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Cochlear implant services for children, young people and adults. Quality standard

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1. Introduction

The British Cochlear Implant Group Charitable Incorporated Organisation (BCIG) aims to advance knowledge, best practice and awareness in the field of hearing implantation, in particular through the dissemination of cochlear implant (CI) research to health professionals and information to the public. It aims to improve the hearing, communication and quality of life of people with deafness and their families. The BCIG provides comprehensive advice on auditory implantation, developing clinical guidelines and standards in collaboration with its members, and liaising with similar organisations worldwide.

This document supersedes our previous Quality Standard 2018. The BCIG Quality Standard has been updated and revised with reference to many NHS documents and resources that highlight themes for the future of sustainable and quality healthcare (NHS, 2014a, 2014b, 2019b, 2022; The Health Foundation, 2021) including emphasis on the following:

- Service delivery should be informed by up-to-date high-quality training, guidelines and evidence.
- Services should be sustainably-resourced to deliver safe and effective intervention and outcomes within available finances and to achieve this be open to evolving using recognised techniques such as continuous improvement cycles.
- An overwhelming drive for services to be accessible, responsive and personalised to meet the needs of a diverse population and to equip service users to self-manage their long-term health conditions.
- Using technology and internet access to provide access to online support.
- Developing blended service models combining both in-person and virtual contacts, to enhance flexibility and capacity to meet growing demands on healthcare services whilst maintaining quality of care.

This Quality Standard was developed by a working party of experienced clinicians across the four UK nations, in collaboration with the British Academy of Audiology (BAA), Cochlear Implanted Children's Support Group (CICS), the National Cochlear Implant Users Association (NCIUA), the National Deaf Children's Society (NDCS), and the Royal National Institute for Deaf People (RNID). The authors were multidisciplinary (Clinical Scientist (Audiology), Consultant Otologist, Rehabilitationist, Speech and Language Therapist).

We recognise that deaf people vary in how they wish to be described. This document uses the terminology 'deaf' throughout (British Association of Teachers of the Deaf, 2021).

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2. Objective

This document sets out the Quality Standard for NHS-funded clinical CI services in the United Kingdom (UK). The BCIG traditionally includes the Republic of Ireland. We are not able to offer advice on regulatory matters within the Republic of Ireland, however, we welcome their involvement and adherence to this Quality Standard. The standard can be used by service providers, clinicians, charities, the public, commissioners and service users and their families to benchmark and improve the quality of cochlear implant care.

3. Cochlear implantation

The aim of cochlear implantation is to improve the hearing and quality of life of people with permanent severe to profound deafness who do not gain adequate benefit from optimally-fitted hearing aids. 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 cells) in the cochlea.

A CI consists of two parts: an internal part (surgically-implanted) and an external part which is worn 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 and switched on. 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 cells.

3.1. Technology

Quality statements
1. CI devices used comply with all UK/EU regulatory frameworks as appropriate and local organisational policies
2. The procurement process allows consideration of quality, effectiveness and reliability, clinical and long-term support, as well as cost

CI systems (implants and processors) offered within the NHS are available from a small number of manufacturers worldwide that meet the quality statements.

The purchase of CIs must be compliant with UK/EU procurement laws. Although CI services should seek to use the most up-to-date devices, the BCIG cautions that prior to purchasing, teams should obtain evidence of effectiveness and reliability, and should obtain assurance of both readily available expert clinical support and long-term commitment from manufacturers.

3.2. Candidacy criteria

Quality statements
3. Candidacy criteria adheres to current NICE guidance

The National Institute for Health and Care Excellence (NICE) has issued guidance for access to cochlear implantation since 2009. In March 2019, this Technology Appraisal Guidance was updated in the publication TA566 (National Institute for Health and Care Excellence, 2019).

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

Adults who are found to be candidates on completion of assessment are offered a unilateral CI. In exceptional circumstances (e.g. blindness) adults may be offered simultaneous bilateral CIs.

For children, simultaneous bilateral cochlear implantation is recommended as an option whenever clinically appropriate. Sequential implantation is not supported unless the patient was unilaterally implanted as a child at the time of the guidance 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 BCIG.

