

NICE Health Technology Appraisal

Cochlear Implants for Deafness in Children and Adults

A joint submission on behalf of:

**British Academy of Audiology
British Cochlear Implant Group
ENT UK**

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Index

	Page
1) Executive Summary	4
2) Introduction	6
• Basic technology of cochlear implants	
• Summary rationale of cochlear implants	
3) Service Delivery	7
• Implementation of service within the United Kingdom	
• Location and framework of centres	
• Staffing	
• Workload and development	
4) Quality Standards	9
• Introduction	
• Adult quality standards	
• Paediatric quality standards	
• British Society of Audiology	
• BCIG Policy Statement on Bilateral Implants	
• BCIG/Ear Foundation Policy Statement on Managing Device Failure	
• BCIG Safety Guidelines	
• BCIG Policy on Transfer of Patient Transfer	
5) Candidature	12
• Introduction	
• Goals of cochlear implantation	
• Assessment for cochlear implantation	
• Patient pathway to evaluation	
• Current candidature	
• Current clinical practice	
• Management of special cases	
• Summary	
6) Binaural hearing	20
• Introduction	
• Benefits of bilateral implants	
• Bimodal listening	
• Cost	
• Summary	
7) Outcomes of paediatric cochlear implantation	23
• Introduction	
• Current clinical opinion	
• Proven benefits	
• Summary	

8)	Outcomes of adult cochlear implantation	28
	<ul style="list-style-type: none"> • Introduction • Subjective benefits • Proven benefits • Predictive factors • Older adults • Cost effectiveness 	
9)	Safety and Risk	30
	<ul style="list-style-type: none"> • Device related • Medical related • Re-implantation • Management • Management in special situations • Summary 	
10)	Access to care and future demand	33
	<ul style="list-style-type: none"> a. Contracting b. Referral sources c. Access to first outpatient appointment d. Assessment e. Population under assessment f. Future demand 	
	References	34
	Appendices	
	1 Cochlear implant centres within the UK – data	46
	2 Staff involved in support of Cochlear Implantation	47
	3 Rate of Cochlear Implantation up to 2005	48
	4 Bilateral Implantation in the UK	49
	5 Prevalence and patient opportunity	50
	6 Economic and outcome analysis of non-use among CI users	51

Health Technology Appraisal

Cochlear Implants for Severe to Profound Deafness in Children and Adults

Executive Summary

General

- Cochlear implantation (CI) has become established as the primary means of (re)habilitating children and adults with a severe to profound sensorineural hearing loss who fail to receive adequate benefit from conventional acoustic amplification.
- CI is a safe intervention and the safety of CIs themselves has been shown following extensive research.
- There are 19 centres providing CI in the UK. As experience has grown quality standards have been developed in order to promote best practice, ensure the highest quality clinical care, minimise risk and to encourage future service developments. Quality standards are reviewed regularly to ensure they reflect current best practice.
- CI requires carefully integrated multi-disciplinary team working with input from a number of professionals.

Candidacy

- Candidacy for CI has evolved as experience has grown and outcomes improve.
- Selected patients with better residual hearing (severe losses) have proven to benefit from CI.
- Assessment for CI must be undertaken on an individual patient basis by an experienced multi-disciplinary team
- All patients should have undergone an appropriate trial of amplification with hearing aid(s).
- The key selection factor for candidature should be functional hearing ability, including failure to develop, progress or maintain speech, language and listening skills, other developmental and medical factors being taken into account.
- The pure tone audiogram does not always reflect the level of hearing difficulty, but is a useful indicator for the majority of cases.
 - Common current paediatric UK practice incorporates an audiometric guideline of profound sensorineural loss (>90dBHL) at 2 and 4kHz, +/- 10dBHL test/retest reliability.
 - Common current adult UK practice incorporates an audiometric guideline of severe to profound sensorineural loss, typically >90dBHL at 2 and 4kHz, +/- 10dBHL test/retest reliability, together with a score of <50% correct on BKB sentence testing in the best aided condition.
- Other groups of patients may benefit including those with auditory dyssynchrony, developmental delay, sudden, fluctuating or progressive losses and those with additional complex needs such as blindness.
- Congenitally deaf children should be implanted early in life to avoid problems of reduced neuroplasticity with increasing age.
- Bilateral implants are recommended for all profoundly deaf patients unable to access binaural hearing via alternative modes such as bimodal listening.
- Bilateral implants are also recommended in clinical cases of need, such as post-meningitis, for additional sensory handicaps, for patients with loss of performance / function in the first ear where re-implantation is not possible in the same ear.
- There are very few absolute medical contraindications to CI. Careful medical assessment will identify medical conditions that may require additional special management; age is not in itself a contraindication.
- Radiological assessment by High Resolution Computed Tomography (HRCT) and / or Magnetic Resonance Imaging (MRI) is essential.
- Otological assessment will identify other diseases of the ear which may require treatment before CI can be undertaken.
- Patient/Parental expectation of CI should be realistic.

Outcomes

- Potential benefits include environmental sound awareness, speech recognition, benefit to lipreading/communication and language development, reduction of tinnitus, enjoyment of music, educational achievements, improved employment prospects/ maintenance or resumption of paid employment, changes in quality of life, psychological well being, telephone use and preservation of residual hearing.
- Selected patients with better residual hearing (ie those with severe losses) than traditional candidates (ie those with profound deafness) have proven to benefit from CI.
- Children with complex additional needs have proven to benefit from CI.
- Patients with diagnosed auditory neuropathy/auditory dyssynchrony require careful consideration and may benefit from cochlear implantation despite having better hearing levels on pure tone audiometry.
- Implantation of young babies is safe and effective.
- Duration of deafness is the factor most frequently cited as having predictive value for outcomes in adults. Early implantation of children is associated with better outcomes.
- Cochlear implants can improve the ability to cope in mainstream education and are related to improvement in some educational attainment
- Bilateral CI offers additional advantages over unilateral implantation including improved localisation of sound, improved speech understanding in quiet, improved speech understanding in background noise, stimulation of both auditory pathways, a guarantee that the better performing ear has been implanted, improvements in speech and language development in children, potential for normal central auditory development in children, music appreciation, subjective reports of improved sound quality and in the event that one device fails, the patient is not left without hearing.
- These benefits give adults the potential of improved employment prospects and many other psychosocial benefits. Children have the potential of higher educational achievement and a reduced requirement of additional educational support.
- Cochlear implants are effective and cost effective in adults and children.

Risk and other factors

- CI is safe but there are some risks, albeit low, both surgical and non-surgical. Annual re-implantation rates for CI device failure in the UK is 0.35% and for infection and other patient related causes is 0.31%. CI re-implantation is safe and effective.
- Non-use of CI remains low at 1.3% in children and 3.0% in adults.
- Funding for CI remains variable with “post code lottery” being a factor.
- Current demand for adult CI does not reflect the incidence of severe to profound hearing loss in the population. There is therefore the potential of increased demand into the future, although not all patients will wish to go forward for CI.

Introduction

Basic technology of Cochlear Implants

Cochlear implantation for both children and adults has become established as a means of auditory (re)habilitation. The cochlear implant (CI) is a surgically implanted neurostimulator which is suitable for patients who have a bilateral severe / profound sensorineural hearing loss who gain limited benefit from optimal acoustic hearing aids. In most cases this deafness is a result of damage to the sensory structures within the cochlea. A cochlear implant will bypass these damaged structures and electrically stimulate the auditory nerve directly, thereby restoring a perception of sound to the patient.

There are three main manufacturers that supply the global market:

- Cochlear Ltd, Sydney, Australia.
- Med El Corporation, Innsbruck, Austria.
- Advanced Bionics Corporation, California, USA.

Whilst the three systems have unique features, they all work on common principles. Sound and speech is received by the microphone on the speech processor, which is then processed and coded into electrical signals. These signals are transmitted by a head coil, across the skin to the internal receiver package implanted in the bone beneath the skin of the scalp. Within the normal cochlea movement of the hair cells triggers the stimulation of the auditory nerve. With a cochlear implant the electrode array electrically stimulates the auditory nerve in the cochlea, which in turn transmits signals to the brain. The arrangement within the cochlea is 'tonotopic' with high frequencies perceived within the basal turn and lower frequencies towards the apex (Bekesy, 1960). CIs work on the principle of the electrode arrays stimulating the appropriate portion of the spiral ganglion (nerve) cells. The sequence of stimulation, or processing strategy, determines how sounds are represented by the device. High rate strategies have been developed and outcomes continue to improve.

Summary rationale of an implant

The rationale for CI is predicated on a number of basic principles:

- Failure to achieve adequate benefit from conventional acoustic amplification in cases of severe to profound sensorineural deafness
- Tonotopic organisation of the cochlea together with the presence of viable spiral ganglion cells and auditory nerve capable of stimulation.
- The ability to gain surgical access to the cochlea
- The ability of the patient to utilise the auditory input from the CI

Service delivery

Implementation of service within the United Kingdom

Multi-channel CIs were introduced to the UK in the late 1980s. Initially, the treatment was only available through private or charitable funding within a very few centres in the UK. Between 1990 and 1994 several centres participated in an audit co-ordinated by the Institute of Hearing Research (IHR). One of the outcomes (Summerfield & Marshall, 1995) identified that CIs were cost effective, giving rise to formal funding from the NHS.

Location and framework of centres (Appendix 1)

Current service delivery is now established within 19 tertiary centres throughout the United Kingdom. There are 14 centres in England, five of which are within London, three centres in Wales, a centre in Northern Ireland and one in Scotland.

The majority of centres manage both paediatric and adult patients, while some services are managed separately. This is primarily due to the fact that children's services are provided at separate hospitals within the same city. In some Teams, services are split across two sites. The transition and transfer of patients from a paediatric team to an adult program in the majority of units is made by the time the young person reaches 19 years of age (National Service Framework for Children). Many programmes have dedicated Adolescent Services to meet the specific needs of this patient group.

Staffing

CI assessment is a multi-disciplinary process and Teams employ a range of professionals. Core to each unit, adult or paediatric, are Clinical Scientists in Audiology, Audiologists, Surgeons, Speech and Language Therapists, Hearing Therapists and Administrative support. Within paediatric services the team also includes Teachers of the Deaf. Some units use or have access to Clinical and/or Educational Psychology, Link Nurses and Paediatricians. Two units have found it beneficial to employ a family liaison officer to help with ethnic family issues. There are over 250 WTE members of staff within the UK. The proportions of the various staff are shown in Appendix 2 All have developed close working relationships with their Radiology departments.

Work load and development (Appendices 1 and 3)

- Current data from centres indicate that there are over 6020 registered patients.
- There is equal distribution between adults and children. However, the trend is for increasing numbers of children to be implanted. During the year April 2006 to March 2007, 414 children and 275 adults received CIs.
- All age groups are assessed, from babies of only a few months of age to adults in their 80's.

Centres have grown naturally to accommodate and concentrate expertise in accordance with good practice and clinical governance. In most circumstances it is more appropriate to develop and expand current centres of expertise as opposed to increasing the overall number of centres. This rationale is based on the principles recommended by Summerfield:

- i) The existing team is experienced and professional and has a track record of sustaining its professional composition over time as team members have come and gone. (i.e. That the team can recruit and retain good people).
- ii) The team keeps track of its patients and maintains high standards of audit with reliable and informative data on outcomes.
- iii) The charges levied for the service are reasonable and realistic.
- iv) Contingency planning has been conducted about preserving the service in the event of the absence of senior members of the team.
- v) Thought has been given to succession planning where senior members of the team are likely to retire within the next five years.
- vi) The hospital where the team is based has done as much as it can to make access easy for patients (e.g. Accessible safe car parks; routes within the hospital well sign-posted).

- vii) The 'patient journey' is straightforward with as much of the treatment as possible being provided under the same roof (pre-operative assessment and imaging; surgery; post-operative tuning and rehabilitation).

Quality Standards

Introduction

Cochlear implantation has been available in the UK for more than fifteen years and there are now over twenty established and experienced cochlear implant programmes in the UK. There are over 6,000 patients with cochlear implants in the UK and current figures indicate that at least 680 patients will receive implants per year. The British Cochlear Implant Group (BCIG) is the organisation that represents all the varied professional groups involved in this field and has been instrumental in encouraging best practice and producing guidelines to ensure that patients receive the highest quality clinical care and that potential risks are identified and minimised.

