2006 Jun;7(2):92-106. 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

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	Vickers D, Kitterick P, Verschuur C, Leal C, Jenkinson L, Vickers F, Graham J. (2016b) Issues in Cochlear Implant Candidacy. Cochlear Implants International. 17(sup1) 1-2. DOI:10.1080/14670100.2016.1163104 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, Kitterick PT.(2016c), Preliminary assessment of the feasibility of using AB words to assess candidacy. Cochlear Implants International Vol. 17, Iss. sup1, 2016. Vickers, F. & Bradley, J. (2016d) Outcomes in implanted teenagers who do not meet the adult candidacy criteria. Cochlear Implants International Vol. 17, Iss. sup1, 2016. Vickers & Kitterick (2017). Delphi process to determine consensus on candidacy for cochlear implantation in the UK. Technical report prepared for the BCIG Vinay & Moore (2008). Speech recognition as a function of high-pass filter cut off frequency for people with and without low-frequency cochlear dead regions. The Journal of the Acoustical Society of America 122, 542 (2007); https://doi.org/10.1121/1.2722055

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

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- Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]

2. Name of organisation	Cochlear Implanted Children's Support Group (CICS Group)
3. Job title or position	Group Coordinator
4a. Brief description of the organisation (including who funds it).	Voluntary independent group providing contact, information, support and events for families whose deaf children either already have cochlear implants, or are undergoing assessment for the procedure. It is run by parents of cochlear implanted children and is funded entirely by donations and small fundraising events such as raffles at events, coffee mornings, etc.
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? x☐ other (please specify): Patient led support and user group
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	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 presented at 70 dBA • For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability
6. Please include any evidence for this suggested wording:	The UK currently has one of the strictest candidacy requirements in the developed world (for countries where audiometric criteria are in place). A survey of international cochlear implant candidacy by Vickers (2016a) found that these could be as low as 70 dB HL. Recent research has also found that CIs would be appropriate for people with lower hearing thresholds than the current guidelines indicate (Lovett 2015 et al., Lamb 2016, Leal 2016 et al., Vickers 2016b et al., Kitterick 2017& Vickers b, Vickers & Kitterick 2017, Jasper et al., 2018).

	Audiometric definition of Severe-Profound Deafness The Candidacy Working Group of BCIG developed a consensus statement on candidacy for cochlear implantation in 2017, the results of which are published online (BCIG Candidacy Working Group 2017). The following are the major conclusions from the consensus statement supporting a change to 80 dB HL. Changing the audiometric 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).[1] 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. The Cochlear Implanted Children's Support Group believes there should be allowance for a threshold of 70 dB HL where clinical judgement is considered, for example in the case of children who have an identified progressive hearing loss. Children with a hearing loss of between 70 dB HL and 80 dB HL are effectively in the position of waiting to fail. These are formative years for development of listening skills and speech. Most are in mainstream schools in classes of between 20 and 30 pupils. This is a noisy environment and many classrooms do not have any acoustic treatments.

[1] 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.

	Definition of insufficient benefit from hearing aids Lowering the threshold to 80 dB HL (or 70 dB HL with clinical judgement) implantation would be available for patients who may get sufficient benefit from hearing aids in quiet but have significant difficulties in noise. **Summary** In summary, lowering the threshold to 80 dB HL and the inclusion of patients who do not get sufficient benefit from their hearing aids in noise will mean that many more patients for whom providing implants is considered clinically necessary would have access to them. The inclusion of using clinical judgement for a threshold of 70 dB HL will help those with an identified progressive loss to access implantation earlier thus alleviating the stress of living through an unknown period of time before they reach the 80 dB HL threshold. This is particularly vital for children in their formative years where the development of listening skills and intelligible speech is crucial to enable them to manage in mainstream education. **"at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally without acoustic hearing aids."** There is also strong evidence that for testing 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 et al., Vickers 2016b et al., Hanvey 2016 et al.). It is known that the important frequencies for speech perception are between 750 – 3000 Hz (Kates 2013) and that individuals with low-frequency hearing losses struggle with speech understanding (Vinay & Moore, 2008) This is further supported by the following BCIG consensus statements: • 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:

"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"**

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

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 Arthur 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 et al., Craddock 2016 et al., Lamb 2016). 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 (Vickers 2016c et al., Sladen2017 et al., Kitterick & Vickers 2017b,Lamb 2016). 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. **"For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability"** We are not proposing any change to the criteria for children beyond what is proposed above in respect of the hearing thresholds and how they are measured. **References** British Cochlear Implant Group Candidacy Working Group) (2017) Consensus statement on candidacy for cochlear implantation. https://www.cicandidacy.co.uk/ British Cochlear Implant Group Quality Standards Cochlear Implant Services for Children and Adults.http://www.bcig.org.uk/bcig-quality-standard-2016/

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The Ear Foundation

Hearing & Communicating in a Technological Era

20 July 2018

To Whom it May Concern

Statement of Support for the Change to NICE Guidelines to Support the Candidacy Section1.5 of TA166

The Ear Foundation is a national UK charity which has supported children and adults with cochlear implants for last 30 years, having raised the funds for the very first cochlear implant in the UK.

