

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Final appraisal document

**Cochlear implants for children and adults with
severe to profound deafness (part review of
TA166)**

This guidance has been updated after a review of the criteria for defining severe to profound deafness and for assessing adequate benefit from acoustic hearing aids set out in recommendation 1.5. See section 4.4 for further details.

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

1 Recommendations

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

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

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

- children

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

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

- 1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.
- 1.4 People who had a unilateral implant before publication of this guidance, and who fall into one of the categories described in 1.2, should have the option of an additional contralateral implant only if this is considered to provide sufficient benefit by the responsible clinician after an informed discussion with the individual person and their carers.
- 1.5 For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (pure-tone audiometric threshold equal to or greater than 80 dB HL) at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 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 the Arthur Boothroyd word test presented at 70 dBA
 - for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability. **[amended 2018]**
- 1.6 Cochlear implantation should be considered for children and adults only after an assessment by a multidisciplinary team. As part of the assessment children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).

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

2 Clinical need and practice

- 2.1 Hearing loss may be caused by interference with the transmission of sound from the outer to the inner ear (conductive hearing loss) or damage within the cochlea, the auditory nerve or auditory centres in the brain (sensorineural hearing loss). In adults the most common cause of sensorineural hearing loss is presbycusis. This is a progressive condition caused by the loss of function of hair cells in the inner ear, leading to deafness. Hearing loss in adults may also be caused by excessive exposure to noise, or by ototoxic drugs, metabolic disorders, infections or genetic factors. Severe to profound hearing loss in children may have a genetic aetiology, or have prenatal, perinatal or postnatal causes. These include conditions such as meningitis and viral infection of the inner ear (for example, rubella or measles), as well as premature birth and congenital infections. Deafness that occurs before the development of language is described as prelingual, whereas deafness that occurs after the development of language is described as postlingual.
- 2.2 Approximately 370 children in England and 20 children in Wales are born with permanent severe to profound deafness each year. Approximately 90% of these children have 2 parents who can hear. About 1 in every 1,000 children is severely or profoundly deaf at 3 years old. This rises to 2 in every 1,000 children aged 9 to 16 years. There are approximately 613,000 people older than 16 years with severe to profound deafness in England and Wales. In the UK around 3% of people older than 50 and 8%

of those older than 70 years have severe to profound hearing loss. Approximately 40% of children who are deaf and 45% of people younger than 60 years who are deaf have additional difficulties, such as other physical disabilities.

2.3 Deafness is not typically associated with increased mortality, and need not be associated with significant morbidity. Some people who are deaf identify with a cultural model of deafness in which deafness is not considered an impairment. These people, who often use sign language as their preferred language and grow up as members of the Deaf community, may not perceive deafness to have a major impact on their quality of life. However, for a child who is born deaf within a hearing family or for a person who becomes deaf and is used to functioning in a hearing environment, deafness can have a significant impact on their quality of life. For children, deafness may have significant consequences for linguistic, cognitive, emotional, educational and social development. Loss of hearing affects an adult's ability to hear environmental noises and to understand speech; this can affect their ability to take part in their daily activities and be part of their usual social and professional networks, which can lead to isolation and mental health problems.

2.4 Services for people who are deaf aim to improve their quality of life by maximising their ability to communicate, using the means most appropriate for the person and their environment, and to enable the person to move safely within their environment. There are approximately 50,000 people in the UK who communicate using British Sign Language. These are generally people who were born deaf or became deaf shortly after birth. Most people who are deaf use oral and aural communication supplemented by lip reading, cued speech (visual cues to clarify the sounds of English), signs (finger spelling or sign-supported English) and the written word. Regardless of the chosen means of communication, people may also use powerful hearing aids to help them identify environmental noises and to hear spoken language. However, for some

people there are too few functioning hair cells for hearing aids to be of use.

- 2.5 National frameworks covering audiology include the NHS newborn hearing screening programme and the NHS modernising hearing aid services programme for children and adults. The NHS newborn hearing screening programme screens all newborn babies within 26 days of birth for possible hearing difficulties. Babies who at screening are identified as having possible hearing difficulties are referred to NHS audiology services. Those who are then confirmed deaf should receive a hearing aid within 2 months. This initial diagnosis is followed by ongoing support, which includes regular audiological assessment and consideration of the appropriateness of a cochlear implant (usually within the first year). Hearing services for adults are coordinated by audiology departments and normally include a review every 4 years, although this varies across the UK.
- 2.6 Potential candidates for cochlear implants are referred to one of the cochlear implant centres in England and Wales, where they receive a multidisciplinary assessment to determine whether cochlear implantation is suitable. Both audiological hearing and functional hearing are assessed as part of the multidisciplinary assessment, as well as other factors such as fitness for surgery, structure of the cochlea, the presence of a functioning auditory nerve and the likely ability of the person to derive benefit from the stimuli produced by the cochlear implant system.
- 2.7 Audiological testing identifies the additional intensity that a pure-tone sound must possess to be detected relative to the intensity that can be detected by young adults without hearing impairment. At the time of the original appraisal, guidelines from the British Cochlear Implant Group suggested that people who could not hear sounds quieter than an average of 90 dB HL when tested at frequencies of 2 and 4 kHz without acoustic hearing aids would be considered for cochlear implantation if

they did not derive adequate benefit from acoustic hearing aids. But after a review of the guidance in 2018 stakeholders agreed that this was out of date (see section 4.4).

