

Quality standards of using cochlear implants in infants, children and adolescents

Position of the Society of Polish Otorhinolaryngologists, Phoniatriests and Audiologists and the Polish Society of Pediatric Otolaryngologists

Henryk Skarżyński

National Consultant in Otorhinolaryngology Chairman of the Committee of Clinical Sciences of the Polish Academy of Sciences
President of the Executive Board of the Polish Society of Pediatric Otolaryngologists Director of the Institute Physiology and Pathology of Hearing, Warsaw/Kajetany
Founding Member of HEARRING group

Grażyna Mielnik-Niedzielska

National Consultant in Pediatric Otolaryngology Member of the Committee of Clinical Sciences of the Polish Academy of Sciences
Former President of the Executive Board of the Polish Society of Pediatric Otolaryngologists
Head of Pediatric Otolaryngology, Phoniatics and Audiology Clinic of the Medical University in Lublin

Krzysztof Kochanek

Secretary of the Committee of Clinical Sciences of the Polish Academy of Sciences
Member of the Executive Board of the Polish Society of Pediatric Otolaryngologists
Member of the Audit Commission of the Polish Society of Biomedical Engineering
Scientific Secretary of the Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany
Maria Curie-Skłodowska University, Department of Logopedics and Applied Linguistics, Lublin

Artur Niedzielski

Member of the Board of the Society of Polish Otorhinolaryngologists, Phoniatriests and Audiologists
Member of the Audit Commission of the Polish Society of Pediatric Otolaryngologists
Head of Pediatric Otolaryngology Clinic, Medical Center for Postgraduate Education, Warsaw
Hospital in Dziekanów Leśny, Pediatric Laryngology Department

Piotr H. Skarżyński

Secretary of the Board of the Society of Polish Otorhinolaryngologists, Phoniatriests and Audiologists
Member of HEARRING group
Deputy Head of the Department of Teleaudiology at the Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany
Director of Science and Development at the Institute of Sensory

Organs, Kajetany International Center of Hearing and Speech
Medicus, Kajetany
Medical University of Warsaw, II Medical Department, Department of Heart Failure and
Cardiac Rehabilitation

Artur Lorens

Member of the Society of Polish Otorhinolaryngologists, Phoniatrists and
Audiologists and the Polish Society of Pediatric Otolaryngologists
Head of the Department of Implants and Auditory Perception at the Institute of
Physiology and Pathology of Hearing, Warsaw/Kajetany
Member of HEARRING group

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"Quality standards for using cochlear implants in infants, children and adolescents" were developed by the team of the National Consultant in Otorhinolaryngology and by the Society of Polish Otorhinolaryngologists, Phoniatrists and Audiologists and the Polish Society of Pediatric Otolaryngologists based on standards issued by the HEARRING group. HEARRING is a scientific network of expert cooperation in the field of auditory implants. It is an association of preeminent international centers offering comprehensive hearing implant solutions for the treatment of hearing impairments.

A set of quality standards has been developed to ensure a high level of health care and the effectiveness of cochlear implants and to provide each child with the best treatment using a cochlear implant optimally matched to the hearing impairment. The standards are a realistic minimum and should be applied alongside current Principles of Best Clinical Practices.

1 Introduction

Cochlear implantation is a multidisciplinary therapy, with a surgical procedure as its key element involving the introduction of an electrode array to the cochlear to provide direct electrical stimulation of the auditory nerve. Numerous scientific studies have shown that it is a safe and effective procedure.

Cochlear implantation is recommended for infants, children and adolescents with hearing loss and partial sensorineural hearing loss, not obtaining satisfactory benefits of using the hearing aids. Cochlear implants bypass the inoperative receptor part of the auditory system to provide electrical signals directly to the hearing nerve.

Widespread neonatal hearing screening enables early detection of congenital hearing loss,

and then taking early intervention. Children who are implanted early enough receive information through the auditory system and thus are less susceptible to functional changes caused by auditory deprivation.

The cochlear implant system consists of two parts: internal and external.

1.1 Internal part

The internal part includes an electronic component in the housing (capsule), electrode array, receiving antenna and magnet for attaching the coil to the head behind the ear.

1.2 External part

The speech processor consists of a control system, a container for batteries/rechargeable batteries and a coil that transmits information through the skin to the internal part.

