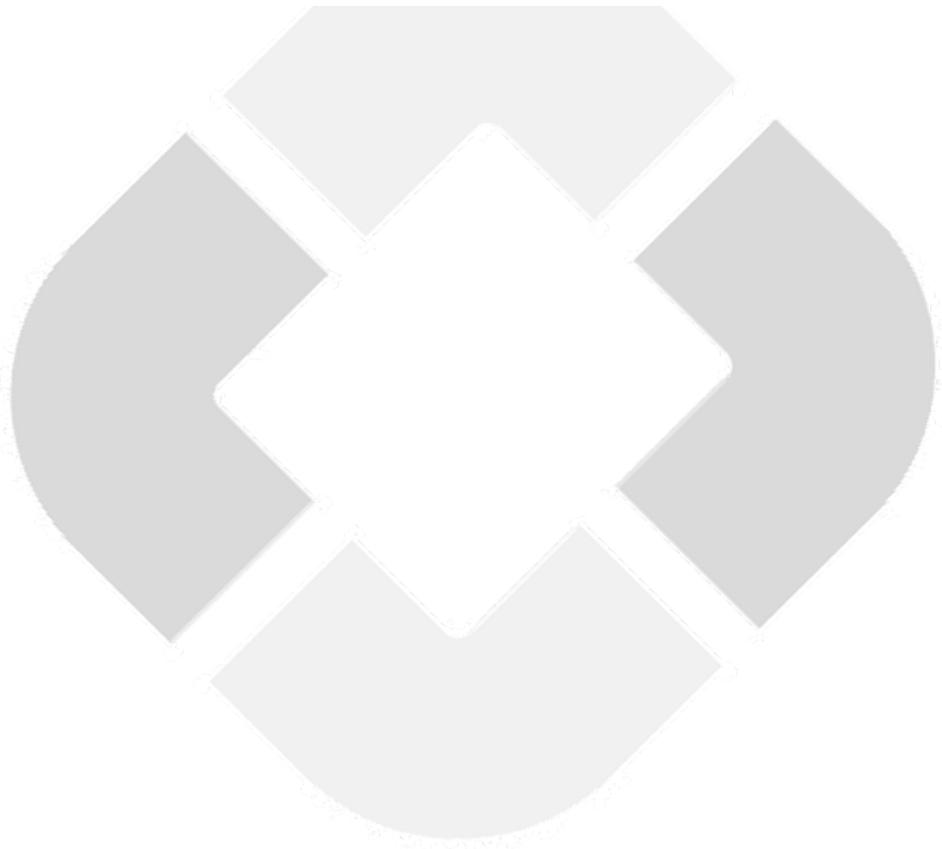


# Quality Standards for Cochlear Implantation in Adults and Older Adults

Revision 2

HEARRING Group  
2017



This clinic is a member of the HEARRING network.

HEARRING is a **learning network of collaborative experts** in the field of hearing implants. It is an association of preeminent international centres offering comprehensive hearing implant solutions for the treatment of hearing loss.

HEARRING members are committed to leading the exploration of new avenues of research in hearing implant science, to advancing clinical procedures and to developing and perfecting surgical techniques. Membership in the HEARRING network is founded on the belief that research, and any subsequent advancement in the field of hearing implants, is possible only through **international collaboration** and the pooling of collective experience from leading clinical centres around the world.

In order to provide each user with the best possible hearing implant solution for the treatment of her/his individual hearing loss, the HEARRING network is committed to the **highest standards of quality**.

HEARRING surgeons are worldwide **leading experts** in restoration AND preservation of hearing.

Because the field is developing quickly and encompasses an ever-growing knowledge base which includes new scientific insights, technologies and materials, HEARRING members' **collaborative research** initiatives are extremely important to the success of each individual member clinic. To meet the challenges of the future, HEARRING will continue to not only develop and advance standards in the field but will also make these standards transparent.

