

Quality Standards for Bone Conduction Implants

HEARRING Group
November 2014



HEARRING is a **learning network of collaborative experts** in the field of hearing implants. It is an association of preeminent international centers 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 centers around the world.

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

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

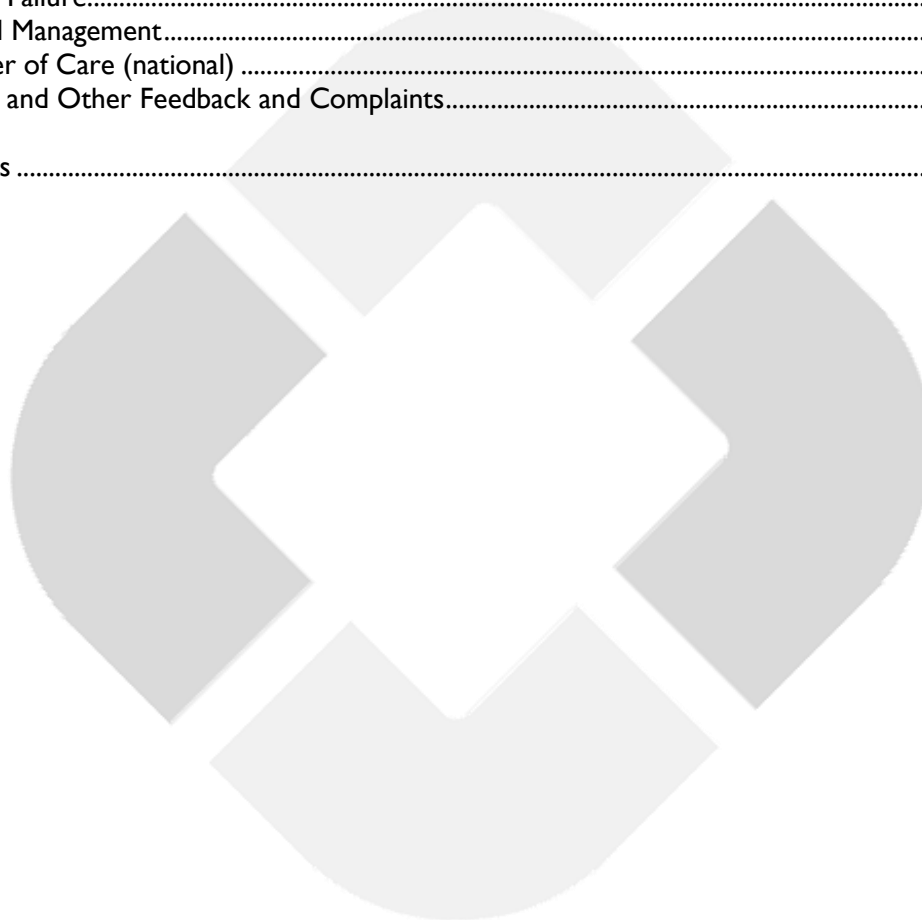
Because the field is developing quickly and encompasses an ever-growing knowledge base which includes new scientific insights, technologies and materials, HEARRING members' **collaborative research** initiatives are extremely important to the success of each individual member clinic. To meet the challenges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

... **network with the experts**



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1 Introduction

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 bone conduction implants, and to provide each patient with the best possible hearing implant solution for the treatment of their individual hearing loss, the network has 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.

Bone Conduction Implants (BCI) cause a direct inner ear stimulation by skull vibration. The amplified vibrations can be adjusted to compensate optimally for different kinds of hearing loss. BCI can be used to treat individuals with conductive and mixed hearing loss (CHL & MHL) as well as those affected by single-sided deafness (SSD).

These devices are for people who cannot use conventional hearing aids (e.g. for medical reasons), or who do not achieve sufficient benefit from them. BCI may also be an alternative to surgery for patients with previous unsuccessful operations and those with high surgical risk. The bone conduction implant is an alternative to acoustic hearing devices, conventional bone conduction or bone anchored hearing devices and in some cases also to middle ear implants.

