Quality standards for adult cochlear implantation

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1. Introduction
Cochlear implantation is a multidisciplinary therapy that involves as a key element the surgical implantation of an electrode array into the cochlea to provide direct electrical stimulation of the auditory nerve. Cochlear implants (CIs) are designed for individuals with hearing impairment to compensate for a moderate-to-profound sensorineural hearing loss, if there is little or no benefit from hearing aids. CIs bypass the non-functioning part of the auditory system in order to deliver electrical signals directly to the auditory nerve. They can be used effectively by both pre-lingually and post-lingually deafened children and adults.

Studies have shown that cochlear implantation is recognized as a safe and effective procedure. A CI consists of two parts, an external component and an internal one.

1.1. Internal
The implant consists of the electronics and their housing, the electrode array, the receiving antenna, and a magnet that holds the coil in place behind the ear.

1.2. External
The audio processor is worn behind the ear and consists of a control unit, a battery pack, and a coil that transmits information through the skin to the implant.

The HEARRING network is committed to the highest standards of quality. In order to ensure a consistently high level of service and the effectiveness of cochlear implantation, and to provide each patient with the best possible hearing implant solution for the treatment of their individual hearing loss, we have established this set of quality standards. The standards are a realistic minimum attainable by all HEARRING member clinics, and should be employed alongside current best practice guidelines.

2. Team structure
2.1. Structure of the adult CI team
An adult CI team may function independently or as part of a wider service within a hearing or hearing implant centre, including paediatric and teens CI services. It is a multidisciplinary team made up of the following key personnel:

(a) Otologists

The responsibility for cochlear implantation and all completed diagnostic procedures will remain with the surgeon.

The senior ENT surgeon will have experience in otology and CI surgery. The otologist will comply with recommendations for a minimum of 20 CI operations to be carried out yearly.

Newly appointed surgeons will have had extended sub-speciality training at an advanced level in otology and CI surgery in appropriate specialist centres in their country or abroad. This will include having attended a temporal bone dissection course for CI surgeons.

Once appointed, a consultant surgeon will work as a member of the consultant CI surgical team, initially under the mentorship of the senior surgical colleague(s), with at least six months of supervision by a senior colleague for an appropriate number of CI operations. The surgeon will participate in the process of auditing CI cases and in maintaining a database of such cases.

(b) Audiologists, clinical scientists, physiologists, rehabilitation therapists, hearing therapists, speech and language therapists, clinical physiologists, engineers, coordinator

These personnel must be qualified to post-graduate level, and hold an accredited MSc or similar qualification according to national standards. This must be supplemented with two years of practical experience and a recognized hearing therapy qualification.

They will furthermore have extensive clinical experience within the field of cochlear implantation, together with knowledge and understanding of the multidisciplinary areas within the programme. Their role may also include wider research responsibilities. The coordinator is responsible for the day-to-day management of the programme and will
ensure that appropriate services are provided for each adult through the CI patient pathway. They will be a core team member, with further specialist training in cochlear implantation and clinical management of the profoundly deaf. The Coordinator will have a high level of clinical, organizational, leadership, and professional skills.

(c) **Administrator/secretary**

The administrator will hold appropriate secretarial qualifications and have a high level of organizational, communication, and information technology skills. They will work closely with the head of service.

(d) **Cochlear implant head of service**

The head of service, in addition to the above, is accountable for the delivery of the multidisciplinary service. They will provide scientific and clinical leadership and will have managerial responsibility for service design, forward planning, finance, patient management, and human resources. They will typically be a senior clinician of their profession and be qualified to PhD level (or have equivalent knowledge and skills) with further specialist training and experience (ideally a minimum of 10 years) within the field of cochlear implantation, together with knowledge and understanding of the multidisciplinary areas within the programme.

(e) **CI team personnel** should be members of the relevant national and/or international CI professional groups.