3.3. Cochlear implant Champions

Quality statements
4. Each CI centre will appoint a Mentor to liaise with local CI Champions

A joint initiative between the British Academy of Audiology (BAA) and the BCIG established the CI Champions scheme (British Academy of Audiology, 2022). The scheme aims to ensure all eligible adults, children and young people (CYP), and their families,

are well-informed about cochlear implants and are offered a timely referral. Local audiology departments appoint a Champion to liaise with a Mentor at a CI centre. The Champion encourages colleagues in their department to identify potential CI candidates and ensures that patients are provided with appropriate information to make an informed decision on referral. Mentors connect with their local Champions and share updates and training, as required, thus establishing and consolidating the seamless care pathway between local audiology departments and CI centres.

3.4. The cochlear implant team

Quality statements

5. The CI clinical team is multidisciplinary including a clinically-experienced Service Lead
6. All CI professionals comply with their professional organisation's regulations and guidelines

The CI service is delivered by a multidisciplinary team of specialist professionals (National Institute for Health and Care Excellence, 2019) 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 Hearing Therapists and/or Auditory Verbal Therapists) and/or Clinical Psychologists. Access should also be available to other appropriate health professionals (e.g. Neuroradiologists, Audiovestibular Physicians, Geneticists, Paediatricians and specialists in Old People's Medicine). The team must have the knowledge and skills to assess and work with CYP and/or adults with a range of complex needs, expectations and priorities.

The Service Lead is an experienced CI clinician with a leadership and management role. They have responsibility for the entire patient pathway and ensuring that relevant Quality Standard and national specifications are met.

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 be met by existing CI centres and if the proposal can demonstrate that it will be cost-effective, able to meet the BCIG Quality Standard and will not destabilise existing clinically and cost-effective services. The BCIG can offer assistance to commissioners who wish to explore the establishment of additional or alternative service provision.

4. Patient and family experience

Quality statements

7. Patients/families/carers have access to current relevant information complying with the NHS Accessible Information Standard
8. Communication needs are met for direct patient contact across the whole care pathway

It is important that patients, their families, carers and associated professionals are given appropriate access to information both during the assessment process and after implantation as necessary. Teams must comply with the NHS Accessible Information Standard (NHS England, 2017). Children and young people should be included in discussions wherever appropriate and supported to participate in decision-making and be active partners in their care (Department of Health, 2003).

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

Information should be accessible to patients in a language that is appropriate to their preferred method of communication, including availability of interpreting services for direct patient contact (face to face or remote). Verbal information should be supported by a written summary.

Appropriately-registered professional British Sign Language and spoken language interpreters should be available at appointments. Other forms of communication support should be available as required, e.g. lipspeakers, Speech-To-Text and other sign language interpretation.

5. Equality of access

Quality statements

9. The CI service commits to and evaluates equality of access to care, and demonstrates plans and actions to address areas of inequality identified

CI services are committed to equality of access including all protected characteristics in all aspects of service delivery (UK government, 2010). Care should be taken to ensure that patients are not disadvantaged in terms of access to assessment, treatment or ongoing care, including consideration of digitally excluded populations (NHS, 2019a). Service audit and monitoring can be used to identify inequality of access leading to a service improvement plan.

6. Delivery of care

Quality statements
10. The CI service provides comprehensive service delivery across the care pathway to ensure continuity of care
11. Service flexibility ensures person-centred care
12. Services support and empower patients to self-manage their cochlear implant care
13. The CI service adheres to current NHS waiting time directives
14. Protocols are in place to expedite time-sensitive cases

CI care in the UK is typically provided by a single CI service, with some services working in close partnership with other providers. Continuity of care leads to better patient experience, reduced costs and better outcomes (Freeman & Hughes, 2010). It is ensured throughout the CI care pathway, which includes pre-implant assessment, surgery, device programming, rehabilitation and equipment maintenance. Information about a patient should flow easily throughout the pathway in order to ensure safe and effective patient management. If a patient requires transfer to another CI centre, the centre will comply with the BCIG transfer process (British Cochlear Implant Group, 2023).

Service flexibility should ensure person-centred care; in some cases, a blended approach (face to face or remote) will be provided. CI services should ensure they have relevant technology, training and permissions (e.g. data governance) to offer care remotely. Shared decision making between the team and the patient/family/carer should be used to plan an appropriate blended service and the frequency of patient contact (scheduled or on-demand) according to patient need. Services will support patients to self-manage their cochlear implant care, recognising that empowerment leads to better long-term outcomes (NHS, 2019b).