The currently available Bone Conduction Hearing Devices (BCHD) can be categorised as shown in Figure 1. The main classification can be considered as non-implantable or conventional BCD and implantable BCD. The implantable BCD may also be divided in Bone Anchored Implants (BAI) and Bone Conduction Implants (BCI) by using the percutaneous or transcutaneous technologies. Finally, BCI can be divided into passive and active implants.

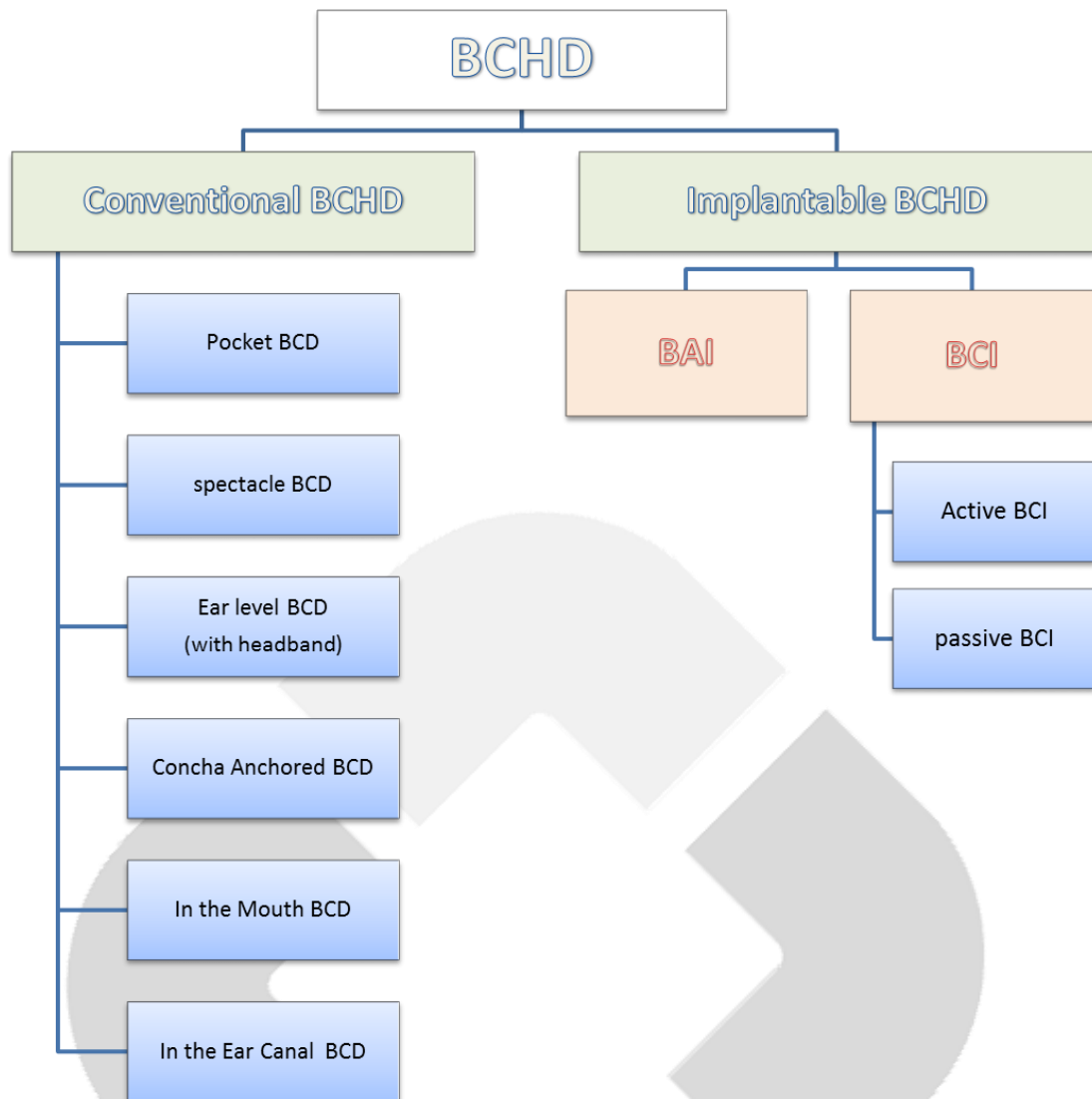


Figure 1: Classification of Bone Conduction Hearing Devices (BCHD); BAI: Bone Anchored Implants; BCI: Bone Conduction Implants

