

Cochlear implant services

Commissioning guidelines



These guidelines have been put together by a taskforce involving representatives from the following organisations:

- RNID
- British Cochlear Implant Group
- South Central Local Specialised Commissioning Group (c/o Hampshire PCT)
- Cochlear Implanted Children's Support Group
- The Ear Foundation
- London Specialised Commissioning Group
- National Cochlear Implant Users' Association
- National Deaf Children's Society
- NORCOM (North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium).

A representative from the Department of Health chaired the taskforce.



Changing the world for deaf and hard of hearing people

Produced in collaboration with



NORCOM



LONDON SPECIALISED COMMISSIONING GROUP NHS



Contents

Introduction	2
Section A commissioning a cochlear implant service	
The policy context	4
Commissioning a specialised service	4
Benefits of collaborative commissioning and risk sharing	5
Commissioning a high quality service/designating a service provider	7
Commissioning an adequate service level	8
Planning	8
Prevalence and predicted volumes	8
Adults	8
Children	8
Comparison with other EU countries	8
Referral and selection guidelines	8
Bilateral implantation	9
Bilateral implants for post-meningitic children	10
Performance monitoring	11
Outcome measures	12
Communication between providers, referrers and PCTs	12
Section B Cochlear implants	
What is a cochlear implant and how does it work	13
The benefits	13
Patient pathway	13
Referral routes	14
Who can benefit from a cochlear implant	14
Timing of cochlear implantation	15
Case studies	15
Assessment - what does it involve?	17
Adult assessment	17
Child assessment	18
Implantation	18
Programming	18
Rehabilitation/habilitation	19
Further information	19
Evidence base	19
Useful websites	21

Cochlear implant services

Introduction

Who are these guidelines for?

You will find these guidelines useful if you are a PCT commissioner responsible for commissioning cochlear implant services.

NICE guidance

NICE has begun a technology appraisal into the 'clinical and cost effectiveness of cochlear implants in severe to profound deafness in children and adults.' This report will issue guidance to the NHS in early 2008 (subject to any appeals).

The NICE guidance will supersede this set of commissioning guidelines, which is an interim resource.

What are cochlear implant services?

Cochlear implant services are a high-cost, low-volume intervention that aims to restore a degree of hearing for severely or profoundly deaf people who get little or no benefit from hearing aids. This includes children born deaf or deafened in childhood (for example, through meningitis), adults who were born hearing but whose hearing has deteriorated, and deafened adults.

The services are part of the Specialised Services National Definitions Set, which means that they should be commissioned collaboratively. Although this happens in some areas it does not in others. At the moment, there is no national agreement on clinical criteria for cochlear implants and no national guidance. As a result, there are large geographical variations in terms of the numbers and types of cases commissioned each year. This has led to inequitable access, with long waiting times, closed lists, and a refusal to accept referrals in some areas (particularly for adults).

It is anticipated that this inequity could be reduced as a result of changes to specialised commissioning announced in the Carter Review, and potentially through the NICE guidance expected in 2008.



Cochlear implant services

The absence of national guidelines is in part due to the government's commitment to devolving decision-making to a local level where commissioners are best placed to identify the needs of their local population and also to the rapidly-changing nature of cochlear implant technology.

The purpose of these guidelines is to give you comprehensive information in an accessible and useful format to help you make informed commissioning decisions.

The guidelines:

- highlight good practice in relation to collaborative commissioning, and the financial benefits of risk sharing
- outline factors that need to be considered when commissioning a high-quality service
- ensure that all relevant information is collated in one document, making it easier for you to find the information you need
- explain how cochlear implants work, and the benefits to the patient
- outline the implantation procedure and the patient pathway
- provide further information.

The guidelines are split into two sections. Section A looks specifically at commissioning considerations, while section B provides broader information about cochlear implants, including how they work, what the benefits to patients are, and the patient pathway.

Section A – Commissioning a cochlear implant service

1 The policy context

Effective commissioning of high-quality cochlear implant services will enable you to meet your obligations in relation to the following government policies:

- **Every Child Matters** – cochlear implantation is a key intervention that significantly improves the life chances of some groups of deaf children.
- **NSF for Children** – cochlear implantation services should work effectively with education and social services where necessary to ensure that deaf children receive comprehensive support in a joined-up way.
- **The Carter Review of commissioning for specialised services** – as a result of this review all PCTs will need to be part of a Specialised Commissioning Group for the purpose of commissioning all specialised services contained in the National Definition Set. Strategic health authorities (SHAs) will be responsible for ensuring this happens. Collaborative commissioning will therefore be mandatory (this was recently reiterated in the NHS Operating Framework for 07/08).

2 Commissioning

High-quality commissioning is the key to delivering efficient and effective services.

Good commissioning should be 'a process that involves planning, monitoring and quality assurance of services, a process or cycle which covers, but is broader than, individual acts of planning and contracting.' (NERA Economic Consulting, *Commissioning in the NHS: Challenges and Opportunities* June 2005). Central to the vision of the White Paper 'Our health, our care, our say' is that 'Commissioning has to be centred on the person using the service.' (Department of Health, 2006).