2.8 Functional hearing is tested with optimum acoustic hearing aids and focuses on a person's ability to perceive speech. At the time of the original appraisal, for adults, functional hearing was usually assessed using Bamford-Kowal-Bench (BKB) sentences. Guidelines from the British Cochlear Implant Group stated that an adult who identified 50% or more of keywords at a sound intensity of 70 dB SPL in quiet conditions was considered to be deriving an adequate benefit from their hearing aids. But after a review of the guidance in 2018 stakeholders agreed that the test and the guidelines were out of date (see section 4.4). Functional hearing in children is assessed through the development and maintenance of speech, language, communication and listening skills that are appropriate for the age, developmental stage and cognitive ability of the child. For this reason no single test is used.

2.9 During the year ending March 2007, 374 adults and 221 children had unilateral cochlear implantations in England and 8 adults and 22 children in Wales. A further 451 adults and 446 children were under assessment. In the UK, in the year ending March 2007, 32 bilateral implantations were performed in children and 11 in adults. A survey of 15 of the 18 cochlear implant centres in England and Wales showed that 704 children and adults had received a unilateral cochlear implant during the financial year ending March 2008. In addition, there were 77 children and adults who had received bilateral cochlear implants. Of these, 39 were simultaneous implants and 38 were sequential implants.

3 The technology

3.1 Cochlear implant systems consist of internal and external components. A microphone and sound processor are worn externally behind the ear. The sound processor is connected to a transmitter coil, which is worn on the

side of the head. Data from the transmitter coil are passed to a receiver–stimulator package that is implanted into a surgically fashioned depression in the mastoid bone. The receiver–stimulator translates the data into electrical pulses that are delivered to an array of electrodes. These are placed surgically within the cochlea. The electrodes stimulate spiral ganglion cells that innervate fibres of the auditory nerve. The activation of electrodes provides a sensation of hearing, but does not restore hearing.

- 3.2 The NHS buys cochlear implant systems under a long-term procurement contract between the 4 companies and the NHS supply chain. The procurement contract in use during this appraisal applied until 31 October 2008 and there was an option for an extension of a further 24 months. The costs of the implant systems noted below are based on information from the NHS supply chain on the national procurement contract. In addition to the main procurement contract, companies offer local discounts based on volume of sales; therefore costs may vary in different settings. Except for the discount for the Neurelec system, discounts for second implant systems are not part of the NHS supply chain contract, but are offered nationally by some companies.
- 3.3 The Clarion CII Bionic Ear System and the HiResolution Bionic Ear System (Advanced Bionics UK) are indicated for adults (18 years or older) with postlingual onset of severe to profound, bilateral sensorineural hearing loss (only hearing sounds with an intensity equal to or greater than an average of 70 dB HL) who derive limited benefit from appropriately fitted hearing aids. For children aged 12 months to 17 years the implants are indicated for profound bilateral sensorineural deafness (only hearing sounds with an intensity equal to or greater than an average of 90 dB HL) who derive limited benefit from acoustic hearing aids. The current NHS supply chain list price of the implant system (which includes the implant and processor) is £16,550 and the price paid by the NHS supply chain for the implant system is £14,900. Information supplied by

the company indicates that a 40% discount on the list price for a second implant (list price for implant without processor and without discount: £10,500) is only offered when the second implant is used for simultaneous bilateral implantation. A 25% discount on the list price of £10,500 is offered when the second implant is used for sequential bilateral implantation. No discounts are offered for the purchase of a second processor. Costs may vary in different settings because of negotiated procurement discounts.

3.4 The Nucleus 24 and Nucleus Freedom cochlear implants (Cochlear Europe) are indicated for adults (18 years or older) who have bilateral postlingual sensorineural hearing loss and who have limited benefit from binaural hearing aids. For children (aged 12 months to 17 years) the implants are indicated for bilateral sensorineural hearing loss if little or no benefit is derived from binaural hearing aids. The implants are also indicated for adults who have prelingual or perilingual profound sensorineural deafness and who obtain no benefit from a hearing aid. However, the package insert notes that these people are likely to have limited benefit from a cochlear implant. The current NHS supply chain list prices of the Nucleus 24 and Nucleus Freedom cochlear implant systems are £14,350 and £15,250 to £15,550 respectively. The price paid by the NHS is based on the volume acquired by each cochlear implant centre and the company offers a 10% discount for every 10 implant systems purchased. Additional information supplied by the company indicates that discounts for a second implant system (implant and processor) for bilateral cochlear implantation are offered on a case-by-case basis. Costs may vary in different settings because of negotiated procurement discounts.

3.5 The Pulsar CI-100 (MED-EL UK) is indicated for people with severe to profound deafness who derive limited benefit from conventional acoustic amplification in the best-aided condition. It is recommended that individuals have a trial of acoustic hearing aids unless this is

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

- 3.6 The Digisonic SP (Neurelec) is indicated for adults and children with bilateral profound to total sensorineural hearing loss. The price paid by the NHS supply chain for the Digisonic cochlear implant system is £12,250. A 50% discount on the second implant system for bilateral implantation is currently in place with the NHS supply chain (equating to £18,375 for 2 implant systems).
- 3.7 Information on discounts was also obtained from a survey of the 18 cochlear implant centres in England and Wales. Responses were received from 15 centres: 3 paediatric centres, 2 adult centres and 10 with paediatric and adult caseloads. Four of the centres that responded did not carry out any bilateral implants during this period. The results of the survey suggested variation in the discounts received by the implant centres. For sequential bilateral implantation, the discounts ranged from 0 to 40% for the second implant. For simultaneous bilateral implantation the range was 0 to 50% for the second implant.