Only bone conduction implants with transcutaneous technology are discussed in this document. All available BCI devices are semi implantable and there are no fully implantable bone conduction implants available on the market yet. Recent studies show that BCIs are safe and clinically useful.

1.1 Active bone conduction implant

As the device is semi implantable, the sound wave is absorbed via microphones, processed in the external audio processor and then transmitted transcutaneously as a wireless signal to the implanted part of the device. This signal causes the vibration of the implanted transducer which is transmitted to the skull and results in inner ear stimulation. The transducer works with a direct drive technology.

The audio processor with the microphone(s), battery and transmitter coil is worn on the head. It must be adapted to the patient's individual requirements. The receiver is implanted into a subperiosteal pocket behind the ear and the transducer is implanted into the mastoid bone. Currently, there is only one active bone conduction implant available on the market.

1.2 Passive bone conduction implant

As the implanted part consists of only magnet pieces with special coating, these devices can be considered as passive implants. The function principle is the magnetic coupling between implanted and external magnets. The processed sound in the audio processor produces the vibration of external magnet, which vibrates the implanted magnet by inducing a magnetic field through the intact skin. The subsequent skull vibration stimulates the inner ear. The external audio processor similar to other devices must be adapted to the patient's individual hearing loss. There are at the moment two devices on the market, which work with these principles.

2 Team Structure

2.1 Structure of the implant team

A bone conduction implant team may function independently or as part of a complete ORL service or hearing implant centre, including paediatric and adolescent services. It is a multidisciplinary team made up of the following key personnel:

a. **Otologists**

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

The senior ENT surgeon will have advanced experience in otology and middle ear surgery.

Newly appointed surgeons will have had extended sub-speciality training in otology and middle ear surgery in appropriate specialist centres in their country or abroad. This will include having attended one or more temporal bone dissection courses for middle ear surgeons.

Once appointed, a consultant surgeon will work as a member of the consultant surgical team; initially under the mentorship of the senior surgical colleague(s) until enough experience is acquired. The surgeon will participate in the process of auditing bone conduction implant cases and in maintaining a database of such cases.

b. **Audiologists, Coordinator**

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

They will furthermore have extensive clinical experience within the field of bone conduction implantation or bone anchored hearing aids, together with knowledge and understanding of the multidisciplinary areas within the program. Their role may also include wider research responsibilities. The Coordinator is responsible for the day-to-day management of the program and will ensure that appropriate services are provided for each patient through the bone conduction implant patient pathway. The Coordinator will have a high level of clinical, organisational, leadership and professional skills.

c. **Personnel requirements**

Personnel requirements for bone conduction implantation should be in line with national standards and guidelines and Good Clinical Practice (GCP). One person can be in charge of several of the roles described above.

All professionals must be suitably qualified, registered with their professional bodies, and compliant with their national requirements.

Newly appointed members of the team who are less experienced must undergo an appropriate program of training and supervision provided by relevant experienced members of the bone conduction implant team.