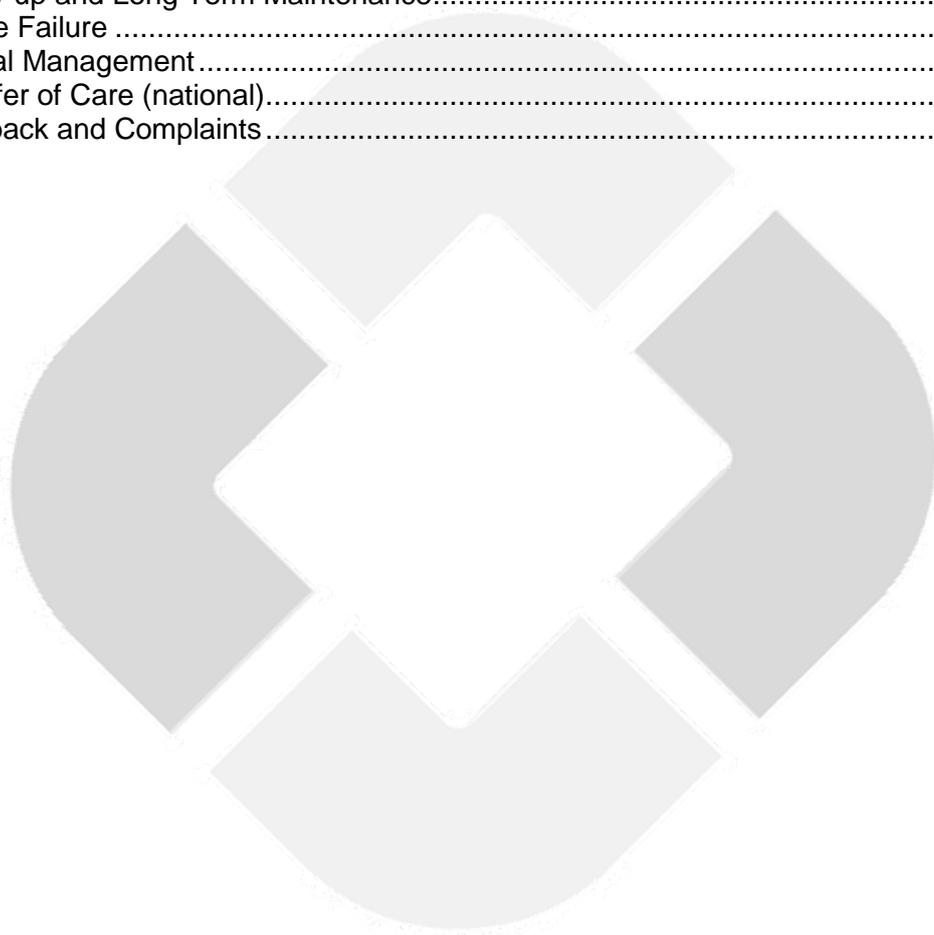
... network with the experts



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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 can be used safely and effectively by children and adults of all ages, including older adults. Many older adults suffer from age-related hearing loss (ARHL), which may be caused by disease, workplace and environmental noise exposure, medications, or a combination thereof. CIs bypass the non-functioning part of the auditory system in order to deliver electrical signals directly to the auditory nerve, thereby providing a hearing percept useful for understanding speech.

Studies have shown that cochlear implantation is recognised as a safe and effective procedure.

In general, the CI procedure is the same for older adults as for younger ones. In this paper adults are referred to as “candidates” prior to implantation, “CI recipients” between surgery and initial fitting, and as “users” after implantation. As noted throughout this paper, a candidate’s / user’s individual cognitive abilities and physical and mental health must be considered and may influence how some of the procedures detailed herein are carried out.

A CI consists of 2 parts: an external component and an internal one.

## 1.1 Internal

The implant consists of the electronics and their housing, an atraumatic electrode array, the receiving antenna, and a magnet that holds the coil in place behind the ear. For the standard CI application, a relatively long electrode array is used to stimulate multiple sites along the cochlea covering the hearing loss area.

## 1.2 External

The CI 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. As an alternative, a single-piece CI audio processor, using similar technology, may be worn on the head and off the ear.