Through our support of families for thirty years and through our research programme, adults repeatedly report that despite no longer managing to hear and communicate adequately in daily life with their hearing aids, the current NICE criteria prevent them from accessing a cochlear implant, which would transform their ability to participate and communicate more effectively at home and at work .Even when a known deteriorating hearing loss is present, adults and children often need to wait for their hearing to deteriorate further, before being offered a cochlear implant. During this waiting period, many struggle significantly at school, home or work.

Knowing that the NICE guidelines are amongst the strictest in Europe and given the improvements in technology, surgery and the weight of evidence from countries which have less restrictive criteria, we welcome the opportunity to recommend less restrictive criteria for children and adults in the UK**,** bringing NICE criteria in line with international standards and reflecting current clinical evidence**.**

The Ear Foundation recommends the following change to the guidance, in line with the British Cochlear Implant Group, The Adult Cochlear Implant Action Group(chaired by Brian Lamb and The Ear Foundation) and Cochlear Implanted Children's Support Group(CICS) :

Defintion of Sever-Profound Hearing Loss

- severe to profound deafness should be considered as hearing sounds that are greater than or equal to 80dBHL (or between 70-80dB with clinical judgement) 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 the new guidance as follows:

- For adults, a phoneme score of 50% or greater on the AB word test presented at 70 dBA
- For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability

Thank you for the opportunity to comment on the existing guidance Section 5 of TA166.

Marjorie Sherman House 83 Sherwin Road Lenton Nottingham NG7 2FB
Tel: +44 (0)115 942 1985 (voice & text) Fax: +44 (0)115 924 9054 Email: info@earfoundation.org.uk Web: www.earfoundation.org.uk

Yours Sincerely

[redacted]

[redacted], The Ear Foundation

References

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]

2. Name of organisation	National Cochlear Implant Users Association (NCIUA)
3. Job title or position	Executive Committee Member
4a. Brief description of the organisation (including who funds it).	We are a registered Charity which is devoted to helping cochlear implant candidates and users. Our Mission statements can be seen at www.nciua.org.uk
4b. Are you (please tick all that apply):	☐ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? X☐ A member of the public who is a member of this Charity (please specify):
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	None

The existing guidance in recommendation 1.5 says: *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.*	
5. Please state what you believe the wording should be changed to: (If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)	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 presented at 70 dBA • For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability
6. Please include any evidence for this suggested wording:	**"For the purposes of this guidance, severe to profound deafness is defined as hearing sounds that are greater than or equal to 80dBHL (≥80dBHL)"** The UK currently has one of the strictest candidacy requirements in the developed world (for countries where audiometric criteria are in place). A survey of international cochlear implant candidacy by Vickers (2016a) found that these could be as low as 70 dB HL. Recent research has also found that CIs would be appropriate for people

	with lower hearing thresholds than the current guidelines indicate (Lovett 2015 et al., Lamb 2016, Leal 2016 et al., Vickers 2016b et al., Kitterick 2017 & Vickers b, Vickers & Kitterick 2017, Jasper et al., 2018). **Audiometric definition of Severe-Profound Deafness** The Candidacy Working Group of BCIG developed a consensus statement on candidacy for cochlear implantation in 2017, the results of which are published online (BCIG Candidacy Working Group 2017). The following are the major conclusions from the consensus statement supporting a change to 80 dB HL. Changing the audiometric 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). [1] 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.

[1] 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.

	Changing 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 currently deemed clinically necessary to provide a cochlear implant based on the available evidence, but it would also capture patients in whom there is considerable uncertainty over the size of 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 size of benefit may be too small to be clinically meaningful.

	"at two or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally without acoustic hearing aids." 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 et al., Vickers 2016b et al., Hanvey 2016 et al.). It is known that the important frequencies for speech perception are between 750 – 3000 Hz (Kates 2013) and that individuals with low-frequency hearing losses struggle with speech understanding (Vinay & Moore, 2008) This is further supported by the following BCIG consensus statements: • 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 **"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"** The Bamford-Kowal-Bench (BKB) test needs reviewing and replacing with a different test as recent research concluded that; "*Use of this measure (the BKB test) alone to assess hearing function has become inappropriate as the assessment is not suitable for use with the diverse range of implant candidates today.*" (Vickers 2016c et al.) 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 Arthur 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 et al., Craddock 2016 et al., Lamb 2016). 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 (Vickers 2016c et al., Sladen 2017 et al., Kitterick & Vickers 2017b, Lamb 2016). 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. **"For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability"** We are not proposing any change to the criteria for children beyond what is proposed above in respect of the hearing thresholds and how they are measured. **References** British Cochlear Implant Group Candidacy Working Group) (2017) Consensus statement on candidacy for cochlear implantation. https://www.cicandidacy.co.uk/ British Cochlear Implant Group Quality Standards Cochlear Implant Services for Children and Adults. http://www.bcig.org.uk/bcig-quality-standard-2016/ Craddock L, Cooper H, Riley A, Wright T (2016) Cochlear implants for pre-lingually profoundly deaf adults. Cochlear Implants International. 17 (sup1) 36-41

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NICE National Institute for Health and Care Excellence

Organisation submission

Cochlear implants for children and adults with severe to profound deafness [ID1469]

(part review of TA166)

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on conditions and their treatment that is not typically available from other sources.

To help you give your views, please use this questionnaire.

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- Your response should not be longer than 10 pages.

