



# Quality Standards for Adult Cochlear Implantation

**British Cochlear Implant Group  
Royal National Institute for the Deaf**

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## 1 Introduction

Cochlear Implantation is a process that involves the surgical implantation of an electrode array in to the cochlea to provide direct electrical stimulation of the auditory nerve. A cochlear implant may be suitable for adults who have a severe to profound sensorineural hearing loss and who derive limited benefit from conventional hearing aids. Studies have shown that cochlear implantation is a recognised safe and effective procedure, for example as indicated in the NICE Technology Appraisal Guidance for cochlear implants<sup>1</sup>, and the findings of the UK Cochlear Implant Study Group<sup>2</sup>. To secure standards of service and the effectiveness of adult cochlear implantation, the British Cochlear Implant Group has produced this set of quality standards together with the RNID. The standards are a realistic minimum attainable by all cochlear implant programmes, and should be employed alongside current best practice guidelines. They are designed to allow informative comparisons between service providers in the U.K.

The abbreviation “QS” is used throughout this document to denote factors defining a quality standard

## 2 Service Structure

### 1. *Structure of the adult cochlear implant team.*

An adult cochlear implant team may function independently or as part of a wider service including paediatric and teens cochlear implant services. It is a multidisciplinary team made up of the following key personnel:

#### a. Cochlear Implant Co-ordinator / Head of Service roles

The Co-ordinator is responsible for the day to day management of the programme and will ensure that appropriate services are provided for each adult through the cochlear implant patient pathway. He/she will be a core team member, qualified at least to MSc level (or equivalent knowledge and skills) in their own professional area, and with further specialist training in cochlear implantation and clinical management of the profoundly deaf. They will furthermore have extensive clinical experience (ideally a minimum of 5 years) within the field of cochlear implantation, together with knowledge and understanding of the multidisciplinary areas within the programme. This role may also include wider research responsibilities. The co-ordinator will have a high degree of clinical, organisational, leadership and professional skills.

The Head of Service, in addition to the above, is accountable for the delivery of the multidisciplinary service. He/she will provide scientific and clinical leadership and will have managerial responsibility for service design, forward planning, finance, patient management and human resources. They will typically be the senior clinician of their profession and be qualified to PhD level (or 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,

#### b. Clinical Scientists (Audiology/Clinical Physics)

Clinical Scientists must be qualified to post-graduate level, hold an accredited MSc (Audiology or Clinical Physics), or equivalent knowledge and skills. This must be supplemented with two years practical experience, and the British Academy of Audiology Certificate of Audiological Competency, or DiplPEM in Medical Physics, together with professional registration with the Health Professions Council.

- c. Clinical physiologists (Audiology), and Rehabilitationists / Hearing Therapists  
The Clinical Physiologist must be qualified to BSc level, or equivalent knowledge and skills, in Audiology, or have a recognised Hearing Therapy qualification. These qualifications must be supplemented with at least two years practical experience. Registration with the Registration Council for Clinical Physiologists is recommended.
- d. Speech & Language Therapists  
The Speech and Language Therapist must have a BSc or equivalent knowledge and skills. The SLT must have a minimum of three years specialist clinical experience including experience with adults and two years experience with hearing impairment, together with professional registration with the Health Professions Council.
- e. Consultant Otolologists  
The ENT surgeon will have an FRCS qualification and will be an NHS Consultant Otolologist with appropriate accreditation and training. He/she will have experience in cochlear implant surgery, and will comply with the recommendations of the British Association of Otolaryngologists (BAO) for the minimum number of cochlear implant operations to be carried out yearly.

Newly appointed surgeons will have had extended sub-speciality training at an advanced level in otology and cochlear implant surgery in appropriate specialist centres in the UK or overseas. This will have included attending a temporal bone dissection course for cochlear implant surgeons.

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

- f. The Administrator / Secretary  
The administrator will hold appropriate secretarial qualifications, a have high level of organisational, communication and information technology skills, and work closely with the Co/ordinator/Head of Service.
- g. Cochlear implant team personnel should be members of the relevant cochlear implant professional groups, e.g. Implant Centre Speech & Language Therapists (ICSLT) and Implant Centre Audiology Group (ICAG).
- 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 BCIG meetings should be available for all team members. All team members should have a plan for their continuing professional development. Membership of BCIG should be encouraged.
- i. All team members should be trained in 'deaf awareness' and practical aspects of communicating with deaf people, as part of their induction.

QS All professionals must be suitably qualified, registered with their professional body, and comply with Health Professional Council requirements (if applicable).