2 Team structure

2.1 The structure of the cochlear implant pediatric team

The cochlear implant pediatric team may function independently or as a part of a larger unit in the cochlear implant center. It is a multidisciplinary team composed of the following specialists:

a. Otolaryngologists

The surgeon is responsible for the cochlear implantation.

The team must include at least two surgeons with experience in otology and surgery of cochlear implants. It is recommended that they perform at least 20 cochlear implantations annually.

Surgeons admitted to the team should have extended specialized training in otology and cochlear implant surgery, acquired in appropriate specialist centers in their country or abroad. This should involve participation in a practical course for surgeons in the field of cochlear implants, including exercises on temporal bone preparations. The newly admitted surgeon should initially work under the supervision of a senior member(s) of the team, at least for the first six months should perform the appropriate number of cochlear implantations under the supervision of an experienced team surgeon.

b. Pediatric anesthesiologist

The surgical team should include an anesthesiologist with skills and experience in dealing with young children. This is extremely important because general anesthesia can be

a source of special risk for children of low body mass. This risk is significantly higher for children under 12 months of age. It can be reduced if anesthesia is performed by an experienced pediatric anesthesiologist.

c. Basic team

The basic team should include people with appropriate training and experience in the selection of hearing aids for pediatric patients with significant to profound hearing loss, very well familiar with issues of cochlear implants, their programming as well as hearing and speech rehabilitation. The team comprises:

1. audiologists,
2. psychologists,
3. speech and language therapists for the hearing impaired,
4. clinical engineers,
5. educators for the hearing impaired.

These people should have a master university degree or equivalent. In addition, they must have at least two years' professional internship.

Furthermore, they should, if possible, have an extensive clinical experience within the field of cochlear implants, together with knowledge and understanding of issues related to the multidisciplinary nature of patient care with a cochlear implant. Their role may also include wider scientific and research responsibilities.

d. Coordinator/manager of the basic team

Coordinator/manager of the team is responsible for the management of the team clinical activities and for the patient support.

A person holding this position must have appropriate clinical experience and a PhD title, have appropriate knowledge (including knowledge of multidisciplinary issues) and competences, supplemented with specialist training and experience (preferably of at least 10 years) in the field of cochlear implants.

e. Administrator/secretary

The administrator should have appropriate qualifications to run the office, good organizational and communication skills and a high level of computer skills. The administrator works closely with the team coordinator/manager.

f. Custodial employee

A custodial employee must be appointed for each family, who will assist and act as an intermediary in contacts with the cochlear implant center. One of the foregoing team members may assume this function.

g. Team members should belong to relevant national and/or international professional associations of

specialists dealing with cochlear implants.

h. Team members should regularly participate in training courses on new scientific and technical solutions in the field of cochlear implants. It is also recommended that they participate in relevant courses, conferences and meetings at the national and international level. All team members should be able to participate regularly in national conferences as well as have a lifelong learning plan for further professional development.

i. All team members should be trained in basic information about deaf culture¹ and practical issues related to communication with deaf people.

j. Newly admitted team members, with less experience, have to undergo an appropriate training and supervision provided by relevant experienced team members.

2.2 Additional support

The basic team should have appropriate skills and experience in accordance with the requirements described in point 2.1.c. If the basic team does not include specialists in the following areas:

- a. tinnitus treatment,
- b. treatment of balance disorders,
- c. radiology,
- d. medical physics,
- e. genetic counselling,
- f. psychology,
- g. psychiatry,
- h. pediatrics,
- i. pedagogy,
- j. sign language translations,
- k. social assistance for the deaf and hard of hearing people,
- l. legal assistance for the deaf and hard of hearing people,

patients should be ensured access to such specialists, if such need arises. These specialists should have appropriate training and experience.

Parents/guardians play a key role in the therapy process of a child with hearing impairment. The duty of members of the cochlear implant team is partnership cooperation with parents/guardians in order to provide them with the necessary support, to enable them to properly stimulate the child's development.

3 Rooms

3.1 All rooms used by the patients must be adapted to the needs of deaf

¹ Spelling with a capital letter G - consistent with the American tradition - refers to the model of deafness, in which deaf people are considered to be a linguistic and cultural minority.

and hearing impaired people. This means, among others use of visual alerts (e.g. patient appointment information), visual alarms (e.g. fire alarm) and appropriate assistive listening devices.

3.2 Clinical rooms should be large enough to comfortably accommodate a child and family members, clinicians and observers or sign language interpreters as well as the necessary equipment.

