Improving access to cochlear implantation:

Change lives and save society money

Brian Lamb OBE, Sue Archbold PhD and Ciaran O'Neill PhD

Report and research supported by an educational grant from Cochlear.

The report is the work of the authors.

The Ear Foundation®

Improving access to cochlear implantation: Change lives and save society money

The benefits of cochlear implantation are proven

To increase access to this technology and make these benefits available for more, we need to:

- Ensure testing is sensitive to the real life challenges for those with hearing loss
- Review funding arrangements to recognise the cost of NOT providing hearing technologies, not only the cost of providing them
- Provide more information on cochlear implantation for the public and related professionals
- Provide training in criteria for referral for professionals
- Review the NICE (National Institute of Health and Care Excellence) guidance on cochlear implantation. The current guidelines can be found at **www.nice.org.uk/guidance/ta166**

There are a number of considerations which make the current NICE guidelines no longer fit for purpose. These include:

- Improvements in technology
- The need for more sensitive testing which reflects the real-life challenges of those with hearing loss, and truly reflects their listening difficulties, rather than a linguistic assessment
- Greater evidence of the impact of cochlear implantation on the quality of life
- Greater evidence of benefit on different groups of adults: those born deaf, the elderly, those with single-sided deafness and those with English as an additional language
- Greater awareness of the benefits of using a hearing aid and a cochlear implant
- Improved surgical techniques preserving residual hearing
- Increased evidence of improved cost effectiveness: lower costs of devices, more effective technology, awareness of the costs of NOT implanting adults.

We recommend:

1. That NICE urgently conducts a formal review of its current guidance on cochlear implants including bilateral implantation
2. As part of that review it considers lowering the current audiological threshold for candidacy and also looks at the suitability of combining current assessment methodologies with new measures
3. Each ear should be considered separately for candidacy
4. That any cost benefit analysis done as part of that review ensures that appropriate utility measures are used and that real world benefits are taken into account
5. That NHS commissioners, NHS Improvement and NHS England and other commissioners take into account the current overwhelming evidence of the benefits of cochlear implants for improving health and wellbeing and the potential cost savings over time to the health and social care budgets in commissioning decisions
6. A screen for candidacy for cochlear implants should be built into routine audiological appointments.

"I feel that so much of my previous life and true self has been restored, regaining my pride and ability to contribute actively in society on an equal basis."

Adult with cochlear implant

SECTION 1:

Hearing loss is a major public health challenge

"Hearing Loss is a major public health challenge."

Action Plan on Hearing Loss (2015)

Hearing is central to our health and well-being. However, losing the ability to communicate through hearing loss is one of the least recognised public health issues of our time. Hearing loss has an enormous impact on the individual but also creates significant costs to health, social care and welfare systems if not addressed. People with hearing loss are more likely to lose their jobs and remain unemployed, they are at greater risk of mental health problems, becoming more dependent on social care, dementia, falls and early death, (Action Plan 2015). Those with severe hearing loss have five times the risk of developing dementia as those with normal hearing Lin (2013). The greater the level of hearing loss the more this impacts on individual wellbeing and increases costs to society. Hearing loss accounts for the most years lived with disability in both sexes over 70 in Western Europe and globally. (see diagram).

"Going deaf . . . it's a different sort of disability which can leave you isolated and if you feel isolated it can lead to depression. You lose self-esteem, you don't want to mix, anything like that because that's what deafness does to you."

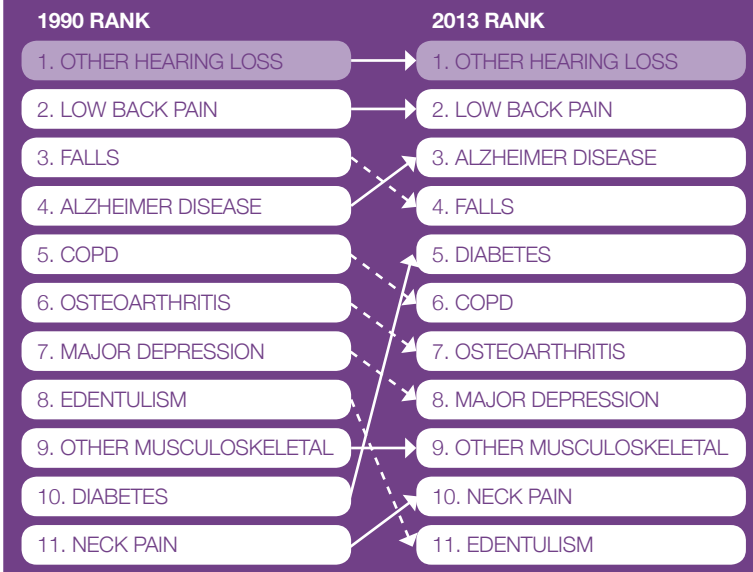
Adult with hearing loss

Today's hearing technology, fitted early, can mitigate these effects.

Hearing Loss is the number one cause of years lived with disability (YLD) in both sexes over 70 in Western Europe and Globally.

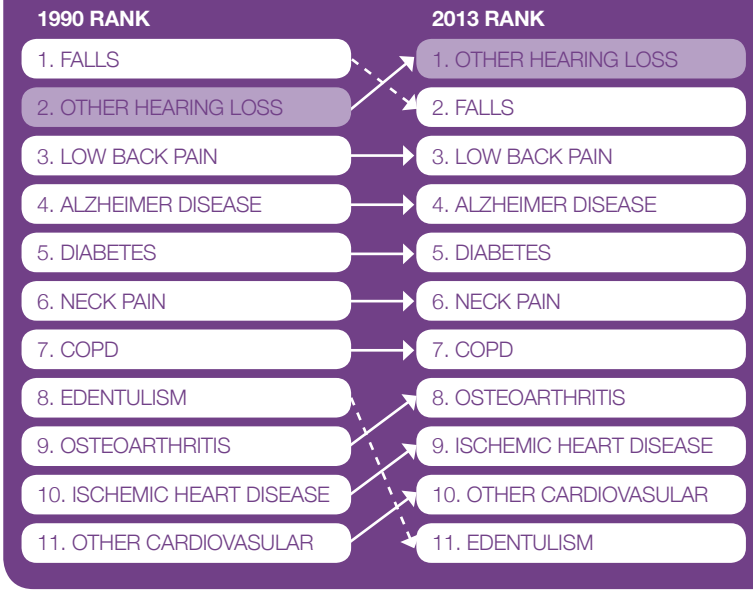
Global

Both sexes, 70+ years, YLDs per 100,000



Western Europe

Both sexes, 70+ years, YLDs per 100,000



Access to hearing aids

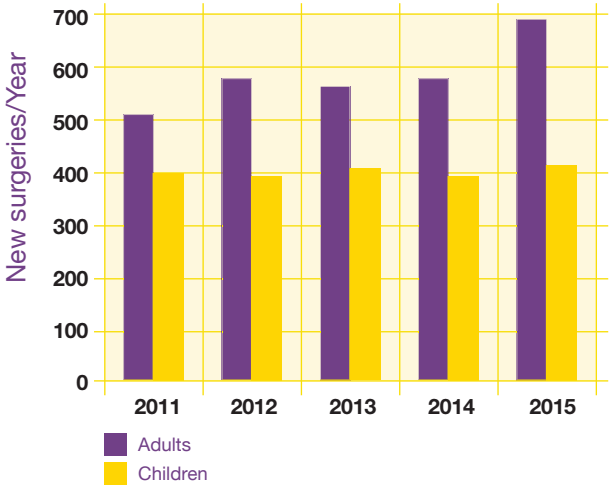
Hearing aids are an acceptable and well used intervention for hearing loss with over 80-90% usage evidenced in recent studies; for example Perez & Edmonds (2012) and HSE (2015). We also know from other systematic reviews that hearing aids are a cost effective intervention: Chao & Chen (2008), Morris, (2013), Joore et al., (2003), Chisholm et al., (2007).

A recent systematic review found that on a number of different quality of life measures people benefit from hearing aids, Ciorba et al., (2012). A number of studies have also found health improvement benefits of hearing aids using quality of life outcome measures, Swan et al., (2012), Barton et al., (2004). Kochin & Rogin (2000) also found positive outcomes with hearing aid users having better social engagement, mental health and physical health than non-users. Wearing hearing aids mitigates the risk of dependence on social care and risk of dying early, Fisher et al., (2014), Contrera et al., (2015). Using hearing aids also had a positive effect on depression, Saito et al., (2010), while programmable hearing aids were found to provide the most efficient effects on quality of life, Cox (2005). It was also found that those with hearing aids had higher levels of employment than those without, with clear positive health and economic implications, Kochin (2010).