QS 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 cochlear implant team.

All team personnel must maintain a programme of continued professional development to ensure ongoing competency.

## 2. Cochlear Implant Team: Additional support

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

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

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

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

## 3 Accommodation

### 1. Accommodation

- a. To ensure ease of communication there should be suitable telecommunication access for deaf patients and their relatives. This should include the necessary facilities for the patient to contact the clinic through a variety of modes, (e.g. speech-to-text, text-to-text, fax, or e-mail).
- b. All patient areas should be appropriate to the needs of a deaf population. This should include consideration of visual alerts (eg patient appointment information), visual alarms (e.g. fire alarms) and appropriate assistive listening devices in the patient clinic.
- c. Clear and practical information about deafness and supporting deaf people in public service environments is given in the UK Council on Deafness Good Practice Guidelines 2001<sup>3</sup>.
- d. External and internal access should conform to the Disability Discrimination Act 2005<sup>4</sup>.
- e. Clinic areas should be large enough to comfortably accommodate the patient, family member, clinician and observer or interpreter together with the necessary equipment.

- f. A suitable room should be available for group work including patient activities and team meetings / training.
- g. There should be a suitable waiting area near the treatment rooms, large enough and with sufficient comfortable chairs to accommodate the number of people likely to be waiting at any one time. The waiting area should be more than a corridor. Where paediatric services co-exist there needs to a separate area provided
- h. The treatment rooms and waiting area should be sufficiently separated that noise from the waiting area does not disturb the treatment, and that privacy is maintained.
- i. Audiological testing will be performed in soundproof accommodation to BS ISO 8253-1 (1998) standards <sup>5</sup>.
- j. Examination rooms must meet current appropriate health and safety guidelines.
- k. All rooms should comply with health and safety regulations

QS Services, facilities and accommodation should comply with current British standards and the Disability Discrimination Act 2005

QS All facilities must comply with Health and Safety Executive regulations <sup>6</sup>

#### 4 Clinical Facilities

1. Clinical facilities should be available for :
  - b. Pure tone Audiometry
  - c. Sound field Audiometry
  - d. Hearing aid testing and fitting
  - e. Probe-tube microphone measurements
  - f. Tympanometry
  - g. Otoacoustic Emissions
  - h. Evoked Response Audiometry
  - i. Speech perception testing
  - j. Objective measurement facilities e.g. neural response telemetry
  - k. Access to balance function testing.
2. All audiological equipment should be calibrated to British Standards at least annually, and a system of daily checking in place.

QS All testing should be carried out to professionally recommended protocols and procedures <sup>7</sup>

QS All equipment must be calibrated at least annually using recommended methods on equipment which in turn is traceable to nationally recognised standards, in accordance with BS EN ISO 8253-1 (1998) and BS EN ISO 8253-2 (1998)

## 5 Referral and Selection Criteria

1. Guidelines for referral of patients for assessment for suitability of cochlear implantation and patient selection criteria should be available in writing.
2. The selection criteria for cochlear implantation in adults should be in line with current NICE Guidance<sup>1</sup> and available in writing on request.
3. In the event of a patient falling outwith the published NICE Guidance, but for whom the cochlear implant team recommend cochlear implantation, the team should apply to the local funding authority for financial support by means of an individual patient Case of Need.
4. Patient selection criteria should be kept under regular review by the British Cochlear Implant Group, to inform NICE regarding recommendations for future developments in this area.
5. Acknowledgement of the receipt of the referral must be undertaken according to current targets and mechanisms set by the Department of Health, and comply with local agreements.

QS The referral and selection criteria for adult cochlear implantation must be in line with NICE Guidance and available in writing on request.

QS Acknowledgement of referral should be sent to the referring agent within the targets set by the Department of Health and in line with locally agreed targets.

## 6 The Assessment Process

1. 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.
2. Co-ordinated management of the pre-implant assessment process by a named Co-ordinator or Head of Service is essential.
3. Waiting times to diagnostic testing and treatment should comply with current national and local targets.
4. Locally agreed patient pathway details should be available on request.