Adult Quality Standards

The BCIG Adult Quality Standards were first produced in 1995 and are currently undergoing further revision. Their purpose is to set realistic minimum standards attainable by implant programmes to secure a high quality and effective service. The quality standards address the following aspects of implant centres:

- Service structure: staffing and training needs.
- Facilities and accommodation
- Selection and referral guidelines
- Pre-operative Assessment including information and counselling needs
- Surgery and in-patient stay
- Post-operative rehabilitation and assessment including long term maintenance
- Audit and service monitoring
- Transfer of care to another centre, as required.

All implant centres offering cochlear implants to adults are expected to meet the Quality Standards. This also ensures that parity of care is offered across existing centres and new programmes in the UK.

Paediatric Quality Standards

In 2005 the BCIG and the National Deaf Children's Society (NDCS) produced revised quality standards for implantation in children, Cochlear Implants for Children and Young People: Guidelines for professionals working with deaf children and young people. These paediatric quality standards "define good practice and drive up standards of care for children and young people who are considered for or who receive a cochlear implant". This document is intended as a point of reference for service providers and commissioners and provides a framework in which to provide high quality care and support. It covers the following aspects:

- Support for the child
 - Local services
 - Within the family
 - In the cochlear implant programme
- Assessment by the multi-disciplinary Team
- Surgery and post-operative care
- Switch-on, follow up and ongoing evaluation.

This joint document is one example of two organisations working together to drive up standards and maintain quality.

British Society of Audiology (BSA)

The BSA produces Recommended Procedures for audiologists and other related professionals. Cochlear Implant professionals also adhere to BSA recommended procedures in the assessment and management of patients before and after implantation. These cover the following aspects:

- Pure tone air and bone conduction threshold audiometry with and without masking and determination of uncomfortable loudness levels
- Rinne and Weber tuning-fork tests
- Cleaning of Specula, etc., and Associated Infection Control
- Caloric test protocol

- Tympanometry
- Taking an Aural Impression
- Hearing assessment in general practice, schools and health clinics: Guidelines for professionals who are not qualified audiologists
- Hallpike Manoeuvre

BCIG Policy statement on bilateral cochlear implantation

The BCIG has a role in unifying practice across the UK and in encouraging high standards of care in line with worldwide published evidence. One such document is the statement on bilateral implantation, based on a 2006 audit of current practice in the UK (see Appendix 4) and worldwide and also on the published evidence.

BCIG supports bilateral implantation:

- ◆ For all profoundly deaf children in order to stimulate both auditory pathways and optimise speech, language and auditory development and maximise potential academic achievement.
- ◆ For all profoundly deaf adults, unable to benefit from bimodal hearing
- ◆ For patients following meningitis or other risk of ossification, where failure to implant may result in obliteration of the cochlea, preventing future auditory stimulation.
- ◆ For patients with additional sensory handicap e.g. the deaf-blind, where there is a greater reliance on binaural hearing. Bilateral implantation offers this patient group improved speech understanding in quiet and in noise, the ability to localise sounds, essential for personal safety, and the important potential to more effectively monitor their environment through hearing.
- ◆ For patients who experience a loss of performance in the first implanted ear or deterioration of device function in the first ear but re-implantation in the same ear is contra-indicated. This may be because some residual function remains in the first device that would contribute to performance with a second implant. Other medical, surgical or anatomical factors may also preclude revision surgery in the first ear.
- ◆ For patients who agree to participate in research studies into bilateral implantation.

For further information, please refer to the section of this report on binaural hearing.

The BCIG and The Ear Foundation framework for good practice: Managing device failure within a cochlear implant service

This jointly produced document is designed to support Teams in the event, however rare, of a device failure. A recent study by Balkany et al, (2005) and the European Consensus Statement on Cochlear Implant Failures and Explantations (2005) produced a common definition of device failure and how to report it. Device failure in the UK is reported to the Medicines and Healthcare Products Regulatory Agency (MHRA). This and other aspects of management of the patient, their family, the technology and the financial implantations are covered:

- Pre-implant counselling
- Baseline measures
- Monitoring of performance
- Managing a suspected failure
- Reporting to the MHRA
- Financial management
- Revision surgery
- Follow-up and after-care

The BCIG Safety Guidelines

This is a biannually updated document, which is produced by the British Cochlear Implant Group with input from experienced members of several UK cochlear implant teams and technical specialists from the major UK suppliers of cochlear implants. The information contained in this document aims to provide realistic guidance to cochlear implant users to enable them to gain the maximum benefit from their implants and to minimise potential problems. The Safety Guidelines cover the following aspects:

- Sporting activities, leisure and play
- Medical matters including general medical advice and also:
 - Information regarding treatments which must never be carried out, e.g. Electro-surgery, therapeutic diathermy, neurostimulation.
 - Information on treatments which can sometimes be used, but with modifications e.g. MRI scanning of the head, ultrasound and X-rays.
- Security systems, e.g. In shops and airports
- Employment issues such as use of hard hats and electrical equipment.
- Air travel including in-flight use of the sound processor.
- Static electricity and interference and ways to avoid them.
- Personal stereos, audio equipment, TV etc
- Advice on cremation of implanted patients

Implant centres typically ensure all patients have a hard copy of these guidelines but they are also available from the BCIG website.

BCIG Policy on Transfer of Patients between Cochlear Implant Centres

Patients will usually be referred to the nearest cochlear implant centre unless the patient or family request to be transferred to a particular centre. If a referral is received from a centre that is not nearest in location, the patient is informed that a closer programme exists and a transfer is offered if requested. In order to ensure that the implant centre is provided with all relevant information, BCIG have produced a short policy, which covers the following aspects:

- The referring centre will confirm that they can support the type of device used by the patient before the referral is made.
- All the relevant documentation will be sent to the receiving centre including full details of the patients contact information, information on the internal and external equipment, recent programs, other results and reports including medical records.
- The receiving cochlear implant centre will acknowledge the referral in writing and confirm that funding has been agreed for continued support of the patient.
- Generally patients will not be referred to another centre less than one year following implantation this is to allow for medical follow up post-operatively, the establishment of a suitable speech processor program and initial rehabilitation provided.

Candidacy for cochlear implantation

Introduction

Candidacy for cochlear implantation has evolved continuously over the past 20 years. In the early days, only post-lingually deafened adults with no hearing at all were considered as candidates. As experience of outcomes with these patients grew worldwide, clinicians and researchers realised that these individuals were outperforming their hearing aided peers, whose underlying hearing levels were better. This experience has continued to date, with patients with better hearing levels gaining huge benefits following implantation. Comparing post-implant performance from the 1980s to the present day shows an increase in speech recognition from, on average, 12% to 90% on sentence recognition (Waltzman, 2006). The increase in performance will be due to a range of factors, not least of which is the improvement in implant technology which has taken place over this time. This has obviously resulted in an increase in the range of candidates to include the prelingually and congenitally deaf, and those with greater hearing sensitivity. Other groups, such as those with additional needs and auditory dyssynchrony have also become successful candidates. In addition, recent years have seen an increase in the number of patients receiving two implants, and evidence for improvement in their hearing abilities and ease of listening is growing.

Goals of cochlear implantation

For the majority of patients, the goals of cochlear implantation are to facilitate understanding of spoken language and the development/improvement in intelligibility of the patient's own speech. There is a more fundamental goal, however, which is to provide the opportunity for the patient to monitor their environment through hearing. Whilst this is a primary aim for all patients, for some with complex needs, this simple benefit may be the key objective and provide a highly valuable increase in their quality of life.

Assessment for cochlear implantation

Assessment for cochlear implantation is a patient-centred multidisciplinary process, which should be undertaken within an experienced specialist team (Niparko et al, 2003). The purpose of the assessment is to identify, for the individual patient, whether cochlear implantation is medically and audiological appropriate for them. The latter aspect is, more precisely, to assess whether their *functional hearing* is likely to be significantly improved with the increased access to audition available through a cochlear implant (Zeng, 2004).

In addition to this, careful exploration of the patient's social and educational environments, together with their expectations from the treatment, influence both the recommendation whether to implant or not, and any particular/additional pre- or post-operative support which will need to be put in place. The patient and, for children their parents (where appropriate), should have the time and opportunity to develop realistic expectations of cochlear implantation, a clear understanding of the implant process and the range of possible outcomes (McCormick & Archbold 2003). They should understand and agree to the long-term commitment necessary to support the process and ensure attendance at appointments (O'Donoghue G M et al 2000). In the case of children, they and relevant local professionals should support the process of cochlear implantation and agree to provide strong oral/aural input whatever the educational setting (O'Neill C et al, 2002).

Skilled pre-operative assessment of patients, by specialist staff experienced in working with the severe/profoundly deaf and in the area of cochlear implantation, is essential and has the following key components:

Medical evaluation:

A full medical history and medical examination are undertaken, and determination of whether the patient is fit for surgery. The aetiology or cause of deafness is ascertained wherever possible and any implications of this on other aspects of health and development identified. For example, identification of Usher Syndrome as a cause of deafness suggests later onset of visual deterioration or blindness. Genetic counselling facilities should be available.

Radiological evaluation:

It is essential that the cochlear and auditory nerve anatomy are imaged prior to surgery. This may affect the choice of ear to implant; although anatomical anomalies are rare, they can affect whether or not it is possible to implant, and what depth of insertion of the electrode array might be possible. Developmental cochlear anomalies, which may present difficulties to surgery can be anticipated by preoperative radiology, High Resolution CT scanning (HRCT) or Magnetic Resonance Imaging (MRI) both of which offer complementary information. The choice of modality is often dependent on the facilities available. MRI is more accurate at identifying cochlear dysplasia, presence of a large vestibular aqueduct, and the presence of the cochlear nerve. In young children imaging is usually performed under a general anaesthetic.

Acquired cochlear pathology such as cochlear osteoneogenesis (bony growth formation in the cochlea) following meningitis requires early scanning in order to detect it as early as possible and facilitate early implantation. Such patients should have their patient pathways fast tracked, in order to facilitate appropriate treatment at the earliest opportunity.

Audiological evaluation:

Whilst the pure tone audiogram for a patient does not always correlate with the level of hearing difficulty which they experience, it is a simple and useful starting point in identifying the majority of patients who are likely to require cochlear implantation. It is recommended that a minimum hearing aid trial with optimum acoustic amplification of 3 months be undertaken with every patient prior to implantation (McCormick & Archbold, 2003; Beiter, Staller & Dowell, 1991).

Within the role of audiological assessment is specialist electrophysiological testing, objective testing in which electrical responses of the cochlear, auditory nerve, auditory brainstem or auditory cortex are measured. These tests can confirm behavioural audiometric results, and provide differential diagnostic information such as evidence of auditory dyssynchrony.

There is consensus in the literature that cochlear implantation should be considered for any patients with severe to profound hearing loss, but this should always be considered together with the functional performance of the patient. The practice of considering sound field aided audiometric thresholds (hearing levels as measured through optimally fitted hearing aids) is not a reliable measure of functional hearing. Hearing aids are set up with the goal of making speech sounds optimally audible, not to make the quietest sounds audible. Modern digital hearing aids can introduce artifactual stimuli into the test, resulting in spurious and unreliable threshold results (MHAS, 2004).

Evaluation of functional hearing

The patient's functional hearing in terms of performance with optimally fitted hearing aids following a valid hearing aid trial is of fundamental importance in assessing candidature. The goal is to determine whether a patient's performance is likely to improve with a cochlear implant. For children this is demonstrated by failure to develop, progress or maintain speech, language and listening skills, measured by a battery of age appropriate assessments and parent/teacher questionnaires (McCormick et al 2003) For young children, speech perception testing is not possible and so an array of age-appropriate assessments and questionnaires are used to explore the benefit of hearing aids. Each patient is evaluated on an individual basis, and as such, in the clinical decision making process different weightings can be applied to the range of factors under consideration (Geers AE, 2006).

For adults, the most widely used measure of functional hearing in the UK is the MRC IHR Bamford-Kowal-Bench (BKB) sentence testing, a speech perception test undertaken in quiet and in noise where possible (Bench et al 1979). The current most commonly used guideline for implantation in the UK is a score of less than or equal to 50% key words correct in the best aided condition, in the ear to be implanted (United Kingdom Cochlear Implant Study Group 2004 b). This current guideline is conservative in comparison to accepted levels in other countries such as the USA and Australia. Guidelines tend to widen over time in line with published evidence and are reviewed regularly to ensure they are up to date and appropriate.