There is compelling new evidence that it is possible to address the potential decline in cognitive functioning through the use of hearing aids. An extensive French study found that self-reported hearing loss is associated with accelerated cognitive decline, in older adults but that hearing aid use attenuates such decline Amieva et al., (2015). By extension we would also expect that long term use of cochlear implants and other hearing technologies would bring similar protective effects by improving hearing.

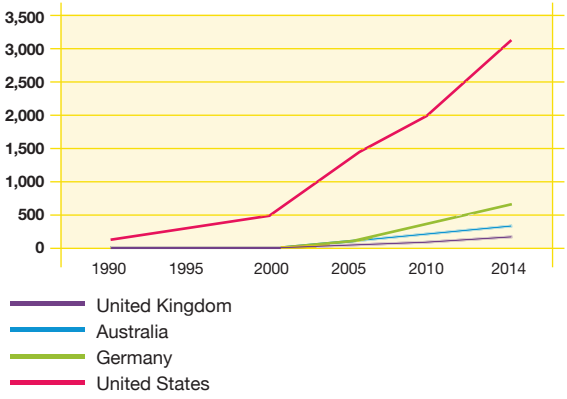
Access to cochlear implantation

Cochlear implantation has become the established intervention for people with greater levels of hearing loss who do not benefit from hearing aids. The number of people who could potentially benefit from cochlear implants in the UK is significant. With a population of 51.4 million over 15 years of age in the UK (Office of National Statistics, 2011) there are an estimated 100,000 people with a profound loss and 360,000 with a severe loss who might benefit from implantation at any one time. However recent figures show that at best only 6.7% of adults with profound hearing loss, the group most likely to meet the current criteria, are implanted, Raine (2013), and on the most recent estimates this is only around 700 adults per annum, Raine (2016).

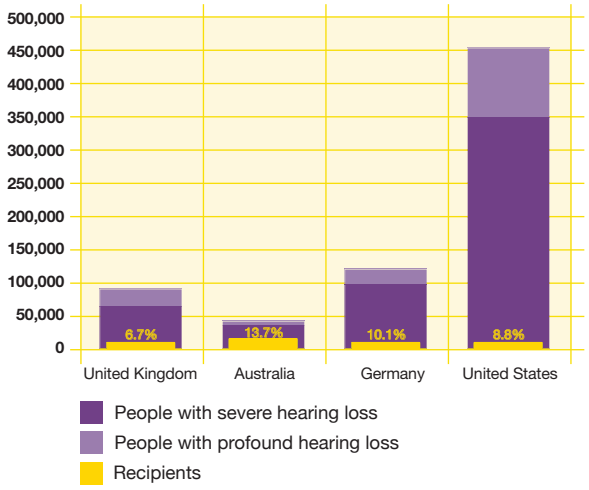


We can see from the following analysis that the number of those who could benefit is far below the number currently being implanted and also that the UK falls behind other countries in implantation rates.

Surgeries on new recipients by country - Seniors



Penetration and prevalence - Adults



Source figures supplied by Cochlear.

"Before implantation I had the strongest bilateral behind the ear hearing aids and wasn't coping very well; I was becoming more withdrawn and depressed. It took me a long time to pluck up the courage and go for the implant mainly because of the bad press from others; for instance the sound will be just like Mickey Mouse and Donald Duck, and it was just like that when I was first connected but only for a few minutes and then it was magic, coming back home after my wife was driving and kept saying what is that sound it was rain on the roof and also many other sounds, the car indicators bleeping the engine running, the cooling fan running; it was magic and the magic is still there."

Adult with hearing loss

The Action Plan on Hearing Loss (NHS, 2015) identifies that "Early identification and intervention are key actions that should make a real difference in reducing risks and attaining better hearing health outcomes throughout life. It is particularly important in reducing the impact and cost of congenital hearing loss and of long term conditions such as adult onset progressive hearing loss." Yet at the moment there is a massive gap between those who could benefit from an implant and those who receive one.

Early access for cochlear implantation would be improved by screening for cochlear implantation being part of routine audiology appointments, ensuring referrals to an implant centre were made as early as possible and improving potential benefit.

Possible reasons are:

- lack of awareness by the public of the impact of hearing loss and the potential of today's hearing technologies
- lack of awareness of cochlear implant criteria by professionals including ENT and audiologists and GPs
- inappropriate testing which does not reflect the real-life challenges of those with hearing loss
- out of date criteria in NICE guidance.

The NICE guidance on cochlear implants (2009) established a clear framework for commissioners and clinicians and supported the development of cochlear implants as a mature and accepted intervention for those with severe to profound hearing loss. However a number of factors have changed since the guidance which suggests that we need a fundamental review.

There are a number of considerations which make the current NICE guidelines no longer fit for purpose. These include:

- Improvements in technology
- The need for more sensitive testing which reflects the real-life challenges of those with hearing loss, and truly reflects their listening difficulties, rather than a linguistic assessment
- Greater evidence of the impact of cochlear implantation on the quality of life
- Greater evidence of benefit on different groups of adults: those born deaf, the elderly, those with single-sided deafness and those with English as an additional language
- Greater awareness of the benefits of using a hearing aid and a cochlear implant
- Improved surgical techniques preserving residual hearing
- Increased evidence of improved cost-effectiveness: lower costs of devices, more effective technology, awareness of the costs of NOT implanting adults.

The current criteria are based on evidence of suitability using old technology from many years ago. There is now a pressing need to move away from the outdated criteria in the current NICE guidelines which are inadvertently but systematically denying access to better hearing for a large number of people.

Developing technology and increasing effectiveness

Cochlear implants have grown in effectiveness since their introduction in the 1980's. Up until 2004/2005 the sound processors were analogue: after that digital processing was introduced, providing greater benefits, as do digital hearing aids compared with analogue. At the same time dual microphones have been introduced for improved directional hearing particularly in background noise; and input (pre-) processing of the sound signal for improved hearing in background noise and in quiet conditions has been introduced.

As cochlear implant technology has developed so has its effectiveness.

For example, Dowell (2012) reviewed the evidence supporting the effectiveness of cochlear implants in adults across several decades and found that average open-set sentence identification averaged less than 40% for sound processors in the 1990s as compared to on average 80% correct scores with modern technology, even without visual cues. This is one indication of the extent to which functional performance in real life situations has changed as the technology has improved.

Further, as cochlear implant centres have gained experience so has the performance of candidates. As Govaerts (2016) noted the average results now are systematically better than 5 or 10 years ago in the implant centres he compared. We also know that surgical techniques have significantly changed improving the effectiveness of the procedure and helped protect residual hearing improving outcomes further.

SECTION 2:

Factors influencing change to the NICE guidelines

We now look at each of the factors in turn.

The need for more sensitive assessment methods and listening tests which reflect challenges in everyday life

Adult hearing loss impacts on communication in everyday life, at home and at work. If hearing loss declines, and hearing aids become less effective, adults are likely to have increasing difficulty in group situations and in noise. However, assessment for cochlear implantation rarely takes account of this; the earlier implantation takes place the more effective it is, but the current guidance force the decision to implant to wait until the adult fulfils the very stringent criteria, by which time they are unlikely to be able to continue to work.

"At times I have acute problems that render me almost incapable of undertaking any teaching or administrative duties because I cannot understand people, the situation I face is that I have to wait until I become completely bloody deaf on my right ear before they are going to do anything."

Adult after assessment

NICE has derived candidacy guidelines for cochlear implants in the UK based on audiometric thresholds (90 dB HL or above at 2 and 4 kHz). The existing UK 90 dB HL criteria for implantation is strictly enforced, resulting in adults who would benefit from implants not being considered even though they have poor access to speech with best fitting HAs. These audiometric thresholds also do not take into account those with more unusual losses, who may not fit the criteria but who may not be able to listen to speech, Cooper (2015).

In addition to the audiometric thresholds, sentence testing is used, with a score of less than 50% on the Bamford Kowal and Bench (BKB) sentences presented in quiet (at 70 dBSPL) being used as one of the candidacy criteria for assessing adults in the UK.

Use of BKB sentence testing alone to assess hearing function has become questionable as the assessment is not suitable for use with the diverse range of implant candidates that clinics now see.

