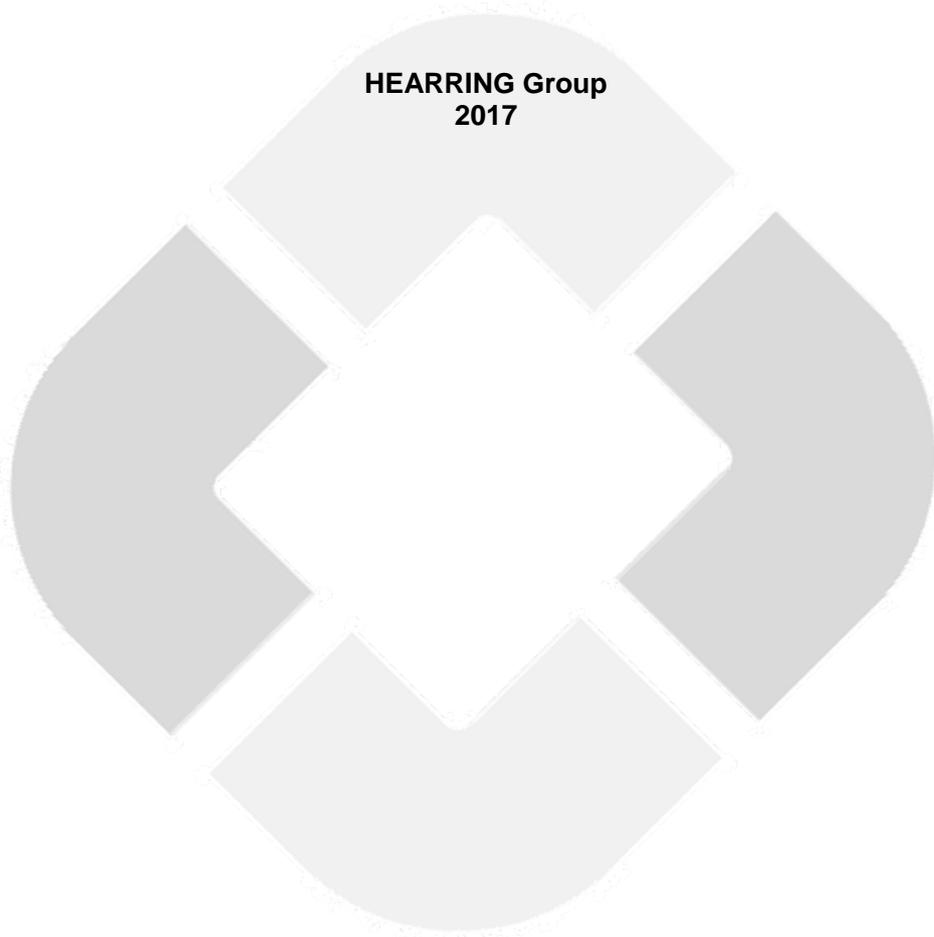


Quality Standards for Cochlear Implantation in Infants, Children, and Young Adults

Version 2.0

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 child 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.

