

# Quality Standards Cochlear Implant Services for Children and Adults



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## 1 Introduction

The British Cochlear Implant Group (BCIG) is a professional association for those directly involved in the provision of clinical services and scientific research in the field of auditory implantation. BCIG provides comprehensive advice on auditory implantation and quality standards in collaboration with its members and shares best practice with the services in which they work. BCIG policies and guidelines are widely recognised, both in the UK and internationally, as a benchmark of good practice.

This document supersedes our previous guidelines of 2016. Earlier versions of our guidelines were drawn up in collaboration with Action on Hearing Loss (formerly the Royal National Institute for the Deaf) and the National Deaf Children's Society respectively and these were incorporated as appropriate into this updated standards document. BCIG is very grateful for contributions over time from Action on Hearing Loss, the National Deaf Children's Society, the Cochlear Implanted Children's Support Group and the National Cochlear Implant Users Association to the development of its guidelines.

## 2 Objective

This document sets out the minimum standard that all clinical CI services in the UK should provide. It includes information on the patient pathway, clinical management steps, professional composition of the CI team and the technology, facilities and infrastructure required. It also includes the related quality standards and measures. Providers of cochlear implant (CI) services should be able to demonstrate to purchasers that they adhere to current BCIG Quality Standards.

## 3 Cochlear implantation

### 3.1 Aim

The aim of cochlear implantation is to improve the hearing and quality of life for those with permanent functional severe to profound deafness who do not gain adequate benefit from optimally fitted hearing aids, and to promote the understanding and use of spoken language.

### 3.2 Technology

A CI is an electronic device. Unlike conventional hearing aids which work by making sounds louder, a CI provides direct electrical stimulation to the nerve endings (spiral ganglion) in the cochlea.

A CI consists of two parts, an internal part (surgically implanted) and an external part (worn either behind the ear, on the side of the head or on the body). Both parts work together. The internal part consists of a receiver/stimulator package and an electrode array. The external part consists of a sound processor and a transmitter coil. Some sound processors combine the processor and coil into a single unit. The processor powers and activates the internal part and the patient can only hear sound when it is worn. The processor is custom programmed to ensure that it delivers appropriate patterns of electrical stimulation to each individual electrode on the electrode array, thus bypassing the damaged hair cells and providing direct stimulation to the auditory nerve. This provides the CI user with a meaningful sound sensation.

CI systems (implants and processors) are commercially available from a small number of manufacturers worldwide. Reliability, quality, service support and cost should be taken into consideration in the device selection process.

The purchase of CIs must be compliant with UK procurement law and given the cost of the systems, will require Contracting Authorities to follow a tender process described by the EU Procurement Directives. This may be undertaken by the individual organisation or by a third party (e.g. regional or national purchasing groups).

Although CI services should seek to use the most up-to-date devices, the BCIG cautions against using unproven 'novel' devices. Teams should request evidence of effectiveness and reliability, and should obtain assurance of both readily available expert clinical support and long-term commitment from manufacturers.

Devices should have been awarded the CE Mark under the auspices of the European Union Medical Devices Regulations. The award of this mark reflects compliance with the safety requirements specified in EU regulations on "Active Implantable Medical Devices", but does not guarantee effectiveness.

### 3.3 Target patient group

Criteria for candidature are based on recommendations made by the BCIG which were upheld by NICE in TA166<sup>1</sup> and subsequent commissioning guidance (e.g. NHS England Circular SSC1442: Cochlear Implantation and patients with ANSD<sup>2</sup>).

Referrals for assessment are accepted for adults and children who gain inadequate or no measurable benefit from acoustic hearing aids.

Under NICE TA166 adults who are found to be candidates on completion of assessment are offered a unilateral cochlear implant. In exceptional circumstances (e.g. dual sensory impairment) adults may be offered simultaneous bilateral cochlear implants.

For children, simultaneous bilateral cochlear implantation is recommended as an option whenever clinically appropriate. Sequential implantation is not supported under NICE TA166 unless the patient was unilaterally implanted as a child at the time of its publication, and remains a child at the time of sequential surgery. In exceptional circumstances sequential bilateral implantation may be required for medical or audiological reasons.

There may be patients who do not meet the above criteria, but for whom cochlear implantation is recommended by the clinical team following a full multidisciplinary assessment. Such cases may, for instance, include patients whose functional hearing is significantly poorer than their pure tone audiogram results. In such cases an individual funding request (IFR) can be made for NHS funding.

Evidence regarding patient selection criteria will be kept under regular review by the British Cochlear Implant Group.

### 3.4 The cochlear implant team

The CI service should be delivered by a multidisciplinary team of specialist professionals with expertise in otology (surgical and nursing), clinical science (audiological scientists and/or clinical physicists), clinical physiology (audiologists and/or hearing therapists) and rehabilitation (speech and language therapists and/or teachers of the deaf and/or auditory verbal therapists). Where clinical psychology is not available as part of the core team, it is recommended that the team has access to clinical psychology services with experience in working with severe/profound deafness. Access should also be available to other appropriate health professionals (e.g. audiovestibular physicians, paediatricians and geriatricians). The team must have the knowledge and skills to assess and work with children and adults with a range of complex needs, additional to their deafness.

The team will include a Head of Service/Coordinator who will have a leadership/management role. This team member should be a clinician, with extensive experience in the field of cochlear implantation, with proven leadership abilities

to ensure the maintenance and development of a highly skilled specialised Service. The Head of Service/Coordinator will have responsibility to ensure that the patient's needs are met throughout the entire patient pathway and that relevant Quality Standards and National Specifications are achieved.