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

2.2 Bone conduction Implant Team: Additional support

The core team should include individuals with skill and experience in fitting of hearing aids, or should 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. Audiological Medicine
- b. Radiology
- c. Psychology
- d. Psychiatry

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

3 Accommodation (where applicable)

- 3.1** To ensure ease of communication there should be suitable telecommunication access for hard-of-hearing 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).
- 3.2** All patient areas should be appropriate to the needs of a hard-of-hearing population. This should include consideration of visual alerts (e.g. patient appointment information), visual alarms (e.g. fire alarms) and appropriate assistive listening devices in the patient clinic.
- 3.3** Clinic areas should be large enough to comfortably accommodate the patient, family members, clinicians and observers or interpreters, together with the necessary equipment.
- 3.4** A suitable room should be available for group work, including patient activities and team meetings / training.
- 3.5** There should be a suitable waiting area near the treatment rooms, large enough and with sufficient comfortable chairs to accommodate the number of people likely to be waiting at any one time. The waiting area should be more than a corridor. Where paediatric services co-exist, a separate area must be provided.
- 3.6** The treatment rooms should be sufficiently separated from waiting areas so that noise from the waiting area does not disturb the treatment, and privacy is maintained.
- 3.7** All facilities and rooms must comply with current relevant health and safety regulation and guidelines

4 Clinical Facilities

4.1 Clinical facilities should be available for:

- a. Pure tone audiometry (including insert ear phones)
- b. Speech perception testing
 - (1) In quiet
 - (2) In noise
- c. Sound field audiometry (including sound localisation tests, if required)
- d. Hearing aid testing and fitting
- e. Tympanometry
- f. Imaging procedures

4.2 Audiological equipment

All audiological equipment must meet nationally recognised standards. Audiological equipment must be calibrated to national standards as required, on an annual basis, using recommended methods, and must undergo a daily on-site system check. All testing should be carried out according to professionally recommended protocols and procedures.

5 Referral and Selection Criteria

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

5.2 Indication and contraindication criteria should fall within manufacturers' recommendations. The SNHL component (e.g.. bone conduction thresholds) must be within the indication field of the selected device. The selection criteria for bone conduction implant surgery include the following

CHL/MHL group:

- a. Patients with conductive or mixed hearing loss due to unilateral or bilateral atresia;
- b. Patients who underwent previous surgeries but still have a persisting air-bone gap of at least 30 dB over the whole frequency range
- c. Patients who cannot use conventional hearing aids due to medical conditions (e.g. ear canal skin problems, infections)

SSD group:

- d. SSD patients understanding the benefit of BCI for whom cochlear implant is not indicated or cannot be used (damaged or absent cochlear nerve)
- e. Patients with poor results with hearing aids utilising contralateral routing of signal.

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

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

- 5.4 Patient selection criteria should be reviewed regularly by the HEARRING Group, to inform national authorities regarding recommendations for future developments in this area.
- 5.5 Acknowledgement of the receipt of the referral to the referring agent must be undertaken according to current targets and mechanisms set by the national Health authority and must comply with local agreements.

6 The Assessment Process

The assessment process shall be performed in the most efficient and timely way possible. The time frame for the overall assessment process shall not exceed 12 weeks.

- 6.1 Unless clinically contra-indicated, all patients must have a comprehensive bone conduction implant assessment. The purpose of this process is to assess the patient's functional hearing abilities and to determine whether these are likely to be significantly improved through an implantation.
- 6.2 Coordinated management of the pre-implant assessment process by a named Coordinator is essential.
- 6.3 Service delivery should consider the aims and objectives of the national governmental authority frameworks.
- 6.4 For each patient, the assessment track must be followed according to a written check-list and recorded in the patient's hospital file.
- 6.5 Following the pre-operative assessment, a written report detailing the outcome of the assessment will be sent to the referring agent within appropriate reporting timescales, or within two weeks of a decision being made by the bone conduction implant team, whichever is the shortest.
- 6.6 Waiting times for diagnostic testing and treatment should be as short as possible and comply with current national and local targets. Current HEARRING targets are six weeks for diagnostics and 12 weeks for treatment.
- 6.7 Details on locally agreed patient pathways should be available on request.
- 6.8 Fast tracking of patients through the assessment process must be available when clinically indicated.
- 6.9 **Pre-operative assessments should include the following:**

6.9.1 *Medical:*

- a. All patients referred to the implant 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 MRI, CT or X-ray is the responsibility of the Consultant Otologist or other locally agreed on appropriately trained and experienced professional.
- c. For each patient, it is the responsibility of the surgeon and the implant team 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 all pre- and post-surgical risks associated with the treatment (e. g. MRI issue etc.)
 - (3) Obtain fully informed patient consent for the treatment.