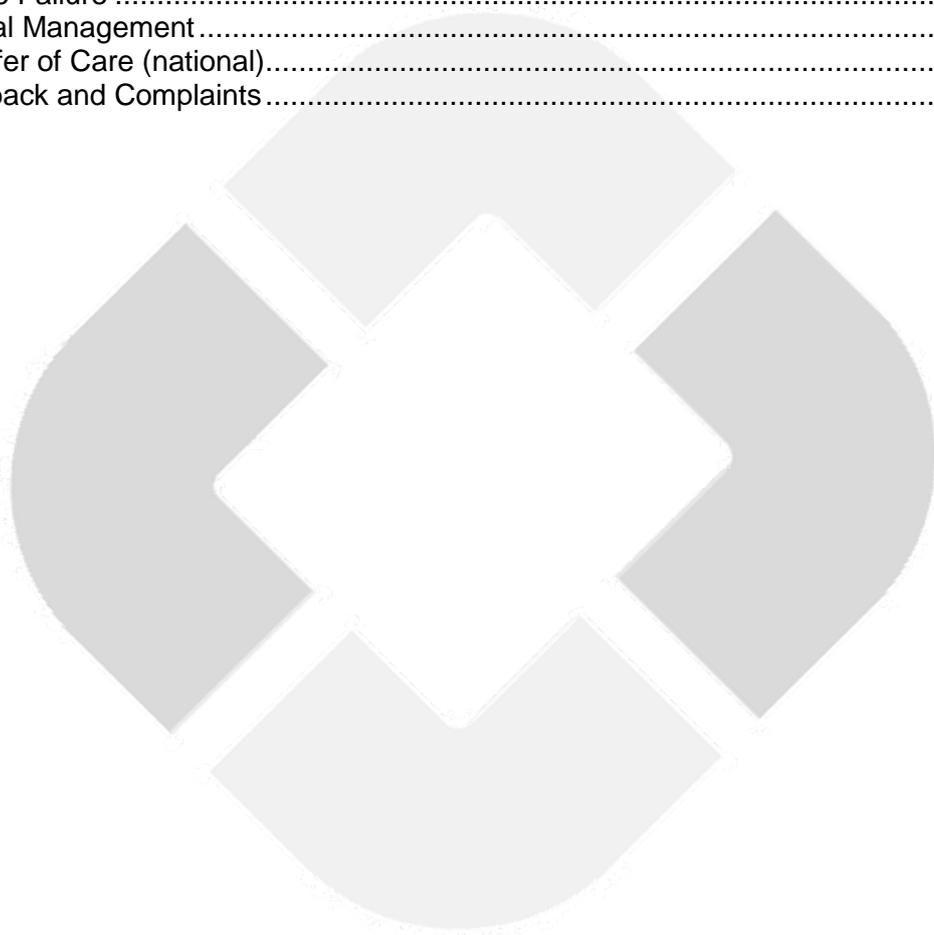
Because the field is developing quickly and encompasses an ever-growing knowledge base which includes new scientific insights, technologies and materials, HEARRING members' **collaborative research** initiatives are extremely important to the success of each individual member clinic. To meet the challenges 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



Table of Contents

1 Introduction	4
2 Team Structure.....	4
3 Accommodation (where applicable).....	7
4 Clinical Facilities.....	7
5 Referral and Selection Criteria.....	8
6 The Assessment and Decision Making Process	8
7 Cooperation of the Cochlear Implant Team with Other Services and Agencies	11
8 Pre-operative Information for Parents / Caregivers, and Consent.....	12
9 Surgery and In-patient Care	13
10 Post-operative Fitting and Tuning of the Audio Processor	14
11 Post-operative Habilitation and Assessment.....	14
12 Follow-up and Long Term Maintenance.....	15
13 Device Failure	16
14 Clinical Management.....	16
15 Transfer of Care (national).....	17
16 Feedback and Complaints.....	17



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. Currently, cochlear implants (CIs) are recommended for infants, children, and young adults with bilateral profound sensorineural hearing loss and who had a hearing aid trial but obtained insufficient benefit from their use. CIs bypass the non-functioning part of the auditory system in order to deliver electrical signals directly to the auditory nerve. Universal neonatal hearing screening has enabled early identification of hearing loss, thereby allowing to earlier intervention. Children, if implanted early enough, have access to auditory information and are therefore less affected by physiological and structural changes due to auditory deprivation. Many studies have shown that cochlear implantation is safe and effective for early habilitation.

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, the electrode array, the receiving antenna, and a magnet that holds the coil in place behind the ear.

1.2 External

The audio processor 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 paediatric cochlear implantation, and to provide each child 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 paediatric CI team

A paediatric CI 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 team should include a minimum of 2 surgeons. The Otologists will have experience in otology and CI surgery. The Otologists will comply with recommendations for a minimum of 20 CI operations to be carried out annually.

Newly appointed surgeons should 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, the surgeon will work as a member of the 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 surgeons will participate in the process of auditing CI cases and in maintaining a database of such cases.

b. *Paediatric Anaesthetist*

The surgical team should include a paediatric anaesthetist with skill and experience in working with young children. This is especially important because anaesthesia poses special risks for children, whose body weight must be considered. This risk is significantly higher in children under 12 months of age. The presence of a specialist paediatric anaesthetist has a significant effect in minimising adverse events associated with general anaesthetic in infants.

c. *Core team*

The core team should include personnel with skill and experience in paediatric fitting of hearing aids to patients with severe to profound hearing loss, and detailed understanding of implants and programming and speech and language therapy. Personnel with these skills can vary from country to country but may include:

1. Audiologists
2. Clinical Scientists
3. Physiologists
4. Habilitation Therapists
5. Speech & Language Therapists
6. Clinical Physiologists
7. Engineers
8. Audiovestibular Physicians / Paediatricians
9. Teachers of deaf children

These personnel should be qualified to post-graduate level, and hold an accredited MSc or similar qualification according to national standards. This must be supplemented with 2 years of practical experience.