About you	
1.Your name	[redacted]

2. Name of organisation	National Community Hearing Association (NCHA)
3. Job title or position	Director of Policy and Strategy
4a. Brief description of the organisation (including who funds it).	The National Community Hearing Association (NCHA) represents community hearing care providers in the UK. We are funded by membership subscriptions. Our members do not provide cochlear implants.
4b. Are you (please tick all that apply):	☒ an employee or representative of a healthcare professional organisation that represents clinicians? ☐ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? ☐ other (please specify):
4c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The existing guidance in recommendation 1.5 says: *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.*	

5. Please state what you believe the wording should be changed to:
 	
(If you have already provided suggested wording in the Review Consultation and wish to use this suggestion, please also indicate here)
	"For the purposes of this guidance
	• *severe to profound hearing loss is defined as a hearing loss of at least 80dBHL at two or more frequencies (0.5, 1,2 or 4 KHz) without hearing aids*
	• *adequate benefit from hearing aids is defined for this guidance as*
	  • *for adults, a score of 50% or greater on the Arthur Boothroyd (AB) monosyllabic word test*
	  • *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability."*

6. Please include any evidence for this suggested wording:	• please see our response to the Review Consultation

Thank you for your time.

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Draft wording of section 1.5:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally 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 the Arthur Boothroyd word test presented at 70 dBA* • *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☐

Please provide any additional comments on the draft wording in the box below:

Name of organisation:

Next steps:

- The draft wording and stakeholder's comments on it will be presented to the Technology Appraisal Committee.
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Please return this form to us by uploading it to NICE Docs using the link below by **5pm on 19 September 2018**.

Draft wording of section 1.5:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally 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 the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☒

Please provide any additional comments on the draft wording in the box below:

No additional comments to add.

Name of organisation:

Next steps:

- The draft wording and stakeholder's comments on it will be presented to the Technology Appraisal Committee.
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- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☐

Please provide any additional comments on the draft wording in the box below:

At UCL we support the changes in content to the guidance as provided in the draft wording. The changes are informed by a strong evidence base and will address the important problems that multi-disciplinary teams who are determining cochlear implant candidacy are facing.

However, there are two amendments that we believe are essential so that the wording is unambiguous and the implementation will be the same across cochlear implant programmes. We have worked closely with colleagues at the Action Group for Adult Cochlear Implantation and have provided the justification for these changes in their response.

We believe that the draft should be amended as follows – changes in **bold** font

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*For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (**pure-tone audiometric threshold equal to or greater than 80 dB HL**) at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) 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 Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please do not hesitate to get in touch for any clarification or for further details.

[redacted] on behalf of University College London

Name of organisation:

Next steps:

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For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally 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 the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☐

Please provide any additional comments on the draft wording in the box below:

For the purposes of clarity, and clinical accuracy, we recommend the following minor amendment to the proposed draft wording:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are equal to or louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally 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 the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

The British Society of Audiology requires that hearing thresholds are measured by Pure Tone Audiometry using a calibrated audiometer.

The recommended procedure, which is universally adopted, requires presentation of pure tones in 5 dB increments, and so 'equal to or louder than 80 dBHL' is an essential correction to ensure clarity and consistency across audiology centres.

There is strong evidence available globally to demonstrate the effectiveness of cochlear implantation at 80 dBHL.

We thank you for your time and consideration.

Name of organisation:

Cochlear Europe Ltd

Next steps:

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

- *for adults, a score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☒

Please provide any additional comments on the draft wording in the box below:

Whilst we broadly agree with the statement above, we would suggest changes on two grounds: 1) revisions to the text reduce the possibility of misinterpretation, and 2) some reconsideration of the criteria etc.

1) <u>Suggested revisions to improve precision, reduce ambiguity, etc.:</u>

"For the purposes of this guidance, severe to profound deafness is defined as hearing only pure tones that are more intense than 80 dB HL at 2 or more frequencies (from 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) in both ears without acoustic hearing aids.

Adequate benefit from acoustic hearing aids is defined for this guidance as:
•for adults, a score of 50% (scored by whole words correct) or greater on the Arthur Boothroyd monosyllabic word test presented at 70 dBA
•for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability."

2) <u>Comments and suggestions on criteria etc.</u>

Whilst the move to AB words is welcome as it better reflects peripheral function with less influence of central language skills (c.f. BKB sentences), the presentation level is relatively high. A presentation level of 60, or 65 dB A may be more appropriate, and more reflective of real-world conversational voice levels.
Real-world conditions seldom involve listening to a single stationary talker in quiet conditions (e.g. open-plan office, restaurant/café, conversation in car / on public transport, etc.). In other words any test of speech-in-quiet is not highly likely to reflect difficulties experienced in everyday life. Consideration should be given to a criterion for a speech-in-noise test as an either-or alternative to AB words in quiet.
The requirement for an English-language speech-based test in addition to audiometric criteria poses some challenges: such a test would be inappropriate for a person without adult-level English language skills – e.g. a candidate using sign-language, or a person only speaking a non-english language. Such candidates would likely be judged for eligibility on audiogram results alone – whereas a proficient English-speaker would have to satisfy both speech and audiogram criteria.

Name of organisation:

MED-EL UK Ltd.

Next steps:

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

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

Please cross this box if you agree with the draft wording ☒

Please provide any additional comments on the draft wording in the box below:

Action on Hearing Loss, formerly RNID, is the UK's largest charity working for people with deafness, hearing loss and tinnitus. Our vision is of a world where deafness, hearing loss and tinnitus do not limit or label people and where people value and look after their hearing. We help people confronting deafness, tinnitus and hearing loss to live the life they choose, enabling them to take control of their lives and removing the barriers in their way. We give people support and care; develop technology and treatments and campaign for equality.