2.1 Commissioning a specialised service

Cochlear implant services are low volume and are defined by the DH as a specialised service. This means that they are provided in relatively few specialist centres (15 in England), to catchment populations of more than a million people, and they cover more than a single PCT. As a result, PCTs are expected to work together to ensure that the specialised service is commissioned effectively.

Review of commissioning arrangements for specialised services

The DH commissioned an independent review of commissioning arrangements for specialised services which reported in May 2006. The review made a series of recommendations that the DH responded to in the commissioning framework annex to *Health reform in England: update and commissioning framework* in July 2006.

The recommendations were broadly accepted, and the most significant in this context are detailed below:

Each SHA will be responsible for ensuring that appropriate and effective collaborative commissioning arrangements for specialised services are in place for PCTs in their area and will performance manage such arrangements.

- Each SHA area will have an SCG (Specialised Commissioning Group) responsible for the commissioning arrangements for all specialised services.

Cochlear implant services

- All PCTs are required to be a member of the SCG, and SCG decisions are binding on PCT members.
- SCGs will be funded from a budget pooled from PCT allocations to cover:
 - the cost of specialised services commissioned on behalf of the PCTs
 - the SCG commissioning team costs.
- SCGs will formally designate specific service providers to provide specified specialised services; designation will be based on an agreed set of criteria (for instance, patient-centred, clinical, service, quality, financial) and will be reassessed every five years.
- SCGs will support the establishment of national/regional clinical databases and the regular audit of specialised services to enable commissioners and providers to monitor clinical outcomes and performance against standards and compare performance between providers and over time.
- SCGs will publish details of their commissioning arrangements, including contact details for the lead commissioner for each specialised service.

The implications of this are that cochlear implant services will in future be commissioned by a SCG operating a pooled budget arrangement. The importance of responding to the review was noted in the NHS Operating Framework for 07/08.

2.2 Benefits of collaborative commissioning and risk sharing

There are significant financial benefits for PCTs in collaborative commissioning and risk-sharing arrangements. Summerfield and Barton, in their paper *Alternative Approaches to Commissioning Cochlear Implantation in England: Discussion Document* (2001), highlighted the following circumstances in which collaborative commissioning is potentially valuable:

1) The service is high cost and low volume, and hence there is considerable variation in demand from year to year, which given the statistics of small numbers creates difficulties in planning.

This applies to cochlear implant services, where the cost per case is high. Financial risk-sharing arrangements can benefit PCTs. According to Summerfield and Barton, when



Cochlear implant services

considering the statistics of small numbers it appears that the optimal population base from which to commission cochlear implantation is three to six million people (the population served by between nine and 19 PCTs). See later for an amended version of the table produced by Summerfield and Barton, updated to include recent changes in the size of PCTs and SHAs. Please note that the numbers of expected cases in the table are based on out-of-date implantation criteria – the importance of the table is to demonstrate the level of risk you may face when commissioning from different population bases.

2) The criteria for intervention are complex, so that costs are associated with commissioners becoming experts in the field. It would be efficient to reduce the numbers who have to become proficient.

This clearly applies to cochlear implant services, which are complex, and the costs involved are relatively large given the small volume of patients each year per PCT.

3) There is large geographical variation in ease of access because different commissioning policies have been adopted in different areas.

Inequitable access exists for cochlear implant services. Collaborative commissioning would need to work for more equity of access to the service, as the PCTs involved in collaborative commissioning would align their policies at least locally, but preferably nationally.

It is therefore clear that PCTs can benefit substantially from collaborative commissioning and risk-sharing arrangements, as by increasing the population base they are commissioning for, there will be less relative fluctuation in patient numbers from year to year and planning will be more effective. This should reduce the number of patients refused access to the service due to a lack of funding, and will also reduce management costs.

Population base (millions of adults and children)	Number of PCTs	Administrative area	Expected number of cases per year**	Lower 95% confidence limit	Upper 95% confidence limit	“Risk”
0.45	1-2*	<i>Approx 1-2 PCTs (PCT average population 320,000)</i>	3	0.77	9.56	219%
1.50	4-5	<i>Approx 5 PCTs</i>	10	5.08	19.06	91%
4.50	14-15	1 SHA	30	20.60	43.41	45%
15.00	47	3 SHA	100	81.78	122.16	22%
49.00	311	<i>England</i>	300	267.45	336.45	12%

Adapted from Summerfield and Barton (2001). *All entries in italics have been amended by the authors of these guidelines to bring the table up to date with changes in the organisational structure of the NHS.

** Please note that the expected number of cases in this table is out of date as it is based on more restrictive criteria and thus lower rates of implantation than are currently used. The importance of the numbers is to demonstrate the variability in demand that can be expected in any one year, depending on the population base, and hence the risk to commissioners.

Cochlear implant services

Case studies of effective collaborative commissioning

When you are setting up collaborative commissioning arrangements it is important to establish a mechanism which fits local circumstances. Appendix 5 of the Carter Review: *Review of Commissioning Arrangements for Specialised Services* (May 2006), has 10 case studies detailing different elements of the arrangements for establishing collaborative commissioning.