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 person 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

The team structure for CI teams working with older adults is similar to those working with younger adults. Compared with implant teams working with young and middle-aged adults, additional personnel are required to address the physical and cognitive/mental health needs particular to older adults. The implant team may function independently or as part of a wider service within a hearing or hearing implant centre. 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 6 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 & 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. All should be sensitive to and aware of the medical, physical, and mental health needs of older adults. The team must be supplemented with 2 years of practical experience and a recognised 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 within the programme. 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 their CI patient pathway. The coordinator will be a core team member, with further specialist training in cochlear implantation and clinical management of people with profound deafness. The Coordinator will have a high level of clinical, organisational, leadership and professional skills.

c. *Anaesthetists for older adults*

Anaesthetics risk can be significantly higher in the elderly. Thus, anaesthetics should be administered by appropriately qualified and experienced personnel. Pre-anaesthetic assessment and optimisation of co-morbidities is essential. Close collaboration with general medical physicians and geriatric physicians is important.

d. *Consulting specialists for older adults*

Neurologists, neuropsychologists, geriatricians, gerontologists, ophthalmology, social workers, physical therapists, occupational therapists, and nursing home personnel may be consulted. The role of these personnel in CI is to ensure that all aspects of the older adult's health and social support system be considered during pre-, peri- and post-operative periods so that benefit from the implant is maximized for each individual. All professionals are expected to have the

education appropriate to their field of practice and licensure and certification commensurate with local standards.

- e. *Administrator / Secretary*  
The administrator will hold appropriate secretarial qualifications and have a high level of organisational, communication and information technology skills. They will work closely with the Head of Service.
- f. *CI 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, user 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.
- g. CI team personnel should be members of the relevant national and / or international CI professional groups.
- h. 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.
- i. As part of their induction all team members should be trained in awareness of Deaf culture and in practical aspects of communicating with people with hearing loss.
- j. 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.
- k. 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.
- l. 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 hearing-impaired candidates/users and their families. This should include the necessary facilities for the candidates/users to contact the clinic through a variety of modes (e.g. speech-to-text, text-to-text, e-mail, SMS, WhatsApp).
- 3.2** All patient areas should be appropriate to the needs of the hearing-impaired population. This should include consideration of visual alerts (e.g. appointment

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

- 3.3 Clinic areas should be large enough to comfortably accommodate the candidate/user, family members, clinicians and observers or interpreters, together with the necessary equipment, including wheelchairs and walkers.
- 3.4 A suitable room should be available for group work, including user 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. Waiting areas should be easily accessible and offer proper facilities for all candidates/users and accompanying persons.
- 3.6 Examination rooms should be sufficiently separated from waiting areas so that noise from the waiting areas does not disturb the counselling and treatment and so that privacy is maintained. Examination rooms should be well lit to accommodate the vision needs of older adults.
- 3.7 Printed and electronic materials should be suitable for adults with age-related vision loss and mild cognitive impairment. For printed materials, a 14-pt font size should be used, and text should be printed on non-glossy paper with good contrast between text and background colours. Sentences should be formulated as simply and as directly as possible; the passive voice is discouraged. Information should not be text dense; rather, bullet points and short sentences should be used. Instructions should be simple and clear and should incorporate line drawings when possible. For electronic materials, the same guidelines apply; however a font-size selector, displayed on the upper-right area, may be used in lieu of a fixed font size.
- 3.8 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:

- a. Pure tone audiometry
- b. Speech recognition testing
  - (1) In quiet
  - (2) In noise
- c. Sound field audiometry (sound localisation tests, if required)
- d. Hearing aid testing and fitting
- e. Probe-tube microphone measurements
- f. Tympanometry
- g. Otoacoustic emissions testing
- h. Objective measurements
  - (1) Evoked response audiometry
  - (2) Electrically evoked potentials
  - (3) Electrocochleography

- i. Balance function testing
- j. Vestibular rehabilitation
- k. Imaging procedures.