5. Fast tracking of patients through the assessment process must be available when clinically indicated.
  6. Pre-operative assessments should include the following:
  7. Medical:
    - a. All patients referred to the cochlear implant programme should have a medical consultation with the team Consultant Otologist or appropriately trained and experienced nurse practitioner.
    - b. The referral of patients for MRI, CT or x-ray is the responsibility of the Consultant Otologist or locally agreed other appropriately trained and experienced professional, in accordance with the Royal College of Nursing Good Practice document: Clinical Imaging Requests from Non-medically Qualified Professionals, which is endorsed by the Royal College of Radiologists.
    - c. Appropriate referral for balance / vestibular assessment should be available if indicated.
    - d. It is the responsibility of the surgeon, themselves or through an appropriately trained nurse practitioner, for each patient:
      - 1 To undertake a medical consultation during the assessment process, and pre-admission, to ensure the patient is medically fit to undergo the treatment
      - 2 To discuss associated risks of the treatment pre- and post-surgery
      - 3 To discuss necessity for vaccination to minimize the risk of pneumococcal meningitis
      - 4 To refer for genetic counselling if required
      - 5 To obtain fully informed patient consent for the treatment
2. Audiological
- a. Each patient must receive a full audiological assessment performed to professionally accepted protocols (see BSA recommended procedures as outlined in section 4).
  - b. The audiological assessment must include:
    - a Otoscope examination of the ears
    - b Determination of hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the patient
    - c Determination of uncomfortable loudness limits
    - d Objective hearing threshold assessment must be available
    - e Determination of bilateral middle ear function using tympanometric techniques
    - f Speech perception testing
  - c. In addition to the above core audiological assessments, the Cochlear Implant Programme must have access to appropriate electrically evoked response audiometry, and otoacoustic emissions.
4. Hearing Aid Evaluation
- a. Each patient should have their current hearing aid provision re-evaluated and where appropriate have new hearing aids fitted or settings revised. Verification of the suitability of amplification should be undertaken using an appropriate combination of the following:

- i. Aided soundfield hearing thresholds
  - ii. Speech perception testing using standardised pre-recorded speech material, and live voice where appropriate.
  - iii. Facilities should be available to measure the electroacoustic performance of hearing aids according to current British and IEC standards and programme them to the most suitable settings.
- 5. Patients fitted with new hearing aids or with a change of hearing aid settings may require access to a structured programme of auditory rehabilitation. It is recommended that trials with new aids or different settings be conducted in accordance with NICE Guidelines. For some patients the period may be extended to several months for clinical reasons.

#### 6. Communication

Pre-operative assessment must include a full assessment of the adult's communication and social strategies. These assessments may take the form of observation, subjective description or evaluation using formal test procedures. The assessment procedure will take into account the patient's age and hearing status and will normally include a detailed case history, and an assessment of the patient's receptive and expressive skills.

The following areas may be assessed

- a. Receptive skills - listening skills for speech
  - 1. lipreading 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 adult typically communicates and where they find most difficulty.

#### 7. Psychological status

Not all patients require a psychological assessment. However, a referral to a qualified psychologist or psychiatrist should be instigated 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 which cannot be addressed through counselling by the cochlear implant programme team.

#### 8. Candidature for unilateral/bilateral implantation

See NICE guidance

QS Patients must undertake informed consent in accordance with the General Medical Council publication "Consent: Patients and Doctors Making Decisions Together"<sup>8</sup>

QS Service delivery should work towards the aims and objectives of the Department of Health National Service Frameworks<sup>9</sup>

QS Patient waiting times to diagnostic assessments and treatment should comply with national Department of Health and locally

agreed targets. Current national targets (at January 2009) are 6 weeks to diagnostics and 18 weeks to treatment.

QS The Consultant Otologist is responsible for ensuring that the patient has been informed of the risks of pneumococcal meningitis and has been given advice regarding vaccination. They should adhere to the current recommendations provided by the medicines and health care products agency<sup>10</sup>

QS Referrals for radiological services must be undertaken according to the Royal College of Nursing Good Practice Guide: Clinical Imaging Requests from Non-medically Qualified Professionals, endorsed by the Royal College of Radiologists<sup>11</sup>.

QS Unless clinically indicated all patients must have a comprehensive cochlear implant assessment. For each patient, the assessment track must be followed according to a written check-list and recorded in the patients hospital file.

QS Following the pre-operative assessment a written report detailing the outcome of the assessment will be sent to the referring agent within the responsible Trusts reporting timescales, or within two weeks of a decision being made by the cochlear implant team, which ever is the shortest.