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 ear by otoscope or microscope
 - (2) Determination of hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the patient (air- and bone- conduction)
 - (3) Objective hearing threshold assessment (should be available)
 - (4) Speech perception testing in quiet and in noise.

6.9.3 *Hearing Aid Evaluation*

A hearing system trial (bone conduction or air conduction hearing device) should be performed if applicable. Each patient should have their current hearing aid configuration re-evaluated and where appropriate have the best available new hearing aids fitted or settings revised. The suitability of amplification should be verified. Particularly in SSD cases, it is important to give patients a realistic impression and therefore a pre-operative trial with simulating devices is recommended. It has been shown that patients will benefit from a bone conduction device as it overcomes the head shadow effect, if sounds are coming from the deaf side.

6.9.4 *Communication*

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

6.9.5 *Psychological status*

Some patients will require a psychological assessment. A referral to a qualified psychologist or psychiatrist should be initiated when there are concerns regarding the candidate's mental health, learning ability, personality and motivation, adaptation to their hearing disorder, or unrealistic expectations about bone conduction implantation that cannot be addressed through counselling by the bone conduction implant program team.

7 Pre-operative Information and Counselling

- 7.1** Basic information and counselling should be given to the patient according to a written check-list and recorded in the patient's hospital file.
- 7.2** Whenever possible, information should be given to patients in an appropriate language.
- 7.3** Interpreters should be offered as and when required and in accordance with local practice.
- 7.4** 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.
- 7.5** Verbal information should be supported by a written summary for the patient whenever required.
- 7.6** 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 bone conduction implantation, e.g. by using a measurement tool such as an expectations questionnaire.
- 7.7** It is recommended that candidates, and where possible a family member / friend, meet adults who have experience with using bone conduction implants. Matching candidates and users in terms of age and duration of hearing loss may be beneficial.
- 7.8** 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 bone conduction implant team.
- 7.9** Waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of assessment.
- 7.10** 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.
- 7.11** If the outcome of the assessment is that a bone conduction implant 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 communicated in a written report to the referring clinician or agency.

8 The Bone Conduction Implant

- 8.1** Information regarding the technical specifications of different bone conduction devices should be made available.
- 8.2** The patient should be given further information on the bone conduction implant devices currently available, and on their advantages and disadvantages. The patient should be given an explanation as to why they have been offered a particular device, or choice of devices. Written information on the device(s) offered should also be made available.

8.3 HEARRING centres only use and implant devices that are legally approved by national authorities.

8.4 The bone conduction implant offered to the patient 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.

9 Surgery and In-patient Care

9.1 The Consultant Implant surgeon is responsible for the overall medical care of the patient.

9.2 The surgical team, which may include a suitably trained nurse practitioner, is responsible for conducting a comprehensive pre-operation discussion of the surgical procedure and potential complications with the patient, and for obtaining the patient's informed consent.

9.3 Surgical techniques employed shall reflect the latest technology and be state-of-the-art. Every effort shall be made to avoid injury to the surrounding structures during implantation (e.g. dura, sigmoid sinus, facial, nerve, and inner ear).

9.4 The surgeon will continue to monitor the patient's progress during the post-operative period, and will be responsible for dealing with any surgical or medical problems that may arise in relation to the implant.

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

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

9.7 Prior to discharge from hospital, advice regarding health and safety with a bone conduction implant must be given to the patient, together with the manufacturer's written safety guidelines.

10 Post-operative Fitting and Tuning of the Audio Processor

10.1 The audio processor should be fitted and programd once the patient's wound has healed satisfactorily.

10.2 The audio processor should be fitted and programd only by experienced clinical personnel (see 2.1.b) who have been fully trained in the relevant protocols and procedures (or by less experienced scientists / audiologists only if under direct supervision).