#### **4.2 Audiological equipment**

All audiological equipment must meet nationally recognised 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 candidates for an assessment of their suitability for cochlear implantation and candidate selection criteria should be available in writing on request.
- 5.2** The selection criteria for cochlear implantation in adults:
  - a. *Post-lingually hearing-impaired adults*  
Adults that usually have severe-to-profound bilateral hearing loss
  - b. *Post-lingually hearing-impaired older adults*  
Post-lingually hearing-impaired adults with ARHL that is moderate-to-profound are considered good candidates to benefit from implantation, if hearing aids provide no or only limited speech understanding.
  - c. *Peri-lingually hearing-impaired adults*  
Depending on individual communication abilities and needs, some peri-lingually hearing-impaired adults obtain benefit from cochlear implantation. Thorough pre-operative assessments and counselling are required.
  - d. *Pre-lingually hearing-impaired adults*  
In general, pre-lingually hearing-impaired adults with or without ARHL are not good CI candidates and are unlikely to receive much benefit due to the very long duration of hearing loss. Special circumstances for implantation may apply after intensive counselling.
  - e. Referral and selection of candidates should be in line with relevant national standards and guidelines.
- 5.3** If a candidate falls outside of the selection criteria but is 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** Candidate selection criteria should be reviewed regularly by the HEARING 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 must be performed in the most efficient and timely way possible. The time frame for the overall assessment process should not exceed 18 weeks.

- 6.1 Unless clinically contra-indicated, all candidates must have a comprehensive CI assessment, the purpose of which is to assess the candidate'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 an appointed 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 candidate, the assessment track must be followed according to a written check-list and recorded in the candidate'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 candidates 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 candidates 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 candidates for MRI, CT, 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 candidate, it is the responsibility of the surgeon, either him/herself or through an appropriately trained nurse to:

- (1) Undertake a medical consultation during the assessment process and pre-admission to ensure that the candidate is medically fit to undergo the treatment
- (2) Discuss all pre- and post-surgical risks associated with the treatment
- (3) Discuss the necessity for vaccination to minimise the risk of pneumococcal meningitis
- (4) Refer the candidate for genetic counselling, if required
- (5) Obtain fully informed patient consent for the treatment

### 6.9.2 *Audiological*

- a. Each candidate must receive a full audiological assessment performed according to professionally accepted protocols.
- b. The audiological assessment should include:
  - (1) Otoscopic examination of the ears
  - (2) Determination of hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the candidate
  - (3) Determination of uncomfortable loudness limits
  - (4) Objective hearing threshold assessment (must be available)
  - (5) Determination of bilateral middle ear function using tympanometric techniques
  - (6) Speech perception testing in quiet and in noise
  - (7) Hearing aid testing and evaluation
- c. 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 candidate should have their current hearing aid configuration re-evaluated and, where appropriate, either 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:

- a. Aided soundfield hearing thresholds
- b. Speech perception testing using standardised pre-recorded speech material and live voice where appropriate
- c. Measurement of electroacoustic performance of hearing aids according to current standards and programming them to optimal settings

### 6.9.4 *Candidates fitted with new hearing aids or given a change of hearing aid settings*

Candidates 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 candidates the period may be extended to several months for clinical reasons.

### 6.9.5 Communication

Pre-operative assessment should include a full assessment of the candidate'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 candidate's age and hearing status and will normally include a detailed case history and an assessment of the candidate's receptive and expressive skills.

The following areas may be assessed:

- a. Receptive skills - listening skills for speech
  - (1) Lip reading skills
  - (2) Comprehension of spoken language
- b. Expressive skills
  - (1) Language skills in all communication modes
  - (2) Intelligibility, voice, and speech sound system
- c. Details should be collated about the environments in which each candidate typically communicates and where he/she has the most difficulty.

### 6.9.6 Psychological status

Some candidates 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 hearing loss, or if they have unrealistic expectations about cochlear implantation that cannot be adequately addressed through counselling by the CI programme team.