(f) **Clinical team members** should attend regular training in developments within the field of cochlear implantation. Attendance at relevant courses, conferences and meetings at national and international levels is desirable. Regular attendance at national meetings should be available for all team members. All team members should have a plan for their continuing professional development.

(g) **All team members** should be trained in awareness of Deaf culture and in practical aspects of communicating with people with hearing loss, as part of their induction.

(h) **Personnel requirements** for cochlear implantation should be in line with national standards and guidelines. One person can be in charge of several of the roles described above.

(i) **Newly appointed members** of the team who are less experienced must undergo an appropriate programme of training and supervision provided by relevant experienced members of a CI team.

2.2. CI team: additional support

The core team should include individuals with skill and experience in fitting of hearing aids to severe and profoundly deaf people, or should have access to this service.

Where the core team does not include professionals from the following services or specialities, it should have access to them as required:

- Audiological medicine
- Tinnitus
- Balance
- Radiology
- Medical physics
- Genetic counselling
- Psychology
- Psychiatry
- Interpreter services
- Social services for the Deaf
- Deaf advocacy.

CI teams may develop partnership services with local services where appropriate. Such partnership services must have appropriate training and expertise.

3. **Accommodation (where applicable)**

3.1 To ensure ease of communication there should be suitable telecommunication access for deaf patients and their relatives. This should include the necessary facilities for the patient to contact the clinic through a variety of modes (e.g. speech-to-text, text-to-text, fax, or email).

3.2 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), visual alarms (e.g. fire alarms), and appropriate assistive listening devices in the patient clinic.

3.3 Clinic areas should be large enough to comfortably accommodate the patient, family members, clinicians, and observers or interpreters, together with the necessary equipment.

3.4 A suitable room should be available for group work, including patient activities and team meetings/training.

3.5 There should be a suitable waiting area near the treatment rooms, large enough and with sufficient comfortable chairs to accommodate the number of people likely to be waiting at any one time. The waiting area should be more than a corridor. Where paediatric services co-exist, a separate area suitable for children must be provided.

3.6 The treatment rooms should be sufficiently separated from waiting areas so that noise from the waiting areas does not disturb the treatment, and privacy is maintained.

3.7 All facilities and rooms must comply with current relevant health and safety regulations and guidelines.

4. **Clinical facilities**

4.1. **Clinical facilities** should be available for

- Pure tone audiometry
- Speech perception testing:
  - (a) In quiet
  - (b) In noise
- Sound field audiometry (sound localization tests, if required)
- Hearing aid testing and fitting
- Probe-tube microphone measurements
- Tympanometry
4.2. Audiological equipment
All audiological equipment must meet nationally recognized standards.

Audiological equipment must be calibrated to national standards as required, on an annual basis, using recommended methods, and must undergo a daily on-site system check.

All testing should be carried out according to professionally recommended protocols and procedures.

5. Referral and selection criteria
5.1 Guidelines for the referral of patients for assessment of their suitability for cochlear implantation, and patient selection criteria, should be available in writing on request.

5.2 The selection criteria for cochlear implantation in adults:
(a) Post-lingually deaf adults
Post-lingually deaf adults with a moderate-to-profound hearing loss are considered good candidates to benefit from cochlear implantation, if hearing aids provide no adequate speech understanding.
(b) Perilingually deaf adults
Depending on individual communication abilities and needs, some perilingually deaf adults obtain benefit from cochlear implantation. Thorough assessment and counselling are required beforehand.
(c) Pre-lingually deaf adults
In general, pre-lingually deaf adults are not good CI candidates. Special circumstances for implantation may apply after intensive counselling.

Referral and selection of candidates should be in line with relevant national standards and guidelines.

5.3 In the event of a patient falling outside of the selection criteria, but being recommended for cochlear implantation by the CI team, the team should apply to the local funding authority for financial support by means of an individual patient Case of Need, if necessary.

5.4 Patient selection criteria should be reviewed regularly by the HEARRING Group, to inform national authorities regarding recommendations for future developments in this area.