4 Evidence and interpretation

The appraisal committee (section 8) considered evidence from a number of sources. See the [committee papers](#) for full details of the evidence.

4.1 Clinical effectiveness

- 4.1.1 The assessment group identified studies of cochlear implants that included adults and/or children with severe to profound deafness. The assessment group included only studies of multichannel cochlear implants that used whole-speech processing coding strategies, because these most closely represent the type of device available to the NHS. The

assessment group included randomised and non-randomised controlled trials, including studies in which participants acted as their own controls.

- 4.1.2 The systematic review by the assessment group comprised 33 studies, of which 13 involved adults and 20 involved children. Meta-analysis of the data was not possible because of heterogeneity between the studies. Only 2 implant systems in the NHS contract (both supplied by Cochlear Europe) were represented in studies included in the systematic review. Three companies – Advanced Bionics UK, Cochlear Europe and MED-EL UK – submitted additional studies reporting the clinical effectiveness of their implant systems. Neurelec did not submit evidence of clinical effectiveness to this appraisal.

Children: unilateral cochlear implantation

- 4.1.3 Eight studies compared a unilateral cochlear implant with non-technological support (that is, without acoustic hearing aids, but permitting lip reading or sign language), and 6 studies compared unilateral cochlear implants with acoustic hearing aids. In 10 of the studies children acted as their own controls and in 4 of the studies there was a separate non-randomised control group. The studies reported benefits from cochlear implants in auditory, speech perception and speech production outcomes. In the 4 studies that reported statistical significance, the benefits were statistically significant. Two of these studies suggested that children who have devices implanted earlier may have better outcomes.

Children: bilateral cochlear implantation

- 4.1.4 Three studies compared bilateral cochlear implants with a unilateral cochlear implant, and 3 studies compared bilateral cochlear implants with a unilateral cochlear implant and a contralateral hearing aid. In 4 studies the children acted as their own controls, whereas the other 2 studies included a non-randomised control group. Benefits were reported for auditory and speech perception outcomes with bilateral cochlear implantation. In the 5 studies that reported levels of statistical significance,

3 reported statistically significant improvements in the ability to identify the direction from which a sound is coming with bilateral cochlear implants. In addition, 2 studies reported statistically significant improvements in speech perception in noisy conditions with bilateral cochlear implants. However, differences for speech perception outcomes in quiet conditions were statistically significant for only 2 out of 7 outcome measures.

Children: quality of life and education outcomes

4.1.5 None of the studies in the assessment group's systematic review reported either quality of life or educational outcomes. Further searches identified 4 studies that measured quality of life and 7 studies that measured educational outcomes. Studies assessing quality of life suggest that a cochlear implant can improve a child's quality of life and their quality of life as perceived by their parents.

4.1.6 The studies of educational outcomes suggest that children who are profoundly deaf and have a cochlear implant may be more likely to be educated within a mainstream school than children with a similar level of deafness but without a cochlear implant. The studies also suggest that children who are profoundly deaf and have a cochlear implant may have a higher level of academic performance than those who are profoundly deaf but have no cochlear implant.

Adults: unilateral cochlear implantation

4.1.7 Four studies compared a unilateral cochlear implant with non-technological support (for example, without acoustic hearing aids, but permitting lip reading or sign language), and 4 studies compared a unilateral cochlear implant with an acoustic hearing aid. In 7 studies participants acted as their own controls; the eighth study included a non-randomised control group. The studies measured speech perception outcomes. Four also measured quality of life and 1 measured an auditory outcome. The studies suggested that there were benefits from the use of cochlear implants in all the outcomes measured. When statistical

significance levels were reported, these benefits were statistically significant, except for the auditory outcome. One study suggested that the benefits of a unilateral cochlear implant may be greater for younger people and people who have been deaf for a shorter time.

Adults: bilateral cochlear implantation

4.1.8 Five studies compared unilateral cochlear implants with bilateral cochlear implants. The assessment group did not identify any studies of adults that compared bilateral cochlear implants with a unilateral cochlear implant and a contralateral hearing aid. Two studies were randomised controlled trials and in the other 3, participants acted as their own controls. There was some overlap in the participants included in 3 of the studies. The studies measured auditory, speech perception and quality-of-life outcomes. Auditory outcomes were statistically significantly better for bilateral cochlear implants than for a unilateral implant. However, the results for speech perception and quality of life were more mixed, with some outcomes suggesting a negative impact of bilateral implantation owing to worsening of tinnitus after the second implantation.

Adults: quality of life

4.1.9 Three studies that measured quality of life were included in the systematic review. However, because of the importance of this outcome, further searches were completed to identify other studies that measured quality of life. Six further studies were identified, all of which reported benefits in quality of life associated with cochlear implants. Four studies reported levels of statistical significance, and 3 of these reported statistically significant benefits for quality of life after cochlear implantation.

4.2 Cost effectiveness

4.2.1 Submissions were received from 3 companies. Two (Cochlear Europe, Advanced Bionics UK) provided de novo economic evaluations. The third (MED-EL UK) provided a narrative summary of existing published economic analyses. The assessment group identified a total of 9 studies

that reported cost effectiveness or cost–benefit ratios from the perspective of the NHS. These reported incremental cost-effectiveness ratios (ICERs) for unilateral cochlear implantation ranging from £2,000 to £20,000 per quality-adjusted life year (QALY) gained for children and £11,000 to £18,000 per QALY gained for adults. In addition, the assessment group carried out a de novo economic evaluation.