### 3.5 Quality measures

	Standard	Measure
3a	The purchase of CI systems must be compliant with UK procurement law	Documentary evidence of purchasing and compliance
3b	The procurement process should allow consideration of quality, effectiveness and reliability, clinical and long term support, as well as cost	Documentary evidence
3c	CI systems must be awarded CE Mark under European Union Medical Device Regulations	Documentary evidence
3d	Candidature criteria should be based on NICE guidance (TA166 2009), associated national guidelines and local commissioning agreements	i) Ongoing departmental audit of compliance ii) Documentary evidence of any local commissioning agreements
3e	The CI clinical team will comprise all essential roles to deliver safe and effective care, and include senior clinical leadership/management role/s	Documentary evidence

## 4 Communication and information

It is important that patients, their families, carers and associated professionals are given appropriate access to information both during the assessment process and post implantation as necessary. Young people should be included in discussions, directly with clinicians as appropriate, wherever appropriate and supported to participate in decision-making about their care.

Patients and parents/carers should be given information about cochlear implantation, the treatment process, relevant organisations (such as national and local charities and self-help organisations), equipment and services for deaf and deafened people, including Deaf community organisations.

Information should be available online for those interested in finding out about cochlear implantation, those under assessment and following implantation. Full use should be made of internet-based communications including video, social media and websites. Links to information from other relevant organisations such as device manufacturers, the British Cochlear Implant Group, third sector organisations and other relevant bodies should be provided.

Whenever possible, information should be provided to patients in a language that is appropriate to their preferred method of communication, including availability of interpreting services within appointments. Verbal information should be supported by a written summary to the patient whenever indicated.

Following implantation patients should be given access to information regarding medic alert systems and local and national support groups.

## 4.1 Quality measures

	Standard	Measure
4a	Patients/parents/ carers should be given up-to-date information, including in writing, about cochlear implants, the treatment process and relevant other organisations	Systems in place to ensure patients are provided with information within specified timescales
4b	Up-to-date information should be available online about cochlear implants, the treatment process and relevant other organisations	Systems in place to ensure to provide online information and links are available
4c	British Sign Language and spoken language interpreters should be available at appointments	Systems in place to ensure interpreting services are available as required

## 5 Equality of access

Cochlear implant services are committed to equality of access including age, disability including learning disability, gender, race, sexual orientation and religion/belief in all aspects of service delivery. Care should be taken to ensure that patients are not disadvantaged in terms of access to assessment, treatment or ongoing care. Services should gather data to enable them to demonstrate equality of access to provision or to identify and correct any inequality for groups including (but not limited to) gender, race and disability.

CI services should monitor and review their clinical pathway on an ongoing basis. Quality Impact Assessments, Equality and Diversity Impact Assessments and service user consultation should be carried out as appropriate prior to introducing any significant changes to service delivery. External and internal access should meet appropriate standards (see Section 13).



## 5.1 Quality measures

	Standard	Measure
5a	The CI service should evaluate access of minority groups (including but not limited to gender, race and disability)	Systems in place to collect and review data
5b	The CI service should demonstrate plans and actions to address areas of inequality identified	Systems in place to demonstrate plans in place and actions taken

## 6 Care pathway

There are five phases of patient management within the cochlear implant care pathway: pre-implant assessment, surgery, device programming, rehabilitation and equipment maintenance.

### 6.1 Continuity of care

The five phases of patient management are not independent of one another; rather, information about a patient established in one phase should be used to determine the maximally safe and effective management in another. Information about patients must flow easily between phases. This may not occur efficiently if separate providers are responsible for different stages of management, which may introduce risks in terms of patient safety, clinical effectiveness and patient experience, except where two or more providers have explicitly grouped together to offer a service partitioned in this way. Hence, the CI service should demonstrate that it can provide for a comprehensive service across all five phases of patient management and Commissioners should normally seek to purchase the complete service for a patient from a single provider.

The NHS should reinforce and consolidate the activities of existing CI services that provide cost-effective services. Additional new CI services should only be considered where there is unmet need in the area which cannot reasonably be met by existing CI centres and if the proposal can demonstrate that it will be cost-effective, able to meet BCIG Quality Standards and will not destabilise existing clinically and cost-effective services. BCIG Council can offer assistance to any Commissioners who wish to explore the establishment of additional or alternative service provision.

## 6.2 Quality measures

	Standard	Measure
6a	The CI service must provide for a comprehensive service across all five phases of patient management: pre-implant assessment, surgery, device programming, rehabilitation, equipment maintenance	i) Systems in place to ensure continuity of care across patient pathways ii) Records of activity

## 7 Pre-implant assessment

The CI service should have the infrastructure to carry out assessment for CI, including a full specialist team and all associated specialist equipment, materials and facilities. Details on these are given in sections 11 to 14 below.

Patients undergo assessment to establish candidacy for cochlear implantation. A wide range of tests and investigations are carried out by the multidisciplinary CI team to determine whether individuals meet the selection criteria and are likely to benefit from cochlear implantation. The CI service and local services should proactively engage with each other to ensure that patients have a comprehensive, thorough and timely assessment. The patients' experience will be improved by ensuring effective liaison and co-operation between these services.

The assessment process usually entails several visits to the CI centre; for children, the CI team rehabilitation professionals should liaise closely with the child's family and local professionals. It is recommended that this is facilitated through the use of home, local clinics and nursery/school visits.

Co-ordinated management of the pre-implant assessment is the responsibility of the Head of Service/Clinical Co-ordinator. Fast tracking of patients through the assessment process must be available when clinically indicated.

### 7.1 Waiting times

The cochlear implant assessment and treatment pathway is subject to NHS waiting time directives. The complexity of the CI assessment pathway, in some cases requiring repeat assessments, watchful waits and other interventions, which may not count towards targets, means that for some individuals the total time to treatment can be longer. Patients should be regularly informed about how they are progressing through the assessment process to provide reassurance and ensure appropriate expectations.

## 7.2 Audiological assessment

Evaluation of hearing status, benefit from hearing aids and functional hearing ability is undertaken by the clinical scientist/clinical physiologist, in compliance with British Society of Audiology recommended procedures and guidance where available (see British Society of Audiology website resources<sup>3</sup>). Equipment must be calibrated to the current British and ISO standards. The team will work in conjunction with local services and medical physics teams as appropriate.