- The first issue is that they use highly predictable materials; the sentences contain contextual and linguistic information which gives candidates with sophisticated language clues which they use automatically. Some candidates may only have minimal access to speech cues but because they have refined cognitive and linguistic skills, they are able to predict the content of the sentence in spite of the severe loss of auditory information. While this skill is unlikely to provide sufficient .benefit for speech perception in everyday complex listening situations, it may result in too high a test score for them to be eligible for implantation.
- The second issue is that BKB sentence scores do not reflect the hearing abilities of some patients at the lower end of the performance scale. Individuals who do not speak English as their primary language may not have the same abilities as a native English speaker to fill in gaps in predictable sentences because their linguistic knowledge is poorer. The same issue arises in pre-lingually deaf adults who may not have levels of English language sufficient to be able to get a representative score on the BKB sentences. Craddock et al., (2016) suggested that the CUNY (City University of New York) audio-visual sentences might be more appropriate or this group.

The evidence also suggests that it would be appropriate to broaden the pre-implant assessment test battery to include the Arthur Boothroyd (AB) monosyllabic speech perception task (scored by both word and phoneme) together with CUNY audiovisual sentence materials in quiet for poorer performing candidates.

There is no evidence at this stage to suggest that it should replace the BKB sentences, but Vickers et al., (2016) identified cases (English as an Additional Language, older adults, British Sign Language users and individuals with low levels of cognitive processing) where it could be beneficial as an additional tool for assessment.

Additionally, speech-in-noise measures should be included when assessing individuals at the higher end of the performance range such as those with residual hearing. A more complex combination of measures for determining candidacy will provide a better assessment of an individual's access to speech understanding in everyday life. This has often been noted by patients themselves. In interviews with patients who were not considered suitable for an implant this response was typical:

> "The conditions they did the testing in were ideal. It was perfect but they made no allowance for the difficulties you get if somebody is talking from the side, or if there is any background noise. They were absolutely perfect conditions and of course under those circumstances you do very well and it makes no allowances for problems you run into in real life from ideal conditions."
>
> Athalye et al., (2015)

We need to also consider using other qualitative measures to better understand an individual's everyday listening experience. These should also form part of the clinical evaluation assessment battery to fully understand the impact that the hearing loss has on an individual's functional hearing and everyday life.

Vickers and Bradley (2016) conclude that a patient administered questionnaire like the speech, spatial and qualities of hearing scale (SSQ) is a preferable tool to measure hearing performance than BKB sentences as it is more realistic in measuring functional benefit and ease of listening in the real world. Loeffler et al., (2010) reviewed some established QoL measures and concluded: " QoL instruments are an essential addition to speech perception tests to quantify the outcome of cochlear implants. Compared to speech perception tests QoL scores allow a more comprehensive insight into patients' daily life and activities." The Njimegen Cochlear Implantation Questionnaire (NCIQ) is more reliable and sensitive than generic tests such as the SF36 and the Health Utilities Index.

More refined assessments are necessary are necesssary and Goman and Summerfield used the views of the public to develop the York Hearing-Related Quality of Life (YHRQL) questionnaire It was designed to be sensitive to the benefits of binaural hearing but also to provide data that could be used to calculate QALYs. This work was initiated in response to the insensitivity of measures such as the EQ-5D and the mismatch between what such measures indicated and what patients report.

Greater acceptability of cochlear implants as an intervention and greater understanding of the improvements in quality of life and potential savings on health, social care and social welfare budgets as a consequence

Both Athalye et al., (2015) and Ng et al., (2016) found that adults perceived improvements in communication, confidence, managing social situations, and additionally positive effects on education and employment, independence and family life after implantation.

The real world effects and self-reported patient benefit are not being reflected in the way audiological criteria are being applied to candidacy currently. Much greater use of patient reported outcome measures such as the SSQ and the speech intelligibility index, amongst other tools in assessing candidacy would help to capture these issues, Chundu and Flynn (2014), Vickers and Bradley (2016).

Patient surveys showed that those implanted value highly the impact the CI has had on their lives in improving confidence, ability to relate to others, maintain employment and improved wellbeing. To gauge the value patients might put on their implant researchers have also asked patients to put a financial value on their implants.

For example, Ng et al. (2016) found that patients put a high financial value on the benefit of their implant. When asked to give their implant a financial value on a monetary scale 60% chose the highest value of above £150.00 per month. However, many also qualified this answer with statements which suggested that their implant was 'priceless'.

> "First job application after implant that I did not have to declare deafness I interviewed for and got the job and recently doubled my initially part time hours; so from meagre benefits to full time employment. PRICELESS!"
>
> Adult with cochlear implant

Greater evidence of benefit in different groups of adults: those born deaf, the elderly, those with single-sided deafness and those with English as an additional language

Traditionally, adults who were born deaf or those who had a long duration of deafness were not considered for implantation. Adults who had pre-lingual onset of deafness and/or long duration of profound post-lingual deafness now show demonstrable improvements in outcomes and quality of life measures.

For example, patients with a mean age of 36 years (range 21-55) were implanted and showed significant improvement for Consonant/Vowel/Consonant word and phoneme score, equally significant improvement on a number of quality of life measures and to have improved speech production, Klop (2007). For some individuals the improvements are only clearly seen using assessment methodologies that are not mentioned in the guidance such as audio-visual speech assessments. Jeffs et al., (2015) provided further support for the idea that cochlear implants provide significant benefits for congenitally or early profoundly deafened candidates who receive cochlear implants as adults. Recipients reported benefit from cochlear implants in the area of identity, hearing in the world and emotional wellbeing. Kumar et al., (2016) also found that early deafened, late implanted patients benefit audiologically from cochlear implantation with improvement in speech discrimination scores greater than expected. Individual assessment is likely to be very important and assessing adults using Quality of Life measures and speech intelligibility scores may have a particular role to play in both pre and post-operative assessment.

Cochlear implants can benefit a wide range of age groups, including the elderly. Park et al., (2011) found that speech recognition improved in all age groups (<50, 50-65, >65) and quality of life all improved markedly and in all age groups

to a similar extent. Further that the effect was not dependant on prior use of a hearing aid.

Kobosko (2015) found that "higher CI satisfaction was associated with lower severity of depressive symptoms, whereas for the elderly, higher CI satisfaction was associated with less severe social dysfunction symptoms." Wellbeing was increased and likely dependence on mental health services could be reduced and psychological support tailored to need.

Vieira (2015) provided further evidence that cochlear implants provided significant improvement in speech understanding in challenging situations, subjective perception of hearing performance, and quality of life. Cochlear implantation also resulted in reduced tinnitus disturbance. Choi (2014) found that rates of long term use in older adults at more than 10 years of follow up exceed 80% – thus showing that early implantation of older adults once low levels of speech recognition are present are associated with greater use. They also concluded that "Clinical strategies and public policies promoting earlier rather than later cochlear implantation in older candidates are likely to lead to more favourable long-term outcomes and cost-effectiveness of cochlear implantation in older adults."

Monsnier (2014) concluded from a large study of elderly people (65-85 years) that cochlear implantation "restores aural communication, reduces their prevalence of tinnitus, improves the quality of life, reduces symptoms associated with depression and improves global cognitive function." Further, "predictive factors in this population provide a convincing argument to recommend treatment with cochlear implantation as early as possible in older patients with confirmed diagnosis of a severe-to-profound hearing loss and with only limited benefit from hearing aid use in one ear."

This evidence provides more support for our conclusion that older people with hearing loss should be routinely considered for implantation earlier than the current guidelines might otherwise allow for based simply on current audiometric criteria.

Vickers et al., (2016) also found that there is a general move away from requiring the candidacy cut off to be met in both ears, and in several countries cases with Single Sided Deafness are implanted with benefit.

In the NHS England Action Plan on Hearing Loss (NHS England, 2015) there is clear endorsement for delivering culturally and linguistically appropriate intervention for both children and for adults. The stated aims include the provision of "person-centred planning, which is responsive to information and social needs' and the promotion of 'inclusion and participation, by ensuring that all public services are accessible and support language and communication needs" (NHS England, 2015, p. 6).

However relying on the current tests may produce very different results for adults and children from groups whose first language is not English as the candidacy criterion are based on a speech perception task (BKB sentences) which contains English sentences with very predictive content. When English is not the first language the individual cannot use the linguistic or contextual cues and there may also be cultural aspects that make the sentences less relevant, Mahon et al., (2016).