## 7 Cochlear Implant Team Liaison with other Services and Agencies

1. All members of the cochlear implant team should meet on a regular basis to ensure effective communication thereby ensuring a quality service for each patient.
2. Contact must be maintained with the referring agent, GP and local professionals.
3. The cochlear implant programme should liaise as appropriate with other agencies including the following:
  - a. Other hospital departments
  - b. Audiology, Radiology, Medical Physics, Wards, Ambulatory Care etc
  - c. Social Services
  - d. Local/national support groups

- e. Community Services
  - f. Educational Services
4. Contact with support services should only be made with the permission of the patient and at the discretion of the cochlear implant team.
  5. The team should maintain regular liaison with Hospital Trust management and, with service commissioners. The team should use what influence it can to ensure that NICE Guidance is followed with respect to device procurement and service commissioning (as well as in service provision) and to encourage equitable access to cochlear implantation throughout the NHS.

QS If the outcome of the assessment demonstrates that the patient would not benefit from a cochlear implant, the report to the referring agent will include:

- Reasons why a cochlear implant is considered to be unsuitable for the adult.
- Recommendations for future management, and referral for other equipment and /or services for deafened adults if appropriate.

## 8 Pre-operative Information and Counselling

1. Whenever possible, information should be given to patients in a language or medium that is appropriate to their preferred method of communication, (e.g. BSL, Braille)
2. Interpreters should be offered as and when required and in accordance with local practice and the Disability Discrimination Act.
3. Teams should examine continuously monitor, review and update the quality and quantity of the information they provide and have a written protocol to determine which information is given at which time.
4. Verbal information should be supported by a written summary to the patient whenever indicated.
5. Throughout the assessment period patients should have a clear understanding of the main benefits and limitations of implantation. They should demonstrate that they have realistic expectations of cochlear implantation, e.g. by using a measurement tool such as an expectations questionnaire.
6. It is recommended that candidates, and where possible a family member /friend, meet adults who have experience of using a cochlear implant. Matching candidates and users in terms of age and duration of deafness and cochlear implant device may be beneficial.
7. Patients' relatives and friends should be encouraged to become involved in all aspects of pre-and post-implant management. This should always be done with the permission of the patient and at the discretion of the cochlear implant team.

8. Issues surrounding cochlear implantation including the views of the deaf community should be discussed and the patient should have an opportunity to meet people who have decided against implantation, if they wish.
9. Waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of assessment..
10. Patients should be given information about cochlear implantation organisations national and local charities and self help organisations, equipment and services for Deaf and Deafened people.
11. The patient should be offered contact between the team and their employers and / or work colleagues. Contact should only be made with the permission of the patient and at the discretion of the cochlear implant team.
12. There should be a timetabled final discussion at the end of assessment between the patient and key team members at which agreement is reached about whether or not to proceed.
13. If the outcome of the assessment is that cochlear implantation is not recommended for a patient, an exit clinic appointment should be offered to discuss this recommendation and provide patient support. Recommendations for future management should be discussed together with the opportunity for re-referral in the future. These issues must be covered in a written report to the referring clinician and copied to the patient's GP.

QS Basic information and counselling should be given to the patient according to a written check-list and recorded in the patient's hospital file.

QS The patient should be given the opportunity to discuss the recommendation not to offer cochlear implantation and be aware of any further management options.

## 9 The Cochlear Implant Device

1. There are three major Cochlear Implant manufacturers currently supplying CI centres in the UK. Further information regarding the technical specifications of these different devices is obtainable from the individual manufacturers (see section 19 for addresses and websites).
  - a. Advanced Bionics
  - b. Cochlear Europe
  - c. Med-El Ltd
2. The patient should be given information on the cochlear implant devices currently available along with 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.

3. The external part of the Cochlear implant device is given to the patient on loan and remains the property of the NHS. The Department of Health has issued guidelines on the insurance and replacement of hearing aids ( Department of Health, guidance notes C100 and C101) <sup>12</sup>

QS The Cochlear implant device offered to the adult will

- Have a proven track record for safety and reliability
- Have CE approval
- Conform to the recommendations of the Medical and Health Care Products Regulatory Agency
- Comply with terms and conditions of the Purchasing and Supplies Agency NHS or equivalent body
- Have high quality clinical and technical support available from the manufacturer
- Meet national purchasing requirements

## 10 Surgery and in-patient care

1. The Consultant Cochlear Implant surgeon is responsible for the overall medical care of the patient.
2. The surgical team, which may include a suitably trained nurse practitioner, is responsible for briefing the patient about the surgical procedure and potential complications and for obtaining the patient's informed consent.
3. The surgeon will continue to check and 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.
4. Information regarding the outcome of surgery must be documented and should be made available to the audiological and rehabilitation teams immediately after the operation.

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

QS Advice regarding health and safety with a cochlear implant must be given to the patient, together with written BCIG and manufacturers safety guidelines, prior to discharge from hospital .