Audiological assessment may include (as appropriate):

- Detailed patient history
- Otoscopic examination of the ears
- Determination of hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the patient's age and abilities
- Determination of uncomfortable loudness limits
- Objective hearing threshold assessment
- Evaluation of middle ear function using tympanometry
- Speech perception assessment
- Spatial and directional hearing assessment
- Evaluation of current hearing aids and hearing aid prescription
- Provision of optimised hearing aids/settings as required (in conjunction with local services as appropriate)
- Patients fitted with new hearing aids or with a change of hearing aid settings may require access to a structured programme of auditory rehabilitation. It is recommended that trials with new aids or different settings be conducted in accordance with NICE Guidelines. For some patients the period may be extended to several months for clinical reasons
- Referral for balance/vestibular assessment
- Provision of specialist advice on managing hearing loss in complex cases e.g. borderline candidates, patients with additional needs and Auditory Neuropathy Spectrum Disorder (ANSD)
- Evaluation of the patient's potential ability to participate in CI programming and identification of possible strategies to overcome limitations where they are identified
- Contribution to the clinical decision making process
- In the event of a patient being found unsuitable for CI, the team provide advice and make recommendations on future management e.g. hearing aid type/settings and accessories

### 7.3 Medical and radiological assessment

The medical CI team will liaise with the local/wider medical team (GP, Paediatrician, Consultant Otolologist, Consultant Radiologist and other appropriate Consultants) to assess and ensure physical fitness for surgery. This may entail having tests, investigations and procedures carried out in their local or other area. All assessments and procedures should be in compliance with policies and guidance of the Royal College of Surgeons where available.

All patients being considered for cochlear implantation should have a medical consultation with the team Consultant Otolologist.

Medical/radiological assessment may include (as appropriate):

- Overseeing medical aspects of the assessment process and pre-admission process to ensure the patient is medically fit to undergo the treatment
- Establishment of aetiology (where possible)
- Referral for genetic counselling
- Referral of patients for MRI, CT or X-ray
- Referral for balance/vestibular assessment
- Advice regarding necessity for vaccination to minimize the risk of pneumococcal meningitis and confirmation of vaccination status
- Confirmation of patient and/or family expectations
- Informing of associated risks of the treatment pre- and post-surgery
- Obtaining fully informed patient consent for surgery

Imaging may be carried out locally to the patient and if so, the images should be viewed on the national Picture Archiving and Communication System (PACS) and the CI service Consultant Radiologist and Consultant Otolologist will provide expert opinion.

### 7.4 Habilitation/rehabilitation assessment

Habilitation or rehabilitation in listening and language development is provided by habilitation professionals such as speech and language therapists, teachers of the deaf, auditory verbal therapists and hearing therapists. Pre-operative assessment will cover a full specialist evaluation of the patient's potential to benefit from cochlear implantation. This will include functional hearing abilities, communication strategies including speech and language, social support network, individual family circumstances, expectations of treatment and commitment to having cochlear implants and the rehabilitation involved. For children, this would also include gaining information about their pre-school educational support or educational environment and peer relationships.

These assessments may take the form of observation, subjective description or evaluation using formal test procedures. The assessment procedure will take into account the patient's age, hearing status and any other medical and/or cognitive issues.

Assessments and evaluation should be undertaken as appropriate in compliance with the guidelines and procedures of the Royal College of Speech and Language Therapists, British Association of Teachers of the Deaf, the AG Bell Academy for Listening and Spoken Language and the British Society of Audiology where available. Equipment should be calibrated to the current British and ISO standards<sup>4</sup>.

The rehabilitation assessment may cover (as appropriate):

- Receptive skills - listening skills for speech
- Lip-reading skills
- Comprehension of spoken language
- Expressive skills
- Language skills in all relevant modes of communication
- Intelligibility, voice and speech sound system
- Quality of life
- Consideration of the environments in which each patient typically communicates and where they find most difficulty
- Expectations setting and management
- Provision of local advice and support
- Device counselling including care and maintenance of the device

For children, a specialist rehabilitation advisor from the team may visit the child in their home and local clinic or education setting. The CI team will provide advice on rehabilitation strategies to parents/carers and local professionals during the assessment process, based on the individual needs and circumstances of the child.

For adults, the assessment is usually centre-based but special arrangements may be put in place for those who are medically unfit to travel. The patient may be assessed in conjunction with their local professionals.

Throughout the assessment period the candidate (where appropriate) and parents/carers should have a clear understanding of the main benefits and limitations of implantation. They should demonstrate that they have realistic expectations of cochlear implantation, e.g. by using a measurement tool such as an expectations questionnaire.

Prior to implantation it is recommended that candidates and their families have an opportunity to hear first-hand experiences of cochlear implantation, either through face to face meetings with implant users and their families, or via DVD/videos/other media.

## **7.5 Psychological assessment**

Cognitive, emotional and behavioural factors can influence the assessment, decision to treat, and post-treatment phases of cochlear implantation. It is recommended that CI services have access to a clinical psychologist with experience in managing patients with severe/profound hearing loss. Clinical psychologists assess the individual patient's or family's needs based on psychological theories and research and provide or recommend appropriate interventions. Clinical psychology input can be indicated at any stage of the patient pathway.

## **7.6 Decision to treat**

Information will be collated from all relevant professionals. On completion of the assessment process, a decision regarding whether or not cochlear implantation is recommended will be taken by the multidisciplinary team together with the patient and parent/carer as appropriate.

The Consultant Otologist carrying out CI surgery is responsible for consenting the patient and/or legal carer about the surgical procedure and potential benefits, risks and complications. Potential complications associated with major ear surgery, with additional specific reference to revision surgery and re-implantation for various reasons including device failure, together with implications of future MRI imaging should be included in the discussion. Waiting times for surgery and information about the hospital stay and postoperative follow-up should be outlined to the patient/carer.