2.3 Commissioning cochlear implant services

Aside from the issue of collaborative commissioning, there are two other aspects of cochlear implant services that will be considered here. These are:

- 1) commissioning a high quality service from a provider organisation/designating a service provider
- 2) commissioning an adequate service volume.

2.4 Commissioning a high quality service/designating a service provider

A good cochlear implant service involves a skilled multidisciplinary team focusing on the patients' needs, and should be part of a wider ENT provision. A service specification for cochlear implant services should consider:

- the predicted demand for the service
- referral guidelines
- the care pathway
- information and audit requirements
- required competencies of, and training for, staff providing the cochlear implant service
- service monitoring criteria.

The Carter Review indicated that SCGs will designate provider services in the future. This has significant implications for the commissioning of cochlear implant services.

For more detailed information on quality standards, see NDCS/BCIG *Cochlear implants for children and young people, guidelines for professionals working with deaf children and young people* (2005), available on the NDCS website www.ndcs.org.uk

Cost of cochlear implant services

Studies using the cost per QALY approach have demonstrated the cost effectiveness of unilateral cochlear implants for both adults and children (see page 20 for references).

It is essential to consider the entire patient pathway when commissioning a cochlear implant service. The patient pathway may start in the community, then enter the acute system, and then return to the community. The funding streams for the service must recognise this.

The national tariff (detailed below) covers the inpatient spell of the procedure, but excludes the costs of assessment, rehabilitation/habilitation in year 1, and ongoing lifelong costs thereafter. These costs must be factored in when commissioning the service.

	Child	Adult
NHS tariff for inpatient spell (07/08)	£ 33,246	£20,164

Cochlear implant services

Costs should be agreed with commissioners locally that are fully inclusive of all activity that will be required for each individual fitted with a cochlear implant. This should include costs incurred as a result of upgrading external processors on a regular basis.

2.5 Commissioning an adequate service level

Planning

Prevalence and predicted volumes

Approximately 500 adults and children currently undergo cochlear implantation per year. However, it is suggested that this is considerably less than the number of people who may benefit from cochlear implants. Manufacturers and academics have put forward a range of estimates of the number of patients who may benefit from cochlear implants but who do not currently have them. As there is currently no national agreement on exact thresholds of performance at which a person would benefit from cochlear implants, it is difficult to say how many people in the current population would benefit from an implant. Any figures put forward can therefore only be a broad estimate, and you should estimate their unmet need locally. The British Cochlear Implant Group has undertaken a national audit of current practice and is developing a position statement on clinical guidelines for cochlear implantation.

Adults

Approximately 250 adults per year currently receive cochlear implants. As stated above it is suggested that there are many more who may benefit, but unfortunately there is no consensus on the level of unmet need.

Children

Approximately 250 children are currently implanted per year, although it is estimated that approximately 350 are born each year who should be considered for an implant, and a further 100 children are deafened by the age of five.

Comparison with other EU countries re rates per million population

A EURO-CIU survey presented at the EURO-CIU AGM in Barcelona in 2006 indicates that the UK has an implantation rate of approximately 90 per million of the population. Although this is a little higher than countries such as Cyprus, Luxembourg and France, it is less than Austria, Sweden, Germany, Denmark, Belgium, Spain and the Netherlands who all implant more than 100 per million of the population. Austria in particular implants over 180 per million of the population. The implantation rate, together with figures on potential levels of unmet need, suggests that the number of cochlear implants currently funded in England may not be enough to meet demand.

Referral and selection guidelines

You should work with the specialist cochlear implant service to develop and agree suitability guidelines within which the service will be commissioned. The details should be provided to local services along with an assessment protocol. It's important for you and the cochlear implant teams to review the referral guidelines regularly, in line with published research and identified good practice in the field (NDCS/BCIG *Cochlear implants for children and young people*, 2005). A key issue for you to note in relation to referral and selection guidelines is the importance of timely referral and assessment for both adults and

Cochlear implant services

children, with prompt approval where appropriate. The earlier a patient is implanted, the better in terms of potential outcomes, and the more cost effective the procedure is.

In addition to agreements at a local level, we recommend that commissioners and providers reach a national agreement based on the criteria of candidacy for implantation. This would improve equity of access.

- For details of the evidence base supporting early implantation, please see page 20
- For further details on selection criteria, please see from page 13.

Bilateral implantation

Research has demonstrated the importance of binaural hearing for localisation abilities and for listening in noise (Litovsky R, Johnstone P, Godar S. *Benefits of bilateral cochlear implants and/or hearing aids in children*. INT J AUDIOL 2006; 45(Suppl 1): 78-91).

Due to the importance of binaural hearing, the debate about the need for bilateral implantation as opposed to unilateral implantation has become an important consideration.

At the moment, bilateral implantation is routinely provided in Norway, Denmark, Sweden, Switzerland and Iceland, and is common in Holland, Germany, Belgium, Spain and the US. However, it is only available in limited circumstances in the UK. Bilateral cochlear implantation is available routinely in Scotland and Northern Ireland for post-meningitic patients.