5.5 Acknowledgement of the receipt of the referral to the referring agent must be undertaken according to current targets and mechanisms set by the National Health Authority, and must comply with local agreements.

6. The assessment process
The assessment process shall be performed in the most efficient and timely way possible.

The time frame for the overall assessment process shall not exceed 18 weeks.

6.1 Unless clinically contra-indicated, all patients must have a comprehensive CI assessment. The purpose of this process is to assess the patient’s functional hearing abilities and to determine whether these are likely to be significantly improved through cochlear implantation.

6.2 Coordinated management of the pre-implant assessment process by a named Coordinator or Head of Service is essential.

6.3 Service delivery should consider the aims and objectives of the national governmental authority frameworks.

6.4 For each patient, the assessment track must be followed according to a written check-list and recorded in the patient’s hospital file.

6.5 Following the pre-operative assessment, a written report detailing the outcome of the assessment will be sent to the referring agent within the appropriate reporting timescales, or within 2 weeks of a decision being made by the CI team, whichever is the shortest.

6.6 Waiting times for diagnostic testing and treatment should be as short as possible and comply with current national and local targets. Current HEARRING targets are 6 weeks for diagnostics and 18 weeks for treatment.

6.7 Details on locally agreed patient pathways should be available on request.

6.8 Fast tracking of patients through the assessment process must be available when clinically indicated.

6.9. Pre-operative assessments should include the following
6.9.1. Medical
(a) All patients referred to the CI centre should have a medical consultation with the team otologist. The otologist should adhere to the current recommendations provided by the medicines and health care products agency.
(b) The referral of patients for magnetic resonance imaging, computed tomography, or X-ray is the responsibility of the otologist or other locally agreed on appropriately trained and experienced professional.
(c) Appropriate referral for balance/vestibular assessment should be available if indicated.
(d) For each patient, it is the responsibility of the surgeon, either themselves or through an appropriately trained nurse practitioner, to:
   - Undertake a medical consultation during the assessment process, and pre-admission, to ensure that the patient is medically fit to undergo the treatment
   - Discuss all pre- and post-surgical risks associated with the treatment
Discuss the necessity for vaccination to minimize the risk of pneumococcal meningitis
- Refer the patient for genetic counselling if required
- Obtain fully informed patient consent for the treatment

6.9.2. Audiological
Each patient must receive a full audiological assessment performed according to professionally accepted protocols.

The audiological assessment must include:
- Otoscopic examination of the ears by microscope
- Determination of hearing thresholds bilaterally using pure tone audiometry or other recognized methods suitable for the patient
- Determination of uncomfortable loudness limits
- Objective hearing threshold assessment (must be available)
- Determination of bilateral middle ear function using tympanometric techniques
- Speech perception testing in quiet and in noise
- Hearing aid testing and evaluation.

In addition to the above core audiological assessments, the CI programme must have access to appropriate electrically evoked response audiometry, promontory stimulation testing, and measurement of otoacoustic emissions.

6.9.3. Hearing aid evaluation
Each patient should have their current hearing aid configuration re-evaluated and where appropriate have their settings revised or the best available new hearing aids fitted. The suitability of amplification should be verified using an appropriate combination of the following:
- Aided soundfield hearing thresholds
- Speech perception testing using standardized pre-recorded speech material, and live voice where appropriate
- Measurement of electroacoustic performance of hearing aids according to current standards and programming them to optimal settings.

6.9.4. Patients fitted with new hearing aids or given a change of hearing aid settings
Patients fitted with new hearing aids or given a change of hearing aid settings may require access to a structured programme of auditory rehabilitation. For some patients the period may be extended to several months for clinical reasons.

6.9.5. Communication
Pre-operative assessment may include a full assessment of the patient’s communication and social strategies. 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 and hearing status and will normally include a detailed case history, and an assessment of the patient’s receptive and expressive skills.

