Quality standards for cochlear implantation in children and young adults

J Martin, C H Raine
Bradford Royal Infirmary, Bradford, UK

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 recognised 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 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 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 paediatric/adolescent CI team
A paediatric or adolescent ‘teens’ 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 two 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) Core team
      The core team should include personnel with skill and experience in fitting of hearing aids to people 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:
      - Audiologists
      - Clinical scientists
      - Physiologists
      - (Re)habilitation therapists
      - Speech and language therapists
      - Clinical psychologists
      - Engineers
      - Audiovestibular physicians/paediatricians
      - Teachers of deaf children.
These personnel should be qualified to post-graduate level, and hold an accredited MSc or similar qualification according to the national standards. This must be supplemented with two 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.

(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) **Coordinator/cochlear implant 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 patient 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.

(e) **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.

(f) **CI team personnel**

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

(g) **Clinical team members**

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.

(h) **All team members**

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.

(i) **Personnel requirements**

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.

(j) **Newly appointed members**

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 section 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:

- Audiological medicine
- Tinnitus
- Balance
- Radiology
- Medical Physics
- Genetic counselling
- Psychology
- Psychiatry
- Paediatrics
- Education
- 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.

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 patients with hearing loss 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 population with hearing loss. 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 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 patient 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.

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
- Pure tone audiometry
- Speech perception testing
  (a) In quiet
  (b) In noise
- Sound field audiometry
- Hearing aid testing and fitting
- Probe-tube microphone measurements
- Tympanometry
- Otoacoustic emissions testing
- Objective measurements
  (a) Evoked response audiometry
  (b) Electrically evoked potentials
  (c) Electrocochleography, e.g. neural response telemetry
- Balance function testing
- Imaging procedures
- Sound localization and spatial awareness.

4.2 Audiological equipment

All audiological equipment should be calibrated to the national standards as required, on an annual basis, and 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 children and young adults are defined very broadly here, as these may be determined by national guidelines.

5.2.1 Children
(a) Children may have pre-lingual or post-lingual hearing loss
(b) Children may have severe to profound bilateral sensorineural hearing loss
(c) Children with partial deafness cochlear implantation may be considered suitable for electric acoustic stimulation (EAS) surgery. Please refer to the appropriate guidelines for EAS.
(d) Families/caregivers should have realistic expectations about the CI process and potential outcomes
(e) Families/caregivers should have appropriate access to follow-up services such as (re)habilitation and educational services to ensure success following the CI surgery
(f) Children 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.

5.2.2 Young adults
(a) Young adults may have pre-lingual or post-lingual hearing loss, which may be sudden or progressive
(b) Young adults should have oral communication abilities.
(c) Young adults should have good use of amplification systems
(d) The selection of young adults should be considered on an individual basis, to ensure compliance with the CI process and use of the device

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

5.3 Patient selection criteria should be reviewed regularly by the HEARING 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 patients must have a comprehensive CI assessment. The purpose of the assessment 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. 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 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 assessment, a written report detailing the outcome of the evaluation will be sent to the referring agent within the relevant 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 patients through the assessment process must be available when clinically indicated.

6.9 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 and their family, it is the responsibility of the surgeon, either themselves or through an appropriately trained nurse practitioner, to:
   (1) Undertake a medical consultation during the assessment process, and pre-admission, to ensure that the patient is medically fit to undergo the treatment.
   (2) Discuss the pre- and post-surgical risks associated with the treatment.
   (3) Discuss the necessity for vaccination to minimize the risk of pneumococcal meningitis.
   (4) Refer the patient 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 patient must receive a full audiological assessment performed according to professionally accepted protocols.
(b) The audiological assessment must include:
   (1) Otoscopic examination of the ears by microscope
   (2) Determination of hearing thresholds bilaterally using pure tone audiometry or other recognized methods suitable for the patient
   (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 appropriate to age
   (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 patient should have their current hearing aid 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) Aided soundfield hearing thresholds
(b) Speech perception testing using standardised pre-recorded speech material, and live voice where appropriate
(c) Facilities should be available to measure the electroacoustic performance of hearing aids according to current standards and to programme 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 (re)habilitation. For some patients the period may be extended to several months for clinical reasons.

6.9.5 Communication
Full assessment of the patient’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 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:
(a) Receptive skills – listening skills for speech:
   (1) With very young children, pre-speech distraction and play skills. For older post-lingually deafened children and adolescents, 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 child or adolescent typically communicates and where they find the most difficulty.

6.9.6 Psychological status for older children/teenagers
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. Older children and teenagers under the age of legal consent should be actively involved in the decision making process.

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

6.9.9 Final outcome
A final discussion between the patient 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 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 treatment strategies, and referral for other equipment and/or services for children and adolescents 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 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 the national restrictions, opportunities for bilateral implantation may vary.