On completion of the assessment pathway a comprehensive report should be provided to the referrer, the patient's GP and the patient as indicated.

If the outcome of the assessment is that cochlear implantation is not recommended for a patient, future management should be discussed together with the opportunity for re-referral in the future as appropriate. These issues should be covered in the written report.

## 7.7 Quality measures

	Standard	Measure
7a	The CI service should have the infrastructure (staffing, facilities and processes) necessary to deliver clinically- and cost- effective services	Systems in place which document and facilitate main aspects of service provision
7b	The CI service should adhere to current NHS waiting time directives	i) Systems in place to facilitate appropriate management of waiting times ii) Ongoing audit
7c	Fast-tracking of urgent cases, such as following meningitis, must be available	Systems in place to ensure fast tracking is supported as required
7d	Equipment must be calibrated to current British and ISO standards	Systems in place and documentary evidence available
7e	Audiological procedures should comply with British Society of Audiology Recommended Procedures and guidance where available	Systems in place to support appropriate clinical practice
7f	All medical/surgical assessments and procedures should be compliant with policies and guidance of the medical and surgical Royal Colleges where available	Systems in place to support appropriate clinical practice
7g	Speech and Language procedures should comply with the policies and guidelines from the Royal College of Speech and Language Therapists where available	Systems in place to support appropriate clinical practice
7h	Teacher of the Deaf procedures should comply with policies and guidance of the British Association of Teachers of the Deaf and British Society of Audiology where available	Systems in place to support appropriate clinical practice
7i	Psychological procedures should comply with the policies and guidance of the British Psychological Society where available	Systems in place to support appropriate clinical practice
7j	Auditory-Verbal Therapists should comply with the policies and guidelines from The AG Bell Academy for Listening and Spoken Language where available	Systems in place to support appropriate clinical practice

## 8 Cochlear implant surgery

The CI service should have the infrastructure to carry out cochlear implant surgery, including surgical skills, theatre team, specialist scientific support, electro-medical equipment, medical/nursing aftercare and appropriate facilities.

CI services should develop a high level of surgical and scientific experience for each type of device which they provide. This can only be achieved by managing a critical mass of children or adults with each particular CI device. It is recommended that each surgeon within a service should carry out a sufficient number of cochlear implant operations per annum to ensure an appropriately high level of skill and experienced is maintained. Experience

within the field in the UK suggests that this should be of the order of 10 cochlear implants per year per surgeon. Each surgeon should regularly audit their surgical outcomes, to ensure their results and rates of complications are in within an acceptable range as described by published audits and case series, e.g. Broomfield et al 2014<sup>5</sup>.

To allow continuity of care, each programme should have a minimum of two experienced ear surgeons capable of performing cochlear implantation and managing any complications. Each surgeon should have a subspecialty interest in Otology and should have received Fellowship training, or equivalent, in cochlear implantation. Where there is a paediatric programme involving implantation in very young infants, the surgeon should also have extensive previous experience of major ear surgery in young children.

Surgery will be carried out using widely accepted minimally traumatic techniques and with reference to manufacturer's surgical manuals. This will include the use of facial nerve monitoring. Prior to wound closure, device function and hearing responses may be evaluated by electrophysiological assessment. Appropriate peri/post-operative imaging should be carried out to determine the position of the device in accordance with local policy.

Information regarding the outcome of surgery must be documented and should be made available to the implant team and the patient immediately after the operation. A written report should be sent to the referring clinician and GP following surgery.

All relevant registration documentation from the manufacturer must be completed, signed and returned.

Prior to discharge the patient should receive written information regarding care of the wound/ear and pain management post-operatively and written guidelines on what to do should medical/surgical problems arise.



## 8.1 Quality measures

	Standard	Measure
8a	The CI service should have the infrastructure to undertake surgeries in a clinically safe and cost-effective manner, including surgical skills, specialist support, electro-medical equipment, medical aftercare including access to intensive care as indicated, and appropriate facilities	Systems in place which document and facilitate main aspects of service provision
8b	The CI service should have a minimum of two experienced ear surgeons. Each surgeon should have a subspecialty interest in Otology and should have received Fellowship training, or equivalent, in cochlear implantation. Where implantation of very young children is delivered, each surgeon should have extensive previous experience of major ear surgery in young children	Systems in place which document and demonstrate that the CI service is adequately and appropriately staffed for provision of care and succession planning
8c	Annual surgical activity levels, of the order of 10 per year per surgeon, must be sufficient to maintain high levels of skill and experience and be subject to regular clinical audit to ensure their results and rates of complications are in within an acceptable range as described by published audits and case series	i) Systems in place to ensure internal monitoring of activity ii) Systems in place for monitoring complications and carrying out clinical audit
8d	Surgery must be carried out using minimally invasive techniques and with reference to the manufacturer's surgical manuals	Systems in place to support appropriate clinical practice
8e	Facial nerve monitoring must be employed during cochlear implant surgery	Systems in place to support appropriate clinical practice
8f	Device function testing should be available as required prior to wound closure	Systems in place to support appropriate clinical practice
8g	Appropriate peri/post-operative imaging should be carried out to evaluate device position prior to discharge from hospital	Systems in place to support appropriate clinical practice
8h	A written report should be sent to the referring clinician and GP following surgery	Systems in place to ensure flow of patient information
8i	Written information should be given to the patient or parent/carer on discharge from hospital on post-operative management, including wound care, pain management and what to do if any problems arise	Systems in place to ensure patients are provided with information within specified timescales

## 9 Device programming

The procedure for activating and programming the device is an ongoing scientific process requiring highly specialist skills. Unlike hearing aids which work by the amplification of sound, cochlear implants work by applying electrical signals to electrodes implanted into the cochlea. Considerable expertise and experience is required, in particular when working with infants and young children. It is crucial that this work is carried out by an appropriately qualified, regulated and experienced healthcare scientist (Clinical Scientists, Clinical Physiologists). The scientific team must consist of at least three healthcare scientists to ensure minimal cover and continuity of patient care, at least one of whom should be a Clinical Scientist (Audiological Scientist or Clinical Physicist) with extensive cochlear implant experience.