The following areas may be assessed:
- Receptive skills – listening skills for speech
  (a) Lip reading skills
  (b) Comprehension of spoken language
- Expressive skills
  (a) Language skills in all communication modes
  (b) Intelligibility, voice, and speech sound system
- Details should be collated about the environments in which each adult typically communicates and where they find the most difficulty.

6.9.6. Psychological status
Some patients will require a psychological assessment. A referral to a qualified psychologist or psychiatrist should be initiated when there are concerns regarding the candidate’s mental health, learning ability, personality and motivation, adaptation to their deafness, or unrealistic expectations about cochlear implantation that cannot be addressed through counselling by the CI programme team.

6.9.7. Candidacy for unilateral/bilateral implantation
Bilateral implantation is recognized as the state-of-the-art approach to ensure the optimal outcome for the individual patient. Whenever possible, bilateral implantation should be considered. However, due to national restrictions, opportunities for bilateral implantation may vary.

7. Cooperation of the CI team with other services
7.1 All members of the CI team should meet on a regular basis to ensure effective communication, thereby ensuring quality service for each patient.
7.2 Contact must be maintained with the referring agent and local professionals.
7.3 The CI programme should cooperate as appropriate with other services, including the following:
- Other hospital departments
- Audiology, radiology, medical physics, wards, ambulatory care, etc.
- Local/national support groups
- Social services
- Community services
- Educational services.
7.4 Contact with support services should only be made with the permission of the patient and at the discretion of the CI team.

8. Pre-operative information and counselling
8.1 Basic information and counselling should be given to the patient according to a written check-list and recorded in the patient’s hospital file.
8.2 Whenever possible, information should be given to patients in a language or medium that is appropriate to their preferred method of communication.
8.3 Interpreters should be offered as and when required and in accordance with local practice.
8.4 Teams should continuously monitor, review, and update the quality and quantity of the information they provide, and should have a written protocol to determine what information is given at which time.
8.5 Verbal information should be supported by a written summary for the patient whenever required.
8.6 Throughout the assessment period, patients should have a clear understanding of the main benefits and limitations of implantation. Unrealistic expectations regarding cochlear implantation must be avoided. If possible, a measurement tool such as an expectations questionnaire should be included in the general assessment protocol.
8.7 It is recommended that candidates, and where possible a family member/friend, meet with experienced CI users. Matching candidates and users in terms of age and duration of deafness and type of CI device may be beneficial.
8.8 Patients’ relatives and friends should be encouraged to become involved in all aspects of pre- and post-implant management. This should be done only with the permission of the patient and at the discretion of the CI team.
8.9 Issues surrounding cochlear implantation, including the views of the deaf community, should be discussed and the patient should have an opportunity to meet people who have decided against implantation, if they wish.
8.10 Waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of assessment.
8.11 Patients should be given information about cochlear implantation organizations, national and local charities and self-help organizations, and equipment and services for deaf people.
8.12 The patient should be offered contact between the team and the patient’s employers and/or work colleagues. Contact should only be made with the permission of the patient and at the discretion of the CI team.
8.13 A final discussion between the patient and key team members should be scheduled for the end of the assessment, at which agreement is reached about whether or not to proceed.
8.14 If the outcome of the assessment is that cochlear implantation is not recommended for a patient, an exit clinic appointment should be offered to explain and discuss this recommendation and provide patient support. The discussion should include recommendations for future management, and referral for other equipment and/or services for deaf adults if appropriate, together with the opportunity for re-referral in the future. These issues must be communicated in a written report to the referring clinician or agency.

9. The CI device
9.1 There are different CI manufacturers supplying CI centres. Information regarding the technical specifications of these different devices should be made available.
9.2 The patient should be given further information on the CI devices currently available, and on their advantages and disadvantages. The patient should be given an explanation as to why they have been offered a particular device, or choice of devices. Written information on the device(s) offered should also be made available.
9.3 HEARRING centres only use and implant devices that are legally approved by national authorities.
9.4 The CI device offered to the patient will:
   • Have a proven track record of safety and reliability
   • Have all necessary approvals (e.g. CE mark, Food and Drug Administration)
   • Conform to the recommendations of the national regulatory agency
   • Have the highest quality clinical and technical support available from the manufacturer
   • Meet national purchasing requirements, where applicable.