6.1. Waiting times

The CI assessment and treatment pathway is subject to National Health Service (NHS) waiting time directives. The CI assessment pathway is complex; active monitoring and other interventions may prolong assessment and/or treatment. Patients should be regularly informed about how they are progressing through the assessment process to provide reassurance and ensure appropriate expectations. Protocols must be in place to expedite assessment and treatment for time-sensitive cases, for example people with increased risk of cochlear ossification and prelingually deaf infants.

7. Assessment of candidacy

Quality statements
15. Assessment includes medical, audiological and rehabilitation components
16. The assessment results and recommendations of the team are communicated effectively
17. Decision regarding future clinical management is taken by a multidisciplinary team in collaboration with the patient/family/carer

A wide range of tests and investigations are carried out by the multidisciplinary CI team to determine whether individuals are likely to benefit from cochlear implantation and meet the candidacy criteria.

7.1. Audiological assessment

Evaluation of hearing status, benefit from hearing aids and functional hearing ability is undertaken in compliance with British Society of Audiology recommended procedures and guidance where available (British Society of Audiology, 2022).

Audiological assessment must include the following:

- 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
- Evaluation of current hearing aids and hearing aid prescription
- Speech perception assessment in accordance with current NICE guidance (TA566) where possible
- Evaluation of middle ear function using tympanometry

Other assessments may also be indicated, e.g. balance assessment, objective testing of hearing thresholds.

7.2. Medical and radiological assessment

The medical CI team will liaise with the patient's local/wider medical team to assess comorbidities and ensure physical fitness for surgery. All patients being considered for cochlear implantation should have a medical consultation with the team Consultant Otologist.

Medical/radiological assessment must include:

- 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) including referral for genetic counselling where indicated
- Referral of patients for imaging investigation
- Advice regarding necessity for vaccination to minimise the risk of pneumococcal meningitis and confirmation of vaccination status

- Selection of device type and consideration of device positioning as dictated by anatomy and underlying pathology
- Informing of associated risks and implications of the treatment
- Obtaining fully informed patient consent for surgery

7.3. Rehabilitation and psychology assessment

Assessment must include:

- General development and additional needs
- Functional listening
- Preferred communication mode
- Social communication skills
- Comprehension of spoken language
- Expressive spoken language
- Language skills in other modalities (e.g. sign)
- Speech intelligibility
- Communication environments
- Expectations (parents/carer/patient)
- Local services availability
- Quality of life
- Speech reading (more often in adults)
- Device counselling, including patient input into device choice
- Expectations management
- Consideration of the impact of comorbidities on outcomes

Assessment may also include evaluation of cognitive, emotional and behavioural factors that can influence the assessment, decision to treat, and post-treatment phases of cochlear implantation. Families will be given the opportunity to make contact with or meet someone who already uses a cochlear implant, recognising the value of peer support.

7.4. Outcome of the assessment

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 MDT together with the patient and parent/carer as appropriate.

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 scanning should be included in the discussion. The Otologist will also discuss the possibility of previously-unidentified anatomical defects of the cochlea that could lead to suboptimal results or other complications. Where implantation is not bilateral – discussion on ear choice is documented. Waiting times for surgery and information about the hospital stay and postoperative follow-up should be outlined to the patient/family/carer.

A report will be provided to the referrer, the patient's GP, other relevant professionals, and the patient/family/carer. If cochlear implantation is not recommended, clear guidance for future management and potential re-referral should be covered. Clinical psychology input can be indicated at any stage of the patient pathway, including if cochlear implantation is not recommended.