The economic submission from Cochlear Europe

- 4.2.2 The company submitted a Markov model that evaluated the cost effectiveness of unilateral and bilateral cochlear implantation compared with 'standard of care' (in which a proportion of people receive acoustic hearing aids) from an NHS and personal social services (PSS) perspective. The decision problem was assessed in relation to the Nucleus and Nucleus Freedom products using costs and failure rates specific to these systems. Health-related utility data were derived from clinical studies and mapped speech recognition scores onto health utility index 3 (HUI3) utility values. The assessment group expressed concern about the way the mapping was undertaken.
- 4.2.3 The comparison of unilateral implantation with 'standard of care' gave an ICER of £10,500 per QALY gained for children with severe to profound sensorineural deafness and £7,100 per QALY gained for adults with postlingual severe to profound sensorineural deafness. The comparison of bilateral implantation and unilateral implantation gave an ICER of £39,000 and £32,900 per QALY gained in adults and children, respectively.

The economic submission from Advanced Bionics UK

- 4.2.4 The company submitted a Markov model that evaluated the cost effectiveness of unilateral cochlear implantation compared with no cochlear implants from an NHS and PSS perspective. Four specific subgroups were identified: children with prelingual profound deafness; children with postlingual profound deafness; adults with postlingual profound deafness; and adults with postlingual severe deafness. Cost-

effectiveness analyses were not presented for bilateral cochlear implantation.

- 4.2.5 Costs were derived from a published study of cochlear implantation in children, and applied to both children and adults. Health-related utility data were derived from published studies using HUI3. The ICERs associated with unilateral implantation at 3 and 6 years were £13,300 and £17,200 per QALY gained, respectively. The ICERs for unilateral implantation in 50-year-old adults with profound and severe deafness were £20,000 and £37,000 per QALY gained, respectively.

The economic submission from MED-EL UK

- 4.2.6 The submission from the company does not include an economic model and primarily summarises some of the existing published economic literature. The submission presents an ICER of approximately £18,000 per QALY gained for unilateral cochlear implantation in children. For adults, estimates of cost effectiveness for unilateral cochlear implantation are presented for the group as a whole and for 2 subgroups: adults with profound deafness who derive no functional benefit from acoustic hearing aids; and adults with profound deafness who derive some functional benefit from hearing aids. The corresponding ICERs were £20,600, £19,200 and £25,400 per QALY gained, respectively.

The economic model from the assessment group

- 4.2.7 The assessment group developed a Markov model to consider 2 questions. The first was the cost effectiveness of unilateral cochlear implantation compared with standard treatment (which may or may not include acoustic hearing aids) in children and adults who were profoundly deaf. The second was the cost effectiveness of providing an adult or a child who is profoundly deaf and currently receiving standard treatment (which may or may not include acoustic hearing aids) with a simultaneous or sequential (defined as 3 years between the first and second implant) bilateral cochlear implant compared with a unilateral cochlear implant.

- 4.2.8 The effectiveness of cochlear implants in the model was based on a separate review of studies that reported health-related utility values for severe or profound deafness for unilateral or bilateral cochlear implantation. The most relevant studies that were identified derived quality-of-life data from the HUI3. For children, changes in quality of life were reported by their parents or their teachers as proxies. In the base-case analyses, utilities were assumed to remain constant over the lifetime of the person.
- 4.2.9 The health-related utility for a child without a cochlear implant was obtained from all children in the UK with profound deafness and no cochlear implant. The health-related utility value from this population was 0.421. The gains in health-related utility from having a cochlear implant were 0.066, 0.212 and 0.232 in the first 2 years following implantation, 2 to 4 years and 4 years onwards, respectively. The health-related utility data for adults were obtained from a prospective cohort study that measured health-related utility before and after cochlear implantation in a group of adults with postlingual severe to profound deafness. The utility value without a cochlear implant was 0.433. The gain in utility associated with having a unilateral cochlear implant was estimated to be 0.197.
- 4.2.10 The health-related utility data for bilateral implantation were obtained from data from 24 adults with postlingual deafness who had a unilateral cochlear implant and were then randomised to receive a second contralateral implant immediately or 11 months later. At 9 months follow-up a comparison of those who had bilateral implants with those waiting for their second implant suggested a difference in utility of 0.10. A subsequent analysis of the whole group (before and after implantation) suggested a utility gain of -0.015. Regression analyses of the trial data, controlling for changes in tinnitus after implantation, suggested that the additional utility gain associated with bilateral cochlear implantation was 0.03. The assessment group used the latter value (0.03) in their analyses.

In the absence of health-related utility data for bilateral cochlear implantation in children, the data from adults were applied to children.

- 4.2.11 The assessment group was unable to identify adequate health-related utility data to model the cost effectiveness of implanting a second device in a person with 1 established cochlear implant. The assessment group did not examine the following subgroups in its economic analysis: children and adults with severe deafness; adults with prelingual deafness; children with postlingual deafness; and children and adults who are both deaf and blind or are deaf and have other disabilities. This was because of the lack of health-related utility data to define either the health-related utility without a cochlear implant or the gain in health-related utility following cochlear implantation.
- 4.2.12 Costs included in the model are taken from 2 large UK costing studies that identified the cochlear implant centre costs associated with cochlear implantation in adults and children. The cost data for adults were taken from the same study from which utility data were taken. The data for children were collected from a survey of UK cochlear implant centres providing cochlear implants for the financial year 1998–99. In the base-case analyses, the cost of the cochlear implant (£14,661) was the mean cost of the 9 devices in the NHS supply chain purchasing contract. For bilateral implantation, the cost of a single device was doubled (£29,222). Discounts on the second implant system were considered in sensitivity analyses.