Recent studies and recent developments in clinical practice suggest that in both adults and children bilateral cochlear implantation may result in improvements in sound localisation and may result in improved speech perception in noise compared with unilateral cochlear implantation. As a result of this, and the benefits reported by patients and the parents of children who have received bilateral implants, there is increasing pressure to give patients or parents of deaf children the choice of bilateral implants in the UK (particularly for children).



Cochlear implant services

Research has shown that the primary benefit of bilateral implantation is directional perception, which enables bilateral users to establish the source of sound more effectively, and to focus on the sounds they want to hear in a noisy environment. This results in improved intelligibility of sounds rather than a simple hearing gain, and thus has important implications for social skills, self-confidence and safety for both adults and children. This is especially important for children as it should help them to communicate earlier and more effectively, improving their language development, and therefore having positive knock-on effects in relation to their educational attainment. However, the cost benefit of bilateral implantation has yet to be demonstrated.

It is important to stress that if given the choice, not all patients or parents of children receiving cochlear implants would opt for bilateral implantation over unilateral implantation. Some patients or parents of children with significant residual hearing in one ear may choose unilateral implantation to avoid eliminating that residual hearing, to allow for future developments. In some cases a cochlear implant in one ear and a hearing aid in the other may be an option. The key issue for patients or parents – where bilateral implants are a possibility – is an informed choice.

Bilateral implantation necessarily involves a significant increase in cost of both the initial implant and the subsequent annual maintenance, although simultaneous implantation is cheaper than sequential implantation. In the context of competing priorities for healthcare resources, you need to consider both the evidence of clinical effectiveness of bilateral implants and the cost effectiveness. The relevant evidence that explains the likely clinical benefits of bilateral implantation is referenced on page 20. We encourage you to consult with public health colleagues on the relative cost effectiveness of the procedure.

Bilateral implants for post-meningitic children

Bilateral implants are particularly important for post-meningitic children. Bone growth within the ear following meningitis can have two important effects.

- It may become more difficult to insert the electrodes, and this often means that fewer electrodes can be made active, and hence the implant is likely to work less well.
- Over time, the ear may become unsuitable for implantation, and were a unilateral implant to fail there would be no possibility of re-implantation in the second ear.



Cochlear implant services

There is therefore an argument for bilateral implants – not in order to provide additional benefit over and above what a single fully functioning implant would be expected to give, but as insurance against future device failure. Scotland and Northern Ireland routinely fund bilateral implantation in these cases.

Performance monitoring

For effective performance monitoring, an example is given below of a minimum data set that PCTs could request from implant centres.

Item on minimum data set (to be specified separately for paediatrics and adult services)	Reason for requesting this/suggested acceptable levels where appropriate
Guidelines for referral	Agreement between PCTs and cochlear implant centres on the guidelines for referral should ensure that a timely service is offered to appropriate patients
Numbers implanted by age and complexity and devices used	To assess the experience of the team
Waiting times (referral to first appointment, referral to decision [excluding planned waits], decision to surgery)	Earlier implantation (shorter duration of deafness) is a significant predictor of outcomes, and therefore short waits are important for ensuring optimal outcomes
Explants and reasons	To assess experience
Re-implantations	To assess experience
Surgical complications	To assess experience
Failures	This is important information for potential patients/families of potential patients
Infections	This is important information for potential patients/families of potential patients
Usage rates over time	High rates of non-usage could indicate poor follow-up care
Measure of outcome, such as speech perception and production (CAP and SIR)	To assess the outcomes attained by the programme
Hardware information – for instance, device upgrade policy, costs and activity; device maintenance activity	To evaluate follow-up care and understand costs
Number of outpatient appointments per year – split by new patients and follow-ups	To assess current activity levels and capacity and assist planning
Staffing	To assess current activity levels and capacity and assist planning

Cochlear implant services

Outcome measures

Cochlear implant centres should use recognised outcome measures in audiology and speech and language ability and the educational progress in the case of a child. Each centre should collect and update these results on at least an annual basis and be available to commissioners and referrers as required.

Communication between providers, referrers and PCTs

It is good practice to establish robust communication mechanisms between the providers of the service, the referring professionals, and the PCTs commissioning the service. This ensures that all the organisations involved can keep track of patients in the system, and you can monitor delivery of the service you have commissioned. It will also help you to plan the service effectively over time.

You can use a variety of communication mechanisms to achieve this. Here are some examples of current good practice in the field.

- Regular face-to-face meetings between the head of the cochlear implant service, other relevant members of the hospital management team and the commissioning team. This is ideally undertaken within the cochlear implant department where commissioners can observe the context of the programme.
- Regular written updates, as per the minimum data set suggestion above.
- Commissioners attending programme open days and relevant information events.
- Planned benchmarking exercises – for example, on a five-yearly basis, by the Commissioning body of other programmes with a similar profile.