The scientific team must possess a high level of experience and expertise for each type of device that they provide. This can only be achieved by supporting a critical mass of children and adults with each particular type of CI device. It is recommended that those involved in CI programming should be seeing an adequate number of patients per week in order to maintain their skills and deliver safe, accurate and effective treatment. They should abide by the relevant professional codes of conduct, e.g. Health and Care Professions Council Standards of Proficiency for Clinical Scientists and standards for continuing professional development.

The scientific team may provide programming appointments at the CI centre or in the CI recipient's local area (in the home, at a clinic, in an educational setting or by the use of telemedicine).

### 9.1 Overview of programming procedure

Once the patient's wound has healed the sound processor should be fitted and custom programmed for the first time (approximately 4 weeks after surgery).

Before initial programming, the Clinical Scientist or Clinical Physiologist should refer to the post-operative imaging report, the operation notes and the intra-operative measurements (if carried out).

The components of the external equipment should be checked and the programming procedure should be explained to the patient and parents/carers.

During programming, each electrode on the electrode array is individually tested and activated by applying appropriate electrical stimuli. Careful observation and monitoring of the patient is required throughout this process. Electrodes that have the potential to cause undesirable non-auditory sensations, such as pain or muscle spasms must be de-activated. Stimulation parameters are optimised for each individual electrode to elicit sound

sensations that vary in pitch and intensity (psychophysics). An appropriate processing strategy is applied to provide a meaningful sound sensation. For bilateral CI recipients, this procedure is carried out for each ear individually.

The parameters are programmed into the patient's sound processor(s). A number of programmes can be created for each ear for a range of listening conditions.

Instructions on the use of the sound processor must be given on or before the day of activation. Supporting materials on the handling, operating and care of the sound processor should be issued to the patient or parent/carer as appropriate.

Appropriate audiological, standardised speech perception and quality of life outcome measures should be performed at regular intervals to enable functional hearing to be monitored.

## **9.2 Programming schedule and access to scientific and technical support**

The procedure for activating and programming the device is an ongoing scientific process. Patients' programming schedules are arranged as part of their Individual Management Plan (IMP). In the first year, regular appointments are required in order to achieve appropriate programming settings which are optimised over time for each individual patient and ear. The number of appointments may vary between patients, but typically a minimum of six appointments are recommended in the first year.

After the first 12 months, patients will typically transition to annual programming. This can take the form of an offered contact, or patient-led follow up. Children or those with more complex requirements may need to be seen more frequently.

Patients will need to be seen in the CI department urgently if they experience non-auditory sensations or a sudden change in sound sensation. They must have rapid access to an experienced Clinical Scientist or Clinical Physiologist for emergency appointments when a cochlear implant device failure is suspected, and within seven working days as a minimum.

For paediatric patients a written report will be sent at appropriate points in time to the parents/carers and relevant professionals as clinically appropriate. If any serious problems arise a written report should be sent to the referring clinician and GP.

Life-long specialist scientific support must be provided for all CI recipients.

### 9.3 Quality measures

	Standard	Measure
9a	Psychophysical measurements should be taken (with reference to the manufacturer's programming manuals) to custom programme the sound processor for each individual ear	Systems in place to support appropriate clinical practice
9b	Those involved in programming should be seeing an adequate number of CI patients on a weekly basis in order to maintain their skills and deliver safe, accurate and effective treatment	<ul style="list-style-type: none"> <li>i) Systems in place for monitoring activity levels for each member of staff</li> <li>ii) Ongoing audit to ensure that all staff are delivering treatment that is safe, accurate and effective</li> </ul>
9c	To monitor functional hearing appropriate audiological, speech perception and quality of life measures should be performed at regular intervals	<ul style="list-style-type: none"> <li>i) Systems in place to support appropriate clinical practice</li> <li>ii) Ongoing audit</li> </ul>
9d	Appropriate programming schedules must be set up according to each patient's individual needs as part of their Individual Management Plan	Systems in place to ensure patient pathways are supported
9e	Rapid access to a Clinical Scientist/Clinical Physiologist within the CI service must be available for cases in urgent clinical need, and within 7 working days in cases of suspected device failure	Systems in place to ensure patient pathways are supported

## 10 Monitoring outcomes and rehabilitation support

The rehabilitation schedule for patients should be adapted to their individual needs and be arranged within their Individual Management Plan (IMP).

### 10.1 Children

For children, outcomes from cochlear implantation lie in the domains of audition, communication (including speech and language), education and quality of life. Rehabilitation professionals from the team work in partnership with the child's local professionals in monitoring progress and providing rehabilitation advice and support.

Each child is assigned a named specialist rehabilitation advisor from the team at the point of referral, and this individual acts as the child's key or link worker. They are the link between the child's local area and the implant centre.

The key/link worker will have at least one appointment in the pre-implant phase and they, or another assigned rehabilitation specialist, will review the patient on a regular basis post-implant according to need. Advice and support is available from the key/link worker, supported by other members of the specialist rehabilitation team, during the monitoring process.

Progress is supported and rehabilitation outcomes monitored after cochlear implantation according to need and, ideally, over the longer term. The frequency of post-implant contacts will change over time and typically is most intense during the first 1 to 3 years, depending on the child's needs and the rehabilitation model in place. A flexible approach should be adopted and agreed in liaison with the child's family and local professionals.

Rehabilitation appointments may be offered at the CI centre or in the CI recipient's local area (in the home, at a clinic or in an educational setting). This may take place closer to home via a "hub and spoke" arrangement or using telemedicine.