Greater awareness of the benefits of using a hearing aid and a cochlear implant: implanting aidable hearing in the contra lateral ear

Those where the contra lateral ear has useable acoustic hearing have been shown to benefit from implantation. Increased audiological knowledge of fitting and technological advances also allows the amplification of residual acoustic hearing and its integration with electrical hearing to be optimized. These individuals (both children and adults) would not necessarily fall within the candidacy range of the current assessment methods and more sophisticated listening tests that are sensitive to the benefits of electro-acoustic hearing are required to establish whether they could benefit from implantation.

For example, Gifford et al., (2010) in a retrospective review of post-operative speech perception performance for 22 adult cochlear implant recipients who demonstrated preoperative Consonant Nucleus Consonant word recognition scores of 30% or higher in the best-aided condition found that non-traditional implant recipients, with higher levels of preoperative speech understanding than traditional patients, demonstrated significant benefit from cochlear implantation. Recent evidence suggests that some UK patients can derive benefits from the combined use of a cochlear implant and a hearing aid, Green et al., (2014), Visram et al., (2012), and clinicians have indicated a willingness to implant a poorer functioning ear, to preserve access to aidable residual hearing, Fielden et al., (2016).

A survey of unilaterally implanted adults indicated that those implanted since the publication of NICE guidance were almost seven times more likely to use a hearing aid than those implanted prior to this. If contra lateral hearing aid use provides additional benefits over implant use alone, it may be appropriate to consider the capacity to use residual hearing following implantation when determining candidacy, Fielden, et al., (2016).

Improved surgical techniques which preserve residual hearing leading to implantation of those with higher levels of hearing

Individuals with greater levels of useable acoustic hearing have also been shown to benefit from implantation. Improved surgical techniques have led to better post-operative preservation of acoustic hearing, Vickers et al., (2016). Additionally, evidence shows us that those with some residual hearing tend to have better outcomes.

Audiometric tests have also come under scrutiny as pre-implant residual hearing is one of the important attributes contributing to the post-operative outcomes, Chundu and Flynn (2014), and therefore criteria which favour a lower threshold would also indicate the prospect of greater post-operative benefit. The potential for greater benefit from electro-acoustic stimulation compared to cochlear implantation alone in those with adequate pre-operative residual hearing should also be taken into account in public and referrer awareness, referral guidelines and cochlear implant candidacy criteria. The current criteria would not necessarily allow for these groups of people to be considered.

Increased evidence of improved cost-effectiveness: lower costs of devices, more effective technology

The benefits of cochlear implantation for individuals and its cost effectiveness as an intervention is well established in a number of systematic reviews such as one conducted by Bond (2009) for NICE. Since then a systematic review by Turchetti, et al., (2011) also concluded “that monolateral cochlear implantation is generally a cost-effective intervention…. Overall Cost/QALY estimates indicate that monolateral cochlear implantation is also a cost-effective intervention for elderly patients” However changes to our understanding of the benefits would also suggest that for unilateral implants a lower candidacy level would still deliver acceptable cost benefit ratios for unilateral implantation.

Additionally, since the NICE guidance we know that the overall context for assessing the cost effectiveness of cochlear implants has changed dramatically. The pricing of implants has reduced by approximately 15% (personal information from industry), meaning that the cost-effectiveness information used by NICE is out of date. While the prices have reduced, the effectiveness of the devices has increased as has the efficiencies of cochlear implant programmes, with increased expertise and improved technology leading to improved cost-effectiveness, compared with the reviewed data of 2009.

Greater evidence in relation to the effectiveness of bilateral cochlear implantation in adults

Binaural hearing, whether with implants or aids, improves the ability to localise sound and listening in noise. We also know that superior sound localization and speech discrimination in noise are experienced by adults with sequential or simultaneous bilateral implants when compared with unilateral implants and bilateral hearing aids, Van Schoonhoven et al., (2013). The effectiveness of bilateral fitting was further supported with Gifford (2015) finding that there were significant improvements in speech understanding when a second implant was provided, even for those who performed well with their first implant. However, while clinically effective there continues to be a debate as to how cost effective bilateral implantation is for adults and NICE did not support bilateral implantation as being cost effective at a QALY of £ 30,000. There are a number of well-known factors including discount factors and how benefit is measured that can dramatically alter the potential calculations in cost benefit analysis of bilateral fittings.

Further, the choice of utility instrument in cost-utility analysis of bilateral CI heavily influences whether the second implant is deemed cost-effective. These have been inconsistent across studies, Lammers (2011), but the most commonly used measure, HUI3, is the most conservative in estimating gains, Kuthubutheen et al., (2014). Therefore many of the cost utility assessments that have used HUI3 are likely to underestimate the benefit to individuals and therefore the cost utility. Cost utility instruments also need to be more sensitive to real world gains in patient experience and benefit. It is clear that not all the potential benefits are accounted for in these tests and we need to look at how these can be refined further (Ramen et al., 2011).

Many of the previous studies on benefits of bilateral implantation do not show how auditory test scores might translate to hearing-related function in real-life situations. Some authors have estimated that in normal-hearing individuals, bilateral squelch contributes 2 dB improvement to (a reduction in) the signal-to-noise ratio required for listening to speech or another signal in the context of background noise and that the head shadow effect contributes about 3 dB improvement, Ramsden et al., (2005). Further, the reported improvements of 0.53 to 11 dB for speech perception in noise in these studies, with most improvements ≥ 2 dB, suggests that bilateral cochlear implantation produces clinically relevant improvements in speech perception in noise Washington State (2013).

Greater understanding of the benefits of bilateral implantation and more sophisticated measurement have been reflected in a number of positive conclusions from systematic reviews and other assessments. In 2013, the Washington State Medicaid Scheme approved coverage of sequential and simultaneous bilateral CI for children and adults, Hayes (2013). Qualifying adults and children are now able to access sequential or simultaneous bilateral CI through the Washington State Medicaid Scheme, Washington State (2013).

In a recent economic evaluation of CI in adults compared sequential bilateral CI with no intervention in the Canadian context Chen et al., (2014) demonstrated the cost effectiveness of sequential bilateral CI in adults in a number of defined settings. A randomised control trial of multiple implant centres in Europe using a cost-utility analysis to compare unilateral with simultaneous bilateral CI in postlingually deafened adults found that compared with accepted societal willingness-to-pay thresholds, simultaneous bilateral CI is a cost-effective treatment for patients with a life expectancy of 5-10 years or longer, Smulders (2016).

Further, a recent Australian study found that when compared with bilateral hearing aids the incremental cost-utility ratio for the CI treatment population was AUD 11,160/QALY and on this basis “Unilateral, sequential, and simultaneous bilateral CI were cost-effective when compared with bilateral hearing aids.” Foteff et al., (2016). They also concluded that technologies that reduce the total number of visits for a patient could introduce additional cost efficiencies into clinical practice.

Studies which also look at self-reported benefits from patients also show that patient perception is that bilateral implants make a significant difference.

For example Noble et al., (2009) also found on a review of self-reported benefits that "it remains evident that bilateral implantation offers substantial benefits across the age spectrum." In addition, of the patients already fitted with one implant all but one said that if they had the choice between a second implant or £15,000 said that they would choose the second implant, Buhagiar and Lutman, (2011).

It is not surprising that the previous studies on which NICE based its judgement in 2009 were not as decisive in favour of bilateral implants because they were dependant on studies done years earlier using old technology when less benefit could be demonstrated. However with the more recent improvements in surgery, clinical practice, patient support and technology ensuring that patient benefit has been dramatically improved on a number of measures this also argues for the criteria for bilateral implantation to be part of a review by NICE.

This 77 year old man decided to have an implant privately after a lot of thought, although he had more hearing than allowed by the criteria. He tells his story here:

"Prior to my implant I had suffered bilateral progressive hearing loss. It had reached a stage where I was unable to use the telephone, enjoy a visit to a restaurant, take part in committee work or have an impromptu chat with a friend in the street….A further drop in my hearing prompted me to research cochlear implants and the NICE criteria – my hearing was, frustratingly, just outside the NICE criteria, despite the significant impact my hearing loss was having on my life. A visit to an ENT consultant in my local hospital confirmed this. Further online investigation led me to the self-funded pathway at AIS. A thorough hearing and multi-disciplinary assessment revealed that I met the self-funded pathway criteria. It was a big decision and great expense but I took the plunge….. five months since 'switch on'. At this stage I am able to communicate easily and hear others in quiet listening environments and can follow conversation without looking at the speaker. I am using the telephone with increasing confidence….. I am attending society meetings again using a Bluetooth microphone clipped to the presenter… The past 5 months have been a tremendous journey. Thanks to the patient and friendly team at the AIS, life is back on track for me, my wife and our family."