They will furthermore have extensive clinical experience within the field of cochlear implantation where possible, together with knowledge and understanding of the multidisciplinary areas within the programme. Their role may also include wider research responsibilities.

d. *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.

e. *Coordinator / CI Head of Service*

The Coordinator / Head of Service is responsible for the day-to-day management of the programme and will ensure that appropriate services are provided for each child through the CI patient pathway. They will provide 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.

- f. *Key Worker*
Each family must be assigned a key worker who will act as a facilitator and link person. A key worker may be one of the above team members.
- 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. 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.
- 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.

2.2 CI Team: additional support

The core team should include individuals with skill and experience as stated in 2.1.b. Where the core team does not include professionals from the following services or specialities, it should have access to them as required:

- a. Audiological Medicine
- b. Tinnitus
- c. Balance
- d. Radiology
- e. Medical Physics
- f. Genetic counselling
- g. Psychology
- h. Psychiatry
- i. Paediatrics
- j. Education
- k. Interpreter services
- l. Social services for the Deaf
- m. Deaf advocacy

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

Parents and caregivers play a crucial role in assessing and influencing their child's needs and progress. The implant team has a duty to work in partnership with them in order to provide the support they need to carry out this role of care and responsibility.

3 Accommodation (where applicable)

- 3.1** To ensure ease of communication there should be suitable telecommunication access for the relatives of the children with hearing loss. This should include the necessary facilities 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 child, family members, clinicians and observers or interpreters, together with the necessary equipment.
- 3.4** Facilities for children should be accessible, safe, suitable, and family friendly, and located either within the CI centre or within the hospital's paediatric ENT/audiology department.
- 3.5** A suitable room should be available for group work, including CI user activities and team meetings / training.
- 3.6** 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.
- 3.7** The treatment rooms should be sufficiently separated from waiting areas so that noise from waiting areas does not disturb the treatment, and privacy is maintained. Examination rooms should be well lit to accommodate the vision needs of children with visual-impairment
- 3.8** All facilities and rooms must comply with current relevant health and safety guidelines and regulations, and be suitable for their purposes.

4 Clinical Facilities

4.1 Clinical facilities should be available for:

- a. Appropriate audiometry, dependant on the child's age
- b. Speech perception testing
 - (1) In quiet
 - (2) In noise
- c. Sound field audiometry, with special test set-ups for infants and young children
- 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, e.g. neural response telemetry

- i. Balance function testing
- j. Imaging procedures
- k. Sound localisation and spatial awareness

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 children for 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 children (and particularly in infants under 12 months) are defined very broadly here, as these may be determined by national guidelines. It should, however, be stated that:
 - a) Children may have severe-to-profound bilateral sensorineural hearing loss
 - b) Families / caregivers should have realistic expectations about the CI process and potential outcomes
 - c) Families / caregivers should have appropriate access to follow-up services such as habilitation and educational services to ensure success following the CI surgery
 - d) Infants may have additional needs, which may or may not be evident at the time of assessment. These should be considered as part of the selection process, but are not seen as exclusion criteria.
- 5.3** Selection criteria should be reviewed regularly by the HEARRING Group, to inform national authorities regarding recommendations for future developments in this area
- 5.4** Acknowledgement of receipt of the referral to the referring agent must be undertaken according to current targets and mechanisms set by the National Health authority, Department of Health, and must comply with local agreements.

6 The Assessment and Decision Making Process

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

- 6.1** Unless clinically contra-indicated, all children must have a comprehensive CI assessment the purpose of which is to assess the child'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. National and/or clinical criteria for candidacy should be used.