Action on Hearing Loss welcomes the opportunity to comment on NICE's proposed update to Recommendation 1.5 of NICE Technology Appraisal (TA) 166: Cochlear implants for children and adults with severe to profound deafness.

We agree with NICE's proposed change to the wording of Recommendation 1.5. This change support the aims The Department of Health and NHS England's *Action Plan on Hearing Loss*,[i] the World Health Organisation's (WHO) recent resolution on deafness and hearing loss[ii] and the recently published NICE *Hearing Loss in Adults Guideline*[iii] which all called for better access to cochlear implants to help reduce the impact of hearing loss.

As highlighted in our response to the previous consultation, we think that the current wording of Recommendation 1.5 is not fit for purpose and excluding some people who could benefit from cochlear implantation. Lowering the audiometric threshold from ≥90 dBHL to ≥80 dBHL and testing at a wider range of frequencies will mean that more people who could benefit from cochlear implants will be able to access to them. Replacing the Bamford-Kowal-Bench (BKB) test with Arthur Boothroyd (AB)

test will also address concerns acknowledged in Appendix B of the NICE Technology Appraisal Review proposal paper regarding the effectiveness of sentence tests as the sole means of assessing hearing function in adults.

Whilst we welcome NICE's proposal, we think that two further changes are needed to remove any uncertainty about how NICE's new proposed wording for Recommendation 1.5 should be interpreted by clinicians:

1. ***"pure-tone audiometric threshold equal to or greater than 80 dB HL"* should be added in brackets immediately after *"80 dB HL"* in the definition for severe to profound deafness.** As highlighted in the Adult Cochlear Implant Action's Group's response to this consultation, this is an important distinction to make, given that an audiometric assessment measures a person's ability to detect sounds more than 50% of the time, not the loudness of sounds. Adding a clarification in brackets should therefore ensure the definition for severe to profound deafness is interpreted consistently and accurately by clinicians.
2. **The definition of adequate benefit from acoustic hearing aids should be changed to make it clear that adults must receive a *phoneme* score of 50% or greater.** As highlighted in the Action Group's response to this consultation, an AB test will produce different results depending on whether a word-based or phoneme-based scoring approach is used. For example, a person with a 50% or greater word score will have much better hearing compared to a person with a 50% or greater phoneme score. As a result, relying on word-based AB test scores alone could underestimate the true functional impact of a person's hearing loss. To ensure Recommendation 1.5 is interpreted in the same way by clinicians, the definition of adequate benefit from acoustic hearing aids should be changed to make it clear that a phoneme-based scoring approach must be used to assess hearing function in adults. This recommendation is informed by analysis of data collected as part of the British Cochlear Implant Group's (BCIGs) recent service evaluation, which explored the best approaches for predicting patient outcomes from cochlear implantation. More information on this evaluation can be found in the Action Group's response to this consultation.

Name of organisation:

Action on Hearing Loss.

Next steps:

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[i] Department of Health and NHS England, 2015. *The Action Plan on Hearing Loss*. Available at: https://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf

[ii] World Health Organization, 2018. Seventieth World Health Assembly update, 30 May 2017. Available at: http://www.who.int/mediacentre/news/releases/2017/vector-control-ncds-cancer/en/

[iii] NICE, 2018. Hearing Loss: assessment and management. Available at: www.nice.org.uk/ng98

Draft wording of section 1.5:

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

- *for adults, a score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☐
Please provide any additional comments on the draft wording in the box below:

Summary

We support the new definition proposed by NICE which reflects the research and practice evidence already presented to NICE (see links at the end of this submission) and that the proposed wording is therefore an appropriate change for section 1.5 of TA166.

However, we feel two adjustments would help with the clarity and clinical accuracy of what NICE is proposing without raising issues of policy or affecting any substantial change in the revised candidacy criteria.

Hearing level:

We strongly welcome the move to 80dBHL across five frequencies. However, we would recommend the inclusion of a small but important technical clarification.

The proposed wording from NICE is as follows:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.

We would request the insertion of a technical clarification to the above statement so that there is no uncertainty as to its audiological interpretation and to ensure the proposed wording reflects the specific evidence referred to in previous submissions. The gold standard measure to determine hearing level is the pure tone audiometric threshold (with units of dB HL) obtained by following the recommended procedure of the British Society of Audiology. An audiometric threshold represents a person's ability to detect ('hear') sounds reliably based on their presentation level, and is not technically a measure of loudness. It is also the case that a person with an audiometric threshold of 80 dB HL may be able to 'hear' sounds quieter than 80 dB HL, but the clinical interpretation of their threshold is that they would not be able to detect those sounds reliably (more than 50% of the

time).

In light of these issues, the wording of this criterion requires a small adjustment to ensure that it can be interpreted consistent and accurately by audiologists when putting the guidance into practice. To avoid changing the wording of the above definition substantially, we therefore propose the addition of a small technical clarification to state the intended technical interpretation of the criterion, as follows:

Our recommended wording:
*For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (**pure-tone audiometric threshold equal to or greater than 80 dB HL**) at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.*

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. We therefore full support the intention to measure at the five frequencies based on our previous submissions.