The key/link worker, or other assigned rehabilitation specialist, will provide written reports and will ensure that all assessments are documented. These will be shared with all professionals within the CI service and made available to local professionals in the child's home area.

The key/link worker, or other assigned rehabilitation specialist, will also provide feedback at CI service team meetings of any local concerns regarding the CI recipient's progress.

## 10.2 Adults

Adult CI recipients should be assessed at the time of initial device activation to establish and agree their rehabilitation needs. All recipients should be provided with practical training to help them get the most out of their cochlear implant in everyday life. Where clinical need is indicated recipients should be provided with a short block of auditory rehabilitation. This may be carried out either by CI centre staff or rehabilitation professionals in the CI recipient's local area, in liaison with the CI team. Rehabilitation may be self-directed, carried out with friends/family, support agencies or local professionals. There are many tools, resources and methodologies for hearing impaired adults. Some are available online from hearing aid and cochlear implant manufacturers, CI teams and support agencies.

### 10.3 Quality measures

	Standard	Measure
10a	For children and adults, appropriate rehabilitation schedules will be set up according to each patient's individual needs as part of their Individual Management Plan	Systems in place to ensure patient pathways are supported
10b	For children and adults, practical support and training should be made available to help maximise the outcome of the treatment	Systems in place to support appropriate clinical practice
10c	For children, CI service rehabilitation staff should work in partnership with local rehabilitation professionals	Systems in place to support appropriate clinical practice
10d	For children, a named link/key rehabilitation worker will be appointed	Systems in place to ensure named key/link rehabilitation worker in place
10e	For children and adults, rehabilitation support and outcomes monitoring should be undertaken as appropriate	Systems in place to ensure patient pathways are supported

## 11 External equipment and maintenance

CI services will provide the essential external equipment for patients. Optional accessories such as decorative covers, audio cables for listening to music, or accessories for participation in water sports may need to be purchased by the patient. Provision of FM systems and connectivity (where this is not integral to the sound processor) for children will ordinarily be the responsibility of the relevant education service. Adults will typically be responsible for providing their own assistive listening devices. Cochlear implant services should ensure that recipients are aware of the availability of assistive listening devices and where to obtain further information about and access to them.

The CI service is required to ensure access for patients to an adequate stock of essential consumables (batteries, cables and essential spare parts). This may be within the CI service or through a support package purchased by the CI service from the CI manufacturer; batteries may be supplied by the CI centre or through local NHS audiology services. Patients should be given information as to where they can buy other non-essential equipment as required.

The sound processor and associated external parts are vulnerable to damage in everyday use through wear and tear, especially in young children. Cochlear implant centres should arrange provision of replacements of supported items to ensure continuity of care. In accordance with NHS requirements<sup>6</sup>, services should aim to provide replacement or loaner equipment to the patient within two working days (excluding public holidays).

The CI centre is not obliged to provide an additional spare processor to patients. However, manufacturers will provide holiday loaners to patients for a fee. Cochlear implant services are not responsible for delivery of replacements and spare equipment to patients who are overseas, or the receipt of returned items back into the UK from abroad, which may incur additional carriage and customs costs.

If a sound processor is lost, the CI service may impose a range of measures, including but not limited to:

- Delaying replacement by approximately 48 hours in order to allow the patient/ carer additional time to look for it
- The patient may be required to attend an appointment at the CI centre to have replacement equipment refitted, programmed or for additional tuition in the care and maintenance of the device, in particular if they have not attended in the past 12 months. This should be arranged in a timely fashion to ensure continuity of care.
- Requirement to register the loss with the police and to supply a police reference number prior to any replacement being made available
- Replacement of the processor with an earlier model
- Delay in any upgrade of that processor for the full upgrade period applicable in that service
- Financial penalties may also be applied if damage, loss or failure is determined to be due to inappropriate care, with appropriate provision for appeal.

If external equipment is lost, or damaged beyond repair, the CI service should again arrange provision of replacement or loaner items in a timely fashion, to ensure continuity of care, but the patient may incur a financial and/or other penalty. They may also be required to attend the CI centre for a programming appointment before a replacement processor can be issued (in particular if they have not attended in the past 12 months). Additional tuition in the care and maintenance of the device may also be required.

Patients and parents/carers should be informed during the CI assessment process about the CI service's policy on the management of equipment which is lost or damaged beyond repair. Any introduction of such a policy within a service, where no penalty previously existed, or significant change to a policy over time should be communicated in writing to all their CI recipients.

CI purchasers should ensure that funding is available for CI services to repair, maintain and replace processors as and when required, in order for patients to maintain continued access to hearing.

Sound processors should be upgraded on average every five years if newer technology is available and it has potential to deliver improved functionality

and/or hearing performance; or if the patient's existing processor(s) have become increasingly unreliable due to wear and tear; or if the patient's current processor type is no longer supported by the relevant manufacturer.

## 11.1 Quality measures

	Standard	Measure
11a	CI services will provide the essential external equipment for patients, and ensure access to essential consumables either directly, or through manufacturers' support services, or (in the case of batteries) through local audiology	Systems in place to ensure appropriate provision of and access to equipment
11b	Replacement or loaner equipment should be provided to the patients within the UK within 2 working days (excluding public holidays). Items lost or damaged due to inappropriate care may be subject to a reasonable additional time delay	i) Systems in place to facilitate dispatch to achieve this target ii) Ongoing audit
11c	The CI service may impose a range of measures which can include financial penalties for equipment which is lost or damaged	Systems in place to facilitate this where this policy is in place
11d	Sound processors should be upgraded on average every five years. Delays may be imposed due to loss of processor/s or damage due to inappropriate care	Systems in place to arrange for funding and provision of processor upgrades

## 12 Maintenance of the internal device (cochlear implant)

Cochlear implant reliability is high overall, but device failures can occur and they should be managed proactively and without delay. Management of suspected and confirmed failures should be considered by the CI service, purchasers and manufacturers as an emergency. The patient should be admitted for surgery as soon as possible to have the defective device replaced.