Section B – Cochlear implants

3 What is a cochlear implant and how does it work?

A cochlear implant is an electronic device that is designed for use by severely or profoundly deaf children and adults who get little or no benefit from hearing aids. The cochlear implant works by directly stimulating the nerves of the inner ear with electrical signals. These signals are interpreted by the brain and recognised as 'sound'. There are two main parts to the cochlear implant – the internal and the external components.

The external components

The external parts consist of a microphone, a speech processor and a transmitter coil held in place behind the ear with a magnet. The microphone picks up the sound from around the user. The signal is then passed to the speech processor and converted into electrical signals. Each speech processor is individually tuned to each wearer's needs. The electrical signals are sent via radio waves across the skin from the transmitter coil to the internal receiver. The microphone and processor can be positioned either behind the ear (in a device that looks very much like a hearing aid) or in a small box that can be worn on the body.

The internal components

The internal parts are surgically implanted and include a receiver with a magnet that is positioned under the skin behind the ear, and a line of electrodes that is surgically inserted into the cochlea. The magnet holds the external transmitter coil directly over the implanted receiver. The receiver picks up the signal from the transmitter coil and sends it to the electrodes. The electrodes directly stimulate the damaged hair cells of the cochlea, which sends the electrical signals along the nerve to the brain.

4 The benefits of a cochlear implant

A cochlear implant offers potential access to sound for severely and profoundly deaf children and adults who do not gain adequate benefit from hearing aids.

For deafened adults and children a cochlear implant improves their ability to understand speech and to restore or maintain their own speech quality, making it easier for other people to understand them. If a deafened adult or child has a cochlear implant, they will also be more likely to hear environmental sounds.

Children who are born deaf or are pre-lingually deafened are more likely to be able to acquire spoken language if they have a cochlear implant and are likely to be able to hear environmental sounds.

Children with a cochlear implant are more likely to be in mainstream education than deaf children who do not use a cochlear implant. There are also positive knock-on effects for childhood development, employment prospects, quality of life and psychological well-being.

Children with additional disabilities can benefit from the access to increased audition provided by a cochlear implant, significantly improving their quality of life.

5 Patient pathway

Detailed diagrams of the pathway for both adults and children have been produced by the 'Do once and share' programme that is part of NHS Connecting for Health. The diagrams are on the website

<http://www.informatics.nhs.uk/doas/index.html>

You will need to register on the site to access the diagrams.

Cochlear implant services

Referral routes

Potential patients will be referred to a specialist cochlear implant centre for assessment. The referral routes into the specialist centres are as follows:

- Adults with a hearing loss will be referred by their GP to the local audiology or ENT clinic, where they will be fitted with a hearing aid for a trial period. If the trial is unsuccessful, a consultant (doctor or clinical scientist) will refer them on to the specialist centre for assessment, if appropriate.
- Babies and children will be referred from newborn hearing screening, GP, health visitor or paediatrician to the local audiology or ENT clinic for hearing aid fitting and trial. If the trial is unsuccessful, a consultant (doctor or clinical scientist) will refer them on to the specialist centre for assessment, if appropriate.

Who can benefit from a cochlear implant?

Potential candidates for cochlear implants include:

- children who were born deaf or developed hearing loss pre-lingually
- post-lingually deafened older children and teenagers who have a severe to profound hearing loss and get limited benefit from hearing aids
- pre-lingually deafened older children and teenagers who have severe to profound hearing loss but who have excellent functional use of residual hearing and are oral communicators
- adults deafened through recent trauma or illness
- adults who were born with some hearing loss, or acquired deafness and whose primary method of communication is speech, but whose hearing loss means that hearing aids are no longer useful.

A variety of assessments will be required to determine the patient's functional hearing with optimally fitted hearing aids – that is, how effectively they use their hearing to access speech and sound in the environment. Although part of the assessment process involves measuring the individual's level of hearing loss, there is no definite threshold at which they are considered suitable for an implant, as people with similar audiograms may get different levels of benefit from the hearing aids. Rather, the functional hearing ability will determine whether a cochlear implant is likely to provide benefit to the individual patient. This is a complex multi-factoral assessment and patients have to be considered on an individual basis.

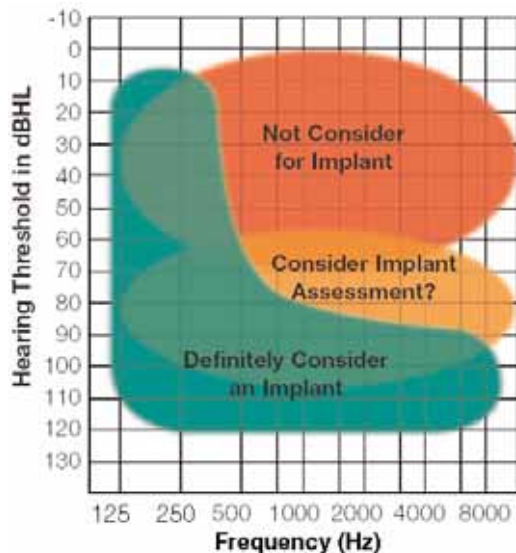


Diagram – Taken from Cochlear Implants 2007, Information document produced by, and available from the Ear Foundation.