8. Cochlear implant surgery

Quality statements
18. The CI surgery is undertaken in a clinically safe environment
19. The CI service has a minimum of two experienced CI surgeons
20. Surgeons maintain high levels of skill and experience evidenced by regular clinical audit
21. Surgery is carried out using minimally invasive techniques
22. Facial nerve monitoring is used
23. Surgery under local anaesthetic is available
24. Device function testing is available
25. Appropriate peri/post-operative imaging is available
26. A written report is sent to the GP following surgery
27. Written information is given to the patient or parent/carer on discharge from hospital

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

CI services should only offer implant devices which they can manage with an appropriate level of expertise. Surgeons within a service will be specifically trained in cochlear implantation, and carry out a sufficient number of CI operations per year to ensure skill and experience is maintained. Experience within the field in the UK suggests that this should be in the order of 10 cochlear implants per year per surgeon. Surgeons must audit their surgical outcomes, to ensure their results and rates of complications are within an acceptable range as described by published audits and case series (Broomfield *et al.*, 2014). Surgeons must keep up to date on new CI surgical techniques.

Each CI centre needs a minimum of two CI surgeons to allow continuity of care. Where there is a paediatric programme involving implantation of infants, the surgeons will have extensive experience in major ear surgery in young children. Succession and handover planning will ensure continuation of surgical expertise and maintenance of patient safety. It is recognised that actively participating in the training of future surgeons is an important aspect of the role of most CI surgeons. Trainees must only undertake stages of surgery that they are judged as competent to perform by the supervising consultant surgeon. If a more senior trainee is operating

independently, a consultant surgeon must be immediately available to offer advice/assistance as required.

Surgeons working in satellite hospitals must demonstrate an equal level of training in and ongoing experience in CI. If working alone, they must demonstrate close links with the CI centre and should actively participate in the MDT process.

Surgery will be carried out using widely accepted minimally invasive/minimally traumatic techniques and with reference to manufacturers' surgical manuals. Facial nerve monitoring must be routinely available and used in all cases involving Specialty Trainees.

Surgery under local anaesthesia (LA) may be offered in selected cases following consideration by the MDT and after detailed consultation with the patient/family/carer (Walters *et al*., 2022). The risks and benefits of LA surgery will be discussed, and written information provided.

Prior to wound closure, device function and auditory responses may be evaluated by electrophysiological assessment. Appropriate peri/post-operative imaging should be available to determine the position of the device if indicated in accordance with local policy.

Information regarding the outcome of surgery must be documented and made available to the CI team and the patient after surgery. A written report is sent to the GP following surgery. All relevant registration documentation from the manufacturer must be completed and returned.

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

9. Device programming

Quality statements
28. Programming is performed in line with manufacturers' recommendations
29. Instructions and supporting materials on the handling, operating and care of the sound processor are accessible to the patient or parent/carer on or before the day of first fitting
30. Appropriate programming schedules are set according to each patient's individual needs
31. Rapid access to appointments is available for cases of urgent clinical need
32. Appropriate management is available for patients with residual hearing in the ipsilateral ear (hybrid/EAS) or contralateral ear (bimodal)

Activating and programming the device is an ongoing process. Patients will require programming appointments throughout the lifetime of their implant(s); this may be delivered face to face, remotely, or through a blended care model. Clinicians will require ongoing training in updated hardware and software. Clinical competency will be maintained via a combination of peer support, manufacturer clinical assistance, and reflective practice as part of Continuing Professional Development.

All post-operative imaging, operation notes and any intraoperative measurements will be reviewed prior to the first fitting. The first fitting should occur at the earliest opportunity once it is medically safe to do so. A suitable sound processor magnet strength will be chosen to achieve the balance between adequate retention and skin health; this may need altering at a later stage, especially as post-operative swelling improves. Patients and families should be advised to check the implant site regularly, and know the signs of a magnet that is too strong.

Patients and/or families may receive their speech processor kit around the time of surgery in order to become familiar with the equipment prior to first fitting. Instructions and supporting materials on the handling, operating and care of the sound processor should be given to the patient or parent/carer on or before the day of first fitting.

Device programming tests the electrodes and sets the electrical dynamic range across the electrode array. Manufacturer software and objective measures provide methods to streamline and expedite this process. Electrodes that have the potential to cause undesirable non-auditory sensations, such as pain or muscle spasm will be de-activated. An appropriate processing strategy is applied to provide a meaningful sound sensation. For people with bilateral CI, this procedure is carried out for each ear individually.

Patients with sufficient residual hearing in the implanted ear should be offered a hybrid/Electro Acoustic Stimulation (EAS) device which can combine acoustic and electrical hearing in the same ear to maximise hearing potential. Similarly, patients with aidable residual hearing in the contralateral ear should be encouraged to continue hearing aid use on this side, for bimodal listening. Some CI systems offer specific hearing aids that have greater compatibility with the CI sound processor and these aids should be available.