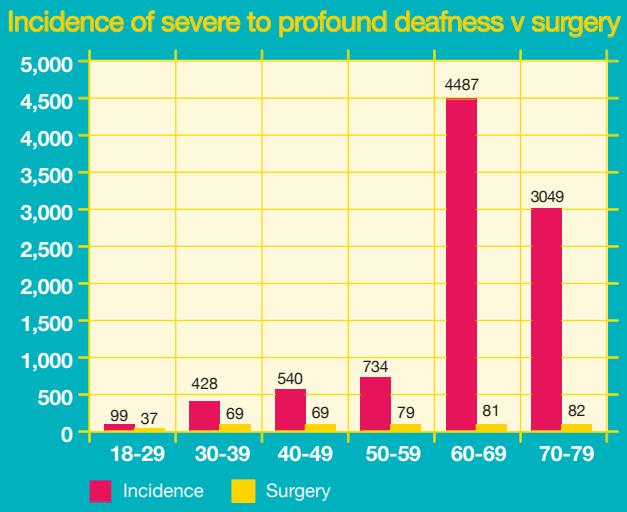
Thanks to South of England Cochlear Implant Programme.

The UK guidelines are now one of the most conservative in the Western world and are falling behind recognised international practice

Vickers, et al., (2016) found that many countries with audiometric guidelines which are much less restrictive. In Australia they use 70 dB HL criteria; Germany, Italy and the USA are also less restrictive than the UK with the majority of clinics using a 75–80 dB HL cut off at frequencies greater than 1 kHz (Raine, 2013, Vickers et al., 2016). Further, in Germany, Italy and Australia implant teams have a greater level of clinical discretion to determine appropriate candidacy using a number of criteria that clinicians find useful, Raine (2013), Vickers et al., (2016). In the UK however there are only limited examples of obtaining funding for special cases.

In countries which do use audiometric criteria, clinics use an average of 75–80 dB HL cut off for frequencies greater than 1 kHz, and this is in line with the recommendation that the UK move to amend audiometric guidelines to be 80 dB HL at 2 and 4 kHz if not moved nearer to the Australian 70dB HL criteria.

We know that fewer adults are being implanted than would be expected to benefit under existing criteria. Raine (2016) suggests that there is a potential annual prevalence of 11, 800 in the 18–80 year cohort and nearly 5000 for >80 years for those with a hearing loss which would benefit from a cochlear implant assuming something like the current guidelines. Yet we know from BCIG data (Raine 2016) that current rates of implantation for this group in the UK is under 700 per anum. The following figure demonstrates the gaps between those who could potentially benefit from cochlear implantation and those who actually receive one currently.



With such a low take up it may appear perverse to worry about how restrictive the current guidelines are. However what we know is that many people who may be at the margins of the current guidelines or missed by them altogether are presenting to audiology clinics and could benefit from implantation. They should not be denied appropriate treatment simply because others that could benefit now under the current guidelines do not come forward due to poor referral practice, individual concerns or lack of funding or willingness to take action. As Govaerts (2016) argues this puts clinicians in a morally difficult position in terms of their responsibility to do best by their patient and that such restrictive guidelines create conflict when it means that they have to withhold treatment to patients they know could benefit.

It would also be economically perverse to withhold treatment from someone if the consequence is that the decision not to treat is likely to increase costs on the health and social care system O'Neil et al., (2016). The only patient centred and moral response as well as best informed health strategy is to ensure that all those who could benefit do so. The funding for supporting this approach can be generated from the future savings to health systems and additional public revenue generated.

The criteria are also too restrictive for certain groups of children

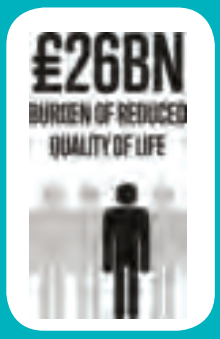
There is evidence that the current criteria for children may also be too restrictive. Paediatric implant recipients that have not met the current criteria have been seen to derive significant benefit from cochlear implantation. Research by Carlson et al. (2015) concluded, after a retrospective case study of implanted children who had less severe hearing loss than specified in the current indications and had open-set word and/or sentence recognition scores greater than 30% for children who are able to participate in speech perception testing; that a large-scale reassessment of paediatric cochlear implant candidacy, including less severe hearing losses and higher preoperative speech recognition, should be undertaken.

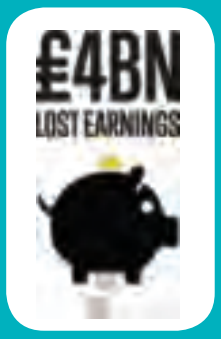
In looking at post-operative benefit Kumar et al., (2016) also found that audiometric tests were not good at capturing benefits for pre-lingually deaf young people arguing that improvements in speech discrimination scores may not be apparent in this group after implantation but more subtle benefits such as improved interpersonal skills, emotional wellbeing, greater satisfaction at work and greater personal satisfaction were reported.

Funding of cochlear implantation should take into account the cost of NOT providing technology

When thinking about changing candidacy for CIs for both adults and children it is not only the cost of the device and intervention that should be considered but also the cost of NOT providing implants to appropriate individuals and the impact that this would have on their lives but on health, social and welfare costs more generally.

In the UK we explored both the additional burden of quality of life costs and the costs of not adopting hearing aids and cochlear implants. Archbold, Lamb, O'Neil, (2015). We estimated the additional burden of quality of life costs were estimated at £26 billion per year, which was made up of £4bn in lost earnings, additional GP costs were estimated at £76 million, and social services costs at £60m. The extent of lost earnings was estimated at £2,136 pa, with both higher unemployment rates and lower earning power in those with hearing loss. In total the study estimated that the costs associated with hearing loss were £30.13 billion per year.





We also looked at what impact increased access to hearing technology between 1992 and 2009 has had on the societal economic burden of hearing impairment over time, O'Neil, et al., (2016). Previous work has demonstrated in cost effectiveness analyses the potential value for money of hearing aids and cochlear implants for both children and adults Bond et al., (2009). Value for money in this context is assessed based on costs, savings and the monetary value associated with changes in health-related quality of life among recipients. They found that increased access to new technologies such as hearing aids and cochlear implants reduced aspects of the economic burden of hearing impairment.

The analysis demonstrates a reduction in the use of GP and social worker services by those with a self-reported hearing impairment relative to those with no such impairment over the period 1992–2009. The reduction in use of GP and social worker services are in the order of £53 to £92 million per annum in terms of financial costs. These are 'savings' in the sense that they represent a reduction in the cost of service delivery that would otherwise have had to have had to be met if those in 2009 exhibited the same patterns of service use as those in 1992.Studies for the UK estimate that the costs of screening 65 year olds and providing interventions would be £255 million over ten years, but the benefits across this period would amount to over £2 billion, including avoided personal, employment, social and healthcare costs, Action on Hearing Loss (2013), Morris (2010). Additionally, a study by Action on Hearing Loss showed that at least £28 million of national savings could be made by properly managing hearing loss in people with severe dementia in the community, thus delaying their need for admission into costly residential care, DCAL Action on Hearing Loss (2013).

In 2006 the loss to the UK economy every year through unemployment related to hearing loss was estimated at £13 billion each year; 2006 prices, Shield, (2006). Recent estimates suggest that in 2013, the UK economy lost £24.8bn in potential economic output due to lower employment rates for those with hearing loss than across the rest of the population, ICL (2014).

The links between hearing loss and depression, which costs the NHS £520m a year, Harker (2011); falls (which cost the NHS at least £1.9bn a year); and dementia (which is estimated to cost £16,700-£37,500 per person affected) indicate that there is a significantly increased cost to the NHS of dealing with the ongoing effects of hearing loss resulting from links with these conditions, Jopling (2015).

With regard to cochlear implantation, Monteiro et al., (2012) found that in patients who had been fitted with a cochlear implant there was a significant increase in median yearly income compared to pre-implantation ($42,672 vs $30,432) and the authors concluded that "Cochlear implantation not only improves quality of life but also translates into significant economic benefits for patients and the Canadian economy." Crucially they also noted that "These benefits appear to exceed the overall costs of cochlear implantation."Candidacy requirements should encompass a more sophisticated understanding of the additional costs of not treating hearing loss by taking account of additional health care and social care costs related to earlier onset dementia, mental health, and reduction in independence, falls and reduction in economic activity (NHS, 2015).