Cochlear implant services

The audiogram may therefore be the starting point of the assessment process. This is supported with appropriate assessment of functional hearing in terms of the patient's ability to adequately access sound, to enable them to develop or maintain:

- access to spoken language
- their own ability to talk and be understood by others, and
- the ability to monitor sounds in their environment.

Current digital hearing aid technology has meant aided thresholds are redundant as criteria for implantation. This parameter is no longer in general use within the field.

The diagram on page 14 shows broadly on an audiogram the unaided thresholds that are typically appropriate for cochlear implantation. However, it is essential to explore how the child or adult can perform with optimally-fitted hearing aids, and tests to find out how well they understand speech are an essential part of assessment for older children and adults.

Timing of cochlear implantation

Children

To get the most out of a cochlear implant a child should be fitted with one as soon as possible. However, children with progressive hearing loss should be monitored over time and implantation should be offered at the most appropriate stage. Patients with complex needs may need a longer assessment period and/or additional investigations.

For references to support this please see page 20.

Teenagers and adults

Generally speaking, to maximise outcomes, those who experience a sudden onset of deafness should be implanted as soon as possible. However, those with progressive losses will require monitoring over a longer period of time appropriate to the course of the disease.

Case studies

These case studies have been provided to demonstrate the range of circumstances in which cochlear implants may be fitted.

Case study 1 – child

MC was identified following newborn hearing screening. Within days of her birth, she had a diagnosis of congenital profound bilateral sensorineural hearing loss confirmed. Despite the genetic component to MC's deafness, she is currently the only deaf member of her family. Her parents used simple sign language as an early support to their spoken communication at home, which helped MC develop early interaction skills. MC was implanted at 20 months on the right side, and initial tuning began in April 2005. MC continues to wear a contra-lateral hearing aid in her left ear, which gives her some information to help localise sounds. At her one-year post-implant review, MC's audiometry results showed responses at an average of 40dB HL across the speech frequencies. When her spoken language was formally assessed using the Preschool Language Scales (PLS3), MC scored within the normal range for her age, achieving an age-equivalent score of two years four months at chronological age two years 11 months. MC communicates using speech, and her family no longer uses sign support to help her understand familiar topics and vocabulary.

Cochlear implant services

Case study 2 – child

TB contracted bacterial meningitis at 20 months. Prior to this, his development had been typical in all areas, including understanding short phrases, and building an expressive vocabulary of familiar names and everyday objects. The infection resulted in a profound bilateral hearing loss. His parents reported that TB stopped vocalising completely when he first lost his hearing, and his behaviour deteriorated as he became more frustrated in communicating. The initial MRI scans indicated that TB's cochleas had not ossified, and he was implanted on the right side, in November 2000, five months after his illness. Five years after being implanted, TB's audiometry results showed responses at an average of 20dB HL across the speech frequencies, and a score of 97% on the BKB sentences using audition only. His speech is intelligible to even unfamiliar listeners, with natural rhythm, intonation and expression patterns.

Case study 3 – child

HL was born prematurely at 24 weeks. He has quadriplegic cerebral palsy with developmental delay, and a left recurrent laryngeal nerve palsy. HL was diagnosed with profound bilateral deafness at four months, and was given hearing aids at 18 months which did little to help him. By three years four months, he was able to sit with support, and his carers were able to interpret his needs and choices from some visual tracking and smiling. He was reported to recognise two Makaton signs, but his difficulties with head control impeded his ability to follow more complex signed language. At age four years eight months, HL was implanted on the right side. After six months, his parents reported that he was noticeably more alert with the processor on, and was beginning to respond to familiar voices and smiling when he recognised his parents' voices. As a result, his mother is able to use her voice to reassure him even when he does not have her in his sight, which has reduced his anxiety and frustration.

Case study 4 – adult

EB was deafened in one ear following a blood clot which had burst blood vessels in her ear. While out walking in April 1996 she fell and banged the back of her head, which resulted in some numbness for a few weeks and then suddenly overnight her ear stopped working, leaving her totally deaf, very scared and wondering how she would cope. EB was referred to Queen Elizabeth Hospital, Birmingham in May 1997 and was successfully fitted with a cochlear implant in January 1998. Although she had expected to understand only a little at first, she was delighted to find that the implant helped her immensely. She says: 'I was like a child, listening to different things again. We went into the children's part of the museum and I listened to the noise of the children playing with the toys. I had come alive again, I was not on the outside looking in, I was in!' EB feels that the implant has altered her life completely and has given her confidence back. She can listen to the radio and television again and regularly visits the theatre and cinema. The implant has also helped with her tinnitus.

Case study 5 – adult

EN encountered progressive bilateral hearing loss and tinnitus from 20 years old, the origin of which was unclear. She was fitted with analogue hearing aids from the age of 31, and with digital aids four years later. However, by the age of 41, she had lost any useful hearing in her left ear, and could only detect the rhythm of speech but not words on the right. EN was implanted on the left side, and initial tuning began in November 2005. EN felt confident to return to work after a few weeks, and reported three months after initial tuning that she could identify sounds around the home, including her daughter calling "Mummy". Six months after initial tuning, EN is able to recognise family

Cochlear implant services

members' voices on the phone, and can identify familiar pieces of music on the radio. She is delighted to be able to hear environmental sounds that she has not heard for many years, such as the sound of the rain on the roof of her car.