Cost effectiveness for children

- 4.2.13 The ICER for unilateral implantation in children who are prelingually deaf and receive an implant at the age of 1 year was £13,400 per QALY gained. The corresponding ICERs for simultaneous and sequential bilateral implantation compared with unilateral implantation were £40,400 and £54,100 per QALY gained, respectively.

4.2.14 Analyses suggested that the estimates of cost effectiveness were sensitive to the time horizon, maintenance costs and utility. Scenario analyses that included educational costs or a later age at implantation had little impact on the estimates of cost effectiveness. Sensitivity analyses suggested that the estimates of cost effectiveness for simultaneous bilateral implantation were sensitive to changes in device costs and the utility gained. With a cost of £14,661 for a unilateral implant system, reductions of 25 and 50% in the cost of the second implant system reduced the ICER for simultaneous bilateral implantation to £36,139 and £31,900 per QALY gained, respectively. Without a cost discount for the second implant system, an increase of the utility gain from 0.03 to 0.04 reduced the ICER from £40,400 to £31,300 per incremental QALY gained.

4.2.15 The assessment group conducted additional 2-way sensitivity analyses to investigate the impact of combining the discounts reported by the cochlear implant centres (see section 3.7) with alternative assumptions about utility gain associated with bilateral implantation for simultaneous bilateral cochlear implantation in children. In the analyses, the cost of a unilateral implant system was assumed to be £15,534, which was the mean of the published list prices of the devices used in the cochlear implant centres. Assuming a discount of 30% on the second implant system and a utility of 0.03 produced an ICER of £36,040 per QALY gained. When the 30% discount was maintained and a utility of 0.04 instead of 0.03 was assumed, the ICER was reduced to £27,886 per QALY gained. Increasing the utility gain to 0.05 further reduced the ICER to £22,740 per QALY gained.

Cost effectiveness for adults

4.2.16 The ICER for unilateral implantation in adults who are postlingually deaf was £14,200 per QALY gained. The corresponding ICERs for simultaneous and sequential bilateral implantation compared with unilateral implantation were £49,600 and £60,300 per QALY gained, respectively.

4.2.17 Analyses suggested that the estimates of cost effectiveness were sensitive to the time horizon, age of the cohort, device costs and utility gain. Scenario analysis using an age-dependent utility gain had little impact on the estimate of cost effectiveness. Sensitivity analyses for simultaneous bilateral implantation showed that the estimates were sensitive to changes in device costs and the utility gained. Reductions of 25 and 50% in the cost of the second implant system reduced the estimate of cost effectiveness to £43,028 and £36,497 per QALY gained, respectively. Without a cost discount for the second implant system, but with a utility gain of 0.04 as opposed to 0.03 the estimate of cost effectiveness was reduced from £49,600 to £37,725 per incremental QALY gained.

4.2.18 Following completion of the assessment report, consultees provided new evidence on the additional utility gain associated with bilateral compared with unilateral implantation for children and adults. One estimate came from a cross-sectional study of 15 children with unilateral cochlear implants and 26 children with bilateral cochlear implants. In this study, parents rated their children's health-related quality of life using the HUI3. The utility of children with a unilateral cochlear implant was reported as 0.72, whereas the utility of children with bilateral cochlear implants was reported as 0.73, reflecting a change in utility of 0.01. A second estimate came from a study of 23 people (children and adults) with bilateral cochlear implants. In this study participants were asked to retrospectively rate their health-related quality of life using the HUI3 before and after receiving a unilateral implant (that is, unilateral compared with no implants). Participants were then asked to rate their health-related quality of life using the HUI3 with bilateral implants. This study reported a utility of 0.69 associated with unilateral cochlear implantation compared with 0.81 for bilateral cochlear implantation, which was reported in the paper as a change in utility of 0.11. A further study asked 180 people including parents, clinicians and students to rate the hypothetical health-related quality of life of children described in vignettes. This study reported utility

values of 0.77 for a child with a unilateral cochlear implant, 0.82 for a child using a unilateral cochlear implant and a contralateral hearing aid, and 0.88 for a child with bilateral cochlear implants.

4.3 Consideration of the evidence

- 4.3.1 The appraisal committee reviewed the data available on the clinical and cost effectiveness of cochlear implants for children and adults with severe to profound deafness, having considered evidence on the nature of the condition and the value placed on the benefits of cochlear implants by people who are deaf, those who represent them, and clinical experts. It was also mindful of the need to take account of the effective use of NHS resources.
- 4.3.2 The committee considered the distinction between audiological and functional deafness. The committee heard from clinical experts that audiological hearing was not necessarily related to functional hearing. Therefore, in clinical practice a person's hearing is assessed not just by audiological tests, but also by a functional test of hearing, specifically their ability to perceive speech in quiet conditions with acoustic hearing aids. The committee concluded that decisions about the appropriateness of cochlear implants should take into consideration a person's functional hearing and the benefit they gain from acoustic hearing aids.
- 4.3.3 The committee considered how functional deafness could be defined in clinical practice. At the time of the original appraisal it heard from clinical experts that guidelines for adults from the British Cochlear Implant Group recommend Bamford-Kowal-Bench (BKB) sentence testing. Using this approach, an adequate benefit from hearing aids is defined as a score of 50% or greater at a sound intensity of 70 dB SPL. But after a review of the guidance in 2018 stakeholders agreed that the test and the criteria were out of date and the committee agreed to update recommendation 1.5 (see section 4.4). The committee heard that tests for children should assess whether speech, language and listening skills are appropriate to the age,