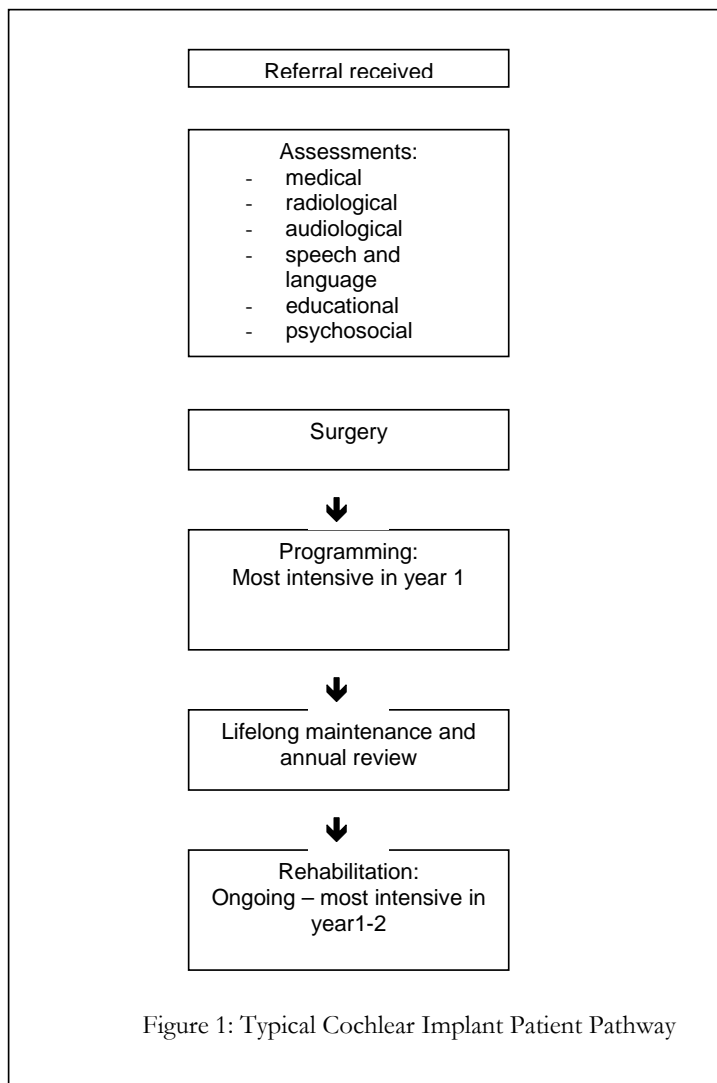
Speech, language and communication evaluation:

Typically, adult cochlear implant candidates have been post-lingually deafened and have an established spoken language base. Careful evaluation of how the patient is coping in terms of maintaining their understanding in everyday situations as well as in quiet clinic surroundings is essential, as is assessment of their ability to maintain their own speech.

In contrast, the vast majority of children on assessment have yet to develop speech and language and, in most cases, any effective communication system. The assessment of the development of these skills, following an effective hearing aid trial, is an essential component of the assessment pathway. A skilled speech and language therapist, experienced in working with the deaf, will assess the child's communication development in the context of their age, developmental and cognitive abilities. Where possible, differentiation between delay and disorder is evaluated, and is used to explore expectations following implantation.

Patient pathway to cochlear implantation

Nationally agreed patient pathways are available on the Department of Health Do Once and Share website: (www.connectingforhealth.nhs.uk/delivery/serviceimplementation/nks/doas), and a simplified pathway is given here in Figure 1.



Current candidature

People with similar audiograms experience different levels of hearing difficulty, because of the complexity of the hearing system. Typically, hearing loss results from damage to the hair cells of the cochlea. However, the extent of this hair cell damage in patients with more severe hearing loss means that simple amplification is not always of benefit, because the receptors are too limited in number, or too damaged, to initiate adequate electrical pulses for the auditory nerve to convey signals to the brain.

Apart from cases such as auditory dyssynchrony (Berlin 2003), therefore, someone with a mild to moderate level of hearing difficulty can benefit from conventional amplification. Conversely, amplification typically provides inadequate benefit to those with profound losses, severe losses may require either amplification or cochlear implantation, and careful individual patient assessment will demonstrate whether hearing aids will suffice, or whether access to the increased audition available through an implant would be required (Haenggeli et al 2006; Fitzpatrick et al 2006; Dowell et al 2006).

The current key issues in candidacy for cochlear implantation are:

i) Relaxation of criteria (audiological and functional hearing)

Driven by sustained improvements in outcomes following implantation over the last 20 years, service providers around the world have relaxed criteria for access to this intervention. The USA guidelines published for individual devices by the Food and Drug Administration (FDA) have continued to relax over time. There has been, to date, no national guidance on criteria for cochlear implantation in the UK. However, the British Cochlear Implant Group is scheduled to issue a position statement on guidelines for cochlear implantation later this year.

Adults:

- In the USA, the FDA has steadily relaxed its adult criteria from 0% recognition of words in sentences to the current level of 50% in the best aided condition, in the ear to be implanted and 60% in the non-implanted ear. This is the level at which the FDA considers the patient receives 'little or no benefit' from hearing aids.
- Patients with greater degrees of residual hearing are receiving benefit from cochlear implantation (Dowell R et al, 2004). In the UK, adult CI service providers have relaxed adult guidelines from a *criteria* of 0% recognition of words in sentences in the earliest days of implantation to the current guideline of 50% in the best aided condition, in the ear to be implanted. Many providers now undertake a probabilistic approach, which incorporates consideration of this absolute value (United Kingdom Cochlear Implant Study Group 2004 c)

Children:

- Whilst it has long been shown that children with profound hearing loss have an improvement in functional hearing following cochlear implantation, there is increasing evidence that selected cases of severe deafness can gain significant and rapid improvements in functional hearing after cochlear implantation (Fitzpatrick et al, 2006; Dettman, et al 2004).
- Patients, particularly children, with additional needs are benefiting from cochlear implantation (see below)

Provision of implantation for patients with complex needs:

- With increased experience and improved outcomes the numbers of patients, particularly children, with complex additional needs has increased.
- Up to 40% of deaf children have at least one additional need, and the improvement in survival rates of premature infants, a co-morbidity of which is frequently deafness, has translated into an increase in referrals for this group in recent years.
- The goal of implantation for such candidates may be an improvement in quality of life for the child and their family. This is a result of the child being better able to monitor their environment and aid communication within their scope for doing so, rather than the possibility of developing spoken language per se. A qualitative study on 20 children with additional needs who had

received a cochlear implant came to the conclusion that ‘all children made communication progress post-implant as described by their families...All families said that if they were to make the decision again, they would choose to have their child implanted’ (Wiley 2005).

ii) Age considerations

It is clear that where cochlear implantation is indicated, implantation should take place as soon as possible (Nicholas JG et al, 2006; Geers AE, 2006; Miyamoto RT et al 2005). Early implantation is associated with highest performance and indeed, there is evidence that congenitally deaf children implanted very early can have speech and language development in the normal range (Miyamoto et al 2005; Geers AE 2006).

In the UK there are no upper or lower age limits for consideration for cochlear implantation. The necessity of hearing evaluation, a hearing aid trial and assessment of functional hearing will necessarily ensure that the youngest a child could receive an implant would be upwards of 4 months of age. In the majority of cases, practicalities have dictated that implantation rarely takes place at less than 9 months in the UK, although streamlining of services to the Department of Health “18 weeks to treatment” target will undoubtedly have a positive impact on this.

iii) Duration of deafness

The duration of profound deafness has been associated with performance post implantation, where outcomes decrease as duration of profound deafness increases. Profound deafness of greater than 30 years has been linked to poorer outcomes for traditional candidates (UK Study Group 2004 b). However, for carefully selected candidates of long duration of deafness, outcomes can be very positive. Here, skilled candidate selection is essential.

iv) Progressive and fluctuating hearing loss

Progressive and fluctuating loss can give rise to a greater degree of difficulty experienced by the patient than the audiogram may suggest at any particular time. The patient has the additional challenges of coping with a changing and deteriorating signal, and these inconsistencies can have a devastating affect on their ability to cope. Patients within these groups require careful multidisciplinary monitoring and intervention in a timely fashion. (Gray RF et al, 2003).

v) Profound unilateral hearing loss

Patients with a profound unilateral loss, or an asymmetric profound/severe loss can also experience high levels of difficulty (see ‘Outcomes of Cochlear Implantation in Children’ section below)

vi) Bilateral cochlear implantation

See section on Binaural Hearing on page 18.

vii) Provision of electroacoustic implants

The principle of electroacoustic stimulation is, essentially, that a hearing aid is combined with a short electrode array cochlear implant. Exploration of this issue is beyond the scope of this appraisal.

Current clinical practice

In 2006/07 the British Cochlear Implant Group (BCIG) undertook an audit of current practise within UK cochlear implant programmes, the key points of which are given below. It is acknowledged that whilst to date there have been no national guidelines for cochlear implantation, clinical practice has been undertaken by a relatively small number of specialist centres in the UK. There is very strong national (and international) professional co-operation and collaboration, and it is the overall view of professionals in the field that whilst wording for the guidelines for individual programmes may vary, there are relatively small differences in practice, and patients would largely expect the same recommendation - whether to implant or not - across the UK.

The aspect in which greater differences have existed in recent times is probably in offering implantation to children with complex needs. Some of the larger programmes with greater numbers, and therefore experience, of the range and extent of such children, have perhaps more readily offered implantation to this group.

The clinical practice audit was undertaken to inform a position statement to be drawn up by BCIG, which is due to be issued in the second quarter of 2007. We request permission to submit this document as a late submission to the NICE Technology Appraisal.

The audit reveals both similarities and differences in the guidelines which UK programmes are currently using. The key points regarding indicators for cochlear implantation, which may be considered to encapsulate a consensus or most common practice, are as follows:

Referral recommendations (children and adults):

All programmes recommend referral of patients with severe to profound hearing loss for assessment for cochlear implantation. Referrals for lower levels of loss are accepted if functional hearing is poor.

Hearing aid trial (children and adults):

All programmes require a valid hearing aid trial to be undertaken, the majority recommending a 3-month trial unless the patient is post-meningitic.

Unaided hearing level (children):

The most common current practice in the UK incorporates a guideline for unaided hearing levels of profound bilateral loss in the high frequencies (>90dBHL at 2 and 4 kHz) with the proviso that all programmes require the flexibility to implant at lower levels for individual patients with poor functional hearing as appropriate. A reliability (test-retest) margin of +/-10dB is applicable in paediatric testing (Hoverstein 1956; Benyon 1995). This is used in conjunction with a multi-disciplinary functional hearing assessment.

Unaided hearing level (adults):

The most common current practice in the UK incorporates guideline for unaided hearing level of severe to profound bilateral loss across the frequency range, typically >90dBHL at 2 and 4kHz, with the proviso that all programmes require the flexibility to implant at lower levels for individual patients with poor functional hearing as appropriate. This is used in conjunction with a functional hearing measure, most commonly a score of <50% correct on BKB sentence testing in the best aided condition.

Aided hearing levels (children and adults):

No programme uses aided hearing thresholds as criterion or guideline for cochlear implantation.

Functional hearing (children):

All programmes concur that they use functional hearing as the primary factor/indicator for implantation.

- Factors include failure to develop, progress or maintain speech, language and listening skills appropriate to age, development and cognitive ability, measured by a multi-disciplinary range of age appropriate assessments and questionnaires. The child should also, likely to benefit from increased access to audition, with increased potential to improvement in linguistic and communication skills. monitoring own environment and psychosocial factors
- The weight of influence of particular components of the assessment of functional hearing on whether to implant or not must be considered on an individual patient basis.

Functional hearing (adults):

All programmes use speech perception testing in conjunction with other assessments, most commonly a score of $\leq 50\%$ correct on BKB sentence testing in the best aided condition with the proviso that all programmes require the flexibility to implant at lower levels for individual patients with poor functional hearing as appropriate.

- Other factors include consideration of probability of benefit from increased access to audition in terms of likelihood of improvement in linguistic skills, communication skills, monitoring own environment, and psychosocial factors.

Additional needs (children and adults):

All programmes state that patients with additional or complex needs are considered on an individual basis, for both children and adults

Age at implantation (children and adults):

No programme has a lower age limit for cochlear implantation in children, nor an upper age limit for adults. Some programmes will impose an upper limit to duration of profound deafness to both children and adults.

Guidelines/criteria (children and adults)

All programmes indicated that their guidelines are continuously evolving in line with developments in clinical experience, technology and peer-reviewed published evidence-based outcomes.

Funding issues (children and adults):

The majority of programmes experience funding problems for patients recommended for CI.