Arthur Boothroyd (AB) Word test:
We strongly welcome the move to replace the BKB test with the AB word test based on the evidence we submitted. However we would request one small but important change to the NICE suggested wording.

The proposed wording from NICE is as follows:
Adequate benefit from acoustic hearing aids is defined for this guidance as:

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We request the inclusion of the specific scoring approach (phoneme score) in the speech-based criteria for the Arthur Boothroyd (AB) word test. This is because the AB word test is scored by both whole word and phoneme score (speech sounds in the word). The words in the test all have the structure of Consonant-Vowel-Consonant e.g. Cat. If the entire word is scored correctly an individual would score "1" on the word score and "3" on the phoneme score. If the word "Cat" was presented and the individual responded with "at", i.e. they hadn't detected the first phoneme they would score "0" for the word score and "2" for the phoneme score. We are referring to percent correct in the guidance and not absolute score so for the examples given the first would give 100% for both word and phoneme score and the second would be 0% and 66% for word and phoneme respectively. Hopefully, this example illustrates how different the two scoring approaches are and that 50% on a word score would be achieved by an individual with far better hearing than for an individual scoring 50% on a phoneme score.

A data-driven analysis informed the 50% phoneme score recommendation for the speech-based

criteria. The analysis was conducted on data collected in a British Cochlear Implant Group National Service Evaluation in which pre-implant speech scores and 12 month post-implant outcomes were recorded.

Our recommended wording:

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 presented at 70 dBA*
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Our full evidence to support the above statements and the wording NICE is proposing can be found at;
https://actiongrouponadultcochlearimplants.files.wordpress.com/2018/01/candidacy-requirements-for-ta166-final-1.pdf
And
https://actiongrouponadultcochlearimplants.files.wordpress.com/2018/07/collated-response-bcig-action-group-for-response-final-16-1-2018-3-11.pdf
And
https://www.cicandidacy.co.uk/

We are happy to discuss any aspects of this submission.

Name of organisation:

Action Group on Adult Cochlear Implants

Next steps:

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Please cross this box if you agree with the draft wording ☐

Please provide any additional comments on the draft wording in the box below:

Summary

The Cochlear Implanted Children's Support Group supports the new definition proposed by NICE which reflects the research and practice evidence already presented to NICE (see links at the end of this submission) and that the proposed wordingis therefore an appropriate change for section 1.5 of TA166.

However, we feel two adjustments would help with the clarity and clinical accuracy of what NICE is proposing without raising issues of policy or affecting any substantial change in the revised candidacy criteria.

Hearing level:

We strongly welcome the move to 80dBHL across five frequencies. However, we would recommend the inclusion of a small but important technical clarification.

The proposed wording from NICE is as follows:
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We would request the insertion of a technical clarification to the above statement so that there is no uncertainty as to its audiological interpretation and to ensure the proposed wording reflects the specific evidence referred to in previous submissions. The gold standard measure to determine hearing level is the pure tone audiometric threshold (with units of dB HL) obtained by following the recommended procedure of the British Society of Audiology. An audiometric threshold represents a person's ability to detect ('hear') sounds reliably based on their presentation level, and is not technically a measure of loudness. It is also the case that a person with an audiometric threshold of 80 dB HL may be able to 'hear' sounds quieter than 80 dB HL, but the clinical interpretation of their threshold is that they would not be able to detect those sounds reliably (more than 50% of the time).

In light of these issues, the wording of this criterion requires a small adjustment to ensure that it can be interpreted consistent and accurately by audiologists when putting the guidance into practice. To avoid changing the wording of the above definition substantially,

we therefore propose the addition of a small technical clarification to state the intended technical interpretation of the criterion, as follows:

Our recommended wording:
*For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (**pure-tone audiometric threshold equal to or greater than 80 dB HL**) at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.*

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The proposed wording from NICE is as follows:
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We request the inclusion of the specific scoring approach (phoneme score) in the speech-based criteria for the Arthur Boothroyd (AB) word test. This is because the AB word test is scored by both whole word and phoneme score (speech sounds in the word). The words in the test all have the structure of Consonant-Vowel-Consonant e.g. Cat. If the entire word is scored correctly an individual would score “1” on the word score and “3” on the phoneme score. If the word “Cat” was presented and the individual responded with “at”, i.e. they hadn’t detected the first phoneme they would score “0” for the word score and “2” for the phoneme score. We are referring to percent correct in the guidance and not absolute score so for the examples given the first would give 100% for both word and phoneme score and the second would be 0% and 66% for word and phoneme respectively. Hopefully, this example illustrates how different the two scoring approaches are and that 50% on a word score would be achieved by an individual with far better hearing than for an individual scoring 50% on a phoneme score.

A data-driven analysis informed the 50% phoneme score recommendation for the speech-based criteria. The analysis was conducted on data collected in a British Cochlear Implant Group National Service Evaluation in which pre-implant speech scores and 12 month post-implant outcomes were recorded.

Our recommended wording:

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 presented at 70 dBA*
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Our full evidence to support the above statements and the wording NICE is proposing can be found at:
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We are happy to discuss any aspects of this submission.

Name of organisation:

Cochlear Implanted Children's Support Group

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Summary

The NCIUA supports the new definition proposed by NICE which reflects the research and practice evidence already presented to NICE (see links at the end of this submission) and that the proposed wording is therefore an appropriate change for section 1.5 of TA166.