development stage and cognitive ability of the child. The committee heard that the most appropriate test would differ according to the age and developmental stage of the child. The committee considered that the BKB sentences may not be appropriate for assessing hearing in adults for whom English is a second language, and for adults with other linguistic or cognitive difficulties. The committee considered that those making the hearing assessments should take these factors into account. In these situations, modification of the testing procedure or alternative tests may be required.

4.3.4 The committee recognised that identifying people for whom cochlear implantation was appropriate took account of not only the results of audiological and functional hearing tests but also other factors such as fitness for surgery, structure of the cochlea, the presence of functioning auditory nerves and the likelihood of benefiting from the stimuli produced by the device. The committee heard from clinical experts that these factors were assessed as part of a multidisciplinary assessment, which would also include a trial of acoustic hearing aids that usually lasts for 3 months, if this was not contraindicated or inappropriate. The committee concluded that it was essential to determine the appropriateness of cochlear implantation through a multidisciplinary assessment, with input from a range of professionals involved in the care of children and adults with cochlear implants. This was in addition to audiological and functional hearing tests and a valid trial of acoustic hearing aids that usually lasted 3 months.

4.3.5 The committee considered the perspective of people who may not consider deafness a disability that needs to be treated. The committee heard from clinical experts that most children who are deaf have families who are hearing and who have no access to Deaf culture. In addition, it is unlikely that adults who become deaf will become proficient users of sign language and integrate into the Deaf community. The committee concluded that for many people deafness would have a significant

adverse impact on their quality of life, and that it was appropriate to consider cochlear implants as a means of reducing this impact.

- 4.3.6 The committee noted that the evidence for clinical and cost effectiveness was derived from data based on cochlear implant systems from 3 companies making cochlear implants (Advanced Bionics UK, Cochlear Europe, MED-EL UK), and that no data for clinical effectiveness were identified for cochlear implant systems from the fourth company (Neurelec). The committee was aware that cochlear implant systems from Neurelec are included in the current NHS procurement contract, but heard from clinical experts that Neurelec implants are rarely used in the NHS. The committee concluded that it was only able to issue recommendations about the devices for which there was evidence available.
- 4.3.7 The committee examined the evidence for the clinical effectiveness of the use of unilateral cochlear implants for adults and children with severe to profound deafness. The committee considered that, despite methodological limitations, the studies showed benefits for providing unilateral cochlear implants compared with hearing aids or non-technological support for people who were appropriately assessed. The committee concluded that unilateral cochlear implants had been shown to be clinically effective.
- 4.3.8 The committee examined the evidence for the cost effectiveness of unilateral cochlear implantation. The committee noted that both the assessment group and the companies obtained similar estimates of cost effectiveness. The committee considered that the analyses of cost effectiveness for unilateral implantation were a reasonable reflection of the costs and benefits. The committee concluded that unilateral cochlear implantation for adults and children with severe to profound deafness who did not derive adequate benefit from acoustic hearing aids would be a cost-effective use of NHS resources.

- 4.3.9 The committee considered the evidence for the clinical effectiveness of bilateral cochlear implants. The committee considered that the additional benefits of bilateral cochlear implantation were less certain than the benefits of unilateral cochlear implantation. This was because of the limitations of the evidence base owing to the small number of studies and the small numbers of participants. However, the committee considered that the studies had shown additional benefits to having a second cochlear implant in relation to speech perception in noisy situations and directional perception of sound. The committee heard from patient experts that they considered that there were other benefits from bilateral cochlear implantation. These benefits included easier, less exhausting communication (for example, determining the direction of the sound in group conversations without unnecessary head movement). The committee concluded that there were additional benefits of bilateral cochlear implants that had not been adequately evaluated in the published studies, although these may vary among individuals.
- 4.3.10 The committee heard from clinical experts that it was important that the auditory nerve was provided with stimulation early in a child's development because it became less sensitive to stimulation as the child became older. Hence, failure to stimulate the auditory nerve early impaired the development of central pathways necessary for the appreciation and understanding of sound. The committee was persuaded on the basis of consultee comments that the potential benefits of bilateral auditory stimulation would apply to both prelingual and postlingual children with severe to profound deafness because neurosensory development continues after the development of language. The committee concluded that making a distinction between children based on the time of language development would not be appropriate.
- 4.3.11 The committee then considered the cost effectiveness of bilateral cochlear implantation. The committee first examined the cost of cochlear implant systems and in particular the availability of nationally agreed discounts for

the second cochlear implant system. The committee noted that the current NHS supply chain contract only included 1 discount on a bilateral system from a single company (Neurelec). The committee then considered the information about discounts provided by the other 3 companies. The committee noted that 2 of the 3 companies reported their discounts as being standardised and nationally available. The committee recognised that these discounts were sometimes given on the implant alone and other times on the whole implant system (that is implant plus processor), and that this would affect the total cost of the system. The committee examined the information on discounts from the survey of cochlear implant centres (described in section 3.7). The committee noted that there was some variation in the size of the discount received by the cochlear implant centres that was not reflected in the information from the companies. The committee noted this did not appear to relate directly to volume of implants purchased. The committee considered that the data showed that discounts of 40% or more on the second implant were being attained by a large proportion of implant centres, and therefore could be considered as being available nationally. Therefore the committee concluded that it was appropriate for this size of discount to be taken into account when considering the estimates of incremental cost effectiveness of bilateral implantation.