Management of special cases

Ossified cochleae

Special surgical techniques and electrode arrays are available if cochlear obliteration has already occurred by the time scanning is undertaken (Chan CC et al 2007; Miller DA, 2005; Raine, 2005), and to facilitate implantation in cochlear anomalies. However, outcomes may be less good if obliteration has occurred (Anderson et al 2005) and patients require ongoing monitoring (Eshraghi et al 2004). Increased early proactive intervention in the UK following meningitis will minimise this issue.

Cochlear/auditory nerve anomalies

A range of electrode arrays is available, and cochlear anomalies do not necessarily preclude implantation. The absence of cochleae and/or auditory nerves is an absolute contraindication to cochlear implantation, but brainstem and even mid-brain implantation may be considered as an alternative in these cases.

Auditory neuropathy / dyssynchrony (AN/AD)

Auditory neuropathy is a condition in which cochlear function is reflected in the presence of otoacoustic emissions and cochlear microphonics, with absent or atypical auditory brainstem responses and speech recognition skills which are poorer than would be expected by consideration of the audiogram alone (Berlin 2003; Rapin I et al, 2003). This is a complex condition which requires careful individual patient evaluation and monitoring. In some cases, AN/AD can demonstrate some improvement with time. However, many of these children also present with additional medical conditions which can also have an effect on their development. Essentially, the functional hearing as reflected in the development of spoken language, in the context of any other difficulties the child may have, is a key factor in the decision whether or not to implant.

The incidence of auditory neuropathy/dyssynchrony can be as much as 10% of children with language and hearing problems (Berlin 2003). It is therefore essential that access is given to cochlear implantation in cases where functional hearing does not correlate with the pure tone audiogram. Patients with relatively good pure tone audiograms but frank neuropathy/dyssynchrony are benefiting from cochlear implantation (Berlin 2007).

Summary

- Cochlear implant outcomes continue to improve and therefore the criteria for patient selection continue to evolve, including for lower degrees of hearing loss and complex additional needs.
- Assessment for CI must be undertaken on an individual patient basis by an experienced multi-disciplinary team
- Post-meningitic patients should be fast-tracked through the process.
- Selected patients with better residual hearing (severe losses) have proven to benefit from CI.
- The key selection factor for candidature should be functional hearing. The pure tone audiogram does not always reflect the level of hearing difficulty and careful multi-disciplinary assessment is required.
- There are no upper or lower age limits for consideration of candidates.
- There is currently a discrepancy between guidelines for adults and the more stringent guidelines for children.
- BCIG is developing a position statement on guidelines for implantation following a 2006/07 audit of current clinic practice, which will be submitted to NICE for information. Any guideline will necessarily require inclusion of special cases.

Binaural hearing

Introduction

Traditionally patients in the UK have been offered unilateral cochlear implants for the treatment of bilateral hearing loss. However, in recent years there has been an increase in the numbers of patients receiving bilateral implants worldwide. Only a relatively small number of these have been in the UK, despite published peer-reviewed evidence supporting bilateral implantation. A recent survey of all Cochlear Implant Programmes in the UK revealed that Teams are now offering bilateral implants to certain groups of patients, either due to particular clinical need or as part of research studies (Craddock, 2006. See Appendix 4). In addition to the total numbers of bilateral patients shown in the Appendix, 32 children and 11 adults have been implanted bilaterally this financial year.

There is a great deal of evidence to show binaural benefit in normally hearing subjects (Hawley et al, 2004) and also in binaural hearing aid fittings (Noble, 2006). These benefits include the ability to localise sound, improved listening in quiet and in background noise. These binaural benefits are due to the head shadow effect (listening with the ear with the most favourable signal to noise ratio), binaural redundancy (listening when the information is the same in both ears) and binaural squelch (the improvement in signal to noise ratio when listening with two ears) (Koenig, 1950). There has been evidence to show that patients implanted bilaterally can benefit from some of these binaural advantages (Peters, 2006; Tyler et al, 2003 and 2006; van Hoesel, 2004).

Benefits of bilateral implants

The benefits of bilateral implantation over unilateral implantation are shown to include:

- Improved localisation of sound (Schoen et al, 2005; Verschuur et al, 2005 ;Litovsky et al, 2004, 2006a; Laszig et al, 2004; Tyler et al, 2003 ;)
- Improved speech understanding in quiet. (Litovsky et al, 2006b ; Laszig et al, 2004; Tyler et al, 2003)
- Improved speech understanding in background noise. (Litovsky et al, 2006b ; Long et al, 2006; Ricketts et al, 2006 ; Ramsden et al, 2005; Laszig et al, 2004; Tyler et al, 2003)
- Stimulation of both auditory pathways. (Tyler et al, 2003)
- A guarantee that the better performing ear has been implanted. (Stark et al, 2004)
- Improvements in speech and language development in children. (Litovsky et al, 2006c; Kuhn-Inacker et al, 2004)
- Potential for normal central auditory development in children (Bauer et al, 2006; Sharma et al, 2005)
- Improved music appreciation (Kolb and Burnham, 2006).
- Subjective reports of improved sound quality (Summerfield et al, 2006).
- In the event that one device fails, the patient is not left without sound.

This last point is particularly pertinent in children. For example, if a child were to be implanted in infancy with a unilateral implant and then suffer a catastrophic device failure in adulthood, where re-implantation in the same ear was not possible, the consequences would be highly detrimental. Firstly, the individual would return to profound deafness after a lifetime of hearing through the implant. Secondly, the only alternative would be to implant the contra-lateral ear which would have had a long period of auditory deprivation. Research has shown that duration of profound deafness is negatively correlated with outcome (UKCISG, 2004) and so there would be no possibility of restoring the same level of functional hearing with a second device. Conversely, the chances of two simultaneous device failures are remote and so bilateral implantation of children would render this risk extremely low.

Bimodal listening

For some patients, however, there may be an alternative to bilateral implantation. Patients with severe to profound losses, with residual audible hearing on the contra-lateral ear, may be able to benefit from bimodal listening (unilateral cochlear implant plus hearing aid worn on the contra-lateral ear). Research has shown that adults with bimodal hearing benefit from:

- Improved localisation (Dunn et al, 2005 ; Ching et al, 2004)

- Improved speech understanding in quiet (Morera et al, 2005)
- Improved speech understanding on noise (Mok et al, 2006; Kong et al, 2005)
- Improved music perception (Kong et al, 2005)

Children with residual hearing aided hearing in the contra-lateral ear may also benefit from bimodal stimulation:

- Improved localisation (Ching et al, 2006a)
- Improved speech perception in noise (Ching et al, 2006b)
- Improved functional hearing (Ching et al, 2005)

Bimodal stimulation can only be offered to patients, both adults and children, who have sufficient residual hearing in the contralateral ear that can be optimally hearing aided. (NB: Children with severe to profound losses with residual hearing should still be offered cochlear implants since this patient group has been shown to demonstrate improved speech recognition over children with hearing aids alone (Mondain et al, 2002)) Moreover, successful bimodal listening rests on the ability to fuse the two signals (electrical and acoustic hearing) from the two devices (Mok et al, 2006) and this may not always be achievable by some patients.

The negative effects of unilateral hearing loss on the educational achievement of children have long been known (Culbertson and Gilbert, 1986) If profoundly deaf children have a unilateral implant, and are unable to use the contra-lateral hearing pathway due to insufficient residual hearing in the contra-lateral ear, they cannot benefit from any binaural advantages. This may jeopardise their potential academic achievement. Hence, the only alternative for profoundly deaf candidates is to offer bilateral implants, as this is the only way to allow them to benefit from binaural hearing.

Binaural hearing through bilateral implants gives profoundly deaf adults the potential of improved employment prospects and many other psychosocial benefits. Children have the potential of higher educational achievement and a reduced requirement of additional educational support.

On the basis of published evidence and current practice in the UK, the following clinical indications have been identified (Craddock, 2006):

- For all profoundly deaf children in order to stimulate both auditory pathways and optimise speech, language and auditory development and maximise potential academic achievement.
- For all profoundly deaf adults, unable to benefit from bimodal hearing.
- For patients following meningitis or other risk of ossification, where failure to implant may result in obliteration of the cochlea, preventing future auditory stimulation.
- For patients with additional sensory handicap e.g. the deaf-blind, where there is a greater reliance on binaural hearing. Bilateral implantation offers this patient group improved speech understanding in quiet and in noise and also the ability to localise sounds, essential for personal safety.
- For patients who experience a loss of performance in the first implanted ear or deterioration of device function in the first ear but re-implantation in the same ear is contra-indicated. This may be because some residual function remains in the first device that would contribute to performance with a second implant. Other surgical or anatomical factors may also preclude revision surgery in the first ear.
- For patients who agree to participate in research studies into bilateral implantation.

The decision as to whether or not to offer bilateral implants should be made by the Cochlear Implant Team on the basis of a full and thorough assessment and this decision-making process should fully involve the patient / parent.

Cost

Bilateral implantation has significant implications in terms of cost.

i) Surgical costs:

Bilateral implants may be implanted in a single surgical session hence a single in-patient episode (Arnoldner et al, 2005; Cohen, 2004). Indeed, evidence shows that greater benefits are obtained with simultaneous bilateral implantation (Litovsky et al, 2006b). Sequential implantation requires two separate surgical sessions and two separate in-patient episodes, increasing cost and anaesthetic risk. There may be compelling medical/surgical reasons for sequential bilateral implantation but the evidence suggests that the delay between the first and second operation should be less than twelve months for optimum benefit (Kuhn-Inacker et al, 2004).

ii) Device costs:

Manufacturers of cochlear implants may offer significant discounts (typically 25 - 50% reduction for the second implant) on the purchase of two systems for bilateral implantation, which represents a cost saving compared to the purchase of two separate systems.

iii) Clinical costs:

Additional clinic time for programming of two devices and rehabilitation are reflected in the maintenance charged to the funding authority and is typically double the cost for a unilaterally implanted patient. However there is some cost saving in that provision of a contra-lateral hearing aid is not required and there is only one clinical assessment.

iv) Cost-utility:

Data have suggested that the cost-utility ratio per quality-adjusted life-year is £61,734 for simultaneous bilateral implantation vs. unilateral implantation, compared to £16,774 for unilateral implantation vs. no intervention (Summerfield et al, 2002). However, it should be noted that these figures were based on normally hearing volunteers' estimates rather than actual data from bilaterally implanted adults, and do not take account of manufacturers discounts, as shown above. Further clinical trials involving analysis of recent data are required to investigate actual cost utility data from simultaneous bilateral implantation, which also takes into account:

- potential savings within educational budgets as bilaterally implanted children may require less in-class support.
- maximising opportunities for improved educational and thereby employment prospects produces more potential contribution to taxation which is returned to the Treasury
- more recent evidence of improved outcomes associated with developments in implant design and technology

Summary

Bilateral implantation has been shown to offer significant advantages over unilateral implantation as shown above. Bilateral implants are made available for the following patient groups:

- Profoundly deaf patients unable to access binaural hearing via alternative modes
- Patients with meningitis or other conditions involving ossification of the cochlea
- Patients with dual sensory handicap e.g. deaf-blind
- Patients who suffer a deterioration or loss of function in the first ear
- Patients who participate in research studies into bilateral implantation

It is anticipated that indications for bilateral implantation may expand as clinical trials demonstrate the effectiveness, including cost-effectiveness of simultaneous bilateral implantation.

Outcomes of cochlear implantation in children

Introduction

Cochlear implantation has been available for children in the UK for almost 20 years. It is a field which has been well researched and audited and there is a wealth of peer reviewed published evidence demonstrating the clinical effectiveness and increasingly, cost-effectiveness.

Randomised controlled trials (RCTs) do not commonly feature in the evidence, because for cochlear implantation like most other medical interventions, clinical practice has largely been driven by clinical experience. To undertake a RCT for a procedure which is already demonstrating strong benefits for patients is costly and time consuming, and the results are only available after a long time period, at which point the results risk being out of date.

Cochlear implantation is a proven effective and cost-effective intervention in adults, and implanted children receive similar improvements to adults (Tyler et al, 2000; and Hildesheimer 2001). Children with profound hearing loss have significant delays in auditory and linguistic skills, despite best amplification and appropriate interventions (Yoshinaga-Itano C et al 1998 and 2000) and need to be given every opportunity to maximise their auditory potential.