However, we feel two adjustments would help with the clarity and clinical accuracy of what NICE is proposing without raising issues of policy or affecting any substantial change in the revised candidacy criteria.

Hearing level:

We strongly welcome the move to 80dBHL across five frequencies. However, we would recommend the inclusion of a small but important technical clarification.

The proposed wording from NICE is as follows:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.

We would request the insertion of a technical clarification to the above statement so that there is no uncertainty as to its audiological interpretation and to ensure the proposed wording reflects the specific evidence referred to in previous submissions. The gold standard measure to determine hearing level is the pure tone audiometric threshold (with units of dB HL) obtained by following the recommended procedure of the British Society of Audiology. An audiometric threshold represents a person's ability to detect ('hear') sounds reliably based on their presentation level, and is not technically a measure of loudness. It is also the case that a person with an audiometric threshold of 80 dB HL may be able to 'hear' sounds quieter than 80 dB HL, but the clinical interpretation of their threshold is that they would not be able to detect those sounds reliably (more than 50% of the time).

In light of these issues, the wording of this criterion requires a small adjustment to ensure that it can be interpreted consistent and accurately by audiologists when putting the guidance into practice. To avoid changing the wording of the above definition substantially, we therefore propose the addition of a small technical clarification to state the intended technical interpretation of the criterion, as follows:

Our recommended wording:

*For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (**pure-tone audiometric threshold equal to or greater than 80 dB HL**) at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.*

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The proposed wording from NICE is as follows:

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- *For adults, a score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA*
- *For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability*

We request the inclusion of the specific scoring approach (phoneme score) in the speech-based criteria for the Arthur Boothroyd (AB) word test. This is because the AB word test is scored by both whole word and phoneme score (speech sounds in the word). The words in the test all have the structure of Consonant-Vowel-Consonant e.g. Cat. If the entire word is scored correctly an individual would score "1" on the word score and "3" on the phoneme score. If the word "Cat" was presented and the individual responded with "at", i.e. they hadn't detected the first phoneme they would score "0" for the word score and "2" for the phoneme score. We are referring to percent correct in the guidance and not absolute score so for the examples given the first would give 100% for both word and phoneme score and the second would be 0% and 66% for word and phoneme respectively. Hopefully, this example illustrates how different the two scoring approaches are and that 50% on a word score would be achieved by an individual with far better hearing than for an individual scoring 50% on a phoneme score.

A data-driven analysis informed the 50% phoneme score recommendation for the speech-based criteria. The analysis was conducted on data collected in a British Cochlear Implant Group National Service Evaluation in which pre-implant speech scores and 12 month post-implant outcomes were recorded.

Our recommended wording:

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 presented at 70 dBA*
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Draft wording of section 1.5:

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

Please cross this box if you agree with the draft wording ☒

Please provide any additional comments on the draft wording in the box below:

Evaluation of speech perception by using tests appropriate to age and speech development is recommended. Medical investigations regarding the cause of hearing loss and associated co morbidities should be part of the assessment

.
There is evidence that babies who have no responses on ABR are very likely to become cochlear implant recipients (Hang et al., 2015) and professionals should refer those children early to the cochlear implant departments.

Medical evaluation is vital in identifying the cause of hearing loss and significant associated medical problems and the decision of giving cochlear implants to children should be tailored to individual needs and parents should be fully informed about outcomes and expectations .

1. De Klejin JL et al Identification of Pure-Tone Audiologic Thresholds for Pediatric Cochlear Implant Candidacy: A Systematic Review. JAMA Otolaryngol Head Neck Surg. 2018 May 24
2. Lovett RE, Vickers DA, Summerfield AQ. Bilateral cochlear implantation for hearing-impaired children: criterion of candidacy derived from an observational study. Ear Hear. 2015;36(1):14-23.
3. Hang AX, Roush PA, Teagle HF, Zdanski C, Pillsbury HC, Adunka OF, Buchman CA Is "no response" on diagnostic auditory brainstem response testing an indication for cochlear implantation in children? Ear Hear. 2015 Jan;36(1):8-13.
4. Berrettini S1, et al. Analysis of the impact of professional involvement in evidence generation for the HTA Process, subproject "cochlear implants": methodology, results and recommendations. Acta Otorhinolaryngol Ital. 2011 Oct;31(5):273-80

Name of organisation:

BAAP (British Association of Audiovestibular Physicians)

Next steps:

- The draft wording and stakeholder's comments on it will be presented to the Technology Appraisal Committee.
- An Appraisal Consultation Document or Final Appraisal Document will be issued depending on whether the committee diverges substantively from the draft wording that went out for technical engagement or the suggestions made by stakeholders during the technical engagement.

Please return this form to us by uploading it to NICE Docs using the link below by **5pm on 19 September 2018**.

Draft wording of section 1.5:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally 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 the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☐

Please provide any additional comments on the draft wording in the box below:

Our recommended wording:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80dB HL (pure-tone audiometric threshold equal to or greater than 80dB HL) at 2 or more frequencies (at 500Hz, 1000Hz, 2000Hz, 3000Hz and 4000Hz) bilaterally without acoustic hearing aids.

Explanatory notes: Adequate benefit from hearing aids for adults (Arthur Boothroyd (AB) Word test)

We strongly welcome the move to replace the BKB test with the Arthur Boothroyd (AB) word test based on the evidence we submitted. However we would request one small but important change to the NICE suggested wording - the inclusion of the specific scoring approach (phoneme score) in the speech-based criteria for the AB word test.