9.1. Programming schedule and access to scientific, technical and medical support

Programming appointments are required until optimal CI use and performance is established. The number of appointments may vary between patients and are typically concentrated within the first year.

After this, most patients will transition to an on-demand service, requesting a face to face appointment as required. Remote models of care may be implemented so that patients can check their device use and performance themselves at home, via an

app or online. Children or those with more complex requirements (e.g. patients with older CIs that do not have telemetry capability, patients with additional disabilities or non-standard maps) may need to be seen more frequently, on an on-schedule basis. Where there is evidence that new methods of programming improve outcomes or patient experience, teams should use them.

Patients will need to be seen in the CI department urgently if they experience significant problems that they cannot resolve themselves e.g. non-auditory sensations, a sudden change in sound percept, significant deterioration in hearing ability or any trauma around the CI site. They must have rapid access to an urgent appointment when a CI device failure is suspected.

Patients/carers must be advised how to recognise and manage medical problems following surgery. Patients (or parents/carers) should be able to contact their CI centre with non-urgent queries during working hours but should also know that their local services (NHS 111/GP/local hospital emergency department) provide a first point of contact if they are medically unwell and need immediate advice or assistance.

The BCIG provides guidelines for Audiologists working within a CI team (British Cochlear Implant Group, 2022a).

10. Rehabilitation

Quality statements
33. All patients are offered person-centred rehabilitation. This will optimise device use and listening to support individual communication goals and quality of life
34. The patient's family and support networks are included with patient/parent permission
35. Staff maintain close links with local services to offer support and advice at all stages
36. The rehabilitation team has appropriate expertise and skill mix to identify and advise on coexisting issues that may impact listening

Rehabilitation professionals from the team work in partnership with the patient, their family and local services (with the patient's permission).

Rehabilitation support can be delivered through a combination of direct (face to face, telemedicine and/or domiciliary) or indirect (contact with local professionals, facilitating self-directed rehabilitation, sign-posting to support groups, company websites and troubleshooting materials).

Rehabilitation support will be most intense for CYP in the first three years and in the first year for adults. After that, the team will offer flexible support to adapt to the patient's needs over the longer term.

The rehabilitation team will offer advice, support and/or training focussing on:

- Optimal/consistent device use
- Listening/Auditory rehabilitation
- Communication mode and social engagement
- Education/employment needs (in liaison with local services)
- Practical advice and support with assistive technology
- Rate of predicted progress with the CI. Patients may have undiagnosed or additional comorbidities that come to light as they progress and live with their implants that may impact on device use and progress. Any issues with the patient's development (in listening or communication) will be raised in a timely manner with the patient, family, MDT and local services. Onward referrals will be made as required.

The BCIG provides guidelines for rehabilitation professionals working within a CI team (British Cochlear Implant Group, 2022a).

11. Equipment and maintenance

Quality statements
37. CI services provide the essential sound processor equipment for patients, and ensure access to essential consumables either directly or through manufacturers' support services
38. Replacement equipment is provided to patients in the UK within 2 working days
39. Patients will use their sound processor model for at least five years, after which an upgrade is offered if it provides improvement
40. CI services ensure patients are aware of the importance of CI site skin health
41. CI services ensure patients are aware of the risk of harm from battery ingestion and use secure battery compartments when required

CI services will provide and maintain the essential sound processor equipment for patients. Optional equipment such as decorative covers, audio accessories for listening to music, or accessories for participation in sports (including water sports) may need to be purchased by the patient. CI services should ensure that patients are informed about assistive listening devices and where to obtain them (UK government, 2022). Provision of assistive listening devices for CYP will typically be the responsibility of the relevant education service.

The CI service will ensure patients have 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.

The sound processor and associated external parts are vulnerable to damage in everyday use through wear and tear, especially in young children. CI centres should arrange provision of replacements of supported items to ensure continuity of care. In

accordance with NHS requirements (NHS Commissioning Board, 2013), services should aim to provide replacement equipment to the patient within two working days (excluding public holidays). CI services are not responsible for management and maintenance of equipment for patients who are overseas.