Current clinical opinion/subjective benefits

Practising clinicians, receiving feedback from patients on a daily basis, report the following subjective benefits for cochlear implant patients which may not have had the opportunity to be fully reflected in the literature:

- *Patients with residual hearing can make outstanding use of cochlear implants.*
 - Implanted patients with more residual hearing pre-operatively, can perform better than their deafer peers, make rapid progress, and require less rehabilitation.
- *Adults and children's peers often underestimate the difficulties experienced by deaf children.*
 - Children with asymmetric losses, severe on one side and profound on the other, frequently function disproportionately poorly. These children would benefit from cochlear implantation of the profoundly deaf ear. They have to concentrate very hard to listen, can struggle in school to keep up, and can become socially isolated as they miss out on vital incidental listening experiences and nuances of language. In school and elsewhere, because many of them talk well, their level of hearing difficulty is significantly underestimated.
 - Children who function well with one cochlear implant have the potential to improve with a second device, not only in terms of directional hearing but also in terms of incidental listening which helps a child to monitor their environment and to remain included within the social group. Many of the issues which apply to the asymmetric group above also apply to unilateral cochlear implant users. Auditory deprivation can lead to a decline in the potential to use the ear over time (Silverman CA et al, 2006).
 - ~~Some profound mixed losses (severe sensorineural with a conductive overlay) are permanent as they are not resolvable by surgery or other means. Following careful assessment and selection, some children in this group will benefit from access to cochlear implantation.~~
- *Children with severe complex needs can benefit from cochlear implantation*
 - Parents report that children with severe complex additional needs can experience valuable improvements to their quality of life through use of a cochlear implant. A child with severe cerebral palsy, epilepsy and learning difficulties, for example, who may have additional medical problems, can keep in touch with the environment through their sense of hearing. During the periods of alertness that a child such as this might experience, the improvement in sense of hearing can be extremely rewarding for the child and their family, dramatically improving the quality of life. The numbers of children such as this who have received

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implants have and will continue to be small, and the value of the improvement for the child and family difficult to measure, which is why there is little published research as yet.

Proven benefits/evidenced effectiveness

There is a wide range of proven benefits and advantages for cochlear implantation in children, including:

- *Cochlear implants are extremely well used*
 - Archbold et al (2007), in a UK study to be published this year, have shown a very high rate of use amongst paediatric cochlear implantees after seven years of device use. Only 3% of the 138 children in the study were non-users, in line with Raine et al (2005). Early publications on usage rates showing much less favourable outcomes were on populations from abroad selected in the early days of cochlear implantation. Selection methods in the UK have always been stricter, and certainly current candidacy selection policies are very well refined, resulting in excellent usage rates and improving the cost effectiveness of the intervention.
 - Beadle et al (2005) provide one of the long term outcomes papers available for children with cochlear implants, and indicate that usage rates are high and progress in performance is still developing in the 5 to 10 years post implantation phase, which would suggest that the potential outcomes for cochlear implanted patients have yet to be fully realised.
- *Improved hearing sensitivity:*
 - Detection of environmental sounds, from bird song and background traffic noise to warning sounds (alarms) and school bells. Being able to tell when someone is talking, important for both understanding information and for social inclusion. (O'Donoghue GM et al 1998)
- *Improved functional hearing and communication skills*
 - A large scale study in the UK comparing implanted and non-implanted hearing impaired children, reported improvements in spoken communication skills, educational achievements and quality of life for children who had received implants before the age of 5 years (Stacey PC et al 2006), demonstrating
 - improved speech perception skills
 - improved spoken communication skills
 - improvement to some aspects of educational achievements
 - improved quality of life
- *improved quality of life*
 - Cost utility analysis has been performed in both adults and children to show a favourable comparison of cochlear implants with other life saving devices in terms of improving the implant user's quality of life (Zeng FG, 2004).
 - Cochlear implants are consistently effective in improving the quality of life of people with profound deafness to understand spoken language and to be understood by others when speaking (Summerfield et al, 1995; Stacey PC et al, 2006)
 - Cochlear implants improve quality of life and allow deaf children to learn spoken language, be educated in mainstream schools and could significantly improve their job prospects (Archbold S et al 1997; Francis SW et al 1999)
 - Parents report improved confidence and communication abilities following cochlear implantation (O'Neill et al 2002)

- *improved ability to cope in mainstream school*
 - Nicholas and Geers (2003) looked at the psychosocial adjustment of 181 school aged deaf children who had been using a cochlear implant for between 4 and 6 years. The children and their parents reported that they coped well both in mainstream school and socially, which compared extremely well with earlier literature on adjustment problems in deaf children.
 - Cochlear implanted children are more likely to attend mainstream than hearing aided children of the same degree of deafness (Archbold et al 2002)
 - Language skills of children using cochlear implants are related to the development of their literacy skills, and compares favourably with that of age-matched normally hearing children (Spencer et al 2003). Areas for additional educational focus have been identified in order to help bridge any gaps which can arise.
 - Age at implantation and duration of deafness are significant factors in the ability of a cochlear implanted child to cope in mainstream (Damen et al 2006)
- *improved educational attainment*
 - Stacey PC et al (2006) have shown that, with careful control of variables, some aspects of educational attainment result from cochlear implantation.
 - Improvements in reading ability have been shown in a study in preparation for publication (Archbold et al 2006).
- *outcomes on bilateral implantation of children*
 - see Binaural Hearing section on page 20.
- *early implantation gives the most successful outcomes*
 - Age at implantation correlates significantly with a range of outcome measures. Researchers have considered a number of cut-off ages in comparison of performance outcomes, the overall consensus being that implantation at a young age is safe and offers the best outcome:
 - There is added value in early implantation over and above that attributable to longer lengths of implant use at any given age, suggesting benefit to implantation below the age of 2.5 years (Connor CM et al 2006).
 - Children implanted by 3 can develop auditory and linguistic skills on a par with normally hearing children although, as these children do experience language delay compared to normally hearing children, they benefit from support in order to help them 'catch up' (Geers et al 2003; Tomblin et al 2005). Vocal and auditory preverbal skills develop much more rapidly in children implanted between 12 and 24 months compared to those implanted between 2 and 3, or 3 and 4 years of age, favouring early implantation (Tait et al 2007).
 - Children implanted below the age of 1 have less language delay, so they can more easily and rapidly attain language skills comparable to their normally hearing peers (Colletti 2005).
 - Performance outcomes depend on a great number of variables and Harrison (2001) points out that it is most important to consider patients on an individual basis.
 - Cochlear implantation has been shown to be safe, including for babies younger than 12 months of age. (Waltzman SB et al 2005).
- *children deafened by meningitis require special consideration*
 - Children deafened by meningitis are at risk of developing bony growth within the cochleae, which can impede insertion of an electrode array such that either implantation becomes

impossible, or only a reduced number of functioning electrodes can be inserted. Performance can be significantly compromised in the latter situation.

- Early implantation is of paramount importance for this group to optimise outcomes.
 - Bilateral implantation is recommended for this group, as the potential for bony growth to develop and obliterate the opposite ear (thereby rendering it unavailable for future treatment) is overcome.
 - Congenitally deaf children outperform pre-lingually deaf children deafened by meningitis, such that advantages of hearing prior to the meningitis are negated by the adverse effects of the illness (Gantz 1994).
- Children with auditory neuropathy/dyssynchrony can benefit from cochlear implantation
 - Children with these diagnoses can do very well with cochlear implants, and have a range of outcomes post-implantation as the general CI population (Buss et al, 2002) Mason et al 2003; Peterson et al 2003; Shallop J, 2001).
 - A recent study of 260 patients (Berlin 2007 awaiting submission) states that cochlear implantation has been valuable in patients with a range of hearing loss, including some with near-normal audiograms with frank neuropathies. Some patients have not required such treatment and individual patient assessment is required.
 - *Children with additional needs benefit from cochlear implantation*
 - Multiple disabilities
 - Children with additional needs, eg multiple handicaps, can benefit from CI, with increased performance compared to the best hearing aided condition (Waltzman 2000; Hamzavi 2000)
 - Greater degree of developmental delay is associated with a lower performance outcome with a cochlear implant in terms of speech perception and speech intelligibility (Edwards LC, 2006), although significant benefits may be achieved with regard to environmental sound awareness and ease of communication. It is particularly important that appropriate goals and expectations are established prior to implantation for this group.
 - Multiply handicapped children obtain demonstrable benefit from implantation, with no increase in surgical complications, although the rate of growth of perceptual skills is slower than for those with no additional difficulties (Waltzman et al 2000)
 - Multi-sensory impairment (Deaf-blind)
 - A recent study has shown an increase in the quality of life of both adults and children with Type 1 Usher syndrome (Damen et al 2006), particularly with regard to the hearing related items. These patients tend to be able to live more independently than non-implanted patients.
 - Post-meningitic (see above)
 - *Paediatric cochlear implantation is cost-effective, and current publications on this subject may underestimate the cost-effectiveness for today's candidates*
 - Cochlear implantation has been shown to be cost effective for profoundly deaf children (Barton et al 2006). There are limitations to this cost-utility analysis, inasmuch as the population considered were 'traditional' candidates with a higher age at implantation than current candidates. The outcome cannot necessarily be reliably extrapolated to today's candidates as it reflects clinical practice some 5 to 10 years ago and does not reflect improved outcomes associated with improvements in devices and speech processing strategies and earlier implantation.
- ## Summary
- Cochlear implant outcomes continue to improve and therefore the criteria for patient selection continue to evolve, including for lower degrees of hearing loss and complex additional needs.
 - Selected patients with better residual hearing (severe losses) have proven to benefit from CI.

- Children with complex additional needs have proven to benefit from CI.
- Cochlear implants are clinically effective in adults and children with severe to profound hearing loss.
- Cochlear implants can provide significant improvement to quality of life
- Cochlear implants can improve the ability to cope in mainstream education and are related to improvement in some educational attainment
- Early implantation and short duration of deafness are associated with best outcomes.
- Implantation of young babies is safe and effective.
- Cochlear implants are cost effective in adults and children.

Outcomes of adult cochlear implantation

Introduction

Traditionally, cochlear implants were only offered to adults with a profound to total deafness who received no benefit from conventional hearing aids. However, scientific evidence now indicates that people with significant residual hearing (severe to profound deafness) who obtain some benefit from acoustic hearing aids pre-operatively may also benefit greatly from a cochlear implant (Cullen et al, 2004; Dowell et al, 2004; Lowther et al, 2006; UK Cochlear Implant Study Group (UKCISG) 2004a). Outcomes of cochlear implantation have changed significantly since their widespread application has become established over the last twenty years or so. Technological improvements in design, including refinement of electrode designs and speech processing, have led to steady gains in the performance and benefit that cochlear implant users can expect to receive (Hochmair et al, 2006; Copeland and Pillsbury, 2004) Significant improvements in speech reception scores attributable to the implementation of new speech coding strategies over recent years have been well documented (David et al, 2003).

The cochlear implant recipient is able to contribute to society, both economically and functionally. The outcome benefit associated with cochlear implantation has been the subject of many reports that show the enhanced achievements of young cochlear implant recipients in hearing, speech and language, relative to their non-hearing peers. This performance improvement extends to post-lingually deafened adults where benefits are evident in the form of enhanced educational attainments, greater social versatility and robustness, and an increased quality of life (Sanderson and Nash, 2001).

Subjective benefits

In adults, there is a wide range of advantages and disadvantages that implant users actually perceive they obtain from their device (Tyler, 1994). The largest proportion of implant users (86%) reported 'speech reception when speechreading (lipreading) can be used' as an advantage. In decreasing order of the percentage of respondents reporting them, the other advantages listed included:

- environmental sound perception (79%),
- psychological effects (49%),
- speech perception when speechreading cannot be used (56%),
- lifestyle and social effects (40%),
- speech production (14%),
- reduction of tinnitus (7%).

Performance levels now have improved significantly since 1994 and particularly with regard to 'speech perception when speechreading cannot be used'. Other reported benefits include improved confidence when lip-reading or reduced tinnitus (Yonehara et al, 2006; Ruckenstein et al, 2001). This is particularly significant when tinnitus was a major problem pre-operatively. Removal of this distressing and psychologically disturbing symptom can in itself provide a huge improvement in quality of life for many implant users (Cooper, 2006).

Proven benefits/efficacy

There is a wide range of benefits of a correctly inserted and programmed cochlear implant, beginning with the detection of environmental sounds. (Padilla Romero et al, 2006) The threshold level of sounds detected tends to vary little between implant listeners and depends on the setting of the sensitivity control or in the input dynamic range of the system, which in the current systems is up to 90dB. Detection of sounds is only the pre-cursor of discrimination, recognition, and comprehension of speech and other sounds, and it is at these progressively higher levels of the process of auditory perception that variability between implant users is observed. Despite the wide range of potential benefits, outcomes from implantation are very often measured only in terms speech discrimination in quiet. Any effort to measure comprehensively the overall benefit from an implant must also include the evaluation of the other areas (Cooper, 2006).