Cochlear implant recipients may also require revision surgery for medical reasons (e.g. infection or device migration). In these cases device removal and subsequent re-implantation may require a two stage procedure or having CI surgery in the contralateral ear.

When a device failure is suspected, implant function testing should be carried out by an experienced Clinical Scientist or Clinical Physiologist from the CI service in the first instance. These should subsequently be validated by a clinical specialist from the CI manufacturer.

Most manufacturers provide a 10 year warranty for the internal component of the cochlear implant device. The warranty replacement should be authorised by the CI manufacturer within 7 days of the tests being carried



out if appropriate. Funding should be sought from purchasers for systems which are out of warranty.

Where re-implantation is required, the CI service should arrange for the surgery to be scheduled as soon as practically possible.

The explanted device should be returned to the manufacturer for analysis. The manufacturer should provide the CI service with a detailed report of the analysis within 3 months of the device being returned.

All device failures should be reported to the relevant UK statutory body at the earliest possible opportunity. Individual countries will have their own reporting systems. In England and Wales it is the MHRA (Medicines and Healthcare Products Regulatory Agency). For Scotland it is the NHS Incident Reporting & Investigation Centre, Health Facilities Scotland and for Eire it is the Health Products Regulatory Authority. The MHRA liaises with these bodies and provides a co-ordinated focus across the United Kingdom. Comprehensive guidance is available at [www.mhra.gov.uk](http://www.mhra.gov.uk).

## 12.1 Quality measures

	Standard	Measure
12a	Suspected device failure will be treated as a clinical emergency by the CI service and the manufacturer. Failure will be confirmed by the CI manufacturer within 7 days of their assessment	i) Systems in place to ensure emergency support is available as required ii) Ongoing audit
12b	Replacement surgery will be carried out as soon as possible	Ongoing audit
12c	The manufacturer should provide a detailed report of the failure analysis of the explanted device within 3 months of receipt	Ongoing audit
12d	The CI service should report all device failures to the country's relevant statutory body, in accordance with their policies and guidance	Documentary evidence of notification

## 13 Facilities

The CI service should have the infrastructure to carry out comprehensive assessment, in-patient and follow up services including appropriate medical, surgical, scientific and rehabilitation expertise, with administrative support.

All patient areas should be appropriate to the needs of a deaf population. This should include consideration of visual alerts (e.g. patient appointment information, fire alarms) and appropriate assistive listening devices in the patient clinic.

Facilities for patients should be accessible, safe, suitable, and family friendly. The team should provide appropriate support for paediatric, adolescent and adult patients (as appropriate) and facilities according to current national standards and recommendations by the Department of Health and/or governments for Scotland, Northern Ireland, Wales and the Republic of Ireland.

The environment should be appropriate for the care of paediatric patients as required. Clinic areas should be large enough to comfortably accommodate the patient, family member or carer, clinician and observer or interpreter together with the necessary equipment. There should be an appropriate and suitably located waiting area such that noise from the waiting area does not disturb the treatment and that privacy is maintained. Suitable room/s should be available for group work including patient activities, team meetings and training.

Audiological testing will be performed in soundproof accommodation to BS EN ISO 8253-1: 2010 standards<sup>7</sup>. All facilities must comply with current building regulations, British Standards and the Health and Safety Executive Regulations. External and internal access should comply with the Equality Act 2010<sup>8</sup>.

Specialist software and ongoing support to facilitate the implementation and management of a cochlear implant service must be available.

### 13.1 Quality measures

	Standard	Measure
13a	The CI service should have the infrastructure (staffing, facilities and processes) necessary to deliver clinically- and cost- effective services	Systems in place which document and facilitate main aspects of service provision
13b	Services should provide appropriate facilities for paediatric, adolescent and adult patients in accordance with national standards and recommendations	Systems in place to ensure compliance with relevant national standards
13c	Facilities should be appropriate to the needs of a deaf population	Systems in place to ensure facilities are appropriate for the needs of a deaf population
13d	Audiological testing will be performed in soundproof accommodation to BS EN ISO 8253-1: 2010 standards	Systems in place to record compliance with national standards
13e	All facilities must comply with current building regulations, British Standards, Health and Safety Executive Regulations and the Equality Act 2010	Systems in place to ensure compliance with relevant national standards

## 14 Electromedical equipment

CI services should be adequately equipped with all electromedical equipment necessary to deliver a safe and effective service. Equipment should be serviced on a regular basis and annual electromedical safety checks should be carried out. All equipment must appropriately calibrated to current British and ISO standards.

An asset register should be in place to plan for equipment to be replaced as and when necessary. A 'training on use of equipment' programme must be undertaken annually to ensure that all staff are fully training in the equipment they utilise.

Specialised equipment and facilities may include:

- Assessment and programming of cochlear implant systems
- Objective measurement testing (evoked response audiometry)
- Otoacoustic emissions
- Pure tone audiometry
- Sound field audiometry
- Speech perception testing in quiet and in noise
- Tests of spatial and directional hearing in quiet and in noise
- Tympanometry and acoustic reflexes
- Balance function testing when appropriate
- Facial nerve monitoring in theatre
- Facilities should be available to measure the electroacoustic performance of hearing aids according to current British and IEC standards and programme them to the most suitable settings

### 14.1 Quality measures

	Standard	Measure
14a	Equipment must be regularly serviced according to national standards and requirements	Systems in place to ensure compliance with national standards
14b	Equipment must be regularly calibrated according to current British and ISO standards	Systems in place to ensure compliance with national standards
14c	All staff must be appropriately trained on use of equipment required to undertake the duties within their role	Systems in place to ensure appropriate training of staff

## 15 Education

It is essential that staff develop and maintain expertise in cochlear implantation and their wider professional field.