10. Surgery and in-patient care
10.1 The consultant CI surgeon is responsible for the overall medical care of the patient.
10.2 The surgical team, which may include a suitably trained nurse practitioner, is responsible for conducting a comprehensive pre-operation discussion of the surgical procedure and potential complications with the patient, and for obtaining the patient’s informed consent.
10.3 The surgeon shall attempt to preserve any residual hearing a patient has, where possible. Therefore, the surgical techniques employed shall reflect the latest knowledge and be state-of-the-art. Every effort should be made to protect the patient’s inner ear/cochlea.
10.4 The surgeon will continue to monitor the patient’s progress during the post-operative period and will be responsible for dealing with any surgical or medical problems that may arise in relation to the implant.
10.5 Information regarding the outcome of surgery must be documented and should be made available to the audiological and rehabilitation teams as soon as reliable data are available.
10.6 An intra- or post-operative radiological examination to check the position of the device and the electrode array should be considered.
10.7 Prior to discharge from hospital, the patient should receive written information regarding post-operative care of the wound/ear and pain management, and written guidelines on what to do should medical/surgical problems arise.
10.8 Prior to discharge from hospital, advice regarding health and safety with a CI must be given to the
patient, together with the manufacturer’s written safety guidelines.

11. Post-operative fitting and tuning of the audio processor
11.1 The audio processor should be fitted and programmed once the patient’s wound has healed satisfactorily.
11.2 The audio processor should be fitted and programmed only by experienced clinical personnel (see 2.1.b) who have been fully trained in the relevant protocols and procedures (or by less experienced scientists/audiologists only if under direct supervision).
11.3 Before the initial programming, relevant team members must:
   (a) Check the external CI components
   (b) Explain the programming procedures.
11.4 Each device should be fitted and programmed according to the manufacturer’s recommended procedures and to maximize benefit for the patient. The appropriate number of programming sessions should be offered to each patient according to clinical need.
11.5 A comprehensive explanation of the use of the audio processor must be provided. Patients should be encouraged to contact the implant programme if they have any queries or concerns.
11.6 Printed materials on handling, operation, and care of the audio processor should be issued to the patient and to relatives/caregivers, as appropriate.
11.7 The patient must have open access to the CI centre (or a designated local partner-service) for checking the entire implant system and for reprogramming the audio processor.
11.8 A written report should be sent to the referring agent following initial processor fitting and at the 1-year treatment interval.
11.9 A written report should also be sent to the referring agent if any serious problems arise.

12. Post-operative rehabilitation and assessment
12.1 Following implant surgery, the patient must be examined by the implant surgical team and have open access to additional appointments as required. The patient should be offered further annual medical review, and checks of the implant and audio processor function.
12.2 Post-operative rehabilitation should begin after initial fitting, according to the individual needs of the patient, to:
   - Facilitate acclimatization to the new sensation of sound
   - Reassure the patient and family/caregiver
   - Outline the rehabilitation programme.
12.3 The rehabilitation programme should be tailored to each individual’s needs. Counselling should support patients and their families regarding expectations, rehabilitation procedures, and continuing commitment to the rehabilitation programme.
12.4 The rehabilitation programme may include evaluation of and training in:
   - Detection of sound, including localization and spatial tests
   - Auditory discrimination
   - Voice quality
   - Speech intelligibility
   - Language comprehension and expression
   - Lip reading
   - Hearing tactics
   - Social skills.
12.5 Sufficient rehabilitation sessions should be offered to optimize CI use. The patient must have open access to the CI centre (or a designated local partner-service) for rehabilitation and counselling as required.
12.6 Appropriate standardized audiological, speech perception, and quality-of-life measures should be performed after initial tuning, at least twice in the first year following surgery, and at regular intervals thereafter, to allow progress to be monitored.
12.7 After the first year following implant surgery, the patient should be offered annual audiological review. This can take the form of a clinic-initiated appointment, or patient-led follow-up. Moreover, patients should have access to additional appointments as required.
12.8 It is recommended that the referrer and local involved professionals receive written reports on patient progress.