The UK is poor at taking account of these additional measures in candidacy criteria because the additional costs tend to get discounted as the cost is taken by another area of public expenditure. Future economic assessment studies should consider the other categories of non-medical direct costs and indirect costs Turche et al., (2011). Making a fuller consideration of total costs across the health and social care system has been done for other conditions in developing health strategies and would more than balance the cost of expanding the current criteria Archbold et al., (2014); Lamb et al., (2015), O'Niell et al., (2016).

Return on investment

Healthcare systems have come under increasing pressure following the financial crisis of 2008 and the subsequent economic downturn while demand for care has continued to rise. It is not surprising that healthcare resources appear increasingly scarce and their use in any area is closely scrutinised. While such scrutiny is appropriate it should not result in a fixation on the expenditure on provision of care to the exclusion of the benefits associated with that care. This can lead to false economies.

In previous work we examined the costs arising from untreated hearing loss which result from the additional use of other services. This included higher healthcare use, lost productivity and higher disutility associated with lower health-related quality of life that can accompany hearing impairment Archbold et al, (2014), O'Neil et al., (2016). The possible savings in these areas should be set against expenditure associated with the provision of hearing technologies to understand the potential economic gain that can be achieved by use of these technologies.

In this report we have extended our work, looking at the potential return on investment of widening access to cochlear implants within the UK under a number of assumptions related to cost, the value attached to benefits arising from cochlear implantation and the time period over which costs and benefits are experienced. In respect of the cost of implantation it is accepted that there is variation due to different pricing of the technology and regional variation in costs, but this is not thought to materially affect the estimates made here.

To make an estimate, we conservatively looked at a ten year time frame, (CI usage will be much longer than this for most candidates) and calculated the return on investment of cochlear implantation. This is estimated to be between 2.3 and 3.1 per profoundly hearing impaired person, depending on whether we value a QALY at the upper or lower end of the range used by NICE to value outcomes (£20,000 to £30,000). Among those who are moderately hearing impaired, the comparable figures are 1.7 and 2.1. In the case of bilateral implantation the return on investment is lower if we assume there are no additional benefits relative to unilateral implantation though the estimates remain uniformly positive – for example in respect of the profoundly impaired, the return on investment is estimated at between 1.5 and 2.0 and; 1.09 and 1.41 respect of those with moderate impairment.

In essence we can therefore say that for every implanted person for every £100 invested you would get £230 to £310 in return saving to public services or additional economic benefit, And for bilateral the figure is between £170 and £210 pounds per implanted person. The multiplier effect is obvious in that the more people implanted the greater the overall saving to society and increased wellbeing.

There may be some uncertainty around our estimates. For example, we have taken conservative estimates on calculating a 10 year period for benefit; the potential healthcare savings may be higher than those we have assumed given emerging evidence implicating hearing impairment in a wide range of conditions. Similarly, we have not included in our estimates the potential impact on others within the household or workplace on health and productivity. Net benefits are likely therefore to be significantly higher in consequence than the conservative estimate of those reported here. That cochlear implantation provides a positive net benefit to the health, social care and welfare systems is in line with other work on the potential cost benefit of implantation researchers have found in other countries. While we have estimated the return on investment associated with increased provision of cochlear implants how far and how quickly cochlear implant programmes could be extended will depend not only on the number of suitable candidates but on service capacity that will require planning and time to achieve. Extending criteria for implantation would not lead to unsustainable demand especially if coupled with further service innovation as outlined in Lamb et al., (2015).

Commissioners across government departments should consider that for any given level of investment in ensuring additional candidates are fitted with implants the long term return on investment to the state is substantial compared with outgoing costs.

SECTION 3:

Changing the Guidelines?

Recent research has proposed that the current criteria should be changed to 80 dB HL at 2 and 4 kHz in the ear to be implanted.

Chandu (2014) following a review of candidacy for an implant in the UK argues that:

"Cochlear implant candidacy should be individually based and needs to take in to account work, quality of life, social impact rather than adhering to pure-tone audiometric guidelines. They should not be considered as strict criteria nor used to deny the benefit of a cochlear implant at the earliest opportunity."

If the cut-off audiometric level was 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 this might still have problems if not coupled with other measures. There are concerns that this change would still not sufficiently cover all of the unusual audiometric configurations that an appropriate candidate could have. It should also be recognized that pure tone audiometry has significant limitations and other measures, such as the speech intelligibility index (a measure to determine degree of access to speech sounds) could be added to the test battery as a way to support candidacy decisions regardless of where the hearing threshold level is set, Leal et al., (2016).

A number of alternative measures or combination of measures has been proposed as an alternative. Raine (2013) has proposed that assessment of performance with monosyllabic words would be more appropriate. The use of monosyllables in testing for qualification purposes has been used in Germany for a number of years where patients achieve <30% correct for Freiberg monosyllables at 70 dB SPL in the bestaided condition Aschendorff et al., (2007), Gifford et al., (2010).

As people with greater residual hearing are being assessed they may score greater than 50% on BKB in quiet and should therefore be tested in noise as well to fully understand the difficulties that the individual faces. In Germany where people with greater levels of hearing are being assessed there has been a move towards testing in noise, Haumann et al., (2012).

A score of less than 50% on the Bamford Kowal and Bench (BKB) sentences presented in quiet (at 70 dBSPL) is part of the candidacy criteria for assessing adults in the UK. Use of this measure alone has become inappropriate. Doran and Jenkinson (2016) have suggested that the Arthur Boothroyd (AB) word test would be a suitable supplement to BKB testing to detect candidates who have some residual hearing but who would benefit. Further Vickers and Bradley (2016) also challenge the current guidelines arguing for a combination of tests which do not rely on a person's pre-existing linguistic knowledge including monosyllabic word tests.

Findings from the British Cochlear Implant Group (BCIG) service evaluation and the BCIG supplement on candidacy issues cited here also suggest that it would be appropriate to broaden the pre-implant assessment test battery to include the Arthur Boothroyd (AB) monosyllabic speech perception task (scored by both word and phoneme) together with CUNY audio-visual sentence materials in quiet for poorer performing candidates. Additionally, speech-in-noise measures should be included when assessing individuals at the higher end of the performance range. A more complex combination of measures for determining candidacy will provide a better assessment of an individual's access to speech. Other more qualitative measures to better understand an individual's everyday listening experience should also form part of the clinical evaluation assessment.

Further, the inherent variability of the assessments is not currently taken into account when applying the criteria.

Given that most routine clinical measures are known to have less than perfect test–retest reproducibility, it would be appropriate to consider the potential effects of this variability on both threshold measurements and speech perception measures to ensure that people are not incorrectly classified as ineligible due to measurement error. The fact that there is a variability of around 5% would argue for much more flexibility around candidacy criteria.

There is more work needed on the most appropriate candidacy measures and consideration of the best combination of these should form part of the review we are calling for. What is not at question is that the current guidelines are no longer fit for purpose and need to be refined to address the issues we have raised here.

"Only one word to describe life with the implant – FANTASTIC – I'm having regular phone calls with people now (without caption support), using neckloop or headsets that work with both the implant & HA (to give full sound)... now working on improving understanding strong accents (e.g. Spanish <with a lot of success> and Greek <very limited success at the moment>). I don't know how I managed without it..."

Adult who was a "borderline" candidate by email

Conclusion

The NICE guidelines were helpful and appropriate when introduced in 2009. Inevitably they relied on evidence often produced years earlier given the long gestation time for scientific research, developing clinical practice and for enhanced outcomes to emerge.

We are now in the positon of having much more complete evidence based on more effective surgical and clinical practice with more powerful technology and better patient care. We also have a clearer understanding of real world patient benefits. The cost of implants has come down significantly compared to 2009 prices and we have a more complete picture of potential benefits with more sensitive measures of outcomes. These factors have dramatically changed our understanding of candidacy.

There are still many issues around cochlear implantation which need further scientific research including refinements which could be made to cost utility studies, further work on commissioning and service models and patient support.

However there is clearly a sufficient accumulation of evidence to show that the current guidelines are not fit for purpose and are systematically denying many people with hearing loss the life changing interventions they need.

Moreover by not extending the criteria it is clear that the health, social care and welfare systems are all storing up future costs which far exceed the costs which would be incurred by enabling greater access to cochlear implantation now. The UK is poor at taking account of the additional costs of not taking action in candidacy criteria as the additional savings of early intervention tend to get discounted or ignored often because the cost of doing nothing is taken by other areas of public expenditure. In a time when the pressures on health budgets are all too obvious it is in the interest of the health service, as envisaged both in the NHS five year forward view (2014) and the Action Plan on Hearing Loss (2015), to ensure that early intervention prevents even more significant costs downstream for health and other public services.