The actual measured benefits from cochlear implantation as reported in the literature include:

- Improvement in sound field thresholds (Firszt et al, 2004)
 - Improved environmental sound awareness (Padilla Romero et al, 2006; Firszt et al, 2004)
 - Improved speech recognition in quiet (Mosnier et al, 2006; Nie et al, 2006 ; Cullen et al, 2004 ; Dowell et al, 2004 ; Firszt et al, 2004)
 - Improved speech recognition in noise (Chatelin et al, 2004; Koch et al, 2004 ; Spahr and Dorman, 2004; Frijns et al, 2003; Parkinson et al, 2002)
 - Benefit to lip-reading/communication (Moody-Antonio et al, 2005)
 - Improved speech and language development (Beadle et al, 2005)
 - Improvements in speech production (Evans and Deliyiski, 2006; Szyfter et al, 1996)
 - Reduction of tinnitus (Yonehara et al, 2006; Ruckenstein et al, (2001)
 - Improved enjoyment of music (Gfeller et al, 2005; Leal et al, 2003)
 - Higher educational achievements (Beadle et al, 2005)
 - Improved employment prospects (Kos et al, 2006; Hogan et al, 2002)
 - Positive changes in quality of life (Wanscher et al, 2006; Mo et al, 2005; UKCISG, 2004b;)
 - Psychological well being (Knutson et al, 2006; Padilla Romero et al, 2006)
 - Telephone use (Anderson et al, 2006a; Castro et al, 2006)
 - Preservation of residual hearing (Frayssse et al, 2006; James et al, 2005; Parkinson et al, 2002)

Predictive factors

Many studies have attempted to calculate the predictive value of pre-operative variables in adults and the factor with greatest predictive value is the duration of profound deafness. A longer duration of deafness, in terms of the percentage of a person's life, is usually associated with poorer speech recognition outcomes in adults (UKCISG 2004a; Geier et al, 1999; Rubinstein et al, 1999; Van Dijk et al, 1999; Blamey et al, 1992). Adults who had been deaf for more than 60% of their lives require longer to achieve their optimum performance (Geier et al, 1999).

Older adults

Statistics reveal that the number of people over 65 is increasing in the UK (Office for National Statistics). The number of older adults with a severe to profound sensorineural hearing loss receiving minimal benefit from hearing aids who could benefit from a cochlear implant is rising due to ageing, awareness of implants among the medical and general population and technological advances. A major problem is the impact of a hearing loss on their participation in family and community life, on their ability to communicate with others, and to continue to live independently (Pedley et al, 2003). In one study, the presence of a measured hearing loss after age 60 was associated with more than a doubling of reported community service use (Mitchell, 2002).

The benefits of implanting older adults with a severe to profound hearing loss include the maintenance or resumption of paid or voluntary employment, financial gains for both the individual and the society through prolonged independent living, improved social interaction and a correlation with improved general health (Anderson et al, 2006b; Chatelin et al, 2004; Pedley et al, 2003; Sanderson et al, 2001).

Cost-effectiveness

There is robust evidence to show that cochlear implantation is a cost effective treatment for severe to profoundly deaf adults (UKCISG, 2004b; Cheng et al, 1999). This also includes adults over the age of 70 provided the duration of profound deafness is less than 40 years. Averaged over the whole cohort, UKCISG found the cost of gaining a QALY was €27,142. Cheng et al performed a meta-analysis on published data from a Medline literature review from 1966 to 1999. Analysis of Quality of Life data indicated an average cost per QALY of \$12,787. These two papers indicate that cochlear implantation is highly cost effective, restores half the health utilities lost as a result of profound deafness and that this treatment compares favourably with other medical interventions.

Safety and Risk

Risks of cochlear implantation

The risks of cochlear implantation can be surgically/medically or device related:

i) Surgically related risks

Surgical complications resulting directly from the operation may occur but have been steadily decreasing in frequency over time in both children and adults (Cohen et al, 2004).

o *Facial nerve damage*

This is very rare in the hands of an experienced surgeon. Facial weakness is uncommon, and is usually transient. Use of facial nerve monitoring during surgery minimises potential risks of facial nerve damage.

o *Taste disturbance*

This is an uncommon report, of course not reported by young children, and tends to resolve a few weeks after surgery. It is rarely permanent.

ii) Medically related

Medically related problems are those problems which occur that are not directly related to the surgery itself.

Major complications may be in the early post-operative period or occur later. They include:

o *Infection of the wound or implant*

This includes the risk of otitis media which may lead to infection of the implant either outside the cochlea or within the inner ear. Major complications may be in the early postoperative period or occur later.

o *Flap related problems*

Although this will typically resolve with treatment, in the worse case scenario the device needs to be explanted, with re-implantation once the infection has resolved.

o *Cholesteatoma formation.*

o *Risk of meningitis*

Meningitis may develop subsequent to surgery, although the incidence is extremely low (Summerfield et al 2005). The Department of Health have issued a vaccination protocol for all patients undergoing implantation in order to minimise this risk.

Minor complications, which are all resolved on appropriate treatment, include:

- o Minor wound infections
- o Haematoma
- o Pain
- o Vestibular upset

The United Kingdom experience audit shows an overall incidence of flap related problems to be 2.1% in adults but with only 0.6% requiring surgical intervention. In children, the figures are 2.4% with 1.2% requiring surgery (Gibbin et al. 2003). Cunningham et al (2004) also quote a major infectious complication rate of 3% in their series of 733 implants. These results show that 0.29% of patients required explantation with a functioning device.

Surgical/medical complication rates can be kept to a minimum in a number of ways:

- Careful pre-operative assessment including appropriate radiology.
- Surgical expertise and experience.
- Training, mentoring and appropriate support for surgeons new to cochlear implant teams (Cohen et al, 1988; Wang et al, 1990; Gibson et al, 1991).
- Awareness of surgical developments which may help reduce complication rates.
- Incorporation of appropriate technological support e.g. Facial nerve monitoring.
- Careful follow-up in order to identify problems early and prevent progression.

- Prompt attention to any potential surgery or device related symptoms. Correct device placement and function can be assessed intra-operatively prior to wound closure via Neural Response Telemetry / Imaging.
- Careful and full liaison between surgeon and anaesthetist.

iii) Device related

Potential device-related complications include malfunctions and failures.

- Failure may be total or partial and may be design/manufacture related or due to trauma, the latter more likely in children.
- Device malfunction occurs when the implant is no longer working within manufacturer's specification, and the fault may or may not be detectable by the user.
 - Devices with minor malfunctions, such as an electrode failure, can be reprogrammed with no/very little loss of performance by the patient. These issues are usually only detected by careful monitoring of the devices on a regular basis by specialist audiology staff (Twomey et al 1997). Pro-active management will minimise the potential for the patient to experience any adverse effects.
 - Devices developing major faults, such that have a significant affect on patient performance or risk of discomfort, will require removal and replacement with a fully function device.

Device failure

Device failure has been the most likely reason for re-implantation. However, recent data from the BCIG audit (BCIG Service Audit 2007) show an annual re-implantation rate for device failure to be 0.35% and for infection and other patient related causes to be 0.31%. Device failure should not be considered as a surgical complication, the cause rarely being surgical mismanagement. In the UK up to 1997 device failure was 2.8% in adults and 2.1% in children (Gibbin et al, 2003). In a series of more than 900 implants from 1985-2003, Lassig et al (2005) noted a device failure rate of 3.7%. In the UK during the course of this financial year 0.35% of all implants failed (BCIG Audit 2007).

Together with device failure, this audit shows there is a potential 0.6% annual re-implantation rate in any implant centre. This has implications for Programmes in planning service delivery. BCIG advises that Cochlear Implant Programmes take account of the resources required to manage such issues in strategic planning of services, in terms of workload and capacity planning.

Re-implantation

Experience has shown that re-implantation is safe and effective (Raine et al, 2004; Woolford et al, 1995) although other studies have shown variable post re-implantation performance, e.g. Henson et al (1999) who also noted that patients need careful counselling regarding the possibility of differences in sound quality and speech recognition performance with the replacement device.

Reporting of device problems

All explanted devices are returned to the manufacturer for formal evaluation and a report ultimately issued on the status of the implant and if appropriate the cause of failure. At the same time as reporting to the manufacturer a report is also sent to the MHRA (Medicines and Healthcare products Regulatory Agency). For further information please refer to the section on Quality Standards on page 31. The MHRA also encourage reporting of more minor problems so that they can collate such information and alert to issues if the evidence so requires.

Risk of non-use

The non-use of implants reported by centres equates to 1.3% in children and 3.0% in adults (BCIG Audit, 2007). There are various factors related to non-use.

- Surgical
 - Related to explantation because of either device failure or medical reasons.
- Non-surgical

- Related to co-morbid illness; elective non-use without obvious reason; audiological complication (Bhatt et al, 2003).

Archbold et al (2007) have shown very good usage rates of cochlear implants in a recent UK audit (see 'Outcomes in paediatric cochlear implantation' section on page 23. Furthermore, internal audit from one centre on non-use in children identified that patient selection in the early stages of their programme and appropriate educational placement was relevant.

Contra-indications to cochlear implantation

There are few absolute medical contraindications to CI in either children or adults and, even in patients with established systemic disease, implantation can be undertaken successfully with minimum risk. Factors to consider are:

- *Medical fitness*
Medically the most important criterion is the absence of significant life limiting disease and the patient should be fit enough to undergo a lengthy operative procedure; surgery can be undertaken under local anaesthesia (Toner et al, 1998) in special cases of need.
- *Absence of the cochleae or auditory nerves*
The absence of cochleae and/or auditory nerves is an absolute contraindication to cochlear implantation, but brainstem and even mid-brain implantation may be considered as an alternative in these cases. Cochlear implantation requires the presence of a functioning auditory nerve on the side to be implanted.

Extremes of age are not a contraindication to CI but both require careful preoperative evaluation and intra-operative management (James et al, 2004; Watson et al, 2003). For further information on age issues please see the section on 'Current Candidature) on page 15.

Summary

- Cochlear Implantation is deemed a very safe procedure with low surgical and medical complication rates.
- Cochlear implants themselves are safe medical devices, which have been researched extensively.
- Good clinical governance requires that relevant and up to date information be provided to patients/parents about both risks and results at the time they are required to make an informed decision about going ahead with surgery. All CI programmes maintain a detailed database to record *inter alia* surgical complications and outcomes to aid this process.
- Risks of surgery may be device related or medical/surgical.

Access to care and future demand

Contracting

Just over 50% of centres are actively involved in negotiations with their commissioners and contracting services. Funding is variable ranging from a core service agreement with additional activity on a case-by-case basis to individual cost by case purchasing requests. Some funding authorities have refused funding for any assessments, some for surgery and others place long delays in their decision making process. This has been colloquially termed 'post code' treatment since access to cochlear implantation varies throughout the UK.

Referral sources

Approximately two-thirds of referrals originate from ENT Consultants with the remainder from Community Paediatrics, Audiological Physicians, General Practitioners or other Hospital Specialities.

Access to first outpatient appointment

Once funding is agreed the median time for first appointment is 6 weeks for paediatrics (range 0 – 12 weeks) and 6 weeks for an adult (range 4 – 12 weeks).

Assessment

Audits indicate the process typically takes approximately 8 months from initial agreement to assess the patient, to surgery. The key issue is that patients are assessed individually; some patients present with more complex needs and this may prolong the assessment to allow for further evaluations. Cases presenting with a history of meningitis are fast tracked so that surgery, if appropriate, can be performed within a few weeks of referral, and hence prior to potential ossification of the cochlea.

Population under assessment (Appendix 1)

At the time of the audit (BCIG Audit March 2007) there were on average 26 children under assessment (range 2 – 82) and 40 adults (range 9 – 80) per implant Team.

Future demand (Appendix 3)

Based on current figures, estimates have been made of future demands for capacity planning and development of services. The implications of the introduction of the "18 week to treatment" initiative will be addressed by individual units.

Historically there have been two populations of patients: a) adults who have been post-lingually deafened seeking assessment and treatment and b) patients recently diagnosed with severe/profound hearing losses. These encompass pre- and peri-lingually deaf children, and teenagers and adults with acute loss or slowly progressive losses who no longer gain sufficient benefit from their hearing aids. Based on the assumption that about 25% of severely deaf people may benefit from an implant, this equates to approximately

300 patients per annum (0 - 3 years)
325 patients per annum (4 – 16 year olds).
1620 + adults > 16 years

Approaching 680 patients will have been implanted unilaterally and 44 bilaterally this financial year. More accurate surveillance and estimate of requirements are clearly needed. There are similar numbers of children undergoing assessment.