The CI centre is not obliged to provide an additional spare sound processor to patients. However, manufacturers may provide holiday loaners to patients for a fee.

The CI service should ensure patients and carers are given full information about different retention and wearing options to minimise the chance of a sound processor being lost. Patients and parents/carers should be encouraged to use 'find my processor' in their processor's app, if available and appropriate. 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 or significant change to a policy over time should be communicated to all people with CI.

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.

Patients will use their sound processor model for at least five years, after which an upgrade is offered if it provides improvement. Patients can be offered the option of receiving the upgrade remotely.

The CI service should ensure patients continue to be aware about the importance of cochlear implant site skin health, including reminders about checking magnet strength. Skin thickness can change, especially in elderly people, and skin breakdown can be very problematic.

Ingestion of batteries can cause significant harm; services will have protocols in place to ensure patients/parents/carers are aware of the risks, and secure battery compartments are used when required (NHS, 2019c).

12. Maintenance of the internal device (cochlear implant)

Quality statements
42. Suspected device failure is treated as a clinical priority by the CI service and the manufacturer. Device function test results are confirmed by the CI manufacturer within 7 days of their assessment
43. Replacement surgery is carried out as soon as possible
44. The manufacturer provides a detailed report of the failure analysis of the explanted device within 3 months of receipt
45. The CI service reports all device failures to the relevant statutory body
46. Patients are informed of the MRI compatibility of their device and will be told to contact their CI centre if they are referred for an MRI scan

CI reliability is high overall, but internal device failures can occur. When a device failure is suspected, implant function testing should be carried out initially by the CI service, and then by the CI manufacturer. Management of suspected and confirmed failures should be considered a priority by the CI service, purchasers and manufacturers. The MDT will make a recommendation, and where appropriate the patient should be offered replacement of the failed device as soon as possible. The CI service will monitor the implant function over time e.g. through impedance monitoring, monitoring outcomes and patient report and will carry out further investigation where indicated.

People with CI 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.

Most manufacturers provide a 10-year warranty for the internal component of the CI device. The device function test results (and authorisation of warranty replacement if appropriate) should be confirmed by the CI manufacturer within 7 days of the tests being carried out. Funding should be sought when the failed device is out of warranty.

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. 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. In Northern Ireland, it is the Northern Ireland Adverse Incident Centre. The MHRA liaises with these bodies and provides a coordinated focus across the United Kingdom. Comprehensive guidance is available at www.mhra.gov.uk.

Patients should be given access to information regarding safety, protecting their internal device and MRI scanning, including an MRI patient information sheet and questionnaire link for feedback after their MRI scan (British Cochlear Implant Group, 2022b).

13. Monitoring outcomes

Quality statements
47. People with CI remain under the care of a cochlear implant team for life
48. Individual outcomes are monitored and inform the ongoing treatment plan

Continued

Continued

Quality statements
49. Written reports are sent at appropriate timepoints to the patient/parents/carers and relevant professionals as clinically appropriate
50. Service audits are undertaken to demonstrate continuous service improvement and compliance with relevant commissioning policies
51. CI services contribute to the BCIG-led annual data collection
52. Annual patient satisfaction survey/s are undertaken
53. Services are committed to evidence-based care and decision making

13.1. Individual outcomes

Appropriate audiological, standardised speech perception, patient-reported, and quality of life outcome measures should be monitored at regular intervals. Both formal and informal measures may be used. The same measures will be used both pre- and post-operatively where possible in order to demonstrate benefit. Benefit from a cochlear implant may be different for each patient.

13.2. Service outcomes

Clinical audit is a quality improvement process aiming to improve patient care and outcomes. CI services should have protocols in place to undertake systematic 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, such as NHS Commissioning Board Service Specification D09/S/A: Cochlear Implants (NHS Commissioning Board, 2013).

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

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

Information about deceased CI 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 the BCIG and its associated professional groups) to review case management and share examples of good clinical and managerial practice.

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

Patient satisfaction surveys should be carried out regularly. Services should share feedback with BCIG as appropriate in order to improve patient care nationally, e.g. the BCIG MRI patient questionnaire.

Services are committed to evidence-based care and decision making to achieve the best patient outcomes and experience.