Recommendations

1. That NICE urgently conducts a formal review of its current guidance on cochlear implants including bilateral implantation
2. As part of that review it considers lowering the current audiological threshold for candidacy and also looks at the suitability of combining current assessment methodologies with new measures
3. Each ear should be considered separately for candidacy
4. That any cost benefit analysis done as part of that review ensures that appropriate utility measures are used and that real world benefits are taken into account
5. That NHS commissioners, NHS Improvement and NHS England and other commissioners take into account the current overwhelming evidence of the benefits of cochlear implants for improving health and wellbeing and the potential cost savings over time to the health and social care budgets in commissioning decisions
6. A screen for candidacy for cochlear implants should be built into routine audiological appointments.

References

Action for Hearing Loss et al., (2013) Hearing Screening for Life. RNID/London Economics 'Cost benefit analysis of hearing screening for older people' 2010.

Amieva, H., Ouvrard, C., Giulioli, C., Meillon, C., Rullie,R. L., Dartigues, JF. Self-Reported Hearing Loss, Hearing Aids, and Cognitive Decline in Elderly Adults: A 25-Year Study. J Am Geriatr Soc. 2015 Oct;63(10):2099-104.

Archbold, S., Lamb, B., O'Neill, C., Atkins, J. 2014. The real cost of hearing Loss: reducing its impact by increasing access to the latest hearing technologies. Ear Foundation.

Archbold S, Lamb B, O'Neill C, Aitkins J. The real cost of hearing loss: reducing its impact by increasing access to the latest hearing technologies. 2013 The Ear Foundation. www.earfoundation.org.uk/research/current-research/the-real-cost-of-adult-hearing-loss

Arnoldner, C, Lin, V.Y. 2013. Expanded selection criteria in adult cochlear implantation. Cochlear Implants International, 14 (Suppl 4): S10–S13.

Aschendorff, A., Kromeier, J., Klenzer, T., Laszig, R. 2007. Quality control after insertion of the nucleus contour and contour advance electrode in adults. Ear Hear 28: 75S–79S.

Athalye, S., Archbold, S., Lutman, M., Mulla, I. (2015) Exploring views on current and future cochlear implant service delivery:the perspectives of users, parents and professionals at cochlear implant centres and in the community, Cochlear Implant International, 17 March 2015.

Bond, M., Mealing, S., Anderson, R., Elston, J., Weiner, G., Taylor, RS., Hoyle, M., Liu, Z., Price, A. Stein. (2009) The effectiveness and cost effectiveness of cochlear implants for severe and profound deafness in children and adults: a systematic review and economic model. K Health Technol Assess 2009. Sep: 13 (44).

Carlson, M.L., Sladen, D.P., Haynes, D.S., Driscoll, C.L., DeJong, M.D., Erickson, H.C. et al. 2015. Evidence for the expansion of paediatric cochlear implant candidacy. Otology & Neurotology, 36(1): 965–971.

Chao, T.K., Chen, T.H. (2008) Cost-effectiveness of hearing aids in the hearing-impaired elderly: a probabilistic approach. Otology and Neurotology 29(6): 776-83

Chen, JM., Amoodi, H., Mittmann, N. Cost utility analysis of bilateral cochlear implantation in adults: A health economic assessment from the perspective of a publicly funded program. Laryngoscope 2014;124:1452–8.

Chisholm et al., (2007) A systematic review of health-related quality of life and hearing aids: Final report of the American Academy of Audiology task force on the health-related quality of life benefits of amplification in adults. Journal of American Academy of Audiology 18: 151-183.

Choi, JS., Contrera, K.J., Betz, J.F., Blake, CR., Niparko, JK., Lin, F.R. (2014) Long-term use of cochlear implants in older adults: results from a large consecutive case series. Otol Neurotol. 2014 Jun;35(5):815-20.

Chundu, S., Flynn, S.L. 2014. Audiogram and cochlear implant candidacy – UK perspective. Cochlear Implants International, 15(4): 241–244.

Craddock L., Cooper H., Riley, Wright. 2016. Cochlear implants for pre-lingually profoundly deaf adults. Cochlear Implants International, 17(S1): 26–30.

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:sup1, 13-16.

Dowel, R, C. (2012) Evidence about effectiveness of cochlear implants in adults. In: Wong, L., Hickson, L. editors. Evidence Based Practice in Audiology. San Diego: Singular Publishing; 2012.

Fielden CA., Hampton R., Smith S., Kitterick, PT., (2016) Access to aidable residual hearing in adult candidates for cochlear implantation in the UK, Cochlear Implants International, 17:sup1, 70-73.

Foteff, C., Kennedy, S., Milton, A H., Melike, D., Florian., P., Sanderson, G. Economic Evaluation of Treatments for Pediatric Bilateral Severe to Profound Sensorineural Hearing Loss: An Australian Perspective. Otology & Neurotology: June 2016 - Volume 37 - Issue 5 - p 454–46.

Gifford, R.H., Dorman, M.F., Shallop, J.K., Sydlowski, S.A. (2010). Evidence for the expansion of adult cochlear implant candidacy. Ear and Hearing, 31(2): 186–194.

Gifford RH, Driscoll CL, Davis TJ, Fiebig P, Micco A, Dorman MF. (2015) A Within-Subject Comparison of Bimodal Hearing, Bilateral Cochlear Implantation, and Bilateral Cochlear Implantation With Bilateral Hearing Preservation: High-Performing Patients. Otol Neurotol. 2015 Sep; 36(8):1331-7. Health Survey for England 2014: VOL 1 Health, social care and lifestyles Health Survey for England 2014. Scholes, S. Mindell, J. Chapter 4: Hearing. (2015)

Hayes Inc. Cochlear Implants: Bilateral Versus Unilateral-A Health Technology Assessment Prepared for Washington State Health Care Authority. April 17, 2013.

Health Survey for England 2014: VOL 1 Health, social care and lifestyles Health Survey for England 2014. Scholes, S. Mindell, J. Chapter 4: Hearing. (2015)

International Longevity Centre (2014) Commission on Hearing Loss: final report. Available at: www.ilcuk.org.uk/ images/ uploads/publication-pdfs/Hearing_loss_Commission_final_ report_-website.pdf

Jeffs, E., Redfern, K., Stanfield, C., Starczewski, H., Stone, S., Twomey, T., Fortnum, H. A. pilot study to explore the experiences of congenitally or early profoundly deafened candidates who receive cochlear implants as adults. Cochlear Implants Int. 2015.

Joore et al., (2003) The cost-effectiveness of hearing-aid fitting in the Netherlands. Archives of Otolaryngology - Head and Neck Surgery 129(3).

Jopling, K. (2015) Hearing Loss and Older People.

Klop, WM., Briaire, JJ., Stiggelbout AM, Frijns JH. (2007) Cochlear implant outcomes and quality of life in adults with prelingual deafness. Laryngoscope. 117(11):1982-7.

Kobosko, J., Jedrzejczak, WW., Pilka, E., Pankowska, A., Skarzynski, H. (2015) Satisfaction With Cochlear Implants in Postlingually Deaf Adults and Its Nonaudiological Predictors: Psychological Distress, Coping Strategies, and Self-Esteem. Ear Hear. 2015 Sep-Oct;36(5):605-18.

Kumar, R,S., Mawman, D., Sankaran, D., Melling, C., O'Driscoll, M., Freeman, S, M., Simon Lloyd, S,K, W. Cochlear implantation in early deafened, late implanted adults: Do they benefit? Cochlear Implants International Vol. 17 , Iss. Sup1, 2016

Kuthubutheen, J., Mittmann, N., Amoodi, H., Qian, W., Chen, J.M. The effect of different utility measures on the cost-effectiveness of bilateral cochlear implantation. Laryngoscope. 2015 Feb;125(2):442-7.

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

Lamb, B., Archbold, S. 2013. Adult Cochlear Implantation: Evidence and experience. The Case for a Review of Provision. Ear Foundation.

Lamb, B., Archbold, S., O'Neill, C. 2015. Bending the spend: expanding technology to improve health, wellbeing and save public money. Ear Foundation.

Lamb B, 2016. Personal communication. NHS Improvement Consultation on Commissioning Specialist Services. Cochlear Implantation.