3.3 Rooms intended for children should be easily accessible, safe and adapted to the needs of the family with the child. These rooms should be located within the cochlear implant or otorhinolaryngology center/pediatric audiology in the hospital.

3.4 A suitable room should be available for team work, such as group activities for cochlear implant users and team meetings/training.

3.5 There should be a suitable waiting area near the consultation rooms. The waiting room must be large enough and with sufficient number of comfortable chairs to accommodate all patients waiting for consultation at one time.

3.6 Consultation rooms should be sufficiently separated from waiting area, so that the noise from the waiting area does not disturb the therapy and treatment and privacy is maintained. Consultation rooms should be well-lit in a way that suits the needs of children with visual disabilities.

3.7 All rooms must comply with the requirements of the relevant health and safety regulations and guidelines and must be adapted to their intended purposes.

4 Clinical facilities

4.1 The center must have clinical facilities to perform the following tests:

- a. pure tone audiometry adjusted to the age of the child,
- b. speech perception testing,
 - in quiet,
 - in noise,
- c. sound field audiometry, with special test equipment for infants and young children,
- d. fitting hearing aids, including in-situ measurements,
- e. tympanometry,
- f. examination of otoacoustic emissions,
- g. examination of auditory evoked potentials,
- h. Tests of the balance function,
- i. imaging procedures,
- j. sound localization tests,

4.2 Audiological equipment

Audiological equipment must meet national standards. It must be calibrated to national standards as required, using recommended methods, and must undergo a daily check. All tests should be performed according to the recommended protocols and procedures.

5 Patient selection criteria for assessment and cochlear implantation

5.1 Written guidelines for referring patients to the assessment for cochlear implantation and selection criteria for implantation should be available at request.

5.2 The cochlear implantation selection criteria for children (in particular, babies under 12 months of age) are very broadly defined here, as they are subject to dynamic changes. However, one should state that:

- a. A child selected for cochlear implantation may have bilateral sensorineural hearing loss from severe to profound or partial deafness.
- b. Parents/guardians of the child should have realistic expectations with regard to the cochlear implant procedure and achievable effects.
- c. Parents/guardians of the child must be provided with adequate access to care and services after cochlear implantation, such as (re)habilitation and education, so that the child can get the best possible results.

5.3 The patient selection criteria for cochlear implantation applicable in the center should be regularly evaluated to ensure their compliance with the current state-of-the-art.

6 Diagnostic assessment and decision-making process

The diagnostic assessment process should be carried out as efficiently and quickly as possible.

6.1 If there are no clinical contraindications, all children should undergo a full diagnostic process for the cochlear implantation. Its purpose is to assess the child's auditory functions and determine whether they can be significantly improved by a cochlear implantation.

6.2 It is necessary to implement before cochlear implantation a consistent management of the patient assessment process carried out by a designated coordinator. The accepted selection criteria for the implant should be used.

6.3 Assessment procedure of each child must be followed according to a written check-list and recorded in his/her hospital file.

6.4 Waiting time for diagnostic testing and treatment should be as short as possible and comply with the relevant guidelines. After completion of the diagnostic process, parents/guardians should receive

information about selection or non-selection of a child for a cochlear implantation.

6.5 When clinically indicated, fast tracking of patient through the assessment process must be available.

6.6 Pre-operative assessment should include the following:

6.6.1 Medical examinations

- a. All children referred to the cochlear implant center must be examined by an otolaryngologist/audiologist from the cochlear implant team.
- b. The referral of a child for MRI, CT or X-ray is the responsibility of the doctor conducting the assessment process.
- c. Referral of the child - if necessary - to examine balance/functions of the vestibular system.
- d. To discuss all pre- and post-surgical risks associated with the procedure.
- e. Discuss the need for vaccination to minimize the risk of pneumococcal cerebrospinal meningitis.
- f. Referral of the child - if necessary - for genetic consultation.
- g. Obtaining a fully informed consent of the patient's parents/guardians to carry out the procedure.
- h. Confirmation that the child has been ophthalmologically tested as optimal vision is essential for a hearing impaired child.

6.6.2 Audiological examination

6.6.2.1 Each child must undergo full audiological assessment performed according to the protocol.

6.6.2.2. The audiological assessment must include:

- (1) otoscopic examination of ears.
- (2) Determination of hearing thresholds bilaterally using pure tone audiometry or other recognized methods suitable for the child's developmental age and condition.
- (3) objective hearing threshold assessment bilaterally, which is one of the basic methods for assessing a cochlear implant candidate. For this purpose, the following tests must be carried out:
 - a. otoacoustic emissions (OAA),
 - b. auditory brainstem responses (ABR) or/and auditory steady-state response (ASSR).
- (4) Evaluation of the functioning of the right and left middle ear using the tympanometric techniques.