### 6.9.7 Candidacy for unilateral / bilateral implantation

Bilateral implantation is recognised as the state-of-the-art approach that is most likely to allow candidates to achieve maximum speech understanding. Whenever possible, bilateral implantation should be considered. However, due to national restrictions, opportunities for bilateral implantation may vary.

## 7 Cooperation of the Cochlear Implant 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 candidate.
- 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:
  - a. Other hospital departments
  - b. Audiology, radiology, medical physics, wards, ambulatory care, etc.
  - c. Local / national support groups
  - d. Social services
  - e. Community services
  - f. Educational services
  - g. For older adults neurology, neuropsychology, geriatrics, gerontology, ophthalmology, physical and occupational therapy, and home care services should also be included

- 7.4 Contact with support services should only be made with the permission of the candidate 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 candidate according to a written check-list and recorded in the candidate's hospital file.
- 8.2 Whenever possible, information should be given to candidates 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 candidate whenever required.
- 8.6 Throughout the assessment period, candidates should have a clear understanding of the main benefits and limitations of CI use. 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, duration of hearing loss, and type of CI may be beneficial.
- 8.8 The candidate's family 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 candidate and at the discretion of the CI team.
- 8.9 All Issues regarding implantation should be discussed and the candidate should have the 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 Candidates should be given information about:
- a. Cochlear implantation organisations
  - b. National and local charities and self-help organisations
  - c. Equipment and services for people with hearing loss
- 8.12 The candidate should be offered contact between the team and the candidate's employers and/or work colleagues. Contact should only be made with the permission of the candidate and at the discretion of the CI team.

- 8.13** A final discussion between the candidate 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 candidate, an exit clinic appointment should be offered to explain and discuss this recommendation and provide candidate support. The discussion should include recommendations for future management, referral for other equipment and/or services for adults with severe-to-profound hearing loss if appropriate, and 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 Cochlear Implant Device**

- 9.1** There are different CI manufacturers supplying CI centres. Information regarding the technical specifications of these different devices should be made available to the candidate.
- 9.2** The candidate should be given further information on the CIs currently available and on their advantages and disadvantages. The candidate should be given an explanation as to why he/she has been offered a particular CI or choice of CIs. Written information on the CI(s) offered should also be made available to the candidate.
- 9.3** HEARING centres only use and CIs that are legally approved by national authorities.
- 9.4** The CI offered to the candidate will:
- a. Have a proven track record of safety and reliability
  - b. Have all necessary approvals (e.g. CE, FDA)
  - c. Conform to the recommendations of the national regulatory agency
  - d. Have the highest quality clinical and technical support available from the manufacturer
  - e. 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 CI recipient.
- 10.2** The surgical team, which may include a suitably trained nurse, is responsible for conducting a comprehensive pre-operation discussion of the surgical procedure and potential complications with the CI recipient and for obtaining informed consent.
- 10.3** The surgeon shall attempt to preserve any residual hearing a candidate 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 candidate's inner ear / cochlea.

- 10.4 The surgeon will continue to monitor the CI recipient'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, especially concerning residual hearing, 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 should be considered in order to check the position of the device and the electrode array.
- 10.7 Prior to discharge from hospital, the CI recipient should:
  - a. Receive written information regarding post-operative care of the wound / ear and pain management
  - b. Receive written guidelines on what to do if medical / surgical problems arise
  - c. Receive counselling on health and safety with an implant
  - d. Receive the manufacturer's written safety guidelines
  - e. Be provided with the implant patient ID card that is delivered with the CI from the CI manufacturer.

## **11 Post-operative Fitting and Tuning of the Audio Processor**

- 11.1 The audio processor should be fitted and programmed once the user's wound has healed satisfactorily.
- 11.2 The audio processor should be fitted and programmed only by experienced clinical personnel (see section 2.1.b) who have been fully trained in the relevant protocols and procedures.
- 11.3 Before the initial programming, responsible team members must:
  - a. Check the external CI components
  - b. Explain the programming procedures
- 11.4 Each CI should be fitted and programmed according to the manufacturer's recommended procedures and to maximise benefit for the user. The appropriate number of programming sessions should be offered to each user according to clinical need.
- 11.5 A comprehensive explanation of the use of the audio processor must be provided to the user. Users should be encouraged to contact the CI team if they have any questions or concerns.
- 11.6 Printed materials on the handling, operation, and care of the audio processor should be issued to the user and to family / caregivers, as appropriate. Large print versions of information sheets should be available for older adults.
- 11.7 The number of programming sessions required by users may vary.
- 11.8 The user must have open access to the implanting CI centre (or a designated local partner-service) for checking the entire implant system and for reprogramming the audio processor.