14. National registry of hearing implants (NRHI)

Quality statements
54. Services comply with data collection and upload requirements of the NRHI when available

15. Patient and public involvement and engagement (PPIE)

Quality statements
55. Changes to practice are co-designed with patient representative groups as appropriate
56. Feedback from patients, referrers and the public is considered, and shared with BCIG as appropriate

CI services should be committed to evaluating 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. Changes to practice and patient information should be co-designed with patient representative groups and evaluated to ensure they achieve their aim.

Services should ask for suggestions for improvement and act upon these where possible. Suggestion boxes or online alternatives should be available e.g. a QR code or a website link for service users to provide feedback.

16. Facilities and equipment

Quality statements
57. The CI service has appropriate facilities and equipment for their patients in accordance with national standards and recommendations
58. Audiological testing is performed in sound-treated accommodation to current British Standards
59. Equipment is calibrated and serviced in accordance with current British and ISO standards, with records appropriately retained
60. Medical equipment is maintained and stored according to NHS guidelines
61. All staff comply with infection control and health and safety policies
62. Clinics have a Wi-Fi network that patients can access
63. All staff are appropriately trained on use of equipment required to undertake their duties

Facilities for patients should be accessible, safe, suitable, and family friendly for a deaf population (including for patients with additional comorbidities). This should include the provision of visual or other devices to alert the patient that the clinician is ready to see them. The team should provide appropriate support and facilities for CYP and adult patients (as appropriate) according to national standards and recommendations by the Department of Health and/or governments for England, Scotland, Northern Ireland and Wales.

There should be an appropriate and suitably located waiting area that does not allow noise to disturb the treatment and to maintain privacy – ideally with a separate area for children. The service should have access to telemedicine options to support patients where this is clinically appropriate. The telemedicine system must have the option of providing captions. A Wi-Fi network accessible by the patient allows demonstration of apps and online resources to patients.

Audiological testing will be performed in sound-treated accommodation to current British Standards. Sound-field testing should comply with the British Society of Audiology guidance (British Society of Audiology, 2019). 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 (UK government, 2010).

Manufacturers will provide specialist software and ongoing clinical and training as required. CI services must have robust systems and IT support in place to comply with data protection regulations and to ensure timely patient management.

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 be appropriately calibrated to current British and ISO standards, with calibration and service records appropriately retained.

An asset register should be in place to plan for equipment to be replaced as and when necessary. A schedule of training must be in place to ensure that all staff are fully trained in the equipment they use.

17. Continuing professional development (CPD)

Quality statements
64. Staff comply with their organisation's staff appraisal scheme
65. Clinical staff meet required professional registration requirements
66. Staff are educated in Deaf Awareness
67. New staff are appropriately trained and mentored

Continued

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). All clinical staff must meet any required professional registration requirements e.g. registration with the Health and Care Professions Council. All staff (clinical, administrative and clerical) should be trained in Deaf Awareness, and practical aspects of communication with deaf people, as part of their induction. New staff must undergo an appropriate process of mentoring under the supervision of a colleague.

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

18. Teaching and training

Quality statements
68. Staff within the CI service are actively involved in educating others in appropriate aspects of cochlear implantation

The CI service should educate others on appropriate 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 services (including CI Champions).

19. Clinical and information governance

Quality statements
69. The CI service complies with all Clinical and Information Governance requirements of their organisation
70. The CI service has appropriate data sharing agreements in place with each CI manufacturer

A 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 should be recorded and monitored and reported to relevant bodies.

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

Data sharing agreements must be in place between the CI service and the CI manufacturers to ensure appropriate patient care.

20. Research

Quality statements
71. Managers and service leads commit to a research-positive culture

Managers and service leads will commit to a research-positive culture to improve patient care and treatment options, give patients wider access to clinical research, and support staff CPD. CI services should actively participate in research and share their knowledge and experience with their peers, for example through the journal Cochlear Implants International, the BCIG Annual Meeting and academic and scientific meetings both nationally and internationally. CI services should participate in multi-centre studies and trials. These activities may require applications for research grants including from industry partners and must adhere to the appropriate governance procedures of the organisation.

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Robert Nash is a consultant otologist at Great Ormond Street Hospital. He has particular interests in auditory implants, chronic otitis media in children, and congenital anomalies of the ear. Through an appointment at University College London, he conducts research into the genetics of hearing loss.

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