Unmet demand is reported by 57% of units with 10% unable to assess and 33% felt that supply and demand was balanced. Some of the reasons given for unmet demand;

- Recognised low level of referral
- Restriction in funding to allow patient access
- Refusal by some commissioners to support adult implantation
- Delays by commissioners in granting approval to assess or treat

Information concerning BCIG audit can be supplied in confidence upon request.

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RNID - Cochlear Implant market situation analysis, 2006.

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Appendix 1

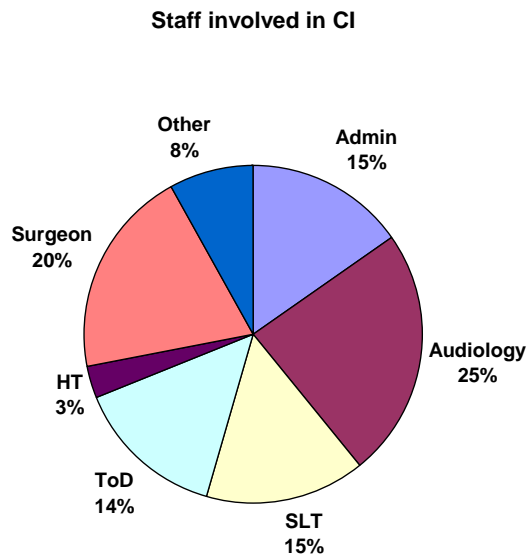
BCIG Service Audit 2007: Cochlear Implant centres within the UK – data

	Adult = A Paediatric = P	Total Registered		Current yr Implanted		Under Assessment		Waiting time 1 st OPD	
		P	A	P	A	P	A	P	A
ENGLAND									
Birmingham **	A + P	197	377	40	34	31	32	4	14
Bradford	A + P	188	179	34	23	57	37	7	7
Bristol **	A + P	102	129	20	21	20	75	6	4
Cambridge	A + P	191	248	27	3	23	0	2	2
London Hospitals:									
GOS	P	242		32		15		11	
Portland	A + P	106	1	18	1	2	3	0	0
RNTNE	A + P	130	530	26	46	8	50	6	6
St George's	P	4		6		8		4	
St Thomas's	A + P	120	167	14	4	31	23	12	12
Manchester **	A + P	372	400	47	43	65	80	5	4
Middlesbrough / Newcastle	A + P	116	117	14	4	31	23	4	4
Nottingham **	A + P	595	120	51	17	82	63	6	6
Oxford	A + P	50	49	9	3	11	9	4	4
Southampton	A + P	186	157	36	22	32	39	4	4
NORTHERN IRELAND									
Belfast	A + P	110	122		14	17	28	12	12
SCOTLAND									
Kilmarnock	A + P	250	250	32	18	33	18	6	6
WALES									
Bridgend	A + P	26	43	3	2	4	12	5	5
Cardiff **	A + P	46		5		8		1	
North Wales	A		102		20	23		6	
TOTAL		3031	2991	414	275	501	492		

** = separate adult and paediatric programmes.

Appendix 2

| BCIG Service Audit 2007: Staff employed in Cochlear Implant Programmes



Glossary;

HT = Hearing Therapists

ToD = Teachers of the Deaf

SLT = Speech and Language Therapists

Audiology = Audiological scientists

Other = Audiological Physicians, Medical Physics, Family Liaison officers, Clinical Psychologists, Paediatricians, Deaf Advocate

Whilst there are a number of part-time staff the work force equates to nearly 260 WTE staff who are involved with specialist service delivery for paediatric and adult care within the UK.

Recruitment, training and retention are a concerns expressed by most centres, especially in audiology.

Appendix 3

Rate of Cochlear Implantation within the UK up to 2005

Figure 1: Cochlear implantation in Adults

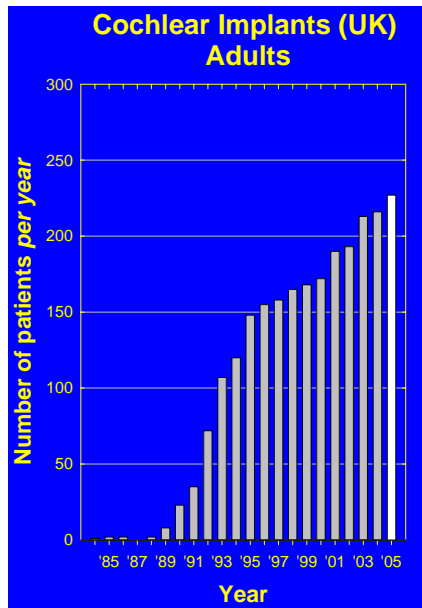
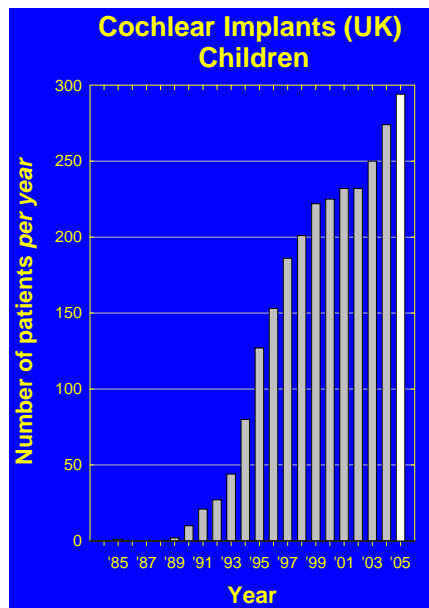


Figure 2: Cochlear implantations in Children



Source www.ibr.mrc.ac.uk

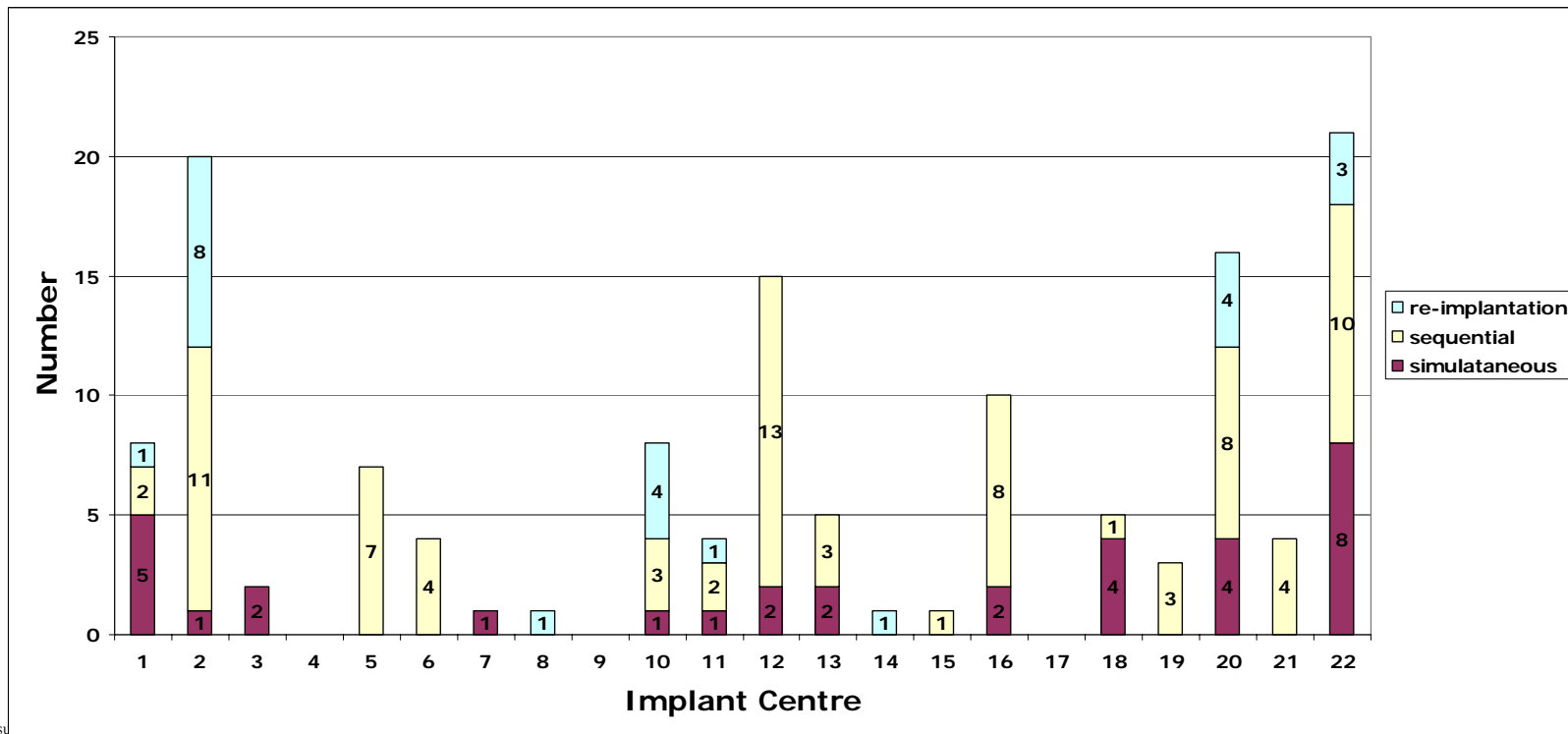
Appendix 4:

Bilateral implantation in the UK: cases per Team to April 2006.

Re-implantation: the patient has been re-implanted in the second ear either because surgery in the first ear was contra-indicated or because residual function of the first device would contribute to the benefit from a second implant.

Sequential: the patient received bilateral implants in two separate surgical sessions, sometimes several years apart.

Simultaneous: bilateral implantation done in the same surgical session.



Appendix 5 Prevalence and Patient Opportunity

Understanding the prevalence of permanent childhood bilateral hearing loss is important. Fortnum *et al*, (2001) reported on a cohort of patients and identified the degree of hearing loss / 1000 live births (table 1). One clear issue is that hearing loss among children is progressive with over doubling the prevalence by the time they reach their early teens.

Table 1 Fortnum et al

Degree of Hearing Loss	Cohort 3 year olds	Aggregate 9 -16 year olds
Severe (71 – 95 dB HL)	0.22 / 1000	0.41 / 1000
Profound (>95 dB HL)	0.27 / 1000	0.44 / 1000

Based on population statistics the total UK population 2004 = 59.7 million / 2005 = 60.0 million <http://ec.europa.eu/eurostat/>

Table 2 -Analysis of 0 – 3 year olds

	2004	2005
UK population 0-3 years	2,697,000	3,030,000
Severely deaf (0.22 / 1000)	593	666
Profoundly deaf (0.27/ 1000)	728	818
Potential CI patients 25% of severely deaf	148	166
Potential patient population	876	984

Based on the assumption that about 25% of severely deaf people with hearing loss > 85 dB HL may benefit from an implant equates to approximately 300 patients per annum

Table 3 - Analysis of 4 – 16 year olds

	2004	2005
UK Population 4 – 16 years	9,767,000	9,725,000
Severely deaf (0.28 / 1000)	2735	2723
Profoundly deaf (0.33/ 1000)	3223	3209
Potential CI patients 20% of severely deaf	684	681
Potential patient population	3907	3890

With approximately a further potential 325 / year in this older age group.

The assessment of prevalence within the adult population is significantly more difficult to assess with any accuracy. The RNID calculated that in the population 16 – 60 there are 108,000 with severe / profound deafness in the UK. With a further 580,000 > 60 years old.

Within the younger group it is thought that 33% would use sign language.

If there is an assumption that the 'backlog' has been treated then there is a crude estimate of some 1,620 patients / year. 268 adults have had surgery this year and an estimated 513 undergoing assessment.

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RNID - Cochlear Implant market situation analysis, 2006.

http://www.rnid.org.uk/mediacentre/key_rnid_facts/facts_and_figures_about_deafness_and_tinnitus/

Economic and outcome analysis of non-use among CI patients

C Raine, Q Summerfield¹, D Strachan, J Martin, C Totten

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¹*University of York, UK*

Objective Analysis and economic impact of non-use of cochlear implants.

Method: Of 340 implant patients treated between 1990 and 2005, 12 children and 2 adults are classified as non-users. Collation of clinical files was used to construct life table of use and assess the reason for becoming a non-user.