4.3.12 The committee then considered the cost effectiveness of bilateral cochlear implantation in adults. The committee noted that the base-case economic analyses provided by the assessment group obtained an ICER for simultaneous bilateral cochlear implantation of approximately £50,000 per QALY gained. The committee noted that the utility data used in this analysis were associated with uncertainty because the data were derived from a small number of adults over a short follow-up period. However, the committee noted that these were the only data available for people who had been studied prospectively before and after they had received a second cochlear implant. Therefore the committee considered that this was the most appropriate source of data for estimating health utility gain

following a second implant. The committee noted concerns from consultees about the impact of tinnitus on the utility results from this study. It accepted the analysis of the study data that had controlled for the impact of tinnitus and gave a health utility gain following a second implant of 0.03. Therefore the committee considered that 0.03 was currently the most appropriate estimate of the additional utility gain for a second implant for adults with severe to profound deafness. The committee noted the assessment group's assumption of no discount for the second implant in their base-case analysis. The committee considered the situation of a 25% to 50% discount on the second implant system as discussed in section 4.2.17. Under these circumstances the ICER for bilateral implantation for adults was between £43,000 and £36,500. The committee noted from the assessment group's analysis that with a utility gain of 0.03, discounts on the second implant system had to be greater than 75% for the ICER for bilateral implantation in adults to fall between £20,000 and £30,000 per QALY gained. Therefore the committee concluded that it was not possible to recommend routine bilateral cochlear implantation in adults as a cost-effective use of NHS resources.

4.3.13 The committee next examined the evidence for the cost effectiveness of bilateral cochlear implantation for children with severe to profound deafness. The committee noted that the assessment group had been unable to identify any health-related quality-of-life data for bilateral cochlear implantation in children, and had used the data from adults for children (that is, an additional gain in health-related utility of 0.03 for the second implant). The committee noted comments from consultees that for children with severe to profound deafness, a utility gain of 0.03 could potentially be an underestimate. These comments focused on the view that bilateral cochlear implantation could afford more quality-of-life gains for children than for adults, through improved language learning and spatial awareness, which would increase opportunities for interaction and communication, the ability to participate in play activities, and benefits from education. The committee was persuaded that additional utility gains

for children above that for adults were plausible. However, the size of these additional gains was associated with considerable uncertainty, given that there were limited data for children, and for adults the additional gains in health-related quality of life were associated with methodological concerns. The committee recognised that the economic analyses were sensitive to utility gains, and that if the gain in utility for children was assumed to be more than for adults, the ICER for bilateral cochlear implantation would be considerably reduced from the base case.

4.3.14 The committee then considered the impact on the ICERs of combining additional gains in utility for simultaneous bilateral cochlear implantation of children with discounts on the second implant. The committee noted that the 40% discount for the second cochlear implant for simultaneous bilateral implantation, which was being received by many cochlear implant centres, equated to approximately 30% off the cochlear implant system (implant plus processor). The committee noted that with a discount of 30% on the implant system and a utility gain of 0.04, the ICER for children would be £27,900 per QALY gained. If the same discount was applied and the utility gain was assumed to be 0.05, then the ICER for children would be £22,700 per QALY gained. The committee was mindful that the size of the additional utility gain following simultaneous bilateral implantation for children was very uncertain, but was persuaded that with the discounts on second implants currently available, it could accept the uncertainty associated with the gains in utility. Therefore the committee concluded that if cochlear implants for bilateral implantation could be acquired at the lowest price, including a discount equivalent to 40% or more off the current list prices of the second implant, then simultaneous bilateral cochlear implantation for appropriately assessed children with severe to profound deafness could be considered a cost-effective use of NHS resources.

4.3.15 The committee recognised that some people who were deaf could also be at risk of ossification of the cochlea (for example, after meningitis). The

committee heard from clinical experts that ossification caused damage to the cochlea, which could make both initial implantation and successful re-implantation in the case of device failure difficult. The committee noted that the incidence of ossification after meningitis is unclear. However, it understood that a minority of people at risk of cochlear ossification went on to have cochlear ossification, and that the extent of the ossification varied. The committee noted the evidence that, in general, device failure rates after successful implantation were low (less than 5% over 15 years), and considered that the probability of cochlear ossification occurring in adults with severe to profound deafness combined with failure of the unilateral implant and an inability to re-implant the first ear was therefore likely to be very small. On balance the committee considered that this very low risk was not in itself a reason to recommend bilateral implantation in this group when for adults overall it had not considered this a cost-effective use of NHS resources.