- 6.3** Service delivery should consider the aims and objectives of the national governmental authority frameworks.
- 6.4** For each child, the assessment track must be followed according to a written checklist and recorded in the child'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. Similarly, waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of the assessment.
- 6.7** Details on locally agreed patient pathways should be available on request.
- 6.8** Fast tracking of children 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 children 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 children 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 child and his/her family, 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 child 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 child for genetic counselling, if required.
 - (5) Obtain fully informed family consent for the treatment.
 - (6) Confirm that an ophthalmic assessment has been performed, as optimum vision is crucial to the child with hearing loss.
- 6.9.2** *Audiological*
- a. Each child must receive a full audiological assessment performed according to professionally accepted protocols.
 - b. The audiological assessment must include:

- (1) Otoscopic examination of the ears
- (2) Determination of hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the developmental age and condition of the child
- (3) Determination of uncomfortable loudness limits
- (4) Objective hearing threshold assessment as the main method to assess CI candidacy. One or all of the following assessments, depending on outcome, should be used:
 - a. Otoacoustic Emissions (OAE)
 - b. Auditory Brainstem Response (ABR)
 - c. Auditory Steady-State Response (ASSR)
- (5) Determination of bilateral middle ear function using tympanometric techniques
- (6) Age-appropriate preverbal testing in quiet and in noise
- (7) Questionnaires for parents regarding their child's hearing behaviour
- (8) Hearing aid testing and evaluation preferably confirmed by non-behavioural methods

6.9.3 *Hearing Aid Evaluation*

Each child should have bilateral hearing aids that allow access to the widest range of sounds as possible and their configuration re-evaluated and where appropriate have the best new hearing aids available fitted or settings revised. The suitability of amplification should be verified using an appropriate combination of the following:

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

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

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

6.9.5 *Communication*

Full assessment of the child's communication and social strategies may be required. These assessments may take the form of observation, subjective description, or evaluation using formal test procedures. The assessment procedure will take into account the child's age and hearing status, and will normally include a detailed case history, and an assessment of the child's receptive and expressive skills.

The following areas may be assessed:

- a. Receptive skills - listening skills for speech
 - (1) With very young children, pre-speech distraction and play skills.
- b. Expressive skills
 - (1) Babbling skills, protowords
 - (2) Intelligibility, voice and speech sound system
- c. Details should be collated about the environments in which each child typically communicates and where they find the most difficulty.

6.9.6 *Psychological counselling for the family*

Some families might require a psychological counselling or assessment. A referral to a qualified psychologist or psychiatrist should be initiated when there are concerns regarding parental stress, lack of strategies to deal with the diagnosis of deafness, personality and motivation, or unrealistic expectations about cochlear implantation that cannot be addressed through counselling by the CI programme team. Cochlear implantation affects everyone in the family and their attitude might affect the child's developmental progress.

6.9.7 *Family support and education*

It is very important to establish the family's / caregiver's commitment to supporting the child and to ensure that they have a clear understanding of the whole process. Involvement of external agencies, typically educational services, is also pivotal to making sure the correct support for long term success is in place.

6.9.8 *Associated organisations*

Children and families / caregivers should be given information about cochlear implantation organisations, national and local charities and self-help organisations, and equipment and services for people with hearing loss.

6.9.9 *Final outcome*

A final discussion between the family and key team members should be scheduled for the end of assessment, at which agreement is reached about whether or not to proceed. If the outcome of the assessment is that cochlear implantation is not recommended for a child, an exit clinic appointment should be offered to explain and discuss this recommendation and provide patient support. The discussion should include recommendations for future treatment strategies, and referral for other equipment and / or services for children with hearing loss if appropriate, together with the opportunity for re-referral in the future. These issues must be covered in a written report to the referring clinician or agency.

6.9.10 *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 and Agencies

- 7.1** All members of the CI team should meet on a regular basis to ensure effective communication, thereby ensuring quality service for each child.
- 7.2** Contact must be maintained with the referring agent and local professionals.
- 7.3** The CI team must evaluate carefully what additional information may be available that would aid the decision-making process. The CI programme should cooperate with and obtain information from other services as appropriate, and in a timely manner, including the following:
 - a. Other hospital departments
 - b. Audiology, radiology, medical physics, wards, ambulatory care, etc.

- c. Newborn hearing screening
- d. Local / national support groups
- e. Social services
- f. Community services
- g. Educational services

7.4 Contact with support services should only be made with the permission of the parents / caregivers and at the discretion of the CI team.