This is because the AB word test is scored by both whole word and phoneme score (speech sounds in the word) and there is an important distinction. The words in the test all have the structure of Consonant-Vowel-Consonant e.g. Cat. If the entire word is scored correctly an individual would score "1" on the word score and "3" on the phoneme score. If the word "Cat" was presented and the individual responded with "at", i.e. they had not detected the first phoneme, they would score "0" for the word score and "2" for the phoneme score. We are referring to percent correct in the guidance and not absolute score, so for the examples given the first would give 100% for both word and phoneme score and the second would be 0% and 66% for word and phoneme respectively. Hopefully, this example illustrates how different the two scoring approaches are and that 50% on a word score would be achieved by an individual with far better hearing than for an individual scoring 50% on a phoneme score.

A data-driven analysis informed the 50% phoneme score recommendation for the speech-based criteria. The analysis was conducted on data collected in a British Cochlear Implant Group National Service Evaluation in which pre-implant speech scores and 12 month post-implant outcomes were recorded.

Our recommended wording:

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 presented at 70dB(A)***
- ***For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability***

Our full evidence to support the above statements and the wording NICE is proposing can be found at:

- https://actiongrouponadultcochlearimplants.files.wordpress.com/2018/01/candidacy-requirements-for-ta166-final-1.pdf
- https://actiongrouponadultcochlearimplants.files.wordpress.com/2018/07/collated-response-bcig-action-group-for-response-final-16-1-2018-3-11.pdf
- https://www.cicandidacy.co.uk/

We are happy to discuss any aspects of this submission.

Name of organisation:

Submitted by British Cochlear Implant Group [redacted]

Next steps:

- The draft wording and stakeholder's comments on it will be presented to the Technology Appraisal Committee.
- An Appraisal Consultation Document or Final Appraisal Document will be issued depending on whether the committee diverges substantively from the draft wording that went out for technical engagement or the suggestions made by stakeholders during the technical engagement.

Please return this form to us by uploading it to NICE Docs using the link below by **5pm on 19 September 2018**.

Draft wording of section 1.5:

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally 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 the Arthur Boothroyd word test presented at 70 dBA*
- *for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.*

Please cross this box if you agree with the draft wording ☐

The Clinical Reference Group for Ophthalmology and Specialised Ears appreciate having the opportunity to review and offer support to NICE regarding the proposed changes to section 1.5 of TAG166.

Consultation has been sought with all professionals and patient representative's involved with cochlear implantation.

The move to 80 dBHL across five frequencies is welcomed.

Current proposed wording is
For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.

For the sake of clarity and correct clinical interpretation which was identified by Audiological Scientists is that the 80 dBHL is inclusive

Without changing the main format of the text proposed by NICE it has been suggested that the following is used:

*For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (**pure-tone audiometric threshold equal to or greater than 80 dB HL**) at 2 or more frequencies (at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.*

It is also strongly supported that the BKB test currently used is replaced with the Arthur Boothroyd (AB) Word test based on sound clinical evidence. However we would request one small but important change to the NICE suggested wording.

Current proposed wording is;
Adequate benefit from acoustic hearing aids is defined for this guidance as:

- *For adults, a score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA*
- *For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability*

Data collected by the British Cochlear Implant group (BCIG) looked at both the whole word score and phoneme score of speech sounds in a word.

The example cited and reasons are;
"The words in the test all have the structure of Consonant-Vowel-Consonant e.g. Cat. If the entire word is scored correctly an individual would score "1" on the word score and "3" on the phoneme score. If the word "Cat" was presented and the individual responded with "at", i.e. they hadn't detected the first phoneme they would score "0" for the word score and "2" for the phoneme score. We are referring to percent correct in the guidance and not absolute score so for the examples given the first would give 100% for both word and phoneme score and the second would be 0% and 66% for word and phoneme respectively. Hopefully, this example illustrates how different the two scoring approaches are and that 50% on a word score would be achieved by an individual with far better hearing than for an individual scoring 50% on a phoneme score.

A data-driven analysis informed the 50% phoneme score recommendation for the speech-based criteria. The analysis was conducted on data collected in a British Cochlear Implant Group National Service Evaluation in which pre-implant speech scores and 12 month post-implant outcomes were recorded. "

The recommendations to wording:
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 presented at 70 dBA*
- *For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability*

Name of organisation:

NHS England

Next steps:

- The draft wording and stakeholder's comments on it will be presented to the Technology Appraisal Committee.
- An Appraisal Consultation Document or Final Appraisal Document will be issued depending on whether the committee diverges substantively from the draft wording that went out for technical engagement or the suggestions made by stakeholders during the technical engagement.

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Cochlear implants for children and adults with severe to profound deafness [ID1469] (part review of TA166) – briefing for committee

1. Background

NICE recently consulted on a proposal to review NICE technology appraisal 166, cochlear implants for children and adults with severe to profound deafness.

We proposed that an update to 1 of the recommendations in the guidance, recommendation 1.5, should be planned into the appraisal work programme.

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. Please see the review proposal paper for more details.

In the responses to this review proposal consultation stakeholders agreed with this approach. We invited submissions from stakeholders and based on those submissions developed draft wording below. This draft wording was circulated to stakeholders for further comment. All stakeholders agreed with the draft wording, with a few minor amendments suggested for clarity.