7. Cooperation of the CI 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 patient.
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:
• Other hospital departments
• Audiology, radiology, medical physics, wards, ambulatory care, etc.
• Newborn hearing screening
• 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 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 patient’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 patients and families who have experience with using a cochlear implant. Matching candidates and users in terms of age and duration of deafness and type of CI device may be beneficial.
8.9 To prepare the child and family for admission to hospital, a pre-operative visit to the paediatric surgical ward should be offered so that they have the opportunity to meet the nursing staff.
8.10 Where a child is considered to be old enough to make an informed choice, their assent should be obtained and their views and wishes should be respected.
8.11 Device 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 devices should be made available. The child and the family should be given further information on the CI devices currently available, and on their advantages and disadvantages. They
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.

HEARRING centres only use and implant devices that are legally approved by national authorities. The CI device offered to the patient will:

(a) Have a proven track record of safety and reliability
(b) Have all necessary approvals (e.g. CE mark, Food and Drug Administration)
(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 the national policy.

9. Surgery and in-patient care

9.1 The otologist is responsible for the overall medical care of the patient.

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

9.3 The otologist shall attempt to preserve any residual hearing a patient has. 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.

9.4 The facial nerve should be monitored throughout the surgery.

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

9.6 Intra-operative or post-operative radiology may be considered to check the positioning of the device and electrode array.

9.7 The otologist 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.

9.8 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 patient’s wound has healed satisfactorily.

10.2 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 (or by less experienced scientists/audiologists only if under direct supervision).

10.3 Before the initial programming, relevant team members must:

- Check the external CI components
- Explain the programming procedures

10.4 In very young children, electrophysiological measurements (e.g. eCAP (electrically evoked compound action potential) or ESRT (electrically evoked stapedius reflex thresholds) recordings) may be used to guide initial stimulation levels.

10.5 Each device should be fitted and programmed according to the manufacturer’s recommended programming procedures and to maximise benefit for the patient. The appropriate number of programming sessions should be offered to each patient 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 queries or concerns.

10.7 Printed materials on the handling, operation, and care of the audio processor should be issued to the patient and to families/caregivers, as appropriate.

10.8 The patient must have access to the CI centre (or a designated local partner-service) for checking the implant system and for reprogramming the audio processor.

10.9 A written report 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 complications arise.

11. Post-operative (re)habilitation and assessment

11.1 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 open access to further annual medical review, and checks of the implant and audio processor function.

11.2 Post-operative (re)habilitation should begin after initial fitting, according to the individual needs of the patient, to:

- Facilitate acclimatisation to the new sensation of sound
- Reassure the patient and the family/caregiver...
11.3 The (re)habilitation programme should be tailored to each individual’s needs. Counselling should support patients and their families regarding expectations, (re)habilitation procedures, and continuing commitment to the (re)habilitation programme.

11.4 The (re)habilitation programme may include evaluation of and training by all professionals involved in:
- Detection of sound, including localization and spatial tests
- Auditory detection, discrimination, and recognition
- Voice quality
- Speech intelligibility
- Language development, comprehension, and expression
- Social skills.

11.5 Sufficient (re)habilitation sessions should be offered to optimise CI use. Parents/caregivers and patients must have access to the CI centre (or a designated local partner-service) for (re)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. Standardized assessments should be used for comparisons.

11.7 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.

11.8 It is recommended that the referrer and locally involved professionals receive written reports on progress.

12. Follow-up and long term maintenance

12.1 The patient and family/caregiver must have access to the CI centre (or a designated local partner-service) for programming, (re)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 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.

12.3 Individual centres should have a policy for replacement of lost or damaged processors that is equitable for all patients.

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 the audio processor for each patient at intervals of no more than 5 years, subject to new technology being available for the relevant 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).

12.7 Children with a CI should have the opportunity to test and assess a personal FM system, as this is the most effective way to improve the signal-to-noise ratio in difficult listening situations (such as in the classroom). The equipment must be fitted by a fully trained member of the CI team together with the local educational service.

13. Device failure

13.1 If an internal device failure is suspected, the patient and/or their parents/caregiver should be offered an appointment promptly 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 required, a clinical/engineering representative from the company should be available at the patient appointment to provide support.

13.3 Upon confirmation of internal device failure, the clinical personnel (see section 2.1.b) must inform the otologist and the head of service/coordinator, and should offer the patient an urgent appointment to discuss options with the otologist.

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

13.5 If re-implantation is agreed upon with the patient, 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:
- Clinical activity
- Staffing levels
- Patient performance outcomes
- Medical and surgical complications
- Device failures
- Research interests and outcomes
- Patient feedback on the service

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.
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.

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

The referring centre must confirm that they can support the type of device used by the patient before the referral is made.

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 worn, 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 general practitioner.

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.

Generally, patients 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 (re)habilitation.

16. Patient and other feedback and complaints

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

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