- 11.9** A written report including a current audiogram should be sent to the referring agent following initial processor fitting and at the 1-year treatment interval.
- 11.10** 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 user must be examined by the implant surgical team and have open access to additional appointments as required. The user should be encouraged to accept regular checks of the implant and audio processor function and the concomitant documentation.
- 12.2** Post-operative rehabilitation should begin immediately after initial fitting, according to the individual needs of the user to:
- a. Facilitate acclimatisation to the new sensation of sound
  - b. Reassure the user and family / caregiver
  - c. Outline the rehabilitation programme
- 12.3** The rehabilitation programme should be tailored to each user's individual needs. Counselling should support users 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:
- a. Detection of sound, including localisation and spatial tests
  - b. Auditory discrimination
  - c. Voice quality
  - d. Speech intelligibility
  - e. Language comprehension and expression
  - f. Lip reading
  - g. Hearing tactics
  - h. Social skills
- 12.5** Sufficient rehabilitation sessions should be offered to optimise CI use. The user must have open access to the CI centre (or a designated local partner-service) for rehabilitation and counselling as required.
- 12.6** To allow progress to be monitored, appropriate standardised audiological, speech perception, and quality of life measures should be performed after initial fitting, at least twice in the first year following implantation, and at regular intervals thereafter.
- 12.7** After the first year following implantation, the user should be offered an annual audiological review. This structured schedule can be adapted to the user's wishes, if necessary. Moreover, users should have access to additional appointments for examination as required.
- 12.8** It is recommended that the referrer and locally involved professionals receive written reports on a user's progress.

## **13 Follow-up and Long Term Maintenance**

- 13.1** The user must have open access to the CI centre (or designated 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 organised 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 users either from the CI programme or from a local audiology department by prior agreement.
- 13.3** Individual centres should have a policy for the replacement of lost or damaged processors that is equitable for all users.
- 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 user'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 user should be offered an appointment promptly (within 1 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 user's next 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 must be reported to the relevant national health authorities.
- 14.5** If re-implantation is agreed upon with the user, it should be carried out using the same surgical techniques.
- 14.6** Planning for revision surgery also depends on the hearing status of the non-implanted ear. If the candidate does not have satisfactory hearing after unilateral device failure (i.e. if they have severe-to-profound hearing impairment or nearly so in the non-implanted ear), re-implantation should be carried out as soon as all required audiological and medical data are available to minimize the burden of auditory deprivation.

- 14.7** Re-implantation and programming should be carried out as detailed above. Further rehabilitation needs should be assessed and provided 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:
- a. Clinical activity
  - b. Staffing levels
  - c. The user's performance outcomes
  - d. Medical and surgical complications
  - e. Device failures
  - f. Research interests and outcomes
  - g. User feedback on the service provided

## **16 Transfer of Care (national)**

- 16.1** A protocol must be in place for the transfer of care of a user to an alternative programme or the acceptance of care of a user from an alternative programme, if requested.
- 16.2** Users will usually be referred to the nearest CI centre, unless the user or family request to be transferred to a particular centre.
- 16.3** Before the referral is made the receiving centre will confirm that they can support the user's type of CI.
- 16.4** All the relevant documentation will be sent to the receiving centre. This will include: full details of the user'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. Reports from consultants should be included.
- 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 user.
- 16.6** Generally, users will not be referred to another centre less than 1 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 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 User/Candidate and caregiver feedback should be systematically collected to inform service review, and should be managed according to local policy.



## **Acknowledgement**

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