(5) Adapted to the age of the patient, test of sound discrimination, including the sounds of speech in quiet and in noise.

(6) A questionnaire survey for parents regarding the hearing behavior of the child.

(7) Examination and evaluation for hearing aids, best confirmed by non-behavioral methods.

6.6.3 Evaluation of the benefits of hearing aids

Prior the cochlear implantation, each child should be provided with hearing aids on both sides to ensure that he or she can hear the widest possible range of sounds. During the assessment process, fitting must be reviewed and, if necessary, the settings may be improved or the new hearing aids fitted to the child. Verify that the reinforcement is appropriate, depending on the age and individual capabilities of the child:

- a. in situ measurements,
- b. sound field audiometry with hearing aids,
- c. ambient sounds and/or speech perception testing using standardized recorded material,
- d. electroacoustic measurements of the features of hearing aids according to applicable standards.

6.6.4 Children who have been fitted with new hearing aids or who have the settings of hearing aids changed may need adaptation to hearing aids and/or appropriately planned auditory (re)habilitation. Some children may need up to several months of the adaptation period.

6.6.5 Evaluation of communication methods

It may be necessary to carry out a full assessment of the child's communication and social strategies. These assessments may take the form of observation, subjective description, or evaluation using a formal test procedures. It must take into account the child's age and hearing status, receptive and expressive skills, as well as individual differences.

The assessment may concern the following areas:

- a. speech receptive skills (pre-verbal behaviors of very small children),
- b. expressive abilities (cooing, gurgling, introduction to word, words, quality of voice and speech intelligibility),
- c. detailed information about the environment in which the child usually communicates and when it is most difficult for him/her should be gathered.

6.7 Psychological support for the family

Some families may need additional support or psychological assessment. A referral to a psychologist

or psychiatrist should be issued if parents/guardians are observed to have high levels of parental stress, inability to deal with the child's deafness diagnosis, lack of motivation to participate in the treatment and rehabilitation process or unrealistic expectations about the effects of cochlear implantation. The referral should be initiated when the indicated concerns cannot be addressed through counselling by the basic team.

6.8 Family support and education

Parents/guardians of the child play a key role in the healing and rehabilitation process. It is very important to make sure that they understand the whole process and are adequately motivated to participate in it. The support provided to the child by external persons and institutions, such as school, is also important to ensure the long-term success of the treatment.

6.9 Supporting organizations

Children and parents/guardians should receive information on organizations supporting users of cochlear implants, charities and self-help associations as well as about devices and services for people with hearing impairments.

6.10 Final outcome

To end the assessment procedure, a meeting with the family should be scheduled to discuss all aspects of cochlear implantation. If the outcome of the assessment indicates that cochlear implant is not recommended for a child, the reasons for the no-selection decision should be explained to the family. Recommendations for future treatment should be presented, if necessary, patients should be referred to other devices and/or medical services, the opportunity of re-referral for cochlear implant assessment in the future should be discussed.

6.11 Candidates for unilateral or bilateral implantation

Bilateral cochlear implantation is now considered the most modern strategy of treatment, giving the patient the best chance of achieving the maximum level of speech understanding. Bilateral implantation should be considered in every justified case, whereas one implantation - in patients with unilateral deafness or asymmetric hearing loss.

7 Pre-operative information for parents/guardians and informed consent

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

7.2 Whenever possible, the information should be given in a language or in a manner consistent with the preferred method of communication adopted in a given family.

7.3 When required, sign language interpreters should be offered.

7.4 Teams should continuously update information they provide to patients; they 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 whenever required.

7.6 Parents/guardians of the child must receive full, objective and current information so that they can make an informed choice for their child and express, when necessary, informed consent to the procedure.

7.7 Throughout the assessment process, all parties should have a clear understanding of the benefits and limitations of cochlear implant treatment.

7.8 It is recommended that the families of candidates for cochlear implantation meet other children and families who have experience with using such devices. Matching candidates and users in terms of age, duration of hearing loss and cochlear implant type may be beneficial.

7.9 In order to prepare the child and parents/guardians for a stay in the hospital, it is necessary to offer a pre-operative visit to a pediatric surgical ward, giving them an opportunity to meet a nursing team.