8 Pre-operative Information for Parents / Caregivers, and Consent

- 8.1** Basic information and counselling should be given according to a written check-list and recorded in the child's hospital file.
- 8.2** Whenever possible, information should be given in a language or medium that is appropriate to the family's 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 whenever required.
- 8.6** Parents / caregivers must be provided with balanced, unbiased and up-to-date information in order to make an informed choice for their child, and to provide an informed consent where necessary.
- 8.7** Throughout the assessment period, all parties and agencies should have a clear understanding of the main benefits and limitations of implantation.
- 8.8** It is recommended that families meet other children and families who have experience with using a CI. Matching candidates and users in terms of age and duration of deafness and type of CI may be beneficial.
- 8.9** To prepare the child and family for admission to hospital, a preoperative visit to the paediatric surgical ward should be offered so that they have the opportunity to meet the nursing staff.
- 8.10** CI selection should be incorporated in the assessment and final decision making process.

There are different CI manufacturers currently supplying CI centres. Information regarding the technical specifications of these different CIs should be made available.

The family should be given further information on the CIs currently available, and on their advantages and disadvantages. They should be given an explanation as to why they have been offered a particular CI, or choice of CIs. Written information on the CI(s) offered should also be made available.

HEARRING centres only use and implant CIs that are legally approved by national authorities

8.11 The CI offered to the child 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

8.12 Information about all recognised risk factors should be communicated in a clear and appropriate way. Written information should always be available. Formal consent for the surgery must be obtained by the Otologist performing the surgery from the parent or legal guardian in accordance with national policy.

9 Surgery and In-patient Care

9.1 The consultant CI surgeon is responsible for the overall medical care of the child.

9.2 Anaesthetics should be administered by appropriately qualified and experienced paediatric personnel.

9.3 The surgeon shall attempt to preserve any residual hearing a child 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 child's inner ear / cochlea.

9.4 The facial nerve should be monitored throughout the surgery.

9.5 Stimulator placement might require special consideration in some very young infants, depending on individual characteristics of their skull and growth of relevant anatomical features.

9.6 Information regarding the outcome of surgery must be documented and should be made available to the audiological and habilitation teams as soon as reliable data are available.

9.7 Intra-operative or post-operative radiology should be considered in order to check the positioning of the device and electrode array.

9.8 The surgeon will continue to monitor the child'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.

9.9 Prior to discharge from hospital, parents / caregivers should:

- a. Receive written information regarding care of the wound / ear and pain management
- b. Receive written guidelines on what to do should medical / surgical problems arise
- c. Be aware of follow-up arrangements

- d. Receive advice regarding health and safety with a CI and manufacturer's written safety guidelines

10 Post-operative Fitting and Tuning of the Audio Processor

- 10.1** The audio processor should be fitted and programmed once the child's wound has healed satisfactorily.
- 10.2** 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.
- 10.3** Before the initial programming, relevant team members must:
 - a. Check the external CI components
 - b. Explain the programming procedures
- 10.4** Electrophysiological measurements (e.g. eCAP or eSRT recordings) may be used to guide initial stimulation levels.
- 10.5** Each CI should be fitted and programmed according to the manufacturer's recommended programming procedures and to maximise benefit for the child. The appropriate number of programming sessions should be offered to each child according to clinical need.
- 10.6** A comprehensive explanation of the use of the audio processor must be provided. Families / caregivers should be encouraged to contact the implant programme if they have any questions or concerns.
- 10.7** Printed materials on the handling, operation and care of the audio processor should be issued to families / caregivers, as appropriate.
- 10.8** The child 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.
- 10.9** 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.
- 10.10** A written report should also be sent to the referring agent if any serious problems arise.

11 Post-operative Habilitation and Assessment

- 11.1** Following implant surgery, the child must be examined by the implant surgical team and have open access to additional appointments as required. The child should be offered open access to further annual medical review, and checks of the implant and audio processor function.