Assessment - what does it involve?

Assessment for both adults and children involves a variety of tests, and takes place over a number of weeks or months. The cochlear implant centre aims to give the patient or parent of a child who is a potential candidate for implantation enough information to make an informed choice. The patient/parent and their family need to be given enough time to consider all the options and make a decision. Details of the assessment process for adults and children are given below.

Adult assessment

This involves:

- a medical examination to assess their fitness for surgery
- an MRI and/or CT scan to assess the cochlea, auditory nerve and brain
- hearing tests and hearing aid trial with the most appropriate hearing aids
- auditory brainstem response in some instances. This is a hearing test which records the electrical activity of the hearing pathway
- evaluation of lipreading skills to provide a baseline assessment for comparison after the implant
- speech recording to assess quality and provide a baseline assessment for comparison after the implant
- completing a questionnaire to obtain a greater understanding of what the patient expects from the implant, the impact of deafness on the patient's quality of life and related issues
- the promontory stimulation test (in some instances) to check the functioning of the hearing nerve
- psychological assessment as required.



Cochlear implant services

Child assessment

This involves:

- collection of information about the child from the child's doctors, audiologist, teachers, and any other professionals involved with the child
- a medical examination to assess their fitness for surgery
- an MRI and/or CT scan to assess the cochlea, auditory nerve and brain
- auditory brainstem response – this is a hearing test which records the electrical activity of the hearing pathway, particularly for complex and borderline or very young cases
- hearing tests and hearing aid trial with the most appropriate hearing aids
- detailed assessments at home and at school – with the assistance of a named key worker – of language abilities, communication, education and expectations
- psychological assessment as required.

Implantation

The operation is carried out under general anaesthetic and surgery takes between two and five hours. The length of stay in hospital is typically one to two days. Following surgery, the external parts (headset and processor) are fitted three to six weeks later, allowing time for the surgical scar to heal.

Follow-up and rehabilitation

There are two elements to the follow-up care: one is programming of the cochlear implant system and the other is rehabilitation/habilitation.

Programming is the process by which the speech processor is 'tuned' to meet the individual's needs, based on how their hearing nerves respond to signals. This is usually carried out by an audiologist. This will usually require up to eight clinic appointments in the first year and then typically one review appointment annually thereafter. Ongoing access to additional intermediate appointments and advice is essential to provide technical troubleshooting and clinical support in the event of a problem with the implant. Failure of the implant system is rare, but when it does happen, urgent access to specialist clinical and medical support is essential, with prompt replacement of the implant if appropriate.



Cochlear implant services

Rehabilitation/habilitation is the process whereby the user learns to make sense of the 'sounds' that they hear. What they hear through the implant will initially be very different to the sounds they remember (or will be totally new to those born deaf), and it takes time for them to become meaningful. A team of professionals supports the user through this process, including specialist speech and language therapists, teachers of the deaf and other professionals. The process can be time intensive, with multiple consultations in the first year following implantation. Follow-up consultations do not necessarily have to happen at the specialist centre, and discussions will take place locally to establish different models for support

6 Further information

Patient pathway

<http://www.informatics.nhs.uk/doas/index.html>

Information on incidence and comparison with other EU countries

R J Byrnes, *Cochlear Implants and the Potential Universe for Treatment in the UK*, 2005

A EURO-CIU survey: number of CI users, 2006

Evidence base for unilateral implantation

Beadle E, McKinley D, Nikolopoulos T, Brough J, O'Donoghue G, Archbold S. Long-term functional outcomes and academic-occupational status in implanted children after 10 to 14 years of cochlear implant use. *Otology & neurotology*: official publication of the American Otological Society, American Neurotology Society (and) European Academy of Otology and Neurotology, 2005;26(6):1152-60.

Edwards L, Frost R, Witham F. Developmental delay and outcomes in paediatric cochlear implantation: implications for candidacy. *International journal of pediatric otorhinolaryngology* 2006; 70(9):1593-1600.

Dowell R, Dettman S, Hill K, Winton E, Barker E, Clark G. Speech perception outcomes in older children who use multichannel cochlear implants: older is not always poorer. *The Annals of otology rhinology & laryngology*, Supplement 2002; 189:97-101.

Geers, A. E., & Brenner, C. (2003). Background and educational characteristics of prelingually deaf children implanted by five years of age. *Ear and Hearing*, 24(1 SUPPL.), 2S-14S.

Geers, A. E., & Brenner, C. (2004). Educational intervention and outcomes of early cochlear implantation, International Congress Series, 1273 (November), 405-408.

Geers, A. E., Nicholas, J. G., & Sedey, A. L. (2003). Language skills of children with early cochlear implantation. *Ear and Hearing*, 24(1 SUPPL.), 46S-58S.