Lammers, M.J., Grolman, W., Smulders, YE., Rovers, M.M. (2011) The cost-utility of bilateral cochlear implantation: a systematic review. Laryngoscope. 121(12):2604-2609.

Llewellyn., C, R Miah., R, Al-Malky., G & Kitterick, T. (2016) Preliminary assessment of the feasibility of using AB words to assess candidacy in adults, Cochlear Implants International, 17:sup1, 17-21.

Lin FR, Yaffe K, Xia J, Xue QL, Harris TB, Purchase-Helzner E, et al. (2013) Hearing loss and cognitive decline in older adults. JAMA Intern Med. 2013; 173.

Loeffler, C., Aschendorff, A., Burger, T., Kroeger, S., Laszig, R., Arndt, S. (2010) Quality of life measurements after cochlear implantation. The Open Otorhinolaryngology Journal, 4, 47-54

Lovett, R.E.S., Vickers, A.D., Summerfield, A.Q. 2015. Bilateral cochlear implantation for hearing impaired children – criterion of candidacy derived from an observational study. Ear & Hearing, 36(1): 14–23.

Mahon M., Rajput K., Vickers D. (2016) Expert opinion: Assessing cochlear implant candidacy and progress for people with English as an additional language, Cochlear Implants International, 17:sup1, 59-61.

Morris, A.E. et al. 'An economic evaluation of screening 60- to 70-year-old adults for hearing loss' Journal of Public Health 2013, 35(1), 139-146.

Monteiro, E., Shipp, D., Chen, J., Nedzelski, J., Lin, V.J. Cochlear implantation: a personal and societal economic perspective examining the effects of cochlear implantation on personal income. Otolaryngol Head Neck Surg. 2012 Apr;41 Suppl 1:S43-8.

Mosnier, I., Bebea,r J.P., Marx, M., Fraysse, B., Truy, E., Lina-Granade, G., Mondain, M., Sterkers-Artières, F., Bordure, P., Robier, A., Godey, B., Meyer, B., Frachet, B., Poncet, C., Bouccara, D., Sterkers O. (2014) Predictive factors of cochlear implant outcomes in the elderly. Audiol Neurootol. 2014; 19 Suppl 1:15-20.

National Institute for Health and Care Excellence Technology Appraisal Guidance. 2009. Cochlear implants for children and adults with severe to profound deafness. NICE technology appraisal guidance [TAG166]. Available from www.nice.org.uk/ta166.

National Institute for Health and Clinical Excellence 2013. www.nice.org.uk/advice/lgb10/chapter/judging-the-cost-effectiveness-of-public-health-activities

National Institute for Health and Clinical Excellence 2011. www.nice.org.uk/guidance/ta235/resources/osteosarcoma-mifamurtide-discounting-of-health-benefits-in-special-circumstances2

Ng Z., Lamb, B., Harrigan, S., Archbold, S., Athalye., Allen, S. (2016) Perspectives of adults with cochlear implants on current CI services and daily life, Cochlear Implants International, 17:sup1, 89-93.

Noble, W., Tyler. RS., Dunn, C.C., Bhulla,R N. (2009) Younger- and older-age adults with unilateral and bilateral cochlear implants: Speech and spatial hearing self-ratings and performance. Otol Neurotol. 30(7): 921–929.

O'Neill, C., Lamb, B., Archbold, S. (2016) Cost implications for changing candidacy or access to service within a publicly funded healthcare system?, Cochlear Implants International, 17:sup1, 31-35.

Park, E., Shipp, D.B., Chen, J.M., Nedzelski, J.M., Lin, V.Y. (2011). Postlingually deaf adults of all ages derive equal benefits from unilateral multichannel cochlear implant. J Am Acad Audiol. 2011 Nov-Dec;22(10):637-43.

Perez, E., Edmonds, A. (2012) A systematic review of studies measuring and reporting hearing aid usage in older adults since 1999: a descriptive summary of measurement tools. PLoS ONE www.plosone.org 7 March 2012, Volume 7, Issue 3.

Raine, C. 2013. Cochlear implants in the UK: Awareness and utilisation. Cochlear Implants International Supplement 1, vol. 14: S32–S37.

Raine, C., Atkinson, H., Strachan, D, R., & Martin, J M. (2016) Access to cochlear implants: Time to reflect, Cochlear Implants International, 17:sup1, 42-46.

Ramen, G., Lee, J., Chung, M., Galyor, J.M., Sen, S., Rao, M., et al. 2011. Effectiveness of cochlear implants in adults with senrorneural hearing loss. Technology Assessment Report for the Tufts Centre.

Ramsden, R., Greenham, P., O'Driscoll, M., et al. (2005) Evaluation of bilaterally implanted adult subjects with the nucleus 24 cochlear implant system. Otol Neurotol. 26(5):988-998.

Sampaio, A.L., Araújo, F.S., Oliveira, C.A. 2011. New criteria of indication and selection of patients to cochlear implant. International Journal of Otolaryngology, 2011:13.

Shield B. Evaluation of the social and economic costs of hearing impairment. A report for Hear it. 2006

Smulders, YE., van Zon, A., Stegeman, I., van Zanten, GA., Rinia, AB., Stokroos, RJ., Free, R.H., Maat, B., Frijns, J.H., Mylanus, E.A., Huinck, W.J., Topsakal, V., Grolman, W. Cost-Utility of Bilateral Versus Unilateral Cochlear Implantation in Adults: A Randomized Controlled Trial. Otol Neurotol. 2016 Jan;37(1):38-45.

Summerfield, A. Q., Lovett, R. E. S., Bellenger, H., Batten, G. "Estimates of the cost-effectiveness of paediatric bilateral cochlear implantation," Ear and Hearing, vol. 31, no. 5, pp. 611–624, 2010.

Turchetti, G., Bellelli, S., Palla, I., & Berrettini, S. (2011). Systematic review of the scientific literature on the economic evaluation of cochlear implants in adult patients. Acta Otorhinolaryngologica Italica, 31(5), 319–327.

Van Schoonhoven, J., Sparreboom, M., van Zanten, BG., et al. The effectiveness of bilateral cochlear implants for severe-to-profound deafness in adults: A systematic review. Otol Neurotol 2013;34: 190–8.

Verschuur, C., Hellier, W., Teo, C. (2016). An evaluation of hearing preservation outcomes in routine cochlear implant care: Implications for candidacy, Cochlear Implants International, 17:sup1.

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, Estibariz., U, O'Driscoll, M., George., N, Pinto., F, Hall., A, Al-Malky., Kitterick, PT. Preliminary assessment of the feasibility of using AB words to assess candidacy in adults. Cochlear Implants Int. 2016 Apr;17 Suppl 1:17-21.

Vickers, F., Bradley, J., Wilson, K. 2015. CI outcomes in children: are the NICE guidelines appropriate for adults? Cochlear Implants International, 16(1): 43–47.

Visram, A. S., Azadpour, M., Kluk, K., McKay, C. M. 2012. Beneficial acoustic speech cues for cochlear implant users with residual acoustic hearing. Journal of the Acoustical Society of America, 131: 4042–4050.

Távora-Vieira, D., Marino, R., Acharya, A., Rajan, G.P. (2015) The impact of cochlear implantation on speech understanding, subjective hearing performance, and tinnitus perception in patients with unilateral severe to profound hearing loss. Otol Neurotol. 2015 Mar;36(3):430-6.

Washington State Health Care Authority: Health Technology Assessment. Health Technology Clinical Committee Final Findings and Decision. 20130517A-Cochlear Implants: Bilateral versus Unilateral. 2013.

Acknowledgements

We are grateful for the advice and support of the members of the Action Group on Adult Cochlear Implants and especially Debbie Vickers and the BCIG Working Party on Candidacy.

This analysis has benefited greatly from the collected articles published in Cochlear Implants International Special Supplement 2016 www.tandfonline.com/toc/ycii20/17/sup1

If you want to explore these issues further you will find our reports at www.earfoundation.org.uk/research/current-research useful to see more of the background and a fuller account of the real cost benefit analysis of not addressing hearing loss.

This report was supported by an educational grant from Cochlear. The work is entirely that of the authors.

Report and research supported by an educational grant from Cochlear.
The work is entirely that of the authors, Brian Lamb OBE, Sue Archbold PhD and Ciaran O'Neill.

October 2016

The Ear Foundation®

Marjorie Sherman House,
83 Sherwin Road,
Lenton,
Nottingham,
NG7 2FB

Tel: 0115 942 1985 **Email:** info@earfoundation.co.uk

www.earfoundation.org.uk

Charity Number: 1068077