## 11 Post-operative Fitting and Tuning of the Speech Processor

1. Speech processors should be fitted and programmed once the patient's wound has healed satisfactorily.
2. Speech processors should be fitted and programmed only by an experienced clinical scientist/physiologist who has been fully trained in the relevant protocols and procedures (and by a less experienced scientist/audiologist **only if** under direct supervision).
3. Before the initial programming relevant team members must:
  - a. check the external cochlear implant components
  - b. explain the programming procedures
4. Each device should be programmed according to the manufacturer's recommended programming procedures.
5. A comprehensive explanation on the use of the speech processor must be given. Patients should be encouraged to contact the implant programme if they have any queries or concerns.
6. Printed materials on the handling, operating and care of the speech processor should be issued to the patient and relatives/carers as appropriate.
7. The number of programming sessions required by each patient may vary, but typically six sessions are recommended, although some patients may require additional appointments according to clinical need.
8. The patient must have open access to the cochlear implant programme (or a designated more local partner-service) for checking the whole implant system and reprogramming of the speech processor.
9. A written report should be sent to the referring clinician and GP following initial processor fitting and at the 1 year treatment interval.
10. A written report should also be sent to the referring clinician and GP if any serious problems arise.

QS The appropriate number of programming sessions should be offered to each patient according to clinical need. Typically, this is currently six programming appointments in the first year.

QS The referring agent should be sent a written report when the speech processor is initially fitted and 1 yr post.

## 12 Post-operative Rehabilitation and Assessments

1. Post operative rehabilitation should begin immediately after initial fitting to:
  - a. facilitate acclimatisation to the new sensation of sound
  - b. reassure the patient and family/carer
  - c. outline the rehabilitation programme
2. The rehabilitation programme should be tailored to each individual's needs. Counselling should support the patient and his/her family regarding expectations, the

rehabilitation procedures, and continuing commitment to the rehabilitation programme.

3. The rehabilitation programme may include evaluation of and training in:
  - a. detection of sound
  - b. auditory discrimination
  - c. voice quality
  - d. speech intelligibility
  - e. language comprehension and expression
  - f. social skills
  - g. lip reading
  - h. hearing tactics
4. The patient must have open access to the cochlear implant programme (or a local partner-service) for rehabilitation and counselling as required.
5. Appropriate audiological, standardised speech perception and quality of life measures should be performed after initial tuning and at regular intervals to enable progress to be monitored.
6. It is recommended that the referrer, the G.P. and local involved professionals should receive written reports on progress.

QS Sufficient rehabilitation sessions should be offered to optimize cochlear implant use.

QS Following implant surgery, the patient must be reviewed 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 a check of the implant and speech processor function.

QS After the first year following implant surgery, the patient should be offered annual audiological review. This can take the form of an offered appointment, or patient-led follow up. In addition patients should have access to additional appointments as required.

QS Standardised audiological and speech perception measures should be performed on at least two occasions in the first year following surgery.

### 13 Follow-up and Long Term Maintenance

1. The patient must have open access to the cochlear implant programme (or a local partner-service) for programming, rehabilitation and surgical reviews as required.

2. Adequate spares/ replacements of external equipment must be available as required. Replacement equipment should be issued or despatched on the same or next working day. Speech processor batteries should be available to implant users either from the cochlear implant programme or from a local audiology department by prior agreement .
3. Individual centres should have a policy for replacement of lost or damaged processors that is equitable for all patients.
4. Teams should have an agreed strategy for upgrade of speech processors and contra-lateral hearing aids.

QS Following the annual review a written report detailing the outcome of the review should be sent to the referring agent within local Trust reporting timescales or two weeks, whichever is the shortest.

QS Arrangements should be in place to upgrade the speech processor for each patient at a minimum of 5 yearly intervals, subject to new technology being available for the appropriate implant system.

## 14 Device Failure

1. If a cochlear implant internal device failure is suspected, the patient should be offered an appointment promptly (and within 7 days) to check the internal and external components.
2. The implant manufacturer should be contacted urgently regarding investigation of the device failure. If indicated, a clinical/engineering representative from the company should be available at the patient appointment to provide support.
3. Upon confirmation of internal device failure the Clinical Scientist / Audiologist must inform the Consultant Surgeon and the Head of Service / Co-ordinator and an urgent appointment should be offered with the implant Consultant Surgeon to discuss re-implantation or other options.
4. If re-implantation is agreed with the patient this should be carried out as soon as medically possible to minimise auditory deprivation.
5. Re-implantation and programming should be carried out as detailed above. Further rehabilitation needs should be assessed and put into place as appropriate.