O'Donoghue GM, Nikolopoulos TP, Archbold SM. Determinants of speech perception in children after cochlear implantation. *Lancet*, 2000; 356(9228):466-8.

Stacey P, Fortnum H, Barton G, Summerfield A. Hearing-impaired children in the United Kingdom, I: Auditory performance, communication skills, educational achievements, quality of life, and cochlear implantation. *Ear and hearing*, 2006; 27(2):161-186.

Svirsky, M. A., Teoh, S. W., & Neuburger, H. (2004). Development of language and speech perception in congenitally, profoundly deaf children as a function of age at cochlear implantation. *Audiology and Neuro-Otology*, 9(4), 224-233.

Cochlear implant services

Thoutenhoofd E. Cochlear implanted pupils in Scottish schools: 4-year school attainment data 2000-2004. *Journal of Deaf Studies and Deaf Education* 2006; 11(2):171-188.

Waltzman S. Cochlear implants: current status. *Expert review of medical devices*, 2006; 3(5):647-655.

Evidence base for early implantation of children

Colletti V, Carner M, Miorelli V, Guida M, Colletti L, Fiorino F. Cochlear implantation at under 12 months: report on 10 patients. *The Laryngoscope*, 2005; 115(3): 445-9.

Connor C, Craig H, Raudenbush S, Heavner K, Zwolan T. The age at which young deaf children receive cochlear implants and their vocabulary and speech-production growth: is there an added value for early implantation? *Ear and hearing* 2006; 27(6): 628-644.

Lesinski S, Illg A, Heermann R, Bertram B, Lenarz T. Paediatric cochlear implantation in the first and in the second year of life: A comparative study. *Cochlear Implants International*, 2004; 5(4): 146-59.

Lesinski S, Illg A, Warnecke A, Heermann R, Bertram B, Lenarz T. Paediatric cochlear implantation in the first year of life: preliminary results. *HNO*, 2006; 54(7): 565-572

Nicholas J, Geers A. Effects of early auditory experience on the spoken language of deaf children at 3 years of age. *Ear and hearing*, 2006; 27(3): 286-298.

Nikolopoulos TP, O'Donoghue GM, Archbold S. Age at implantation: its importance in pediatric cochlear implantation. *The Laryngoscope*, 1999; 109(4): 595-9.

Iler Kirk, K. et al. Effects of age at implantation on spoken word recognition in children entering elementary school.

Sharma, A. et al. The influence of a sensitive period on central auditory development in children with unilateral and bilateral implants. *Hearing Research*, 2005; 203(1-2): 134-43.

Evidence base for cost-effectiveness of unilateral implantation

Barton G R, Stacey P C, Fortnum H M, Summerfield A Q. Hearing impaired children in the United Kingdom, IV: cost-effectiveness of paediatric implantation. *Ear and Hearing* 2006, Oct; 27(5): 575-88

UK Cochlear Implant Study Group (2004) Criteria of candidacy for unilateral cochlear implantation in post-lingually deafened adults II: cost effectiveness analysis. *Ear and Hearing*, 2004; 25(4): 336-60

Evidence base for impact of cochlear implants on educational outcomes

Stacey PC, Fortnum H, Barton G, Summerfield AQ (2006) Hearing Impaired Children in UK 1: Auditory Performance, Communication Skills, Educational Achievement, Quality of Life and Cochlear Implantation. *Ear & Hearing*. 27, 161-186

Evidence base for bilateral implantation

Das, S, Buchman, C. Bilateral cochlear implantation: current concepts. Current opinion in Otolaryngology and Head and Neck Surgery. 2005; 13: 290-293

Kuhn-Inacker, H. et al Bilateral cochlear implants: a way to optimise auditory perception abilities in deaf children? *International Journal of Paediatric Otorhinolaryngology*, 2004; 68: 1257-1266

Cochlear implant services

Litovsky R, Johnstone P, Godar S. Benefits of bilateral cochlear implants and/or hearing aids in children. *INT J AUDIOL*, 2006; 45(Suppl 1): 78-91.

Litovsky R, Parkinson A, Arcaroli J, Sammeth C. Simultaneous bilateral cochlear implantation in adults: a multicenter clinical study. *Ear and hearing* 2006, 27(6): 714-731.

Stark, T. et al. Bilateral cochlear implantation in varying duration of deafness. *Laryngorhinootologie*, 2004; 83(1): 20-2

Useful websites

RNID

www.rnid.org.uk

British Cochlear Implant Group

www.bcig.org.uk

Cochlear Implanted Children's Support Group

www.cicsgroup.org.uk

Ear Foundation

www.earfoundation.org.uk

National Cochlear Implant Users Association

www.nciua.demon.co.uk

National Deaf Children's Society

www.ndcs.org.uk

We're RNID, the charity working to change the world for the UK's 9 million deaf and hard of hearing people.

There are a number of
ways to find out more

www.rnid.org.uk

Contact us

Telephone 020 7296 8171

Or write to us

informationline@rnid.org.uk

Health Team

19-23 Featherstone Street

London EC1Y 8SL

Fax 020 7296 8069