This draft wording is presented in section 3 below for your approval.

2. Current wording of recommendation 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.

3. Draft wording - updated after stakeholder comments

For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than ~~98~~0 dB HL (pure-tone audiometric threshold equal to or greater than 80 dB HL) at 2 or more frequencies ~~of 2 and 4 kHz~~(at 500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.

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

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

4. Rationale

- The draft wording is based on the British Cochlear Implant Group (BCIG) submission which was endorsed by British society of Audiology and British Academy of Audiology.
- The same or very similar criteria were proposed by Cochlear Europe (a company), Action on Hearing Loss, Adult Cochlear Implant Action Group, Cochlear Implanted Children's Support Group, National Cochlear Implant Users Association and the National Community Hearing Association.
- The BCIG submission drew on their consensus statement on candidacy for cochlear implantation. This was formulated by representatives from over 30 stakeholder organisations who considered 600 scenarios reflecting potential cochlear implant candidature situations. Agreement was reached on whether in each of these scenarios implantation was a) **appropriate** (the benefits of intervention were judged to outweigh the risks) and b) **necessary** (it would be improper care not to provide implantation).

Definition of severe to profound deafness should be hearing only sounds louder than 80 db HL

- Under the current criteria (90 dB HL), in 96% of the 600 scenarios captured, implantation is appropriate **and** necessary. However, this threshold only captures 15% of the scenarios where implantation is judged appropriate.
- Under the proposed criteria (80 dB HL), in 97% of the scenarios captured, implantation would be appropriate and necessary but it would capture >30% of the scenarios where implantation is appropriate.
- The 80 dB HL threshold would not capture any clinical scenarios where implantation is not considered appropriate.

Threshold for severe to profound deafness should not be as low as 70 db HL

- Lowering the threshold to 70 dB HL would have the benefit of capturing more scenarios where implantation is appropriate (>40%).
- However, it would capture more clinical scenarios in which implantation is appropriate but not considered necessary - the proportion of scenarios where implantation is considered appropriate and necessary falls to 76%.
- It would also capture approximately 12% of scenarios in which implantation is not appropriate.

	≥70 db HL	≥80 db HL	≥90 db HL
Type of scenarios captured by criteria:			
Appropriate	>40%	>30%	15%
Appropriate and necessary	76%	97%	96%
Not appropriate	12%	0%	0%

Testing should be at a wider range of frequencies

- Audibility of speech across the speech spectrum as a whole is a predictor of clinical outcomes and speech perception abilities.
- The important frequencies for speech perception are between 750 Hz and 3000 Hz and individuals with low-frequency hearing losses struggle with speech understanding.

The Bamford-Kowal-Bench (BKB) sentence test is not appropriate for assessing benefit of acoustic hearing aids

- 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 those with lower (or no) understanding of spoken English often cannot be assessed using this test.

- The BKB test is administered in quiet surroundings when the patient is in their best-aided condition and is not an accurate way of assessing whether they are receiving sufficient benefit from hearing aids.

The Arthur Boothroyd (AB) test is more appropriate for assessing benefit of acoustic hearing aids

- Countries such as Germany, Belgium and the Netherlands use a consonant vowel consonant (CVC) phoneme test, instead of a sentence test, to assess candidacy, and CVC tests are commonly used throughout the literature to assess cochlear implant performance.
- A word-based test scored by phonemes will expand the number of candidates who can be assessed by this method as a standard approach.
- The AB word lists are an example of a CVC phoneme test that is widely used across the UK.
- A recent study indicated that in order to achieve an 80% or better chance of achieving a higher score following implantation, the most accurate parameter amongst those considered is phoneme score of <50% using the AB.

5. Impact of changing the criteria on cost effectiveness

The main driver of the economic model was an increase in utility of 0.197 after implantation for adults. This was based on the best available evidence, a study of profoundly deaf people (mean audiological hearing threshold of 115dB with a range of 85dB to 140dB). However, the committee did not think that the utility gain would be lower in people with severe to profound deafness. No new utility data is available for people with severe to profound deafness.

Changing the criteria in section 1.5 of the guidance is not expected to have a material impact on the cost-effectiveness of unilateral implants in adults. This is because:

- Having concluded that the utility gain was likely to be similar in people with severe to profound deafness and profound deafness, the original criteria were based on evidence from the British Cochlear Implant Group (BCIG) rather than the utility study. The BCIG stated during the technology appraisal that people who cannot hear sounds quieter than an average of 90 dB HL without acoustic hearings aids *would be considered* for cochlear implantation if they *do not derive adequate benefit* from acoustic hearing aids. i.e. this is the group for whom at that time the BCIG thought cochlear implants were appropriate and necessary. The proposed criteria are those now suggested by the BCIG based on new research to determine at what threshold implantation is appropriate and necessary and the best way of assessing adequate benefit (see section 4). As such, it seems likely that the utility gain would be similar to that used in the original modelling.

- Even if the utility gain is lower than the 0.197 used in the original modelling, scenario analysis in the assessment group report showed that at a willingness to pay threshold of £30,000/QALY unilateral implantation only becomes cost-ineffective when the utility gain associated with unilateral cochlear implantation falls below a value of approximately 0.10. At a willingness to pay threshold of £20,000/QALY unilateral implantation becomes cost-ineffective below approximately 0.15

- In addition, since TA166, there has been a ~15% reduction in costs, so the corresponding threshold values would now be lower.