7.10 The device selection should be part of the assessment procedure and finalize the decision-making process.

Currently, cochlear implant systems are supplied by various manufacturers. Patients should be given information on the technical specifications of different devices.

Parents/guardians of the child should receive extensive information on currently available devices, their advantages and disadvantages. They should be given an explanation as to why they are offered a particular device, or choice of devices. Written information on the device(s) offered should also be made available.

Centers must offer and implant only cochlear implants that have obtained legally valid certificates of approval for use.

7.11 The cochlear implant recommended to the child must:

- a. have a proven track of safety and reliability.

- b. have all necessary certificates and approvals for use.
- c. have the highest quality clinical and technical support ensured by the manufacturer.
- d. meet the applicable national purchasing requirements for such devices.

7.12 Information on all known risk factors associated with cochlear implantation should be given in a clear and appropriate way for the patient. Such written information should always be available. Before implantation, parents/guardian must sign a formal consent for surgery.

8 Surgery and in-patient care

8.1 The implant surgeon is responsible for the overall medical care of the child during the procedure and after implantation.

8.2 Anesthesia should be performed by appropriately qualified and experienced pediatric staff.

8.3 The surgeon should make every effort to preserve the internal structure of the cochlea and existing residual hearing. Surgical techniques employed must reflect the latest medical technology and be state-of-the-art.

8.4 During the implantation, every effort shall be made to avoid injury to the facial nerve.

8.5 The placement of the implant capsule may require special caution in the case of very small infants. The individual properties of their skull and degree of development of significant anatomical elements should be taken into account.

8.6 Information on the outcome of surgery must be documented and made available to the cochlear implant team and (re)habilitation team.

8.7 Consideration should be given to performing intraoperative or post-operative imaging to assess the position of the implant capsule and/or electrode.

8.8 The surgeon performing the cochlear implantation will continue to monitor the child's progress in the post-operative period and will be responsible for dealing with any surgical or medical problems that may arise in relation to the implant.

8.9 Prior to the child's discharge from hospital, parents/guardians should:

- a. receive written information on proper wound/ear care and pain management.
- b. receive written guidelines on what to do, should any medical or surgical problems arise.
- c. know the schedule of follow-up visits and further steps.

- d. receive advice on the safety and hygiene of using the cochlear implant and the manufacturer's written safety guidelines.

9 Post-operative fitting and tuning of the speech processor

9.1 The speech processor should be fitted and programmed once the post-operative wound has healed sufficiently.

9.2 The speech processor should only be fitted and programmed by experienced clinical employee (see point 2.1.c), fully trained in the relevant protocols and procedures.

9.3 Before initializing the speech processor (activating the implant system), relevant team member must:

- a. Check the external parts of the cochlear implant system.
- b. Explain the process of implant programming.

9.4 Each cochlear implant should be fitted and programmed according to the manufacturer's recommended programming procedures and to maximize the child's auditory benefits. The appropriate number of processor programming sessions should be offered to each patient according to their needs.

9.5 It is recommended to perform objective measurements, such as impedance telemetry, electrically evoked compound action potential (eCAP) or electrically evoked stapedius reflex threshold (eSRT). The results of these measurements can be used to determine stimulation levels.

9.6 Parents/guardians should be given thorough explanations about the use of the speech processor. They should be encouraged to contact specialists from the cochlear implant team if they have any queries or concerns.

9.7 Printed materials on the handling and operation of the speech processor should be issued to parents/guardians.

9.8 The child must have open access to the cochlear implant center (or designated local partner center) for checking the implant system or for reprogramming the speech processor.

10 (Re)habilitation and post-operative assessment

10.1 Following cochlear implant surgery, the child must be examined by an otolaryngologist and have open access to additional consultations if necessary.

The child should be offered a long-term care (annual medical consultation and checks of the implant and speech processor function).

10.2 Post-operative (re)habilitation should begin after the implant system is activated, according to the patient's individual needs.

10.3 The (re)habilitation program may include classes focused on:

- a. detection of sounds and their localization,
- b. auditory differentiation and sound recognition,
- c. voice quality,
- d. speech intelligibility,
- e. development of language, understanding and speaking,
- f. social functioning.