Results: Life table shows that majority of children use their implant for 4 years with a probability of 0.7 using their devices over 11 years. The 2 adults soon stopped using their implant because of psychological issues or lack of enjoyable stimulation.

Economic analysis shows that initial costs are high reflecting the surgery and implant costs. Subsequent years reflect programming issues and maintenance. When considering non-use there are two effects, first, no more costs are incurred and second, no more years of use are accumulated once a child has become a non-user. Thus non-use reduces both costs and years.

There are two methods of comparing costs. Costs of gaining a year of use as a function of time, shows that there little impact from the twelve non-users on the average cost of management. As a ratio of no non-use and observed non-use – the ratio is 1.07 by 13 years of implantation.

Conclusion: The non-use has added 7% to the average cost of implanting and maintenance. Audit identifies that initial patient selection in the beginning of the programme was in retrospect an important issue and following comprehensive assessment with the Children's Implant Profile significantly reduced non-use. Unfortunately, the adults were not identifiable before surgery.

Presentation CI Conference Vienna 2006 (Based on internal audit 2005).

Economic analysis of non-use among children implanted in the Yorkshire Paediatric Cochlear Implant Programme

Summerfield Q, Raine C, Martin J YCIS Internal audit 2005

- 1.1 One hundred and fifty five children were implanted in the Yorkshire Paediatric Cochlear Implant Programme between 1st August 1991 and 28th February 2005. For each child, we have three pieces of data: the date of implantation, whether the child was a user or a non-user on 28th February 2005, and, if the child was a non-user, the number of years for which the child used the implant. Among the 155 children there were 12 non-users.
- 1.2 First, we conducted a survival analysis using SPSS v 12.0.1 with the Life Tables method. This analysis estimated the proportion of the sample of children who remained users at the end of each year following implantation. Figure 1 shows the results. The heights of the grey bars are the best estimates of the proportion of children in the programme who are still using their implants at different times after implantation. The available data include many children who have had the opportunity to use their devices for at least a short period of time, but fewer children who have had the opportunity to use their devices for a long period of time. Accordingly, the confidence intervals on the estimates, shown by the error bars, are smaller for short intervals than long intervals. The data show that nearly all children continue to use their devices for the first 4 years after implantation, but that a smaller proportion of about 0.7 continue to use their devices for 11 or more years.

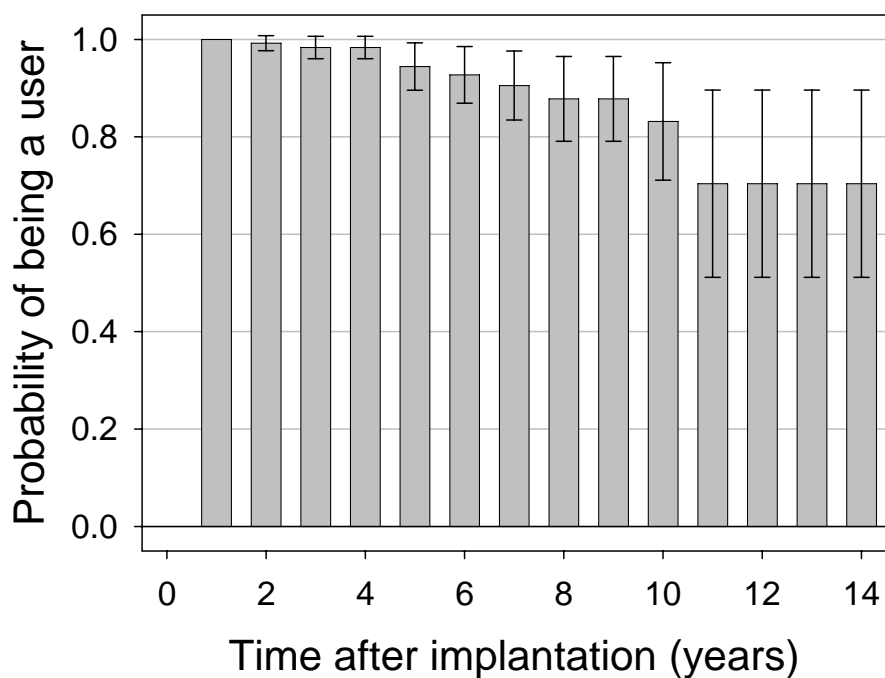


Figure 1: Cumulative probability of children being users of an implant at different times after implantation. Error bars are 95% confidence intervals.

The second analysis used the data in Figure 1 to estimate the impact of non-use on the cost of gaining a 'year of use'. *First, consider what the cost of gaining years of use would be if there were no non-use.* The phases of management and the charges levied by the Yorkshire Programme are listed in the first two columns of Table 1. We use the charges as a proxy for the costs of provision, assuming that charges are set to cover costs but not to make a profit. The cumulative cost is listed in the third column and the cumulative years of use are listed in the fourth column. Note that costs are incurred in assessment and implantation, but no years of use are gained until the end of the first year following implantation. Costs are highest in the early years. Therefore the cost of gaining a year of use is highest early on, but declines as more years of use are accumulated.

Table 1

Phase	Cost	Cumulative cost	Cumulative years of use	Cost of gaining a year of use
Assessment	£1197			
Implantation	£26049	£27,246.00	0	
1 st year of use	£4805	£32,051.00	1	£32,051.00
2 nd year of use	£3415	£35,466.00	2	£17,733.00
3 rd year of use	£2888	£38,354.00	3	£12,784.67
4 th year of use	£2888	£41,242.00	4	£10,310.50
5 th year of use	£2888	£44,130.00	5	£8,826.00
6 th year of use	£2888	£47,018.00	6	£7,836.33
7 th year of use	£2888	£49,906.00	7	£7,129.43
8 th year of use	£2888	£52,794.00	8	£6,599.25

9 th year of use	£2888	£55,682.00	9	£6,186.89
10 th year of use	£2888	£58,570.00	10	£5,857.00
11 th year of use	£2888	£61,458.00	11	£5,587.09
12 th year of use	£2888	£64,346.00	12	£5,362.17
13 th year of use	£2888	£67,234.00	13	£5,171.85

1.3 Now we consider the corresponding calculation that takes account of non-use. The results are shown in Table 2. Non-use has two effects. First, (in this simple analysis, at least), no more costs are incurred by the Programme once a child has become a non-user. Thus, non-use lowers costs. Second, however, no more years of use are accumulated once a child has become a non-user. Thus non-use reduces both costs and years of use.

Table 2

Phase	Proportion completing phase	Cost	Cumulative cost	Cumulative years of use	Cost per year of use
Assessment	1.0000	£1,197.00			
Implantation	1.0000	£26,049.00	£27,246.00	0	
1 st year of use	0.9922	£4,767.52	£32,013.52	0.9922	£32,265.19
2 nd year of use	0.9833	£3,357.97	£35,371.49	1.9755	£17,905.08
3 rd year of use	0.9833	£2,839.77	£38,211.26	2.9588	£12,914.45
4 th year of use	0.9442	£2,726.85	£40,938.11	3.9030	£10,488.88
5 th year of use	0.9271	£2,677.46	£43,615.58	4.8301	£9,029.95
6 th year of use	0.9052	£2,614.22	£46,229.79	5.7353	£8,060.57
7 th year of use	0.8778	£2,535.09	£48,764.88	6.6131	£7,373.98
8 th year of use	0.8778	£2,535.09	£51,299.97	7.4909	£6,848.30
9 th year of use	0.8316	£2,401.66	£53,701.63	8.3225	£6,452.58
10 th year of use	0.7037	£2,032.29	£55,733.91	9.0262	£6,174.68
11 th year of use	0.7037	£2,032.29	£57,766.20	9.7299	£5,936.98
12 th year of use	0.7037	£2,032.29	£59,798.48	10.4336	£5,731.34
13 th year of use	0.7037	£2,032.29	£61,830.77	11.1373	£5,551.68

1.5 Figure 2 is a plot of the cost of gaining a year of use as a function of the number of years after implantation. The solid line shows the results of the first calculation, assuming no non use. The dotted line shows the results of the second calculation that was based on the pattern of non-use summarised in Figure 1. Note that the two lines do not differ very much. This is telling us that there is relatively little impact from the 12 non-users on the *average* cost of managing a child.

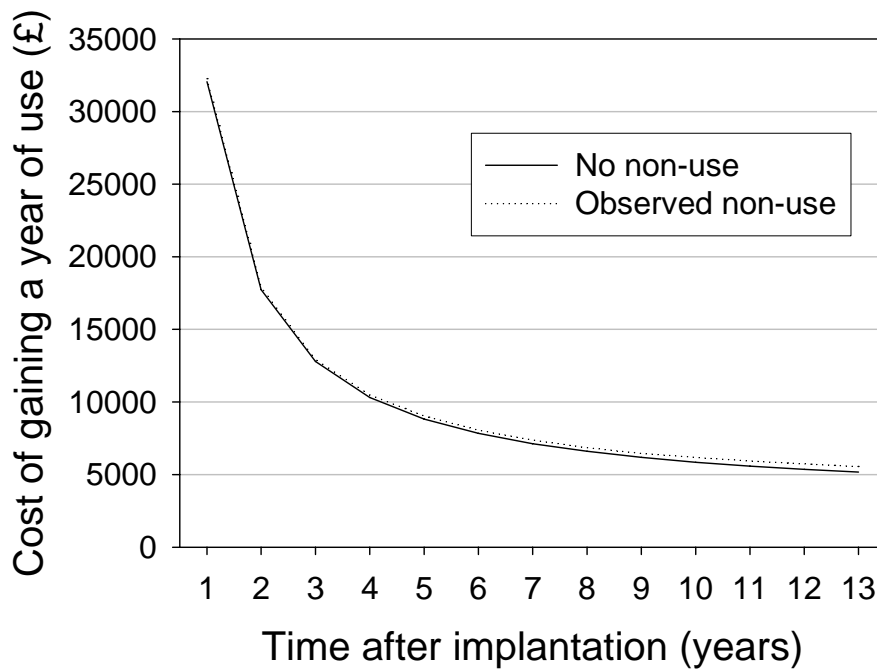


Figure 2: The cost of gaining a year of use as a function of time after implantation assuming no non-use (solid line) and the pattern of non-use shown in Figure 1 (dotted line).

1.6 The impact of non-use is shown in a different way in Figure 3 which is a plot of the ratio of the dotted to the solid line in Figure 2. The ratio has risen to 1.07 by 13 years after implantation. In other words, by 13 years after implantation, non use has added 7% to the average cost of implanting and maintaining a child.

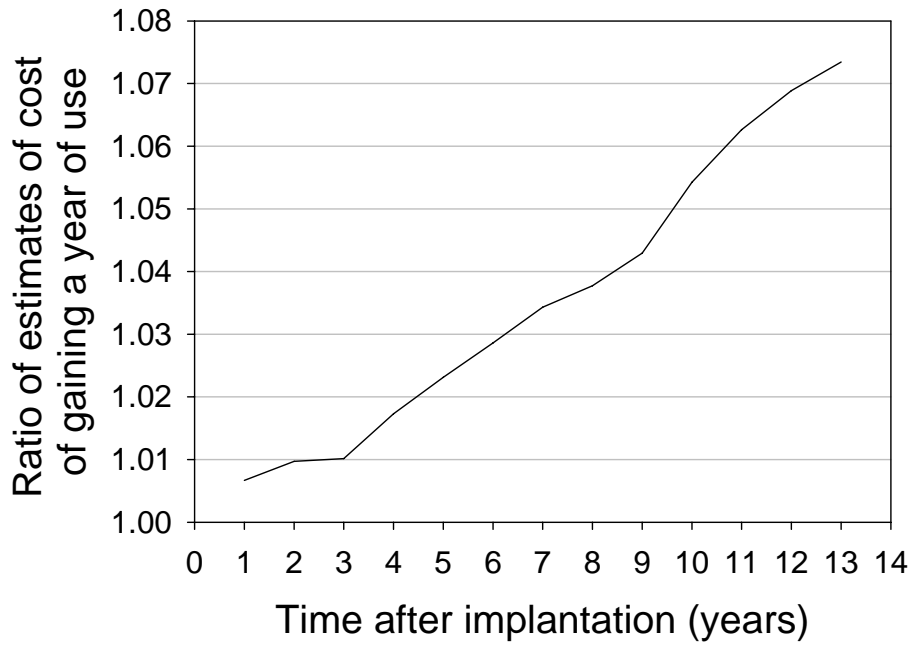


Figure 3: Ratio of the cost of gaining a year of use between the situation with the observed pattern of non-use summarised in Figure 1 and an alternative scenario in which there is no non-use.

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