- 11.2** Post-operative habilitation should begin immediately after initial fitting, according to the individual needs of the child to:
- a. Facilitate acclimatisation to the new sensation of sound
 - b. Reassure the child and the family / caregiver
 - c. Outline the habilitation programme
- 11.3** The habilitation programme may include evaluation of and training by all professionals involved in:
- a. Detection of sound, including localisation and spatial tests
 - b. Auditory detection, discrimination and recognition
 - c. Voice quality
 - d. Speech intelligibility
 - e. Language development, comprehension, and expression
 - f. Social skills
- 11.4** The habilitation programme should be tailored to each individual's needs. Counselling should support children and their families regarding expectations, habilitation procedures, and continuing commitment to the habilitation programme.
- 11.5** Sufficient habilitation sessions should be offered to optimise CI use. Parents / caregivers and children must have open access to the CI centre (or a designated local partner-service) for habilitation and counselling as required.
- 11.6** Appropriate measures should be performed at regular intervals to monitor progress in audiological, speech perception, educational and communicational outcomes. Standardised assessments should be used for comparisons.
- 11.7** After the first year following implantation, the child should be offered an annual audiological review. This can take the form of a clinic-initiated appointment, or patient-led follow-up. Moreover, children should have access to additional appointments as required.
- 11.8** It is recommended that the referrer and locally involved professionals receive written reports on the child's progress.

12 Follow-up and Long Term Maintenance

- 12.1** The child and family / caregiver must have open access to the CI centre (or a designated local partner-service) for programming, habilitation, and surgical reviews as required.
- 12.2** 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 implant users either from the CI programme or from a local audiology department by prior agreement.
- 12.3** Individual centres should have a policy for the replacement of lost or damaged processors that is equitable for all children.
- 12.4** Teams should have an agreed-upon strategy for upgrading audio processors and contralateral hearing aids.

- 12.5** Arrangements should be in place to upgrade each child's audio processor every 5 years (at minimum), subject to new technology being available for the appropriate implant system.
- 12.6** Following annual reviews, a written report detailing the outcome of the reviews should be sent to the referring agency and other relevant agencies (e.g. educational).

13 Device Failure

- 13.1** If an internal device failure is suspected, the parents / caregiver should be offered an appointment promptly (within 1 day) to check the device's internal and external components.
- 13.2** 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 child's next appointment to provide support.
- 13.3** Upon confirmation of internal device failure, the clinical personnel (see 2.1.b) must inform the Otologist and the Head of Service / Coordinator, and should offer the child an urgent appointment to discuss options with the Otologist.
- 13.4** The device failure must be reported to the relevant national authorities.
- 13.5** If re-implantation is agreed upon with the child, it should be carried out as soon as medically possible and appropriate, to minimise auditory deprivation.
- 13.6** Re-implantation and programming should be carried out as detailed above. Further (re)habilitation needs should be assessed and provided for as appropriate.

14 Clinical Management

- 14.1** All aspects of the CI service should have adequate systems of record-keeping to facilitate auditing and planning.
- 14.2** 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 child's performance outcomes
 - d. Medical and surgical complications
 - e. Device failures
 - f. Research interests and outcomes
 - g. Child and family/caregiver feedback on the service provided

15 Transfer of Care (national)

- 15.1** A protocol must be in place to transfer the ongoing care of adolescent CI users into the adult section or programme at an appropriate age. The protocol must take into account their educational needs and must be agreed upon by the CI team.
- 15.2** A protocol must be in place for the transfer of care of a child or an adolescent to an alternative programme or the acceptance of care of a child or an adolescent from an alternative programme, if requested.
- 15.3** Children will usually be referred to the nearest CI centre, unless the family request to be transferred to a particular centre.
- 15.4** The referring centre must confirm that they can support the type of CI used by the child before the referral is made.
- 15.5** All the relevant documentation will be sent to the receiving centre. This will include: full details of the child's address, telephone number, and email address, information on the internal device and external processor used, recent programmes, eCAP results (or similar), aided audiograms, speech perception results, (re)habilitation reports and results, medical details of surgery and any complications, and contact details for the GP.
- 15.6** The receiving CI programme will acknowledge the referral in writing and confirm that the funding has been agreed on for continued support of the child.
- 15.7** Generally, children 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 habilitation.

16 Feedback and Complaints

- 16.1** Documentation provided by the CI programme should include written information about the complaints procedures within the hospital and other relevant services.
- 16.2** Child and family/caregiver feedback should be systematically collected to inform service review, and should be managed according to local policy.

Acknowledgement

The “Quality Standards for Cochlear Implantation in Children and Young People” were developed by Christopher H. Raine, M.D. (Bradford, UK) and the HEARRING Group, based on the British Cochlear Implant Group Standards.