All team members must participate in their organisation's appraisal scheme. All staff must participate in Continuing Professional Development (CPD) through e.g. personal reading, attending workshops, academic and scientific meetings and professional group meetings. All clinical staff must meet any professional registration requirements required for their post, e.g. registration with the Health and Care Professions Council. All team members should be trained in Deaf Awareness and practical aspects of communication with deaf people, as part of their induction. Newly appointed members of a team who are less experienced must undergo an appropriate process of mentoring under the supervision of a senior colleague.

All clinical and medical team members should be encouraged to join the BCIG.

### 15.1 Quality measures

	Standard	Measure
15a	All staff must undergo their organisation's staff appraisal scheme	Systems in place to ensure staff meet appraisal requirements
15b	All staff must participate in CPD and meet the requirements of their professional body as appropriate	Systems in place to ensure staff maintain CPD requirements
15c	All clinical staff must meet any professional registration requirements required for their post	Systems in place to record and monitor registration requirements and adherence
15d	All team members should be trained in Deaf Awareness	Systems in place to ensure all CI team staff are trained in Deaf Awareness
15e	All new staff must be appropriately trained and mentored	Systems in place to ensure new staff undergo required training programme

## 16 Training

The CI service should be actively involved in educating others on all aspects of cochlear implantation. This may include undergraduate and postgraduate teaching of clinical and medical staff, student placements and supervision, teaching of non-specialist staff, and provision of updates to referrers and local professionals.

### 16.1 Quality measures

	Standard	Measure
16a	Staff within the CI service should be actively involved in educating others in the area of auditory implantation	Record of teaching and training commitments undertaken

## 17 Clinical and information governance

The CI service should comply with all Clinical and Information Governance requirements of their organisation.

A safety programme should be in place for monitoring and ensuring patient safety. A risk register should be maintained and all adverse events logged and investigated. All surgical complications and device failures should be recorded and monitored and reported to purchasers through standard reporting procedures.

Patient related data should be stored and handled according to current Information Governance and Data Protection requirements.

### 17.1 Quality measures

	Standard	Measure
17a	The CI service should comply with all Clinical Governance requirements of their organisation	Systems to monitor and ensure compliance
17b	The CI service should comply with all Information Governance requirements of their NHS Trust or healthcare organisation	Systems to monitor and ensure compliance

## 18 Clinical audit

Clinical benefit is evaluated through performance assessments and questionnaires, with performance measures being obtained before implantation and over time thereafter. Clinical audit should be carried out systematically. CI services should undertake comprehensive monitoring of

their service routinely and aim to provide a clinically- and cost- effective service of the highest quality.

The audits should demonstrate compliance with relevant commissioning policies or purchasing agreements, such as NHS Commissioning Board Service Specification D9a: Cochlear Implants (2012/13)<sup>6</sup>. An appropriate reporting mechanism should be agreed between the service and commissioners/purchasers, such as production of an Annual Report containing key service outcomes.

CI services should identify Key Performance Indicators (KPIs). These measures may include, but are not limited to:

- Safe and successful cochlear implant surgery, e.g. report on unplanned re-admissions within 30 days of surgery and explantation/re-implantation due to medical complications
- Cochlear implant device use
- Specific outcome measures

Information about deceased cochlear implant recipients should be provided to manufacturers to inform device cumulative survival rate data.

Professionals working in CI services should liaise regularly with peers from other CI services throughout the UK (e.g. through BCIG and its associated professional groups) to review case management and share examples of good clinical and managerial practice.

CI services may benefit from participation in BCIG-led data sharing initiatives in order to inform clinical practice and service development in the UK. As a minimum, BCIG will annually collate figures on new cochlear implant activity in the UK and figures for the cumulative CI cohort.

## 18.1 Quality measures

	Standard	Measure
18a	Comprehensive clinical audit should be carried out systematically, including KPIs such as safe and successful surgery, device usage and specific outcome measures	Systems in place to facilitate and record clinical audit
18b	Audits should demonstrate compliance with relevant commissioning/purchasing policies	Documentary evidence of compliance with relevant commissioning policies
18c	CI services should provide information on deceased recipients to manufacturers	Systems in place for appropriate information exchange with manufacturers
18d	CI services should contribute to the BCIG-led annual data collection	Systems in place to facilitate audit

## 19 Service improvement and patient/public involvement

CI services should be committed to reviewing and improving their services on an ongoing basis. They should aim to provide a service that meets the needs of all patients and their families.

They should mutually engage with referrers and their services, providing them with updates on the CI service and clinical pathways, and the opportunity for service improvement and development.

Patient satisfaction surveys should be carried out on a regular basis to monitor patient opinion of the service.

Services should ask for suggestions for improving the service and act upon these where possible. Suggestion boxes should be available in waiting rooms.

### 19.1 Quality measures

	Standard	Measure
19a	Annual patient satisfaction survey/s should be undertaken	Systems in place to facilitate annual patient satisfaction surveys
19b	Suggestion boxes should be available in waiting areas	Suggestion boxes in place within service waiting areas
19c	Feedback from service users, referrers and the public should be acted upon	Evidence of CI service acting upon feedback

## 20 Research

Cochlear implant services should actively participate in research and share their knowledge and experience with their peers through the BCIG journal *Cochlear Implants International*, the BCIG Annual Meeting and professional groups in cochlear implantation, amongst other academic and professional forums. CI services should participate in multi-centre studies and trials and share examples of good practice. These activities may require applications for research grants including from industry partners and must adhere to the appropriate governance procedures of the organisation.

### 20.1 Quality measures

	Standard	Measure
20a	All audit, service evaluation and research activities must comply with the organisation's governance requirements	Systems in place to ensure compliance with governance requirements for research and audit

## 21 Review

This document will be due for review in two years of the publication date.



## 22 Acknowledgments

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