4.3.16 The committee recognised that there were additional considerations for people who are deaf and also have other disabilities. The committee heard from clinical experts that specifically for people who are both deaf and blind, the gains in quality of life following bilateral implantation are greater than for people who are not blind. This is because people who are deaf and blind rely more on auditory stimuli for spatial awareness. The committee recognised that in addition to people who are deaf and blind, there are people with other co-disabilities who also rely on auditory stimuli as a primary sensory mechanism for spatial awareness. The committee considered that these individuals would be most appropriately identified by healthcare professionals as part of a multidisciplinary assessment. The committee was persuaded by the evidence from clinical experts that bilateral cochlear implantation did produce greater quality-of-life gains for deaf people who are blind or have other co-disabilities that increase reliance on hearing as a primary sensory mechanism for spatial awareness than it did for people who are deaf and who do not have other disabilities of this nature. The committee agreed that the inclusion of

discounts equivalent to 40% or more off the list prices of the second implant was appropriate in the cost effectiveness analyses, as these reflected current nationally available discounts. The committee was mindful of the uncertainty over the magnitude of the additional quality of life gains associated with bilateral cochlear implantation in this group of people, but was persuaded that using the currently available discounts would result in an acceptable cost effectiveness estimate. Therefore the committee was persuaded that if cochlear implants for bilateral implantation were acquired at the lowest price, including currently available discounts on list prices equivalent to 40% or more off the second implant, then it was appropriate to recommend bilateral cochlear implantation in this group of people as a cost-effective use of NHS resources.

- 4.3.17 The committee noted that sequential implantation was associated with higher cost-effectiveness estimates than simultaneous bilateral implantation for both children and adults, and therefore concluded that sequential bilateral implantation is not an appropriate use of NHS resources. However, the committee recognised that some children who have previously received unilateral implants may now be considered to have met the criteria in the current guidance for simultaneous bilateral implantation. Similarly, this is the case for adults who are deaf and have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness. The committee considered that it is important to promote equity of treatment between groups of people who are in the same circumstances except that one group had previously had a unilateral cochlear implant and the other becomes eligible now. However, the committee was mindful that the duration of deafness and length of time since unilateral implantation could reduce the benefits of any additional contralateral cochlear implant. The committee was persuaded that in situations where the responsible clinician considers that an additional contralateral cochlear implant would provide sufficient benefit, people in the above 2 groups who have already

received a unilateral cochlear implant prior to publication of this guidance should have the option of an additional contralateral implant. However, the committee considered that an additional implant should be offered only after a fully informed discussion between the individual person, their carers and clinicians involved in their care.

4.3.18 The committee noted that in the economic analyses cochlear implants had been modelled as a class. The committee was aware from clinical experts that there may be differences between the devices, in particular the processing strategies used. The committee did not consider that it had been demonstrated that the different cochlear implant systems were associated with different cost-effectiveness profiles. Therefore it was not appropriate to preferentially recommend a specific device. However, the committee did consider that if there was more than one cochlear implant system that was considered clinically appropriate, the least costly implant system, taking into account discounts as available, should be used. The committee recognised that the cost of a system would depend on the support package offered, the long-term reliability of the device and whether it was to be used unilaterally or bilaterally.

4.4 *Partial update*

4.4.1 In 2018, as part of a review of this guidance, stakeholders highlighted that the eligibility criteria in recommendation 1.5 were out of date and did not reflect clinical practice.

- The British Cochlear Implant Group (BCIG) suggested that the definition of severe to profound deafness should be hearing only sounds louder than or equal to 80 db HL without acoustic hearing aids, which was supported by most stakeholders.
- Stakeholders also suggested that testing should be at a wider range of frequencies than stated in the original guidance. They noted that important frequencies for speech perception are between 750 Hz and 3000 Hz.

- Stakeholders further highlighted that the Bamford-Kowal-Bench (BKB) sentence test was no longer considered appropriate for assessing benefit of acoustic hearing aids. The consensus among the professional and patient organisations was that the Arthur Boothroyd word test is a more appropriate test.

4.4.2 Changing the criteria in section 1.5 of the guidance is not expected to have a substantial impact on the cost effectiveness of cochlear implants. This is because:

- The criteria in the original guidance captured the population for whom the BCIG thought cochlear implants were appropriate and necessary. The proposed amendments to the criteria do not broaden the population outside of this group. Rather, new research shows that the group for whom cochlear implants are appropriate and necessary can be better identified through the updated criteria. The population therefore continues to reflect the population considered in the cost-effectiveness modelling.
- Since NICE's technology appraisal guidance 166 was published, there has been around a 15% reduction in device costs, which would improve their cost effectiveness.

4.4.3 The committee considered that the wording suggested by stakeholders was appropriate and would not have a substantial impact on the cost effectiveness of cochlear implants. It concluded that the criteria in section 1.5 of the guidance should be updated to:

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 (500 Hz, 1,000 Hz, 2,000 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 the Arthur Boothroyd word test presented at 70 dBA
- for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

5 Implementation

- 5.1 Section 7(6) of the [National Institute for Health and Care Excellence \(Constitution and Functions\) and the Health and Social Care Information Centre \(Functions\) Regulations 2013](#) requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- 5.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.
- 5.3 When NICE recommends a treatment ‘as an option’, the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has severe to profound deafness and the doctor responsible for their care thinks that cochlear implants are the right treatment, they should be available for use, in line with NICE’s recommendations.

6 Recommendations for further research

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

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

7 Review of guidance

- 7.1 The guidance on this technology will be considered for review 3 years after publication. The guidance executive will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Sanjeev Patel

Vice-chair, appraisal committee

November 2018

8 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by [committee B](#).

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The [minutes](#) of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Rebecca Trowman

Technical lead (2009)

Zoe Garrett

Technical adviser (2009)

Ross Dent

Technical adviser (2018)

Eloise Saile

Project manager (2009)

Jeremy Powell

Project manager (2018)

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