10.4 The (re)habilitation program should be tailored to the individual needs of each patient.

10.5 The offered number of re(habilitation) sessions should be sufficient to obtain optimal benefits from the implant. Parents/guardians and children must have open access to a cochlear implant center (or a designated local partner center) in order to take advantage of (re)habilitation and counseling if necessary.

10.6 At regular intervals, appropriate measurements should be made to monitor changes in audiology, speech perception, speech and language development as well as school performance. Standardized measurements should be used to enable comparison of results.

10.7 After the first year following implant surgery, the child should be offered annual audiological reviews. This can take the form of a follow-up visit scheduled by the cochlear implant center or initiated by the patient. Moreover, parents/guardians should be able to make additional appointments for the child, as required.

10.8 It is recommended to consider sending written reports on the child's progress to local professionals involved in the childcare.

11 Follow-up and long-term maintenance

11.1 The child and parents/guardians must have open access to the cochlear implant center (or a designated local partner center) for tuning the speech processor, rehabilitation or surgical consultation.

11.2 Adequate accessories, spare parts or replacements of the speech processor must be available, as required, at service points authorized by the device manufacturers. The service should be organized in such a way that necessary parts can be issued or dispatched to the patient on the same or the next working day. Speech processor batteries should be available to implant users at service points.

11.3 Individual centers should implement a policy for replacement of lost or damaged processors that ensures equal treatment for all children.

11.4 Implant centers should have a developed strategy for upgrading speech processors, as required.

12 Device failure

12.1 If there is a suspicion of failure of the internal part of the implant system, parents/guardians should be offered an appointment promptly (no later than within 3 days) to check the operation of internal and external components.

12.2 If necessary, the manufacturer of the cochlear implant system should be immediately contacted for checking the device and providing the appropriate technical support, in particular a company representative should be available during the child's appointment in the center.

12.3 Upon confirmation of internal part of the cochlear implant system failure, the clinical personnel (see 2.1.c) must inform the surgeon and coordinator/team manager and the patient should be offered an urgent appointment to discuss further steps to be taken.

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

12.5 If re-implantation decision has been made, the procedure should be carried out as soon as medically possible and appropriate, to minimize time of auditory deprivation.

12.6 Re-implantation and programming of the speech processor should be carried out as described above. Further (re)habilitation needs of the patient should be assessed and appropriate care be ensured, if required.

13 Cochlear implant program management

The cochlear implant center should conduct internal audit in the following areas:

- a. clinical activity,
- b. employment levels,
- c. children treatment results,
- d. medical and surgical complications,
- e. device failures,
- f. scientific and research activity interests and results,
- g. children and families/guardians feedback on the provided services.

14 Cooperation of cochlear implant team with other teams and institutions

14.1 All members of the cochlear implant team should take part in regular meetings that enable good communication in the team and thus the high quality of care provided to each patient.

14.2 Members of the cochlear implant team should maintain contact with the GP who referred the patient to cochlear implantation assessment, and with local specialists involved in the process of patient's (re)habilitation.

14.3 The cochlear implant team should consider what additional information may be useful in the patient care process. The team should cooperate and obtain relevant and up-to-date information from other institutions, such as:

- a. other wards and hospital clinics,
- b. audiological, X-ray, medical physics teams, as well as outpatient departments and other,
- c. screening testing of newborns,
- d. support groups,
- e. local government institutions,
- f. educational institutions.

14.4 Supporting institutions should be contacted only with the consent of the patient's parents/guardians, at the discretion of the cochlear implants team.

15 Transfer of care (national)

15.1 A protocol must be in place for the transfer of care, as soon as children - cochlear implant users reach the appropriate age, to the adult program.

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15.2 At the request of the parent/guardian, a protocol should be implemented for childcare transfer to another cochlear implant program and acceptance of childcare by another program.

15.3 The center to which patient care is transferred must confirm that they support the type of cochlear implant system used by the child.

15.4 Upon the patient's consent or consent of his/her parents/guardians, his/her documentation should be sent to the receiving center. The documentation will include: full address of the patient, telephone number and e-mail address, information on the internal device and speech processor used, recent processor programs, eCAP results, eSRT, sound field audiometry results in the implant, speech perception results, reports and results of (re)habilitation, medical details of surgery and any complications.

15.5 Patient care should not be transferred to another center less than one year after implantation. This allows continuation of post-operative treatment, setting of appropriate processor programming and initial (re)habilitation of the patient.

16 Feedback and complaints

Feedback received from children and parents/guardians should be systematically collected to assess and review the cochlear implant program implementation.

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