QS If device failure is suspected the patient must be offered an appointment promptly (within 7 days) to check the external and internal components of the implant device<sup>13</sup>

QS The device failure should be reported on-line to the MHRA

Adverse Incidents section<sup>14</sup>.

QS If re-implantation is agreed this should be carried out as soon as medically possible and appropriate to minimise any auditory deprivation.

## 15 Audit and Service Monitoring

1. All aspects of the cochlear implant service should have adequate systems of record-keeping to facilitate audit and planning. Service provision should be monitored against locally agreed protocols and the targets and the standards set out in this document.

QS The implant programme should perform regular audit and comply with BCIG requests for national audit data.

The audit should cover:

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

## 16 Transfer of Care

1. A protocol must be in place to transfer the ongoing care of adolescent cochlear implant users into the adult section or programme at an appropriate age. The protocol must take into account their educational needs and be agreed by the cochlear implant team.
2. A protocol must be in place for the transfer of care of an adult to an alternative programme or the acceptance of care of an adult from an alternative programme, if requested. This protocol must comply with the following BCIG policy on Transfer of Patients Between Cochlear Implant Centres.
3. Patients will usually be referred to the nearest cochlear implant centre unless the patient or family request to be transferred to a particular centre.
4. The referring centre will confirm that they can support the type of device used by the patient before the referral is made.

5. All the relevant documentation will be sent to the receiving centre. This will include; full details of the patients address, telephone number, email address, information on the internal device and external processor worn, recent MAPs, NRT results (or similar), aided audiograms, speech perception results, rehabilitation reports and results, medical details of surgery and any complications, contact details for the GP.
6. The receiving cochlear implant programme will acknowledge the referral in writing and confirm that the funding has been agreed for continued support of the patient.
7. Generally patients will not be referred to another centre less than one year following implantation this is to allow for medical follow up post operatively the establishment of a suitable MAP and initial rehabilitation provided.

## 17 Patient and Other Feedback and Complaints

1. Documentation provided by the cochlear implant programme should include written information about the complaints procedures within the hospital trust and other relevant services.
2. Patient and carer feedback should be managed according to local policy and should be systematically collected to inform service review.

## 18 References

1. Cochlear implants for severe to profound deafness in children and adults National Institute of Health and Clinical Excellence TAG 166, Issued January 2009
2. Criteria of candidature for unilateral cochlear implantation in post-lingually deafened adults I: Theory and measures of effectiveness. UK Cochlear Implant Study Group *Ear & Hearing* 25 (4):310-335, August 2004) .
3. UK Council on Deafness - Good Practice Guide. Available from: UKCoD Westwood Park London Rd Little Hokesley Colchester CO6 4BS
4. Disability Discrimination Act 2005 and 1995 Part iii: Access to Goods and Services : Code of Practice – Rights of Access, Goods Facilities, Services and Premises Available on [www.disability.gov.uk](http://www.disability.gov.uk)
5. International standards: International Organisation for Standardisation (ISO)8253-1 (1989) and ISO 8352-2 ( 1992) Standards for Acoustic Audiometric Test Methods, available from [www.iso.org](http://www.iso.org)
6. Health and Safety Standards available on <http://www.hse.gov.uk/healthservices/index.htm>
7. British Society of Audiology (BSA)2003 Recommended procedures available on [www.thebsa.org.uk](http://www.thebsa.org.uk)
8. “Consent: Patients and Doctors Making Decisions Together” [http://www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance/Consent\\_guidance.pdf](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance/Consent_guidance.pdf)
9. Department of Health National Service Frameworks available on [www.dh.gov.uk/nsf](http://www.dh.gov.uk/nsf)
10. Medicines and health care products agency: [www.mhra.gov.uk](http://www.mhra.gov.uk) (Ref MDA/2004/046 16<sup>th</sup>Sept 04)
11. Royal College of Nursing Good Practice Guide: Clinical Imaging Requests from Non-medically Qualified Professionals: <http://www.rcr.ac.uk/publications.aspx?PageID=310&PublicationID=242>
12. Department of Health Guidance notes C100 and C102 - available on [www.dh.gov.uk](http://www.dh.gov.uk)
13. BCIG recommendations for managing device failures, available on [www.bcig.org](http://www.bcig.org)
14. MHRA Adverse Incidents, available at [www.mhra.gov.uk](http://www.mhra.gov.uk)