13. Follow-up and long term maintenance
13.1 The patient must have open access to the CI centre (or a local partner-service) for programming, rehabilitation and surgical reviews as required.
13.2 Adequate spare parts and replacements of external equipment must be available as required. This service should be organized in such a way that replacement equipment can be issued or dispatched on the same or the next working day. Audio processor batteries should be available to implant users either from the CI programme or from a local audiology department by prior agreement.
13.3 Individual centres should have a policy for replacement of lost or damaged processors that is equitable for all patients.
13.4 Teams should have an agreed-upon strategy for upgrading audio processors and contralateral hearing aids.
13.5 Arrangements should be in place to upgrade each patient’s audio processor every 5 years (at minimum), subject to new technology being available for the appropriate implant system.
13.6 Following the annual review, a written report detailing the outcome of the review should be sent to the referring agent.
14. **Device failure**

14.1 If an internal device failure is suspected, the patient should be offered an appointment promptly (within one day) to check the device’s internal and external components.

14.2 The implant manufacturer should be contacted promptly regarding investigation of the device failure. If indicated, a clinical/engineering representative from the company should be available at the patient appointment to provide support.

14.3 Upon confirmation of internal device failure, the clinical personnel (see 2.1.b) must inform the otologist surgeon and the head of service/coordinator and an urgent appointment with the implant otologist surgeon should be offered to the patient, to discuss re-implantation or other options.

14.4 The device failure should be reported to the relevant national authorities.

14.5 If re-implantation is agreed upon with the patient, it should be carried out as soon as medically possible and appropriate, to minimize auditory deprivation.

14.6 Re-implantation and programming should be carried out as detailed above. Further rehabilitation needs should be assessed and provided for as appropriate.

15. **Clinical management**

15.1 All aspects of the CI service should have adequate systems of record-keeping, to facilitate auditing and planning.

15.2 The implant programme should perform regular audits and comply with the requirements of the responsible national authorities. Audits should cover:

- Clinical activity
- Staffing levels
- Patient performance outcomes
- Medical and surgical complications
- Device failures
- Research interests and outcomes
- Patient feedback on the service.

16. **Transfer of care (national)**

16.1 A protocol must be in place for the transfer of care of an adult to an alternative programme or the acceptance of care of an adult from an alternative programme, if requested.

16.2 Patients will usually be referred to the nearest CI centre, unless the patient or family request to be transferred to a particular centre.

16.3 The receiving centre will confirm that they can support the type of device used by the patient before the referral is made.

16.4 All the relevant documentation will be sent to the receiving centre. This will include: full details of the patient’s address, telephone number, and email address, information on the internal device and external processor used, recent programmes, ART (Auditory Nerve Response Telemetry) results (or similar), aided audiograms, speech perception results, rehabilitation reports and results, medical details of surgery and any complications, and contact details for the GP.

16.5 The receiving CI programme will acknowledge the referral in writing and confirm that the funding has been agreed on for continued support of the patient.

16.6 Generally, patients will not be referred to another centre less than one year after implantation. This is to allow for post-operative medical follow-up, the establishment of suitable device programming, and the provision of initial rehabilitation.

17. **Patient and other feedback and complaints**

17.1 Documentation provided by the CI programme should include written information about the complaints procedures within the hospital and other relevant services.

17.2 Patient and caregiver feedback should be systematically collected to inform service review, and should be managed according to local policy.

**Acknowledgement**

The Quality Standards for Adult Cochlear Implantation are based on the British Cochlear Implant Group Standards.