10.3 Before the initial programming, relevant team members must:

- a. Check the bone conduction implant components
 - b. Explain the programming procedures
- 10.4** Each device should be fitted and programmed according to the manufacturer's recommended procedures and to maximise benefit for the patient. The appropriate number of programming sessions should be offered to each patient according to clinical need.
- 10.5** A comprehensive explanation of the use of the audio processor must be provided. Patients should be encouraged to contact the implant program if they have any queries or concerns.
- 10.6** Printed materials on the handling, operation and care of the audio processor should be issued to the patient and to relatives / caregivers, as appropriate.
- 10.7** The patient must have open access to the implant centre (or a designated local partner-service) for checking the entire implant system and for reprogramming the audio processor.
- 10.8** A written report should be sent to the referring agent following initial processor fitting and at the one-year treatment interval.
- 10.9** A written report should also be sent to the referring agent if any serious problems arise.
- 10.10** The patient must have open access to the implant centre (or a local partner-service) for counselling as required.

11 Post-operative 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** Appropriate standardised audiological, speech perception, and quality of life measures should be performed after initial fitting, on at least two occasions in the first year following surgery, and at regular intervals to allow progress to be monitored.
- 11.3** After the first year following implant surgery, the patient should be offered annual audiological review. This can take the form of a clinic-initiated appointment, or patient-led follow-up. Moreover, patients should have access to additional appointments as required.
- 11.4** It is recommended that the referrer and local involved professionals receive written reports on patient progress.

12 Follow-up and Long Term Maintenance

- 12.1** The patient must have open access to the implant centre (or a local partner-service) for programming 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 implant program 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 the annual review, a written report detailing the outcome of the review should be sent to the referring clinician or institution.

13 Device Failure

- 13.1** If an internal device failure is suspected, the patient should be offered an appointment promptly (within one day) to check the device's internal and external components.
- 13.2** The implant manufacturer should be contacted 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.
- 13.3** Upon confirmation of internal device failure, the clinical personnel (see 2.1.b) must inform the Otologic Surgeon and an appointment with the implant Otologist Surgeon should be offered to the patient, to discuss re-implantation or other options.
- 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 rehabilitation needs should be assessed and provided for as appropriate.

14 Clinical Management

- 14.1** All aspects of the implant service should have adequate systems of record-keeping, to facilitate auditing and planning.
- 14.2** The implant program should perform regular audits and comply with the requirements of the responsible national authorities. Audits should cover:
- a. Clinical activity
 - b. Staffing levels
 - c. Patient performance outcomes
 - d. Medical and surgical complications
 - e. Device failures

- f. Research interests and outcomes
- g. Patient feedback on the service

15 Transfer of Care (national)

- 15.1** A protocol must be in place for the transfer of care of an adult to an alternative program or the acceptance of care of an adult from an alternative program, if requested.
- 15.2** Patients will usually be referred to the nearest implant centre, unless the patient or family request to be transferred to a particular centre.
- 15.3** The referring centre will confirm that they can support the type of device used by the patient before the referral is made.
- 15.4** All the relevant documentation will be sent to the receiving centre. This will include: full details of the patient's address, telephone number, and email address, information on the internal device and external processor used, recent programs, aided audiograms, speech perception results, medical details of surgery and any complications, and contact details for the GP.
- 15.5** The receiving implant program will acknowledge the referral in writing and confirm that the funding has been agreed on for continued support of the patient.
- 15.6** Generally, patients will not be referred to another centre less than one year after implantation. This is to allow for post-operative medical follow-up and the establishment of suitable device programming.

16 Patient and Other Feedback and Complaints

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

Acknowledgement

The “Quality Standards for Bone Conduction Implantation” were developed by Prof. Dr. Javier Gavilán and the HEARRING Group, based on the ‘Standards of Practice in the field of Hearing Implants’.

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